

**YALE JOURNAL OF HEALTH  
POLICY, LAW, AND ETHICS**

**VOLUME 1**

**2001**





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# Our Commitment to Eliminate Racial and Ethnic Health Disparities

**David Satcher, M.D., Ph.D.\***

Both the life expectancy and the overall health of Americans have improved greatly over the last century, but not all Americans are benefiting equally from advances in health prevention and technology. There is compelling evidence that race and ethnicity correlate with persistent health disparities in the burden of illness and death. For example, compared with their white counterparts, black babies are twice as likely to die during their first year of life, and American Indian babies are 1.5 times as likely. The rate of diabetes among Native Americans is three to five times higher than the rest of the American population, and among Hispanics it is twice as high as in the majority population. Although constituting only 11% of the total population in 1996, Hispanics accounted for 20% of new tuberculosis cases. Also, women of Vietnamese origin suffer from cervical cancer at nearly five times the rate for white women.

Current information about the biologic and genetic characteristics of these populations does not solely explain these health disparities. These disparities result from complex interactions among genetic variations, environmental factors, specific health behaviors, and differences in health care access and quality. While the diversity of the American population may be one of our nation's greatest assets, it also represents a range of health improvement challenges—challenges that must be addressed by individuals, communities, and the nation. The demographic changes that are anticipated during the next decade magnify the importance of addressing disparities in health status; groups currently experiencing poorer health status are expected to grow as a proportion of the total U.S. population. Therefore, the future health of America depends substantially on our success in improving the health of racial and ethnic minorities. A national focus on disparities in health status is also particularly important

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as major changes unfold in how health care is delivered and financed.

In a February 1998 radio address, then-President Clinton committed the nation to an ambitious goal by the year 2010: to eliminate the disparities experienced by racial and ethnic minority populations in six health-related areas, including cancer screening and management, cardiovascular disease, diabetes, HIV/AIDS, immunization rates, and infant mortality. These six health areas were selected for emphasis because they reflect areas of disparity that are known to affect multiple racial and ethnic minority groups at all life stages. Clinton's goal parallels the focus of *Healthy People 2010*—the nation's health objectives for the twenty-first century—which Donna Shalala, former Secretary of the Department of Health and Human Services (DHHS), and I released in January 2000.

Achieving this vision will require a major national commitment to identify and address the underlying causes of higher disease and disability levels in racial and ethnic minority communities. These causes include poverty, lack of access to quality health services, environmental hazards in homes and neighborhoods, and the scarcity of effective prevention programs tailored to the needs of specific communities. The effort will require improved collection and use of standardized data to correctly identify all high-risk populations, and to monitor the effectiveness of health interventions targeting these groups. Research dedicated to a better understanding of the relationships between health status, race, ethnicity, and socioeconomic background will help us acquire new ways to eliminate disparities and to apply our existing knowledge.

## I. THE ROLE OF THE COMMUNITY

While leaders in the federal government have both the opportunity and the obligation to set the direction for the nation, our responsibility does not end here. To reduce health care disparities in our nation, we must reach out to communities. Creating real and meaningful partnerships is essential to achieving a balanced community health system. This system needs to make access to quality care available to all, and balance early detection of disease with health promotion and disease prevention. Drawing on community involvement, from schools, faith-based organizations, and civic and local groups, this project is realizable. Health and quality of life rely on many community systems and factors, not simply on a well-functioning health and medical care system. Making changes within existing systems can effectively and efficiently improve the health of a large segment of the community. Also, environmental and policy approaches, such as better street lighting and policies to fortify foods, tend to have a greater impact on the whole community than do

individual-oriented approaches.

Communities experiencing the greatest success in addressing health and quality-of-life issues have drawn upon public health, health care, businesses, local governments, schools, civic organizations, voluntary health organizations, faith-based organizations, park and recreation departments, and other interested groups and private citizens. Communities that are eager to improve the health of specific at-risk groups have found that they are more likely to be successful if they work collaboratively within their communities, and if the social and physical environments are conducive to supporting healthy changes.

As noted in the Conference Edition of *Healthy People 2010*, community health promotion programs should include community participation from at least three of the following sectors: government, education, business, faith-based organizations, health care, media, voluntary agencies, and the public. Programs should also include community assessments to determine community health problems, resources, and perceptions and priorities for action, as well as measurable objectives that address at least one of the following: health outcomes, risk factors, public awareness, or services and protection. Monitoring and evaluation processes are other key components. Finally, comprehensive, multifaceted, and culturally relevant interventions with multiple targets for change are critical.

Health promotion programs need to be sensitive to the diverse cultural norms and beliefs of the people for whom the programs are intended. Achieving such sensitivity continues to be a challenge, as the nation's population becomes increasingly diverse. To ensure that interventions are culturally sensitive, linguistically competent, and appropriate for people of all races, ethnicities, genders, sexual orientations, ages, and disability statuses, members of the populations served, and their gatekeepers, must be involved in the community assessment and planning process.

Community assessment helps to identify the cultural traditions and beliefs of the community, and the education, literacy level, and language preferences necessary for the development of appropriate materials and programs. In addition, community assessments can help identify levels of social capital and community capacity, as well as the skills, resources, and abilities needed to manage health improvement programs in communities.

Educational and community-based programs must be supported by accurate, appropriate, and accessible information derived from a scientific base. Increasing evidence supports the effectiveness of health education and health promotion in schools, workplaces, and health care facilities. Examples of gaps in research include the dissemination and diffusion of

effective programs, new technologies, and approaches to disadvantaged and special populations.

Communities also need to be involved as partners in conducting research to ensure that the content of prevention efforts is tailored to meet their needs. Their research should also enhance the appropriateness and sustainability of science-based interventions and prevention programs, as well as ensure that the lessons of research are transferred back to the community. Sustainability is necessary for successful research to be translated into programs of lasting benefit to communities.

## II. STRATEGIES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

In launching *Healthy People 2010*, DHHS's first step was to examine its current programs to assure that they focus on opportunities to reduce health disparities and fully maximize the best scientific and community-derived knowledge about how to deliver effective clinical and preventive services. Gaps in knowledge were identified, and research agendas were developed to address them. New programs or modifications of existing programs were recommended when appropriate. In addition, the Department provided a national framework for public and private sector collaboration to eliminate health disparities in the six areas first highlighted by former President Clinton.

### A. Cancer Screening and Management

Cancer is the second leading cause of death in the United States, accounting for more than 544,000 deaths each year. The lifetime chance of developing cancer is nearly 50% for men and nearly 40% for women in the United States. About half of those who develop cancer will die from it. Minority groups suffer disproportionately, with disparities in both cancer mortality and incidence rates. For men and women combined, blacks have a cancer death rate about 35% higher than that for whites (171.6 *vs.* 127 per 100,000). The death rate for cancer among black men is about 50% higher than it is for white men (226.8 *vs.* 151.8 per 100,000). Mortality from prostate cancer for black men is more than twice that of white men (55.5 *vs.* 23.8 per 100,000). The death rate for lung cancer is about 27% higher for blacks than for whites (49.9 *vs.* 39.3 per 100,000).

Paralleling the death rate, the incidence of lung cancer in black men is about 50% higher than in white men (110.7 *vs.* 72.6 per 100,000). Native-Hawaiian men also have elevated rates of lung cancer compared with white men. Native Alaskans suffer disproportionately higher rates of cancers of the colon and rectum than do whites. Vietnamese women in the United

States have a cervical cancer incidence rate more than five times greater than white women (47.3 *vs.* 8.7 per 100,000). Hispanic women also suffer elevated rates of cervical cancer. White, non-Hispanic males are nine times more likely to contract invasive melanoma of the skin than their black counterparts (3.7 *vs.* 0.4 per 100,000), and more than nine times more likely to die from it (2.9 *vs.* 0.3 per 100,000).

For some cancers, early detection can dramatically reduce the risk of death. Regular mammography screening and appropriate follow-up care can reduce deaths from breast cancer by about 30% for women fifty years of age and older. Screening by Pap smear for cervical cancer, along with appropriate follow-up care, can virtually eliminate the risk of developing this disease. Colorectal cancer screening is recommended for people forty-five to eighty years old, but data on screening rates is scarce. Screening for prostate cancer remains controversial, and there is a significant need for public education about what is known, what is not known, and what is believed about prostate cancer screening and treatment.

Breast and cervical cancers, however, have proven screening modalities for which screening data are available. Despite the considerable gains in screening in the black community, the mortality rate from breast cancer for black women is greater than for white women. Some of the reasons for this disparity include the fact that many black women have not had a mammogram, many more are not screened regularly, and still others are screened but have limited follow-up and treatment services available to them. Hispanic, American-Indian and Alaska-Native, and Asian and Pacific-Islander women also have low rates of screening and treatment, limited access to health facilities and physicians, and face barriers related to language, culture, and negative provider attitudes, all of which negatively affect their health status. Eliminating these differences is critical, and will be the focus of attention for the DHHS initiative to help identify and understand approaches that have proven successful in some communities. The tracking of breast and cervical cancer will serve as an indicator for assessing our overall efforts to reduce and eventually eliminate disparities in the prevention and management of all cancers.

During Breast Cancer Awareness Month in October 1998, DHHS announced new efforts to encourage mammography screening among special populations, including older, low income, and minority women, who tend to have the highest breast cancer mortality rates. The Health Care Financing Administration (HCFA) and the National Cancer Institute (NCI) co-sponsored an educational campaign about the new annual Medicare mammography benefit and the importance of regularly scheduled screening mammograms. In addition, HCFA offered

mammograms to older African-American and Hispanic-American women in Atlanta, Chicago, Cleveland, Los Angeles, Philadelphia, Washington, D.C., and San Antonio. HCFA is also working with the NCI to develop and disseminate culturally appropriate breast cancer materials geared toward Asian-American and Pacific-Islander women. The Centers for Disease Control and Prevention (CDC) offers the National Breast and Cervical Cancer Early Detection Program, which provides free or low-cost mammograms to uninsured, low-income, elderly, minority, and Native-American women throughout the country. One million mammograms have been conducted through this program.

The federal battle against minority cancer received a boost when the NCI announced a \$60 million program to address the unequal cancer burden within certain populations in the United States over the next five years. Eighteen grants at seventeen institutions will create or implement cancer control, prevention, and research and training programs in minority and underserved populations. The cooperative relationships established by the networks will be used to foster cancer awareness activities, support minority enrollment in clinical trials, and encourage and promote the development of minority junior biomedical researchers.

### *B. Cardiovascular Disease*

Cardiovascular disease, primarily in the form of coronary artery disease (CAD) and stroke, kills nearly as many Americans as all other diseases combined, and is among the leading causes of disability in the United States. It is the leading cause of death for all racial and ethnic groups. The annual national economic impact of cardiovascular disease is estimated at \$259 billion, as measured in health care expenditures, medications, and lost productivity due to disability and death. The major modifiable risk factors for cardiovascular disease are high blood pressure, high blood cholesterol, cigarette smoking, excessive body weight, and physical inactivity. Prevention through modification of these risk factors seems to provide the most potential for reducing morbidity, disability, and mortality due to cardiovascular disease. Minorities suffer disproportionately from cardiovascular disease. For instance, while the age-adjusted death rate from CAD in the population as a whole declined 20% from 1987 to 1995, the decrease in the black population during the same period was only 13%. Compared with rates for whites, CAD mortality was 40% lower for Asian Americans, but 40% higher in blacks.

People with high blood pressure, also known as hypertension, are three to four times more likely to develop CAD when compared to controls with normal blood pressure, and may have as much as seven times the risk



of suffering a stroke. Reduction in blood pressure significantly reduces stroke mortality and can also help to reduce deaths from CAD. Racial and ethnic minorities tend to have higher rates of hypertension, develop hypertension at an earlier age, and are less likely to undergo treatment to control their high blood pressure. For example, from 1988 to 1994, 35% of black males, aged twenty to seventy-four, had hypertension, while the rate in the general population was 25%. When age differences are taken into account, Mexican-American men and women also have elevated blood pressures when compared to the population at large. The prevalence of hypertension in minorities may be a direct cause of their higher overall risk of cardiovascular disease.

Being overweight is also a risk factor for cardiovascular disease that disproportionately affects minorities. Risk of heart attack and CAD increases with increasing body mass index (BMI) and with weight gain. Among adult women, the age-adjusted prevalence of being overweight continues to be higher for black women (53%) and Mexican-American women (52%) than for white women (34%), which may contribute to a heightened cardiovascular morbidity risk in these minority groups.

High cholesterol is another risk factor for cardiovascular disease that is more common in certain ethnic and racial minorities, many of whom do not check their cholesterol levels as often as do whites. It has been shown that each 1% reduction in serum cholesterol level has been associated with a greater than 1% reduction in risk of death from CAD. However, the current rates for regular screening for cholesterol show that only 50% of American Indians and Alaska Natives, 44% of Asian Americans, and 38% of Mexican Americans have had their cholesterol checked within the past two years, as compared to a rate of 67% for all U.S. adults.

Tobacco use, a leading cause of cardiovascular disease, also varies in ethnic and racial minority groups, and is at an overall rate of about 25% for adults in the United States. American Indians and Alaska Natives have the highest prevalence of tobacco use at 39%, while African Americans have a rate of about 26% among adults.

Finally, physical activity helps prevent heart disease, and the overall number of adults who report no participation in physical activity is 29%. However, the rates of African Americans and Hispanics who report no participation in physical activity are higher than the average, at 39% and 35%, respectively.

The National Institutes of Health (NIH) has many programs designed to address heart health in minorities. For example, one pilot program in Washington, D.C., called “Salud Para su Corazon (For the Health of Your Heart),” works through the Latino community using Latino traditions to

provide science-based health messages, educational materials, and action strategies to improve heart health in Latinos. Because of the program's success in changing behaviors and increasing awareness, the National Heart, Lung and Blood Institute at the NIH is encouraging the use of this model in other Latino communities nationwide.

### *C. Diabetes*

Diabetes, the seventh leading cause of death in the United States, is a serious public health problem affecting nearly sixteen million Americans. The estimated total cost of diabetes for the United States in 1993 was \$98 billion. The rate of diabetes for blacks is approximately 70% higher than for whites, and the rate in Hispanics is double that of whites. The prevalence of diabetes among American Indians and Alaska Natives is nearly three times that for the total population, and the Pima Indians of Arizona have the highest known prevalence of diabetes in the world.

Cardiovascular disease is the leading cause of death among people with diabetes; it accounts for over one-half of all diabetes-related deaths. Achieving mortality reduction among high-risk populations will require targeted efforts to reduce cardiovascular risk factors among these groups. Diabetics also face the probability of multiple acute and chronic complications, other than cardiovascular disease, including end-stage renal disease (ESRD), blindness, infections, and peripheral neuropathies, which may lead to lower extremity amputations. All of these complications, which have the potential to be delayed and possibly prevented, are more pronounced in minority populations. Preventive interventions should target high-risk groups.

Rates for diabetes-related complications such as ESRD and amputations are higher among blacks and American Indians compared to the rates in the total population. Even among similarly insured populations, such as Medicare recipients, blacks are more likely than whites to be hospitalized for septicemia, debridement, amputations, and other complications of poor diabetic control. There is concern that some people in minority populations are developing type II (non-insulin-dependent) diabetes in adolescence, and therefore are more likely to face a lifetime of diabetes and its potential complications. Undiagnosed and poorly controlled diabetes increases the likelihood of serious complications; for every two people who are aware of their illness, there is one person who remains undiagnosed.

Although the increasing burden of diabetes is alarming, the good news is that many major public health problems can be prevented with early detection, improved care, and diabetes self-management education. For

public policy makers, health care providers, community leaders, and individuals with diabetes, the disease presents an opportunity to apply prevention strategies known to make a significant impact. Recent studies in diabetes have confirmed that careful control of blood glucose levels is a strategy that works for preventing the complications of diabetes. The challenge is to make proper diabetes management part of every day clinical and public health practice.

Toward the goal of reducing the public health burden of diabetes, the Indian Health Service awarded 286 grants in 1998 to Indian communities for programs focused on primary prevention of diabetes and promotion of healthy lifestyle choices, including mental health services and substance abuse prevention and treatment programs. These programs will reach more than 100,000 American Indians and Alaska Natives suffering with diabetes, as well as another 30,000-50,000 who are at risk or have undiagnosed cases. Comparing the 1994-96 Indian adjusted death rates with the overall U.S. population, the American-Indian and Alaska-Native populations have diabetes death rates that are 3.5 times greater than the overall population.

In addition, the Health Resources and Services Administration (HRSA) launched an intensive effort to help its community health centers diagnose and treat diabetes. These centers are the health care provider of choice for ten million people, 65% of whom are racial and ethnic minorities. Also, HCFA announced in November that the Medicare program would be taking steps to ensure that all patients with renal failure, regardless of race or ethnicity, are evaluated for transplantation. The purpose is to ensure equal opportunity for transplantation as part of the patient's long-term care plan.

#### *D. HIV/AIDS*

HIV infection and AIDS are major problems for the American people and our health care system. There are an estimated 650,000 to 900,000 Americans living with HIV infection. Racial and ethnic minorities are disproportionately affected by this problem. These minorities constitute approximately 25% of the total U.S. population, yet they account for nearly 54% of all AIDS cases. While the epidemic is decreasing in some populations, the number of new AIDS cases among blacks is now greater than the number of new AIDS cases among whites. In fact, in 2000, 70% of new AIDS cases were in blacks (48%) and Hispanics (22%).

There are several different HIV epidemics occurring simultaneously in the United States, each affecting specific populations. For example, although the number of AIDS diagnoses among gay and bisexual white

men has decreased dramatically since 1989, the number of AIDS diagnoses among gay and bisexual black men has increased. Similarly, AIDS cases and new HIV infections related to intravenous drug use appear to be increasingly concentrated in minorities; of these cases, about 75% were among minority populations (56% black and 20% Hispanic). Of HIV/AIDS cases reported among women and children, more than 75% are among racial and ethnic minorities.

Statistics show that during 1995 and 1996, AIDS death rates declined 23% for the total U.S. population, while declining only 13% for blacks and 20% for Hispanics. Contributing factors for these mortality disparities include late identification of disease and lack of health insurance to pay for drug therapies. Inadequate recognition of risk, detection of infection, and referral to follow-up care are major issues for some high-risk populations. About one-third of persons who are at risk of HIV/AIDS have never been tested.

HIV-counseling and testing programs must better facilitate the early diagnosis of HIV infection and ensure that HIV-infected persons have access to care and treatment services that will enable them to benefit from treatment advances. A continued emphasis on behavioral risk reduction and other prevention strategies targeted to at-risk populations is still the most effective way to reduce HIV infections. Efforts should include risk-reduction counseling, street and community outreach, preventative case management services, and help for at-risk individuals in gaining access to HIV testing, treatment, and related services.

DHHS has introduced many initiatives to combat the HIV/AIDS epidemic in America. In October 1998, DHHS joined the Congressional Black Caucus in announcing a special package of initiatives in response to the severe and ongoing problem of HIV/AIDS in racial and ethnic minority communities. The comprehensive new initiative invested an unprecedented \$156 million in fiscal year 1999 to improve the nation's effectiveness in preventing and treating HIV/AIDS in African-American, Hispanic, and other minority communities. DHHS received \$251 million from Congress in fiscal year 2000 to continue to combat HIV/AIDS in minority communities. Resources have also been broadened for research on HIV/AIDS and minorities, including an increased emphasis on behavioral research linking substance abuse and HIV-infection rates. Funding for community-based organizations to provide new services, technical assistance, and faith-based HIV-prevention programs has been made available through the CDC. There are many opportunities to address the racial and ethnic disparities in HIV/AIDS care and treatment, all of which will benefit America as a whole.

*E. Immunization Rates*

The reduction in incidence of vaccine-preventable diseases is one of the most significant public health achievements of the past hundred years. One major factor in this success is the development and widespread use of vaccines, which are among the safest and most effective preventive measures available. Childhood immunization rates are at an all time high for all people in the United States. Immunization rates are lower for minority populations as compared with whites, but the gap is narrowing, and minority rates are increasing at a rapid rate. Preschool immunization is high in almost all states, but areas of need continue to exist.

In addition to the very young, older adults are at increased risk for many vaccine-preventable diseases. Approximately 90% of all influenza-associated deaths in the United States occur in people aged sixty-five and older, the fastest growing demographic group in the population. Each year an estimated 30,000 adults die from influenza and pneumococcal infections, despite the availability of safe and effective vaccines to prevent these conditions and their complications. There is a disproportionate burden of these diseases in minority and underserved populations. Although the levels of vaccination against pneumococcal infections and influenza among people sixty-five years and over have increased slightly for blacks and Hispanics, the coverage in these groups remains substantially below the general population.

DHHS has crafted several plans to achieve the goal of increasing minority immunization rates. For example, there is a Spanish-language childhood immunization public awareness campaign to create and distribute culturally relevant and language appropriate educational materials. The theme, “Vacunelo a Tiempo y Todo el Tiempo (Vaccinate Your Children On Time, Every Time),” encourages parents and caregivers to talk with their child’s health care provider to make sure their child is up to date on immunizations by age two.

In an effort to increase immunization rates among older adults, DHHS launched an initiative providing limited Medicare coverage for flu shots for the elderly in 1993. An aggressive outreach strategy by HCFA to inform minority seniors about immunizations includes the mailing of some eight million postcards in four languages to Medicare beneficiaries as reminders, as well as television and radio announcements in Spanish.

*F. Infant Mortality*

Infant mortality (IM) is an important measure of a nation’s health, as well as a worldwide indicator of health status. Although IM in the United

States has declined steadily over the past several decades, and is at a record low of 7.2 deaths per 1,000 live births (1996), the United States still ranks twenty-fourth in infant mortality among industrialized nations. Significant racial and ethnic disparities in our nation's infant mortality rate (IMR) may be the principal reason for our poor international showing. These disparities exist both between and within racial and ethnic groups. For instance, compared to a white baby, an American-Indian baby and a black baby are 1.5 and 2 times, respectively, more likely to die in their first year of life. Infant death rates among blacks, American Indians and Alaska Natives, and Hispanics were all above the national average in 1995 and 1996; black babies fared the worst at 14.2 deaths per 1,000 live births (1996), a rate nearly twice that of white infants, whose IMR was only 6 per 1,000 (1996).

IMRs also differ within certain ethnic and minority groups. For instance, while the overall American Indian IMR is 9 per 1,000 (1995), some Native-American communities have IMRs approaching twice the national rate. Similarly, the overall Hispanic IMR of 7.6 per 1,000 (1995) does not reflect the diversity within Hispanic communities; the IMR for Puerto Ricans, for example, was significantly higher than the Hispanic aggregate at 8.9 per 1,000 (1995).

The IMR of a nation is greatly affected by its ability to provide effective prenatal care to all pregnant women. Disparities among races and ethnic groups in quality and access to prenatal care is a major failure of our health care system, and a primary reason for our high IMR, relative to other industrialized nations. It is a known fact that women who receive prenatal care in the first trimester have better pregnancy outcomes than women who receive little or no prenatal care. The likelihood of delivering a very low birth weight (VLBW) infant (defined as less than 1,500 grams or 3 lbs. 4 ozs.) is 40% higher among women who receive late or no prenatal care, compared with women who begin receiving such care in the first trimester. VLBW infants are about sixty-five times as likely to suffer an early death than infants who weigh at least 1,500 grams. It is also a fact that while 84% of white women receive early prenatal care, only 71% of black and Hispanic women receive prenatal care in the first trimester.

There is also a great deal of disparity seen in the IMRs of blacks relative to whites when looking at many of the leading causes of infant death. For example, there is a black to white ratio of 2.8:1 for deaths from respiratory distress syndrome, a ratio of 2.7:1 for deaths from infections specific to the perinatal period and newborns affected by maternal complications of pregnancy, and a ratio of 2.6:1 when considering sudden infant death syndrome (SIDS). However, the greatest black-white disparity,

at a ratio of 4.1:1, exists in pre-term births (PTBs) and unspecified low birth weight. Overall, PTBs occur in 17.7% of black mothers, but in only 9.7% of white mothers. Differences in various medical conditions and social practices may contribute to this racial disparity in PTBs, including higher rates of both chronic hypertension and bacterial vaginosis among black women. Minority infants are also far more likely than white infants to die of SIDS, with blacks and some American-Indian and Alaska-Native populations at greatest risk.

We can significantly reduce infant mortality by increasing our efforts to address the disparities that contribute to the higher IMRs seen in our ethnic and racial minority populations. In particular, PTB and SIDS rates seem responsive to variations in the prevalence of other identifiable risk factors that are more common in certain minority populations, such as socio-economic and demographic factors, certain medical conditions, quality of, and access to, health care, and practices like placing babies on their backs to sleep. We can work toward addressing all of these issues and measure their impact on reducing the rates of infant deaths due to PTB and SIDS.

To further reduce our nation's IMR, we must focus on modifying the behaviors, lifestyles, and conditions that affect birth outcomes. These include smoking, substance abuse, poor nutrition, and other psychosocial problems such as domestic violence and abuse, lack of prenatal care, medical problems, and chronic illness. We need to pay special attention to how these factors differentially impact racial and ethnic minorities.

As DHHS continues its efforts to reduce IM and increase prenatal care through HRSA programs, the National Institute of Child Health and Human Development (NICHD) has also broadened its efforts to reduce SIDS. As part of the "Back To Sleep" campaign that encourages parents and caregivers to place children on their backs to prevent SIDS, NICHD distributed packages of "Back To Sleep" educational materials to all licensed day care centers in the United States, including many that serve black and Hispanic communities.

In conjunction with "SIDS Awareness Month" in October 1999, DHHS announced a new initiative to develop and implement a community-based approach to eliminate the disparity in SIDS rates impacting black babies. The new campaign is being led by NICHD, and will be carried out by a partnership with the National Black Child Development Institute, HRSA, the American Academy of Pediatrics, the SIDS Alliance, and the Association of SIDS and Infant Mortality Programs.

## CONCLUSION

In attempting to eliminate disparities among different sub-populations, the goals of each of these six health areas present very different challenges. In some areas, such as immunizations, we are cognizant of what will help to eliminate the disparities. In others, where knowledge about how to reduce these disparities is less developed, there is a need to understand the causes and to find more effective methods to reach individuals and communities that have not benefited from established interventions. Advances in medicine and increased access to care can only partially address the difficult, complex, and often controversial issues surrounding racial and ethnic disparities in health status. Education, environment, income, and other socioeconomic factors contribute substantially to health outcomes.

The DHHS has developed a formal Racial and Ethnic Initiative. Steps to advance this Initiative include publishing a state-by-state look at risks for chronic diseases and injury for the five major racial and ethnic groups, completed in March 2000. This work identifies wide disparities, even among members of the same racial and ethnic group living in different states. DHHS has also developed an informational World Wide Web site for the Initiative to be used by interested media and communities (<http://www.raceandhealth.hhs.gov>), and has organized internal workgroups, for each of the six areas, that are looking at existing programs at DHHS and making recommendations. As part of this program, data collection systems are being reviewed and recommendations are being made on how to improve data collection for racial and ethnic minorities.

The goals of the initiative to eliminate racial and ethnic disparities are consistent with the principles upon which the U.S. Public Health Service was founded in 1798. At that time, the City of Philadelphia had, only a few years earlier, suffered an epidemic of yellow fever, which killed 10% of the city's population and sent half of the population fleeing the city altogether. When it was learned that the epidemic was spread from merchant ships coming to Philadelphia from the West Indies, our founding fathers saw the value of providing a national hospital system to care for merchant seamen. And so we learned that to the extent we care for the most vulnerable populations, we do the most to protect the overall health of the nation. The goal of eliminating disparities in health care by 2010 is ambitious. Yet in the twenty-first century, neither history nor humanity can settle for less. The pursuit of these goals will result in a stronger, improved public health system that better responds to the needs of everyone.



### Site of Medical Care: Do Racial and Ethnic Differences Persist?

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Prior to the 1960s, Americans generally obtained health care in racially segregated facilities or from health providers of their own race or ethnicity. Racial, geographic, and economic factors influenced where minority Americans could get their health care. Minority Americans, who were disproportionately low income, relied on a combination of sources of care, such as public hospitals and private charity care, because they were unable to afford the cost of a private doctor. Even middle-income minority Americans largely relied upon racially segregated sources of care because these were the only options available to them.<sup>1</sup>

In the past four decades, substantial progress has been made in reducing differences in the major sources of health care used by whites and blacks, as well as other racial/ethnic minority groups. Nonetheless, striking racial/ethnic disparities in health care use and health outcomes persist. While these disparities are well documented,<sup>2</sup> factors underlying these differences are not well understood. The most frequently advanced explanations for current health care disparities focus on the characteristics of the patient (e.g., economic conditions or preferences) or the individual provider (e.g., competence or biases). However, it is conceivable that differences in the primary sources of care used by white patients and minority patients might explain some variations in the content of care. Structural or institutional factors—patient-provider relationships, referral

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§ The authors gratefully acknowledge funding support for this project from the Henry J. Kaiser Family Foundation and computer programming support from Ase Sewall of Sewall Inc.

networks, and the availability of resources such as highly trained staff and state-of-the-art technology—of varying sources of care may influence the care that patients obtain. Improving knowledge of the extent to which racial/ethnic differences persist in the site of medical care will inform future investigations of the causes of health care disparities.

This study, based on original research, examines whether the major sources of ambulatory medical care of whites, African Americans, and Latinos, given similar insurance coverage, differ substantially in the United States. The intent of the study is to assess whether, at the start of the twenty-first century, race/ethnicity continues to be a primary determinant of where medical care is obtained.

## I. BACKGROUND

African Americans and Latinos are the two largest racial/ethnic minority groups in the United States, accounting for nearly 25% of the U.S. population and representing about 84% of the minority population in 1999.<sup>3</sup> Today, they represent nearly equal shares of the U.S. population. While the two population groups differ in a number of respects, particularly in their diversity of ethnic origins and language, they share a commonality of experiences in the United States. Both populations reside largely in racially segregated neighborhoods and have poverty rates three times those of whites. Both have cultural beliefs and practices that sometimes conflict with western medicine and, thus, may result in a lack of confidence in the medical system. Both have faced a history of discriminatory policies and practices that have limited their health care access and compromised their trust in the health system. In addition, changes in federal policy and large demographic shifts in our nation's cities have had direct effects on the medical care that is available to both population groups.<sup>4</sup>

Improving access to "mainstream" medical care was an implicit, if not explicit, goal of Medicaid and Medicare, programs enacted in 1965 to expand health insurance coverage to low-income and elderly Americans.<sup>5</sup> Since providers were required to comply with the 1964 Civil Rights Act, these new programs had the direct effect of reducing financial barriers to care, as well as indirectly reducing racial barriers to care. Title VI of the Act prohibits discrimination by any facility receiving federal funds. Numerous studies have documented the important role of Medicaid and Medicare in reducing differentials in care between low-income and upper-income Americans across racial and ethnic groups.<sup>6</sup>

Concurrent with federal efforts to reduce financial barriers to care were initiatives designed to expand the supply of health care resources in

low-income communities. The Community and Migrant Health Centers Program and the National Health Service Corps were among the major initiatives of the “War on Poverty” that helped to expand the supply of health providers in medically underserved areas.<sup>7</sup> Not surprisingly, most medically underserved areas were in low-income neighborhoods, and many were also in racial/ethnic minority communities. Additionally, as a result of litigation in the 1960s that explicitly defined the “free care” obligation of hospitals built with federally provided construction funds, access to private hospital-based sources of care improved for those unable to pay.<sup>8</sup>

In the 1970s another demographic shift occurred that also had an impact on the health care system. Many of the inner-city hospitals found that their mostly white, middle class patient-base had moved to suburban communities and a large, low-income, mostly minority patient-base remained in inner city communities.<sup>9</sup> In addition, many private physicians were reluctant to establish practices in low-income communities, thus increasing the importance of urban hospitals as sources of outpatient care for the poor.<sup>10</sup>

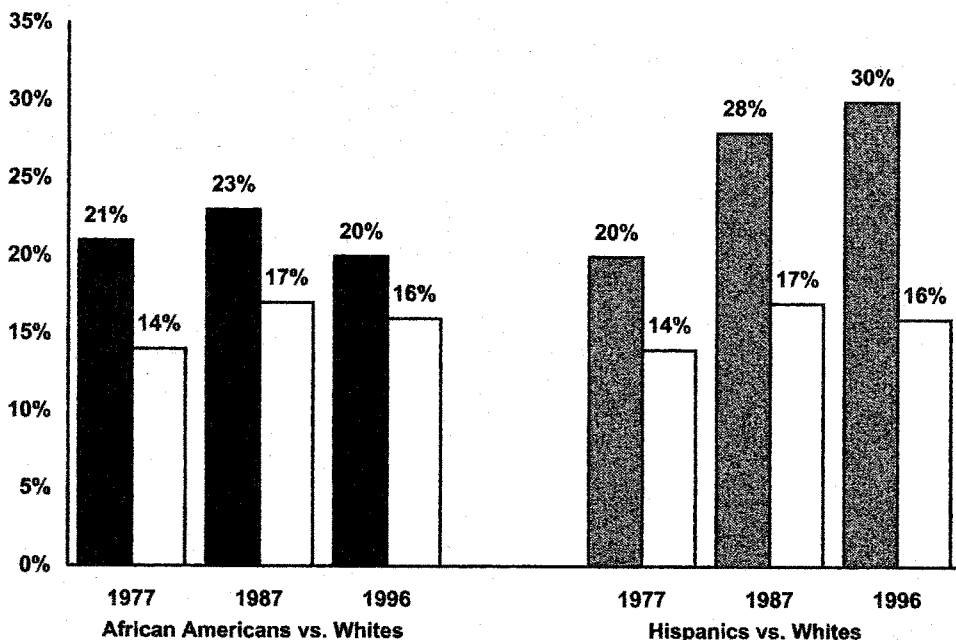
The rise of managed care in the late 1980s and throughout the 1990s produced another major shift in the health delivery system. Increasing health care costs were driving both public and private payers to search for alternatives to control the rate of growth in health spending and many believed that managed care was the solution. Reflecting national trends, nearly two-thirds of privately insured African Americans and Latinos were enrolled in a managed care plan by 1996.<sup>11</sup> Managed care enrollment among the publicly insured was slightly lower, but still approximately 45% of African Americans and 35% of Latinos covered by Medicaid were estimated to be enrolled in a managed care plan in 1996.<sup>12</sup> This shift to managed care likely increased the number of patients using private physicians rather than hospital-based providers and clinics for their care, particularly among the Medicaid population.

Health insurance, whether obtained through a managed care or fee-for-service plan, has become the primary means used to pay for medical care, and is an important determinant of an individual’s ability to obtain care.<sup>13</sup> Compared to those with coverage, the uninsured face greater obstacles to receiving care and to developing an ongoing relationship with a health provider. In addition, studies have found that type of insurance is a strong determinant of whether individuals have a usual source of medical care.<sup>14</sup> People who lack insurance are significantly less likely to have a usual source of care and are more likely to rely on institutional providers such as hospitals or clinics for their care than persons who are insured.

A recent study by Weinick et al. provides evidence that racial/ethnic

differences persist in the share of the population lacking a usual source of care.<sup>15</sup> In 1996, roughly 16% of whites compared to 20% of African Americans and 30% of Latinos report not having a usual source of medical care. Especially troubling is that the gap between Latinos and whites without a usual source of medical care widened between 1977 and 1996 (figure 1). For African Americans and whites, the gap remained about the same.<sup>16</sup>

**Figure 1. No Usual Sources of Medical Care, 1977 to 1996**



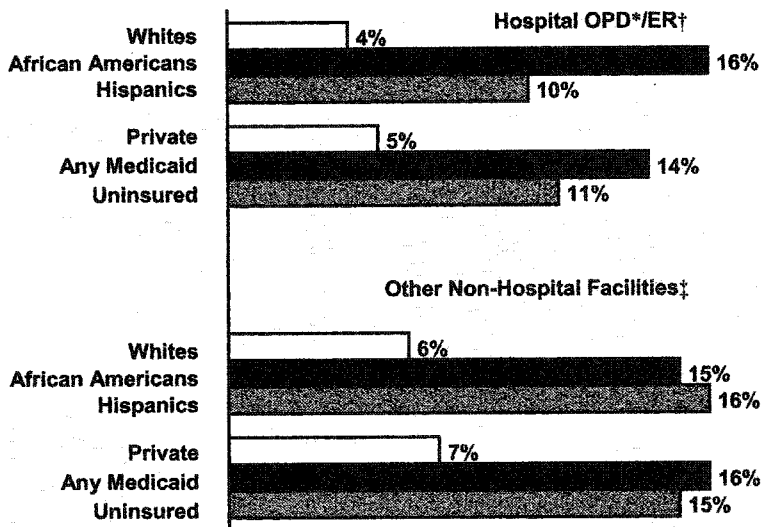
Data: NATIONAL MEDICAL CARE EXPENDITURE SURVEY 1977, NATIONAL MEDICAL EXPENDITURE SURVEY 1987, and MEDICAL EXPENDITURE PANEL SURVEY 1996.

Source: Robin M. Weinick et al., *Racial and Ethnic Differences in Access to and Use of Health Care Services*, 57 MED. CARE RES. & REV. 36, 42 (Supp. 1 2000).

Factors related to type of insurance also influence where care is obtained. For example, Medicaid beneficiaries, regardless of race, have faced challenges in accessing “mainstream” sources of care such as private sector office-based physicians. In 1993, for example, Medicaid payment rates for private sector office-based physicians were 73% of Medicare rates and about 47% of private rates.<sup>17</sup> Low payment rates, concerns about practicing in high-poverty areas, and bureaucratic hassles have been cited as major reasons for low participation in Medicaid among private physicians.<sup>18</sup>

While we do know that insurance affects where individuals go for care, very little is known about whether race/ethnicity has an effect, independent from insurance status, on the site of care. Cornelius et al. documented that insurance status and race/ethnicity are separately associated with the usual sources of medical care.<sup>19</sup> African Americans and Latinos were more likely than whites to use hospital outpatient departments (OPDs), community-based clinics, and emergency rooms (ERs) as regular sources of care in the 1980s. Also, the publicly insured and the uninsured were more likely than the privately insured to obtain care from these sources (figure 2). What was unknown was whether the findings by race were largely a function of differences in the health insurance coverage of the population groups.

**Figure 2. Site of Care: Findings from the 1980s by Race/Ethnicity and Insurance**



\* OPD: outpatient department; † ER: emergency room; ‡ Includes health centers, school clinics, and walk-in centers.

Data: NATIONAL MEDICAL EXPENDITURE SURVEY 1987.

Source: Llewellyn Cornelius et al., *Usual Sources of Medical Care and Their Characteristics*, in NATIONAL MEDICAL EXPENDITURE SURVEY (Agency for Health Care Policy and Research, U.S. Dep't Health & Human Serv. ed., 1991).

Given the role of insurance coverage today, a comparison of the major sources of medical care used by whites, African Americans, and Latinos, controlling for type of insurance, is a critical first step in understanding whether race is independently associated with where medical care is obtained. This is particularly important in light of the fact that minority Americans are more likely to be uninsured or covered by Medicaid than whites.<sup>20</sup> Thus, comparisons by race, unadjusted for differences in

insurance coverage or other population characteristics, such as age or income, can lead to a misinterpretation of the effects of race/ethnicity on the site of medical care.

## II. METHODS AND DATA

To assess whether race/ethnicity continues to be a factor associated with where an individual obtains medical care, data are examined using two indicators stratified by insurance coverage: 1) the proportion of people with no usual source of care, and 2) the proportion of people whose usual source of care was an office-based provider, a hospital clinic or an OPD, or a hospital ER. We examine the likelihood of having a hospital-based provider as a usual source of care using descriptive and logistic regression analysis. The analysis compares the sources of care of whites, African Americans, and Latinos under age sixty-five. Findings are examined separately for children under age eighteen and adults ages eighteen to sixty-four because these groups differ greatly in their health needs and health insurance coverage.

This study analyzes data from the 1996 Medical Expenditure Panel Survey (MEPS), the third in a series of surveys conducted by the Agency for Healthcare Research and Quality of the U.S. Department of Health and Human Services. The MEPS is a nationally representative survey that collects detailed information on the financing and use of medical care by individuals and families in the United States. Data are collected during multiple interview rounds. The MEPS full-year consolidated data file is used for this analysis. Detailed information on the survey is available.<sup>21</sup> The unweighted sample size for this analysis was 18,603 persons under age sixty-five. Estimates presented in this analysis are weighted to represent the non-institutionalized U.S. population. The statistical package SUDAAN (professional software for SURvey Data ANALysis) was used to obtain weighted population estimates and standard errors. This package calculates weighted estimates to correct for the complex multistage sampling design of the MEPS.

Information on the usual source of care of each family member is obtained from the Access to Care Supplement of the MEPS. The usual source of care is defined from a question that asks: Is there a particular doctor's office, clinic, health center, or other place that (PERSON) usually goes if he/she is sick or needs advice about his/her health? Any family member who has a particular person or place they usually go for care or advice is considered to have a usual source of care. Three categories of a usual source or site of care were created: 1) office-based provider; 2) hospital clinic or OPD; and 3) ER. The categories are self-explanatory

except office-based provider, which reflects the health care system's evolving assortment of financing and service delivery arrangements. Included within office-based providers are physicians in solo practice, physicians or other providers in larger group practices, health maintenance organizations or other types of managed care plans, as well as private and public community health clinics. MEPS, unlike its predecessor the National Medical Expenditure Survey (NMES), categorizes persons whose usual source of care is a community clinic or health center as having an "office-based" provider.

Respondents' races/ethnicities are based on self-reported information. Three mutually exclusive racial/ethnic categories were created: white, African American or black, and Latino or Hispanic. All persons of Hispanic origin, regardless of race, are classified as Latino or Hispanic. People reporting their racial/ethnic identity solely as Asian, American Indian, Alaska Native, or "other" are excluded from this analysis. This decision was made, in large part, because there are too few individuals in MEPS who identify themselves as Asian, American Indian/Alaska Native, or "other" for reliable population-specific estimates.

Insurance coverage, one of the major independent variables in this study, is defined based on a series of questions. Since family members can have health coverage from multiple sources, a hierarchical variable was created to define insurance coverage that gave priority to private coverage (employment-based or privately purchased) and then Medicaid. Individuals without private or Medicaid coverage were classified as uninsured. Individuals with "other sources of public coverage," such as CHAMPUS or Medicare, were excluded from the analysis. Their numbers in the sample were too small for meaningful interpretation of the patterns of care.

Separate logistic regression models for children and adults are used to assess the effects of race/ethnicity on the likelihood of having a hospital-based provider as a usual source of medical care. In addition, two other models are run for each age group. One model evaluates the effects of including persons who identify the ER as a usual source of care, and the other evaluates the effects of excluding this population. Although the ER is not an appropriate usual source of care, we included this population in one of the models since some respondents identify the ER as serving this purpose. Finally, we also tested an interaction term for race and insurance to assess whether the findings observed by race/ethnicity are consistent across all of the insurance categories.

## III. RESULTS

Consistent with national estimates, there are considerable racial/ethnic differences in the socio-demographic characteristics of African Americans, Latinos, and whites (table 1). Most notably, African Americans and Latinos are poorer than whites and a larger proportion are uninsured. Latinos have the highest uninsured rate among all racial and ethnic groups. Whites are more likely to be privately insured than African Americans or Latinos. African Americans are more likely to have Medicaid than Latinos or whites. Racial/ethnic differences in health coverage as well as differences in other factors are important to consider when comparing usual sources of care. For African Americans and Latinos, the sources of medical care of the publicly insured and uninsured are as important to examine as the sources of care of the privately insured. Moreover these

**Table 1. Study Population by Race/Ethnicity: Persons Under Age 65, 1996 (weighted estimates)\***

	All*	African Americans	Latinos	Whites
Total Population (numbers in millions)	218.7	28.6	25.9	154.2
<i>Gender</i>				
Female	50.6	53.2	49.6	50.2
Male	46.5	46.8	50.4	49.8
<i>Insurance Status</i>				
Private	70.4	51.9	43.9	78.3
Medicaid	10.5	23.9	20.0	6.4
Uninsured	19.1	24.2	36.1	15.3
<i>Family Income</i>				
Poor ( $\leq$ FPL)†	15.4	28.4	30.5	10.4
Near Poor (101-200 % FPL)†	17.6	24.8	25.0	14.9
Non Poor ( $>$ 200% FPL)†	74.7	46.8	44.6	74.7
<i>Health</i>				
Fair/Poor	7.9	11.6	10.6	6.7
Excellent/Good	92.1	88.4	89.4	93.3
<i>Region</i>				
South	35.1	54.6	31.4	32.1
West	21.2	9.0	45.7	19.3
Midwest	24.1	19.0	6.3	28.1
Northeast	19.6	17.3	16.6	20.5
<i>Metropolitan Statistical Area (MSA)</i>				
MSA	78.9	84.3	90.8	75.9
Non-MSA	24.7	15.7	9.2	24.1

\* Population estimates for "All" are based on the total sample under age sixty-five ( $n=18,603$ ) in the Access to Care Supplement and thus, include persons with missing data on race/ethnicity. The site of care analysis excluded persons with missing race/ethnicity data and also persons with sources of public coverage other than Medicaid. The percents are based on this population ( $n=17,578$ ) and may not sum to 100% due to rounding.

† FPL: federal poverty level.

Data: MEDICAL EXPENDITURE PANEL SURVEY 1996.



differences in health coverage highlight the importance of making racial comparisons among similarly insured population groups.

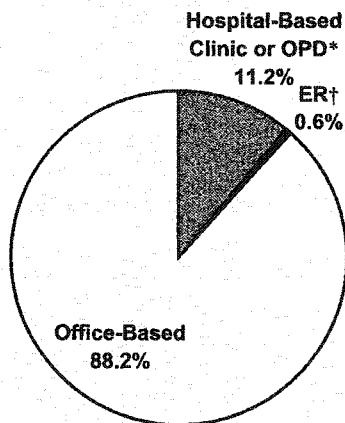
#### *A. No Usual Source of Care*

On average, the vast majority of white, African-American, and Latino children and adults have a usual source of medical care. However, a sizable share of the population, 18.5%, lack a usual source of medical care. Applying this percentage to the non-elderly population in 1996 yields approximately 40.4 million people without a usual source of medical care. The uninsured, regardless of race/ethnicity, are more likely to lack a usual source of care than persons with private coverage or Medicaid. However, striking racial/ethnic differences even exist among persons with similar insurance coverage. This analysis focuses on the site of care for individuals who identify a usual source of medical care.

#### *B. Use of a Particular Site of Care*

Among persons with a usual source of care, office-based providers (generally physicians) are clearly an important source of care, regardless of race/ethnicity and health coverage. Analysis of the MEPS data shows that office-based providers are the usual source of care for most (88.2%) persons under age sixty-five (figure 3). Only 11.2% of respondents under age sixty-five identify a hospital-based clinic or OPD as a usual source of care, and less than 1% (0.6%) identify an ER as a usual source of care.

**Figure 3. Site of Care for Persons With a Usual Source of Care, Persons Under Age 65, 1996.**



\* OPD: outpatient department; † ER: emergency room.  
Data: MEDICAL EXPENDITURE PANEL SURVEY 1996.

Despite the perception that ERs are widely misused by minority Americans, only a small fraction of respondents identify the ER as their usual source of care. Racial differences are observed when examining the usual sources of medical care for children and adults.

Health insurance does not appear to be a major factor affecting the use of an office-based provider as a usual source of care by white children, but it does appear to play a role for African-American and Latino children (table 2). About 90% of white children who are either covered by Medicaid or private insurance, or who are uninsured, have an office-based provider as a usual source of care. African-American and Latino children with private coverage report the use of an office-based provider at rates similar

**Table 2. Site of Usual Source of Care by Insurance and Race/Ethnicity, Children 0-17, 1996**

	Office-Based Provider % (SE)*	Hospital Clinic or OPD† % (SE)*	ER‡ % (SE)*
<i>Private Health Insurance</i>			
White	93.6 (0.8)	6.3 (0.8)	0.1 (0.1)
African American	89.5 (2.3)	10.1 (2.2)	0.4 (0.4)
Latino	85.9 (2.4)	13.7 (2.4)	0.4 (0.3)
<i>Medicaid</i>			
White	90.1 (2.3)	9.9 (2.3)	0.0 (0.0)
African American	74.6 (3.8)	22.8 (3.7)	2.7 (1.8)
Latino	80.3 (3.2)	18.8 (3.1)	0.9 (0.6)
<i>Uninsured</i>			
White	90.8 (2.3)	8.3 (2.1)	0.9 (0.6)
African American	73.7 (6.1)	24.1 (6.2)	2.2 (1.9)
Latino	81.6 (3.2)	17.2 (3.1)	1.2 (0.8)

\* Standard error (SE) is given in parentheses; † OPD: outpatient department; ‡ ER: emergency room.

Data: MEDICAL EXPENDITURE PANEL SURVEY 1996.

to those of white children. However, minority children who are covered by Medicaid or who are uninsured are far more reliant on a hospital clinic or OPD as a usual source of care than are white children. Among Medicaid beneficiaries, more than twice as many African-American children (22.8%) as white children (9.9%) use a hospital-based provider as their usual source of care. Similarly, almost twice as many Latino children (18.8%) as white children rely on a hospital-based provider. As for the uninsured, African-American (24.1%) and Latino (17.2%) children are at least twice as likely as their white counterparts (8.3%) to use a hospital-based clinic or OPD as their usual source of care.

Findings on the usual sources of medical care of adults parallel those of children (table 3). Racial/ethnic differences are largest among adults enrolled in Medicaid and among the uninsured. A hospital-based clinic or OPD is the usual source of care for approximately twice as many African-American (29%) and Latino (25%) adults with Medicaid as their white

**Table 3. Site of Usual Source of Care by Insurance and Race/Ethnicity, Adults 18-64, 1996**

	Office-Based Provider % (SE)*	Hospital Clinic or OPD† % (SE)*	ER‡ % (SE)*
<i>Private Health Insurance</i>			
White	91.5 (0.7)	8.3 (0.7)	0.1 (0.0)
African American	85.6 (1.9)	13.7 (1.8)	0.7 (0.4)
Latino	84.1 (1.9)	15.4 (1.9)	0.5 (0.3)
<i>Medicaid</i>			
White	85.7 (2.5)	12.5 (2.3)	1.8 (0.9)
African American	68.6 (3.7)	29.0 (3.6)	2.3 (1.1)
Latino	74.2 (3.7)	25.0 (3.7)	0.8 (0.6)
<i>Uninsured</i>			
White	86.7 (1.7)	11.2 (1.5)	2.1 (0.7)
African American	72.7 (3.7)	23.7 (2.9)	3.6 (1.8)
Latino	78.8 (3.3)	20.1 (3.2)	1.1 (0.6)

\* Standard error (SE) is given in parentheses; † OPD: outpatient department; ‡ ER: emergency room.  
Data: MEDICAL EXPENDITURE PANEL SURVEY 1996.

counterparts (12.5%). Similar findings are observed for the uninsured, with uninsured African Americans and Latinos being nearly twice as likely to obtain care from a hospital clinic or OPD as whites. Also, the percentages who identify an ER as a usual source of care are small and are not statistically different by race/ethnicity.

### *C. Multivariate Analysis*

When holding measures of socio-demographic and health status constant, race/ethnicity persists as a factor significantly and strongly associated with the use of a hospital-based provider as a usual source of medical care. Findings are strikingly similar for children and adults (tables 4 and 5), and excluding those who identify the ER as a usual source of care does not appreciably change these results.

African Americans and Latinos, regardless of insurance coverage, are more likely than whites to have a hospital-based provider as a usual source of medical care. For example, African-American children are 2.5 times as likely as their white counterparts, and Latino children are twice as likely as their white counterparts, to have a usual source of medical care that is not an office-based provider. The racial differential persists for adults as well, although the effect is modestly diminished. The lack of a statistically significant interaction term for race and insurance coverage provides evidence that these findings consistently apply across racial/ethnic groups and insurance categories. Thus, privately insured African Americans and Latinos are more likely than their privately insured white counterparts to use hospital-based providers as a usual source of medical care. Similarly, African Americans and Latinos with Medicaid are more likely than their

**Table 4. Likelihood (Relative Odds) That Usual Source of Care is a Hospital-Based Provider: Children 0-17**

<b>Selected Characteristics</b>	<b>Model 1 Hospital OPD*, Clinic, ER† (95% CI)‡</b>	<b>Model 2 Hospital OPD*, Clinic (95% CI)‡</b>
<i>Race/Ethnicity</i>		
African American	2.55 (1.70-3.84)§	2.50 (1.63-3.82)§
Latino	1.97 (1.39-2.81)§	1.99 (1.38-2.86)§
White	1.00	1.00
<i>Age</i>		
0-12	0.88 (0.69-1.14)	0.87 (0.67-1.13)
13-17	1.00	1.00
<i>Gender</i>		
Female	0.91 (0.73-1.13)	0.90 (0.72-1.13)
Male	1.00	1.00
<i>Family Income</i>		
Poor (≤ FPL)**	1.31 (0.85-2.02)	1.30 (0.83-2.03)
Near Poor (101-200% FPL)**	1.33 (0.90-1.97)	1.23 (0.99-2.26)
Non Poor (≥ 201% FPL)**	1.00	1.00
<i>Health</i>		
Fair/Poor	1.44 (0.90-2.28)	1.48 (0.93-2.36)
Good/Excellent	1.00	1.00
<i>Insurance Coverage</i>		
Medicaid	1.55 (0.98-2.46)	1.51 (0.93-2.44)
Uninsured	1.56 (1.05-2.33)§	1.50 (0.99-2.26)
Private	1.00	1.00
<i>Region</i>		
South	0.83 (0.51-1.33)	0.74 (0.45-1.22)
West	1.32 (0.91-1.91)	1.28 (0.88-1.87)
Northwest	1.15 (0.78-1.70)	1.13 (0.76-1.68)
Northeast	1.00	1.00
<i>Metropolitan Statistical Area</i>		
MSA	0.92 (0.61-1.39)	0.94 (0.62-1.42)
Non-MSA	1.00	1.00

\* OPD: outpatient department; † ER: emergency room; ‡ 95% confidence intervals (95% CI) are given in parentheses; §  $p < 0.05$ ; \*\* FPL: Federal Poverty Level.

Data: MEDICAL EXPENDITURE PANEL SURVEY 1996.

white counterparts with Medicaid to use hospital-based providers as a usual source of medical care.

Insurance status is also associated with where medical care is obtained. Uninsured children are roughly 1.5 times as likely as privately insured children to use a hospital-based provider as a usual source of care. Similarly, uninsured adults are at least 1.4 times as likely as privately insured adults to use a hospital-based provider as a usual source of care. There is some indication that Medicaid beneficiaries and the privately insured, other factors being equal, do not differ substantially in their major sources of health care. In other words, when comparing individuals, for example, of similar race/ethnicity or health status, those with Medicaid

**Table 5. Likelihood (Relative Odds) That Usual Source of Care is a Hospital-Based Provider: Adults 18-64**

<b>Selected Characteristics</b>	<b>Model 1 Hospital OPD*, Clinic, ER† (95% CI)‡</b>	<b>Model 2 Hospital OPD*, Clinic (95% CI)‡</b>
<i>Race/Ethnicity</i>		
African American	2.34 (1.79-3.06)§	2.35 (1.80-3.07)§
Latino	1.81 (1.36-2.41)§	1.89 (1.42-2.52)§
White	1.00	1.00
<i>Age</i>		
18-29	0.94 (0.77-1.14)	0.93 (0.77-1.13)
30-64	1.00	1.00
<i>Gender</i>		
Female	0.94 (0.83-1.05)	0.95 (0.84-1.07)
Male	1.00	1.00
<i>Family Income</i>		
Poor (≤ FPL)**	1.72 (1.24-2.38)§	1.59 (1.14-2.21)§
Near Poor (101-200% FPL)**	1.24 (0.96-1.62)	1.17 (0.88-1.55)
Non Poor (≥ 201% FPL)**	1.00	1.00
<i>Health</i>		
Fair/Poor	1.14 (0.89-1.47)	1.14 (0.89-1.46)
Good/Excellent	1.00	1.00
<i>Insurance Coverage</i>		
Medicaid	1.40 (1.00-1.97)	1.37 (0.97-1.93)
Uninsured	1.50 (1.20-1.87)§	1.37 (1.09-1.73)
Private	1.00	1.00
<i>Region</i>		
South	1.08 (0.76-1.54)	1.04 (0.73-1.50)
West	2.09 (1.50-2.92)§	2.11 (1.51-2.94)§
Northwest	1.81 (1.27-2.57)§	1.85 (1.30-2.64)§
Northeast	1.00	1.00
<i>Metropolitan Statistical Area</i>		
MSA	1.07 (0.71-1.62)	1.07 (0.70-1.64)
Non-MSA	1.00	1.00

\* OPD: outpatient department; † ER: emergency room; ‡ 95% confidence intervals (95% CI) are given in parentheses; §  $p < 0.05$ ; \*\* FPL: Federal Poverty Level.

Data: MEDICAL EXPENDITURE PANEL SURVEY 1996.

and private coverage do not statistically differ in the likelihood of having a hospital-based provider as their usual source of care.

Finally, the regression results show that two factors, in addition to race and insurance, are associated with where adults obtain health care (table 5). Family income and geographic region also are related to the usual source of care for adults. Adults with family incomes at or below the federal poverty level are more likely to use a hospital-based clinic as a usual source of care than non-poor adults. Also, adults living in the West and Midwest are more likely than adults in the Northeast to use a hospital-based provider as a usual source of care.

## IV. DISCUSSION

This study examines the progress achieved in reducing the racial divides in one of many possible indicators of health care access—the site of medical care. The study provides evidence that the vast majority of Americans, regardless of race/ethnicity, currently identify an office-based setting as a regular source of care. Moreover, only a small fraction of Americans rely on a hospital ER as a regular source of care. However, African Americans and Latinos, regardless of insurance status, continue to be far more reliant than whites on what some consider to be “non-mainstream” sources of care, with African Americans and Latinos being about twice as likely as whites to rely on a hospital-based provider as a regular source of care. The uninsured also were more likely than the insured to rely on a hospital-based provider as a regular source of care.

While the finding regarding the uninsured is consistent with other research,<sup>22</sup> the continuing role of race/ethnicity as a factor associated with where an individual obtains health care was a less predictable finding. Studies in the 1980s had shown that minority Americans were more likely to use community or hospital-based clinics, but these studies left unanswered whether utilization patterns were a function of racial/ethnic differences in insurance coverage or income. This study provides strong evidence that race—independent of insurance coverage and income—continues to be associated with where ambulatory health care is obtained. The study findings counter the perception that whites, African Americans, and Latinos obtain health care from the same types of providers. While that fact is true for the vast majority of the population, there is a sizable subset of African Americans and Latinos who show a pattern of accessing the health care system that is different from the patterns observed in most Americans.

These findings are consistent with those of a recent study by Gaskin, which examines use patterns of inpatient hospital care.<sup>23</sup> Analyzing 1994 hospital discharge data from nine states, Gaskin found that residents of racial and ethnic minority neighborhoods were more likely than the general population to use public hospitals and major teaching hospitals.<sup>24</sup> Taken together, the findings provide evidence that racial/ethnic background continues to shape choices regarding the site of medical care. It also is conceivable that the findings may understate racial differences in the sites of medical care since respondents who identify community health clinics (private or public) as a regular source of care are defined as having an office-based provider.

As previously noted, structural or institutional factors of varying settings of care may affect the content of care. These factors may explain some of the racial/ethnic differentials in care that have been observed. Research has shown that the organizational setting of care can affect the cost, quality, and patient satisfaction associated with care.<sup>25</sup> Other factors, however, such as an individual's health and social needs, should also be considered in evaluating the content and appropriateness of care provided by a health care setting. A physician's office, for example, may be more conducive to a satisfying doctor-patient relationship but less convenient for some diagnostic tests. A hospital-based outpatient clinic might provide more technically sophisticated care than a physician's office but may have less potential for the development of a strong provider-patient relationship. Questions about differences in the quality of care in various settings, including various types of office-based settings, deserve to be systematically explored in future research and the findings included in the dialogue on possible factors contributing to racial/ethnic differences in health care.

This study raises a number of other issues for further investigation. Perhaps most important among these issues is the question of what factors explain the effect that race/ethnicity continues to have on where an individual obtains health care. Race/ethnicity might be a proxy for any number of factors such as the availability of private physicians in minority communities, patterns of residential segregation, or financial barriers such as co-payment requirements. It also might reflect preferences of patients for the flexible hours or other conveniences of hospital-based sources of care, a possibility consistent with the findings of a study that compared the characteristics of regular users of hospital OPDs and regular users of private physicians.<sup>26</sup> The findings also might reflect historical patterns of utilization or choices made by patients because some sources of care may be perceived as more welcoming or culturally competent. These two factors may be linked since an individual may initially choose a source of care based on family tradition, but is unlikely to remain with that source of care solely for that reason. In sum, the finding could reflect barriers to care, patient preferences, or, of course, some combination of these factors.

The finding that race/ethnicity continues to exert strong influences on where individuals receive health care raises a multitude of questions. Further work is needed to explore the incentives and disincentives for obtaining care from different sites. It also will be important to assess whether there are systematic differences among the different sites in the content of care or the patient-provider relationship (e.g., communications

and trust), and whether these differences have implications for the health care outcomes of African Americans and Latinos.



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# The Meanings of “Race” in the New Genomics: Implications for Health Disparities Research

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*The challenge is then to analyze the causes of racism while avoiding the implication that race exists.*

—Steven Miles, 1993

*A foolish consistency is the hobgoblin of little minds, adored by little statesmen and philosophers and divines.*

—Ralph Waldo Emerson, “Self-Reliance,” 1841

Eliminating the well-documented health disparities found within the United States population is a laudable public policy goal. Social justice demands that we understand the sources of health inequality in order to eliminate them. A central dilemma is: To what extent are health disparities the result of unequal distribution of resources, and thus a consequence of varied socioeconomic status (or blatant racism), and to what extent are

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§ The authors gratefully acknowledge the financial support of The Greenwall Foundation, SmithKline Beecham Corporation, the Department of Energy (Ethical, Legal, and Social Implications [ELSI] Program), and the National Human Genome Research Institute (ELSI Program). Thomas Denberg generously provided comments on an earlier draft of the manuscript. Lorraine Caron, Sara Tobin, and LaVera Crawley from the Stanford Center for Biomedical Ethics also reviewed sections of the manuscript and offered helpful advice. Finally we wish to thank the editors of the *Yale Journal of Health Policy, Law, and Ethics* for their invitation to participate in a stimulating conference launching the new *Journal*, and for their patience and careful editorial assistance.

inequities in health status the result of inherent characteristics of individuals defined as ethnically or racially different? How we conceptualize and talk about race when we ask these questions has profound moral consequences.

Prior to the Human Genome Project (HGP), scientific efforts to understand the nature of biological differences were unsophisticated. The new technologies for genomic analysis will likely transform our thinking about human disease and difference, offering the promise of in-depth studies of disease incidence and its variations across human populations. In her opening remarks at a meeting of the President's Cancer Panel, which focused on health disparities in cancer treatment in the United States, Dr. Karen Antman noted that racial differences in cancer rates have been reported for decades, "but for the first time, science now has the opportunity to quantify such differences genetically."<sup>1</sup> Will the light refracted through the prism of genomic knowledge illuminate straightforward explanations of disease etiology, offering simple solutions to health inequalities? Or are there consequences, currently hidden in the shadows, that require our attention?

Protesting that their genes are being singled out as "mutant," individuals of Ashkenazi Jewish descent fear being targeted for genetic testing for breast cancer.<sup>2</sup> They ask, might not targeted testing lead ultimately to stigmatization and discrimination? The genetic variation in question, BRCA-1, is believed to be more prevalent among Ashkenazi Jewish women and has resulted in the identification of this population as "high risk." Researchers report that the frequency of BRCA-1 mutations in the general population is 1 in 1666,<sup>3</sup> compared to 1 in 107<sup>4</sup> among Jewish women of Eastern European origin. No one has a definitive explanation for this higher incidence among Ashkenazi Jewish women, although geneticists hypothesize a "founder's effect." Discord among Jewish groups has become pronounced, as the benefits and risks associated with targeted genetic testing and research are considered. While many scientists of Ashkenazi Jewish descent have supported testing as critical to the prevention and treatment of unsuspecting women who carry the breast cancer gene mutations, others, fearful of the potential harm of stigmatization, have discouraged participation. The issue is further complicated by the fact that breast cancer can neither be definitively cured, even if diagnosed early, nor prevented with certainty, although drastic measures, such as surgical removal of the breasts, are possible.

Increasing ability to detect genetic mutations linked to disease susceptibility has not been paralleled by therapeutic discoveries. This disjuncture has contributed to the conflict about population-based testing

and disagreement about the calculus of the largely unknown risks and benefits to individuals and populations. Knowing one has a BRCA mutation does not mean that one will ultimately develop cancer. Individuals must interpret complex, uncertain information to make sense of their cancer risk, and are often confused as to how to make sense of genetic information. The additional burden of contemplating the ramifications of targeted testing of their community, including the possibility of categorical discrimination and prejudice, is a daunting challenge. The mutations found most commonly among those of Ashkenazi ancestry were identified by chance. Blood stored for other purposes, notably screening for Tay Sachs, a heritable disease, was available for research. Other mutations in the BRCA-1 and BRCA-2 genes are specific to certain groups, generally isolated populations such as those in Iceland or Finland. How will knowledge that common diseases are associated with socially identifiable populations affect the treatment of those individuals? But more importantly, how will an increasingly sophisticated knowledge of molecular genetics affect our understanding of the nature of "difference" among human groups?

The discovery of genetic mutations associated with breast cancer has been heralded as one of the initial, and most dramatic successes of the HGP.<sup>5</sup> For the first time a common adult onset disorder was linked with a genetic abnormality. Ironically, this discovery also reveals a potentially dangerous, although unintended, consequence of genomic technology—the association of disease with an identifiable human population, in this instance, Ashkenazi Jews. Unfortunately, the lessons of history provide strong evidence that scientific research on the relationship of "race" to disease may have negative outcomes, in spite of good intentions. Sickle cell anemia provides the best-studied example. Indeed, it was the first "racialized" disease.<sup>6</sup> The association of sickle cell anemia with the black "race" was complete, a one-to-one correspondence; it took decades to recognize that the illness was not a marker of race. Treatment initiatives, in particular mandated screening programs, reflected existing social bias and prejudice.<sup>7</sup> Given the consequences of twentieth century Nazi racial science, individuals of Ashkenazi descent have particular reason to fear the notion that they are somehow biologically distinct. As we discuss in detail below, there is widespread agreement that *Homo sapiens* consist of a single population; that biologically distinct races do not exist. Will the tools of the new genomics, allowing us to map biological variation precisely, reinforce the idea that the human population can be divided into discrete biological entities? What policies might avert this end?

## I. MEDICINE THROUGH A GENOMIC PRISM

Recent announcements celebrating the completion of the full sequencing of the human genome trumpeted the emergence of a “new genomic medicine.”<sup>8</sup> Having the full human gene sequence available will quicken the pace of genetic discovery, and many believe it will transform all domains of medicine, including our understanding of the etiology of illness (and the meaning of health), disease prevention, diagnostics, treatment, and the development of targeted drugs, through the emergence of pharmacogenomics.<sup>9</sup> Indeed, for the foreseeable future, our scientific investigations—and basic understanding—of disease and illness will be conducted within a genomic paradigm.

The high-throughput genetic technologies now available, including high-speed sequencing machines and micro-array technologies, allow scientists to correlate specific genetic mutations with disease (or other “traits”) much faster than in the past. We believe that the advent of genomic medicine has coincided with a resurrection of a genetic epistemology of difference among human groups that is predicated on the existence of “race,” through which populations are conceptualized as having inherent, immutable biological differences. Three social and scientific trends have refocused attention on the meaning and significance of difference at the level of biology.

The first is the U.S. government’s health disparities initiative—the national public health goal of eliminating health inequality among racially and ethnically identified populations by the year 2010.<sup>10</sup> The second is the recent announcement of the earlier than anticipated completion of the HGP. This joint public and private effort has produced expectations that gene-sequencing research will lead to important discoveries, such as solutions for diabetes, cancer, and other major diseases. It has also created a paradox. Public announcements of the genome have highlighted the news that human beings from throughout the world share a virtually identical genome; proclamations about the mapping and sequencing of the genome included conspicuous attention to the fact that human beings share 99.9% of their DNA.<sup>11</sup> The cover of *Science*, announcing the completion of the HGP, included an array of human faces of all ages— young and old—and individuals of varying phenotypes: African, Asian, etc. Hence the paradox. Although the political message of the unity of the human species was highlighted, the third force contributing to the salience of race in genomic medicine is the increasing body of genetic research focused on variation among populations. Although the vast majority of the human population shares the same genes, it is the minute differences

between individuals and among groups that researchers focus on as they seek to explain the incidence and severity of disease at the molecular level, through the examination of single nucleotide polymorphisms, or SNPs.

In light of these trends, it is of critical importance to examine the deployment of the race concept in health disparities research as the tools of the new genomic medicine come into widespread use. Increased funding for health-related genomics research, including the creation of new DNA repositories to serve as resources for genetic analyses, presents an opportunity to consider how existing understandings of racial and ethnic difference might shape the trajectory of research and the form of health care policies. We approach the issues from the broad disciplinary perspective of anthropology, including anthropological genetics, cultural anthropology, and medical anthropology.

In this paper we provide a strong critique of the continued use of race as a legitimate scientific variable. We offer an historical analysis of how the concept of race has changed in the United States and discuss the reification of race in health research. We discuss how genetic technology has been deployed in “proving” racial identity, and describe the consequences of locating human identity in the genes. The implications of the continued use of race in the new genomic medicine—in particular the creation of racialized diseases—is highlighted. We warn about the consequences of a shift toward population-based care, including targeted genetic screening for racially identified “at-risk” groups, including the potential for stigmatization and discrimination. A less commonly identified hazard is the epistemological turn towards genetic reductionism. We suggest that the application of a naïve genetic determinism will not only reinforce the idea that discrete human races exist, but will divert attention from the complex environmental, behavioral, and social factors contributing to an excess burden of illness among certain segments of the diverse U.S. population. The intersection of the genomics revolution with the health disparities initiative should serve as a catalyst to a long overdue public policy debate about the appropriate use of the race concept in biomedical research and clinical practice.

## II. INTERROGATING THE CONCEPT OF “RACE”

Why have we enclosed race in “scare quotes?” The power of race, or racial thinking, is derived from the supposition that race is biological and hence, immutable—inextricable from the essential character of individuals. Historically, race has been identified through physiological characteristics such as skull size, skin color, facial features, and other qualities readily available for scrutiny by the passing observer. The first

classificatory system dividing human beings into distinct races is credited to French naturalist Georges-Louis Leclerc (Comte de Buffon) in 1749.<sup>12</sup> Slightly later, in the eighteenth century, botanist Carolus Linnaeus identified four racial groups: *americanus*, *asiaticus*, *africanus*, and *europaeus*.

**Racial Classification of *Homo Sapiens*, Carolus Linnaeus *Systema Naturae*, 1758**

***Americanus rubescus* (Americans red)**—reddish, obstinate, and regulated by custom

***Europaeus albus* (Europeans white)**—white, gentle, and governed by law

***Asiaticus luridus* (Asians yellow)**—sallow, severe, and ruled by opinion

***Afer niger* (Africans black)**—black, crafty, and governed by caprice

His classificatory scheme is an amalgam of physical features and behavioral traits that reflect the social attitudes and political relations of the times, although presented in seemingly neutral, scientific terms. These racial distinctions arrange groups in a hierarchical fashion that reflect particular social values. This results in an ideology of race that is used to explain, predict, and control social behavior. Historians point out that the concept of immutable, biologically based human races developed in concert with western exploration and colonialism, providing a scientific justification for economic exploitation and practices such as slavery.<sup>13</sup> Prior to that time, the idea of distinct human sub-species whose differences were attributed to biology did not exist. The Greek term “barbarian,” for example, reflects a hierarchical ranking according to one’s closeness to civilization, and particularly to language, not a biologically based scheme.

When considering the relationship of “race” to health, one needs to pay attention to the conceptual underpinnings of race and racial thinking, not simply the terminology used. Other deployments of racial concepts elide social, behavioral, and environmental factors that contribute to the onset of disease. The conceptual problem—conflating biology with group identity—is not solved simply by a change in vocabulary. Emerging historically in response to the anthropological critique of race and racial thinking, the concept of “ethnicity” emphasizes the cultural, socioeconomic, religious, and political qualities of human groups, including language, diet, dress, customs, kinship systems, and historical or territorial identity.<sup>14</sup> In contrast to race, ethnicity has been conceptualized as socially articulated, reflecting common political interests and perspectives of individuals.<sup>15</sup> However, the appropriation of ethnicity in



health research often belies this distinction. Ethnicity, as well as "culture," has been used as a surrogate for biological difference in epidemiological and health services research. We argue that this confusion in terminology is potentially dangerous and requires serious attention. How we define difference has moral consequences.

A recent edition of *Webster's Medical Dictionary* defines race as, "a division of mankind possessing traits that are transmissible by descent and sufficient to characterize it as a distinct human type."<sup>16</sup> This usage of the term race reflects an outmoded concept that attempts to convey biological difference among human population groups as the defining feature of seemingly distinct human sub-populations. The definition is unfortunately characteristic of the careless approach to definition found within much of biomedical discourse and writing. A definition found in a key dictionary of epidemiology reflects a similar bias, defining race as "...persons who are relatively homogenous with respect to biological inheritance (see also ethnic group)."<sup>17</sup> By contrast, the fields of physical or biological anthropology and population genetics have long held that the idea that distinct human races exist is scientifically incorrect, as well as harmful.

The widely accepted consensus among evolutionary biologists and genetic anthropologists is that biologically identifiable human races do not exist; *Homo sapiens* constitute a single species, and have been so since their evolution in Africa and throughout their migration around the world.<sup>18</sup> Population genetics provides the best evidence for this conclusion: The genetic variation within a socially recognized human population is greater than the genetic variation between population groups.

In evolutionary biology the idea of race, although rarely used because of its fundamental ambiguity, is considered a synonym for subspecies. The term subspecies refers to a geographically circumscribed, genetically differentiated population. As Alan Templeton describes in a recent review in the *American Anthropologist*:

Genetic surveys and the analyses of DNA haplotype trees show that human 'races' are not distinct lineages, and that this is not due to recent admixture; human "races" are not and never were "pure." Instead, human evolution has been and is characterized by many locally differentiated populations coexisting at any given time, but with sufficient genetic contact to make all of humanity a single lineage sharing a common evolutionary fate.<sup>19</sup>

Of course this does not mean that human populations long exposed to climatic variation or geographic isolation have not acquired health-related biological differences. Clearly such features exist, generally the result of

random events, such as genetic drift or population bottlenecks. The point is that meaningful genetic and biological differences do not always map clearly onto social categories of human difference, whether defined as race, ethnicity, or culture. Population geneticists use the concept of “clinal variation”—which specifies deviation across a geographic gradient—when analyzing meaningful sub-divisions of *Homo sapiens*. Sometimes genetically meaningful population differences correlate with social categories of difference; the populations of Iceland and parts of Finland provide examples. However, in a population as diverse as the United States this is often not the case. The political categories of difference used in much health research, for example “Hispanic,” are biologically and genetically meaningless.

Before proceeding, we need to make one point clear. Arguing against the legitimacy of race as a category in biomedical research is not meant to suggest that the social category of race is not real, or that race as a key dimension of stratified societies does not exist. On the contrary, racial divisions have been a defining feature; some would say the defining feature, of U.S. history. Race is socially, not biologically, meaningful; it is “real” because we have acted as if certain people, at certain points in time, were inferior based on innate or “essentialized” characteristics.

Our preferred language when discussing human populations that have been categorized by race is to describe them as “racialized” groups. Although we use words like race and ethnicity in this paper, in general we prefer to use the race concept as an adjective rather than a noun. This terminology allows us to grant legitimacy to the social aspects of race while at the same time calling into question the idea that distinct human races exist. It also recognizes that who is defined as racially and ethnically different changes over time, a point to which we return below.

Terminology matters. We will argue against using race as a biological category in health research. However, we do not deny that health status varies among U.S. racialized populations. Genetic and biological differences should be studied directly, not through the distorting lens of a previous era’s racial thinking. There may, however, be one exception in health disparities research. Studies of the health effects of racism *per se* may be one arena where using traditional political categories of race is justified.<sup>20</sup>

### III. ELIMINATION OF HEALTH DISPARITIES AS A NATIONAL PRIORITY

The National Institutes of Health (NIH), following the political leadership of the Surgeon General David Satcher, published the nation’s blueprint for improved health in *Healthy People 2010*.<sup>21</sup> A main objective of

the plan is the elimination of glaring health disparities among segments of the population, particularly those identified as members of minority racial and/or ethnic groups. The report states that current information about the biological and genetic characteristics of African Americans, Hispanics, American Indians, Alaska Natives, Asians, Native Hawaiians, and Pacific Islanders does not explain the health disparities experienced by these groups compared with the white, non-Hispanic population in the United States. Although *Healthy People 2010* posits that these disparities are the result of complex interactions among genetic variation, environmental factors, and specific health behaviors, nonetheless, the categories of difference used to define the U.S. population are primarily racial categories—as opposed to other measures such as socioeconomic status, environment, or behavior.

Leaving aside for a moment the question of terminology, the statistics included in the report are alarming. Death rates due to heart disease and all cancers are more than 40% and 30% higher, respectively, for African Americans than for whites; for prostate cancer, it is more than double that for whites. African-American women have a higher death rate from breast cancer despite having a mammography-screening rate that is nearly the same as the rate for women identified as white. Hispanics living in the United States are almost twice as likely to die from diabetes than are non-Hispanic whites. Hispanics also have higher rates of high blood pressure and obesity than non-Hispanic whites. African Americans, American Indians, and Alaska Natives have an infant mortality rate almost double that for whites.

Asians and Pacific Islanders, on average, are reported as being one of the healthiest population groups in the United States. However, when this broad census category is divided into its many sub-populations, disparities for specific groups are quite marked. Women of Vietnamese origin, for example, suffer from cervical cancer at nearly five times the rate of white women. The case of Asian Americans, as with other groups, reflects the multiple terms, such as race, ethnicity, and national origin, used to describe American populations. Although unclear, it appears that Asian and Pacific Islanders are being treated as a single racial group. What remains consistent, however, is a comparison to an implicit category of "whiteness," that while tacitly evoked in each comparison, is left largely undefined. In addition, the nature of the relationship between racialized identity and disease is left unexplained. Categorizing individuals according to race labels, which are then associated with incidence of disease, conflates many complex factors that might contribute to disease in a population.

As with other government agencies, the NIH makes use of the racial classification scheme mandated by the Office of Management and Budget (OMB). This scheme is familiar to most of us because it is used by the U.S. Census Bureau. The passage of the NIH Revitalization Act of 1993 required that NIH-funded research projects include human subjects who are women as well as members of minority groups.<sup>22</sup> While these regulations were intended to correct the historical exclusion of women and minorities from participation in clinical trials, one unintended effect of the legislation has been the uncritical inclusion of one or two populations—often defined according to census categories unrelated to health outcomes—into a research design without adequate rationale for anticipated differences between populations. Such practices reinforce notions of racial difference and often come at the expense of a more nuanced study of the similarities among groups and the differences within broadly defined racial groups.

A critical review of the use of race is necessary in light of its profound effect on the production of medical knowledge. Statistics describing health differences between whites and racialized populations, such as those published in *Healthy People 2010*, are the result of epidemiological research that focuses on race as a category of inherent distinction. This research, in turn, establishes the agenda for progress in improving health status and determines the measures of success in achieving the NIH goals. The racial taxonomy used by epidemiologists impacts directly on the research design of studies examining the biological basis of difference among groups, initiating a trajectory of inquiry that is uncritical of the relationships among racialized groups, genetic characteristics, and environment.

#### IV. THE MUTABILITY OF RACIAL CATEGORIES

The taxonomy of race used in health research is primarily political. To understand fully the historical mutability of categories of race, we will discuss the evolution of census categories in the United States. Through comparison with categories used by other nations, the problematic nature of race as a scientific variable becomes evident. The U.S. Census Bureau has collected information on race since the first census in 1790. Historically, the Census Bureau has used widely varying principles and criteria in classifying the population, including national origin, tribal affiliation and membership, and physical characteristics. During the nineteenth century, African Americans were identified through a calculus based on percentage of African “blood.” The term *mulatto* was used to describe an individual born of one black and one white parent. Although it was largely abandoned at the beginning of the twentieth century, other

terms measuring descent such as, *quadroon* and *octoroon*, were used to refer to individuals with one-quarter and one-eighth black ancestry, respectively. In the 1920s the United States extended this racial paradigm by instituting the infamous "one-drop rule" by which individuals with even one ancestor of African origin were classified as black. This framework of identifying race focused on lineage and implicitly defined "whiteness" by a standard of genetic "purity," despite physiological markers that may give the appearance of whiteness or blackness. This rule, although no longer embraced officially by the government, reflects a belief in the biological basis for group differences that continues to characterize racial thinking in the United States.

During the twentieth century, twenty-six different schemes were used to categorize racial difference in the U.S. population.<sup>23</sup> Certain groups, such as Jews who at one time were defined as non-white, were "de-racialized" later in the century. Since 1977, the federal government has sought to standardize data on race and ethnicity among all of its agencies through the OMB's issuance of the Statistical Policy Directive Number 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting." In these standards, four racial categories were established: American Indian or Alaskan Native, Asian or Pacific Islander, black, and white. In addition, an "ethnicity" category was codified in identifying individuals as of "Hispanic origin" or "Not of Hispanic origin." The OMB guidelines stipulate that Hispanics may be of any racial category, although in practice, many who self-define as Hispanic check "other" when answering the race question, reflecting widespread confusion about the meaning of terms such as race and ethnicity.<sup>24</sup>

In 1997, in preparation for the 2000 census, the OMB revised these racial and ethnic categories, citing that they no longer reflect the diversity of the population. The reconsideration of these categories emerged in large part due to lobbying efforts by various groups seeking to broaden the choices available to respondents. As a result, the category of "Native Hawaiian or Other Pacific Islander" was added to the existing four as well as the choice of "Some Other Race." In addition, the ethnicity category was modified to "Hispanic or Latino" and "Not Hispanic or Latino." Although testimony presented in public and congressional hearings indicated a strong desire to include the option of "multiracial" among the census categories, the OMB decided against this, but allows respondents to choose more than one of the existing racial categories in identifying themselves.<sup>25</sup> These new standards on racial and ethnic categorization were used in the 2000 Census and are effective immediately for data collection by federal agencies, including the NIH. The categories on the actual census

questionnaire included a wide range of different groups that are then collapsed into the five racial groups and two ethnicities. These are listed below:

<b>U.S. Census Categories, 2000</b>			
<input type="checkbox"/> White	<input type="checkbox"/> Black, African-	<input type="checkbox"/> American Indian	<input type="checkbox"/> Asian Indian
<input type="checkbox"/> Chinese	American or	or Alaska Native	<input type="checkbox"/> Korean
<input type="checkbox"/> Vietnamese	Negro	<input type="checkbox"/> Japanese	<input type="checkbox"/> Samoan
<input type="checkbox"/> Other Pacific	<input type="checkbox"/> Filipino	<input type="checkbox"/> Gaumanian or	
Islander	<input type="checkbox"/> Native Hawaiian	Chamorro	
	<input type="checkbox"/> Other Asian	<input type="checkbox"/> Some Other Race	

A separate question asks respondents for their ethnicity. The choices are Mexican, Mexican American or Chicano; Puerto Rican; Cuban; and other. The taxonomy that emerges from this multi-tiered approach to defining difference is not readily apparent. Recognizing the plurality and diversity among populations identified as Hispanic or Latino, the OMB designated these as ethnic or social categories in which groups share common cultural history, practices, and/or beliefs. Quite similarly, the category of Asian American consists of no less than twenty-five different populations of diverse origins. What makes Asian Americans a “race” and Latinos and Hispanics an “ethnic group” is difficult to determine.

The racial categories used by the census reflect terms of group identity that have emerged historically from the shared social and political experience of particular immigrant groups, which in turn have been influenced significantly by the historical immigration policies of the U.S. government. In light of this, the use of a racial taxonomy in the arena of biological research is particularly problematic. The designation of these terms as “racial,” and their adoption and use in scientific research sponsored by federal agencies such as the NIH, threatens to reconstitute these groups according to assumptions of biological connections that are not valid.

When the U.S. Census Bureau’s racial categories are compared to those employed by other nation-states, the arbitrariness and historical contingency of racial taxonomies becomes evident. The table below shows the 2001 Canadian Census Bureau categories. Of note is the fact that Canada does not explicitly highlight the historical concept of race by asking a “race” question, nonetheless, the category seems to be implicit. As a catalog of the “visible minority population” in Canada, these categories reflect a potpourri of terms indicating skin color, nationality, regional and territorial identity, ethnicity, and political sovereignty (as in the category of

Canadian Census Categories, 2001			
<input type="checkbox"/> White	<input type="checkbox"/> Chinese	<input type="checkbox"/> South Asian	<input type="checkbox"/> Black
<input type="checkbox"/> Filipino	<input type="checkbox"/> Latin American	(East Indian, Pakistani, Sri Lankan)	<input type="checkbox"/> Arab
<input type="checkbox"/> West Asian (Afghan, Iranian)	<input type="checkbox"/> Southeast Asian (Cambodian, Indonesian, Laotian, Vietnamese)	<input type="checkbox"/> Japanese	<input type="checkbox"/> Aboriginal (North American Indian, Metis, Inuit)
		<input type="checkbox"/> Korean	

"aboriginal").<sup>26</sup> As is the case with the U.S. Census, one's identity is not easily determined. How should an individual of Japanese descent who was born in Brazil and carries Brazilian citizenship describe herself? Is she a Latin American or Japanese? Knowing the reasons behind such questions might greatly influence how one "chooses" to identify oneself. The answer may change depending on the purpose of the question, for example: to determine the immigration rates of specific populations, to calculate the number of foreign residents in a particular district, or to assess the incidence of genetically related disease among a population. Of interest is the fact that the Canadian sub-group known to express a unique array of rare genetic illness (due to a founder effect)—French Canadians in Quebec—is not included. Identification of this group by primary language spoken further complicates the classification dilemma when the social goal is amelioration of health status.

The absence of a universal taxonomy of race is further documented by examining the census categories utilized by the United Kingdom. Whereas "Asian" in the United States includes a broad range of populations with origins throughout the Asian continent, in the United Kingdom the term is limited to those from the Indian subcontinent. In the United States, the categorization of these individuals depends on their historical location. Early in the twentieth century, individuals whose origins were South Asian were categorically identified as "Hindu," regardless of whether they actually subscribed to the Hindu religion. This was incongruous for many groups and the policy changed to classify individuals from the Indian subcontinent as "white," in spite of the large phenotypic variation in skin color dependent on distance from the equator found throughout the world.

More recently, South Asians in the United States were added to the long laundry list of groups that constitute the category of Asian American. The table below indicates that, in contrast to the conventional wisdom on race in the United States, Chinese in the United Kingdom are not

considered Asian, but rather are combined in a separate racial category with all “other” racial groups. While this categorization scheme may be the result of the small numbers of Chinese and other groups in the United Kingdom, combining all other non-identified populations with Chinese further reveals the lack of scientific rigor in the classification of race.

**United Kingdom Census Categories, 2001**

- |   |   |   |
|---|---|---|
| <input type="checkbox"/> White (British, Irish, Other White)                                  | <input type="checkbox"/> Mixed (White and Black Caribbean, White and Black African, White and Asian, and Other Mixed) | <input type="checkbox"/> Asian or Asian British (Indian, Pakistani, Bangladeshi, Other Asian) |
| <input type="checkbox"/> Black or Black British (Black Caribbean, Black African, Other Black) | <input type="checkbox"/> Chinese or Other Ethnic Group (Chinese, Other Ethnic Groups)                                 |   |

In defining systems of classification, Bowker and Star identify three properties.<sup>27</sup> The first is that there are “consistent, unique classificatory principles in operation.”<sup>28</sup> The principles establish the rules of order as in, for example, genealogical descent. In the case of racial categorization, it is difficult to identify what rules are operative as they are often varied, inconsistent, and context specific. Physical appearance, geographic origin, language, and birthplace are just a few of the criteria used to determine racial identity. Despite its ubiquity, race has yet to be explicitly defined. The second property of a classification system according to Bowker and Star is that the “categories be mutually exclusive.”<sup>29</sup> The principles must be sufficiently specific so that entities may not be put in more than one category. The reality of human diversity confounds this second criterion, as the generally disguised presupposition of “racial purity” is fundamental to racial classification. Since *Homo sapiens* consist of a single species, genetic purity is a myth. The exclusionary social functions of race exist in sharp contrast to the porosity of group boundaries, leaving this classification system ill-equipped to address the reality of biological difference across the human population, which is continuous, rather than divided into discrete segments. Finally, the third criterion is that a classification system must be complete and able to absorb even those entities not yet identified.

The historical mutability of racial categories—as illustrated by the Census Bureaus in the United States and abroad—and the inconsistent use of terms in both defining and describing race indicate that a classification system based on race is inevitably historically contingent. The possibility of it ever becoming a rigorous system with scientific utility is questionable. This does not mean that racial categorization is an unimportant factor in



studying the cause of health disparities throughout the world. Rather, the ever-changing taxonomy of race is a reminder that any research utilizing the concept of race and/or ethnicity must include an interrogation of the economic, political, and cultural factors that inform the struggle over how these categories are defined and used.<sup>30</sup> In the new genomic medicine, the uncritical use of racial and ethnic categories by those interested in biological difference often distorts the relationship between genetics, disease, and group difference.

## V. THE USE OF GENETIC TECHNOLOGY IN ASCRIBING IDENTITY

The promise of genomic medicine is improved health. Perhaps medicines will be developed that target diseases found more frequently in people with a particular ancestry, or genetic epidemiological research carried out with an isolated population will identify a biological marker for schizophrenia. But might there be other consequences of the genomics prism? Will the reductionist paradigm transform, and perhaps "geneticize" our understanding of identity? The rapid production of genetic information through collaborations such as the HGP and the concomitant rise of gene mapping technologies suggest a need to reexamine current models of human identity. Genetic epidemiological studies often compare populations defined by social categories of racial and ethnic difference. Results indicating significant genetic variation may continue a cycle of reaffirming patterns that are built *a priori* into the research design. This conundrum, while not unique to genomics research, is further complicated by the current trajectory of studies that attempt to locate race or ethnic identity in the genes. The technically optimistic believe that genetic "evidence" may definitively identify individuals as belonging to certain groups. We remain skeptical of such claims. That categories of race and ethnicity are always historically constructed and context driven suggests a need to carefully consider the consequences of using genetics to define ethnic or racial identity.

### A. DNA Testing: Proof of Native-American Ancestry?

The eagerness to use genetic technology and research in determining race and ethnicity has resulted in a renewed faith that genetics will be able to reveal who and what we are. Recently, House Bill 809 was presented to the Vermont legislature by state representative, Fred Maslack, which stipulated that results from genetic testing would be accepted as definitive "proof" of Native-American ancestry.<sup>31</sup> The genetic criteria that would be used in making this determination were not explained nor were the

potential uses for the genetic test described.<sup>32</sup> While the bill stipulated that this would be offered to individuals on a voluntary basis, one cannot contemplate the deployment of a genetic standard of race without considering the potentially discriminative and prejudicial ways this might be used, setting aside for the moment whether such testing could ever be “accurate” or what accuracy would mean. Given that humans have developed socially meaningful mechanisms for determining group membership, the central question is: Why is genetic testing necessary? If an individual has lived in a Native-American community, has adopted the history and cultural practices and beliefs of her tribe, and is embedded in a nexus of social relationships that recognize her as a member, then what does a “negative” genetic test mean for her and perhaps, more importantly, to the group as whole? By supplanting history and experience with a standard of relatedness measured by genetic similarity, human cultural identity is relegated to a simplistic biological standard.

### *B. The “Kenniwick Man” Controversy*

The use of genetic testing in this arena is justified by racist thinking and serves to reify archaic concepts of race, attempting to “reveal” truths about identity through genealogy. Another example is provided by the “Kenniwick Man” controversy in which 9,000 year old skeletal remains were declared the property of a consortium of Native-American tribes—an illustration of the power of racial politics in the United States. The Kenniwick Man is of great interest to geneticists, evolutionary biologists, and anthropologists in challenging theories of human migration to the Americas. Attempts to reconstruct the skull of Kenniwick Man led several scholars to conclude it seemed more similar to that of modern Europeans than of Native Americans. This resulted in speculation that the original settlers of North America were not groups from Asia as originally postulated, but were individuals of European origin. Headlines that declared Kenniwick Man as “white” reflect not only the careless shorthand used by the media in interpreting scientific data, but the need to assign race in the quest to determine the evolution of human species.<sup>33</sup> It was concluded that DNA testing of the remains might fail to prove a link to modern Native-American tribes although archeological evidence seemed to confirm that Kenniwick Man resided in a human group that may have included ancestors of more recent Native Americans. The debate remains murky, illustrating the problematics of proving ancestry. Most recently some anthropologists have determined that Kenniwick Man has more in common with the Ainu of Japan than with Northern Siberians or Native Americans. The tug-of-war over Kenniwick Man was resolved by the

existence of the Native American Graves Protection and Repatriation Act (NAGPRA)<sup>34</sup> which stipulates that property—including human remains taken from tribal lands—be returned to Native Americans to be disposed of as they wish.<sup>35</sup> Upon his return, Kennewick Man will be reburied at an unidentified location on Native American territories. The existence of this legal agreement was convenient in dissipating this potentially explosive issue and allowed resolution despite the ambiguity of scientific evidence in determining the racial identity of Kennewick Man.

### *C. The Role of Genetics in Defining African-American Identity*

It would be misleading to claim that the search for identity through genetic testing has only been proposed by those residing outside of the groups in question. Reconstructing genealogy has been of great interest to African Americans seeking to locate their ancestral homelands, lost through the social disruptions of slavery. Genes are gaining increasing attention as an alternate way to reveal connections between contemporary African Americans and current populations in Africa. Recently, a geneticist from Howard University advertised the service of DNA analysis for African Americans who wanted to determine their pre-slavery heritage by locating their point of origin in Africa. Through a website entitled, African Ancestry, Rick Kittles urged African Americans to send in blood samples as a means of examining their "genetic makeup and developing a genetic fingerprint."<sup>36</sup> Although he abandoned his original plan of selling his services to interested individuals for \$300 per test due to mounting public and scientific criticism, Kittles' endeavors represent a general embrace of genetics as a medium through which validation of identity may be achieved. Of concern are the potential negative consequences of locating African-American identity in the realm of genetics. These concerns are not fore-grounded, indeed they remain unaddressed. This is surprising given the warnings of scholars like Patricia King, who writes, "in a racist society that incorporates beliefs about the inherent inferiority of African Americans in contrast with the superior status of whites, any attention to the question of differences that may exist is likely to be pursued in a manner that burdens rather than benefits African Americans."<sup>37</sup>

### *D. African Burial Project*

The African Burial Project is conducting similar genetic analyses with skeletal remains of long-deceased slaves, seeking to use genetics as a positive force in historical explication. Having received over \$5 million from the U.S. General Services Administration and Congress, the African

Burial Project attempts to match DNA extracted from skeletal remains found in 1992 at an urban construction site in the United States with genetic samples of populations all across Africa and the Caribbean.<sup>38</sup> Michael L. Blakey, the director of the project, has explained that the outcome of the DNA database created and the genetic analysis of samples could “help restore the specifics of identity that were deliberately damaged by slaveholders in order to make enslaved Africans seem less human.”<sup>39</sup> Blakey has indicated that upon the completion of the burial project, the DNA database will be made available to individuals in search of their African heritage.

The tests utilized in the African Burial Project have analyzed mitochondrial and Y-chromosome DNA that is passed down essentially unchanged through generations from mother to child and father to son, respectively. Results from such testing are limited in that each reveals only half of the lineage story. In addition, by attempting to locate similarities between the DNA of contemporary African Americans and modern Africans, the Kittles and Blakey projects implicitly adhere to the “one-drop rule” of racial categorization by ignoring the potentially significant degree of admixture between populations. The suggestion that identity is defined primarily by origins in Africa, rather than through social group membership based on shared historical experience, supports an ideal of genetic purity. Identity is “geneticized.”

A reverse example can be found in the recent “discovery” that the youngest son of Sally Hemings, Eston Hemings-Jefferson was fathered by Thomas Jefferson.<sup>40</sup> Despite a long history of folk narrative that confirmed these family relations, the Hemings-Jefferson relationship became “fact” only when genetic evidence was marshaled.<sup>41</sup> What is interesting is how the genetic information affected the current racialized identities of the living progeny of the Hemings-Jefferson union. Besides validating the beliefs of some who had long believed that Jefferson was their distant relative, the news did little to change their lives in meaningful ways, nor has it changed their conceptions of their identities or how others define them. The Monticello Association, a private organization of some 700 descendents of Jefferson and his wife, Martha, continue to dispute claims by Hemings’ descendents that they be included in the group, or be allowed burial in the cemetery at Monticello.<sup>42</sup>

The story of proving one’s lineage based on discovery of a genetic forefather is a powerful theme within the broader discourse on racial difference. Denial of the inevitable interaction among human populations is necessary to the story of race, an idea that is contingent on notions of biological purity for the maintenance of group boundaries. To

acknowledge the constant admixture between groups and intra-population genetic variation would render the concept of race meaningless.

### *E. Testing for Race/Ethnicity*

Through probabilistic techniques, genetic testing of continental ancestry is technically possible. Other research efforts seek to identify genetic markers that are highly correlated, not only with populations residing in (or with origins from) geographic areas that have been racially categorized, but also with phenotypic features associated with race.<sup>43</sup> A particular trajectory of genetic research is reflected in linkage and association studies that attempt to detect racial and ethnic differences in cases that are physically ambiguous. An example is the effort to determine genetic linkages of individuals of mixed descent. Using statistical procedures, one such study has claimed that 70-90% of ancestry information could be "extracted" even when "admixture" had occurred up to ten generations before.<sup>44</sup> The implications of this line of research are far reaching. The use of genetic technologies in directly determining race and ethnicity not only redirects identity from the social domain into the physical substrates of the body, but also, more importantly, shifts the power of defining who and what humans are into the arena of biomedicine. Testing for race/ethnicity may be justified as a means of improving the health status of minority populations, for example by targeting disease prevention programs to individuals from certain groups. This approach, however, reinforces the idea that disease results from essential characteristics within the individual.

## VI. GENETIC DETERMINISM AND REDUCTIONISM

The powerful tools of molecular discovery, in concert with the promise of molecular medicine, represent a dominant cultural discourse on science and health. An unintended byproduct of the genomics revolution is a naïve, almost religious faith in the power of genetics. The gene has become a powerful cultural icon;<sup>45</sup> genetic explanations have a pride of place in the popular imagination. Of course geneticists are well aware that genes act in concert with the environment, and that a full understanding of the genetic component of common illnesses requires sophisticated, multi-factorial research. Nonetheless, the paradigm of genetic reductionism may powerfully affect health disparities research by placing undue emphasis on genetics at the expense of other explanatory mechanisms, moving attention—and funding for research—away from features of the social and political environment that lead to ill health.

Genetic reductionism reflects a trend favoring an integrated theory of knowledge production that begins with faith in one particular approach to the scientific endeavor. In his most recent book, *Consilience*, Edward O. Wilson argues for a “unity of knowledge” that transgresses disciplinarity.<sup>46</sup> Heralding the advent of the Enlightenment era of scientific discovery, Wilson states, “Reductionism, given its unbroken string of successes during the next three centuries, may seem today the obvious best way to have constructed knowledge of the physical world, but it was not so easy to grasp at the dawn of science.”<sup>47</sup> The opposition between culture and science is one that Wilson critiques by discussing the role of epigenetic rules. He argues that while genes are the fundamental basis for human behavior, cultural factors may influence the selection and hence, survival of particular genes. Wilson treats culture as mechanistic. Just as ethnicity is relegated to a static list of attributes associated with particular groups, culture has been relegated to mental or cognitive constructs that are unchanging and essentializing.<sup>48</sup> In Wilson’s reductionist model of knowledge production, culture is subsumed within a genetic epistemology. Reductionist science leads to a particular approach to health research, and a particular, similarly decontextualized, approach to ethnic or cultural identity.

Alternatives to a reductionist understanding of ethnic or racialized identity allow a different approach to health research. Recent work in the social sciences on race and ethnicity has emphasized notions of “situational ethnicity,”<sup>49</sup> in which identity is dependent on the specific contexts in which individuals find themselves. In addition, the concept of “plastic ethnicity”<sup>50</sup> highlights individual and group agency as opposed to structural inscriptions of identity. The significance of such theories for health disparities research is an understanding that racial and ethnic identities—including health-related beliefs—take on different qualities and cannot be treated as stable entities even within an individual life course. We possess “multiple identities;”<sup>51</sup> one’s gender, religion, nationality, or age may take on lesser or greater importance at different times and in different places, contributing to a number of cultural identities.

Reductionist research that locates ethnic identity in genetic variation confounds the notion of malleable identity. The implication of such research is that self-identity may be supplanted by a genetically based identification of individuals and groups. The result of such a shift in which identity is no longer a product of self-definition, but rather, is ascribed by science, has serious implications for how race and ethnicity will be conceived. Critical to this shift in identity politics is the explanatory power of genetic discourse in its “appearance and allure of specificity”<sup>52</sup> in

classifying individual identity.

## VII. THE REIFICATION OF RACE IN HEALTH RESEARCH

Historically, race, genetics, and disease have been inextricably linked, producing a calculus of risk that implicates race with relative health status. Racialized groups have been associated with particular diseases. Sometimes these associations are accurate and sometimes they reflect underlying social prejudice. It is against this backdrop that investigations into health inequalities in the United States play out. Troy Duster, a sociologist who has examined these associations, has identified this process as the "prism of heritability" in which disease is uncritically linked to individuals because of racial assignment and categorically disassociated from other populations.<sup>53</sup> He cautions that race-based etiological theories may become hegemonic, effectively eliminating explanations of illness that take account of environmental or behavior factors associated with social class. Melbourne Tapper has studied this process with respect to the identification and management of sickle cell anemia in colonial Africa.<sup>54</sup> Tapper reveals that the political project of colonialism was further justified by the dominant discourse on race that identified sickle cell anemia as a "black disease" and contributed to a definition of "whiteness" that was predicated on the notion of invulnerability and health. Similarly, in the United States, prejudicial attitudes toward African Americans and immigrants from the Mediterranean region fueled racial rhetoric around sickle cell anemia and thalassemia. In the twentieth century, the association of race with disease was utilized by those who were politically opposed to miscegenation and immigration of people from southern Europe.

Given this history, particular caution must be employed when using the race concept in health-related research. Some have argued that the concept should be abandoned, based on the overwhelming scientific evidence that human races do not exist. Others argue for retaining the term, but limiting its application to the social, as opposed to the biological, realm. Recently, the American Anthropological Association, the official professional organization of physical, biological, social, and cultural anthropologists and archeologists in the United States, released a statement emphasizing the social and historical construction of race. Reflecting a general consensus among social scientists, physical and biological scientists and other scholars, the statement contended that race could not be considered a valid biological classification:

The "racial" worldview was invented to assign some groups to perpetual

low status, while others were permitted access to privilege, power, and wealth. The tragedy in the U.S. has been that the policies and practices stemming from this worldview succeeded all too well in constructing unequal populations among Europeans, Native Americans, and peoples of African descent. Given what we know about the capacity of normal humans to achieve and function within any culture, we conclude that present-day inequalities between so-called "racial" groups are not consequences of their biological inheritance but products of historical and contemporary social, economic, educational, and political circumstances.<sup>55</sup>

Despite such proclamations, race continues to be used erroneously, even harmfully, as a scientific variable, particularly in biomedical research designed to explain health behavior. Its use is ubiquitous; from 1910 to 1990, race was used in 64% of articles appearing in the *American Journal of Epidemiology*.<sup>56</sup> One author suggests that historians will find our current terminology to be inherently racist, rather than scientifically useful.<sup>57</sup> A review of biomedical literature claiming links between race and disease reveals that researchers rarely describe their racial and ethnic measurement or classification methods. In a review of articles published in *Health Services Research*, Williams noted, "Terms used for race are seldom defined and race is frequently employed in a routine and uncritical manner to represent ill-defined social and cultural factors."<sup>58</sup> Lack of precision—naïvely conflating biology and culture—makes it impossible to tease out the causes of health disparities between economically disadvantaged racialized populations and more privileged groups.

The lack of consistency in the use of terminology for concepts of race, ethnicity, ancestry, and culture is manifest in the wide variance in terms used to identify individual and group identities.<sup>59</sup> Terms such as white, Caucasian, Anglo, and European are routinely used interchangeably to refer to certain groups; whereas black, colored, Negro, and African American are used to refer to comparison groups.<sup>60</sup> And white-black comparisons are straightforward in contrast to the confused use of terms like Hispanic and Asian. Fundamental ambiguity in the concept of race obscures the role that genetic variation plays in our current understanding of disease. Socially defined notions of race are treated as legitimate biological variables; race itself is often used as a proxy for disease risk. Epidemiological studies employ race as shorthand for social and environmental factors that are associated with particular racialized groups.<sup>61</sup> When treated in this way, race is understood to have some contributory effect to particular conditions and diseases, but in a very imprecise way. For example, reports that black smokers are ten times more



likely to develop *helicobacter pylori* infection—a cause of duodenal ulcers—than white smokers,<sup>62</sup> treats skin color as an independent variable, and thus circumvents an explicit engagement with the complex interaction of social, environmental, and perhaps, biological factors that may have produced the statistically significant findings.

Research utilizing race serves to “naturalize” the boundaries dividing human populations, making it appear that the differences found reflect laws of nature.<sup>63</sup> In fact, the use of race and ethnicity in biomedical research is problematic because it is caught in a tautology, both informed by, and reproducing, “racialized truths.”<sup>64</sup> We assume that racial differences exist, and then proceed to find them. While the scientific validity of racial distinctions between human populations has long since been disputed, the cultural logic of stratifying populations by race/ethnicity exerts a powerful pull—it is a highly ritualized scientific practice enshrined in law and government regulation.

#### *A. Race, Smoking, and Nicotine Metabolism*

Recent research on smoking and nicotine metabolism illustrates the implications of the reification of the race concept in health research. The use of tobacco is singled out as a leading health indicator in the *Healthy People 2010* vision statement. According to the report, adolescent rates of cigarette smoking have increased in the 1990s among white, African-American, and Hispanic high school students after years of declining rates during the 1970s and 1980s. A central goal of the *Healthy People 2010* mission is to decrease the rate of tobacco use through prevention programs and to focus research on treatment programs for existing smokers.

Epidemiological and behavioral research on cigarette smoking has clearly identified sociodemographic variation in smoking rates. “Race” is highlighted as a significant predictor of smoking behavior, yet its exact salience is difficult to tease out. Studies indicate that although a larger proportion of blacks<sup>65</sup> than whites smoke, several differences in tobacco use exist between these groups. Blacks consume fewer cigarettes<sup>66</sup> and begin smoking later in life than whites.<sup>67</sup> Blacks smoke cigarettes higher in tar and nicotine<sup>68</sup> and are specifically targeted by the tobacco industry as potential consumers.<sup>69</sup> Smoking among African Americans has been associated with a higher incidence of lung cancer, cardiovascular disease, low birth weight, and infant mortality.<sup>70</sup>

Research on a genetic basis for differences between African Americans and non-Hispanic European Caucasians has focused on differences in the metabolism of tobacco. The logic of such studies is founded on the notion

that racial groups may have distinct genetic characteristics that result in different biochemical processes such as variations in nicotine metabolism.<sup>71</sup> Recently it has been reported that racial and ethnic differences may exist in the serum cotinine levels of cigarette smokers.<sup>72</sup> Levels of cotinine, a metabolite of nicotine, indicate relative exposure to tobacco smoke. In this study, sponsored by the National Center for Chronic Disease Prevention and Health Promotion, non-Hispanic black smokers had significantly higher levels of serum cotinine than either white or Mexican-American smokers despite reporting to have smoked the same number of cigarettes a day. The study concluded that these differences may explain why blacks find it harder to quit and are more likely to experience higher rates of lung cancer than white smokers. The authors suggest that biological differences may account for the differential health status of certain groups. Studies like this contribute to a trajectory of research that links race and genetics to disease. However, by assuming a tight link between nicotine metabolism and race, researchers may overlook other biological or environmental mechanisms that could explain the elevated cotinine. They also rule out racism on the part of physicians as an explanation of excess cancer deaths among blacks. A recent study found racial differences in referral for potentially curative surgery among patients diagnosed with early-stage lung cancer associated with smoking.<sup>73</sup>

Research on the relative incidence of disease among racialized groups reflects a paradigm of inquiry that presumes racial differences exist. "Race biology," as described by Gary King, reflects current sociopolitical beliefs, values, and agendas regarding racial differences and is "predisposed to and rewarded for investigating 'inherent differences' rather than commonality."<sup>74</sup> Research findings—such as differences in nicotine metabolism—provide the promise of drug therapies based on presumed genetic differences between racialized groups. Such targeted medicines are a hallmark of the new genomic medicine.

### *B. Race and Pharmacogenomics*

The emergence of the field of pharmacogenomics is based on the promise of individually tailored drugs; therapeutics will be tailored to the unique genetic makeup of specific populations. Those more likely, or less likely, to respond to a particular medicine, or those likely to have a severe adverse event, will be identified through genomic analysis. Pharmaceutical companies believe that such tests, and the medicines based on them, will be an important feature of health care in the future; intense and highly competitive research is underway.

Pharmacogenomics creates drugs for individuals by matching

medicines to patients' personal genetic codes.<sup>75</sup> However, in practice, research targets variation within pre-defined racialized groups, not individuals. According to a recent article in the *Washington Post*, "[r]ace influences which people are genetically predisposed to lack various enzymes needed to break down medications. Without those enzymes, the medication can have either a heightened or lessened effect."<sup>76</sup> In this case, race is identified as the independent variable that explains the necessary presence or absence of a biochemical agent that aids the metabolism of the drug. The use of the word "lack" redirects focus from the limitations of synthetic pharmacopoeia to the biological shortcomings associated with particular racialized groups. Who will be defined as "normal?" Racial thinking, or the belief that race is defined by biological differences between groups of individuals, informs the search for genetically tailored therapeutics intended to compensate for deviations from an unstated standard of genomic normality.

Although the idea of individually tailored therapy is the goal, it appears likely that products will actually be targeted according to race. One can only speculate on the cultural impact of the commercialization of drugs for racialized populations and the decision by pharmaceutical companies to bring to market therapeutics created for a certain group of consumers. The Food and Drug Administration (FDA) recently approved a new glaucoma drug, Travatan, which is marketed as, "the first glaucoma drug to demonstrate greater effectiveness in black patients."<sup>77</sup> Close reading of the FDA-approved package insert discloses that "[i]t is not known at this time whether this difference [in efficacy] is attributed to race or to heavily pigmented irides."<sup>78</sup> This turn toward a population-based approach to health care product marketing raises the possibility that drug development will build upon and strengthen current notions of racial difference. Health disparities do exist; individuals who self-identify as black are more likely to suffer from glaucoma-related blindness. But will medicines targeted by race alleviate those differences in health outcomes or disguise other explanations of disparities, such as lack of access to routine preventive eye care? The danger is that more and more diseases will be "racialized," and at the same time, the idea that racial differences exist and are inherent is reinforced. Careful policy guidelines on the marketing of medicines (and other health care products) to racially defined groups are needed. These guidelines must pay attention to language in order to avoid the suggestion that biologically distinct human races exist. One policy suggestion is to insist on neutral words such as "ancestry" when discussing population-level genetic variation, avoiding potentially misleading terms.

Pharmacogenomics research is the study of the genetic basis for differential drug responses between individuals. Identifying those genetic differences depends upon access to research databases that reflect a wide range of difference across the human population. Genetic variations, called SNPs, provide the raw material for research. SNPs occur at the rate of one in approximately 300 base pairs. The promise of SNPs research is the discovery of genes involved in human disease, such as asthma, diabetes, heart disease, schizophrenia, and cancer. (At the molecular level, sickle cell anemia is the result of a variant SNP.) SNPs are believed to play a major role in how humans respond to environmental insults such as bacteria, viruses, toxins, and chemicals (e.g. nicotine), including drugs and other therapies. The NIH, as well as private companies, have set up databases including a "representative" sample of human DNA. Because these databases must reflect the human population, how researchers conceptualize the racial or ethnic background of blood samples reveals a great deal about existing taxonomies of race.

Initially, databases were set up reflecting known social categories of difference. The Coriell Cell Repository, for example, includes cell lines—called "human variation panels"—from an amalgam of people, including such conceptually distinct categories as African American, Caribbean, Greek, Caucasian, Chinese, South American (Andes), and Southwestern American Indian.<sup>79</sup> Recognizing the issues we have identified in this paper, the NIH took a very different tact in setting up its "DNA Polymorphism Discovery Resource."<sup>80</sup> Established in 1998, samples were collected from 450 male and female U.S. citizens, apparently with the intention of reflecting the country's diversity. In order to avoid the creation of a database that could be mined and studied for difference by race, individual samples are not identified racially, rather, continental origin for the entire panel is presented.

#### DNA Polymorphism Discovery Resource

Population Group	Proportion of Admixture	Number of Individuals	Number of Genomes by Continent			
			Europe	Africa	America	Asia
European American	0.01	120	119	1	0	0
African American	0.17	120	20	100	0	0
Mexican American	0.39	60	36	5	19	0
Native American	0.05	30	2	0	28	0
Asian American	0.10	120	12	0	0	108
Totals		450	189	106	47	108

It remains to be seen whether this strategy will overcome the strong tendency of researchers who wish to stratify their samples according to "traditional" categories of race. It is, however, an example of a rare public

policy choice—a decision to avoid the imposition of categories of difference that do not adequately reflect actual genetic variation in the human population.<sup>81</sup>

#### VIII. TARGETED POPULATION-BASED RESEARCH AND SERVICES: AVOIDING SOCIAL HARMS

The association of the BRCA-1 mutation with Ashkenazi Jews is merely one of many correlations that have been, and continue to be, drawn between a disease and a racially identified population. The search for genetic variation in concert with categories of race threatens to perpetuate the racialization of disease. Two major strategies for discovering the relationship between human disease and variations in genetic polymorphisms have become standard. The first is a search for polymorphisms through sequencing in which any variation in gene sequences from a reference sequence is by definition identified as a new polymorphism. The second is a population genetics approach in which variation is detected within and between "identified" populations. Biomedical research focused on discovering associations between allelic frequencies and the occurrence of disease produces probability statements. For most common diseases, a particular genotype does not cause a specific disease in the same manner that genes determine blood type. Rather, genes are one factor among many that contribute to illness and are best understood in terms of statistical risk assessment. While genetic testing may be able to determine the presence or absence of genes or gene complexes, it cannot determine whether associated diseases and disorders will result; testing provides a set of probabilities only.

As noted in our discussion of pharmacogenomics research, the use of race in the identification of genomic materials is the critical initial step in the chain of knowledge production that results in correlations between racialized groups and risk of disease. Racial or ethnic labeling of an individual DNA donor by cell repositories and independent researchers may affect the health and welfare not only of that individual, but of the group with which that individual has been identified. Correlations that are derived from racial categorization of genomic materials used in research may result in policies regarding targeted genetic screening. Such recommendations have been made for various populations, including Europeans/Caucasians for cystic fibrosis testing, African Americans for sickle cell anemia, and Southeast Asians for beta-thalassaemia. A potential benefit of such targeted testing is the early identification of disease—or pregnancy termination depending on the timing of testing—in individuals who may not have been tested without being identified as belonging to a

particular population.

However, the conflation of race with risk of disease has negative implications for both the identified population and for society at large. Public health benefits are not the only outcome. Stigma and discrimination is a risk associated with the diagnosis of disease for any individual, particularly if curative measures are not available. While genetic markers are not definitive predictors of the onset of complex, common diseases, as opposed to rare Mendelian single-gene disorders, their value in determining relative risk is important in the delivery of health care. Insurance companies and managed care organizations, in particular, have economic stakes in controlling the potential costs of "high risk" clients.<sup>82</sup> In addition, social prejudice could arise in the identification of correlations between genes and disease. The calculus of risk may result in social consequences for individuals in the anticipation that they will fall ill.<sup>83</sup>

However, harm may extend beyond the individual at risk for a particular disease. When racially identified genetic markers are associated with illness, "race" itself becomes the surrogate risk factor. The potential harms associated with targeted genetic testing befall socially identifiable groups. The categorization of individuals according to race erases the individual specificity of genetic signatures. Associations become interpreted as causative relationships and race emerges as the salient scientific variable in the reporting of research findings.

Consequences are twofold: First, "race" itself becomes a source of stigma. Breast cancer becomes a "Jewish disease," and Jews become associated with high rates of cancer. Second, ideas of genetic reductionism are reinforced. The elision of economic factors such as poverty, employment, and unequal access to resources that are manifested in differences in nutrition, housing, and access to healthcare are subsumed within a genetics discourse that reifies notions of physiological difference. Ironically, such racial thinking renders the effects of racism on the relative health status of groups of individuals invisible. By pursuing targeted population testing in the shift to a genomic approach to healthcare, significant non-genetic factors will be left unaddressed. In addition, racially targeted programs may result in the neglect of individuals not identified with "at-risk" populations who may be afflicted with the diseases in question.

#### *A. Protecting Identified Populations from Harms*

If the potential harms of racially targeted testing extend beyond the individual to entire social groups, does our current, individually focused system for protecting human subjects in research (or requiring informed

consent for clinical services) provide adequate protection? Institutional review boards (IRBs) were created to provide mechanisms for oversight against potential risks to human subjects. Presently, IRBs are limited in their ability to evaluate future social harms that may arise from interpretation of research findings, such as genetic research targeted to racially identified populations. Their legislative mandate is protecting *individual* research participants and assuring informed consent.

Current oversight mechanisms do not address potential harms to communities with which individual human subjects are identified. For example, IRBs are not charged with the responsibility of assessing the risk of discrimination and stigmatization to identified populations from research that attempts to link genetic markers to disease and racialized groups. However, acknowledgement of such harms has fueled a growing debate over whether individuals, alone, should consent to research participation, or whether others who subscribe (or are ascribed membership) to the same racialized group should also participate in this process since they will share in the consequences of the research. As a result of these debates, increasing attention has been placed on the role of racial and ethnic communities in creating effective oversight measures in genetic research. The continued use of racial categories in the new genomic medicine may lead to the reevaluation of the established informed consent process that solely involves individual human subjects. What should be the role of groups as gatekeepers for research? How can we determine the need for public fora to consider the fears, desires, and perspectives of communities?<sup>84</sup>

Several scholars have argued that IRBs should implement new mechanisms that supplement individual consent with group permission.<sup>85</sup> In July 1999, the National Institute of General Medicine Sciences (NIGMS) conducted a workshop to address the ethical implications of identifying genetic materials with racial and ethnic populations in the Human Genetic Cell Repository created through a contract with the Coriell Institute. A key set of recommendations developed through the workshop was the creation of special "Oversight Groups for Populations-Based Samples" (OGPBS) for each racially and/or ethnically based community. These groups would presumably assure that samples would be acquired with the consent of the communities from which samples are collected, and with attention paid to the implications of future research.<sup>86</sup>

In September 2000, the NIGMS held the first "Community Consultation on the Responsible Collection and Use of Samples for Genetic Research" in which approximately sixty participants from a broad range of identified populations were invited to provide input on the best

approaches to minimize risks to communities. Central to the discussions among the participants was the ambiguous definition of racial and ethnic populations. In addition, participants of the NIGMS sponsored community consultation meeting debated the need for community consent *vs.* community consultation. Such discussions were in concert with a philosophical argument that charging groups—as opposed to individuals—with the moral authority to bestow informed consent is conceptually flawed and logistically confusing. In dispute are the assumptions that: 1) there exists a singular, self-evident social body that represents a particular individual human subject; 2) this social body has the moral authority to “speak” for all members of a particular group; and 3) consent from representatives of this social body absolves researchers of responsibility for prospective harms. Despite these challenges to the notion of group consent, there has been widespread support for the need for consultation and participation of communities in the research process. In developing culturally appropriate mechanisms to protect both individuals and communities, it is critical to acknowledge that individual decisions are inherently social decisions in which the collective is already deeply embedded. An anthropological approach that begins with the notion of “local moral worlds”<sup>87</sup> will be helpful in attempting to make meaningful the perspectives, beliefs, and actions of individuals within the context of a social group.

#### IX. ABANDONING RACE, RE-CRAFTING THE LANGUAGE OF DIFFERENCE: IMPLICATIONS FOR HEALTH CARE RESEARCH AND POLICY

In order to meet the vital policy goal of eliminating health disparities among diverse U.S. populations, it is critical to distinguish between biological and sociocultural contributions to the increased morbidity, mortality, and truncated access to services experienced by minority populations and the poor.<sup>88</sup> This can only be accomplished through careful attention to our categorization of “difference” in the conduct of research, in clinical and public health practice settings, and in our national health policy. A simplistic use of the category of race as a proxy for difference will inevitably limit the utility of information obtained through the study of the very real genetic variation that exists among U.S. populations with ancestry from all parts of the world. That variation, already well documented, will be fore-grounded as the use of genetic technologies expands. Increasingly, health-disparities research—both clinical and epidemiologic—will include comparisons that focus on variation at the level of DNA. We expect that emerging genomic technologies and the use of DNA repositories will play a large role in medical research in the future, thereby reinforcing the



notion that DNA is the primary factor underlying health differences between individuals.

We have argued that the way human difference is conceptualized and used in health-disparities research has profound moral consequences—that potential ill effects abound. Yet readers have undoubtedly noticed the seemingly inconsistent use of the term “race” in our analysis. On the one hand, we have highlighted the historical contingency and lack of scientific specificity of the concept. On the other hand, we have made clear that health disparities occur more often among racialized populations. Race does not exist, but racialized groups do, and the effects of this racialization are real. As Emerson suggests, “A foolish consistency is the hobgoblin of little minds....”<sup>89</sup> It is imperative *not* to think and talk about race in the simplistic, one-dimensional way characteristic of other scientific “variables.” Rather, we must use extreme care and caution when invoking categories of difference in biomedicine, moving between concepts depending on the context and the purpose of the research. In health care, we are convinced it is legitimate to use traditional categories of racial difference only when engaged in studies of the pernicious effects of racism itself. When searching for the causes of health inequality, we must carefully tailor our approach to the demands of a specific research question, not simply follow conventional rituals of population stratification. Doing so will not only avoid reinforcing the destructive notion that biological races exist, it will also lead to a fuller understanding of health disparities. Of course this will require change in law and government regulation, as well as the way we think about race.

#### *A. The Dangers of Genetic Reductionism*

The prism of genetic reductionism yields dangers throughout health care. The effects are subtle and not easily remedied by top-down regulatory change. One potent implication of the conflation of genotype with phenotype in the new genomic medicine is a reconceptualization of disease etiology. By adopting a genetics-based explanatory model of illness, genes—rather than symptoms—become the critical way in which illness is identified. This may result in a shift in how disease is defined, which inevitably affects treatment and prevention strategies. Geneticists are engaged in research that links single genes, or more often, gene complexes, to particular diseases and/or conditions. While these genetic characteristics do not, in and of themselves, indicate the inevitability of the onset of illness, they are portrayed as of primary significance in determining one’s risk of developing a particular disease. Despite the complex interplay of environmental and genetic factors in the eventual

onset of disease, increasing emphasis has been placed on the existence of “genetic markers” for disease. Such genetic reductionism undermines the lived experience of patients while privileging genetic signatures characterized by the presence or absence of “good” and “bad” genes. As a result, health will be measured less by one’s condition in the present, and more through a calculus of risk for disease in the future.<sup>90</sup>

From such speculation, new definitions of healthy and unhealthy populations may emerge. Implicit to this new understanding of disease is a shifting boundary between normality and abnormality. Relying on a comparative and relational framework, the standard of health may be based on a human genome that is free of mutation. However, the labeling of genes as dysfunctional is complex and highly contextual, and has often been linked—without justification—to racialized populations. As mentioned previously, the now classic morality tale of sickle cell trait illustrates this point. The protective effect of the trait for individuals residing in areas where malaria is endemic is clear. In the United States, however, sickle cell trait serves no benefit in protecting against a disease that no longer poses a substantial threat. Rather, its deleterious effects for individuals who carry two copies of the altered gene have transformed a gene that is highly functional in malaria-ridden areas to a dangerous and dysfunctional mutation. The assignment of normality and abnormality is contingent on changing environmental conditions. As one of the first molecular diseases, sickle cell anemia clearly reveals the racialization of illness. The disease was believed to be confined to a particular racialized group, and race became the salient factor in explaining its etiology; from the outset of scientific and medical investigation it was identified as a “black disease.”<sup>91</sup>

Our research paradigms and public policies must work to avoid the racialization of new diseases, with the associated stigmatization of populations. The legacy of mistrust created by the abuse of African-American subjects in medical research, symbolized by the Tuskegee syphilis study, serves as an ironic brake on genetics research. Black participants in the large-scale National Health and Nutrition Examination Survey (NHANES) were less likely than whites to allow their blood or other specimens to be stored for future research, regardless of guarantees of anonymity and privacy.<sup>92</sup> Fear of stigmatization overrides confidence in medical progress. The potential benefit of studying gene-environment interaction in human populations with varied ancestry may be lost.

A further consequence of over-reliance on the paradigm of genetic reductionism is the erasure of etiological explanations of critical importance in accounting for health disparities: environment, social

structure, poverty, or interactions among complex factors. When disease is "located" within the individual, strategies to ameliorate ill health tend to be similarly focused. The social dimensions of health and disease are ignored, or at best paid lip-service only. Resources—both governmental and private—flow to projects that embrace genomics and offer the possibility of products marketed to individuals who are encouraged to take responsibility for their own health. We do not dispute the promise of this scientific approach, rather we wish to point out how the light cast by genomics leaves alternative explanations of ill health in the shadows.

A final consequence of the genomic prism is the potential "rebiologization" of race as a conceptual category. Throughout the twentieth century, scholars, particularly anthropologists, have fought against the "essential" explanations of racial difference inherent in western thought since the time of Linneaus. In previous eras fundamental biological difference was assumed, but could not be directly assessed through genetic studies. The powerful technologies developed in support of the HGP are transformative, allowing the precise study of difference at the DNA level. We believe that caution is indicated in projects that employ powerful genetic technologies to study social categories of human difference. A possible, although not inevitable, outcome of the popular efforts to "prove" identity or origin through genetic research is that racial difference will once again be located in biology. Even research that focuses on disease etiology, as opposed to ethnic classification, has the potential for harm. It is possible, for example, that genetic research on breast cancer that targets individuals of Ashkenazi descent will have dual consequences: stigmatizing the population through the creation of a new racialized disease, while at the same time contributing to the idea that this population is somehow biologically distinct, that it constitutes a separate "race." We need to consider if alternative approaches to research design might avoid these dilemmas.

#### *B. Avoiding Racial Classification Through "Individualized" Research and Practice*

An alternative to the use of racial categories in health-related genomics research is a disciplined focus on patterns of genetic variation that are not influenced by prior racial categorization of individual research subjects or patients. SNPs research could utilize powerful genomic technologies to identify genetic signatures that are then classified according to similarity or difference, and correlated with health outcomes. In this way, variation at the genetic level might dictate new categories for making meaningful comparisons across human populations based on molecular difference. This relies on the ability to sample and make

comparisons within large populations. To achieve this, it is critical that we dispense with *a priori* racial classifications. Such a shift in methodology saves us from the tautological quandary of searching for differences in places where they are expected, thus reifying the idea of racial difference and ignoring the true range of genetic variation across the human population. In the same way, clinical policies and public health interventions that do not rely on racial or ethnic classification can be developed. Examples include existing newborn screening programs that are not targeted by socially defined racial categories, but examine genetic variation directly. Testing only people who are identified as black for sickle cell disease reinforces the racialization of disease and misses a significant proportion of cases. Given the current climate of research and policy, such strategies will not always be easy to implement. It is difficult to disabuse researchers, pharmaceutical companies, and public health managers of the idea that one must always classify by race.

### *C. Refining the Language of Race in Health Care Policy*

The intersection of the genomics revolution with the health-disparities initiative provides an opportunity to refine our language. Prompted by the HGP, Joseph Graves, Jr., an evolutionary biologist, has called for a "Manhattan Project" on how we use the concept of race in the United States.<sup>93</sup> In fact, journal editors and editorial boards in a number of fields have recognized the need to re-examine the ritualistic use of racial and ethnic classifications in biomedical publications. Holding scientists accountable for their use of racial categories and racialized populations in their research is a promising intervention. Often populations are stratified into racialized groups in a research design without any rationale for why differences might be expected. In response to the lack of precision and potential danger of careless use of concepts such as race and ethnicity, the *British Medical Journal* took an early stand, issuing a statement in 1996.<sup>94</sup> More recently, *Pediatrics* issued guidelines requiring that authors explain why they chose to stratify research samples as they did, rather than rely on formulaic use of racial or ethnic categories.<sup>95</sup> *Nature Genetics* has also issued editorial guidelines, stating that there is no justification to use race as a proxy for genetic variation:

The laudable objective to find means to improve the health conditions for...specific populations must not be compromised by the use of race or ethnicity as pseudo-biological variables. *Nature Genetics* will therefore require that authors explain why they make use of particular ethnic groups or populations, and how classification was achieved.<sup>96</sup>

We support these editorial policies and hope that such moves will lead to a critical re-examination of the meaning of race in health research and a heightened understanding of how racial classifications influence the production of medical knowledge.

The NIH held a conference in June 2000, called "Higher Levels of Analysis," which developed consensus recommendations including a call for a comprehensive re-examination of how foundational concepts like race, ethnicity, culture, and social class are measured and implemented in biomedical research.<sup>97</sup> One problem is that current practices of identification based on OMB directive 15 are governed by legal statute, and change would require legislative action. Whenever a researcher submits a proposal involving work with human subjects to the NIH, he or she must demonstrate that participants will be recruited to represent the diverse U.S. population, using census categories as descriptors of difference. The fact that these categories are primarily political, and may not be meaningful for a particular project, has been ignored. Ironically, the original intent of the legislation was to improve the health care of American minority populations, by requiring that women and minorities be included in all clinical trials funded by the NIH, unless the researcher could adequately explain why certain populations were excluded from research. This laudable policy goal has the unintended effect of discouraging researchers from using more subtle distinctions. It also conveys the idea that these concepts are scientifically meaningful, in spite of significant evidence of conceptual confusion in their implementation in health research.<sup>98</sup> Robert Hahn of the Centers for Disease Control and Prevention has participated in federal efforts to re-craft our classifications of race in the health arena, including the NIH conference mentioned above.<sup>99</sup> In spite of the recognized need, barriers to change are significant. Another irony is that governmental efforts to protect racialized populations from the potentially stigmatizing consequences of genetic research may play into the notion of bounded, biologically distinct groups. Care needs to be taken in how community consultation is carried out or how group consent is implemented.

Another key focus for policy discussion is the marketing of drugs, medical devices, or genetic tests to specific populations. The glaucoma drug Travatan provides an example of a targeted therapeutic agent. One scenario that must be addressed is the possibility that genetic tests will be marketed to socially identifiable groups based on variations in rates of certain mutations across the human population. This is already a well-established policy dilemma in genetic testing for a number of conditions. For example, over 900 discrete mutations in the gene associated with cystic

fibrosis have been identified, and specific mutations are found at different rates in individuals grouped according to ancestry from different continents. For example, delta 508, the first mutation identified, is more common among individuals of Northern European origin and is found less frequently among individuals whose origin is Asia. When screening tests are created, which collection of mutations should be included? Should targeted tests be developed or is it feasible to test all groups for all mutations? These are the dilemmas facing clinical laboratories that develop and conduct genetic tests.<sup>100</sup> Using a test known to have been developed with geographically limited genetic data is potentially harmful, yet creating specific tests for socially identifiable populations could intensify community harms if carelessly done. Attention to the language of difference used in FDA-approved package inserts for drugs and devices, and in educational materials, must be part of our "Manhattan Project."

We have emphasized that it is not enough simply to substitute a more "politically correct term"—such as ethnicity or culture—and continue to make use of an archaic race concept. The scientific evidence is clear that genetic variation does not neatly map onto socially meaningful groups. What alternatives exist to using the word race? When considering the health effects of racism, we prefer the term "racialized" group or population, to emphasize that the concept of race is historically contingent. How we speak is a direct reflection of how we think; the language of race is a non-trivial policy issue. Great care must be taken, particularly in the highly charged domain of human genetics research. In order to avoid the erroneous assumption that human races exist, one policy-making body has made a conscious decision to avoid use of the word race when discussing biological difference or genetic variation. Instead, the Secretary's Advisory Committee on Genetic Testing has used the concept of "ethno-cultural groups" when referring to human populations that might be adversely affected by genetic testing.<sup>101</sup>

#### *D. The Dilemma of Difference*

Finally, we recognize that a major challenge to eliminating the careless use of "race" in health research stems from a disjuncture between the goals of scientific investigation and those of public policy. Good science precludes the naïve use of race. Yet, the policy goal of eliminating health disparities among racially and ethnically identified populations significantly influences how health research is designed and conducted. When alternative approaches to *a priori* racial categorization of human subjects are employed, research results must be reinterpreted in terms of political categories in order to determine progress towards the realization

of the public health goal of reducing inequality. If researchers are to be held accountable for their use of race, we must develop policies that allow both scientific and policy goals to be met, using the social and political concept of race, or of racialized groups, only when salient.

Debates about the significance of race in the new genetics are in this way no different than those about public policies like affirmative action. Calling attention to race in order to ameliorate inequality has the unintended effect of perpetuating the social divisions one wishes to eliminate. Legal scholar Martha Minow has called this the "dilemma of difference."<sup>102</sup> Minow asks: When does treating people differently lead to the goal of equal treatment and opportunity, and when does it stigmatize or hinder them when differences are ignored? It is imperative not to conduct research in a way that conveys the idea that biologically distinct human races exist. At the same time, real health inequalities must be remedied; genuine genetic variation across the human population must be better understood. A close examination of the historical practices of racial classification reveals the complexity that has plagued the deployment of race since the concept entered modern discourse. The racialization of human groups, historically linked to the maintenance of rigid, hierarchical boundaries rooted in unequal access to resources and opportunities, stands in direct opposition to the social justice goals of *Healthy People 2010*. The advent of the HGP, and the development of genetic technologies, provide great opportunity for reducing health inequalities. Achieving that goal requires careful attention to the moral significance of "race" in health-disparities research.

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populations separated by natural or social boundaries. As with the use of DNA analysis in forensics, if one can measure many hundreds or thousands of genetic differences, the accuracy of the technology improves. However, the ultimate accuracy of such an approach depends on the source of the initial reference samples that are selected to define the group. Hence the problem of circularity.

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# The Proposed Patients' Bill of Rights: The Case of the Missing Equal Protection Clause

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Following the footsteps of most other states, Massachusetts opened its Office of Patient Protection in January 2001. Established under what the media hailed as a "landmark" patients' bill of rights, the Massachusetts legislature created a state agency empowered to review medical decisions made by health maintenance organizations (HMOs) that are challenged by patients.<sup>1</sup> However, after opening its doors, the agency now faces an immediate and major problem—the lack of any patient complaints. On January 27, 2001, the *Boston Globe* reported the agency's activity as follows: "[I]n their first three weeks, the medical crusaders in this little office have been more like those proverbial Maytag repairmen—twiddling their thumbs in boredom. The office, established under a landmark patients' bill of rights as a referee between HMOs and clients, has yet to hear a single beef."<sup>2</sup>

While the problem may be due to a lack of knowledge about the availability of the appeals process, the immediate result of this Massachusetts reform mirrors the longer-term experience of other states. Health policy researchers at Georgetown University analyzed the limited reliance of patients on the right to appeal HMO decisions and found that patients rarely exercise their newly found due process rights to appeal treatment denials. For example, in the first five years of Florida's external review process (from 1993 to 1998), only 403 cases arose in a population of 4.4 million state residents enrolled in managed care plans.<sup>3</sup> Despite the relatively small impact of this health care reform effort by various states, it appears that Congress will soon pass similar "landmark" federal legislation.

In the past year, the presidential candidates and the U.S. Congress

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† The author thanks Dr. John Crongeyer for providing excellent editing support and Erica Valenti for her able research assistance. He dedicates this article to Professor Jay Katz, who inspired a generation of Yale law students to study the interface of law and medicine.

have introduced proposals that would place a patients' bill of rights at center stage in the current debate over health care reform. Our political leaders call for increased accountability of managed care organizations (MCOs). They advocate guarantees for certain patient rights (including a broader choice of physicians), establish procedures reviewing denials of treatments by MCOs, and entitle patients to sue their health plans for damages in state courts if a MCO's denial of care causes harm.<sup>4</sup> This congressional plan for national reform is patterned after what a majority of states have already adopted. In the 2000 presidential election campaign, Republican and Democratic candidates alike recognized the great importance of health care reform and expressed specific support for the patients' bill of rights.<sup>5</sup> As a result, it appears quite likely that Congress will make the patients' bill of rights one of the most highly publicized health care reforms of recent times.

This Article consists of six parts. Part I describes the important role of managed care plans in health care delivery and considers why the public perceives a compelling need for regulating MCOs through a patients' bill of rights. Part II outlines the major reforms contemplated by Congress that may be included in the patients' bill of rights. The proposed reforms provide: (1) protection only for those enrolled in private managed care plans that are self-insured or employer-sponsored; (2) appeals of disagreements between MCOs and patients over treatment decisions; and (3) access to specialists and emergency rooms. Part III illustrates how these proposed reforms place a heavy emphasis on regulating MCOs by assigning due process rights to patients of privately funded health plans.

The essay then offers a vision of a patients' bill of rights that bases its reform on principles of both equality and due process. Empirical research demonstrates that although managed care systems appear to provide roughly adequate health care for the general public, they may not be providing equal treatment for the poor and elderly. Furthermore, empirical research also indicates that race accounts for the largest disparities in treatments. Part IV describes how the patients' bill of rights could safeguard the rights of more patients by extending protections to publicly financed managed care programs such as Medicaid. Part V suggests that certain due process protections, such as the right to appeal treatment decisions, will have only a limited impact on patient care. If reformers of managed care desire to achieve a broader and more equitable result, they should seek reforms that encourage health care providers to offer patients treatment approaches more consistent with national standards of medical care. Part VI discusses the impact that the principle of equality would have on improving access by minorities to appropriate



health care. This type of reform would emphasize the importance of encouraging MCOs to integrate their care with local and state agencies in order to promote public health.

## I. THE IMPORTANT ROLE OF MANAGED CARE IN HEALTH CARE DELIVERY

In response to escalating costs associated with the traditional fee-for-service approach, employers and insurers have turned to MCOs as a financial solution. Managed care systems represent an increasingly dominant approach to health care delivery. The two major types of MCOs are HMOs and preferred provider organizations (PPOs). HMO health plans place at least some of their providers at risk for medical expenses and rely on designated providers as gatekeepers. PPOs, on the other hand, contract with independent providers for services at a discount. Because employers and insurers pay HMOs and PPOs fixed rates based on the health characteristics and size of an employee group, HMOs and PPOs have a direct financial incentive to minimize costs.<sup>6</sup> HMOs enrolled over eighty-one million Americans by 1999, and the number enrolled in various forms of PPOs now reportedly rivals those in HMOs.<sup>7</sup> More than 70% of Americans who receive health insurance through their employers are enrolled in MCOs.<sup>8</sup>

MCOs rely on two primary mechanisms to minimize costs: (1) managing the quality of care delivered; and (2) limiting patient visits to specified provider groups.<sup>9</sup> First, MCOs may manage the quality of care delivered by arranging for primary care physicians to serve as the gatekeepers and to coordinate access to hospitals and specialists. MCOs may also encourage reasonable utilization of medical services through the education of providers, utilization reviews, and treatment/referral guidelines. Second, MCOs can contract with panels of providers and limit patient visits to these panels. This arrangement allows MCOs to contract at financial discounts by guaranteeing provider groups exclusive rights to certain volumes of patients. If a provider group is not willing to provide care at sufficient discounts, the MCOs may contract with other provider groups.

Overall, managed care systems appear to improve the control of medical costs. Total expenditures have decreased, while enrollment in managed care plans has increased.<sup>10</sup> Rising medical costs in the late 1980s spurred the development of the managed care industry. In the early 1990s, costs stabilized and then rose again before reaching a plateau in the mid-1990s. Medical costs were expected to rise 5-7% in 1999.<sup>11</sup>

Although managed care slowed increases in medical costs during the 1990s, the public distrusts managed care systems. This distrust stems from

concern that MCOs place undue pressure on doctors to reduce costs. Former Vice President Al Gore, during his presidential campaign in 2000, said, “[t]here’s an emergency in America all right, and it’s the lack of a strong, enforceable patients’ bill of rights.” Promising to give doctors power to make all medical decisions—rather than leaving them up to cost-conscious HMOs—Gore said the insurance company has no “right to play God.”

The Gore campaign also unveiled a health care advertisement deriding health insurance managers as “some bean-counter[s] behind a computer terminal who should not be able to deny patients certain treatment because it costs the HMO too much.”<sup>12</sup> Gore’s political speech reflects the public’s general wariness of the financial motivations of MCOs.

Notably, however, Gore’s attack does not contain specific references to any objective proof that the quality of care provided by MCOs is less than that associated with fee-for-service insurance coverage. Health care service researchers who have compared objective quality measurements of managed care plans with fee-for-service arrangements have reached conclusions that do not raise substantial concerns about the quality of overall care provided. Experts who have reviewed the medical literature have concluded that the quality of managed care plans is roughly equivalent to fee-for-service insurance plans.<sup>13</sup> The studies focusing on health outcomes have not found a significant difference in the general population between fee-for-service plans and managed care arrangements.<sup>14</sup> Surveys of private health plans, however, clearly show that comprehensive managed care plans offer better coverage for medical services, such as vision and dental care, than fee-for-service arrangements.<sup>15</sup> The proposed reforms for managed care do not appear to be in response to specific and objective evidence regarding quality of care, but instead seem to respond to the public’s more general concern about the financial incentives of MCOs to reduce costs. As a result, reformers in Congress do not focus on specific ways to improve medical treatment, advocating due process protections of patient choices instead.

## II. THE PROPOSED PATIENTS’ BILL OF RIGHTS

Congress appears to be moving in the direction of adopting a patients’ bill of rights that is designed to protect middle-class participants in managed care systems.<sup>16</sup> Republicans and Democrats plan to regulate some or nearly all private managed care plans. The proposed patient protections focus on procedural measures that emphasize individual initiative. The patients’ bill of rights requires particular resource allocations that reflect middle-class values.

*A. Coverage*

The two political parties disagree as to the proportion of mainstream members of managed care plans that will be protected by the patients' bill of rights. Republicans would limit certain resource allocation protections to the forty-eight million Americans who get their coverage from self-insured plans. Democrats favor further extensions of these protections to employer-sponsored plans that apply to an additional seventy-five million Americans. Both parties have proposed extending the internal and external review procedures to all self-insured and fully insured employer-sponsored plans.<sup>17</sup>

*B. Procedural Fairness*

Both presidential candidates emphasized their concern about leaving it up to managed care administrators to deny medical diagnostic tests and treatments, rather than leaving these decisions in the hands of doctors.<sup>18</sup> The public worries that financial pressure on MCOs creates too strong an incentive to reduce the amount of diagnostic testing and treatments even if medically necessary. The Republican and Democratic versions of the patients' bill of rights give patients the right to an external review of a health plan's benefit decision by independent medical reviewers.<sup>19</sup> Additionally, the Democrats would like to give physicians, not health plans, the authority to determine when medical testing and treatments are necessary and forbid MCOs from giving physicians financial incentives to withhold care.<sup>20</sup>

The greatest controversy, however, arises from the Democratic position in favor of allowing patients to sue if an injury results from a denial of care.<sup>21</sup> Currently, patients do not have this legal right to sue because courts have interpreted the Employee Retirement Income Security Act of 1974 (ERISA)<sup>22</sup> as barring such suits against MCOs in state court because of federal preemption.<sup>23</sup> Congressional Republicans oppose removing this preemption and would rely mainly on external appeals to medical reviewers.

Both Republican and Democratic proposals provide various consumer protection provisions.<sup>24</sup> These protections include a ban on "gag clauses" in physician contracts that forbid physicians from making disclosures to patients. The consumer protection provisions also require MCOs to disclose specific types of health plan information.

### *C. Access to Health Care*

Congressional proposals require that patients have access to certain providers and services. The proposals require MCOs to provide coverage for patients' visits to emergency rooms if a prudent layperson would consider the visit to be an emergency.<sup>25</sup> The proposals would also give patients direct access to gynecologists and pediatricians without the necessity of a referral from a primary care physician, and provide continuity of care for patients previously treated by certain specialists who have left the network.<sup>26</sup>

### *D. Summary*

The patients' bill of rights represents a congressional effort to extend certain procedural and substantive rights to members of mainstream managed care plans. Congress appears ready to provide health care reform to members of self-insured and, perhaps, all privately insured programs. The procedural protections emphasize individual initiative to pursue internal and external medical review procedures. The proposed reform gives members of private managed care plans broader access to emergency rooms and specialists.

## III. THE FOCUS ON DUE PROCESS RIGHTS

The name for this legislative reform—the “patients’ bill of rights”—analogously refers to the U.S. Constitution’s Bill of Rights. This terminology highlights the perceived importance of this proposed reform. This reform establishes procedural protections of patients’ choices of treatment within managed care systems. The proposed rights for patients bear a striking similarity to rights guaranteed by the Due Process Clause of the U.S. Constitution. Just as the Due Process Clause guarantees criminals a right to a fair trial and to appeal jury verdicts, the proposed patients’ bill of rights gives patients the right to external reviews of medical decisions and to sue HMOs. Similarly, just as police must read criminal suspects their *Miranda* rights while under custody, the patients’ bill of rights would require health plans to disclose certain information about coverage and ban gag clauses in physicians’ contracts.

Moreover, the proposed reform’s emphasis on protecting particular kinds of patients’ choices bears some similarity to a different aspect of the Due Process Clause that involves “substantive” due process rights. The Supreme Court in *Roe v. Wade*<sup>27</sup> established that the Due Process Clause guaranteed a woman’s right of access to a particular medical procedure, an

abortion, that cannot be interfered with by the government or even by her spouse. Similarly, Congress now contemplates establishing a patient's right to access specialists and emergency rooms without approval by his or her primary care physician.

Abortion rights and the proposed patients' rights share yet another similarity. Those who are financially unable to afford to exercise these rights cannot benefit from the existing rules. In *Harris v. McRae*,<sup>28</sup> the Supreme Court held that the government is not required to provide financial support to the indigent who seek abortions under Medicaid even if medically necessary. Similarly, the proposed patients' bill of rights would not extend its protections to the indigent who receive their medical care through Medicaid managed care plans. The government remains committed in both cases to enforcing the due process guarantees for the majority who can afford to exercise their rights in the private realm. On the other hand, the government does guarantee a right of equal access by the poor who constitute a minority in the community. Thus, the real challenge is to make this "equal" access truly meaningful.

While proponents of the patients' bill of rights rely on due process as the main framework for reforming managed care, they neglect an important perspective within the U.S. Constitution—our society's commitment to equality. The current proposal for reforming managed care systems consists of a bill of rights that lacks an equal protection clause. This Article considers how the current proposal could be revised if reformers of managed care instead relied on a principle of equality that would protect minorities including racial/ethnic groups, the poor, and the elderly.

Researchers in health care services have identified substantial disparities in health care delivery involving racial/ethnic minorities, the poor, and the elderly. Dr. Jack Geiger, an expert in this field, stated in an editorial in *The New England Journal of Medicine* that "race was the overriding determinant of disparities in care" and that "[t]hese issues are all the more urgent because of the risk that managed competition and capitated payment systems may increase the likelihood of discriminatory judgments, not least in the urban teaching hospitals that are essential resources for inner-city populations."<sup>29</sup>

#### IV. EXPANDING THE APPLICATION OF THE PATIENTS' BILL OF RIGHTS

The emphasis by the patients' bill of rights on individual choice, due process protections, and limiting its jurisdiction to private health plans will result in an important regulation that largely benefits the employed middle class. This essay critiques the proposed reform and then advocates

the addition of a complementary perspective based on equality of choices, equal protection, and responsiveness to socioeconomic diversity. The patients' bill of rights should promote health care delivery that is inclusive in its application, not just its conception. Reformers should extend the reform's application to Medicaid managed care plans.

Both Republicans and Democrats propose to extend the patients' bill of rights to privately insured health care plans, thus covering only those that are self-insured and possibly those that are employer-sponsored.<sup>30</sup> This proposed reform will not extend to Medicaid managed care plans, which have become the dominant delivery model for low-income beneficiaries. Medicaid managed care plans include more than seventeen million beneficiaries—more than half of the Medicaid-eligible population.<sup>31</sup>

The federal government encouraged the development of Medicaid managed care programs by establishing a waiver process in 1993 that allowed states to enroll Medicaid recipients in managed care programs.<sup>32</sup> Medicaid enrollments in managed care programs have skyrocketed since the initiation of the waiver process. States have substantially increased their reliance on Medicaid managed care systems in the absence of strong empirical evidence that they result in any substantial improvements in care.<sup>33</sup> On the other hand, state Medicaid programs estimate that the rates of savings range from 5-34%.<sup>34</sup> Thus, the current benefits of managed care may lie in their financial benefits, not their direct health effects.

It is unfair to guarantee special legal protections to members of private managed care plans while failing to provide these same guarantees to members of publicly financed managed care programs including Medicaid. The U.S. Supreme Court recently described in *Pegram v. Herdrich* how HMOs must engage in rationing medical care to reduce medical costs.<sup>35</sup> The Court noted that this "rationing necessarily raises some risks while reducing others (ruptured appendixes are more likely; unnecessary appendectomies are less so)."<sup>36</sup> The Court also indicated that this decision-making involves "judgments of social value, such as optimum treatment levels and health care expenditure."<sup>37</sup> The patients' bill of rights is premised on the belief that health care has a high social value that warrants special protections to encourage these optimum treatment levels and expenditures. By not making the patients' bill of rights applicable to Medicaid, we are further segregating the health care system of the lower socioeconomic class and increasing differences in the quality of health care provided.

The poor and the elderly may have a greater need to be protected by a system that safeguards patients' rights. Dr. John Ware and other Boston area physicians analyzed differences in health outcomes of chronically ill

adults treated in HMOs and fee-for-service systems over a four-year period, and they published their results in the *Journal of the American Medical Association* in 1996.<sup>38</sup> After conducting this observational study of 2,235 patients, they found that the average patient's physical and mental health outcomes did not differ between managed care and fee-for-service systems.<sup>39</sup> The elderly and poor in HMOs, however, were nearly twice and more than twice, respectively, as likely to decline in health compared to other patients in fee-for-service systems.<sup>40</sup>

While the application of the patients' bill of rights to Medicaid would increase expenses, it is not an impractical concept. Many of the proposed reforms are similar to rights that have been established for publicly funded managed care plans associated with Medicare. Under Medicare regulations, patient protections include the right to external reviews, prohibitions of certain financial incentives for physicians, and standards establishing consumers' rights to access specialists and other services.<sup>41</sup> Moreover, some states have similar protections for their Medicaid managed care plans. States may establish these patient protections through their contracts with MCOs.<sup>42</sup> Reformers should examine these state contracts and choose those patient protections that have proven effective for uniform application across states.

## V. PROMOTING EQUALITY THROUGH INFORMED CONSENT

The proposed patients' bill of rights establishes appellate review for patient challenges to denials of treatment by MCOs. While the procedural due process protections—including internal and external review procedures—are important in individual cases, they will only benefit a small percentage of managed care enrollees. Among those patients who are denied a treatment request, few seek external reviews. While the procedural rights of review are important patient protections, reform that is based on the principle of equality should have more expansive effects. In particular, the reforms currently proposed will not broadly impact the daily decisions and the important conversations that occur between physicians and patients. Empirical studies have pointed out that physicians, not MCOs, may be offering less care, even if medically necessary, to patients in managed care plans compared to those in fee-for-service arrangements. The advice and recommendations offered by physicians to patients ultimately impacts care to a greater extent than MCO policies or treatment denials.

Researchers at Harvard Medical School recently published a study regarding the preeminent importance of doctor-patient communications on health care in *The New England Journal of Medicine*.<sup>43</sup> They compared the

use of coronary angiography after acute heart attacks among Medicare beneficiaries in managed care plans and fee-for-service arrangements. They analyzed data from more than 50,000 beneficiaries and evaluated patient care based on guidelines proposed by the American College of Cardiology and the American Heart Association. Among those patients for whom angiography is useful and effective, 46% of fee-for-service beneficiaries underwent angiography compared to 37% of managed care beneficiaries. Thus, in situations where angiography is believed to be medically useful, physicians order it less often for those enrolled in managed care programs than for those in fee-for-service arrangements.

The study offered two other important conclusions. In both managed care and fee-for-service arrangements, the level of angiography use was much higher among patients initially admitted to a hospital with angiography facilities than among those admitted to a hospital without such facilities. Thus, the physical infrastructure of health care delivery may have a decisive impact on what is offered to patients. The most striking conclusion, however, is that physicians in both groups ordered angiography for less than half of those patients for whom it would have been medically useful.

Physicians have a greater impact on patient choices than MCOs. MCOs deny physician recommendations in just 3% of cases overall and in only 1% of cases involving hospitalization and surgical requests.<sup>44</sup> In cases where angiography is believed to be medically useful, physicians ordered it in less than half of the cases, whether or not their patients were in managed care or fee-for-service plans. If we are serious about protecting the choices of patients, we must focus reform on finding ways to profoundly influence physician-patient relationships and what physicians are recommending to their patients.

Dr. Jay Katz described in his book, *The Silent World of Doctor and Patient*,<sup>45</sup> the need in an age of medical science and sophisticated technology for more honest and complete conversations between physicians and patients. Although his book was published more than fifteen years ago, its message remains important in today's managed care settings. To achieve effective physician-patient relationships, we need to go beyond the banning of gag clauses in physician contracts or simply requiring MCOs to add more fine print in managed care contracts with patients. Managed care plans may provide an important infrastructure for educating physicians, identifying health priorities, and monitoring data to ensure that adequate treatments are more universally provided.

In addition, MCOs should make their treatment guidelines more accessible to patients through their physicians. For example, when a



patient suffers from a heart attack, a physician should discuss the evaluation and treatment options (including obtaining an angiogram) with the patient and his or her family. The physician should also disclose if the managed care plan's guidelines differ from national recommended guidelines, and should discuss the availability of angiography facilities. In short, to make the patients' bill of rights truly effective, reformers should move in the direction of enhancing physician-patient relationships in ways such as these.

## VI. PROMOTING PUBLIC HEALTH THROUGH MANAGED CARE

The proposed patients' bill of rights does not address disparities in health care treatments and outcomes of racial/ethnic minorities. Physicians tend to pursue less aggressive therapies for African-American patients compared to white patients. Researchers affiliated with the Health Care Financing Administration (HCFA) analyzed Medicare administrative data from 1993 to study the relationship between race and the utilization of health care services.<sup>46</sup> These data demonstrated that physicians performed certain procedures—including mammography, coronary angioplasty, coronary artery bypass surgery, and hip repair surgery—less frequently on African-American patients. Many other research studies have confirmed some of these findings and have also shown that black patients receive fewer nephrology referrals, less frequent surgeries for lung cancer, and have generally poorer health outcomes.<sup>47</sup> Because managed care places increased economic pressures on physician judgments, there may be an increased likelihood of discriminatory results in treatments and health outcomes.

The results of one recently published study offered surprising and controversial results. The study included 147 Veterans Administration (VA) hospitals for six common medical diagnoses (pneumonia, angina, congestive heart failure, chronic obstructive pulmonary disease, diabetes, and chronic renal failure).<sup>48</sup> Prior studies of VA hospitals have indicated that there are racial differences in the treatment of specific diseases.<sup>49</sup> The more recent study found that African-American patients had lower mortality rates than whites for each of the six diagnoses.

Critics of this study pointed out that it is difficult to know if the empirical results are "real." It may be that the differences in outcomes between African-American and white patients were due to differences in the severity of their illnesses and other co-morbidities at the time of admission.<sup>50</sup> Even the authors of the VA study conclude that the outcomes may be attributable to the nature of the VA system as an equal-access health care system.<sup>51</sup> The VA system has few financial barriers and may

therefore offer better access to care for African-American patients.

Obviously, further research needs to be done to better understand racial differences in treatments and outcomes. Researchers should study managed care systems where the financial pressures may be more pressing than fee-for-service systems. For example, researchers should conduct more empirical research on the effects of deductibles and co-payments, the quality of translational services, the presence of minority physicians, and the geographic proximity of health care delivery to minority groups.

The current debate over the proposed patients' bill of rights is an example of what Professor Mary Ann Glendon calls "rights talk."<sup>52</sup> It tends to lead to discussions that ignore our responsibilities and "regularly promotes the short-run over the long-term, crisis intervention over preventive measures, and particular interests over the common good." Managed care plans should increase their collaboration with local and state agencies to improve access to health care programs by racial/ethnic minorities and the indigent. Public health programs include immunizations, injury prevention, diabetes detection and treatment, cancer screening, heart disease risk management, and protection from environmental hazards. Racial/ethnic minorities and the indigent are among the chief beneficiaries of public health programs because of the higher disease incidences, reduced access, and poorer health outcomes in their populations. Managed care plans may provide an important structure for collecting data, identifying priorities, supporting outreach programs, and promoting incentives to improve the success of public health activities.<sup>53</sup>

Reformers should base their reforms on programs that have promoted public health through health care financing systems. An example of a successful Medicaid program is early periodic screening, diagnosis, and treatment (EPSDT) for children under twenty-one years of age. This program entitles children to vision, dental, hearing, and screening services. Studies have demonstrated that EPSDT programs can improve children's health, although their implementation has been limited to less than 40% of poor children.<sup>54</sup>

#### EPILOGUE: THE CASE OF THE MISSING EQUAL PROTECTION CLAUSE

It is ironic that Congress has analogized the proposed reform in health care to the Bill of Rights in the U.S. Constitution and yet appears to create a patients' bill of rights that is missing an equal protection clause. After all, the most renowned civil rights case is *Brown v. Board of Education*.<sup>55</sup> Declaring that "education is perhaps the most important function of state and local governments," the U.S. Supreme Court held that the segregation

of public elementary schools based on race violated the equal protection of laws guaranteed by the Fourteenth Amendment. In its opinion, the Court rationalized its holding based, in part, on empirical studies of children taught in segregated schools that purportedly showed that their educational and mental development was retarded because of segregation.<sup>56</sup>

The Court also issued a companion case, *Bolling v. Sharpe*,<sup>57</sup> on the same day as *Brown*. In *Bolling* the Court considered whether racial segregation in the District of Columbia public schools violated the Bill of Rights. Because these schools received federal funding, the Court could not, as it had in *Brown*, rely on the Fourteenth Amendment's equal protection clause that applies to state action. The Court had to interpret the Fifth Amendment that restricts federal action. Unlike the Fourteenth Amendment that contains both equal protection and due process clauses, the Fifth Amendment only has a due process clause. In *Bolling*, the Court thus considered the case of a missing equal protection clause. The Court nevertheless declared that "it would be unthinkable that the same Constitution would impose a lesser duty on the Federal Government,"<sup>58</sup> and required, therefore, that the District of Columbia public schools must be desegregated just as in *Brown*. The Court believed that segregation in public education should no longer be tolerated. Equality, in that context, was too important a principle to ignore.

Today, few would contend that the *Brown* or *Bowling* cases were incorrectly decided. Yet, we have learned that desegregating public school systems did not lead to true equality in education. Our ongoing struggle to provide adequate education and health care remain parallel and require our full commitment to promoting adequate quality in both public and private domains. We are confronted today with congressional proposals that would create a patients' bill of rights without an equal protection clause. If we proceed along our current pathway in health care reform, Congress will pass a patients' bill of rights establishing due process protections for middle-class citizens who are provided health insurance through their employers. Congress is not likely to entitle the poor who must rely on Medicaid programs to the same due process rights. The citizen belonging to a private managed care plan will be entitled by federal law to appeal denials of treatment, to have direct access to certain specialists, as well as other important rights. However, the Medicaid patient affiliated with the identical managed care organization may be denied the same treatment and may not be entitled to appeal the denial or have equal access to the desired providers. Based on available empirical research, the poor and the elderly suffer worse physical health outcomes in managed

care systems compared to fee-for-service plans, while this finding has not been found to be true for the middle class.<sup>59</sup> The largest disparities in health care delivery have been associated with race. By ignoring this empirical information, the proposed patients' bill of rights will re-enforce the segregation of health care between the "haves" and "have nots."

The Massachusetts Office of Patient Protections has yet to consider even a single patient complaint. If this trend continues, it will mirror the experiences in thirty-seven other states with similar offices where patients come in at a trickle.<sup>60</sup> The proposed patients' bill of rights should be more than a much ballyhooed gesture to support the middle-class who are enrolled in privately insured managed care plans. Instead, it should be a true bill of rights with due process and equal protection guarantees that ensure rights to decent medical care by all—including racial/ethnic minorities, the poor, and the elderly.

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# Race and Discretion in American Medicine

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Rarely has a piece of social science research received more attention than the 1999 study by Kevin Schulman and others reporting large differences in physicians' responses to identical heart disease symptoms presented by black and white actors portraying patients.<sup>1</sup> The 720 physician-subjects who participated in the study<sup>2</sup> referred lower proportions of African-American than white age and sex matched "patients" for cardiac catheterization, a costly, state-of-the-art diagnostic measure, even after the researchers controlled for physicians' subjective impressions of disease likelihood and severity. Critics quickly found errors in the authors' statistical methodology—errors that exaggerated these racial disparities.<sup>3</sup> *The New England Journal of Medicine*, in which the article appeared, then took the extraordinary step of issuing a partial retraction.<sup>4</sup>

Yet publication of the Schulman study did more than any other single event to put the matter of racial disparities in health and medical care on the American public policy agenda—and to frame political discussion of the topic. Hundreds of prior publications reported powerful evidence of racial gaps in life expectancy, morbidity from various illnesses, access to health insurance and services, and the clinical management of disease.<sup>5</sup> But the Schulman study's use of African-American and white actors with identical scripts presented a stark picture of pure racial bias, uncomplicated by the potentially mediating roles of educational background, economic status, or other social cues. The study received

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† Preparation of this Article was supported in part by a Robert Wood Johnson Foundation Investigator Award in Health Policy Research. I thank Jack Geiger, Patricia King, Tom McGuire, David Mechanic, Ruth Mendel, and Diane Orentlicher for their comments and suggestions; Elizabeth Pope and Genevieve Grabman for their research assistance; and Barbara Krimgold for inspiring me to address this subject. I am also grateful to Brian Smedley and Adrienne Stith of the Institute of Medicine (IOM) for their extraordinary background research in support of the IOM's Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, on which I serve. This Article, however, reflects my views alone.

national media attention, and months later a congressional appropriations report termed its findings “alarming.”<sup>6</sup> Report language spotlighting the Schulman study accompanied federal legislation funding an Institute of Medicine (IOM) inquiry into the scope, impact, and causes of racial bias in American medicine. A variety of other public and private sector initiatives targeted racial bias in American health care as a topic for research, discussion, and intervention.<sup>7</sup>

Racial disparities in health care provision that persist even when researchers control for income, education, and health insurance status are the primary focus of these initiatives. Efforts to understand the reasons for these disparities have focused on psychological, social, and cultural influences that affect providers’ clinical judgments and patients’ expressed preferences. In this Article, I explore institutional, economic, and legal factors that contribute to these disparities. This contribution, which I contend is larger than commentators on health care disparities typically acknowledge, occurs through interaction between organizational and legal arrangements and physicians’ exercise of clinical discretion. Because these arrangements are amenable to pragmatic intervention, they deserve close attention.

My focus in this Article is on racial disparities in medical care provision—that is, on differences in the services that clinically similar patients receive when they present to the health care system. Racial disparities in health status, which is not greatly influenced (on a population-wide basis) by medical care, are beyond my scope here. Disparities in medical care access—potential patients’ ability, financial and otherwise, to gain entry to the health care system in the first place, are also outside my focus. But I begin this Article by putting the problem of racial disparities in medical care provision within the larger context of disparities in health status and medical care access.

In Part I, I concede: (1) that medical care is almost certainly less important as a determinant of health than are social and environmental influences, and (2) that inequalities in Americans’ ability to gain entry to the health care system probably play a larger role in medical treatment disparities than do racial differences in the care provided to people who succeed in gaining entry. I then briefly examine the moral politics behind the appearance of racial disparity in health care provision on the national policy agenda, ahead of disparities in health status and medical care access. In Part II, I consider the links between clinical discretion and racial disparities in health care provision. I argue that pervasive uncertainty and disagreement, about both the efficacy of most medical interventions and the valuation of favorable and disappointing clinical outcomes, leave

ample room for discretionary judgments that produce racial disparities. Neither existing institutional and legal tools, nor prevailing ethical norms, impose tight constraints on this discretion. As a result, provider (and patient) presuppositions, attitudes, and fears that engender racial disparities have wide space in which to operate. In Part III, I refine this argument, pointing to a variety of extant organizational, financial, and legal arrangements that interact perniciously with psychological and social factors to potentiate racial disparities. Part IV considers the impact of the managed care revolution, contending that its cost containment strategies both contribute to racial differences in health care provision and create opportunities for reducing some of these disparities. Part V closes with some recommendations as to how health care institutions and the law might respond pragmatically to racial disparities even as they pursue other important policy goals.

## I. INTRODUCTION: THE POLITICS OF DISPARITY IN HEALTH AND MEDICAL CARE

Notably missing from the national political agenda, though well documented in the research literature, are the larger problems of population-wide racial gaps in health status and access to medical care. Epidemiological research in the United States and abroad indicates that health care is only modestly important as a determinant of population-wide health. Variations in medical spending account for only a small portion of population-wide class and race-related differences in health status: life expectancy, infant mortality, and the incidence of many diseases correlate much more closely with income, education, environmental conditions, race, and ethnicity.<sup>8</sup> Racial disparities in health care access arise in large part from socio-economic disadvantage and the consequently unequal affordability of medical coverage and services.<sup>9</sup> Disparities in the health care Americans receive that persist after researchers factor out measures of socio-economic status are narrower.

Scholars in a diverse range of fields, from health services research to bioethics to developmental economics, have highlighted disparities in both health care affordability and health status, debated their causes, and proposed solutions. But there is no serious prospect of public action to ameliorate these disparities. Universal health insurance coverage would greatly reduce racial differences in health care access that result from disparities in ability to afford coverage, yet universal coverage has been off the American political agenda since the collapse of the Clinton administration's reform plan in 1994. The more intractable problem of racial disparities in health status has attracted some of the research

attention recently paid to social determinants of health,<sup>10</sup> but our politics has not focused on these disparities as a problem in urgent need of a public policy response.

Why has racial bias in the clinical judgments physicians make on behalf of equivalently insured and socio-economically situated Americans generated a greater political response than has the racially unequal impact of allowing more than forty million Americans to go without medical coverage?<sup>11</sup> And, why have racial disparities in health status—a thing distinct from health care provision and not much influenced by it—received less political attention than has racial bias in physician judgment? The answers to both questions, I suspect, implicate our national tolerance for socio-economic inequality as a factor in disparities we deem unacceptable when they result purely and simply from racial bias. As a matter of law—and of politics—we tend to treat racial disparities in Americans' enjoyment of myriad goods, services, and benefits as less troublesome when they are mediated through socio-economic differences than when they arise from the overt bigotry of identifiable actors. Thus, racial disparities in access to health care (and in physicians' clinical recommendations) due to differences in insurance coverage<sup>12</sup> are more "acceptable" than up-front racial bias at the bedside, despite the known correlation between coverage status and race (and despite the causal role of prior racial subordination in present socio-economic disadvantage).

Racial disparities in health status are not readily tied to identified, racially biased actors. To the extent that these disparities arise from the disproportionate presence of minorities in lower socio-economic strata, they are subject to dismissal as epiphenomena of socio-economic inequality. Even the disparities that persist when indicia of socio-economic class are factored out cannot easily be linked to particular perpetrators. Explanations for these lingering health disparities have invoked stress from diminished social connection and repeated experiences of prejudice,<sup>13</sup> as well as myriad losses of material opportunity that fail to register in assays of socio-economic status.<sup>14</sup> The pervasive, often subtle discrimination these explanations entail cannot be traced to a small circle of identifiable perpetrators.

The politics of racial disparity in health matters has important practical implications. Framing the problem of racial disparity as one of bias in clinical judgments concerning patients who differ by race but are similarly situated in terms of insurance status and income draws attention away from race-related economic disadvantage and from illness-inducing stress arising from pervasive racial bias. To the extent that focusing on racial bias in therapeutic decisionmaking makes it politically more difficult

to direct public attention (and resources) toward the larger problem of race-related economic and social disadvantage (and its health consequences), there is tension between different approaches to the relationship between race and health. This tension is two-fold—between efforts to reduce bias in clinical judgment and to make coverage and care more affordable and between devotion of resources to medical care and to programs targeting the social and economic determinants of health status.

I do not mean by this to suggest that racial disparities in care provided to similarly insured and economically situated patients are other than deeply troubling and deserving of a robust public policy response. To the contrary, our national political attentiveness to matters of racial justice is intermittent and partial at best, and I believe we should seize opportunities when they arise.<sup>15</sup> And it may even be that, rather than pulling attention away from other forms of race-related disadvantage, public focus on racial disparities in clinical decisionmaking could inspire national concern about other kinds of health disadvantage that disproportionately affect some racial groups.

In any event, racial disparity in medical decisionmaking has emerged on the public policy stage as both a health policy and a civil rights issue. More than many other civil rights problems, it has attracted bipartisan concern. We should endeavor to translate this visibility and concern into a pragmatic strategy for addressing racial bias in health care provision. In so doing, we should also keep our eye out for larger lessons, about how racially biased outcomes can result, even absent overt bigotry, from the decentralized exercise of discretion within the complex, fragmented institutional arrangements characteristic of much of contemporary American life.

To these ends, I will try, in the remainder of this essay, to identify ways by which the organization and legal governance of health care provision may foster racial disparities in clinical decisionmaking—and how legal change therefore might make a positive difference. I will also consider law's limits in this regard, as both an explanation for these disparities and a tool for ameliorating them. I am mindful that racial bias, in medical care as in other endeavors, is not solely, even primarily, a function of institutional or legal arrangements, and that not all health care disparities arise from providers' racial prejudices. Institutions and law nonetheless make a large difference, and modest change in the health care industry's legal environment might substantially reduce disparities in care provision.

## II. CLINICAL DISCRETION AND RACIAL DISPARITY

My starting point for considering the role of institutions and the law is

the enormous discretion clinical caretakers routinely exercise and the similarly wide discretion of those who decide whether insurers will pay—utilization reviewers and, increasingly, treating physicians who act as gatekeepers. Most medical decisions do not rest firmly on empirical evidence. There are typically multiple diagnostic and therapeutic options, and wide variations in the incidence of many common medical and surgical procedures have been documented within small geographic areas and between individual practitioners.<sup>16</sup> Absence of professional consensus about appropriate diagnostic and therapeutic measures often reflects the lack of undergirding scientific evidence. The paucity of scientific support for most medical decisions both contributes to clinical practice variations and makes it impossible in many cases to reach evidence-based conclusions as to which practice variations constitute over and underuse. Lack of agreement on how to value favorable (and unfavorable) clinical outcomes even when possible outcomes are empirically predictable amplifies medical practice variations.<sup>17</sup> These variations create room for clinical discretion constrained more by different local and institutional traditions than by science-based medical practice parameters.

#### *A. Legal and Administrative Constraints on Clinical Discretion*

Neither private health insurance contracts nor the statutes governing publicly financed coverage (principally Medicare and Medicaid) contain language that meaningfully limits this discretion. Contractual and statutory provisions typically mandate coverage for all “medically necessary” care, subject only to categorical exclusions such as “investigational” therapy and care received “out-of-network” or not in accordance with required referral procedures. What constitutes “medical necessity” in particular cases is up to individual caretakers and utilization reviewers. The problem of general standards and the broad discretion they confer is, of course, familiar to lawyers. Courts and regulatory agencies manage the indeterminacy and inconsistency that come with this discretion in three principal ways. The classic method is the issuance of successive, published, more or less reasoned decisions in particular cases. This enables parties (and legal decisionmakers) in subsequent disputes to narrow the scope of discretion and limit the resulting indeterminacy and risk of inconsistency through efforts to reason by analogy from prior decisions. An alternative approach, more commonly followed by regulatory agencies, is the issuance of detailed decision rules all at once, in a comprehensive attempt to interpret general (typically statutory) standards. A third approach, taken tacitly by legal decisionmakers, is to cloak the exercise of discretion instead of trying to constrain it.<sup>18</sup> Reliance on juries (which deliberate in secret and neither

give reasons nor set precedents) and on grievance and arbitration procedures that decide cases confidentially without creating precedent is illustrative. This approach does nothing about the problem of indeterminacy but keeps inconsistencies decorously veiled.

The first and second approaches are simply not feasible in the health care sphere. Nothing resembling the formal process of successive published opinions occurs when physicians make the scores of clinical judgments they render every day.<sup>19</sup> To try to replicate such formality at the bedside would freeze the fluid process of diagnosis and therapy. To be sure, new information technology is making it increasingly possible to record major clinical decisions and their outcomes anonymously yet accessibly. But tracking down and comparing case histories in order to assess the relevance of prior outcomes for a present clinical situation will remain a complex, costly endeavor, subject to the infinite variability of clinical scenarios and to our ignorance about which comparable patient features are relevant to the clinical question at hand. Such comparisons, moreover, typically constitute cognitive error,<sup>20</sup> perhaps the most common cognitive error in traditional therapeutic reasoning. It is the aggregation of outcomes data from many prior patients similarly situated with respect to some clinical features that renders comparison with a current patient rational in statistical terms, so long as the current patient meets inclusion criteria for the group of prior patients.<sup>21</sup>

The second approach, promulgation of detailed decision rules for all or most possible contingencies, has the potential, in theory, to substantially limit clinical discretion. Health plans that base their utilization management decisions on sets of clinical practice protocols written by plan managers or acquired from consulting firms<sup>22</sup> have tried this approach to some degree, and the difficulties they have encountered point to its limitations. Empirical uncertainty about the outcomes of most medical interventions undermines the perceived legitimacy of health plans' practice (and payment) protocols. Absent scientific support, such protocols are easy to challenge when they become the basis for denial of services. Competing understandings of "appropriate" care leave courts, review panels, and other decisionmakers without evidentiary grounds for choice.<sup>23</sup> Even a much-intensified national program of clinical outcomes research would leave this problem largely in place. Would-be authors of comprehensive payment protocols confront a classic "bounded rationality"<sup>24</sup> problem: the awe-inspiring complexity and variability of human physiology renders anticipation, clear definition, and empirical study of most clinical contingencies impossible. The scope of practitioners' discretion is further widened by the subjectivity and inevitable

incompleteness of clinical observation and interpretation. Myriad clinical signs and symptoms are open to varying perceptions and characterizations. Clinical laboratory findings, in conjunction with symptoms and signs, are often susceptible to multiple interpretations. Clinical narratives are selective—and no less centered around a point of view than is an attorney's statement of facts on a client's behalf.<sup>25</sup> Even if we could craft a comprehensive set of evidence-based rules for clinical decisionmaking, this subjectivity and incompleteness would make application of the rules a matter of considerable discretion for both the treating physician and the utilization manager.

The third approach, which looks to cloak discretion rather than constrain it, is more closely akin to what actually happens in health care settings. Most of the time, physicians exercise their broad discretion invisibly, making no record apart from clinical progress notes and submissions to utilization reviewers. Only when clinical judgments become the subject of medical conferences, insurance coverage disputes, or legal or regulatory proceedings, do these judgments emerge from the veils of patient confidentiality and professional collegiality. Physicians' practice styles may become known to some degree within their home institutions, but their decisions do not create governing precedent, and their inconsistencies go mostly unnoticed. Utilization management in individual cases is no more transparent. Health plans' coverage decisions are commonly influenced by medical practice and payment protocols, but these protocols are often proprietary. Individual coverage decisions are not reported publicly and do not set precedents that limit discretion in subsequent cases. Inconsistencies between a health plan's utilization management decisions are likely to go unseen except in the rare cases when litigation ensues.

### *B. Ethical Responses to Clinical Discretion*

The pervasive role of clinical discretion in medical practice has long been recognized by medical ethicists. The classic medical ethics answer to the problem of discretion has been the Hippocratic Oath's uncompromising commitment to the well-being of each patient.<sup>26</sup> To be sure, as I have observed elsewhere, physicians commonly serve social purposes that are at odds with this commitment's literal meaning. Medical cost containment, public health, and clinical evaluation for legal purposes are among the functions that create tension between this commitment and society's expectations.<sup>27</sup> Yet in their everyday clinical work, the overwhelming majority of physicians see undivided loyalty to individual patients as an ethical lodestar.<sup>28</sup> Beyond this commitment, and the



concomitant duty to maintain professional competence, the Hippocratic ethical tradition prescribes no rules for the exercise of clinical discretion. Classic medical ethics, rooted in the Hippocratic tradition, is akin to virtue ethics, reliant on the goodness of the doctor as a moral agent, rather than rule-based moral reasoning.<sup>29</sup> It parallels the law's reliance on fiduciary obligation in numerous situations marked by a principal's inability to monitor the performance of her agent.<sup>30</sup> These approaches entail a common strategy—encouragement of right conduct through interventions designed to insulate agents (including physicians) from bad intentions, especially those engendered by conflicts of interest. They share, therefore, the premise that discretionary judgments arising from right intentions do not, as a rule, warrant additional oversight or constraint.

For the past thirty years or more, the bioethics movement has challenged this benign view of well-intentioned discretion in the medical sphere. Committed to the new paradigm of patient autonomy and concerned about professional paternalism, bioethics commentators have insisted that physician discretion be tempered by the obligation to seek patients' informed consent. The paradigm of patient autonomy relies upon physician disclosure of risks, benefits, and clinical alternatives to give patients meaningful veto power over their doctors' discretion. But as skeptics about this veto power have observed,<sup>31</sup> physicians have wide latitude to frame clinical alternatives and to shape the contours of disclosure about them. Large variations in clinical practice, within the realm of professional acceptability, translate into vast discretion in the presentation of therapeutic options. Informed consent law's formal equality—its requirement that all material options, and their risks and benefits, be disclosed—is thus subverted by the heterogeneity of medical practice. This occurs openly in jurisdictions that defer to professional standards of materiality in defining disclosure duties and tacitly in jurisdictions that mandate disclosures material to the “reasonable patient.”<sup>32</sup> Thus the scope of patients' veto power over their doctors' exercises of clinical discretion is in large measure the product of this discretion. Moreover, patients fearful and dependent in moments of dire medical need are not inclined to assert the veto power they have. To go against the doctor's advice is to go out on one's own, something we are least willing to do when we feel most vulnerable.

### *C. Race and the Exercise of Clinical Discretion*

The substantive content of clinical discretion is thus largely beyond the reach of the ethical paradigms that nominally govern it. Physician discretion remains a wild card in American medicine, ill-constrained by

contractual obligation, legal requirements, or ethical norms. And, absent the exercise of this discretion in identical fashion for members of different racial groups, racial disparities in clinical decisionmaking are inevitable. What accounts for racial and other group differences in the exercise of clinical discretion? Comprehensive assessment of the evidence bearing on this question is far beyond this Article's scope, and a sure answer is well beyond our reach. But partial, provisional answers are possible, and they point the way toward pragmatic interventions that hold out significant potential for the reduction of racial disparities.

To begin with, the weakness of existing constraints on clinical discretion opens the way for beliefs and attitudes that operate beyond the reach of overt institutional and legal rules. Physicians' expectations and suspicions concerning therapeutic compliance and the presence of such co-morbid factors as substance abuse, poor living conditions, and lack of family and social support figure prominently in clinical judgments concerning patients' ability to adhere to risky and costly courses of treatment.<sup>33</sup> Suppositions about patients' truthfulness, self-discipline, laziness or industry, level of suffering, tolerance for pain, and intelligence influence both diagnostic impressions and treatment recommendations.

To the extent that race-related preconceptions affect these expectations and suppositions, racial disparities in clinical judgment ensue. A large, multidisciplinary literature documents and models the formulation and operation of such preconceptions. Cognitive psychologists have analyzed racial stereotypes and prejudice in functional terms, as automatic (or unconscious) category-based responses that conserve the mind's cognitive resources at the price of reduced responsiveness to human individuality.<sup>34</sup> Although stereotypes and prejudice can rise to the level of conscious bigotry, they more often operate unconsciously, as automatic cognitive placement of persons into categories with fixed sets of characteristics or as conscious placement of persons into categories with unconsciously surmised characteristics. Psychodynamic and sociocultural models of stereotyping and prejudice likewise recognize the import of unconscious preconceptions.<sup>35</sup> Below the waterline of conscious categorization and presupposition, stereotypes and prejudice have free reign, shielded from human self-awareness. Medical judgment informed by such stereotypes is bound to yield racially disparate results, even absent conscious intent.

Beyond this, the attenuation of empathy across racial lines in clinical relationships can engender unconscious devaluation of minority patients' hopes, fears, and life prospects, with invidious consequences for clinical judgment, in the absence of conscious bigotry. Cultural and language

barriers between patients and providers can both amplify this effect and impede communication about symptoms, treatment options, and patient preferences.<sup>36</sup> To the extent that the time pressures, sleeplessness, and subservience to authority inherent in medical training imbue an inclination toward automatic, unreflective reactions to clinical situations,<sup>37</sup> these features of medical training enlarge the role of stereotypes, prejudice, and barriers to empathy in clinical practice.

Patients' attitudes, beliefs, and capabilities also affect clinical judgment and action in ways that are beyond the control of overt institutional and legal rules. Patients' trust and doubts about medical advice, tolerance for pain and discomfort, attitudes about long-term/short-term trade offs, and levels of social and emotional support influence physicians' recommendations and patients' willingness to accede to them. To the extent that these features correlate with race, they are additional sources of clinical disparity. Some commentators have collapsed these aspects of patients' experiences into a single category of patient "preferences,"<sup>38</sup> drawing a dichotomy between such "preferences" and racial discrimination as competing explanations for health care disparities. This reductionistic account overlooks the interactive links between patients' "preferences" and their experiences of discrimination. For many African Americans, doubts about the trustworthiness of physicians and health care institutions spring from collective memory of the Tuskegee experiments<sup>39</sup> and other abuses of black patients by largely white health professionals.<sup>40</sup> This legacy of distrust, which, some argue, contributes to disparities in health care provision by discouraging African Americans from seeking or consenting to state-of-the-art medical services, is thus itself a byproduct of past racism. In more intimate ways, minority patients' negative experiences with care providers can diminish their preferences for robust treatment and thereby engender racial disparities. Physicians' suspicions, stereotypes, negative expectations, and reduced empathy across racial lines can affect patients' feelings about their clinical relationships and thereby dampen patients' interest in vigorous diagnostic and therapeutic measures. Efforts to distinguish patient "preferences" from provider racial discrimination neglect the ways by which patients' negative responses to the latter can profoundly affect the former.

Beyond this dampening effect on minority patients' medical "preferences," health care providers' stereotypes, prejudices, and diminished empathy across racial lines can make it more difficult for minority patients to negotiate clinical bureaucracy. Maneuvering through the catch-22's, cul-de-sacs, and nests of discretion within hospitals and managed care bureaucracies is essential to the accessing of clinical

resources. Clinical caretakers are critical actors in this maneuvering. To the extent that their advocacy efforts are adversely influenced by race-related impressions and lesser personal engagement, racial minority status translates into disadvantage in negotiating medical bureaucracy, and thus into disparate real-world access to clinical services despite formal equality. In addition, to the extent that the discretionary judgments of gatekeeping bureaucrats—e.g. HMO pre-authorization reviewers and hospital staff who prioritize patients on waiting lists for tests and treatments in short supply—are influenced by racial insensitivities and stereotypes, these gatekeepers make a separate contribution to health care disparities. The subjective sense of disempowerment often associated with racial minority status<sup>41</sup> can further widen the disparities that ensue from clinical administration. People who feel less able to assert their needs tend either to do so with less vigor or, more invidiously, to feel bitter, even resentful, and to act in a manner that conveys this bitterness, thus rendering clinical administrators less empathic.

### III. INSTITUTIONS, INCENTIVES, AND THE LAW

If beliefs and attitudes beyond the controlling authority of institutional and legal governance play such a large part in the racially disparate exercise of clinical discretion, what role, if any, do health care institutions and law have in engendering health care disparities? I submit that this role is large, and that organizational design, economic incentives, and the legal and regulatory environment interact perniciously, in unexamined ways, with the psychological factors I have discussed to potentiate disparities in clinical judgment. My starting point for making this claim is the unpalatable truth that setting limits on the care we provide is a crucial task for clinical institutions and health law. Writing for a unanimous Supreme Court last year in *Pegram v. Herdrich*, Justice David Souter put this point bluntly with regard to managed care, declaring that “whatever the HMO, there must be rationing and inducement to ration” and that “rationing necessarily raises some risks while reducing others . . . .”<sup>42</sup> The need for limit-setting is no less for other health plans that must operate within a budget, whether fiscal constraints are imposed by competitive pressures in the health insurance marketplace or voters’ limited tolerance for the tax burden of publicly funded medical coverage.

#### *A. Fee-for-Service Payment and Demand-Supply Mismatches*

When physicians are paid on a fee-for-service basis and managed care is not a factor, demand-side limit-setting plays a minimal role. Clinical

caretakers committed to the Hippocratic ethic of undivided loyalty to individual patients and aware of their insured patients' low out-of-pocket costs are motivated to demand (on behalf of their patients) virtually all services with potential benefits that outweigh clinical risks. To be sure, the psychological factors I have discussed, including unconscious stereotyping, prejudice, and reduced empathy across racial lines, may influence the weighing of clinical benefits and risks, generating demand-side racial disparities. But under fee-for-service physician compensation, supply-side constraints on care probably play a larger role in engendering racial disparities. Supply-side constraints arise from limited physician time (due to barriers to entry maintained by the medical profession),<sup>43</sup> restrictions on hospitals' ability to raise capital for new facilities and equipment,<sup>44</sup> regulatory and market-driven constraints on hospital payment rates, and regulatory programs (especially "Certificate of Need" requirements) that limit hospital investment in new facilities, services, and equipment.<sup>45</sup> These supply-side constraints, alongside generous insurance coverage, create a myriad of demand-supply mismatches within hospitals<sup>46</sup> and other clinical institutions.

These demand-supply mismatches have great potential to generate racial disparities in care because of the interplay between the mechanisms that mediate these mismatches and the nature of race-related disadvantage within clinical institutions. As the economist Jeffrey Harris has observed, excess demand for a hospital's services creates multiple internal queues for services.<sup>47</sup> Absent bright-line, easy-to-apply criteria for prioritizing among patients in a queue, the politics of personal influence and professional hierarchy shapes resource allocation. Attending physicians with the professional stature and/or political skills to push their patients to the head of the queue in clinically ambiguous situations will do so on behalf of those to whom they feel most committed. Conversely, housestaff and less influential attending physicians will have more difficulty moving their patients up the queue. Moreover, treatment of patients in hospital clinics and other settings characterized by rapid staff turnover and lack of continuity of care renders committed physician advocacy on behalf of these patients less likely, whatever the professional standing and influence of their attending doctors. Patients cared for by high-status physicians in settings that support continuity of clinical relationships thus have preferred access to services when demand-supply mismatch conditions exist.

To the extent that people of color are more likely to see low-status providers,<sup>48</sup> who are less able (or inclined) to maneuver effectively within clinical bureaucracies on their patients' behalf, racial disparities in care are

likely to ensue from these status disparities. More research into which patients tend to access the most (and least) elite physicians—and into whether these differences give rise to disparities in clinical services received—is much needed. But it has long been recognized that hierarchies of professional stature and commitment to patients within clinical institutions parallel hierarchies of patient socio-economic class.<sup>49</sup> Well-off and influential patients tend to link up with elite academic and private physicians, to sustain their relationships with these physicians, and to benefit from these physicians' sponsorship and advocacy in hospital and other institutional settings.<sup>50</sup> Middle-class patients tend to access a lower level of sponsorship and advocacy, from private physicians without elite status and influence.<sup>51</sup> Working poor and unemployed patients, especially the uninsured, tend to find their way to a bottom tier of public clinics staffed by rotating house officers and salaried attendings with little institutional cache.

Social networks, family contacts, and levels of assertiveness can be as important as financial wherewithal in distributing patients across these echelons of professional status, sponsorship, and advocacy. Little is known about the links between these factors and race, and about the extent to which race (and its social consequences)—divorced from economic status—pushes patients up or down across these echelons. But evidence suggests that members of disadvantaged racial minority groups are more confined than whites (of similar economic status) in their range of social contacts and less inclined to challenge professional authority.<sup>52</sup> If this is the case, it would hardly be surprising were it to be shown that African Americans and other people of color find their way into the health care system at lower strata of professional sponsorship and advocacy than can be accounted for by economic class alone. And to the extent that lower levels of sponsorship and advocacy mean lesser access to services in short supply, racial disparities in care are to be expected. More speculatively, feedback from the supply side to the demand side may aggravate these disparities. Aware of chronic demand-supply mismatches, physicians, especially those at lower status levels, might modulate their clinical orders to bring demand more into line with supply constraints.<sup>53</sup>

### *B. Medical Tort Law and Clinical Discretion*

The law of health care provision has been largely hands-off, in practice, concerning the links between clinical discretion and racial disparities. Medical malpractice law, in theory, prescribes a unitary level of care, regardless of health insurance status or ability to pay.<sup>54</sup> But tort doctrine has long deferred to physician standards of care, under the sway

of the lingering fiction that there is a single “correct” standard, discernable from physician-experts through the adversary process. Disparities in clinical resource use ensuing from physician discretion and the influences I have just discussed tend to fall within the bounds of tacitly accepted clinical variation. Lower intensity care provided to a minority patient can thus typically be defended as consistent with one or another widely accepted standard of care. A tort plaintiff can attack care provided pursuant to a particular standard by pointing to an alternative standard and relying upon expert testimony to argue that this alternative should have been followed. But so long as the defense can marshal its own expert to support the adequacy of the care provided, the plaintiff’s need to carry the burden of proof presents a daunting obstacle to success. Medical malpractice cases commonly turn clinical practice variations into battles of the experts, unresolvable on rigorous empirical grounds, over which standard constitutes “reasonable care.” Absent the high-quality data about efficacy of alternative approaches that would be needed to resolve clinical practice variations in the first place, proof of causation-in-fact presents another large barrier to plaintiffs. Technologically less intensive approaches often cannot be shown to yield inferior clinical outcomes. Moreover, even when there is strong empirical support for the superior efficacy of one approach compared to another, the medical tort system sends a weak behavioral signal. Only a small proportion of arguable errors of clinical judgment—arguable based on empirical grounds for preferring one approach to another—result in medical malpractice suits.<sup>55</sup> Even smaller proportions yield monetary settlements or judgments, and poor people and members of disadvantaged minority groups are less likely than other Americans to sue their doctors.<sup>56</sup>

### *C. Medicaid and Programmatic Fragmentation*

Other sources of law bearing on the behavior of doctors and clinical institutions have been similarly hands-off with regard to racial disparities. The Medicaid program’s meager payment rates for doctors and hospitals have consigned this program’s poor, disproportionately minority beneficiaries to largely separate, often segregated systems of hospital and neighborhood clinics,<sup>57</sup> with their own norms of medical practice, inevitably shaped by their tight resource constraints. The reluctance of private physicians to accept Medicaid rates as payment in full has not only kept Medicaid patients out of private doctors’ offices; it has consigned them to “ward” or “community service” status as inpatients, cared for primarily by housestaff as opposed to private attendings.<sup>58</sup> Congressional repeal of the Boren Amendment, which required Medicaid payments to

doctors and hospitals to be “reasonable and adequate”<sup>59</sup> and gave health care providers a federal cause of action against state Medicaid programs,<sup>60</sup> has entrenched Medicaid’s low payment scales and largely separate systems of care. More research is needed on the question of how, if at all, standards of care within these separate systems differ from mainstream medical practice—and on whether racial disparities occur within the Medicaid program. But given the pervasiveness of clinical practice variations in American medicine and the pressure on practitioners in any system to adapt their clinical judgments and conduct to the system’s resource constraints, it would be surprising if practice within Medicaid-oriented systems were not less technology-intensive than mainstream care. And, given the segregation of Medicaid-oriented systems from each other, by neighborhood and community and therefore, in practice, by race, it would be surprising if racial disparities within the Medicaid program did not ensue.<sup>61</sup> As I will discuss later,<sup>62</sup> the recent shift in federal policy toward the easy granting of statutory waivers to permit start-up of Medicaid managed care programs is creating new possibilities for clinical fragmentation and disparity.

#### *D. EMTALA*

Judicial interpretation of the federal Emergency Medical Treatment and Active Labor Act (EMTALA)<sup>63</sup> has drained its force as a deterrent to disparate treatment in the emergency room. The Act requires hospitals that operate emergency rooms and participate in Medicare or Medicaid to screen all emergency room patrons for “emergency medical conditions” regardless of their ability to pay, to provide stabilizing treatment for such conditions, and to refrain from discharging patients or transferring them to other facilities on economic grounds.<sup>64</sup> Federal appellate panels in several circuits have held that EMTALA’s mandatory emergency screening examination need not meet national standards of care, but need only measure up to the screening hospital’s regular practice.<sup>65</sup> The practical consequences for plaintiffs<sup>66</sup> are enormous. Deprived of the opportunity to search nationally for experts to testify about the appropriate standard of care, they must look to physicians familiar with emergency room screening practice at the hospital they intend to sue—or to other evidence of this hospital’s emergency room procedures. The resulting “code of silence” problem is obvious: avoidance of the “code of silence” barrier was a principal reason for the shift from community to national standards of care in medical malpractice law. The cursory evaluation and transfer or discharge of members of disadvantaged minority groups—whether for financial reasons, racial animus, or unconscious prejudice—is thereby



rendered more likely to occur with impunity. State laws mandating emergency room screening and stabilizing treatment—a topic beyond my scope in this Article—have generally been construed and applied with similar permissiveness.<sup>67</sup>

### *E. The Unfulfilled Potential of Title VI*

In theory, Title VI of the Civil Rights Act of 1964 has enormous potential as a tool for reduction of racial disparities in health care provision. Title VI bars discrimination based on race by all who receive “federal financial assistance” and extends beyond intentional discrimination to reach many facially neutral practices with disparate racial impact. Title VI has achieved some of its potential, most notably through enforcement action by the U.S. Department of Health and Human Services (DHHS) and DHHS’s predecessor agency<sup>68</sup> against hospitals’ employment of such discriminatory practices as denial of admitting privileges to African-American physicians,<sup>69</sup> refusal of admission to patients lacking attending physicians with staff privileges, high prepayment requirements for black patients, and discriminatory routing of ambulances.<sup>70</sup> In these cases, the DHHS Office of Civil Rights has compelled such measures as revision of requirements for staff privileges, elimination of prepayment requirements, and changes in ambulance routes.<sup>71</sup> Title VI’s coverage of entities that receive “federal financial assistance” encompasses all hospitals that receive Medicare or Medicaid payments, making its potential reach remarkably broad.

Yet more might have been achieved, had more been attempted. The federal regulations promulgated pursuant to Title VI did not offer detailed compliance instructions to health care institutions<sup>72</sup> and, more significantly, held that Medicare’s payments to physicians do not constitute “federal financial assistance.”<sup>73</sup> The later, fateful decision put private physicians out of Title VI’s reach, even though virtually all other federal payments to private actors are treated by the regulations as “federal financial assistance,” triggering Title VI protections.<sup>74</sup> Treating physicians’ income from Medicare as “federal financial assistance” would have given DHHS a powerful civil rights enforcement tool, applicable not only to racial disparities in the care provided to Medicare patients, but also to disparate treatment of non-Medicare patients by physicians who accept Medicare. Since most physicians in private practice accept Medicare,<sup>75</sup> and since physicians remain the key decisionmakers with respect to use of hospital resources and services, extending Title VI’s reach to Medicare coverage of physician services would subject most of the private health care sector to Title VI enforcement.

Detailed reviews of Title VI's application to medical care have been performed by others.<sup>76</sup> I will limit myself here to the observation that the principal, still unfulfilled promise of Title VI in the health sphere lies in translation of what is now known about racial disparities in health care provision into practices and policies that reduce these disparities, especially when they can be shown to contribute to differences in health status. More specific regulatory guidance (grounded in findings from empirical research), more robust DHHS monitoring and enforcement, and application of Title VI to private physicians would represent important steps in this direction. Title VI's reach beyond intentional discrimination to policies with disparate racial impact enables civil rights enforcement to make use of institution-specific statistical evidence of disparities in health care provision. Such evidence may suffice to state a *prima facie* case of discrimination, requiring a health care provider to justify policies and practices that result in racially disparate clinical decisions.<sup>77</sup> Proof of institution-specific disparities—and of causal links between such disparities and particular policies and practices—will pose daunting challenges. Litigation involving statistical evidence of clinical disparities is likely to be expert-intensive and hence costly.<sup>78</sup> But the ongoing revolution in electronic clinical record keeping is making such evidence increasingly accessible to civil rights enforcement authorities.

The promise of such evidence would be much greater were private parties permitted to seek legal relief, under Title VI, from policies with disparate racial impact. But in April 2001, in *Alexander v. Sandoval*,<sup>79</sup> the U.S. Supreme Court held that Title VI did not create a private right of action concerning policies with disparate impact, absent discriminatory intent. Title VI's future as a health policy tool will thus be shaped largely by the federal executive branch, through its civil rights enforcement policies.

#### *F. Clinical Role Conflict and Patient Distrust*

Beyond all this, the law of health care provision has taken a stance of not-so-benign neglect toward features of American medicine that invite distrust among disadvantaged minorities. Law, in action, tolerated Tuskegee, or at least failed to prevent it.<sup>80</sup> The law today tolerates physician participation in an array of activities that are at odds with the Hippocratic commitment of undivided loyalty to patients<sup>81</sup> and that especially effect disadvantaged groups. The prison doctor, whose therapeutic role is often confused by conflicting duties to keep order<sup>82</sup> and determine criminal responsibility, is hardly a benign figure in the lives of inmates, and African Americans are disproportionately represented in U.S. prisons. The

physician who both attends to the medical needs of Immigration and Naturalization Service (INS) detainees and prescribes drugs to sedate those who resist deportation<sup>83</sup> is a similarly problematic figure in the eyes of many Latinos and others who have had personal or family experience with INS detention. Academic physicians overly focused on the training and research purposes of patient encounters, and psychiatrists at state mental hospitals who prescribe high neuroleptic doses to maintain order, are other examples to which the most disadvantaged Americans are disproportionately exposed. The likely result of the law's sometimes overt and other times tacit acceptance of such role conflict is further erosion of trust—and of willingness to go along with robust, state-of-the-art clinical interventions when well-meaning physicians make them available.

#### IV. THE MANAGED CARE REVOLUTION

Managed care has introduced new institutional dynamics that both contribute to racial disparity in health care provision and create openings for progress toward eliminating some disparities. Prospective utilization management by administrators remote from the bedside, use of financial incentives to influence physician judgment, and the proliferation of differently designed coverage options have large implications for clinical discretion and thus for inter-group disparities. The law has responded sluggishly to these market-driven developments, which are occurring too quickly for courts and regulators to keep pace.<sup>84</sup>

##### *A. Prospective Utilization Management*

Utilization management by remote case reviewers has created new possibilities for disparity in health care provision. To the extent that prospective utilization review applies detailed coverage rules in a standardized fashion (whether or not the rules are well grounded in scientific evidence of clinical efficacy), it has the potential to make clinical care more uniform. But the subjectivity and ambiguity of clinical situations make such standardization elusive, and the complexity and individuality of human pathophysiology render rules for all contingencies impossible.<sup>85</sup> The result is that success in competition for resources within a health plan depends in large part on committed, effective advocacy by clinical caretakers—an asset that, for reasons discussed earlier,<sup>86</sup> members of disadvantaged minority groups are less likely than others to have. The outcomes of competition for resources within a plan also turn on utilization managers' discretion. There has been almost no research into subjective influences on utilization reviewers' decisions in ambiguous cases.

But it seems likely that empathy with particular patients (as portrayed clinically by their caretakers) and the colder calculus of who is most likely to appeal (and ultimately to sue)<sup>87</sup> each play roles. Both of these factors favor the affluent, the educated, and the most advantaged racial and ethnic groups. Research is much needed into how members of disadvantaged minority groups fare in comparison with others at accessing services and resources within particular health plans.

### *B. ERISA Immunity for Utilization Management*

Health plans' immunity from medical malpractice suits for their utilization management decisions<sup>88</sup> has empowered preauthorization reviewers to exercise their discretion unconstrained by law in many states. A series of federal appellate court rulings in the 1990s construed the Employees Retirement Income Security Act (ERISA) to preempt general state tort and contract law bearing upon administration of benefits by employer-provided health plans.<sup>89</sup> These decisions, moreover, interpreted ERISA to bar federal actions for consequential damages, closing the door to meaningful tort liability.<sup>90</sup> But over the past several years, a number of states have enacted laws imposing a variety of safeguards and remedies, including independent medical review of disputed claims denials, and a split between the circuits emerged in 2000 concerning whether these statutes circumvent ERISA preemption.<sup>91</sup> As this Article goes to press, the future of health plan accountability for denial of benefits is uncertain. Congressional compromise this year on so-called "Patients' Bill of Rights" legislation could redefine now-entrenched battle lines, or the Supreme Court could intervene to clarify this confusing area.

### *C. Physician Financial Incentives as a Management Tool*

A decade ago, proponents of managed care envisioned a world of competing, vertically integrated health plans, able to control costs through bulk purchasing power and administrative authority over clinical decisions.<sup>92</sup> But by the end of the 1990s, a very different medical marketplace had emerged, characterized by what one close observer calls "virtual integration"—rapidly shifting contractual alliances between health plans (which eschewed vertical integration as insufficiently adaptable to changing conditions) and hospitals and physician groups.<sup>93</sup> A striking feature of this new managed care marketplace is its wholesale shift from the paradigm of cost control via centralized management of clinical decisionmaking to an alternative model—devolution of financial risk, and thus responsibility for cost control, to practicing physicians.<sup>94</sup> Economic

rewards for frugality and penalties for pricey tests, treatments, and referrals have become lodestars for contemporary clinical practice.<sup>95</sup> The result has been greatly increased reliance on the discretion of gatekeeping clinical caretakers to set limits and manage scarcity. This means more room for free play of the cognitive, affective, and social and cultural factors discussed earlier, which influence clinical discretion in racially disparate ways. It also makes medical resource allocation more of a function of physicians' suspicions and fears about who will protest, if denied a test or treatment, and who might sue. By dispensing with the bureaucratic inefficiencies and irritants of remote utilization review, the managed care industry is forgoing this latter method's limited prospects for standardization in favor of an approach that risks abdicating the pursuit of clinical consistency.

Financial incentives in themselves are not pernicious; moreover, they are inevitable. But the simple, open-ended incentives to withhold care that many managed health plans now employ sacrifice opportunities for supporting quality and rewarding equity within budgetary constraints. One can imagine more nuanced incentive schemes that reward measurable efficacy and engagement with patients as well as financial savings. Payment tied to appropriate health promotion and disease screening practice,<sup>96</sup> patient satisfaction, and measurable treatment successes,<sup>97</sup> as well as to frugality, has the potential to reduce racial disparities in care by pushing physicians toward colorblind benchmark practices. In this regard, last year's U.S. Supreme Court holding, in *Pegram v. Herdrich*,<sup>98</sup> was dismaying for its categorical rejection of efforts to read regulatory constraints on physician incentives into ERISA's ambiguous language.<sup>99</sup> But it is possible that consumer unhappiness over financial rewards to physicians for withholding care could push health plans toward these more nuanced incentive programs through market means.

#### *D. Fragmentation and Health Care Disparities*

We have not yet achieved the health care system some erstwhile market advocates urge,<sup>100</sup> characterized by multiple tiers of medical coverage offering overtly different, contractually defined standards of care. Such a regime might be more honest in its acknowledgment of clinical disparity than the system we now have. Health insurance contracts continue to promise "medically necessary" care, without overt reference to economizing or to cost-benefit tradeoffs. Yet multiple coverage options offering different benefits packages, degrees of choice of provider, levels of access to elite physicians and hospitals, and levels of preauthorization review and financial incentives to physicians to practice frugally segment

today's medical marketplace—by personal wealth and health status as well as consumer and employer preference. Managed care plans comprised largely or entirely of Medicaid recipients and other poor Americans have expanded coverage for the neediest but further segmented the market. We have only sketchy empirical knowledge about the differing levels of intensity of care provided by low-end versus high-end health plans, and it has not been shown that low-end coverage, by itself, produces inferior medical outcomes.<sup>101</sup> But it is reasonable to surmise that, all else being equal, less generous coverage predicts lower intensity of care, since care must be provided within a budget. And it is reasonable to surmise, therefore, that population groups disproportionately represented in lower-end plans receive, on average, a lower intensity of care. Studies of racial disparity in health care provision have attempted to control for insurance status broadly categorized (e.g. Medicare, Medicaid, or private coverage), but they have not broken medical coverage down into categories along this segmented spectrum. They thus leave open the possibility that proven racial disparities in care result, to some degree, from the disproportionate presence of disadvantaged groups in lower-end plans.

Little is known about the distribution of disadvantaged minority groups across this country's fragmented medical marketplace, beyond the fact that they are disproportionately represented in Medicaid-only plans. But we do know that fragmentation of health care financing and provision engenders the development of disparate clinical practice norms, arising from distinct institutional cultures and provider and patient characteristics, as well as from different levels of fiscal constraint. The extreme example of South African medicine under apartheid illustrates the point. The architects of apartheid built an almost bizarrely fragmented health system by intentional design, creating multiple, parallel institutions, with different per capita resource constraints, for different, officially recognized racial groups.<sup>102</sup> Within these parallel institutions, sharply different clinical practice and resource allocation norms emerged. Individual clinicians, working, for the most part, in only one or a few settings, could adhere to the norms "appropriate" to their employment settings without having to confront, in day-in, day-out fashion, the very different norms applicable in others. Fragmentation in American health care does not come close to this disturbing extreme, and structural features of the U.S. health care marketplace protect against a large movement in this direction. The phenomenon of "virtual integration," for example, entails participation by most providers—doctors and hospitals—in multiple health plans,<sup>103</sup> and human cognitive limits and the complexity of medical practice make it unlikely that individual clinicians will be able to learn and adhere to

multiple, dramatically different standards of care for differently insured patients.<sup>104</sup> Still, the South African caricature is a useful warning about the risks involved, from a racial and social justice perspective, in a system of health care coverage choice that devolves too far toward market and administrative fragmentation.

## V. SOME RECOMMENDATIONS

Institutional design and legal governance cannot, by themselves, meet the moral challenge posed by racial disparities in American health care provision. Efforts to intervene at the psychological and social levels, in the course of medical education, apprenticeship, and ongoing professional life, are essential if the stereotypes and prejudgments that engender racially disparate clinical judgments are to be effectively addressed. Patient education and reassurance efforts that take great care to avoid even the appearance of “blaming the victim” are also vital. Yet institutions and law make a large difference. They can potentiate, or attenuate, the operation of the psychological processes that produce disparity. I will conclude with some brief suggestions about how our health care institutions and law might respond pragmatically to the problem of racial disparity even as they pursue other important policy goals.

### *A. Rule-Based Cost Control*

To the extent possible, given the gaps in our knowledge about medical care’s efficacy and the impossibility of anticipating all clinical contingencies, medical limit-setting should be based on rules. The classic advantages of rules over general, discretionary standards—consistency, predictability, and at least the appearance of disinterested objectivity—make detailed rules preferable from the point of view of reducing racial disparities in medical care. Pragmatic balances must be sought between these advantages of rules and their rigidities, and in this regard there may be tensions between the goal of reducing racial disparities and the virtues of greater clinical flexibility. Requirements by private accrediting entities and state regulatory bodies that health plans’ clinical practice protocols be published, with supporting evidence and argument, and thus open to professional and consumer review would aid in the deliberative balancing of the virtues of rules and discretion. Clinical rules that are not backed by evidence and argument should not be entitled to deference in administrative or legal proceedings that involve challenges to health plans’ application of such rules. But where rules do have empirical support, even if the evidence is at best debatable, administrative and legal

decisionmakers should give substantial weight to the social importance, in a racially and culturally diverse nation, of making agonizing allocative choices in a manner that achieves some consistency in appearance and practice.

*B. The Architecture of Physician Financial Incentives*

Pursuit of cost control the crude way, by simply paying physicians more to do less, makes gatekeeping clinical caretakers' stereotypes and selective empathy into medical resource allocation policy at the macro level. By raising the social stakes attached to clinical discretion, it amplifies the social impact of these stereotypes and failures of empathy. To the extent that health plans abdicate the management of care by abandoning efforts to craft and implement reasonable, evidence-based clinical practice protocols, these stereotypes and failures of empathy can play out, unfiltered, as plan policy. Economic incentives, either to provide more or fewer services, are unavoidable, and blanket condemnations of all incentives are naïve. But some limits on incentives to withhold treatment are desirable to control the pressure on physicians to abandon their fiduciary commitments to patients<sup>105</sup> and allow their worst reactions to racial difference to come to the fore.<sup>106</sup> The U.S. Supreme Court's decision in *Pegram v. Herdrich* foreclosed federal restrictions on physician incentives under ERISA, but it left room for state limits on rewards to physicians for withholding care.<sup>107</sup>

More finely crafted physician incentives can have a positive role in efforts to reduce racial disparities in care. Greater economic rewards for time spent engaging patients and their families can contribute to overcoming barriers of culture, communication, and empathy, and the cost of these incentives can be covered by reducing the large premium paid to physicians for time spent performing procedures. Insurance coverage for the modest cost of language translation services can yield large improvements in communication (and physician empathy) for some patients. Payment schemes that reward measures of patient satisfaction and confidence would further encourage the bridging of barriers related to racial difference. Incentives to adhere to evidence-based protocols for frugal practice and to engage in age and gender appropriate disease screening would encourage efficient, quality care generally and penalize race-related deviations. Payment linked to favorable clinical outcomes, where reasonably measurable—e.g. control of diabetes, asthma, and high blood pressure—would provide additional encouragement. Industry movement toward more nuanced incentive schemes along these lines could be catalyzed by private accrediting bodies, encouraged by business



and professional leaders, and even initiated by public payers.

### *C. Strengthening Doctor-Patient Relationships*

The connection between a patient's access to clinical resources within a hospital or health plan and her doctor's stature, skill, and commitment as an advocate underscores the importance of strengthening minority patients' bonds with physicians positioned (and willing) to play the advocate's role vigorously. It may not be realistic to insist on an end to the wealthiest, most influential patients' superior ability to gain access to the clinical judgment and institutional clout of the most elite physicians. Yet we can aspire to the goal of ensuring that every patient, whether insured privately or publicly, through Medicare or Medicaid, has a sustained relationship with an attending physician, not merely a house officer, who is able to navigate the health care bureaucracy effectively on the patient's behalf. Federal and state performance standards for Medicaid managed care plans should include minimum requirements for the stability of patients' assignments to primary care providers<sup>108</sup> (and these providers' accessibility),<sup>109</sup> reasonable maximum patient loads per primary physician, and minimum time allotments for patient visits. Regulations governing health plans' participation in Medicare should include similar standards, as should private accrediting bodies' prerequisites for all health plans. More controversially, patients from historically disadvantaged groups might be given the option to select primary care providers from similar backgrounds, since ample evidence shows that such concordance is associated with greater patient satisfaction and more consistent provision of preventative care.<sup>110</sup> On the other hand, the explicit color-consciousness this would entail risks entrenching the racial biases to which this remedy responds. At a minimum, evidence of the clinical benefits of racial concordance weighs in favor of robust commitment to affirmative action in medical school admissions, residency recruitment, and professional hiring.

### *D. "De-Fragmentation" of Health Care Financing and Delivery*

The disproportionate presence of members of disadvantaged racial minorities in lower-end health plans may be a major source of racial disparities in health care provision, since efforts to control for insurance status in studies of clinical disparity have not taken detailed account of variations among health plans.<sup>111</sup> Research into the distribution of racial minorities across the fragmented American health care marketplace, the differences in intensity of care between lower and higher end health plans, and the relationship (if any) between these differences in intensity and the

quality of clinical outcomes should be a national priority. In the meanwhile, it is reasonable to surmise that efforts to reduce the socioeconomic segmentation of the medical marketplace would probably diminish racial disparities in service provision. Fragmentation engenders different clinical cultures, with different practice norms, tied to varying per capita resource constraints.

Concrete regulatory steps can limit such fragmentation. Movement toward managed care as a tool for both containing the Medicaid program's costs and extending its coverage reach can be accompanied by a requirement that participating health plans enroll some minimum number (expressed in percentage terms) of private subscribers. Plans that participate in Medicaid (or other public programs for the poor and near-poor) can be required to contract with hospitals and physician networks that serve minimum percentages of patients who purchase coverage without public subsidies. At times, regulatory restraint may be in order. State legislators should resist doctors' efforts to win regulatory protection from health insurers' insistence that providers accept patients from all plans an insurer offers. Health insurers' bargaining power on this issue is a force against fragmentation. Were physicians able to pick from among the varied coverage "products" each firm offers—by limiting the numbers of patients they accept from low-end plans or by simply refusing to participate in these plans—they would self-segregate toward different medical marketplace segments, making segment-by-segment differences between practice styles more pronounced.

The question of how much fragmentation is too much is ultimately political, tied to the larger debate over the relative importance of equity, liberty, and reward for enterprise in American life. As such, this question is beyond my scope here. But the economic segregation of Medicaid patients into a bottom-end system of Medicaid-only HMOs, decrepit public hospitals, and separate public clinics strains the lower boundaries of decency. Medicaid's statutory promise, in 1965, of mainstream care for the poorest Americans can only be kept through national and state commitments to supply the resources needed for these Americans to buy into the medical mainstream. And for America's more than forty million uninsured, to whom no such promise has yet been made, the indecency is patent.

## CONCLUSION

The approaches to institutional design and legal governance that I have urged cannot, by themselves, eliminate racial disparities in health care provision. Myriad presuppositions, stereotypes, and other

psychological barriers to empathy and understanding influence clinical judgment in ways that are beyond the reach of organizational and legal arrangements. Yet institutions do matter. Cost-control that is rule-based when empirically feasible; financial rewards for patient satisfaction, health promotion, and favorable outcomes; and efforts to encourage stable doctor-patient relationships and resist market segmentation along race-correlated lines promise to channel clinical discretion in ways that reduce racial disparity. Health plans and regulators can accomplish much along these lines while pursuing other policy goals, including efficiency and quality.

The case for institutional and legal steps toward reduction of racial disparities in clinical care is morally compelling. On the other hand, the targeting of disparities in health care decisionmaking without a corresponding effort to reduce racial differences in health status and access to medical services raises painful questions about health policy priorities. Should we take pragmatic advantage of the political “moment” by waging a vigorous campaign against disparities in medical decisionmaking while tolerating, for a time, differences in health status and medical care access? Are racial disparities in medical care provision important apart from their impact on health status, or should their import be assessed in instrumental terms, based purely on their health impact? And in a society that accepts, as a philosophical matter, many forms of inequality that arise from market outcomes, what are the moral prerequisites for public intervention to ameliorate health-related racial disparities that spring from economic inequality?

These questions merit deep reflection and robust public debate. But a larger implication of the overwhelming evidence of racial disparity in health care provision is clear. This evidence constitutes indisputable proof that the national task of racial healing is not nearly finished—that tacit, often unconscious stereotyping, prejudice, and selective empathy persists, indeed pervades our social life and damages many Americans physically as well as spiritually. In the health sphere, as in other areas of our national life, the most pernicious “racial profiling” is that which we do unreflectively, even unconsciously, as a matter of routine.

## References

1. Kevin A. Schulman et al., *The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization*, 340 NEW ENG. J. MED. 618 (1999).
2. These physicians, who were not told that the purpose of the study was to assess the influence of race (and sex) on clinical decisionmaking, were shown scripted, videotaped interviews of hypothetical patients; given additional clinical information about their "patients;" then asked to make follow-up clinical recommendations. *Id.*
3. Lisa M. Schwartz et al., *Misunderstandings About the Effects of Race and Sex on Physicians' Referrals for Cardiac Catheterization*, 341 NEW ENG. J. MED. 279 (1999).
4. The editors concluded, in a reply to letters critical of the Schulman paper's conclusions, that "the evidence of racism and sexism in this study was overstated" by the paper's statistical presentation of the study's findings. Gregory D. Curfman & Jerome P. Kassirer, *Race, Sex and Physicians' Referrals for Cardiac Catheterization (the editors reply)*, 341 NEW ENG. J. MED. 287 (1991). The Journal's editors, it should be noted, did not deny the existence of racial disparities in American health care.
5. John Z. Ayanian, *Race, Class, and the Quality of Medical Care*, 271 JAMA 1207 (1994); Durado D. Brooks et al., *Medical Apartheid*, 266 JAMA 2746 (1991); Robert M. Mayberry et al., *Racial and Ethnic Differences in Access to Medical Care*, 57 MED. CARE RES. & REV. 108 (Supp. 2000); Gregory Pappas et al., *The Increasing Disparity in Mortality Between Socioeconomic Groups in the United States, 1960 and 1986*, 329 NEW ENG. J. MED. 103 (1993).
6. HOUSE COMM. ON LABOR, HEALTH & HUMAN SERV., & EDUC. APPROPRIATIONS, 196TH CONG., REPORT TO ACCOMPANY H.R. 3064, at 1 (2000).
7. AM. MED. ASS'N, AMA TEAMS UP WITH U.S. SURGEON GENERAL SATCHER TO ELIMINATE DISPARITIES OF CARE AND IMPROVE COUNTRY'S HEALTH (2000); AM. PUB. HEALTH ASS'N, INFLUENTIAL AND DIVERSE LEADERS JOIN STEERING COMMITTEE OF APHA/HHS CAMPAIGN TO ELIMINATE RACIAL AND ETHNIC HEALTH DISPARITIES (2000); U.S. DEP'T OF HEALTH & HUMAN SERV., TRANS-NIH COLLABORATION WITH NIOSH INITIATES STUDIES OF RACIAL AND ETHNIC DISPARITIES IN HEALTH, *available at* <http://raceandhealth.hhs.gov/sidebars/sbwhats30.htm> (last visited Apr. 24, 2001).
8. Robert J. Blendon et al., *Access to Medical Care for Black and White Americans*, 261 JAMA 278 (1989); Council on Ethical and Judicial Affairs, *Black-White Disparities in Health Care*, 263 JAMA 2344 (1990) [hereinafter *Black-White Disparities*]; Council on Scientific Affairs, *Hispanic Health in the United States*, 265 JAMA 248 (1991); Arline T. Geronimus, *Excess Mortality Among Blacks and Whites in the United States*, 335 NEW ENG. J. MED. 1552 (1996); Pappas et al., *supra* note 5, at 103.
9. Marsha Lillie-Blanton & Thomas Laveist, *Race/Ethnicity, the Social Environment, and Health*, 43 SOC. SCI. MED. 83 (1996).
10. See, e.g., Leigh Hopper, *Rice, Baylor, UT-Houston Join to Study Social Causes of Sickness*, HOUS. CHRON., Apr. 8, 1999, at A1; *Racial and Ethnic Disparities in Health Persist between Majority and Minority Americans*, Says

*Patient Care(R) Magazine*, PR NEWSWIRE, May 15, 2000, Financial News.

11. There is a strong relationship between race/ethnicity and the lack of health insurance in adults. Thirty-one percent of low-income (less than 200% of the Federal Poverty Level), white non-Hispanics are uninsured, accounting for 50% of the low-income uninsured and 31% of the entire uninsured population. Black non-Hispanics are uninsured at a rate of 34%, account for 16% of the low-income uninsured, and comprise 50% of the uninsured population as a whole. Fifty-three percent of low-income Hispanics lack health insurance. Low-income Hispanics account for 29% of the low-income uninsured and 19% of the uninsured population. John Holahan & Niall Brennan, *Who Are the Uninsured?* (URBAN INSTITUTE, NEW FEDERALISM: NATIONAL SURVEY OF AMERICA'S FAMILIES, NO.14) (2000), at [http://newfederalism.urban.org/html/series\\_b/b14/b14.html](http://newfederalism.urban.org/html/series_b/b14/b14.html) (last visited Apr. 24, 2001).

12. Some market-oriented commentators argue openly for judicial recognition of multiple tiers of health care quality, tied to insurance contract terms mandating different cost-benefit trade-offs and levels of access to technology—and thus linked to consumers' ability to pay. RICHARD A. EPSTEIN, *MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTHCARE?* (1997); CLARK C. HAVIGHURST, *HEALTH CARE CHOICES OF HEALTH REFORM* (1995). Such an approach to medical tort law and the interpretation of insurance contracts would legitimize racial disparities in physician judgment that arise from

differences in medical coverage.

13. There is ample evidence, epidemiological and biological, of connections between psychosocial stress and a variety of illnesses, including cancer and cardiovascular disease. *See generally* Johan Denollet, *Personality as Independent Predictor of Long-term Mortality in Patients with Coronary Heart Disease*, 347 LANCET 417 (1996); Dorte Hansen et al., *Serious Life Events and Congenital Malformations: A National Study with Complete Follow-up*, 356 LANCET 875 (2000); David Spiegel, *Psychosocial Intervention in Cancer*, 85 J. NAT'L. CANCER INST. 1198 (1993). Neuroendocrine pathways that suppress immune function, increase blood pressure, and influence metabolism of cholesterol and other potentially harmful substances are thought to be responsible. *See generally* E.J. Burkner et al., *Serum Lipids, Neuroendocrine, and Cardiovascular Responses to Stress in Men and Women with Mild Hypertension*, 19 BEHAV. MED. 155 (1994); M. Fredrikson & J.A. Blumenthal, *Serum Lipids, Neuroendocrine and Cardiovascular Responses to Stress in Healthy Type A Men*, 34 BIOL. PSYCHOL. 45 (1992).

14. E.g., Arline T. Geronimus, *Black/White Differences in the Relationship of Maternal Age to Birthweight: A Population-Based Test of the Weathering Hypothesis*, 42 SOC. SCI. MED. 589 (1996); Arline T. Geronimus, *The Weathering Hypothesis and the Health of African-American Women and Infants: Evidence and Speculations*, 2 ETHNICITY & DISEASE 207 (1992).

15. It is hardly obvious that efforts to assert, in political debate, the competing importance of social and economic

determinants of health and health care access would result in reallocation of available resources from activities targeting racial disparities in clinical judgment to programs targeting social and economic inequality. Such an advocacy strategy might backfire, resulting in diminished efforts against racial bias in medical decisionmaking without a corresponding increase in efforts to ameliorate socio-economic inequities and their health effects.

16. John E. Wennberg, *Understanding Geographical Variations in Health Care Delivery*, 340 NEW ENG. J. MED. 52 (1999).

17. M. Gregg Bloche, *Medical Care and the Enigma of Efficiency* (2000) (unpublished manuscript, on file with author), available at [http://papers.ssrn.com/paper.taf?abstract\\_id=184275](http://papers.ssrn.com/paper.taf?abstract_id=184275) (last visited Apr. 24, 2001).

18. See GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES* 57 (1978) (characterizing this approach as decisionmaking by "aresponsible" agencies and noting its effectiveness at concealing compromises between values we hold dear).

19. To be sure, medical malpractice lawyers often advise physicians to write progress notes giving reasons for clinical decisions so as to facilitate defense against potential tort claims. But these notes, in confidential patient records, do not create a public register of successive, related decisions.

20. ALVAN R. FEINSTEIN, *CLINICAL JUDGMENT* 328-49 (1967).

21. The probabilities derived from such an aggregation of prior outcomes

make possible predictive judgments about a current patient (so long as he or she meets the inclusion criteria) despite our ignorance about which features from prior cases are relevant to the clinical issue at hand.

22. Milliman & Robertson Inc., a Seattle-based consulting firm, developed a set of guidelines that were adopted by major health plans. Allen R. Myerson, *Helping Health Insurers Say No*, N.Y. TIMES, Mar. 20, 1995, at D1.

23. Contractual designation of the practice protocols to be used for payment determinations (and even incorporation of such protocols into insurance contracts) can resolve, in a formalistic manner, the question of which protocols apply, but it cannot resolve skepticism about the scientific legitimacy of the contractually mandated protocol.

24. HERBERT A. SIMON, *MODELS OF BOUNDED RATIONALITY* (1982).

25. Indeed, medical students and residents are taught to present cases, in work rounds and conferences, in a manner that conveys the presenter's hierarchy of diagnostic suspicions and makes the case for the diagnostic and therapeutic interventions the presenter proceeds to recommend. See generally JEFF GUSKY, *MEDICAL STUDENT'S WARD SURVIVAL MANUAL* 71-85 (1st ed. 1982).

26. The Oath states, in relevant part: "In every house where I come I will enter only for the good of my patients." STEDMAN'S MEDICAL DICTIONARY 799 (26th ed. 1995).

27. M. Gregg Bloche, *Clinical Loyalties and the Social Purposes of Medicine*, 281 JAMA

268 (1999).

28. Daniel Sulmasy et al., *Physicians' Ethical Beliefs about Cost-Control Arrangements*, 160 ARCHIVES INTERNAL MED. 649, 651-52 (2000).

29. Another parallel is to the feminist ethic of care, which also eschews rule-oriented rationalism in favor of good motives (though it construes goodness somewhat differently, in terms of empathy and compassion). See Marilyn Friedman, *The Social Self and the Partiality Debates*, in FEMINIST ETHICS 161 (C. Card ed., 1991).

30. See Robert Cooter & Bradley J. Freedman, *The Fiduciary Relationship: Its Economic Character and Legal Consequences*, 66 N.Y.U. L. REV. 1045, 1053-1056 (1991).

31. See generally Jay Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137 (1977) (arguing that the law of informed consent does little to open the way for meaningful patient autonomy).

32. Even in "reasonable patient" jurisdictions, see, e.g., *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972), treating physicians' practice styles determine the clinical options that patients are told about in fact. In the rare case when a patient brings suit on informed consent grounds, other physicians accessed by the patient-turned-plaintiff typically are the source of information about clinical options (and risks and benefits) not originally disclosed. Thus disclosure, in action, is largely a function of the physicians and clinical practice styles a patient encounters. For computer literate (and generally well-off) patients, the internet is emerging as an alternative, state-of-the-art source of information about clinical options. See

generally SCI. PANEL ON INTERACTIVE COMMUNICATION & HEALTH, WIRED FOR HEALTH AND WELL-BEING: THE EMERGENCE OF INTERACTIVE HEALTH COMMUNICATION (Thomas R. Eng & David H. Gustafson eds., 1999). This new source of medical information inequality further strains the formal equality expressed in informed consent doctrine.

33. *Black-White Disparities*, supra note 8.

34. See generally Susan T. Fiske, *Stereotyping, Prejudice, and Discrimination*, in 2 THE HANDBOOK OF SOCIAL PSYCHOLOGY 357, 377 (Daniel T. Gilbert et al. eds., 4th ed. 1998).

35. Within the psychodynamic paradigm, racial and other group stereotypes satisfy a person's needs for self-esteem and redirect his negative feelings about himself onto others. The sociocultural paradigm treats these stereotypes as social learning passed to people within a culture (and useful for rationalizing differential treatment of social groups). John F. Dovidio, *Stereotyping*, in THE MIT ENCYCLOPEDIA OF THE COGNITIVE SCIENCES 804 (Robert A. Wilson & Frank C. Keil eds., 1999).

36. Cindy Brach & Irene Fraser, *Can Cultural Competency Reduce Racial and Ethnic Health Disparities? A Review and Conceptual Model*, 57 MED. CARE RES. & REV. 181-217 (2000); see also U.S. COMM'N ON CIVIL RIGHTS, 1 THE HEALTH CARE CHALLENGE: ACKNOWLEDGING THE DISPARITY, CONFRONTING DISCRIMINATION, AND ENSURING EQUALITY 193 (1999); Lisa Cooper-Patrick et al., *Race, Gender, and Partnership in the Patient-Physician Relationship*, 282 JAMA 583 (1999).

37. A substantial literature addresses, criticizes, defends, and attempts to explain the punishing time pressures, sleeplessness, and other stresses of clinical training. See generally John M. Colford, Jr. & Stephen J. McPhee, *The Ravelled Sleeve of Care: Managing the Stresses of Residency Training*, 261 JAMA 889-93 (1989); Jenny Firth, *Levels and Sources of Stress in Medical Students*, 292 BRIT. MED. J. 1177-80 (1986); Mitchel L. Zoler, *Residency Reform Spreads as Programs Combat Stress*, 29 MED. WORLD NEWS 49-50 (1988).
38. John Z. Ayanian et al., *The Effect of Patients' Preferences on Racial Differences in Access to Renal Transplantation*, 341 NEW ENG. J. MED. 1661-69 (1999).
39. For several decades after the advent of curative antibiotic therapy for syphilis, African-American patients with this illness were left untreated by researchers who wanted to observe the devastating, long-term neurological and other effects of syphilis. Allan Brandt, *Racism and Research: The Tuskegee Syphilis Experiment*, in TUSKEGEE TRUTH'S: RETHINKING THE TUSKEGEE SYPHILIS STUDY (Susan M. Reverby ed., 2000).
40. Patricia A. King, *Race, Justice, and Research*, in BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH 88 (Jeffrey P. Kahn et al. eds., 1998).
41. Vernellia R. Randall, *Slavery, Segregation and Racism: Trusting the Health Care System Ain't Always Easy! An African American Perspective on Bioethics*, 15 ST. LOUIS U. PUB. L. REV. 191 (1996) (arguing that deep-rooted African-American fear and distrust of the health care system prevents many African Americans from seeking treatment).
42. *Pegram v. Herdrich*, 530 U.S. 211, 221 (2000).
43. James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459, 1465-66 (1994).
44. Henry Hansmann, *The Rationale for Exempting Nonprofit Organizations from Corporate Income Taxation*, 91 YALE L.J. 54, 72-75 (1981).
45. Paul L. Joskow, *Certificate-of-Need Regulation*, in CONTROLLING HOSPITAL COSTS: THE ROLE OF GOVERNMENT REGULATION 76 (1981).
46. *Id.*
47. Jeffrey E. Harris, *Pricing Rules for Hospitals*, 10 BELL J. ECON. 224-43 (1979) (discussing internal organization and allocation within hospitals).
48. Such clinicians might include interns and residents, junior attending physicians, and more senior physicians with less prestigious credentials and appointments.
49. RAYMOND S. DUFF & AUGUST B. HOLLINGSHEAD, *SICKNESS AND SOCIETY* (1968).
50. *Id.* at 234.
51. *Id.*
52. Helen R. Burstin et al., *Do the Poor Sue More? A Case-Control Study of Malpractice Claims and Socioeconomic Status*, 270 JAMA 1697 (1993).
53. Cognitive dissonance might well render this change in clinical ordering behavior unconscious, making it impossible to assay this effect by surveying physicians potentially involved.



54. This feature of medical tort law has been sharply criticized in recent years by market-oriented scholars who would prefer to see the courts recognize multiple tiers of clinical obligation, derived from contractual arrangements between health care payers, providers, and patients. *See, e.g.,* MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS, AND ECONOMICS OF RATIONING MECHANISMS 213-15 (1997); E. Haavi Morreim, *Playing Doctor: Corporate Medical Practice and Medical Malpractice*, 32 U. MICH. J. L. REF. 939 (1999).

55. PAUL C. WEILER, A MEASURE OF MALPRACTICE 69-70 (1993) (summarizing Harvard/New York State medical malpractice study data).

56. Burstin et al., *supra* note 52.

57. *E.g.,* Sidney D. Watson, *Medicaid Physician Participation: Patients, Poverty, and Physician Self-Interest*, 21 AM. J.L. & MED. 191 (1995).

58. Patients without private doctors who hold hospital staff privileges face a Catch-22 when they need hospital admission: since their outpatient clinic doctors cannot care for them as inpatients, they must either find private physicians with hospital privileges (difficult due to Medicaid's low payment rates) or be admitted as "ward" or "service" patients, cared for primarily by resident physicians.

59. 42 U.S.C.A. § 1396a(a)(13)(C) (1982 & Supp. V 1987), repealed by Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4712(c), 111 Stat. 509 (1997). A State plan for medical assistance must "provide...for payment...of hospital services, nursing facility services, and

services in an intermediate care facility for the mentally retarded provided under the plan through the use of rates (determined in accordance with methods and standards developed by the State...) which the State funds, and makes assurances satisfactory to the [Health and Human Services] Secretary, are reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable State and Federal laws, regulations, and quality and safety standards and to assure that individuals eligible for medical assistance have reasonable access...to inpatient hospital services of adequate quality."

60. *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498 (1990) (holding that the Boren Amendment created substantive federal right enforceable by health care providers).

61. The causal connections between administrative fragmentation, racial segregation, and inequality in social programs have been explored by commentators in other policy contexts, especially housing. *See, e.g.,* Philip D. Tegeler, *Housing Segregation and Local Discretion*, 3 J.L. & POL'Y 209, 234-35 (1994). *See also* COMM. ON IMPROVING THE FUTURE OF U.S. CITIES THROUGH IMPROVED METRO. AREA GOVERNANCE, NAT'L RESEARCH COUNCIL, GOVERNANCE AND OPPORTUNITY IN METROPOLITAN AMERICA (Alan Altshuler et al. eds., 1999). The connection, by design, between unusual bureaucratic fragmentation and shocking inequalities in health care provision was dramatically evident in the South African health care system under apartheid. AM. ASS'N FOR THE

ADVANCEMENT OF SCI. & PHYSICIANS FOR HUMAN RIGHTS, HUMAN RIGHTS & HEALTH: THE LEGACY OF APARTHEID (Audrey. R. Chapman & Leonard. S. Rubenstein eds., 1998) [hereinafter THE LEGACY OF APARTHEID].

62. *Supra* text accompanying notes 100-104.

63. EMTALA, 42 U.S.C. § 1395dd (1995).

64. EMTALA, which requires all of this regardless of emergency room patients' ability or willingness to pay, has been sharply (and, I think, reasonably) criticized as yet another unfunded federal mandate, and thus a hidden government levy on those who cross-subsidize the mandate's cost. *See, e.g.*, David Hyman, *Patient Dumping and EMTALA: Past Imperfect/Future Shock*, 8 HEALTH MATRIX 29, 53 (1998).

65. *See, e.g.*, *Summers v. Baptist Med. Ctr. Arkadelphia*, 69 F.3d 902, 904 (8th Cir. 1995) ("EMTALA is not a federal malpractice statute and it does not set a national emergency health care standard; claims of misdiagnosis or inadequate treatment are left to [state law]"); *Eberhardt v. City of Los Angeles*, 62 F.3d 1253 (9th Cir. 1995) (holding that EMTALA creates no national standard of emergency care); *Baber v. Hosp. Corp. of Am.*, 977 F.2d 872 (8th Cir. 1992) (holding that EMTALA does not create a national medical malpractice standard and that EMTALA liability for emergency medical screening comes only if the facility fails to comply with its own procedures).

66. EMTALA confers a private cause of action against hospitals (but not physicians) upon patients who are

discharged or transferred without an adequate emergency screening evaluation or stabilizing treatment. *See* EMTALA, *supra* note 63, at §1395dd(d)(2)(A).

67. RAND E. ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 60-61 (1997).

68. The Department of Health, Education, and Welfare.

69. Some hospitals pursued the facially neutral strategy of refusing to grant privileges to physicians who were not members of their local medical societies. The catch, for African-American doctors (and their patients) in some localities, was that these medical societies (which received no "federal financial assistance" and were thus beyond Title VI's reach) refused admission to blacks. DAVID B. SMITH, HEALTH CARE DIVIDED: RACE AND HEALING A NATION 16-21 (1999).

70. *E.g., id.* at 200-25.

71. Sara Rosenbaum et al., *U.S. Civil Rights Policy and Access to Health Care by Minority Americans: Implications for a Changing Health Care System*, 57 MED. CARE RES. & REV. 236, 247 (Supp. I 2000).

72. *Id.* at 238; *see also*, U.S. COMM'N ON CIVIL RIGHTS, *supra* note 36, at 77 (asserting deficiencies in Title VI regulations).

73. The 1988 Amendment of 29 U.S.C. § 794, Nondiscrimination under Federal Grants and Programs, added subsection b, which defined "program or activity" as "the operations of...an entire corporation, partnership, or other private organization, or an entire sole proprietorship—(i) if assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole or (ii) which is

principally engaged in the business of health care." 29 U.S.C. § 794(b)(3)(A).

74. Rosenbaum et al., *supra* note 71, at 239.

75. Over thirty-nine million Americans are enrolled in Medicare today. See Statistics on Medicare Enrollment Trends of the Health Care and Financing Administration: 1966-1999, at <http://www.hcfa.gov/stats/enrltrnd.htm#t1> (last visited Apr. 24, 2001).

76. U.S. COMM'N ON CIVIL RIGHTS, *supra* note 36; Rosenbaum et al., *supra* note 71.

77. Mark Barnes & Elizabeth Weiner, *Evidence of Race-Based Discrimination Triggers New Legal and Ethical Scrutiny*, 8 BNA HEALTH L. RPTR. 1984 (1999) (suggesting that statistical evidence of racial disparity in the treatment of patients may serve as the basis for charges of race and/or ethnicity-based discrimination).

78. *Id.*

79. Alexander v. Sandoval, 69 U.S.L.W. 4250 (2001).

80. See King, *supra* note 40.

81. See Bloche, *supra* note 27.

82. Washington v. Harper, 494 U.S. 210, 243-45 (1990) (Stevens, J., dissenting) (challenging a prison policy that authorized treatment of a mentally ill state prisoner with antipsychotic drugs against his will without judicial hearing).

83. William Booth, *U.S. Accused of Sedating Deportees; Tranquilizers Given to Those Who Resist*, WASH. POST, Oct. 7, 1993, at A1.

84. M. Gregg Bloche, *A Step Ahead of the Law*, in THE PRIVATIZATION OF HEALTH CARE REFORM (M. Gregg Bloche ed., forthcoming).

85. *Supra* text accompanying notes 22-25.

86. *Supra* text accompanying notes 48-51.

87. Discovery in the pending HMO class action litigation could shed some light on whether these factors play a role, as plaintiffs' attorneys obtain health plans' internal memoranda, e-mail, and other communications concerning utilization management policy.

88. See generally, Peter D. Jacobson & Scott D. Pomfret, *Form, Function, and Managed Care Torts*, 35 HOUS. L. REV. 985 (1998) (arguing that the formalistic ERISA preemption analysis applied by courts allowed managed care organizations to escape liability for their negligence when providing health care and health care financing).

89. *E.g.*, Corcoran v. United HealthCare, 965 F.2d 1321 (5th Cir. 1992) (holding that ERISA preempted Louisiana tort action for wrongful death of unborn child).

90. Under ERISA, these decisions held that a plaintiff alleging improper denial of benefits could recover only the dollar value of the treatment denied—e.g. the \$300 dollar cost of a CT scan inappropriately withheld, and not for other resulting damages—e.g. wrongful death if the CT scan would have revealed the plaintiff's fatal (but treatable) illness.

91. Compare Corp. Health Ins., Inc. v. Tex. Dep't of Ins., 215 F.3d 526 (5th Cir. 2000) (concluding that ERISA preempts the provisions of a Texas statute that establishes a system of appellate review of HMO benefits decisions), with Moran v.

Rush Prudential HMO, 230 F.3d 959 (7th Cir. 2000) (holding that ERISA does not preempt an Illinois statute that requires HMOs to submit claim denials for review by an independent physician).

92. Alain Enthoven & Richard Kronick, *A Consumer-Choice Health Plan for the 1990s: Universal Health Insurance in a System Designed to Promote Quality and Economy*, 320 NEW. ENG. J. MED. 29 (1989).

93. JAMES C. ROBINSON, *THE CORPORATE PRACTICE OF MEDICINE: COMPETITION AND INNOVATION IN HEALTH CARE* 63-89 (1999). Forces driving this market trend included consumers' desire for more choice from among providers and plan designs than vertically integrated health plans could offer and industry executives' anticipation of possible regulatory and legal developments that would subject vertically integrated plans to heightened liability risk and public oversight. Bloche, *supra* note 27.

94. *Id.*

95. Thomas Rice, *Physician Payment Policies: Impacts and Implications*, 18 ANN. REV. PUB. HEALTH 549 (1997).

96. Examples include rewards to pediatricians for retention of patients in well child care, and rewards to internists, gynecologists, and urologists whose patients are screened appropriately for colon, breast, and prostate cancer.

97. Examples include rewards for keeping patients with chronic, treatable but relapsing illnesses such as asthma and schizophrenia out of the hospital.

98. *Pegram*, 530 U.S. at 221.

99. M. Gregg Bloche & Peter D. Jacobson, *The Supreme Court and Bedside*

*Rationing*, 284 JAMA 2776 (2000).

100. See HALL, *supra* note 54.

101. A confounding problem in such research is the fact that measures of health status are highly correlated with indices of socio-economic status, making it difficult to draw conclusions about causality from correlations between low-end coverage (hard in itself to define operationally in view of the many features of medical coverage) and either health outcomes or levels of intensity of care.

102. THE LEGACY OF APARTHEID, *supra* note 61, at 18-24.

103. ROBINSON, *supra* note 93, at 35-62.

104. M. Gregg Bloche & Kevin Quinn, *Professionalism and Personhood*, in PERSONHOOD IN HEALTH CARE (David Thomasma ed., forthcoming).

105. Peter D. Jacobson & Michael T. Cahill, *Applying Fiduciary Responsibilities in the Managed Care Context*, 26 AM. J.L. & MED. 155 (2000).

106. The complex question of how to fashion such limits is beyond my scope here. It is one of the most important challenges for health care law, and it has received insufficient attention from scholars and policymakers thus far.

107. Bloche & Jacobson, *supra* note 99, at 2777.

108. Potential measures of stability include mean frequency of changes in patients' assignments to primary care physicians, percentages of patients who change primary caretakers at rates that exceed "red flag" thresholds, and rates at which hospitalized patients are attended by their outpatient primary physicians.

109. Potential measures of accessibility

include waiting times for routine and urgent care appointments and frequencies at which patients are seen by physicians other than their primary care providers.

110. Somnath Saha et al., *Patient-Physician Racial Concordance and the Perceived Quality and Use of Health Care*, 159 ARCHIVES INTERNAL MED. 997 (1999).

111. *Supra* text accompanying notes 101-103.



# Understanding Disparities in the Use of Medicare Services

Marian E. Gornick, M.A.,<sup>\*</sup> Paul W. Eggers, Ph.D.<sup>†</sup> and Gerald F. Riley, M.S.P.H.<sup>‡§</sup>

Unexpectedly, the use of health care services has been found to differ substantially across subgroups of a population covered by health insurance. In the Medicare program, persons at risk of poor health tend to use fewer of the types of services that healthier persons use to improve health and prevent disease. Relatively little is known about why patterns of health care among the elderly differ by race and socioeconomic status (SES).<sup>1</sup> That disparities occur so persistently in a program such as Medicare, which was expected to equalize access to care, indicates that there are limitations to what health insurance alone can do to assure equal access to health care. The challenge is to determine what our society can do to ameliorate disparities in health care.

Health policy experts from an earlier era can provide some insight into the dilemma of disparities in health care. Two books, published half a century ago, contain papers by members of the New York Academy of Medicine on social medicine,<sup>2</sup> a term intended to evoke the complex interrelationships between health and society. Social medicine was defined in one paper as “medical science in relation to groups of human beings.”<sup>3</sup> Underlying the concept of social medicine was the belief that medical science ought to approach health, not just in terms of treating a patient’s illness, but also in terms of the whole of an individual’s life and society. The multitude of factors that influence health status and health care led

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§ The authors very much appreciate the invitation from Leslie Meltzer and Jason Silvers to participate in this inaugural issue of the *Journal*. We also appreciate the review and recommendations made by Jay Horton and the *Journal* staff in the preparation of this Article.

one member of the Academy to observe that the problem of medical care is "more complex than it is taken to be."<sup>4</sup> One paper noted that social security and welfare programs do not change the existing social and economic order but mitigate the hardships created by it, noting (with considerable prescience) that health insurance "does not guarantee health to the insured wage earner nor yet does it make public health measures superfluous."<sup>5</sup> To understand the influence of poverty, education, and occupation on health, members of the Academy advocated an expansion of medical school curricula to include knowledge from the social sciences. As one writer stated, "Medicine's recognition of the part the social sciences play in the total health, either of the individual or of groups, will constitute a milestone in human progress."<sup>6</sup>

Approaching health care from the perspective of social medicine remains an elusive task. A recent paper highlighted the continuing tensions between public health advocates and medicine, and the lack of agreement about the best approaches for effective health care.<sup>7</sup> One aspect of social medicine, however, that is generally agreed upon is the need for greater cultural sensitivity and appreciation of racial and ethnic diversity. As this paper illustrates, however, disparities in health care are also associated with SES within all racial and ethnic groups.

Although the need for a social medicine perspective is widely accepted today, some recognized experts who have studied health disparities in recent years, point to a set of facts that seem to indicate that health care plays a relatively minor role in health inequalities, and that solutions to disparities in health lie in an arena outside of the health care delivery system.<sup>8</sup> Their arguments include the following:

First, after Great Britain introduced the National Health Service (NHS) in 1948, inequalities in health did not diminish. Second, large declines in mortality in the United States can be traced to public health measures, such as ensuring clean water, which have led to a decrease in infectious diseases. Third, the greatest impact of medical care is in the case of acute care needs. Many "high-tech" procedures, such as coronary artery bypass surgery, radiation, chemotherapy, kidney dialysis, and organ transplantation, have been most effective in saving the limited number of patients with life-threatening illnesses who would otherwise die without these procedures. Fourth, disparities in health are not directly related to the health care delivery system. Rather, there is a strong association between disparities in health and disparities in the distribution of income. Countries such as the United States have relatively high inequalities in income and in health, while countries such as Costa Rica, Japan, and Sweden have relatively low inequalities in income and in health. Fifth,



social capital—networks in a community of families, schools, and other organizations and institutions that provide support to members of the community and enhance mutual respect and trust—is one of the most significant factors affecting health and tends to be least developed in poorer communities.

The study described in this Article does not refute these facts. However, the Medicare experience shows that inequalities in health care can persist even among insured populations. Moreover, we are not convinced that medical care's greatest impact is on treating life-threatening illnesses. On the contrary, we believe that the analyses presented here suggest the need for a greater emphasis on medical care targeted toward health monitoring and disease prevention, especially among vulnerable subgroups of the population in order to prevent life-threatening illnesses and disability.

This Article focuses on disparities by race and SES in the use of health promotion services, including immunizations and various cancer screening tests, and what might be done to improve patterns of utilization. Disparities by race in the use of cancer screening services are of particular concern because of the higher cancer death rates of blacks as compared to other racial and ethnic groups in the United States.<sup>9</sup> Black women, in particular, are more likely than white women to have advanced-stage breast cancer when first diagnosed, and to die of the disease, even though the incidence of breast cancer is lower among black women than white women.<sup>10</sup>

This study does not attempt to analyze the impact of disparities in the use of health promotion services, although there is a large and varied literature on the benefits of certain preventive and screening services. It seems likely that the greater use of preventive and screening services by elderly whites is reflected, at least in part, in their more favorable health outcomes. However, the literature is often complex and explores the benefits from different perspectives. For example, some studies have analyzed the increase in life expectancy from a particular immunization or cancer screening service. In general, these studies report a relatively small increase in life expectancy from using any one preventive service. In one study, the gain in life expectancy for influenza immunization (distributed across the U.S. population) was estimated at one week; similarly, the gain in life expectancy for pneumococcal immunization was estimated at one week.<sup>11</sup> From another perspective, studies have analyzed the impact of mammography screening on the stage of breast cancer at the time of diagnosis. One study reports that screening helps to explain the black-white differences in stage of cancer at diagnosis,<sup>12</sup> which clearly supports recommendations for early detection and community education to

improve survival rates among black women.<sup>13</sup>

The major purpose of this Article is to discuss new analyses of patterns of use of preventive services. Before discussing the new findings, the Article summarizes previous studies about disparities in Medicare utilization and plausible explanations for these disparities. Then it describes the new analyses, which test two hypotheses about the use of preventive services. For example, it tests the hypothesis that women who use mammography are more likely than non-users of mammography to receive influenza immunizations. Along a similar line of inquiry into health behaviors, it tests the relationships between smoking habits and the use of preventive services, analyzing, for example, whether men who quit smoking are more likely than men who currently smoke to have prostate examinations. These questions were explored because the findings could have implications and provide clues for ways to ameliorate disparities in health care.

The Article is divided into three parts. Part I summarizes what is known about Medicare utilization patterns and the health of the elderly. Part II discusses the two hypotheses that were tested concerning the factors associated with disparities in utilization. Part III considers the implications of the new findings.

## I. OVERVIEW OF DISPARITIES

Prior to Medicare, access to health care was a major concern for people age sixty-five and older.<sup>14</sup> Analyses showed that elderly blacks, and those with the lowest incomes, received fewer physician visits and were admitted to the hospital at a lower rate than elderly whites and those with the highest incomes.<sup>15</sup> Only about 50% of the group age sixty-five and older, most of whom were no longer actively employed, had hospital insurance.<sup>16</sup> It was expected that Medicare would eliminate barriers to health care for all of the elderly. After Medicare was implemented, the rate of physician visits and hospital admissions for blacks and the poor approached the rate for whites and higher-income groups;<sup>17</sup> by the mid-1980s, hospitalization rates for blacks began to exceed the rates for whites.<sup>18</sup> In the 1980s, however, more detailed data became available after Medicare introduced new payment policies that required hospitals and physicians to send in information about patients' diagnoses and procedures. The new information showed substantial disparities by race and SES in the use of many services performed in the hospital and in ambulatory care settings.<sup>19</sup>

The data shown in this section were derived from several sources. Utilization patterns were derived from the ongoing data system Medicare maintains for administrative purposes, known as "administrative data." The

administrative data are comprised of several types of files, including enrollment files and bills sent in for payment. Hospital admission rates are based on hospital discharge bills; rates of physicians' services, such as office visits or colonoscopy, are based on physicians' bills. Although an effort is underway to update race and ethnicity codes, at this time utilization patterns can be drawn reliably only for black and white enrollees. Medicare's administrative data do not contain information about the health of the enrollees or about their SES. To analyze the effects of SES on the use of Medicare services, Medicare enrollment files were linked to data on medium income at the zip code level derived from the 1990 U.S. Census. Data were also drawn from an ongoing survey known as the Medicare Current Beneficiary Survey (MCBS), which collects socioeconomic and health information from a sample of beneficiaries. In addition, data were derived from information published by the National Center for Health Statistics and the National Cancer Institute.

#### *A. Medicare Utilization Patterns*

The administrative data in this section reflect the experience of enrollees receiving services in the fee-for-service sector (about 86% of the total in 1998). Similar information is not currently available for enrollees in HMOs.

Three distinct utilization patterns can be identified from the Medicare administrative data.<sup>20</sup> First, compared to white beneficiaries, blacks use fewer preventive and health promotion services (such as influenza immunizations and physician office visits). Second, blacks receive fewer tests (such as colonoscopy and cardiac catheterization) to diagnose illness, and undergo fewer common surgical procedures (such as coronary artery bypass surgery and hip replacement) to treat disease. Third, blacks have higher rates of use of certain procedures associated with poor outcomes of chronic conditions—"last resort" procedures—(such as amputation of all or part of the lower limb). Furthermore, these same three patterns tend to occur for white or black persons with lower SES, compared to those with higher SES.

The disparities in utilization patterns are often striking. The first pattern, the use of health promotion services, is illustrated in Table 1 by rates of physician office and ophthalmology visits.

In 1990, the rate of physician office visits was 4,996 visits per 1,000 white enrollees and 4,379 visits per 1,000 black enrollees, resulting in a black:white rate ratio of 0.88, or 12% fewer visits for blacks compared to whites; in 1998, the black:white ratio registered 0.81. Ophthalmology visits in both 1990 and 1998 were lower for blacks than whites, resulting in a

black:white ratio each year of 0.88. In contrast, in both 1990 and 1998 physician visits to hospitalized patients were substantially higher for blacks than whites; the black:white ratio registered 1.22 in 1990 and 1.41 in 1998. The rapid acceleration in the black:white ratio of physician hospital visits mirrors the trend of higher hospital admission rates for blacks compared to whites.

The second pattern, involving the use of tests and surgical procedures to monitor and improve health, is also illustrated in Table 1. In 1990, disparities by race in the use of tests and common surgical procedures are indicated by the black:white ratios for sigmoidoscopy (0.57), colonoscopy (0.84), cataract removal (0.80), and carotid endarterectomy (0.28). As shown, these ratios changed very little by 1998.

**Table 1. Use of Selected Medicare Services for Enrollees Age 65 and Older, By Race, and Ratio of the Rates, 1990 and 1998**

Medicare Services	1990 (rates per 1,000)			1998 (rates per 1,000)		
	White	Black	Ratio (B:W)	White	Black	Ratio (B:W)
<i>Visits</i>						
Physician's Office	4,996	4,379	0.88	6,553	5,281	0.81
Physician's Visits to Hospitalized Patients	3,237	3,943	1.22	2,912	4,112	1.41
Ophthalmology Visits	710	622	0.88	790	695	0.88
<i>Tests</i>						
Sigmoidoscopy	47.8	27.1	0.57	33.8	21.1	0.62
Colonoscopy	35.2	29.6	0.84	69.5	58.5	0.84
<i>Surgical Procedures</i>						
Cataract Removal	40.7	32.7	0.80	63.0	43.6	0.69
Carotid Endarterectomy	1.66	0.47	0.28	3.98	1.35	0.34
Treatment of Retinal Lesions	7.08	11.43	1.61	11.09	17.47	1.57
Amputation of All or Part of a Lower Limb	1.7	5.7	3.43	1.9	6.9	3.68

Source: PAUL EGGERS, HEALTH CARE FIN. ADMIN., MONITORING THE IMPACT OF MEDICARE PHYSICIAN PAYMENT REFORM ON UTILIZATION AND ACCESS (2000).

Finally, Table 1 illustrates the third pattern, the greater use among black beneficiaries of procedures associated with poor outcomes of chronic disease. The black:white ratio for procedures to treat retinal lesions was 1.61 in 1990 and 1.57 in 1998; the black:white ratio for amputations of all or part of the lower limb was 3.43 in 1990 and 3.68 in 1998.

In 1993, Medicare began to cover influenza immunizations. During the first year of coverage, the black:white ratio was only 0.47. However, over time, the ratio improved only slightly, reaching 0.53 in 1997 (table 2).

In 1991, Medicare began to cover mammography every two years. For the period 1992-93 the black:white ratio was 0.74; this ratio went up and

down slightly over time, registering 0.76 for the period 1997-98 (table 3).

**Table 2. Influenza Immunization Rates for Medicare Enrollees Age 65 and Older, By Race, 1993-1997**

Year	White (per 100)	Black (per 100)	Ratio (Black/White)
1993	36.5	17.3	0.47
1994	41.9	20.6	0.49
1995	43.2	21.6	0.50
1996	45.5	23.4	0.51
1997	46.1	24.3	0.53

Source: Health Care Financing Administration, Office of Information Services, National Claims History and Denominator File (2000) (unpublished data developed by the Office of Strategic Planning and the Office of Clinical Standards and Quality, on file with authors).

**Table 3. Biennial Mammography Rates for Female Medicare Enrollees Age 65 and Older, By Race, 1992-1998**

Period	White (per 100)	Black (per 100)	Ratio (Black/White)
1992-1993	38.2	28.1	0.74
1994-1995	40.4	30.9	0.77
1996-1997	42.5	33.7	0.79
1997-1998	46.1	35.1	0.76

Source: Health Care Financing Administration, Office of Information Services, National Claims History and Denominator File (2000) (unpublished data developed by the Office of Strategic Planning and the Office of Clinical Standards and Quality, on file with authors).

For both black and white beneficiaries, income also is associated with the use of services (table 4). For example, in 1993 the number of ambulatory physician visits per black beneficiary was 8.0 visits per year for those with incomes greater than \$20,500 and 7.1 visits for those with incomes less than \$13,101. The corresponding figures for white beneficiaries were 9.0 visits and 7.3 visits. Similarly, the percent of black women obtaining a mammogram ranged from 20.4% for those with highest incomes to 16% for those with lowest incomes. For white women, the corresponding figures were 31% and 20.8%. The opposite pattern is shown to occur for rates of emergency room visits and amputations of all or part of the lower limb, which generally increased as income declines. For example, between the highest and lowest income groups, the rate of amputations per 1,000 black beneficiaries per year increased from 5.8 to 7.0 surgeries, and the rate per 1,000 white beneficiaries increased from 1.5 to 2.2 surgeries. These patterns of Medicare utilization by income are of particular concern because, as shown next, there are also substantial disparities in the health of the elderly by income.

### *B. Health Status Of The Elderly*

Every major health measure indicates that health status is worse for

Table 4. Rates for Selected Medicare Services, By Race and Income, 1993

Race and Income	Ambulatory Physician Visits (per person)	Emergency Room Physician Visits (per 100)	Mammography (per 100)	Amputation of Lower Limb (per 1000)
<i>White</i>				
Total (All Incomes)	8.1	35.0	26.0	1.9
\$20,501 and over	9.0	29.6	31.0	1.5
\$16,301 to \$20,500	8.3	34.6	27.2	1.8
\$13,101 to \$16,300	7.6	36.8	24.1	2.1
Less than \$13,101	7.3	39.9	20.8	2.2
<i>Black</i>				
Total (All Incomes)	7.2	50.6	17.1	6.7
\$20,501 and over	8.0	44.2	20.4	5.8
\$16,301 to \$20,500	7.4	45.8	19.9	5.9
\$13,101 to \$16,300	7.7	52.2	21.1	6.1
Less than \$13,101	7.1	51.6	16.0	7.0
<i>Ratio (Black/White)</i>				
Total	0.89	1.45	0.66	3.64
Income Adjusted	0.93	1.37	0.75	3.30

Source for amputations data: Marian E. Gornick et al., *Effects of Race and Income on Mortality and Use of Services Among Medicare Beneficiaries*, 335 NEW ENG. J. MED. 791 (1996). For other data: HEALTH CARE FIN. ADMIN., MONITORING THE IMPACT OF MEDICARE PHYSICIAN PAYMENT REFORM ON UTILIZATION AND ACCESS (1995) (HCFA pub. No. 03358).

elderly blacks compared to elderly whites.<sup>21</sup> For example, although life expectancy has increased over time for both blacks and whites, in 1998 life expectancy at age sixty-five for white men was 1.8 years greater than for black men; and for white women, life expectancy was 1.9 years greater than for black women.<sup>22</sup> However, in 1950, black men and women at age sixty-five had life expectancies that were similar to their white counterparts,<sup>23</sup> clearly indicating that in the second half of the twentieth century, gains in health have been slower for blacks. Other major measures of disparities in health are total death rates and death rates by cause (table 5).

In 1998, for all causes combined, the death rate for blacks (5,551 deaths per 100,000) was 8.4% higher than the death rate for whites (5,122). Death rates for blacks were higher than for whites for four of the six leading causes of death (heart disease, malignant neoplasms, cerebrovascular disease, and diabetes).

There is an increased emphasis in the nation on prevention and early detection of cancer to reduce the burden of this disease. Early detection of cancer by ongoing patient monitoring and cancer-screening tests is especially important because patients treated for early-stage cancer (cancer localized in the primary site) have the best outcomes. As shown in Table 6, there are differences by race in stage of cancer at the time of diagnosis and in five-year survival rates.

**Table 5. Deaths per 100,000 Population for All Causes and for Six Leading Causes of Death, Age 65 and Older, By Race, U.S., 1998**

Cause of Death	White	Black
All Causes	5,122	5,551
Diseases of the Heart	1,774	1,893
Malignant Neoplasms	1,115	1,285
Cerebrovascular Diseases	404	455
Chronic Obstructive Pulmonary Diseases	300	176
Pneumonia and Influenza	246	217
Diabetes Mellitus	132	261

Source: Sherry L. Murphy, *Deaths: Final Data for 1998*, in NAT'L VITAL STAT. REP., July 24, 2000, at 30, 34 tbl.8.

For the period 1986-93, the percent of blacks with localized cancer, when first diagnosed, was lower than the percent of whites with localized cancer, for every major cancer site; similarly, five-year survival rates were lower for blacks than whites for every major cancer site.

**Table 6. Percent of Patients of All Ages with Localized Cancer at Time of Diagnosis, and Five-Year Survival Rates for Patients Diagnosed at Ages 65-74, By Race, 1986-93**

Cancer Site	White		Black	
	Localized Cancer at Diagnosis (%)	Five-year Survival (%) (Age at Diagnosis 65-74 years)	Localized Cancer at Diagnosis (%)	Five-year Survival (%) (Age at Diagnosis 65-74 years)
All Sites	—	58.8	—	44.7
Colon and Rectum	38	64.4	32	51.9
Lung and Bronchus	15	13.7	13	10.0
Breast	60	87.6	49	73.2
Corpus and Uterus	75	85.3	51	47.3
Prostate	59	93.6	54	80.0
Urinary Bladder	74	82.6	57	60.9

Source: SEER CANCER STATISTICS REVIEW, 1973-1994, NAT'L CANCER INST., NAT'L INST. OF HEALTH (Lynn A. Gloeckler Ries et al. eds., 1997) (NIH pub. No. 97-2789).

### *C. Socioeconomic Status*

There are also disparities by SES in the health of the elderly, as shown in four measures of health from the 1996 MCBS (table 7). Compared to blacks, whites rated their health better and reported less diabetes, hypertension, and disability. On these same four measures, high-income whites rated their health better and reported less morbidity and disability

**Table 7. Percent of Medicare Enrollees Reporting Selected Health Status Measures, Age 65 and Older, By Race and Income, 1996**

Health Status Measure	White (%)	Black (%)
<i>Rates Health Fair or Poor</i>		
Total (All Incomes)	25	42
\$25,000 or Lower	30	43
\$25,001 or Higher	16	29
<i>Has Diabetes</i>		
Total (All Incomes)	13	25
\$25,000 or Lower	15	24
\$25,001 or Higher	12	27
<i>Has Hypertension</i>		
Total (All Incomes)	49	66
\$25,000 or Lower	51	66
\$25,001 or Higher	45	70
<i>Limited in ADL* or IADL†</i>		
Total (All Incomes)	43	53
\$25,000 or Lower	50	55
\$25,001 or Higher	29	33

\* ADL: Activities of Daily Living; † IADL: Instrumental ADL

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1996) (data on file with authors).

than low-income whites. For example, health was rated as only fair or poor by 16% of whites with high incomes compared to 30% of whites with low incomes. Similarly, fewer high-income whites reported that they had diabetes or hypertension than low-income whites. Among blacks, health was rated as only fair or poor by 29% of those with high incomes compared to 43% of those with low incomes; however, for diabetes and hypertension, the associations between income and health were inconsistent. Inconsistencies in the association between income and health for blacks have been found by others,<sup>24</sup> and may be explained by a number of factors, including greater intergenerational changes in income among blacks. For example, early childhood health care (a time when blacks were poorer) may be reflected in the health of older persons (a time when more blacks are better off economically).

But for blacks and whites there is a notable consistency in the relationships between income and disability. As shown in Table 7, a smaller proportion of blacks and whites with high incomes experienced limitations in activities of daily living compared to their counterparts with low incomes.

#### *D. Potential Causes and Explanations*

The relatively poor health outcomes among minorities and the low-income elderly enrolled in Medicare raise concerns about the appropriateness and effectiveness of the health care provided to vulnerable



subgroups of the population. Little is known about the causes and explanations for disparities in the Medicare population. Studies have shown, however, that differences in risk factors such as diabetes and blood pressure explain very little of the excess mortality of blacks,<sup>25</sup> and that differences in patient characteristics cannot explain differences between blacks and whites in the use of certain elective procedures.<sup>26</sup> The distinct patterns of utilization for different types of services suggest that there are likely to be a multitude of pathways through which disparities occur, involving characteristics both of the beneficiaries and the health care system. For example, health promotion services (such as ambulatory physician visits, immunizations, and mammography) are often self-initiated by beneficiaries, although physicians and other health care providers play an important part in recommending preventive services. It may be that high-income and better-educated people are more likely to initiate the use of preventive services because they understand their value, and because the services are provided in safe and comfortable environments. But the use of common surgical procedures is generally a result of a referral to a specialist for evaluation and treatment. It may be that physicians are less likely to refer persons at the low end of the social and economic scale for services such as colonoscopy and cerebrovascular procedures because they believe that such patients may not follow orders, are likely to break appointments, or cannot afford to pay for the service. These, however, are only conjectures, and require further study.

## II. NEW ANALYSES

New analyses were undertaken based on the rationale that individuals often self-initiate the use of preventive services; and physicians and other health care providers also make recommendations to their patients to schedule various preventive services. A reasonable conjecture is that some beneficiaries focus more than others on a number of actions to promote and maintain health, such as getting mammograms, Pap smears, and influenza immunizations, and have healthy behaviors, such as exercise and good nutrition. Similarly, it is likely that some providers emphasize prevention more than others, such as recommending immunizations and cancer screening tests.

It seems plausible that a behavior such as smoking correlates with the use of health promotion services. Medicare beneficiaries age sixty-five and older were teenagers (an age when smoking is most likely to begin) more than forty years ago, before the Surgeon General's report on smoking in the 1960s. However, thirty-five years or more have elapsed, and the health hazards of smoking have been widely publicized. Many former smokers,

interested in healthy behaviors, no longer smoke. Because quitting smoking involves a conscious effort to prevent disease, and is often difficult, it seems reasonable that Medicare beneficiaries who quit smoking will tend to use more preventive services than beneficiaries who are current smokers.

With regard to women, it seems plausible that women who are knowledgeable and concerned about early detection of women's diseases will focus on an array of services, including mammography and Pap smears. Similarly, physicians who are concerned with women's health issues (gynecologists in particular) are likely to recommend mammography and Pap smears. Thus, we expect to find that women who get mammograms are more likely than non-users of mammography to get Pap smears.

In essence, it seems plausible that certain characteristics of the beneficiaries, reflecting factors such as knowledge about health promotion, influence behaviors relating to prevention. Health care providers also influence behaviors relating to prevention. Moreover, we expect to find that these behaviors are exhibited not as an isolated event, such as getting an influenza immunization, but are consistent across an array of preventive and screening services covered by Medicare, including mammography, Pap smears, and prostate examinations. It also seems plausible that if people have altered their smoking habits and quit, they will be more likely to use preventive services than current smokers. Although the present study does not attempt to analyze the many other behaviors that impact health, such as exercise and weight control, exploring the relationships between smoking behavior and the use of preventive services is likely to provide additional insight into health behaviors.

To determine if this line of reasoning helps to explain disparities in the use of Medicare services, we have focused on two hypotheses about behaviors for groups of beneficiaries differing by race, income, and education. We analyzed combinations of services and behaviors such as obtaining both a mammogram and an influenza immunization; a mammogram and a Pap smear; an influenza immunization and a prostate exam; and quitting smoking and a prostate exam. We tested the following two hypotheses:

**Hypothesis One:** Beneficiaries who use any one preventive service, such as mammography, tend to use a second preventive service, such as influenza immunizations. This will be true for blacks and whites, high-income and low-income groups, and high school graduates and non-graduates.

Hypothesis Two: Beneficiaries who quit smoking also tend to use preventive services. This will be true for blacks and whites, high-income and low-income groups, and high school graduates and non-graduates.

### *A. Methods*

*1. Data Source.* The Medicare Current Beneficiary Survey of 1998, an in-person household survey with a sample size of nearly 18,000 persons age sixty-five and older, was used for the following analyses.<sup>27</sup> The survey collected information on social and economic variables (including household income and educational attainment), health status, and the use of a number of services. Four racial groups were used to classify beneficiaries: white, black, American Indian, and Asian/Pacific Islander. Information was also collected about ethnicity. This study is confined to white and black beneficiaries to assure adequate sample sizes. All respondents were questioned about their use in the past year of influenza immunizations, pneumococcal immunizations, and eye exams. Women were also asked about mammography and Pap smears, and men were asked about prostate exams (either digital rectal exams or Prostate Specific Antigen (PSA) tests). Two questions on smoking were used in the survey: "Have you ever smoked?" and, if the answer was yes, "Do you smoke now?"

Although persons under age sixty-five who are disabled or who have end-stage renal disease may be covered by Medicare, this study was confined to those age sixty-five and older. Moreover, this study includes only non-institutionalized persons.

The analyses reported here, including responses on race, household income, and educational achievement, are based on survey responses. The MCBS can be linked to Medicare claims information, but in this study only survey responses were used. Thus, rates of influenza immunization are based on what respondents reported. Sample responses were weighted to the total Medicare population, and results were tested for statistical significance.

Different data sources can produce different findings, particularly surveys and administrative data. Variations can occur for several reasons, including recall biases by survey respondents, missing bills from administrative data, different populations, and different time frames. For example, the utilization data reported in Tables 1-4 are primarily from administrative data and include information for persons living in the community and in institutions, who received services in the fee-for-service sector only, whereas the information reported next, from the MCBS, include only those living in the community, who received services in both the fee-for-service and managed care sectors. Also, the mammography rates

reported above from Medicare administrative data are two-year rates, whereas the survey asks women if they have received a mammogram in the past twelve months.

2. *Analyses.* Hypothesis One was tested by tabulating responses about the use of influenza immunizations, pneumococcal immunizations, and eye exams. For women, responses were tabulated for the use of mammography and Pap smears; and for men, responses were tabulated for the use of prostate exams (digital rectal, PSA, or both). All data were broken out by race, income, and education. Hypothesis Two was tested by tabulating responses about the use of the preventive services according to lifetime smoking status and according to present smoking status. For ease of presentation, only a few of the findings are illustrated in this Article. However, they fully represent all of the analyses we performed.

3. *Statistical Significance.* Tests for statistical significance were performed using the unweighted sample. For Tables 12, 13, and 15, chi-square tests were computed separately for whites and blacks and for both income groups, to test for statistical significance between having one preventive service and a second preventive service. All differences shown in the tables were significant ( $p < 0.05$ ), except for high-income black women in Table 12—the exception very likely due to the small sample size for high-income black women. For both Tables 14 and 16, chi-square tests were performed to test for differences between smoking status and use of a preventive service. Tests were not significant for Tables 14A and 16A (Lifetime Smoking Status) but were significant for Tables 14B and 16B (Present Smoking Status) ( $p=0.001$ ). For Table 17, chi-square tests were performed to test for differences between blacks and whites in both income groups and in both educational groups. All tests were significant ( $p \leq 0.02$ ).

## B. Results

1. *Sociodemographics.* As shown in Table 8, of all Medicare beneficiaries age sixty-five and older in 1998, 2.5 million were black (7.8% of the total) and 28 million were white (88.1% of the total). The remaining 4.1% of the total included Asian/Pacific Islanders (1.8%), American Indians (0.6%), other, and unknown.

Blacks and whites differed substantially by household income and education. Among whites, 18 million people (64%) had incomes of \$25,000 or less, and the remaining 10 million people (36%) had incomes greater than \$25,000; among blacks, 2.2 million people (88%) had incomes of \$25,000 or less, and the remaining 300,000 people (12%) had incomes that exceeded \$25,000.

**Table 8. Distribution of Medicare Beneficiaries Age 65 and Older, and Percent Who Completed High School, By Race and Income, 1998**

	White		Black	
	Low Income*	High Income†	Low Income*	High Income†
Beneficiaries (millions)	18.0	10.0	2.2	0.3
Completed High School	58%	85%	33%	75%

\* Low income = \$25,000 or less; † High income = More than \$25,000.

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

Income and educational attainment are strongly related. Among whites, only 58% in the low-income group (\$25,000 or less) completed high school, while 85% in the high-income group (more than \$25,000) completed high school. Among blacks, the corresponding percentages were 33% and 75%, respectively. Although income and educational attainment are strongly related for both blacks and whites, the relatively small proportion of high-income blacks results in a large overall difference in the percent of blacks (38%) and whites (68%) who had completed high school. The disparities by race in income and educational attainment underscore the importance of examining differences in utilization patterns between blacks and whites by income or educational levels.

2. *Use of Preventive Services and Smoking Status.* As Medicare administrative data illustrate (tables 1-4), race and income are associated with the use of preventive services. Responses from women in the 1998 MCBS show similar associations (table 9). More high-income white women

**Table 9. Percent of Women Age 65 and Older Who Reported Receiving a Mammogram, an Influenza Immunization, and a Pap Smear in the Past Year, By Race and Income, 1998**

	White		Black	
	% of High Income Women*	% of Low Income Women†	% of High Income Women*	% of Low Income Women†
Mammogram	60	42	55	43
Influenza Immunization	74	68	62	51
Pap Smear	46	30	36	30

\* High income = More than \$25,000; † Low income = \$25,000 or less.

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

than high-income black women received mammograms, influenza immunizations, and Pap smears. The same was true for low-income women with regard to influenza immunizations. In each racial group, the proportion receiving mammograms, influenza immunizations, and Pap smears was higher among women financially more secure.

Among men, race and income are also associated with getting an

influenza immunization and with screening for prostate disease (digital rectal and/or PSA test), as shown in Table 10.

**Table 10. Percent of Men Age 65 and Older Who Reported Receiving a Prostate Examination and an Influenza Immunization, By Race and Income, 1998**

	White		Black	
	% of High Income Men*	% of Low Income Men†	% of High Income Men*	% of Low Income Men†
Prostate Exam	74	60	70	50
Influenza Immunization	75	69	52	49

\* High income = More than \$25,000; † Low income = \$25,000 or less.  
Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

Interestingly, with regard to smoking among women age sixty-five and older (table 11), more high-income women smoked sometime in their lifetime than low-income women (49% and 42%, respectively). Smoking behavior has changed significantly among women, with only 9% of high-income women and 11% of low-income women currently smoking.

Table 11 also reveals that among men, the same proportion of high-income and low-income men (80%) smoked sometime during their life. Similar to women, smoking among men has dropped significantly. In 1998, 12% of high-income and 16% of low-income men were current smokers.

**Table 11. Percent of Women and Men Age 65 and Older Who Reported They Had Smoked Sometime in Their Lifetime and Percent Who Currently Smoke, By Income, 1998**

	Women (Black and White)		Men (Black and White)	
	% of High Income Women*	% of Low Income Women†	% of High Income Men*	% of Low Income Men†
Have Ever Smoked	49	42	80	80
Currently Smoke	9	11	12	16

\* High income = More than \$25,000; † Low income = \$25,000 or less.  
Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

*3. Testing Hypothesis One for Women.* The relationship between the use of mammography and the use of influenza immunization lends substantial support to Hypothesis One. Table 12 shows that among high-income white women who had a mammogram, 80% also had an influenza immunization, but that among high-income white women without a mammogram, only 65% had an influenza immunization. Similarly, among low-income white women who had a mammogram, 77% also had an influenza immunization whereas among low-income white women without a mammogram, only 61% had an influenza immunization. For black women, the association was most evident for low-income women: among those who had a

**Table 12. Percent of High-Income and Low-Income Women Age 65 and Older Obtaining an Influenza Immunization, By Mammography Status and Race, 1998**

	High Income*		Low Income†	
	% with Influenza Immunization		% with Influenza Immunization	
	White	Black	White	Black
<i>Mammogram Status</i>				
Had Mammogram	80	66	77	60
Did Not Have Mammogram	65	57	61	44

\* High income = More than \$25,000; † Low income = \$25,000 or less.

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

mammogram, 60% had an influenza immunization, whereas among those who did not have a mammogram, 44% had an influenza immunization.

Hypothesis One is further confirmed by the striking relationships between getting a mammogram and getting a Pap smear for women of both races and both income groups (table 13). Of the high-income white women who had a mammogram, 66% had a Pap smear, but of the high-income white women without a mammogram, only 15% had a Pap smear. Similarly, of the high-income black women who had a mammogram, 59% had a Pap smear, but of the high-income black women without a mammogram, only 9% had a Pap smear. The relationship between getting a mammogram and getting a Pap smear is similarly striking for low-income women. Of low-income women without a mammogram, only 9% of black and white women, got a Pap smear, while of their low-income counterparts who got a mammogram, 58% of both black and white women also got a Pap smear.

**Table 13. Percent of High-Income and Low-Income Women Age 65 and Older Obtaining a Pap Smear, By Mammography Status and Race, 1998**

	High Income*		Low Income†	
	% with Pap Smear		% with Pap Smear	
	White	Black	White	Black
<i>Mammogram Status</i>				
Had Mammogram	66	59	58	58
Did Not Have Mammogram	15	9	9	9

\* High income = More than \$25,000; † Low income = \$25,000 or less.

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

*4. Testing Hypothesis Two for Women.* Hypothesis Two is confirmed by the consistent relationships between smoking habits and use of mammography (both races combined, table 14). Lifetime smoking status (part A of the table) has very little relationship with the percent of women who get mammograms. For high-income women, among those who have smoked,

58% had a mammogram, and among those who never smoked, a similar proportion, 61%, had a mammogram. For low-income women, among those who have smoked, 42% had a mammogram, and among those who never smoked, 42% had a mammogram.

In dramatic contrast, present smoking status (part B of the table) is strongly associated with the use of mammography. Among high-income women who quit smoking, 62% had a mammogram, while among high-income women who currently smoke, only 42% had a mammogram. Among low-income women who quit smoking, 45% had a mammogram whereas among low-income women who currently smoke, only 34% had a mammogram.

**Table 14. Percent of Women Age 65 and Older Obtaining a Mammogram, By Lifetime and Present Smoking Status, and Income, 1998**

	<b>A. Lifetime Smoking Status</b>		<b>B. Present Smoking Status</b>	
	<b>% with Mammogram</b>		<b>% with Mammogram</b>	
	<b>Have Smoked</b>	<b>Never Smoked</b>	<b>Quit Smoking</b>	<b>Currently Smokes</b>
<i>Income</i>				
High Income*	58	61	62	42
Low Income†	42	42	45	34

\* High income = More than \$25,000; † Low income = \$25,000 or less.

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

*5. Testing Hypotheses One and Two for Men.* The relationships between having a prostate screening test and having an influenza immunization (table 15) are similar to those noted earlier between having a mammogram and having an influenza immunization. For both income groups, among men of both races who had a prostate examination, a higher proportion had an influenza immunization compared to men without a prostate exam. The association is particularly evident for black men. Among high-income black men who had a prostate exam, 58% had an influenza immunization, while among those without a prostate exam,

**Table 15. Percent of High-Income and Low-Income Men Age 65 and Older Obtaining An Influenza Immunization, By Prostate Exam Status and Race, 1998**

	<b>High Income*</b>		<b>Low Income†</b>	
	<b>% with Influenza Immunization</b>		<b>% with Influenza Immunization</b>	
	<b>White</b>	<b>Black</b>	<b>White</b>	<b>Black</b>
<i>Prostate Exam Status</i>				
Had Prostate Exam	80	58	75	62
Did Not Have Prostate Exam	63	37	61	36

\* High income = More than \$25,000; † Low income = \$25,000 or less.

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).



only 37% had an influenza immunization. Corresponding figures for low-income black men were 62% and 36%, respectively.

Hypothesis Two is further confirmed by the relationships for men between lifetime smoking status, and present smoking status and the use of prostate screening tests (table 16). Lifetime smoking status among men is not related to use of prostate tests (part A), just as lifetime smoking status among women is not related to the use of mammograms. For high-income men who have smoked, 74% had a prostate screening test. Among those who never smoked, 74% had a prostate screening test. Similarly, for low-income men, lifetime smoking status had no association with prostate screening. Fifty-eight percent who had smoked and 59% of those who had never smoked had a prostate screening test.

But present smoking status is strongly associated with having a prostate screening exam (part B). Among high-income men who quit smoking 76% had a prostate screening test, while among high-income men who currently smoke, 62% had a prostate exam. Among low-income men who quit smoking, 62% had a prostate exam, while among low-income men who currently smoke, only 45% had a prostate exam.

**Table 16. Percent of Men Age 65 and Older Obtaining a Prostate Exam, By Lifetime and Present Smoking Status, and Income, 1998**

	<b>A. Lifetime Smoking Status</b>		<b>B. Present Smoking Status</b>	
	<b>% with Prostate Exam</b>		<b>% with Prostate Exam</b>	
	<b>Have Smoked</b>	<b>Never Smoked</b>	<b>Quit Smoking</b>	<b>Currently Smokes</b>
<i>Income</i>				
High Income*	74	74	76	62
Low Income†	58	59	62	45

\* High income = More than \$25,000; † Low income = \$25,000 or less.

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

As noted earlier, women were asked about the use of five preventive services: influenza immunizations, pneumococcal immunizations, mammograms, Pap smears, and eye exams. Men were asked about four: influenza immunizations, pneumococcal immunizations, prostate cancer screening tests by either digital rectal exam or the PSA test, and eye exams. To summarize the use of preventive services in 1998 by race, income, and education, men and women were grouped according to whether they were low users (0-2 preventive services) or high users (more than two preventive services). As shown in Table 17, race, income, and education are all associated with patterns of use. Among high-income men, 43% of black men were high users, and 63% of white men were high users. The percentages fell for low-income men: Thirty-eight percent of black men

were high users, and 52% of white men were high users. Similar patterns are found for women: Among high-income women, 57% of black women were high users, and 68% of white women were high users. Again, the percentages fell for low-income groups. For both blacks and whites, education is strongly associated with the use of preventive services. For example, among black men who graduated from high school, 46% were high users of preventive services, while among black men with less than a high school education, only 35% were high users.

**Table 17. Percent of Medicare Enrollees Age 65 and Older Who Were Low Users (0-2) and High Users (3 or more) of Preventive Services, By Sex, Income, Education, and Race, 1998**

Income, Education, and Race	Male*		Female†	
	0-2 Services	3-4 Services	0-2 Services	3-5 Services
<i>High Income‡</i>				
Black	57	43	43	57
White	37	63	32	68
<i>Low Income§</i>				
Black	62	38	59	41
White	48	52	47	53
<i>High School Graduate</i>				
Black	54	46	50	50
White	40	60	38	62
<i>Less than High School</i>				
Black	65	35	63	37
White	50	50	53	47

\* For men, four preventive services are included: influenza immunization, pneumococcal immunization, digital rectal exam or PSA, and eye exam.

† For women, five preventive services are included: influenza immunization, pneumococcal immunization, mammogram, Pap smear, and eye exam.

‡ High income = More than \$25,000; §Low income = \$25,000 or less.

Source: Health Care Financing Administration, Medicare Current Beneficiary Survey (1998) (data on file with authors).

### III. DISCUSSION

Differences by race and SES in the use of common surgical procedures among Medicare beneficiaries raise concerns, but the implications of these differences are not always clear. To understand whether differences in the use of a particular surgical procedure signifies disparities in access to services requires more clinical information than is available in administrative or survey data. Arguments can be made that differences in surgery rates (for example, for heart disease) may not necessarily reflect inequalities in access because groups can differ in need and preferences. For some surgical procedures there may be alternative treatments, such as changes in diet, lifestyle, and medication, which could prove as effective as using the more invasive surgical approach.

In contrast, similar arguments cannot be made for disparities in

influenza immunization. All elderly persons are at risk of contracting influenza, an illness that has been shown to exact an enormous burden on health and costs of care.<sup>28</sup> Moreover, although there are alternative screening tests for certain cancer sites, screening for cancer is widely endorsed for early detection and treatment to decrease the burden of this disease. Thus, disparities in the use of preventive services, juxtaposed against disparities in health, provide substantial evidence that new approaches are needed to equalize access to services that promote health.

Financial barriers may be a factor influencing disparities in the use of preventive services covered by Medicare. Mammography, for example, has a 20% co-insurance requirement, and that may contribute to the lower rate among black women. However, influenza immunizations can be obtained "free," yet influenza immunization rates differ more by race and SES than mammography rates do. This finding led to the fundamental question: Do some Medicare beneficiaries tend not to use health promotion services while others tend to use them? And are these tendencies related to race, income, and education?

The new analyses show that there is a pattern in the use of preventive services: The use of any one preventive service is associated with the use of a second preventive service. White or black, rich or poor, well-educated or not, groups that use one preventive service are more likely to use a second than those who do not use the first preventive service.

An especially strong relationship was found between the use of mammograms and Pap smears. If a group of elderly women do not get mammograms, we can expect no more than 10% will get Pap smears. But if they do get mammograms, we can expect a six-fold increase in their use of Pap smears. Although many individuals initiate the use of a preventive service, it is common experience that health care providers play an important role in encouraging their patients during a visit (and sometimes with a postcard reminder) to schedule an influenza immunization, mammogram, Pap smear, eye exam, and other screening tests, such as colonoscopy and sigmoidoscopy.

The similarity of the relationships between smoking habits and the use of a preventive service, such as mammography or prostate screening, reinforces our conclusion that actions and behaviors are important in thinking about ways to ameliorate disparities in health care. Smoking was used in this study because it provided insight into behaviors. Current Medicare beneficiaries were teenagers before the publication of the Surgeon General's report on smoking. Very likely, their past smoking habits were formed before the consequences of smoking were well known. Therefore, it is not surprising to find that there is no relationship between

whether the beneficiary smoked sometime during his or her lifetime and the use of health promotion services. However, those who quit smoking likely broke the habit in the hope of improving their chances for good health. Not surprisingly, quitting smoking is related to the use of preventive services. In contrast, current smokers, including those who may have tried, but were not able to break the habit, use fewer preventive services.

The connection between the use of one preventive service with the use of another preventive service may help shed some light on the puzzle raised by studies that find relatively small effects on life expectancy from the use of a single preventive service, such as the influenza immunization.<sup>29</sup> Our study suggests that the use of a preventive service is not an isolated event, but rather is interconnected with the use of other preventive services and with other health behaviors. Thus, calculations of the benefits of any one preventive service very likely provide only a partial picture of its full impact on health outcomes. Research is needed to find methods for studying the interactions and how they affect life expectancy.

The findings from this study raise questions about the views held by some that health care plays only a minor role in explaining disparities in health outcomes. The Medicare experience indicates an association between measures of mortality, morbidity, and disability, and patterns of use of preventive and health promotion services. These associations suggest a need to strengthen "low-tech" prevention and monitoring through appropriate and effective use of physicians' visits, immunizations, and cancer screenings, especially among the most vulnerable beneficiaries.

There are several policy implications of this study. First, the consistency in behaviors relating to prevention suggests that efforts and resources expended to raise the level of use of any one preventive service (e.g., influenza immunizations among the elderly), may have a multiplicative effect by, for example, raising the level of mammography among women and prostate screening among men. Therefore, providers are likely to have the greatest impact by recommending not just an influenza immunization, for example, but a whole array of wellness and screening services.

Second, the new analyses suggest that there are markers for identifying populations most at risk for not using preventive services. For example, identifying women without an influenza immunization, or women who currently smoke, may help in identifying those who have not had a mammogram. Moreover, patterns of use of preventive services found among the elderly, with regard to prevention, may apply to younger age groups. We need to determine if there are similar patterns of prevention

among persons under age sixty-five (including children) enrolled in private and public health care, and if the patterns can also serve as markers in identifying younger people at risk for not using preventive services. Other factors related to health behaviors, including smoking habits, weight, and exercise among persons under age sixty-five may also serve as markers for identifying groups at risk for not using preventive services.

Third, the Census Bureau estimated that forty-three million people in the nation were uninsured in 1999.<sup>30</sup> It is likely that the uninsured are less willing to pay out-of-pocket for “discretionary” services, such as immunizations and cancer screening procedures, than they are for emergency and acute care needs. Thus, habits of obtaining wellness services are weakened by lack of health insurance, and very likely have an impact on health disparities in the nation.

Fourth, this study explored potential causes and remedies solely for disparities by race and SES in the use of preventive services covered by Medicare. There is a pressing need to understand the reasons for disparities in the use of diagnostic tests, such as colonoscopy, and in the use of common surgical procedures, such as cataract removal, coronary artery revascularization procedures, and hip and knee replacement. That research will be much more difficult than the present study because clinical data are required to control for factors relating to need.

In summary, efforts to embrace a social medicine perspective are needed as much today as when the New York Academy of Medicine raised that issue half a century ago. By providing access to care, Medicare has played an important role in improving the health of the elderly of our nation. Since the inception of the program, life expectancy has increased substantially for those age sixty-five and older. However, at age sixty-five, white beneficiaries today can expect to live nearly two years longer than their black counterparts. In light of the disparities by race and SES in the health of the elderly, Medicare utilization patterns raise concerns. Elderly blacks and the least advantaged beneficiaries use fewer disease prevention and health promotion services, use fewer of the common surgical procedures generally performed to improve health and functioning, and yet they are more likely to undergo procedures associated with the failure to manage chronic diseases, such as diabetes or hypertension. These patterns indicate a need to understand the causes of such disparities in the use of Medicare services.

The present study focused on the use of preventive and screening services because they are recommended for all beneficiaries. We found that beneficiaries who use one preventive service are more likely to use a second, compared to beneficiaries who do not use the first service. It is

deeply troublesome, therefore, that a recent study found that race, ethnicity, and SES are associated with physician recommendations for mammography.<sup>31</sup> It seems clear that a greater emphasis is needed on health promotion and prevention of morbidity and disability, especially for vulnerable subgroups of the elderly. The substantial changes that have occurred in smoking behavior among current Medicare beneficiaries show that habits can be altered. And, our analyses show that quitting smoking is associated with a greater likelihood of using preventive services. Although we have used the concept of behavior, we believe that the efforts of individuals, the health care delivery system, and society are needed if we are to ameliorate inequalities in health care and in health.

## References

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### *Pegram v. Herdrich*

**530 U.S. 211 (2000)**

On June 12, 2000, the U.S. Supreme Court, in a unanimous decision written by Justice Souter, held that treatment decisions made by health maintenance organizations (HMOs), acting through their physician employees, are not fiduciary acts within the meaning of the Employee Retirement Income Security Act (ERISA).

The petitioners in the case were Carle Clinic Association, P.C., Health Alliance Medical Plans, Inc., and Carle Health Insurance Management Co, Inc. [hereinafter Carle]. Carle functioned as a for-profit HMO, and its physician owners provided medical services to participants whose employers had contracted with it. Respondent Cynthia Herdrich was covered by Carle through her husband's place of employment.

The events in question began when a Carle physician, Dr. Lori Pegram, examined Herdrich, who was experiencing abdominal pain. Pegram discovered a mass in Herdrich's abdomen and subsequently scheduled an abdominal ultrasound. Instead of immediately scheduling the study at a local facility, Pegram scheduled the ultrasound for eight days later at a facility staffed by Carle, which was more than fifty miles away from Herdrich's home. During the eight days that Herdrich was waiting for the ultrasound, her appendix ruptured, causing peritonitis.

Herdrich recovered \$35,000 from a state malpractice action against Pegram. However, the U.S. Supreme Court only considered Herdrich's claim that the provision of medical services under Carle's terms—which reward physician owners for limiting medical care—entailed an inherent or anticipatory breach of an ERISA fiduciary duty, since these terms created an incentive to make decisions in the physicians' self-interest, rather than the exclusive interests of patients. The Court of Appeals for the Seventh Circuit agreed with Herdrich and held that Carle was acting as a fiduciary when Pegram made the decision to postpone Herdrich's care. The U.S. Supreme Court reversed, finding that Herdrich did not have an ERISA claim against her HMO.

Six authors from various disciplines were asked to consider the impact of the Court's decision. Their responses follow.

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## ***Pegram v. Herdrich*: A Victory for HMOs or The Beginning of the End for ERISA Preemption?**

**Phyllis C. Borzi, J.D., M.A.\***

On June 12, 2000, a unanimous Supreme Court held that treatment decisions made by an HMO, acting through its physicians, are not fiduciary acts under ERISA.<sup>1</sup> Thus the Carle HMO was not liable under ERISA for the harm caused when Pegram, one of Carle's physician/owners, required Herdrich to wait an additional eight days before undergoing a necessary diagnostic procedure and, when Herdrich's appendix ruptured during her wait for the procedure, then required her to receive emergency treatment at a Carle-owned facility fifty miles away, rather than at a nearby hospital.

At first blush, this seemed like yet another judicial decision insulating managed care organizations (MCOs) from liability under ERISA. Advocates of expanding patients' rights to sue health plans under legislation before Congress<sup>2</sup> might have been expected to bombard members of Congress with outraged communications decrying *Pegram* as another illustration of how inadequate ERISA was in protecting participants in employer-sponsored group health plans. But the early euphoria or dismay quickly dissipated as ERISA experts began to focus on the larger legal questions raised by Justice Souter's opinion. In particular, much discussion has ensued regarding the implications of the *Pegram* decision for preemption cases under which plaintiffs have been permitted to bring state law actions alleging substandard quality of care from their health plans.

*Pegram* is a complex, yet fascinating, case that reveals the Supreme Court poised on the brink of another major erosion of ERISA preemption,

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even though the case itself did not involve ERISA preemption at all, but rather the scope of ERISA's fiduciary provisions. Under ERISA, state laws that relate to ERISA-covered employee benefit plans are generally preempted. However, certain state laws relating to ERISA group health plans may be saved from preemption if they are laws regulating insurance that do not treat plans as insurance companies.<sup>3</sup>

At its core, *Pegram* asks a question of intense interest to patients in managed care plans everywhere: Does the common HMO practice of providing financial rewards for doctors who reduce utilization of medical services violate ERISA's fiduciary rules? In other words, is the use of financial incentives for HMO doctors to ration care per se illegal under ERISA? A unanimous Supreme Court said no, because decisions that intertwine questions of eligibility for coverage and treatment judgments ("mixed eligibility decisions") are not fiduciary acts under ERISA.<sup>4</sup>

Most commentators believed that the Court would find that decisions regarding how to structure the MCO delivering medical care to participants under an ERISA-covered plan were not fiduciary decisions. So the Court's ultimate conclusion was hardly a bombshell. However, how the Court reached that result, as well as some of the observations the Court made, and conclusions it drew in arriving at its result, were both surprising and revealing.

*Pegram* involved a medical malpractice action brought in state court against both the treating physician and Carle. After the malpractice case was brought, Herdrich added two counts of state law fraud. Arguing that the fraud claims were preempted by ERISA, the defendants removed the case to federal court and sought summary judgment on the fraud counts.<sup>5</sup> The district court granted the defendant's motion on one count, but permitted the plaintiff to amend her complaint to allege that the HMO's practice of rewarding physicians (who also owned the health plan) violated ERISA's fiduciary standards. Herdrich alleged, among other things, that the HMO had breached its fiduciary duty under ERISA because the financial incentives for plan providers were structured to encourage reductions in treatment as a way to increase the bonus pool available at the end of the year. The district court granted the defendant's motion for summary judgment on the amended fraud claim.

Herdrich appealed, and the Seventh Circuit, reversing the district court, held that the HMO was acting as a fiduciary when its physicians made their treatment decisions.<sup>6</sup> The decisions made by Carle physicians, including the operation of the doctor-referral process, the nature and duration of patient treatment, and the extent to which participants were required to use Carle-owned facilities were all held to be fiduciary acts.

Thus the circuit court allowed the plaintiff to proceed to trial on the breach of fiduciary duty allegations.

Justice Souter, writing for a unanimous Supreme Court, reversed the Seventh Circuit and held that treatment decisions made by an HMO, acting through its physicians, are not fiduciary acts.<sup>7</sup> To reach that conclusion, Justice Souter first explained how HMOs operate, describing the various mechanisms used by HMOs to control costs as comparable to “other risk-bearing organizations” and “traditional insurers.”<sup>8</sup> Justice Souter observed that HMOs customarily issue general guidelines to physicians concerning the appropriate levels of care, complemented by a system of financial incentives designed to encourage doctors to provide less care. The countervailing force against these financial incentives to ration care is “the professional obligation to provide covered services with a reasonable degree of skill and judgment in the patient’s interest.”<sup>9</sup> However, “no HMO organization could survive without some incentive connecting physician reward with treatment rationing,” Justice Souter concluded.<sup>10</sup> Although Herdrich’s claim focused on Carle’s for-profit character, ultimately the Court found that to be irrelevant.

The Court next looked at the requirements of ERISA. Carle was charged with a breach of fiduciary duty in connection with carrying out its obligations under the State Farm medical plan. For the first time, the Court tackled two critical questions that lower courts often ignore: What is a “plan” under ERISA, and is the HMO itself an ERISA plan? Relying on the plain dictionary meaning of “plan” (i.e., a scheme decided on in advance), the Court concluded that a plan is “a set of rules that define the rights of a beneficiary and provide for their enforcement.”<sup>11</sup> Thus:

...when employers contract with an HMO to provide benefits to employees subject to ERISA, the provisions of documents that set up the HMO are not, as such, an ERISA plan, but the agreement between the HMO and an employer who pays the premiums may, as here, provide elements of a plan by setting out rules under which beneficiaries will be entitled to care.<sup>12</sup>

Fiduciaries exercise discretion or control over the plan investments and plan administration.<sup>13</sup> But when HMOs contract with an ERISA plan, not every act an HMO performs is a fiduciary act. The Court distinguished between the HMO’s exercise of discretion over its own business (not a fiduciary act) and its exercise of discretion over the ERISA plan (a fiduciary act).<sup>14</sup> In addition, the Court noted that at common law, trustees

only wore their fiduciary hats, whereas under ERISA they can wear several hats, although only one at a time.<sup>15</sup> Justice Souter used the example of an employer who, when acting as an employer or as a settlor of a plan, can take actions that disadvantage participants (e.g., amending the plan to provide less generous future benefits), yet when the employer is acting as a fiduciary, the duty of loyalty and the exclusive benefit rule preclude such actions.<sup>16</sup>

Herdrich argued that Carle and its physicians/agents breached their fiduciary duty under ERISA to act solely in the interest of participants and beneficiaries because their medical treatment decisions were influenced by financial incentives to maximize profits. However, the Court rejected that argument for two reasons: (1) since a plan sponsor's decision about the content of the ERISA plan is a settlor, not a fiduciary, decision, the HMO's comparable decision to include financial incentives in its organizational structure cannot be a fiduciary act either, and (2) since the financial incentive structure adopted by Carle preceded its contract to deliver benefits to State Farm's employees under the company's ERISA plan, acts prior to the establishment of the plan could hardly be fiduciary acts with respect to that plan.<sup>17</sup> When Carle became a fiduciary as a result of its plan administration activities, however, the question arose whether the HMO's treatment decisions (which were alleged to be compromised by the existence of the financial incentives) were fiduciary decisions.

In making that determination, the Court first distinguished between "pure eligibility decisions" and "treatment decisions."<sup>18</sup> The former depend on whether or not the plan covers a particular treatment or provider, while the latter are "choices about how to go about diagnosing and treating a patient's condition: given a patient's constellation of symptoms, what is the appropriate medical response?"<sup>19</sup> Because treatment and eligibility are often inextricably bound, "mixed eligibility decisions" (i.e., those involving medical judgment by a physician) are not fiduciary decisions under the Court's analysis, but rather must be measured against state malpractice standards.<sup>20</sup>

In considering why a plaintiff might be interested in pursuing a breach of fiduciary duty case under ERISA in the first place, the Court posits that in states that do not allow malpractice actions against HMOs, the plaintiff may believe that he or she will be able to go after a deeper pocket than the treating physician if federal fiduciary duty claims could be brought against the HMO. But the Court gives short shrift to its own speculation. What is significant about this speculation is that the Court appears to assume that these state liability laws are valid (i.e., not preempted by ERISA), thus implicitly endorsing them.<sup>21</sup>

Interestingly, the Court also makes several important points in footnotes to the opinion. Although *dicta*, these comments both illustrate and illuminate the next set of battles likely to come under Court scrutiny. First, the Court raises the intriguing possibility that even though Carle's decision to include financial incentives for its doctors does not violate ERISA's fiduciary rules, Carle may be required to disclose the existence of these financial incentives, even if they are not illegal. This is because Carle's discretion with respect to plan administration makes it a fiduciary to an ERISA plan.<sup>22</sup> Second, the Court indicates that because this case involves a breach of fiduciary duty claim under ERISA § 502(a)(3)<sup>23</sup> and not a claim for benefits under ERISA § 502(b)(1)(A),<sup>24</sup> the Court does not need to address the question of whether, if the same set of facts came before the Court styled as a benefit claim case,<sup>25</sup> various state causes of action would be preempted. This latter statement is the source of some of the most intense speculation regarding the ultimate direction in which the Court is heading.

*Pegram* tells us that challenges under ERISA regarding the nature of managed care itself (i.e., the structure of an MCO delivering care to participants in an ERISA-covered plan) will not be successful. However, other aspects of how the MCO actually provides that care (the "when-and-how question"<sup>26</sup>) as it administers an ERISA plan are fair game—but probably under state law, not ERISA.

In reiterating its primary holding that mixed eligibility decisions (i.e., those that involve medical judgment) are not fiduciary acts, the Court is breaking new ground with profound implications for ERISA's current preemption jurisprudence. Until this point, courts have generally rejected state law challenges to so-called "coverage" decisions, even those involving medical judgment.<sup>27</sup> With the exception of the *Dukes v. U.S. Healthcare, Inc.* line of cases described below,<sup>28</sup> lower courts have routinely found preempted state law causes of action in cases involving challenges to decisions that defendants have successfully argued concern coverage questions—whether or not the treatment or services sought are covered by the plan. As the Court acknowledges in *Pegram*, these questions are rarely simple. Rather, they often concern questions of medical judgment such as whether a particular treatment is "medically necessary."<sup>29</sup> But is that determination a coverage decision or a medical one? Prior to *Pegram*, if a court found that an aspect of the decision was a coverage question, even if medical judgment was also involved, state law was preempted.

After *Pegram*, the Court appears to be on the brink of an even more fundamental restriction on the sweep of ERISA preemption than the Third Circuit's approach in *Dukes*.<sup>30</sup> *Dukes* is the seminal case in which courts

imposed vicarious liability on HMOs for the negligence of their doctors. In *Dukes*, the circuit court distinguished between allegations concerning coverage and those concerning the quality of care the participant received. Because the *Dukes* court agreed that the dispute was not centered on the plaintiff's failure to receive the services promised under the ERISA plan, but rather the allegations that the care the plaintiff received was substandard, the Third Circuit held that the state law negligence case was not preempted by ERISA. The court noted that had the case only involved coverage questions, state law would have been preempted.

*Dukes* is significant, not only for the standards the court sets, but also because it marked the first time that the U.S. Department of Labor, as *amicus curiae*, weighed in to support the argument that state law medical malpractice claims were not preempted. The courts that have refused to follow *Dukes*<sup>31</sup> have done so in part because they believe that the distinction between coverage and quality is an artificial one designed simply to provide more generous relief under state law in cases that would otherwise be limited by ERISA's narrow remedies.

But applying *Pegram*'s analysis to allegations of medical malpractice in preemption cases may be even more helpful to plaintiffs. The claims at issue in *Dukes*, in the view of the Supreme Court in *Pegram*, were either simple treatment decisions, or at worst, mixed eligibility decisions. Even under the *Dukes* rationale, however, if the decision implicated coverage issues, the Third Circuit would have found state law preempted, even if the decision was a "mixed eligibility decision." However, applying the *Pegram* rationale, the Court would presumably decide differently and uphold the application of state law because a decision requiring the exercise of medical judgment (such as whether or not an otherwise non-excluded service or treatment was medically necessary) is a "mixed eligibility decision."

Thus the Court in *Pegram* appears to be ready to push even more types of decisions out of the ERISA ambit and into state courts by holding that HMO decisions requiring physician judgment, even those also involving coverage issues, are not covered by ERISA. Although consistent with the overall direction of this Supreme Court in upholding state prerogatives over federal regulation, *Pegram* holds the potential for further eroding ERISA preemption. This is good news for participants who are injured by delay or denial of treatment by HMOs and who are attempting to hold HMOs more accountable for their allegedly negligent decisions in connection with ERISA-covered group health plans.



## References

1. *Pegram*, 530 U.S. 211 (2000).
2. *E.g.*, H.R. 2990, 106th Cong. § 1302 (1999); H.R. 2723, 106th Cong. (1999). On October 6, 1999, the U.S. House of Representatives passed H.R. 2990, which incorporated both the provisions of the original H.R. 2990, the Quality Care for the Uninsured Act of 1999, and H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999. The bill passed by the House amended Title I of ERISA to expand the current right to sue and the remedies available for participants in ERISA-covered plans (both fully insured and self-insured). It permitted injured participants to recover damages under state personal injury or wrongful death laws in certain circumstances after all applicable administrative appeals, both internal and external, had been exhausted. Punitive damages would be available under state law only if the group health plan or health insurance issuer had not complied with the decision of the external reviewer. The Senate passed a much more limited version of the bill. When the 106th Congress adjourned, no final action was taken on the bills, although they were the subject of heated debate and discussion.
3. ERISA § 514, 29 U.S.C. § 1144 (1994).
4. *Pegram*, 530 U.S. at 230.
5. Herdrich prevailed on her original state malpractice claims, and the jury awarded her \$35,000. See *Herdrich v. Pegram*, 154 F.3d 362, 367 (7th Cir. 1998) for history of the case.
6. *Id.* at 370 (“We can reasonably infer that Carle and HAMP were plan fiduciaries due to their discretionary authority in deciding disputed claims.”). *Id.*
7. *Pegram*, 530 U.S. at 231.
8. *Id.* at 219.
9. *Id.*
10. *Id.* at 220.
11. *Id.* at 223.
12. *Id.*
13. The test of whether a person is a fiduciary under ERISA is a functional one. Under ERISA § 3(21), a person is a fiduciary “to the extent” that the person: (1) exercises any discretionary authority or control over the management of the plan or the management or disposition of its assets, (2) renders investment advice regarding plan assets for a fee or other direct or indirect compensation, or has the authority or responsibility to do so, or (3) has any discretionary authority or control over plan administration. 29 U.S.C. § 1002(21) (1994).
14. *Pegram*, 530 U.S. at 223.
15. *Id.* at 225.
16. *Id.* at 225-26.
17. *Id.* at 227.
18. *Id.* at 228.
19. *Id.*
20. *Id.* at 237.
21. *Id.*
22. The Court notes that although the fraud claims in the original complaint filed by Herdrich in state court could be described as claims alleging that failure by Carle to disclose the existence of its financial incentives was itself a fiduciary breach, the amended complaint before the Court does not raise that point and therefore the issue is not properly before the Court. *Id.* at 228 n.8.
23. 29 U.S.C. § 1132(a)(3) (1998).
24. 29 U.S.C. § 1132(a)(1)(B) (1998). Individuals who are challenging improper

benefit denials can file suit under ERISA § 502(a)(1)(B). Herdrich could have brought a benefit claim action challenging the HMO's decision to make her wait eight days to have the sonogram or the decision requiring her to bypass her local hospital and seek emergency treatment at a distant Carle-owned facility as violating her rights as a beneficiary under the terms of the ERISA plan. This action could have been brought in either state or federal court. Instead of suing under ERISA, where remedies for successful plaintiffs in benefit claims actions are limited to the provision of the denied benefit, plaintiffs typically allege various state law negligence claims, such as the medical malpractice counts raised by Herdrich in her original suit. Then the issue before the courts would have been whether those state law claims were preempted by ERISA § 514. Under ERISA § 514, state laws that "relate to" ERISA plans and are not otherwise saved by ERISA's insurance savings clause are preempted. 29 U.S.C. § 1144 (1998).

25. *Pegram*, 530 U.S. at 229 n.9.

26. *Id.* at 228-29.

27. *E.g.*, *Corcoran v. United HealthCare, Inc.*, 965 F.2d 1321 (5th Cir. 1992), *cert. denied*, 506 U.S. 1033 (1992). In *Corcoran*, the treating obstetrician sought precertification for a hospital stay during the plaintiff's high-risk pregnancy. In performing utilization review for the employer's self-funded medical plan, the defendant determined that hospitalization was not necessary and instead authorized ten hours per day of home nursing care. During a period when no nurse was on duty, the fetus went into distress and died. The Fifth Circuit affirmed the district

court's decision that ERISA preempted the plaintiffs' state law tort claim for the wrongful death of their child allegedly resulting from defendant's erroneous medical decision. Although the defendant made medical decisions and gave medical advice, the court determined that it did so in the context of determining the availability of benefits under an ERISA plan and therefore its decision to deny hospitalization was a coverage decision. Accordingly, the court held that plaintiffs' malpractice claims related to the plan and were preempted by ERISA.

28. *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350 (3d Cir. 1995); *cert. denied*, 516 U.S. 1009 (1995). These cases distinguish between claims that the plaintiff allegedly failed to receive covered services under the plan and claims in which the plaintiff alleges that the services provided under the plan were substandard ("quality of care" cases). In the former cases, state law is preempted by ERISA. In the latter cases, however, courts have permitted the plaintiff to pursue state law tort challenges to the quality of care received.

29. Plans and insurance contracts routinely cover only specified services when medically necessary. That necessitates an individualized decision at the point at which treatment is requested—with respect to a particular patient, an otherwise covered service (i.e., a service that is not excluded under the terms of a plan) ought to be provided because it is medically necessary to treat this patient, given his or her symptoms or condition.

30. *Dukes*, 57 F.3d 350, *cert. denied*, 516 U.S. 1009. Two other circuits have followed this approach; one has explicitly rejected it.

*Compare* Rice v. Panchal, 65 F.3d 637 (7th Cir. 1995), *amended, reh'g denied en banc, sub nom* Rice v. Kanu, 1995 U.S. App. LEXIS 31419 (7th Cir. 1995), *and* Pacificare of Ok. v. Burrage, 59 F.3d 151 (10th Cir. 1995), *with* Hull v. Fallon, 188 F.3d 939 (8th Cir. 1999), *cert. denied*, 528 U.S. 1189 (2000). In addition, the Third Circuit recently expanded upon the *Dukes* principles in *In re U.S. Healthcare, Inc.*, 193 F.3d 151 (3d Cir. 1999) (this case is sometimes referred to as *Bauman v. U.S. Healthcare*).

31. *E.g.*, Hull, 188 F.3d 939, *cert. denied*, 528 U.S. 1189 (2000).



## A Perspective from Within the White Coat

R. Dobbin Chow, M.D.\*

*I do solemnly swear by that which I hold most sacred that I will be loyal to the profession of medicine and just and generous to its members. I will lead my life and practice my art in uprightness and honor, . . . it shall be for the good of the sick, to the utmost of my power, I holding myself aloof from wrong, from corruption, from the tempting of others...*<sup>1</sup>

—Oath of Hippocrates

One can easily generate a noisy and angry discussion in any physicians' dining room in the United States by bringing up the subject of managed care systems and their use of financial incentives to control physicians' behavior. Generally, the reaction will range from a palpable frustration among the younger physicians to a feeling of resignation in the senior colleagues. The latter group will then reflect back on the era before managed care, when compensation was on a *per diem* basis. The more vocal younger generation will continue to vent their spleens about the illogical and unfair nature of their compensation systems, and then realize that they must quickly return to their respective offices, lest their productivity be undermined.

Having entered clinical practice during the adolescence of managed care, I can provide one clinician's perspective, but cannot pretend to speak for all physicians. There are many of my colleagues who have taken to arms, securing M.B.A. degrees and reviewing HMO contracts every evening before bed. It is easy to discern who these people are: They talk about covered lives, contractual withholds, and capitation systems. I am not among their number. Naïve as it is to say, I chose to enter medicine to take care of patients, and I assumed that I would be compensated fairly and live comfortably. If indeed, I had wanted to maximize my future income, I would have sought my fortune in the business world, or failing that, the legal profession.

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I am a general internist, a physician for adults, spending most of my time in the office setting seeing scheduled patients. Approximately 40% of the patients for whom I provide primary care are insured by managed care programs. An equal fraction are insured through Medicare, Medicaid, or commercial insurance. Finally, a significant, but small proportion have no insurance at all. The managed care patients belong to one of perhaps a dozen different plans with which I am enrolled, each with their own panels of specialists, drug formularies, laboratories for blood tests, and radiology facilities. The managed care administrators monitor my prescribing habits, compliance with recommended health maintenance measures (e.g., provision of influenza vaccines or screening mammography on appropriate patients), rates of hospitalization, and utilization of emergency room visits. They review data from pharmacies, office charts, and charges from hospitals and emergency departments. They prefer that I prescribe generic medications and keep patients out of hospitals and emergency rooms. They generate utilization reports on an annual basis, comparing my practice patterns to national averages.

I like to believe that I treat all patients the same, regardless of their insurance. However, there are very practical economic dilemmas that I face on a daily basis. For patients who do not have a prescription plan, generic medications are almost mandatory. A common example is the new class of arthritis drugs, which have the same effectiveness as the older ones, but do not have the potential side effect of causing stomach ulcers. However, the newer drugs cost \$3.00 a pill, whereas the older generic arthritis medications, such as ibuprofen, cost pennies a pill. HMOs allow me to prescribe the newer medications, but only after obtaining formal approval from their medical directors. Needless to say, this is a tedious and time-consuming process. Similarly, authorization must be obtained for subspecialty consultations outside of the primary HMO referral base. In general, the HMO medical directors are loath to approve such requests, claiming that similar care can be rendered within their plans. One example might be acute leukemia, a cancer that is optimally treated at special centers such as Johns Hopkins Hospital. However, the HMO may wish to restrict care to their local hospital, which can certainly treat the leukemia, but perhaps without the experience that Hopkins would provide. However, the HMO may have a pre-arranged contractual arrangement such that the local hospital takes care of all the HMO enrollees for a flat fee.

The unflagging responsibility of a primary care physician is that of the patient's advocate. Indeed, that is part of Hippocrates' Oath. My goal is to provide quality care within whatever practical constraints exist for each

individual patient. Such constraints might be lack of a prescription plan, dependence on public transportation, or presence of a language barrier. For each of these respective scenarios, I might offer sample medications provided by pharmaceutical companies, complete applications for bus passes for seniors, and provide language translation lines. Patients often need our assistance in extracting from their insurer what is rightfully theirs, such as medical equipment, access to home visiting nurses, or ambulance transportation. On the other hand, limiting referrals, laboratory testing, or consultations are important ways for HMOs to control costs. If the patient's HMO becomes an obstacle to provision of what I perceive to be optimal care, then I must try to petition the medical director to allow an exception. If the HMO administrator chooses to deny payment for the more effective but higher cost radiology study or medication, then the HMO should be liable for any adverse outcome related to that decision. For example, if the HMO declines to pay for the aforementioned new arthritis medication, and the patient develops a gastric ulcer on the traditional arthritis medication, then the fault lies with the HMO. However, if I neglected to request authorization for the new arthritis medication, then the fault lies with me. In general, the HMO fully realizes this position, and will allow higher cost expenses when necessary. However, the effort spent on the application, and the time delay of days to weeks in securing approval, can be frustrating. Offices with at least three general internists usually have at least one administrative staff member dedicated entirely to managing referrals.

What limits the expense and breadth of my treatment for each patient? In general, there is an accepted standard of care for most clinical situations. This prevents physicians from ordering MRI scans of the head for every patient with a headache, or CAT scans of the abdomen for each patient with "stomach" pain. Physicians also have a responsibility to society to limit utilization of medical resources and practice in a cost-effective fashion. However, that responsibility is distinct from any responsibility physicians may have to the HMO to reduce costs. The HMO may well have a fiduciary responsibility to its shareholders to maintain profit and reduce costs, but in the optimal situation, its health care providers should feel beholden only to the well-being of the patients in the plan.

Any incentive that compromises the physician's role as the patient's advocate creates an untenable position. Contractual arrangements with HMOs are complex and varied, but many have incentives that attempt to influence physician behavior. According to a survey of California physicians in 1996, 38% reported having financial incentives in the form of a bonus, yielding a median of 7% (or approximately \$10,500) of net

practice income.<sup>2</sup> It is entirely reasonable to provide financial incentives to reward those physicians who work harder for the betterment of their patients. Examples of acceptable incentive programs are those tied to patient satisfaction results or productivity parameters. Measurement of quality of care is a controversial and inexact science, and all medical systems find inherent difficulties in developing an ideal incentive system.

Clearly, incentive programs that seek to improve the financial status of the HMO may, at times, directly conflict with patients' well-being. For example, consider a physician who has 10% of his salary withheld each year, but is eligible to receive the lump sum at the end of the year if he meets certain targets in terms of hospital and emergency room costs. This physician may feel conflicted at the end of the year if he is on the verge of qualifying for his "withhold," and is evaluating ill patients who might otherwise benefit from hospitalization or emergency room visits. If the physician errs on the side of not hospitalizing ill patients, and an adverse event occurs, then who is at fault?

The *Pegram* decision holds that the physician alone is liable. Most clinicians do not agree with this decision, but that may be related to their dissatisfaction with managed care in general. I hope the focus and attention that *Pegram* brings to this issue will make physicians reconsider their contractual relationships with their respective managed care systems. I believe clinicians will want to avoid such adverse financial incentives based on ethical standards alone, and seek alternatives that reward hard work and quality of care. If physicians decline to participate with those managed care programs that utilize financial disincentives, such programs will have fewer providers from which patients may choose. Programs with limited panels of physicians will be less desirable to potential patients. If such incentive programs continue to exist, the *Pegram* decision will reinforce the responsibility of physicians to provide high quality care, irrespective of the impact of the cost of that care on the physicians' reimbursement.

Although ill-received by physicians, the *Pegram* decision should not significantly alter the practice of medicine. If the *Pegram* decision ruled that the HMO was liable, this would become a cloak behind which poor medical decisions are substantiated. I hope that little will change in the day-to-day practice of medicine as a result of this decision; that clinicians will continue to treat in their patients' best interests rather than in their own. As long as there are concerns about the cost of health care, efforts will continue to control costs. Physicians must individually and in unison guard against these efforts if patient care is jeopardized as a result.



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## Dividing Loyalties: Caring for Individuals and Populations

Nancy S. Jecker, Ph.D.\*

Are health maintenance organization (HMO) physicians obligated to act exclusively in the interest of the individual patient? Does the mere existence of financial incentives to limit patient care violate this obligation? To what extent are doctors responsible for the population of patients served by a health plan, or for promoting a fair distribution of health care among society as a whole?

These questions come to the fore in the recent U.S. Supreme Court case, *Pegram v. Herdrich*.<sup>1</sup> In *Pegram*, Herdrich claimed that the terms of the Carle HMO organization, rewarding its physician owners for limiting medical care, entailed an inherent or anticipatory breach of the physician's fiduciary duty under ERISA. Specifically, the terms of the HMO created "an incentive to make decisions in the physician's self-interest, rather than the exclusive interests of plan participants."<sup>2</sup> Her claim rested on showing first, that treatment decisions made by the HMO, acting through its physician employees, were fiduciary acts under ERISA. Second, her claim required showing that the terms of the HMO violated fiduciary obligations under ERISA to act "solely in the interest of" plan participants and beneficiaries when providing benefits and defraying the reasonable expenses of administering the plan.<sup>3</sup>

It is important to underscore that the breach of duty Herdrich alleges is neither the decision to delay care, nor the harm resulting from this decision. Thus, "Herdrich does not point to a particular act by any Carle physician owner as a breach. She does not complain about Pegram's actions, and...the ERISA count could have been brought, and would have been no different, if Herdrich had never had a sick day in her life."<sup>4</sup> The alleged breach of fiduciary duty consists instead in the HMO's scheme of awarding physicians a year-end distribution consisting of the profit derived from the spread between subscription income and expenses of care and administration. In short, Herdrich alleges that it was wrong for Carle physicians to care for patients under the influence of incentives that

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enabled them to profit financially from their own choices to minimize the medical services they provide. She claimed this practice was legally, if not ethically, wrong because it violated an obligation to act solely for the patient's interest.

The Supreme Court did not deny that there is a fiduciary duty to act exclusively for the interest of plan beneficiaries. Instead, it held that Congress did not intend Carle, or any other HMO, to be treated as a fiduciary to the extent that it makes "mixed" eligibility decisions acting through its physicians. Although "pure" treatment decisions are fiduciary in nature, both "pure" eligibility decisions and "mixed" eligibility and treatment decisions are not fiduciary in nature. In the case of Herdrich, Pegram's decision about treating her was inextricably mixed with the eligibility decision about whether Carle would cover immediate care. Pegram's treatment decision that Herdrich's condition did not warrant immediate action implied an eligibility decision that Carle would not cover immediate care, which it would have covered if the treatment decision had been otherwise. The Court held that these decisions made by an HMO, acting through its physician employees, are not fiduciary acts within the meaning of ERISA.

Did the presence of financial incentives to reduce care violate Pegram's professional obligation to serve the patient? It is often assumed that traditional ethics of medicine require physicians to act single mindedly to promote the interests of the individual patient under their care. Scholars cite the Hippocratic Oath, which requires physicians to swear allegiance to patient welfare by "follow[ing] that method of treatment which, according to my ability and judgment I consider for the benefit of my patients."<sup>5</sup> Adherents to this approach claim that "...physicians are required to do everything that they believe may benefit each patient without regard to costs or other societal considerations."<sup>6</sup> They lament the loss of a historical "golden age" prior to the advent of managed care, when "it was generally agreed that the doctor's sole obligation was to take care of each patient...to act only in the patient's interest."<sup>7</sup> Since the advent of managed care, physicians have been dubbed "double agents,"<sup>8</sup> responsible not only to advocate for their own patients, but also to advocate for the entire population of patients served by a health plan. Proponents of unrestricted patient advocacy assert that if health care rationing must occur, it is health care organizations and the broader society, not physicians at the bedside, who should take the initiative in designing rationing policies. Not only does rationing conflict with the physician's duty to serve as the patient's advocate, it also risks pitting the physician's personal financial interests against the patient's medical needs.<sup>9</sup>

Yet in response it has been argued that the professional duty to advocate on behalf of individual patients is limited, and must be placed in the broader context of other ethical duties of the physician.<sup>10</sup> These include the duty to promote the welfare of society as a whole, or, at a minimum, to promote the welfare of the population of patients served by a health plan. Challengers to “traditional ethics” note that this response finds roots not only in contemporary debates about the “new ethics” of managed care, but also in the historical traditions of ethics in medicine. The Hippocratic corpus itself makes reference to the physician’s social responsibility, citing for example a duty to care for indigent and vulnerable patients: “Sometimes give your services for nothing. . . . And if there be an opportunity of serving one who is a stranger in financial straits, give full assistance to all such. For where there is love of man, there is also love of the art.”<sup>11</sup> During the modern era, the newly formed American Medical Association held in 1847 in its very first Code of Ethics, “As good citizens, it is the duty of health professionals to be ever vigilant for the welfare of the community.”<sup>12</sup>

Managed care itself has a long history in medicine, with the very first prepaid medical care programs in the United States organized in 1787 by fraternal societies and mutual benefit associations. Although the dominant method of physician reimbursement during the late nineteenth and early twentieth centuries was fee-for-service, physicians also provided care on credit, offered unlimited services for a fixed-fee per annum, and worked as “company doctors” for industries such as railroads, mining, and lumber.<sup>13</sup> Under these arrangements, care was managed and methods of physician reimbursement created incentives for physicians to limit costly care.

Yet the crux of the argument against unrestricted patient advocacy is not the historical traditions of ethics and medicine. For even if single-minded advocacy historically occurred and was defensible, the context of modern medical practice makes this approach untenable. As Jonsen and Hellegers note, the professional practice of medicine today occurs within a social context: modern medicine is “an institution that incorporates a profession.”<sup>14</sup> The institutional setting of medicine arises as a modern necessity because the solo physician diagnosing and treating a single patient has “gradually been surrounded by the indispensable cooperation of other people, by accessory producers, by physical environments, by customary and legal prescriptions.”<sup>15</sup> Medicine comprises a social institution responsible not only for the care of individual sick people, but also for distributing the benefits and burdens of social life. Professional accountability is not exclusive to the patient, but to the society that the institution of medicine serves. As a consequence, the ethics of the medical

profession cannot be adequately understood in a vacuum; it requires a doctrine of the common good and social justice. While fidelity to one's patients and to the bond between patient and physician is an important value, it is not an ethical absolute. Instead, fidelity must be considered in tandem with other important values, such as social justice.<sup>16</sup>

Moreover, the view of the solo physician as devoid of social and economic constraints does not accurately portray physicians' own perceptions of their professional role.<sup>17</sup> Sulmasy and colleagues reported that 80.8% of physicians randomly selected from seventy-five U.S. metropolitan areas believed that changes in the health care system in the past decade have diminished physicians commitment to an ethic of undivided loyalty to patients.<sup>18</sup> Although physicians worry that financial incentives to limit care diminish patient trust in them,<sup>19</sup> research shows that the vast majority of patients trust their physicians.<sup>20</sup> Although fee-for-service indemnity patients have higher levels of trust than salary, capitated, or fee-for-service managed care patients, the overwhelming majority of patients in all groups trust their physicians.<sup>21</sup>

In response, opponents of managed care might argue that even if trust remains high, it has declined and will continue to do so. Yet those who regard managed care as necessary and beneficial can argue that whether trust has declined is an empirical question that has yet to be answered. Moreover, even assuming trust has declined since the advent of managed care, this change may be only temporary. Ultimately, patients (and physicians) will adapt to and accept managed care practice.

As noted already, contemporary physicians recognize limits to an ethic of undivided loyalty to patients. These limits may spring from social responsibilities to use scarce resources in a fair and consistent fashion. Or they may result from specific obligations to a population of patients served by a health plan. In addition, society recognizes, even mandates, societal duties of physicians. For example, in the case of patients with communicable diseases, such as tuberculosis, society mandates disease reporting to protect the public's health despite the strong ethic of confidentiality in the individual physician-patient relationship.<sup>22</sup> In the case of tuberculosis, the safety of a group of people supercedes the privacy rights of an individual patient when it comes to a highly communicable and potentially deadly disease.

Generally speaking, the physician's duty to protect the health and welfare of the society is owing in part to the fact that physicians are recipients of numerous benefits from society. Massive amounts of money are regularly spent to fund medical education, the research on which medical practice rests, the institutions in which most medical activity

occurs, and the demand for medical services. Accepting such societal benefits places physicians under an obligation to practice medicine in a manner that benefits, or at least avoids harming, the society granting them.<sup>23</sup>

If the above reasoning is sound, there are ethical limits to patient advocacy. The question remains however, whether financial incentives in general, and the specific financial incentives under which Pegram operated, are ethically defensible. Research points to the fact that physicians who operate under personal financial incentives to reduce services find these arrangements more ethically troubling than their colleagues who do not practice under such circumstances.<sup>24</sup> Moreover, incentive structures that align personal financial gain for physicians with reduced services for patients, may create unique professional challenges.

For many physicians, the professional commitment to serve the patient's interests includes an obligation to accept personal sacrifice.<sup>25</sup> This sacrifice may require exposing oneself to medical risks, such as risking infection when this is necessary to care for the patient. Or personal sacrifice may entail assuming financial risks, such as risking financial losses to care for an indigent patient. Physicians who perceive self-sacrifice on behalf of patients as integral to professional identity may experience personal financial incentives to reduce care as a threat to their self-understanding as professionals.<sup>26</sup> Rather than putting the patient first, physicians are invited to put themselves first. Rather than sacrificing themselves for the patient, physicians are invited to sacrifice the patient for themselves.

In response, it can be argued that this conception of the physician's professional role takes for granted that the chief client of the medical profession is, and should be, the individual patient. But the alternative conception we have been considering regards the physician's chief clients to include not only the individual patient, but also the population of patients served by a health plan, and even the society as a whole. Rather than regarding the interests of doctor and patient as necessarily conflicting, we might instead say that the physician's financial interests are aligned with the interests of the population the physician serves. In other words, the balance is tipped in favor of one client (the population) rather than another (the patient) by aligning the physician's financial interests accordingly. More broadly understood, the entire population of patients served by a health plan benefits when resources are distributed more fairly among subscribers. Provided the financial incentives imposed on physicians improve fairness, the burden of saying no to individual patients will be eased, although it will remain difficult.

Consider a somewhat analogous case. The chief client of a lawyer initially seems to be the party whose case the lawyer represents or to whom the lawyer gives advice. However,

Lawyers are told and they announce in their self-descriptions and codes of conduct that they have obligations to the whole justice system; therefore, there are things that they as professionals may not ethically do, even if doing them would advance the situation of the party they represent or advise. So it appears that the answer to the question about the chief client of the legal profession is complex, involving not only the persons lawyers represent or advise but the whole justice system and/or perhaps the whole larger community served by that system.<sup>27</sup>

Once this complexity emerges in case law, analogous cases in medicine appear more complex. Rather than viewing Pegram's dilemma exclusively as a conflict between herself and her patient, the dilemma can now be recast in a fuller form. Should the financial incentives under which the physician operates be balanced in favor of the individual patient the doctor cares for, or the wider population of patients the physician serves? The physician can ethically support putting the population first or putting the patient first in a particular case without basing either decision on putting herself first. According to this approach, personal financial gains and losses are associated with favoring one client group over another, not merely with favoring oneself over one's client.

If these arguments are compelling, the presence of financial incentives to reduce patient care can be ethically defensible. On the one hand, the requirements of social justice make the position of unrestricted patient advocacy untenable in the context of resource or fiscal scarcity. On the other hand, the existence of financial incentives to reduce individual patient care is compatible with a conception of professional identity that requires putting clients first. Ultimately, the physician must decide whether to put individuals or populations first, irrespective of personal financial reward.

If the mere existence of financial incentives to limit care does not suffice to show that Pegram violated her fiduciary duty to Herdrich, how should we judge Pegram's actions? How should we judge the particular incentives the Carle HMO established? Even if the particular financial incentives Pegram operated under were morally licit, the decision to delay Herdrich's ultrasound by requiring that it be performed at a facility more than fifty miles away may be unethical for reasons we have not considered. Pegram may have wrongly based the decision to delay care on maximizing her personal financial gain. Pegram may have advocated too zealously for



the population of patients served by the HMO. She may have medically misjudged the urgency of Herdrich's situation. Pegram may have avoided making hard choices by denying the risks associated with her decision. That is, she may have wanted and believed she could have it all: reduced costs for the HMO, personal financial rewards for herself, and quality care for the patient.

These points obviously raise more questions than they answer. Furthermore, even if it is permissible to hold physicians accountable for cost containment by creating financial incentives to limit care, it does not follow that it is permissible to hold physicians alone accountable.<sup>28</sup> HMOs are also ethically responsible for their influence on clinical decisions and treatment outcomes. HMOs should not, for example, be allowed to create unethical financial incentives to plan physicians with impunity. Although Pegram may exert an influence on Carle's financial incentives (e.g., by choosing to accept or appeal its terms), Pegram did not establish these incentives. As long as the Carle HMO itself is not held legally accountable, physicians and patients have no legal remedy for unethical financial incentives. The concern this raises is that ERISA does not regulate how HMOs create incentive structures to motivate contracting physician's compliance with cost containment measures. And the ERISA preemption makes it more difficult for states to regulate such compensation and incentive arrangements. Some commentators conclude that "[f]rom a policy perspective, ERISA has created a regulatory vacuum in which states cannot act and there is no comparable federal regulatory mechanism."<sup>29</sup>

The best recourse for physicians includes collectively designing care management practices, such as those that are currently being developed under the heading of practice guidelines, protocols, critical pathways, and disease state management.<sup>30</sup> The advantage of these approaches is that they increase the value of services delivered to patients through improved outcomes and reduced costs. They also provide information for physicians and managed care plans about standards of medical practice. And they involve physicians in designing the rules to which they will be subject. To the extent that physicians work in tandem with managed care plans to establish guidelines for the care of patients, they will be better able to make individual treatment decisions in a fair and consistent manner.

In summary, I have argued that physicians are not ethically obligated to act exclusively in the interests of their individual patients. The "mixed" nature of many medical decisions reflects the fact that physicians serve multiple clients: individual patients, patient populations, and the society at large. The existence of financial incentives to limit advocacy on behalf of one client group in order to achieve a fairer balance among all groups is

consistent with standards of justice in health care. Finding the most ethical balance among the multiple clients that physicians serve is still undetermined. A fair process for making this determination should involve not only physicians and health care plans, but ultimately the entire population of patients affected by these decisions.

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## ***Pegram v. Herdrich*: The Supreme Court Confronts Managed Care**

**Timothy S. Jost, J.D.\***

ERISA, adopted a quarter century ago to reform private pension law, imposed by the end of the twentieth century a seemingly insurmountable barrier to managed care reform. The Supreme Court's decision in *Pegram v. Herdrich*<sup>1</sup> blocked one path out of the ERISA morass—broader use of breach of ERISA fiduciary obligations suits in federal court. On the other hand, it opened another path to holding HMOs accountable in malpractice cases in state court—and suggested that ERISA might impose fiduciary obligations to disclose incentives on HMOs. It is therefore an important decision.

ERISA was intended to give the federal government primary authority for regulating employee pension and benefits plans. As the vast majority of Americans with private health insurance (88%) obtain it through their place of employment, ERISA effectively gives the federal government primary responsibility for regulating private health insurance. Section 514(a) of ERISA<sup>2</sup> provides that ERISA “supersedes” all state laws that “relate to” employee benefits plans. Early Supreme Court decisions read this clause very broadly as preempting state laws that had any “connection with or reference to” a benefits plan.<sup>3</sup> In particular, *Pilot Life v. Dedaux* read ERISA as preempting state tort law challenges to egregious coverage denials.<sup>4</sup> While § 514 contains a “savings clause” excluding the traditional state function of insurance regulation from preemption,<sup>5</sup> the Supreme Court initially read this provision very narrowly to cover only regulation of traditional insurance functions.<sup>6</sup> Moreover, § 514(b)(2)(B) prohibits the states from “deeming” ERISA plans themselves to be insurers,<sup>7</sup> which the Court has read as precluding state regulation of self-funded plans.<sup>8</sup> The net effect of the Court's early interpretations of these provisions was to severely restrict the ability of the states to regulate employee benefits plans.

ERISA, of course, neither leaves health plans entirely unregulated nor

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health plan beneficiaries without any remedy. ERISA itself imposes fiduciary obligations on plan administrators<sup>9</sup> and minimal procedural obligations on plans with respect to benefit determinations.<sup>10</sup> Section 502 of ERISA permits a plan beneficiary to bring a civil action "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan."<sup>11</sup> ERISA further provides for equitable relief against acts or practices that violate ERISA,<sup>12</sup> including violations of the fiduciary obligations imposed by ERISA.<sup>13</sup> Again, however, the Supreme Court has interpreted ERISA's remedial provisions very narrowly, limiting beneficiary recoveries under § 502 actions to compensatory contractual damages, and precluding individual damage actions for breach of fiduciary obligations.<sup>14</sup>

ERISA's remedial scheme may have made sense in the 1970s, when a benefit denial was effectively a dispute over whether the plan, provider, or beneficiary would end up bearing the cost of a service already provided. In today's managed care environment in which benefit denials are prospective or concurrent, however, ERISA has left beneficiaries effectively without remedy when urgently needed care is refused. Because of ERISA preemption, the states have limited authority to fix this problem.<sup>15</sup> Federal managed care reform, however, has been blocked by intense lobbying and the political gridlock that has seized Washington for the past decade.

Into this legal environment came Cynthia Herdrich. Herdrich sued Carle and her physician, Pegram, a physician owner of Carle, in state court for malpractice and for fraud. Carle, under well-established ERISA jurisprudence, removed the case into federal court, where Herdrich's fraud claims were dismissed as preempted by ERISA. Herdrich ultimately recovered \$35,000 in a jury verdict on the malpractice claims, but also amended her complaint to state a claim that the defendants had breached their ERISA fiduciary obligations.

Herdrich's claim attacked the structure of the Carle plan. Carle's physicians were, Herdrich alleged, vested with the authority to determine which services they would provide their beneficiaries, and rewarded with a year-end bonus if they denied services, saving on costs.<sup>16</sup> Herdrich sued under ERISA provisions, which make a fiduciary personally responsible to the plan for any ill-gotten gains obtained through breach of fiduciary obligations.<sup>17</sup> Under ERISA's remedial structure, Herdrich could not benefit personally from a favorable judgment on this claim, but the Court could award the benefit plan profits resulting from Carle's alleged breach, enjoin the continuation of Carle's incentive structure, and award Herdrich attorneys' fees. Though the trial court dismissed Herdrich's ERISA claim, the Seventh Circuit Court of Appeals reversed this judgment in a divided

judgment.<sup>18</sup> The Seventh Circuit *en banc* refused a rehearing on the case, but four judges dissented from the rehearing denial in a decision written by Judge Easterbrook.<sup>19</sup>

When the Herdrich case reached the Supreme Court, three different, carefully reasoned opinions had already been written in the case by Seventh Circuit judges Coffey, Flaum, and Easterbrook. Judge Coffey's majority Seventh Circuit opinion held that Herdrich ought to be allowed to proceed to trial on her theory that Carle had violated its "fiduciary obligations to act solely in the interest of the Plan participants and beneficiaries," by creating an incentive system that "depleted plan resources so as to benefit physicians who, coincidentally administered the Plan, possibly to the detriment of their patients."<sup>20</sup> Coffey's opinion included a lengthy diatribe against HMOs, curiously faulting them for transferring the responsibility for decisions involving medical care from physicians to insurance executives, even though Herdrich's case challenged the decision of a treating physician as corrupt.<sup>21</sup>

Judge Flaum's Seventh Circuit dissent rejected Herdrich's fiduciary claim, recognizing well-established ERISA law that tolerates some conflicts of interest on the part of administrators, who must not only provide benefits to particular beneficiaries, but must also look after the interests of the plan as a whole. Flaum also warned against the court taking on the job of determining permissible managed care incentive programs on a case by case basis.<sup>22</sup> Flaum did, however, suggest that the court should have followed the lead of the Eighth Circuit's decision in *Shea v. Esensten*,<sup>23</sup> requiring ERISA plans to disclose their financial incentive programs to plan sponsors and beneficiaries.<sup>24</sup>

Easterbrook's *en banc* dissent went much further. It observed that the Carle HMO, rather than the services it provided its patients, was the benefit afforded by the ERISA plan.<sup>25</sup> Thus the physicians who owned Carle could not be plan fiduciaries, and, presumably, beneficiaries had no ERISA recourse, even under § 502, against Carle for the denial of services. Easterbrook matched Coffey's anti-managed care diatribe with his own complaints about managed care backlash.

In reversing the Seventh Circuit's decision, Justice Souter, writing for a unanimous Supreme Court, took yet another course, which preserves the ability of ERISA plans to manage the delivery of health care, leaves the door open to beneficiaries who are adversely affected by such arrangements to obtain relief, and, perhaps most importantly, protects the institutional interests of the federal courts.

The Court first attempted to characterize Carle's status as a plan administrator. The Court identified the ERISA plan at issue as the

contractual arrangement between Carle and the plan sponsor, Herdrich's husband's employer.<sup>26</sup> Thus the Carle HMO itself was not an ERISA plan, and its internal arrangements were not directly subject to ERISA supervision. On the other hand, the Court rejected Easterbrook's position, as it recognized that Carle could be a plan fiduciary with respect to at least some coverage decisions—i.e. medical services themselves were ERISA benefits, not just access to the Carle HMO.

The Court, however, decisively rejected the position of Judge Coffey, asserting that Congress could not have intended ERISA to outlaw HMOs. Indeed Congress, only a year before ERISA was adopted, had enacted a law explicitly encouraging the formation of HMOs as part of Nixon's health care reform plan.<sup>27</sup> Moreover, in perhaps the most widely noted passages of the case, the Court explicitly accepted that "whatever the HMO, there must be rationing and inducement to ration."<sup>28</sup> While the Court recognized that the lower court sought only to ban excessive incentive plans, not HMOs as a whole, the Court concluded that establishing workable standards for determining when HMO incentive systems violated ERISA fiduciary obligations would prove an impossible task.<sup>29</sup> The decision, therefore, disappointed those who saw the case as an opportunity to define the role of trust and loyalty in the managed care setting.<sup>30</sup>

The Court resolved the dilemma before it by creating a distinction new to ERISA jurisprudence. Beginning with *Dukes v. U.S. Healthcare*<sup>31</sup> in the mid-1990s, a series of lower court decisions, seeking to rectify the injustice wrought by *Pilot Life* on persons injured by ERISA HMOs, had adopted a distinction between benefit coverage (eligibility) decisions—for which there was no remedy under state law—and medical treatment decisions—which were subject to state malpractice suits. Acknowledging that HMO determinations often cannot be simply characterized as purely eligibility or treatment decisions, the *Pegram* Court recognized a new category of "mixed eligibility and treatment decisions," which decided whether a particular service would be covered, but made this determination based on medical judgment.<sup>32</sup> While this category would exclude pure coverage decisions (whether ultrasound was a covered procedure or appendicitis a covered condition under the plan), it would sweep in the vast majority of decisions currently made by managed care plans, including, in the Court's words, "physicians' conclusions about when to use diagnostic tests; about seeking consultations and making referrals to physicians and facilities other than [the HMO's]; about proper standards of care, the experimental character of a proposed course of treatment, the reasonableness of a certain treatment, and the emergency character of a medical condition."<sup>33</sup>

In the Court's opinion, these mixed decisions are not subject to



ERISA's fiduciary requirements, i.e. the HMO won the case. On the other hand, this result was based on a belief that these decisions are already subject to state malpractice law, which would be preempted if these decisions were subject to ERISA's fiduciary requirements.<sup>34</sup> In reaching this result the Court seems to have significantly moved the line established by *Dukes* and its progeny.<sup>35</sup> Though the Court's discussion of this issue is technically dicta, the decision strongly suggests that HMOs themselves are now liable in state court under state malpractice law for a host of decisions previously thought to be immunized by ERISA preemption. Indeed, *Pegram* quite explicitly contemplates direct state corporate negligence litigation against HMOs themselves in states that permit such litigation.<sup>36</sup> Since mixed eligibility and treatment decisions are apparently not governed by ERISA, it is not necessary for states to adopt legislation authorizing such litigation under the savings clause,<sup>37</sup> and even self-insured plans are subject to suit. In sum, those who favor holding HMOs accountable for injuries that result from denial of treatment, lost a small battle, but advanced significantly in a much larger war.<sup>38</sup>

Those who seek accountable managed care advanced also, at least slightly, on another front as well. While not addressing Judge Flaum's dissent directly, the Supreme Court, in note eight, suggested that ERISA plans may in fact have a fiduciary obligation under ERISA to "disclose characteristics of the plan and of those who provide services to the plan, if that information affects beneficiaries' material interests."<sup>39</sup> Although the value of plan incentive disclosure is contested,<sup>40</sup> the question about whether such disclosure is required remains open after *Pegram*.

The biggest winners under *Pegram*, however, were arguably the federal courts. Had the Court adopted the Seventh Circuit's position in *Pegram*, every ERISA HMO would have been exposed to fact-intensive, time-consuming federal litigation contesting its incentive structure. *Pegram* not only spares the federal courts this burden, but also suggests that a large number of mixed eligibility and treatment cases, now being litigated in the federal courts under the complete preemption doctrine, can be moved back to the state courts as simple malpractice cases. In the end, therefore, *Pegram* may not be so much about rationing health care as about rationing the limited resources of the federal courts.

## References

1. *Pegram*, 530 U.S. 211.
2. 29 U.S.C. § 1144(a) (1998).
3. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 (1983).
4. 481 U.S. 41 (1987). In *Pilot Life*, and in another case decided on the same day, the Court read § 502 of ERISA, which permits beneficiaries to sue to recover benefits wrongfully denied, both to preempt state court actions aimed at contesting benefit denials and state court jurisdiction over actions contesting benefit decisions (so called, "complete preemption"). *Pilot Life*, 481 U.S. at 52-54; *Metropolitan Life Ins. v. Taylor*, 481 U.S. 58, 63-66 (1987).
5. 29 U.S.C. § 1144(b)(2)(A) (1998).
6. *Pilot Life*, 481 U.S. at 50-51.
7. 29 U.S.C. § 1144(b)(2)(B) (1998).
8. *FMC Corp. v. Holliday*, 498 U.S. 52 (1990).
9. 29 U.S.C. § 1104(a)(1) (1998).
10. 29 U.S.C. § 1133 (1998).
11. 29 U.S.C. § 1132(a)(1)(B) (1998).
12. 29 U.S.C. § 1132(a)(3) (1998).
13. 29 U.S.C. §§ 1109, 1132(a)(2) (1998).
14. *Mertens v. Hewitt Assoc.*, 508 U.S. 248 (1993); *Massachusetts Mut. Life Ins. v. Russell*, 473 U.S. 134 (1985).
15. *See, e.g., Corporate Health Ins., Inc. v. Texas Dept. of Ins.*, 215 F.3d 526 (2000) (holding that a Texas statute permitting civil suits against HMOs for physician negligence is not preempted by ERISA, but independent review requirements are preempted).
16. *Pegram*, 530 U.S. at 216 n.3.
17. 29 U.S.C. § 1109(a) (1998).
18. *Herdrich v. Pegram*, 154 F.3d 362 (7th Cir. 1998).
19. *Herdrich v. Pegram*, 170 F.3d 683 (7th Cir. *en banc* 1999).
20. *Herdrich*, 154 F.3d at 380.
21. *Id.* at 374-78.
22. *Id.* at 383.
23. 107 F.3d 625 (8th Cir. 1997), *cert. denied*, 522 U.S. 914 (1997).
24. *Herdrich*, 154 F.3d at 384.
25. *Herdrich*, 170 F.3d at 686.
26. *Pegram*, 530 U.S. at 222.
27. The Health Maintenance Organization Act of 1973, 42 U.S.C. § 300e (1998); *Pegram*, 530 U.S. at 233.
28. *Pegram*, 530 U.S. at 221.
29. *Id.* at 221-23, 234-35.
30. Gregg M. Bloche, *U.S. Health Care After Pegram: Betrayal at the Bedside*, HEALTH AFF., Sept.-Oct. 2000, at 224.
31. 57 F.3d 351 (3d Cir. 1995).
32. *Pegram*, 530 U.S. at 229-30.
33. *Id.*
34. *Id.* at 253-36.
35. *See* William M. Sage, *UR Here: The Supreme Court's Guide for Managed Care*, HEALTH AFF., Sept.-Oct. 2000, at 219, 223.
36. *Pegram*, 530 U.S. at 235-36.
37. *See UNUM Life Ins. v. Ward*, 526 U.S. 358, 377 n.7 (1999) (suggesting that the savings clause might cover such legislation).
38. It must be noted, however, that this war is far from over. For one thing, the Court in note nine explained that it was not deciding whether a denial of emergency care, like that at issue in *Pegram*, was subject to litigation under § 502(a)(1)(B), and suggested that the right to a § 502(a)(1)(B) action might have ramifications for rights under state law. Given the power that 502 preemption has previously exercised, this note may bode ill

for those who would pursue state malpractice claims against HMOs. Further, a week after deciding *Pegram*, the Court vacated and remanded, for reconsideration in light of *Pegram*, a Pennsylvania Supreme Court case that had recognized expansive liability against an ERISA HMO under state malpractice law and significantly narrowed the scope of § 514 preemption. *United States Healthcare Sys. of Pa. v. Pennsylvania Hosp. Ins.*, 530 U.S. 1241 (2000).

39. *Pegram*, 530 U.S. at 228.

40. See William M Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999) (analyzing arguments for and against incentive disclosure).



## ***Pegram's* Significance for Managed Health Care**

**Louis Saccoccio, J.D.\***

On June 12, 2000, in a unanimous opinion written by Justice Souter, the U.S. Supreme Court, reversing a decision of the U.S. Court of Appeals for the Seventh Circuit, held in *Pegram v. Herdrich*<sup>1</sup> that "mixed eligibility" decisions made by HMO physicians are not fiduciary decisions under ERISA.<sup>2</sup> In so ruling, the Court upheld the concept that the reasonable sharing of financial risk with HMO<sup>3</sup> network physicians for providing health care to a given patient population does not run afoul of ERISA's fiduciary requirements. This result is a significant victory for managed health care plans, their network physicians, and their members.

Although the decision's impact on the viability of physician risk sharing is clearly positive, the decision's impact on the question of HMO liability under ERISA remains less clear. Some, including the U.S. Department of Labor, argue that this case represents a shift in ERISA preemption law. They argue that *Pegram* now precludes ERISA preemption of state law causes of action aimed at HMO coverage determinations that involve questions of medical-necessity or experimental or investigational treatments. A more reasonable reading of the case, consistent with its facts, however, leads to the conclusion that *Pegram* represents nothing more than a common sense answer to a simple question. What law should apply when a treating physician makes a treatment decision that may arguably raise issues of eligibility for coverage? *Pegram's* answer does not represent a shift in the law regarding ERISA preemption of HMO coverage decisions.

The importance of *Pegram* does not end, however, with its resolution of the question of the scope of ERISA's fiduciary requirements in the realm of a physician's practice of medicine. The greater impact of the *Pegram* decision may lie in its language addressing the proper role of the courts in addressing the social and policy questions that arise from managed health care. In this regard, the Court in *Pegram* unambiguously stated that the debate about managed care belongs not in the courts, but in the legislature. This clear message already is having an impact in class action

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litigation filed against health plans where broad allegations under ERISA and the Racketeer Influenced and Corrupt Organizations Act (RICO)<sup>4</sup> seek to challenge (some would say destroy) managed health care practices.

Cynthia Herdrich originally brought medical negligence claims against Dr. Lori Pegram, and Carle Clinic Association (Carle), as well as state law fraud claims against Carle and its HMO, Health Alliance Medical Plans, in Illinois state court.<sup>5</sup> The medical negligence counts went to trial in state court resulting in a \$35,000 verdict for Herdrich. Carle and Health Alliance Medical Plans removed the state fraud claims to federal court alleging that they were preempted by ERISA. The federal district court dismissed the state fraud complaint, but allowed Herdrich to amend her claims to state a claim under ERISA. Herdrich's amended claim alleged a breach of ERISA fiduciary duty on the part of the defendants. The claim was premised on the fact that the physician owners of the HMO potentially were entitled to year-end bonuses based on the difference between the cost of providing medical care and HMO revenues. Herdrich argued that this created an improper incentive to limit treatment. The federal district court subsequently granted the defendants' motion to dismiss the amended ERISA claim for a failure to state a proper claim, and Herdrich appealed.

The U.S. Court of Appeals for the Seventh Circuit reversed the decision, finding that Herdrich had alleged sufficient facts to make a claim for breach of fiduciary duty under ERISA.<sup>6</sup>

The issue before the Supreme Court in *Pegram* was the application of ERISA's fiduciary duty principles to HMO treating physicians who make "mixed eligibility decisions."<sup>7</sup> The Court had no occasion to address the issue of whether HMO coverage decisions involving medical-necessity issues fall outside the scope of ERISA's preemption of state law. Nevertheless, the issues are closely enough related to pose the question of whether *Pegram* has brought a shift in the law that narrows the application of ERISA preemption with respect to HMO coverage decisions involving medical necessity.

Any application of the *Pegram* decision to the question of ERISA preemption of state law for liability arising from HMO coverage determinations must be made in light of the facts before the Court. The heart of the case before the Supreme Court was simply a treating physician's misdiagnosis of appendicitis. As a result, Herdrich was able to convince an Illinois state court jury that Pegram failed to properly diagnose her condition, and was awarded \$35,000 in damages for her injuries. However, because it was alleged that Pegram's year-end compensation was based in part on the financial health of the HMO, Herdrich argued that Pegram's misdiagnosis, coupled with her ostensible

interest in the financial health of the HMO, raised the issue of breach of fiduciary duty under ERISA.

The Court rejected Herdrich's claim that the HMO, acting through its physician owners, breached its duty to act solely in the interest of beneficiaries by making decisions affecting medical treatment while allegedly being influenced by the terms of the HMO physician compensation structure. In doing so, the Court expressed doubt that Congress intended physicians to be treated as ERISA fiduciaries to the extent that they make "mixed eligibility decisions" during the course of treating their patients.<sup>8</sup>

The Court correctly recognized that when examining the question of whether a treating physician acted for good medical cause, as opposed to his or her own financial interest, the answer to that question "would require reference to standards of reasonable and customary medical practice in like circumstances."<sup>9</sup> The Court noted however, that this is the very standard used in medical malpractice cases: "[F]or all practical purposes, every claim of fiduciary breach by an HMO physician making a mixed decision would boil down to a malpractice claim, and the fiduciary standard would be nothing but the malpractice standard traditionally applied in actions against physicians."<sup>10</sup> As a result, the Court saw no reason to turn traditional medical malpractice cases into ERISA fiduciary cases simply because the treating physician assumed some of the financial risk for the treatment of the patient.

Thus, *Pegram* is a case about treating physicians, medical malpractice, and ERISA fiduciary implications of malpractice in light of physician risk sharing. The Court rightly recognized that it would be folly to convert standard malpractice actions, involving treating physicians that take place within the HMO context, into ERISA fiduciary actions. However, this conclusion is a far cry from the position taken by some in the trial bar and by the Department of Labor (see below) that *Pegram* stands for the proposition that HMO coverage decisions involving questions of medical necessity are now subject to state tort actions.

In September 2000, the Department of Labor filed an *amicus curiae* brief before the Supreme Court of Pennsylvania in *Pappas v. Asbel*.<sup>11</sup> This case is again before the Pennsylvania Supreme Court after the U.S. Supreme Court, on June 19, 2000, vacated the Pennsylvania court's earlier decision and remanded the case for reconsideration in light of *Pegram*.<sup>12</sup> The Department of Labor's brief in *Pappas* sets out its interpretation of how it believes *Pegram* narrows ERISA preemption of state tort claims for negligence. As discussed below, the Department of Labor's interpretation ranges far beyond the holding in *Pegram*.

The issue before the Pennsylvania Supreme Court in its initial decision in *Pappas* was whether state law negligence claims against an HMO, U.S. Healthcare, were preempted by ERISA.<sup>13</sup> The claim arose from an alleged delay in the HMO's authorization to transfer the plaintiff to a hospital capable of treating his condition. The Pennsylvania Supreme Court held in this initial decision that negligence claims against HMOs do not "relate to" ERISA plans, and are therefore not preempted.<sup>14</sup>

Interestingly, the Department of Labor previously had filed an *amicus curiae* brief with the U.S. Supreme Court supporting U.S. Healthcare's petition for *certiorari* in *Pappas*.<sup>15</sup> In that earlier brief, the Department of Labor argued that the Supreme Court of Pennsylvania's decision was overbroad and incorrect. The Department of Labor stated that ERISA's fiduciary standards preempt state law because an HMO's coverage decision is considered an act of health care plan administration even when medical judgment about how to treat a patient is involved.<sup>16</sup>

In the brief filed before the Supreme Court of Pennsylvania in *Pappas* on remand from the U.S. Supreme Court, the Department of Labor now argues that the case should be remanded to the Court of Common Pleas to decide whether U.S. Healthcare made a "mixed eligibility decision."<sup>17</sup> The Department of Labor claims that "*Pegram* holds that treatment decisions and mixed treatment and eligibility decisions by physician employees of an HMO are governed by state malpractice standards and not by ERISA fiduciary standards."<sup>18</sup> According to the Department of Labor, if the Court of Common Pleas finds that U.S. Healthcare made a "mixed eligibility decision," as used by the U.S. Supreme Court in *Pegram*, then there is no preemption, and the state law claims may proceed against U.S. Healthcare.<sup>19</sup>

The Department of Labor's interpretation of *Pegram*, as set out in its recent *amicus* brief, attempts to expand the holding of *Pegram* far beyond what the plain language of the decision supports. It extends the concept of "mixed eligibility decisions" beyond the HMO treating physician addressed in *Pegram* to the HMO itself, with no support or basis.

The foundation for the *Pegram* decision was a clear reluctance by the Court to expand the concept of ERISA fiduciary principles to physicians treating patients, with its resulting interference with traditional state medical malpractice law. In contrast, HMO coverage decisions within the context of ERISA employee benefit plans, even when involving medical necessity, have traditionally been recognized as benefit determinations within the purview of ERISA preemption.<sup>20</sup> Contrary to the position taken by the Department of Labor, *Pegram*, dealing as it does with the decisions of treating physicians, does little to change the landscape of ERISA



preemption for HMO coverage decisions.

Maybe more significant than the holding of *Pegram*, is Justice Souter's discussion of managed care and the respective roles of the federal judiciary and Congress as it pertains to addressing the debate about managed care. After all, the holding that "mixed eligibility decisions" made by HMO treating physicians should be left to state medical malpractice law does little more than confirm what is probably already common practice. As a direct example, Herdrich proceeded with and won a judgment in a state malpractice action in her case. However, with the filing in the last eighteen months of multiple class action lawsuits against several large health plans alleging general violations of ERISA and RICO,<sup>21</sup> *Pegram* gives the lower federal courts clear direction as to how they should react to these cases and their attempts to set health care policy through litigation.

The Court recognized that for more than twenty-seven years, Congress has promoted the formation of HMO practices, and stated that:

If Congress wishes to restrict its approval of HMO practice to certain preferred forms, it may choose to do so. But the Federal Judiciary would be acting contrary to the congressional policy of allowing HMO organizations [sic] if it were to entertain an ERISA fiduciary claim portending wholesale attacks on existing HMOs solely because of their structure, untethered to claims of concrete harm.<sup>22</sup>

The impact of this message already has been felt in a recent decision that should directly influence the outcome in the numerous class action lawsuits mentioned above. The case, *Maio v. Aetna*, was decided by the U.S. Court of Appeals for the Third Circuit on August 11, 2000.<sup>23</sup> It affirmed the dismissal of a class action lawsuit filed against Aetna and its regional subsidiaries that was based on alleged violations of RICO. Significantly, the Third Circuit relied in part upon the Supreme Court's analysis in *Pegram* when finding that the plaintiffs failed to state a claim under RICO.

In its opinion, the Third Circuit examined the plaintiffs' damage theory in light of *Pegram*. The court indicated that absent specific allegations by the plaintiffs that the quality or quantity of their benefits under the health plans had been diminished, the "only theoretical basis for appellants' claim that they received an 'inferior health care product' is their subjective belief that Aetna's policies and practices are so unfavorable to enrollees that their very existence . . . demonstrates that they overpaid for the coverage they received."<sup>24</sup>

Looking to *Pegram*, the Third Circuit rejected this theoretical basis for recovery. The court stressed that under this theory the plaintiffs would be asking the court to pass judgment on Aetna's policies and practices leading

to a “myriad of practical problems, which undoubtedly arise in a situation in which the federal courts are asked to determine the social utility of one particular HMO structure as compared to another.”<sup>25</sup> The court refused to accept the plaintiffs’ notion implied by their complaint that it should evaluate the social utility of Aetna’s health plans. To stress this point, the court indicated that this theory would require the trier of fact to “inappropriately act as a state regulatory commission and determine the value of Aetna’s product.”<sup>26</sup>

The Third Circuit’s refusal to pass judgment on a health plan’s otherwise legal policies and practices with its “myriad of practical problems” gives a clear signal that *Pegram*’s most significant impact may come from its clear message of restraint to the federal judiciary in the debate about managed care.

The Court’s decision in *Pegram* has given the federal courts direction when addressing physician compensation arrangements and risk sharing in the context of ERISA. It has validated the concept that the treatment decisions of physicians, even if mixed with ERISA eligibility questions, are to be left to the purview of state medical malpractice law. Moreover, the Court’s resolution of these issues does not mean a shift in how the federal courts should analyze ERISA preemption questions relating to HMO medical-necessity decisions. Contrary to the views of the Department of Labor, *Pegram* did not hold that HMO coverage decisions involving medical-necessity issues are subject to state medical malpractice law.

*Pegram*’s most significant impact, however, may be in its call for judicial restraint when federal courts are faced with broad challenges to managed health care practices. The Court’s clear message was that the courts were not the appropriate venue for making health care policy; that responsibility remains with Congress.

## References

1. *Pegram*, 530 U.S. 211.
2. 29 U.S.C. § 1001 (1994).
3. Although the form of managed health care plan in *Pegram* was an HMO, the analysis in this paper equally applies to other managed health care plans to the extent that they share the financial risk for the delivery of health care services with their network providers.
4. The Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961-68 (1994).
5. For a summary of the procedural background of *Pegram* in the lower courts, see *Herdrich v. Pegram*, 154 F.3d 362, 365-67 (7th Cir. 1998).
6. *Id.*
7. The term “mixed eligibility decision” is one created by the Court. It arises from the Court’s view that *Pegram*’s treatment decision that *Herdrich*’s condition did not warrant immediate attention resulted in the HMO’s not covering immediate care, while it would have done so had *Pegram* made the proper diagnosis and judgment to treat. *Pegram*, 530 U.S. at 229-30. The Court’s use of the term “eligibility” appears to be interchangeable with the concept of coverage.
8. *Pegram*, 530 U.S. at 236.
9. *Id.* at 235.
10. *Id.*
11. *Amicus Curiae Brief for the Department of Labor, Pappas v. Asbel*, 555 Pa. 342, 724 A.2d 889 (Pa. 1998) (No. 00098).
12. *Amicus Curiae Brief for the Department of Labor, United States Healthcare Sys. Of Pa., Inc. v. Pennsylvania Hosp. Ins. Co.*, 530 U.S. 1241 (2000) (No. 98-1836).
13. *Pappas v. Asbel*, 555 Pa. 342, 724 A.2d 889, 890 (Pa. 1998).
14. *Id.* at 893-94.
15. *Amicus Curiae Brief for the Department of Labor, supra* note 12.
16. *Id.* at 6-10.
17. *Amicus Curiae Brief for the Department of Labor, supra* note 11, at 17.
18. *Id.* at 10-11.
19. *Id.* at 11-12.
20. *E.g.*, *Cannon v. Group Health Serv. of Ok., Inc.*, 77 F.3d 1270 (10th Cir. 1996); *Kuhl v. Lincoln Nat’l Health Plan of Kan. City, Inc.*, 999 F.2d 298 (8th Cir. 1993); *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321 (5th Cir. 1992), *cert. denied*, 506 U.S. 1033 (1992).
21. MDL-1334, MDL-1364, MDL-1366, and MDL-1367 pending before the U.S. District Court for the Southern District of Florida (on file with the author).
22. *Pegram*, 530 U.S. at 234.
23. 221 F.3d 472 (3d Cir. 2000).
24. *Id.* at 496.
25. *Id.* at 499.
26. *Id.*



# Mismanaged Care: The Challenges Facing Judicial Interpretation of Contemporary Health Policy

**Mark Schlesinger, Ph.D.\***

At a time when the U.S. Supreme Court stands accused of undermining the legitimacy of American democracy, it might seem superfluous to question its wisdom in the interpretation of more mundane matters of public policy. But the Court is rarely given an opportunity to tinker with electoral outcomes. By contrast, it is constantly in the business of interpreting congressional legislation. Doing so involves more than simply establishing the constitutionality of a law. It also requires sensitivity to the substantive implications of a ruling, as reflected in the Court's analysis of congressional intent.<sup>1</sup> These judgments are made difficult when the substantive implications are hard to discern or confusingly complicated. These difficulties can compromise sensible judicial interpretation of laws that shape contemporary health policy.

Few domains of public policy rival medical care in sheer complexity. Even experts in the field have, at best, a limited understanding of the constituents of effective treatment.<sup>2</sup> To complicate things further, American medicine is characterized by dramatic and persistent change, in both the nature of medical services and in the institutional arrangements through which they are financed and delivered. Labels and conceptual frameworks often lag behind these changes, creating a confusing disjunction between the basic features of the health care system and the terms in which that system is typically described.<sup>3</sup> These circumstances can greatly complicate the task of judicial review. It is difficult to discern a coherent sense of congressional intent from laws written by those who have at best a partial understanding of the health care system. Only about a quarter of the congressional staff with responsibilities for health care have had any training in the field.<sup>4</sup> Elected officials face even bigger challenges, since they must have a working knowledge about a wide range of policy concerns. Evidence suggests that they are not always up to these

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challenges, basing health policy decisions on deliberations that can be most charitably described as “ill-informed.”<sup>5</sup> Even when congressional intent can be clearly established, it can be difficult to apply to a health care system that has changed dramatically from the time at which the legislation was enacted.

The Court’s recent decision in *Pegram v. Herdrich*<sup>6</sup> illustrates these challenges to judicial review. Cynthia Herdrich and her attorneys offered an innovative interpretation of the responsibilities of fiduciaries defined under ERISA. They suggested that if a health insurance plan was connected in some fundamental manner to an employee benefit plan defined by ERISA, then physicians who owned the health plan (as did Lori Pegram, the clinician whose judgment was in question) were effectively acting as fiduciaries for the benefit plan. Giving them a financial incentive to withhold medical care, under this formulation, compromised their roles as fiduciaries.

To interpret (and dispute) these claims, Justice Souter needed to make sense of the arrangements that exist between health plans and employers, as well as those between health plans and physicians. Despite having been able to draw upon a flock of *amicus* briefs for expert guidance, Justice Souter’s portrayal of the managed care industry bears only a partial resemblance to the American health care system documented by most research. As a result, his claims about the consequences of supporting Herdrich are questionable. Equally problematic, his efforts to interpret congressional intent related to ERISA are compromised by the fact that few in Congress in 1974 could have imagined ERISA being widely applied to health care, let alone the managed care practices that emerged during the 1980s and 1990s. Nor could they have anticipated the implications of physician ownership of managed care plans, since in 1974 virtually all managed care plans operated on a not-for-profit basis.<sup>7</sup> The Court’s consideration of *Pegram* evoked widespread attention, including extensive coverage in the press and abundant commentary in the academic literature. In my judgment, efforts to derive any sort of substantive meaning or implications from *Pegram* are problematic, given the questionable understanding of the American health care system that undergirds the decision.

In this commentary, I trace three important forms of misunderstanding. First, viewing the health care system through the lens of ERISA leads to a distorted portrait of the ways in which resources are allocated and the types of fiduciary roles that ought to be protected. Second, Justice Souter misrepresented the importance of financial incentives to the continued viability of managed care plans. Third, he

presented a muddled analysis of the role of profits in the operation of health plans. Consequently, even if one embraces the line of argument suggested in this decision, a more realistic reading of the system to which that logic is applied may lead to very different conclusions than those drawn in this case.

The distortions produced by viewing health policy through ERISA stem from the origins of law. Congress never intended ERISA to apply to medical care.<sup>8</sup> Indeed, it explicitly excluded insurance from the sorts of benefit plans that ERISA exempted from state regulation. However, when large employers subsequently self-insured (i.e., assumed risk for the health care costs of their employees), the health plans with which they contracted were treated as administrators of the benefit plan, rather than as forms of health insurance. Courts have subsequently ruled that a wide range of managed care practices are exempt from state regulations under ERISA, weakening the protections that would otherwise be afforded to enrollees in these plans.<sup>9</sup> As Justice Souter notes, these potential developments were not foreseen in congressional debate, which focused almost entirely on pension plans and benefits. Consequently, ERISA provisions were not crafted in a manner sensitive to the differences between medical care and programs designed to finance a person's retirement. Viewing contemporary health care practices through their reflection in ERISA plans is thus rather like checking one's appearance in a funhouse mirror at a carnival. The image is distorted in a variety of ways, which can be seen as either perversely amusing or horrifying, depending on one's mood. Some practices are stretched almost beyond recognition. Other distinguishing features are scrunched together, making it impossible to separate one from another.

Generally speaking, one would not base important decisions—like getting a new haircut or deciding upon a new wardrobe—on how one looked in a mirror of this sort. Yet that is precisely the circumstance facing the Court in this case. It sought sensible policy, but could view that policy only through its reflection under ERISA. Arguably, in order to derive more sensible policies, one must derive a set of principles from congressional debate about ERISA, then adapt those principles to the distinctive characteristics of the contemporary health care arena. Consider how such an approach might have altered the conclusions reached in this case.

The scope of ERISA's application depends on what is included in a benefit plan. Herdrich's claim that physician-owners were fiduciaries under ERISA was given some plausibility by prior decisions of lower courts, which had stretched the scope of benefit plans (and hence exemption from state regulation) beyond all recognition, to cover a range of managed care

practices including the delivery of medical care.<sup>10</sup> This interpretation is in some sense understandable, since the real health benefits available to enrollees depend on how health professionals respond to these managed care practices. But it fails to recognize the institutional diversity of the American health care system. A few health plans, such as the Yale Health Plan, do provide services to the employees of a single firm. In this case, the equation of health plan and benefit plan makes sense. However, in most cases, the health plan treats employees of many different firms under complex contractual arrangements. Pegram, for instance, worked for Carle, which contracted to provide health care to State Farm employees. In many HMOs, the physicians are not even direct employees of the health plan, but instead practice in groups, which in turn contract with the HMO. To argue that a benefit plan under ERISA extends to the decisions of clinicians thus requires that a benefit plan subsume these multiple layers of contracts and organization. This is roughly equivalent to suggesting that a pension benefit plan under ERISA extends to include the traders on the floor of the stock exchange who are handling the business of the mutual fund in which the firm's pension assets are invested. A logical connection can be made, but it is pretty far-fetched to treat this as a unified benefit plan.

Justice Souter recognized that these earlier decisions were problematic. He attempted to establish a new boundary between benefit plans and health plans, defined by whether the practice was established as part of an explicit negotiation between plan administrators and the employers who were purchasing the health benefits. This is a striking shift from the decisions of many lower courts and would help clarify applications of ERISA to medical care. But this approach underestimates the adaptability of contracting practices in American medicine. Justice Souter's new standard is vulnerable to the same sort of regulatory avoidance that led to the unexpected expansion of ERISA into health care during the 1980s. In order to keep their practices outside the purview of state regulators, managed care plans need only to specify those practices—in even the vaguest of terms—in their negotiations with employers.<sup>11</sup> This would encourage more centralized rationing of health care within a plan, whether or not this is the best way to determine appropriate health care. Many health policy experts would argue that it is not.<sup>12</sup>

Under ERISA, there is one and only one fiduciary role, that of the plan administrator who is expected to ensure that the financial returns for beneficiaries are robust and secure. This is a sensible construction for pension plans, under which the returns to any individual do not draw resources away from other beneficiaries. However, this is not the case for



health care plans. Given their fixed budget, expanding access to health care for any one beneficiary necessarily reduces the resources available to other enrollees. In order to protect the well-being of enrollees under these arrangements, there are necessarily three distinctive fiduciary roles: (1) one to represent the interests of the individual patient, a role conventionally played by the physician, (2) one to represent the collective beneficiary interests in husbanding resources for future use, and (3) one to ensure that the relative influence of the first two fiduciaries is held in appropriate balance.<sup>13</sup> The second of these roles is often assigned to administrators of the health plan, the third role to employers or some third-party regulator.<sup>14</sup>

Justice Souter persuasively argued that physicians should not be held to the same standard as fiduciaries in pension schemes. But equal treatment was not necessarily the right standard for judging fiduciary performance. One could instead argue that ERISA required that those who act as fiduciaries under the plan do so in a manner that is uncompromised by financial incentives or institutional obligations, whatever roles the fiduciaries are expected to perform. Under this interpretation, each of the three fiduciary roles in a health benefit plan would need to be protected, even though each differs in functions and expectations from those assumed by fiduciaries in pension plans.

From this standard, the physician-ownership arrangements questioned by Herdrich could be challenged in either of two ways. First, these arrangements could be seen as compromising the ability of physicians to act as fiduciaries for their patients. The financial incentives associated with ownership create a conflict of interest, potentially undermining the representation of patients' well-being. Second, physician ownership could be characterized as a failure of the employer's fiduciary responsibilities. By creating an incentive for physicians to act in ways that are congruent with those of plan administrators, these arrangements upset the balance between the first and second fiduciary roles described above. Arguably, an employer acting as a fiduciary for workers should not contract with health plans that are organized under these terms.

In short, Justice Souter erred in arguing that because physician-owners could not be judged by the same standards as fiduciaries under pension plans, they could not be considered fiduciaries in any sense. He further erred by conflating the multiple fiduciary roles in health care, assuming that physicians in an HMO necessarily had to balance the interests of individual patients against those of the plan as a whole. Such a balance must be struck in Carle, in which physicians are both clinicians and owners. But there is nothing inherent in managed care that requires such

arrangements, which was precisely what Herdrich was questioning in the first place.

A second crucial misunderstanding in *Pegram* emerges early in the decision. Herdrich had challenged the arrangements for paying physicians in Carle a year-end distribution—that is, a share of the profits in the plan. These arrangements were portrayed as distinctively powerful in undermining the fiduciary obligations that physicians should be expected to hold.

Justice Souter rejected this claim, on grounds that appear to confuse the incentives facing a managed care plan with those facing the physicians affiliated with that plan. He is correct in suggesting that “the essence of an HMO is that salaries and profits are limited by the HMO’s fixed membership fees,” necessitating “rationing” of health care.<sup>15</sup> But he goes beyond this defining feature of prepaid health plans to claim that “no HMO organization could survive without some incentive connecting physician reward with treatment rationing.”<sup>16</sup> This is neither logical nor factually accurate. The health plan must act to stay within budget. It may do so through a variety of administrative requirements: utilization review, physician or patient education programs, co-payment requirements for enrollees, or limitations on coverage of particular types of treatment. Financial incentives for physicians represent another means of rationing. They certainly are not essential for a health plan to be viable. Past studies suggest that somewhere between 40% and 70% of physicians affiliated with managed care plans have financial incentives incorporated into these contracts.<sup>17</sup> These arrangements are not uncommon, but neither are they so ubiquitous that one cannot imagine having health care sensibly allocated in their absence. Nor are financial incentives necessarily more desirable for keeping health plans within budget than are the other arrangements described above. Indeed, they are arguably more problematic, precisely because they obscure for patients the reasons that they are being denied access to medical care. For example, if an HMO’s utilization review office turns down a proposed treatment as “medically unnecessary,” the patient can identify both the source of the decision and the rationale. If the patient and clinician feel that this decision is unsound, they can ask for an appeal. Indeed, the physician is required to do so under professional codes of ethics.<sup>18</sup> By contrast, if the physician herself makes a decision that a treatment is not cost-effective in response to financial incentives, patients are unlikely to even recognize that they have been denied treatment. Nor do they have an obvious advocate to whom they can turn if they feel that such a decision is flawed.

Justice Souter’s claim that financial incentives are a necessary part of

managed care is a curious one, since he cites (though not for this purpose) some of the very studies that document that many physicians do not have incentives in their contracts with health plans. But it is even more curious in its implications. Justice Souter purports to be cautious about having the Court reach judgments about sound health policy, on the grounds that such decisions involve “complicated factfinding” and “debatable social judgments” that ought to be left to Congress.<sup>19</sup> Yet by claiming that all health plans must rely on financial incentives, he is indirectly assuming that all incentive arrangements must be treated as equivalent by the Court (while acknowledging that, in practice, they may have quite unequal consequences). This means that “the decisions listed in Herdrich’s complaint cannot be subject to a claim that they violate fiduciary standards unless all such decisions by all HMOs acting through their owner or employee physicians are to be judged by the same standards and subject to the same claims.”<sup>20</sup>

This places an extraordinary burden of proof on those seeking to challenge ERISA practices as applied to health care. It is rather like claiming that particular voting practices cannot be challenged on grounds of equal protection, unless every voting practice in every jurisdiction is subject to the same challenge. As recent events demonstrate (e.g., *Bush v. Gore*<sup>21</sup>) the Court would clearly not take such a position in a voting rights case. If complex policy domains, such as medical care, cause the Court to adopt fundamentally different presumptions, then they create a disturbing sort of double standard in judicial review.

The third fundamental misunderstanding that is evident in *Pegram* involves the role of profits and profit-making in American medicine. The confusion emerges in several forms, in the latter part in the decision. It begins with the relief that was requested by Herdrich—“the return of profit from the pockets of the Carle’s owners, with the money to be given to the plan for the benefit of the participants.”<sup>22</sup> The Court concludes that this remedy would entail “nothing less than elimination of the for-profit HMO,”<sup>23</sup> a daunting prospect in an industry that by the mid-1990s had more than two-thirds of its plans operating as for-profit enterprises.<sup>24</sup> To Justice Souter, this implication argued strongly for a rejection of Herdrich’s claims.

Herdrich and her attorneys did not intend to attack profit-making in managed care *per se*—they questioned only those profit-making arrangements in which physicians shared in the ownership of the plan. This is not an unreasonable position. Physician ownership of health facilities has been shown to alter their clinical judgment.<sup>25</sup> Past experience in the managed care industry suggests that physician entrepreneurs may

run their health plans in distinctive ways in hopes of attracting corporations to buy them out, at a healthy profit to themselves.<sup>26</sup> One could discourage or prohibit physician ownership without affecting the ability of health plans to sell stock more generally in order to raise capital, to become part of large investor-owned corporations, or to attract entrepreneurs to enter the industry in hopes of making their fortune.

It is true that the remedy that Herdrich requests sounds antithetical to profit-making health plans. Once again however, the ERISA context distorts the central claim in question. ERISA has provisions that limit the financial penalties that can be invoked in legal actions against fiduciaries. The requested relief is the only one available that would create sufficiently large incentives that would induce health plans to change their practices; that is, to drop profit-sharing for physicians. Were this done, profit-making in managed care could go on unfettered, if this was the intent of policymakers. In fact, the historical record suggests otherwise. The Court cites the fact that "for over 27 years the Congress of the United States has promoted the formation of HMO practices," dating back to the Health Maintenance Organization Act of 1973.<sup>27</sup> Curiously, the Court neglected to point out that this same Act incorporated strong preferences for nonprofit HMOs over their for-profit competitors. Indeed, much of the congressional debate around the legislation involved whether to provide subsidies solely to nonprofit health plans. There is certainly nothing in this early history to suggest that it was the intent of Congress to encourage profit-making in managed care in general, nor to make it possible for physicians to share in this bounty.

Throughout *Pegram*, there is a curious disjunction between what the Court claims as its goals and the substance of the arguments that it uses to bolster its decision. Although Justice Souter clearly believes that the Court should not make decisions based on its own interpretation of appropriate health policy, that is precisely what it does in denying the validity of Herdrich's claims. One of the primary criteria by which these claims are judged is in terms of "how this fiduciary standard would affect HMOs."<sup>28</sup> This requires that the Court accurately assess the nature of the managed care industry and predict the consequences of a particular interpretation of ERISA. It rejects some claims because of the "upheaval that would follow,"<sup>29</sup> and others based on the "risk to the efficiency of federal courts"<sup>30</sup> that might result from legal actions pursued under the auspices of ERISA. In short, cases of this sort rest heavily on the Court's ability to assess and predict the substantive consequences of particular interpretations of the law.

As we have seen, the Court is woefully inept in these efforts. This is not

simply because the judiciary is ill-equipped to draw inferences about complex policies in technologically vibrant sectors of American society. It is also because the Court fools itself. In purporting to restrict its scope of discretion, by deferring to other branches of government, it only masks the extent to which its decisions are still based on presumptions about policy and its consequences. The more these choices are cloaked, the more apt they are to be made in a poorly informed manner, and the more likely it is that their implications will be misread by the public and the media. Candor about the limitations of judicial interpretation will not in itself remedy these problems, but they can be made more visible, and hence more readily understood, by those whose lives are affected by the judgments.

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5. The general challenges facing elected officials are discussed by BRYAN D. JONES, RECONCEIVING DECISION-MAKING IN DEMOCRATIC POLITICS: ATTENTION, CHOICE AND PUBLIC POLICY 78-101 (1990) and DOUGLAS ARNOLD, THE LOGIC OF CONGRESSIONAL ACTION (1994). Whiteman offers a compelling example involving congressional deliberations about how to pay physicians under the Medicare program. "The same may be true about all of the gory details of the physician payment issue; we may not want to know them. Our elected officials certainly don't know them. During a briefing for members of the Senate Finance Committee, in preparation for the conference committee negotiations with the House, 'it was clear these guys were coming from nowhere land.' Staff members were cringing on the sidelines, exchanging 'looks of astonishment at each of the questions the members were raising' and hoping that their own member would not embarrass them." WHITEMAN, *supra* note 4, at 51.
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11. William M. Sage, *UR Here: The Supreme Court's Guide for Managed Care*, HEALTH AFF., Sept.-Oct. 2000, at 219, 221.
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16. *Id.*

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19. *Pegram*, 530 U.S. at 221.

20. *Id.* at 222.

21. 121 S. Ct. 525 (2000).

22. *Pegram*, 530 U.S. at 233.

23. *Id.*

24. Schlesinger et al., *supra* note 7. Justice Souter makes the even less plausible

claim that Herdrich's claims might well portend the end of nonprofit HMOs as well. Since these nonprofit plans already operate under a nondistribution constraint that forbids profit-sharing with those affiliated with the plan, this claim is most implausible. *Pegram*, 530 U.S. at 234 n.11.

25. See BRADFORD H. GRAY, *THE PROFIT MOTIVE AND PATIENT CARE: THE CHANGING ACCOUNTABILITY OF DOCTORS AND HOSPITALS* (1991).

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28. *Id.* at 232.

29. *Id.* at 233.

30. *Id.* at 237.





## DEVELOPMENTS AND TRENDS IN THE LAW

### Question:

**How are states regulating the use of drugs and alcohol during pregnancy?**

In March 2001, the United States Supreme Court announced its decision in *Ferguson v. City of Charleston*, which struck down the Medical University of South Carolina's policy of testing the urine of pregnant women for cocaine without consent, and reporting positive results to local authorities. The Court held that involuntary drug testing of pregnant women violated the Fourth Amendment's prohibition on unreasonable searches and seizures. In light of the Court's decision, the future of state regulation in this area is unclear. The following article by Jean Reith Schroedel and Pamela Fiber considers how states currently approach the regulation of drugs and alcohol during pregnancy and how the Supreme Court's decision may affect the future. Following their piece is a synopsis of each state's existing case and statutory law on the subject, which has been produced by the *Journal's* editorial staff.



# Punitive Versus Public Health Oriented Responses to Drug Use by Pregnant Women

Jean Reith Schroedel, Ph.D.\* and Pamela Fiber, M.A.†‡

During the past fifteen years, the term fetal abuse has been applied to physical and developmental harms caused by prenatal drug exposure, but not to other preventable threats to fetal well-being.<sup>1</sup> Although *Roe v. Wade* established the legal rationale for fetal abuse prosecutions,<sup>2</sup> which held that a state may have a compelling interest in intervening in a woman's pregnancy after the fetus reaches viability, states did not initially use *Roe* to prosecute pregnant women whose substance abuse threatened fetal well-being.<sup>3</sup> The situation began to change in the mid-1980s, when media attention on the problems of "crack babies"<sup>4</sup> combined with technological advances in *in utero* fetal health monitoring to create a public outcry against pregnant substance abusers.<sup>5</sup>

Governmental responses to prenatal drug exposure have proceeded under two venues: the criminal justice system and state legislatures. The purpose of the criminal justice system is to determine whether a crime has been committed and, if so, to punish the guilty parties—not to determine the most effective policy to combat a particular social ill. Not surprisingly, therefore, most policies emanating from the criminal justice system are punitive in nature.<sup>6</sup> Also, most decision-making within the criminal justice system occurs on an ad hoc basis, without substantial input from experts. Police, prosecutors, and judges are rarely forced to confront facts that contradict their framework of analysis.<sup>7</sup>

In contrast, the legislative process is, by nature, a slow one that emphasizes deliberation and provides many opportunities for expert witnesses to provide input. As a result, there are substantial differences

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‡ The authors wish to thank the Lyn and Norman Lear Foundation for its support.

between legislative and judicial responses to the problem of substance abuse by pregnant women.<sup>8</sup> Politicians may try to impress their constituents by introducing legislation to “deal with” a “hot” topic, but these measures often experience formidable obstacles that prevent their enactment. With the exception of Nebraska, all states have bicameral legislatures, which means that there are many opportunities for experts to interject themselves into the legislative process. While this does not guarantee that all laws are well considered, a range of viewpoints are typically evaluated prior to the adoption of a particular policy. With respect to substance abuse by pregnant women, legislatures are far more likely than the criminal justice system to promulgate a variety of policies, both punitive and public health-oriented ones.

### I. CRIMINAL JUSTICE SYSTEM RESPONSES TO PRENATAL DRUG EXPOSURE

Law enforcement officials, judges, and prosecutors have been at the forefront of efforts to criminalize fetal abuse, charging pregnant women with a range of offenses, including child abuse, child neglect, child endangerment, and delivery of drugs to a minor.<sup>9</sup> These charges require the fetus to be defined legally as a “person.” Since 1985, criminal prosecutions of pregnant women have ensued in at least thirty-four states;<sup>10</sup> with most women being charged with child abuse or a similar offense. Although prosecutors have had some success obtaining convictions under existing child abuse and child neglect statutes, application of such laws to prenatal substance abuse entails legal gymnastics that have made reversals fairly common upon appeal. In the early 1990s, high courts in Florida, Kentucky, Ohio, and Nevada ruled that the fetus was not a “person” or a “child,” resulting in reversal of convictions for a lack of legislative intent.<sup>11</sup>

To avoid these complications, prosecutors began exploring other strategies to hold substance abusing pregnant women criminally liable. One favored tactic takes advantage of laws prohibiting the delivery of drugs to minors to contend that the infant remains attached to the mother via the umbilical cord for several minutes after birth and could still be receiving narcotics through the umbilical cord. A positive toxicology screen is used to prove the charge. For these charges to be sustained, the usual standard of criminal culpability must be liberalized. However, conviction for criminal conduct requires *mens rea*, or criminal intent, which is very difficult to establish in these cases. Typically, this entails either “objective” evidence of recklessness and/or negligence or “subjective” intent with purposeful and knowing action.<sup>12</sup> Any serious attempt to assign criminal intent to these cases is likely to fail because of the social and economic conditions over which a pregnant woman has no control.

Other prosecution attempts remained true to the prenatal nature of the harm. In 1995, the Wisconsin Court of Appeals upheld an order placing a fetus in protective custody of the state to protect it from possible prenatal exposure to narcotics. This necessitated placement of the mother in a drug treatment center. The Wisconsin Supreme Court subsequently overturned this ruling, reasoning that the legislative branch has the responsibility of creating new law, not the judiciary.<sup>13</sup>

In *Whitner v. State*, the Supreme Court of South Carolina ruled that a viable fetus is a “child” or a “person,” and is thereby entitled to legal protection.<sup>14</sup> The court reinstated an eight-year sentence against Cornelia Whitner, whose son tested positive for cocaine immediately after his birth. The U.S. Supreme Court denied review of the case in 1998.<sup>15</sup> However, a related case from South Carolina was granted certiorari just two years later.<sup>16</sup>

During the 2000 term, the Supreme Court heard oral arguments in its first fetal abuse case, *Ferguson v. City of Charleston*.<sup>17</sup> The pending issue was whether state hospitals can turn over urine test results of pregnant women to law enforcement officials for the purpose of prosecuting the women. In 1989, the Medical University of South Carolina (MUSC), in conjunction with local law enforcement, implemented a policy that mandated the testing of pregnant women suspected of cocaine use. Under the policy, maternity patients were to be tested when any of the following signs of cocaine use were present: (1) separation of the placenta from the uterine wall; (2) intrauterine fetal death; (3) no prenatal care; (4) late prenatal care (beginning after 24 weeks); (5) incomplete prenatal care (fewer than five visits); (6) pre-term labor without an obvious cause; (7) history of cocaine use; (8) unexplained birth defects; or (9) intrauterine growth retardation without an obvious cause.<sup>18</sup> Physicians and hospital staff were given official sanction to conduct urine tests without warrants and without notifying patients that the findings could result in arrest and prosecution.

During the five years of collaboration between MUSC and the prosecutor’s office, nearly 280 women, almost all African-American, were threatened with prosecution or arrested.<sup>19</sup> In 1990, the American Civil Liberties Union (ACLU) reported that more than half of all arrests for prenatal exposure to harmful narcotics occurred in South Carolina. All of the women arrested in South Carolina were poor and a majority were African-American. According to the ACLU, South Carolina hospitals often decided to screen for narcotics use if a woman had not received early prenatal care—yet the state Medicaid program did not pay for prenatal care prior to nineteen weeks of pregnancy, causing a delay in poor women receiving prenatal care.<sup>20</sup>

Racial issues aside, *Ferguson* hinged on the Fourth Amendment's protection from warrantless searches. Under the Fourth Amendment, a search is considered reasonable when legitimate government interests outweigh the intrusion on the rights of the individual. South Carolina argued that the search policy implemented by MUSC served "special governmental needs, beyond the normal need for law enforcement," and that those special governmental needs made it impracticable for governmental officials to obtain a warrant or even comply with the probable cause requirement.<sup>21</sup> However, the Court has never applied this doctrine when the intention was to arrest and prosecute.<sup>22</sup>

Critics charge the test and arrest approach followed in Charleston is both bad law and ineffective public policy. Forcing doctors at public hospitals to participate in the policy violates the confidential nature of the physician-patient relationship<sup>23</sup> and threatens the reproductive freedom of women.<sup>24</sup> The policy discriminates against poor and minority women because they are more likely to visit a state hospital than a private hospital.<sup>25</sup> Moreover, critics argue not only that pregnant users will avoid seeking prenatal care out of fear of prosecution,<sup>26</sup> but also that incarceration actually works against the goal of improving fetal health.<sup>27</sup>

## II. LEGISLATIVE RESPONSES TO PRENATAL DRUG EXPOSURE

More than two-thirds of all state legislatures have passed laws specifically designed to combat the problem of prenatal drug exposure.<sup>28</sup> The legislative responses to prenatal substance abuse can be divided into two basic categories: punitive and public health oriented approaches. Punitive approaches maintain that pregnant addicts must be coerced into behaving responsibly, while public health approaches emphasize education, medical treatment, and the provision of social services to pregnant addicts.

Regardless of their approach, states have been unwilling to commit new revenues to combating the problem. For example, two recent California governors—Deukmejian and Wilson—acknowledged that they vetoed bills passed by the state legislature because of the high cost associated with social services to drug-affected infants and their families.<sup>29</sup> And in Oregon, the relevant statute expressly notes the financial woes that accompany provision of services to pregnant substance abusers: "Because the growing numbers of pregnant substance users and drug- and alcohol-affected infants place a heavy financial burden on Oregon's taxpayers and those who pay for health care, it is the policy of this state to take effective action that will minimize these costs."<sup>30</sup> A few paragraphs later, the same statute states that "the Department of Human Services shall study, within

the resources of the department, the problem of substance-using pregnant and postpartum women and their infants.<sup>31</sup>

Despite the efforts of some politicians to move past the revenue problem and enact harshly punitive measures, most of the new laws have been surprisingly mild. During the late 1980s and early 1990s, many state legislatures introduced bills that singled out pregnant addicts for additional criminal penalties, but none actually passed.<sup>32</sup> By 1994, the number of such proposals had so dramatically dropped that only two state legislatures (Indiana and Mississippi) considered bills, and neither were enacted.<sup>33</sup>

### *A. Punitive Legislative Enactments*

Punitive responses of state legislatures can be divided into two broad categories: civil commitment statutes and those involving social service agencies, primarily child welfare departments. The first approach is arguably the harshest because it mandates that substance-abusing women be involuntarily committed for the length of their pregnancy and allows the state to take custody of the child after birth. Under the social service agency approach, the worst punishment is that the woman may lose custody of the child after birth. At least a dozen state legislatures considered passing new civil commitment laws after state courts refused to stretch involuntary commitment laws to cover pregnant substance abusing women.<sup>34</sup> Three states—Minnesota, Wisconsin, and South Dakota—passed laws that allow for the involuntary commitment of substance abusing women, but they do not assure that the women are placed in appropriate facilities.<sup>35</sup> The Minnesota measure, for example, only applies to pregnant women who abuse “hard” drugs, such as cocaine and heroin.<sup>36</sup> Marijuana was specifically excluded, and recent attempts to add alcohol to list of proscribed substances failed. The civil commitment laws in Wisconsin and South Dakota are far more draconian; both cover alcohol, a legal substance, as well as a wide range of narcotics.<sup>37</sup> Furthermore, Wisconsin’s civil commitment law justifies state action based on the “adult expectant mother’s *habitual lack of self-control* in the use of alcohol beverages, controlled substances or controlled substance analogs, exhibited to a severe degree, unless the adult expectant mother is taken into custody.”<sup>38</sup>

Civil commitment laws are actively being considered by state legislatures in Alaska, South Carolina, Texas, and Iowa. For example, this term, Iowa’s Senate, but not its Assembly, passed S.B. 2216, providing for civil commitment of certain chronic substance abusers. Although no two states have enacted identical measures, eighteen require the involvement of social service agencies (usually child welfare departments) when there is

evidence of prenatal drug exposure.<sup>39</sup> A number of states, like Minnesota, make it child neglect for a woman to give birth to a child addicted to alcohol or drugs.<sup>40</sup>

The general laws of fourteen states require that medical providers and other professionals report to the appropriate state agencies positive toxicology tests in pregnant women and newborns, as well as any other evidence of possible drug use by pregnant women. Seven states have laws that mandate the reporting of prenatal drug exposure to the child welfare department (or an equivalent social service agency).<sup>41</sup> The other seven states require that suspected cases of prenatal substance abuse be treated identically to cases of suspected child abuse or neglect, following the normal reporting requirements.<sup>42</sup>

Because social service agencies in some of the remaining states have promulgated regulatory policies that require mandatory reporting of prenatal drug use, the practice extends beyond the eight states. For example, in 1988 the Department of Health and Rehabilitative Services in Florida promulgated a policy requiring anyone who has cause to suspect that a newborn is drug dependent to report it to the Florida Abuse Registry.<sup>43</sup> Child Protective Services investigators are then sent to determine the existence of abuse or neglect. However, a single positive toxicology screen is not *prima facie* evidence of abuse or neglect.<sup>44</sup>

The harshest use of the child welfare system occurs in states that treat a positive toxicology screen or other evidence of prenatal drug exposure as *prima facie* evidence of child abuse, neglect, or its equivalent. For example, Minnesota defines "neglect" as including:

[P]renatal exposure to a controlled substance, as defined in Section 253B.02, subdivision 2, used by the mother for a nonmedical purpose, as evidenced by withdrawal symptoms in the child at birth, results of a toxicology test performed on the mother at delivery or the child at birth, or medical effects or developmental delays during the child's first year of life that medically indicate prenatal exposure to a controlled substance.<sup>45</sup>

Five additional states also find that prenatal drug exposure constitutes *prima facie* evidence of abuse, neglect, or its equivalent. Missouri classifies exposed children as "being at risk of abuse or neglect,"<sup>46</sup> Nevada defines them as "in need of protection,"<sup>47</sup> and Oklahoma states that they are "in need of special care and treatment."<sup>48</sup> Indiana describes children with fetal alcohol syndrome and those born with even a trace amount of a controlled substance as "in need of services,"<sup>49</sup> while Iowa considers the presence of an illegal drug in a newborn's system to be evidence of "child abuse."<sup>50</sup> Other states are considering similar legislation.<sup>51</sup>



Other states do not specify that prenatal exposure to narcotics is *prima facie* evidence of child abuse or neglect. For example, Oregon provides only that “it is the policy of this state that the provider encourage and facilitate counseling, drug therapy and other assistance to the patient in order to avoid having the child when born, become subject to protective services.”<sup>52</sup> On the other hand, Wisconsin specifically includes prenatal drug exposure within its definition of abuse, and also requires that: “Because of that compelling interest [in the potential life of the fetus], the court may order protective custody of that child even though such custody requires custody of the mother as well and the court may not have jurisdiction over the mother.”<sup>53</sup> Laws like those in Oregon and Wisconsin have generated far less attention than similar criminal cases involving prenatal drug exposure because most of these laws handle child welfare issues through the civil rather than criminal process. However, hundreds of women have lost custody of their babies on the basis of a single positive drug screen at birth.<sup>54</sup>

In 1999, Virginia passed a law that allows an emergency removal order by the court if there is reason to suspect that a child is abused or neglected.<sup>55</sup> Such reasoning may include:

...a finding made by an attending physician within seven days of a child's birth that the results of a blood or urine test conducted within forty-eight hours of the birth of the child indicate the presence of a controlled substance not prescribed for the mother by a physician, or...a diagnosis by an attending physician made within seven days of a child's birth that the child has fetal alcohol syndrome attributable to *in utero* exposure to alcohol.<sup>56</sup>

California law states that “a positive toxicology screen at the time of the delivery of an infant is not in and of itself a sufficient basis for reporting child abuse or neglect,” but it does trigger an assessment of whether the child is at risk.<sup>57</sup> The language in six other states with reporting requirements (Illinois, Kansas, Kentucky, Massachusetts, Utah, and Virginia) is ambiguous about the evidentiary significance of prenatal drug exposure for child abuse or neglect charges. However, such exposure has been interpreted as *prima facie* evidence of abuse in Illinois.<sup>58</sup>

Most states with reporting requirements do not specifically state whether evidence of drug use during pregnancy can be used in a criminal case against the woman. Four states—California, Kansas, Kentucky, and Virginia—expressly prohibit the use of this information in a criminal prosecution of the woman.

*B. Public Health Oriented Legislation*

Most recent legislative enactments have embodied the public health approach, which views drug addiction as a disease that is best treated as a medical and psychiatric condition.<sup>59</sup> Thirty-three states have adopted laws that utilize a public health approach.<sup>60</sup> These laws can be divided into three broad categories based on whether they: (1) require research on the problem, (2) initiate preventative public education campaigns, or (3) provide drug treatment for pregnant addicts. One commonality is that none entail large public expenditures.

Although the specific mandates vary, thirteen states require additional research into the problems caused by substance abuse during pregnancy.<sup>61</sup> Some states mandate the creation of a task force or commission to study the problem, while other states instruct an existing public agency to undertake a new study. Arkansas, California, Louisiana, Minnesota, North Carolina, and North Dakota limit the scope of such research programs to the needs of drug-exposed infants and children.<sup>62</sup> Connecticut, Illinois, Nevada, New Hampshire, Oklahoma, and Oregon take a more holistic approach, requiring the study of both children and their mothers.<sup>63</sup> Washington requires the Department of Health to develop screening criteria to be used to identify pregnant addicts and then to use those in creating a training protocol to be used by medical providers.<sup>64</sup> No state limits the scope of research to the mothers only, which reflects the stigmatization and secondary status of drug abusing women even in states that emphasize the public health approach.

Sixteen states have passed laws designed to educate women about the harmful effects of using drugs when pregnant.<sup>65</sup> The content of the campaigns and their target audience varies from state to state. Some states require preventative education campaigns directed at the general public while other states have more specific target audiences. Among the former group, Arizona and Connecticut high schools must provide preventative drug education that covers the adverse effects of drug use by pregnant women.<sup>66</sup> Alaska distributes pamphlets with marriage licenses, which describe the harms caused by fetal alcohol syndrome and perinatal drug exposure,<sup>67</sup> and Delaware mandates that all professional counselors and medical practitioners must post and give written and verbal warning to pregnant patients about the possible problems, complications, and harms caused by narcotic use during pregnancy.<sup>68</sup>

Among the states that target specific groups, most focus on pregnant women as a class. Colorado, Kansas, Louisiana, Massachusetts, and South Dakota have laws requiring that health care providers inform all pregnant

women of the adverse consequences of prenatal drug exposure. Minnesota simply requires that health care professionals be trained in effective drug prevention methods designed to reduce the number of drug exposed infants. Iowa law requires that birth center clients receive drug education,<sup>69</sup> and Maryland has a similar requirement for pregnant women receiving medical assistance.<sup>70</sup> North Dakota, Oregon, and Wisconsin target "high-risk" women patients in their education campaigns, although North Dakota's program is limited to prevention of fetal alcohol syndrome.<sup>71</sup>

None of these initiatives directly meets the drug treatment needs of pregnant women already addicted to narcotics. Researchers unanimously agree that residential drug treatment programs that address the broader social context of women's addiction are the most effective means of combating the problem of prenatal drug exposure.<sup>72</sup> Most drug treatment programs were established in the 1950s and 1960s when heroin was the primary illegal drug and male addicts far outnumbered female ones.<sup>73</sup> The current situation is quite different. Women are at least as likely as men to be addicted to drugs. Roughly 60% of "crack" addicts are women.<sup>74</sup> Yet a National Institute on Drug Abuse study found that only one-quarter of addicts receiving treatment in 1990 were women, and only a minuscule proportion of these were pregnant.<sup>75</sup> The same survey found that only 0.1% of all addicts in treatment had access to childcare at their treatment centers.<sup>76</sup> Fears of insurance liability for drug-affected children are an important reason why many treatment providers refuse to accept pregnant women in their programs.

Despite the well-documented shortage of drug treatment programs willing to accept them,<sup>77</sup> the federal government has done very little to expand the number of available treatment slots for pregnant addicts. States receiving federal drug-treatment block grants were not required to allocate any funds for treatment of female addicts, much less pregnant addicts, until fiscal 1985, when block grant recipients had to spend 3% of their funds for alcohol and drug abusing women. That figure was later increased to 5%.<sup>78</sup>

State governments have not chosen to pick up the slack left by the federal government. Neither state legislatures nor local governments have responded to the problem of prenatal drug exposure by increasing public funding for drug treatment targeted at pregnant addicts.<sup>79</sup> For example, in this legislative term, Connecticut failed to pass a bill that would have funneled proceeds of the sale of bonds to the Department of Correction to develop facilities and alternative sentencing programs for pregnant and parenting women.<sup>80</sup> The facilities would have housed pregnant or parenting women with a history of substance abuse who have one or more

children under the age of six at the time of entry into the program. It also would have allowed at least one child to reside with the mother in the facility.

Illinois is the only state that statutorily has earmarked part of a special fund for the provision of drug treatment services for pregnant addicts. Money from the Illinois Substance Abuse Services Fund is used to pay for the hospitalization of pregnant women with substance abuse problems.<sup>81</sup> The Fund also pays for services to drug-affected newborns and supplements existing county funding for more generalized substance abuse treatment. Three other states, Florida,<sup>82</sup> Pennsylvania,<sup>83</sup> and Rhode Island,<sup>84</sup> have passed laws that pledge the state to providing additional substance abuse treatment to pregnant women.

At least seven states passed laws authorizing the creation of pilot projects providing drug treatment to pregnant addicts.<sup>85</sup> Their limited scope and often uncertain funding render the chances of success doubtful. Two other states—Nebraska and Tennessee—have tried to improve access to existing services. Nebraska has implemented a case management program to ensure that high risk pregnant women, not covered by medical insurance, gain access to needed services, and Tennessee employs older women from the community to act as “resource mothers” for high-risk pregnant teenagers.<sup>86</sup> Neither of these programs expands the number of treatment slots available for pregnant addicts.

Instead of new programs, six states acted to prohibit drug treatment facilities from discriminating against pregnant women. Kansas, Louisiana, and Missouri have passed laws with specific anti-discrimination clauses,<sup>87</sup> and the latter two are also part of a group of five states that make treatment services for pregnant women a priority. Arizona, Georgia, and Maryland are the other states that prioritize the treatment of pregnant addicts.<sup>88</sup>

Last November California voters overwhelmingly passed Proposition 36, which provides for a massive expansion in the number of drug treatment slots in the state.<sup>89</sup> Instead of incarceration, most drug addicts will be placed on probation and required to undergo treatment. The new law also mandates the creation of a Substance Abuse Treatment Trust Fund to provide for additional treatment slots. The Fund will receive a \$60 million appropriation from the General Fund in fiscal year 2000-01 and \$120 million for five subsequent fiscal years. Although the initiative does not make any special provisions for pregnant women or at-risk women, they would almost certainly benefit from the program.

## CONCLUSION

As we have seen, two distinctly different policy approaches to substance abuse during pregnancy have been followed in the past fifteen years. Although punitive responses have been predominant within the criminal justice system, state legislative responses have been far more mixed. Only two state legislatures, those in Indiana and Utah, have solely adopted punitive means to combat drug abuse by pregnant women. An additional eighteen states have passed laws that approach the problem from both the punitive and public health perspectives. The remaining fifteen state legislatures have solely adopted public health measures. The failure of all levels of government to provide funding for these programs is a major impediment to their success. Perhaps the enactment of Proposition 36 will allay politicians' fears that voters equate drug treatment with the coddling of criminals.

Although prognosticating about future trends is always a risky proposition, it is particularly difficult at this time. As we have seen, both punitive and public health oriented measures have been adopted in the recent past. In its recent 6-3 decision in *Ferguson*, the U.S. Supreme Court held that involuntary drug testing of pregnant women violated the Fourth Amendment's prohibition on unreasonable searches and seizures.<sup>90</sup> The Court rejected the Fourth Circuit's argument that such tests were "minimally intrusive" and permissible under the "special needs" exception. While this decision will make it more difficult for prosecutors to pursue criminal actions against pregnant drug users, the Court carefully avoided addressing one of the central issues posed by these cases: whether the fetus can be legally defined as a "person." By doing so, the Court left open the possibility that prosecutors could continue to prosecute women for delivering drugs to their fetuses. The court only proscribed involuntary drug screening of the women, and not other means of gathering evidence of drug exposure. The most obvious way that such evidence could be obtained is by running drug screens on infants immediately following birth. Despite this caveat, the *Ferguson* decision, at the very least, should slow the rush toward increasingly punitive responses to drug use by pregnant women. It might even help shift the locus on policy initiatives away from the courts, which have been overwhelmingly punitive, and into the state legislatures.

Predicting what is likely to occur within the state legislatures, though, is equally difficult. Although most state laws have a public health orientation, there continues to be strong support for getting tough on pregnant drug users. The adoption of civil commitment statutes, especially

those that make it an offense for a pregnant woman to imbibe a legal substance—alcohol—is one indication of the continuing popularity of punitive measures. Finally, the question of whether the new Bush administration will opt for punitive or public health oriented initiatives remains.

## References

1. Even though poverty contributes to a wide range of physical and developmental maladies, society refuses to provide adequate housing, nutrition, and medical care to pregnant women who are unable to procure these goods on their own. Moreover, there has been no comparable effort to criminalize individual male actions that threaten fetal well-being. The term "fetal abuse" has only been applied to harm caused by pregnant women's use of drugs or alcohol, but not to harm caused by physical assaults on pregnant women. See, e.g., RACHEL ROTH, *MAKING WOMEN PAY: THE HIDDEN COSTS OF FETAL RIGHTS* (2000); Paul Peretz & Jean Reith Schroedel, *The Road not to Travel: A Comment on Deborah Mathieu's Proposal to Mandate Outpatient Treatment for Pregnant Substance Abusers*, 15 POL. & LIFE SCI. 67, 67-69 (1994).

2. 410 U.S. 113 (1973).

3. For a detailed history of the legal spillover from *Roe v. Wade* into other fetal policy areas, see Jean Reith Schroedel et al., *Women's Rights and Fetal Personhood in Criminal Law*, 7 DUKE J. GENDER L. & POL'Y 89 (2000).

4. Significantly, the greatest actual increase in cocaine use occurred in the 1970s when many middle-class whites experimented with the drug. The media, however, did not focus attention on drug use until the mid-1980s, when a cheap, inhaleable form of the drug—crack—became prevalent in the inner cities. Craig Reinerman & Harry G. Levine, *The Crack Attack: Politics and Media in the Crack Scare*, in *CRACK IN AMERICA: DEMON DRUGS AND SOCIAL JUSTICE* 18 (Craig Reinerman & Harry Levine eds., 1997) [hereinafter

*CRACK IN AMERICA*]. By the late 1990s crack use had declined dramatically, but drug use by pregnant women had not. A new drug, crack—a form methamphetamine—has become the drug of choice, but it has generated little media attention. Whether the lack of interest is due to public weariness about drug-exposed babies or to the fact that most of the crack-using pregnant women are white rather than minority women is debatable. JEAN REITH SCHROEDEL, *IS THE FETUS A PERSON? A COMPARISON OF POLICIES ACROSS THE FIFTY STATES* 102 (2000).

5. Much attention has been given to public opinion polls showing strong public support for making substance abusing pregnant women subject to criminal sanctions, but as Rachel Roth shows in her analysis of all the relevant polls, there is at least as much support for drug treatment as there is for incarceration. ROTH, *supra* note 1, at 157-58.

6. Somewhat ironically, the Supreme Court recognized nearly four decades ago that drug addiction is a medical problem rather than a criminal one. *Robinson v. California*, 370 U.S. 660 (1962).

7. Although police and district attorneys do not typically consult with policy experts prior to deciding whether to make an arrest or prosecute, there are opportunities for expert opinion to play a role in the courtroom. Judges have broad discretion over the type of expert testimony that can be presented. For research on judges and prosecutors' knowledge about the most effective responses to drug addiction among pregnant women, see Barrie Becker & Peggy Hora, *The Legal*

*Community's Response to Drug Use During Pregnancy in the Criminal Sentencing and Dependency Contexts: A Survey of Judges, Prosecuting Attorneys, and Defense Attorneys in Ten California Counties*, 2 S. CAL. REV. L. & WOMEN'S STUD. 527 (1993).

8. SCHROEDEL, *supra* note 4, at 118-20.

9. See, e.g., *Johnson v. State*, 602 So. 2d 1288, 1290 (Fla. 1992); *State v. Gray*, 584 N.E.2d 710, 710 (Ohio 1992); *Whitner v. State*, 492 S.E.2d 777, 778 (S.C. 1997); *People v. Hardy*, 469 N.W.2d 50, 51 (Mich. Ct. App. 1991); *Department of Social Services v. Nash*, 419 N.W.2d 1, 2 (Mich. Ct. App. 1987); *In re Theresa J.*, 158 A.D.2d 364 (N.Y. App. Div. 1990); *State v. Deborah J.Z.*, 596 N.W.2d 490, 491 (Wis. Ct. App. 1999).

10. Criminal prosecutions have taken place in the following states: Alabama, Alaska, Arizona, California, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Nebraska, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, and Wyoming.

11. For example, in 1992 the Ohio Supreme Court overturned a child abuse conviction for prenatal exposure to narcotics on the grounds that the term "child" refers only to a "born" child. *State v. Gray*, 584 N.E.2d 710 (Ohio 1992).

12. Molly McNulty, *Pregnancy Police: Implications of Criminalizing Fetal Abuse*, YOUTH LAW NEWS 33-37 (1990).

13. *State ex. rel. Angela M.W. v. Kruzicki*, 197 Wis. 2d 532; 541 N.W.2d 482

(Wis. Ct. App. 1995), *rev'd*, 209 Wis. 2d 112; 561 N.W.2d 729 (Wis. 1997).

14. *Whitner*, 492 S.E.2d 777.

15. *Whitner v. South Carolina*, 523 U.S. 1145 (1998).

16. *Ferguson v. City of Charleston*, 528 U.S. 1187 (2000).

17. *Id.*

18. Carmen Vaughn, *Circumventing the Fourth Amendment via the Special Needs Doctrine to Prosecute Pregnant Drug Users: Ferguson v. City of Charleston*, 51 S.C. L. REV. 857 (2000).

19. Center for Reproductive Law & Policy, *On the Docket: CRLP in the Courts*, at [http://www.crlp.org/rfn\\_98\\_09.html](http://www.crlp.org/rfn_98_09.html) (last visited Apr. 22, 2001). Even though the Supreme Court did not consider race discrimination issues in *Ferguson*, one *amicus curiae* brief argues that the criteria used to identify possible drug users were "thinly veiled proxies for low socioeconomic status or race." Brief of Amicus Curiae NARAL Foundation et al. at 23-26, *Ferguson v. City of Charleston*, 528 U.S. 1187 (2000) [hereinafter NARAL Brief]. The NARAL foundation also charges that the choice of a single hospital, one that serves a disproportionately poor and African-American population, was discriminatory, as was the decision to prosecute only women who tested positive for cocaine even though the screening test could detect other drugs. The brief also cites evidence showing that the individual responsible for choosing which patient's would be tested held racist beliefs and intervened to prevent at least one white woman from arrest after she tested positive. *Id.*



20. Janna Merrick, *Caring for the Fetus to Protect the Born Child? Ethical and Legal Dilemmas in Coerced Obstetrical Intervention*, 13 WOMEN & POL. 63, 63-81.

21. Vaughn, *supra* note 18, at 861.

22. Vivian Berger, *No Way to Treat a Baby*, NAT'L L.J., Nov. 13, 2000, at A21.

23. Vaughn, *supra* note 18, at 858.

24. LYNN M. PALTROW, CRIMINAL PROSECUTIONS AGAINST PREGNANT WOMEN (1992).

25. NARAL Brief, *supra* note 19.

26. SCHROEDEL, *supra* note 4; American Medical Association Board of Trustees Report, *Legal Interventions During Pregnancy: Court-Ordered Medical Treatment and Legal Penalties for Potentially Harmful Behavior by Pregnant Women*, 264 JAMA 2663, 2667 (1990).

27. Correctional institutions in the United States have not adopted the guidelines for minimum obstetrical and gynecological care promulgated by the American College of Obstetricians and Gynecologists, or any of the relevant medical associations. The American Medical Association, American Academy of Pediatrics, American Nurses Association, American Public Health Association, and American Society of Addiction Medicine, have all issued statements opposing the incarceration of pregnant addicts. Center for Reproductive Law and Policy, *Reproductive Freedom in Focus: Punishing Women for their Behavior, A Public Health Disaster*, 5-6 (on file with author). Furthermore, less than half of state prisons for women have policies governing the care of pregnant addicts. To make matters worse, drugs are widely available in prisons

and jails. See, e.g., Charles C. Egley et al., *Outcome of Pregnancy During Imprisonment*, 37 J. REPROD. MED. 131, 132 (1992); Janet S. Wilson & Renee Leasure, *Cruel and Unusual Punishment: The Health Care of Women in Prison*, 16 NURSE PRAC. 32, 35 (1991).

28. As of December 2000, the fifteen states without such laws are: Alabama, Alaska, Hawaii, Idaho, Maine, Michigan, Mississippi, Montana, New Mexico, New York, South Carolina, Texas, Vermont, West Virginia, and Wyoming. Some of these states had repealed earlier enactments and others had allowed the funding for earlier initiatives to expire. Also in some states, the relevant social service agencies have regulations and policies, written and unwritten, designed to address the problem.

29. LAURA E. GOMEZ, MISCONCEIVING MOTHERS: LEGISLATORS, PROSECUTORS, AND THE POLITICS OF PRENATAL DRUG EXPOSURE 41 (1997).

30. OR. REV. STAT. § 430.905 (1999).

31. OR. REV. STAT. § 430.910 (1999).

32. Although no state has passed statutes singling out pregnant women for additional sanctions for abusing narcotics, New Jersey passed a law doubling the criminal penalties against persons who distribute a controlled substance to a pregnant woman. N.J. STAT. ANN. § 2C:35-8 (West 1996).

33. Under Indiana House Bill 1184 (1994), a woman who gave birth to a drug affected child would have been guilty of a Class D Felony. Mississippi House Bill 670 (1994) also would have made it a felony for a woman to use a controlled substance during the last trimester of a pregnancy if it

resulted in the birth of an addicted child. The Indiana bill died, and committee killed the Mississippi bill.

34. *See, e.g., Kruzicki*, 561 N.W.2d 729 (holding that extending an involuntary civil commitment statute to cover pregnant substance abusing women would be usurping the role of the legislature).

35. *See, e.g., Judy Pasternak, Wisconsin OKs Civil Detention for Fetal Abuse*, L.A. TIMES., May 2, 1998, at A1, A13 (noting that at the Wisconsin legislature's debate over its civil commitment statute, representatives from the state's social service agencies testified that there was an acute shortage in drug treatment slots, and that the number of pregnant addicts voluntarily seeking treatment far exceeded the number of slots available in the state).

36. MINN. STAT. § 253B (1997).

37. S.D. CODIFIED LAWS § 34-20A-70 (Michie 1998); WIS. STAT. § 48.193 (1999).

38. WIS. STAT. § 48.193 (1999) (emphasis added).

39. The laws of the following states contain at least some punitive component: California, Illinois, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Minnesota, Missouri, Nevada, Ohio, Oklahoma, Oregon, South Dakota, Tennessee, Utah, Virginia, Wisconsin. Social service agencies in some of the other states have adopted regulations that are punitively oriented. From the standpoint of the target population, the effect of these regulations may be substantially the same as statutes. However, trying to encompass all of the regulatory changes, as well as case and statutory laws would be a massive undertaking, so we will leave that to future

researchers.

40. MINN. STAT. § 626.556 (2000).

41. The seven states that require reporting of suspected cases of prenatal drug exposure to child welfare agencies or their equivalent are: California, Illinois, Kansas, Minnesota, Missouri, Utah, and Virginia. CAL. PENAL CODE § 11165.13 (2001); 325 ILL. COMP. STAT. 5/7.3b (2000); KAN. STAT. ANN. § 65-1,163 (1999); MINN. STAT. § 626.556 (2000); MO. REV. STAT. § 191.741 (1999); Utah Code Ann. § 62A-4a-404 (2000); VA. CODE ANN. § 32.1-127 (Michie 2000).

42. In Kentucky a positive newborn toxicology test must be evaluated to determine whether abuse or neglect has occurred and whether an investigation is necessary. KY. REV. STAT. ANN. § 214.160 (Banks-Baldwin 2001). The remaining six states, Indiana, Iowa, Nevada, Oklahoma, Oregon, and Wisconsin, do not specifically require suspected prenatal drug exposure to be reported. However, they do categorize such infants as "need[y]," subject[s] of protective services," or "abused," thereby triggering normal reporting requirements.

43. JESSICA PEARSON & NANCY THOENNES, THE IMPACT OF LEGISLATION AND COURT DECISIONS DEALING WITH DRUG-AFFECTED BABIES 58-60 (1995).

44. *Id.*

45. MINN. STAT. ANN. § 626.556 (2000). According to Pearson and Thoennes, the prenatal drug laws in Minnesota are "perhaps the strongest in the nation," but the punitive intent of the laws is undercut by the state's traditional approach to treating substance abuse as a public health

problem rather than a criminal matter. PEARSON & THOENNES, *supra* note 43, at 49-50.

46. MO. ANN. STAT. § 191.737 (2000).

47. NEV. REV. STAT. 432B.330 (1999).

48. OKLA. STAT. tit. 10, § 7001-1.3 (2000).

49. IND. CODE § 31-34-1-10 (1997).

50. IOWA CODE § 232.68 (1997).

51. For example, in 1999 a Virginia Senate bill proposed expanding the definition of "abused or neglected child" to include "newborn infants testing positive for a controlled substance not prescribed by a physician, born dependent on such drug, or diagnosed by a physician with a condition which is attributable to *in utero* exposure to illegal drugs or fetal alcohol syndrome." S. 576 (Va. 1998). The legislative session ended before the bill was considered on the floor.

52. OR. REV. STAT. § 430.915 (1999).

53. WIS. STAT. § 48.02 (2000).

54. Loren Siegal, *The Pregnancy Police Fight the War on Drugs*, in CRACK IN AMERICA, *supra* note 4.

55. VA. CODE ANN. § 63.1-248.3 (Michie 2000).

56. *Id.*

57. CAL. PENAL CODE § 11165.13 (West 2001).

58. PEARSON & THOENNES, *supra* note 43, at 67-68.

59. Drug addiction is classified as a disease by the American Psychiatric Association. AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL OF DISORDERS (1994). The International Classification of Diseases also includes drug dependence as a medical

condition. INTERNATIONAL CLASSIFICATION OF DISEASES, 1 ICD-9-CM 49-50 (5th ed., 9th rev., 1997).

60. The thirty-three states with at least some public health oriented laws are: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Florida, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Virginia, Washington, and Wisconsin.

61. The thirteen states that require studies are: Arkansas, California, Connecticut, Illinois, Louisiana, Minnesota, Nevada, New Hampshire, North Carolina, North Dakota, Oklahoma, Oregon, and Washington. North Dakota limits the research to the problem of fetal alcohol syndrome.

62. *E.g.*, LA. REV. STAT. ANN. § 46:2514 (West 2000); N.D. CENT. CODE § 15-11-35 (2000).

63. *E.g.*, 55 ILL. COMP. STAT. 5/5-1086.1 (2000); N.H. REV. STAT. ANN. § 442.395 (2001).

64. WASH. REV. CODE § 70.83C.020 (2000).

65. The sixteen states with preventative public education initiatives designed to warn women of the dangers of using drugs while pregnant are: Arizona, Colorado, Connecticut, Delaware, Iowa, Louisiana, Kansas, Maryland, Massachusetts, Minnesota, New Jersey, North Carolina, North Dakota, Oregon, South Dakota, and Wisconsin. Again, the focus in North

Dakota is on the prevention of fetal alcohol syndrome. New Jersey also limits its education campaign to warning against the use of alcohol during pregnancy.

66. ARIZ. REV. STAT. § 15-712 (2000); CONN. GEN. STAT. §17a-701 (1999).

67. ALASKA STAT. § 25.05.111 (Michie 2000).

68. DEL. CODE ANN. tit. 16, § 190 (2000).

69. MINN. STAT. § 145.9265 (2000).

70. MD. CODE ANN., [HEATH-GEN. I] § 8-403.1 (2001).

71. N.D. CENT. CODE § 15-11-35 (2000); OR. REV. STAT. § 430.905 (1999); WIS. STAT. § 48.245 (2000).

72. See, e.g., CAROL TRACY ET AL., WOMEN, BABIES, AND DRUGS: FAMILY-CENTERED TREATMENT OPTIONS 13 (1990); LaRay Brown, *Women and Children Last: Barriers to Drug Treatment for Women*, 22 HEALTH/PAC BULL. 15, 18 (1992); George DeLeon & Nancy Jainchill, *Residual Therapeutic Communities for Female Substance Abusers*, 67 J. N.Y. ACAD. MED. 277, 279 (1991); Kathleen J. Farkas & Theodore V. Parran, Jr., *Treatment of Cocaine Addiction During Pregnancy*, 20 CLINICS PERINATOLOGY 29, 39 (1993).

73. For an excellent history of substance abuse among women in the United States and governmental responses to the problem, see STEPHEN R. KANDALL, *SUBSTANCE AND SHADOW: WOMEN AND ADDICTION IN THE UNITED STATES* (1996).

74. Gillian Walker et al., *A Descriptive Outline of a Program for Cocaine-Using Mothers and Their Babies*, 3 J. FEMINIST FAM. THERAPY 7 (1991).

75. NATIONAL INSTITUTE OF DRUG

ADDICTION, *DRUG SERVICES RESEARCH SURVEY: FINAL REPORT, PHASES I AND II*, at 35 (Biggl Inst. for Health Policy at Brandeis University, 1992).

76. *Id.* at 45.

77. See, e.g., LAURA FEIG, OFFICE OF HUMAN SERV. POL'Y, U.S. DEP'T OF HEALTH AND HUMAN SERV., *DRUG EXPOSED INFANTS AND CHILDREN: SERVICE NEEDS AND POLICY QUESTIONS* 16 (1990); Wendy Chavkin, *Mandatory Treatment of Pregnant Substance Abusers: Irrelevant and Dangerous*, 15 POL. & LIFE SCI. 50, 53 (1996); Kary L. Moss, *Substance Abuse During Pregnancy*, 13 HARV. WOMEN'S L.J. 278, 288 (1990); Lynn M. Paltrow, *Perspective of a Reproductive Rights Attorney*, 1 FUTURE CHILD. 85, 85 (1991); Tiffany M. Romney, *Prosecuting Mothers of Drug-Exposed Babies: The State's Interest in Protecting the Rights of a Fetus Versus the Mother's Constitutional Rights to Due Process, Privacy and Equal Protection*, 17 J. CONTEMP. L. 325, 341 (1991).

78. Health Services Amendments of 1985, Pub. L. No. 99-117 (Oct. 7, 1985).

79. Chavkin, *supra* note 77, at 50.

80. S. 604 (Conn. 2000).

81. 55 ILL. COMP. STAT. 5/5-1086.1 (2000).

82. In 1996 the Florida state legislature created the Pregnancy Outcomes Program, committing each county health program to provide services to indigent pregnant women at risk of medical complications due to drug or alcohol abuse. FLA. STAT. 154.011 (1996).

83. In 1997 Pennsylvania enacted a law mandating that the state Department of Health has a "duty" to provide residential drug and alcohol treatment and related

services to pregnant women with substance abuse problems. PA. ADMIN. CODE § 2123 (1997).

84. In 1996 the Rhode Island state legislature instructed the Department of Human Services to "provide enhanced services" to a wide range of pregnant women eligible for state funded medical assistance. Although outpatient drug treatment was among the enumerated services, the exact level of commitment is yet to be determined. R.I. GEN. LAWS § 42-12.3-3 (1996).

85. The seven states that passed laws enabling pilot projects to be developed are California, Colorado, Kentucky, Minnesota, Ohio, Virginia and Washington. The Ohio and Virginia laws specifically require that these programs will use only available funds. Washington state also has been the site of two federally funded demonstration projects that provide drug treatment and other services to pregnant women and mothers with substance abuse problems. For a description of the federal projects, see PEARSON & THOENNES, *supra* note 43.

86. NEB. REV. STAT. § 68-1058 (2001); TENN. CODE ANN. § 68-24-104 (2001).

87. KAN. STAT. ANN. § 65-1,165 (2000); LA. REV. STAT. ANN. § 46:2505 (West 2000); MO. REV. STAT. § 191.731 (1999).

88. The failure to expand treatment slots is even more paradoxical when one considers recent research that shows that drug treatment is a far more cost-effective means of combating narcotics addiction than is incarceration. C. PETER RYDELL & SUSAN S. ERVINGHAM, CONTROLLING COCAINE: SUPPLY VERSUS DEMAND PROGRAMS (RAND Corporation ed., 1996). This was

corroborated in a study performed by the California Department of Alcohol and Drug Programs, which found that for every dollar spent on drug treatment taxpayers saved seven dollars that would otherwise be spent on crime and health care. NAT'L OPINION RESEARCH CTR., CAL. DEP'T OF ALCOHOL & DRUG PROGRAMS, EVALUATING RECOVERY SERVICES: THE CALIFORNIA ALCOHOL AND DRUG TREATMENT ASSESSMENT 1 (1994).

89. Substance Abuse & Crime Prevention Act of 2000 (Proposition 36) (to take effect July 1, 2001), *available at* <http://www.adp.cahwnet.gov/SACPA/pro p36.shtml> (last visited Apr. 22, 2001).

90. *Ferguson v. City of Charleston*, 121 S. Ct. 1281 (2001).



# Synopsis of State Case and Statutory Law

## The Journal's Editorial Staff

### ALABAMA

#### *Case Law and Statutes*

No court cases or statutes strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### ALASKA

#### *Case Law*

*State v. Grubbs*, No. 4FA S89-415 (Alaska Super. Ct. Oct. 2, 1989): The court sentenced a twenty-three year old woman, who allegedly used cocaine during pregnancy, to six months in prison and five years probation for criminally negligent homicide in the death of her two week-old son. An autopsy revealed that her infant son died of a heart attack caused by prenatal cocaine use.

#### *Statutes*

##### *Education*

ALASKA STAT. § 18.05.037 (Michie 2001): The Department of Health and Social Services shall prepare or obtain distributable information on fetal alcohol effects and the fetal health effects of chemical abuse and battering during pregnancy. The department shall make this information available to public hospitals, clinics, and other health facilities in the state for distribution to their patients.

ALASKA STAT. § 25.05.111(b) (Michie 2001): When a marriage license is issued, the licensing officer shall also give to the parties written information about fetal alcohol effects and the fetal health effects of chemical abuse and battering during pregnancy. The Department of Health and Social Services shall prepare or obtain this information and submit it in distributable form to each licensing officer in the state.

## ARIZONA

**Case Law**

*State v. Reinesto*, 894 P.2d 733 (Ariz. Ct. App. 1995): A lower Arizona court criminally indicted a woman for child abuse when her child was born addicted to heroin. The court of appeals dismissed these charges, holding that the use of drugs during pregnancy does not constitute child abuse under ARIZ. REV. STAT. § 13-3623, which defines child abuse as applying to "any person who causes a child. . .to suffer physical injury or. . .who causes or permits the person or health of the child. . .to be injured or who causes or permits a child. . .to be placed in a situation where the person or health of the child...is endangered." The holding was based on the conclusion that child abuse under this statute does not apply to fetuses because the legislature had not included any reference to fetuses or unborn children, whereas it had clearly included them in other statutes.

*Appeal in Pima County Juvenile Severance Action*, 905 P.2d 555 (Ariz. Ct. App. 1995): The court of appeals ruled that a mother's ingestion of alcohol during pregnancy did not constitute adequate grounds for a finding of child abuse under Arizona's severance statute, ARIZ. REV. STAT. § 8-533(B) (2). Severance of parental rights under this statute is allowed on grounds "that the parent has neglected or willfully abused a child." The court concluded that the definition of "child" under the severance statute as "a person less than eighteen years of age" did not include a fetus, and thus that injury to a fetus did not constitute child abuse for the purposes of severing parental rights.

**Statutes***Education*

ARIZ. ADMIN. CODE 9-20-18, Exhibit A (2000): People undergoing methadone treatment must receive a consent form that contains a section entitled "Female Patients of Child-Bearing Age," which warns that "methadone is transmitted to the unborn child and will cause physical dependence."

ARIZ. REV. STAT. § 15-712(A) (2000): Instruction on the nature and harmful effects of alcohol, tobacco, narcotic drugs, marijuana, and other dangerous drugs on a human fetus may be included in the courses of study in grades six through twelve.

*Reporting*

ARIZ. REV. STAT. § 13-3620(B) (2000): A health care professional who is [subject to the statute] and whose routine newborn physical assessment of a newborn infant's health status or whose notification of positive toxicology screens of a newborn infant gives the professional reasonable grounds to believe that the newborn infant may be affected by the presence of alcohol or a substance shall immediately report this information, or cause a report to be made, to child protective services. For the purposes of this subsection, "newborn infant" means a newborn infant who is under thirty days of age.



*Treatment*

ARIZ. REV. STAT. § 8-812(A), (C) (2000): A Child Protective Services expedited substance abuse treatment fund was established to provide expedited substance abuse treatment to parents or guardians with a primary goal of facilitating family preservation or reunification, including, if necessary, services that maintain the family unit in a substance abuse treatment setting.

ARIZ. REV. STAT. § 36-141(B) (2000): In allocating any new and existing undedicated monies available to the Division of Behavioral Health for alcohol and substance abuse, the deputy director shall give priority to treatment services for pregnant abusers of alcohol and other drugs.

## ARKANSAS

*Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

*Statutes**Third-Party Liability*

ARK. CODE ANN. § 16-124-104 (Michie 2001): An individual who was exposed to an illegal drug in utero can bring an action in circuit court for damages against a person who knowingly distributed, or knowingly participated in the chain of distribution of, an illegal drug against the individual.

*Treatment*

ARK. CODE ANN § 20-85-101 (Michie 2001): The Family Treatment and Rehabilitation Program for Addicted Women and Their Children is designed to (1) develop a statewide program of treatment, rehabilitation, prevention, intervention, and relevant research for families affected by maternal addiction by coordinating existing health services, human services, and education and employment resources; (2) develop resources for local treatment and rehabilitation programs for families affected by maternal addiction by providing policy research, technical assistance, and evaluation of program outcomes; (3) identify gaps in service delivery to families affected by maternal addiction and propose solutions; (4) enter in contracts for the delivery of services under the program; (5) solicit, accept, retain and administer gifts, grants or donations of money, services or property for the administration of the program; and (6) provide centralized billing for providers who agree to provide a comprehensive array of specialized coordinated services under or through the program.

## CALIFORNIA

**Case Law**

*In re Troy D*, 263 Cal. Rptr. 869 (Cal. Ct. App. 1989): Appellant mother's infant son was born prematurely and tested positive for amphetamines and opiates. A dependency petition was filed alleging that he came within the provisions of California's child dependency statute. The trial court declared the child a dependent and ordered him detained with his grandmother. The court of appeals affirmed, noting that the child's detrimental condition was caused by appellant's unreasonable acts of ingesting dangerous drugs while pregnant with him, thereby creating a legal presumption that he was a person described by the statute.

*Reyes v. Superior Court of San Bernardino County*, 141 Cal. Rptr. 912 (Cal. Ct. App. 1977): Petitioner mother used heroin during the last two months of her pregnancy, and her twin sons were born addicted to heroin. The state charged her with two counts of felony child endangering, but the court of appeals set the charges aside, finding that California's child endangerment statute was not intended to refer to an unborn child, and therefore Reyes' prenatal conduct did not constitute felonious child endangering within contemplation of the statute.

*People v. Jones*, No. 93-5, Transcript of Record (Cal. J. Ct. July 28, 1993): The Siskiyou County court held that the legislative history of the murder statute did not support its application in a case where a woman's newborn allegedly died because of her prenatal drug use.

*Jaurigue v. People*, No. 18988, slip op. (Cal. Super. Ct. Aug. 21, 1992): The court dismissed fetal homicide charges against a woman who delivered her child stillbirth, allegedly as a result of her prenatal drug use. The court found that neither legislative history nor the statute's language suggested that a woman could be prosecuted for murder for the death of her fetus.

**Statutes***Criminal Statutes*

CAL. PENAL CODE § 1170.82 (Deering 2001): The unlawful selling, furnishing, administering, or giving away of controlled substances to pregnant women, among others, shall be a "circumstance in aggravation of the crime" in imposing a term.

*Education*

CAL. BUS. & PROF. CODE § 2191(f) (Deering 2001): In determining its continuing education requirements, the Division of Licensing for Medical Professionals shall consider including a course in the special care needs of drug-addicted infants to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with these infants.

CAL. EDUC. CODE § 51203 (Deering 2001): Instruction on the effects of alcohol, narcotics, and other dangerous substances upon prenatal development shall be included in the curriculum of all secondary schools.

CAL. EDUC. CODE § 52853 (Deering 2001): California's Education Code

provides for staff development programs on how to successfully work with pupils who have been prenatally substance exposed.

CAL. HEALTH & SAFETY CODE § 11868.5 (Deering 2001): The State Department of Alcohol and Drug Programs shall distribute a brochure to hospitals, public health nurses, child protective services, and alcohol and drug facilities, on the care and treatment of infants under the age of six months who have been exposed to drugs. The brochure shall include, but not be limited to, the following: signs and symptoms of an infant who has been exposed to drugs; the health problems of infants who have been exposed to drugs; and the special feeding and care needs of infants who have been exposed to drugs.

CAL. HEALTH & SAFETY CODE § 130125 (Deering 2001): The California Children and Families Program's guidelines shall address, among other things, avoidance of tobacco, drugs, and alcohol during pregnancy.

### *Evaluation of Programs*

CAL. HEALTH & SAFETY CODE § 124195 (Deering 2001): The Department of Health must submit a report to the state legislature detailing, among other things, the incidence of high-risk pregnant or parenting adolescents who are abusing alcohol and/or drugs; an assessment of the effectiveness of counseling services in reducing the incidence of high-risk pregnant and parenting adolescents who are abusing alcohol and/or drugs; the effectiveness of the component of other health programs aimed at reducing substance use among pregnant and parenting adolescents; and the need for an availability of substance abuse treatment programs that are appropriate, acceptable, and accessible to teenagers.

### *Funding*

CAL. HEALTH & SAFETY CODE § 11757.59 (Deering 2001): Funds distributed for the expansion of the pilot project, Services for Alcohol and Drug Abusing Pregnant and Parenting Women and Their Infants, shall be used by counties to fund residential and nonresidential alcohol and drug treatment programs for pregnant women, postpartum women, and their children, and to fund other support services directed at bringing pregnant and postpartum women into treatment and caring for alcohol- and drug-exposed infants.

CAL. HEALTH & SAFETY CODE § 130105 (Deering 2001): Six percent of the California Children and Families Trust Fund will be deposited in a Mass Media Communications Account for public communications on subjects including the prevention of tobacco, alcohol, and drug use by pregnant women.

### *Identification, Testing, and Reporting*

CAL. HEALTH & SAFETY CODE § 123600 (Deering 2001): The Health and Welfare Agency shall develop and disseminate a model needs assessment protocol for pregnant and postpartum substance abusing women in conjunction with the appropriate professional organizations in the areas of hospital administration, substance abuse prevention and treatment, social services, public health, and appropriate state agencies.

CAL. PENAL CODE § 11165.13 (Deering 2001): A positive toxicology screen at

the time of the delivery of an infant is not in and of itself a sufficient basis for reporting child abuse or neglect. However, any indication of maternal substance abuse shall lead to an assessment of the needs of the mother and child. If other factors indicate risk to a child, then a report shall be made. However, a report based on risk to a child that relates solely to the inability of the parent to provide the child with regular care due to the parent's substance abuse shall be made only to a county welfare or probation department, and not to a law enforcement agency.

CAL. WELF. & INST. CODE § 14148.91(b) (Deering 2001): The State Department of Health Services must report to the legislature and the governor by March 15 of every year the number of newborn babies with fetal alcohol syndrome, the number of babies born with drug dependencies, and whether the mother smoked, consumed alcoholic beverages, or used controlled substances without a prescription, during pregnancy.

#### *Legislative Findings*

CAL. HEALTH & SAFETY CODE § 11781 (Deering 2001): Alcohol and drug treatment is not being accessed by women in proportion to the problems they experience. This can be attributed to, among other things, lack of educational materials appropriate to the community, geographical remoteness, language differences, and lack of representation.

CAL. WELF. & INST. CODE § 14148.9 (Deering 2001): There is a strong statistical relationship between early entry into prenatal care and healthy birth outcomes. One goal of the program established pursuant to this article is to combine efforts with other programs to measurably reduce the number of women who smoke, use drugs, or engage in other unhealthy practices during pregnancy.

#### *Pilot Programs and Task Forces*

CAL. HEALTH & SAFETY CODE § 11757.53 (Deering 2001): The Office of Perinatal Substance Abuse is established to coordinate pilot projects related to perinatal substance abuse; provide technical assistance to entities attempting to address the problem; serve as a clearinghouse of information regarding strategies and programs that address perinatal substance abuse; and review proposals of, and develop proposals for, state agencies regarding the funding of programs relating to perinatal substance abuse.

CAL. HEALTH & SAFETY CODE § 11757.55(c) (Deering 2001): An interagency task force shall develop a coordinated state strategy for addressing the treatment needs of pregnant women, postpartum women, and their children for alcohol or drug abuse.

#### *Third-Party Liability*

CAL. HEALTH & SAFETY CODE § 11705 (Deering 2001): An individual who was exposed to an illegal controlled substance in utero may bring an action for damages caused by an individual's use of an illegal controlled substance against a person who sold, administered, or furnished an illegal controlled substance to the individual user of the illegal controlled substance.

*Treatment*

CAL. CODE REGS. tit. 9, § 10360 (2001): The Department of Alcohol and Drug Programs has promulgated special regulations for drug treatment counselors who discover that a patient is pregnant.

CAL. CODE REGS. tit. 15, § 3074.3 (2001): The Department of Corrections has created a special program called the Family Foundations Program, which is a twelve-month residential substance abuse treatment program for pregnant and/or parenting female inmates who have been determined by the court to benefit from participation, recommended by the court for placement, and are accepted by the Department to participate. Female inmates in the program will be placed in a Family Foundations facility in the community as an alternative to serving their prison term in a state prison institution.

CAL. HEALTH & SAFETY CODE § 104564 (Deering 2001): California requires all counties participating in the "Comprehensive Perinatal Outreach Program" to maintain providing early outreach, pregnancy screening, patient advocacy, targeted case management, health education, and referral to drug and alcohol treatment and perinatal care services to pregnant women.

CAL HEALTH & SAFETY CODE § 104568 (Deering 2001): For purposes of this chapter, "outreach" includes, but is not limited to, coordinated local systems of care-providing pregnancy testing, screening for risk factors, care coordination, referral to appropriate services, including, but not limited to, alcohol and drug treatment, transportation, child care, patient incentives, and assurance of continuous prenatal care including recruitment and retention of physicians.

CAL. HEALTH & SAFETY CODE § 11757.61 (Deering 2001): Counties that receive funding under the Act are required to establish "perinatal coordinating councils" that are to evaluate the extent of the perinatal alcohol and drug abuse problem in the county, coordinate countywide efforts to provide services to affected women and infants, and promote community understanding of the issues surrounding perinatal alcohol and drug abuse.

CAL. HEALTH AND SAFETY CODE § 11998.1 (Deering 2001): Every county drug and alcohol abuse treatment or recovery program that serves women gives priority for services to pregnant women.

CAL. HEALTH & SAFETY CODE § 124190 (Deering 2001): A comprehensive coordinated substance abuse prevention, intervention, and counseling program, shall include programs that have demonstrated a capacity for developing interagency cooperative approaches to reduce the incidence of high-risk pregnant or parenting adolescents. The programs must maximally utilize existing available programs and facilities; have developed goals and objectives for reducing the incidence of high-risk pregnant and parenting adolescents; be culturally and linguistically appropriate to the population being served; and include staff development training by substance abuse counselors.

CAL. PENAL CODE § 1174.4 (Deering 2001): Pregnant women with an established history of substance abuse, or pregnant or parenting women with an established history of substance abuse who have one or more children under six

years old, may participate in an alternative sentencing program.

CAL. WELF. & INST. CODE § 14132.36 (Deering 2001): To the extent that federal financial participation becomes available, residential care for alcohol and drug-exposed pregnant women and women in the postpartum perinatal period is a covered service.

CAL. WELF. & INST. CODE § 14132.90 (Deering 2001): Outpatient drug-free services and day care habilitative services are benefits for alcohol and drug-exposed pregnant women under the Medi-Cal Benefits Program.

## COLORADO

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### *Statutes*

#### *Education*

COLO. REV. STAT. § 25-31-104 (2000): A nurse home visitor program is established to help educate mothers on the importance of nutrition and avoiding alcohol and drugs, including nicotine.

#### *Funding*

COLO. REV. STAT. § 19-3.5-105(1)(f) (2000): Colorado's Children's Trust Fund Board shall expend moneys of the trust fund for the establishment, promotion, and maintenance of prevention programs, including pilot programs, to prevent and reduce the occurrence of prenatal drug exposure.

COLO. REV. STAT. § 25-1-203(2)(g) (2000): The Health Division may make grants to approve public programs that provide education and counseling regarding the use and abuse of alcohol and drugs; programs for prevention of alcohol and drug abuse; and training of teachers, health professionals, and others in the field of alcohol and drug abuse.

#### *Identification*

COLO. REV. STAT. § 26-4-508.2 (2000): Health care practitioners are encouraged to identify pregnant women at risk of a poor birth outcome due to substance abuse during the prenatal period and in need of special assistance to reduce such risk. Any health care practitioner who makes such a determination is encouraged to refer such woman to any entity approved and certified by the Department of Health for the performance of a needs assessment.

#### *Legislative Findings*

COLO. REV. STAT. § 25-1-212 (2000): Colorado is at risk of having poor birth outcomes due to substance abuse during the prenatal period, and early identification of such high-risk pregnant women and substance abuse treatment will greatly reduce the occurrence of poor birth outcomes. In recognition of such

problems, a treatment program for high-risk pregnant women is created.

#### *Treatment*

COLO. REV. STAT. § 25-1-213 (2000): Any entity that qualifies to provide services to the treatment program for high-risk pregnant women, shall make available, in addition to alcohol and drug counseling and treatment: Risk assessment services; care coordination; nutrition assessment; psychosocial counseling; intensive health education, including but not limited to parenting education and education on risk factors and appropriate health behaviors; home visits; transportation services; and other services deemed necessary by the Division of Alcohol and Drug Abuse of the Department of Human Services, the Department of Public Health and Environment, and the Department of Health Care Policy and Financing.

COLO. REV. STAT. § 26-4-302 (2000): The Colorado Medical Assistance Act provides drug and alcohol treatment, including outpatient and residential care, excluding room and board, to pregnant women identified, or women who would be eligible for aid to families with dependent children.

## CONNECTICUT

#### *Case Law:*

*In re Valerie*, 613 A.2d 748 (Conn. 1992): The supreme court ruled that a mother's parental rights of her infant could not be terminated under CONN. GEN. STAT. § 45a-717(f)(2) for her prenatal cocaine use. The court found that the mother could not be a "parent" under the statute until the child is born, and that the infant was not a "child" under the statute until the moment of birth. Therefore, prenatal drug use could not meet the statutory definitions for parental conduct that denied care necessary for physical well-being.

#### *Statutes*

##### *Education*

CONN. AGENCIES REGS. § 19a-59c-4(k)(3)(E) (2000): All local Women, Infants, and Children (WIC) agencies are to provide information to pregnant participants on the dangers of drug, alcohol, and tobacco use during pregnancy. Local WIC agencies are to make appropriate referrals.

##### *Task Force*

CONN. GEN. STAT. § 17a-711 (2001): The Department of Mental Health and Addiction Services shall establish a committee on substance-abusing pregnant women and their children, which will make recommendations to the Department in the development and oversight of treatment programs.

##### *Treatment*

CONN. GEN. STAT. § 17a-710 (2001): The State Department of Mental Health and Addiction Services is required to develop comprehensive programs to provide outreach, treatment, education, medical care, vocational services, and housing to

pregnant women who use drugs and their children, to the extent that private and public funds are available. The Department must include in the state substance abuse plan goals to overcome treatment barriers that are specific to pregnant women and women with children, and to provide increased treatment services and programs to pregnant women. The Department is required to submit an annual report to a legislative committee on the development of programs and statistical and demographic information about women seeking treatment availability.

CONN. GEN. STAT. § 19a-7e (2001): The Department of Public Health and the Office of Health Care Access, in consultation with the Department of Social Services, shall establish a three-year demonstration program to improve access to health care for uninsured pregnant women under 250% of the poverty level. Services to be covered by the program include substance abuse counseling and other ancillary services, which may include substance abuse treatment and mental health services, as required by the patient's condition, history, or circumstances.

## DELAWARE

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### *Statutes*

#### *Education*

DEL. CODE ANN. tit. 16, § 190 (2000); DEL. CODE ANN. tit. 24, § 1770(a) (2000): Professionals who treat, advise, or counsel pregnant women must post and give written and verbal warnings about the possible problems, complications, and injuries to women and/or a fetus resulting from women's consumption or use of alcohol, cocaine, marijuana, heroin, or other narcotics during pregnancy.

## DISTRICT OF COLUMBIA

### *Case Law*

*United States v. Vaughn*, No. F-2172-88B (D.C. Super. Ct. Aug. 23, 1988): The court ordered a drug test on a pregnant woman who was arrested and charged with second-degree theft. After testing positive for cocaine, the woman was sentenced to "a long enough term in jail to be sure that she would not be released until her pregnancy was concluded."

### *Statutes*

#### *Education*

D.C. CODE ANN. § 25-147 (2000): Any person who owns or operates a business establishment that sells alcoholic beverages for consumption, either on or off the premises, must post a sign in a conspicuous place that reads: "Warning: Drinking



alcoholic beverages during pregnancy can cause birth defects.”

### *Treatment*

D.C. CODE ANN. § 32-1602 (2000): All D.C. residents are eligible for substance abuse treatment, regardless of ability to pay, but any minor, pregnant woman, or the parent, guardian, or other person who has legal custody of a minor has priority for admission to the treatment facility over any single adult who does not have a minor child.

## FLORIDA

### *Case Law*

*State v. Johnson*, 602 So. 2d 1288 (Fla. 1992): During her two pregnancies, petitioner used drugs within twenty-four hours of giving birth. She was convicted of delivering a controlled substance to an infant. The appeals court affirmed the convictions, and certified a question to the supreme court as to whether the statute permitted prosecution of a mother who ingested a controlled substance prior to giving birth, and delivered the controlled substance to the infant during the time following the birth, but before the umbilical cord was severed. The supreme court held that petitioner could not be prosecuted because the legislative history indicated that the legislature had rejected a provision that authorized criminal penalties against mothers who delivered drug-affected babies. Such prosecutions violated public policy because they could discourage women from seeking prenatal care.

*State v. Carter*, 602 So. 2d 995 (Fla. Dist. Ct. App 1992): The appeals court affirmed the lower court’s decision to dismiss child abuse charges against a woman who allegedly used illegal drugs while pregnant.

*State v. Gethers*, 585 So. 2d 1140 (Fla. Dist. Ct. App. 1991): Appellee was charged with child abuse for allegedly injuring her unborn child as a result of her use of cocaine during pregnancy. The trial court dismissed on the grounds that the statute did not criminalize the alleged conduct. On appeal, the state contended that the child abuse statute was amended to include injuries to an unborn child that are sustained during gestation. The court of appeals rejected the state’s position and affirmed the dismissal of charges, finding that the legislature specifically rejected criminal prosecution of mothers who gave birth to drug dependent children. The court noted that the state’s construction of the statute was at odds with the public policy of preserving the family life of the parents and children. Moreover, the court noted that potential criminal liability would also encourage addicted women to terminate or conceal their pregnancies.

### *Statutes*

#### *Child Abuse*

FLA. STAT. ch. 39.01 (2000): Among the definitions of “harm” to a child’s health and welfare is when a parent, legal custodian, or caregiver responsible for

the child's welfare exposes a child to a controlled substance or alcohol. Exposure to a controlled substance or alcohol is established by the mother's use of a controlled substance or alcohol during pregnancy when the child, at birth, is demonstrably adversely affected by such usage; or continued chronic and severe use of a controlled substance or alcohol by a parent when the child is demonstrably adversely affected by such usage.

FLA. STAT. ch. 39.828 (2000): The court shall appoint a guardian advocate for an initial term of one year upon a finding that any child named in a petition is or was a drug dependent newborn.

### *Education*

FLA. STAT. ch. 20.43(7)(b) (2000): The State Department of Health is authorized to purchase promotional messages that recognize that alcohol consumption or other substance abuse during pregnancy is detrimental to the public's health.

FLA. STAT. ch. 383.311(2)(d) (2000): Clients and families utilizing birth centers in the state are to be provided information on the effects of smoking and substance abuse.

FLA. STAT. ch. 985.416(4)(e) (2000): The Department of Juvenile Justice must encourage individual district juvenile justice boards to propose an "innovation zone" within their district. In the list of program models for the innovation zone projects, the legislature includes: An infant mortality prevention program that is designed to discourage unhealthy behaviors such as smoking and alcohol or drug consumption, reduce the incidence of babies born prematurely or with low birth weight, reduce health care cost by enabling babies to be safely discharged earlier from the hospital, reduce the incidence of child abuse and neglect, and improve parenting and problem-solving skills.

### *Identification*

FLA. STAT. ch. 383.14 (2000): The Department shall promote the identification and screening of all infants born in this state and their families for factors including substance abuse. Identification, perinatal screening, and intervention efforts shall begin prior to and immediately following the birth of the child by the attending health care provider.

### *Legislative Findings*

FLA. STAT. ch. 391.301 (2000): There is an identifiable and increasing number of infants who need developmental evaluation and intervention due to parent risk factors, such as substance abuse. It is the intent of the legislature to establish developmental evaluation and intervention services so that families with high-risk or disabled infants may gain the services and skills they need to support their infants.

### *Services to Children*

FLA. STAT. ch. 411.202(6) (2000): A drug-exposed child is found to be in need of early childhood assistance if there is documented evidence that the mother used illicit drugs or was a substance abuser, or both, during pregnancy and the

child exhibits abnormalities as defined under law.

FLA. STAT. ch. 230.2305(2) (2000): The Pre-Kindergarten Early Intervention Program, whose target population is children who come from low-income families, will also include three- and four-year olds who may not be economically disadvantaged but who are prenatally exposed to alcohol or harmful drugs.

#### *Task Force*

FLA. STAT. ch. 411.232 (2000): Florida created a Children's Early Investment Program to reduce the numbers of cocaine babies born in the state.

#### *Treatment*

FLA. ADMIN. CODE ANN. r. 64F-4.001 - .010 (2000): Florida regulations for the Department of Health establish a system for reporting and treating drug dependent newborns and pregnant women. The system includes giving out information about the adverse effects of prenatal exposure to alcohol and drugs, reporting pregnant drug users to the appropriate agencies, providing treatment to those women, and investigating the circumstances surrounding the pregnancy. The regulations require reporting abuse under the state's abuse registry.

FLA. STAT. ch. 154.011(4) (2000): Under the Improved Pregnancy Outcome Program, financially eligible women at risk for adverse pregnancy outcomes due to any potential medical complication shall not be denied access to prenatal care. Potential medical complications may arise out of, but not be limited to, alcohol abuse, drug abuse, or delay in obtaining initial prenatal care. The inability of the primary care program to provide funding for hospitalization or other acute services shall not preclude an eligible patient from obtaining prenatal services.

FLA. STAT. ch. 381.0045 (2000): The Targeted Outreach for Pregnant Women Act establishes an outreach program for high-risk pregnant women who may not seek proper prenatal care. Among other services, the program shall link women with substance abuse treatment, when available, and act as a liaison with Healthy Start coalitions, children's medical services, Ryan White-funded providers, and other services of the Department of Health.

## GEORGIA

### *Case Law*

*State v. Luster*, 419 S.E.2d 32 (Ga. Ct. App. 1992): The court found that although a pregnant woman can be prosecuted for drug possession, she cannot be prosecuted for delivery of narcotics to her fetus. Under Georgia law, "deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled substance.... The court ruled that, "the word 'person' in a criminal statute may not be construed to include a fetus unless the legislature has expressly included it, since at common law a fetus was not considered a person." (citing *Billingsley v. State*, 360 S.E.2d 451 (Ga. Ct. App. 1987)).

## ***Statutes***

### ***Education***

GA. CODE ANN. § 3-1-5 (2000): All retailers of alcoholic beverages for consumption on the premises must post a warning in a conspicuous place that reads: "Warning: Drinking alcoholic beverages during pregnancy can cause birth defects." Failure or refusal to post the sign shall result in a fine not to exceed \$100.00 for each violation.

### ***Third-Party Liability***

GA. CODE ANN. § 51-1-46 (2000): Any person injured by an individual drug abuser may bring an action for damages against a person who participated in illegal marketing of the controlled substance used by the individual abuser. Plaintiffs under the statute can include a child whose mother was an individual abuser while the child was in utero.

### ***Treatment***

GA. CODE ANN. § 26-5-5 (2000): At a minimum, drug abuse treatment and education programs shall establish criteria for providing priority to drug-dependent pregnant females.

GA. CODE ANN. § 26-5-20 (2000): Any program licensed or funded by the Department of Health shall implement a priority admissions policy for the treatment of drug-dependent pregnant females that provides for immediate access to services for any such female applying for admission, contingent only upon the availability of space.

## **HAWAII**

## ***Case Law***

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

## ***Statutes***

### ***Education***

HAW. REV. STAT. § 572-5(d) (2000): The department or its authorized agents shall furnish to each applicant for a marriage license information, to be provided by the department, relating to fetal alcohol and drug syndromes.

### ***Third-Party Liability***

HAW. REV. STAT. § 663D-3 (2000) (to be repealed June 30, 2003): The Drug Dealer Liability Act allows an individual who was exposed to an illegal drug in utero to bring an action to recover damages against the distributors and marketers of the illegal drug actually used by the mother.

## IDAHO

**Case Law**

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

**Statutes***Child Abuse*

1991 Op. Att'y. Gen. Idaho 5: Idaho's Attorney General stated that Idaho's Child Protective Act, IDAHO CODE § 16-1603, "could be amended by the Idaho Legislature to provide specific legal rights and protections for the unborn," as the state does have a compelling interest in protecting potential human life from gestational drug abuse, but the Act presently would not permit the state to intervene in the case of gestational drug abuse, and an action brought under the Act would likely be dismissed for lack of jurisdiction.

## ILLINOIS

**Case Law**

*People v. Bedenkop*, 625 N.E.2d 123 (Ill. App. Ct. 1993): A woman was charged with possession of a controlled substance with intent to deliver, and delivery of a controlled substance, after her newborn tested positive for cocaine. The trial court sentenced her to two years of probation, and her child was placed in foster care. After she allegedly failed to appear at a probation hearing, the trial judge sentenced her to seven years in prison. On appeal, the Appellate Court of Illinois reversed the decision and remanded the case back to the trial court, finding that the woman was deprived of her due process rights. The appellate court also noted the trial judge's comment "that he was sentencing [the] defendant to seven years not to punish her, but to prevent her from becoming pregnant." In response, the appellate court stated, "[s]ince the trial court recognized that he could not force defendant to be sterilized, he should also have realized that he could not sentence defendant to seven years imprisonment as a means of pregnancy prevention."

**Statutes***Child Abuse*

325 ILL. COMP. STAT. 5/3 (2001): Under the Abused and Neglected Child Reporting Act, a neglected child includes a newborn infant whose blood, urine, or meconium contains any amount of a controlled substance or a metabolite thereof, with the exception of a controlled substance or metabolite thereof whose presence in the newborn infant is the result of medical treatment administered to the mother or the newborn.

705 ILL. COMP. STAT. 405/2-3 (2001): Under the Juvenile Court Act, a neglected or abused minor also includes a newborn infant whose blood, urine, or

meconium contains any amount of a controlled substance or a metabolite thereof, with the exception of a controlled substance or metabolite thereof whose presence in the newborn infant is the result of medical treatment administered to the mother or the newborn.

705 ILL. COMP. STAT. 405/2-18 (2001): Prima facie evidence of abuse or neglect is established with proof that a minor has a medical diagnosis at birth of withdrawal symptoms from narcotics or barbiturates, proof that a minor has a medical diagnosis of fetal alcohol syndrome, or proof that a newborn infant's blood, urine, or meconium contains any amount of a controlled substance, which is not the result of medical treatment administered to the mother or the newborn.

750 ILL. COMP. STAT. 50/1(D)(k) (2001): There is a rebuttable presumption that a parent is unfit with respect to any child to which that parent gives birth where there is a confirmed test result that at birth the child's blood, urine, or meconium contained any amount of a controlled substance or metabolites of such substances, the presence of which in the newborn infant was not the result of medical treatment administered to the mother or the newborn infant; and the biological mother of this child is the biological mother of at least one other child who was adjudicated a neglected minor.

### *Criminal*

720 ILL. COMP. STAT. 570/407.2 (2001): Delivery of a controlled substance to woman known to be pregnant is a Class 1 felony. The perpetrator is subject to a term of imprisonment twice the maximum otherwise authorized under law.

720 ILL. COMP. STAT. 600/3 (2001): Anyone who sells or delivers, for commercial consideration, any item of drug paraphernalia to a woman known to be pregnant is guilty of a Class 2 felony.

### *Education*

20 ILL. COMP. STAT. 505/34.11 (2001): The grandparent child care program, which provides services to grandparents who have custody of their grandchildren, must establish an informational and educational program for grandparents and other relatives who provide primary care for children at risk of child abuse, neglect, or abandonment, or who were born to substance-abusing mothers.

20 ILL. COMP. STAT. 2310/2310-440 (2001): The Department of Public Health is required to conduct an ongoing, statewide education program to inform pregnant women of the medical consequences of alcohol, drug, and tobacco use and abuse.

235 ILL. COMP. STAT. 5/6-24a (2001): The General Assembly finds that there is a need for public information about the risk of birth defects (specifically fetal alcohol syndrome) when women consume alcoholic liquor during pregnancy. The United States Surgeon General has recommended abstinence from alcohol during pregnancy. Since fetal alcohol syndrome and fetal alcohol effects are preventable, the General Assembly finds that it is in the public interest to provide warning about the risk of alcohol-related birth defects at places where alcoholic liquors are sold. Every holder of a retail license, whether the licensee sells or offers for sale alcoholic liquors for use or consumption on or off the retail license premises, shall

cause a sign with the message "Government warning: According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects" to be framed and hung in plain view.

### *Funding*

55 ILL. COMP. STAT. 5/5-1086.1 (2001): The legislature mandated the establishment of a Substance Abuse Services Fund in certain counties. Monies in the substance abuse fund shall only be appropriated by the county board to be used within the county where collected for the establishment and maintenance of facilities and programs for the medical care, treatment or rehabilitation of all persons suffering from substance abuse problems, including the hospitalization of pregnant women who are addicted to alcohol, cannabis, or controlled substances, and for needed care of their newborn children.

720 ILL. COMP. STAT. 570/411.2 (2001): Some collected fines are used for the treatment of pregnant women who are addicted to alcohol, cannabis, or controlled substances and for the needed care of minor, unemancipated children of women undergoing residential drug treatment.

### *Identification and Reporting*

325 ILL. COMP. STAT. 5/7.3b (2001): All persons required to report child abuse may refer to the Department of Human Services any pregnant person in the state who is addicted as defined in the Alcoholism and Other Drug Abuse and Dependency Act. The Department of Human Services shall notify the local Infant Mortality Reduction Network service provider or Department funded prenatal care provider in the area in which the person resides. The service provider shall prepare a case management plan and assist the pregnant woman in obtaining counseling and treatment from a local substance abuse service provider licensed by the Department of Human Services or a licensed hospital, which provides substance abuse treatment services. The local Infant Mortality Reduction Network service provider and Department funded prenatal care provider shall monitor the pregnant woman through the service program.

### *Legislative Findings*

740 ILL. COMP. STAT. 20/2 (2001): Abuse of cannabis and controlled substances causes death or severe and often irreversible injuries to newborn children.

### *Third-Party Liability*

740 ILL. COMP. STAT. 57/25 (2001): The Drug Dealer Liability Act provides a civil remedy for damages to persons in a community who are injured as a result of illegal drug use. Such persons include infants who are injured as a result of exposure to drugs in utero.

### *Treatment*

20 ILL. COMP. STAT. 301/5-10 (2001): To ensure a multidisciplinary delivery of services to addicted pregnant women and to instruct them about the effects of substance abuse on infants and guidelines on the symptoms, care, and comfort of drug-withdrawing infants, the Department of Health must conduct and report

demographic research, seek funding for, and establish effective outreach programs targeted to, women at risk, maintain up-to-date referral lists of treatment providers, create and publish educational materials, and create a manual for service providers to assist them in identifying women at risk.

20 ILL. COMP. STAT. 301/35-5 (2001): In order to promote a comprehensive, statewide, and multidisciplinary approach to serving addicted pregnant women, the Department of Health shall have responsibility for an ongoing exchange of referral information among those who provide medical and social services to pregnant women, whether or not there exists evidence of alcoholism or other drug abuse or dependency, and providers of treatment services to women affected by alcoholism or other drug abuse or dependency.

20 ILL. COMP. STAT. 301/35-10 (2001): The Adolescent Family Life Program is designed to document the incidence of and coordinate services to high-risk pregnant adolescents who use alcohol in excess, who are addicted to a controlled substance, or who habitually use cannabis during pregnancy.

305 ILL. COMP. STAT. 5/5-5 (2001): Health care providers are required to recommend, to any pregnant woman who is suspected of drug abuse or is addicted, referral to a local substance abuse treatment provider or to a licensed hospital that provides substance abuse treatment services. The Department of Health and the Department of Human Services may provide information about substance abuse during pregnancy in a public awareness campaign. The statute prohibits the Illinois Department of Public Aid and the Department of Human Services from sanctioning a recipient based solely on her substance abuse.

## INDIANA

### Case Law

*Herron v. State*, 729 N.E.2d. 1008 (Ind. Ct. App. 2000): The state charged a woman with neglect of her newborn based on her ingestion of cocaine during pregnancy and the subsequent birth of her child with cocaine present in his system. The trial court denied the mother's motion to dismiss, and on appeal, the Indiana Court of Appeals found that the "neglect of a dependent statute," IND. CODE § 35-46-1-4, did not apply to the defendant's drug use during pregnancy because an unborn child is not a dependent. The court noted that the statute defined a dependent as "an unemancipated person who is under eighteen years of age," or "a person of any age who is mentally or physically disabled." The court concluded, "we cannot expand the General Assembly's definition of a dependent and, consequently, the intended application of the neglect of a dependent statute, beyond the fair meaning of the words used. IC 35-46-1-1 and IC 35-46-1-4 do not criminalize conduct that occurs prior to a child's birth."

*State v. Barnett*, No. 021304-9308-CF-61 1, order (Ind. Super. Ct. 1994): The court dismissed reckless homicide charges against a woman who allegedly used drugs during pregnancy, and whose baby was born alive and subsequently died.



***Statutes******Child Abuse***

IND. CODE. § 31-9-2-14 (2000): Child abuse or neglect refers to a child who is alleged to be in need of services.

IND. CODE § 31-34-1-10 (2000): A child is in need of services if (1) the child is born with fetal alcohol syndrome or any amount of a controlled substance or a legend drug in the his/her body; and (2) the child needs care, treatment, or rehabilitation that he/she is not receiving, or is unlikely to be provided or accepted without the coercive intervention of the court.

IND. CODE § 31-34-1-11 (2000): A child is in need of services if the child (1) has an injury, abnormal physical or psychological development, or is at a substantial risk of a life threatening condition as a result of the mother's use of alcohol, a controlled substance, or a legend drug during pregnancy; and (2) the child needs care, treatment, or rehabilitation that the child is not receiving or is unlikely to be provided or accepted without the coercive intervention of the court.

IND. CODE §§ 31-34-1-12, 31-34-1-13 (2000): A child is not in need of services if a mother uses legend drugs or controlled substances with a physician's prescription and makes a good-faith attempt to follow the prescription.

IND. CODE § 31-34-2-2 (2000): A law enforcement official may take into custody anyone who is believed to be the alleged perpetrator of an act against a child who the law enforcement officer believes to be a child in need of services as a result of the alleged perpetrator's act. The individual is to be taken into custody only for the purpose of removing the alleged perpetrator from the residence where the child believed to be in need of services resides.

IND. CODE § 31-34-20-1 (2000): If a child is found to be in need of services, a juvenile court may order a variety of remedies, including removing the child from the home, requiring the parents of the child or the child to receive services, fully emancipating the child, or entering a protective order on behalf of the child.

***Third-Party Liability***

IND. CODE § 34-24-4-2 (2000): The Drug Dealer Liability Act allows individuals who were exposed to an illegal drug in utero to bring an action for damages caused by an individual drug user's use of an illegal drug.

***Iowa******Case Law***

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

***Statutes******Child Abuse***

IOWA CODE § 232.68(2)(f) (2001): Child abuse includes when an illegal drug

is present in a child's body as a direct and foreseeable consequence of the acts or omissions of the person responsible for the care of the child.

### *Education*

IOWA CODE § 135G.9 (2001): Among the information to be given to clients and families utilizing birth centers is information on the effects of smoking and substance abuse on a developing fetus.

### *Task Force*

IOWA CODE § 235C.1-.3 (2001): A Council on Chemically Exposed Infants and Children is established to help the state develop and implement policies to reduce the likelihood that infants will be born chemically exposed, and to assist those who are born chemically exposed to grow and develop in a safe environment. The Council is responsible for: collecting data on chemically exposed infants and the costs of caring for such infants; making recommendations on public awareness campaigns and training for medical providers; developing strategies for identification and intervention; seeking funding to enhance treatment services to women and children; developing strategies for identifying chemically exposed infants when they enter the school system and providing special services to them; assisting in expanding "appropriate placement options for chemically exposed infants and children who have been abandoned by their parents or cannot safely be returned home;" and determining whether treatment providers are discriminating against substance abusing pregnant women.

### *Testing and Reporting*

IOWA CODE § 232.77(2) (2001): If a health practitioner discovers in a child physical or behavioral symptoms of the effects of exposure to cocaine, heroin, amphetamine, methamphetamine, or other illegal drugs, or combinations or derivatives thereof, which were not prescribed by a health practitioner, or if the health practitioner has determined through examination of the natural mother of the child that the child was exposed in utero, the health practitioner may perform a medically relevant test on the child. The practitioner shall report any positive results of such a test on the child to the department. A positive test result obtained prior to the birth of a child shall not be used for the criminal prosecution of a parent for acts and omissions resulting in intrauterine exposure of the child to an illegal drug.

### *Treatment*

IOWA CODE § 125.32A (2001): Any state substance abuse treatment program may not discriminate against a person seeking treatment solely because the person is pregnant, unless the program in each instance identifies and refers the person to an alternative and acceptable treatment program.

**KANSAS*****Case Law***

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

***Statutes******Education***

KAN. STAT. ANN. § 65-1,161 (2000): The Secretary of Health and Environment shall provide educational materials and guidance to health care professionals who provide health services to pregnant women for the purpose of assuring accurate and appropriate patient education. Such materials and guidance shall address the services that are available to pregnant women from local health departments and the perinatal effects of the use of tobacco, the use of alcohol, and the use of any controlled substance.

KAN. STAT. ANN. § 65-1,162 (2000): The Secretary of Health and Environment shall provide an educational program to health care professionals who provide health care services to pregnant women for the purpose of assuring accurate and appropriate patient education regarding the effects of drugs on pregnancy and fetal outcome; taking accurate and complete drug histories; and counseling techniques for drug abusing women to improve referral to and compliance with drug treatment programs.

KAN. STAT. ANN. § 65-1,166 (2000): The Secretary of Health and Environment shall maintain a toll-free information line for the purpose of providing information on substance abuse treatment and referrals for substance abusing pregnant women.

***Identification and Reporting***

KAN. STAT. ANN. § 65-1,163 (2000): The Secretary of Health and Environment shall develop a risk assessment profile to assist health care providers screen pregnant women for prenatal substance abuse. Any health care provider who identifies a pregnant woman as at-risk for prenatal substance abuse may refer such woman, with her consent, to the local health department for service coordination.

***Treatment***

KAN. STAT. ANN. § 65-1,165 (2000): A pregnant woman referred for substance abuse treatment shall be a first priority user of substance abuse treatment available through social and rehabilitation services. All records and reports regarding such pregnant woman shall be kept confidential. Family oriented substance abuse treatment is available. Substance abuse treatment facilities that receive public funds shall not refuse to treat women solely because they are pregnant.

## KENTUCKY

*Case Law*

*Commonwealth v. Welch*, 864 S.W.2d 280 (Ky. 1993): A woman was charged with criminal abuse because her newborn suffered from neonatal abstinence syndrome as a result of the mother's intermittent drug use during pregnancy. The trial court found her guilty of criminal abuse under KY. REV. STAT. ANN. § 508.110. The court of appeals vacated the conviction of criminal abuse and on appeal, the Kentucky Supreme Court affirmed the court of appeal's decision. The court held that KY. REV. STAT. ANN. § 508.110 could not be used to prosecute a mother for injury to an unborn child because it would violate legislative intent. The court also observed that the Kentucky Maternal Health Act of 1992 amends KY. REV. STAT. ANN. § 218A.990 to enhance punishment for those who traffic controlled substances to a pregnant woman, but provides no additional punitive measures for maternal drug use during pregnancy. The court stated that the General Assembly thus had not intended to criminalize maternal self-abuse that leads to damage in the newborn, but had opted instead to create public health initiatives to combat the problem.

*Statutes**Education*

KY. REV. STAT. ANN. § 200.703 (Michie 2001): The Healthy Babies Work Group shall collaborate on development and implementation of a public awareness campaign to inform the citizens of the Commonwealth about the benefits of good nutrition, folic acid, smoking cessation, healthy lifestyle choices that lead to healthy babies, the effects of alcohol and substance abuse on fetal and early childhood development, and the need for a vision examination of children at age three.

*Identification and Reporting*

KY. REV. STAT. ANN. § 214.160 (Michie 2001): Attending health care practitioners may screen pregnant women for alcohol or substance dependency or abuse by administering a toxicology test to a pregnant woman and/or her newborn infant within eight hours after delivery. The attending physician has the duty to evaluate positive test results and to determine whether to make a report to the state. Toxicology testing cannot be done without first providing notice of the purpose of the test to the woman, and no prenatal screening for alcohol or other substance abuse or positive toxicology finding shall be used as prosecutorial evidence.

*Task Forces and Research*

KY. REV. STAT. ANN. § 214.175 (Michie 2001): The Cabinet for Health Services may conduct periodic anonymous surveys to determine the prevalence within the Commonwealth of drug and alcohol use during pregnancy. These periodic surveys may include, but are not limited to, toxicology tests to determine the presence of alcohol, controlled substances, or other drugs, which have not been prescribed due to medical necessity. Testing may be done without a physician's order and

without the consent of the patient or parent. Results of individual toxicology tests are confidential, not admissible in court, and are to be compiled in an anonymous, aggregate fashion.

KY. REV. STAT. ANN. § 222.021 (Michie 2001): There is hereby created within the Cabinet for Health Services a Substance Abuse, Pregnancy, and Women of Childbearing Age Work Group. The Work Group shall carry out the planning and coordinating activities of the Commonwealth with regard to smoking cessation and prevention, and substance dependency and abuse, among pregnant women and other women of childbearing age.

KY. REV. STAT. ANN. § 222.037 (Michie 2001): The Cabinet for Health Services may establish four or more pilot projects within the Commonwealth to demonstrate the effectiveness of different methods of providing community services to prevent smoking, alcohol, and substance abuse by pregnant females; improving agency coordination to better identify the pregnant smoker and substance abuser and other females who have smoking and substance abuse problems; linking with community services and treatment for the chemically dependent woman, her children, and other family members; and gaining access to early intervention services for infants in need.

## LOUISIANA

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### *Statutes*

#### *Legislative Mandates*

LA. REV. STAT. ANN. § 46:2505 (West 2000): The Department of Health and Hospitals shall establish a program to provide addictive disorders services to eligible pregnant women. Such services shall ensure the availability of appropriate addictive disorders treatment programs that do not discriminate against pregnant women or women with young children. The program will increase public awareness about addictive disorders; develop criteria giving pregnant women priority access to publicly funded addictive disorders treatment programs; develop residential treatment programs designed for addiction-disordered women and children; and encourage health care professionals to identify addiction-disordered pregnant women and make referrals to programs.

#### *Task Forces*

LA. REV. STAT. ANN. § 40:2018 (West 2000): The Commission on Perinatal Care and Prevention of Infant Mortality is created to research state laws that impact perinatal care, compile information about infant mortality, and propose a plan for an equitable system of financing comprehensive health and social services for indigent pregnant women and infants. Among the goals of the Commission to

educate women of child-bearing age on the hazards of smoking, alcohol, pharmaceutical products, and other drugs during pregnancy and nursing.

LA. REV. STAT. ANN. § 46:2511 (West 2000): The legislature recognizes the need for increased public awareness regarding the desire for drug- and alcohol-free pregnancies to reduce the incidence of chemically exposed infants. The Council to Prevent Chemically Exposed Infants is thus established to assist the state in developing policies to reduce the likelihood that infants will be born chemically exposed.

LA. REV. STAT. ANN. § 46:2514 (West 2000): The Council shall gather data and make recommendations to assist the state in developing policies to reduce the number of infants who are born chemically exposed and shall report its findings and recommendations. The council is directed to submit a report regarding state laws, policies, or programs to reduce the incidence of chemically exposed infants and to improve effective treatment services for pregnant women and chemically exposed infants; about how to improve services to pregnant substance users; and on conducting a public education campaign aimed at the general public, health care professionals, and at-risk populations.

#### *Third-Party Liability*

LA. REV. STAT. ANN. § 9:2800.63 (West 2000): An individual who was exposed to an illegal controlled substance in utero may bring an action for damages caused by an individual's use of an illegal controlled substance against the person who sold, administered, or furnished an illegal controlled substance to the individual user, and other people enumerated in the statute.

## MAINE

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### *Statutes*

#### *Adoption*

ME. REV. STAT. ANN. tit. 18-A, § 9-30.4 (West 2000): A current medical, psychological, and developmental history of the child for adoption is to be provided to prospective parents. This record is to include an account of the child's prenatal care and medical condition at birth, results of newborn screening, any drug or medication taken by the child's biological mother during pregnancy, any subsequent medical, psychological or psychiatric examination and diagnosis the biological parents' use of drugs and alcohol, the health of the biological mother during her pregnancy, and the health of the biological parents at the time of the child's birth.

## MARYLAND

*Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

*Statutes**Child Abuse*

MD. CTS. & JUD. PROC. § 3-801.1 (2001): There is a presumption that a child is not receiving ordinary and proper care and attention if the child was born addicted to or dependent on cocaine, heroin, or a derivative thereof, or was born with a significant presence of cocaine, heroin, or a derivative thereof in the child's blood as evidenced by toxicology or other appropriate tests.

MD. CODE ANN., FAM. LAW § 5-313(d)(1)(iv) (2001): In determining whether it is in the best interest of the child to terminate a natural parent's rights to the child...the court shall consider the factors in subsection (c) of this section and whether the child was born: (a) addicted to or dependent on cocaine, heroin, or a derivative thereof; or (b) with a significant presence of cocaine, heroin, or a derivative thereof in the child's blood as evidenced by toxicology.

MD. CODE ANN., FAM. LAW § 5-710(b) (2001): Promptly after receiving a report from a hospital or health practitioner of suspected neglect related to drug abuse and conducting an appropriate investigation, a local department of social services may file a petition alleging that the child is in need of assistance, offer the mother admission into a drug treatment program, and initiate a judicial proceeding to terminate a mother's parental rights, if the local department offers the mother admission into a drug treatment program within ninety days after the birth of the child and the mother does not accept admission to the program or its equivalent within forty-five days after the offer is made or fails to fully participate in the program or its equivalent.

*Task Force*

MD. ANN. CODE, art. 41, § 18-316 (2001): A task force was established to study increasing the availability of substance abuse programs. One task includes the development of a comprehensive strategy for funding substance abuse programs and examining the availability of substance abuse programs designed for women, pregnant women, and women with children.

*Treatment*

MD. CODE ANN., FAM. LAW § 5-706.3 (2001): The Department of Human Resources, in conjunction with the Department of Health and Mental Hygiene, is required to develop intervention systems in four of the state's counties to provide drug treatment for mothers whose children are born exposed to drugs, as well as supportive services for the family of the children.

MD. CODE ANN., HEALTH-GEN. § 8-403.1 (2001): In consultation with the Office of Maternal Health and Family Planning, the Administration shall develop a

referral procedure to require alcohol abuse and drug abuse treatment programs or facilities that are owned or operated by the state or any of its political subdivisions, or that receive partial or full funding from the state, to operate an alcohol abuse and drug abuse treatment program to accept pregnant or postpartum women for treatment on a priority basis.

MD. CODE ANN., HEALTH-GEN. § 15-103(b)(9) (2001): Each managed care organization shall provide or assure alcohol and drug abuse treatment for substance abusing pregnant women and all other enrollees of managed care organizations who require these services.

## MASSACHUSETTS

### *Case Law*

*Commonwealth v. Pellegrini*, 608 N.E.2d 717 (Mass. 1993): A woman was prosecuted for possession of narcotics after her newborn tested positive for cocaine metabolites. In reversing the trial court's decision to dismiss the case, the Massachusetts Supreme Judicial Court did not decide the issue of whether a newborn's hospital records, which revealed cocaine metabolites in the child's urine, could be used to prosecute the mother for possession of narcotics. However, the court did cite MASS. GEN. LAWS ch. 119, § 51A, stating that the legislature has recognized that prenatal exposure to a controlled substance is probative of neglect by the mother. The case was remanded to the superior court.

### *Statutes*

#### *Education*

MASS. GEN. LAWS ch. 29, § 2GG(C) (2001): Funding for the support of community health centers and their programs of prenatal and maternal care is contingent on their incorporation of smoking cessation assistance and guidance regarding the harmful effects of smoking on fetal development.

MASS. REGS. CODE tit. 105, § 142.620(E) (2001): All Department of Health operated and maintained birth centers must provide a program of prenatal education that shall include the importance of nutrition, preparation for birth and breast feeding, and information on adverse effects of smoking, alcohol, and other drugs.

#### *Funding*

MASS. REGS. CODE tit. 130, § 418.410 (2001): The Division of Medical Assistance will pay for special substance abuse treatment services for pregnant women.

#### *Reporting*

MASS. GEN. LAWS ch. 119, § 51A (2001): If a child is determined to be physically dependent upon an addictive drug at birth, the provider must immediately report such condition to the Department of Public Welfare by oral communication.



*Treatment*

MASS. REGS. CODE tit. 105, § 130.615(H) (2001): Every maternal-newborn service shall have written protocols for the hospital management and support of patients from identified groups in the population served by the facility, who have special needs, e.g., adolescents, and mothers with known cognitive impairments, psychiatric or substance abuse problems.

MASS. REGS. CODE tit. 105, § 750.720 (C)(5) (2001): All methadone treatment programs in the state must take precautions with pregnant women on methadone maintenance programs because of all its attendant dangers during pregnancy. Dosage levels shall be maintained as low as possible, and the treatment center must make arrangements for the provision of prenatal and delivery services.

## MICHIGAN

*Case Law*

*People v. Hardy*, 469 N.W.2d 50 (Mich. Ct. App. 1991): Hardy was prosecuted for the delivery of drugs to her newborn infant. The prosecutor focused on the time between when the infant was born (hence obtaining legal personhood) and the moment the umbilical cord was cut, and charged that the blood flow via the umbilical cord constituted drug delivery to a minor. The court of appeals rejected this argument, noting that the drug delivery statutes did not specifically cover prenatal drug use, that “penal statutes are strictly construed, absent a legislative statement to the contrary. . .,” and that the courts are not the place to interpret laws broadly.

*In Re Baby X*, 293 N.W.2d 736 (Mich. Ct. App. 1980): Baby X, within twenty-four hours of birth, began exhibiting symptoms of drug withdrawal. The Department of Social Services petitioned the probate court to assert jurisdiction over the child because of the mother’s neglect, and the probate court granted that petition. The Michigan Court of Appeals held that “a newborn suffering narcotics withdrawal syndrome as a consequence of prenatal maternal drug addiction may properly be considered a neglected child....” The court did not rule on whether prenatal drug use was sufficient for permanent loss of parental rights, but only that it was sufficient for temporary loss of custody.

*People v. Bremer*, No. 90-32227-FH, slip op. (Mich. Cir. Ct. Jan. 31, 1991): The circuit court dismissed drug delivery charges on principles of statutory construction, due process, and privacy, holding that the interpretation of the drug delivery law to cover ingestion of cocaine by a pregnant woman would be a radical departure from existing law.

*People v. Cox*, No. 90-53454-FH, slip op. (Mich. Cir. Ct. July 9, 1990): The circuit court granted the motion to dismiss on grounds that the drug delivery statute is not intended to regulate conduct during pregnancy and that prosecution would not be in the best interest of public health, safety, and welfare.

## *Statutes*

### *Adoption*

MICH. COMP. LAWS § 710.27 (2000): The prospective adoptive parent is to be provided with a written document containing an account of the child's prenatal care; medical condition at birth; and any drug or medication taken by the child's mother during pregnancy.

### *Reporting*

MICH. COMP. LAWS § 722.623a (2000): A person who by law is required to report suspected child abuse or neglect, and who knows, or from the child's symptoms has reasonable cause to suspect, that a newborn infant has any amount of alcohol, a controlled substance, or a metabolite of a controlled substance in his or her body, shall report this information to the agency for child protection.

### *Third-Party Liability*

MICH. COMP. LAWS § 691.1607 (2000): A person injured by an individual drug abuser may bring an action for damages against a person who participated in illegal marketing of the substance used by the individual abuser. If the plaintiff is a child whose mother was an individual abuser while the child was in utero, then the defendant is presumed to have injured the plaintiff and to have acted willfully and wantonly.

## MINNESOTA

## *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

## *Statutes*

### *Child Abuse*

MINN. STAT. § 626.556(2)(c) (2000): Neglect is defined as, among other things, prenatal exposure to a controlled substance used by the mother for a nonmedical purpose, as evidenced by withdrawal symptoms in the child at birth, results of a toxicology test performed on the mother at delivery or the child at birth, or medical effects or developmental delays during the child's first year of life that medically indicate prenatal exposure to a controlled substance.

### *Education*

MINN. STAT. § 214.12(3) (2000): The board of medical practice and the board of nursing shall require that family practitioners, pediatricians, obstetricians and gynecologists, and other licensees who have primary responsibility for diagnosing and treating fetal alcohol syndrome in pregnant women or children receive education on the subject of fetal alcohol syndrome and fetal alcohol effects, including how to: (1) screen pregnant women for alcohol abuse; (2) identify affected children; and (3) provide referral information on needed services.

MINN. STAT. § 340A.410 (2000): Any licensed retailer of alcoholic beverages must post a sign that includes a warning statement regarding drinking alcohol while pregnant.

*Identification, Testing, and Reporting*

MINN. STAT. § 253B.02(2) (2000): A chemically dependent person includes a pregnant woman who has engaged in habitual or excessive use, for a nonmedical purpose, of any of the following controlled substances or their derivatives during pregnancy: cocaine, heroin, phencyclidine, methamphetamine, or amphetamine.

MINN. STAT. § 383B.225(5)(16) (2000): All sudden or unexpected deaths and all deaths which may be due entirely, or in part, to any factor other than natural disease must be reported to the medical examiner for evaluation. These deaths include, among others, deaths of unborn or newborn infants in which there has been maternal use of, or exposure to, unprescribed controlled substances.

MINN. STAT. § 626.5561 (2000): Mandated reporters of child abuse and neglect must immediately report to the local welfare agency if the person knows, or has reason to believe, that a woman is pregnant and has used a controlled substance for a nonmedical purpose during the pregnancy. If the report alleges a pregnant woman's use of a controlled substance for a nonmedical purpose, the local welfare agency shall immediately conduct an appropriate assessment and offer services indicated under the circumstances. Services offered may include, but are not limited to, a referral for chemical dependency assessment, a referral for chemical dependency treatment if recommended, and a referral for prenatal care.

MINN. STAT. § 626.5562 (2000): A physician shall administer a toxicology test to a pregnant woman under the physician's care if the woman has obstetrical complications that are a medical indication of possible use of a controlled substance for a nonmedical purpose, within eight hours after delivery to determine whether there is evidence that she has ingested a controlled substance. If the test results are positive, the physician shall report the results under section 626.5561. A negative test result does not eliminate the obligation to report under section 626.5561, if other evidence gives the physician reason to believe the patient has used a controlled substance for a nonmedical purpose.

MINN. STAT. § 626.5563 (2000): The definition of "abuse of alcohol" includes women who required alcohol detoxification during pregnancy or who had positive alcohol-screening tests. In addition, if a woman is referred for substance abuse screening and fails to either complete screening or comply with recommendations, a report must be filed with a local welfare agency. Local welfare agencies are required to react to such reports within five working days by conducting an assessment and offering services.

*Task Force*

MINN. STAT. § 145.9265 (2000): The commissioner of health, in coordination with the commissioner of children, families, and learning, and the commissioner of human services, shall design and implement a coordinated prevention effort to reduce the rates of fetal alcohol syndrome and fetal alcohol effects, and reduce the number of drug-exposed infants.

*Treatment*

MINN. STAT. § 254A.17 (2000): The state shall develop comprehensive maternal and child health and social service programs to address the needs of children exposed to controlled substances and alcohol at birth. Treatment programs are to be developed for children between the ages of six and twelve, who are in need of chemical dependency treatment. Early intervention programs are to be developed to identify and provide services to children and families at risk due to substance abuse.

MINN. STAT. § 254B.01(3) (2000): Considered chemically dependent, under MINN. STAT. § 253B.02(2), women who use a controlled substance during pregnancy qualify for treatment and prevention services, including halfway houses, aftercare, psychological care, and case management.

**Mississippi***Case Law and Statutes*

No court cases or statutes strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

**Missouri***Case Law*

*In re F.N.M.*, 951 S.W.2d. 702 (Mo. Ct. App. 1997): An infant was born twelve weeks premature due to prenatal exposure to alcohol, marijuana, cocaine, and heroin. The Missouri Division of Family Services took custody of the newborn upon release from the hospital. The court terminated the mother's parental rights, in part due to her use of drugs during pregnancy. Although there were several other factors involved in the court's decision, the court stated that the "mother's drug and alcohol abuse during pregnancy directly caused her son's physical problems."

*Statutes**Education*

MO. REV. STAT. § 191.735(2) (2001): Multidisciplinary teams are trained in health issues affecting pregnant mothers and their babies, care in the home for medically complex infants, developmental impairments of exposed infants, and treatment resources for drug-abusing families.

MO. REV. STAT. § 191.725 (2001): Every licensed physician who provides obstetrical or gynecological care to a pregnant woman shall counsel all patients as to the perinatal effects of smoking cigarettes, the use of alcohol, and the use of any controlled substance. Such physicians shall further have all patients sign a written statement, the form of which will be prepared by the director of the Department of Health, certifying that such counseling has been received.

MO. REV. STAT. § 191.727 (2001): A program will be created to provide education to physicians who care for pregnant women. The program will discuss how to take complete drug histories from pregnant patients, the effects of cigarettes, alcohol, and controlled substances on pregnancy, and counseling techniques.

MO. REV. STAT. § 191.733 (2001): The Department of Health shall establish and maintain a toll-free information line for the purpose of providing information on resources for substance abuse treatment, and for assisting with referrals for substance abusing pregnant women.

MO. CODE REGS. ANN. tit. 9, § 30-3.850(45)(F) (2001): The Department of Mental Health's Comprehensive Substance Treatment and Rehabilitation programs must provide clients with basic information regarding the effects of alcohol and other drug abuse upon pregnancy and child development.

#### *Funding*

MO. REV. STAT. § 191.835 (2001): The Division of Alcohol and Drug Abuse of the Department of Mental Health shall establish a community grants program, to be known as "Community 2000," which shall make funds available to municipalities for the purpose of preventing alcohol and drug abuse. One of the goals of the local commissions must be the reduction of prenatal and perinatal exposure to alcohol and other drugs.

#### *Identification, Referral, and Reporting*

MO. REV. STAT. § 191.741 (2001): Upon notification by a physician or health care provider that a pregnant woman has been identified as having a high-risk pregnancy, the Department of Health shall offer service coordination services to such woman. Service coordination services shall include a coordination of social services, health care, and mental health services.

MO. REV. STAT. § 191.737 (2001): A physician may refer a woman to the Department of Health when her newborn has signs and symptoms consistent with controlled substance or alcohol exposure at birth, or after a positive toxicology test for controlled substances performed at birth on the mother or the child. The Department of Health shall coordinate social services, health care, mental health services, and needed education and rehabilitation services.

#### *Research*

MO. REV. STAT. § 191.745 (2001): The Department of Health is required to conduct periodic tests on samples of pregnant women and infants for the presence of alcohol and drugs to determine the prevalence of prenatal substance abuse. The testing is to be done anonymously.

#### *Treatment*

MO. REV. STAT. § 191.743 (2001): Any physician or health care provider who provides services to pregnant women shall identify all such women who have high-risk pregnancies. The physician or health care provider shall upon identification inform such woman of the availability of services and the option of referral to the Department of Health. Upon consent by the woman identified as having a high-

risk pregnancy, the physician or health care provider shall make a confidential report to the Department of Health.

MO. REV. STAT. § 191.731 (2001): A pregnant woman referred for substance abuse treatment shall be a first priority user of available treatment. All records and reports regarding a pregnant woman shall be kept confidential. The Division of Alcohol and Drug Abuse shall ensure that family oriented substance abuse treatment be available, as appropriations allow. Substance abuse treatment facilities, which receive public funds, shall not refuse to treat women solely because they are pregnant.

MO. CODE REGS ANN. tit. 9, § 30-3.610 (2001): The Department of Mental Health established minimum criteria for admission to methadone clinics but priority for admission shall be given to women who are pregnant.

## MONTANA

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### *Statutes*

#### *Treatment*

MONT. ADMIN. R. 8.4.505 (2000): A drug or alcohol abusing pregnant woman is considered to have a high-risk pregnancy and can only be treated by a primary care physician. A licensed direct entry midwife cannot accept high-risk pregnant women as patients.

## NEBRASKA

### *Case Law*

*State v. Arandus*, No. 93072, slip op. (D. Neb. June 17, 1993): The district court granted a motion to quash the indictment of a woman for child abuse due to her prenatal alcohol use. It concluded that the legislature did not intend for Nebraska's child abuse statute, NEB. REV. STAT. 28-707(1)(a), to apply to unborn children.

### *Statutes*

#### *Services*

NEB. REV. STAT. § 68-1058 (2001): This statute provides case management services to high-risk pregnant women eligible for medical assistance under section 1915(g) of the federal Social Security Act. In determining risk, factors including, but not limited to, age, education, alcohol or drug dependency, weight, and medical and psychosocial conditions will be considered. Case management services are services that will assist eligible individuals in gaining access to needed

medical, social, educational, and other services.

## NEVADA

### *Case Law*

*Washoe County, Nev. v. Cathy Encoe*, 885 P.2d 596 (Nev. 1994): The Supreme Court of Nevada considered whether NEV. REV. STAT. 200.508, a statute criminalizing child endangerment, applies to a mother's prenatal substance abuse, which results in the transmission of an illegal substance to her child through the umbilical cord between the time the child leaves the womb, and the time the umbilical cord is severed. After her newborn tested positive for methamphetamines, the mother was charged with willfully endangering her child pursuant to NEV. REV. STAT. 200.508, which reads in part, "a person who. . .willfully causes a child who is less than 18 years of age to suffer. . .as a result of abuse or neglect. . .is guilty of a gross misdemeanor unless a more severe penalty is prescribed...." Although the state conceded that a fetus cannot be considered a child under this statute, it maintained that the mother violated the statute while the umbilical cord was still intact, immediately after delivery. The Supreme Court of Nevada held that prosecuting a woman for delivering controlled substances "to her child through the umbilical cord is a strained and unforeseen application of NRS 200.508. To interpret this section to cover a mother's ingestion of illegal substances prior to the birth of her child would be a radical incursion upon existing law."

### *Statutes*

#### *Child Abuse*

NEV. REV. STAT. 432B.330(1)(b) (2001): A child is considered to be in "need of protection," if, among other things, "[h]e is suffering from congenital drug addiction or the fetal alcohol syndrome, because of the faults or habits of a person responsible for his welfare." If a child is found to be "in need of protection," the state will investigate the need for social services.

#### *Taskforce*

NEV. REV. STAT. 442.355 (2001): In 1999, the legislature created the Advisory Subcommittee on Fetal Alcohol Syndrome of the Advisory Board on Maternal and Child Health. The subcommittee's purpose is to develop and carry out programs relating to the prevention and treatment of fetal alcohol syndrome.

#### *Public Assistance*

NEV. REV. STAT. 422.29316 (2001): Although generally a person convicted of a drug felony after August 22, 1996, is not eligible to receive federal public assistance, a pregnant woman who has been convicted of a drug felony, and who is participating in, or has successfully completed, a drug treatment program, does not fall within that categorical exception.

NEV. REV. STAT. 442.395 (2001): If a pregnant woman is referred to the health

division by a provider of health care or other services for information about programs designed to prevent and treat fetal alcohol syndrome, any report relating to the referral or other associated documentation is confidential and may not be used in any criminal prosecution of the woman.

## NEW HAMPSHIRE

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### *Statutes*

#### *Education*

N.H. REV. STAT. ANN. § 457:23II (2000): Couples who apply for marriage licenses must receive a brochure, prepared by the Department of Health and Human Services, concerning fetal alcohol syndrome. In addition, couples must sign an affidavit on the back of the marriage license, which affirms that they have both received and discussed this brochure.

#### *Taskforce*

N.H. REV. STAT. ANN. § 132:19 (2000): This statute establishes a perinatal alcohol, tobacco, and other drug use task force. The task force is composed of legislators and other state representatives, medical and public health professionals, and members of the community.

N.H. REV. STAT. ANN. § 132:20 (2000): The duties of the task force include investigating and studying the problems of alcohol, tobacco, and other drug use as they relate to pregnant women and their infants, recommending legislative actions to provide necessary relief, collaborating with other state agencies to address the problems, holding public hearings, and submitting an annual report detailing the key findings and actions taken by the task force.

#### *Treatment*

N.H. REV. STAT. ANN. § 318-B:10.VIII(a) (2000): Methadone may be administered, prescribed, and dispensed to pregnant and postpartum heroin addicts, and administered as part of an alcohol and drug abuse treatment program.

## NEW JERSEY

### *Case Law*

*New Jersey v. Barker*, No. 96-02-605 (N.J. Super. Ct. Feb. 14, 1997): The defendant delivered a pre-viable fetus at twenty-four weeks of pregnancy. State prosecutors subsequently charged her with first-degree aggravated manslaughter and second-degree endangering the welfare of a child, alleging that she used



illegal controlled substances during her pregnancy, which caused the death of her premature fetus. The court dismissed both charges, holding that the New Jersey legislature did not intend for criminal statutes to apply to prenatal conduct.

## ***Statutes***

### ***Adoption***

N.J. STAT. ANN. § 9:3-41.1 (West 2001): Adoption agencies are required to provide prospective adoptive parents with information concerning the child's background, including the parent's complete medical histories any drugs or medications taken during pregnancy and any other conditions of the parent's health that may be a factor influencing the child's present or future health.

### ***Criminal***

N.J. STAT. ANN. § 2C:35-8 (West 2001): Enhanced sentencing of twice the term of imprisonment, fine, penalty, or parole ineligibility is to be imposed on a person who is convicted of distributing controlled substances to a pregnant woman. A person charged under this statute cannot use the defense that he/she did not know that the woman was pregnant.

### ***Custody***

N.J. STAT. ANN. § 30:4C-11 (West 2001): This statute enables various parties, including family relatives or public officials, to apply to the Division of Youth and Family Services when a child's safety or welfare is endangered. The application may ask for the division to accept and provide care to, or custody of, the child as required. The provisions of this section are deemed to include an application on behalf of an unborn child when the prospective mother is within this state at the time of application for such services.

### ***Education***

N.J. STAT. ANN. § 33:1-12a (West 2001): Under the Alcoholic Beverage Control Act, most persons who hold a Class C license must post notices, prepared by the Department of Health, that warn "patrons that alcohol consumption during pregnancy has been determined to be harmful to the fetus and can cause birth defects, low birth weight and Fetal Alcohol Syndrome, which is one of the leading causes of mental retardation."

### ***Identification and Reporting***

N.J. ADMIN. CODE tit. 8, § 20-1.2(a)1.i.(28) (2001): State regulations provide that any infant born in the state who is diagnosed with a birth defect must be reported to the State Department of Health, Special Child Health Services Program. The list of birth defects includes fetal alcohol syndrome and probable fetal alcohol syndrome.

## NEW MEXICO

**Case Law**

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

**Statutes***Education*

N.M. STAT. ANN. § 60-6E-2 (Michie 2000): New Mexico requires an Alcohol Server Education program for persons employed in the alcoholic beverage service industry. The program includes the study of the prevention of fetal alcohol syndrome and is intended, among other things, to prevent fetal alcohol syndrome and reduce the frequency of alcohol-related birth defects.

N.M. STAT. ANN. § 60-6A-30 (Michie 2000): With few exceptions, any person holding a liquor license shall post in a conspicuous place a sign in both English and Spanish that reads as follows: "Warning: Drinking alcoholic beverages during pregnancy can cause birth defects."

*Task Force*

N.M. STAT. ANN. § 6-4-8B(12) (Michie 2000): The Legislature created the "DWI program fund" for the purposes specified in the statute, which include the appropriation of funds "to the school of medicine at the university of New Mexico for prevention, research and intervention in the field of fetal alcohol syndrome."

*Reporting*

N.M. ADMIN. CODE tit. 8, § 27.3.24.1.1 (2001): When a child is placed in substitute care or presented to a substitute care provider for the purpose of placement in foster care, the provider shall be given various pieces of information about the child, including whether the child is "at risk for or diagnosed with Fetal Alcohol Syndrome."

*Services*

N.M. ADMIN. CODE tit. 7, § 30.8.7.25 (2001): One of the requirements for family infant toddler early intervention services is that the child is an "eligible" child. An "eligible" child is defined as one with an "established condition," which includes fetal alcohol syndrome.

## NEW YORK

**Case Law**

*In re Nassau County Dep't of Social Services*, 661 N.E.2d 138 (N.Y. 1995): The New York Court of Appeals considered whether a newborn's positive toxicology screen for a controlled substance is enough, by itself, to conclude that a newborn is neglected. The court found that additional evidence is generally required for a finding of neglect.

*In re Alex MM*, 688 N.Y.S.2d 707 (N.Y. App. Div. 1999): The state took temporary custody of a three-week old infant due to his mother's use of cocaine during pregnancy and the child's positive test result for cocaine at birth. The court affirmed the state's temporary action and permanently terminated the mother's parental rights after she failed to maintain contact or communication during the temporary removal.

*In re Unborn Child*, 683 N.Y.S.2d 366 (N.Y. Fam. Ct. 1998): The court considered whether the N.Y. Family Court Act § 1012 (2000), which defines a neglected child, applies to an unborn fetus. In this case, a woman continued to use cocaine during her pregnancy and failed to abide by a court order to obtain drug rehabilitation. The court stated that the legislature "demonstrate[s] intent to protect the unborn. . . It defies logical reasoning that our laws and society would preclude a mother from illegally introducing narcotics and other illegal drugs into her child, and yet not protect the unborn child from those same dangers while the child is still in the womb." Therefore, to protect an unborn child from a substantial risk of harm from prenatal use of illegal drugs, a court can issue an order precluding a pregnant mother from continuing to use such drugs during the remainder of the pregnancy.

*In re Detention of Tanya P.*, No. 530069/93, slip op. (N.Y. Sup. Ct. 1995): The court found that involuntary commitment of a woman who used drugs during her pregnancy, in order to protect her fetus, was unconstitutional.

*People v. Morabito*, 580 N.Y.S.2d 843 (N.Y. City Ct. 1992): A mother who ingested cocaine during pregnancy was criminally charged under N.Y. PENAL LAW § 260.10, which makes it a crime to endanger the welfare of a child. The court, however, dismissed the charge, finding that the word "child" in § 260.10 did not include a fetus.

*In re Fathima Ashanti*, 558 N.Y.S.2d 447 (N.Y. Fam. Ct. 1990): The court considered whether an infant who is born with a positive cocaine toxicology is entitled to be protected under the Family Court Act, and whether a mother's use of drugs during pregnancy can be the basis of a neglect determination. The court interpreted New York's child abuse and neglect statutes to include unborn children, stating that it would "be consistent with medical and scientific advances to treat the fetus while still in the mother's womb." The court held that the birth of a child with a positive toxicology screen for cocaine, with signs of drug withdrawal and low-birth weight, mandates judicial intervention for the protection of the child.

*In re Dep't of Social Services*, 543 N.Y.S.2d 637 (N.Y. Fam. Ct. 1989): The court considered a neglect petition against a mother who used cocaine during her pregnancy, and subsequently delivered a child addicted to cocaine. The court denied the dismissal of a neglect petition, holding that prenatal drug use, combined with a positive toxicology at birth, if proven, is sufficient to warrant a finding of neglect.

*In re Sharon Fletcher*, 533 N.Y.S.2d 241 (N.Y. Fam. Ct. 1988): The family court considered whether a mother's prenatal drug use alone can form the basis for a finding of neglect under § 1012(f) (i) (B) of the Family Court Act. The court stated

that "there is no inference to be drawn from the Family Court Act that a mere use, or even occasional uses, of a controlled substance prior to a child's birth puts it in imminent danger of harm." Therefore, additional evidence is required to find neglect.

### *Statutes*

#### *Adoption*

N.Y. DOM. REL. LAW § 112(2-a) (McKinney 2001): Adoption agencies are required to provide prospective adoptive parents with information concerning the child's history, including the health and medical history of the parents at the time of the birth of the adoptive child and any drugs or medication taken during the pregnancy by the child's mother.

#### *Education*

N.Y. AGRIC. & MKTS LAW § 200(13) (McKinney 2001): Any confectionery containing a defined amount of alcohol must contain the warning: "Notice: This product contains alcohol used as a flavoring and, as with any product that contains alcohol women should not consume alcohol during pregnancy because of the risk of birth defects."

N.Y. ALCO. BEV. CONT. LAW § 105-b (McKinney 2001): Any person who has a license to sell alcoholic beverages for consumption must post warning signs, in conspicuous places, stating, "Government Warning: According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects."

N.Y. PUB. HEALTH LAW § 2522(1)(d) (McKinney 2001): The public health department must distribute information concerning alcohol and drug use to both parents in prenatal assistance programs.

#### *Services*

N.Y. PUB. HEALTH LAW § 2541(5) (McKinney 2001): This statute, discussing an early intervention program for infants and toddlers with disabilities, defines disability to include any child with a "diagnosed physical or mental condition that has a high probability of resulting in developmental delay, such as...fetal alcohol syndrome."

#### *Treatment*

N.Y. SOC. SERV. LAW § 409-a(10) (McKinney 2001): Any money received from the federal government under section 201 of Federal Public Law 105-89 shall be used to provide "preventive services," which include "substance abuse treatment services provided to pregnant women or a caretaker person in an outpatient, residential or in-patient setting."

N.Y. COMP. CODES R. & REGS. tit. 10, § 85.40(e)(2)(iii) (2001): The Pre-natal Care Assistance Program requires that each pregnant woman has a care plan, and that the care plan must "encourage and assist the pregnant woman in obtaining necessary medical, nutritional, psychosocial, drug and substance abuse services appropriate to her identified needs and provide follow-up to ensure ongoing

access to services.”

N.Y. COMP. CODES R. & REGS. tit. 10, § 405.21(c)(8)(iii) (2001): Under the Department of Health’s minimum standards for hospitals, hospitals must assure the availability of prenatal childbirth education classes for all prebooked women which address the effects of alcohol and other drugs on the fetus.

## NORTH CAROLINA

### *Case Law*

*State v. Inzar*, Nos. 90CRS6960, 90CRS696 1, slip op. (N.C. Super. Ct. Apr. 9, 1991): The state charged a woman, who allegedly used crack during her pregnancy, under a statute that prohibited the delivery of a controlled substance to a person. The court dismissed the charges finding that a fetus is not a person within the meaning of the statutes.

### *Statutes*

#### *Criminal*

N.C. GEN. STAT. § 90-95 (e) (5) (2000): It is a Class D felony to sell or deliver a controlled substance to a pregnant woman. A person charged under this statute cannot use the defense that he/she did not know that the woman was pregnant.

#### *Treatment*

N.C. ADMIN. CODE tit. 10, r. 14C.1154(a)(b) (2001): The Department of Health and Human Services shall administer a program to provide comprehensive services to substance abusing pregnant women or substance abusing women with dependent children. Services may include primary medical, prenatal and pediatric care immunization, childcare, transportation, gender specific substance abuse treatment, and therapeutic intervention for children that address their developmental needs.

N.C. ADMIN. CODE tit. 10, r. 14C.1156(c)(7) (2001): The Department of Human Resources Division of Mental Health administers a grant program for the federal Substance Abuse Prevention and Treatment Block Grant. To be eligible for the block grant funds, an area program must include substance abuse services for pregnant and parenting women and adolescents.

## NORTH DAKOTA

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

## Statutes

### Education

N.D. CENT. CODE § 15-11-35 (2000): A fetal alcohol syndrome center is established in the Department of Neuroscience at the University of North Dakota School of Medicine. The state board of higher education shall appoint a person from the department of neuroscience as director of the fetal alcohol syndrome program and that person shall prepare an annual report on the status of fetal alcohol syndrome in North Dakota. The center shall develop prevention activities in groups that are at high risk for fetal alcohol syndrome.

### Services

N.D. CENT. CODE § 15-11-36 (2000): The child evaluation and treatment program at the University of North Dakota Medical Center Rehabilitation Hospital shall develop a clinic to provide both initial diagnostic assessment and reevaluation of children with fetal alcohol syndrome. The diagnostic assessment must include a comprehensive multidisciplinary assessment of psychological, speech and language, educational, occupational therapy, physical therapy, optometric, and audiological evaluations. Reevaluations must be individualized according to a child's needs. The center shall provide consultative services to schools, community agencies, and parents to assist in serving children diagnosed with fetal alcohol syndrome.

## Ohio

### Case Law

*In re Baby Boy Blackshear*, 736 N.E.2d 462 (Ohio 2000): In a child custody hearing, the Ohio Supreme Court considered whether a newborn who is addicted to cocaine is an abused child under OHIO REV. CODE ANN. § 2151.031. The court held that "when a newborn child's toxicology screen yields a positive result for an illegal drug due to prenatal maternal drug abuse, the newborn is, for purposes of R.C. 2151.031(D), per se an abused child." The court stated that after birth, the newborn is a child, and the discovery of cocaine is from a post-birth, not a prenatal, test.

*State v. Gray*, 584 N.E.2d 710 (Ohio 1992): The Ohio Supreme Court considered whether a mother could be prosecuted for child endangerment, pursuant to OHIO REV. CODE ANN. § 2919.22(A), for substance abuse occurring before the birth of the child. OHIO REV. CODE ANN. § 2919.22(A) states that "no person, who is the parent. . . of a child under eighteen years of age. . . shall create a substantial risk to the health or safety of the child, by violating a duty of care, protection, or support." The court found that this statute does not create a duty that is breached when a parent uses cocaine prior to the child's birth because a mother does not become a "parent" until after the child is born.

*State v. Andrews*, No. JU 68459, slip op. (Ohio C.P. June 19, 1989): The court found that a child endangerment statute is not intended to apply to any situation

other than that of a living child placed at risk by actions that occurred after its birth. It stated that “[t]he plain interpretation of the word parent is mother or father of a child who has been born alive.”

### **Statutes**

#### *Identification, Testing, and Reporting*

OHIO REV. CODE ANN. § 5111.017 (Anderson 2001): The Department of Job and Family Services shall establish a program for substance abuse assessment and treatment referral for pregnant women who are recipients of medical assistance, and who are required to receive medical services through a managed care organization. Each pregnant woman shall be screened for alcohol and other drug use at her first prenatal medical examination. If it is determined that the recipient may have a substance abuse problem, the medical provider must (a) refer the recipient to an organization certified by the Department of Alcohol and Drug Addiction Services for assessment and (b) inform the recipient of the possible effects of alcohol and other drug use on the fetus.

OHIO REV. CODE ANN. § 3793.15 (Anderson 2001): A program is to be developed by the Department of Alcohol and Drug Addiction Services to determine the number of addicted pregnant women in the state, determine the number of infants born drug-exposed, determine a way to intervene to eliminate addiction during pregnancy, provide for the continued monitoring of addicted pregnant women after the birth of their children, and provide for drug rehabilitation for such children.

## OKLAHOMA

### **Case Law**

*In re Unborn Child Julie Starks*, 18 P.3d 342 (Okla. 2001): After a pregnant woman was arrested for possession and use of methamphetamines, the Oklahoma Department of Human Services took custody of the woman's fetus. The trial court, citing OKLA. STAT. tit. 10, § 7001-1.1, ordered that the fetus remain in the Department's custody. The Supreme Court of Oklahoma vacated the trial court's ruling, and held that “Oklahoma Children's Code does not apply to a fetus, viable or nonviable. The state fails to present any fact or inference from facts to support legislative intent that it so apply.”

*State v. Alexander*, No. CF-92-2047, Transcript of Decision (Okla. Dist. Ct. Aug. 31, 1992): A woman who had ingested illegal drugs during her pregnancy was charged with unlawful possession of a controlled substance, and the unlawful delivery of that controlled substance to a minor. The Oklahoma District Court dismissed the charges, finding that the presence of drugs in the pregnant woman's system did not constitute possession, and that the transfer of the drug through the umbilical cord to the newborn cannot be considered “volitional.”

## *Statutes*

### *Adoption*

OKLA. STAT. tit. 10, § 7504-1.1(b)(3) (2000): Adoption records must contain information including the consumption of drugs, medications, or alcohol by the biological father or the biological mother at the time of conception and by the biological mother during her pregnancy with the minor.

### *Child Abuse*

OKLA. STAT. tit. 10, § 7001-1.3A.14.c (2000): When used in the Oklahoma's Children's Code, a "deprived child" is a child who at birth tests positive for alcohol or a controlled dangerous substance and who is determined to be at risk for future exposure to such substances.

### *Education*

OKLA. STAT. tit. 10, § 7220B (2000): The Oklahoma legislature finds that an increasing number of children under the age of eighteen years, including many children who would otherwise be at risk of abuse or neglect, are in the care of a grandparent. In response, the Department of Human Services shall establish an informational and educational program including, but not limited to, the area of parental substitute authority, for grandparents who provide primary care for children who are at risk of child abuse, neglect, or abandonment or who were born to substance-abusing mothers. As a part of the program, the Department shall develop, publish, and distribute an informational brochure for grandparents who provide primary care for children who are at risk of child abuse, neglect, or abandonment or who were born to substance-abusing mothers.

### *Identification, Reporting, and Prevention*

OKLA. STAT. tit. 10, § 7003-5.3(H)(2) (2000): When a child, who at birth tested positive for alcohol or a controlled dangerous substance and who was determined to be at risk for future exposure to such substances, has been removed from the home, the Department of Human Services may require that the mother of such child complete a treatment program prior to the return of the child to a safe home.

OKLA. STAT. tit. 10, § 7103(A)(2) (2000): Every physician or surgeon, including doctors of medicine, licensed osteopathic physicians, residents and interns, or any other health care professional attending the birth of a child who tests positive for alcohol or a controlled dangerous substance shall promptly report the matter to the Department of Human Services.

OKLA. STAT. tit. 63, § 1-546.4 (2000): On or before November 1, 2000, the Department of Mental Health and Substance Abuse Services and the State Department of Health shall jointly complete an epidemiological and demographic study to identify the prevalence in Oklahoma of pregnant women who abuse or are addicted to drugs or alcohol to the extent that the health or safety of the child is at risk, current services and service resources related to substance abuse and women who abuse or are addicted to drugs or alcohol both prenatal and postnatal, and current public expenditures for such services.



OKLA. STAT. tit. 63, § 1-550.3 (2000): The Department of Human Services shall establish and maintain an up-to-date Record of Infants Born Exposed to Alcohol and Other Harmful Substances. Such record shall include data necessary for surveys and scientific research, and other data, which is necessary and proper to further the recognition, prevention and treatment of infants born addicted to, or prenatally exposed to, harmful substances.

#### *Legislative Findings*

OKLA. STAT. tit. 63, § 1-546.1 (2000): The state has a substantial interest in protecting children from the harm that results from the abuse of drugs or alcohol by their mothers during pregnancy, both for the sake of the child and because of the potential cost to the state in providing medical and other care to such children. The legislature recognizes that the preferable and most effective means of preventing birth defects and health problems due to substance abuse by pregnant women is to provide readily available and accessible prenatal care and appropriate substance abuse treatment services, but further recognizes that in some instances it may be necessary to use the authority of the state to intervene for the purpose of preserving and protecting the health and well-being of the child.

#### *Task Force*

OKLA. STAT. tit. 63, § 1-546.2, 3, & 5 (2000): As part of the Oklahoma Prenatal Addiction Act, the legislature created a Joint Legislative Task Force on Prenatal Addiction and Treatment whose goal is to prepare and report on specific recommendations for the design and implementation of a collaborative program to encourage and assist pregnant women who abuse or are addicted to drugs or alcohol to obtain prenatal and postnatal medical care and substance abuse treatment services. In addition, a district attorney may convene a multidisciplinary team to assist in making a determination of the appropriate disposition of a case of a pregnant woman who is abusing or is addicted to drugs or alcohol to the extent that the unborn child is at risk of harm.

#### *Third-Party Liability*

OKLA. STAT. tit. 63, § 2-424 (2000): As part of the Drug Dealer Liability Act, any individual who was exposed to an illegal drug in utero can bring an action for damages caused by use of an illegal drug by an individual against the persons enumerated in the statute.

#### *Treatment*

OKLA. STAT. tit. 43A, § 3-417 (2000): Alcohol and other drug abuse treatment centers must have adequate facilities to treat substance abusing pregnant women.

OKLA. STAT. tit. 43A, § 3-602.2 (2000): Women who enter narcotic treatment programs must receive pregnancy tests, at least on an annual basis.

OKLA. STAT. tit. 63, § 1-546.4 (2000): The Department of Mental Health and Substance Abuse Services shall prohibit all substance abuse treatment services from refusing to treat pregnant women if space and staff expertise is available.

## OREGON

*Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

*Statutes**Adoption*

OR. REV. STAT. § 418.325 (1999): Prior to adoption, children must be tested for the hereditary or congenital effects of parental use of drugs or controlled substances. The information must be available for prospective parents.

*Education*

OR. REV. STAT. § 106.081 (1999): When the county clerk issues a marriage license, the county clerk shall also give to the licensees a pamphlet describing fetal alcohol syndrome, its causes, and its effects. The Health Division of the Department of Human Services shall provide the pamphlet to the counties.

OR. REV. STAT. § 471.551 (1999): Any person in possession of a valid retail liquor license, who sells liquor by the drink for consumption on the premises or sells for consumption off the premises, shall post a sign informing the public of the effects of alcohol consumption during pregnancy.

*Identification, Testing, and Reporting*

OR. REV. STAT. § 430.920 (1999): The attending health care provider must assess pregnant women for drug and alcohol usage. If the results indicate that the patient uses or abuses drugs or alcohol, or uses unlawful controlled substances, the provider must tell the patient about the potential health effects of continued substance abuse and recommend counseling by a trained drug or alcohol abuse counselor. In addition, the provider must supply demographic information to the local public health administrator without revealing the identity of the patient.

OR. REV. STAT. § 430.955 (1999): The Health Division, the Office of Alcohol and Drug Abuse Programs, and the Oregon Health Sciences University shall develop a standardized screening instrument designed to identify the use of substances during pregnancy. In addition, the boards responsible for the licensing of health care providers and appropriate professional organizations may be requested to conduct a series of training sessions for health professionals who provide maternity care on how to assess drug use in pregnancy.

*Legislative Findings*

OR. REV. STAT. § 430.905 (1999): Because the growing numbers of pregnant substance users and drug- and alcohol-affected infants place a heavy financial burden on Oregon's taxpayers, and those who pay for health care, it is the policy of Oregon to take effective action that will minimize these costs. Special attention must be focused on preventive programs and services directed at women who are at risk of becoming pregnant substance users, as well as on pregnant women who use substances or who are at risk of substance use or abuse. The legislature

recommends using a holistic approach to achieve desired results.

### *Research*

OR. REV. STAT. § 430.910 (1999): The Department of Human Services shall study the problem of substance-using pregnant and postpartum women and their infants. The study shall focus on prevention, education, and treatment located in community, inpatient, outpatient, and residential settings.

### *Treatment*

OR. REV. STAT. § 430.915 (1999): If during routine pregnancy or prenatal care, the attending health care provider determines that the patient uses or abuses drugs or alcohol the provider should encourage and facilitate counseling, drug therapy, and other assistance to the patient in order to avoid having the child, when born, become subject to protective services.

OR. REV. STAT. § 430.925 (1999): Oregon shall develop pilot projects in local health departments that are designed to alleviate the health related problems of pregnant and postpartum women and their infants, which arise from substance use.

OR. REV. STAT. § 430.950 (1999): The Director of Human Services shall appoint a management team to advise the Office of Alcohol and Drug Abuse Programs on the preparation of standards for county grant applications and to advise and assist counties and regions in planning for treatment of pregnant substance abusers. The management team shall work with divisions of the Department of Human Services and with other state agencies to plan for such treatment programs.

## PENNSYLVANIA

### *Case Law*

*Commonwealth v. Kemp*, No. 114-Pitt-1993, slip op. (Pa. Super. Ct. Feb. 22, 1994): The trial court dismissed charges of reckless endangerment and endangering the welfare of a child against a woman who allegedly used cocaine during pregnancy. The trial court found that neither "child" nor "person" includes an unborn fetus. This decision was affirmed by the Pennsylvania Superior Court.

### *Statutes*

#### *Education*

PA. STAT. ANN. tit. 71, § 554 (West 2000): The Department of Health will establish programs to train the staff of child protective agencies to identify pregnant women and mothers who are in need of drug or alcohol treatment. They will also establish referral networks between state agencies.

#### *Legislative Findings*

PA. STAT. ANN. tit. 11, § 875-103 (West 2000): Under the Early Intervention

Services System Act, a child under the age of three with fetal alcohol syndrome is considered to be handicapped.

### *Hospital Policies*

28 PA. CODE § 137.21(b)(12) (2001): Every hospital must maintain a written set of obstetrical service policies and procedures that includes policies and procedures for the care and treatment of drug-dependent newborns.

28 PA. CODE § 139.12(c)(4) (2001): A hospital's neonatal intensive care unit must care for high-risk infants. A high risk infant is defined to include an infant whose mother is drug addicted or habituated.

### *Treatment*

PA. STAT. ANN. tit. 71, § 553 (West 2000): The Department of Health will offer grants to provide comprehensive services for substance using pregnant women and mothers. The Department of Health will also maintain and report statistics on the number of women referred to treatment, those denied treatment, and those placed on waiting lists. The statute includes a provision, which ensures the confidentiality of records regarding identifiable individuals enrolled in treatment programs.

## RHODE ISLAND

### *Case Law*

*In re Michael F.*, 665 A.2d 880 (R.I. 1995): The Department of Children, Youth and Families took temporary custody of an infant five days after birth because he was born addicted to cocaine. After the parents failed to seek appropriate drug rehabilitation services, the Supreme Court of Rhode Island determined that both parents were unfit to care for the child and terminated their parental rights. *See also In re Eric K.*, 756 A.2d 769 (R.I. 2000).

### *Statutes*

#### *Child Abuse*

R.I. CODE R. 03-040-420(D)(4) (2000): An expert may be used at a trial to offer evidence and/or support documents revealing a child's medical diagnosis of failure to thrive or fetal alcohol syndrome, or drug withdrawal.

#### *Education*

R.I. GEN. LAWS § 15-2-3.1 (2001): With each marriage license, the town or city clerk must provide a pamphlet describing the causes and effects of fetal alcohol syndrome.

#### *Identification and Reporting*

R.I. CODE R. 03-040-430 (2000): Babies born with drugs in their systems, as evidenced by a positive toxicology screen at birth or observable withdrawal symptoms, babies born to mothers who admit using drugs during pregnancy or who have been observed ingesting drugs, and babies born with fetal alcohol

syndrome must be reported to the Child Abuse Hotline. When such a call is made, the information alleging drug and/or alcohol abuse is put into the [Child Abuse and Neglect Tracking System] computer as an Early Warning, and an investigation may be initiated.

## SOUTH CAROLINA

### *Case Law*

*Ferguson v. City of Charleston*, 121 S. Ct. 1281 (2001): The U.S. Supreme Court struck down the Medical University of South Carolina's policy of testing the urine of pregnant women for cocaine without consent, and reporting positive results to local authorities. In this case, women were arrested after testing positive for cocaine during their pregnancies, and, in most cases, subsequently not complying with mandated treatment. The Court ruled that the special needs exception to the Fourth Amendment's warrant and probable cause requirements does not apply to a hospital's drug-testing protocol enacted largely for law enforcement, as opposed to medical purposes (the program forced most patients to choose between arrest and treatment).

*Whitner v. State*, 492 S.E.2d 777 (S.C. 1997): The South Carolina Supreme Court upheld the criminal conviction of a woman who ingested cocaine during pregnancy. In reaching its decision, the court declared that "child" in South Carolina's parental conduct laws, in particular, S.C. CODE ANN. § 20-7-50, includes viable fetuses.

*State v. McKnight*, Indictment No. 2000 GS26432 (Horry County Ct. May 17, 2001): A woman was convicted of homicide by child abuse and sentenced to twelve years in prison for killing her unborn fetus by smoking crack cocaine during her pregnancy.

### *Statutes*

#### *Child Abuse*

S.C. CODE ANN. § 20-7-736 (Law. Co-op. 2000): It is presumed that a newborn child is an abused or neglected child that cannot be protected from further harm without being removed from the custody of the mother upon proof that: (1) a blood or urine test of the child at birth or a blood or urine test of the mother at birth shows the presence of any amount of a controlled substance, or (2) the child has a medical diagnosis of fetal alcohol syndrome.

#### *Public Assistance*

S.C. CODE ANN. § 43-5-1190 (Law. Co-op. 2000): A Family Independence (FI) recipient who, while receiving FI benefits, gives birth to a child with evidence of the effects of maternal substance abuse, and the child subsequently is shown to have a confirmed positive toxicology test, is ineligible for FI assistance unless the recipient submits to random drug tests and/or participates in an alcohol or drug treatment program approved by the Department of Alcohol and Other Drug

Abuse Services. Upon completion of the program, if a subsequent random test or subsequent conviction for a controlled substance violation occurs, the recipient is ineligible for FI benefits.

#### *Third-Party Liability*

S.C. CODE ANN. § 44-54-40 (Law. Co-op. 2000): Any individual who was exposed to an illegal controlled substance in utero can bring an action for damages against the persons enumerated in section B of this statute.

#### *Treatment*

114 S.C. CODE ANN. REGS. 1130(Q) (2001): Participants in the state's Family Independence Program who give birth to a child who tests positive for drugs must participate in an alcohol or drug treatment program approved by the Department of Alcohol and Other Drug Abuse Services.

### **SOUTH DAKOTA**

#### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

#### *Statutes*

##### *Child Abuse*

S.D. CODIFIED LAWS § 26-8A-2(9) (Michie 2000): The term, abused or neglected child, includes a child who was subject to prenatal exposure to abusive use of alcohol or any controlled drug or substance not lawfully prescribed by a practitioner.

##### *Civil Commitment*

S.D. CODIFIED LAWS § 34-20A-63 (Michie 2000): A pregnant woman abusing alcohol or drugs may be committed to an approved treatment facility for emergency treatment.

S.D. CODIFIED LAWS § 34-20A-70 (Michie 2000): A pregnant woman who is abusing alcohol or drugs can be committed to any approved treatment facility upon the petition of a spouse, relative, physician, the administrator of a treatment facility, or any other responsible person. In order to commit a pregnant woman, the petition must allege that she is an alcoholic or drug abuser who habitually lacks self-control as to the use of alcoholic beverages or other drugs.

##### *Education*

S.D. CODIFIED LAWS § 34-23B-1 (Michie 2000): Any primary health care provider of obstetrical care to a pregnant woman and any counselor who provides services to a pregnant woman shall educate all pregnant patients as to the prenatal effects of drugs and alcohol. The Department of Health and the Department of Human Services will offer educational materials and guidance for the purpose of assuring accurate and appropriate patient education. *See also* S.D. CODIFIED LAWS §

34-23B-2 (Michie 2000) (educating health care professionals for this purpose); S.D. CODIFIED LAWS § 34-23B-5 (Michie 2000) (developing screening materials and criteria for use by primary providers for identification of high- and moderate-risk drug and alcohol use during pregnancy).

S.D. CODIFIED LAWS § 34-23B-3 (Michie 2000): Upon receipt of funds for such programs, the Secretary of Education and Cultural Affairs shall make available to all school districts age-appropriate drug and alcohol education curricula concerning the physiological effects caused by the use of drugs and alcohol on the developing child before and after birth for inclusion in their drug and alcohol education programs in grades one through twelve.

S.D. CODIFIED LAWS § 34-23B-4 (Michie 2000): The Department of Health and the Department of Human Services shall maintain a toll-free information line for the purpose of providing information on resources for substance abuse treatment and for assisting with referral for substance abusing pregnant women.

S.D. CODIFIED LAWS §§ 35-4-99, 100 (Michie 2000): The Department of Human Services shall create a nine by twelve inch sign to be displayed at all licensed alcohol premises that explains the dangers faced by pregnant women who consume alcohol. Failure to display such sign is a petty offense.

### *Reporting*

S.D. CODIFIED LAWS § 26-8A-3 (Michie 2000): All medical professionals and other persons who suspect child abuse or neglect under S.D. CODIFIED LAWS § 26-8A-2 (Michie 2000) are to make a report to appropriate authorities.

### *Third-Party Liability*

S.D. CODIFIED LAWS § 34-20C-4 (Michie 2000): Any person who was exposed to an illegal drug in utero may bring an action for damages caused by another person's use of an illegal drug.

## TENNESSEE

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### *Statutes*

#### *Education*

TENN. CODE ANN. § 57-1-211 (2001): Any licensee that sells alcoholic beverages shall post, in a prominent place easily seen by its customers, a warning sign supplied by the alcoholic beverage commission that drinking alcoholic beverages during pregnancy can cause birth defects, including fetal alcohol syndrome and fetal alcohol effects. Failure to post the sign, as required by this section, shall result in a fine not to exceed \$25.00 for each day the licensee is in violation.

*Opinions of the Attorney General*

The Attorney General (AG) of Tennessee issued an Opinion on March 27, 1995, that the child abuse statutes in Tennessee could not be legally applied to cases in which a mother used cocaine during pregnancy that resulted in the injury of the child. The AG relied on TENN. CODE ANN. §§ 39-15-401, 402 on child abuse and aggravated child abuse, respectively, which do include the fetus in the definition of child.

*Treatment*

TENN. CODE ANN. § 66-29-151(b) (2001): Services for low-income pregnant substance abusers may be available through the Health Access Incentive Account program.

TENN. CODE ANN. § 68-1-1403 (2001): Lay women from the community shall be recruited and provided with intensive training to serve as "resource mothers" for pregnant and parenting teens to, among other things, reinforce recommendations of health care providers and give basic health information and advice in areas such as nutrition, avoidance of smoking and alcohol, infant development, and infant care.

TENN. CODE ANN. § 68-24-104(e)(1) (2001): Through grants contracted with community based agencies, the commissioner is authorized to plan, establish, and administer pilot projects to develop effective and efficient prevention and treatment services for low-income, pregnant substance abusers. Each of the pilot projects should, to the extent possible within available funding, provide public information, community outreach, residential beds for rehabilitation, outpatient slots for treatment, family intervention services, specialized support services, enhanced physician oversight, and documentation and recordkeeping.

**Texas***Case Law*

*Chenault v. Huie*, 989 S.W.2d 474 (Tex. App. 1999): Huie used illegal narcotics, including cocaine, during her pregnancy, and after the birth, her child was found to have both cocaine and alcohol in her blood. The child subsequently showed signs of developmental problems and was diagnosed as having cerebral palsy attributed to Huie's drug use. The court concluded that Texas does not recognize a cause of action in tort for injuries to a child that result from the mother's negligent or grossly negligent conduct while she was pregnant with the child, and that it should not judicially create a legal duty that would have the effect of dictating a pregnant woman's conduct toward her unborn child.

*Collins v. Texas*, 890 S.W.2d 893 (Tex. App. 1994): Collins smoked crack cocaine while she was pregnant, thereby causing her child to be born addicted to the drug and suffer withdrawal symptoms. The state indicted Collins for reckless injury to a child. The trial court found her guilty, but the Court of Appeals reversed on grounds that Collins did not have notice that her voluntary ingestion



of cocaine while pregnant could subject her to prosecution after her child was born exhibiting symptoms of cocaine withdrawal because the law was impermissibly vague. Furthermore, the court noted that the Penal Code does not proscribe any conduct with respect to a fetus, and the legislature, by its definitions of "child," "person," and "individual," has specifically limited the application of penal laws to conduct committed against a human being who has been born and is alive at the time the harm is caused.

## *Statutes*

### *Child Abuse*

TEX. FAM. CODE ANN. § 261.001 (Vernon 2000): The use of a controlled substance constitutes child abuse where such use results in physical, mental, or emotional injury to a child. A child is also abused under the statute if he/she was born addicted to alcohol or a controlled substance and who, after birth, experiences observable withdrawal from the alcohol or controlled substance; exhibits observable or harmful effects in the child's physical appearance or functioning; or exhibits the demonstrable presence of alcohol or a controlled substance in the child's bodily fluids as the result of the mother's use of the controlled substance or alcohol.

### *Services to Children*

25 TEX. ADMIN. CODE § 32.404 (West 2001): In order to receive Early Childhood Intervention case management services, the recipient must be eligible for Medicaid and have a developmental disability, which includes fetal alcohol syndrome or fetal alcohol effects.

### *Termination of Parental Rights*

TEX. FAM. CODE ANN. § 161.001 (Vernon 2000): The court may order termination of the parent-child relationship if the court finds by clear and convincing evidence that the parent has used a controlled substance in a manner that endangered the health or safety of the child or if the parent has been the cause of the child being born addicted to alcohol or a controlled substance

### *Treatment*

40 TEX. ADMIN. CODE § 144.522 (West 2001): Drug and alcohol treatment programs must establish screening procedures to identify members of priority populations, including pregnant injecting drug users and pregnant substance abusers, and admit them before all others.

40 TEX. ADMIN. CODE § 144.525 (West 2001): If a treatment program does not have an appropriate provider for the applicant, the provider shall arrange for treatment (through admission or referral) in a program with the most appropriate level of care accessible to the applicant. If the applicant is placed on a waiting list, the provider may admit the client to a less intensive program on an interim basis.

40 TEX. ADMIN. CODE § 148.114 (West 2001): All programs that admit females of child-bearing age shall have at least one staff person with documented knowledge of pregnant substance-abusing females and their care. When a

pregnant female is admitted, all members of the treatment team shall receive information needed to provide appropriate care.

## UTAH

### *Case Law*

*State ex rel. M.E.C.*, 942 P.2d 955 (1997): M.E.C. was born premature and tested positive for cocaine. The Division of Child and Family Services (DCFS) immediately placed M.E.C. in protective custody and petitioned for custody of the baby based on neglect. The juvenile court granted DCFS's petition, and the mother subsequently relinquished her rights to M.E.C.

### *Statutes*

#### *Reporting*

UTAH CODE ANN. § 62A-4a-404 (2000): When any person attends the birth of a child or cares for a child, and determines that the child, at the time of birth, has fetal alcohol syndrome or fetal drug dependency, he shall report that determination to the Division of Child and Family Services as soon as possible.

UTAH CODE ANN. § 62A-4a-411 (2000): Any person, official, or institution required to report a case of fetal alcohol syndrome or fetal drug dependency who willfully fails to do so is guilty of a class B misdemeanor.

#### *State Custody*

UTAH CODE ANN. § 62A-4a-409 (2000): The state Division of Family Services shall make a thorough pre-removal investigation upon receiving either an oral or written report of alleged abuse, neglect, fetal alcohol syndrome, or fetal drug dependency, when there is reasonable cause to suspect the existence of the alleged harm. A division worker or child protection team member may take a child into protective custody, and deliver the child to a law enforcement officer, or place the child in an emergency shelter facility approved by the juvenile court, at the earliest opportunity subsequent to the child's removal from its original environment.

UTAH CODE ANN. § 62A-4a-412 (2000): A report of fetal alcohol syndrome or fetal drug dependency as defined by law is confidential and may only be made available to (1) a police or law enforcement agency investigating a report of known or suspected child abuse or neglect; (2) a physician who reasonably believes that a child may be the subject of abuse or neglect; (3) an agency that has responsibility or authority to care for, treat, or supervise a child who is the subject of a report; or (4) an office of the public prosecutor or its deputies.

## VERMONT

**Case Law**

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

**Statutes***Adoption*

VT. STAT. ANN. tit. 15A, § 2-105 (2001): Prospective adoptive parents are to be provided with information about the background of an adoptive child, including an account of the minor's prenatal care, medical condition at birth, and any drug or medication taken by the minor's mother during pregnancy.

## VIRGINIA

**Case Law**

*Commonwealth v. Smith*, CR-91-05-4381, slip op. (Va. Cir. Ct. Sept. 16, 1991): The court dismissed child abuse charges, under VA. CODE ANN. § 18.2-371.1, against a woman who allegedly used drugs during pregnancy. The court found that the child abuse statute is not intended to apply to fetuses or prenatal conduct.

*Commonwealth v. Wilcox*, No. A-44116-01, slip op. (Va. Dist. Ct. Oct. 9, 1991): The court dismissed child abuse charges against a woman who allegedly used cocaine during her pregnancy. The court found that the application of the relevant statute would extend the statute beyond the creative construction intended by the legislature.

**Statutes***Child Abuse*

VA. CODE ANN. § 16.1-241.3 (Michie 2000): A preliminary protective order or emergency removal order may be made alleging that an investigation has been commenced in response to a report of suspected abuse or neglect of the child, based on perinatal drug addiction or fetal alcohol syndrome.

VA. CODE ANN. § 63.1-248.3(A1) (Michie 2000): Among the reasons to suspect that a child is abused or neglected are: (i) a finding made by an attending physician within seven days of a child's birth that the results of a blood or urine test conducted within forty-eight hours of the birth of the child indicate the presence of a controlled substance not prescribed for the mother by the physician; (ii) a finding by an attending physician made within forty-eight hours of a child's birth that the child was born dependent on a controlled substance which was not prescribed by a physician for the mother and has demonstrated withdrawal symptoms; (iii) a diagnosis by an attending physician made within seven days of a child's birth that the child has an illness, disease, or condition which, to a reasonable degree of medical certainty, is attributable to in utero exposure to a

controlled substance, which was not prescribed by a physician for the mother or the child; or (iv) a diagnosis by an attending physician made within seven days of a child's birth that the child has fetal alcohol syndrome attributable to in utero exposure to alcohol.

### *Testing*

VA. CODE ANN. § 54.1-2403.1 (Michie 2000): Physicians providing care to pregnant women must screen their patients for substance abuse. Physicians are required to provide warnings and information about poor birth outcomes to women who test positive. These results are not admissible in any criminal proceeding.

### *Third-Party Liability*

VA. CODE ANN. § 38.2-5001 (Michie 2000): Disability or death of a newborn resulting from maternal substance abuse does not fall with the statutory definition of "birth-related neurological injury."

### *Treatment*

12 VA. ADMIN. CODE § 30-50-510.B.5 (West 2000): The Department of Medical Assistance Services has established expanded prenatal care services that include residential substance abuse treatment services for pregnant and postpartum women. The program is a comprehensive, intensive residential treatment program to improve pregnancy outcomes by eliminating the substance abuse problem.

VA. CODE ANN. § 2.1-51.15:1 (Michie 2000): In order to respond to the needs of substance abusing women and their children, the Secretary of Health and Human Resources shall develop criteria for (i) enhancing access to publicly funded substance abuse treatment programs in order to effectively serve pregnant substance abusers; (ii) determining when a drug-exposed child may be referred to the early intervention services and tracking system available through Part H of the Individuals with Disabilities Education Act, 20 U.S.C. § 1471; (iii) determining the appropriate circumstances for contact between hospital discharge planners and local departments of social services for referrals for family oriented prevention services, when such services are available and provided by the local social services agency; and (iv) determining when the parent of a drug-exposed infant, who may be endangering a child's health by failing to follow a discharge plan, may be referred to the child protective services unit of a local department of social services.

VA. CODE ANN. § 32.1-127 (B)(6) (Michie 2000): Upon identification of a postpartum substance-abusing woman, a licensed hospital must notify the local community services board, which will implement and manage a discharge plan for the woman and her newborn.

VA. CODE ANN. § 37.1-182.1 (Michie 2000): The Board of Mental Health, Mental Retardation and Substance Abuse Services shall promulgate regulations that ensure that programs licensed to provide substance abuse treatment develop policies and procedures, which provide for timely and appropriate treatment for pregnant substance abusing women.

## WASHINGTON

**Case Law**

*State v. Dunn*, 916 P.2d 952 (Wash. Ct. App. 1996): Both Dunn and her newborn child tested positive for cocaine at the child's birth. The state charged Dunn with second degree criminal mistreatment of her viable unborn child, relying on WASH. REV. CODE § 9A.42.030(1)(a). The Court of Appeals unanimously upheld the trial court's decision to dismiss the second-degree criminal mistreatment charges for cocaine consumption during pregnancy because the state failed to establish that Dunn's unborn child was a "child" for the purposes of the criminal mistreatment statute.

**Statutes***Education*

WASH. REV. CODE § 66.16.110 (2001): Each state liquor store must post, in a conspicuous place, notices not less than one inch high, warning people that consumption of alcohol shortly before conception or during pregnancy may cause birth defects, including fetal alcohol syndrome and fetal alcohol effects.

*Identification and Testing*

WASH. REV. CODE § 70.83E.020 (2001): The Department of Health shall develop screening criteria for use in identifying pregnant or lactating women addicted to drugs or alcohol who are at risk of producing a drug-affected baby. The Department shall also develop training protocols for medical professionals related to the identification and screening of women at risk of producing a drug-affected baby.

WASH. REV. CODE § 70.96A.500 (2001): The Department of Health shall contract with the University of Washington fetal alcohol syndrome clinic to provide fetal alcohol exposure screening and assessment services. The services shall include training health care staff in community-based fetal alcohol exposure clinics to accurately diagnosis individuals with fetal alcohol exposure, development of written or visual educational materials for individuals diagnosed with fetal alcohol exposure, establishment of diagnostic clinics statewide if funds allow, and preparation of an annual report detailing information relating to diagnostic accuracy and reliability.

*Legislative Findings*

WASH. REV. CODE § 70.83C.005 (2001): The state recognizes that the use of alcohol and other drugs during pregnancy can cause medical, psychological, and social problems for women and infants. The state further recognizes that the best way to prevent problems for chemically dependent pregnant women and their resulting children is to engage the women in alcohol or drug treatment. The legislature further recognizes that pretreatment services should be provided at locations where chemically dependent women are likely to be found, including public health clinics and domestic violence or homeless shelters. Therefore the

legislature intends to prevent the detrimental effects of alcohol or other drug use to women and their resulting infants by promoting the establishment of local programs to help facilitate a woman's entry into alcohol or other drug treatment.

### *Research*

WASH. REV. CODE § 13.34.805 (2001): To the extent funds are appropriated, the state shall measure the reduction in the birth rate of drug-affected infants among women and shall compare the reduction with the rate of birth of drug-affected infants born to women referred to chemical dependency treatment programs. The study shall identify the factors that promote or discourage the ability of women to avoid giving birth to drug-affected infants.

WASH. REV. CODE § 70.83E.030 (2001): The Department of Health shall investigate the feasibility of medical protocols for laboratory testing or other screening of newborn infants for exposure to alcohol or drugs. The Department of Health shall consider how to improve the current system with respect to testing, considering such variables as whether such testing is available, its cost, which entity is currently responsible for ordering testing, and whether testing should be mandatory or targeted.

### *Services*

WASH. REV. CODE § 13.34.803 (2001): The Departments of Health shall develop a comprehensive plan for providing services to mothers who (a) have delivered a drug or alcohol exposed or affected infant, and (b) who meet the definition of at-risk eligible persons under the law. In developing the plan, the Department shall inventory the community-based programs that may be accessed to provide services to these mothers and their children; evaluate implementing services for these mothers through extension of the maternity care access system; and evaluate the fiscal impact of the plan. In performing the fiscal evaluation, the Department shall calculate potential long-term cost savings to the state resulting from reduced use of the medical, juvenile justice, public assistance, and dependency systems by children and mothers receiving services under the plan.

WASH. REV. CODE § 70.96A.510 (2001): The Department of Social and Health Services, the Department of Health, the Department of Corrections, and the Office of the Superintendent of Public Instruction shall execute an interagency agreement to ensure the coordination of identification, prevention, and intervention programs for children who have fetal alcohol exposure, and for women who are at high risk of having children with fetal alcohol exposure.

### *Treatment*

WASH. REV. CODE § 13.34.800 (2001): A model project is to be developed to provide services to women who give birth to infants exposed to the nonprescription use of controlled substances or abuse of alcohol by the mother during pregnancy.

WASH. REV. CODE § 70.83C.020 (2001): The Secretary of the Department of Health shall develop three pilot demonstration projects, two in public health clinics and one in conjunction with a domestic violence program. Specially trained counselors at each site are to identify substance-abusing women before, during,

and after pregnancy; educate women and agency staff on the effects of alcohol and drugs on health, pregnancy, and unborn children; ascertain a woman's need for treatment; facilitate her entry into treatment; and advocate on a woman's behalf with social service agencies or other entities to ensure and coordinate treatment.

WASH. REV. CODE § 74.09.790 (2001): Under the Maternity Care Access Program, pregnant women who are substance abusers may receive support services, defined to include public health nursing assessment and follow-up, health and childbirth education, psychological assessment and counseling, outreach services, nutritional assessment and counseling, needed vitamin and nonprescriptive drugs, transportation, family planning services, and child care. Support services may also include alcohol and substance abuse treatment for pregnant women who are addicted or at risk of being addicted to alcohol or drugs to the extent funds are made available for that purpose.

#### WEST VIRGINIA

#### **Case Law**

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

#### **Statutes**

##### *Education*

W. VA. CODE § 60-6-25 (2000): All establishments licensed to sell alcohol, either for consumption on or off the premises, shall display signs provided by the alcohol beverage control commissioner warning of the possible danger of birth defects that may result from the consumption of alcohol during pregnancy. Failure to comply with this rule may result in a fine of not less than one hundred dollars nor more than one thousand dollars per violation. The proceeds of fines collected for violations of this section shall be deposited in a fund known as the "fetal alcohol syndrome fund," which will be used to educate the public concerning the dangers of fetal alcohol syndrome.

#### WISCONSIN

#### **Case Law**

*Wisconsin ex rel. Angela M.W. v. Kruzicki*, 561 N.W.2d 729 (Wis. 1997): The County Department of Health and Human Services sought a protective custody order in juvenile court over the viable fetus (and hence the pregnant woman) when an obstetrician reported the possibility of child abuse by Angela M.W., who repeatedly tested positive for cocaine during pregnancy. The juvenile court granted the custody order, and a divided court of appeals determined that the juvenile court did not exceed its jurisdiction. The Wisconsin Supreme Court

reversed, finding that the statute allowing the state to take protective custody of a "child" does not include the fetus.

*State v. Deborah J.Z.*, 596 N.W.2d 490 (Wis. Ct. App. 1999): At the time J.Z. delivered her child, she had a blood alcohol concentration of 0.30%. Her child was born with a blood alcohol level of 0.199%. The state charged J.Z. with attempted first-degree homicide and first-degree reckless injury. The court of appeals dismissed the charges, finding that an unborn child is not a "human being" as defined by Wisconsin law.

## **Statutes**

### *Child Abuse*

WIS. STAT. § 48.02(am) (2000): Child abuse, when used in referring to an unborn child, includes serious physical harm inflicted on the unborn child, and the risk of serious physical harm to the child when born, caused by the habitual lack of self-control of the expectant mother of the unborn child in the use of alcohol beverages, controlled substances, or controlled substance analogs, exhibited to a severe degree.

### *Civil Commitment*

WIS. STAT. § 48.133 (2000): The juvenile court has exclusive original jurisdiction over an unborn child alleged to be in need of protection or services. When an expectant mother habitually lacks self-control in the use of alcoholic beverages, controlled substances, or controlled substance analogs, exhibited to a severe degree, and there is a substantial risk that the physical health of the unborn child will be seriously affected or endangered unless the expectant mother receives prompt and adequate treatment for that habitual lack of self-control, the court also has exclusive original jurisdiction over the expectant mother described in this section. Other parts of this section deal with procedures for taking the pregnant woman into state custody. WIS. STAT. §§ 48.193, 48.19(1)(cm), 48.205(1m), 48.205(1)(d), 48.213(1)(b), and 48.21(1)(b) (2000).

### *Education*

WIS. STAT. § 46.03(34) (2000): The Department of Health and Family Services shall acquire, without cost if possible, pamphlets that describe the causes and effects of fetal alcohol syndrome and the dangers to a fetus of the mother's use of cocaine or other drugs during pregnancy. These pamphlets shall be distributed free of charge to each county clerk in sufficient quantities so that each county clerk may provide pamphlets to marriage license applicants under WIS. STAT. § 765.12(1) (2000).

WIS. STAT. § 765.12(1) (2000): With each marriage license the county clerk shall provide a pamphlet describing the causes and effects of fetal alcohol syndrome.

### *Funding*

WIS. STAT. § 46.86(1) (2000): The Department of Health and Family Services may award not more than \$125,500 each fiscal year in grants to counties and



private nonprofit entities for treatment of pregnant women and mothers with alcohol and other drug abuse treatment needs. The grants shall be used to establish community-based programs, residential family-centered treatment programs, or home-based treatment programs. The program under a grant must include alcohol and other drug abuse treatment services, parent education, support services for the children of the women who are enrolled in the program, vocational assistance, and housing assistance.

WIS. STAT. § 46.86 (3m) (2000): The Department of Health and Family Services may not distribute more than \$900,000 in each fiscal year to fund a multidisciplinary prevention and treatment team in Milwaukee County for cocaine-abusing women and their children.

### *Legislative Findings*

WIS. STAT. § 48.01(am) (2000): Wisconsin recognizes that unborn children have certain basic needs that must be provided for, including the need to be free from physical harm due to the habitual lack of self-control of their expectant mothers in the use of alcoholic beverages, controlled substances, or controlled substance analogs, exhibited to a severe degree.

### *Testing and Reporting*

WIS. STAT. § 146.0255(2) (2000): A hospital employee who provides health care, a social worker, or an intake worker, may refer an infant or an expectant mother of an unborn child to a physician for testing of bodily fluids for controlled substances if the professional suspects controlled substances are in bodily fluids. If the results of the test indicate that the infant or expectant mother has controlled substances or controlled substance analogs in their bodily fluids, a physician shall make a report. Under this subsection, a physician may not test an expectant mother without first receiving her informed consent.

### *Treatment*

WIS. STAT. § 48.01(am) (2000): When an expectant mother of an unborn child suffers from a habitual lack of self-control in the use of alcohol beverages, controlled substances, or controlled substance analogs, exhibited to a severe degree, in order to ensure that the needs of the unborn child, the court may determine that it is in the best interest of the unborn child for the expectant mother to be ordered to receive treatment, including inpatient treatment, for that habitual lack of self-control.

WIS. STAT. § 51.42(3)(4m) (2000): A county department of community programs must, within the limits of available funds, provide for the program needs of persons suffering from alcoholism or drug abuse. If state, federal, and county funding for alcohol and other drug abuse treatment services are insufficient to meet the needs of all eligible individuals, first priority for services is given to pregnant women who suffer from alcoholism or alcohol abuse, or who are drug dependent.

WIS. STAT. § 51.46 (2000): For inpatient or outpatient treatment for alcohol or other drug abuse, the first priority for services that are available in privately operated facilities, whether on a voluntary or involuntary basis, is for pregnant

women who suffer from alcoholism, alcohol abuse, or drug dependency.

## WYOMING

### *Case Law*

No court cases strictly dealing with the regulation of drug and alcohol use by pregnant women were found.

### *Statutes*

#### *Adoption*

WYO. STAT. ANN. § 1-22-116 (Michie 2000): Prospective adoptive parents shall be provided with the medical history of the child subject to adoption, and this history shall include, but not be limited to any drugs or medication taken during pregnancy by the child's natural mother and any other information that may be a factor influencing the child's present or future health.

#### *Education*

WYO. STAT. ANN. § 35-27-102 (Michie 2000): Under the Public Health Nursing Infant Home Visitation Subprogram, pregnant women with a substance abuse problem are eligible for prenatal contacts, home visitation services, and information about medical care for infants.

### Limiting Technology in the Process of Negotiating Death

Nancy Dubler, LL.B.\*

*Managing Death in the Intensive Care Unit: The Transition from Cure to Comfort.* Edited by J. Randall Curtis and Gordon D. Rubenfeld. New York: Oxford University Press, 2001. Pp. 388.

Death is a negotiated event; it happens by design. Whereas accident or negligence may occasionally intervene as an independent cause, 70% of the 1.3 million Americans who die in health care institutions do so after a decision has been made and implemented to forego some or all forms of medical treatment.<sup>1</sup> One can only assume that this percentage has increased during the last decade as technological advances increasingly permit support of single organ function at the expense of integrated conscious existence.

Two powerful forces in health care evolved in the 1990s to affect the course and conduct of medicine at the end of life. Both are reflected, although not presented in sufficiently sharp focus, in the series of essays collected in the thoughtful volume, *Managing Death in the Intensive Care Unit: The Transition from Cure to Comfort*, edited by J. Randall Curtis and Gordon D. Rubenfeld. First, death has re-emerged as an acceptable outcome of medical practice, even in the intensive care unit, for patients whose prognosis is hopeless. Second, financial disincentives for long-term hospital stays must make us wary of determining the prognosis of hopelessness too easily. Capitated systems and prospective payment mechanisms provide incentives for shortened lengths of stay. This financial fact of life must not be permitted to contaminate decisions about death.

These evolutions, one clinical and one economic, have combined to force health care organizations and institutions to reevaluate their practices and protocols for managing patients at the end of life and especially in expensive intensive care units. In the aggregate, the results may be beneficial to patients and families as new perceptions and practices

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limit the endless process of dying that had become the norm in many health care centers. But not surprisingly, dangers of discrimination, creation of levels of care linked to layered reimbursement, and unnecessarily hastened deaths lurk in newly found perceptions of palliative and hospice care.

Most of the chapters in this book are well conceptualized and clearly written, and some provide valuable tools for professionals seeking to offer appropriate and compassionate care to patients and their families. Both physicians and nurses provide data, algorithms, and scripts to assist intensive care unit (ICU) staff in providing compassionate care. Having recently attended a working group of clinicians and clergy where physicians were virtually begging for scripts to follow in the uncomfortable arena of spiritual values, I find that many chapters provide clearly useful and practical guidelines that address how to speak to, evaluate, and treat the dying patient in pain, and how to approach and support the family.

Nonetheless, there are certain micro- and macro-ethical themes addressed in the book that require more explicit development. If staff members are to be able to negotiate effectively between and among the parties who must cooperate in order to permit a "good" death, they must have the perceptions and skills to assess, evaluate, and manage conflict.<sup>2</sup> Misunderstandings, disagreements, and disputes are inevitable in the context of life and death decisions when individual history and preference must combine with present prognosis according to principles of probability. Techniques of mediation and negotiation can facilitate a dynamic process that reflects, but is independent of, ethical principles of individual choice.

Nowhere is this point more evident than in the various discussions of the notion of "futility" that emerge in multiple chapters. As in many discussions, futility is conceptualized by all of the authors as a binary mode—either care is futile or non-futile. Yet, I would argue that except for those rare instances in which the cases reported in the medical literature demonstrate "no possible benefit," the notion of futility exists somewhere on a sliding scale of benefit and burden. But what it more commonly reflects is the fact that communication between the surrogates and the physician has broken down. The term futility is a trump card played by the physician to deny requested care and to end the discussion. What is needed at that point is not the blunt instrument of physician-exercised power—the doctrine of futility—but rather a nuanced process to bring the family to recognize the scant possibility of benefit and burdens of continued care.<sup>3</sup> In such circumstances, techniques of mediation that set the stage, level the playing field, invite discussion, identify positions, and

seek consensus among conflicting conceptions of a good care plan will be far more helpful than asserting and insisting on physician power to decide—the essence of the futility discussion.<sup>4</sup> In pursuit of that consensus, time-limited trials and variations in ICU visitation rules may provide the redress of medical power that makes agreement possible. As death reflects more of a negotiated process rather than a discrete event, collaboration and negotiation will need to replace the raw exercise of power that appealing to “futility” represents.

When examining the likely effects of easier access to death for patients, families, medicine, and society, a microanalysis that focuses on forging a patient-care plan must be accompanied by a macroanalysis emphasizing more global themes. These themes include differential access to care, the problem of the uninsured and underinsured, the wise stewardship of scarce institutional resources, corporate contracting arrangements that search out cost-effective care, and the ever-present dangers of racism and discrimination in provision of services. This analysis should take place in the context of the principle that ICU care is, and should remain, a scarce resource whose use is restricted to those patients whose prior health status and level of function can be restored. This is so because limitation of health care expenditures is an ethical and not merely an economic issue. If we, as a society, are to have effective public education, infrastructure, cultural institutions, and other indicia of a good society, then we must limit the costs of medicine.<sup>5</sup>

The assumption of the appropriateness of scarcity leads me to contest one of the premises of this volume, that it presents the “state of the art in caring for dying patients in the ICU.”<sup>6</sup> It may be that determining when a patient is dying is an ICU function, but this is only valid as the precursor to transfer from the ICU to a more appropriate level of care. No rule is absolute, but if the ICU remains a limited resource it must be used wisely by admitting those who can benefit and denying admission or transfer to those who cannot. Intensive care units need to save the lives of salvageable patients but do not necessarily need to manage the resulting deaths.<sup>7</sup> Other sites and staffs in the hospital may be better at, and more cost-effectively situated for, end-of-life care. Nonetheless, ICUs must be better prepared for the eventuality that some proportion of patients will die in the units.

I would also disagree that “good end-of-life care is like an art: it is difficult to define, but you know it when you see it.”<sup>8</sup> This book belies the statement. A good professional knowledge base, quality communication skills (rated as high as clinical skills by family members), and a willingness to face the modest benefit that continued care will likely provide, combine

to offer a basis for presentation of options and negotiation of a coordinated care plan.<sup>9</sup> There are some artful elements, but many of the necessary techniques can be learned.

At the level of individual rights, a series of chapters in the book focus on the need for discussion with the patient, which is generally not possible when the person is in the ICU. As an alternative, the author discusses reliance on advance directives and family narratives. In these chapters, the author constructs pleas for a change in climate and perspective to emphasize truth telling. I would argue that if this is to occur, however, it must be accompanied by a new principle of "intellectual modesty." Often there is no truth to tell; the doctor can only relay past data and fashion a prognosis in light of published studies. When those studies offer dire predictions, respect for the patient, compassion for the family, and regard for the integrity of medicine should combine to offer a realistic prognosis. Clinical exposure and discussion of medical uncertainty is the only fair way to prepare family members for the death of the patient.

However, there is another perception about families that receives little attention in any of these essays. While the notion that families need support is addressed, their need for protection is equally important.<sup>10</sup> It is commonplace for ICU clinical staff to reach the decision that a patient is dying and take appropriate steps to avoid prolonging the process. Decisions to permit death are part of the regular business of diagnosis and prognosis within the realm of illness and disease. But family members have no comparable intellectual framework and no matching emotional distance. For them, the death of the patient will leave an unfillable void. Compassion for family members requires that medical staff shoulder the responsibility for the decision to permit death without disempowering families' rights to make decisions.<sup>11</sup> This is no easy matter. The legal rules, ethical principles, and medical conventions of decision making by family members preclude the medical team from usurping the decision.<sup>12</sup> But compassion requires that medical staff absorb the burden of the decision so that the family does not perceive itself as the cause of the patient's death; this is the artful part of end-of-life care.

One of the negative consequences of medical decision making in this litigious era is the insistence that if the patient or family have the right to decide, then they must shoulder the burden of the decision. This theme is evident in the risk-management notions of informed consent that emphasize the litany of risks over the balance of risks and benefits. In order to protect against the later possibility of legal liability, the locus of decision must be clearly separated from the medical professionals involved in care. That is a foolish consequence of our tort system and the litigious

society it encourages, and it is also a terrible basis for allocating the components of the decision-making process at the end-of-life. If institutions want to focus on liability for end-of-life care, they should be concerned about the fact that physicians who are not specialists in intensive care have half the success of intensivists in treating very sick patients. This provides powerful support for specially trained intensive care staff and a warning to institutions that permit community-based physicians to supervise the care of imperiled patients.<sup>13</sup>

But this sea change in medical perspective and the goals of physician communication will require a robust discussion within society, rather than a debate cloaked in the framework of court cases whose fact patterns often distort the discussion to force the narrative to conform to preexisting common law principles. This re-conceptualization of the debate began with the emergence of palliative care as a separate consulting discipline. The public discussion in the media of a “good” death has also contributed to this change. Reconstructing the grim reaper not as the enemy, but as a welcome friend, will take time and require reframing the goals of medicine.<sup>14</sup> But it will require changes in “hospital culture, physician practices, and societal expectations” to really move practice.<sup>15</sup>

This book is another entry into the expanding discussion of end-of-life care. It applies to the ICU, but even more so to other medical staff who treat dying patients and support their families. It reflects the reality that medicine is adjusting its Olympian stance to the realities of chronic disease and the aging of the population. Patients and families have noticed that the SUPPORT study revealed that over 50% of patients die in moderate to severe pain, and that endless days in the ICU may extend dying, but may not reverse a declining quality of life.<sup>16</sup> Medicine has acted as prince of the realm of death for the last fifty years. It has ushered in new techniques for treating illness. It must now learn to ease death as it previously enhanced life.

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## Gostin on Public Health Law

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*Public Health Law: Power, Duty, Restraint.* By Lawrence O. Gostin. Berkeley: University of California Press and the Milbank Memorial Fund, 2000. Pp. 518.

When I was invited to review Professor Larry Gostin's new book, *Public Health Law: Power, Duty, Restraint*,<sup>1</sup> I immediately said yes despite the fact that my schedule could scarcely bear another deadline. I had the privilege in May 1999 to read and comment on some early chapters of Gostin's book for the Milbank Memorial Fund, which is a co-publisher of the book.<sup>2</sup> Those early chapters whet my appetite for the completed book, which has now been published.<sup>3</sup>

Before I had read a single word of the final product, I was primed to consume what promised to be an outstanding contribution to understanding the complex relationship between public health and law. Gostin's earlier scholarship on public health law has proved important to my efforts to address the neglected relationship between international law and public health. I could not pass up the opportunity to devour and digest Gostin's book and do my part to disseminate the learning it contains.

The book's publication coincides well with this *Journal's* debut. The *Journal* is a unique product of the collaborative energies of faculty and students from medicine, public health, and law—all disciplines for which Gostin has been a teacher and colleague. Gostin intends for his book to speak to the many disciplines affected by, and struggling to contribute to, the pursuit of healthier human populations. And when Gostin speaks, people listen.

Gostin's book further arrives at a timely moment because concern about the status of public health in the United States seems to be increasing. Concern about emerging and re-emerging infectious diseases, the growing threat of antimicrobial resistance, the implications of the West Nile virus outbreak in the Northeast, and fears about bio-terrorism have all concentrated attention in recent years on the fragmented and underfunded condition of public health in the United States. While public

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health officials have been sounding warnings for years, others, such as journalist Laurie Garrett,<sup>4</sup> have now picked up the message of alarm, and are making the case for public health to a larger audience in order to stimulate remedial action.

In this time of ferment and concern for public health in the United States, *Public Health Law* makes a seminal contribution that, I predict, will dominate for the foreseeable future how students and scholars from multiple disciplines approach the role of law in American public health.

## I. LAW AND THE PUBLIC'S HEALTH IN THE UNITED STATES

The basic message of *Public Health Law* is that "law is essential for creating the conditions for people to lead healthier lives."<sup>5</sup> Many people, including health-care professionals, often view medicine and law as antagonistic disciplines. But this popular perception confuses health care and public health. In his Preface, Gostin points out that the contemporary study of the relationship between law and health is dominated by "medicine and personal health care services—clinical decision-making, delivery, organization, and finance."<sup>6</sup> Gostin argues that the population-health perspective provided by public health has been missing in the work done on health care law or health law.<sup>7</sup> Gostin designed his book to address this neglect.<sup>8</sup>

Curiously, although Gostin states that public health law has been "perennially neglected" as a field of study, he does not explain why such neglect occurred and what the consequences are for public health.<sup>9</sup> One could read the book and conclude that law as an instrument of public health has not been neglected but has instead been used extensively for decades at all levels of government in a wide variety of contexts to promote and protect the public's health. After all, Gostin identifies an impressive collection of legal issues in public health that governments and courts have been addressing for a long period of time. In fact, such a book could not have been written if there was not already a large body of law in existence. What, then, does Gostin mean when he says that public health law has been neglected?

The reader must discern the reasons why public health law has been neglected from the structure and argument of the book: Public health law has been neglected because of its broad, diffuse scope and immense complexity; and this neglect has produced law that compromises the ability of the United States to balance properly public health objectives and individual rights and liberties. The neglect that public health generally has endured for the past few decades may also contribute to the neglect of public health law, but Gostin does not explore this important factor.

When Gostin refers to the perennial neglect of public health law, he also means that neither legal nor public health scholars or practitioners have ever really conceived of “public health law” as a distinct field of inquiry. In American democratic society, law and legal frameworks shape every endeavor. Public health is no different. But, while many areas of social action have attracted significant conceptual and practical legal attention from scholars and practitioners, public health has largely been ignored as a field of legal analysis. The neglect is primarily intellectual rather than practical because governments and public health agencies have continued to rely on and add to public health law in their everyday activities.

But, when we realize how much law shapes public health as a social value and determines governmental activity in this area, the intellectual neglect of public health law means that we lack a framework to understand how and why law is critical to the objective of public health. We see the individual trees but not the forest—the larger ecosystem in which law and the protection of population health intertwine in ways that we should understand given the importance of the values of the rule of law and public health. While I would have liked Gostin to explore why public health law has been neglected, this desire does not detract from his correct identification of the problem and his ambitious attempt to organize, explain, analyze, and seek to improve how the public health law ecosystem functions.

It is important to emphasize the enormity of the task Gostin set himself in addressing the lack of interest in public health law in the United States. The first challenge relates to the concept of “public health,” which public health practitioners define very broadly. Gostin cites the Institute of Medicine’s definition of “public health” as “what we, as a society, do collectively to assure the conditions for people to be healthy.”<sup>10</sup> This definition reveals that public health cannot be narrowly viewed as, for example, merely the low prevalence of infectious diseases in society. Public health is concerned with the whole panoply of possible threats to human health, which gives public health law an enormous scope.

The second challenge arises in explaining how the American legal system—a very complicated, sophisticated, textured machine—works in the context of public health. The machinery defies simplification, even before one considers sorting out how the machinery operates in the vast terrain of public health. Thus, the ambition in Gostin’s book is quite breathtaking.

I stress the enormity of the task because some people, both in public health and law, may find that Gostin does not analyze with sufficient depth many of the public health and legal issues, principles, and problems the

book addresses. Lawyers may find themselves hungry for more detailed legal analysis, while public health experts may find that the law overshadows public health concepts and principles. These understandable reactions should be tempered with an appreciation of Gostin's attempt to conceptualize public health law as a discrete field valuable to both the legal and public health professions.

Gostin defines "public health law" as follows:

Public health law is the study of the legal powers and duties of the state to assure the conditions for the people to be healthy (e.g., to identify, prevent, and ameliorate risks to health in the population) and the limitations on the power of the state to constrain the autonomy, liberty, proprietary, or other legally protected interests of individuals for the protection or promotion of community health.<sup>11</sup>

Chapter 1 of the book explores this definition to delineate the conceptual boundaries of the role of law in public health—or what Gostin calls the theory of public health law. This theory identifies five essential features of public health law: (1) the special responsibility of the government for public health activities; (2) the focus on the health of populations; (3) the relationship between the state and the population or between the state and individuals or private enterprises that place the greater community at risk; (4) the provision by the government of population-based services grounded in the scientific methodologies of public health; and (5) the power of the government to coerce individuals and private enterprises in order to protect the larger community from health risks.<sup>12</sup>

One of the great strengths of the book is that it grounds the study of public health law in the larger framework of the rule of law in the United States. As Gostin argues:

Public health law should not be seen as an arcane, indecipherable set of technical rules buried deep within state health codes. Rather, public health law should be seen as broadly as the authority and responsibility of the government to assure the conditions for the population's health. As such, public health law has transcending importance in how we think about government, politics, and policy in America.<sup>13</sup>

Gostin successfully demonstrates the fundamental duty governments have at the local, state, and federal levels to protect and promote the public's health and how central law is to the fulfillment of this governmental duty. The book serves not only as an overview of the role of law in public health but also as an exploration of the rule of law's

importance to the American way of government.

Readers who are knowledgeable about the current crisis in American public health might, however, scratch their heads when Gostin argues that public health law has transcending importance in U.S. politics and governance. The gradual crumbling of the U.S. public health system provides weak evidence that anything connected to public health is transcendent in the United States. Clearly Gostin's argument is normative not descriptive, but these observations suggest that Gostin could have given a more contemporary public health context to support his aspiration "to create a record of the field of public health law at the turn of the millennium."<sup>14</sup>

Also missing from the book's theory of American public health law is any perspective that public health in the United States is connected to international and global issues and forces, actors, and rules that complicate the use of law to promote and protect public health.<sup>15</sup> In a time when local, national, and international public health officials and experts are struggling to come to grips with what has been called the globalization of public health, it was strange to see no discussion in *Public Health Law* of matters beyond American shores. For example, Gostin argues that constitutional, statutory, administrative, and tort law represent the "analytical methods and tools of public health law."<sup>16</sup> Conspicuously absent from the methods and tools of American public health law is international law. The United States is a party to many treaties that directly and indirectly relate to public health, including the Constitution of the World Health Organization (WHO), the International Health Regulations, the World Trade Organization, North American Free Trade Agreement, and international legal agreements on environmental protection. The United States is also a key player in the development of new international law, such as WHO's proposed framework convention on tobacco control. Why is international law not part of the theory and practice of American public health law?<sup>17</sup>

In some respects, Gostin's decision not to include international and global issues was refreshing because it communicated the continuing importance of local, state, and national efforts on public health and did not treat the globalization phenomenon in public health through the repetition of shallow globo-rhetoric. Still, Gostin's approach treats public health law in the United States as if America is isolated and unaffected by the public health problems in, and threats from, other countries. It does not seem prudent to me "to provide an honest account of the doctrine and the controversies facing the field [of public health law] in the year 2000"<sup>18</sup> without including any analysis of international legal issues directly relevant

to public health.

## II. THE STRUCTURE AND DYNAMICS OF AMERICAN PUBLIC HEALTH LAW

Part One of *Public Health Law* analyzes the conceptual foundations of American public health law. After the definition and theory of public health law are provided in Chapter 1, Gostin gives an overview of the structure and dynamics of the American system of public health law. Chapter 2 (Public Health in Constitutional Design) and Chapter 3 (Constitutional Limits on the Exercise of Public Health Powers: Safeguarding Individual Rights and Freedoms) explore the structure of American public health law through the governing framework established by the U.S. Constitution. The key structural elements Gostin examines in Chapters 2 and 3 are federalism, the separation of powers, and notions of limited government to protect individual liberties.

Grounding public health law in the American constitutional system is critical because the governmental duties to assure the conditions necessary for a healthy population are divided, distributed, and disciplined by the Constitution. Gostin effectively communicates the complicated constitutional principles that guide the pursuit of public health. If I have any quarrel with the way Gostin structures his analysis of federalism, it is with his treatment of state public health powers after his analysis of the federal role in public health. Under the Constitution, direct public health powers belong to state governments, not the federal government; most public health policy, law, and expenditures originate, as a result of the constitutional design, at the state level. Gostin's analysis in Chapter 2 gives pride of place to the federal government's public health powers and role.<sup>19</sup> Gostin does, however, discuss the conflicts that federalism creates in public health between the federal government and state governments by analyzing the *Lochner* era through to the Supreme Court's more recent decisions (*Lopez*,<sup>20</sup> *New York*,<sup>21</sup> and *Seminole Tribe*<sup>22</sup>) that contain a "new federalism" that limits more the power of the federal government to regulate intrastate activities.

Gostin's analysis of the federal government's powers in the public health context focuses on the constitutional authorities to tax, spend, and regulate interstate commerce. The federal government's powers to regulate commerce with foreign nations, make treaties with foreign nations, and conduct the nation's foreign policy are important powers in the public health context that Gostin does not mention. It is these federal powers that have sustained the United State's involvement in international public health efforts since the nineteenth century, including U.S. leadership and participation in the creation and operation of the Pan

American Sanitary Bureau, Office International d'Hygiène Publique, and the WHO. Gostin's failure to mention these federal powers in the constitutional design reflects the book's lack of an international perspective on American public health law.

Chapter 3 expands on the notion of limited government by analyzing the constraints the Constitution places on government power in order to protect individual rights, and how these limits affect the pursuit of public health. The tension between the government's power to act on behalf of the public's health and the constitutional protection of individual rights dominate *Public Health Law*. Not only does Gostin explore this tension conceptually in Chapter 3, but he also focuses on this issue in Part Two of the book, which contains six chapters. He also raises this theme in other chapters.<sup>23</sup> More than half of *Public Health Law* is, thus, devoted to the public health-individual rights tension.

In the Preface, Gostin questions "the primacy of individual freedom (and its associated concepts—autonomy, privacy, and liberty) as the prevailing social norm."<sup>24</sup> He also questions the assertion associated with the late Jonathan Mann that respect for human rights and public health are synergistic.<sup>25</sup> While Gostin admits that there is validity in the Mannesque position, he asserts that public health and individual rights "sometimes cannot coexist."<sup>26</sup> I return to this issue in my discussion of Part Two of the book below.

The final chapter of Part One—Chapter 4 (Public Health Regulation: A Systematic Evaluation)—provides an overview of the dynamics of public health law in the United States. While Chapters 2 and 3 were mainly descriptive, Chapter 4's focus on public health regulation is prescriptive because Gostin develops criteria to guide policymakers and courts in their respective considerations of public health law. Because public health regulation involves trade-offs between public goods and private interests, governments must justify intervention to promote population health. Gostin identifies three classical justifications for public health intervention: (1) the harm principle—competent adults have freedom of action unless they pose a risk to others; (2) the protection of incompetent persons, such as children or the mentally ill, to ensure their health and safety; and (3) the regulation of self-regarding behavior, or paternalism.

Gostin argues that the state bears the burden of justification and has to demonstrate the existence of significant risk to the public health in order to intervene. He explores risk analysis in public health law by presenting four factors to consider: the nature of the risk, its duration, the probability of harm, and the severity of harm. While these factors closely align with science, Gostin properly cautions that social values also play a role in risk

assessment and management.

But the government's job is not finished when it has identified a significant health risk because it must also show that (1) the intervention has a good chance of being effective because the means and ends are reasonably related; (2) the public health benefits are proportional to the economic and other costs; and (3) the intervention produces a fair distribution of benefits, costs, and burdens in society.

Gostin acknowledges that this framework for making public health decisions does "not invariably lead to the best policy because any analysis is fraught with judgments about politics and values and is confounded by scientific uncertainty."<sup>27</sup> Gostin hopes, however, that his systematic analysis provides a structure that will help public health authorities and politicians craft and apply consistent standards when making policy and law.

### III. BALANCING CIVIL LIBERTIES AND PUBLIC HEALTH OBJECTIVES IN AMERICAN PUBLIC HEALTH LAW

Part Two of *Public Health Law* contains five chapters, each of which analyzes what Gostin believes is a conflict between the enjoyment of civil liberties and the effective pursuit of public health. See Table 1 for an overview of Part Two.

It would be foolhardy and impossible for me to try to comment in detail about the massive amount of public health and legal materials Gostin expertly organizes and analyzes in these chapters. He succeeds in covering very complicated legal areas comprehensively yet concisely, as well as always tying his discussion firmly to the objectives of public health. Gostin combines analysis of the background legal principles and frameworks with exploration of current hot topics in public health law, such as health information privacy, HIV screening of pregnant women and infants, and litigation against the tobacco and firearms industries.

My concerns with Part Two are, on the whole, minor. The sections in Chapter 9 on public health and the rise of the administrative state and the regulatory tools of public health agencies struck me as information the reader needed in Part One of the book when Gostin was laying down the basics of public health law. Chapter 10's focus on tort law seemed somewhat out of place in the part of the book dealing with the conflict between civil liberties and government regulation for public health purposes, but I could not identify a better place to put this material given the structure of the book.<sup>28</sup> Gostin could also have grappled more with the problem many people see in the tort litigation on tobacco and firearms: The courts are effectively being asked and allowed to make public health



**Table 1. Summary of Part Two of *Public Health Law***

Chapter	Topic	Examples of Issues Analyzed
Chapter 5	Personal Privacy	<ul style="list-style-type: none"> <li>- Public health surveillance</li> <li>- Mandatory disease reporting</li> <li>- Partner notification</li> <li>- Population-based research</li> <li>- Ethical underpinnings and legal status of health informational privacy</li> <li>- Confidentiality</li> <li>- Model public health information privacy law</li> </ul>
Chapter 6	Freedom of Expression	<ul style="list-style-type: none"> <li>- Theories of health communication</li> <li>- Public health communications</li> <li>- Commercial speech and public health</li> <li>- Compelled commercial speech</li> <li>- Regulation of cigarette advertising (case study)</li> </ul>
Chapter 7	Bodily Integrity	<ul style="list-style-type: none"> <li>- Compulsory vaccination</li> <li>- Testing and screening</li> <li>- Compulsory screening and unreasonable search and seizure</li> <li>- Compulsory screening and disability discrimination</li> <li>- HIV screening or pregnant women and infants (case study)</li> </ul>
Chapter 8	Autonomy and Liberty	<ul style="list-style-type: none"> <li>- History of personal control measures</li> <li>- Isolation, quarantine, and compulsory hospitalization</li> <li>- Compulsory physical examination and medical treatment</li> <li>- Criminal law and knowing or willful exposure to infection</li> </ul>
Chapter 9	Regulation of Economic Behavior	<ul style="list-style-type: none"> <li>- History of commercial regulation</li> <li>- Public health and the rise of the administrative state</li> <li>- Regulatory tools of public health agencies</li> <li>- Economic liberty and public health—contracts, property uses, and “takings”</li> </ul>
Chapter 10	Tort Law and Public Health	<ul style="list-style-type: none"> <li>- Theories of tort liability</li> <li>- Mass tort litigation and epidemiology in the courtroom</li> <li>- Public health value of tort litigation</li> <li>- The “tobacco wars” (case study)</li> <li>- Tort litigation and firearms (case study)</li> <li>- Limitations of tort law for public health</li> </ul>

policy where legislatures have failed to take action. Finally, I could not help but think of all the parallels between Gostin’s analysis in Part Two on civil liberties and the discourse in international human rights law about public health actions by governments. Gostin has previously applied his approach to individual rights in the public health context in the context of international law,<sup>29</sup> and Part Two easily lent itself to mentioning the similarities in approach in domestic law and international law concerning the tension between individual rights and the pursuit of public health.

One of the greatest strengths of Part Two of *Public Health Law* is that Gostin provides ways to make the conflict between civil liberties and public health regulation more palatable by laying out substantive and procedural

principles that can help ensure that infringement of individual rights for public health reasons are scientifically justified, non-discriminatory, and the least restrictive measures possible. In Gostin's hands, the inevitable conflicts between civil rights and public health law are principled, constrained conflicts that demonstrate continuing respect for individual rights and commitment to protecting the public's health. Such an approach supports powerfully the contribution that respect for individual rights can make to general public health.

IV. THE FUTURE OF AMERICAN PUBLIC HEALTH LAW

Part Three of *Public Health Law* focuses on the future of public health law in the United States. Chapter 11 analyzes the need for public health law reform and provides principles to guide such reform. Gostin argues that his final chapter answers the critique of American public health law issued by the Institute of Medicine (IOM) in 1988. The IOM called for reform of public health law to clarify the authority and responsibility of public health agencies and to empower them to deal effectively with contemporary public health threats. Gostin takes up the IOM's challenge by: (1) outlining the inherent problems of public health; (2) setting out three conceptual principles that each public health statute should contain; and (3) laying out the guidelines for public health law reform (table 2).

Gostin's analysis in Chapter 11 remains at a general level, and he does not apply his reform principles to specific public health problems facing the United States today. I understand why Gostin chose this approach,<sup>30</sup>

**Table 2. Problems, Principles, and Guidelines: Reform of Public Health Law in the United States**

Inherent Problems of Public Health	Politics, money, leadership, jurisdiction, legitimacy, and trust
Principles All Public Health Statutes Should Have	<p>The law should empower public health agencies to regulate individuals and businesses for the public's health.</p> <p>The law should restrain government in its exercise of power to achieve the benefits of liberty and freedom.</p> <p>The law should impose duties on government to promote the public's health.</p>
Guidelines for Public Health Law Reform	<p>Create modern, consistent, and uniform public health laws.</p> <p>Define a mission and essential functions for public health agencies.</p> <p>Provide a full range of public health powers.</p> <p>Impose substantive limits on the exercise of public health powers.</p> <p>Impose procedural requirements on the exercise of public health powers.</p> <p>Provide strong protection against discrimination.</p> <p>Provide strong protection for privacy and security of public health information.</p>

but I found myself wanting to know what Gostin thinks are the priorities for public health law reform in the United States today. While Gostin mentions perennial difficulties that confront public health, he does not discuss the depth of the problems now confronting American public health. Public health literature, especially in connection with infectious diseases, contains a great deal of hand-wringing and teeth-gnashing about eroding public health capabilities in the United States. Gostin's argument for public health law reform has an abstract, detached feel to it because the general American political, economic, and social commitment to public health as an endeavor is weak, and has been so for many years. The political resurrection of public health seems a precondition for plans to reform public health law.

Gostin mentions the conceptual and practical obstacles public health faces, and he argues that it "needs opportunities to draw attention to its resource requirements and achievements, and to develop constituencies for programs."<sup>31</sup> He claims that the "lawmaking process provides just such an opportunity,"<sup>32</sup> and that the law reform process can rebuild support and commitment for public health. If antimicrobial resistance cannot get the attention of legislators and politicians in the United States, then I have a hard time believing that advocating general legal reform efforts will stimulate and sustain a public health renaissance in the United States. Legal reform efforts, I imagine, need to be parasitic on specific efforts to deal with public health threats. Interesting legal reform efforts have, for example, taken place in at least one state trying to cope with threats of possible pandemic influenza and bio-terrorism.<sup>33</sup>

In Chapter 11, Gostin does not focus on any specific public health threats facing the United States. In other writings, Gostin and colleagues made specific arguments and recommendations about public health law reform with respect to the problem of infectious diseases.<sup>34</sup> Gostin was also involved in promoting model principles for health information privacy.<sup>35</sup> It was easier to grasp those recommendations because they flowed from an analysis of specific, contemporary problems in American public health. But Gostin does not connect his general ideas on public health law reform to the concrete challenges confronting American public health today and in the foreseeable future. In other chapters, Gostin provided case studies of current public health problems to illustrate the application of general legal principles, rules, and precedents. Chapter 11 perhaps needed some application of the general law reform guidelines to actual public health problems.

For example, many experts believe that the general aging of the U.S. population will present public health challenges, the likes of which

American public health has not previously confronted. How should public health law be reformed, if at all, in the face of the public health concerns created by the aging of the population? Antimicrobial resistance is another growing crisis in American public health that relates to infectious diseases. How should Gostin's law reform guidelines be applied to the problem of antimicrobial resistance, and what would be the scope and shape of the resulting legal reform?<sup>36</sup>

Another reason I yearned for some discussion of specific public health threats in Chapter 11 is that such discourse might have revealed Gostin's priorities for public health law reform. As Part One demonstrated, public health law is a massive field. In Chapter 11, Gostin does not indicate whether he thinks public health law reform is needed more urgently in, say, infectious diseases than in environmental protection. Where should public health law reform realistically be targeted first? Is there one area of public health law (e.g., infectious diseases) that provides the most fertile opportunity to apply all or most of Gostin's law reform guidelines?

Gostin's approach to public health law reform does have the advantage of not being linked to specific public health problems that may not be perceived as urgent in five or ten years time. His general approach might not, therefore, become outdated, giving his ideas on public health law reform longevity and permanence. My concern is, however, that by not identifying specific public health problems and the lack of priorities for legal reform, Gostin's arguments may lack immediacy and impact. Instead of supporting the normative goal of making public health law transcendent in American society and governance, Gostin's approach in Chapter 11 may unintentionally invite further neglect.

My concern will be proved baseless if the readers of *Public Health Law* understand and then apply Gostin's ideas on legal reform to specific areas that require attention. Previously, reform of public health law was a problem in search of principles. Gostin has now provided the principles with which to approach the problem both generally, and in connection with any specific public health threat facing the United States. Despite my concerns about Chapter 11, this is a seminal and noble achievement.

## CONCLUSION

*Public Health Law* will quickly become the leading intellectual and practical guide to American public health law. In the United States, the study of law is populated by works of enduring significance whose authors became synonymous with a field of law: Corbin on Contracts, Prosser on Torts, etc. Now, both the public health and legal disciplines have Gostin on Public Health Law. Let neither my praise nor my criticism herein deflect

the readers of this *Journal* from appreciating the accomplishment and contribution Gostin's book represents for all those interested in the future of public health in the United States.

## References

1. LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* (2000) [hereinafter *PUBLIC HEALTH LAW*]. Gostin has also produced a reader in public health, law, and ethics that is designed to be used with *PUBLIC HEALTH LAW* in schools of law, public health, medicine, health administration, and other fields. LAWRENCE O. GOSTIN, *PUBLIC HEALTH, LAW, AND ETHICS: A READER* (forthcoming 2002). The reader is not reviewed herein.
2. Memorandum from David P. Fidler to Daniel M. Fox, Milbank Memorial Fund, and Lynne Withey, University of California Press, providing comments on draft chapters of *PUBLIC HEALTH LAW* (May 19, 1999) (on file with author).
3. A three part series by Professor Gostin, published in *JAMA* in June 2000, also provided a sneak preview of the finished book. Lawrence O. Gostin, *Public Health Law in a New Century – Part I: Law as a Tool to Advance the Community's Health*, 283 *JAMA* 2837 (2000); *Part II: Public Health Powers and Limits*, 283 *JAMA* 2979 (2000); and *Part III: Public Health Regulation: A Systematic Evaluation*, 283 *JAMA* 3118 (2000).
4. LAURIE GARRETT, *BETRAYAL OF TRUST: THE COLLAPSE OF GLOBAL PUBLIC HEALTH* (2000); LAURIE GARRETT, *THE COMING PLAGUE: NEWLY EMERGING DISEASES IN A WORLD OUT OF BALANCE* (1994).
5. *PUBLIC HEALTH LAW*, *supra* note 1, at 309.
6. *Id.* at xvii.
7. Exceptions to this general neglect of public health law are FRANK P. GRAD, *THE PUBLIC HEALTH LAW MANUAL* (2d ed. 1990) and KENNETH R. WING, *THE LAW AND THE PUBLIC'S HEALTH* (4th ed. 1995).
8. The neglect of law by public health, and the neglect of public health by law, is also apparent at the international level. In the 1990s, the neglect of the relationship between international law and public health became the source of a growing body of scholarship, to which Gostin contributed. See LAWRENCE O. GOSTIN & ZITA LAZZARINI, *HUMAN RIGHTS AND PUBLIC HEALTH IN THE AIDS PANDEMIC* (1997).
9. *PUBLIC HEALTH LAW*, *supra* note 1, at 327.
10. *Id.* at 13.
11. *Id.* at 4. The subtitle of the book—*Power, Duty, Restraint*—summarizes the key attributes in Gostin's definition of public health law.
12. *Id.*
13. *Id.* at 327.
14. *Id.* at xxi.
15. I identified only two moments in the book when the analysis drew in things international. The first involved a brief description of the controversies that arose around clinical trials in developing countries of anti-HIV drugs. *Id.* at 124. The second contained an even shorter mention of international law on quarantine matters. *Id.* at 206.
16. *Id.* at xviii.
17. In reading *Public Health Law*, I sensed Gostin's desire to lay out the "concept" of public health law. I recalled the effort of the great English scholar of jurisprudence, H.L.A. Hart, to capture what he called the "concept of law." H.L.A. HART, *THE CONCEPT OF LAW* (1961). In explaining the concept of law, Hart attempted to deal with international law because he apparently believed that he could not ignore this realm of law. *Id.* at

208-31. With Hart in mind, I wondered why Gostin chose not to include international law in his "concept of public health law."

18. PUBLIC HEALTH LAW, *supra* note 1, at xxii.

19. In the Preface, Gostin explains this approach by stating that he "felt it important to develop a common understanding of the constitutional basis for the exercise of public health powers and the limits on those powers." *Id.* at xxiii. Thus, Gostin "decided not to examine the rich constitutional history and structures at the state level, which are equally important to the field of public health but whose inclusion would have made the book too diverse and detailed." *Id.*

20. *United States v. Lopez*, 514 U.S. 549 (1995).

21. *New York v. United States*, 505 U.S. 144 (1992).

22. *Seminole Tribe v. Florida*, 517 U.S. 44 (1996).

23. See, for example, Gostin's discussion of "The Synergy Between Human Rights and Public Health" in Chapter 4. PUBLIC HEALTH LAW, *supra* note 1, at 107-109.

24. *Id.* at xxi.

25. *Id.* at xx (stating that "My friend, the late Jonathan Mann, was particularly eloquent in urging the conclusion that public health and human rights are synergistic; preserving and promoting individual rights most often advances human well-being.").

26. *Id.* at 109.

27. *Id.* at 107.

28. Perhaps Chapters 9 and 10 could have been combined into a separate part focused on public health and the direct

and indirect regulation of economic behavior. Whether this alternative structure would have really improved the book is very questionable because the substance of Gostin's analysis in these chapters is excellent.

29. See GOSTIN & LAZZARINI, *supra* note 8.

30. PUBLIC HEALTH LAW, *supra* note 1, at 310 ("It is important to emphasize that no single model of law reform is likely to fit the entire spectrum of public health ranging from the regulation of food, drugs, and water supply to the workplace, environment, and infectious diseases. The proposed guidelines, therefore, represent general themes important to good governance of public health agencies engaged in a variety of public health activities.").

31. *Id.* at 326.

32. *Id.* at 327.

33. See COLO. REV. STAT. § 24-32-2103 (2000).

34. LAWRENCE O. GOSTIN ET AL., IMPROVING STATE LAW TO PREVENT AND TREAT INFECTIOUS DISEASE (1998); Lawrence O. Gostin et al., *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59 (1999).

35. Lawrence O. Gostin et al., *The Public Health Information Infrastructure: A National Review of the Law on Health Information Privacy*, 275 JAMA 1921 (1996); Lawrence O. Gostin & James G. Hodge, Jr., *Model State Public Health Privacy Act*, at <http://www.critpath.org/msphpa/privacy.htm> (last visited Apr. 20, 2001).

36. Gostin discusses the problem of drug resistance in Chapter 8 and mentions

possible policy options for addressing it—government incentives for, or regulation of, physician prescribing; government provision of compliance-enhancing services for vulnerable patients; compulsory measures to ensure antibiotics and anti-retrovirals are not misused, ranging from civil commitment to the less restrictive approach of directly observed therapy. PUBLIC HEALTH LAW, *supra* note 1, at 221-23.



## Of Cloned Embryos, Humans, and Posthumans

Evelyne Shuster, Ph.D.\*

*Cloning and the Future of Human Embryo Research.* Edited by Paul Lauritzen. Oxford: Oxford University Press, 2001. Pp. 291.

Since Ian Wilmut's report in *Nature*<sup>1</sup> that he had cloned an adult sheep by transferring the nuclei of its somatic cells into an enucleated egg, two other announcements in Britain and the United States have renewed the debate on human embryo research and increased speculation about the prospect of human cloning. In the summer of 2000, a panel of scientists in Britain recommended that Parliament permit research on stem cells derived from human embryos created by somatic cell nuclear transfer, a technique used to produce "Dolly," the cloned sheep.<sup>2</sup> British scientists emphasized in their proposal that cloning techniques would be applied only to produce stem cells for treatment purposes (therapeutic cloning), and that under no circumstances would they contemplate approving somatic cell nuclear replacement to produce a child (reproductive cloning). Nonetheless, critics and the public fear that, in the absence of an enforceable global treaty to ban the practice, cloning techniques developed and perfected in Britain will inevitably be applied elsewhere to produce human clones.

A week after the British proposal, the U.S. National Institutes of Health (NIH) issued new guidelines to permit federally funded scientists to conduct research on human embryonic pluripotent stem cells, so long as these stem cells are derived by private parties from unused frozen embryos created for infertility treatment in private clinics (spare embryo research). The strong support of celebrities like Christopher Reeve and Michael J. Fox, as well as the millions of people and their families whose lives may be improved by stem cell research, may help assure that these regulations remain in effect during George W. Bush's presidency. While people in the United States and abroad generally approve the creation and destruction of human embryos for stem cell research, there is virtually no

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support for creating children by cloning or for attempting to genetically engineer embryos to make "better babies."

Reproductive cloning has raised near unanimous public condemnation and has spurred a flurry of laws and legislative proposals to outlaw cloning humans. Opponents have argued that reproductive cloning robs children of their right to personal identity and commodifies them by treating children as interchangeable, thereby devaluing human life and threatening human rights and dignity.<sup>3</sup> Cloning proponents argue that reproductive cloning is no different from currently used methods of assisted reproduction, and that cloning would offer infertile couples just another way to have genetically related children, with the added bonus of almost absolute genetic control over their offspring.

The new proposals that favor research into therapeutic cloning to broaden our understanding of, and hopefully to find new treatments for, diseases have tamed the public outcry at doing research on a slippery slope that could lead to human reproductive cloning. But no responsible scientist or physician currently suggests attempting to help create a child by cloning because it is not safe. Questions of safety and efficiency are legitimate concerns and may eventually be answered, at least partially, by stem cell research. Once therapeutic cloning research begins, there may be no sufficient safeguards to prevent sliding down a slippery slope from therapeutic to reproductive cloning, and then to genetic engineering. The ethical issues surrounding human embryo research (including the ethics of human cloning) are thus even more relevant today than they were at Dolly's birth in 1997.

Philosopher Paul Lauritzen, the editor of the series of essays that make up *Cloning and the Future of Human Embryo Research*, is on the right track in wanting to put Dolly's birth in the context of embryo research. As Lauritzen explains in his introduction: "cloning is an outgrowth of IVF [in vitro fertilization] technology, and we are unlikely to formulate an adequate view of cloning unless we take this fact into account."<sup>4</sup> We thus need to see the birth of the cloned sheep, "as an intermediate step—perhaps the penultimate step—leading from the birth of the first IVF baby, Louise Brown, toward the birth of the first cloned human baby."<sup>5</sup>

Framing reproductive cloning within the realm of embryo research is defensible; but broadening the frame to place cloning within the realm of human reproduction is much more problematic. Nonetheless, Lauritzen takes human reproduction as the focal point of this work, following the lead of the 1994 report of the NIH Human Embryo Research Panel (HERP),<sup>6</sup> and the President's National Bioethics Advisory Commission (NBAC) Report on human cloning.<sup>7</sup>

Lauritzen correctly notes that when NBAC decided to avoid the issues related to embryo research (to sidestep the pitfalls of abortion politics that mired HERP), it created two additional problems. First, it allowed NBAC to proceed as if the status of the preimplantation embryo, and thus of embryo research, had already been resolved, which is simply not the case. Second, it gave the impression that the cloning issues identified by NBAC were unrelated to the status of embryo. Thus, “[o]nce we recognize the continuity between cloning and human embryo research, we are also in a position to see that there are two obvious points of departure for this volume.”<sup>8</sup>

This selection of essays is a direct result of choosing an embryo/reproduction framework. The book is composed of three parts: Part 1, “Moral Status of the Preimplantation Embryo;” Part 2, “Debates Surrounding Cloning and Embryo Research;” and Part 3, “Public Policy Issues.” There are three appendices reproducing the Executive Summaries of the HERP report and the NBAC report, including excerpts from Chapter 2 of the NBAC report entitled, “The Science and Application of Cloning.” The fourteen contributors to the twelve chapters are drawn mainly from the field of philosophy and religion (only three authors are from the legal profession). To me this is most welcome in an era where philosophy and religion have ceased to strongly offer their critiques in terms of majesty and sanctity, respectively. Six of the fourteen contributors were either members of HERP, NBAC, or both, and for the most part, their chapters offer little new. Nonetheless, the chapters read as if they were written for the book, and the knitting together of ideas that intertwine them is a credit to the book’s editor.

Specifically, the first four of the five chapters in Part I of the book are well argued and sufficiently open-ended for legitimate metaphysical discussion of the moral status of the embryo. These chapters provide excellent information, particularly with regard to the meaning of the phrase “respect for embryos.”<sup>9</sup> As Bonnie Steinbock accurately observes in the first chapter, “giving meaning to this concept of ‘special respect’ or ‘serious moral consideration,’ however, remains problematic.”<sup>10</sup> She takes the position that human embryos have interests rather than rights because they lack sentience, consciousness, or even simple awareness of any kind. Thus, she argues, neither embryos nor gametes are harmed, wronged, or deprived of anything by being used in research or destroyed. She nonetheless insists that respect for human embryos can still be a meaningful concept regardless of the way embryos are disposed of so long as they are used to generate worthwhile benefits for humankind.<sup>11</sup> Steinbock adopts a version of utilitarian philosophy according to which the

right act is a function of the good it generates. The obvious difficulty is determining what counts as a good and what counts as a harm, and how to measure them to determine the right balance between the good of scientific progress and the harm society could incur in terms of less respect for human life by using embryos instrumentally.

Courtney Campbell responds to Steinbock in the book's second chapter (Source or Resource? Human Embryo Research as an Ethics Issue). Campbell laments the pervasive influence of scientific reductionism that causes us to view embryos as consumer products like a box of Cheerios. He asks "whether the embryo is a source of life or a re-source of science."<sup>12</sup> Would it be too much to ask to show regret, anguish, or some form of verbal expression of how unfortunate it is to perform research on embryos? He believes that the moral consideration of respect for embryos as illustrated by HERP and Steinbock is "merely a political facade used to disguise and make publicly palatable scientific interests in having access to embryos for research."<sup>13</sup> But Campbell stops short of saying that if respect for human embryos is to have any meaning at all, destructive embryo research should not be done.

The third and fourth chapters, by Maura Ryan (Creating Embryos for Research: On Weighing Symbolic Costs) and James Keenan (Casuistry, Virtue, and the Slippery Slope: Major Problems with Producing Human Embryonic Life For Research Purposes) focus on whether there is any justification for creating human embryos for research. Keenan, for example, stresses that the way we view embryos determines how we use them. And thus, "our willingness to manipulate the embryo determines our understanding of the nature of the human embryo."<sup>14</sup> Rather than trying to settle the issue of the nature of embryos (on which people may never agree), we should speak about what it is that humans do when we produce human embryos for research. How does this affect the way we are as humans qua humans, and our human dignity? This is a fair question since, as Richard McCormick has observed, what we do to embryos we do to ourselves, and this affects who we are and the way we view each other as human beings.<sup>15</sup>

The fifth chapter, by Alta Charo (Every Cell is Sacred: Logical Consequences of the Argument from Potential in the Age of Cloning), provides a bridge to the second part of this volume. She rightly points to the problems (if not the absurdity) that logically follow from the argument that we ought to respect embryos because of their potential to become human beings. This argument, she contends, would have us granting similar respect to sperm and eggs because both are necessary to produce embryos, and also to any somatic cell, each of which cloning techniques

can use to produce a human embryo (of course with a human egg).

The second part of the book includes three essays, two of which are authored by Dan Brock and Ronald Green, and are very supportive of human cloning. The other essay by Laurie Zoloth (*Born Again: Faith and Yearning in the Cloning Controversy*), is the strongest and most original in the collection. Zoloth, a Jewish scholar, properly labels cloning to produce a child “replication” rather than reproduction, and insightfully speculates that replication cloning is intriguing “because it offers an answer to the inevitability of alterity, estrangement, and death.”<sup>16</sup> Zoloth argues that cloning represents the human desire for immortality, and points to our fear of death and our longing for eternal return even if this is only by way of genetic recycling. To her, cloning is neither about infertility (which can be more easily managed with other means), nor about children. Cloning is about self-absorption and narcissistic dreams (or nightmares).

Zoloth rightly maintains, for example, that “if cloning were about children, we would need to be thinking about the 100,000 children in foster care in America,” (and I would add, the ten million AIDS orphans in Africa) “and the way that race, illness, or oddity makes children unadoptable, untakeable.”<sup>17</sup> Zoloth muses that genetic replication cloning is an answer to our deepest, “staggering mesmerizing panic at our own mortality,”<sup>18</sup> and “reflects the deepest of yearnings: for redemption and resurrection into a better, purer, and transformed self, a self given a second chance at an embodied human journey.”<sup>19</sup> This is why the “cloning controversy reaches so deeply into the popular imagination.”<sup>20</sup> Her excellent essay makes for valued reflection that is likely to lead us to the heart of the human soul, desire, and human frailty, and to the fundamental question of why we contemplate human cloning. But because it is so ambitious, it seems out of place in this part of the book.

The third and final part of the book includes four essays on public policy issues, and illustrates the complexities and pitfalls at the intersection of ethics and public policy, as well as the difficulties of achieving consensus in bioethics. Carol Tauer, for example, points to “the current impasse in public policy and the impasse in moral debate on human embryo research, showing that the moral debate flounders because of different views as to where the burden of proof lies.”<sup>21</sup> She properly asks: “Do those who defend embryo research have to show why it is morally justifiable, or do those who oppose it have to show why it is morally wrong?”<sup>22</sup>

The last essay in the book, by Heidi Forster and Emily Ramsey (*The Law Meets Reproductive Technology: The Prospect of Human Cloning*), highlights the limits of legislative proposals on cloning in the United States and abroad. Regarding the United States, the authors raise the question of

whether there is a fundamental constitutional right to clone. In their answer, they cite the argument that "opponents of human cloning assert that cloning does not fall within our previously recognized constitutional liberties because cloning is distinguishable from currently practiced reproductive technologies."<sup>23</sup> In this view, they quote Steinbock with approval: "cloning correlates with 'replication' not 'reproduction,' and is not constitutionally protected."<sup>24</sup> The point should not be lost; if the "opponents" are right, those who seek constitutional protection for cloning as just another method of reproduction will be disappointed, just as those bioethicists who recently sought constitutional protection for physician-assisted suicide as a form of autonomy were disappointed.

This category point, i.e., cloning is genetic replication, not human reproduction, also made by Zoloth, is at the heart of the cloning debate, and has not been resolved. Ignoring or marginalizing it does not resolve or even move the debate along. If raised at the outset of the book, rather than at the end of the book, this category controversy would have had the potential to shatter the entire book's framework. It would have rendered irrelevant the familiar landmarks of embryo research and human reproduction (exemplified by the HERP and NBAC reports) that bear the stamp of time, geography, and culture, and with which we have become accustomed to seeing cloning's supporters use to try to tame the creative and wild profusion of ideas about cloning.

If cloning is not reproduction, then it represents a discontinuity with current reproductive techniques, and thus there can be no similarities between them: they are different in kind rather than degree. I think this view is correct, and that the cleavage between cloning and reproduction makes the concept of reproductive cloning itself an oxymoron. Reproduction is sexual; cloning is asexual and produces a child without the genetic input of two members of the opposite sex. Asexual cloning is genetic replication because the child so conceived has only a copy of an already existing genome that has been replicated. Of course we can try to make genetic relationships "fit" into our current mold, but it is not easy. In asexual genetic replication, the clone child will be the twin sister or brother of his or her genetic "original." But the genetic original will also fill the social role of parent. But this is neither an unproblematic twin relationship nor an unproblematic parent-child relationship. Unlike "natural" identical twins, created by sexual reproduction, the cloned child is a "delayed twin," born after (usually long after) the birth of her genetic twin original. This "delayed twin" condition is unique to cloning, and creates intractable problems of filiation.

The central ethical issue is not the status of the human embryo created

by the Dolly technique, but the liberty of the resulting child. In delayed genetic replication, the child must be compared to his or her “original,” almost necessarily in a lopsided fashion. Vital restraints are likely to be imposed on that child to follow in the wake of its genetic original, or to avoid the “mistakes” made by the original. As Hans Jonas insightfully argued more than twenty-five years ago, genetic replication robs the resulting child of his or her right to an open future, a crime Jonas believed should not be committed even once.<sup>25</sup> Of course, genes do not exclusively determine who we are. Environment matters mightily. But this statement does not change the intent or content of cloning, which must exclusively be to make a genetic duplicate. That is all cloning is, and that is all cloning can do. The prevailing international view is that creating a genetic replica of an existing person is degrading to children by limiting their liberty and thereby violating fundamental principles of human rights and human dignity.

Moreover, far from being a treatment for infertility (as Green argues), cloning abolishes the very concept of infertility itself. This is because in asexual replication it would no longer matter for the purposes of having a genetically related child whether the would-be parents are gametically fertile or not. Each of our somatic cells can be used for replication cloning, and thus everyone is able to self-replicate (assuming eggs are available and women are willing to gestate the resulting embryos). If replication cloning is equated with reproduction, to speak of cloning as treatment for infertility is meaningless.

The unique characteristic of cloning demonstrates that it introduces a fundamental difference in producing a child. One cannot simply assume continuity between cloning and other methods of assisted reproduction. The difference in kind in producing a child by cloning requires an analysis of the threshold above which there are differences, and below which there are similarities. Such analysis is indispensable for the establishment of even the simple form of ordering such as the one adopted in this volume. Failure to recognize this, is the book’s most substantive weakness.

I recently read a piece by *New York Times* columnist, George Johnson that caused me profound uneasiness and prompted me to reflect on how a culture experiences the proximity of things, establishes support of things we apprehend in one great leap, and determines the order by which these things must be considered. In this piece, Johnson shows how “it has become natural to think of [the Internet] biologically” and quotes scientists who say they have found a universal law, “a power law,” that supports a number of listed things ranging from cells to the Internet.<sup>26</sup> Included in this list are: (1) a flourishing ecosystem of computers, (2) a

sprawling brain of Pentium-powered neurons, (3) the networks of molecules in a cell, (4) the networks of species in an ecosystem, (5) the networks of people in a social group, (6) the Internet, and (7) the metabolic networks of life-sustaining chemical reactions inside cells. Johnson thus asks: How does this kind of ordering arise? In what kind of structure do these seemingly diverse categories exist?

French philosopher Michel Foucault raises similar questions in his book, *The Order of Things*, when he asks: What do we do when we classify? What is the ground for establishing the validity of classification? On what support and according to what grid of identities, similarities, and analogies have we become accustomed to sort out so many different and similar things?<sup>27</sup> Foucault observes (in the context of a simple kind of enumeration) that while each of the things listed can be assigned a precise meaning and a demonstrable content, there is a “monstrous quality” in the enumeration that destroys the common ground on which the meeting of each of these things is possible. In his words: “Absurdity destroys the *and* of the enumeration by making impossible the *in* where the things enumerated would be divided up.”<sup>28</sup>

The category into which we “fit” human cloning constitutes the common ground that links similar and different things, and each thing to all the others. If, for example, we add cloning to the list of assisted reproductive technologies, which includes *in vitro* fertilization, artificial insemination, embryo splitting, embryo manipulation, infertility, etc., then cloning will take on the quality of the things enumerated in that category. Likewise, if we add cloning to the list of species alteration, which includes asexual replication, egg manipulation, germline modification, etc., then cloning will take on a much more sinister aspect.

“Fitting” cloning into the species alteration category is consistent with what Ian Wilmut himself has said about his project to improve animals in the context of animal cloning:

We do not seek simply to clone animal—to produce facsimiles of existing creatures. This was never our agenda; it is just what other people thought was important. *Cloning for us is and always has been an exercise in science finding out how cells work and a technology that enables the genetic transformation of animals.*<sup>29</sup>

As Wilmut explains, somatic cell nuclear transfer was not even invented for genetic replication but rather primarily to be used for germline genetic modification to “improve” or “genetically enhance” embryos that would produce animals with altogether new characteristics (like the ability to produce specific proteins useful in the production of



human drugs).<sup>30</sup> This category point makes the possible application of somatic cell nuclear transfer cloning to humans much more troublesome. It is fair to say that it would have made for a much more up-to-date book had a discussion of human genetic enhancement through embryo manipulation been included.

The pairing of somatic cell nuclear transfer cloning and genetic enhancement is powerful because it makes genetic replication (of embryos) a means to the end of genetic transformation of the human species. Genetic engineering through new or improved genes that can be added to somatic cells (later used as the nuclei of embryos) to produce “smarter” people, people with enhanced memory, and people resistant to diseases and environmental insult, may be much more appealing to most people than simple genetic replication. And if we want to try to stop the eugenic project of genetically enhancing embryos to improve the “quality” of our children, to the extent that human cloning techniques are necessary to make genetic enhancement efficient, outlawing human replication cloning will effectively outlaw human genetic enhancement as well.

We must think globally and at the species level about proposed interventions that threaten to change the inherent characteristics of what it means to be human. For this we need a mechanism to protect the integrity of the human species, and a way to shift the burden of proof to those who would change it, rather than to those who would protect it. But American bioethicists are ill-equipped to provide a valuable contribution because of their almost exclusive focus on the patient-physician relationship. This focus gives American bioethicists a lot to say about reproductive treatment for individuals and couples, but almost nothing to say about species integrity or alteration. The lack of any species-level debate or global vision is reflected in this book, and means that this selection of essays can provide only a limited introduction to human cloning, and even less about the more challenging question of human species alteration by genetic manipulation of which human cloning is the harbinger.

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## BOOK NOTES

***At Risk in America: The Health and Health Care Needs of Vulnerable Populations in the United States.* By Lu Ann Aday. New York: John Wiley & Sons, 2001. Pp. 416.**

This updated second edition provides a detailed analysis of key population groups most vulnerable to disease and injury in the United States today—homeless persons, refugees and immigrants, people living with AIDS, alcohol and substance abusers, high-risk mothers and infants, victims of family or other violence, and the chronically or mentally ill. Aday reviews the major theories and knowledge concerning these at-risk groups and offers new approaches and methodologies for tracing the social determinants and societal influences on health. She examines the specific health needs and risks faced by these groups, their experiences in the health care system, the current policies and programs that serve them, and the research and policy initiatives that might be undertaken to help reduce their vulnerability.

***Bioethics: Ancient Themes in Contemporary Issues.* Edited by Mark G. Kuczewski and Ronald Polansky. Cambridge: The MIT Press, 2000. Pp. 310.**

In this book contemporary bioethicists and scholars of ancient philosophy explore the importance of classical ethics on such pressing bioethical concerns as managed care, euthanasia, suicide, and abortion. Although the contributors write within the limits of their own disciplines, through cross references and counterarguments, they engage in fruitful dialogue. Contributors include Georgios Anagnostopoulos, Julia E. Annas, Robert Bartz, Tod Chambers, Christopher E. Cosans, Kathryn Montgomery Hunter, Mark G. Kuczewski, Alex John London, Christopher Megone, Ronald Polansky, David Thomasma, and Daryl Tress.

***Confessions of a Medicine Man: An Essay in Popular Philosophy.* By Alfred I. Tauber. Cambridge: The MIT Press, 2000. Pp. 184.**

Tauber probes the ethical structure of contemporary medicine in an argument accessible to lay readers, healthcare professionals, and ethicists alike. Through personal anecdote, historical narrative, and philosophical discussion, Tauber composes a moral portrait of the doctor-patient relationship. He seeks to show how our basic conceptions of health, the body, and, most fundamentally, our notion of selfhood, frame our experience of illness.

***Equal Treatment for People with Mental Retardation: Having and Raising***

***Children.* By Martha A. Field and Valerie A. Sanchez. Cambridge: Harvard University Press, 2000. Pp. 448.**

Engaging in sex, becoming parents, raising children: these are among the most personal decisions we make. For people with mental retardation, these decisions are consistently challenged, regulated, and outlawed. This book is a comprehensive study of the American legal doctrines and social policies, past and present, that have governed procreation and parenting by persons with mental retardation. It argues that people with retardation should have legal authority to make their own decisions. Despite the progress of the normalization movement, which has moved so many people with mental retardation into the mainstream since the 1960s, negative myths about reproduction and child rearing among this population persist. Field and Sanchez trace these prejudices to the eugenics movement of the late nineteenth and early twentieth centuries. They show how misperceptions have led to inconsistent and discriminatory outcomes when third parties seek to make birth control or parenting decisions for people with mental retardation. They also explore the effect of these decisions on those they purport to protect. The book is a sustained argument for reform of the legal practices and social policies it describes.

***Genetics and Public Health in the 21st Century: Using Genetic Information to Improve Health and Prevent Disease.* Edited by Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson. Oxford: Oxford University Press, 2000. Pp. 664.**

In anticipation of the expected growth at the interface of genetics and public health, this book delineates a framework for the integration of advances in human genetics into public health practice. It provides a comprehensive review of public health genetics, including chapters on important general issues, such as newborn and other genetic screening, the delivery of genetic services, and the ethical, legal, and social implications of the use of genetics within public health. Contributors come from a wide range of fields, including epidemiology, biostatistics, health policy and management, health services research, behavioral and social sciences, ethics, law, health economics, and laboratory sciences.

***Health Care & Spirituality: Listening, Assessing, Caring.* Edited by Richard B. Gilbert. Amityville: Baywood Publishing, 2002. Pp. 336.**

This book is an anthology of the human predicament—the health care professional's story and the health care work place. The book notes that spirituality is continually introduced to new treatments, new challenges, new people, new regulations, new expectations, and new time limits. It addresses the marginalization that accompanies disease, trauma, and dying, and finds that care

provided by professionals is easily marginalized by the language of the “bottom line,” regulations, managed care, and human limits. The theme of the book is listening, to the patient’s whole story; assessing, or giving meaning in conversation with the patient; and caring, for the whole person and the whole story.

***Inner Hygiene: Constipation and the Pursuit of Health in Modern Society.* By James C. Whorton. Oxford: Oxford University Press, 2000. Pp. 344.**

This book explores the serious health threat of constipation, and discusses the extraordinary variety of preventive and curative measures that have been developed to save people from the toxic effects of intestinal irregularity. The book examines the evolution over the last two centuries of the belief that constipation is a disease brought on by an unnatural lifestyle of urban, industrial society. Particular attention is given to the many constipation therapies that people have used, including laxatives, enemas, mineral waters, bran cereals, yogurts, electrotherapy, calisthenics, rectal dilation devices, and many other remedies. The story is carried up to the present and demonstrates that many constipation therapies from the nineteenth and twentieth centuries are continuing into the twenty-first century.

***Is There a Duty to Die?* Edited by James M. Humber and Robert F. Almeder. Totowa: Humana Press, 2000. Pp. 232.**

Leading philosophers and bioethicists revisit the disturbing question raised in 1987 by Dr. Margaret Battin: Is there is “a duty to die” in order to guarantee a just cross-generational distribution of limited health care resources? The essays collected here—including a new article by Battin—discuss the topic in-depth, providing a critical review of the literature and many new arguments. The debate includes not only those who support such a “duty” and those who say such a “duty” cannot be denied, but also those who doubt such a “duty to die” exists or question whether—if it did exist—it could be implemented without severe problems. The book offers a discussion across a wide range of opinions on the meaning of “duty to die,” examining every sort of argument for and against the idea.

***Life’s End: Technocratic Dying in an Age of Spiritual Yearning.* By David Wendell Moller. Amityville: Baywood Publishing, 2000. Pp. 210.**

This work explores how the American value of individualism and the widespread commitment to technology have given rise to particular forms of governing the process of dying that are unique to the professional dominance of death in the hospital setting. It focuses on how the values of technology in the broader society are applied in the framework of medicalized care of dying patients, and discusses

the consequences this has for their lives. Additionally, this book analyzes how the value of individualism, so ubiquitous in the broader society, influences the treatment of dying patients and their definition of the meanings of their own dying. It shows how the dominant values of the American cultural system are institutionalized in the medical treatment of dying patients. The explicit purpose of this book is to analyze dying and death in the cosmopolitan, modern setting. It demonstrates that the foundation for the medicalization of death, which piercingly shapes the life experience of dying persons and loved ones, is a product of the ways of life in the broader culture.

***Narrative and the Cultural Construction of Illness and Healing.* Edited by Cheryl Mattingly and Linda C. Garro. Berkeley: University of California Press, 2001. Pp. 288.**

Inspired by the possibilities of narrative, the essays in this volume present stories drawn from a range of ethnographic contexts. Stories of illness and healing are often arresting in their power, and they can illuminate aspects of practices and experiences surrounding illness, which might otherwise be neglected. Recognizing the value of increased theoretical consciousness among those eliciting and analyzing narratives, these contributors explore narrative from a variety of perspectives.

***New Dimensions in Bioethics: Science, Ethics, and the Formulation of Public Policy.* Edited by Arthur W. Galston and Emily G. Shurr. Norwell: Kluwer Academic Publishers, 2000. Pp. 248.**

In the last three decades, bioethics has matured into a field of study with several areas of concentration, including medical ethics, environmental ethics, and more recently, genetic ethics. This collection of essays aims to enlarge the traditionally restrictive vision of bioethics, which is often limited to medical ethics. By combining essays relevant to medical ethics with companion essays on environmental and genetic ethics, the book emphasizes similarities in the methodologies used to analyze diverse bioethical problems, whether dealing with genes, people, or the environment. In this way, the book hopes to contribute to the intellectual unity of the subject and to suggest changes in the way bioethics can be taught and studied at both the graduate and undergraduate level.

***Nutrition and Health in Developing Countries.* Edited by Richard D. Semba and Martin W. Bloem. Totowa: Humana Press, 2001. Pp. 568.**

A leading corps of clinical nutritionists, epidemiologists, and public health practitioners discuss nutritional issues that impact the populations of developing

countries. Topics covered include deficiencies in essential vitamins and minerals, malnutrition, low birth weight, malaria, child growth and development, HIV, and tuberculosis.

***Prenatal Testing and Disability Rights.* Edited by Erik Parens and Adrienne Asch. Washington: Georgetown University Press, 2000. Pp. 392.**

As prenatal tests proliferate, the medical and broader communities perceive that such testing is a logical extension of good prenatal care—it helps parents have healthy babies. But prenatal tests have been criticized by the disability rights community, which contends that advances in science should be directed at improving their lives, not preventing them. Often used to decide whether to abort a fetus that would have been born with mental or physical impairments, prenatal tests arguably reinforce discrimination against, and misconceptions about, people with disabilities. In these essays, authors on both sides of the issue engage in an honest and occasionally painful debate about prenatal testing and selective abortion. The contributors include both people who live with and people who theorize about disabilities, scholars from the social sciences and humanities, medical geneticists, genetic counselors, physicians, and lawyers. Although the essayists do not arrive at a consensus about the disability community's objections to prenatal testing and its consequences, they do offer recommendations for ameliorating some of the problems associated with the practice.

***Promoting Healthy Behavior: How Much Freedom? Whose Responsibility?* Edited by Daniel Callahan. Washington: Georgetown University Press, 2000. Pp. 200.**

These essays examine the ethical and social problems that create subtle obstacles to changing Americans' unhealthy behavior. The contributors raise profound questions about the role of the state or employers in trying to change health-related behavior, about the actual health and economic benefits of even trying, and about the freedom and responsibility of those of us who, as citizens, will be the target of such efforts.

***Recent Health Policy Innovations in Social Security.* Edited by Xenia Scheil Adlung and Aviva Ron. Somerset: Transaction Publishers, 2001. Pp. 350.**

This book concentrates on health insurance policy innovations in selected countries in Africa, the Americas, Asia, and Europe. In addition, it addresses recent institutional economic findings with regard to application of information technology in health insurance systems. Topics discussed include new approaches in extending coverage in a health insurance system and confronting resource

scarcity. Many of the innovations presented here have already been integrated into existing reforms, and the authors refer to concrete developments in individual countries and regions.

***Strategies for the New Health Care Marketplace: Managing the Convergence of Consumerism and Technology.* By Dean C. Coddington, Elizabeth A. Fischer, Keith D. Moore. New York: John Wiley & Sons, 2001. Pp. 448.**

This book, written by a team of acclaimed experts, examines the factors changing today's health care system: the growth in demand for services, the increasing influence of consumers on how services are provided, and the dramatic new advances in treatment made possible by technology.

***The Cloning Sourcebook.* By Arlene Judith Klotzko. Oxford: Oxford University Press, 2001. Pp. 368.**

This book gives an insider's perspective on the people and the science of large-animal cloning. It examines the medical benefits that will result from xenotransplantation and pharmaceutical development in transgenic animals. The book also explores the financial stakes and business stories behind the science of cloning. Klotzko considers the prospects for human cloning, taking into account legal regulations, social and ethical concerns, and costs of this new technology.

***The Political Economy of Social Inequalities: Consequences for Health and Quality of Life.* Edited by Vicente Navarro. Amityville: Baywood Publishing, 2000. Pp. 536.**

In the last two decades of the twentieth century, social inequalities within and among countries has had a negative impact on the health and quality of life in the developed and underdeveloped nations. This volume analyzes the reasons for this increase in inequalities and its consequences for the well-being of populations. Scholars from a variety of disciplines and countries analyze the different dimensions of this topic.

***Transplantation Ethics.* By Robert M. Veatch. Washington: Georgetown University Press, 2000. Pp. 448.**

Three decades after the first heart transplant surgery stunned the world, organs, including eyes, lungs, livers, kidneys, and hearts, are transplanted every day. But despite its increasingly routine nature—or perhaps because of it—transplantation offers enormous ethical challenges. A medical ethicist who has been involved in the organ transplant debate for many years, Veatch, explores a variety of questions



that continue to vex the transplantation community, offering his own solutions in many cases. Ranging from the most fundamental questions to recently emerging issues, This book is a complete and systematic account of the ethical and policy controversies surrounding organ transplants. Veatch structures his discussion around three major topics: the definition of death, the procurement of organs, and the allocation of organs. He lobbies for an allocation system—administered by nonphysicians—that considers both efficiency and equity, that takes into consideration the patient's age and previous transplant history, and that operates on a national rather than a regional level.

***Xeno: The Promise of Transplanting Animal Organs into Humans.* By David K.C. Cooper and Robert P. Lanza. Oxford: Oxford University Press, 2000. Pp. 304.**

This volume explores the medical, ethical, legal, and social issues surrounding the future of organ transplantation. The current critical shortage of human donor organs has stimulated promising new research into the field of xenotransplantation—the transplantation of organs from one animal species to another. In this book, Cooper and Lanza recount the several historical attempts to transplant animal organs into humans. In addition, they draw attention to both the immense potential and promise of this form of therapy, and they consider the social and ethical questions posed by such procedures. With profound implications for human health and longevity in the next millennium, this book is essential reading for anyone interested in the future of medicine.

