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Do We Still Need a Federal Patients' Bill of Rights?

Sylvia A. Law, J.D.*

Since 1997, proposals for a federal patients' bill of rights have enjoyed strong, bipartisan political support, from Congress,¹ presidential candidates,² and the two major political parties in their party platforms.³ Despite widespread approval, nothing has been adopted, and, furthermore, nothing has even come close.⁴ This Article examines developments in markets, state law, and federal court decisions that attest to the continued need for a federal patients' bill of rights.

Part I begins with a pair of narratives illustrating the deep-rooted problems that have generated the extraordinary consensus that federal legislation is needed to protect patients' rights. Part II briefly describes the application of the Employee Retirement Income Security Act of 1974 (ERISA) to disputes about health care coverage, highlighting the regulatory vacuum created by ERISA's preemption of state law and managed care's exacerbation of the resulting problems. Parts III and IV address two controversies plaguing proposals for a federal patients' bill of rights. First, while the Supreme Court, in *Pegram v. Herdrich*,⁵ authorized some state remedies for the negligent medical decisions of ERISA plans, it

* Sylvia A. Law is the Elizabeth K. Dollard Professor of Law, Medicine, and Psychiatry and Co-Director of the Arthur Garfield Hays Civil Liberties Program at the New York University School of Law. She received her B.A. from Antioch College in 1964 and her J.D. from the New York University School of Law in 1968. Professor Law would like to thank Douglas E. Julie, New York University School of Law, Class of 2004, for "providing magnificent research and editorial help, and pressing me to think sensibly about ERISA issues."

¹ The most influential of the early bills was the Patient Access to Responsible Care Act (PARCA) introduced by Representative Charles Norwood (R-GA) in April 1997. H.R. 1415, 105th Cong. (1997). The legislation was co-sponsored by 230 House members and a parallel bill was introduced in the Senate. S. 644, 105th Cong. (1997).

² *The 2000 Campaign; Exchanges Between the Candidates in the Third Presidential Debate*, N.Y. TIMES, Oct. 18, 2000, at A26.

³ See *The Democrats: The Party Program; Excerpts from Platform Approved by Democratic National Convention*, N.Y. TIMES, Aug. 16, 2000, at A26; *The Republicans; Excerpts from Platform Approved by Republican National Convention*, N.Y. TIMES, Aug. 1, 2000, at A16. While both parties share an abstract commitment to "patients' rights," they disagree on the details. See *infra* Part V.

⁴ See *infra* Part V (discussing the details of the political battle over proposals for a federal patients' bill of rights).

⁵ 530 U.S. 211 (2000) (discussing managed care liability for negligence).

provided little guidance on when managed care organizations (MCOs) are liable for unreasonable medical decisions that cause death or disability. Second, although the Supreme Court, in *Rush Prudential HMO, Inc. v. Moran*,⁶ upheld some state programs for independent medical review of denials of recommended care, it left many people without access to such review. Part V describes two proposals for a federal patients' bill of rights, focusing on the two questions considered in Parts III and IV. The Article concludes that even though *Pegram* and *Moran* have significantly changed the shape of the law, we still need a federal patients' bill of rights. However, the legislation supported by the House leadership in the 107th Congress would diminish rather than expand patients' rights, and may be unnecessarily complex and unwisely disrespectful of the capacity of the states to address complex problems.⁷

I. EXPERIENCE WITH MANAGED CARE HAS GENERATED SERIOUS CONCERN

This section frames the issues by presenting two recently litigated disputes between patients and MCOs—disputes of a sort that has become all-too-typical in the managed care arena.

Florence Corcoran's story⁸ is often cited by advocates to demonstrate the need for a patients' bill of rights.⁹ Corcoran, a long-time employee of South Central Bell Telephone Company, became pregnant in 1989. Her obstetrician, Dr. Jason Collins, recommended that she be hospitalized for the final months of her pregnancy. During Corcoran's first pregnancy, Collins had recommended the same course and, when the fetus went into distress, it was delivered by caesarean section. Collins communicated with the medical director of Bell explaining the factors that put Corcoran at

⁶ 122 S.Ct. 2151 (2002) (discussing the preemption of state laws providing for independent review of managed care judgments of medical necessity).

⁷ This Article, like the major provisions of the proposed federal patients' rights legislation, focuses on the processes whereby MCOs decide whether medical treatment is necessary and thus covered by insurance. In an ideal world, the concept of "patients' rights" would also encompass concern for the fourteen percent of the United States population that has no health insurance coverage. U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE: CURRENT POPULATION REPORTS 60-215 (2000), available at www.census.gov/prod/2001pubs/p60-215.pdf. In addition, a more sensible concept of patients' rights would address the alarmingly high rate of medical errors that result in countless injuries and in approximately 98,000 hospital deaths per year. L.T. KOHN ET AL., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 9 (Nat'l Acad. Press 2001).

⁸ *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321 (5th Cir. 1992), cert. denied, 506 U.S. 1033 (1992).

⁹ See, e.g., Edward M. Kennedy, *The Urgent Need To Pass Real Patient Protections*, at <http://kenedy.senate.gov/~kenedy/statements/01/06/2001627405.html> (June 19, 2001).

risk. Bell's medical director sought a second opinion from another obstetrician who said that Collins' recommendation was sound and that "the company would be at considerable risk denying her doctor's recommendation."¹⁰ Bell rejected the advice and denied approval for hospitalization. Corcoran stayed at home, attended a few hours a day by a visiting nurse. While the nurse was not present, the fetus went into distress and died.

The experiences of Basile Pappas¹¹ exemplify another common problem. Pappas was admitted to a community hospital emergency room at 11 a.m. complaining of paralysis and numbness in his arms and legs. The emergency room doctor, a neurologist, and a neurosurgeon all agreed that he needed emergency surgery that their small hospital was unable to provide. The doctors arranged to transfer him to Jefferson University Hospital. At 12:40 p.m., as Pappas was about to leave by ambulance, his MCO notified the doctors that he should be transferred to another university hospital that participated in his insurance plan. After lengthy negotiations, the doctors persuaded the second hospital to accept him. He was transferred at 3:30 p.m. As a consequence of the delay, Pappas suffered permanent quadriplegia.

II. ERISA'S VACUUM: LIMITED FEDERAL REMEDIES AND THE PREEMPTION OF STATE REMEDIES

The very problems that Congress seeks to address were created by Congress, with the help of the Supreme Court, through ERISA.¹² Traditionally, states regulated insurance, including health insurance, through legislation, administrative oversight, and the common law of torts and contracts.¹³ States also regulated medical care through the licensing of doctors, hospitals, and other health care providers.¹⁴ They defined what is unreasonably negligent behavior through common law and statutes.¹⁵ These bodies of state law are complex and take divergent approaches to common problems.¹⁶

¹⁰ 965 F.2d at 1322.

¹¹ *Pappas v. Asbel*, 768 A.2d 1089 (Pa. 2001), *cert. denied sub nom.* U.S. Healthcare Sys. of Pa., Inc. v. Pa. Hosp. Ins. Co., 122 S.Ct. 2618 (2002).

¹² 29 U.S.C. §§ 1001 *et seq.* (2002).

¹³ R. ROSENBLATT ET AL., *LAW AND THE AMERICAN HEALTH CARE SYSTEM* 139-59 (1997).

¹⁴ *Id.* at 967-74.

¹⁵ *Id.* at 842-90.

¹⁶ Sylvia A. Law & Barry Ensminger, *Negotiating Physicians' Fees: Individual Patients or Society? (A Case Study in Federalism)*, 61 N.Y.U. L. REV. 1, 57-63 (1986) (describing the diversity of state approaches to issues of health care access, quality, and costs).

ERISA was adopted to address the plight of workers denied of expected pension benefits.¹⁷ Its central provisions require that employer-sponsored pension plans meet substantive federal standards regulating funding, participation, vesting, benefit accrual, and disclosure of information.¹⁸ ERISA also deals with employee welfare benefit plans, including employer-sponsored health insurance. ERISA preempts state laws that “relate to” employee benefit plans. But rather than providing more protective federal rules as it does for pension plans, ERISA provides little federal regulation of welfare plans, creating a regulatory vacuum. In the late 1980s and throughout the 1990s, the Supreme Court grappled with the scope of ERISA’s preemption.

A. Section 514

ERISA’s explicit preemption clause—section 514—provides that ERISA “shall supercede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan. . . .”¹⁹ This broad federal preemption is modified by a savings clause that provides that nothing in ERISA “shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking or securities.”²⁰ This exemption allows states to regulate health insurance. When an employee benefit plan purchases health insurance for its members, it may be subject to state insurance regulation. However, when an employee benefit plan “self-insures,” it may not be subject to state regulation. This complex distinction is explored below.²¹

B. Section 502

ERISA’s second preemption of state law is not expressed but implied. Section 502(a) of the Act allows a plan participant or 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,” or for breach of fiduciary duty.²² In 1987, in *Pilot Life Insurance Co. v. Dedeaux*,²³ the plaintiff alleged

¹⁷ 29 U.S.C. § 1001(a) (2002).

¹⁸ *Id.* § 1002(1).

¹⁹ *Id.* § 1144(a). “State laws” includes “all laws, decisions, rules, regulations, or other State action having the effect of law, of any State.” *Id.* § 1144(c)(1).

²⁰ *Id.* § 1144(b)(2)(A).

²¹ See *infra* text accompanying notes 132-37.

²² 29 U.S.C. § 1132(a)(1)(B) (2002).

²³ 481 U.S. 41 (1987).

that his insurance company had willfully refused to pay the disability benefits promised by the policy. He invoked Mississippi's tort remedy for willful refusal to settle contract claims, seeking redress for the injuries that had resulted. The Supreme Court, in an opinion by Justice O'Connor, held that ERISA preempted the claim for two reasons. First, the Mississippi tort remedy for willful refusal to settle contract disputes was not limited to insurance claims, and hence could not be saved as a form of insurance regulation.²⁴ Second, "the civil enforcement provisions of ERISA § 502(a) [are] the exclusive vehicle for actions by ERISA-plan participants and beneficiaries asserting improper processing of a claim for benefits. . . ."²⁵

Further, even though section 502(a) provides that a plan beneficiary may bring suit "to obtain other appropriate equitable relief" to "redress such violations" or to "enforce . . . the terms of the plan" or the provisions of ERISA, federal courts have held that this does not authorize people like Corcoran or Pappas to seek extra-contractual damages when medically necessary services are denied and injury results.²⁶ Finally, and most importantly, in 1989, in *Firestone Tire & Rubber Co. v. Bruch*, the Supreme Court, again in an opinion by Justice O'Connor, interpreted ERISA to say that if a plan retains discretion to determine what benefits are covered, federal courts deciding claims under section 502 may reverse only if the claimant meets a very demanding standard—showing that the plan's actions were "arbitrary and capricious."²⁷

The thick federal preemption of state law is not limited to "laws dealing with the subject matters covered by ERISA. . . ."²⁸ For example, states have long recognized that insurance companies sometimes deny beneficiaries of legitimate entitlements. In response, many states provide that when an insurance company willfully denies benefits, beneficiaries can recover consequential damages in addition to the contract payments that had wrongfully been denied.²⁹ However, the Supreme Court held that ERISA preempts state remedies for willful refusal to provide insurance coverage³⁰ and that federal law provides no remedy for even egregiously wrongful practices beyond payment of the benefits promised by the

²⁴ *Id.* at 50.

²⁵ *Id.* at 52.

²⁶ *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1321, 1334-35, 1337-39 (5th Cir. 1992). Other circuit courts have followed this holding. *ROSENBLATT ET AL.*, *supra* note 13, at 1016.

²⁷ 489 U.S. 101, 110-15 (1989).

²⁸ *Shaw v. Delta Airlines, Inc.*, 463 U.S. 85, 98-99 (1983).

²⁹ *ROSENBLATT ET AL.*, *supra* note 13, at 142-47.

³⁰ *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987); *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63-66 (1987).

contract.³¹

C. *The Rise of Managed Care*

The rise of managed care has aggravated the problems created by ERISA preemption. Until the 1980s most Americans with insurance had coverage that allowed them free choice of providers at the time of care and paid doctors and hospitals on a fairly open-ended fee-for-service or reasonable-cost basis.³² To hold down costs, MCOs require prior authorization for many treatments, restrict access to specialists, limit the doctors and hospitals from whom plan participants may obtain care, provide doctors financial incentives to limit care, restrict coverage of prescription drugs, and impose other constraints on medical care.³³ Thus, the rise of managed care, together with ERISA's regulatory vacuum with respect to employer-sponsored health insurance, has left tens of thousands of Americans without legal redress for death or injury due to MCOs providing substandard care or wrongfully denying or delaying promised care.

Why would Congress prohibit states from applying ordinary common and statutory law to employment-based health insurance plans? Or, to put the question differently, if Congress preempts state authority, why doesn't Congress regulate these plans? The answer is simple: big business and big labor persuaded Congress that a state and federal regulatory vacuum would allow them to negotiate fairer and more effective medical insurance plans than what federal or state government would mandate.³⁴ In 2001, only 13.5% of wage and salary workers were union members.³⁵

III. *PEGRAM V. HERDRICH: WHEN ARE MANAGED CARE ORGANIZATIONS LIABLE FOR INJURIES CAUSED BY UNREASONABLY DELAYING OR DENYING TREATMENT?*

In 1995, a unanimous Supreme Court decision signaled an increased willingness to examine the sweep of ERISA's preemption. In *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*,³⁶ the

³¹ See *infra* Part IV.

³² See Law & Ensminger, *supra* note 16, at 12-14.

³³ See *Pegram v. Herdrich*, 530 U.S. 211, 218-19 (2000).

³⁴ See Marie Gottschalk, *The Missing Millions: Organized Labor, Business, and the Defeat of Clinton's Health Security Act*, 24 J. HEALTH POL., POL'Y & L. 489, 494-97 (1999).

³⁵ Press Release, Bureau of Labor Statistics, Union Members Summary, <http://www.bls.gov/news.release/union2.nr0.htm> (Jan. 17, 2002).

³⁶ 514 U.S. 645 (1995).

Court held that New York's comprehensive hospital rate regulation law did not "relate to" ERISA plans, even though the vast majority of plans affected were self-insured, employment-based insurance plans.³⁷ Since *Travelers*, the Supreme Court has narrowed the range of state laws that "relate to" an ERISA plan under section 514, broadening state authority to regulate.³⁸

Throughout the 1990s, lower federal courts struggled to implement the Supreme Court's ambiguous message about remedies for plan members who suffer injury when medically necessary services are delayed or denied. Many courts initially read ERISA's preemption broadly, finding the weak contractual remedies provided under section 502 to be exclusive.³⁹ Other courts, motivated by sympathy for injured patients and the new understanding of ERISA triggered by the Supreme Court's functional, "common sense" approach to statutory interpretation in *Travelers*, construed ERISA to permit state actions for extra-contractual damages when medical decisions denying benefits resulted in death or disability.⁴⁰

A. *Corcoran*

Corcoran is a poignant example of judicial willingness to read ERISA to deny remedies to injured patients. The Corcorans filed a wrongful death action in state court alleging that they had lost their baby because of the negligence of their insurer's utilization review program. ERISA allowed the insurer to remove the claim to federal court and to argue that federal law preempted the state tort claims. The Fifth Circuit accepted that argument, finding that the medical director's decision to deny coverage for hospitalization "related to" the administration of an ERISA plan.⁴¹ Corcoran asserted that the decision to deny hospitalization was a medical decision, and that it should therefore be governed by state medical malpractice law. The insurer argued that the decision was merely one of

³⁷ A unanimous Supreme Court found that in interpreting the "relate to" language "[w]e simply must go beyond the unhelpful text and the frustrating difficulty of defining its key term, and look instead to the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive." *Id.* at 656.

³⁸ *E.g.*, *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.* 519 U.S. 316 (1997) (holding that ERISA does not "relate to" an ERISA apprenticeship program and hence California's prevailing wage statute was not preempted); *De Buono v. NYSA-ILA Medical & Clinical Servs. Fund*, 520 U.S. 806 (1997) (holding that a New York tax on gross receipts of health care facilities was not preempted by ERISA, as applied to labs owned by ERISA plans).

³⁹ See *infra* text accompanying notes 42-45.

⁴⁰ See *infra* text accompanying notes 46-57.

⁴¹ *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1328-39 (5th Cir. 1992).

coverage under the plan and that, under the insurance contract, it had reserved broad discretion to make coverage decisions. The Fifth Circuit held that the utilization review program “makes medical decisions as part and parcel of its mandate to decide what benefits are available under the ... plan.”⁴² The court read section 514 to save ERISA plans from inconsistent rules that might be imposed through state negligence law. Having characterized the decision as one involving what benefits are available under the plan, the Fifth Circuit held that Corcoran’s only remedy under section 502 was a federal injunction ordering the insurer to pay the owed benefits.⁴³ The court was unmoved by the fact that Corcoran was in the late stages of a difficult pregnancy and could obtain relief only by showing that the insurer’s actions were arbitrary and capricious. The court stated: “[T]he acknowledged absence of a remedy under ERISA’s civil enforcement scheme for medical malpractice committed in connection with a plan benefit determination does not alter our conclusion.”⁴⁴ From 1992 to 1995, most lower courts reached the same conclusions.⁴⁵

B. Dukes

In 1995, the Third Circuit, in *Dukes v. U.S. Healthcare, Inc.*,⁴⁶ diverged from this bleak assessment of the remedies available to ERISA plan members. Darryl Dukes’ MCO primary care physician wrote him a prescription for blood sugar studies at a participating hospital. For unknown reasons, the hospital refused to perform the tests. Dukes died within days from an extremely high blood sugar level that could have been treated had it been detected. Dukes’ widow sued in state court alleging malpractice by all treating professionals and imputing vicarious liability on the MCO. The MCO removed the case to federal court, which relied on *Corcoran* to dismiss the claims against the MCO.⁴⁷

The Third Circuit reversed, holding that section 514’s preemption of claims that “relate to” employee benefit plans does not apply to state medical malpractice claims against an MCO. The Third Circuit noted that

⁴² *Id.* at 1332.

⁴³ *Id.* at 1334-35, 1337-39.

⁴⁴ *Id.* at 1333.

⁴⁵ ROSENBLATT ET AL., *supra* note 13, at 1016-18; *see, e.g.*, Kuhl v. Lincoln Nat’l Health Plan, 999 F.2d 298 (8th Cir. 1993), *cert. denied*, 510 U.S. 1045 (1994).

⁴⁶ 57 F.3d 350 (3d Cir. 1995), *cert. denied*, 516 U.S. 1008 (1995).

⁴⁷ *Dukes v. U.S. Health Care Sys., Inc.*, 848 F. Supp. 39, 42 (E.D. Pa. 1994). *See also* Spain v. Aetna Life Ins. Co., 11 F.3d 129 (9th Cir. 1993); Visconti v. U.S. Health Care, 857 F. Supp. 1097 (E.D. Pa. 1994).

“a suit ‘to recover benefits due . . . under [the] terms of the plan’ is concerned exclusively with whether or not the benefits due under the plan were actually provided. The statute simply says nothing about the quality of benefits received.”⁴⁸ The Third Circuit emphasized that Mrs. Dukes’ claim that the MCO negligently selected and monitored doctors and hospitals did not involve an attempt to define new rights under the terms of the plan. Instead, Dukes was attempting to assert preexisting rights under general state agency and tort law:

Inherent in the phrases “rights under the terms of the plan” and “benefits due . . . under the terms of [the] plan” is the notion that plan participants and beneficiaries will receive something to which they would not otherwise be entitled. But patients enjoy the right to be free from medical malpractice regardless of whether or not their medical care is provided through an ERISA plan.⁴⁹

The Third Circuit noted that “HMOs (health maintenance organizations) play two roles, not just one” in connection with the medical treatment provided to a plan beneficiary.⁵⁰ On the one hand, HMOs function in an administrative capacity, determining eligibility for benefits.⁵¹ Challenges to eligibility determinations or contract coverage may only be brought under section 502. On the other hand, HMOs play “their role as the arranger of the [plan beneficiary’s] medical treatment.”⁵² When they “provide, arrange for, or supervise the doctors who provide the actual medical treatment for plan participants,” and plaintiffs allege that the care provided violated state malpractice standards, there is no “claim for benefits” and hence no preemption under section 502.⁵³ Nothing “in the legislative history, structure, or purpose of ERISA suggest[s] that Congress viewed § 502(a)(1)(B) as creating a remedy for a participant injured by medical malpractice.”⁵⁴

In short, *Dukes* recognizes a distinction between disputes about “quantity of benefits” or “utilization review” on the one hand, and “quality of benefits” or “arranging for the provision of medical care” on the other.⁵⁵ Because section 502 only encompasses claims “to recover benefits due . . . under the terms of [the] plan,” it does not apply to complaints about the

⁴⁸ 57 F.3d at 357 (ellipses and brackets in original).

⁴⁹ *Id.* at 358.

⁵⁰ *Id.* at 361.

⁵¹ *Id.* at 360.

⁵² *Id.* at 361.

⁵³ *Id.* at 360.

⁵⁴ *Id.* at 357.

⁵⁵ *Id.* at 358-60.

quality of services actually provided. Hence, state remedies are not preempted.⁵⁶ Since 1995, most courts have followed the *Dukes* approach.⁵⁷

C. Pegram

In 2000, the Supreme Court considered the same issues in a different context.⁵⁸ Cynthia Herdrich had employment-based health insurance with a physician-controlled MCO. Herdrich experienced acute abdominal pain and consulted her MCO doctor, Lori Pegram. Dr. Pegram found a six – to – eight-inch inflamed mass in Herdrich's abdomen and ordered an ultrasound. Pegram decided that Herdrich could wait for eight days to have the test done at a MCO-controlled facility fifty miles away. While waiting for her test, Herdrich's appendix burst, causing peritonitis.

Pegram was a co-owner of the MCO, and her compensation increased if she limited testing. Herdrich sued in state court, seeking to hold Pegram and the MCO liable for negligence and fraud. The MCO removed the action to federal court and argued that Herdrich's claims were preempted by ERISA. In light of *Dukes* and its progeny, most plaintiff attorneys would have contended that the dispute was one about "quality of benefits" and the "arranging for the provision of medical care." Herdrich's lawyer, however, chose not to contest the removal to federal court. Rather, counsel formulated a claim for breach of fiduciary duty under ERISA section 502 based on the allegation that the MCO provided doctors financial incentives inconsistent with their responsibilities to patients. Herdrich sought to have the MCO profits returned to patients. The Seventh Circuit held that a federal claim for breach of fiduciary duty is cognizable "where physicians delay providing necessary treatment to, or withhold administering proper care to, plan beneficiaries for the sole purpose of increasing their bonuses."⁵⁹

The Supreme Court reversed. Justice Souter, writing for a unanimous Court, observed that MCOs always "take steps to control costs,"⁶⁰ and that Congress has expressed a policy judgment favoring MCOs.⁶¹ The Court found that ERISA plans are odd fiduciaries in that they always have conflicts between saving money and providing care.⁶² Employers have wide

⁵⁶ *Id.* at 356.

⁵⁷ ROSENBLATT ET AL., *supra* note 13, at 1032-37, 640-57 (1997 & Supp. 2000-01).

⁵⁸ Pegram v. Herdrich, 530 U.S. 211 (2000).

⁵⁹ Herdrich v. Pegram, 154 F.3d 362, 373 (1998).

⁶⁰ Pegram v. Herdrich, 530 U.S. at 219.

⁶¹ *Id.* at 233.

⁶² "In every case charging breach of ERISA fiduciary duty, then, the threshold question is not whether the actions of some person employed to provide services under a plan

discretion to determine the content of the plan and those decisions are not fiduciary.⁶³ Citing *Dukes*, the Court recognized a distinction similar to that drawn by the Third Circuit:

[P]ure “eligibility decisions” turn on the plan’s coverage of a particular condition or medical procedure for its treatment. “Treatment decisions,” by contrast, 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?⁶⁴

The Court noted that eligibility and treatment decisions are often “inextricably mixed.”⁶⁵ Congress “did not intend . . . HMOs to be treated as a fiduciary to the extent that it makes mixed eligibility decisions acting through its physicians.”⁶⁶ The Court concluded that “mixed treatment and eligibility decisions by HMO physicians are not fiduciary decisions under ERISA”⁶⁷

While the Court rejected Herdrich’s effort to hold the MCO liable on a federal claim for breach of fiduciary duty, it ruled that ERISA would not preempt a state law claim for negligence, malpractice, and vicarious liability. The Court noted:

[T]he defense of any HMO [to a federal claim of breach of fiduciary duty] would be that its physician did not act out of financial interest but for good medical reasons, the plausibility of which would require reference to standards of reasonable and customary medical practice in like circumstances. That, of course, is the traditional standard of the common law. . . . Thus, for 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. What would be the value to the plan participant of having this kind of ERISA fiduciary action? *It would simply apply the law already available in state courts and federal diversity actions today.*⁶⁸

It would come as news to Corcoran that ERISA did not preempt her

adversely affected a plan beneficiary’s interest, but whether that person was acting as a fiduciary (that is, was performing a fiduciary function) when taking the action subject to complaint.” *Id.* at 226.

⁶³ *Id.* (citing *Lockheed Corp. v. Spink*, 517 U.S. 882, 887(1996)).

⁶⁴ *Id.* at 227.

⁶⁵ *Id.* at 229.

⁶⁶ *Id.* at 231.

⁶⁷ *Id.* at 211.

⁶⁸ *Id.* at 235 (emphasis added).

state negligence claim against her MCO for its mixed eligibility / medical-necessity decision. In denying Herdrich's federal claim for breach of fiduciary duty, the Court appears to affirm the availability of state negligence law to test the reasonableness of mixed medical and eligibility decisions made by ERISA plans. The Department of Labor (DOL), the federal agency responsible for enforcing section 502, reads *Pegram* as holding "that treatment decisions and mixed eligibility and treatment decisions by physician employees of an HMO are governed by state malpractice standards and not ERISA fiduciary standards."⁶⁹ Most academic commentators agree that *Pegram* allows state law to impose basic malpractice norms on MCO medical care decisions.⁷⁰

D. The Importance of Pegram

Lower courts have disagreed over the implications of *Pegram* as well as whether particular MCO actions are fairly characterized as "eligibility decisions" or "treatment decisions." The Third Circuit, a pioneer in *Dukes*, found that an MCO doctor's refusal to hospitalize a depressed patient, who subsequently committed suicide, "falls on the standard of care, not the denial of benefits side of the line," and hence that the medical malpractice claim could proceed in state court.⁷¹ Similarly, the Pennsylvania Supreme Court held that Pappas' claim that delayed approval of emergency surgery constituted a "mixed eligibility and treatment decision," the adverse

⁶⁹ Brief of Amici Curiae Department of Labor at 7, *U.S. Healthcare Sys. of Pa., Inc. v. Pa. Hosp. Ins. Co.*, 530 U.S. 1241 (2000) (No. 98-1836).

⁷⁰ Phyllis C. Borzi, *Pegram v. Herdrich: A Victory for HMOs or the Beginning of the End for ERISA Preemption?*, 1 YALE J. HEALTH POL'Y, L. & ETHICS 161, 166 (2001) ("[T]he 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."); Timothy S. Jost, *Pegram v. Herdrich: The Supreme Court Confronts Managed Care*, 1 YALE J. HEALTH POL'Y, L. & ETHICS 187, 191 (2001) ("[T]he 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."); Wendy K. Mariner, *Slouching Toward Managed Care Liability: Reflections on Doctrinal Boundaries, Paradigm Shifts, and Incremental Reform*, 29 J. L. MED. & ETHICS 253 (2001) (arguing for a "personal medical information" standard that asks: "To make this decision, does the MCO need to know personal medical information about the individual patient? If the answer is yes, the decision is about the quality of care that the individual patient should have. If the answer is no, then the decision is a benefit coverage decision."). But see Louis Saccoccio, *Pegram's Significance for Managed Health Care*, 1 YALE J. HEALTH POL'Y, L. & ETHICS 195, 200 (2001) ("[*Pegram*] does not mean a shift in how the federal courts should analyze ERISA preemption questions relating to HMO medical-necessity decisions. . . . [I]t did not hold that HMO coverage decisions involving medical-necessity issues are subject to state medical malpractice law.").

⁷¹ *Lazorko v. Pa. Hosp.*, 237 F.3d 242, 250 (3d Cir. 2000).

consequences of which are properly redressed through state medical malpractice law.⁷²

By contrast, in *Pryzbowski v. U.S. Healthcare, Inc.*,⁷³ the Third Circuit held that delayed referral to a specialist recommended by treating doctors was a decision about plan coverage, rather than quality of care. As Wendy Mariner observes, "it is difficult to distinguish a decision to deny coverage of an out-of-network hospital, as in *Pappas*, from the decision to deny coverage of an out-of-network physician in *Pryzbowski*."⁷⁴ While Mariner makes a telling point, the Third Circuit offered one possible ground for distinction. It noted that Pryzbowski's dispute with her MCO extended over seven months and "could have been the subject of a civil enforcement action under § 502(a)."⁷⁵ A savvy patient in Pryzbowski's situation might have concluded that such delay justified hiring a lawyer and seeking injunctive relief in federal court.⁷⁶ Certainly, it is more reasonable to tell Pryzbowski that she should have sought an injunction than to tell that to Pappas, whose emergency was measured in minutes and hours, not weeks and months. Nonetheless, as Part IV explains, for reasons of both process and substance, it is highly unlikely that a federal court would have provided Pryzbowski an effective remedy against MCO delay under section 502.

The Fifth Circuit, author of *Corcoran*, has construed *Pegram* even more narrowly. In response to *Corcoran* and similar cases, Texas had adopted a patients' bill of rights that included a right to prompt, independent review of MCO judgments of medical necessity. Following *Pegram*, the Fifth Circuit rejected Texas' argument that independent review was designed solely to assure that medical care met minimal malpractice standards.⁷⁷ In cases seeking redress for injuries caused by allegedly negligent MCO decisions denying coverage for necessary treatment, lower courts in the Fifth Circuit have insisted that, despite *Pegram*, *Corcoran* remains binding law and hence preempts such state medical malpractice claims against MCOs.⁷⁸

⁷² *Pappas v. Asbel*, 768 A.2d 1089 (Pa. 2001). See *infra* text accompanying note 88.

⁷³ 245 F.3d 266 (3d Cir. 2001).

⁷⁴ Mariner, *supra* note 70, at 265.

⁷⁵ 245 F.3d at 273.

⁷⁶ *Id.* at 273-74.

⁷⁷ *Corporate Health Ins., Inc. v. Tex. Dep't of Ins.*, 220 F.3d 641 (5th Cir. 2000).

⁷⁸ See *Tran v. Kaiser Found. Health Plan*, No. 3:00-CV-1559-P, 2001 U.S. Dist. LEXIS 14039 (D. Tex. Sept. 7, 2001); *Calad v. CIGNA Healthcare of Tex.*, No. 3:00-CV-2693-H, 2001 U.S. Dist. LEXIS 8538 (D. Tex. June 20, 2001).

E. Managed Care and State Liability Rules

For aggrieved patients, the question of ERISA preemption is only the first step.⁷⁹ Even if ERISA does not preempt compensation for their injuries, complex questions remain. *Pegram* holds that plaintiffs are entitled to the remedies offered by “the law already available in state courts.”⁸⁰ When a person or organization causes injury, state common law and statutes ordinarily determine whether compensation is available. Recovery depends upon substantive liability principles, procedural rules, evidentiary standards, limits on damages, the ability to find a lawyer, the attitudes of judges and juries, and other factors—all of which vary by state.

One point is clear, however. Even in the context of ERISA plans and managed care, doctors may be liable for medical malpractice if they do not meet professional norms. Corcoran could have sued Collins for not keeping her in the hospital despite the MCO’s determination that the bill would not be paid, even though Collins struggled on her behalf against the MCO.⁸¹ Indeed, Pappas recovered damages against the doctors who did their best to get him emergency treatment that they themselves were unable to provide.⁸² In short, if a doctor violates professional medical standards, he or she can be held liable, even if the MCO refuses to cover the recommended care.⁸³ “Medical malpractice plaintiffs need only show

⁷⁹ Curiously, while the Third and Fifth Circuits have grappled with whether *Pegram* allows state law negligence claims against MCOs that delay or deny medically necessary treatment, there are few cases in other circuits. Given the millions of people insured through ERISA plans, and the frequency of contestable judgments of medical necessity, this lack of legal activity is hard to understand. For cases supporting state liability, see *Isaac v. Seabury & Smith*, No. IPO1-1437B/S, 2002 U.S. Dist. LEXIS 12413 (S. D. Ind. July 5, 2002) (holding that after *Pegram*, a complaint alleging negligence in making a medical-necessity determination is not completely preempted by ERISA and that state courts should decide whether the defendant was negligent and whether the state cause of action conflicts with ERISA) and *Rivers v. Health Options Connect, Inc.*, 96 F. Supp. 2d 1370 (S.D. Fla. 2000) (holding that after *Dukes*, a well-pleaded complaint alleging negligence in a medical-necessity determination is not removable to federal court). For a case supporting ERISA preemption, see *Cicio v. Vytra Healthcare*, 208 F. Supp. 2d 288 (E.D.N.Y. 2001) (holding that despite *Pegram*, state negligence claims challenging medical-necessity determinations are preempted by ERISA).

⁸⁰ 530 U.S. 211, 235 (2000) (emphasis added).

⁸¹ *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321 (5th Cir. 1992).

⁸² *Pappas v. Asbel*, 724 A.2d 889, 889-91 (Pa. 1998), *rev'd on other grounds*, 768 A.2d 1089 (Pa. 2001).

⁸³ *Wickline v. State*, 239 Cal. Rptr. 810 (Cal. Ct. App. 1986), *petition for review dismissed*, 741 P.2d 613 (Cal. 1987). The patient’s doctor recommended extended hospitalization. When the insurer denied approval, the patient was discharged. Her condition worsened and her leg had to be amputated. The court rejected her negligence claim against the MCO. The court noted that “it was for the patient’s treating physician to decide the course of

that the deviation from the standard of medical care occurred; they are not required to show why it occurred.”⁸⁴ “A health care provider’s deviation from the standard of care is actionable whether it was occasioned by inadvertence, ignorance, mistake, superstition” or the MCO’s financial incentives for denial of coverage.⁸⁵

While holding physicians liable for malpractice provides some protection to patients, concentrating liability on physicians is troublesome for several reasons.⁸⁶ First, many patients are understandably reluctant to sue the doctor who went the second and third mile attempting to persuade an MCO to approve appropriate treatment. Second, when MCOs create powerful financial and bureaucratic incentives encouraging doctors to refuse or delay care, it seems fundamentally unfair to immunize the MCO from liability if the incentives they create lead to unnecessary death and disability. Third, the standards for holding physicians liable for medical malpractice are, contrary to popular belief, highly demanding. A doctor can be liable only on the basis of expert testimony that the physician did something that no reasonable doctor would have done, and that the act or omission caused the plaintiff’s injury.⁸⁷

If a doctor is an employee, then under ordinary principles of vicarious liability, the employer hospital or MCO can be held liable for the physician’s negligence.⁸⁸ However, most doctors are independent contractors, not employees, thus immunizing hospitals and MCOs from liability under conventional formulations of vicarious liability.⁸⁹ In the hospital context, many courts have relied on concepts of apparent or ostensible agency to hold hospitals vicariously liable, particularly where the doctor is selected by the hospital rather than the patient.⁹⁰ In the managed care context, since *Dukes*, virtually all courts, including the Fifth Circuit, have held that ERISA does not preempt claims seeking to hold an MCO

treatment that was medically necessary to treat the ailment. . . . The decision to discharge is, therefore, the responsibility of the patient’s own treating doctor.” *Id.* at 819.

⁸⁴ *Lancaster v. Kaiser Found. Health Plan of Mid-Atlantic States, Inc.*, 958 F. Supp. 1137, 1146 (E.D. Va. 1997).

⁸⁵ *Id.*

⁸⁶ The American Medical Association supports consumers in seeking ERISA reform, emphasizing patient protection and professional judgment. See Robert Pear, *Patients’ Rights Bill Revised in Bid for Passage in Senate*, N.Y. TIMES, Sept. 13, 2000, at A21.

⁸⁷ ROSENBLATT ET AL., *supra* note 13, at 844-78.

⁸⁸ *Pappas v. Asbel*, 724 A.2d 889 (Pa. 1998) (holding that a hospital is vicariously liable for the negligence of physician employees), *rev’d on other grounds*, 768 A.2d 1089 (Pa. 2001); *Lancaster v. Kaiser Found. Health Plan of Mid-Atlantic States, Inc.*, 958 F. Supp. at 1146 (holding the same for MCOs).

⁸⁹ ROSENBLATT ET AL., *supra* note 13, at 921-27.

⁹⁰ *Id.*

vicariously liable for the negligence of its participating physicians.⁹¹

But, even if ERISA does not preempt vicarious liability claims, plaintiffs must show that a doctor can fairly be called an agent of an MCO. Most patients have little idea how physicians in their MCOs are selected. Thus, it is difficult to claim “ostensible agency” resting on the assertion that the patient assumed the MCO was exercising control over the selection and supervision of participating physicians. While early cases were divided,⁹² more recent cases have held MCOs vicariously liable under the doctrine of “apparent authority” for the acts of their independent contractor physicians. For example, in 1999, the Illinois Supreme Court held an MCO liable for a specialist’s negligence under an apparent agency theory even though the plaintiff’s primary care doctor selected the specialist. “Plaintiff’s reliance upon . . . [the MCO] was inherent in . . . [the MCO’s] method of operation.”⁹³

Another major question is whether MCOs can be held directly, or corporately, liable for constructing programs that are unreasonably likely to allow or encourage medical negligence. *Pegram* makes plain that managing care, including the use of financial incentives and utilization review to assure that care is necessary, is not per se unreasonable⁹⁴ and is not subject to federal challenge under section 502 as a violation of fiduciary obligations.⁹⁵ On the other hand, the Supreme Court has opened the door to the possibility that treatment decisions—choices about how to diagnose and treat a patient’s condition—and mixed eligibility / treatment decisions may be challenged under state negligence law.⁹⁶ Given this tension, it is difficult to know whether state tort remedies might nonetheless be preempted under section 514 “until some more precise definition is afforded to any duties being ascribed to . . . [ERISA plans] under state tort law.”⁹⁷

Similarly, because ERISA has been broadly construed to preempt state

⁹¹ The Third, Fifth, Seventh, and Tenth Circuits have held that medical negligence claims against HMOs for vicarious liability are not within the scope of section 502(a) and, therefore, are not completely preempted because they involve conduct by the HMO in its capacity as provider and arranger of health services and not as plan administrator. *Id.* at 356; *see, e.g., Corporate Health Ins., Inc. v. Tex. Dep’t of Ins.*, 215 F.3d 526 (5th Cir. 2000), *reh’g and reh’g en banc denied*, 220 F.3d 641 (5th Cir. 2000); *Rice v. Paschal*, 65 F.3d 637, 646 (7th Cir. 1995); *Pacificare of Okla., Inc. v. Burrage*, 59 F.3d 151, 154-55 (10th Cir. 1995).

⁹² ROSENBLATT ET AL., *supra* note 13, at 1037-45.

⁹³ *Petrovich v. Share Health Plan of Ill., Inc.*, 719 N.E.2d 756, 769 (Ill. 1999).

⁹⁴ 530 U.S. 211, 220-21 (2000). *See also, Pappas v. Asbel*, 768 A.2d 1089 (Pa. 2001) (Saylor, J., dissenting).

⁹⁵ 530 U.S. at 226.

⁹⁶ *Id.* at 232.

⁹⁷ *Pappas v. Asbel*, 768 A.2d at 1098 (Saylor, J., dissenting).

negligence claims asserting that MCOs unreasonably constructed programs to deny care, there is little law describing what is reasonable in the managed care context. Concern with costs is not, by itself, a mark of negligence. It is only when risk and severity of injury exceed the costs of precautions that the law concludes that a defendant's actions were unreasonable.⁹⁸ The notion that there are only two polar positions—complete freedom to impose utilization controls and financial incentives to deny care, or absolute prohibition of any consideration of cost—is foreign to the basic precepts of negligence law. Because of ERISA preemption, the nation is left with the formidable task of defining what constitutes “reasonable” cost-containment measures.

State courts have begun this task for MCOs that are not governed by ERISA.⁹⁹ For example, in 2000, the Illinois Supreme Court held that the doctrine of institutional or corporate negligence allowed Shawndale Jones to sue her MCO for institutional wrongdoing.¹⁰⁰ Jones could sue because she was insured through Medicaid and her claim was therefore not preempted by ERISA. The three-month-old plaintiff had become feverish, constipated, and fussy. After a long delay, her MCO-assigned doctor recommended castor oil over the telephone. Jones' condition deteriorated and her mother took her to an emergency room. Jones was diagnosed with bacterial meningitis and suffered serious permanent disability. Her MCO-assigned doctor served as the primary care physician for 4,500 patients, even though national professional standards provide that no more than 3,500 patients should be assigned to a single primary care physician. Furthermore, the MCO's promotional brochure promised that there would be one primary care physician for each 2,000 enrollees.¹⁰¹ The court held that it is “reasonably foreseeable that assigning an excessive number of patients to a primary care physician could result in injury, as ... care may not be provided,”¹⁰² and that imposing a duty on MCOs to maintain a safe physician-patient ratio would not prove overly burdensome.¹⁰³

⁹⁸ *United States v. Carroll Towing Co.*, 159 F.2d 169, 172 (2d Cir. 1947) (opinion by Hand, J.).

⁹⁹ ERISA does not apply to Medicare, Medicaid, and health plans organized for state and federal employees.

¹⁰⁰ *Jones v. Chicago HMO Ltd. of Ill.*, 730 N.E.2d 1119 (Ill. 2000).

¹⁰¹ *Id.* at 1126.

¹⁰² *Id.* at 1134.

¹⁰³ *Id.*

IV. *RUSH PRUDENTIAL HMO, INC. v. MORAN*: HOW CAN PEOPLE WITH INSURANCE ENFORCE THE RIGHTS TO WHICH THEY ARE ENTITLED UNDER THEIR INSURANCE CONTRACTS?

All of the remedies discussed previously are directed toward providing payment to injured patients or their decedents when medical care is unreasonably delayed or denied. Such damages, in addition to compensating for losses suffered, may also encourage MCOs to act more reasonably in designing cost-containment programs. However, preventing unnecessary deaths and injuries is far better than providing compensation after the fact. Patients and doctors have a powerful interest in a fair and expedient process to challenge ERISA plan decisions denying care recommended by treating physicians. For the Corcorans, after-the-fact money damages for the loss of their baby is surely a poor substitute for a review process that might have prevented their child's death.

ERISA offers two solutions. First, ERISA requires that plans provide all plan participants and beneficiaries opportunity for a "full and fair review" of adverse decisions on claims for benefits under covered plans.¹⁰⁴ Second, ERISA allows plan participants to sue in federal court to recover benefits due, or to obtain injunctive relief.¹⁰⁵

In 2000, the Clinton administration DOL issued regulations strengthening the internal "full and fair" review of ERISA plans.¹⁰⁶ The rules require ERISA plans to (1) establish and disclose claims procedures, including the medical guidelines that plans consider; (2) issue decisions within ninety days from receipt of a claim, or seventy-two hours in the case of an urgent claim; and (3) avoid using any process, including filing fees, that "unduly inhibits or hampers" the initiation or processing of claims.¹⁰⁷ While the DOL recognized that independent external review is essential for ensuring rapid access to adequate medical care, it did not have the authority to compel such review. The DOL did suggest, however, that in the absence of a congressionally created federal external review process,

¹⁰⁴ 29 U.S.C. § 1133 (2002) (codifying ERISA section 503).

¹⁰⁵ See *supra* text accompanying note 26.

¹⁰⁶ 65 Fed. Reg. 70,246, 70,254 (Nov. 21, 2000), modifying 29 C.F.R. § 2560 (1998). These rules went into effect on January 1, 2001, and apply to all claims filed on or after January 1, 2002. The Bush Administration suspended all federal regulations issued in the last months of the Clinton Administration that did not take effect before January 20, 2001. See Memorandum of Andrew Card to All Executive Agencies, at www.whitehouse.gov (last visited Nov. 20, 2002). Hence, the "full and fair" review regulations remain in effect.

¹⁰⁷ 65 Fed. Reg. 70,246, 70,266 (Nov. 21, 2000).

ERISA should not preempt state-based external review.¹⁰⁸ Since 1999, all but a few states have enacted laws providing independent professional review when doctors and insurance plans disagree over whether a particular treatment is medically necessary.¹⁰⁹ Circuit courts were split on whether ERISA preempts such laws.¹¹⁰

A. Moran

Last year, in *Rush Prudential HMO, Inc. v. Moran*, the Supreme Court resolved this circuit conflict, affirming state power to mandate independent review for MCOs that purchase insurance.¹¹¹ Justice Souter, who wrote for a unanimous Court in *Travelers*,¹¹² wrote for a five-to-four majority in *Moran*. Justice Thomas authored the dissent. All of the Justices agreed that state-mandated independent review requirements “relate to ERISA plans” and are thus preempted, unless saved as a form of insurance regulation.¹¹³ All agreed that independent professional review requirements are a form of insurance regulation, at least with respect to plans that purchase insurance rather than self-insure.¹¹⁴ The majority and dissent diverged on whether the independent review provisions are preempted because they “seek to supplant or add to the exclusive remedies in § 502.” Each relied on the Court’s 1987 decision in *Pilot Life Insurance Co. v. Dedeaux*¹¹⁵ to support its position.

Pilot Life held that Mississippi’s common law tort action for bad faith

¹⁰⁸ Brief of Amici Curiae Department of Labor, *Rush Prudential HMO, Inc. v. Moran*, 122 S.Ct. 2151 (2002).

¹⁰⁹ *Rush Prudential HMO, Inc. v. Moran*, 122 S.Ct. 2151, 2178 (2002). This section relies upon PATRICIA BUTLER, KEY CHARACTERISTICS OF STATE MANAGED CARE ORGANIZATION LIABILITY LAWS: CURRENT STATUS AND EXPERIENCE (Kaiser Family Found. 2001); STEPHANIE LEWIS, A GUIDE TO THE FEDERAL PATIENTS’ BILL OF RIGHTS DEBATE 3 (Kaiser Family Found. 2001); KAREN POLITZ ET AL., ASSESSING STATE EXTERNAL REVIEW PROGRAMS AND THE EFFECTS OF PENDING FEDERAL PATIENTS’ RIGHTS’ LEGISLATION (Kaiser Family Found. 2002) [hereinafter KAISER PATIENTS’ RIGHTS 2002].

¹¹⁰ Compare *Corporate Health Ins., Inc. v. Tex. Dep’t of Ins.*, 220 F.3d 641 (5th Cir. 2000) (holding that Texas’ requirement that MCOs submit disputes about medical necessity to an independent review organization is preempted by ERISA), with *Moran v. Rush Prudential HMO, Inc.*, 230 F.3d 959 (7th Cir. 2000) (holding that Illinois’ requirement that HMOs submit disputes about medical necessity to independent review is a form of insurance regulation that is saved from ERISA preemption).

¹¹¹ 122 S.Ct. 2151 (2002).

¹¹² 514 U.S. 645 (1995).

¹¹³ 122 S.Ct. at 2154, 2178. The dissent agreed that state external review requirements regulate ERISA plans. *Id.* at 2175-76.

¹¹⁴ *Id.* at 2163, 2177-78.

¹¹⁵ 481 U.S. 41 (1987).

refusal to settle contract claims was preempted as applied to decisions made by ERISA plans. The Court based its conclusion on two independent grounds. First, it found that bad faith refusal to settle a claim was not limited to insurance companies and hence was not saved as state regulation of insurance.¹¹⁶ This can be distinguished from the Illinois law considered in *Moran*, which solely targeted insurance. Second, the *Pilot Life* Court stated in dicta that Congress did not intend to allow the exclusive remedies of section 502 to “be supplemented or supplanted by varying state laws.”¹¹⁷

Relying on this dicta, the *Moran* dissent found that section 502 creates “an interlocking, interrelated, and interdependent remedial scheme” that represent a “‘careful balancing of the need for prompt and fair claims settlement procedures against the public interest in encouraging the formation of employee benefit plans’” centered upon “‘the development of ‘a federal common law of rights and obligations.’”¹¹⁸ For the dissent, the “interlocking, interrelated, and interdependent remedial scheme” mandated by Congress required only “full and fair” internal plan review—with no independent expert opinion—and federal court claims for contract benefits under a deferential standard that upholds discretionary plan decisions unless they are “arbitrary and capricious.”¹¹⁹

Thus, the dissent’s “federal common law of rights and obligations” under section 502 is a common law of enormous deference to the decisions of plan administrators.¹²⁰ Justice Souter found that such deference “overstates the rule expressed in *Pilot Life*.”¹²¹ The majority acknowledged that there is some tension “between the congressional policies of exclusively federal remedies and the ‘reservation of the business of insurance to the States.’”¹²² However, it found that the Illinois independent review requirements provide “no new cause of action under state law and authorizes no new form of ultimate relief. . . . [T]he relief ultimately available would still be what ERISA authorizes in a suit for

¹¹⁶ *Id.* at 48-50.

¹¹⁷ *Id.* at 56.

¹¹⁸ 122 S.Ct. at 2172, 2174 (quoting *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. at 54, 56, and citing *Massachusetts Mutual Life Insurance Co. v. Russell*, 473 U.S. 134, 146 (1985)).

¹¹⁹ See *supra* note 27 and accompanying text.

¹²⁰ The cases in which federal courts reverse insurance plan medical-necessity determinations under section 502 are rare and involve egregious wrongdoing. See e.g., *Doe v. Travelers Ins. Co.*, 167 F.3d 53, 58 (1st Cir. 1999) (reversing a plan decision rejecting the unanimous opinion of all the experts who examined the patient and the plan’s own guidelines); *Bedrick v. Travelers Ins. Co.*, 93 F.3d 149 (4th Cir. 1996) (same).

¹²¹ 122 S.Ct. at 2166.

¹²² *Id.* at 2165 (quoting *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. at 744).

benefits under" section 502.¹²³ The majority rejected *Firestone's* assumption that plans have absolute discretion to insist that federal courts review claims for benefits under section 502 using an "arbitrary and capricious" standard. Rather, it ruled:

Not only is there no ERISA provision directly providing a lenient standard for judicial review of benefit denials, but there is no requirement necessarily entailing such an effect even indirectly. [*Firestone* merely] held that a general or default rule of *de novo* review could be replaced by deferential review if the ERISA plan itself provided that the plan's benefit determinations were matters of high or unfettered discretion. Nothing in ERISA, however, requires that these kinds of decisions be so "discretionary" in the first place. . . . In this respect, [the Illinois independent review requirement] prohibits designing an insurance contract so as to accord unfettered discretion to the insurer to interpret the contract's term.¹²⁴

As a consequence of *Moran*, people in states with independent review laws who have coverage through an insured ERISA plan have access to independent professional review of medical-necessity disputes between plans and treating physicians. Nonetheless, serious limitations remain on the remedies authorized by *Moran*.

B. Independent Review and Timing

Questions of timing are important. Had they been in effect, would state requirements of independent external review have helped Florence Corcoran and Basile Pappas? Pappas probably would not have benefited. Many state programs and the proposals for a federal bill of rights require

¹²³ 122 S.Ct. at 2167. The majority and dissent also disagreed in their characterizations of the remedy provided by the mandated independent professional review. The dissent asserted that the Illinois law "is . . . most precisely characterized as an arbitration-like mechanism to settle benefits disputes. . . . There is no question that arbitration constitutes an alternative remedy to litigation." *Id.* at 2175. The majority found that "[t]he Act does not give the independent reviewer a free-ranging power to construe contract terms, but instead, confines review to a single term: the phrase 'medically necessity,' used to define the services covered under the contract." *Id.* at 2168. Thus, the review process "does not resemble either contract interpretation or evidentiary litigation before a neutral arbiter, as much as it looks like a practice (having nothing to do with arbitration) of obtaining another medical opinion. The reference to an independent reviewer is similar to the submission to a second physician, which many health insurers are required by law to provide before denying coverage." *Id.* at 2169. The dissent replied that "while a second medical opinion is nothing more than that—an opinion—a determination under . . . [the Illinois law] is a conclusive determination with respect to the award of benefits." *Id.* at 2177.

¹²⁴ *Id.* at 2170.

decisions within seventy-two hours in emergencies.¹²⁵ While seventy-two hours is a tight limit for due process purposes, for patients seeking emergency care, three days is too long. In contrast, Corcoran might have obtained the recommended care given a seventy-two-hour time limit for urgent decisions. Even though her MCO was willing to reject the recommendations of all the experts it consulted, it is possible that a judgment by an independent, external reviewer would have carried more weight. In short, the remedies authorized by *Moran* best serve people who can pay for care out-of-pocket and then file a federal claim for contract benefits bolstered by independent reviewer determination that a treatment was medically necessary.

C. The Self-Insurance Problem

Under *Moran*, state-mandated independent review is only available to people covered by plans that purchase insurance. State insurance regulations, saved from ERISA preemption, only protect beneficiaries in plans that are not “self-insured.”¹²⁶ In 1997, about one-third of the 150 million participants in private, employment-based plans nationwide received benefits through employer-sponsored, “self-insured” group health plans.¹²⁷

To avoid state regulation, many plans that purchase insurance characterize themselves as “self-insured.” They accomplish this by buying “stop-loss” insurance to cover claims over a specified amount. Of course, if the “stop-loss” attachment point is sufficiently low, the employer is really just buying insurance, rather than providing a self-insured plan. In the early 1990s, the Maryland Insurance Commissioner issued rules requiring that, to be considered “stop-loss” insurance, the attachment point had to be at least \$10,000 per participant per year. In 1998, the Fourth Circuit held that the Maryland law was preempted by ERISA and was not saved by the insurance savings clause; the Supreme Court declined review.¹²⁸ The National Association of Insurance Commissioners has sought to develop ways of extending state insurance regulation to these “stop-loss” policies.¹²⁹

¹²⁵ See references cited *supra* note 117 (state programs) and *infra* note 154 (federal bills).

¹²⁶ *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. at 732.

¹²⁷ Employee Benefit Research Institute, *Self-Funded ERISA Health Plans*, EBRI NOTES, June 1999, at 4. See, Troy Paredes, Note, *Stop-Loss Insurance, State Regulation, and ERISA: Defining the Scope of Federal Preemption*, 34 HARV. J. ON LEGIS. 233, 234 (1997).

¹²⁸ *Am. Med. Security, Inc. v. Bartlett*, 111 F.3d 358 (4th Cir. 1997), *cert. denied*, 524 U.S. 936 (1998).

¹²⁹ Dan Lonkevich, *NAIC Revisits Regulating Stop-Loss Insurance Sold to Self-Insured Health Plans*, NAT'L UNDERWRITER, Oct. 5, 1998, at 54.

The Third, Fourth, Sixth, and Ninth Circuits have uniformly rejected these efforts.¹³⁰

Thus, under the prevailing understanding of the difference between insured and self-insured plans under ERISA, it seems an employer who retains the first ten dollars of liability for employee health insurance can purchase stop-loss insurance and remain free of state insurance regulation under ERISA. From a policy standpoint, it is difficult to imagine why participants in insured ERISA plans are entitled to state-mandated independent review while participants in "self-insured" plans are not. Indeed, the Supreme Court, while recognizing this distinction, questioned its sensibility.¹³¹

D. Bad Faith Refusal To Settle

The tort of bad faith refusal to settle insurance claims is tremendously important to purchasers of insurance.¹³² Without such a tort action, rational insurers can deny payments and hope that beneficiaries lack the ability or will to litigate. If the insurer guesses wrong, under traditional contract principles, it pays only the benefits due under the contract. It is no worse off than if it had paid the claim initially. In response to this problem, state courts recognized tort causes of action for bad faith refusal to settle insurance claims,¹³³ and most states adopted insurance regulations to provide such remedies.¹³⁴

Some state legislatures and courts learned from Mississippi's experience and crafted remedies limited to insurance, reconciling their regulatory goals with ERISA's insurance savings clause.¹³⁵ In 1999, in *UNUM Life Insurance Co. of America v. Ward*, the Supreme Court found that California's "notice prejudice" rule is a form of insurance regulation and

¹³⁰ See *Bill Gray Enters. v. Gourley*, 248 F.3d 206, 214 (3d Cir. 2001) (noting that there is a consensus among all four circuits that have decided whether stop-loss or excess insurance makes a "self-funded" employee benefit plan insured for the purpose of ERISA preemption).

¹³¹ *Metro. Life Ins. Co.*, 471 U.S. at 747 ("Arguments as to the wisdom of these policy choices must be directed at Congress.").

¹³² Tom Baker, *Constructing the Insurance Relationship: Sales Stories, Claims Stories, and Insurance Contract Damages*, 72 TEX. L. REV. 1395 (1994).

¹³³ See, e.g., *Gruenberg v. Aetna Ins. Co.*, 510 P.2d 1032 (Cal. 1973).

¹³⁴ See Baker, *supra* note 132, at 1408.

¹³⁵ *Moran* affirms *Pilot Life's* holding that to be saved under the insurance savings clause, "a law must not just have an impact on the insurance industry, but must be specifically directed toward that industry." 122 S.Ct. 2151, 2159 (2002).

hence not preempted by ERISA.¹³⁶ The rule stipulates that an insurance company's defense based on an enrollee's failure to give timely notice of a claim is not valid unless the company could show actual prejudice. Some courts have read *Ward* to allow state tort remedies for bad faith refusal to settle so long as a remedy is limited to insurance claims and insurance companies.¹³⁷

However, courts remain divided as to whether ERISA's insurance savings clause saves a claim of bad faith refusal to settle.¹³⁸ *Moran* did not address bad faith refusal to settle. One way of reading the case stresses the importance of the point that independent review laws "provide[] no new cause of action under state law and authorizes no new form of ultimate relief." As *Moran* emphasizes, plaintiffs who use independent review can still only obtain contractual damages.¹³⁹ Tort remedies for bad faith refusal to settle could be viewed as a "new form of ultimate relief." On the other hand, even if section 502 provides the exclusive remedy for enforcing ERISA contracts, a tort action for bad faith refusal to settle could be seen as separate from the exclusive contract remedy. Alternatively, *Moran* could

¹³⁶ 526 U.S. 358, 359 (1999). As a matter of common sense, a rule that by its very terms "is directed specifically at the insurance industry and is applicable only to insurance contracts" regulates insurance. *Id.* at 359. In addition, the "notice-prejudice" rule satisfied "all the criteria used to determine whether a state law regulates the 'business of insurance' within the meaning of the McCarran-Ferguson Act." *Id.* at 373. First, it "has the effect of transferring or spreading a policyholder's risk" by shifting "the risk of late notice and stale evidence from the insured to the insurance company." *Id.* at 374. Second, "the notice-prejudice rule serves as 'an integral part of the policy relationship between the insurer and the insured.' . . . California's rule changes the bargain between insurer and insured; it 'effectively creates a mandatory contract term' that requires the insurer to prove prejudice before enforcing a timeliness-of-claim provision." *Id.* Third, the rule was limited to entities in the insurance industry. *Id.* at 375. Finally "a state regulation [needn't] satisfy all three McCarran-Ferguson factors in order to 'regulate insurance' under ERISA's saving clause." *Id.* at 373.

¹³⁷ See, e.g., *Lewis v. Aetna U.S. Healthcare, Inc.*, 78 F. Supp. 2d 1202 (N.D. Okla. 1999) (holding that ERISA does not preempt common law torts for insurance bad faith); *Colligan v. UNAM Life Ins. Co. of Am.*, 2001 WL 533742 (D. Colo. Apr. 23, 2001) (same).

¹³⁸ Compare *Rosenbaum v. UNUM Life Ins. Co. of Am.*, No. CIV.A 01-6758, 2002 WL 1769899 (E.D. Pa. July 29, 2002) (holding that Pennsylvania's law on bad faith refusal to settle insurance claims is not preempted by ERISA as it falls under the insurance savings clause), with *Sprecher v. Aetna U.S. Healthcare, Inc.*, 2002 WL 1917711, at *5, *7 (E.D. Pa. July 19, 2002) (holding that Pennsylvania's law on bad faith refusal to settle insurance claims is preempted because it does not serve as "an integral part of the policy relationship between the insurer and the insured" and hence does not regulate insurance, and that "because Pennsylvania's bad faith statute provides a form of ultimate relief in a judicial forum that adds to the judicial remedies provided by ERISA, it is incompatible with ERISA's exclusive enforcement scheme and falls within *Pilot Life's* categorical preemption").

¹³⁹ 122 S.Ct. at 2167.

be construed as authorizing state insurance regulators to require a mandatory insurance term that says "if we, the insurance company, willfully and in bad faith refuse to settle a claim, we will compensate you for the injuries you suffered as a consequence of our bad faith."¹⁴⁰ As yet another alternative, a general state law creating remedies for any willful refusal to perform a contract could be seen as "not related" to an ERISA plan. Since *Travelers*, the "relate to" provision has been limited to laws targeted at ERISA plans.¹⁴¹ A tort action for bad faith refusal to settle could be just another constraint in the panoply of generally applicable state laws with which ERISA plans, like everyone else, must comply.¹⁴²

E. State Experience with Independent Review

Few patients utilize state-mandated review programs. New York, which adopted an independent review program in 1999, has had the highest incidence of utilization. Between 1999 and 2000, 902 New York patients out of an estimated 8.4 million covered by the state's independent review

¹⁴⁰ *McEvoy by Finn v. Group Health Coop. of Eau Claire*, 570 N.W.2d 397 (Wis. 1997), illustrates the operation of the common law tort of bad faith refusal to pay an insurance claim in the health insurance context. Thirteen-year-old Angela McEvoy suffered from anorexia nervosa, a potentially fatal eating disorder. As no one in her health plan had ever treated this condition, her doctors recommended that she be referred to a special clinic at the University of Minnesota. The HMO approved six weeks of treatment but no more, despite the recommendations of all treating doctors. The HMO urged the girl to join a newly formed in-plan outpatient group therapy session for compulsive overeaters. When her weight fell from ninety-six pounds to seventy-four pounds in two months, her mother took her back to the clinic and paid for her care out-of-pocket. Because McEvoy's mother was a state employee, her claim was not preempted by ERISA and she was able to bring a claim for extra-contractual damages and collect for the injuries she suffered.

¹⁴¹ *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.* 519 U.S. 316 (1997).

¹⁴² A tort remedy for bad faith refusal to pay a contract obligation might be characterized as "one of 'myriad state laws' of general applicability that impose some burdens on the administration of ERISA plans but nevertheless do not 'relate to' them within the meaning of the governing statute." *De-Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 815 (1997). The Supreme Court further observed:

As we acknowledged in *Travelers*, there might be a state law whose economic effects, intentionally or otherwise, were so acute "as to force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers' and such a state law 'might indeed be preempted under § 514.'" That is not the case here.

Id. at 816 n.16 (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645, 668 (1995)). The author has not been able to find a case in which an ERISA plan beneficiary has sought to invoke a general state law prohibiting bad faith refusal to settle contract claims, arguing that a general state law does not "relate to" an ERISA plan.

law sought review.¹⁴³ This means that 0.01% of eligible, privately insured New York patients have taken advantage of their right to independent review.¹⁴⁴ The experience in other states is similar, though even fewer patients sought review.¹⁴⁵ A 2001 national survey suggests that the number of patients who experience difficulty with health care plans is vastly larger than the number that seek independent review in states that allow it.¹⁴⁶ Furthermore, early evidence indicates that many claims presented for independent review have merit: "The rate at which independent reviewers overturn health plan denials ranged from a low of 21 percent in Arizona and Minnesota to a high of 72 percent in Connecticut, and averaged 45 percent across all states."¹⁴⁷

The small number of patients who seek independent review, combined with the fact that independent review reverses plan decisions denying coverage in a relatively high number of cases, leads some consumer advocates to suggest that many state independent review programs create unjustifiable barriers.¹⁴⁸ One major factor limiting patient access to independent review is the requirement that patients exhaust internal complaint and appeals processes within their plans before seeking review.¹⁴⁹ In New York, health plans can require two or more internal appeals. That, combined with a brief window to file for review,¹⁵⁰ means that "consumers who remain in the plan system beyond the first appeal are likely to miss the filing deadline for external review and, thus, become

¹⁴³ KAISER PATIENTS' RIGHTS 2002, *supra* note 109, at Exhibit A.

¹⁴⁴ *Id.* at vii.

¹⁴⁵ California reported 421 cases between 1999 and 2001. In Florida, 223 cases were filed between July 2000 and July 2001. In 2000, Texas had 404 cases, Arizona had 282, and Maryland had 255. In all other states, the volume of appeals was significantly smaller. *Id.* at Exhibit A.

¹⁴⁶ KAISER FAMILY FOUND. & HARVARD SCH. OF PUB. HEALTH, NATIONAL SURVEY ON CONSUMER EXPERIENCES WITH AND ATTITUDES TOWARD HEALTH PLANS, at <http://www.kff.org/content/2001/3172/ChartPack.pdf> (Aug. 29 2001). When asked if they have personally had any problems with their health plan in the past year, twenty-two percent of respondents cited problems with billing or payment for services, fourteen percent had problems with the plan not covering a particular treatment or service, seven percent reported delays in receiving care or treatment, and six percent said they had been denied care or treatment.

¹⁴⁷ KAISER PATIENTS' RIGHTS 2002, *supra* note 109, at v-vi.

¹⁴⁸ *Id.*

¹⁴⁹ Except for Missouri, every state that offers independent review requires exhaustion of internal plan remedies. *Id.* at 12, 14.

¹⁵⁰ Six states have no filing deadline. Twenty-four states have filing deadlines of thirty to sixty days. In Arizona, a patient has only five days from completion of the internal review process and receipt of the final notice of the denial to request an independent review. *Id.* at 13-14.

ineligible for this protection.”¹⁵¹ On the one hand, it makes no sense to demand that patients pursue internal, possibly biased, review processes beyond the time during which they can seek independent view. On the other hand, it seems wise to allow plans to correct their own mistakes and to place some limit on when patients can invoke independent review. Striking the right balance between these competing considerations is difficult.

V. PATIENTS, DOCTORS, AND EMPLOYERS: WOULD THE TWO PROPOSALS FOR A FEDERAL PATIENTS' BILL OF RIGHTS HELP OR HURT?

The three most controversial provisions of the two proposals for a federal patients' bill of rights involve independent review of disputes between MCOs and treating physicians, the remedies available to patients who suffer injury or death when MCOs delay or deny recommended medical care, and the availability of extra-contractual damages when MCOs willfully refuse to settle legitimate claims.¹⁵²

A. Independent Review

As a consequence of state legislation and the Supreme Court's decision in *Moran*, independent review is now available to patients enrolled in insured plans in all but eight states.¹⁵³ The bills supported respectively by the Senate and House leadership both require independent review of MCO decisions on medical necessity, demand its usage before filing suit,

¹⁵¹ *Id.* at 12.

¹⁵² Many provisions in the proposed bill are not controversial and are supported by both the Senate and House. For example, both Houses would require that plans (1) provide information to enrollees about how they operate; (2) allow enrollees access to out-of-network specialists when a plan's network does not include an appropriate specialist; (3) pay for emergency care at the nearest hospital when a person reasonably believes that he or she is in distress; (4) provide coverage for mammography; and (5) allow people to use a pediatrician, obstetrician, or gynecologist as a primary health care provider. William G. Schiffbauer, *Analysis of Patients' Bill of Rights Legislation in the 107th Congress*, BNA'S HEALTH CARE DAILY RPT. (July 16, 2001). Some of the problems targeted by such provisions have already been addressed in the marketplace, *Id.*, or through specific federal legislation. See e.g., Women's Health and Cancer Rights Act of 1988, 29 U.S.C. § 1185b (2002) [hereinafter WHCRA] (amending ERISA to require group health plans to provide coverage for "all stages of reconstruction of the breast on which the mastectomy has been performed"); Newborns' and Mothers' Health Protection Act, Pub. L. No. 104-204, §§ 601 *et seq.*, 110 Stat. 2874 (1996) (amending ERISA to prohibit plans from restricting hospital lengths of stay for "normal vaginal" deliveries to less than 48 hours). *Howard v. Coventry Health Care of Iowa, Inc.* held that neither WHCRA nor ERISA provides a private cause of action for a WHCRA violation. 293 F.2d 442 (8th Cir. 2002).

¹⁵³ See *infra* note 155.

and allow a federal cause of action under ERISA section 502 to provide contractual benefits deemed medically necessary by independent review.¹⁵⁴ Both bills extend these protections to patients in self-insured plans and to patients in the eight states without independent review programs,¹⁵⁵ imposing a uniform filing fee of up to \$25 for all claims.¹⁵⁶ Nonetheless, there are important differences between the Senate and House independent review proposals.

First, the Senate bill would establish minimum standards for independent review organizations, but would allow states to go further in assuring that external review was informed, unbiased, and fair.¹⁵⁷ The House bill would preempt state rules governing internal and external appeals for patients in “self-insured” ERISA plans, preserving the disparity between insured and self-insured plans.¹⁵⁸ Second, under the House bill, if independent review upholds a plan’s decision to deny a claim for benefits, the burden of proof falls on the patient to demonstrate through clear and convincing evidence that the plan did not exercise ordinary care in making its decision.¹⁵⁹ Under the Senate’s bill, states would be allowed to lower the burden of proof below a federal maximum; most states require claimants to show that it is more likely than not that the plan’s negligence caused the harm, that is, the traditional preponderance of the evidence standard.¹⁶⁰ Third, the Senate bill allows independent reviewers to “uph[o]ld, reverse[], or modif[y]” a benefit denial,¹⁶¹ while the House rewrote its bill with the explicit purpose of denying independent reviewers the authority to modify a decision.¹⁶² Experience with state independent review programs demonstrates that the reviewer’s ability to modify a MCO decision is

¹⁵⁴ S. 1052, 107th Cong. (2001); H.R. 2563, 107th Cong. (2001).

¹⁵⁵ The eight states that do not have independent review programs are Arkansas, Idaho, Mississippi, Nebraska, Nevada, North Dakota, South Dakota, and Wyoming. Linda Greenhouse, *Court, 5-4, Upholds Authority of States To Protect Patients*, N.Y. TIMES, June 21, 2002, at A1.

¹⁵⁶ S. 1052 § 104(b)(2)(A); H.R. 2563 § 503 (b)(2)(iv).

¹⁵⁷ S. 1052 § 401; LEWIS, *supra* note 109, at 6.

¹⁵⁸ H.R. 2563 § 152. *See also* BOSTON UNIV. SCH. OF PUB. HEALTH, PATIENT RIGHTS PROGRAM WHITE PAPER: DIFFERENT SYSTEMS OF LIABILITY TO PATIENTS 8, at <http://www.patient-rights.org/publications/pub0003.html> (Sept. 7, 2001).

¹⁵⁹ H.R. 2563 § 402(a) (adding new ERISA section 502(n)(1)(B)). *See also* LEWIS, *supra* note 109, at 8; BOSTON UNIV. SCH. OF PUB. HEALTH, *supra* note 158.

¹⁶⁰ LEWIS, *supra* note 109, at 6; BOSTON UNIV. SCH. OF PUB. HEALTH, *supra* note 158, at 10. In a few states, such as Georgia, state law creates a rebuttable presumption in favor of the health plan if it wins the external review decision. BUTLER, *supra* note 109, at 3.

¹⁶¹ S. 1052 § 104(d)(3)(A).

¹⁶² H.R. 2563 § 104 (adding new ERISA section 503(C)(h)(1)(B)). The word “modify” was expressly deleted from the bill by the Norwood Amendment. BOSTON UNIV. SCH. OF PUB. HEALTH, *supra* note 158, at 37.

important.¹⁶³

In sum, the House version of independent review, far from protecting patients rights, may actually take them away, at least from those who have recently won protection under state laws and *Moran*. It strips independent reviewers of the power to modify plan decisions and makes it more difficult to enforce benefits claims in federal court. If states are allowed to pursue different approaches to independent review, ten years from now we are likely to know a lot more about what is fair and effective, both for patients and plans. Despite the Republicans' traditional embrace of states' rights, the House version of the bill would significantly limit state-sponsored independent review programs that seem to be working well. Governors across the country have expressed dismay that this would thwart state efforts to protect patients' rights.¹⁶⁴

B. Recovery of Damages for Unnecessary Death and Disability Caused by Negligent MCO Medical Decisions

With regard to liability for MCO negligence in determining medical necessity, again the Senate and House bills have much in common. Both require exhaustion of internal remedies and independent review.¹⁶⁵ Both impose limits on non-economic and punitive damages.¹⁶⁶ In 2002, people

¹⁶³ KAISER PATIENTS' RIGHTS 2002, *supra* note 109, at vi.

¹⁶⁴ Robert Pear, *States Dismayed by Federal Bills on Patient Rights*, N.Y. TIMES, Aug. 13, 2001, at A1.

¹⁶⁵ S. 1052 § 402(a)(n)(9); H.R. 2563 § 402(a)(n)(3)(A).

¹⁶⁶ Under the House bill, similar damages are provided for personal injury or death resulting from contract violation or medical malpractice. Successful plaintiffs may be awarded economic damages (e.g., medical expenses, lost wages) and non-economic damages (e.g., pain and suffering). H.R. 2563 § 402(a) (adding new ERISA section 502(n)(1)(A)). However, non-economic damages cannot exceed \$1.5 million. *Id.* (adding new ERISA section 502(n)(4)(A)). Punitive damages are permitted, also up to a limit of \$1.5 million, but only when a plan refuses to comply with the decision of an independent reviewer. *Id.* (adding new ERISA section 502(n)(4)(B)). Finally, the House bill permits states to limit non-economic and / or punitive damages to less than the \$1.5 million maximum. *Id.* (adding new ERISA § 502(n)(4)(C)).

The Senate bill distinguishes between claims based on contract violation and those based on medical negligence. In federal court actions for injuries resulting from contract violations, plaintiffs may recover compensatory economic and non-economic damages, without any cap. Punitive damages are not allowed. S. 1052 § 402(a) (adding new ERISA section 502(n)(1)). In state court actions based on medical decisions, damages remain a matter of state law, though states are not allowed to impose punitive damages unless the plaintiff shows by clear and convincing evidence that the health plan caused injury or death by acting with "willful or wanton disregard for the rights or safety of others." *Id.* (adding new ERISA section 514(d)(1)(C)). Finally, the Senate bill authorizes a federal action seeking civil penalties of up to \$5 million if the patient proves, by clear and convincing

who speak for Congress and the President asserted that the major stumbling block to enacting a federal patients' bill of rights is the limitation on damages.¹⁶⁷ The disputes about damages, while real, mask more fundamental questions about whether injured people can recover at all.

The House bill authorizes ERISA plan beneficiaries to sue if a designated plan decision-maker fails to exercise ordinary care in denying the claim for benefits or in failing to authorize coverage in compliance with the written determination of an independent medical reviewer.¹⁶⁸ If the plan fails to exercise ordinary care in *denying* coverage, and the patient suffers death or disability, the plan may be held liable for compensatory damages.¹⁶⁹ The House bill provides that this new cause of action can be brought in either federal or state courts, but ERISA provides the controlling substantive law.¹⁷⁰ Finally, and most significantly, the House requires a patient to demonstrate that the negligence in denying coverage was *the proximate cause* of the death or injury suffered.¹⁷¹

By contrast, the Senate bill draws a sharp distinction between "medically reviewable decisions" and decisions about coverage, eligibility, and cost sharing.¹⁷² This distinction is similar to that articulated by *Dukes*, *Pegram*, and other cases. With respect to decisions about coverage, eligibility, and cost sharing that do not involve a medically reviewable

evidence, that a health plan acted in "bad faith and flagrant disregard for the rights of the participant." *Id.* (adding new ERISA section 502(n)(10)(B)).

As a practical matter, the most important difference in terms of damages is that the House would limit non-economic damages to \$1.5 million, while the Senate would not. However, a majority of states impose limits on non-economic damages that may be awarded in malpractice cases. Mark D. Clore, *Medical Malpractice Death Actions: Understanding Caps, Stowers, and Credits*, 41 S. TEX. L. REV. 467, 471 (2000). Twenty-one states have a mandatory cap on damages in malpractice cases. *Id.* Some limit only non-economic damages; others limit either general or punitive damages. *Id.* Finally some states, such as Texas, limit all damages except for medical care and related expenses. *Id.* The Senate bill would allow states to apply their caps to claims challenging medically reviewable decisions. Malpractice caps have a seriously "disparate impact on patients who have suffered the most severe injuries from negligent treatment." Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 405 (1994). Because of this unfairness, at least six state courts have found that medical malpractice damage limitations violate state constitutions. ROSENBLATT ET AL., *supra* note 13, at 910-11.

¹⁶⁷ Robert Pear, *White House and Senate Hit Impasse on Patients' Rights*, N.Y. TIMES, Aug. 2, 2002, at A1.

¹⁶⁸ H.R. 2563 § 402(a) (adding new ERISA section 502(n)(2)(F)).

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.* (emphasis added).

¹⁷² S. 1052 § 402(a)(1) (amending section 502 to add a new section (n)).

dispute, claims will remain in federal court, and federal standards will apply. Moreover, the current remedies under ERISA section 502 are modified to allow patients to recover economic and non-economic damages (but not exemplary or punitive damages) if the plan fails to exercise ordinary care and "such failure is a proximate cause of personal injury to, or the death of, the participant or beneficiary."¹⁷³

For "medically reviewable decisions," the Senate bill modifies section 514's preemption of state laws to create a new savings clause stipulating that nothing in ERISA, including section 502, shall be construed to invalidate "any cause of action under State law of a participant or beneficiary under a group health plan . . . to recover damages resulting from personal injury or for wrongful death against any person if such cause of action arises by reason of a medically reviewable decision."¹⁷⁴ A "medically reviewable decision" is defined broadly to include denials based on "a determination that the item or service is not covered because it is not medically necessary and appropriate," "is experimental or investigational," or on any grounds "that require an evaluation of the medical facts by a health care professional in the specific case. . . ."¹⁷⁵ Further, "denial of claim for benefits" is defined broadly to include "a denial (in whole or part) of, or a failure to act on a timely basis upon, the claim for benefits and includes a failure to provide benefits. . . ."¹⁷⁶ In short, the Senate bill basically follows the approach suggested by *Pegram*, allowing state courts to apply traditional malpractice norms to claims that unreasonable medical decisions by MCOs have contributed to death or disability.

C. Remedies Against Insurers Who Willfully Refuse To Settle Legitimate Claims

Finally, the Senate bill allows federal courts to impose a "civil assessment" paid to the claimant if the claimant establishes by clear and convincing evidence that the plan "demonstrated bad faith and flagrant disregard for the rights" of the claimant and its decision was a proximate cause of personal injury or death.¹⁷⁷ This provision restores and federalizes the state tort of bad faith refusal to settle insurance claims that was preempted by the *Pilot Life's* interpretation of ERISA.¹⁷⁸ The House version has no comparable provision.

¹⁷³ *Id.* (emphasis added).

¹⁷⁴ *Id.* § 402(d).

¹⁷⁵ *Id.* § 104(d)(2).

¹⁷⁶ *Id.* § 102(e)(3).

¹⁷⁷ *Id.* § 402(a)(10) (amending ERISA section 502 to add a new section (n)).

¹⁷⁸ 481 U.S. 41 (1987).

CONCLUSION

As a general matter, apart from technical arguments of statutory interpretation, which have no purchase in the legislative context, ERISA plans oppose increased patient protections on two grounds. First, recognition of patients' rights might drive up insurance costs and hence discourage employers from offering health insurance. Second, to the extent that patients' rights are protected by allowing expanded state regulation, divergent state requirements hinder the ability of national insurance plans to administer uniform programs.¹⁷⁹

With regard to economic ramifications, David M. Studdert and his colleagues conducted informal interviews with more than fifty senior MCO executives asking how the proposed bills might impact health care costs and access to coverage.¹⁸⁰ Many executives said that if the preemption of liability were lifted, they would keep better records.¹⁸¹ Others stated that they might liberalize coverage determinations and make greater use of external review, even when it was not mandated.¹⁸² Studdert's group therefore concluded that the direct costs of liability are uncertain.¹⁸³ Efforts to estimate costs are complicated by differences between the Senate and House versions, and by the fact that many provisions have already been adopted voluntarily or imposed through specific federal legislation.¹⁸⁴ Twenty-five percent of the privately insured population, or 35 million people—mostly government employees—are not covered by ERISA and already have most of the rights guaranteed by the most expansive versions of the federal patients' rights legislation.¹⁸⁵ Nevertheless, in 1998, the consulting group Coopers & Lybrand, L.L.P. investigated the litigation experience of this population and estimated that extending the federal patients' bill of rights to ERISA plan beneficiaries would add between three and thirteen cents a month to the cost of premiums.¹⁸⁶ Similarly, a

¹⁷⁹ See, e.g., Brief for Petitioner, *Rush Prudential HMO, Inc. v. Moran*, 122 S.Ct. 2151 (2001) (No. 00-1021); Brief of Amici Curiae Am. Ass'n of Health Plans, Inc. et al., *Rush Prudential HMO, Inc. v. Moran*, 122 S.Ct. 2151 (2001) (No. 00-1021).

¹⁸⁰ David M. Studdert et al., *Expanded Managed Care Liability: What Impact on Employer Coverage*, HEALTH AFF., Nov.-Dec. 1999, at 7.

¹⁸¹ *Id.* at 9.

¹⁸² *Id.* at 16.

¹⁸³ *Id.* at 24.

¹⁸⁴ See *supra* note 152.

¹⁸⁵ RAND E. ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 137 (The Foundation Press 1997).

¹⁸⁶ COOPERS & LYBRAND, L.L.P., *IMPACT OF POTENTIAL CHANGES TO ERISA*, at <http://www.kff.org/content/archive/1415/erisa.html> (June 1998). The report was prepared for the Kaiser Family Foundation.

Congressional Budget Office (CBO) study the same year estimated that the cost of ending the ERISA preemption of state law would be 1.2% of premiums of all employer-sponsored plans, while a 2002 CBO study estimated that the liability provisions of the Senate bill would increase premiums by 0.8%.¹⁸⁷ Indeed, state experience with independent review, which shows that few patients take advantage of such evaluation,¹⁸⁸ suggests that independent review is unlikely to have a major impact on the cost of health insurance.

Meanwhile, the availability of independent review and the possibility of damage suits might motivate MCOs to approve care in marginal cases. Admittedly, given the small number of people who pursue independent review, a cost-conscious MCO manager might rationally decide to preserve stringent standards for approving care. However, the same incentive holds under the current scheme, if not more so, in light of limited liability. Hence, cost alone would not override the need for a federal patients' bill of rights. Insurance plans' concerns over their ability to apply uniform national standards presents a more compelling challenge, but as mentioned, state experimentation will help determine what uniform standards would be fair and effective, both for patients and plans.

The Senate proposal allows for such experimentation without hurting patients. Consider what could have happened with Corcoran and Pappas if the ERISA revisions proposed by the House or the Senate were in effect. Under the House's new version of section 502, Corcoran could have brought a claim in either federal or state court alleging that the MCO violated federal law by negligently denying coverage. If the external reviewer had determined that the recommended care was not medically necessary, Corcoran would have borne the heavy burden of proving the judgment wrong by clear and convincing evidence. In her case, the external reviewer found that the recommended care was medically necessary, so Corcoran might have met this heavy burden. However, the plan could still have prevailed simply by showing, by a preponderance of the evidence, that the external reviewer was wrong. Moreover, Corcoran's biggest problem would have been to show that the MCO's denial of the recommended hospitalization was *the* proximate cause of her injury. In the twentieth century, we came to appreciate that the search for *the* proximate cause of most phenomena is both illusive, and, in the liability context, designed to protect defendants. The MCO would have been correct in asserting that many causes contributed to the tragic loss of Corcoran's

¹⁸⁷ Jean P. Hearne & Hinda Ripps Chaikind, *Patient Protection and Managed Care: Legislation in the 107th Congress* (Congressional Research Service).

¹⁸⁸ See *supra* notes 143-47 and accompanying text.

baby. Yet, Corcoran needed extraordinary care precisely because of her high-risk pregnancy. Under the Senate bill, patients like Corcoran may or may not have a cause of action under section 502 because their claims involve a “medically reviewable decision” that the bill leaves to state common law, which is notoriously diverse. Nevertheless, this fate seems preferable to the House’s proximate cause standard, which would ensure that few if any ERISA plan beneficiaries will ever establish liability.

Likewise, Pappas would have faced greater difficulties under the House bill. The House version only authorizes a federal cause of action for negligent *denial* of treatment. Pappas was never denied treatment. Under the Senate bill, the devastating delay he was subjected to was a “medically reviewable decision” for which he could have sued in state court.

In sum, while it permits state experimentation that could benefit both plans and beneficiaries, the Senate patients’ bill of rights affords true patient protections. First, it restricts ERISA preemption, allowing all plan participants to invoke ordinary state negligence principles for injuries resulting from “medically reviewable decisions.” Second, it provides a federal remedy for serious bad faith refusals to settle. By contrast, the House version, far from protecting patients’ rights, takes them away. While acknowledging the value of independent review, the House bill so restricts the remedies available that it subverts state external review protections that have been affirmed, at least for independently insured people, by *Moran*. If the Supreme Court’s decision in *Pegram* allows patients to seek redress in state court for medical decisions that result in injury, with the full range of traditional state remedies and ordinary standards of negligence and causation, the House bill effectively reverses the Supreme Court and reasserts managed care’s bubble of immunity for wrongdoing.

Prior Agreements in International Clinical Trials: Ensuring the Benefits of Research to Developing Countries

Alice K. Page, J.D., M.P.H.*†

When biomedical research is conducted in the developing world, the disparity in power between rich and poor nations manifests itself in two ways. In most cases, the industrialized world sets the agenda and carries out the research. The involvement of developing countries is limited (a gradual change, however, is evident), and only in a few instances do they function as full and equal partners.¹ Moreover, although it assumes very few research burdens, the industrialized world receives the great majority—and in some cases, all—of the research benefits because, unlike the developing world, it can afford to buy a proven intervention. The burdens of research, in contrast, are borne by developing countries whose poorest inhabitants serve as research subjects but rarely share in its benefits. Many interventions are well beyond the economic reach of both research subjects and their governments.²

* Alice K. Page works on research ethics-related matters in the Office of Research and Graduate Studies at the University of Wisconsin-Madison Medical School.

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¹ 1 NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH: CLINICAL TRIALS IN DEVELOPING COUNTRIES 3 (2001) [hereinafter 1 NBAC]; NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF RESEARCH RELATED TO HEALTHCARE IN DEVELOPING COUNTRIES 24-30 (2002).

² This discussion is grounded in distributive justice, an ethical principle that seeks a fair and equitable distribution of social benefits and burdens. In the research context, distributive justice demands that no one group or class of persons assumes the risks and inconveniences of research if that group or class is unlikely to benefit from the fruits of that research. This concept extends to international collaborative research, which involves an arrangement between researchers and sponsors from industrialized and developing countries and their local institutions, but not necessarily the countries themselves, (although the Ministry of

Under these circumstances, for the research to be ethical, research benefits must be fairly and equitably apportioned to the host community,³ a term which may be difficult to define in a particular research setting. One of the greatest challenges facing international research ethics is crafting practical and economically feasible solutions to help ensure that citizens of developing countries are not exploited for the benefit of the industrialized world. Data from a survey conducted for the benefit of the United States National Bioethics Advisory Commission (NBAC) indicate that, to some extent, post-trial availability of research benefits is a consideration in research hosted by developing countries.⁴ Nevertheless, forty-eight percent of researchers in developing countries and thirty-three percent of U.S. researchers who responded believed that the interventions tested in their research were unlikely to become available to most host community residents in the foreseeable future.⁵

This Article examines the use of prior agreements in international clinical trials⁶ to ensure provision of drugs and other research benefits to developing countries where research is conducted. Post-trial access to the

Health usually must grant approval for the research). See 1 ANNA MASTROIANNI ET AL., *WOMEN AND HEALTH RESEARCH: ETHICAL AND LEGAL ISSUES OF INCLUDING WOMEN IN CLINICAL STUDIES* 78 (Anna Mastroianni et al. eds., 1994) (“[J]ustice is to be construed as a universal requirement, not confined within the borders of any one nation.”). As Ruth Macklin writes:

To meet the requirements of distributive justice in international research ... [b]eneficiaries of the research outcomes must include people in the developing countries where research is conducted, as well as the developed country that sponsors the research. These conditions make it clear that it is not only the benefits and burdens accruing to the research participants, but also the potentially beneficial outcomes of the research that count in determining equity.

Ruth Macklin, *Justice in International Research*, in *BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH* 132 (Jeffrey P. Kahn et al. eds., 1998). See also 1 MASTROIANNI ET AL., *supra* (noting that in its discussion of distributive justice, the report issued by the Institute of Medicine states that “[b]eneficiaries of the research outcomes must include people in the developing countries where the research is conducted, as well as in the [developed country that sponsors the research]”); Solomon R. Benatar, *Distributive Justice and Clinical Trials in the Third World*, 22 *THEORETICAL MED.* 169, 169-76 (2001); D.R. Cooley, *Distributive Justice and Clinical Trials in the Third World*, 22 *THEORETICAL MED.* 151, 151-67 (2001).

³ “Host community,” “host population,” and “host country” are terms that are often used interchangeably.

⁴ NANCY KASS & ADNAN A. HYDER, *ATTITUDES AND EXPERIENCES OF U.S. AND DEVELOPING COUNTRY INVESTIGATORS REGARDING U.S. HUMAN SUBJECTS REGULATIONS B-141* (2000). This background paper was prepared for NBAC and is available in Volume II of its report, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*.

⁵ KASS & HYDER, *supra* note 4, at B-141.

⁶ Primarily Phase III clinical trials that directly demonstrate the effectiveness of a new intervention to a statistically and clinically significant degree were examined. Determining when this type of clinical trial has occurred is no simple matter.

benefits of research is an issue that has not yet had the benefit of careful study and public discussion. Other than the World Health Organization (WHO), which for years has been using prior agreements in its collaborations with industry to promote development of health-related products, agreements for making research benefits available to host countries after a study is completed have only recently begun to surface in international clinical trials. Consequently, the number of agreements in place today is limited.

Two closely related assumptions guide the discussion. First, to be ethically acceptable, clinical research conducted or sponsored by an industrialized country⁷ in a developing country should be responsive to the health needs and priorities of the population on which it is carried out.⁸ In other words, research should aim to improve the health of the population from which subjects are drawn. Second, there is an ethical obligation to ensure that the developing country, and not just the individual research participants, benefits from the research.⁹ This obligation can be characterized as a means of applying or implementing the first premise. Unless there is a reasonable likelihood that developing countries will partake in the fruits of research in a timely manner, research cannot be responsive to the needs of the subject population or be expected to improve its health.¹⁰ However, there may be instances where provision of research benefits other than (or in addition to) effective interventions is warranted.¹¹

⁷ The term "industrialized country" can include a government agency, pharmaceutical company, university, non-governmental organization (NGO), or any other entity or organization, public or private, and the individuals who represent them.

⁸ COUNCIL FOR INT'L ORGS. OF MED. SCIS., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS Guideline 10 (2002) [hereinafter CIOMS] ("Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that . . . the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out. . .").

⁹ WORLD MED. ASS'N, WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS Principle 19 (adopted 1964, revised 2000) [hereinafter WMA] ("Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research."); Robert A. Crouch & John D. Arras, *AZT Trials and Tribulations*, HASTINGS CENTER REP., Nov. 1998, at 26, 26; Leonard H. Glantz et al., *Research in Developing Countries: Taking 'Benefit' Seriously*, HASTINGS CENTER REP., Nov. 1998, at 38, 40.

¹⁰ CIOMS, *supra* note 8, Guideline 10 ("Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that . . . any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.").

¹¹ See *infra* Part I.

The Article is divided into three parts. Part I explains what prior agreements are and how they are being used in international clinical trials. Part II urges the use of prior agreements to help overcome some of the barriers to making effective interventions available in developing countries. It also refutes current arguments against the use of prior agreements. Part III discusses the various types of prior agreements currently in use and offers concluding observations.

I. HOW PRIOR AGREEMENTS CAN BE USED TO MAKE RESEARCH BENEFITS AVAILABLE

“Prior agreements,” also known as “community benefit agreements,” generally refer to arrangements made before research begins that lay out a realistic plan for making effective interventions or other research benefits available to the host community after a study is completed. The use of the term “agreement” generally does not have any legal connotation in the international research context, and while some of these agreements may be legally binding instruments, others are not. In the area of Human Immunodeficiency Virus (HIV) vaccine trials, for example, “[p]revious experience indicates that manufacturers usually agree verbally to explore alternatives to make products available, but they rarely do so in writing.”¹²

It is difficult to formulate general rules regarding the nature and scope of prior agreements. Every study conducted is unique, and the needs and circumstances of developing countries vary so greatly and often change and evolve over time. The parties to these agreements usually include some combination of producers, research sponsors, and potential users of effective interventions or other research benefits. Industry, academia, and organizations of various kinds are frequently producers and sponsors, while non-profit health organizations and governments of developing countries are most likely to be users.

The role of researchers in the prior agreement process warrants some discussion. Since researchers are not directly responsible for providing effective interventions to host communities (they neither control research funds nor set policy), in some, if not many, instances, they are not parties to these agreements. Researchers from both industrialized and developing countries still play an important role, however, in ensuring that issues pertaining to post-trial obligations are fully considered as part of protocol development and review. It is also essential that, throughout a study and for some time afterward, researchers maintain an ongoing dialogue about

¹² Jose Esparza, *AIDS Vaccine Research in Asia: Needs and Opportunities, Report from a UNAIDS/WHO/NIID Meeting, Tokyo, 28-30 October 1998*, 13 AIDS 1, 10 (1999).

these issues with national and community health officials as well as with sponsors of both the study and / or post-trial benefits. Their commitment to research as well as their knowledge and expertise about the health problem they are studying place researchers in a unique position to advocate for the use of an intervention in the host community after a study is completed. The Nuffield Council on Bioethics, in its recent report, *The Ethics of Research Related to Healthcare in Developing Countries*, notes:

[T]he researcher should present findings in such a way that healthcare policy-makers can understand their implications and, at the least, the findings can be used for advocacy purposes with respect to the future provision of the intervention....[T]hey can draw attention to problems which have been neglected, or conditions whose impact has been underestimated, and demonstrate that there are feasible solutions.¹⁵

Important questions related to representation of the study population in the negotiation process also need to be addressed. Who should serve as the representative and how is that determined? What authority does that party have to serve in that capacity? How is the acceptability of a prior agreement to the study population to be determined? In one sense, as advocates for the use of a study intervention in the host community after a trial is completed, researchers serve as representatives for the study population. Yet, in almost all cases, the study population will also be represented by a governmental unit (or units) of some kind, which has given permission for the study to be conducted. Generally, it will be a ministry of health at the national level; often, a local governmental body will be involved as well. However, unless these governmental units are both willing and able to take action, effective interventions are unlikely to be made widely available in a host community. Because of resource scarcity, priority setting by developing countries is extremely difficult, and without external funding, many countries would be unable to make interventions available after a study is completed.

In at least two ways, prior agreements can provide research benefits to populations from which study participants are drawn. One way is to stipulate that an intervention, if proven effective, will be made available to the host community at a cost it can afford. This could be accomplished by providing the intervention to the class of individuals represented by the trial participants for a specified period of time at a specified cost. Exactly what this would entail in a given situation depends upon a number of factors, particularly the health problem that an intervention is intended to

¹⁵ NUFFIELD COUNCIL ON BIOETHICS, *supra* note 1, at 122.

address. Alternatively, if a country's need for a particular drug can be adequately quantified and the shelf life of the drug and other factors render it appropriate to do so, the country could make bulk purchases of the drug at a subsidized price.

Prior agreements can also provide derivative benefits—research benefits other than the studied intervention. The first meeting of the Global Forum for Bioethics in Research in 1999¹⁴ reached the consensus that researchers, sponsors, and host governments should seek arrangements that emphasize derivative benefits such as technology transfer and capacity building, rather than simply making effective interventions available.¹⁵ Similarly, the Nepal Health Research Council's recently published research ethics guidelines state that sponsors "should consider means in which the research capability of Nepal can be strengthened. . . ."¹⁶

Derivative benefits can come in many forms. With technology transfer, a pharmaceutical company could agree to grant host governments a free or low-cost license to produce a drug in exchange for a commitment from those governments to manufacture and distribute the drug to their constituents. Capacity building asks researchers and sponsors to help develop a host country's capacity for designing and conducting clinical trials, for scientific and ethical review of proposed research, and for implementing research results after a trial is completed. These efforts, which find support in documents such as the Council for International Organizations of Medical Sciences (CIOMS) *International Guidelines for Biomedical Research Involving Human Subjects*¹⁷ and the Joint United Nations Programme on HIV / AIDS (UNAIDS) *Guidance Document, Ethical*

¹⁴ Karen Hofman, *The Global Forum for Bioethics in Research: Report of a Meeting, November 1999*, 28 J. L., MED. & ETHICS 174, 174 (2000) ("Held in Bethesda (Maryland) on November 7-10, 1999, the intent was to bring together individuals involved in medical research in low- and middle-income nations to share views with each other and with organisations that support clinical research.").

¹⁵ *Id.* at 175.

¹⁶ NEPAL HEALTH RESEARCH COUNCIL, NATIONAL ETHICAL GUIDELINES FOR HEALTH RESEARCH IN NEPAL §7(d), at 9 (2002).

¹⁷ CIOMS, *supra* note 8, Guideline 20 ("In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible in such countries contribute effectively to national or local capacity to design and conduct biomedical research, and to provide scientific and ethical review and monitoring of such research. Capacity-building may include, but is not limited to . . . establishing and strengthening independent and competent ethical review processes / committees, strengthening research capacity, developing technologies appropriate to health-care and biomedical research, training of research and health-care staff, [and] educating the community from which research subjects will be drawn.").

Considerations in HIV Preventive Vaccine Research,¹⁸ are aimed at lessening the mismatch in developing countries between the high burden of disease and the lack of technical capacity to make use of existing knowledge or to generate new knowledge to address health problems. Another derivative benefit is the provision of various forms of health care. For instance, post-trial maintenance of a primary care clinic established in conjunction with a study might be extremely beneficial to a host community. A final example of a derivative benefit is a commitment from researchers to continue working with a developing country (after a trial) to solve particular health problems.

One advantage of derivative benefits is that significant aid can still be provided to a host community when research is not expected to produce an effective intervention for a number of years—for “only rarely does a single research study lead to the discovery of a new intervention that can be introduced promptly into routine care”¹⁹—or when an experimental intervention proves ineffective. This, in turn, may help lessen the perception that the industrialized country is exploiting the developing country. In addition, where research sponsors are either unable or unwilling to make effective interventions available, capacity building may provide a realistic, less costly alternative.

The benefits that are actually negotiated will depend upon a number of factors. As mentioned, the health problem addressed by a research protocol is one such factor. Will there be a need for the intervention once the study is completed? Can the health problem be cured or is it a chronic or terminal condition? What will be the cost of the intervention or other benefit? The nature and number of sponsors responsible for providing the intervention is also relevant. Is the sponsor, for example, a non-governmental organization (NGO) or a pharmaceutical company?

Likewise, the conditions in a host country as well as its capabilities will influence the agreement. One of the most important considerations in every case is the host country's health care system. In poorer countries, provision of an effective intervention would probably be appropriate in most instances. The suitability of providing derivative benefits will depend upon the nature of the benefit and the economic and technological state

¹⁸ JOINT UNITED NATIONS PROGRAMME ON HIV / AIDS, *ETHICAL CONSIDERATIONS IN HIV PREVENTIVE VACCINE RESEARCH: UNAIDS GUIDANCE DOCUMENT* Guidance Point 3 (2000) [hereinafter UNAIDS] (“Strategies should be implemented to build capacity in host countries and communities so that they can practise meaningful self-determination in vaccine development, can ensure the scientific and ethical conduct of vaccine development, and can function as equal partners with sponsors and others in a collaborative process.”).

¹⁹ NUFFIELD COUNCIL ON BIOETHICS, *supra* note 1, at 121.

of a developing country. For example, technology transfer makes sense for countries with strong local pharmaceutical industries (or countries that are developing them), while building research capacity or obtaining researcher commitments would be appropriate for many, if not all, developing countries.

Whether it suffices to provide derivative benefits instead of an intervention that has proven to be effective is a question that is, in itself, extremely controversial. Some contend that it is ethical to conduct research on a population that will not receive any direct benefit from that research so long as that population is compensated in some other important way, such as by increasing the host community's ability to conduct research or constructing a water sanitation plant in a community that lacks clean water. Others argue that the fruits of the research must accrue directly to the population from which research subjects are drawn.

A. *The Ethics of Conducting Research in Developing Countries*

As mentioned, biomedical research conducted in developing countries by industrialized countries must be responsive to the health needs and priorities of the host community to be ethically acceptable. This fundamental principle of international research ethics is well documented in prominent international guidelines such as the CIOMS *Guidelines*²⁰ and the World Medical Association (WMA) *Declaration of Helsinki*.²¹ It also forms the cornerstone of the NBAC report, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*.²² The implementation of this principle, however, is much more difficult. As former National Institutes of Health Director Harold Varmus and former Surgeon General David Satcher noted, "[o]ne of the great challenges in medical research is to conduct clinical trials in developing countries that will lead to therapies that benefit the citizens of these countries."²³

Some have argued that, to be ethically acceptable, research must "offer the potential of actual benefit to the inhabitants"²⁴ of a developing country by providing host communities affordable access to an effective intervention. It is not enough that the tested intervention is provided to trial participants. Without guaranteeing affordable access to the population from which participants are drawn, the developing country

²⁰ CIOMS, *supra* note 8.

²¹ WMA, *supra* note 9.

²² 1 NBAC, *supra* note 1, at 8.

²³ Harold Varmus & David Satcher, *Ethical Complexities of Conducting Research in Developing Countries*, 337 NEW ENG. J. MED. 1003, 1003 (1997).

²⁴ Glantz et al., *supra* note 9, at 39.

receives little benefit. If the knowledge gained from research is used primarily for the benefit of the industrialized world, the research may rightly be characterized as exploitative and therefore unethical.²⁵ Exploitation, as the term is used herein, refers to exploitation "in execution, or in the final analysis," not intent. Even if researchers and sponsors are well intentioned, "their research may nevertheless violate ethical canons if its positive fruits are not made reasonably available to former research subjects and other inhabitants of the host country."²⁶

The argument that research must benefit the host community can be taken even further. Leonard Glantz and his colleagues argue that it is not enough to make an effective intervention available to a host community by removing financial barriers to access if there is no means of getting the intervention to the population that needs it: "Where the health care infrastructure is so undeveloped that it would be impossible to deliver the intervention even if it were free, research would be unjustified in the absence of a plan to improve the country's health care delivery capabilities."²⁷ Consistent with this argument, the CIOMS *Guidelines* declare that "[e]xternal sponsors are ethically obligated to ensure the availability of ... [health care] services that are a necessary part of the commitment of a sponsor to make a beneficial intervention or product developed ... reasonably available to the population or community concerned."²⁸

Although there are many explanations for conducting research in developing countries, there are generally two sound reasons for doing so. One is that no known effective intervention exists for a serious health problem in a developing country. Research is the best method for developing solutions to such health problems. The other reason arises from the reality of health economics in developing countries. Developing countries often lack the resources to purchase existing interventions. Many of them may not be able to provide even the most rudimentary health care. Under these circumstances, there are many experimental interventions that should be tested precisely because they offer the promise of an affordable, albeit perhaps imperfect alternative. The question of affordability is extremely important in both scenarios. In either case, if the intervention will be too expensive, its effectiveness is irrelevant. Because

²⁵ Crouch & Arras, *supra* note 9, at 26; Carlos Del Rio, *Is Ethical Research Feasible in Developed and Developing Countries?*, 12 *BIOETHICS* 328, 330 (1998); Glantz et al., *supra* note 9, at 39.

²⁶ Crouch & Arras, *supra* note 9, at 30.

²⁷ Glantz et al., *supra* note 9, at 41.

²⁸ CIOMS, *supra* note 8, Guideline 21.

such research will not benefit the host country, it should not be done.²⁹

II. WHY PRIOR AGREEMENTS SHOULD BE USED IN INTERNATIONAL CLINICAL TRIALS: A RESPONSE TO CRITICISMS OF PRIOR AGREEMENTS

Most stakeholders in the research enterprise would probably agree that, at least in principle, the use of prior agreements is ethically desirable and should be encouraged in international clinical trials. Prior agreements can help researchers, sponsors, ethics review committees, host governments, and other parties involved focus on whether the host community will truly benefit from the proposed research. On a practical level, however, a variety of individuals and organizations, primarily researchers, research sponsors (both public and private), host governments, and ethicists object to requiring prior agreements as a condition for research approval. These criticisms, discussed below, have most often arisen in the context of general discussions about such agreements rather than in specific instances where the use of an agreement was at issue.

A. Prior Agreements Delay or Prevent Research

One criticism of requiring prior agreements as a condition for research approval is that it will only delay or prevent new drug research in developing countries.³⁰ Sponsors may be reluctant to commit financially to providing effective interventions, which in turn might affect their willingness to support research in developing countries. One response is that, even if this is true, host populations lose nothing because the research benefits would not be available to them anyway.³¹ In addition, prohibiting research protects the host community against exploitation by the industrialized world.

Moreover, the use of prior agreements and the advancement of research beneficial to developing countries are not mutually exclusive goals. First, to assume that all, or even most, effective interventions will simply be distributed to developing countries free of charge is erroneous. While it is true that a few countries cannot afford to buy interventions even

²⁹ Leonard H. Glantz, Testimony Before the National Bioethics Advisory Commission 150, 152-55 (Jan. 13, 2000), *available at* <http://www.georgetown.edu/research/nrcbl/nbac/transcripts/index.html#jan00>.

³⁰ Glantz et al., *supra* note 9, at 41; Reidar K. Lie, *Justice and International Research*, in *BIOMEDICAL RESEARCH ETHICS: UPDATING INTERNATIONAL GUIDELINES* 27, 29 (Robert J. Levine et al. eds., 2000).

³¹ Glantz et al., *supra* note 9, at 41.

at a subsidized cost, others can buy interventions as long as they are not expected to do so at industrialized-world prices.³² Still others can be licensed to produce the tested interventions.

Second, while in many instances, research sponsors will play a primary role in providing effective interventions, this will not always be the case. Normally, public agencies that sponsor research are too constrained financially to make interventions available post-trial. However, when such an obligation arises, public agencies become responsible for locating another funding source for the intervention, such as an organization involved in promoting health or development. Similar creative funding arrangements may provide incentives for private industry to research diseases occurring primarily in the developing world. By distributing financial burdens more widely, the actual or perceived barrier to research imposed by prior agreements can be reduced. Much-needed research can move forward while, at the same time, developing countries are protected from exploitation.

B. There Are Formidable Financial, Logistical, and Other Obstacles to Prior Agreements

A second criticism is that, in practice, many aspects of prior agreements can be extremely problematic.³³ Affordability, distribution, and appropriate product use must all be considered prior to conducting

³² The pharmaceutical industry routinely claims that high drug prices are required to finance the high cost of research and development as well as to compensate for research failures and the large number of drugs that are never profitable. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 1, at 32; PHARMACEUTICAL RESEARCH & MFRS. ASS'N OF AM., 2002 PHARMACEUTICAL INDUSTRY PROFILE 20-23 (2002). However, the prices that industry insists upon go well beyond what others believe to be necessary to prevent innovation from suffering. For example, certain experts argue that industry devotes much larger shares of each revenue dollar to marketing and paying CEO salaries and shareholder dividends than to research and development. See, e.g., DONALD DRAKE & MARIAN UHLMAN, *MAKING MEDICINE, MAKING MONEY* (1993); Alan Sager & Deborah Socolar, *Affordable Medications for Americans: Problems, Causes, and Solutions*, Paper presented to the Prescription Drug Task Force, United States House of Representatives, July 27, 1999, at 14-17, *available at* http://www.nysenior.org/News/reports/affordable_medicines.pdf. Also, the United States government has played a significant role in the research and development of drugs from which industry ultimately profits, including several antiretroviral drugs used to treat AIDS. See Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, 29 INT'L J. HEALTH SERVICES 765, 767-69 (1999); Mary T. Griffin, *AIDS Drugs and the Pharmaceutical Industry: A Need To Reform*, 17 AM. J.L. & MED. 363, 397 (1991); Margaret Duckett, *Compulsory Licensing and Parallel Importing: Background Paper*, International Council of AIDS Service Organizations § 5, at <http://www.icaso.org/icaso/docs/compulsoryenglish.htm> (July 1999).

³³ Lie, *supra* note 30, at 29.

research. The UNAIDS *Guidance Document* identifies specific issues that need to be addressed to ensure availability of an effective intervention, including “payments, royalties, subsidies, technology and intellectual property, as well as distribution costs, channels, and modalities, including vaccination strategies, target populations, and number of doses.”³⁴

In certain cases, a host community may be hard to define. How and by whom should that determination be made? Do the people of the host country constitute the community? What if the research participants represent populations that are not confined by national borders? What about research participants from earlier trials that have some bearing on product development? Does the obligation to provide the benefit extend to these populations? Difficulties could also arise with respect to provision of the intervention. Who should be responsible for providing it? What does making the intervention “available” mean in a particular situation? Does it mean for some designated period of time or for as long as the intervention is needed? Will the intervention be provided free of charge or will there be some nominal cost? If the latter, how will that cost be determined? If there is agreement on these terms, parties still face equally difficult and important concerns, such as implementation, treatment monitoring and compliance, and general medical care for the community that will receive the research benefit. Feasible plans must be developed and incorporated into the prior agreement.

It is easy for critics to dismiss the use of prior agreements because there are as yet no answers to some of these difficult issues. However, the difficulties inherent in the negotiation and implementation of prior agreements do not outweigh the ethical imperative to secure them. The resolution of critical health problems always requires grappling with complex and challenging issues, and the concerted efforts and talents of multiple partners from diverse environments and disciplines are often needed. Collaborative efforts are routinely employed to address drug funding and / or distribution problems in developing countries in a non-research context, such as a NGO purchase or a donation by a pharmaceutical company. With a NGO purchase, it must be determined whether a product will be distributed free of charge or, if not, what the charge will be to a host country. With both NGO purchases and company donations, decisions must be made regarding how and to whom drugs will be distributed. These same types of problems can be resolved for international clinical trials.

Negotiating prior agreements also requires parties to focus on

³⁴ UNAIDS, *supra* note 18, at 14.

expected research benefits in a detailed and concrete way that helps minimize delays in availability. There may be cases where those reviewing a protocol, such as an institutional review board (IRB) / ethics review committee or a country's ministry of health, know (or should know) that an intervention will not be widely available in the host community after the trial is completed. For example, an experimental drug might require refrigeration, but a prospective host community may lack such storage capability. Developing a plan for funding and distribution would bring that fact to light. If the problem cannot realistically be overcome, parties would need to reevaluate whether the trial can be conducted ethically. Whether or not such availability issues prove insurmountable, there is no reason to believe that they cannot be addressed before research begins, or that they are somehow easier to address after a study is finished.

If obstacles to availability can be overcome, parties need to reach an understanding on how a host community will actually benefit from proposed research. A host country's entire population need not benefit immediately, but sufficient numbers should benefit over a reasonable period of time so that a meaningful contribution to the overall welfare of the developing country or countries is evident. Debates over the CIOMS *Guidelines* definition of "reasonable availability" have yet to produce a precise resolution, so arriving at a definition that would satisfy everyone remains a formidable challenge. There are, for example, questions about the scope and content of "reasonable availability" as well as "about the exactitude and stringency of the required prior assurances."³⁵ The development of an internationally acceptable standard is, however, a highly desirable goal that is of utmost importance to conducting ethical research in developing countries and should continue to be a subject of discussion. Ideally, such a standard should be broad enough to afford the flexibility needed for a variety of cultural and moral contexts without departing from the ethical principle that it embraces. The CIOMS *Guidelines* acknowledge that "the issue of 'reasonable availability' is complex and will need to be determined on a case-by-case basis"³⁶ and suggest several relevant considerations.³⁷

In the meantime, the use of prior agreements would permit case-by-

³⁵ Crouch & Arras, *supra* note 9, at 30.

³⁶ CIOMS, *supra* note 8, Commentary on Guideline 10.

³⁷ *Id.* (suggesting factors such as "the length of time for which the intervention or product developed, or other agreed benefit, will be made available to research subjects, or to the community or population concerned; the severity of a subject's medical condition; the effect of withdrawing the study drug (e.g., death of a subject); the cost to the subject or health service; and the question of undue inducement if an intervention is provided free of charge").

case determinations without first reaching a consensus on the difficult and divisive issue of reasonable availability. Prior agreements may even facilitate agreement by providing specific examples of successful or unsuccessful benefit-sharing arrangements.

C. It Is Not the Prevailing International Standard

A third criticism of requiring prior agreements in international clinical trials is that making effective interventions and other research benefits available to host communities is not the prevailing international standard. It is far from being universally accepted by researchers, sponsors, ethicists, public health officials, politicians, industry, and others with an interest in the research enterprise.³⁸

One response to this argument is that ethics is not about “what is,” but rather, “what ought to be.”³⁹ An ethical obligation to make effective interventions available to host communities can be traced as far back as the *Belmont Report*, which was issued in 1979 by the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In its discussion of the principle of justice and the distribution of the burdens and benefits of research, the National Commission touches indirectly upon the issue of making effective interventions available to those populations upon which they were tested. It states:

[W]henver research supported by public funds leads to the development of therapeutic devices and procedures, justice demands that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.⁴⁰

The following international documents lend additional support for an obligation to make effective interventions and other research benefits

³⁸ Lie, *supra* note 30, at 29.

³⁹ Solomon R. Benatar, *Justice and International Research: A Response to Reidar K. Lie*, in *BIOMEDICAL RESEARCH ETHICS: UPDATING INTERNATIONAL GUIDELINES* 41, 47 (Robert J. Levine et al. eds., 2000); Ruth Macklin, *After Helsinki: Unresolved Issues in International Research*, 11 *KENNEDY INST. OF ETHICS J.* 17, 20 (2001).

⁴⁰ NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMED. & BEHAVIORAL RESEARCH, *THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES IN THE PROTECTION OF HUMAN SUBJECTS* 5 (1979).

available to host communities: the CIOMS *Guidelines*,⁴¹ the *Declaration of Helsinki*,⁴² the UNAIDS *Guidance Document*,⁴³ the WHO *Operational Guidelines for Ethics Committees that Review Biomedical Research*,⁴⁴ and the Ethics Committee of the Human Genome Organisation *Statement on Benefit-Sharing*.⁴⁵ They all demand resolution of product-availability and benefit-sharing issues before research begins. A number of them impose an affirmative obligation to provide effective interventions to a host community.⁴⁶

The UNAIDS *Guidance Document* was the first of its kind to focus explicitly on resolving drug access problems as part of international clinical trials. Not only does it insist on addressing availability before research begins, but also, it identifies in general terms the parties who should be

⁴¹ CIOMS, *supra* note 8, Guideline 10 ("Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that ... any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.").

⁴² WMA, *supra* note 9, Principle 19. The latest revision of the *Declaration of Helsinki* contains a new provision concerning the need for the accrual of some potential benefit to host countries.

⁴³ UNAIDS, *supra* note 18, Guidance Point 2 ("Any HIV preventive vaccine demonstrated to be safe and effective ... should be made available as soon as possible to all participants in the trials in which it was tested, as well as to other populations at high risk of HIV infection. Plans should be developed at the initial stages of HIV vaccine development to ensure such availability.").

⁴⁴ WORLD HEALTH ORG., OPERATIONAL GUIDELINES FOR ETHICS COMMITTEES THAT REVIEW BIOMEDICAL RESEARCH (2000). The WHO *Operational Guidelines*, which "establish an international standard for ensuring quality in ethical review," *id.* at 1, recommend that "a description of the availability and affordability of any successful study product to the concerned communities following the research" be considered as an element of review by ethics committees. *Id.* ¶ 6.2.6.6.

⁴⁵ HUMAN GENOME ORG. ETHICS COMM., STATEMENT ON BENEFIT-SHARING (2000). The Human Genome Organisation (HUGO) is the international organization of scientists involved in the Human Genome Project, the global initiative to map and sequence the human genome. The HUGO Ethics Committee endorses the equitable distribution of the benefits of genetic research. Its *Statement on Benefit-Sharing*, which provides that "all humanity" share in the benefits of genetic research, suggests that there be prior discussion with individuals and communities about benefit-sharing and, more specifically, about "affordability and accessibility of eventual therapy, and preventive and diagnostic products of research." *Id.* § G. The most far-reaching provision in the *Statement* calls for for-profit entities engaging in genetic research to donate a percentage of their annual net profit (e.g., 1%-3%) "to the health care infrastructure or for vaccines, tests, drugs, and treatments, or, to local, national, and international humanitarian efforts." *Id.*

⁴⁶ CIOMS, *supra* note 8; NAT'L CONSENSUS CONFERENCE, GUIDELINES FOR THE CONDUCT OF HEALTH RESEARCH INVOLVING HUMAN SUBJECTS IN UGANDA (1997); NAT'L HEALTH COUNCIL, RESOLUTION NO. 251 (1997) [hereinafter NHC RESOLUTION NO. 251]; NAT'L HEALTH COUNCIL, RESOLUTION NO. 196/96 ON RESEARCH INVOLVING HUMAN SUBJECTS (1996) [hereinafter NHC RESOLUTION NO. 196/96]; UNAIDS, *supra* note 18; WMA, *supra* note 9.

part of that process and the relevant issues to consider. Guidance Point Two states:

Any HIV preventive vaccine demonstrated to be safe and effective ... should be made available as soon as possible to all participants in the trials in which it was tested, as well as to other populations at high risk of HIV infection. Plans should be developed at the initial stages of HIV vaccine development to ensure such availability.⁴⁷

Parties “should include representatives from relevant stakeholders in the host country, such as representatives from the executive branch, health ministry, local health authorities, and relevant scientific and ethical groups.”⁴⁸ Including host country representatives greatly improves the chances that the values and culture of that country will be taken into account. Others parties should include “representatives from the communities from which participants are drawn, people living with HIV / AIDS, and NGOs representing affected communities” as well as “international organizations, donor governments and bilateral agencies, representatives from wider affected communities, international and regional NGOs, and the private sector.”⁴⁹

In recent years, various provisions relating to post-trial benefits have begun to appear in the ethics guidelines of several industrialized and developing countries, including the United Kingdom,⁵⁰ Canada,⁵¹ Nepal,⁵² Uganda,⁵³ and Brazil.⁵⁴ The guidelines promulgated by the United Kingdom,⁵⁵ Canada,⁵⁶ and Nepal⁵⁷ simply demand resolution of access

⁴⁷ UNAIDS, *supra* note 18, at 13.

⁴⁸ *Id.* at 14.

⁴⁹ *Id.*

⁵⁰ MED. RESEARCH COUNCIL OF THE U.K., MEDICAL RESEARCH COUNCIL INTERIM GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS IN DEVELOPING SOCIETIES: ETHICAL GUIDELINES OF MRC-SPONSORED STUDIES (1999) [hereinafter MRC-UK].

⁵¹ MED. RESEARCH COUNCIL OF CAN. ET AL., CANADIAN TRI-COUNCIL POLICY STATEMENT, ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS (1998) [hereinafter MRC-CA].

⁵² NEPAL HEALTH RESEARCH COUNCIL, *supra* note 16.

⁵³ NAT'L CONSENSUS CONFERENCE, *supra* note 46.

⁵⁴ NHC RESOLUTION NO. 251, *supra* note 46; NHC RESOLUTION NO. 196/96, *supra* note 46.

⁵⁵ MRC-UK, *supra* note 50, Specific Consideration 9 (“In anticipation of any beneficial results of therapeutic research, there should normally be discussion in advance with relevant parties in the developing society ... about subsequent availability of the relevant product to local inhabitants.”).

⁵⁶ MRC-CA, *supra* note 51, Commentary to art. 7.2 (stating that the Research Ethics Board should examine “the issue of continuing access after the trial”).

⁵⁷ NEPAL HEALTH RESEARCH COUNCIL, *supra* note 16, app. III. The model checklist developed for use by ethics review boards includes consideration of the “possibility of [the]

issues before research begins without imposing any affirmative obligation to make interventions available once a trial is completed. In contrast, Uganda⁵⁸ and Brazil⁵⁹ require more than just advanced discussions. In many cases, ethics guidelines do not carry the force of law or no mechanisms exist for effective enforcement. Nevertheless, in the future, one might reasonably expect to see increasing numbers of international and national research ethics guidelines embrace product-availability and benefit-sharing obligations.

Indeed, there is increasing recognition of the need to make moral progress in international research. Unlike before, there are efforts to refine vague benefit-sharing provisions such as “reasonable availability,”⁶⁰ “reasonable likelihood,”⁶¹ and “a reasonable effort.”⁶² Accordingly, we must rethink our ethical obligations and interpret them in ways that are appropriate to the ever-changing environment in which clinical research is conducted in developing countries. Today, private industry, rather than government, sponsors and conducts the lion’s share of international research.⁶³ Coupled with the global imbalance of power and disparities in

intervention (vaccine, drug, or supplementation) being available to the participants population if found effective.” *Id.*

⁵⁸ NAT’L CONSENSUS CONFERENCE, *supra* note 46, § V(D)(4). Uganda imposes an obligation to provide interventions to research participants as well as to the host community, but distinguishes the obligations owed to these two groups. It mandates:

The investigator must provide assurances that, if the investigational product is found to be beneficial, the investigator will make every effort to ensure its provision, without charge, to participants in the trial following the conclusion of the trial. In addition, the investigator shall make a reasonable effort to secure the product’s availability to the local community in which the research occurred.

Id.

⁵⁹ NHC RESOLUTION NO. 251, *supra* note 46; NHC RESOLUTION NO. 196/96, *supra* note 46. Research should “guarantee the individuals and communities where the research was undertaken a return on the benefits obtained in the research.” NHC RESOLUTION NO. 196/96, *supra* note 46, § III.3(n). Research participants must be ensured “the benefits resulting from the research project, in terms of social return, access to procedures, products or research agents.” *Id.* § III.3(p). Still further, “in case of research conducted abroad or with external cooperation” evidence “of commitments and advantages to the research subjects and to Brazil, which will result from the implementation of the research” must be submitted to the ethics review committee. *Id.* § III.3(s). Finally, as part of the research protocol, “[a]ccess to the medicine being tested must be assured by the sponsor or by the institution, researcher, or promoter, if there is no sponsor, in the event its superiority to the conventional treatment is proven.” NHC RESOLUTION NO. 251, *supra* note 46, § IV.1(m).

⁶⁰ CIOMS, *supra* note 8.

⁶¹ WMA, *supra* note 9.

⁶² NAT’L CONSENSUS CONFERENCE, *supra* note 46, § V(D)(4).

⁶³ Richard A. Rettig, *The Industrialization of Clinical Research*, HEALTH AFF., May-Apr. 2000, at 129, 131.

access to health care, the ethical obligation to engage in post-trial benefit-sharing should extend beyond the publicly supported research envisioned by the National Commission over twenty years ago. Although it is not the prevailing international standard, the obligation to make effective interventions available to host communities after a trial is over is still an ethical standard to which we ought to aspire for all clinical research conducted in the developing world. Approving protocols based on this standard forces researchers and sponsors to be realistic about their reasons for conducting research in a developing country.

D. Researchers Cannot Realistically Influence Health Policy

A fourth criticism is that requiring prior agreements as a condition of research approval “would go far beyond the influence one can reasonably expect of researchers concerning changes in a country’s health policy.”⁶⁴ In other words, how often would a developing country’s policy change as a result of research so that effective interventions will get to the people that need it?⁶⁵

The answer to this question is “sometimes.” One example from the Nuffield Council report that illustrates the limited influence of researchers to make effective interventions available is the iodination of salt to combat goiter in Nigeria. In that case, it took the Nigerian Ministry of Health fifteen years to act.⁶⁶ However, another example from the Nuffield Council report involving the use of nevirapine to reduce mother-to-child transmission of HIV in Uganda is indicative of a study that successfully influenced national health policy.⁶⁷

⁶⁴ Lie, *supra* note 30, at 29.

⁶⁵ Alfred Sommer, Testimony Before the National Bioethics Advisory Commission 155, 162-68 (Sept. 16, 1999), *available at* <http://www.georgetown.edu/research/nrcbl/nbac/transcripts/index.html#sep99>.

⁶⁶ NUFFIELD COUNCIL ON BIOETHICS, *supra* note 1, at 123. According to a Nigerian researcher at Harvard University:

In 1975 a group of scientists led by the Chairman of the Nigeria Medical Research Council presented research data to the Nigerian Department of Health which revealed the high prevalence of goitre in the country. Attention was drawn to the impact of iodine deficiency not only in causing goitre but also by reducing the intellectual capacity of children born to iodine-deficient mothers. The group urged the government to introduce iodination into the two salt factories in which the government had investments. UNICEF had offered to cover the cost of modifying the equipment to accommodate the iodination process.

Id.

⁶⁷ *Id.* at 124. In this study, nevirapine was administered to HIV-infected pregnant women at the onset of labor and to the babies within forty-eight to seventy-two hours after delivery. The study showed that in the experimental arm, there was a fifty percent reduction in

The problem, in most instances, is not the inability of researchers to influence national health policy (or that developing countries are forced into prior agreements that they do not want). Rather, it is that access to effective interventions, which goes far beyond affordability, is an issue that researchers, sponsors, IRBs, ethics review committees, and / or host governments have either failed to address altogether or neglected to address in sufficiently explicit and realistic terms. As Solomon Benatar pointed out, "research considerations cannot be divorced from considerations of health, and health cannot be divorced from the economic and political considerations that affect health."⁶⁸ These and other related issues, such as the financing, delivery, and appropriate use of interventions, must be considered during discussions on post-trial benefits. Also, although researchers play an important advocacy role in the prior agreement process, making effective interventions available cannot be the sole province of researchers. It is crucial to involve sponsors, host governments, host communities, international aid agencies, and other interested parties.

There may be circumstances under which one or more of these parties will not make a firm commitment until after research clarifies an intervention's prospect of benefit, safety concerns, and the effectiveness of alternatives. Testifying before NBAC, one international health researcher noted:

[I]n a ... vaccine study in an[] African country . . . the Health Ministry resented the requirement that some commitment be made up front feeling that that was a patronizing requirement and that they would be able to make a commitment when they saw the results of the study and could do an appropriate analysis of cost and benefit. And that gets to some of the perceived paternalism and rigidity of the current guidelines.⁶⁹

Moreover, the results of a trial may strengthen the position of the host country in negotiating with sponsors, manufacturers, and private philanthropies.

transmission of HIV-infection from mother to child at fourteen to sixteen weeks compared to the control group, which received only zidovudine (AZT). Laura A. Guay et al., *Intrapartum and Neonatal Single-Dose Nevirapine Compared with Zidovudine for Prevention of Mother-to-Child Transmission of HIV-1 in Kampala, Uganda: HIVNET 012 Randomised Trial*, 354 LANCET 785 (1999).

⁶⁸ Benatar, *supra* note 39, at 41.

⁶⁹ Jack Killen, Testimony Before the National Bioethics Advisory Commission 115, 120 (Sept. 16, 1999), *available at* <http://www.georgetown.edu/research/nrcbl/nbac/transcripts/index.html#sep99>.

In the complex and uncertain environment in which research is conducted in developing countries, a commitment to a continuing process of discussion and negotiation about post-trial benefits, undertaken by the parties before research begins, is the first step. During their initial discussions about proposed research, developing countries should make known to researchers their positions concerning availability of the intervention or other benefits after the study is concluded. Assuming that a developing country wants to ensure that an effective intervention will be made available to its population at that time, a prior agreement can assist in this effort through the development of a plan for implementation.

E. Prior Agreements Would Create a Double Standard with Regard to Clinical Research Conducted in the U.S. and Other Industrialized Countries

A fifth criticism of using prior agreements for research conducted in developing countries is that such a requirement creates a double standard.⁷⁰ However, the fact that use of prior agreements is not the current ethical standard for industrialized countries does not justify a similar practice elsewhere; it simply describes the existing state of affairs in the industrialized world. Moreover, perhaps use of prior agreements in the industrialized world is a goal that we should set to ensure that effective interventions are available to those who need them. Whenever research is conducted in populations with limited access to health care, justice requires pre-trial consideration of post-trial access to effective interventions.

F. Prior Agreements Can Always Be Breached

A final criticism is that parties might breach prior agreements.⁷¹ Although breach is always possible, it does not justify rejecting the use of prior agreements. Furthermore, the threat of debarment from future research and ostracism by the international research community would serve, in many cases, as an effective deterrent.⁷² Finally, depending on whether there is general compliance with non-binding prior agreements, parties may insist on legally binding documents with enforceable remedies.

III. PRIOR AGREEMENTS IN USE TODAY IN INTERNATIONAL CLINICAL TRIALS

Economic globalization and the Acquired Immunodeficiency

⁷⁰ NUFFIELD COUNCIL ON BIOETHICS, *supra* note 1, at 180.

⁷¹ Glantz et al., *supra* note 9, at 41.

⁷² *Id.*

Syndrome (AIDS) epidemic have made the industrialized world more acutely aware of the magnitude of health problems in developing countries and the imbalance in the global burden of disease. These factors have impressed upon us the need for moral progress and for reform of the existing system that keeps the developing world in poor health and poverty and impedes every aspect of its advancement. Increasingly, pre-trial measures are being undertaken to make effective interventions and other research benefits widely available in developing countries where research is conducted. Different types of prior agreements employed by WHO, the International AIDS Vaccine Initiative (IAVI), and VaxGen are discussed below. WHO has successfully used prior agreements to make effective interventions available in developing countries; the other two initiatives, although promising, are newly developed and untested. These examples were chosen because of the availability of a sufficient, although somewhat limited, amount of information concerning the agreements themselves and the context in which they're negotiated.

A. The World Health Organization (WHO)

WHO, the world's leading international health organization, is an inter-governmental unit of the United Nations system. In conjunction with its role "of harnessing support from among a variety of players to meet its health development agenda,"⁷³ WHO collaborates with industry to promote research and development of new health-related products and technologies for prevention, diagnosis, control, and treatment of diseases that are of priority to WHO. An essential element of these collaborations is the negotiation of prior agreements to ensure that final products will be made widely available to developing countries at low cost. WHO's partners include pharmaceutical and biotech companies as well as manufacturers of health-related instruments and equipment. In 2000, it was estimated that WHO has employed well over a dozen prior agreements.⁷⁴

Generally, WHO cooperates with industry in two ways. First, it may design, conduct, or fund studies, trials, and other development work on proprietary industry products in which WHO expresses an interest and / or is invited to collaborate. Second, it may license certain intellectual property that it owns to industry for further development into a final product, with or without technical or financial support. WHO usually

⁷³ WORLD HEALTH ORG., WHO GUIDELINES ON INTERACTION WITH COMMERCIAL ENTERPRISES 2 (preliminary version July 1999) [hereinafter WHO COMMERCIAL GUIDELINES].

⁷⁴ E-mail from P.D. Griffin, Scientist, World Health Organization, to Alice Page, Senior Policy Analyst, National Bioethics Advisory Commission (July 18, 2000) [hereinafter Griffin July Email] (on file with author).

acquires intellectual property through research performed by institutions that it funds. However, such property is of little direct benefit to WHO because it lacks the facilities, resources, and “know-how” to further utilize it.

Prior agreements between WHO and its industrial partners are mindful of WHO’s interest in ensuring that successful products are made available to the public health sector (in particular, to the public health sector of developing countries on preferential terms) as well as industry’s interest in obtaining a reasonable return on its investment.⁷⁵ The agreements follow standard principles set forth in WHO’s *Policy on Patents*⁷⁶ and its *Guidelines on Interaction with Commercial Enterprises*⁷⁷ and are negotiated on a case-by-case basis. As a result, their final terms and conditions may differ depending on a variety of factors, such as ownership of the intellectual property rights in question, the stage of a product’s development at the time of negotiations, and past and expected future contributions to the collaboration by parties. The negotiations are then memorialized in a legally binding document called a Memorandum of Understanding (MOU).⁷⁸

In all its collaborations, WHO requires that products and technologies developed with WHO support will be made generally available to both the public and to public sector agencies. The MOU defines “public sector agency” as “a government, or a department or agency thereof, or a recognized non-profit organization or entity, including the WHO and any other organization within the United Nations system.”⁷⁹ Agreements usually provide that a product will be made available to the public either by the industry partner or through a license to WHO if the industry partner decides to abandon the project. The industry partner must further agree to make a product available to public sector agencies of developing countries “in sufficient quantities to meet the needs of such agencies” for distribution in the public sector.⁸⁰

In addition to quantity commitments, pricing commitments are also sought. Pricing commitments obtained from industry partners may differ depending on whether a product will be distributed through the private sector. If distribution will occur through both the private and public

⁷⁵ WORLD HEALTH ORG., POLICY ON PATENTS: INFORMATION PAPER ON WHO PATENTS POLICY § 2.3 (1985).

⁷⁶ *Id.*

⁷⁷ WHO COMMERCIAL GUIDELINES, *supra* note 73.

⁷⁸ WORLD HEALTH ORG., DRAFT MEMORANDUM OF UNDERSTANDING (1999) [hereinafter WHO DRAFT MOU].

⁷⁹ *Id.* § 15(a), at 6.

⁸⁰ *Id.* § 6, at 3.

sectors, the price for public sector agencies “shall be (i) preferential compared to the Private Sector price, and (ii) set at the lowest possible level permitting a commercially reasonable return on combined worldwide sales of the Compound for Distribution in both Public and Private Sectors.”⁸¹ A product can be sold in the private sector at whatever price the industry partner chooses. Pricing commitments from industry partners can also take the form of “cost, plus a modest mark-up” or a maximum price, depending on the circumstances.⁸² “Cost, plus a modest mark-up” can be used at any stage of collaboration, provided terms can be defined and agreed upon. In contrast, a maximum-price commitment can only be used if product development is at such a point that parties can determine what it will cost to make a product.⁸³ If a product will not be distributed through the private sector, availability to public sector agencies shall be “at the lowest possible, commercially reasonable price.”⁸⁴ The same applies for bulk purchases. To a much lesser degree, WHO may receive royalties that are then invested in the public interest either to offset the cost of products or to fund further research to meet the needs of developing countries.⁸⁵

A final item that is negotiated in each case is the period of years for which product availability is assured. Although there is no fixed time, “at the end of the agreed period of time the company concerned must agree to provide technology transfer to enable the country or countries concerned to continue either to manufacture the product themselves or through a sublicensing agreement to have somebody else manufacture it for them....”⁸⁶

B. *The International AIDS Vaccine Initiative (IAVI)*

IAVI is an international scientific, non-profit organization founded in 1996 with the single aim of accelerating the development of safe, effective, and accessible HIV vaccines for global use. IAVI’s research focus is on vaccines for developing countries. Through the investment of what it calls “social venture capital,” IAVI’s goal is to develop vaccines that “would be

⁸¹ *Id.* § 6(b), at 3.

⁸² E-mail from P.D. Griffin, Scientist, World Health Organization, to Alice Page, Senior Policy Analyst, National Bioethics Advisory Commission (Feb. 11, 2000) (on file with author).

⁸³ Griffin July Email, *supra* note 74.

⁸⁴ WHO DRAFT MOU, *supra* note 78, § 6, at 3.

⁸⁵ P.D. Griffin, Testimony Before the National Bioethics Advisory Commission 111, 115 (Jan. 13, 2000), *available at*

<http://www.georgetown.edu/research/nrcbl/nbac/transcripts/index.html#jan00>.

⁸⁶ *Id.* at 144.

inexpensive to manufacture, easy to transport and administer, stable under field conditions, and require few inoculations.”⁸⁷ IAVI is driven by the belief that a vaccine represents the world’s best hope to end the AIDS epidemic.

In 1998, IAVI issued a *Scientific Blueprint for AIDS Vaccine Development*⁸⁸ that links promising vaccine approaches with countries in which to test them. IAVI seeks to accelerate product development and clinical trials through public-private partnerships between vaccine developers, manufacturers, and those who will test the vaccines. Because the epidemic is most severe and the need for a vaccine is greatest in developing countries, most of IAVI’s efforts are focused there. These collaborations seek to ensure that people in developing countries for whom particular vaccines are designed benefit from those vaccines once they are developed.

To date, IAVI has invested \$20 million to create six vaccine development partnerships (VDPs) with individuals and entities from both industrialized and developing countries.⁸⁹ It also contributes expertise “as

⁸⁷ Victor Zonana, *Commonwealth Leaders Urge Greater Support for AIDS Vaccines*, IAVI REP. (International AIDS Vaccine Initiative, New York, N.Y.), Nov.-Dec. 1999, at 5, available at <http://www.iavi.org/reports/63/nov-dec-1999-4.html>.

⁸⁸ INT’L AIDS VACCINE INITIATIVE, 1998 SCIENTIFIC BLUEPRINT FOR AIDS VACCINE DEVELOPMENT, available at <http://www.iavi.org/about/98sblblueprint.htm>.

⁸⁹ The first VDP, the Oxford / Kenya Partnership, is an academic partnership created in 1998 with the University of Oxford and the University of Nairobi to develop for East Africa two separate vaccine constructs to be used in combination. Phase I clinical trials began in Oxford in 2000 (now in Phase II) and in Nairobi in early 2001. IAVI’s goal is to begin a Phase III trial in East Africa by 2004-2005, assuming the vaccine continues to perform well. INT’L AIDS VACCINE INITIATIVE, IAVI-SPONSORED AIDS VACCINE APPROACHES IN DEVELOPMENT AND TESTING, at <http://www.iavi.org/vaccinedev/pipeline.htm> (last visited Sept. 12, 2002) [hereinafter IAVI VACCINE APPROACHES]; INT’L AIDS VACCINE INITIATIVE, VIRTUAL COMPANY MODEL: VACCINE DEVELOPMENT PARTNERSHIPS, at <http://www.iavi.org/vaccinedev/vdp.htm> (last visited Sept. 12, 2002) [hereinafter IAVI VDP]; 1 NBAC, *supra* note 1, at 105.

The other VDPs encompass a “second generation” of vaccines designed to address “critical outstanding technical challenges.” IAVI VACCINE APPROACHES, *supra*. The second VDP, the Targeted Genetics / Children’s Research Institute / South Africa Partnership, formed in 2000, is with Targeted Genetics Corporation (TGC) of Seattle, Washington, and the Children’s Research Institute (CRI) in Columbus, Ohio. Its purpose is to develop a vaccine for southern and eastern Africa. A vector technology developed by TGC will be utilized to deliver HIV genes as a form of genetic immunization. TGC’s manufacturing process is based on a cell line originally developed by a researcher at CRI, which holds the patent to the technology. The vaccine is designed to give longstanding protection from a single dose and, therefore, may be particularly appropriate for areas where vaccine delivery is difficult. *Id.*; IAVI VDP, *supra*; 1 NBAC, *supra* note 1, at 105.

The third VDP, the Institute for Human Virology / Uganda Partnership, also formed in 2000, is with the Institute of Human Virology at the University of Maryland and the Ugandan Ministry of Health. The vaccine under development uses genetically modified *Salmonella* bacteria as an oral delivery system for DNA. The ease of delivery and extremely

needed, in areas ranging from project management to regulatory affairs and infrastructure for clinical trials.”⁹⁰ IAVI’s focus on industrial participation in vaccine development is based on the belief that private sector involvement and ingenuity are crucial.⁹¹ IAVI has been instrumental in structuring prior agreements with industry partners that give developing countries access to IAVI-supported vaccines at reasonable prices and in sufficient quantities. According to IAVI President Seth Berkley, “[d]ealing with the access issue at the start of the process represents a wholly new approach to vaccine development that will ultimately benefit both industrialized and developing countries.”⁹² IAVI’s prior agreements with its industrial partners call for reasonable pricing policies for the public sector in developing countries. The public sector includes government health agencies and not-for-profit organizations serving developing countries.⁹³ In return for financing the early stages of vaccine development, companies agree to make a vaccine available to the public sector in developing countries in quantities reasonable to demand and at manufacturing cost plus a reasonable profit, which is defined. If companies do not comply, IAVI retains the right to transfer the intellectual property and background technology to another manufacturer. If manufacturing costs seem unreasonable, IAVI can obtain alternative bids for production. If a third

low cost make this a very promising vaccine for large-scale field use. It is hoped that clinical trials can begin in 2003 in Uganda and the United States. IAVI VACCINE APPROACHES, *supra*; IAVI VDP, *supra*; 1 NBAC, *supra* note 1, at 105. The fourth VDP is with Therion Biologics Corporation, the Indian Council of Medical Research, and the Indian Ministry of Health and Family Welfare. The partnership is designed to develop vaccines for India as well as a program for community participation and capacity building to conduct clinical trials in that country. Therion will manufacture vaccine doses for early trials, then transfer the technology to an Indian company for manufacture. IAVI VACCINE APPROACHES, *supra*; IAVI VDP, *supra*.

The other VDPs are with (1) Aaron Diamond AIDS Research Center and (2) Bioption AB. IAVI VACCINE APPROACHES, *supra*.

⁹⁰ IAVI VDP, *supra* note 89.

⁹¹ A successful AIDS vaccine will necessarily rely on technologies covered by new and existing patents. Realistically, however, development of an AIDS vaccine by pharmaceutical and biotechnology industries alone is unlikely for four reasons. First, the development costs of a vaccine are high. Second, a very large percentage of the potential vaccine market probably will be in developing countries without resources to buy a vaccine. Third, because of variation in the predominant viral strains in industrialized and developing countries, vaccines may have to be country-specific. Fourth, the highly charged political issue of HIV / AIDS presents a disincentive for vaccine development. Thomas C. Nchinda, *Initiatives in Health Research*, in THE 10/90 REPORT ON HEALTH RESEARCH 121, 122 (Sheila Davey ed., 1999).

⁹² Zonana, *supra* note 87.

⁹³ INT’L AIDS VACCINE INITIATIVE, DRAFT INDUSTRIAL COLLABORATIVE AGREEMENT para. 1(b), at 1 (1999).

party can produce the vaccine at lower cost, the signatory company must match that price or contract the third party for manufacturing. A vaccine can be sold at market price in the industrialized world and in private markets in the developing world. If an industry partner cannot meet its overall obligations, IAVI retains the right to choose from several options to ensure global accessibility.⁹⁴

Investment in industry is not the only component of IAVI's strategy. IAVI is also working with the World Bank on the creation of vaccine purchase funds to provide additional financial incentives for industry to engage in vaccine development. According to Berkley, vaccine purchase funds are "mechanisms that can create a market in the developing world to purchase these vaccines and to distribute them. The idea would be that we—before the vaccine is ever made—would have a mechanism in place to have the vaccines purchased."⁹⁵ The creation of purchase funds is based on the notion that although companies should not lose money on the vaccines they produce, the financial return that companies can expect (and must be willing to accept) will differ according to the market in question. The profit margin in the developing world would be next to nothing; however, companies that are willing to deal in those markets receive other important benefits, such as economies of scale and entrée into those markets.⁹⁶

When asked if the types of agreements IAVI has forged will work in other contexts, Berkley explained that he sees IAVI's quest for an AIDS vaccine "as a chance to begin to develop the mechanisms that make sense, that can be used across the whole range of different products. When we sit down and compare the issues on malaria to HIV, they are not that different."⁹⁷

In addition to updating its 1998 *Blueprint* with *Scientific Blueprint 2000: Accelerating Global Efforts in AIDS Vaccine Development*,⁹⁸ IAVI created another blueprint, *AIDS Vaccines for the World: Preparing Now To Assure Access*.⁹⁹ The latter document "presents a strategy for addressing the many economic, political, and logistical obstacles to immediate and widescale (sic) access in

⁹⁴ *Id.* para. 9, at 5-7; INT'L AIDS VACCINE INITIATIVE, IAVI BACKGROUNDER 2 (1999).

⁹⁵ Seth Berkley, Testimony Before the National Bioethics Advisory Commission 271, 302-03 (Jan. 13, 2000), *available at* <http://www.georgetown.edu/research/nrcbl/nbac/transcripts/index.html#jan00>.

⁹⁶ *Id.*

⁹⁷ *Id.* at 308.

⁹⁸ INT'L AIDS VACCINE INITIATIVE, SCIENTIFIC BLUEPRINT 2000: ACCELERATING GLOBAL EFFORTS IN AIDS VACCINE DEVELOPMENT (2000).

⁹⁹ INT'L AIDS VACCINE INITIATIVE, AIDS VACCINES FOR THE WORLD: PREPARING NOW TO ASSURE ACCESS (2000).

the developing world” and seeks to avoid “the typical [ten- to twenty-year] delay in introducing new vaccines to poor countries....”¹⁰⁰ Most recently, IAVI updated its research and development agenda for 2002 to 2004¹⁰¹ and, to achieve that agenda, created a “virtual vaccine company model” consisting of VDPs, centralized laboratories and reagent production, large-scale development and manufacturing partnerships, partnerships for Phase III clinical trials in developing countries, and “core regulatory dossier design.”¹⁰²

C. VaxGen

VaxGen, a California-based biotechnology company, developed an AIDS vaccine known as “AIDSVAX.”¹⁰³ AIDSVAX is the first AIDS vaccine candidate in the world to enter Phase III efficacy studies. VaxGen raised money to finance its own trials in an effort to get the vaccine tested as quickly as possible.¹⁰⁴ Two trials are underway. The first is taking place in the United States, Puerto Rico, and the Netherlands. Between June 1998 and October 1999, more than 5,400 participants were recruited, mostly men who have sex with men. Bangkok, Thailand is the site of the second trial. Recruitment of 2,500 participants, all intravenous drug users at high risk of HIV infection, began in March 1999 and concluded in August 2000. Primary results from the Thai study are expected later this year.¹⁰⁵

Thailand was chosen as a study site for several reasons. One is the strong professional relationship that has developed between key

¹⁰⁰ IAVI Releases Blueprints for Speeding Vaccine Development and Ensuring Access, IAVI REP. (International AIDS Vaccine Initiative, New York, N.Y.), Sept.-Nov. 2000, at 9, available at http://www.iavi.org/reports/103/IAVI_Blueprints3.htm. The Blueprint calls for the following five steps: (1) “[d]evelopment of effective pricing and global financing mechanisms”; (2) “[d]evelopment of mechanisms to reliably estimate demand for specific vaccines and to ensure sufficient production capacity to meet initial demand for an effective vaccine”; (3) “[d]evelopment of appropriate delivery systems, policies, and procedures for the most at-risk populations, especially adolescents and sexually active adults”; (4) “[h]armonization of national regulations and international guidelines governing vaccine approval and use”; and (5) “[e]stablishment of a mass vaccination program in developing countries for at least one under-used pediatric vaccine.” *Id.* at 9.

¹⁰¹ INT’L AIDS VACCINE INITIATIVE, THE IAVI RESEARCH AND DEVELOPMENT AGENDA 2002-2004, <http://www.iavi.org/pdf/rd-agenda.pdf> (July 2002).

¹⁰² IAVI VDP, *supra* note 89.

¹⁰³ Bill Snow, *VaxGen: Pushing the Envelope*, in HIV VACCINE HANDBOOK: COMMUNITY PERSPECTIVES ON PARTICIPATING IN RESEARCH, ADVOCACY, AND PROGRESS 195, 197 (Bill Snow ed., 1999).

¹⁰⁴ *Id.* at 199.

¹⁰⁵ VAXGEN, OUR VACCINE CANDIDATES: VAXGEN CLINICAL TRIALS, at <http://www.vaxgen.com/vaccine/trials.html> (last visited Nov. 14, 2002).

individuals at VaxGen and Thai researchers.¹⁰⁶ Another reason is that the HIV virus strains present in Thailand are homogeneous, making it easier to test AIDSVAX.¹⁰⁷ Finally, WHO and UNAIDS supported the building of infrastructure to conduct vaccine trials, and UNAIDS and the United States Centers for Disease Control and Prevention (CDC) have supported cohort development over a number of years. A cohort of intravenous drug users from methadone clinics run by the Bangkok Metropolitan Association was first compiled, from which research participants were subsequently recruited for the vaccine trial.¹⁰⁸

The Thai government, the Bangkok municipal government, and Mahidol University have been very proactive in working with VaxGen. Despite the implementation of other interventions, Thailand has one of the fastest growing rates of HIV infection in the world, and the government has made the development of an AIDS vaccine a health priority.¹⁰⁹ As a condition to hosting the study, the Thai government required, first, that any vaccine tested in Thailand have a reasonable likelihood of preventing infection by the particular strains of HIV most prevalent in the country. VaxGen specifically developed AIDSVAX B/E to prevent further infections by the two viral subtypes, B and E, that are prominent in those infected through sexual exposure and intravenous drug use.¹¹⁰ The Thai government also required that the country receive research benefits in two forms: the product itself and capacity building.¹¹¹

In its discussions with the Thai Ministry of Public Health, VaxGen informally agreed that, should there be a licensed product, the country would receive special treatment from the company in making the product available in Thailand.¹¹² Specifically, VaxGen agreed to make a concerted effort to decrease the cost of the vaccine for Thailand. If feasible, because Thailand has a strong local pharmaceutical industry, arrangements could be made for bulk shipment of the vaccine with filling and finishing in Thailand.¹¹³ One Thai AIDS researcher described this arrangement as a

¹⁰⁶ E-mail from Marlene Chernow, Vice President of Product Development and Regulatory Affairs, VaxGen, to Alice Page, Senior Policy Analyst, National Bioethics Advisory Commission (May 1, 2000) [hereinafter Chernow E-mail] (on file with author).

¹⁰⁷ Esparza, *supra* note 12, at 10; Chernow E-mail, *supra* note 106.

¹⁰⁸ Esparza, *supra* note 12, at 9; Chernow E-mail, *supra* note 106.

¹⁰⁹ Esparza, *supra* note 12, at 2, 6, 10; Chernow E-mail, *supra* note 106.

¹¹⁰ Esparza, *supra* note 12, at 9; Chernow E-mail, *supra* note 106.

¹¹¹ Chernow E-mail, *supra* note 106.

¹¹² E-mail from Donald Francis, President, VaxGen, to Alice Page, Senior Policy Analyst, National Bioethics Advisory Commission (Nov. 17, 1999) (on file with author).

¹¹³ *Id.*

“letter of intent” and the first of its kind for any vaccine trial in the world.¹¹⁴ Discussions on how to make the vaccine available after study completion are ongoing. Although there is a formal agreement governing the Phase III study itself, the Thai government has requested nothing beyond the “letter of intent” for making the product available.

Many of the benefits that will accrue to Thailand take the form of capacity building. Thai researchers highly value the transfer of such knowledge and technology, which is occurring in three ways as the result of a verbal commitment between VaxGen and Thailand, not as part of the “letter of intent.”¹¹⁵ First, VaxGen is transferring its data management capabilities to Thailand. A complete data center has been established so that Thai researchers have state-of-the-art hardware and software. VaxGen is also teaching the Thai data management unit how to collect, monitor, and validate data to comply with international clinical research guidelines. Second, the company has developed a repository of laboratory specimens. Thai researchers are learning how to store, track, locate, and connect data to specimens. Third, VaxGen is training Thai researchers in clinical research and good clinical practices for conducting Phase III trials. Thailand’s previous experience has been limited to Phase I and II trials.¹¹⁶ Overall, the goal is to enable Thailand to function independently and conduct Phase III trials on its own.

In 2000, several allegations were published in the *Washington Post* concerning post-trial benefits sought by Thailand for either research participants or the country itself that VaxGen would not agree to provide.¹¹⁷ First, VaxGen allegedly refused to pledge care for research participants who become HIV-positive during the trial. Thai health authorities finally agreed to provide the best local therapy, which is far less effective than what subjects would receive if the trial were carried out in the United States. Second, VaxGen allegedly refused to guarantee that its vaccine, if proven effective, would be sold to Thailand at a reduced price: “A ‘gentlemen’s agreement’ the company wrote in 1998 to Thai health officials suggested that if the Thais helped with packaging the vaccine, VaxGen might be able to reduce the country’s costs for the vaccine.”¹¹⁸ However, according to VaxGen’s President, the company “can’t give (the)

¹¹⁴ *Thailand: From “Guinea Pig” Fears to Phase III Trial: An Interview with Natth Bhamarapravati*, IAVI REP. (International AIDS Vaccine Initiative, New York, N.Y.), Sept.-Oct. 1999, at 6-7, available at <http://www.iavi.org/reports/75/sep-oct-1999-6.html>.

¹¹⁵ Chernow E-mail, *supra* note 106.

¹¹⁶ Esparza, *supra* note 12, at 4; Chernow E-mail, *supra* note 106.

¹¹⁷ Mary Pat Flaherty & Doug Struck, *Life by Luck of the Draw*, WASH. POST, Dec. 22, 2000, at A1.

¹¹⁸ *Id.*

vaccine away and bankrupt the company.”¹¹⁹ Finally, VaxGen purportedly rejected Thailand’s requests for profit sharing or for a manufacturing plant to be located in the country. One Thai representative who reviewed the study and is now a member of the Thai Senate said, “[W]e were making test subjects available and we were agreeable to that. But on the other hand, we did not have that much bargaining power. Our situation was desperate.”¹²⁰ VaxGen has invested almost \$600,000 in equipment and facilities that will remain in Bangkok when the study is over.¹²¹

CONCLUSION

Many opportunities and challenges remain for the use of prior agreements in international clinical trials. Some agreements, such as those employed by WHO, have proven successful. Agreements forged by other entities such as IAVI and VaxGen await the judgment of time. What conclusions about prior agreements can be drawn from these examples? Because they are limited in number, and specific factual information about them and the contexts in which they were negotiated is scarce, it is difficult to extract general principles concerning the use of prior agreements in international clinical trials. However, several observations are in order.

It may be important to distinguish, at least in some cases, between situations where a developing country is a party to a prior agreement and those where a developing country, although not a party to an agreement, is its ultimate intended beneficiary. Out of necessity, industry is very likely to play a prominent role in most, if not all, of these arrangements. However, the presence of a third party acting on behalf of, or in conjunction with, a developing country may be critical to the successful negotiation of benefits.

WHO and IAVI have been able to secure fair pricing agreements from industry for the sale of study interventions to developing countries. To what can their success be attributed? Perhaps most importantly, these organizations have strong ties to the industrialized world and have entered into research collaborations on behalf of developing countries. WHO is a powerful, well-established international health organization headquartered in Europe, while IAVI, although a relatively new company based in the United States, is becoming increasingly well-funded by major donors such as the Bill & Melinda Gates Foundation, the Rockefeller Foundation, the World Bank, and the governments of industrialized countries.¹²²

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² IAVI VACCINE APPROACHES, *supra* note 89.

Furthermore, WHO and IAVI have more experience than many developing countries in negotiating agreements to develop and distribute health care goods and services collaboratively. In addition to economic resources, they possess (or can purchase) the scientific, medical, technological, business, and legal know-how that developing countries may lack. These organizations utilize legally enforceable contracts in their collaborative partnerships.

In contrast, some developing countries are simply unaware of the possibility of obtaining post-trial benefits through prior agreements. Those that negotiate prior agreements may find themselves severely disadvantaged by inequities in bargaining power. These inequities may become especially problematic when a developing country negotiates directly with industry without the assistance of a third party. Because help from the industrialized world is needed to combat AIDS, tuberculosis, malaria, and other diseases that are ravaging their populations, developing countries might accept arrangements that are far less than what distributive justice¹²³ requires. In VaxGen's case, such a small company may not be financially positioned to subsidize all the benefits Thailand requested.¹²⁴ Yet, larger and wealthier sponsors still may not have agreed to Thailand's demands.

Two further observations, also drawn from the VaxGen example, relate to the capacity-building benefits provided to the Thai government. First, the importance of securing such benefits should not be underestimated. Although the provision of successful interventions may help developing countries address particular health problems in the short term, building research capacity better situates developing countries to solve their own health problems in the long run. Second, capacity building in the VaxGen case is proceeding solely on the basis of a verbal commitment. This attests to the importance of the strength of the relationship between collaborative partners and their mutual commitment to the goal of the collaboration.

Finally, while the use of prior agreements in international research is in its infancy and, with a few exceptions, remains largely idealistic, prior agreements show great promise as a way to prevent exploitation of developing countries and of the individuals who serve as research subjects. The endorsement of such agreements in international and national ethical guidelines is a step forward. However, even if the problems inherent in

¹²³ See *supra* note 2.

¹²⁴ That VaxGen was unwilling to provide state-of-the-art treatment for research participants who became HIV-infected during the trial is not surprising. The high cost of such treatment in AIDS vaccine trials makes this issue one of the most contentious in international research ethics today.

their interpretation and enforcement can be overcome, their widespread use in international collaborative research should be anticipated with cautious optimism. Many human rights treaties, for example, have been in existence for decades and yet, acceptance of, or adherence to, those treaties is far from universal. Only ongoing discourse and debate can persuade individuals and organizations that prior agreements should be used in international research.¹²⁵ By no means do prior agreements provide a perfect solution, but, as is always the case, solutions to difficult and complex problems must begin somewhere.

¹²⁵ CIOMS' recent draft revision of its research guidelines directly endorsed prior agreements and defined the term. COUNCIL FOR INT'L ORGS. OF MED. SCIS., DRAFT REVISION OF THE CIOMS INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS Guideline 6 (2001). This was the first time the term "prior agreement" appeared in international research ethics guidelines. However, in the final version, that provision was eliminated after what must have been a lively and controversial discussion that is likely to be repeated again and again.

Legal Issues Concerning Public Health Efforts To Reduce Perinatal HIV Transmission

Zita Lazzarini, J.D., M.P.H. * and Lorilyn Rosales, J.D.^{†‡}

Since its inception in 1981, the Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome (HIV / AIDS) epidemic has raised challenging legal and ethical questions for public health officials, physicians, policymakers, patients, lawyers, and ethicists. Although HIV / AIDS mostly affects adults in their prime working years, it has also emerged as a pediatric health problem. Current estimates indicate that in the absence of effective maternal treatment, eight hundred thousand children worldwide born to HIV-infected mothers will be infected each year. Yet, one of the most significant advances of the epidemic has been the discovery that antiretroviral medications taken by the mother during pregnancy and delivery, and by the child after birth, can greatly reduce the risk of HIV transmission.¹ As a result, the United States and the rest of the global community have the opportunity to take proactive steps toward the reduction and virtual elimination of perinatal HIV transmission.²

This Article explores the legal issues related to the reduction of perinatal HIV transmission in the United States to demonstrate that proper education, along with voluntary testing and treatment during pregnancy, can significantly reduce such transmission. Part I examines the history of this topic from a medical perspective, focusing on studies of efforts to reduce perinatal transmission. Part II looks at the evolution of recommendations, policies, and laws regarding the testing and treatment

* Zita Lazzarini is the Director of the Division of Medical Humanities, Health Law, and Ethics at the University of Connecticut Health Center.

† Lorilyn Rosales is an associate at Pullman & Comley, L.L.C.

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¹ See *infra* Part I.

² Perinatal HIV transmission is the transmission of HIV from mother to child during pregnancy or during birth.

of HIV-positive pregnant women. Part III examines existing state laws regarding HIV testing and counseling, while Part IV reviews legal challenges to these and related laws. With the current medical, legal, and policy information in mind, Part V makes recommendations concerning state legal interventions to reduce perinatal HIV transmission. Part VI concludes that a carefully crafted policy of routine testing that incorporates informed consent is the key to a viable strategy to reduce HIV transmission.

I. THE MEDICAL PROBLEM OF PERINATAL HIV TRANSMISSION AND TREATMENT

To comprehend the scope and challenge of the problem of perinatal HIV transmission, it is important to place perinatal transmission in the context of the HIV epidemic among women and men worldwide. In its report on the global HIV / AIDS epidemic, the United Nations Joint Programme on AIDS (UNAIDS) estimated that forty million men, women, and children were living with HIV / AIDS at the end of 2001.³ In addition, approximately 2.5 million women with HIV / AIDS become pregnant every year.⁴ From such pregnancies, an estimated eight hundred thousand infants were infected in 2001.⁵

Since the vast majority of pediatric HIV infections are acquired perinatally, the most effective means of preventing pediatric HIV infection is to prevent infection of women in general.⁶ Even for women who are already infected, intervention can substantially reduce HIV transmission from mother to child.

Until the early 1990s, the only known methods to reduce perinatal HIV transmission were to counsel women to avoid pregnancy and to discourage HIV-positive mothers from breastfeeding.⁷ In 1994, however, a study by the Pediatric AIDS Clinical Trial Group 076 (PACTG 076) revealed that maternal and neonatal zidovudine (ZDV) treatment reduced perinatal HIV transmission by sixty-six percent.⁸ While twenty-five percent

³ JOINT UNITED NATIONS PROGRAMME ON AIDS, REPORT ON THE GLOBAL HIV / AIDS EPIDEMIC 8 (2002), available at http://www.unaids.org/epidemic_update/report_july02/.

⁴ *Id.* at 128.

⁵ Robert Steinbrook, *Preventing HIV Infection in Children*, 346 NEW ENG. J. MED. 1842, 1842 (2002).

⁶ Kevin M. De Cock et al., *Prevention of Mother-to-Child HIV Transmission in Resource-Poor Countries: Translating Research into Policy and Practice*, 283 JAMA 1175, 1178 (2000).

⁷ Lynne M. Mofenson & James A. McIntyre, *Advances and Research Directions in the Prevention of Mother-to-Child HIV-1 Transmission*, 355 LANCET 2237, 2237 (2000).

⁸ Edward M. Connor et al., *Reduction of Maternal-Infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment*, 331 NEW ENG. J. MED. 1173, 1173

of infants of mothers taking placebo were infected, the figure dropped to about eight percent with ZDV-treated mothers.⁹

Subsequent innovations in the treatment of pregnant women and newborns further reduced rates of perinatal HIV transmission. For instance, highly active combination antiretroviral therapies for the mother, or the combination of maternal ZDV treatment and a caesarean delivery, reduce transmission to less than two percent.¹⁰ In fact, since adopting combination therapy for pregnant women in 1994 both the United States and Western Europe have witnessed a sharp decline in perinatal HIV transmission.¹¹ Specifically, in the United States, the number of reported cases of perinatal HIV transmission has decreased every year since 1992, from 901 new cases in 1992, to approximately 144 newly infected infants in 1999.¹² Thus, treating HIV-infected pregnant women with certain antiretroviral drugs in a timely fashion can significantly reduce rates of perinatal HIV transmission.

II. POLICY DEVELOPMENTS REGARDING THE REDUCTION OF PERINATAL HIV TRANSMISSION

Since the success of the PACTG 076 protocol and other interventions in preventing perinatal transmission, American public health officials and clinicians have recognized the importance of determining the HIV status of pregnant women for early and timely treatment. Accordingly, the policies of government-sponsored agencies and professional organizations regarding perinatal HIV transmission have altered, changing both the way pregnant women are targeted for counseling and HIV testing, and the way

(1994).

⁹ *Id.*

¹⁰ Lynne M. Mofenson, *Perinatal Exposure to Zidovudine B—Benefits and Risks*, 343 NEW ENG. J. MED. 803, 803 (2000).

¹¹ Unfortunately, the rapid decline in perinatal HIV cases in the United States and other developed countries was not matched worldwide. Approximately ninety-five percent of people with HIV / AIDS live in developing countries. U.S. AGENCY FOR INT'L DEV., GLOBAL HEALTH, HIV / AIDS: FREQUENTLY ASKED QUESTIONS, at http://www.usaid.gov/pop_health/aids/News/aidsfaq.html (last visited Dec. 8, 2002). According to UNAIDS, at the end of 2001, there were three million children living with HIV. JOINT UNITED NATIONS PROGRAMME ON AIDS, *supra* note 3, at 8. In 2001, the United Nations Children's Fund (UNICEF) reported that of eight hundred thousand children with HIV, most (ninety percent) were infected during birth or through breastfeeding. UNITED NATIONS CHILDREN'S FUND, MOTHER-TO-CHILD TRANSMISSION OF HIV 2 (2002), available at <http://unicef.org/pubsgen/hiv-mothertochild/fact-sheet-mtct-en.pdf>. For most HIV-infected women in the world, therapy to reduce the risk of perinatal transmission remains unavailable.

¹² Centers for Disease Control and Prevention, *HIV and AIDS—United States, 1981-2000*, 50 MORBIDITY & MORTALITY WKLY. REP. 430, 433 (2001).

HIV tests are explained and administered. While these reforms have made perinatal testing more broadly inclusive, they have also tended to de-emphasize the role of pretest counseling and informed consent.

A. Policy Development by Governmental Agencies, Congress, and the IOM

Although HIV / AIDS appeared on the global scene in the early 1980s, the U.S. moved relatively slowly in developing a policy response. In 1985, the Centers for Disease Control and Prevention (CDC) issued guidelines for HIV counseling and testing that focused on high-risk women, *e.g.*, intravenous drug users and women whose sexual partners were HIV-infected or at risk for infection.¹³ Specifically, the CDC recommended testing for women who were pregnant or who might become pregnant if they (1) had evidence of HTLV-III / LAV¹⁴ infection; (2) used drugs intravenously for non-medical purposes; (3) were born in countries where heterosexual transmission is thought to play a major role; (4) engaged in prostitution; or (5) had been sex partners of intravenous drug abusers, bisexual men, men with hemophilia, men born in countries where heterosexual transmission is thought to play a major role, or men who otherwise had evidence of HTLV-III / LAV infection.¹⁵ The CDC recommended that an infected women be "advised to consider delaying pregnancy . . . [and] be advised against breast-feeding to avoid postnatal transmission to a child who may not yet be infected."¹⁶ However, the CDC did not advocate routine counseling and testing for women not in the aforementioned groups "due to the low prevalence of infection and concern about interpretation of test results in a low-prevalence population."¹⁷

In 1988, the Presidential Commission on the Human Immunodeficiency Virus Epidemic issued a report calling for a national plan to help fight the spread of HIV and AIDS.¹⁸ Although the report made a number of broad suggestions to promote research and help protect the

¹³ Centers for Disease Control and Prevention, *Recommendations for Assisting in the Prevention of the Perinatal Transmission of Human T-Lymphotropic Virus Type III / Lymphadenopathy-Associated Virus and Acquired Immunodeficiency Syndrome*, 34 MORBIDITY & MORTALITY WKLY. REP. 721, 724-26 (1985) [hereinafter CDC Recommendations].

¹⁴ HTLV-III / LAV, which was the early designation for HIV, stands for human T-lymphotropic virus type III / lymphadenopathy-associated virus.

¹⁵ CDC Recommendations, *supra* note 13, at 724.

¹⁶ *Id.* at 725.

¹⁷ *Id.*

¹⁸ REPORT OF THE PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC (1988). President Reagan appointed the commission in May 1987.

public, it did not address the specific issue of perinatal HIV transmission.¹⁹ The ensuing Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 allocated funding to help states, cities, and hospitals with a disproportionate number of AIDS cases provide treatment and support services for persons with HIV and AIDS.²⁰ Like the commission report, however, this legislation did not explicitly mention perinatal HIV transmission.

In response to the 1994 PACTG 076 results, the CDC recommended counseling on the risks of HIV and voluntary testing for all pregnant women, as well as counseling on treatment and prevention of perinatal transmission for infected women.²¹ The CDC's official 1995 guidelines specifically added that pregnant, HIV-infected women should be offered antiretroviral treatment and that all HIV-exposed newborns should be monitored for early diagnosis and treatment.²² In these guidelines, the CDC emphasized the benefits of routine, voluntary testing as opposed to mandatory testing, which might deter women from seeking prenatal care.²³ In support of its position, the CDC relied on data from routine HIV counseling and testing programs showing that high levels of testing could be achieved without mandatory testing.²⁴

In 1996, Congress reauthorized the Ryan White CARE Act, amending and approving the specific spending priorities and programs originally contained in the legislation. During the reauthorization hearings, Congress struggled with various means to reduce perinatal HIV transmission. The final amendments required all states to adopt the CDC guidelines on HIV counseling and voluntary testing for pregnant women.²⁵

¹⁹ See *id.* The Commission's suggestions included local and state government promotion of HIV testing and counseling and the enactment of HIV-specific criminal statutes penalizing conduct that created a risk of transmitting HIV. As a result of these recommendations, all fifty states adopted various forms of HIV / AIDS legislation to promote HIV awareness, case reporting, and testing. See Stephen V. Kenney, Comment, *Criminalizing HIV Transmission: Lessons from History and a Model for the Future*, 8 J. CONTEMP. HEALTH L. & POL'Y 245, 260 (1992).

²⁰ 42 U.S.C. §§ 300ff *et seq.* (1990).

²¹ See Centers for Disease Control and Prevention, *U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women*, 44 (RR-7) MORBIDITY & MORTALITY WKLY. REP. 1, 8, 10 (1995) [hereinafter CDC 1995 Recommendations].

²² *Id.* at 10–11.

²³ *Id.* at 6.

²⁴ *Id.* While the CDC's support of voluntary rather than mandatory testing is well founded, it is crucial for all pregnant women to be properly counseled about the benefits of being tested as well as their options, including their right to refuse testing.

²⁵ 42 U.S.C. § 300ff-33(a) (1996). To demonstrate compliance, states had to show a fifty percent reduction in AIDS cases stemming from HIV transmission, a ninety-five percent

In particular, under the final amendments, if a state failed to adopt the CDC guidelines, it risked losing the funding it received under the Ryan White CARE Act of 1990.²⁶ The amendments also required that each state annually assess its incidence of perinatal HIV transmission and evaluate potential reasons for failure to prevent perinatal transmission.²⁷ Compliant states could avail themselves of the \$10 million set aside for HIV counseling, testing of pregnant women, prenatal care for women with a high risk of infection, and implementation of the CDC guidelines.²⁸ In addition, compliant states with the highest rates of HIV infection among pregnant women received priority for these funds.²⁹

Moreover, in the 1996 amendments to the Ryan White CARE Act, Congress requested that the National Academy of Sciences evaluate state efforts to reduce perinatal HIV transmission. The Institute of Medicine (IOM) initiated the requisite study in 1997 and issued its report in 1999. The report concluded that despite reductions in perinatal HIV transmission, the number of babies born with HIV was higher than attainable levels of prevention.³⁰ Specifically, prenatal HIV testing had not become universal practice, and consequently many infected women did not receive adequate treatment. Furthermore, the report noted that some health care providers did not offer tests to patients whom they believed were "low risk," and other providers neglected to do so because they found the pretest counseling requirements burdensome.³¹ The IOM concluded that, in light of the advances in antiretroviral therapy and its significant potential to reduce perinatal HIV transmission, "the United States should adopt a national policy of *universal* HIV testing, with patient notification, as a *routine* component of prenatal care."³² As the executive summary of the IOM report explains:

There are two key elements to the committee's recommendation. The first is that HIV screening should be *routine with notification*. This means that the test for HIV would be integrated into the standard battery of prenatal tests and women would be informed that the HIV test is being

HIV testing rate of women with two prenatal visits or more prior to thirty-four weeks gestation, or state legislation or regulations requiring the testing of all newborns whose mothers have not been tested for HIV. *Id.* § 300ff-34(e)(2).

²⁶ *Id.* § 300ff-33(b).

²⁷ *Id.* § 300ff-34(a)-(b).

²⁸ *Id.* § 300ff-33(c).

²⁹ *Id.*

³⁰ INST. OF MED., REDUCING THE ODDS: PREVENTING PERINATAL TRANSMISSION OF HIV IN THE UNITED STATES 5-6 (Michael A. Stoto et al. eds., 1999).

³¹ *See id.* at 107.

³² *Id.* at 6 (emphasis added).

conducted and of their right to refuse it. . . . The second key element to the recommendation is that screening should be *universal*, meaning that it applies to all pregnant women, regardless of their risk factors and of prevalence rates where they live.³³

In 2000, Congress again reauthorized the Ryan White CARE Act, providing \$30 million to support grants for partner counseling and referral services for individuals who tested positive for HIV.³⁴ The 2000 amendments also asked the Secretary of Health and Human Services to contract with the IOM to study the status of perinatal HIV transmission.³⁵ Furthermore, provisions pertaining to perinatal transmission were altered to authorize an additional \$30 million in grants for the counseling, testing, and treatment of pregnant women.³⁶ While existing programs received the first \$10 million, a percentage of the remaining funds was reserved for states that could demonstrate a substantial decrease in perinatal transmission and for states that required newborn testing. Thus, states that were most aggressive in their efforts to prevent perinatal HIV transmission received the most funding.

In 2001, the CDC issued long-awaited revisions of its recommendations for HIV counseling and testing of pregnant women.³⁷ The revised guidelines differed from the 1995 guidelines insofar as they emphasized HIV testing as a routine part of prenatal care. To achieve the goal of testing all pregnant women for HIV, the CDC recommended that the test process be simplified so that pretest counseling would no longer be a barrier; that various types of informed consent be allowed; that health care providers explore and address a woman's reasons for refusing testing; and that HIV testing and treatment be offered to women who had not received prenatal testing and antiretroviral drugs.³⁸ Furthermore, in November of 2002, the CDC issued comprehensive recommendations for the use of antiretroviral drugs during pregnancy that reiterated the importance of

³³ *Id.* (emphasis original).

³⁴ Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 2000, Pub. L. No. 106-345, § 2631, 114 Stat. 1319.

³⁵ *Id.* § 213. The Secretary of Health and Human Services, with the aid of the IOM, was to examine the following: (1) the number of newborns born with HIV where the attending obstetrician was unaware of the mother's HIV status; and (2) barriers existing in states that prevent an obstetrician from routinely testing pregnant women or testing newborns when the HIV status of the mother is unknown. The Secretary was to recommend ways to remove such barriers and reduce transmission. *Id.*

³⁶ *Id.* § 212.

³⁷ Centers for Disease Control and Prevention, *Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women*, 50(RR-19) MORBIDITY & MORTALITY WKLY. REP. 59 (2001) [hereinafter CDC revised guidelines].

³⁸ *Id.* at 59.

early testing and treatment of pregnant women to prevent HIV transmission to their fetuses.³⁹

In sum, at least two important themes emerged from the CDC's 2001 revisions and 2002 recommendations. First, the CDC endorsed making HIV testing a routine part of prenatal care (*i.e.*, one that all physicians and midwives should pursue with all pregnant patients). Second, the CDC recommended the simplification of the informed consent requirements for HIV testing. Although the CDC continues to recommend that HIV testing of pregnant women be voluntary, these revisions demonstrate a shift in the CDC's position toward more routine HIV testing of pregnant women.

B. Perinatal HIV Transmission Policies of Professional Organizations

The shift in emphasis toward more routine testing of pregnant women for HIV appears not only in federal legislation and CDC guidelines, but also in the policies of professional organizations closely involved in prenatal care. While some organization policies have closely mirrored those of the IOM, others have retained more emphasis on informed consent and voluntary testing than either the CDC (in its 2001 recommendations) or the IOM. Although not binding on their members or on public or private policy, position statements and recommendations from professional organizations attest to a developing standard of care among providers of prenatal and newborn care. These recommendations also indicate the level of professional support for official policies and laws adopted by legislatures and health agencies. Indeed, these positions can influence the development of the CDC's recommendations, and Congress often uses adoption of CDC recommendations as a criterion for receiving certain categories of federal funding.⁴⁰ Therefore, the policies of professional organizations can potentially impact cash-strapped states and health agencies.

Among professional organizations, the American College of Obstetricians and Gynecologists (ACOG) took one of the more aggressive positions by launching a campaign for universal HIV screening of all pregnant women.⁴¹ The ACOG is motivated by scientific advances made in

³⁹ See Centers for Disease Control and Prevention, *U.S. Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions To Reduce Perinatal HIV-1 Transmission in the United States*, 51 (RR-18) MORBIDITY & MORTALITY WKLY. REP. 1 (2002).

⁴⁰ See, for example, the 1996 Amendments to the Ryan White CARE Act, described *supra* in Part IIA.

⁴¹ Press Release, American College of Obstetricians and Gynecologists, HIV Tests Urged for

the “prevention of perinatal transmission of HIV, testing for HIV, and the treatment of HIV-infected women.”⁴² The ACOG recommends that all pregnant women in the U.S. be tested for HIV as a routine part of prenatal care.⁴³ Although the ACOG does not advocate mandatory testing, its goal is to implement universal testing with notification and the right to refuse.⁴⁴

Other professional organizations also endorse routine HIV counseling and testing for pregnant women, but insist that testing be of the opt-in variety rather than of the opt-out variety advocated by the ACOG and the IOM. For example, while the American College of Nurse Midwives (ACNM) recognizes the importance of preventing perinatal HIV transmission, it opposes mandatory testing as a condition of prenatal care.⁴⁵ Instead, the ACNM recommends that “all women should be counseled on HIV risk behaviors and risk reduction strategies. Following counseling, all women should be offered HIV testing with informed consent.”⁴⁶ Reiterating the importance of identifying HIV-positive pregnant women, the American Academy of Pediatrics (AAP) recommends “documented, routine HIV education, and routine testing with consent, for all pregnant women in the United States” as well as “utilization of consent procedures that facilitate rapid incorporation of HIV education and testing into the routine medical care setting.”⁴⁷

The American Public Health Association (APHA) also opposes mandatory HIV testing of pregnant women. Its 1995 policy statement, entitled “Opposition to Mandatory HIV Testing of Pregnant Women,” explicitly urged the federal government to prohibit mandatory testing of pregnant women.⁴⁸ As an alternative, the APHA recommends that the Department of Health and Human Services educate health care providers on HIV counseling and voluntary testing for pregnant women, and that health care providers “routinely recommend counseling and voluntary

All Pregnant Women: Ob-Gyns Launch Campaign for Universal HIV Screening, at http://www.acog.org/from_home/publications/press_releases/nr05-23-00-2.cfm (May 23, 2000).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ American College of Nurse Midwives, Reducing Perinatal Transmission of HIV / AIDS: A Tip Sheet for ACNM State Legislative Contacts (Nov. 1999) (on file with the Yale Journal of Health Policy, Law, and Ethics).

⁴⁶ *Id.*

⁴⁷ American Academy of Pediatrics, *Perinatal Human Immunodeficiency Virus Testing (RE9507)*, 95 PEDIATRICS 303, 306 (1995), available at <http://www.aap.org/policy/re9507.html>.

⁴⁸ AM. PUB. HEALTH ASS'N, OPPOSITION TO MANDATORY HIV TESTING OF PREGNANT WOMEN

(1995), available at

<http://www.apha.org/legislative/policy/policysearch/index.cfm?fuseaction=view&id=115>.

testing with informed consent to women, especially pregnant women.”⁴⁹ Similarly, the American Medical Association (AMA) endorsed the CDC’s 1995 recommendations with regard to HIV counseling and voluntary testing for pregnant women.⁵⁰ In 1998, the AMA issued a recommendation for routine voluntary testing, stating that, “a system for offering HIV tests in the intrapartum period, using a good faith effort to ensure an informed process of consent, is reasonable.”⁵¹

In short, the consensus among many professional organizations involved in the delivery of care for pregnant women favors routine testing with consent—as opposed to mandatory testing—to prevent perinatal HIV transmission. In particular, while the ACOG recommends that women be given the right to refuse testing, the ACNM, the AAP, the AMA, and the APHA have been more protective of women’s rights, recommending that pregnant women be counseled and given an opportunity to consent prior to testing. Thus, although the public health justification for HIV testing of pregnant women is very strong, it appears most professionals would not override a pregnant woman’s right to participate in the testing decision.

III. EVALUATING EXISTING STATE LAWS ON HIV TESTING AND COUNSELING

Since 1981, every state has adopted HIV-specific laws. While thirty-seven states have general HIV testing statutes, only seventeen have prenatal testing statutes,⁵² and only four have newborn testing statutes.⁵³ To understand the legal measures in place to reduce perinatal HIV transmission, it is important to examine the structure of HIV testing and counseling laws in each state.

A. General HIV Testing Statutes

General HIV testing statutes establish each state’s overall approach to HIV testing, pretest counseling, and the role of informed consent in the testing process. In states and territories with no specific statute covering HIV testing of pregnant women, general HIV testing statutes govern how pregnant women may be tested. Three types of informed consent policies are found in many of these statutes: (1) voluntary testing with written

⁴⁹ *Id.*

⁵⁰ See CDC 1995 Recommendations, *supra* note 21.

⁵¹ Howard Minkoff & Mary Jo O’Sullivan, *The Case for Rapid HIV Testing During Labor*, 279 JAMA 1743, 1744 (1998).

⁵² Arkansas, California, Connecticut, Delaware, Florida, Indiana, Iowa, Maryland, Michigan, New Jersey, Pennsylvania, Rhode Island, Tennessee, Texas, Virginia, Washington, and West Virginia have prenatal testing statutes.

⁵³ Connecticut, Indiana, New York, and Rhode Island have newborn testing statutes.

informed consent; (2) voluntary testing with informed consent (which may be written or oral, or not specified in the statute); and (3) testing based on general consent to medical testing and treatment.

1. Voluntary Testing with Written Informed Consent

Fifteen states have statutes classified as voluntary testing with written informed consent.⁵⁴ The statutes require documentation via a general consent form for medical or surgical treatment that specifically includes consent for HIV antibody or antigen testing,⁵⁵ a form that contains specific information about the risks and benefits of HIV testing and counseling,⁵⁶ or a form that simply contains a written statement signed by the patient indicating that she consents to HIV testing, without delineating the risks and benefits of testing.⁵⁷ Of the fifteen states that require voluntary testing with written informed consent, twelve also require health care providers to include pretest counseling as part of HIV testing.⁵⁸ Among these twelve states, nine specify what pretest counseling entails.⁵⁹ Maine's statute is typical:

"Pre-test counseling" must include [f]ace-to-face counseling that includes, at a minimum, a discussion of: (1) the nature and reliability of the test being proposed; (2) the person to whom the results of the test may be disclosed; (3) the purpose for which the test results may be used; (4) any reasonably foreseeable risks and benefits resulting from the test; and (5) information on good HIV preventative practices and HIV risk reduction plans; and [a] written memorandum summarizing the

⁵⁴ Alabama, Arizona, California, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Nebraska, New York, North Dakota, Pennsylvania, Rhode Island, and Wisconsin have such statutes.

⁵⁵ See, e.g., ALA. CODE § 22-11A-51(b) (2002) ("A general consent form should be signed for medical or surgical treatment which specifies the testing for HIV infection by any antibody tests or other means and may be considered as meeting the standard of informed consent. . .").

⁵⁶ See, e.g., CONN. GEN. STAT. § 19a-582(b) (2002) (requiring that informed consent include a statement that the health care provider explained to the patient a variety of matters related to HIV testing).

⁵⁷ See, e.g., CAL. HEALTH & SAFETY CODE § 120990(a) (Deering 2002) ("The person giving the test shall have a written statement signed by the subject or conservator or other person . . . confirming that he or she obtained the consent from the subject.").

⁵⁸ Arizona, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Nebraska, New York, North Dakota, Pennsylvania, and Rhode Island have such requirements.

⁵⁹ Arizona, Illinois, Maine, Maryland, Michigan, Nebraska, New York, North Dakota, and Pennsylvania have such provisions.

contents of the discussion⁶⁰

In contrast, three states, Hawaii, Massachusetts, and Rhode Island, prescribe pretest counseling in more general terms, thereby leaving more discretion to the health care provider. For example, Massachusetts defines pretest counseling as simply “a face-to-face meeting . . . between the member [of the community] and a physician, physician assistant, nurse practitioner, registered nurse, or counselor . . . for the purpose of providing counseling before HIV testing.”⁶¹

2. *Voluntary Testing with Informed Consent (Non-Specific)*

The second category of statutes requires informed consent but does not insist on written consent. For example, Indiana’s statute provides:

[A] person may not perform a screening or confirmatory test for the antibody or antigen to the human immunodeficiency virus (HIV) without the consent of the individual to be tested or a representative. . . . A physician ordering the test or the physician’s authorized representative shall document whether or not the individual has consented.⁶²

Sixteen states follow this pattern,⁶³ with eleven requiring pretest counseling.⁶⁴

3. *General Medical Consent*

While the majority of states require informed consent specifically for HIV testing, several states do not require such specific consent. In particular, Texas⁶⁵ and Kentucky⁶⁶ permit HIV testing based on general consent to medical treatment.⁶⁷

In Texas, the relevant statute provides that “[a] person who has signed a general consent form for the performance of medical tests or procedures

⁶⁰ ME. REV. STAT. ANN. tit 5, § 19204-A (West 2002).

⁶¹ MASS. REGS. CODE tit. 130, § 405.402 (2002).

⁶² IND. CODE § 16-41-6-1 (2002).

⁶³ The sixteen states are Colorado, Connecticut, Delaware, Florida, Indiana, Louisiana, Missouri, Montana, New Hampshire, New Mexico, North Carolina, Ohio, Oregon, Virginia, Washington, and West Virginia.

⁶⁴ The eleven states are Connecticut, Delaware, Florida, Louisiana, Missouri, Montana, New Mexico, Ohio, Virginia, Washington, and West Virginia.

⁶⁵ TEX. HEALTH & SAFETY CODE ANN. §§ 81.105, 81.106 (Vernon 2002).

⁶⁶ KY. REV. STAT. ANN. § 214.181(2)–(3) (Banks-Baldwin 2002).

⁶⁷ In addition to these two states, Arkansas, Georgia, Illinois, and Mississippi allow testing based on general consent *when specific circumstances pertain*, as described in Subsection 4 *infra*.

is not required to also sign or be presented with a specific intent form relating to medical tests or procedures to determine HIV infection.”⁶⁸ In addition, the statute allows oral consent if there is evidence that the HIV test has been explained to the individual and consent was obtained.⁶⁹

Kentucky’s law also affords substantial opportunity for HIV testing without informed consent. In particular, testing without informed consent is permissible (1) when an individual “has signed a general consent form for the performance of general medical procedures and tests” or (2) “[i]n any emergency situation where informed consent of the patient cannot reasonably be obtained before providing health-care services.”⁷⁰ The Kentucky General Assembly clearly wanted to encourage widespread testing, as evidenced in the statute’s description of the legislative intent.⁷¹ In fact, under Kentucky’s scheme, it is difficult to imagine a clinical setting in which HIV testing of patients without their consent would be prohibited.

4. *Exceptions to General Informed Consent Requirements*

Even states that generally require consent for HIV testing may have exceptions that permit testing without consent under specific circumstances. For example, New York normally requires written informed consent, but a party “is to submit to a physical, mental or blood examination by a designated physician after the commencement of an action in which the mental or physical condition . . . of a party is *in controversy*, upon notice by the other party.”⁷² The Supreme Court of New York has held that, where a party voluntarily informs the opposing party of his or her HIV or AIDS status, an HIV test may be administered without the informing party’s consent.⁷³ Meanwhile, Missouri allows the Department of Health and Senior Services to obtain a court order to test certain individuals after reasonable efforts have been made to obtain informed consent if “there are reasonable grounds to believe that an individual is infected with HIV and there is clear and convincing evidence of a serious and present threat to others posed by the individual if

⁶⁸ TEX. HEALTH & SAFETY CODE ANN. § 81.106 (Vernon 2002).

⁶⁹ *Id.* § 81.105.

⁷⁰ KY. REV. STAT. ANN. § 214.181(2)–(3) (Banks-Baldwin 2002).

⁷¹ *Cf.* KY. REV. STAT. ANN. § 214.635 (Banks-Baldwin 2002) (requiring the state to estimate the potential impact of HIV infection on state expenditures).

⁷² *People v. Durham*, 553 N.Y.S.2d 944, 947 (N.Y. Sup. Ct. 1990) (emphasis added by the court) (citing N.Y. C.P.L.R. 3121 (McKinney 2002)).

⁷³ 553 N.Y.S.2d at 947.

infected.”⁷⁴ Likewise, Georgia allows testing to protect the public only after obtaining the subject’s consent or upon successful petition for a court order.⁷⁵ A court must find “clear and convincing evidence that the person is reasonably likely to be infected with HIV and that there is a compelling need to protect the public health.”⁷⁶ Such statutory language establishes a relatively high threshold both for evidence that an individual is infected, and for evidence that the individual poses a threat to the community. Moreover, in Missouri and Georgia, court adjudication of these issues provides due process protections.

While Georgia, Missouri, and New York thus permit HIV testing without consent in relatively limited circumstances, at least three other states, Arkansas, Illinois, and Mississippi, carve out potentially broad exceptions to consent.

Arkansas permits HIV testing without full informed consent when (1) a physician determines that the testing is necessary for appropriate diagnosis and treatment of a patient, and the patient has provided general consent to the physician for medical treatment;⁷⁷ or (2) a health care provider risks becoming infected with HIV after he or she has come in direct contact with the blood or bodily fluids of an individual.⁷⁸ The second exception affords only a modicum of discretion as long as “exposure” is clearly defined. However, the first exception could cover virtually any situation where a physician thinks a patient is infected and the patient has sought any kind of medical care. Similarly, Mississippi allows testing without consent “if the hospital or physician determines that the test is necessary for diagnostic purposes to provide appropriate care or treatment to the person to be tested, or . . . to protect the health and safety of other patients or persons providing care and treatment to the person to be tested.”⁷⁹ Such unfettered discretion could lead to abuse by individual physicians or by institutions. To reduce the likelihood of abuse, states

⁷⁴ MO. ANN. STAT. § 191.674(1) (West 2002).

⁷⁵ GA. CODE ANN. § 31-17A-2 (2002).

⁷⁶ GA. CODE ANN. § 31-17A-3 (2002).

⁷⁷ ARK. CODE ANN. § 20-15-905(c)(1) (Michie 2002) (“Informed consent, information, and counseling are not required for the performance of an HIV test when, in the judgment of the physician, such testing is medically indicated to provide an appropriate diagnosis and treatment to the subject of the test provided that the subject of the test has otherwise provided his or her consent to such physician for medical treatment.”).

⁷⁸ ARK. CODE ANN. § 20-15-905(b)(1) (Michie 2002) (“Consent is not required for a health care provider or health facility to perform a test when a health care provider or employee of a health facility is involved in a direct skin or mucous membrane contact with the blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his medical judgment.”).

⁷⁹ MISS. CODE ANN. § 41-41-16 (2000).

could either promulgate clear criteria for applying exceptions to informed consent or require an impartial decision-maker to determine in each instance whether an exception applies.

A different ambiguity—that of potential conflict *between* HIV testing provisions—plagues Illinois law. While one statute demands written consent,⁸⁰ another allows HIV testing *based only on general consent to treatment* if a physician determines testing is medically necessary.⁸¹ Specifically, the latter statute states:

[W]ritten informed consent, information and counseling are not required for the performance of an HIV test . . . when in the judgment of the physician, such *testing is medically indicated to provide appropriate diagnosis and treatment to the subject of the test*, provided that the subject of the test has otherwise provided his or her consent to such physician for medical treatment.⁸²

Absent clear legislative intent to the contrary, such exceptions should be narrowly interpreted in light of the general consensus favoring informed consent and voluntary testing.

B. Prenatal HIV Testing Statutes

Of the fifty states and the District of Columbia, only seventeen have specific prenatal HIV testing statutes.⁸³ In states without such statutes, the general HIV testing laws apply, and most such states have policies and programs addressing perinatal HIV transmission.⁸⁴ These policies and initiatives most commonly emphasize education, counseling, and providing testing for all pregnant women.⁸⁵ The seventeen states that have prenatal testing statutes generally feature two types of statutes: (1) routine offer of and informed consent required for prenatal HIV testing; or (2) routine prenatal HIV testing with an implicit or explicit “opt-out” provision.

1. Routine Offer of and Informed Consent Required for Prenatal HIV Testing

Eleven states routinely offer HIV counseling and testing to pregnant women and make testing itself voluntary, based explicitly on informed

⁸⁰ 410 ILL. COMP. STAT. 305 / 4 (2002).

⁸¹ 410 ILL. COMP. STAT. 305 / 8 (2002).

⁸² *Id.* (emphasis added).

⁸³ See *supra* note 52.

⁸⁴ Zita Lazzarini et al., Abstract, *State Efforts To Reduce Perinatal HIV Transmission*, 12 PROC. INT’L CONF. AIDS 4410 (1998).

⁸⁵ *Id.*

consent, pursuant to a specific prenatal testing provision.⁸⁶ California's statute exemplifies this scheme:

The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall offer human immunodeficiency virus (HIV) information and counseling to every pregnant patient. The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall offer an HIV test . . . to every pregnant patient. . . . If the pregnant woman voluntarily consents to testing, the provider shall arrange for HIV testing directly or by referral. . . .⁸⁷

The only significant difference between such specific statutory regimes and those predicated on general HIV testing statutes requiring informed consent is that the former specifically require physicians to offer all pregnant women HIV testing one or more times during pregnancy.

2. Routine Prenatal HIV Testing with an Explicit or Implicit Opt-Out Provision

Six states routinely conduct prenatal HIV testing pursuant to a specific statute.⁸⁸ Routine testing means that the HIV test is incorporated into the battery of tests that pregnant women normally receive. Usually, women are informed of the general nature of the battery of tests, but the tests will be performed unless the woman actively objects or refuses ("opts out"). Florida's statute exemplifies this opt-out scheme:

The prevailing professional standard of care in this state requires each health care provider and midwife who attends a pregnant woman to counsel the woman to be tested for human immunodeficiency virus. . . . If a pregnant woman objects to HIV testing, reasonable steps shall be taken to obtain a written statement of such objection.⁸⁹

Ideally, under an opt-out system, pregnant women would receive sufficient information about individual tests to provide them with notice of testing and a meaningful opportunity to accept or refuse. One concern of patient advocates, however, is that routine testing may mean that a patient will not receive any real notice or that she will not realize she can refuse or delay the HIV test.⁹⁰ The language in some prenatal HIV testing statutes

⁸⁶ These states are California, Connecticut (which has both voluntary and routine testing provisions), Delaware, Indiana, Iowa, Maryland, New Jersey, Tennessee, Virginia, Washington, and West Virginia.

⁸⁷ CAL. HEALTH & SAFETY CODE § 125107(b)-(d) (West 2002).

⁸⁸ These states are Arkansas, Florida, Illinois, Michigan, Rhode Island, and Texas.

⁸⁹ FLA. STAT. ANN. § 384.31(2) (West 2002).

⁹⁰ Ruth R. Faden et al., *Warrants for Screening Programs: Public Health, Legal, and Ethical*

bears out this concern. For example, Michigan's statute provides:

A physician or an individual otherwise authorized by law to provide medical treatment to a pregnant woman shall take or cause to be taken, at the time of the woman's initial examination, test specimens of the woman . . . [for] HIV or an antibody to HIV. . . . This subsection does not apply if, in the professional opinion of the physician or other person, the tests are medically inadvisable or the woman does not consent to be tested.⁹¹

Although the language clearly indicates that testing, while routine, should be voluntary (based on consent), the law could also permit routine testing without real notice or right to opt out. This statute does not include a clear mechanism for notification, counseling, or refusal.

At least one state, Connecticut, requires routine offer and testing with informed consent during pregnancy, as well as routine testing with an opt-out provision at delivery. Specifically, a physician providing prenatal care is required to inform the patient that HIV testing is "routine" and offer her HIV testing at two different times during pregnancy (usually in the first and third trimesters).⁹² On these occasions, the patient can opt in by giving her informed consent to be tested. At delivery, however, a woman who has no evidence of prior testing in her records, or no records at all, will be tested routinely unless she objects in writing.⁹³

Routine HIV testing is motivated by the desire to provide all pregnant women with counseling and testing. Yet, existing laws may needlessly de-emphasize consent, since their goal could arguably be achieved by mandating counseling and offering voluntary testing (with informed consent) at multiple stages of pregnancy. By subjecting pregnant women to

Frameworks, in WOMEN AND THE NEXT GENERATION: TOWARDS MORALLY ACCEPTABLE PUBLIC POLICY FOR HIV TESTING OF PREGNANT WOMEN AND NEWBORNS 3 (Ruth R. Faden et al. eds., 1991).

⁹¹ MICH. COMP. LAWS ANN. § 333.5123 (West 2002).

⁹² CONN. GEN. STAT. ANN. § 19a-593(a) (West 2002) ("Each health care provider giving prenatal care to pregnant women in this state shall inform her, or ascertain from the woman's medical record that such information has already been provided to her, that HIV testing is a part of routine prenatal care and shall inform her of the health benefits to herself and her newborn of being tested for HIV infection.").

⁹³ CONN. GEN. STAT. ANN. § 19a-593(b) (West 2002) ("If, during the current pregnancy, an HIV-related test has not been documented in the patient's medical record at admission for delivery of the baby, then the health care provider responsible for the patient's care shall inform the pregnant woman as required under subsection (a) of this section and shall also inform her of the health benefits to herself and her newborn of being tested for HIV infection either before delivery or within twenty-four hours after delivery and, in the absence of specific written objection, shall cause such test to be administered.").

different standards for HIV testing, the routine testing laws that are currently in place undermine women's autonomy and decrease incentive for health care professionals to educate pregnant women about HIV. During pregnancy, women are *more* likely to accept HIV testing and modify risky behaviors if they understand the potential benefits both to themselves and their fetuses. Therefore, any provision that makes it *less* likely that physicians will take time to educate pregnant women about the relevant risks and benefits should be avoided.

In short, the most important element of any HIV testing law is whether it affords a substantive right to choose supported by truly informed consent. As illustrated by the routine testing laws, the notion that testing is voluntary may be illusory when women are not told that they can refuse. For example, unless the law requires that a pregnant woman be notified of her right to refuse, either she or her physician may assume that she cannot refuse, or that refusal could result in penalties for the patient or for the physician. Under such circumstances, only careful scrutiny of the actual practices of health care professionals can determine whether patients have a realistic opportunity to make an informed choice about HIV testing.

C. Newborn HIV Testing Statutes

Of the fifty states and the District of Columbia, only four states have specific newborn HIV testing provisions.⁹⁴

Connecticut requires testing of all newborns for whom there is no record of maternal testing during pregnancy or delivery.⁹⁵ The relevant statute states that "[t]he administrative officer or other person in charge of each institution caring for newborn infants shall cause to have administered to every such infant in its care an HIV-related test . . . as soon after birth as is medically appropriate."⁹⁶ The provision is intended as a final backstop for determining the need for intervention. Nonetheless, it provides one exception—an infant will not be tested if the parents object on religious grounds.⁹⁷

Indiana permits but does not require physicians to test newborns

⁹⁴ Because HIV antibody testing of newborns immediately after birth measures exposure to HIV rather than actual infection, newborn testing reveals the mother's true infection status, not the baby's. Thus, most infants who initially test "positive" for HIV antibodies will revert to "negative" over time. Detecting exposure in a newborn is still useful, however, to determine whether treatment with antiretrovirals to reduce the risk of infection is appropriate.

⁹⁵ CONN. GEN. STAT. ANN. § 19a-55(a) (West 2002).

⁹⁶ *Id.*

⁹⁷ CONN. GEN. STAT. ANN. § 19a-55(b) (West 2002).

without parental consent if the mother had not been tested and a physician believes testing is medically necessary.⁹⁸ If such testing occurs, the mother must receive notification and counseling.⁹⁹ As in Connecticut, parents may prevail on religious grounds, but they must submit such objections in writing.¹⁰⁰

Rhode Island generally requires informed consent¹⁰¹ but allows several exceptions. One such exception is when “the person to be tested is under one year of age.”¹⁰²

Finally, New York regulations illustrate the state’s goal of universal prenatal HIV counseling and testing:

[H]ospital maternity staff are to approach all women in labor who do not have an HIV test result from prenatal care and offer them expedited HIV testing with preliminary results available as soon as possible, but no later than 48 hours. . . . For those women without prenatal HIV test results who decline HIV testing during delivery, hospitals are required to conduct expedited HIV testing of all newborns with preliminary results available in the same time frame.¹⁰³

The state Department of Health explicitly warns that “[w]omen should be aware that their newborn will be tested even if they choose not to be [sic] and that it is better to be tested for HIV during pregnancy than to wait until delivery.”¹⁰⁴

IV. CHALLENGES TO STATE HIV TESTING LAWS

State newborn testing provisions, exceptions to general informed consent, and opt-out regimes reflect the federal trend toward routine HIV testing at the cost of women’s autonomy. Accordingly, much commentary has been devoted to the constitutionality, public health justifications, and ethical issues surrounding general,¹⁰⁵ prenatal,¹⁰⁶ and newborn HIV

⁹⁸ IND. CODE § 16-41-6-4(a) (2002).

⁹⁹ IND. CODE § 16-41-6-4(b) (2002).

¹⁰⁰ IND. CODE § 16-41-6-4(c) (2002).

¹⁰¹ R.I. GEN. LAWS § 23-6-12 (2002).

¹⁰² R.I. GEN. LAWS § 23-6-14(1) (2002).

¹⁰³ N.Y. STATE DEP’T OF HEALTH, CHANGES IN THE STATE’S NEWBORN HIV SCREENING PROGRAM (1999), available at <http://www.health.state.ny.us/nysdoh/aids/pindex.htm>.

¹⁰⁴ *Id.*

¹⁰⁵ See, e.g., Sean Anderson, *Individual Privacy Interests and the “Special Needs” Analysis for Involuntary Drug and HIV Tests*, 86 CALIF. L. REV. 119 (1998); Scott Burris, *Law and the Social Risk of Health Care: Lessons from HIV Testing*, 61 ALB. L. REV. 831 (1998); Stacey B. Fishbein, *Pre-Conviction Mandatory HIV Testing: Rape, AIDS, and the Fourth Amendment*, 28 HOFSTRA L. REV. 835 (2000); Kathleen Fultz, *Mandatory AIDS or HIV Testing*, 21 J. JUV. L. 152 (2000);

testing.¹⁰⁷

A. Ethical Issues

While conflicts between the principles of autonomy and beneficence in health care are now usually resolved in favor of patient autonomy, concerns over fetal welfare complicate matters in the perinatal context.¹⁰⁸ With perinatal HIV testing in particular, public health officials and clinicians must weigh the burdens on a woman's autonomy against the potential benefits of early diagnosis and treatment to both the woman and her fetus. Earlier in the HIV / AIDS epidemic, neither mandatory nor routine testing provided much benefit to pregnant women. However, since 1995, advances in antiretroviral treatment and success in reducing perinatal transmission provided a strong public health justification for

Kellie E. Lagitch, *Mandatory HIV Testing: An Orwellian Proposition*, 72 ST. JOHN'S L. REV. 103 (1998); Brenda E. Perez, *Competing Rights and Policies in Mandatory Testing for HIV: People v. Doe*, 24 AM. J. CRIM. L. 617 (1997); Justin P. Runke, *Fourth Amendment Balancing Act: Special Needs of Rape Victims Justify Court-Ordered HIV Testing of the Accused*, 29 SETON HALL L. REV. 1094 (1999).

¹⁰⁶ See, e.g., Elizabeth B. Cooper, *Why Mandatory HIV Testing of Pregnant Women and Newborns Must Fail: A Legal, Historical, and Public Policy Analysis*, 3 CARDOZO WOMEN'S L.J. 13 (1996); Dorian L. Eden, *Is It Constitutional and Will It Be Effective? An Analysis of Mandatory HIV Testing of Pregnant Women*, 11 HEALTH MATRIX 659 (2001); Sheree Gootzeit, *Expedited HIV Testing: An Unnecessary Test That Is Allowing the State To Trample on a Woman's Constitutional Rights*, 7 CARDOZO WOMEN'S L.J. 187 (2001); Theresa M. McGovern, *Mandatory HIV Testing and Treating of Childbearing Women: An Unnatural, Illegal, and Unsound Approach*, 28 COLUM. HUM. RTS. L. REV. 469 (1997); Juliet J. McKenna, *Where Ignorance Is Not Bliss: A Proposal for Mandatory HIV Testing of Pregnant Women*, 7 STAN. L. & POL'Y REV. 133 (1996); Evans McMillion, *The Case Against Mandatory HIV Testing of Pregnant Women: The Legal and Public Policy Implications*, 5 DUKE J. GENDER L. & POL'Y 227 (1998); Jennifer Sinton, *Rights Discourse and Mandatory HIV Testing of Pregnant Women and Newborns*, 6 J. L. & POL'Y 187 (1997).

¹⁰⁷ See, e.g., Kelly D. Bryce, *Mandatory HIV Testing of Newborns: Is There a Better Way To Achieve the State's Goal of Preventing Transmission of HIV to Newborns and Ensuring Them Treatment?*, 4 QUINNIPIAC HEALTH L.J. 69 (2000); Michele M. Contreras, *New York's Mandatory HIV Testing of Newborns: A Positive Step Which Results in Negative Consequences for Women and Their Children*, 20 WOMEN'S RTS. L. REP. 21 (1998); Colin Crawford, *Changing Positions and Entrenched Polemics: A Brief History of the Association to Benefit Children's Views on Pediatric HIV Testing, Counseling, and Care*, 24 FORDHAM URB. L.J. 729 (1997); Colin Crawford, *An Argument for Universal Pediatric HIV Testing, Counseling, and Treatment*, 3 CARDOZO WOMEN'S L.J. 31 (1996); Melinda Madison, *Tragic Life or Tragic Death—Mandatory Testing of Newborns for HIV—Mothers' Rights Versus Children's Health*, 18 J. LEGAL MED. 361 (1997); Catherine H. McCabe, *Ryan White Care Amendments: Mandatory HIV Testing of Newborns and a Woman's Right to Privacy*, 1 DEPAUL J. HEALTH CARE L. 373 (1996); Eileen M. McKenna, *The Mandatory Testing of Newborns for HIV: Too Much, Too Little, Too Late*, 13 N.Y.L. SCH. J. HUM. RTS. 307 (1997).

¹⁰⁸ Frank A. Chervenak & Laurence B. McCullough, *Common Ethical Dilemmas Encountered in the Management of HIV-Infected Women and Newborns*, 39 CLINICAL OBSTETRICS & GYNECOLOGY 411, 412 (1996); Paquita de Zulueta, *The Ethics of Anonymized HIV Testing of Pregnant Women: A Reappraisal*, 26 J. MED. ETHICS 16, 18 (2000).

testing. Accordingly, the debate has shifted significantly in favor of increased testing.¹⁰⁹

B. Legal Challenges to General Testing Laws

Despite the prevalence of general HIV testing statutes,¹¹⁰ these provisions have sparked scant litigation. The most recent case, *Sierakowski v. Ryan*,¹¹¹ arose over the Illinois AIDS Confidentiality Act,¹¹² which affords physicians discretion to test without patient consent. In *Sierakowski*, although the plaintiff refused an HIV test during a routine hospital visit, he was tested nonetheless and notified of the results at his next appointment. Sierakowski alleged that the Illinois statute violated his rights under the Fourth and Fourteenth Amendments. The District Court for the Northern District of Illinois dismissed the suit,¹¹³ and the Seventh Circuit affirmed.¹¹⁴ According to the circuit court, Sierakowski did not have Article III standing because his test results were negative.¹¹⁵ The court found that not only were his alleged injuries abstract and conjectural, but also “[t]here [was] nothing in the proposed amended complaint or the record below to suggest that future injury [was] likely and that Sierakowski face[d]

¹⁰⁹ Some commentators have argued that various anonymous HIV testing programs, including the Survey of Child-Bearing Women (SCBW), unethically withhold information from pregnant women, similar to the withholding of information from subjects in the infamous Tuskegee study of syphilis. See Ronald Bayer, *Rethinking the Testing of Babies and Pregnant Women for HIV Infection*, 7 J. CLINICAL ETHICS 77 (1996); William Raspberry, *Shades of Tuskegee*, WASH. POST, Sept. 22, 1997, at A19. This claim turns the principle of autonomy on its head by arguing that it is the withholding of information obtained from non-consensual testing that offends or violates a pregnant woman's autonomy. Cf. Amy L. Fairchild & Ronald Bayer, *Uses and Abuses of Tuskegee*, 284 SCIENCE 919 (1999) (highlighting the withholding of treatment, not information); Gershon B. Grunfeld, *Dissimilarities Between Tuskegee Study and HIV / AIDS Programs Emphasized*, 82 AM. J. PUB. HEALTH 1176 (1992) (same). The SCBW was a “screening project in which all newborns were screened for HIV . . . to try to get some idea of what HIV infection prevalence was among their mothers and from there to generalize on HIV infection in the United States.” Linda Valleroy, Address at the 70th Meeting of the Blood Products Advisory Committee, Department of Health and Human Services, Food and Drug Administration (Dec. 14, 2001) (transcript available at <http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3817t2.htm>). The survey found a 0.2- to 0.3-percent prevalence of HIV in the general population of the United States. *Id.* Those asserting that withholding information from pregnant women is unethical successfully lobbied to end Public Health Service support for the SCBW.

¹¹⁰ Currently, there are thirty-seven states with general HIV testing statutes on the books. See *supra* Part III.

¹¹¹ 223 F.3d 440 (7th Cir. 2000).

¹¹² 410 ILL. COMP. STAT. 305 / 8 (2002).

¹¹³ *Sierakowski v. Ryan*, No. 98-C7088, 1999 U.S. Dist. LEXIS 6573 (N.D. Ill. Apr. 26, 1999).

¹¹⁴ 223 F.3d at 441.

¹¹⁵ *Id.* at 443.

an immediate threat of harm.”¹¹⁶ By deciding the case on the narrowest possible grounds (applying the findings only to Sierakowski), the court overlooked the possibility that other patients could be harmed and provided no guidance to other health care providers and patients on when non-consensual testing is permitted.¹¹⁷

Sierakowski remains the only case that directly challenged the legitimacy of a general HIV testing statute. Other cases arose over statutory application. In *Doe v. High Tech Institute, Inc.*,¹¹⁸ for example, although the Colorado statute allows testing without consent under certain circumstances, the plaintiff's situation did not fall within statutory exceptions. The plaintiff was told that his blood sample was obtained only for rubella testing. There was no other demonstrable reason for taking the plaintiff's blood, and there was no legitimate reason for testing the sample for HIV. The court held that “a person has a privacy interest in his or her blood sample and in the medical information that may be obtained from it,” and that “an additional, unauthorized test . . . can be sufficient to state a claim for relief for intrusion upon seclusion.”¹¹⁹ In other words, it is illegal to obtain a blood sample for non-HIV testing purposes and then subject the sample to HIV testing without medical justification.

In suits challenging the propriety of an HIV test conducted without consent, state courts often stress the defendant's intent. For example, in *Doe v. Ohio State University Hospital & Clinics*, the court ruled that a plaintiff must demonstrate that the defendant “knew” he or she did not have the patient's consent.¹²⁰ Mere knowledge that consent is legally required does not establish that, on the occasion when the defendant performed the test in dispute, the defendant knew he or she was violating the statute.¹²¹

¹¹⁶ *Id.*

¹¹⁷ Future plaintiffs challenging the Illinois provision might consider an alternative argument. Rather than seeking injunctive relief, which would prohibit future incidents, they might seek damages for the non-consensual testing to which they have already been subjected by claiming that the testing violated their rights under the Fourth and Fourteenth Amendments. An action for damages rather than injunctive relief would avoid the problem of standing presented in *Sierakowski* because a plaintiff in a case for damages would only have to show that an injury had occurred, not that the injury was likely to occur again. The threat of a viable legal action would help prevent physicians from overstepping their bounds, thus reducing invasions of privacy like that in *Sierakowski*.

¹¹⁸ 972 P.2d 1060 (Colo. Ct. App. 1998).

¹¹⁹ *Id.* at 1068. “Intrusion upon seclusion” is a variant of invasion of privacy.

¹²⁰ 663 N.E.2d 1369, 1373 (Ohio Ct. App. 1995).

¹²¹ *Id.*

C. Legal Challenges to Perinatal Testing Laws

As of 2002, thirty-seven states require prenatal syphilis testing.¹²² Other states mandate testing for disorders such as hepatitis B, phenylketonuria (PKU), and sickle cell disorder.¹²³ Research in both state and federal databases yields a paucity of cases challenging statutes requiring prenatal or newborn testing for diseases such as PKU and syphilis,¹²⁴ and commentators have noted the absence of legal challenges to other prenatal testing programs.¹²⁵ Based on the lack of litigation over perinatal screening in general, it is not surprising that perinatal HIV testing statutes have not been widely challenged.

Moreover, where perinatal testing laws have spawned legal protest, plaintiffs generally have not prevailed. In one such case, the Connecticut Hospital Association filed a complaint against Connecticut Governor John Rowland, seeking pre-enforcement injunctive relief from the state's newborn HIV testing statute.¹²⁶ The Association claimed that the provision, which requires the screening of newborns whose mothers refused testing or for whom test results were not available, violates the Fourth and Fourteenth Amendment rights of pregnant women and newborns. The district court denied immediate injunctive relief, and hospitals soon became accustomed to the changes. Hence, the Connecticut Hospital

¹²² Three other states (Louisiana, Maine, and Missouri) require the patient's consent for testing. New Hampshire repealed its statutory mandate in 1986. Minnesota requires that midwives recommend testing. The remaining eight states (Florida, Iowa, Michigan, Mississippi, North Carolina, Oregon, Virginia, and Wisconsin) have no testing requirement.

¹²³ Eden, *supra* note 106, at 669.

¹²⁴ Research was conducted using Westlaw. Searches were performed both in the federal cases database and in the all-states database. A separate search was conducted in both databases for sickle cell testing. This yielded only eighteen cases, none of which involved legal challenges specifically aimed at sickle cell testing. Rather, the cases dealt with medical malpractice in diagnosis or treatment.

¹²⁵ See, e.g., R. Curtis McNeil, *Prenatal HIV Testing Under Ohio Revised Code Section 3701.242: The Doctors' [sic] Dilemma and the State's Shame*, 22 DAYTON L. REV. 301, 309 (1997) ("No recorded cases have challenged the ability of the State of Ohio to require gonorrhea testing. . . . Although prenatal syphilis testing has been the law throughout the United States for over 50 years, research has not uncovered a single reported case, in any state or federal jurisdiction, where the authority of the state to require these tests has even been questioned."). The only successful challenges to non-HIV, mandatory prenatal testing programs appear to have come against testing for sickle cell disease. These challenges were accompanied by growing public awareness that sickle cell screening clearly discriminated against African-Americans. The public outcry, more than individual litigation, led to a change in federal law that required voluntary testing aimed at preventing, diagnosing, and treating the disease while maintaining confidentiality. Kristin M. Raffone, *The Human Genome Project: Genetic Screening and the Fundamental Right of Privacy*, 26 HOFSTRA L. REV. 503, 521 (1997).

¹²⁶ Conn. Hosp. Ass'n v. Rowland, No. 3:99CV1923 (D. Conn. Oct. 16, 2000).

Association ultimately did not pursue its challenge, and the case ended with a stipulation of dismissal on July 19, 2001.

Some commentators perceive the lack of legal challenges to prenatal and newborn testing in general as evidence of tacit moral acceptance of these practices. According to one observer, "[w]hen a woman seeks prenatal treatment, she is consenting to be tested for what is mandated by the state in which she is seeking treatment. She submits to testing and treatment."¹²⁷ This characterization of prenatal testing casts the decision to seek prenatal care as a privilege. From this perspective, the prospect of testing is no more objectionable than the drug test that a prospective employee implicitly consents to when she applies for a job. Yet, this characterization overlooks the coercive nature of attaching conditions to a decision to seek prenatal care. A pregnant woman is virtually bound to seek medical care at some stage of pregnancy unless she is willing to risk her own life and that of her fetus by giving birth without the assistance of medically trained personnel. Thus, pregnant women are faced with a starkly limited range of alternatives: they can avail themselves of medical assistance, which may involve unwanted testing, or receive no care at all. For public health and policy reasons, it seems unsound to so constrain women's choices. This unfortunate outcome can be avoided by giving women a real choice as to prenatal testing.

D. Beyond Testing Statutes

Even if all, or nearly all, pregnant women accept HIV testing, reduction of perinatal HIV transmission requires additional steps. At present, the best medical advice for an HIV-infected woman is that she receive antiretroviral treatment according to current guidelines (usually combination therapy), adhere to the medication schedule through delivery, give her baby antiretrovirals as prescribed, and not breastfeed.¹²⁸ Based on existing data, it may also be advisable for some women to deliver via caesarean section.¹²⁹ Such measures come into play *after testing* and are, currently, fully voluntary. Nevertheless, as evidence mounts on the efficacy of these interventions in reducing mother-to-child transmission, pressure to comply with these treatments and procedures will increase. Therefore, it is relevant to consider whether, and under what circumstances, a woman's

¹²⁷ Eden, *supra* note 106, at 670.

¹²⁸ See generally CDC Recommendations, *supra* note 13.

¹²⁹ The American College of Obstetrics and Gynecology, *supra* note 41, recommends that "HIV-positive pregnant women with high viral loads . . . be counseled by physicians about both the benefits and risks of elective caesarean delivery to help reduce the rate of perinatal transmission."

physician can force her to undergo medical interventions for the benefit of her fetus rather than herself. While there does not appear to be any cases in which health officials or prosecutors sought to force a pregnant woman with HIV to accept treatment, the issue of forced intervention in a pregnancy has arisen in other contexts that bear reviewing.

1. Court-Ordered Caesarian Deliveries

During the past several decades, courts have issued a series of opinions concerning physicians who sought court orders to perform caesarean sections on women who, for religious or other reasons, refused the surgery. The seminal case is that of *Angela C.* in 1990.¹³⁰ Angela C. was diagnosed with a recurrence of cancer late in her pregnancy and faced death before her due date. Before falling into a coma, she refused the request of one of her doctors to perform a caesarean section to try and save her premature fetus. The District of Columbia Court of Appeals concluded that the lower court had erred in granting the order for surgery over the mother's objections, upholding the right of a mother to refuse interventions that pose a risk to her merely for the benefit of her fetus.¹³¹

The case of Angela C. provides strong support for a pregnant woman's right to make choices about medical treatment during pregnancy, even when those decisions are contrary to medical advice and may have serious consequences for herself or her fetus.¹³² According to *Angela C.*, a pregnant woman with HIV should retain the right to accept or refuse antiretroviral therapy or a caesarean section regardless of the potential benefit to the fetus because both pose some risk to her.

¹³⁰ *In re A.C.*, 573 A.2d 1235 (D.C. 1990).

¹³¹ *Id.* at 1243. Neither Angela nor her baby survived despite the surgery.

¹³² State courts have followed the holding in *Angela C.* even when the fetus is much closer to full term (and thus clearly "viable"). For example, in *In re Baby Boy Doe*, 632 N.E.2d 326 (Ill. App. Ct. 1994), the court found that a mother may refuse a caesarean section immediately before delivery even though physicians predicted serious harm to the infant without intervention. However, the case of Angela C. did not fully resolve the issue of maternal surgery, as local and state courts have both granted and denied orders requested by physicians. See Robin M. Trindel, *Fetal Interests v. Maternal Rights: Is the State Going Too Far?*, 24 AKRON L. REV. 743 (1991). Compare *Pemberton v. Tallahassee Mem. Reg'l Med. Ctr.*, 66 F. Supp. 2d 1247 (N.D. Fla. 1999) (holding that forced caesarean section performed in the interests of an unborn baby does not violate the mother's constitutional rights), and *Jefferson v. Griffin Spalding County Hosp. Auth.*, 274 S.E.2d 457 (Ga. 1981) (upholding a forced caesarean order), with *In re Baby Boy Doe*, 632 N.E.2d 326, 333 (Ill. App. Ct. 1994) (finding that a forced caesarean section, undertaken for the benefit for the fetus, cannot pass constitutional muster).

2. Court-Ordered Medical Care

Other recent cases, however, suggest possible limitations on women's autonomy during pregnancy. In 2000, a Massachusetts prosecutor obtained an order to confine a pregnant woman until delivery where the woman and her husband refused to seek any prenatal care or medical assistance for birth, and where an earlier child was believed to have died from lack of medical care.¹³³ After birth, the healthy child was placed in state custody. The parents were detained on contempt charges for refusing to provide information on the fate of a third child, who the couple maintained died as a result of a miscarriage.¹³⁴

Although this case has not been appealed or published, and thus provides little legal precedent, it illustrates a prosecutor's discretion to characterize a pregnant woman's choices as dangerous to her fetus. An aggressive prosecutor in this or another jurisdiction could attempt to intercede in the pregnancy of an HIV-positive woman to force either treatment with antiretrovirals or other interventions at delivery.

3. Drug Use During Pregnancy

A separate series of cases involves criminal charges against women for actions during pregnancy that could harm their fetuses. In many cases, prosecutors jailed women and removed their children from custody for "delivery" of drugs to the fetus during pregnancy or birth.¹³⁵ Appellate courts have largely upheld these decisions. In addition, some states automatically seek custody of children suffering from withdrawal symptoms due to maternal drug use during pregnancy.¹³⁶

In 2001, the U.S. Supreme Court decided *Ferguson v. City of Charleston*,¹³⁷ which involved a South Carolina hospital's practice of testing

¹³³ See Paul E. Parker, *Thrust into the Spotlight—Judge Takes the High Road*, PROVIDENCE J.-BULL., Feb. 4, 2002, at B01; David Wedge, *Judge Confines Cult Mom to Secure Hospital, Judge's Ruling Locks Up Defiant Pregnant Cult Mom*, BOSTON HERALD, Sept. 1, 2000, at 001; Editorial, *Woman Imprisoned over Prenatal Care*, L.A. TIMES, Sept. 12, 2000, at B8.

¹³⁴ Paul E. Parker, *Judge Jails Sect Couple for Defying Court's Order*, PROVIDENCE J.-BULL., Feb. 6, 2002, at A01; Denise Lavoie, *Mass. Seeks Alleged Sect Baby*, AP ONLINE, Jan. 30, 2002, available at 2002 WL 11685641 AP.

¹³⁵ CTR. FOR REPROD. L. & POL'Y, PUNISHING WOMEN FOR THEIR BEHAVIOR DURING PREGNANCY: AN APPROACH THAT UNDERMINES WOMEN'S HEALTH AND CHILDREN'S INTERESTS, at http://www.crlp.org/pub_art_punwom.html (Sept. 11, 2000).

¹³⁶ Practice Commentaries, N.Y. Fam. Ct. § 1012 (2002). Thus, for almost two decades, it has been well-settled law in some states that "[a] newborn baby having withdrawal symptoms is prima facie a neglected baby." In re Vanessa F., 351 N.Y.S.2d 337, 340 (Surr. Ct. N.Y. 1974); cf. In re "Male" R., 422 N.Y.S.2d 819 (N.Y. Fam. Ct. 1979).

¹³⁷ 532 U.S. 67 (2001).

pregnant women for drugs and providing the results directly to law enforcement officials for prosecution purposes. The Court held that such a practice violated a woman's constitutional rights under the Fourth Amendment. The Court ruled that if health officials intend to collect information for criminal prosecution, they must ensure that women are aware of their constitutional rights.¹³⁸ Thus, *Ferguson* suggests that some prenatal testing regimes may violate the Fourth Amendment prohibition against unreasonable search and seizure. However, the case also acknowledges public health claims related to prenatal testing. Therefore, if a prenatal HIV testing statute does not set criminal penalties and includes provision of notice to women that testing would be performed, a court following *Ferguson* might uphold the law regardless of consent.

4. Child Protection Provisions

HIV-related cases that have invoked state child welfare or protection powers have mainly been concerned with medical care of a child after birth. For example, in an Oregon child custody case, an HIV-infected woman refused ZDV treatment for her newborn and wanted to breastfeed against medical advice.¹³⁹ A family court intervened and granted legal custody of the child to the state. The mother and father retained physical custody on the following conditions: they were not to breastfeed the child, and they had to submit to monitoring by social services to ensure compliance with the order.

Another case involved a woman in Maine who did not want to give her HIV-infected toddler antiretrovirals.¹⁴⁰ The woman had already suffered through the illness and death of another child from AIDS and "expressed her distrust of the drug therapy and declined to permit her son to participate (in experimental treatment studies) at that time."¹⁴¹ Health officials sought an order that would require the woman to give ZDV to her child or else grant the state custody of her child.¹⁴² The court denied the request, reasoning that a woman who had already cared for and lost one

¹³⁸ *Id.* at 85.

¹³⁹ PAUL PHILPOT, THE GROUP FOR THE REAPPRAISAL OF AIDS, TYSON FAMILY LOSES IN OREGON COURT; EUGENE JUDGE DENIES HIV-POSITIVE MOM RIGHT TO BREAST FEED, ASSIGNS CUSTODY OF INFANT TO STATE (1999), *available at* <http://www.rethinkingaids.com/Archive/1999/RA9906TysonsLose.html>.

¹⁴⁰ *In re Nikolas E.*, 720 A.2d 562 (Me. 1998) (holding that a mother's decision to delay experimental drug therapy did not constitute serious parental neglect that would warrant a child protection order). *But see* *A.D.H. v. Dep't of Human Res.*, 640 So.2d 969, 970 (Ala. Civ. App. 1994).

¹⁴¹ *Id.* at 563.

¹⁴² *Id.*

child to AIDS could weigh the potential side effects and benefits of treatment and determine what was best for her child.

Both the Oregon and Maine courts struggled to determine what would be best for the child in question. The key difference may have been that the Oregon child was uninfected, and all the testimony in the case suggested that avoiding breastfeeding could prevent infection. The child in Maine, on the other hand, was infected and already quite ill. Thus, it seems the Oregon court ruled against parental autonomy because intervention could protect a healthy child from a deadly infection, while the Maine court preserved parental decision-making where child medications are difficult to take, have significant side effects, and will not effect a cure.

Indeed, the Oregon and Maine cases address the medical care of a child after birth, not choices that women make during pregnancy. Parental decisions regarding children's care are governed by a set of rules and case law that differs significantly from those governing the decisions of pregnant women. For instance, child protection authorities have much greater latitude to act in "the best interests of the child" after birth.¹⁴³ Nonetheless, child welfare cases may be relevant to the issue of perinatal testing and treatment because they illustrate the powerful pressures that can come into play when public health authorities believe a parent is endangering a child (or future child).

5. *Criminal Exposure and Transmission Laws*

Some commentators worry that women who refuse testing, treatment, or interventions at delivery could be prosecuted under state laws that specifically criminalize knowing exposure to, or transmission of, HIV, or even under criminal laws such as assault, attempted murder, or reckless endangerment.¹⁴⁴ In fact, of the twenty-four states that have HIV-specific laws criminalizing exposure or transmission,¹⁴⁵ only Oklahoma's law

¹⁴³ E.g., CONN. GEN. STAT. § 17a-103b(a) (2002).

¹⁴⁴ Nan D. Hunter, *Complications of Gender: Women and HIV Disease*, in AIDS AGENDA: EMERGING ISSUES IN CIVIL RIGHTS, 5, 27-30 (Nan D. Hunter & William B. Rubenstein eds., 1992); Andre A. Panossian et al., *Criminalization of Perinatal HIV Transmission*, 19 J. LEGAL MED. 223 (1998); Christina M. Shriver, *State Approaches to Criminalizing the Exposure of HIV: Problems in Statutory Construction, Constitutionality, and Implications*, 21 N. ILL. U. L. REV. 319 (2001); Heather Sprintz, *The Criminalization of Perinatal AIDS Transmission*, 3 HEALTH MATRIX 495 (1993); RICHARD ELLIOT, CAN. HIV / AIDS LEGAL NETWORK & CAN. AIDS SOC'Y, CRIMINAL LAW & HIV / AIDS: FINAL REPORT (1997), available at <http://www.aidslaw.ca/Maincontent/issues/criminallaw/finalreports/CRFR-COVER.html>.

¹⁴⁵ Zita Lazzarini et al., *Evaluating the Impact of Criminal Laws on HIV Risk Behavior*, 30 J. L. MED. ETHICS 239 (2002).

currently exempts *in utero* exposure.¹⁴⁶ However, a query of all fifty state health departments on the possible use of criminal provisions against pregnant women revealed that no department had knowledge of any attempts or intentions on the part of health officials to use criminal law in this manner.¹⁴⁷ Officials in only one state, Washington, had specifically examined their criminal HIV transmission law for applicability to pregnancy and concluded that the statute would only apply if a woman *intended* to infect her infant.¹⁴⁸

Given the apparent lack of interest in prosecuting perinatal HIV transmission, it seems unlikely that a woman who complies with public health recommendations for HIV testing and treatment during pregnancy would be charged with knowing exposure or transmission, even if her child became infected. A more likely scenario for possible criminal charges would involve women who refuse treatment, do not comply with treatment regimens, insist on breastfeeding, or avoid prenatal care altogether. Such choices would clearly run against the weight of public health and clinical recommendations.

In sum, based on the lessons of *Angela C.* and related cases, a pregnant woman with HIV who refuses her physician's advice to have a caesarean delivery or take antiretrovirals would not likely be compelled to undergo surgery or accept treatment. Nonetheless, prosecutors might pursue criminal charges in spite of health department policies to the contrary. It remains unclear, moreover, whether health officials or physicians might use the threat of criminal prosecution or child custody actions to coerce women into accepting antiretroviral treatment or other medical interventions during pregnancy or birth.

V. RECOMMENDATIONS FOR REDUCING PERINATAL HIV TRANSMISSION

In its report, *Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States*, the IOM recommended universal testing with patient notification as a routine component of prenatal care.¹⁴⁹ The IOM stated that implementing such a policy would require numerous other steps,

¹⁴⁶ OKLA. STAT. tit. 21 § 1192.1 (2002) ("It shall be unlawful for any person knowing that he or she has Acquired Immune Deficiency Syndrome (AIDS) or is a carrier of the human immunodeficiency virus (HIV) and with intent to infect another, to engage in conduct reasonably likely to result in the transfer of the person's own blood, bodily fluids containing visible blood, semen, or vaginal secretions into the bloodstream of another, or through the skin or other membranes of another person *except during in utero transmission of blood or bodily fluids.*") (emphasis added).

¹⁴⁷ Lazzarini et al., *supra* note 84.

¹⁴⁸ *Id.* at 4410.

¹⁴⁹ INST. OF MED., *supra* note 30, at 6.

including (1) educating prenatal care providers; (2) improving provider practices and bringing the clinical practice guidelines of professional organizations in line with enumerated best practices; (3) contractually imposing success in universal testing as a performance measure; (4) improving coordination of care and access to high-quality HIV treatment so that all women who are tested can take advantage of the most successful intervention strategies currently available; and (5) addressing underlying reasons that drive some HIV-infected women to refuse testing or treatment.

The IOM also noted that substantial federal and state funds are needed for a coordinated effort to meet these specific objectives and to achieve the overarching goal of reducing perinatal HIV transmission. Specifically, the IOM noted that certain groups of women are most likely to “fall through the cracks” of the current counseling, testing, and treatment systems and urged the government to take extra steps to reach these women. Such women include those in correctional settings, women without access to prenatal care, and women who do not intend to become pregnant. In addition, the IOM urged efforts that would reduce primary infection in women since such efforts can contribute markedly to reducing perinatal HIV transmission.

Overall, the IOM recommendations address a broad range of issues and would improve prenatal care for all women as well as reduce HIV infection. Unfortunately, much of the attention at the state level has focused on laws related to testing and on the manner of testing (*e.g.*, voluntary, mandatory, or routine). Some legislators appear to have followed the IOM’s assumption that the consent process must be changed or eliminated to increase levels of testing among pregnant women. Yet there is little empirical evidence to support that this is the only way, or the best way, to increase testing rates and reduce HIV transmission.

A comprehensive perinatal HIV transmission policy ought to include mechanisms directed at changing the behavior of health care professionals, such as (1) training health care workers to provide effective HIV education and counseling to pregnant patients, (2) incorporating education, counseling, and testing of pregnant women as performance measures;¹⁵⁰ and 3) reimbursing physicians, nurses, and midwives who spend time educating and counseling pregnant women. A comprehensive program should also address the needs of pregnant women more directly. Public education campaigns in many states have already raised awareness of the benefits of HIV testing during pregnancy without reducing women’s

¹⁵⁰ See Zita Lazzarini & Deborah Elman, *Legal Options for Achieving Public Health Outcomes*, 8 J. PUB. HEALTH MGMT. & PRAC. 65 (2002).

control over their bodies. In addition, as the IOM noted, it is critical to reach women least likely to receive prenatal care, encouraging them to seek care as early in pregnancy as possible and to make health-promoting changes while pregnant.

Finally, where states have moved to routine testing, officials need to examine how routine testing is actually implemented to ensure that “routine” does not amount to “compulsory.” While, in theory, routine testing with the option to opt-out confers a greater degree of autonomy than mandatory testing, in practice, this may not be the case. Adoption of the rhetoric of “routine” testing may subject women to testing with little or no meaningful information about the test or their right to refuse and still receive medical care. Under such circumstances, not only do women lose the opportunity to make an autonomous choice about medical care, but also—and more importantly—health care providers lose the opportunity to educate them, either because women opt not to receive any care at all, or because the testing process involves no real dialogue about HIV testing and treatment.

Indeed, given the problems that may arise from routine testing with an opportunity to opt out, an opt-in method may be more effective and prudent. In other words, a pregnant woman should have to give her express permission for an HIV test to be performed. Once provided with the necessary counseling, the majority of pregnant women might choose to opt in, thus furthering the goal of testing all pregnant women.¹⁵¹ At the same time, the express-permission requirement would assure that some discussion of the test takes place and promote use of the opportunity to educate.

VI. CONCLUSION

Although most states (1) emphasize the importance of informed consent for HIV testing, both prenatally and generally, and (2) recognize the privacy and constitutional interests accompanying a person’s medical information, many jurisdictions allow HIV testing without full informed consent in certain circumstances. With general testing provisions, common exceptions to informed consent include protecting health care providers and the public, as well as enhancing the ability of health care providers to diagnose and treat patients effectively. The majority of the seventeen states that have statutes specifically addressing prenatal testing also require informed consent for testing. However, since the IOM issued its report in

¹⁵¹ See CDC Revised Guidelines, *supra* note 37, at 68.

1999,¹⁵² some have modified their laws to require “routine” testing at some point in pregnancy, and two states have instituted mandatory newborn testing programs. Similarly, professional organizations have developed a substantial consensus on the value of routine (universal), voluntary HIV testing during pregnancy, though they differ subtly on the meaning of routine testing, the role of informed consent, and the extent of health care providers’ duties to educate pregnant women on the risks of HIV as part of the testing process. The push to achieve routine testing risks eliminating any real opportunity both to educate women and to provide women with a real choice to accept or refuse testing. Focus on legal reform may also obscure another important issue—whether HIV-infected women can be persuaded to accept treatment, and if so, whether they can be persuaded to adhere to prenatal and postnatal medication regimens.

Yet, the efficacy of prenatal treatments in preventing HIV transmission provides a strong public health justification for ensuring that all women know their HIV status and have the opportunity to receive antiretroviral therapy, for themselves and for their children. Widespread adoption of prenatal counseling and testing and acceptance of treatment by HIV-infected women have already significantly reduced the annual incidence of HIV transmission to newborns. With one hundred or fewer cases per year since 2000, the U.S. has achieved remarkable success. Nevertheless, some preventable transmission continues to occur. Thus, the challenge of how best to reduce or eliminate new cases without sacrificing important values and compromising women’s role in their own health care remains. An effective way to balance a woman’s autonomy with the welfare of her fetus would be to adopt comprehensive HIV prevention measures that focus on changing the behavior of health care providers, educating pregnant women, making testing “routine” in the sense that the test is available to all women at every stage of pregnancy, ensuring that all pregnant women know they should be tested, and providing adequate prenatal care for all women before changing or eliminating the requirement of informed consent. Such a strategy would provide women a real choice to delay or refuse testing and treatment while still educating them about HIV.

¹⁵² See INST. OF MED., *supra* note 30.

Question:

Should Congress grant the Food and Drug Administration greater authority to regulate tobacco products?

In 2002, Senators Edward Kennedy and Mike DeWine introduced legislation that would intensify federal regulation of tobacco manufacturing and advertising. The following Commentaries discuss the feasibility and appropriateness of such government oversight from various perspectives.

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The Need for FDA Regulation of Tobacco Products

Senator Edward M. Kennedy*

Smoking is the number one preventable cause of death in America. Empowering the Food and Drug Administration (FDA) to regulate tobacco products is the most important action we can take to substantially reduce the number of men and women who suffer and die from smoking-induced disease each year.

We cannot, in good conscience, continue to allow the federal agency most responsible for protecting the public health to remain powerless to deal with the enormous risks of tobacco—the most lethal of all consumer products. That is why Senator Mike DeWine and I introduced legislation expanding the FDA's jurisdiction to cover tobacco products and why twenty other senators have already co-sponsored it.¹ That is also why we are confident that the Senate will pass legislation granting the FDA the necessary authority to take on this enormously important task.

The provisions of this bill track the bipartisan compromise on the terms of FDA jurisdiction that was reached during Senate consideration of comprehensive tobacco control legislation in 1998. Fifty-eight senators supported the comprehensive bill at that time. That legislation was never enacted because of disputes over tobacco taxation and litigation, not over FDA authority.

The legislation is a fair and balanced approach to FDA regulation. It creates a new section in FDA jurisdiction for the regulation of tobacco products, with standards that allow for consideration of the unique issues raised by tobacco use. It is sensitive to the concerns of tobacco farmers, small businesses, and nicotine-dependent smokers. Nevertheless, it clearly gives the FDA the power it needs in order to prevent youth smoking and to reduce addiction to this highly lethal product. The FDA would be given broad authority to consider all the relevant factors related to tobacco use, and to take such action as it determines “is appropriate for the protection

* Senator Edward M. Kennedy is the Ranking Member of the Senate Committee on Health, Education, Labor, and Pensions, which has jurisdiction over the Department of Health and Human Services and tobacco issues.

¹ S. 2626, 107th Cong. (2002).

of the public health.”² The agency is expressly directed to analyze the impact of a proposed rule “with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product.”³

I believe that any attempt to weaken the 1998 language would undermine the FDA’s ability to deal effectively with the enormous health risks posed by smoking. This concern is shared by a number of independent public health experts. The bipartisan compromise agreed to in 1998 is still the best opportunity for senators to come together and grant the FDA the regulatory authority it needs to substantially reduce the number of children who start smoking and to help addicted smokers quit. Nothing less will do the job.

Within the past year, some tobacco companies have even acknowledged the need for FDA regulation of their products. However, the proposals presented by the industry and its allies in Congress would only create a toothless regulatory tiger. While giving the agency nominal jurisdiction, their legislation would erect serious legal barriers to the FDA’s ability to effectively regulate tobacco products in the public interest. Such a statute would create a false sense of security amongst smokers and potential smokers that tobacco products were being made safer to use, while, in fact, the FDA would be handcuffed in its ability to meaningfully protect the public. As the legislative debate moves from whether tobacco products should be regulated by the FDA to what kind of authority the FDA should have, those who are genuinely concerned with public health must be vigilant against such industry-inspired ploys.

The stakes are vast. Every day, another five thousand children try their first cigarette, and two thousand of them become daily smokers. Nearly a thousand of them will die prematurely from tobacco-induced diseases. Cigarettes kill well over four hundred thousand Americans each year. That is more lives lost than from automobile accidents, alcohol abuse, illegal drugs, AIDS, murder, suicide, and fires combined. Our response to a public health problem of this magnitude must consist of more than halfway measures.

We must deal firmly with tobacco company marketing practices that target children and mislead the public. The FDA needs broad authority to regulate the sale, distribution, and advertising of cigarettes and smokeless tobacco. The tobacco industry currently spends over nine billion dollars a year to promote its products. Much of that money is spent in ways designed

² *Id.* § 906(d).

³ *Id.*

to tempt children to start smoking, before they are mature enough to appreciate the enormity of the health risks. The industry knows that more than ninety percent of smokers start smoking as children and are addicted by the time they reach adulthood.⁴

Documents obtained from tobacco companies prove, in the companies' own words, the magnitude of the industry's efforts to trap children into dependency on their deadly products. Recent studies by the Institute of Medicine and the Centers for Disease Control and Prevention show the substantial role of industry advertising in decisions by young people to use tobacco products. If we are serious about reducing youth smoking, the FDA must have the power to prevent industry advertising designed to appeal to children wherever it will be seen by children. The proposed legislation will give the FDA the ability to stop tobacco advertising that glamorizes smoking from appearing where it will be seen by significant numbers of children.

Contrary to industry claims, the major tobacco companies have not abandoned their aggressive marketing strategy aimed at children. The Master Settlement Agreement (MSA) entered into between the major tobacco companies and forty-six states in 1998 contained an industry promise not to "take any action, directly or indirectly, to target youth."⁵ Within months of making that commitment, the industry massively increased the amount it spent on marketing. In 1999, expenditures on tobacco advertising and promotion rose by 22.3% to \$8.24 billion. In 2000, they rose by an additional 16.2% as cigarette manufacturers spent a record \$9.57 billion on marketing.⁶ According to the Federal Trade Commission, this was the highest level of spending which had ever been reported by the industry.

Much of the spending increase has been on marketing that is known to appeal to youths. A March 2002 survey found that while only twenty-seven percent of adults had seen tobacco advertisements in the preceding two weeks, sixty-four percent of teenagers recalled seeing tobacco ads during that period.⁷ The industry is still promoting cigarettes in the ways most likely to reach children.

One study documented a twenty-five percent increase in tobacco advertising in magazines with more than fifteen percent youth readership

⁴ U.S. DEP'T HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL (1994).

⁵ Master Settlement Agreement 15 (1998), *available at* <http://www.naag.org/issues/tobacco/index.php?smode=919>.

⁶ FED. TRADE COMM'N, CIGARETTE REPORT FOR 2000 (2002).

⁷ INT'L COMMUNICATIONS RESEARCH, TEEN EXCEL STUDY FROM MARCH 6-10 2002 (2002).

in the first year after the MSA was signed.⁸ The industry spent \$120 million dollars in the nine-month period covered by the study, most of it promoting the five brands favored by underage smokers. The following year, an analysis of advertising penetration found that magazine ads for fifteen youth-oriented brands of cigarettes reached eighty percent of children between twelve and seventeen years of age at least seventeen times during 2000.⁹ The increased level of tobacco advertising in youth-oriented magazines following the MSA received a great deal of public attention. The adverse publicity and the threat of new litigation from state Attorneys General led several of the major tobacco companies to reduce the level of magazine advertising. Last year, a California judge fined R.J. Reynolds \$20 million for its advertising in youth-oriented magazines, which the court found to be a violation of the MSA's prohibition on targeting youth.¹⁰

The greatest increases in spending have occurred in the areas of in-store marketing and promotion, known to be particularly effective in reaching children. Discount promotions such as "buy one, get one free" make cigarettes more affordable to kids, who are particularly price sensitive. Payments to retailers for prime shelf space at children's eye level make cigarettes more visible to kids in convenience stores. Free promotional gifts such as hats, jackets, and mini-radios have a strong appeal for teens. The evidence clearly demonstrates that the tobacco industry has not given up on its efforts to seduce a new generation of children into smoking. When one form of marketing to youth becomes too transparent and controversial, the industry merely moves its dollars to another, subtler, way of reaching kids. Only a comprehensive set of enforceable marketing standards developed by the FDA can prevent continued industry efforts to make nicotine addicts of our children.

The proposed legislation will give the FDA full authority to regulate tobacco advertising "consistent with and to the full extent permitted by the First Amendment."¹¹ The Supreme Court has repeatedly stated that for commercial speech to come under the cloak of First Amendment protection, it must promote lawful activity and not be misleading. There is a voluminous record of evidence documenting the fact that tobacco

⁸ Diane Turner-Bowker & William L. Hamilton, *Cigarette Advertising Expenditures Before and After the Master Settlement Agreement: Preliminary Findings*, at <http://www.tobaccofreekids.org/reports/addicting/magazines/connolly.pdf> (May 15, 2000).

⁹ Charles King & Michael Siegal, *The Master Settlement Agreement with the Tobacco Industry and Cigarette Advertising in Magazines*, 345 NEW ENG. J. MED. 504, 504 (2001).

¹⁰ *People ex rel. Lockyer v. R.J. Reynolds Tobacco Co.*, No. GIC 764118, 2002 WL 1292994 (Cal. Super. Ct. June 6, 2002).

¹¹ S. 2626, 107th Cong. § 906(d) (2002).

companies target much of their advertising at children, even though it is unlawful to sell cigarettes to minors in nearly every state. Tobacco ads designed to encourage kids to smoke are not promoting a lawful activity. Much of the industry's advertising is grossly misleading on the critical health consequences of smoking. Substantial limitations can be constitutionally imposed on tobacco advertising, as long as the restrictions are narrowly tailored to prevent these evils.

The FDA's authority must also extend to the sale of tobacco products. Most states make it illegal to sell cigarettes to children under eighteen, but surveys show that these laws are rarely enforced and are frequently violated. The FDA must have the power to limit the sale of cigarettes to face-to-face transactions in which the age of the purchaser can be verified by identification. This means an end to self-service displays and most vending machine sales. There must also be serious enforcement efforts with real penalties for those caught selling tobacco products to children. This is the only way to ensure that children under eighteen are not able to buy cigarettes.

In determining what regulations would most effectively reduce the number of children who smoke, the FDA conducted the longest rulemaking proceeding in its history. Seven hundred thousand public comments were received in the course of that rulemaking. At the conclusion of its proceeding, the FDA promulgated rules on the manner in which cigarettes are advertised and sold. Due to litigation, most of those regulations were never implemented. If we are serious about curbing youth smoking as much as possible, as soon as possible, it makes no sense to require the FDA to reinvent the wheel by conducting a new, multi-year rulemaking process on the same issue. The proposed legislation will give the youth-access and advertising restrictions already developed by the FDA the immediate force of law, as if those regulations had been issued under the new statute. The FDA will have the authority to modify regulations in future years, as experience and new scientific developments warrant.

The legislation also provides for stronger warnings on all cigarette and smokeless tobacco packages, as well as in all print advertisements. These warnings will be more explicit in their description of the medical problems that can result from tobacco use. The FDA is given the authority to change the text of these warning labels periodically, to keep their impact strong.

Nicotine in cigarettes is highly addictive. Medical experts say it is as addictive as heroin or cocaine. Yet, for decades, tobacco companies vehemently denied the addictiveness of their products. No one can forget the parade of tobacco executives who testified under oath before Congress as recently as 1994 that smoking cigarettes is not addictive. Overwhelming

evidence in industry documents, obtained through investigation, proves that the companies not only knew of the addictive nature of nicotine for decades, but actually relied on it as the basis for their marketing strategy. As we now know, cigarette manufacturers chemically manipulated nicotine in their products to make it even more addictive.

The tobacco industry has a long, dishonorable history of providing misleading information about the health consequences of smoking. These companies have repeatedly sought to characterize their products as far less hazardous than they really are. Furthermore, they made minor innovations in product design seem far more significant for the health of the user than they actually were. The FDA must have clear and unambiguous authority to prevent such misrepresentations in the future. The largest disinformation campaign in the history of the corporate world must end.

Given the addictiveness of tobacco products, it is essential that the FDA regulate them for the protection of the public health. Since over forty million Americans are currently addicted to cigarettes, no responsible public health official believes that cigarettes should be banned. A ban would leave those forty million people without a way to satisfy their drug dependency. The FDA should be able to take the necessary steps to help addicted smokers overcome their addiction, and to make the product less toxic for smokers who are unable or unwilling to stop. To do so, the FDA needs the authority to reduce or remove hazardous ingredients from cigarettes, to the extent it is scientifically feasible. The inherent risk in smoking should not be unnecessarily compounded.

Modern cigarettes have become much more than shredded tobacco rolled in a paper tube; they are highly engineered products, potentially containing hundreds of ingredients. Some of these ingredients are inherent in the tobacco leaf, but many are added in manufacturing. For this reason, the tobacco companies have vigorously opposed ingredient disclosure. When cigarettes are lit, the burning process actually generates more than four thousand chemicals in the smoke. Many of them are toxic, and could be reduced or eliminated if health considerations were given appropriate weight in the cigarette design process.

The tobacco companies have deliberately made their products even more addictive than they would be naturally. Ammonia is used to convert naturally occurring nicotine to the free base form in order to enhance its addictiveness. Additives such as menthol may also make cigarettes more addictive by easing the ability to inhale smoke more deeply into the lungs. Particle physicists working for the industry have designed aerodynamic smoke particles that can reach the deepest cavities in the lungs. The FDA needs unfettered authority to analyze the impact of cigarette ingredients

and product design. This knowledge can then be used by the FDA to set performance standards that will incrementally make the product less lethal and less addictive.

Recent statements by several tobacco companies make clear that they plan to develop what the industry characterizes as “reduced risk” cigarettes. The proposed legislation will require manufacturers to submit such “reduced risk” products to the FDA for analysis before they can be marketed. No health-related claims will be permitted until they have been verified to the FDA’s satisfaction. These safeguards are essential to prevent deceptive industry marketing campaigns, which could lull the public into a false sense of health safety.

If the tobacco industry is permitted to market “reduced risk” products without strict supervision by the FDA, the companies will heavily promote minor product modifications that have no real impact on the health risks posed to smokers. This was the case with “light” and “low tar” products, presented in an earlier era as offering a safer way to smoke. Those claims have now been conclusively disproved in a number of independent studies, including one by the National Cancer Institute issued last year. Unregulated claims of reduced risk can create the false perception amongst smokers that they no longer need to quit and amongst non-smokers that it is less dangerous to start.

Claims such as “reduced carcinogens” and “less of the toxins,” currently appearing in advertisements for new products, imply much but convey little actual information about the health risks. A reduction in the level of one or two of the many different carcinogens present in cigarettes may have only a negligible impact on the risk to the smoker of developing cancer. Merely demonstrating a reduction in the level of one toxin does not establish that the new product significantly reduces the overall health risk. Only independent testing under FDA oversight can determine whether a significant reduction in risk has actually been achieved. To be genuinely “reduced risk,” a tobacco product must demonstrate a substantial net reduction in overall health risk to the public.

Congress must vest the FDA with not only the responsibility for regulating tobacco products, but also with full authority to do the job effectively. The proposed legislation will give the FDA the legal authority it needs to (1) reduce youth smoking by preventing tobacco advertising targeting children; (2) prevent the sale of tobacco products to minors; (3) help smokers overcome their addiction; (4) make tobacco products less toxic for those who continue to use them; and (5) prevent tobacco companies from misleading the public about the dangers of smoking.

We cannot allow the tobacco industry to stop us from doing what we

know is right for America's children. Empowering the nation's foremost public health agency to regulate the consumer product posing the greatest health hazard is long overdue. It will save thousands of lives each year.

Bridging the Divide: A Shared Interest in a Coherent National Tobacco Policy

Steven C. Parrish*

If you meet a sectary, or a hostile partisan, never recognize the dividing lines; but meet on what common ground remains,—if only that the sun shines, and the rain rains for both; the area will widen very fast, and ere you know it the boundary mountains, on which the eye had fastened, have melted into air.

— Ralph Waldo Emerson¹

In its 2000 study on the polarized nature of the debate over core tobacco policy issues, the American Council on Science and Health observed:

A common feature of modern society is the convening of conferences and other forums where traditionally antipathetic parties come together to communicate in a genuine effort to understand one another and resolve lingering distrust and animosity. It is striking that the same cannot yet be said of the right and the left in the tobacco policy debate, where the opposing camps have engaged in little genuine dialogue.²

Three years later, the distrust and animosity persist. Important, yet reconcilable, differences on specific tobacco policy questions remain, but some in the industry and the public health community continue to focus on the differences rather than on how to resolve them. A proposal empowering the Food and Drug Administration (FDA) to regulate all aspects of the design, manufacture, and distribution of tobacco products, acknowledged by one of its critics as differing “in only about five percent” from a preferred proposal,³ is nonetheless excoriated by some leading

*Steven C. Parrish is Senior Vice President, Corporate Affairs, of Altria Group, Inc., the parent company of Philip Morris USA, Philip Morris International, and Kraft Foods.

¹ RALPH WALDO EMERSON, *Prudence*, in *ESSAYS: FIRST SERIES* 207, 225 (Cambridge, Houghton Mifflin Co. 1883).

² CLIFFORD E. DOUGLAS ET AL., AM. COUNCIL ON SCI. & HEALTH, *BRIDGING THE IDEOLOGICAL DIVIDE: AN ANALYSIS OF VIEWS ON TOBACCO POLICY ACROSS THE POLITICAL SPECTRUM* 54-55 (2000).

³ John Reid Blackwell, *Reinventing Tobacco*, RICH.-TIMES DISPATCH, Aug. 12, 2002, at D12.

tobacco control groups as “worse than having no legislation at all,”⁴ “not requir[ing] any meaningful changes”⁵ in behavior by the industry, and “not even represent[ing] a starting point for further negotiations.”⁶ Some in the industry lambaste the same piece of legislation as placing “the future of tobacco farmers and their families at risk”⁷ and imposing “a huge regulatory burden that would be difficult, if not impossible, for smaller manufacturers to sustain.”⁸

Something here does not compute. How can a single policy option be completely meaningless and, at the same time, threaten to drive an entire industry out of business? We seem to have reached a point where the hostility and rancor developed during nearly fifty years of the so-called “tobacco wars” have reached such a fevered pitch that, even where there are policy solutions with the potential to benefit all parties to the debate, the existence of the battle itself and the desire to sustain it have become ends in themselves. My company, for one, sees no benefit in continued fighting, and would like to find common ground that will both advance public health and permit our tobacco businesses to conduct their operations in a respectful, responsible—and, yes, profitable—way.

In this Commentary, I offer a view as to how the current impasse developed, and then explore the possibility of drawing back from the abyss. I first acknowledge the role that the tobacco industry has played in generating an unprecedented level of mistrust within the public health community. Then, I offer some observations about the strategy of demonizing tobacco companies. Finally, after an explanation of why I think the industry would benefit from meaningful, effective regulation of tobacco products by the FDA, I examine a specific policy question presented by the various legislative alternatives and suggest that a sensible, meaningful solution is possible.

A COMBATIVE HISTORY

Clearly, our tobacco companies, together with the rest of the industry,

⁴ Press Release, Matthew L. Myers, Campaign for Tobacco-Free Kids, Rep. Davis’ Sham FDA Bill Protects the Tobacco Industry, Not the Public Health (June 14, 2001), *available at* <http://www.tobaccofreekids.org/Script/DisplayPressRelease.php3?Display=368>.

⁵ *Id.*

⁶ Press Release, Campaign for Tobacco-Free Kids, Public Health Groups Express United Opposition to Davis FDA Bill (June 25, 2001), *available at* <http://www.tobaccofreekids.org/Script/DisplayPressRelease.php3?Display=372>.

⁷ Press Release, Brown & Williamson Tobacco Corp., Brown & Williamson Says FDA Legislation Supported by Philip Morris Poses Threat to Farmers (Aug. 6, 2001), *available at* http://www.bw.com/Index_sub2.cfm?ID=6.

⁸ *Id.*

played a major role in the development of the level of anger that is now directed against them—not just by many in the public health community, but by many in the general public as well. Put simply, ours was a culture of arrogance, bred by insularity and enabled by spectacular business success. Our tobacco companies evolved an approach towards important societal issues such that, if a given position was legally defensible, it was good enough for us. There was a bunker mentality, an “us-against-them” attitude, a belief that anyone who disagreed with us was an enemy out to destroy us.

This approach manifested itself in many ways and, over time, had a disastrous impact on our corporate reputation. Take, for example, our public positioning on key smoking and health issues. We focused on what was not known rather than listening as part of a meaningful dialogue. We argued over definitions rather than advancing solutions.

It seems clear, in retrospect, that had our companies simply deferred to the Surgeon General’s famous conclusion in 1964 that smoking causes lung cancer and not uttered a word of criticism against it, irrespective of the views of internal scientists, much of the rhetoric and ill-will directed at us today would be without foundation. Perhaps even more strikingly, had they accepted the Surgeon General’s revised definition of addiction in 1988 rather than argue about which definition had greater validity, that famous image of the seven CEOs raising their hands before a congressional committee would never have become ingrained in America’s collective consciousness. The reservoir of public anger that has built up against us would have been deprived of one of its primary wellsprings, and there could have been a foundation for problem solving instead of continued conflict.

Another example is the approach that was taken regarding cigarette marketing. Essentially, with certain exceptions, the approach was to advertise as aggressively as the law permitted because that was a fundamental business right. The industry did not have sufficient appreciation that, from society’s perspective, the unique dangers posed by cigarettes call for both rigorous regulation and significant voluntary restraints, regardless of the protection that the First Amendment guarantees commercial speech.

What resulted from this combative approach? In 1990, *Fortune* magazine ranked Philip Morris Companies as America’s second most admired corporation.⁹ In 1997, we ranked 147th.¹⁰ This dramatic plunge

⁹ Sarah Smith, *America’s Most Admired Corporations*, FORTUNE, Jan. 29, 1990, at 58.

¹⁰ Edward A. Robinson, *America’s Most Admired Companies*, FORTUNE, Mar. 3, 1997, at 68.

not only made it easier for some to argue that we do not deserve a “place at the table” when important tobacco policy issues are discussed, but also paved the way for an overt strategy of industry demonization and vilification as a means of reducing tobacco consumption.

“KEEPING THEM PARIAHS”

The vilification and demonization have taken many different forms, from caricatures of tobacco company executives as oily, laughing liars, to explicit comparisons to Hitler. An excerpt from a *Health MS* television spot illustrates the phenomenon:

“He killed 11,000 people a day.”

“That is impossible. . . .”

“He liked them young. Sold them poison loaded with an addictive drug. And when they got too old or died, he just went after more kids.”

“How did he get away with it for so long?”

“He ran a tobacco company.”

What started out as an “edgy” technique has now been embraced by some of the tobacco control movement’s leading lights. As articulated by one prominent advocate, “[i]f we can keep them perceived as pariahs in America, then we’ve got a much better chance of forcing them into reform.”¹¹ In the words of another:

[T]he company’s goal [in seeking FDA regulation] was to gain legitimacy. . . . [T]hey knew that regulation had the potential to make their products less controversial. We had helped make the tobacco companies pariahs, and I wanted to be sure that nothing I did would help put the stamp of government approval on tobacco now.¹²

In 1998, when the Senate rejected proposed national tobacco legislation in the form of the McCain Bill, former Surgeon General Dr. C. Everett Koop

¹¹ Gordon Fairclough, *Philip Morris TV Ad Campaign Seeks To Repair Cigarette Maker’s Image*, Wall St. J., Oct. 13, 1999, at B16 (quoting William Novelli).

¹²DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY 389 (2001).

famously demanded to know “[w]here’s the outrage?”¹³ These vilification campaigns appear to be, at least in part, an attempt to generate some.

Nietzsche once wrote, “[W]hoever lives for the sake of combating an enemy has an interest in the enemy’s staying alive.”¹⁴ Whether it is right for governments to sponsor campaigns attacking a legal, tax-paying industry comprised of thousands of its own citizens, or to teach our children—even as a means of discouraging them from smoking—to insult and despise their neighbors, is a subject that could consume an essay much longer than this one. So could the question of whether it even makes sense, from a public health perspective, to engage in a strategy that appears, at least to some, to be an attempt to drive existing tobacco companies into bankruptcy through litigation so that they can be replaced by new ones.¹⁵ What is relevant here is the dilemma for the public health community concerning how to react when a company embraces one of that community’s primary policy goals. Which is more important, maintaining a tobacco company’s enemy status, or risking that status by putting in place the kind of regulation that could directly reduce the harm caused by smoking? Is it better to resolve the controversy or perpetuate it?

A TOBACCO COMPANY’S DESIRE FOR FDA REGULATION

When I first announced at a conference sponsored by the Center on Addiction and Substance Abuse, in February 2000, that we had decided to actively advocate the passage of legislation giving the FDA comprehensive authority to regulate tobacco products, there was, understandably, much skepticism. After all, we were still engaged in litigation over the FDA’s earlier attempt to regulate cigarettes as medical devices. Over time, however, our actions have convinced at least some that, whatever our motives, we are, in fact, serious about this. As one tobacco control lobbyist put it, “in the beginning I was cynical and thought this was a concerted ploy by the industry, but now I do think there is a real split.”¹⁶ There are

¹³ MICHAEL PERTSCHUK, *SMOKE IN THEIR EYES: LESSONS IN MOVEMENT LEADERSHIP FROM THE TOBACCO WARS* 248 (2001).

¹⁴ Friedrich Nietzsche, *Man Alone with Himself, Aphorism 531, The Enemy's Life*, in *HUMAN, ALL TOO HUMAN* 240 (Marion Faber & Stephen Lehmann trans., Univ. of Nebraska Press 1984) (1878).

¹⁵ PERTSCHUK *supra* note 13, at 256 (“To be sure, the portfolio values of large investors, including worker pension plans, would be significantly diminished. But the current tobacco company executives would only continue, with full pay and corporate perks, to manage the enterprise under the bankruptcy courts’ mandate to *maximize* sales and profits for the benefit of creditors.”) (emphasis original).

¹⁶ Samuel Lowenberg, *Smoke Screen: Why Is Philip Morris Supporting FDA Regulation of Cigarettes?*, SLATE, July 25, 2002, at <http://slate.msn.com/?id=2068476> (quoting Paul

several reasons for the evolution in our thinking.

First, all the major tobacco companies had accepted FDA regulation in the 1997 proposed settlement. As flawed as the final product may have been, we learned a great deal from the process. For example, as part of the negotiations, we painstakingly parsed every section of the FDA medical device statute and attempted to address the parts that simply did not make sense for tobacco products. Although there were many examples, the most obvious one was the need to find a regulatory standard to replace the concept of “safety and efficacy” required for medical products. This process demonstrated to us that, by putting the rhetoric and posturing aside, product regulation—if done thoughtfully and carefully—could address both public health concerns and our obligations to our shareholders.

Another key event for us was our decision in 1997 to change our policy approach to the issues of addiction and disease causation in smokers. We decided to adopt a policy of deferring to public health officials on these issues and to refrain from publicly debating them. In 2000, our tobacco companies updated this policy again, this time to make it clear that they agree with the consensus that cigarette smoking is addictive, and causes lung cancer and other fatal diseases. And once you begin actively communicating that you are selling a product that is both deadly and addictive, it is not much of a leap to come to the conclusion that there needs to be significant additional regulation. Tobacco control advocates who cite the irony that cigarettes are the only products consumers ingest that are not subject to a comprehensive regulatory regime are absolutely right.

We are also acutely aware of our poor credibility, and the fact that FDA oversight is an essential component of restoring America’s confidence in the business practices of the tobacco industry. The most painful example of this for me relates to the allegations—on national television—of nicotine “spiking.” The allegation was made; we denied it and commenced litigation over it; the network admitted that it had made a mistake and publicly apologized; and today, years later, many people still believe that we “spike” our cigarettes. In retrospect, it is obvious to me that, had the FDA been regulating tobacco products during this time, and had we been able to respond by saying, “we do not ‘spike’—and you should check with the FDA because it regulates our manufacturing processes,” the incident could have been convincingly put to rest in a way that did not fuel public anger and mistrust. So, the belief that one reason we seek FDA regulation

is to regain respectability is well founded. But hopefully everyone can agree that solving the problem is more important than having the issue.

Finally, our tobacco businesses have concluded that FDA regulation will assist them by establishing clear rules for the industry on issues like warning labels and manufacturing requirements that will be enforced uniformly on a nationwide basis. The FDA's administrative rulemaking process would pull together divergent points of view, and permit the agency to make decisions about issues such as "light" cigarettes that reflect both public health and industry perspectives. This is most important in the emerging area of potentially reduced-risk or reduced-exposure products, where it is clear that FDA oversight of comparative claims will be essential to both protecting consumers and guiding manufacturers.

PERFORMANCE STANDARDS—A KEY, RESOLVABLE DIFFERENCE

We are convinced that there is a basis to bridge remaining policy differences over FDA regulation. One difference is the scope of the FDA's power to impose mandatory design changes—called "performance standards"—to remove harmful components from tobacco products. It is an example where the disagreement, though real, ought to be amenable to a reasonable solution.

Philip Morris USA's position has evolved in the past three years. From an initial rejection of any authority that "reduces the product's palatability," it first evolved to a view that the FDA should be able to require the removal of any harmful added ingredients, but not properties inherent to tobacco. Now, Philip Morris USA has accepted a legislative proposal where any performance standard can be imposed if the FDA finds it to be "appropriate to protect public health,"¹⁷ so long as the standard would not render cigarettes "unacceptable for adult consumption."¹⁸ Tobacco control advocates support legislation containing the identical "protect public health" standard, but omitting the adult acceptability language.¹⁹ Both versions contain the same language regarding "the reduction or elimination of other harmful constituents or harmful components of the product."²⁰

Every regulated consumer product is governed by a statutory standard reflecting Congress's policy judgment as to the values governing the

¹⁷ See, e.g., The National Youth Smoking Reduction Act, S. 190, 107th Cong. § 907 (2001).

¹⁸ *Id.*

¹⁹ See, e.g., The Youth Smoking Prevention and Public Health Protection Act, S. 2626, 107th Cong. § 907 (2002).

²⁰ *Id.*; S. 190.

rulemaking process. Just as medical devices need to be “safe and effective,”²¹ a motor vehicle standard may only be imposed if it is “reasonable, practicable, and appropriate for the particular type of motor vehicle. . . .”²² Similarly, the Consumer Products Safety Act requires a finding regarding “the probable effect of [safety standards] upon the utility, cost, or availability of . . . products.”²³ Our view is that the FDA should recognize tobacco products as legitimate for adults to use if they wish; that the agency should operate within some reasonable boundaries, making it clear its mission is not to phase tobacco products out entirely. To us, it seems entirely plausible that, under a pure “public health” standard, the FDA could conclude it is better for public health, overall, to ban tobacco products because that would result in millions of people quitting, and that having millions more seeking black market products, with all the attendant consequences, would be an acceptable tradeoff. Even if this conclusion is valid from a health perspective, it is not necessarily good public policy.

The opposition to any notion of “consumer acceptability” has been justified by concerns that the term’s vagueness will lead to “endless litigation,” and that “a reduction of tobacco consumption by 1% or less could be the basis for an industry claim that a new performance standard has left the product unacceptable to adults.”²⁴ There are responses to these concerns. It is unclear why consumer acceptability should be any more susceptible to court challenge than equally vague standards such as “the increased or decreased likelihood that existing users of tobacco products will stop using such products.”²⁵ And, under the well-known *Chevron*²⁶ doctrine, the FDA would be afforded substantial deference by the courts in determining what the language means. The point here is not to resolve the issue, or prove that we are “right” about it, but simply to suggest that workable language must exist that would both introduce some notion of reasonableness into the FDA’s performance standard calculus, and meet the public health objective of tough, meaningful authority that will lead to a reduction in youth smoking, real changes in tobacco products, and a significant reduction in the harm they cause.

²¹ 49 U.S.C. § 30111(b)(3) (2002).

²² *Id.*

²³ 15 U.S.C. § 2058(f)(1)(C) (2002).

²⁴ Memorandum from Matthew L. Myers, President, Campaign for Tobacco-Free Kids, to Steven C. Parrish, Senior Vice President, Corporate Affairs, Altria Group, Inc. 7 (Sept. 19, 2002) (on file with author).

²⁵ S. 2626 § 907.

²⁶ *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

CONCLUSION

In his book about the 1997 proposed tobacco settlement, Michael Pertschuk observes:

It is never easy . . . for warriors to transform themselves into peacemakers, to shift from the comfort of combating a securely demonized enemy to the moral ambiguity involved in acknowledging an enemy as simultaneously a bargaining partner. . . . But the accumulating pressures on the industry in 1997—especially from its own investors—created an opportunity different in kind and dimension from anything that had come before. Yet . . . many others were [not] capable of stepping back and asking themselves whether a time had indeed come to suspend the fighting—not end it forever—and negotiate.²⁷

Today, nearly six years later, there is still no FDA authority to regulate tobacco products. According to tobacco control advocates, each day of each of those years, thousands of kids have started to smoke, and hundreds of thousands of adults have died from smoking-related diseases. My company wants very much to resolve the impasse, and we are convinced that the remaining policy differences can be resolved through mutually respectful discussions that seek resolution rather than vilification. I hope very much that, together, we can bridge the divide and achieve our common goal.

²⁷ PERTSCHUK, *supra* note 13, at 256.

Government Policy Towards Smoking: A View from Economics

Jonathan Gruber, Ph.D.*

The past six years have witnessed an enormous change in the treatment of smoking by policymakers. In 1995, federal and state excise taxes on cigarettes were one-third lower, in real terms, than their peak level in the mid-1960s. Since 1995, however, taxes have risen forty percent, or twenty-two cents per pack, and now stand at seventy-eight cents per pack.

From the traditional economics perspective, this shift in government policy is unwarranted. In the standard economics model, fully informed, forward-looking, rational consumers decide whether or not to smoke, weighing the benefits of doing so in terms of smoking enjoyment against the costs in terms of health and other risks. The only call for intervention in such a model are the *externalities* that smokers impose on others, such as increased medical costs for public insurance programs. But such externalities are, in fact, fairly small by most measures, and their costs are offset by the savings from the earlier mortality of smokers, who pay a lifetime of Social Security taxes but often do not live long enough to collect the benefits. As a result, the traditional economics model would suggest that the “optimal” tax on cigarettes may be below the 1995 level.

The traditional model, however, has little evidence in its support. This model is predicated on the description of a smoking decision at odds with laboratory evidence, the behavior of smokers, econometric analysis, and, quite frankly, common sense. Moreover, alternative models, deviating only modestly from this traditional formulation, have radically different implications for government policy, rationalizing large taxes on cigarettes and other types of regulatory controls.

In this Commentary, I describe this “new economics of smoking.” First, I discuss how the new model differs from the old. Second, I offer evidence that supports the evolution in thinking. Finally, I discuss the implications of the new formulation for government policy and the legal arena.

* Jonathan Gruber is a Professor of Economics at the Massachusetts Institute of Technology and the Director of the National Bureau of Economic Research's Program on Children.

THE TRADITIONAL ECONOMICS MODEL

The traditional economics model of smoking follows the standard economics approach to modeling any decision that involves tradeoffs over time. Smoking a cigarette today increases utility today, but lowers future utility by reducing health. Fully informed, forward-looking, rational consumers trade present gains against future costs, deciding to smoke only if the former outweighs the latter.

Of course, smoking differs from many other activities. It is well established that smoking is a highly addictive behavior. But, Nobel Prize winning economist Gary Becker (and his prominent co-author, Kevin Murphy) showed in the late 1980s that addiction does not, per se, invalidate the conclusions of the standard model, but merely complicates the analysis.¹ The consumer must consider not just the costs and benefits of a given cigarette, but also the fact that smoking a cigarette increases his level of addiction, committing him to future consumption. The underlying principle is the same: individuals will only smoke if the benefits of smoking exceed its costs, including both the monetary and health costs of future cigarettes to which the addicted smoker is committing himself.

This “rational addiction” approach to modeling addictive behaviors appeals to economists and has been adopted, either explicitly or implicitly, as the standard model in the field. The key implication of this approach is that the appropriate role for government (and, by extension, the legal system) is solely a function of the externalities that smokers impose on others. Since the decision to smoke, like all other consumption decisions, is governed by rational choice, the fact that smokers impose enormous costs on themselves is irrelevant. The costs they impose on others, alone, give rise to a mandate for governmental action.

A large amount of literature is devoted to measuring the externalities of smoking. While some controversy exists within this literature, there is a fairly strong consensus that the net externalities are small, on the order of forty cents per pack or less. This seemingly low estimate reflects the convenient fact that smokers die, on average, about six years earlier than non-smokers. Thus, the increased health costs that smokers impose on others, in terms of group insurance and public programs, are offset by their premature death, reducing Social Security benefit payments and Medicare health expenditures. Indeed, some claim that these offsetting savings are so large that smoking actually generates net positive benefits for society.

¹ Gary S. Becker & Kevin M. Murphy, *A Theory of Rational Addiction*, 96 J. POL. ECON. 675-700 (1988).

If the external costs of smoking are small, then the traditional economics model suggests a limited governmental role in regulating smoking. The appropriate level of taxation, or legally induced price increases, is at the level of the externality, which is most likely below or near existing tax levels.

A NEW ECONOMICS APPROACH

However, there is evidence suggesting that the traditional economics model is not appropriate for assessing the role of governments and legal systems in regulating tobacco use. First, the decision to begin smoking is made primarily by youths,² whose ability to make fully informed, appropriately forward-looking decisions is questioned by society in many contexts (as manifest in laws such as minimum drinking, driving, and voting ages). Moreover, my own research convincingly demonstrates that long-term consequences result from deciding to smoke as a youth; simply put, smoking as a youth causes smoking as an adult.³ If youths are not perfectly rational, fully informed, forward-looking decision-makers, then the fact that smoking is addictive does matter, as it causes “mistakes” by youths to have implications throughout their lives. While there is some evidence that youths are fully informed about the health risks of smoking and may even overestimate those risks, it is clear that they dramatically underestimate the addictive nature of smoking. Fifty-six percent of high school seniors who smoke say they will quit within five years, but only thirty-one percent actually do. Moreover, for smokers who average at least one pack of cigarettes per day, the smoking rate five years later among those who stated that they would not be smoking (seventy-four percent) is actually higher than the smoking rate among those who stated that they would still be smoking (seventy-two percent). Such self-delusion can lead to mistakes with lifelong implications. Indeed, I estimate that the dramatic rise in smoking among youths in the 1990s will, given the health damage of smoking, result in 3.2 million fewer years of life for high school seniors surveyed in that period.⁴

Further, there is evidence that adults are unable to quit smoking even if they desire to do so. According to one study, over eighty percent of smokers try to quit in a typical year, the average smoker trying to quit every eight and one-half months. However, fifty-four percent of serious attempts

² More than seventy-five percent of smokers start before age nineteen.

³ Jonathan Gruber, *Youth Smoking in the 1990s: Why Did It Rise and What Are the Long-Run Implications?*, AM. ECON. REV., May 2001, at 85-90.

⁴ *Id.* at 90.

to quit fail within the first week.

These facts have motivated Botond Koszegi and me to develop an alternative formulation of smoking that changes the traditional formulation in just one critical way: it allows smokers to be time-inconsistent.⁵ This approach, now widely used within the new field of "behavioral economics," is one in which there is conflict between what the smoker would like for himself today and what he would like for himself tomorrow.⁶ Today's "self" is impatient: faced with the tradeoff between the short-term pleasures of smoking and the long-term health damages it creates, he will greatly discount the latter and decide to smoke. Tomorrow's "self," however, is considerably more patient and would prefer to quit smoking. Unfortunately, tomorrow never comes. With each new day, the future self that was once patient is now the impatient current self. So, the smoker continues to smoke, to his long-term detriment.

The time-inconsistent formulation of preferences is supported by the extensive literature on individual choice over time. The hallmark of time inconsistency is that individuals will have different levels of patience when making decisions over different timeframes. In the time-consistent case, a tradeoff between any pair of days is the same regardless of when that pair of days arises; impatience between one day and the next is the same now as it is in ten years. But, experiments consistently show that this is not the case; when making decisions about the future, consumers are more patient than when they make those same decisions about today. Individuals are considerably more willing to declare that their diets will start tomorrow than to actually start their diets today. The problem is that when tomorrow comes, pushing back the diet's start date is too easy. Therein lies the conflict: one would always like to start the diet tomorrow, but one never reaches a point of actually making that sacrifice.

The key implication of time-inconsistent preferences is that one's future self would like to somehow constrain one's current self to behave more patiently. Thus, time-inconsistent consumers will demand commitment devices that can induce behavior that is more appropriate in the present. Indeed, the search for such commitment devices is the hallmark of most recommended strategies for quitting smoking. People regularly set up socially managed incentives to refrain from smoking by betting with others, telling others about their decision, or otherwise

⁵ JONATHAN GRUBER & BOTOND KOSZEGI, A THEORY OF GOVERNMENT REGULATION OF ADDICTIVE BADS: OPTIMAL TAX LEVELS (Nat'l Bureau of Econ. Research, Working Paper No. 8777, 2002).

⁶ The traditional economics model assumes that today's self and all future selves agree on the advisability of smoking, leading to no regret or inability to carry out plans to quit.

making it embarrassing to smoke. Both academic publications and self-help books recommend various punishment and self-control strategies. Clearly, smokers need commitment devices to help them overcome their addiction problems.

Unfortunately, the private market imperfectly provides such self-control devices. For every possible device, another device can undo it. A person can always cheat on his bets with others, or not go to support-group meetings and smoke instead. There is no way to truly commit oneself to eschew smoking, or not buy cigarettes, through the private market.

The government, on the other hand, can provide an excellent commitment device—cigarette taxation. By raising the price of cigarettes, smoking becomes more costly for today's self, which would lower today's smoking and thus help achieve what the long-term self would desire. There is extensive literature documenting that smoking falls as cigarette prices rise. The best estimates suggest that each ten-percent rise in cigarette price lowers consumption by five to six percent. For youths, price sensitivity is even higher.

Thus, the time-inconsistent formulation suggests a new rationale for government intervention beyond the damage that smokers inflict on others. In this model, the damage that smokers cause to themselves is also relevant. This is because, from their own long-term perspective, smokers are smoking too much. Their long-term selves recognize this failure and would like to reduce smoking, but, without a legal commitment device, their current selves are unable to do so. Thus, the government can do what the private sector cannot—make smoking more costly in a way that cannot be evaded, thereby combating one's short-term impatience on behalf of one's long-term interests.

It is important to highlight that the new formulation does not depart radically from the traditional economics model. I continue to assume that consumers are perfectly rational, forward-looking, and fully informed. In every respect but one (time consistency), I retain the features of decision-making that economists have used for years to model behavior. However, the two models do have one key difference in their predictions. Under the traditional formulation, higher taxes on cigarettes make smokers worse off; the government would be constraining their rational choice. In contrast, under the alternative formulation, higher taxes make smokers better off; the government would help them achieve the self-control that they cannot secure through the private market. In a recent study, Sendhil Mullainathan and I directly tested this prediction by assessing whether the self-reported

well being of smokers falls or rises when cigarette taxes increase.⁷ Data from both the United States and Canada consistently associated higher taxes with higher levels of reported well being. While the study is not an ideal experimental evaluation of the alternative models, its findings are much more consistent with the time-inconsistent formulation than with the traditional model.

IMPLICATIONS OF THE NEW APPROACH FOR GOVERNMENT POLICY

While the new smoking model changes the traditional model in only one way, it has dramatic implications for public policy. The reason is simple; while the net damage that smokers do to others is small, the damage that smokers do to themselves is enormous. Smoking has many negative health effects, but Koszegi and I focus on only one—the cost in terms of shortened lives.⁸ As mentioned, smokers, on average, live about six years less than non-smokers. Economists, most notably Kip Viscusi, have spent years showing how we can use our revealed risk preferences to value lost life. Viscusi's central estimates, derived from such examples as the higher pay required by workers in risky jobs, suggest that the value of a life is something on the order of seven million dollars.⁹

Based on the average number of cigarettes smoked over the course of a smoker's life, the reduction of years lived, and the value of life-years lost, Koszegi and I compute that the cost of smoking one pack of cigarettes, in terms of the value of life lost, is thirty-five dollars per pack.¹⁰ This is an enormous figure, approximately one hundred times the typical estimate of the externalities caused by smoking. Given the extent to which smokers damage themselves by smoking, any model proposing that some of these internalities be reflected in government policy will suggest very large optimal taxes on cigarettes.

Koszegi and I computed the implications of these internalities under the time-inconsistent model. We first considered a very modest degree of time inconsistency, far below those in most laboratory experiments.¹¹ Even in that case, we found that the optimal tax on cigarettes, above and beyond

⁷ JONATHAN GRUBER & SENDHIL MULLAINATHAN, DO CIGARETTE TAXES MAKE SMOKERS HAPPIER? (Nat'l Bureau of Econ. Research, Working Paper No. 8872, 2002).

⁸ Gruber & Koszegi, *supra* note 5.

⁹ Kip W. Viscusi, *The Value of Risks to Life and Health*, 31 J. ECON. LIT. 1912, 1930 (1993).

¹⁰ This estimate is derived by using estimates for the typical value of (1) a life-year, as determined by Viscusi, *id.* at 1920-24, and (2) the minutes of life lost per cigarette smoked, MANNING ET AL., THE COSTS OF POOR HEALTH HABITS 8-9, 62 (Harvard Univ. Press 1989). This is clearly an average and not a marginal calculation.

¹¹ Gruber & Koszegi, *supra* note 5.

any external effects, is one to two dollars. For more severe time inconsistency, which is consistent with laboratory evidence on preferences, the tax is much higher, from five to ten dollars per pack. This estimate does not even incorporate the types of misperceptions held by youths, which might make the tax even higher. Thus, the new smoking model suggests a much more aggressive role for government regulation than does the traditional model.

Another common argument against cigarette taxation is made on distributional grounds. Smoking in the United States is concentrated socio-economically, with the smoking rates of the lowest income quartile roughly twice those of the highest quartile. Expenditures on tobacco products, as a share of family income, falls from 3.2 percent in the bottom income quintile to only 0.4 percent in the top income quintile. This inverse relationship raises the concern that increased cigarette taxes will excessively burden those with the lowest incomes.

The alternative approach to modeling smoking challenges the standard perception that cigarette taxes are highly regressive because cigarette taxes confer greater benefit in terms of “self-control” to consumers who are most price-sensitive. Lower-income groups are much more price-sensitive than higher-income groups. Indeed, my own estimates suggest that the price elasticity of cigarette demand in the bottom quartile of the income distribution is roughly negative one. In other words, when cigarette prices rise, there is no net increase in cigarette spending for the lowest income group. For higher-income groups, price sensitivity is only about one-third that of their lower-income counterparts.

Given these differences, cigarette taxes are, in general, not very regressive since the greater self-control benefits for lower-income groups compensate for the higher taxes they pay as a share of income.¹² Indeed, if self-control problems are great, then cigarette taxes can be highly progressive under the time-inconsistent approach. With a price elasticity of negative one, the poor, as a group, spend no more of their incomes on cigarettes after tax increases than they did before. The savings among those who smoke less offsets the higher spending among those who still smoke the same amount. But, as a group, the poor are much healthier because of the reduction in smoking. So, overall, they are better off from the higher prices.

Thus, the time-inconsistent model overturns the two main arguments against cigarette taxation: (1) that the externalities are small (the alternative model suggests that internalities should matter as well), and (2)

¹² Gruber & Koszegi, *supra* note 5.

that cigarette taxes are regressive (since the self-control value of price increases makes taxes more progressive).

CONCLUSIONS

There has been much hue and cry about recent increases in taxes on cigarettes, with particular focus on New York City, where higher state taxes combined with a city surtax have pushed the price of cigarettes to seven dollars or more per pack. Under the new economics view I outlined in this Commentary, this is a very sensible price level for cigarettes. Since the government provides the quitting device that individuals cannot find in the private sector, individuals are made better off by such high taxes. And, the fact that the poor quit at a considerably higher rate than the rich means that the poor are particularly better off. Cigarette taxes are progressive when analyzed under the time-inconsistent model.

Obviously, more evidence is needed before one approach is accepted as the "right" formulation for modeling smoking decisions. Yet, it is important to recognize that even economics can move beyond the limitations of standard models to capture, more realistically, the dynamics behind such decisions as smoking. When analysis does move beyond standard limitations, the implications for public policy can be quite radical.

Could Science-Based Regulation Make Tobacco Products Less Addictive?

Jack E. Henningfield, Ph.D.* and Mitch Zeller, J.D.†‡

The marketplace for all tobacco products centers on creating and sustaining an addiction to nicotine. This addiction ensures a lifetime of tobacco use by millions of customers. It was with this notion in mind that a top executive for Brown & Williamson Tobacco Corporation wrote, in 1963, that cigarette companies were not in the business of selling tobacco products but, rather, were “in the business of selling nicotine, an addictive drug.”¹

Thirty-three years later, in the 1996 United States presidential campaign, candidate Bob Dole stated, “Some people who have tried [tobacco] can quit easily. Others don’t quit. So I guess it’s addictive to some and not to others.”² Mr. Dole’s conclusions that some people can quit and that not all become addicted are true at face value. His statements may not have seemed so remarkable had he not been supporting tobacco company interests, arguing against the general conclusion that tobacco is addictive. The idea that not all users of addictive drugs become addicted was acknowledged by the U.S. Surgeon General in 1988.³ In fact, it is true

* Jack E. Henningfield is Vice President of Research and Health Policy for Pinney Associates, Inc. and an Adjunct Professor in the Department of Psychiatry and Behavioral Sciences at the Johns Hopkins University School of Medicine.

† Mitch Zeller is Vice President for Policy and Strategic Communications for Pinney Associates, Inc. and is former Associate Commissioner and Director of the Office of Tobacco Programs of the U.S. Food and Drug Administration.

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¹ John Slade et al., *Nicotine and Addiction: The Brown and Williamson Documents*, 274 JAMA 225, 228 (1995).

² Jacob Sullum, *Give Dole a Break*, N.Y. TIMES, July 12, 1996, at A27.

³ SURGEON GENERAL, U.S. DEP’T OF HEALTH & HUM. SERVS., THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION at v, 253 (1988).

of all addictive drugs.⁴

Nonetheless, some characteristics are unique to cigarettes. First, there is a higher risk of addiction to nicotine in cigarettes than to any other addictive drug. Second, there is a higher risk of premature death associated with cigarette smoking than with other addictive drugs.

The Food and Drug Administration (FDA) concluded that seventy-seven to ninety-two percent of adult cigarette smokers meet the criteria for dependence. In contrast, pure nicotine products used to treat tobacco dependence vary in addictiveness, with very low levels associated with nicotine patches and gum and somewhat higher levels with nasal nicotine spray. Overall, however, the risk of addiction to these pharmaceuticals is very low compared to that of cigarettes.⁵

What is it about cigarettes that make them so addictive? Are they designed with the intent to create and sustain addiction? Could product regulation contribute to tobacco disease reduction by reducing the addictiveness of the products? One argument in favor of pursuing such an approach is the inescapable reality that the toxicity of tobacco products makes it extremely unlikely they can be rendered safe. Since cigarette smoke contains a toxic cocktail of more than four thousand chemicals, the most we can hope for is a reduction in the level of toxicity by setting standards for allowable contents and design features.⁶

While efforts to make tobacco products less deadly are worthwhile and should be pursued, we propose that it may be feasible to reduce the addictiveness of cigarettes and thereby lessen the risk that experimenters would become addicted. This may also make it easier for addicted persons to quit.⁷ The following Commentary will examine the scientific foundation and implications for such a regulatory approach. Although our focus will be on cigarettes, similar principles appear applicable to smokeless tobacco and other tobacco products.

⁴ See Gary A. Giovino et al., *Epidemiology of Tobacco Use and Dependence*, 17 EPIDEMIOLOGIC REV. 48, 60 (1995).

⁵ SURGEON GENERAL, *supra* note 3, at 213-14.

⁶ See WORLD HEALTH ORG., ADVANCING KNOWLEDGE ON REGULATING TOBACCO PRODUCTS, Recommendations 2 & 3 (2001), available at <http://www5.who.int/tobacco/index.cfm>; Matthew L. Myers, *Could Product Regulation Result in Less Hazardous Tobacco Products?*, 3 YALE J. HEALTH POL'Y L. & ETHICS 139 (2002).

⁷ But see Neal L. Benowitz & Jack E. Henningfield, *Establishing a Nicotine Threshold for Addiction—The Implications for Tobacco Regulation*, 331 NEW ENG. J. MED. 123 (1994) (offering an earlier proposal to render cigarettes pharmacologically non-addictive by removing their nicotine); Jack E. Henningfield et al., *Reducing the Addictiveness of Cigarettes*, 7 TOBACCO CONTROL 281 (1998).

ESSENTIAL TERMS AND CONCEPTS

The risk of tobacco-caused disease is directly related to the amount (*e.g.*, cigarettes per day) and duration (*e.g.*, years) of tobacco use. Addiction is the biological force that drives most tobacco users to patterns of persistent daily exposure to high levels of deadly tobacco toxins. The cornerstone of the FDA's evaluation of whether or not nicotine in tobacco met criteria for classification as a *drug* hinged on the finding that use of cigarettes and smokeless tobacco was largely driven by addiction to nicotine. *Nicotine* is a powerful and potent drug (about five to ten times more potent than cocaine in the alteration of mood and behavior) that naturally occurs in the tobacco plant.⁸ It has been used as a pharmacological tool to explore the workings of the nervous system. It has also been used as a pesticide at high dosages. In small doses, nicotine and nicotine analogues have potential medical uses such as the treatment of Alzheimer's disease and ulcerative colitis.⁹

Addiction is the general term that is used synonymously with the more technical term *dependence* to label regular, compulsive, and maladaptive self-administration of a *psychoactive* drug such as morphine, cocaine, alcohol, or nicotine.¹⁰ If an addicted person uses a drug regularly and persistently, his or her body may develop *physiological dependence*, such that a *withdrawal* syndrome may emerge within several hours to one day after drug administration is terminated.¹¹ Dependence and withdrawal can be diagnosed according to objective criteria outlined by both the American Psychiatric Association and the World Health Organization.¹² The strongest reactions, desired and undesired, that are often experienced upon initial drug exposure tend to diminish over time as a person develops *tolerance* for the drug. Tolerance is typically accompanied by an increase in dosage until a stable level develops. Higher levels of tolerance and drug intake are associated with higher levels of addiction, and in turn, a higher risk of

⁸ See Jack E. Henningfield & Rosemary Nemeth-Coslett, *Nicotine Dependence: Interface Between Tobacco and Tobacco-Related Disease*, 93 CHEST 37S (1988).

⁹ See David J.K. Balfour & Karl O. Fagerstrom, *Pharmacology of Nicotine and Its Therapeutic Use in Smoking Cessation and Neurodegenerative Disorders*, 72 PHARMACOLOGY & THERAPEUTICS 51 (1996); Paul A. Newhouse et al., *Nicotinic System Involvement in Alzheimer's and Parkinson's Diseases—Implications for Therapeutics*, 11 DRUGS & AGING 206 (1997).

¹⁰ Bridgette E. Garrett et al., *Tobacco Addiction and Pharmacologic Interventions*, 2 EXPERT OPINION ON PHARMACOTHERAPY 1545, 1546 (2002).

¹¹ For example, smoking a pack-per-day for a month or more is assumed sufficient to lead to abstinence-associated withdrawal in many people.

¹² See AM. PSYCHOL. ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 181, 244-45 (4th ed. 1994); WORLD HEALTH ORG., THE ICD-10 CLASSIFICATION OF MENTAL AND BEHAVIORAL DISORDERS: CLINICAL DESCRIPTION AND DIAGNOSTIC GUIDELINES, 75-78 (1992).

adverse health consequences.

The effects of psychoactive drugs are strongly determined by the amount or *dose* that reaches the brain, as well as its *speed* of absorption into the bloodstream. The amount of a drug that is absorbed into the bloodstream from a given formulation is referred to as its *bioavailability*. For example, only about ten to thirty percent of the 10 milligrams of nicotine contained in a conventional cigarette is typically absorbed,¹³ while about fifty percent of the nicotine from a 2-milligram piece of nicotine gum is typically absorbed.¹⁴ The speed of absorption through the lining of the mouth is enhanced when the molecules of the drug have been liberated of their electrical charges (*i.e.*, convert to their *free base* or *un-ionized* form), which is accomplished for many psychoactive drugs by use of substances to increase the alkalinity or pH.

DESIGNED TO ADDICT

The FDA's nicotine investigation hinged on the determination of whether tobacco product manufacturers intentionally controlled the nicotine dosing characteristics of their products to facilitate the development and maintenance of nicotine addiction. The FDA found that cigarettes and smokeless tobacco products were highly controlled with respect to their nicotine content, their bioavailable nicotine, and the rate at which the delivered nicotine could be absorbed into the bloodstream.

The FDA also found that many aspects of cigarette design and manufacture, including the use of *reconstituted tobacco*¹⁵ and various chemical ingredients, were routinely employed to control nicotine delivery. Its analysis suggests that cigarette design could be employed either to increase or decrease the addictive effects of cigarettes by, for example, increasing what was variously referred to as the nicotine "kick" or "impact" of cigarettes. In other words, it is evident that addictiveness is not an all-or-nothing attribute of a product. Rather, a product can apparently be engineered to become more or less addictive by controlling its physical properties. With respect to drug products, this concept is well understood, and drug manufacturers are required to design their products so as to achieve desired effects while minimizing addictive ones.

Addictiveness is measured in animal and human studies estimating the level of risk that substance use will lead to addiction according to objective

¹³ Reginald V. Fant et al., *Nicotine Replacement Therapy*, 26 PRIMARY CARE 633, 634 (1999).

¹⁴ *Id.* at 639.

¹⁵ Reconstituted tobacco is a paper-like product formed from tobacco material and other substances.

criteria.¹⁶ These studies are used by the FDA and the Drug Enforcement Administration (DEA) to determine whether or not a drug is addictive and, if so, its level of addictiveness. This information in turn helps the FDA and the DEA determine product labeling and marketing restrictions.

Because addictiveness can be affected by increases in drug dosage and the speed of delivery, drug manufacturers design *formulations*, or *drug delivery systems*, to maximize desired effects while minimizing undesired effects such as addiction.¹⁷ In fact, despite the increasingly widespread availability of nicotine delivering medications, these products have not emerged as gateways to nicotine addiction. Although a small fraction of users continue taking the products for a year or more (apparently out of the justifiable fear that they will relapse into smoking), the vast majority use them for less than three months and find them far easier to discontinue than cigarettes.

These examples are not presented to imply that the addictiveness of cigarettes can be reduced to the level of nicotine gum, but rather to illustrate that drug design can increase or decrease psychoactive effects by controlling the speed of drug delivery and other characteristics. If nicotine medications and other drug products can be designed to minimize their addictive effects, and if tobacco products are designed to increase their addictive effects, could tobacco products be designed with the opposite intent?

IT'S THE DOSE

In the course of the FDA's investigation of tobacco products, it became apparent that major elements in product design related to nicotine dose control, *i.e.*, providing consumers with the most palatable and addictive forms of nicotine possible. The FDA learned that tobacco companies faced a great challenge in ensuring adequate nicotine delivery in the years following the 1964 Surgeon General's report amidst the increasing health concerns of smokers. Smokers wanted less tar and nicotine. The industry, however, understood what it was hiding from consumers—nicotine at dosages high enough to readily sustain addiction is critical to smoking

¹⁶ See Donald R. Jasinski et al., *Abuse Liability Assessment in Human Subjects*, 5 TRENDS IN PHARMACOLOGICAL SCI. 196 (1984). See also NAT'L INST. ON DRUG ABUSE, U.S. DEP'T OF HEALTH & HUM. SERVS., NIDA RESEARCH MONOGRAPH 92: TESTING FOR ABUSE LIABILITY OF DRUGS IN HUMANS (Marion W. Fischman & Nancy K. Mello eds., 1989).

¹⁷ Although nearly any vehicle for drug delivery might, in principle, be considered a drug delivery system, whether a substance is regulated as a drug, drug delivery system, or combination drug and delivery system depends on many factors. WORLD HEALTH ORG., ADVANCING KNOWLEDGE ON REGULATING TOBACCO PRODUCTS, *supra* note 6.

satisfaction and cigarette preference. Truly low-nicotine cigarettes were shown as far back as 1945—in a study funded by the American Tobacco Company—to be unsatisfactory for many smokers.¹⁸ Subsequent internal research shows that, to make smoking satisfying, most smokers require cigarettes that can readily deliver more than approximately 0.8 milligrams of nicotine per cigarette.¹⁹

PRODUCT DESIGN FEATURES THAT SUBVERT THE FEDERAL TRADE COMMISSION METHOD

To provide a standardized method for determining tar and nicotine yields, the Federal Trade Commission (FTC) adopted a machine test developed by the American Tobacco Company in the 1930s.²⁰ Although the FTC recognized that intake from individual smokers could vary, it assumed that the method would provide consumers with a fair means of differentiating among cigarette brands on the basis of their expected, relative deliveries of tar and nicotine. This testing method was also intended to provide cigarette manufacturers an incentive to design their cigarettes so that tar and nicotine deliveries would be reduced. Instead, the industry deliberately designed cigarettes to yield tar and nicotine deliveries on the machine test that they knew were substantially lower than the levels delivered in “real world” smoking by actual smokers.²¹

The FTC testing method essentially involves the use of smoking machines programmed to take 35-milliliter puffs every minute until the cigarette has burned to 3 millimeters below the filter paper overwrap, which holds the filter to the tobacco tube portion of the cigarette (typically leaving two to four puffs worth of tobacco unsmoked).²² By contrast, humans take puffs at a rate nearly double that of the machines—at intervals of thirty to forty seconds—and can smoke beyond the point that machines stop.²³ Since each puff becomes more concentrated in tar and

¹⁸ J.K. Finnegan et al., *The Role of Nicotine in the Cigarette Habit*, 102 SCI. 94 (1945).

¹⁹ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,887 (Aug. 28, 1996) (to be codified at 21 C.F.R. pt. 801).

²⁰ J.A. Bradford et al., *Nature of Cigarette Smoke: Technique of Experimental Smoking*, 28 INDUS. & ENG'G CHEMISTRY 836 (1936).

²¹ Richard D. Hurt & Channing R. Robertson, *Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial*, 280 JAMA 1173, 1178 (1998).

²² NAT'L CANCER INST., U.S. DEP'T OF HEALTH & HUM. SERVS., SMOKING AND TOBACCO CONTROL MONOGRAPH 7: THE FTC CIGARETTE TESTING METHOD FOR DETERMINING TAR, NICOTINE, AND CARBON MONOXIDE YIELDS OF U.S. CIGARETTES 9-14 (1996).

²³ James C. Zacny & Maxine L. Stitzer, *Human Smoking Patterns: The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes*, in NAT'L CANCER INST.,

nicotine, just a few extra puffs can result in a substantially greater intake.

Cigarette manufacturers could have designed their cigarettes so that tar and nicotine intake by smokers would generally correspond to FTC test ratings. In fact, such cigarettes have been used by researchers.²⁴ Alternatively, they could have suggested to the FTC how to conduct tests that would measure maximal exposures and not substantially under-represent what humans would receive (this is the standard for food and drug labeling).

However, cigarette companies were faced with a dilemma. Consumers increasingly expressed the desire for reduced-tar and nicotine-rated cigarettes, but the flavor and satisfaction derived from smoking was strongly related to the amount of tar and nicotine delivered. Diminished levels of nicotine resulted in unsatisfying cigarettes and withdrawal symptoms, fostering growing concern in the tobacco industry that substantial reductions in nicotine delivery could lead to the erosion of the entire cigarette market.²⁵ Therefore, cigarette companies used creative designs to beat the FTC test method, allowing them to advertise their cigarettes with lower tar and nicotine ratings while still delivering full doses of both. In practice, this meant there was virtually no relation at all between cigarette ratings and actual human nicotine blood levels.²⁵ One study showed that tar deliveries from typical smoking are approximately two to three times greater than FTC-rated levels.²⁶

One tobacco company document bluntly stated its challenge as follows: "Irrespective of the ethics involved, we should develop alternative designs (that do not invite obvious criticism) which will allow the smoker to obtain significantly enhanced deliveries should he so wish."²⁷ Another document raised the following questions before approving cigarettes that tested low on machine tests yet provided no demonstrated safety benefit:

Should we market cigarettes intended to reassure the smoker that they are safer without assuring ourselves that they are indeed so or are not less

U.S. DEP'T OF HEALTH & HUM. SERVS., *SMOKING AND TOBACCO CONTROL MONOGRAPH 7: THE FTC CIGARETTE TESTING METHOD FOR DETERMINING TAR, NICOTINE, AND CARBON MONOXIDE YIELDS OF U.S. CIGARETTES* 154-56 (1996).

²⁴ See Roland R. Griffiths et al., *Human Cigarette Smoking: Manipulation of Number of Puffs Per Bout, Interbout Interval and Nicotine Dose*, 220 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 256 (1982); Jack E. Henningfield et al., *Abuse Liability and Pharmacodynamic Characteristics of Intravenous and Inhaled Nicotine*, 234 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 1 (1985).

²⁵ Hurt & Robertson, *supra* note 21, at 1176.

²⁶ See Mirjana V. Djordjevic et al., *Doses of Nicotine and Lung Carcinogens Delivered to Cigarette Smokers*, 92 J. NAT'L CANCER INST. 106 (2000).

²⁷ Hurt & Robertson, *supra* note 21, at 1176.

safe? For example, should we “cheat” smokers by “cheating” League Tables (the British equivalent of the FTC test)? Should we use our superior knowledge of our products to design them so that they give low League Table positions but higher deliveries on human smoking?²⁸

In essence, the FTC test came to the rescue of the tobacco industry and proved to be among its most powerful marketing tools because it gave manufacturers a course to follow and a credible “government-endorsed” communication.²⁹ It enabled the industry to achieve its dual goal of marketing cigarettes for their reduced nicotine (and tar) while actually sustaining addictive nicotine dosage levels. Manufacturers cited the FTC test to support their claims of reduced tar and nicotine even as they designed cigarettes to nimbly dodge the test and give smokers all the tar and nicotine they desired—for a satisfying smoking experience that maintained their addiction.

The following design features allow cigarettes to provide several times higher levels of exposure to tar and nicotine than their FTC ratings:

- Whether advertised as “ultra-low” or “full-strength,” all cigarettes contain several times more nicotine than consumers “need” per cigarette.
- Cigarettes can “hide” more nicotine under the filter overwrap, thus making more tobacco available to a smoker than to the FTC machine.
- Ventilation holes in the filter allow up to ninety percent ambient air to be collected with each puff on the machine, but the holes are frequently covered by the fingers and / or lips of human smokers because they are typically hidden and there is no direction not to cover them.
- Increased use of burn accelerants make cigarettes burn faster between puffs and, therefore, send more “sidestream” smoke into the ambient air that is not collected by the machine. Human smokers inhale some of this sidestream smoke and also puff more frequently, so a larger fraction of the tobacco is inhaled.

In the course of beating the FTC method, tobacco companies simultaneously developed techniques to provide more “kick” per milligram of delivered nicotine.³⁰ Several design features undoubtedly contributed to

²⁸ *Id.* at 1178.

²⁹ See Judith Wilkenfeld et al., *It's Time for a Change: Cigarette Smokers Deserve Meaningful Information About Their Cigarettes*, 92 J. NAT'L CANCER INST. 90 (2000).

³⁰ “Kick” is a tobacco industry term often used to describe the pharmacological effect of

both the subversion of the FTC method and the enhancement of addictive effects. This enabled the industry to produce cigarettes that were even more addictive, and, at the same time, claim lower nicotine yields in its advertising.

The following techniques could have plausibly increased the kick per milligram of delivered nicotine:

- Chemically control the pH of the tobacco to increase the transfer of nicotine from tobacco to smoke aerosol in a free base gas form that is not detected by the FTC machine but that may have a strong impact on upper airway receptors and be more readily absorbed.
- Engineer the cigarette so that the smoke will be at an optimal pH to increase the fraction of nicotine in the smoke that is quickly absorbed.
- Employ aerosol-engineering techniques to increase the fraction of smoke particles that can be inhaled deep into the lung and thus enable more complete absorption of nicotine (and probably carcinogenic lung toxins as a side effect).
- Increase acetaldehyde in the smoke as shown by Philip Morris researchers to enhance the addictive effects of nicotine.
- Add menthol and / or other ingredients to enable larger and more deeply inhaled puffs, thereby increasing nicotine doses.

Based on our understanding of pharmacology and drug design, and on information in tobacco industry documents, the following design features and ingredients may have made smoking more pleasant, even though they may have also made cigarettes more toxic:

- Cigarette ventilation dilutes the smoke, requiring larger volumes to obtain the same nicotine doses. (This is analogous to diluting vodka with water, thereby producing a milder beverage but one that is no less intoxicating than the undiluted version.)
- Leuvenalic acid appears to have been used to smooth the smoke a user inhales.
- Menthol provides a throat-soothing effect, which could make highly toxic smoke feel smoother and lighter.
- Glycerin can carry nicotine particles deep into the lung as well as provide a “smoother” smoke.

nicotine that is important in keeping smokers hooked.

It is important to note that there has been little systematic evaluation of these pleasure-enhancing modifications by experts outside the tobacco industry. These features are presented as examples of cigarette characteristics that may have the intended effects that we postulate. In principle, the FDA could require the tobacco industry to disclose the effects of such alterations and to justify their application.

USING REGULATORY AUTHORITY TO ALTER PRODUCT CHARACTERISTICS AND REDUCE ADDICTIVENESS

So far, we have examined *controllable* ingredients and design features that plausibly enhance the addictiveness of cigarettes, increase their toxicity, and / or contribute to misleading estimates of human exposure to nicotine and tar. To protect the public, Congress could grant the FDA authority to prohibit their use or set performance standards. For example, if particle size can be controlled to decrease the fraction of particles that can be absorbed in the lungs, the FDA might set an allowable absorption percentage. Similarly, if ammonia increases the addictive kick of nicotine doses, and if menthol enhances the rapid absorption of nicotine deep into the lungs and increases carcinogenicity, such compounds might be prohibited. Finally, if pH manipulations increase the speed of nicotine absorption, standards might be set to diminish the rate of absorption.

In general, performance standards can be based on allowable ingredient levels, design and manufacturing techniques, or empirical tests of actual performance. There are precedents from food and drug regulation that can be adapted to many aspects of tobacco product regulation.³¹ This does not imply the need to tell manufacturers how to make their products; it merely ensures that public health considerations drive the FDA's scrutiny of product design and manufacture. Such oversight stands in stark contrast to the current unregulated environment in which tobacco companies are free to use any methods at their disposal, including techniques that maximize rather than minimize addictiveness. In principle, a wide range of standards could be set that would not render cigarettes unacceptable, incapable of delivering nicotine, or even non-addictive. However, if such strategies could contribute to incrementally reduced cigarette addictiveness, then they warrant exploration. The idea is similar to striving for incremental reductions in cigarette toxicity through performance standards such as allowable maximums for nitrosamines, pesticide residues, arsenic, carbon monoxide, and other substances. Such

³¹ 21 C.F.R. §§ 1, 801 *et seq.* (2002); Jack E. Henningfield et al., *A Proposal To Develop Meaningful Labeling for Cigarettes*, 272 JAMA 312 (1994).

performance standards are unlikely to lead to safe and non-addictive cigarettes in the near future, but if they reduce disease prevalence and morbidity, their exploration is justifiable.

We are well aware of the potential unintended consequences of what we propose. For instance, non-smokers may initiate tobacco use under the mistaken impression that cigarettes have been made non-addictive, rather than merely less addictive. There is also the possibility that being a little bit addictive is no different than being a little bit pregnant. Such broad, population-based concerns should be at the forefront of the FDA's examination of whether regulatory powers should be used to make tobacco products less addictive.

IMPLICATIONS FOR OTHER TOBACCO PRODUCTS

Available data and documents indicate that it is also possible to reduce the addictiveness of smokeless tobacco products by setting ceiling levels on the use of buffering compounds. In addition, it is possible to determine product characteristics that are particularly appealing to and effective in establishing smokeless tobacco use among children. Such appealing designs and ingredients could be restricted.

Cigars and pipes pose a separate dilemma. It is important not to leave any category out of a regulatory framework lest we send the implicit message that there is less concern about that product category. However, the challenge is greater with cigars and pipes because there are far fewer data on these products.

IMPLICATIONS FOR LABELING AND ADVERTISING

The major tobacco companies do not label or advertise their tobacco products as addictive.³² This is a major flaw in the existing consumer warning system. There has been extensive theoretical discussion on how much nicotine would render a cigarette addictive. Until such values are empirically established, all tobacco products should include a strong addiction warning.³³

³² The fact that there is no regulatory barrier to such warnings has been demonstrated by several small companies, which provide some form of addiction warning on their tobacco products. See, e.g., Star Scientific, Inc., Stonewall™ brand snuff, at <http://www.starscientific.com>; Vector Tobacco, Omni™ cigarettes, at <http://www.omnicigs.com>.

³³ All nicotine-containing tobacco products should include a strong warning that they are addictive. Such warnings provide vitally important consumer information but should in no way relieve manufacturers of responsibility, or any accompanying legal liability, for creating and sustaining addiction among consumers.

As for how to appropriately label a cigarette with sub-biologically active levels of nicotine, we leave the question for another day. The challenges involved are extraordinarily complex; they comprise a whole other category of issues that require comprehensive regulatory oversight. For now, however, it bears mentioning that non-alcoholic beer typically contains small amounts of alcohol.³⁴ Similarly, "fat-free" foods may contain trace levels of fats but their labels may say that there is "not a significant source of calories from fat."³⁵ Perhaps a label such as "may promote nicotine addiction" should be considered for "nicotine-free" or "de-nicotinized" cigarettes, given the uncertainty of 1) what nicotine content might qualify as "nicotine-free" or "de-nicotinized," and 2) whether exempting "nicotine-free" or "de-nicotinized" cigarettes from bearing an addiction warning will actually lead to nicotine addiction through a graduation process.³⁶

CONCLUSION

Considering the extent to which determinants of addiction risk for cigarettes and other forms of tobacco are controllable, it is plausible that a regulatory approach can reduce the addiction risk of tobacco products. Regulation could reduce tobacco use and tobacco-caused disease without banning tobacco products and without rendering them nicotine-free. This approach is worth exploring, especially if it is simply not possible to make tobacco products substantially less toxic.

³⁴ Beer can be labeled as "non-alcoholic" if it contains less than 0.5% alcohol by volume, provided that the label includes the statement "contains less than 0.5 percent alcohol by volume." 27 C.F.R. § 7.71e (2002).

³⁵ "Fat-free" food contains less than 0.5 grams of fat per serving (considered a "trivial level" of fat). A 0-gram standard is analytically impossible to measure. *See* Food Labeling; General Requirements for Health Claims for Food, 58 Fed. Reg. 2478-2536 (Jan. 6, 1993) (to be codified at 21 C.F.R. pt. 101).

³⁶ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,887 (Aug. 28, 1996) (to be codified at 21 C.F.R. pt. 801).

Could Product Regulation Result in Less Hazardous Tobacco Products?

Matthew L. Myers*

In 1964, the first Report of the Surgeon General of the United States concluded that cigarette smoking caused, or contributed to, many serious diseases, including lung cancer. Public health efforts to reduce tobacco use have had substantial success, but today, almost one-quarter of all Americans smoke and more than four hundred thousand Americans die yearly from tobacco use. It is clear that current public health efforts must be expanded. Despite our best efforts, it is also likely that many Americans will continue to start smoking, while others will be unable or unwilling to quit. Therefore, it is appropriate to ask what, if anything, can be done to reduce the harm suffered by those who continue to use tobacco.

There is widespread agreement that cessation and prevention remain the best methods for reducing the toll of tobacco use. If some smokers cannot or will not quit, an additional strategy should at least be considered—one that focuses on whether tobacco products can be developed that significantly reduce the risk of disease. This seemingly simple strategy raises concerns that involve complex scientific, behavioral, ethical, and regulatory questions that fall into three broad categories:

1. *What is the impact on the individual?* Is it scientifically possible to develop a tobacco product that will significantly reduce the disease risk of smoking? Even if it is technically possible to produce less hazardous products, what must be done to promote the development of such products while protecting consumers against bogus or unproven health claims?
2. *What is the impact on the public?* If reduced-risk products can be developed, what will be the impact on efforts to discourage initial use or to encourage cessation? What if introducing a less hazardous tobacco product leads to a net negative impact on public health by removing a major motivation to quit smoking or by encouraging

* Matthew L. Myers is President of the Campaign for Tobacco-Free Kids.

people to start? Is it possible to create a situation—either through regulation or economic incentives—that maximizes the positive impact of the introduction of a less hazardous product while minimizing its negative impact? If not, what should be done?

3. *What are the effects on the marketplace?* There are two important considerations. First, what should be done to insure that the greatest incentives are provided for the development of the least dangerous substitutes for current tobacco products, including pharmaceutical products containing nicotine? Second, if it is technically possible to produce a tobacco product that would be widely used and less hazardous than products currently on the market, why not require all tobacco products to meet what would be an ever-improving safety standard? Rarely has discussion of the potential benefits of reduced-risk products also included a debate about whether, or under what circumstances, major technological safety advances should be applied to all tobacco products. Yet, it makes little sense to encourage the development of less hazardous products without considering how to maximize the number of smokers benefiting from them.

These issues are not new. Almost immediately after the release of the first Report of the Surgeon General, scientists began examining whether changes in tobacco products themselves could reduce their harm. As early as 1966, the Public Health Service concluded that “the lower the tar and nicotine content of cigarette smoke, the less harmful would be the effect.”¹

The tobacco industry had already discovered that promoting filtered cigarettes and low-tar cigarettes reassured concerned smokers and was good for business. As early as the 1950s, major cigarette manufacturers began widespread advertising of filtered cigarettes, with a variety of explicit and implicit health claims.² Despite a series of cases in the last half of the 1950s in which the Federal Trade Commission (FTC) challenged many of these health claims, cigarette manufacturers continued to advertise tar numbers. This advertising practice lasted until 1960, when the FTC issued guidelines proscribing such implicit health claims absent a standardized testing method.

With the release of the 1964 Report of the Surgeon General, the

¹ SURGEON GENERAL, U.S. DEP’T OF HEALTH & HUM. SERVS., *THE HEALTH CONSEQUENCES OF SMOKING: THE CHANGING CIGARETTE* at v (1981).

² NAT’L CANCER INST., U.S. DEP’T OF HEALTH & HUM. SERVS., *SMOKING AND TOBACCO CONTROL MONOGRAPH 7: THE FTC CIGARETTE TESTING METHOD FOR DETERMINING TAR, NICOTINE, AND CARBON MONOXIDE YIELDS OF U.S. CIGARETTES* at iii (1996).

interest of both the public health community and tobacco manufacturers in lower-tar cigarettes—potentially less hazardous tobacco products—increased significantly. After lengthy negotiations between the tobacco industry and the FTC, in 1967, the FTC approved a machine testing method that it concluded would provide uniform, standardized data about the tar and nicotine yield of mainstream cigarette smoke. However, even the FTC recognized that machine testing did not replicate actual human smoking.

Three years later, the FTC went one step further. In 1970, it started a rulemaking procedure to require tobacco companies to include machine-test ratings in their advertisements. The FTC subsequently dropped its rulemaking proceedings in favor of voluntary compliance by the major cigarette manufacturers. The introduction of the FTC testing method had an immediate effect. The sales-weighted average of tar and nicotine deliveries of cigarettes dropped dramatically in the following years. Additionally, the percentage of filter-tipped cigarettes rose and the percentage of smokers who used cigarettes with tar levels below 15 milligrams skyrocketed.

However, all these changes took place in the absence of any government regulation of tobacco products or their construction, and with minimal regulation of marketing. No public authority existed with the power to require that tobacco manufacturers disclose (1) the methods they used to alter their products to register lower test scores on the FTC machine, (2) what they added to their cigarettes, or (3) what they knew about consumer use of their products. There was no scientific or regulatory body with the authority to examine actual consumer exposure to the harmful substances in the newly designed tobacco products, or to monitor their health impact. Finally, no regulatory agency possessed the authority to restrain marketing claims that, though accurately reflecting FTC machine test scores, actually misled the public into thinking these products had been proven safer.

While the public health community was interested in newly designed products for their potential health benefit, internal tobacco industry documents indicate that the tobacco industry sold these products to keep people smoking.³ To accomplish this goal, the tobacco industry did not need to make products that were actually safer; it only needed to make products that would be perceived by the public as safer. According to its

³ M.E. Johnston, Philip Morris Companies, Inc., Special Report No. 248: Market Potential of a Health Cigarette 4, *at* <http://www.pmdocs.com/getallimg.asp?if=avpidx&DOCID=2040452500/2523> (June 1966).

own documents, that is exactly what it did.⁴

The results were not surprising. The introduction of the FTC testing method was a marketing bonanza for cigarette companies but an abysmal failure for those seeking to reduce the disease risks associated with smoking. Thirty-four years after the introduction of the FTC testing method, the National Cancer Institute (NCI) issued a report that was a devastating indictment of the effort to reduce the disease risks of tobacco products.⁵ The NCI reported that while cigarette design changed dramatically over the last fifty years in response to the FTC testing method, the disease risks of smoking did not.⁶ It also noted that many of the design changes made by tobacco manufacturers reduced tar and nicotine ratings on the FTC machine but did not alter the actual exposure of consumers to the harmful constituents of cigarette smoke.⁷ As a result, the NCI concluded:

[T]ar and nicotine measurements made by the FTC method for current cigarettes have little meaning for the smoker, either for how much he or she will receive from a given cigarette or for differences in the amount of tar and nicotine received when he or she smokes different brands of cigarettes.⁸

The NCI further concluded that the “[w]idespread adoption of lower yield cigarettes in the United States has not prevented the sustained increase in lung cancer among older smokers.”⁹ It added that “epidemiological and other scientific evidence . . . do[] not indicate a benefit to public health from changes in cigarette design and manufacturing over the last fifty years.”¹⁰ The NCI found that many smokers had switched to lower-yield cigarettes out of concern for their health, falsely believing the cigarettes to be less risky.¹¹ Some switched because they believed that lower-yield cigarettes would be a step towards quitting. The NCI report showed that those who switched instead of quitting paid a heavy price.

Recently, the NCI findings were reaffirmed by a report from the World

⁴ *Id.* at 2.

⁵ NAT'L CANCER INST., U.S. DEP'T OF HEALTH & HUM. SERVS., SMOKING AND TOBACCO CONTROL MONOGRAPH 13: RISKS ASSOCIATED WITH SMOKING CIGARETTES WITH LOW MACHINE-MEASURED YIELDS OF TAR AND NICOTINE (2001).

⁶ *Id.* at 1.

⁷ *See id.* at 1-11.

⁸ *Id.* at 1.

⁹ *Id.* at 10.

¹⁰ *Id.*

¹¹ *Id.* at 198.

Health Organization's Scientific Advisory Committee on Tobacco Product Regulation. This committee found:

It is now clear that the combination of compensatory changes in smoking patterns by smokers and cigarette design changes (particularly ventilation holes in filters) which increased the yield of smoke can restore the smoke delivery of the so-called low-yield cigarettes to that of full flavor cigarettes with much higher machine measured yields. However, as a consequence of the conventional format for conveying tar and nicotine information, the consumer believes that "low yield" cigarettes provide an alternative to smoking cessation. This belief persists even though it is now accepted that "low yield" cigarettes do not offer any proven health benefit in comparison to higher yield cigarettes.¹²

The "tar derby"¹³ of the last half of the twentieth century was just a warm-up for the next act by the tobacco industry. Increasing consumer concern about the health effects of traditional tobacco products, combined with growing skepticism about low-tar products, has led to an entirely new generation of tobacco products—often with more specific and more sophisticated claims implying that these products have been proven safer. For example, Vector Tobacco, Inc. claims that its product, Omni, is the "only cigarette to significantly reduce carcinogens that are among the major causes of lung cancer."¹⁴ Brown & Williamson Tobacco Corporation claims its cigarette, Advance, provides "All of the taste . . . Less of the toxins™."¹⁵ In marketing Advance, Brown & Williamson claims its TRIONIC filter and patented curing process significantly inhibit the formation of tobacco-specific nitrosamines.

This is the low-tar derby all over again. In the absence of government regulation, the manufacturers of this new generation of potentially reduced-harm products do not have to pre-clear these claims and do not have to scientifically substantiate claims. They also do not have to disclose how they make their products, how they allegedly reduce the levels of the advertised toxic substances, or what they add to these products in the manufacturing process. Moreover, they do not have to produce any evidence regarding actual human exposure or any human data that would

¹² SCIENTIFIC ADVISORY COMM. ON TOBACCO PROD. REGULATION, WORLD HEALTH ORG., CONCLUSIONS ON HEALTH CLAIMS DERIVED FROM ISO / FTC METHOD TO MEASURE CIGARETTE YIELD 1 (2002).

¹³ NAT'L CANCER INST., *supra* note 2, at iii.

¹⁴ Vector Tobacco, Inc., <http://www.omnicig.com/prodBenefits.asp> (last visited Dec. 17, 2002).

¹⁵ Brown & Williamson Tobacco Corp., <http://www.bw.com/apps/pdf/advanceonserts.pdf> (last visited Dec. 17, 2002).

justify their conclusion that their products actually reduce risk by reducing exposure to one or more toxic substances.

Is there any evidence that this new generation of tobacco products will actually result in risk reduction? A committee of the Institute of Medicine (IOM) examined this precise question.¹⁶ Its conclusions demonstrate how little progress we have made in developing a science base to support the search for verifiably less hazardous tobacco products.

1. There is little direct evidence available to serve as a basis for judgment as to the potential for harm reduction of specific new tobacco and pharmaceutical products.¹⁷
2. Although many components of tobacco are known to be toxic, little is known of the specific dose-response relations of the individual toxins as they occur in cigarette smoke or of the interactions between the constituents of tobacco smoke. There is little direct evidence that removal of specific substances from tobacco smoke or from tobacco actually reduces risk or harm to human health.¹⁸
3. In considering the health effects of modified tobacco products, it is important to remember that the health consequences of the use of any such product are determined not by the toxic agents removed from the product but by the actual exposure to the toxins that remain. Harm reduction is the net difference in harm between the products as actually used.¹⁹
4. No one knows the dose-response relations of, the specific toxins in, the pathogenic mechanisms of, or the interrelationship between the many components of tobacco smoke with enough precision to make scientifically reliable quantitative judgments about the risk or actual harm reduction associated with use of any tobacco product.²⁰
5. Since even the availability of harm reduction products may deter some from following the healthier course of abstinence or cessation, assessment of health claims should be based on an estimate of the

¹⁶ COMM. TO ASSESS THE SCI. BASE FOR TOBACCO HARM REDUCTION, INST. OF MED., CLEARING THE SMOKE (Kathleen Stratton et al. eds., 2001).

¹⁷ *Id.* at ix.

¹⁸ *Id.* at viii.

¹⁹ *Id.*

²⁰ *Id.* at ix.

effect of the product on the prevalence of smoking in the population, as well as the effect on the health risk to the individual smoker.²¹

Based on the reports of the IOM and the NCI, the lesson that should be learned from our prior experience is that in the absence of effective government regulation, harm reduction, based on the voluntary action of tobacco manufacturers, has been a failure. Further, absent government oversight, harm reduction is virtually certain to continue to fail for at least two reasons. First, the interest of tobacco manufacturers in selling their products is served by products that are perceived to be safe, even if they are not. Second, the public health community, on its own, lacks the resources to develop the science needed to assess which products offer the greatest potential for risk reduction, the ability to monitor product changes or the health impact of these products, and the authority to restrain how these products are marketed.

Nonetheless, neither the most recent report from the NCI nor the report from the IOM contradicts the original belief that a reduction in actual exposure to the harmful components of tobacco products will reduce risk. On the contrary, both agree that it is still reasonable to expect a relationship between the magnitude of exposure and the incidence of disease. Specifically, the IOM concludes that “[f]or many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible.”²²

For nearly forty years, scientists have believed it feasible to reduce the death toll from tobacco use by altering tobacco products. However, we have made little progress in accomplishing that goal and in developing the scientific and regulatory tools to do so. Harm reduction, as a public health strategy, is worth pursuing only if it is preceded by the adoption of a meaningful regulatory system under the United States Food and Drug Administration (FDA). The IOM agrees with the need for regulation, concluding that the regulation of all tobacco products, both conventional and potentially reduced-risk products, is necessary to assure a scientific basis for judging the effects of these products and to assure that the health of the public is protected.²³

Indeed, the success of a proposed harm reduction strategy depends upon adequate FDA authority to oversee its development. The FDA’s authority must include the following:

²¹ *Id.*

²² *Id.* at 5.

²³ *Id.* at 6.

1. Tobacco companies must be required to disclose how they make their products and what they put into them. They must be required to test, and disclose to the FDA, substances in mainstream and side-stream smoke and the quantities in which they are received and metabolized. They must also be required to disclose all internal research relevant to health considerations.
2. When tobacco companies make any change in the design or composition of a tobacco product, they must be required to disclose that information to the FDA as well as any additional information required to evaluate the potential impact of the change.
3. The FDA must have the authority to set performance standards for all tobacco products for the purpose of reducing the harms they cause. This should include authority to require the reduction or removal of a component of the product, or its smoke, that the agency has identified as a harmful or potentially harmful substance, when technology exists to do so. The FDA's authority to require the removal of such a substance should be based on the conclusion that its removal is best for public health, considering the impact on both the individual smoker and the public as a whole. However, once a substance has been identified as potentially harmful, the FDA should not bear the burden of proof that the substance's removal will reduce disease risk.
4. The FDA must have broad authority to set standards for the promotion of less hazardous tobacco products, recognizing that its overall goal must be to reduce harm to both individual smokers and the population at large. The FDA's consideration of whether a product may be promoted as less hazardous must be based on the best available scientific assessment of actual risk and not just exposure, except where there is a scientific basis for correlating specific exposure with risk. The FDA's assessment of the product is just the starting point. The assessment must also examine actual exposure based on how the product will be used, who will use the product, and why. It should also consider the product's likely impact on smoking cessation and initiation. Therefore, the FDA's authority must extend to the marketing of these products and post-market surveillance, enabling the FDA to periodically reevaluate the actual impact of a product.
5. The FDA must have resources to develop the science base to effectively

evaluate different tobacco products and assess the behavioral impact of different marketing tools and claims. Harm reduction, as a strategy involving tobacco products, should not take place in isolation from either the FDA's consideration of the potential role of non-tobacco pharmaceutical products for smokers who cannot or choose not to quit, or its authority to set standards for all tobacco products. At present, pharmaceutical products containing nicotine have been approved for use exclusively as cessation tools. The potential for these products as long-term substitutes for tobacco users who cannot or will not quit has not been explored, despite the fact that these products have already met rigorous safety standards for short-term use. Similarly, if a harm reduction strategy leads to the introduction of less hazardous tobacco products that become widely used by consumers, the FDA should have the authority to require that all tobacco products meet its safety standards.

Until now, the debate about whether or not tobacco products can be made less hazardous and whether or not harm reduction is a legitimate public health strategy has taken place in an unregulated environment. If the goal is saving lives, harm reduction in the absence of regulation should be rejected as a public health strategy. Science continues to suggest that it is possible both to reduce the harm of tobacco products and to use harm reduction to reduce the death toll from tobacco use—if and only if the FDA is given broad, meaningful authority over both conventional and new tobacco products.

DEVELOPMENTS AND TRENDS IN THE LAW

Question:

How are states regulating smoking in public places?

Prompted in part by a 1993 Environmental Protection Agency report placing secondhand smoke in the same category as asbestos and other environmental toxins, many states have enacted laws prohibiting smoking in public places. The following Commentary by Connecticut Attorney General Richard Blumenthal examines tobacco regulation from a state perspective. A survey of state statutory and case law on smoking in public places follows the Commentary, with statutes grouped according to the type of public place in question. Laws that generally address smoking in public places are listed under the heading "Public Places." Particularized statutes that govern smoking in specific environments are listed under their own respective categories.

Tobacco Control: A State Perspective

Richard Blumenthal, J.D. *

Although the November 1998 Master Settlement Agreement (MSA) was a victory for anti-tobacco forces, it left Big Tobacco unvanquished, shifting the battleground to individual states like Connecticut. Since 1998, I have focused my efforts in Connecticut on the key goals of preventing youths from starting to smoke, protecting non-smokers from the dangers of secondhand smoke, and treating tobacco addiction. The obstacles to these goals are no less frustrating and dismaying than before the MSA, however, with progress impeded by the enormous political and economic power of Big Tobacco.

A major frustration has been Connecticut's failure to use the \$3.6 billion tobacco settlement—with \$500 million already paid to the state—to fight tobacco. Our intent in suing Big Tobacco and creating the settlement was to use Big Tobacco's own money to fight tobacco through outreach and education that would stop children from beginning to smoke and through cessation programs and other treatment for people of all ages who are addicted to nicotine. Connecticut is virtually last among states in using settlement money to advance vital public health goals. Furthermore, the average age that people in Connecticut begin smoking is eleven, with sixty more children starting to smoke every day.

Our fight against secondhand smoke dates back to at least 1993. In that year, the Connecticut legislature banned smoking in municipal and state-owned buildings, grocery stores, and hospitals.¹ In spite of the compelling evidence regarding the dangers of secondhand smoke, the legislature attached a major limitation at the tobacco lobby's behest. Specifically, the legislature prohibited municipalities from regulating smoking in other public places, such as restaurants and bars. This preemption of local laws has been an obstacle to further progress against tobacco for almost ten years.

We now know that this preemption was a key element of Big Tobacco's strategy throughout the United States in the early to mid-1990s.² Big

* Richard Blumenthal is the Attorney General of Connecticut.

¹ See CONN. GEN. STAT. § 19a-342 (2002).

² See ROBIN HOBART, AM. MED. ASS'N, PREEMPTION: TAKING THE LOCAL OUT OF TOBACCO

Tobacco concluded that its best chance to fight the anti-tobacco movement was to ensure that the only legislative arena where legislation could be passed that would restrict smoking was at the state level, where Big Tobacco enjoys superior access and a strong track record of success.

In addition, and quite unfortunately, some restaurant and bar owners have supported this preemption of local regulation. Although these owners and their employees have much to gain from smoke-free workplaces, they fear business will drop if smoking is banned in their establishments. Furthermore, Big Tobacco has a long history of funding and supporting restaurant associations and other trade groups who oppose smoke-free legislation. While the owners' fears are understandable, they are in fact unjustified. Numerous studies confirm that no-smoking laws do not hurt revenues of restaurants and bars.³ In fact, there appears to be no objective evidence that these laws harm businesses. There is evidence, moreover, that smoke-free workplaces result in fewer work-related injury claims and fewer sick days.

In the face of this continuing and dismaying opposition to this basic public health measure, I have been proud to be a leader in a broad-based statewide coalition—Mobilize Against Tobacco for Children's Health (MATCH). MATCH's membership now includes 120 organizations, including the American Heart Association, the American Lung Association, the American Cancer Society, the American Academy of Pediatrics, the Connecticut Parent Teacher Association, the Connecticut Association of Directors of Health, major hospitals, and many others.

With MATCH in a leadership role, and with the strong support of the elected officials of many municipalities, we have continued the fight to end state preemption of local no-smoking ordinances—and we have made progress. Currently, more than one hundred of the 169 top, elected municipal officials in Connecticut support allowing towns to regulate exposure to secondhand smoke. In 2001, for the first time, the state Senate passed a bill to end preemption. Unfortunately, the leadership of Connecticut's House of Representatives did not put the bill to a vote in either 2001 or 2002, even though a majority of the House membership had indicated their support of the legislation. The fight will continue, but public health continues to suffer defeat by the power of Big Tobacco and legislative inertia.

CONTROL 5 (2002), *available at* http://www.ama-assn.org/ama/upload/mm/375/preemption_guide.pdf.

³ See CAMPAIGN FOR TOBACCO-FREE KIDS, SMOKE FREE RESTAURANT AND BAR LAWS DO NOT HARM BUSINESS (2001), *available at* <http://www.tobaccofreekids.org/research/factsheets/pdf/0144.pdf>.

In the key area of preventing smoking initiation by young people, we have been active on many fronts. There is strong evidence that people who do not start smoking as children probably never will. Of course, people who become addicted as children are rarely able to quit without help, and they and society suffer the severe health consequences. Children smoke largely because they are targeted by industry advertising and marketing. While this targeting may be increasingly subtle, its effectiveness is obvious in the appalling numbers of children who start smoking each year.

I expect that Connecticut will continue to join with other concerned states in bringing legal actions to fight tobacco advertising aimed at children. One recent important victory in this area was a decision by a superior court in California.⁴ In that case, Connecticut joined California and several other states in challenging cigarette advertising by R.J. Reynolds (RJR) that was placed in magazines that targeted young people. The plaintiffs alleged that RJR was violating a key provision of the 1998 MSA between the major tobacco manufacturers and forty-six states. The MSA states that one of its primary objectives is “to reduce Youth smoking,”⁵ and it provides that no signatory manufacturer “may take any action, directly or indirectly, to target Youth.”⁶ “Youth” is defined as those under the age of eighteen,⁷ the lowest minimum legal age for the purchase of cigarettes in the United States.

In his decision, Judge Ronald Prager concluded that RJR indirectly targeted youth in its print advertising program. Specifically, he ruled:

The evidence reveals that after it entered into the MSA, RJR made absolutely no changes to its advertising campaigns, failed to include the goal of reducing Youth exposure to tobacco advertising in its marketing plans and failed to take any actions to track whether or not it was meeting its professed goal of reducing Youth smoking. Further, while RJR made some changes to its marketing strategies in subsequent years, the changes were minimal and had little, if any, impact in reducing Youth exposure to its tobacco advertising. As a result, since the MSA was signed, RJR has exposed Youth to its tobacco advertising at levels very similar to those of targeted groups of adult smokers.⁸

The court penalized RJR in the amount of \$20 million, plus attorneys’

⁴ *People ex rel. Lockyer v. R.J. Reynolds Tobacco Co.*, No. GIC 764118, 2002 WL 1292994 (Cal. Super. Ct. June 6, 2002).

⁵ Master Settlement Agreement 2 (1998), *available at* <http://www.naag.org/issues/tobacco/index.php?smod=919>.

⁶ *Id.* at 15.

⁷ *Id.* at 13.

⁸ *R.J. Reynolds*, 2002 WL 1292994, at *1.

fees, and ordered it to take steps to measurably demonstrate that it had significantly reduced youth exposure to its print advertising. This case is a major success for everyone concerned about youth smoking, and Connecticut is prepared to join other states in similar efforts if evidence of illegal practices by tobacco manufacturers is found.

Last session, our legislature raised the state cigarette tax by fifty cents per pack, to a total of \$1.11 per pack. This tax increase should not only boost state revenues, but also cause a demonstrable decrease in smoking, especially among youth. In fact, according to the American Lung Association, "[t]here is general consensus among tobacco researchers that every 10 percent increase in the price of cigarettes decreases cigarette consumption by 4 percent in adults and by 7 percent in children."⁹

However, higher taxes do not address a growing problem—increasing sales through mail order of cigarettes and tobacco products, especially over the Internet. These sales raise two profound concerns: uncontrolled youth access and evasion of state taxes. The access problem is obvious—many children have easy access to the Internet, and our investigations with the Connecticut Department of Revenue Services and the National Association of Attorneys General have shown that Internet tobacco sales outlets almost never make a meaningful effort to enforce age restrictions. In addition, these outlets generally neither sell properly taxed cigarettes nor properly report their sales to state taxing authorities. While it is unclear how many children are ordering cigarettes over the Internet, we know anecdotally how easily kids can purchase them. We also know that some illegal bulk Internet purchasers have made their untaxed purchases for the purpose of illegal resale, and those persons are likely to be just as willing to sell to minors as they are to break other laws.

My office has created a task force with the state's Department of Revenue Services to attack this important problem. I am prepared to take whatever legal steps are necessary to see that these out-of-state operations do not continue to evade our laws. I will support broad congressional action to clamp down on illegal tobacco sales because this is clearly a national problem. Meanwhile, I have already begun to work with parcel delivery businesses that may be delivering untaxed cigarettes into our state to remind them of their legal obligations. I expect to receive their cooperation, but I will take legal action against both sellers and carriers if necessary.

Connecticut is also making progress in other ways in its continuing

⁹ AM. LUNG ASS'N, STATE LEGISLATIVE ACTIONS ON TOBACCO ISSUES: MIDTERM UPDATE 2 (Aug. 2002) (citing J. TAURAS ET AL., *IMPACTEEN*, EFFECTS OF PRICE AND ACCESS LAWS ON TEENAGE SMOKING INITIATION: A NATIONAL LONGITUDINAL ANALYSIS (2001)).

efforts to reduce children's access to tobacco. After lengthy negotiations and working with other states, Connecticut reached landmark agreements with certain major tobacco retailers, including ExxonMobil, Walgreens, and BPAmoco. Each of these businesses has agreed to take extensive voluntary steps to reduce the risk of tobacco sales to minors. All of these businesses will ban self-service tobacco displays, limit in-store advertising, and provide clear and clearly enforced rules for all staff about underage tobacco sales. These rules include clear instructions to every employee to require proof of age for all tobacco purchasers who appear to be under age twenty-seven, as well as clear disciplinary policies for violations. Perhaps most importantly, these businesses have agreed to institute compliance programs to continually test the efficacy of these policies by hiring independent companies to make unannounced visits to test compliance at all stores. These businesses have also agreed to take action against employees and managers who are not properly enforcing the law and company policy. These programs should be a significant step forward in reducing youth access to tobacco, and I will continue to press for similar agreements with other retailers.

In contrast to this progress, Connecticut's record of spending funds from the MSA has been abysmal. A national report from the Campaign for Tobacco-Free Kids ranked Connecticut forty-fifth out of fifty states and the District of Columbia in using this money to protect children from tobacco addiction and disease.¹⁰ The report also gave Connecticut the dubious distinction of being "by far the worst state in New England in funding tobacco prevention."¹¹ In addition, the report lists Connecticut as one of the ten most disappointing states of 2001 in its allocation of funds for tobacco prevention and cessation programs.¹²

As of January 2003, Connecticut has received approximately \$534 million in tobacco settlement funds, averaging over \$133 million per year. The 2002-2003 budget recently approved by the Legislature and signed by the Governor, however, provides a total of barely \$125,000 for tobacco prevention, a reduction from \$1 million in 2001 and \$4 million in 2000.¹³ In contrast, the Centers for Disease Control and Prevention (CDC) recommends that effective annual tobacco control spending for

¹⁰ CAMPAIGN FOR TOBACCO-FREE KIDS ET AL., SHOW US THE MONEY: AN UPDATE ON THE STATES' ALLOCATION OF THE TOBACCO SETTLEMENT DOLLARS vi (2002), *available at* <http://www.tobaccofreekids.org/reports/settlements/2002/fullreport.pdf>.

¹¹ *Id.*

¹² *Id.*

¹³ 2003 Conn. Pub. Acts. 03-02 §§ 1, 4.

Connecticut be in the range of \$21 to \$54 million.¹⁴ The continued failure of Connecticut's governor and legislature to spend any significant portion of the tobacco settlement for its intended purpose—tobacco control and prevention—has been extremely disappointing for anti-tobacco forces.

Finally, the states alone will never be able to accomplish all that needs to be done. Not only are they often outgunned and outspent by Big Tobacco's billions, but federal law places grave limitations on their ability to act. Two disturbing decisions of the U.S. Supreme Court make clear that Congress must act to create fully effective tobacco control. In 2000, the Supreme Court ruled, 5-4, that the Food and Drug Administration (FDA) could not regulate cigarettes and most other tobacco products as nicotine delivery devices, even though that is precisely what they are.¹⁵ This setback was important because the FDA had begun to move aggressively to fine tobacco retailers who sold to minors and had developed anti-tobacco advertising to discourage children from smoking. In 2001, the Court ruled that the Federal Cigarette Labeling and Advertising Act, which provides for mandatory health warnings for cigarette packaging and advertising, preempts similar state regulations and bars many state cigarette advertising restrictions.¹⁶

In sum, the Supreme Court has concluded that Congress has barred both the FDA and the states from significant aspects of tobacco control. Only Congress can correct this situation, and all legislators should act to protect our citizens from the deadly and preventable scourge of tobacco addiction and death. Recent achievements offer hope of additional success if we are as relentless and tireless as Big Tobacco has been against us.

¹⁴ CAMPAIGN FOR TOBACCO-FREE KIDS ET AL., *supra* note 10, at 8.

¹⁵ Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

¹⁶ Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001).

Synopsis of State Case and Statutory Law

The *Journal's* Editorial Staff

ALABAMA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

No statutes dealing with the regulation of smoking in public places were found.

ALASKA

Case Law

Univ. of Alaska v. Univ. of Alaska Classified Employees Ass'n, 952 P.2d 1182 (Alaska 1998): The Supreme Court of Alaska held that university employees had contractually waived their right to bargain collectively for a smoking policy by accepting a collective bargaining agreement.

Statutes

Public Places

ALASKA STAT. § 18.35.300 (Michie 2002): Smoking is prohibited in the following places except as allowed under ALASKA STAT. § 18.35.310: a public transportation vehicle or a waiting, baggage, or boarding area for such vehicle; a place of employment, building, or other structure owned, leased, or operated by the state or a political subdivision of the state; any public or private postsecondary educational institution or adult day care facility; a courtroom or jury room; any room under the control of a state house of legislature when a public or private meeting or assembly is not in progress; a nursing home, rest home, residential health care institution, or any public or private office that mainly offers mental health services; a food service establishment with a seating capacity of at least fifty persons; a grocery store or a store primarily for the retail sale of food products; any place of employment where the owner or other person who controls the premises has posted a sign stating that smoking is prohibited by law; a correctional

facility; and a Pioneers' Home.

ALASKA STAT. § 18.35.305 (Michie 2002): Smoking is prohibited in public or private elementary and secondary schools, preschools, and child day care facilities. For private homes serving as schools or day care facilities, the prohibition applies during the hours of and in the rooms used for schooling or day care. The prohibition does not apply to a properly ventilated smoking area that complies with a collective bargaining agreement and is not accessible to minors. Smoking is also prohibited in rooms or other areas under control of the state or a political subdivision thereof while a public meeting or assembly is in progress; in offices where dental care, health care, or the healing arts are practiced; in public or private laboratories associated with and located in such offices; in public and private hospitals; in other non-residential health care facilities except for a public or private office that mainly offers mental health services; and in elevators.

ALASKA STAT. § 18.35.320 (Michie 2002): A person in charge of a place in ALASKA STAT. § 18.35.300, with the exception of a taxi or limousine for hire and an elevator, may designate portions of the place for smoking. Such person shall make reasonable accommodations to protect the health of non-smokers. A smoking section may not be designated for students in or on the grounds of an elementary or secondary school. The person who chairs the Rules Committee in a house of legislature is responsible for designating smoking sections in areas under the control of the house.

ALASKA STAT. § 18.35.310 (Michie 2002): The prohibitions in ALASKA STAT. § 18.35.300 do not apply to a part of a place or vehicle designated for smoking under ALASKA STAT. § 18.35.320, or to a limousine for hire or taxi if the driver and all passengers consent to smoking. The prohibitions on smoking in ALASKA STAT. §§ 18.35.300-18.35.305 do not apply to smoking on stage as part of a theatrical performance.

ARIZONA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

ARIZ. REV. STAT. § 36-601.01 (2002): Smoking is prohibited in the following public spaces: elevators, health care facilities, indoor theaters, libraries, art museums, lecture halls, concert halls, and buses used by the public. Smoking is permitted in these places if it is confined to areas designated and posted as smoking areas.

Schools

ARIZ. REV. STAT. § 36-798.03 (2002): Tobacco products are prohibited on school grounds, inside school buildings, on school parking lots or playing fields, in school buses or vehicles, and at off-campus, school-sponsored events. The prohibition does not apply to an adult who uses tobacco products as a necessary component of a school-sanctioned tobacco prevention program.

State Buildings

ARIZ. REV. STAT. § 36-601.02 (2002): Smoking is prohibited in any building owned or directly leased by the state. The following persons are exempt from the prohibition: patients receiving treatment at state hospitals; inmates in correctional facilities; persons residing in residential facilities owned or leased by the state; and persons using tobacco products for religious or ceremonial purposes.

ARKANSAS

Case Law

No cases dealing with the regulation of smoking in public places were found.

*Statutes**Public Places*

ARK. CODE ANN. § 20-27-703 (Michie 2002): Smoking is prohibited in a doctor's or dentist's waiting room, in hospital corridors, in nurses' stations in hospitals and clinics, in all hospital rooms except private patient rooms, and in school buses. However, smoking is not prohibited in these areas if the smoking is limited to areas designated as smoking areas. Hotels, motels, and restaurants are excluded from prohibitions on public smoking.

Child Care Facilities

ARK. CODE ANN. § 20-78-217 (Michie 2002): Smoking is banned within the physical confines of licensed day care centers.

Schools

ARK. CODE ANN. § 6-21-609 (Michie 2002): Smoking is prohibited in or on any property owned or leased by a public school district, including school buses.

State Buildings

ARK. CODE ANN. § 22-3-220 (Michie 2002): Smoking is prohibited in the state capitol building.

ARK. CODE ANN. § 25-1-102 (Michie 2002): The chief administrative officer of each state agency, commission, board, office, department, or other authority of the state shall promulgate a smoking policy for the general office space of the state agency. The policy shall take into consideration the rights of both non-smokers and smokers.

CALIFORNIA

Case Law

City of San Jose v. Dep't of Health Servs., 66 Cal. App. 4th 35 (Cal. Ct. App. 1998): San Jose argued that no provision of state law preempted enforcement of its smoking ordinance at long-term health care facilities licensed by the California Department of Health Services. The court ruled that smoking ordinances are not preempted by the Department's rules and regulations allowing smoking in enclosed areas since CAL. HEALTH & SAFETY CODE § 118910 does not proclaim an intent to preempt local governments from regulating smoking and even expressly authorizes local governments to ban smoking completely in any manner not inconsistent with law.

Statutes*Public Places*

CAL. LAB. CODE § 6404.5 (Deering 2002): Smoking is prohibited in an enclosed space at a place of employment. Exceptions include the following: sixty-five percent of the guest rooms in a transient lodging establishment (hotel or motel); areas of a transient lodging establishment lobby designated for smoking by the establishment; meeting and banquet rooms in a transient lodging establishment while no food or beverage service is being provided and where no exhibition is occurring; tobacco shops; motor trucks cabs, where only smoking employees are present; warehouse facilities; theatrical production sites where smoking is an integral part of the show; medical facilities where smoking is integral to the research or treatment being conducted; private residences, except when in use as licensed family day care centers; patient smoking areas in long-term care facilities; and ventilated break rooms designated by employers for smoking. Employers with a total of five or fewer employees, either full-time or part-time, may permit smoking where all of the following conditions are met: the smoking area is not accessible to minors; all employees who enter the smoking area consent to permitting smoking; and air from the smoking area is exhausted directly to the outside.

Child Care Facilities

CAL. HEALTH & SAFETY CODE § 1596.795 (Deering 2002): Smoking is prohibited in private residences licensed as family day care homes during the hours of operation as family day care homes and in those areas of the home where children are present. Smoking is prohibited on the premises of a licensed day care center.

Child Recreation Areas

CAL. HEALTH & SAFETY CODE § 104495 (Deering 2002): Smoking is prohibited in public playgrounds and children's sandboxes.

Health Care Facilities

CAL. HEALTH & SAFETY CODE § 1286 (Deering 2002): Smoking is prohibited in patient care areas, waiting rooms, and visiting rooms. A patient room may be designated as smoking if all persons assigned to such room have requested a room where smoking is permitted. The prohibition does not apply to skilled nursing facilities and intermediate care facilities.

Public Transportation

CAL. HEALTH & SAFETY CODE § 118925 (Deering 2002): Smoking is prohibited in any vehicle of a passenger stage corporation or entity receiving any transit assistance from the state, and in any Amtrak vehicle or aircraft except to the extent permitted by federal law.

CAL. HEALTH & SAFETY CODE § 118935 (Deering 2002): At least seventy-five percent of any waiting area for public transportation must be designated as non-smoking.

Schools

CAL. EDUC. CODE § 48901 (Deering 2002): No school may permit student use of any product containing tobacco or nicotine while the students are on campus, attending school-sponsored activities, or under the supervision and control of school district employees.

State Buildings

CAL. GOV'T CODE § 19994.31 (Deering 2002): Smoking is prohibited inside state buildings and passenger vehicles and within five feet of main entrances and exits to state buildings.

Local Power to Restrict Smoking

CAL. HEALTH & SAFETY CODE § 118910 (Deering 2002): State law does not preempt local laws imposing tighter restrictions on smoking.

COLORADO

Case Law

Elliott v. Bd. of Weld County Comm'rs, 796 P.2d 71 (Colo. Ct. App. 1990): The Board of Weld County Commissioners passed a resolution prohibiting smoking in all county buildings. Plaintiffs, prisoners in the county jail, argued that they had a liberty and property right to smoke under a state statute requiring public facilities to provide a smoking area. The court found that COLO. REV. STAT. § 25-14-105 authorizes counties to regulate smoking in public places and that other state statutes do not require the provision of smoking areas in public places.

*Statutes**Public Places*

COLO. REV. STAT. § 25-14-103(1) (2002): Smoking is prohibited in the following public places: elevators, museums, galleries, and libraries; waiting rooms and meeting rooms owned or operated by the executive and judicial branches of the state; any building used for the public exhibition of motion pictures, stage dramas, lectures, musical recitals, or other such performances; any sporting arena, except in a lobby reasonably separated from the spectator area; certain designated seating areas of motion picture theaters with adequate ventilation; public transportation vehicles when open to the public except in designated smoking areas; and hospital elevators, corridors, and areas where combustible supplies or flammable substances are stored or are in use. Additionally, hospitals must allow patients to choose a non-smoking room and accommodate such choice when possible; prohibit employees from smoking in patient rooms; and require that visitors obtain express approval from all patients before smoking in a patient room. Hospitals may also prohibit smoking on all or part of their premises.

COLO. REV. STAT. § 25-14-104 (2002): The owner or manager of a public place not specified in COLO. REV. STAT. § 25-14-103(1) may post signs that either prohibit smoking or provide smoking and non-smoking areas.

Restaurants

COLO. REV. STAT. § 25-14-103(2) (2002): Restaurants and taverns are encouraged to seat non-smokers in areas separate from smokers. Any public place where food is sold or served that does not designate smoking and non-smoking areas is required to post a conspicuous sign at its entrance indicating whether or not provisions have been made for non-smokers.

Schools

COLO. REV. STAT. § 25-14-103.5 (2002): Smoking and the use of tobacco products are prohibited in and around school property, which includes school buildings, school grounds, and all vehicles used for the purpose of transporting students, workers, visitors, or any other persons. The prohibition applies to public nursery schools, day care centers, child care facilities, head start programs, kindergarten, elementary, and secondary schools through grade twelve, and all students, staff, faculty, and visitors.

State Buildings

COLO. REV. STAT. § 25-14-103.7 (2002): Smoking is prohibited in all state legislative buildings. A legislative building is any building owned or operated by the legislative branch, except that a legislative council or its designee may designate smoking areas in legislative buildings and shall establish a smoking policy for office space within legislative buildings.

COLO. REV. STAT. § 2-2-404(1.5) (2002): The Senate and the House of

Representatives each has the exclusive authority to adopt rules governing smoking in their respective chambers, antechambers, committee rooms, and legislators' office space.

Workplace

COLO. REV. STAT. § 25-14-103(4) (2002): Persons in charge of offices and commercial establishments that employ the general public are encouraged to designate physically separate non-smoking areas in working environments, including employee lounges and cafeterias.

Local Power To Restrict Smoking

COLO. REV. STAT. § 25-14-105 (2002): Local governments can adopt ordinances that regulate smoking. Such regulations shall control in case of any inconsistency with state statutes.

CONNECTICUT

Case Law

Local 1186 v. Bd. of Labor Relations, 620 A.2d 766 (Conn. 1993): The Connecticut Board of Labor Relations dismissed an union's complaint regarding a school board's unilateral imposition of a smoke-free policy. The court held that the school board must negotiate with school employees if its smoke-free policy has a substantial secondary impact on employee working conditions. Whether a smoking ban has a substantial secondary impact is a factual matter that must be decided on a case-by-case basis. The school board's policy exceeded the bounds of CONN. GEN. STAT. ANN. § 19a-342(b), which prohibits smoking in a public school only while school is in session or student activities are being conducted.

Statutes

Public Places

CONN. GEN. STAT. ANN. § 19a-342(b) (West 2002): Smoking is prohibited in any building owned or leased and operated by the state except in smoking areas; in any area of a health care institution other than a smoking area, provided that the smoking area is not the institution's only waiting area; in any area of a retail food store open to the general public; in any public area of a restaurant having a seating capacity of seventy-five or more persons unless a sign is posted indicating smoking is permitted in such area (provided that no such restaurant shall be designated, in its entirety, as a smoking area, that smoking may be prohibited in rooms used for private social functions, and that a sign is posted at the entrance of the restaurant indicating the availability of non-smoking areas); notwithstanding CONN. GEN. STAT. ANN. § 31-40q, within a public school building while school is in session or student activities are being conducted; and in any passenger elevator.

The prohibition does not apply to correctional facilities, dormitory rooms in any public institution of higher education, psychiatric facilities, public housing projects, or classrooms where demonstration smoking is taking place as part of a medical or scientific experiment or lesson.

Child Care Facilities

CONN. AGENCIES REGS. § 19a-79-7a(d)(9) (2002): Smoking is prohibited in all child care centers or group day care homes and outdoor areas. The prohibition does not apply to designated smoking areas, provided these areas are separate, properly ventilated, and secluded from any children present at the facility.

Public Transportation

CONN. GEN. STAT. ANN. § 53-198 (West 2002): Smoking is prohibited while traveling upon or operating a public bus, railroad car, or school bus. The prohibition does not apply to any special bus or to any part of a regular bus or passenger railroad car designated for smoking.

Workplace

CONN. GEN. STAT. ANN. § 31-40q(b) (West 2002): An employer may designate an entire business facility as a non-smoking area. In each business facility where smoking is permitted, an employer shall establish non-smoking work areas sufficient to accommodate non-smokers. In areas within a business facility where smoking is permitted, existing physical barriers and ventilation systems shall be used to the extent practicable to minimize the effect of smoking in adjacent non-smoking areas.

DELAWARE

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

DEL. CODE ANN. tit. 16, § 2903 (2002): Smoking is prohibited in any indoor enclosed area to which the general public is invited or in which the general public is permitted, including but not limited to public meetings; elevators; government-owned or government-operated buses, vans, trains, taxicabs, and limousines; grocery stores; gymnasiums; jury waiting and deliberation rooms; courtrooms; child day care facilities; health care facilities including hospitals, health care clinics, doctor's offices, or other care-related facilities; any workplace not exempted; restrooms, lobbies, reception areas, hallways, and other common-use areas; restaurants; public gaming facilities; indoor sports arenas; lobbies, hallways, and other common areas in apartment buildings, condominiums, and other

multiple-unit residential facilities; lobbies; hallways, and other common areas in hotels and motels, and in no less than seventy-five percent of the sleeping quarters within a hotel or motel that are rented to guests; bowling alleys and billiard or pool halls; retirement facilities and nursing homes, not including any private residence; public buildings; auditoria, theaters, museums, and libraries; public schools, non-public schools, and other educational and vocational institutions; and motorsports speedways, taverns, or taprooms.

DEL. CODE ANN. tit. 16, § 2904 (2002): The prohibitions in DEL. CODE ANN. tit. 16, § 2903 do not apply to private homes, residences, or automobiles (unless such homes or residences are being used for child care or day care, or unless such automobiles are being used for the public transportation of children or as part of health care or day care transportation); any indoor area where private social functions are being held when seating arrangements are under the control of the function's sponsor and not the owner or manager of the area; limousines under private hire; a hotel or motel room rented to one or more guests provided that the total percentage of such rooms is less than twenty-five percent of the hotel or motel; or any fundraising activity or function sponsored by a volunteer fire, ambulance, or rescue company or fraternal benefit society, so long as the activity or function takes place upon property owned or leased by the sponsoring organization.

Public Transportation

DEL. CODE ANN. tit. 11, § 1330 (2002): Smoking in any trackless trolley coach or public bus is prohibited.

State Buildings

DEL. CODE ANN. tit. 16, § 2902 (2002): A public building is any building owned or operated by the state, including the legislative, executive, and judicial branches of state government; any county, city, town, village, or any other political subdivision of the state, public improvement or special district, public authority, commission, agency, or public benefit corporation; or any other separate corporate instrumentality or unit of state or local government. A public meeting is any meeting open to the public pursuant to the laws of Delaware and its political subdivisions.

DISTRICT OF COLUMBIA

Case Law

No cases dealing with the regulation of smoking in public places were found.

*Statutes**Public Places*

D.C. CODE ANN. § 7-1703 (2002): Smoking is prohibited in any elevator, except in a single-family dwelling; any public selling area of a retail store, except a tobacco shop; any public assembly or hearing room which is owned or leased by the District of Columbia government, except the District of Columbia National Guard Armory and the Robert F. Kennedy Memorial Stadium; any educational facility; when transporting passengers within the corporate limits of the District of Columbia, any passenger vehicle owned or operated by the District of Columbia or any passenger vehicle for hire except in a limousine where all occupants have consented; and any area of a health care facility frequented by the general public, although the operator of a health care facility may designate separate smoking areas. Additionally, when a health care facility allows patients to smoke in bed space areas, it shall make a reasonable effort to determine each patient's smoking preference and assign patients to a bed space area with other patients who have similar smoking preferences. Smoking is also prohibited in any restaurant except as permitted by D.C. CODE ANN. § 7-1703.01, and in any public or private workplace, except as provided in D.C. CODE ANN. § 7-1703.02.

D.C. CODE ANN. § 7-1708 (2002): Smoking is allowed in a tobacco shop, a theatrical performance where smoking is part of the performance, a tavern or nightclub, and a room or hall used for private social functions.

Public Transportation

D.C. CODE ANN. § 35-251(b)(1) (2002): It is unlawful for a person to smoke aboard a public passenger vehicle seating at least twelve passengers, including vehicles owned or operated by the Washington Metropolitan Transit Authority, that is transporting passengers within the District of Columbia; aboard a rail transit car owned or operated by the Washington Metropolitan Transit Authority that is transporting passengers within the District of Columbia; or while within a rail transit station owned or operated by the Washington Metropolitan Transit Authority and located within the District of Columbia.

Restaurants

D.C. CODE ANN. § 7-1703.01 (2002): The owner, manager, or person in charge of any restaurant having a seating capacity of fifty or more must designate at least twenty-five percent of the total seating capacity as non-smoking. Bar and lounge areas are excluded from the total seating capacity calculation. Any new construction for the purpose of establishing a restaurant or major renovation to an existing restaurant with a seating capacity of fifty or more must have a non-smoking area that is at least fifty percent of the total seating capacity.

Workplace

D.C. CODE ANN. § 7-1703.02 (2002): Private and public employers in the

District of Columbia must adopt, implement, and maintain a written smoking policy that includes an area where smoking is permitted. Physical barriers or a separate room shall be used to minimize smoke dissemination to non-smoking areas. The designation of a smoking area is a subject of collective bargaining.

FLORIDA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

FLA. STAT. chs. 386.203, 386.204 (2002): Smoking is prohibited at public meetings and in public places except in designated smoking areas. Public places include government buildings; public means of mass transportation and their associated terminals when these places are subject only to state smoking regulations; elevators; educational facilities; public school buses; libraries; courtrooms; jury waiting and deliberation rooms; museums; theaters; auditoriums; arenas; recreational facilities; restaurants; retail stores, except where the primary business is the sale of tobacco or tobacco-related products; grocery stores; places of employment; health care facilities, except as provided in FLA. STAT. ch. 386.205; day care centers; and common areas of retirement homes and condominiums. Smoking is permitted when an entire room or hall is used for a private function, and seating arrangements are under the control of the function sponsor.

FLA. STAT. ch. 386.205 (2002): The person in charge of a public space may designate smoking areas. However, smoking areas may not be designated in elevators, school buses, public means of mass transportation subject only to state smoking regulations, restrooms, hospitals, doctors' or dentists' waiting rooms, jury deliberation rooms, county health departments, day care centers, schools or other educational facilities, or common areas (defined as any hallway, corridor, lobby, aisle, water fountain area, restroom, stairwell, entryway, or conference room in any public place). A patient's room in a hospital, nursing home, or other health care facility may be designated as a smoking area if approved by the attending physician and agreed to by all patients assigned to that room. No more than one-half of the rooms in any health care facility may be designated as smoking areas. In workplaces where there are smokers and non-smokers, employers must develop, implement, and post a policy regarding designation of smoking and non-smoking areas. An entire area may be designated as a smoking area if all workers routinely assigned to work in that area agree. No more than one-half of the total square footage of any public place may be designated a smoking area. No more than thirty-five percent of the seats in a restaurant's dining room may be located in a

designated smoking area. A smoking area may not contain common areas expected to be used by the public.

Schools

FLA. STAT. ch. 386.212 (2002): It is unlawful for any person under eighteen years of age to smoke tobacco in, on, or within one thousand feet of the real property comprising a public or private elementary, middle, or secondary school between the hours of 6 a.m. and midnight. The prohibition shall not apply to any person occupying a moving vehicle or within a private residence.

Preemption of Local Law

FLA. STAT. ch. 386.209 (2002): State smoking laws and regulations supersede any municipal or county ordinance on the subject.

GEORGIA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

GA. CODE ANN. § 16-12-2 (2002): Smoking is prohibited in enclosed public elevators clearly demarked by "no smoking" signs; in any place on a public transportation vehicle clearly demarked by a "no smoking" sign; in any public area clearly demarked by a "no smoking" sign; and on any property operated by a day care center, group day care center, or family day care center during hours of operation. State and local authorities may enact more restrictive laws, rules, regulations, or ordinances to prohibit smoking.

HAWAII

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

HAW. REV. STAT. ANN. § 328K-2 (Michie 2002): Smoking is prohibited in elevators in buildings open to and used by the public; in semi-private rooms, wards, waiting rooms, lobbies, and public hallways of public and private health facilities (but smoking is permitted in a private or semi-private room when there is no objection by any patient occupying such room); in any room that is primarily used for performances open to the public; in museums, libraries, and galleries; in

facilities in government-owned buildings, including meeting or conference rooms, auditoriums or enclosed sports areas, enclosed community centers, waiting areas, and baggage claim and check-in counters in airports; in business establishments, including banks, credit unions, financial services loan companies, retail stores, and savings and loan associations; in public restrooms; in taxis when carrying passengers; and on cruise ships. All restaurants shall provide non-smoking areas that are reasonably proportionate to customer preference and can ban smoking entirely.

HAW. REV. STAT. ANN. § 328K-3 (Michie 2002): Smoking is prohibited in small businesses or in retail stores with less than five thousand square feet of floor space.

Child Care Facilities

HAW. REV. STAT. ANN. § 346-158 (Michie 2002): Smoking is prohibited in all group child care homes, group child care centers, and family child care homes during hours of operation.

Schools

HAW. ADMIN. RULES § 8-31-3 (2002): Smoking and other use of tobacco products is prohibited at all times on public school campuses, school vehicles, and off-campus sites under the operational control of the principal or designee, except as part of bona fide classroom instruction or a theatrical production approved by the principal.

Workplace

HAW. REV. STAT. ANN. § 328K-13 (Michie 2002): Each employer shall adopt a written smoking policy containing the following provisions: First, if any non-smoking employee objects to the employer about smoke in the workplace, the employer, using already available means of ventilation or separation of office space, shall try to reach a reasonable accommodation between the preferences of smoking and non-smoking employees. Second, if an accommodation satisfactory to all affected employees cannot be reached, the preference of a simple majority of employees in the affected area shall prevail. If the employer's decision is unsatisfactory to non-smoking employees, a simple majority of all non-smoking employees can appeal to the Director of Health for the determination of a reasonable accommodation.

HAW. REV. STAT. ANN. § 328K-14 (Michie 2002): HAW. REV. STAT. ANN. § 328K-13 does not govern smoking on any property owned or leased by the federal government or in private enclosed office workplaces occupied exclusively by smokers.

IDAHO***Case Law***

No cases dealing with the regulation of smoking in public places were found.

Statutes***Public Places***

IDAHO CODE § 39-5503 (Michie 2002): Smoking is prohibited in public places and at public meetings except in designated smoking areas. Public places are enclosed indoor areas used by the general public, including but not limited to restaurants with a seating capacity of thirty or more customers, retail stores, grocery stores and stores that sell food primarily for off-site consumption, public conveyances, educational facilities, hospitals, nursing homes, auditoriums, arenas, and meeting rooms. The prohibition does not apply to bars, bowling alleys, and rooms or halls used for a private social function where seating is controlled by the sponsor of the function. These venues may be designated as smoking areas in their entirety.

IDAHO CODE § 39-5504 (Michie 2002): Except where smoking is prohibited by the fire marshal or by law, proprietors may designate smoking areas in public places. A good faith effort shall be made to minimize smoke in non-smoking areas. In the case of public places consisting of a single room, reserving and labeling one side of the room as a non-smoking area is satisfactory.

IDAHO CODE § 39-5505 (Michie 2002): Smoking is prohibited in elevators accessible to the public.

IDAHO CODE § 18-5904 (Michie 2002): Smoking is prohibited at state and local government hearings and at meetings to which the public is invited.

Public Transportation

IDAHO CODE § 39-5510 (Michie 2002): Smoking is prohibited on non-chartered buses.

State Buildings

Exec. Order No. 96-02, 96-4 I.A.B. 24 (1996): Smoking is prohibited in all state-owned and state-leased buildings and facilities and other areas occupied by state employees, except for custodial care and full-time residential facilities, for which the smoking policy may be determined by the directors of such facilities.

ILLINOIS***Case Law***

No cases dealing with the regulation of smoking in public places were found.

*Statutes**Public Places*

410 ILL. COMP. STAT. 80 / 3, 4 (2002): Smoking is prohibited in public places except in portions established and posted under 410 ILL. COMP. STAT. 80 / 5 as smoking areas. Public places are enclosed indoor areas used by the public or serving as places of work, including but not limited to hospitals, restaurants, retail stores, offices, commercial establishments, elevators, indoor theaters, libraries, art museums, concert halls, public conveyances, educational facilities, nursing homes, auditoriums, arenas, and meeting rooms. Bowling alleys, bars, hotel rooms, rooms or halls used in their entirety for private social functions, factories, warehouses, other places of work not usually frequented by the general public, and private enclosed offices occupied exclusively by smokers are exempt from the smoking prohibition.

410 ILL. COMP. STAT. 80 / 5 (2002): The proprietor of a public place (or, in the case of property control by the state or any unit of local government, the official appointed or elected to control it) may establish an area on the premises where smoking shall be permitted, unless otherwise prohibited by law or ordinance.

Child Care Facilities

225 ILL. COMP. STAT. 10 / 5.5 (2002): Smoking is prohibited, on any day when the center is in operation, in any area of a day care center in which children are allowed, regardless of whether or not any children are present at that moment.

Health Care Facilities

210 ILL. COMP. STAT. 50 / 3.155 (2002): Patients, individuals who accompany a patient, and emergency medical services personnel may not smoke while inside an ambulance.

Schools

105 ILL. COMP. STAT. 5 / 10-20.5b (2002): School boards must prohibit smoking on school property when such property is being used for any school purpose.

Preemption of Local Law

410 ILL. COMP. STAT. 80 / 11 (2002): 410 ILL. COMP. STAT. 80 preempts local restrictions on smoking in public places.

INDIANA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

IND. CODE ANN. § 16-41-37-4 (Michie 2002): Smoking is prohibited in any public building except in designated smoking areas; the retail area of any grocery store or drug store designated as non-smoking by the store's proprietor; and the dining area of a restaurant designated as non-smoking by the restaurant's proprietor.

IND. CODE ANN. § 16-41-37-2 (Michie 2002): A public building is an enclosed structure or part thereof that is occupied by a state or local agency, or used as a classroom building or dining area at a state educational institution; a public school; a licensed health facility; a station for paid firefighters or police officers; a licensed child care center or home or registered child care ministry; a licensed hospital or county hospital; or a provider's office.

IND. CODE ANN. § 16-41-37-5 (Michie 2002): The official in charge of a public building shall designate a non-smoking area and may designate a smoking area in the building.

IOWA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

IOWA CODE ANN. § 142B.2 (West 2002): Smoking is prohibited in a public place or public meeting except in a designated smoking area. The prohibition does not apply in cases where an entire room or hall is used for a private social function and seating arrangements are under the control of the sponsor of the function. The prohibition also does not apply to factories, warehouses, and similar places of work not usually frequented by the general public, except that an employee cafeteria in such workplace shall have a designated smoking area.

IOWA CODE ANN. § 142B.1 (West 2002): A public meeting is a gathering in person of the members of a governmental body. Public places include but are not limited to workplaces of at least two hundred and fifty square feet; restaurants with a seating capacity greater than fifty; retail stores and malls; offices and meeting rooms; public conveyances, lobbies, and elevators; educational facilities; hospitals and other health care and medical facilities; and auditoriums, theaters, libraries, art museums, concert halls, and indoor arenas. Public places do not include retail stores where the majority of sales result from the sale of tobacco; the portions of a store where tobacco is sold; private offices occupied only by smokers; motel rooms;

rooms used for student residence at an educational facility; or rooms used by residents of a health care facility.

Schools

IOWA CODE ANN. § 279.9 (West 2002): School rules shall prohibit the use of tobacco by any student.

KANSAS

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

KAN. STAT. ANN. §§ 21-4009, 21-4010 (2002): Smoking is prohibited in public places and at public meetings except in designated smoking areas. Public places are indoor areas open to the public or used by the general public, including but not limited to restaurants; retail stores; public means of mass transportation; passenger elevators; health care institutions or any other place where health care services are provided to the public; educational facilities; libraries; courtrooms; state, county, or municipal buildings; restrooms; grocery stores; school buses; museums; theaters; auditoriums; arenas; and recreational facilities. Smoking areas may be designated by proprietors of public places except in the case of elevators, school buses, public transportation, and other places where smoking is prohibited by the fire marshal or by law. Where smoking areas are designated, existing physical barriers and ventilation must be used to minimize the toxic effects of smoke in non-smoking areas.

KAN. STAT. ANN. § 21-4011 (2002): The person in charge of a public place has the authority to determine the percentage of the area that is to be designated for smoking.

Child Care Facilities

KAN. STAT. ANN. § 65-530 (2002): Smoking is prohibited in the enclosed space of day care homes, group day care homes, and family day care homes when children are being cared for and the children are unrelated to the person who maintains the home.

Health Care Facilities

KAN. STAT. ANN. § 21-4017 (2002): Smoking is prohibited in health care facilities, but smoking areas may be established within licensed long-term care units if such smoking areas are well ventilated.

Schools

KAN. STAT. ANN. § 72-53,107 (2002): The use of tobacco products is

prohibited in school buildings.

State Buildings

KAN. STAT. ANN. § 21-4016 (2002): Smoking is prohibited in any room, hallway, or other place in the state capitol.

KENTUCKY

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Schools

KY. REV. STAT. ANN. § 438.050 (Michie 2002): Smoking is prohibited on school property while children are present, except by adult employees and by students in rooms designated for that purpose.

State Buildings

KY. REV. STAT. ANN. § 61.165 (Michie 2002): State, county, and municipal governments may adopt policies regarding smoking in government buildings. Such policies must provide accessible indoor smoking areas in buildings where smoking is otherwise restricted and allow smoking in open public areas where ventilation and air exchange are adequate and smoking is not otherwise legally restricted.

LOUISIANA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

LA. REV. STAT. ANN. § 40:1300.42 (West 2002): Smoking tobacco in any form is prohibited in the following public places: passenger elevators used by or open to the public and clearly marked with a "no smoking" sign; public transportation vehicles used or open to the public and clearly marked with a "no smoking" sign; child care facilities; and any areas designated and posted by the state fire marshal as hazardous. The prohibition does not apply to riverboat gambling facilities and off-track betting parlors, although separate areas or rooms may be designated as non-smoking in these facilities.

LA. REV. STAT. ANN. § 40:1300.43 (West 2002): The owner or manager in control of a public place may designate a separate room on each floor for smoking. Owners and operators of taxis or limousines may designate their vehicles

as smoking or non-smoking. A business that derives over half of its gross revenues from the sale of alcoholic beverages may be designated as a smoking area in its entirety. The owner or manager of a restaurant may maintain flexible smoking and non-smoking areas according to customer demand.

LA. REV. STAT. ANN § 40:1261 (West 2002): Smoking is allowed in all areas of the Louisiana Superdome except the arena.

Health Care Facilities

LA. REV. STAT. ANN. § 40:2115 (West 2002): Smoking is prohibited in enclosed areas of all hospitals that are air conditioned or heated. A hospital governing board may designate a well-ventilated area for smoking. Smoking may be permitted in patient rooms at the discretion of a hospital governing board only upon the order of the patient's primary treating physician, with the consent of all patients in the patient room, and in accordance with all standards established by the Joint Commission on Accreditation of Health Care Organizations and all applicable state and federal regulations.

Schools

LA. REV. STAT. ANN. § 17:240 (West 2002): Smoking or otherwise using tobacco is prohibited in any elementary or secondary school building. Smoking is also prohibited on any bus transporting school children attending any public elementary or secondary school; and on the grounds of any public or private elementary, secondary, or special-education school, except in specifically designated smoking areas.

Workplace

LA. REV. STAT. ANN § 40:1300.24 (West 2002): Each employer who operates an office in the state must maintain a written record of a smoking policy that provides, at a minimum, that any employee may object to the employer about smoke in the workplace. The employer must attempt to reach a reasonable accommodation between non-smoking and smoking employees. An official in charge of a state, parish, or municipal building where smoking in the office is restricted must, if allowed, designate a smoking area in a separate room in existing facilities. Educational and health care facilities are not required to designate smoking areas. The requirements herein do not apply to courtrooms or other areas used by the state judicial branch.

LA. REV. STAT. ANN § 40:1300.25 (West 2002): LA. REV. STAT. ANN § 40:1300.24 does not apply to a private home used as an office or to an office used exclusively by smokers, even if such office is visited by non-smokers.

Preemption of Local Law

LA. REV. STAT. ANN §§ 40:1300.26, 40:1300.46 (West 2002): State agencies, parishes, municipalities, and other political subdivisions may not impose smoking rules that are more restrictive than those of LA. REV. STAT. ANN §§ 17:240, 40:1300.24-40:1300.26, 40:1300.42-40:1300.43, 40:2115.

MAINE

Case Law

Schlear v. Fiber Materials, Inc., 574 A.2d 876 (Me. 1990): A former employee filed a wrongful discharge action claiming that she was fired after she reported alleged violations of the Workplace Smoking Act, ME. REV. STAT. ANN. tit. 22, § 1580-A. The court held that the plaintiff met her burden of demonstrating that there was no mutually agreed-upon smoking policy between the employees and the employer and that the employer's unilateral imposition did not prevent application of the Workplace Smoking Act. (The case has been overruled on other grounds.)

Statutes*Public Places*

ME. REV. STAT. ANN. tit. 22, § 1542 (West 2002): Smoking is prohibited in all enclosed areas of public places and all restrooms made available to the public. Smoking is not prohibited in an enclosed area of a public place at times when it is not open to the public; theaters or other enclosed structures when a performer is smoking as part of a performance; areas where smoking is part of a religious ceremony or a cultural activity by a defined group; taverns or lounges; motel or hotel rooms rented to members of the public; portions of public places consisting of private offices where no member of the public is present; private residences unless used as a day care or babysitting service, in which case smoking is prohibited in those areas used to care for children during the time care is provided; public places where bingo or beano games are conducted; retail stores that sell primarily tobacco products; and privately chartered buses.

ME. REV. STAT. ANN. tit. 22, § 1580 (West 2002): No person may smoke in any room used for jury meetings or deliberation unless all members present consent.

Health Care Facilities

ME. REV. STAT. ANN. tit. 22, § 1580-B (West 2002): Smoking is prohibited in all enclosed areas of a hospital, except that a hospital may establish an enclosed and adequately ventilated smoking area for patient use. A hospital may designate its entire facility as non-smoking.

ME. REV. STAT. ANN. tit. 22, § 1825 (West 2002): Smoking is prohibited in nursing homes except in specifically designated areas.

Schools

ME. REV. STAT. ANN. tit. 22, § 1578-B (West 2002): All students and school employees are prohibited from using tobacco in the buildings or on the grounds of any elementary or secondary school while school is in session. Tobacco use may be permitted in classrooms only as part of a bona fide demonstration during a class lesson, and when prior notice has been given to the school's administrator. A local school board or school employees may establish designated smoking areas

through collective bargaining.

Workplace

ME. REV. STAT. ANN. tit. 22, § 1580-A (West 2002): All employers shall establish or negotiate through the collective bargaining process a written policy that prohibits smoking except in designated smoking areas. The policy may prohibit smoking throughout the business facility.

MARYLAND

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

MD. CODE ANN., LAB. & EMPL., §§ 2-105, 2-106, 5-312 (2002): The Commissioner of Labor and Industry has the authority to promulgate regulations protecting occupational safety, including prohibitions on smoking. However, the regulations may not restrict smoking in any portion of a private residence that is not open to the public for business purposes; in any bar, tavern, or nightclub; or in the designated smoking area (not to exceed forty percent of total space) of any restaurant, hotel, or gathering open to the public.

MD. CODE ANN., HEALTH—GEN § 24-502 (2002): Smoking is prohibited in the public area of a retail store. A retail store is any store employing twenty or more full-time employees with the primary purpose of selling goods, wares, food for consumption elsewhere, or merchandise. The prohibition does not apply to restaurants, restaurant areas of retail stores, tobacconists, restrooms in retail stores, or work areas of the store that are closed to the public or that can be physically isolated by a room with doors closed.

MD. ANN. CODE art. 89, § 64 (2002): Smoking is prohibited in public elevators.

Health Care Facilities

MD. CODE ANN., HEALTH—GEN § 24-205 (2002): Smoking is prohibited in hospitals. Exceptions include mental disorder facilities, facilities where average patient stay is more than thirty days, and acute care hospitals where an attending physician authorizes smoking as part of patient care. Directors of nursing homes, health clinics, or physician offices shall regulate smoking on the respective premises. Smoking areas must be considered safe and must protect non-smokers from smoke. Smoking is prohibited where non-smoking patients sleep.

Public Transportation

MD. CODE ANN., PUB. UTIL. § 9-206 (2002): Smoking is prohibited on intrastate buses.

MD. CODE ANN., TRANSP. § 7-705 (2002): Smoking is prohibited in transit

vehicles and transit facilities owned or controlled by the state, and on trains owned or controlled by the state or operated by a railroad company under contract to the state to provide passenger railroad service.

Workplace

MD. REGS. CODE tit. 9.12.23, § .01 (2002): Smoking is prohibited in enclosed workplaces within the limits of MD. CODE ANN., LAB. & EMPL., §§ 2-105, 2-106, 5-312. Employers can offer designated smoking areas with special ventilation.

MASSACHUSETTS

Case Law

Tri-Nel Mgmt., Inc. v. Bd. of Health, 741 N.E.2d 37 (Mass. 2001): Plaintiffs, operators of a bar, challenged the Barnstable County Board of Health's ban on smoking in all food service establishments, lounges, and bars. MASS. GEN. LAWS ch. 111, § 31 allows boards of health to make reasonable health regulations. Plaintiffs argued that the defendant's ban was not reasonable, that the amount of smoke exposure in restaurants and bars was not sufficient to cause adverse health effects. The court found substantial evidence to the contrary and noted that under MASS. GEN. LAWS ch. 270, § 22, nothing restricts a municipality's authority to regulate smoking more strictly than state law.

Statutes

Public Places

MASS. ANN. LAWS ch. 270, § 22 (Law. Co-op. 2002): Smoking is prohibited in public elevators; in retail food stores; in or upon public mass transit conveyances, indoor platforms, and enclosed outdoor platforms; and at open meetings of governmental bodies. Smoking is also prohibited in other public buildings and enclosures, including courthouses, schools, colleges, universities, museums, libraries, trains, airplanes, waiting areas of airports, waiting areas of health care facilities, group child care centers, school-aged day care centers, and family day care centers, except in areas specifically designated for smoking. An area shall be designated as a smoking area only if non-smoking areas of sufficient size and capacity are available to accommodate non-smokers. Smoking is prohibited in any restaurant with a seating capacity of seventy-five or more persons, except in an area that has been specifically designated as a smoking area. Smoking is prohibited in the state house, in other state-owned buildings, and in any space occupied by a state agency or department that is located in another building, including any private office in any such building or space. This last restriction does not apply to residents or patients of state hospitals, the Soldiers' Home in Massachusetts, the Soldiers' Home in Holyoke, or substance abuse treatment centers under state jurisdiction.

MASS. ANN. LAWS ch. 54, § 73 (Law. Co-op. 2002): Smoking is prohibited at a polling place during an election or at a town meeting.

Health Care Facilities

MASS. ANN. LAWS ch. 111, § 72X (Law. Co-op. 2002): All public and private nursing homes must designate no-smoking sections in common areas, including lobbies, cafeterias, conference rooms, and employee lounges. Smoking by employees of such nursing homes is prohibited in all patient care areas.

Schools

MASS. ANN. LAWS ch. 71, § 2A (Law. Co-op. 2002): Students enrolled in either primary or secondary public schools are prohibited from using tobacco products of any type on school grounds during normal school hours.

Local Power To Restrict Smoking

MASS. ANN. LAWS ch. 111, § 31 (Law. Co-op. 2002): Local boards of health are empowered to make reasonable health regulations.

MICHIGAN

Case Law

Michigan Restaurant Ass'n v. City of Marquette, 626 N.W.2d 418 (Mich. Ct. App. 2001): The court held that a city ordinance completely prohibiting smoking in restaurants conflicted with a food establishment's statutory right to designate a certain percentage of its seating capacity for smokers under MICH. COMP. LAWS ANN. § 333.12905.

Keller v. City of Grand Rapids, No. 223083, 2001 Mich. App. LEXIS 1242 (Mich. Ct. App. Aug. 7, 2001): The plaintiff alleged he was harassed out of his job in part because he filed a police report complaining about his employer's failure to comply with and enforce smoking rules under MICH. COMP. LAWS § 333.12605. The court held that the evidence was sufficient to support his claim.

*Statutes**Public Places*

MICH. COMP. LAWS § 333.12603 (2002): Except as otherwise provided, smoking is only allowed in designated smoking areas in a public place or at a meeting of a public body. As defined in MICH. COMP. LAWS § 333.12601, a public place is an indoor area owned or operated by the state and used by the general public, as a workplace for public employees or a meeting place of a public body, including such places as offices, educational facilities, nursing homes, county medical care facilities, auditoriums, arenas, meeting rooms, and public conveyances; or an indoor area not owned by the state or local government and used by the public, including educational facilities, nursing homes, county medical care facilities, auditoriums, arenas, theaters, museums, and concert halls. The smoking prohibition does not apply to a place used for a private function if the seating is controlled by the sponsor of the function and not by the owner or operator of the place. The prohibition also does not apply to food service establishments, licensed premises, or private educational facilities after regularly

scheduled school hours.

MICH. COMP. LAWS § 333.12605 (2002): The owner or operator of a public place may designate a smoking area unless smoking is prohibited by law. If a smoking area is designated, physical barriers and ventilation systems must be used to minimize the toxic effects of smoke in both smoking and adjacent non-smoking areas. If smoking is permitted in a public place, a written policy to separate smokers from non-smokers must be developed that, at a minimum, provides that non-smokers be located closest to a fresh-air source, gives individuals hypersensitive to tobacco smoke special consideration, and establishes a procedure to receive, investigate, and take action on complaints.

MICH. COMP. LAWS § 408.820 (2002): It is unlawful to smoke or carry lighted tobacco in passenger elevators in all buildings in the state.

Child Care Facilities

MICH. COMP. LAWS § 333.12604 (2002): Smoking is prohibited in all child care institutions and child care centers, and on real property that is under the control of a child care institution or center.

Health Care Facilities

MICH. COMP. LAWS § 333.12604a (2002): Smoking is prohibited in the common area or treatment area of a private practice office or in a health care facility.

Restaurants

MICH. COMP. LAWS § 333.12905 (2002): All public areas of a food service establishment must be non-smoking. A public area includes but is not limited to a bathroom, a coatroom, an entrance, or other area used by patrons. Food service establishments with seating capacities of less than fifty may designate smoking areas of up to seventy-five percent of seating capacity. Food service establishments with a seating capacity of fifty or more that are not owned by private clubs may designate smoking areas of up to half of their seating capacity.

Schools

MICH. COMP. LAWS § 750.473 (2002): Use of a tobacco product is prohibited on school property, which is defined as a building or other real estate controlled by a school district. The prohibition does not apply to outdoor areas, such as open-air stadiums, during weekends or other days without regularly scheduled school hours, or after 6 p.m. on days with regularly scheduled school hours.

MINNESOTA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

MINN. STAT. ANN. § 144.414(1) (West 2002): Smoking in public places or at public meetings is prohibited except in designated smoking areas. The prohibition does not apply where an entire hall is used for a private social function and seating arrangements are under the control of the function's sponsor; or to workplaces not usually frequented by the general public, except that the Commissioner of Health shall establish rules to prohibit smoking in factories, warehouses, and those places where close proximity or inadequate ventilation causes smoke pollution detrimental to the health and comfort of non-smoking employees.

MINN. STAT. ANN. § 144.413(2) (West 2002): Public places include but are not limited to restaurants, retail stores, offices and other commercial establishments, public conveyances, public schools, hospitals, nursing homes, arenas, meeting rooms, and common areas of rental apartment buildings. Public places do not include private enclosed offices occupied exclusively by smokers even though such offices may be visited by non-smokers.

MINN. STAT. ANN. § 327.742 (West 2002): Smoking is prohibited in hotel rooms designated as non-smoking.

Child Care Facilities

MINN. STAT. ANN. § 144.414(2) (West 2002): Smoking is prohibited in day care centers, family homes, and other such homes during their hours of operation.

Health Care Facilities

MINN. STAT. ANN. § 144.414(3) (West 2002): Smoking is prohibited in any area of a hospital, health care clinic, doctor's office, or other care-related facility other than a nursing home, boarding care facility, or licensed residential facility. The prohibition does not apply to patients in certain chemical dependency or mental health treatment programs, or to participants in peer-reviewed scientific studies related to the health effects of smoking.

Schools

MINN. STAT. ANN. § 144.4165 (West 2002): Tobacco use is prohibited in public schools and in all facilities and vehicles that a school district owns, leases, rents, contracts for, or controls. The restriction does not prohibit the lighting of tobacco by an adult as part of a traditional Indian cultural or spiritual ceremony.

State Buildings

MINN. STAT. ANN. § 16B.24(9) (West 2002): Smoking is prohibited in all buildings managed or leased by the state except in veterans homes with designated smoking areas.

MISSISSIPPI

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes***State Buildings***

MISS. CODE ANN. § 29-5-161 (2002): Smoking is prohibited outside of designated smoking areas in state office buildings. Designated smoking areas are limited to enclosed private offices, employee break areas, and outdoor areas. This section preempts and supersedes any municipal or county ordinance.

Public Transportation

MISS. CODE ANN. § 97-35-1 (2002): Smoking of cigars and pipes (but not cigarettes) is prohibited on any passenger bus or coach while transporting passengers on any state highway.

Schools

MISS. CODE ANN. § 97-32-29 (2002): Smoking is prohibited on educational property, which includes public school buildings, buses, campuses, grounds, recreational areas, and other property owned, used, or operated by any local school board or school. Educational property does not include property of state institutions of higher learning, public community or junior colleges, or vocational-technical complexes where only adult students are in attendance.

MISSOURI

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes***Public Places***

MO. REV. STAT. §§ 191.765, 191.767 (2002): Smoking is prohibited in public places and at public meetings of government bodies except in designated smoking areas. Public places are enclosed indoor areas used by the general public or serving as workplaces, including but not limited to the following: retail or commercial establishments; health care facilities, including hospitals, nursing homes, physicians' offices, and ambulatory clinics; vehicles used for public transportation, including buses, taxicabs, and limousines for hire; restrooms; elevators; libraries; educational facilities; day care facilities; museums; auditoriums; art galleries; public areas and waiting rooms of public transportation facilities; gymnasiums; theater lobbies; concert halls; arenas; swimming pools; corridors; and shopping malls. No public place shall have more than thirty percent of its entire space designated as a smoking area. State executive departments and institutions of higher education are required to designate smoking areas where state employees may smoke during the work day, provided such areas can be adequately ventilated at minimal cost. Restaurant proprietors are required to designate areas of sufficient size to accommodate the usual and customary demand for non-

smoking areas by customers or patrons.

MO. REV. STAT. § 191.769 (2002): Exemptions from the smoking prohibition include the following: entire rooms or halls used for private social functions; limousines for hire and taxicabs, where the driver and all passengers agree to smoking; performers onstage, where smoking is part of the production; smoke shops and parlors; bars, taverns, restaurants that seat less than fifty people, bowling alleys, and billiard parlors; private residences; and enclosed indoor arenas, stadiums, and other facilities with seating capacities of over fifteen thousand that may be used for sporting events.

Child Care Facilities

MO. REV. STAT. § 191.776 (2002): Smoking is prohibited in child care facilities when the children cared for are present.

Schools

MO. REV. STAT. § 191.775 (2002): Smoking is prohibited in indoor areas of public elementary and secondary schools, and on buses used solely to transport students.

MONTANA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

MONT. CODE ANN. § 50-40-104 (2002): The proprietor or manager of an enclosed public place shall either designate non-smoking areas with easily readable signs, designate part of the public place for non-smokers and post easily readable signs designating smoking areas, designate the entire area as a smoking area by posting a visible sign, or designate and reserve the entire area as a non-smoking area. The proprietor or manager of an intrastate bus that is not chartered must prohibit smoking in all parts of the bus. As defined in MONT. CODE ANN. § 50-40-103, an enclosed public place is an indoor area, room, or vehicle used by the general public or serving as a workplace.

MONT. CODE ANN. § 50-40-105 (2002): "No smoking" signs must be conspicuously posted in intrastate buses that are not chartered, and in the elevators, museums, galleries, kitchens, and libraries of any establishment doing business with the general public.

MONT. CODE ANN. § 50-40-107 (2002): The following are exempt from Part 1 of the Montana Clean Indoor Air Act, MONT. CODE ANN. §§ 50-40-101 to 50-40-109: restrooms; taverns or bars where meals are not served; vehicles or rooms

seating six or fewer members of the public; school district buildings and facilities designated as tobacco-free by the school district board of trustees; community college buildings or facilities designated as tobacco-free by the community college district board of trustees; and state government buildings declared as smoke-free.

Health Care Facilities

MONT. CODE ANN. § 50-40-106 (2002): Prior to admission, health care facilities must ask all inpatients their preference for a smoking or non-smoking patient room and accommodate such preference when possible. Smoking is prohibited in all kitchen areas, laboratories, corridors, storage areas for supplies and materials, and areas where flammable substances are stored or in use. Health care facilities must designate a non-smoking area for all waiting rooms, prohibit employees from smoking in patient rooms, and require visitors to obtain express approval from all patients in a patient room, or from the patients' physicians, prior to smoking. Health care facilities may ban smoking on all or part of their premises. All areas not specified herein may be smoking areas unless designated otherwise.

Schools

MONT. CODE ANN. § 20-1-220 (2002): The use of any tobacco product is prohibited in a public school building or on school property during school hours. The prohibition does not apply to non-student adults in a smoking area designated by the school administrator or board of trustees of the school district.

State Buildings

MONT. CODE ANN. § 50-40-201 (2002): In offices and work areas maintained by a political subdivision, with the exception of a school or community college facility designated as tobacco-free by its board of trustees, the governing body of the political subdivision shall arrange convenient non-smoking and smoking areas. The governing body has the authority to designate any building it maintains as smoke-free.

MONT. CODE ANN. § 50-40-207 (2002): Buildings owned, leased, or occupied by the state must be smoke-free. With buildings leased and occupied by the state and another entity, agency heads shall make the state-occupied portions of the building smoke-free and are encouraged to work with building owners and other tenants to make the entire building smoke-free.

NEBRASKA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

NEB. REV. STAT. § 71-5707 (2002): Smoking is prohibited in a public place or at a public meeting except in designated smoking areas. The prohibition does not apply when an entire room is used for a private social function and the seating arrangements are controlled by the sponsor of the function.

NEB. REV. STAT. § 71-5704 (2002): Public places include any enclosed indoor areas used by the general public or serving as workplaces, including but not limited to the following: restaurants, retail stores, other commercial establishments, offices, public conveyances, educational facilities, hospitals, nursing homes, auditoriums, arenas, and meeting rooms. The smoking prohibition does not apply to private enclosed offices occupied exclusively by smokers even though these offices may be visited by non-smokers.

Child Care Facilities

NEB. REV. STAT. § 71-5707(3) (2002): No person shall smoke at licensed child care programs. The prohibition does not apply if the child care program is located in the home of the provider.

State Buildings

NEB. REV. STAT. § 71-5707(4)-(7) (2002): Smoking is prohibited in all vehicles and buildings owned or leased by the state, and within ten feet of any entrance to such buildings. The following buildings in which people reside may be exempt: veterans homes; private residences; facilities and institutions controlled by the Department of Health and Human Services Regulation and Licensure; and overnight lodging facilities and buildings managed by the Game and Parks Commission, but no more than twenty-five percent of the overnight lodging facilities at each park location shall permit smoking. Designated smoking areas may not exceed fifty percent of the space used by the public in state-owned buildings at the Nebraska State Fairgrounds. Smoking may be permitted in no more than forty percent of the residential housing units owned or leased on each campus under the control of state institutions of higher learning.

Workplace

NEB. REV. STAT. § 71-5707(2) (2002): The Department of Health and Human Services Regulation and Licensure shall establish rules to restrict or prohibit smoking in factories, warehouses, and similar places of work not usually frequented by the general public, where the close proximity of workers or the inadequacy of ventilation causes smoke pollution detrimental to the health and comfort of non-smoking employees.

NEVADA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

NEV. REV. STAT. § 202.2491 (2002): Smoking tobacco of any form is prohibited in any public elevator, public area of a food store, or school bus. Smoking is also prohibited in any public waiting room, lobby, or hallway of any health care facility or office; hotel or motel when so designated by the operator; child care facility; or bus used by the general public except that the person in control of such a place may designate a smoking area in a separate room or area if smoking in such area is not otherwise prohibited. Operators of child care facilities may not allow children in any area designated as smoking and must prevent smoke from adversely affecting those in other areas. For buildings or office space owned or occupied by the state or any subdivision thereof, those in charge must designate a separate area that may be used for smoking. The two exceptions are schools, which needn't designate smoking areas for students if they prohibit student smoking, and corrections facilities, which needn't prohibit smoking in any area. Furthermore, restaurants seating fifty or more are required to include non-smoking areas, except that businesses deriving more than fifty percent of gross receipts from either alcohol or gambling may designate their entire area for smoking.

Food Stores

NEV. REV. STAT. § 202.24915 (2002): Under certain conditions, a food store may allow smoking in an area of the store designated for gambling.

Preemption of Local Law

NEV. REV. STAT. § 202.249 (2002): No governing body within the state may impose more stringent restrictions on smoking than those prescribed by statute.

NEW HAMPSHIRE

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

N.H. REV. STAT. ANN. § 155:66 (2002): Smoking is prohibited in all public educational facilities; child care agencies during hours of operation, except foster family homes and foster family group homes; hospitals and other acute-care facilities; grocery stores; and elevators, tramways, gondolas, and other such public conveyances. Besides the exceptions in N.H. REV. STAT. ANN. § 155:67, smoking is also prohibited in all enclosed places of public access and publicly owned

buildings and offices, including workplaces, and in enclosed places owned and operated by social, fraternal, or religious organizations when made available to the general public, except in effectively segregated, smoking-permitted areas designated by the person in charge. If smoking cannot be effectively segregated, then smoking must be totally prohibited. The person in charge may declare any facility non-smoking in its entirety.

N.H. REV. STAT. ANN. § 155:67 (2002): Smoking is permitted in the following venues or situations: public conveyances rented for private purposes; buildings owned and operated by social, fraternal, or religious organizations when used by the membership of the organization, their guests, or their families, or when they are rented or leased for private functions from which the public is excluded and arrangements are under the control of the sponsor of the function and not the organization; guest rooms of hotels, motels, and resorts; halls, ballrooms, dining rooms, and conference rooms of hotels, motels, restaurants, resorts, and publicly accessible buildings or portions thereof, excluding those that are publicly owned, when rented or leased for private functions from which the public is excluded and arrangements are under the control of the sponsor of the function and not of the proprietor or person in charge of the facility; resident rooms in dormitories operated by postsecondary educational institutions; resident rooms in public housing facilities; resident rooms in facilities such as nursing homes, sheltered care facilities, residential treatment and rehabilitation facilities, and prisons and detention facilities; restaurants with seating for fewer than fifty people; cocktail lounges; patients with extraordinary medical conditions or psychiatric disorders, or in an alcohol and drug withdrawal program, provided that the patient's physician has written an order allowing the patient to smoke.

Schools

N.H. REV. STAT. ANN. § 126-K:7 (2002): Smoking is prohibited in any public educational facility or on the grounds of any public educational facility.

NEW JERSEY

Case Law

LDM, Inc. v. Reg'l Health Comm'n, 764 A.2d 507 (N.J. Super. Ct. Law Div. 2000): Plaintiffs, which included commercial eating and drinking establishments, sought a preliminary injunction enjoining the enforcement of a local ordinance that prohibited smoking in all indoor public places in Princeton Township and Princeton Borough. The court found that state law preempted municipal regulation of smoking except for fire safety purposes, that the ordinance was not passed for fire safety purposes, and that, in any event, the defendant health commission lacked the authority to pass fire safety ordinances.

Statutes

Public Places

N.J. STAT. ANN. § 26:3D-40 (West 2002): The manager, owner, proprietor, or other person in control of an indoor public space must provide areas for non-smokers to conduct business or participate in activities free from the annoyance and health hazard of smoke. Smoking is prohibited in pharmacies, drug stores, and any area where hearing aids are sold at retail. Smoking areas for employees may be permitted in any indoor public place as long as they are separate areas not generally accessible to the public, except where prohibited by municipal ordinance for fire prevention purposes.

N.J. STAT. ANN. § 26:3D-39 (West 2002): An indoor public place under N.J. STAT. ANN. § 26:3D-40 is a structurally enclosed area generally accessible to the public in theaters, gymnasiums, libraries, museums, concert halls, auditoriums, or other such facilities that are neither owned or leased by a governmental entity nor qualify as a health care facility or waiting room of a person licensed to practice the healing arts. The definition excludes certain facilities such as racetracks; licensed casinos; football, baseball, and other sporting event facilities; bowling alleys; and dance halls.

N.J. STAT. ANN. § 26:3D-3 (West 2002): Smoking is prohibited in every passenger elevator in every building except for a single-family dwelling.

Child Care Facilities

N.J. STAT. ANN. § 30:5B-5.3 (West 2002): Smoking is prohibited in an indoor area when children are present and, unless the area is separately ventilated to the outside, also when children are not present. Smoking is prohibited in all vehicles when used for center-sponsored transportation.

Food Stores

N.J. STAT. ANN. § 26:3D-34 (West 2002): Smoking is prohibited in all enclosed retail food and marketing stores.

Health Care Facilities

N.J. STAT. ANN. § 26:3D-9 (West 2002): Smoking is prohibited in all health care facilities. However, unless otherwise prohibited by law for fire prevention purposes, smoking may be permitted in private rooms or rooms where all patients consent upon admission to allow smoking; in at least one lobby or waiting room if there is more than one lobby or waiting room, or if there is only one lobby or waiting room as long as there is an adequate section of the area provided for non-smokers; in cafeterias or other dining areas with an occupancy of fifty or more persons if an adequate section is provided for non-smokers; and in a totally enclosed office space used by employees unless otherwise prohibited by the health care facility. Smoking is also prohibited in the waiting rooms of the offices of all persons licensed to practice the healing arts, but if there is more than one waiting

room in an office, at least one may be designated as a smoking area unless otherwise prohibited by municipal ordinance.

Public Transportation

N.J. STAT. ANN. § 32:1-146.4 (West 2002): A person may not smoke in any area or building of an air terminal owned or operated by the Port Authority of New York, or where the Port Authority has posted signs prohibiting smoking in any area, bulkhead, dock, pier, wharf, warehouse, or other structure of a marine terminal owned or operated by the Port Authority. Smoking is also prohibited on the open deck of a ship or other floating craft when berthed or moored to such dock, wharf, or pier, or to a vessel made fast thereto.

N.J. STAT. ANN. § 32:1-146.8 (West 2002): No person may smoke or carry a lighted cigarette or other instrument in or about any area, building, car, or other rolling stock of the Hudson Tubes or Hudson Tubes extensions where smoking has been prohibited by the Port Authority Trans-Hudson Corporation and signs have been posted.

Restaurants

N.J. STAT. ANN. § 26:3E-7 (West 2002): For public health reasons, restaurants are encouraged to establish non-smoking areas.

Schools

N.J. STAT. ANN. § 26:3D-17 (West 2002): Except for the board of education of a school district, the governing body or individual with control of the administration of any public or private school, college, university, or professional training school shall make and enforce suitable regulations to control smoking on the premises except in those areas where smoking is prohibited by law for fire prevention purposes. The governing body may designate certain areas where smoking is permitted, but smoking in classrooms, lecture halls, and auditoriums must be prohibited except as part of classroom instruction or a theatrical production. The board of education of each school district must make and enforce regulations to prohibit smoking of tobacco anywhere in its buildings or on its grounds, except as part of classroom instruction or a theatrical production.

State Buildings

N.J. STAT. ANN. § 26:3D-48 (West 2002): With the exception of areas occupied by the New Jersey Legislature, the supervisor of each unit of government in a government building is required to establish written rules governing smoking, except where smoking is prohibited by law for fire prevention purposes. The Senate and General Assembly shall separately adopt rules governing smoking in their respective chambers and other areas occupied by them and their personnel and shall adopt joint rules in those areas occupied by the committees and personnel of both houses. Smoking is prohibited in the following government places: places of meeting or public assembly, during a public meeting to which the public is invited or legally entitled to attend; offices open to the general public;

and libraries, indoor theaters, museums, lecture or concert halls, gymnasiums, and other such facilities open to the public, except that smoking may be permitted at such places on special occasions by persons seated at tables where food and beverages are consumed, in areas adjacent to these facilities that are designated as smoking areas, or when used for private functions or under a specified private lease. Restaurants with occupancy of fifty or more persons located in government buildings must have designated non-smoking areas.

Workplace

N.J. STAT. ANN. § 26:3D-25 (West 2002): Each employer shall establish written rules that govern smoking in the portion of a building for which the employer is responsible. The rules shall include designated non-smoking areas and may include designated smoking areas unless otherwise prohibited by law for fire prevention purposes. Rules regarding smoking that are not contrary to law may be established by the employer or negotiated as a term or condition of any agreement or contract of employment.

NEW MEXICO

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Schools

N.M. ADMIN. CODE tit. 6, § 12.4.8 (2002): Each local school board shall implement a policy that will prohibit tobacco use by students, school staff, parents, and school visitors in school buildings, on school property, and by students at school functions away from school property.

State Buildings

N.M. STAT. ANN. § 24-16-4 (Michie 2002): Smoking is prohibited in public places or at a public meeting except in smoking-permitted areas. No part of the state capitol or capitol north shall be designated as a smoking-permitted area.

N.M. STAT. ANN. § 24-16-3 (Michie 2002): A public meeting is any meeting required by law to be an open meeting. A public place is any enclosed indoor area in a building owned or leased by the state or any of its political subdivisions.

N.M. STAT. ANN. § 24-16-5 (Michie 2002): Smoking-permitted areas in public places include: fully enclosed offices or rooms occupied exclusively by smokers; rooms or halls used by a person or group for a non-governmental function where the seating arrangements are under the control of the sponsor of the function; smoking-permitted areas designated by the proprietor or person in charge of a public place or public meeting; and smoking-permitted areas in a place of employment.

N.M. STAT. ANN. § 24-16-6 (Michie 2002): The person in charge of a public place or public meeting shall designate as a smoking-permitted area, by appropriate signs, a contiguous area or contiguous areas that shall not exceed fifty percent of the public place.

Workplace

N.M. STAT. ANN. § 24-16-7 (Michie 2002): For places of employment, each employer shall adopt, implement, and maintain a written smoking policy that shall contain, at a minimum, provisions relating to the following: the prohibition of smoking in elevators and nurse's aid stations or similar facilities for the treatment of employees; the provision and maintenance of a contiguous non-smoking area of not less than one-half of the seating capacity and floor space in cafeterias, lunchrooms, and employee lounges; and the provision of smoke-free work areas upon request in places where smokers and non-smokers work in the same room.

NEW YORK

Case Law

Newark Valley Cent. Sch. Dist. v. Pub. Employment Relations Bd., N.E.2d 443 (N.Y. 1994): The New York Court of Appeals considered whether a ban on smoking in school buses when no students were on board could be collectively bargained or was preempted by statute and thus properly adopted by the school district unilaterally. The court found that the school district's unilateral action was improper because smoking restrictions above the statutory minimum are subject to collective bargaining.

Boreali v. Axelrod, 517 N.E.2d 1350 (N.Y. 1987): Pursuant to a broad legislative mandate granting it authority to regulate public health matters, the New York Public Health Council promulgated a comprehensive code to govern smoking in public places. Affected businesses and individuals challenged the code. The New York Court of Appeals held that the Council had exceeded the scope of its mandate and that balancing health concerns, cost, and privacy interests was a function of the legislature.

Jarrett v. Westchester County Dep't of Health, 646 N.Y.S.2d 223 (N.Y. Sup. Ct. 1996): Petitioners challenged a smoking ban in the county jail in which they were housed. The court upheld the ban, ruling that while an inmate may be considered a member of the "public," an inmate does not have the same rights as the public at large. The Commissioner of Correction was required to implement a smoking ban in the jail, and the manner of implementation clearly fell within the discretionary authority of jail administrators. The court held that the total ban on tobacco-related products rationally furthered the safe and efficient operation of the jail, and that the total smoking ban did not violate petitioners' rights to equal protection.

Bompane v. Enzolabs, Inc., 608 N.Y.S.2d 989 (N.Y. Sup. Ct. 1994): Plaintiff employee prevailed on a motion for summary judgment where she sued her employer claiming she had been fired in retaliation for complaining to the county health department about her employer's non-compliance with smoke-free work area rules under N.Y. PUB. HEALTH § 1399-o.

Fagan v. Axelrod, 550 N.Y.S.2d 552 (N.Y. Sup. Ct. 1990): Tobacco users challenged the constitutionality of New York's Clean Indoor Air Act. The court found that the regulation was a valid use of the state's police power, restricting not access to public places, but only the right to smoke.

Bd. of Educ. v. Cohalan, 515 N.Y.S.2d 691 (N.Y. Sup. Ct. 1987): The court held that a county ordinance prohibiting smoking in meeting places was not an unconstitutional usurpation of the state's role in education simply because smoking would be prohibited in public school buildings used as meeting places.

Alamin v. Dep't of Corr. Servs., 660 N.Y.S.2d 746 (N.Y. App. Div. 1997): Plaintiff sought an order compelling respondents to comply with smoking ban guidelines at the Green Haven Correctional Facility. The court upheld the lower court's dismissal of the petition because plaintiff failed to exhaust administrative remedies. Moreover, the court found that respondents' noncompliance with the smoking ban did not subject them to legal proceedings or liability.

Statutes

Public Places

N.Y. PUB. HEALTH § 1399-o (McKinney 2002): Smoking is prohibited in the following venues: auditoriums; elevators; gymnasiums; enclosed indoor public swimming pool areas; indoor areas in food stores; classrooms; public mass transportation, including subways and underground subway stations, and buses, vans, taxicabs, and limousines when carrying passengers; ticketing and boarding areas in public transportation terminals; youth centers and facilities for detention; child care service facilities except those provided in a private home; child day care centers; group homes for children; public institutions for children; and residential treatment facilities for youth. Smoking is also prohibited on school grounds, except by adult faculty and staff in designated smoking areas during non-school hours. Additionally, smoking is prohibited in public indoor areas including but not limited to the following: all public and private colleges, universities, and other educational and vocational institutions; general hospitals and residential health care facilities; public buildings; theaters; museums; libraries; retail stores; commercial establishments used to carry on any trade, profession, vocation, or charitable activity; indoor arenas; waiting rooms; banks and other financial institutions; restrooms; waiting areas in public transportation terminals; service areas in cafeterias and businesses selling food; and zoos. However, owners, operators, or managers of public indoor areas may designate smoking areas that

do not include any prohibited venues. Smoking may be permitted in the concourse area of a bowling alley, but at least twenty-five percent of the area must be designated as non-smoking. Bingo operators are required to provide a non-smoking area sufficient to meet demand. Food service establishments must designate a non-smoking area sufficient to meet demand and may designate a separate, enclosed room as a smoking area.

N.Y. PUB. HEALTH § 1399-q (McKinney 2002): Smoking restrictions do not apply to private homes, residences, and automobiles; indoor areas where private social functions are being held when seating arrangements are controlled by the sponsor of the function and not the owner of the place; any indoor area open to the public for conventions or trade shows if advertisements announce that smoking will not be restricted; hotel or motel rooms; tobacco businesses; limousines under private hire; private boxes in indoor arenas; and bars.

N.Y. PUB. HEALTH § 1399-r (McKinney 2002): The owner, operator, or manager of a place has the right to designate the entire place, or any part, as a non-smoking area. Smoking provisions apply to the legislative, executive, and judicial branches of state government and any political subdivision of the state. Smoking may not be permitted where prohibited by any other law, rule, or regulation of any state agency or any political subdivision of the state. Any county, city, town, or village can adopt and enforce additional local laws, ordinances, or regulations that comply with at least the minimum applicable standards set forth in the state's smoking laws.

N.Y. ELEC. § 5-204(7) (McKinney 2002): Smoking is prohibited in any place of voter registration located in a church or school.

Public Transportation

N.Y. UNCONSOL. ch. 170, § 1 (McKinney 2002): No person shall smoke in any area or building of an air terminal owned or operated by the Port Authority. Smoking is also prohibited where the Port Authority has posted signs to that effect in any area, bulkhead, dock, pier, wharf, warehouse, or other structure of a marine terminal owned or operated by the Port Authority. Smoking is prohibited on the open deck of a ship or other floating craft when berthed or moored to such dock, wharf, or pier, or to a vessel made fast thereto.

Schools

N.Y. EDUC. § 409(2) (McKinney 2002): Smoking is prohibited on school grounds. Smoking by adult faculty and staff may be permitted in designated areas during non-school hours. School grounds include any building, structure, and surrounding outdoor grounds in a public or private preschool, nursery school, elementary school, or secondary school's property boundaries.

Workplace

N.Y. PUB. HEALTH § 1399-o(6) (McKinney 2002): Employers are required to adopt a written policy that provides non-smoking employees with a smoke-free

work area, that allows for a smoking work area if all employees agree to such a designation, and that provides non-smoking areas in cafeterias, lunch rooms, and lounges sufficient to meet demand. The policy must also prohibit smoking in auditoriums, gymnasiums, restrooms, elevators, classrooms, hallways, employee medical facilities, rooms or areas containing communal office equipment, and company vehicles unless all passengers agree to allow smoking. The policy must prohibit smoking in conference rooms and meeting rooms unless everyone agrees to allow smoking. The employer may designate a separate, enclosed room not open to the public for use as a smoking area. Any provisions in a smoking policy more restrictive than the minimum requirements of N.Y. PUB. HEALTH § 1399-o are subject to applicable laws governing collective bargaining if a collective bargaining unit exists.

N.Y. LAB. § 283 (McKinney 2002): Smoking is prohibited in factories. Smoking may be permitted in protected areas of the factory where the safety of employees will not be endangered.

NORTH CAROLINA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

State Buildings

N.C. GEN. STAT. §§ 143-597, 143-599 (2002): Smoking may be prohibited in no more than eighty percent of the interior space of state-controlled buildings. Where feasible, the twenty percent designated for smoking must be of equal quality to the non-smoking space. The following spaces may be designated as non-smoking in their entirety: libraries open to the public; museums open to the public; auditoriums, arenas, or coliseums, or appurtenant buildings thereof, so long as smoking areas are designated in lobby areas; educational buildings primarily involved in health care instruction; primary or secondary schools or child care centers, except for teachers' lounges; enclosed elevators; public school buses; hospitals, nursing homes, and rest homes; local health departments; non-profit organizations or corporations whose primary purpose is to discourage the use of tobacco products by the general public; and tobacco manufacturing, processing, and administrative facilities.

Preemption of Local Law

N.C. GEN. STAT. § 143-601 (2002): Local laws, rules, and ordinances shall not be amended or enacted to restrict smoking more strictly than state law.

NORTH DAKOTA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

N.D. CENT. CODE § 23-12-10 (2002): Smoking is not permitted outside of designated smoking areas in a place of public assembly. Unless otherwise provided, such smoking areas may not occupy more than fifty percent of the total area available to the public and must be situated to minimize smoke drift. The proprietor of a food establishment with a seating capacity of fifty or more persons may temporarily expand the designated smoking area beyond fifty percent of the total available area if the smoking area becomes fully occupied and the additional space for expansion is vacant.

N.D. CENT. CODE § 23-12-9 (2002): A place of public assembly includes enclosed theaters; auditoriums; gymnasiums; elevators; libraries; public transportation vehicles; rooms in which a person is confined for health care reasons, including the waiting room, restroom, lobby, or hallway of a hospital, nursing home, rest home, or other health care facility; waiting areas in all public transportation terminals; any building or other enclosed structure owned or leased by the state, its agencies, or its political subdivisions; all public education buildings; and all other portions of buildings or enclosed structures if such areas have seating capacities of fifty or more persons and are available to the public, such as restaurants and other food service establishments. A place of public assembly does not include private enclosed rooms of residence, establishments licensed primarily for on-premises consumption of alcoholic beverages, or areas used to serve alcoholic beverages that are physically separate rooms within food service establishments.

Child Care Facilities

N.D. CENT. CODE § 50-11.1-02.2 (2002): Smoking is prohibited in an early childhood facility at any time during which a child is receiving services from that facility.

OHIO

Case Law

D.A.B.E., Inc. v. Toledo-Lucas County Bd. of Health, 773 N.E.2d 536 (Ohio 2002): The Supreme Court of Ohio held that OHIO REV. CODE ANN. § 3791.031 does not authorize a local board of health to prohibit smoking in all public places. The court found that no state law vests local boards of health with unlimited authority

to adopt regulations addressing public health concerns.

Statutes

Public Places

OHIO REV. CODE ANN. § 3791.031 (West 2002): Each place of public assembly must designate a non-smoking area. Places of public assembly include enclosed theaters, opera houses, auditoriums, classrooms, elevators, and rooms in which persons are confined for health care. Places of public assembly also include all enclosed structures owned by the state, including hospitals, state institutions for the mentally ill and retarded, university and college buildings, office buildings, libraries, museums, and vehicles used for public transportation. All other buildings or enclosed structures with a seating capacity of fifty or more persons that are available to the public must designate a non-smoking area. Places of public assembly do not include restaurants, food service establishments, dining rooms, cafes, cafeterias, or places licensed to sell liquor.

Child Care Facilities

OHIO REV. CODE ANN. § 5104.015 (West 2002): Smoking is prohibited in all indoor and outdoor spaces of a child care or family care facility. Smoking may be allowed during hours of operation in areas where children being cared for cannot see the smokers, and where the children are not exposed to smoke.

Schools

OHIO REV. CODE ANN. § 3313.751(B) (West 2002): No student shall smoke or possess tobacco in any area under the control of a school district or educational service center, or at any activity supervised by any school operated by a school district or educational service center.

OKLAHOMA

Case Law

Swanson v. City of Tulsa, 633 P.2d 1256 (Okla. Crim. App. 1981): Defendant was convicted under a city ordinance prohibiting smoking in a "no smoking" elevator. The Court of Criminal Appeals upheld the conviction, finding that the city had the power to punish defendant's act as a criminal offense and that the relevant ordinance was not impermissibly vague.

Statutes

Public Places

OKLA. STAT. tit. 21, § 1247 (2002): Possession of lighted tobacco in any form is a public nuisance and dangerous to public health when it occurs in the following public places: elevators, indoor theaters, libraries, art galleries, museums, permanent indoor roller skating rinks, concert halls, and buses. For each of these

places, except elevators, areas separated from the principal room or rooms may allow smoking. All buildings owned or operated by the state must be designated as non-smoking, but each may have one designated smoking room. Buildings owned or operated by a county or municipal government may be designated as entirely non-smoking or as non-smoking with one designated smoking room, or may remain under the smoking policy in effect prior to the effective date of state indoor tobacco laws.

OKLA. STAT. tit. 63, § 1-1523 (2002): Smoking is prohibited at a meeting of a public body and in designated non-smoking areas in a public place. OKLA. STAT. tit. 63, § 1-1522 defines a public place to include an indoor area owned or operated by the state or a local governmental agency used by the general public or serving as a workplace for public employees or as a meeting place for a public body, or a place used by the general public that is a public or private educational facility, health facility, auditorium, arena, theater, museum, restaurant seating at least fifty persons, place with a license for on-premises alcohol consumption, concert hall, or other facility used for the performance or exhibition of the arts. Smoking is also prohibited in a nursing facility, but smoking areas may be designated for residents and their guests, and separate smoking areas may be designated for employees. Smoking is prohibited in child care facilities during hours of operation. Health facilities may prohibit all smoking or designate smoking and non-smoking areas. Early childhood educational facilities and educational facilities from kindergarten through the twelfth grade must prohibit all smoking while school is in session. Career and technology centers may designate certain smoking areas outside of buildings. Educational facilities may designate areas of smoking for adults outside buildings during such activities as athletic contests. Educational facilities are not preempted from having more restrictive policies regarding smoking. Restrictions on smoking do not apply to places used for private functions if the seating arrangement is under the control of the sponsor of the event and not the owner of the place, or to licensed premises in bowling alleys, licensed racetracks, prisoner housing areas in municipal or country jails, or separate or enclosed areas in licensed bars.

OKLA. STAT. tit. 63, § 1-1524 (2002): A restaurant seating at least fifty persons may have designated smoking and non-smoking areas or may be exclusively one or the other. Smoking and non-smoking areas may be designated by the state or local governmental agency or person who owns or operates a public place except when smoking is prohibited by law.

Preemption of Local Law

OKLA. STAT. tit. 63, § 1-1527 (2002): State smoking restrictions preempt any other regulations promulgated to control smoking in public places and are intended to standardize laws that governmental subdivisions may adopt to control smoking. Any laws adopted by cities and towns shall include the same state

provisions and enforcement provisions shall not be more stringent.

OREGON

Case Law

Oregon Restaurant Ass'n v. City of Corvallis, 166 Or. App. 506 (Or. 2000): Plaintiff challenged the validity of defendant city's ordinance prohibiting smoking in enclosed public spaces. The court held that the Oregon Indoor Clean Air Act contained no hint that the legislature intended to create a positive right to smoke in public places where it did not expressly forbid smoking.

Statutes

Public Places

OR. REV. STAT. § 433.845 (2002): Smoking is prohibited in enclosed indoor areas open to the public, except in areas designated as smoking areas pursuant to OR. REV. STAT. § 433.850. Smoking is prohibited in rooms during times that jurors are required to use them.

OR. REV. STAT. § 433.850 (2002): A proprietor or person in charge of a public place may designate areas in which smoking is permitted. No public place may be designated in its entirety as a smoking area except cocktail lounges and taverns; enclosed offices or rooms occupied exclusively by smokers; rooms or halls being used for private social functions where the seating arrangements are under the control of the sponsor of the function; retail businesses primarily engaged in the sale of tobacco or tobacco products; and restaurants with seating capacity for thirty or fewer patrons or with air filtration systems.

OR. REV. STAT. § 479.015 (2002): Smoking is prohibited in public elevators.

OR. REV. STAT. § 192.710 (2002): Smoking is prohibited at public meetings. A public meeting is any meeting or hearing of a government body open to the public, in buildings or rooms rented, leased, or owned by a subdivision of the state.

Health Care Facilities

OR. REV. STAT. § 441.815 (2002): Smoking is prohibited in hospital rooms in which more than one patient is accommodated, unless the room is specifically designated for smoking, and in other areas where patient care is provided. The person in charge of a hospital must designate reasonable areas in lobbies and waiting rooms—and a reasonable number of rooms in the hospital—where smoking is not permitted.

State Workplaces

OR. REV. STAT. § 243.350 (2002): The Personnel Division shall adopt rules restricting smoking in places of employment operated by state departments or agencies. The rules of the division shall set standards for the designation of

smoking areas, require departments and agencies to designate areas where smoking is permitted (or to ban smoking completely), require departments and agencies that provide employee lounges to provide smoke-free lounges for non-smoking employees, and prohibit smoking in places not designated as smoking areas. The rules adopted do not apply to enclosed offices occupied exclusively by smokers, even though the offices may be visited by non-smokers.

PENNSYLVANIA

Case Law

Quinn, Gent, Buseck & Leemhuis v. Unemployment Comp. Bd. of Review, 606 A.2d 1300 (Pa. Commw. Ct. 1992): Upon learning of her employer's complete ban of smoking in the workplace, an employee promptly resigned. The court held that the employee did not qualify for unemployment compensation benefits because there was insufficient evidence to show that the smoking ban produced real and substantial pressure to quit her job. The court noted that the state Clear Air Act requires employers to develop a smoking policy, but did not require any particular type of policy.

Statutes

Public Places

PA. STAT. ANN. tit. 35, § 1230.1 (West 2002): No person may smoke in areas designated as non-smoking by the proprietor or person in charge of a public place or at a public meeting. A public place is an enclosed indoor area owned or operated by a state or local governmental agency, used by the general public or serving as a workplace for public employees or as a meeting place for a public body, including an office, educational facility, health facility, auditorium, arena, meeting room, or public conveyance; or an enclosed indoor area not owned or operated by a governmental agency that is used by the general public and is a workplace, an educational facility, a health facility, an auditorium, an arena, a theater, a museum, a restaurant, a concert hall, or any other facility used for a performance or exhibit of the arts. The following places are exempt from the smoking ban: private social functions where the area used is controlled by the sponsor and not the proprietor; factories, warehouses, and similar workplaces not frequented by the general public; restaurants seating fewer than seventy-five persons; bar areas in a liquor licensee establishment; lobbies and hallways in public places; hotel and motel rooms; and tobacco retail stores. Restaurants with seventy-five or more seats shall provide patrons with non-smoking and smoking areas reasonably addressing clientele needs and shall make reasonable efforts to prevent smoking in designated non-smoking areas. Regulation of smoking in restaurants with fewer than seventy-five seats is left to the discretion of the

proprietor.

PA. STAT. ANN. tit. 35, § 1225 (West 2002): Smoking is prohibited in any auditorium, balcony, or gallery of any theater or motion picture theater.

Health Care Facilities

PA. STAT. ANN. tit. 35, § 361 (West 2002): No person may smoke tobacco or any other substance in a hospital patient care area or a patient room designated as non-smoking. Only patients may smoke in patient rooms designated as smoking rooms. No person may smoke in a public area of a hospital designated as a non-smoking area. Upon admission, a patient may choose a smoking or non-smoking room; after making reasonable efforts to comply with the patient's choice, the hospital administrator may place the patient in any room.

Schools

PA. STAT. ANN. tit. 35, § 1223.5 (West 2002): Tobacco use or possession by students is prohibited in school buildings and on vehicles and property owned by, leased by, or under the control of a school district. Tobacco use by a person other than a student is prohibited in school buildings and on vehicles and property owned by, leased by, or under the control of a school district. However, the Board of School Directors may designate certain areas on school property where tobacco use by persons other than students is permitted, provided that such areas are at least fifty feet from school buildings, stadiums, or bleachers.

Workplace

PA. STAT. ANN. tit. 35, § 1230.1(g) (West 2002): Employers are required to develop, post, and implement a policy to regulate smoking in the workplace. No law or regulation shall be construed to impair or affect any contractual agreement or any collective bargaining agreement, right, or procedure.

Local Power To Restrict Smoking

PA. STAT. ANN. tit. 53, § 3702 (West 2002): City councils in cities of the first and second class can enact ordinances prohibiting smoking in retail stores arranged to accommodate three hundred or more persons or that employ twenty-five or more employees. However, no such ordinance may prohibit smoking in any restaurant, restroom, beauty parlor, executive office, or any room designed for smoking in such store.

RHODE ISLAND

Case Law

Amico's, Inc. v. Mattos, 789 A.2d 899 (R.I. 2002): The Supreme Court of Rhode Island upheld a local ordinance restricting smoking in licensed restaurants and bars. The court ruled that a county's power to regulate, pursuant to state licensing statutes, is not preempted by state clean air laws.

Sch. Comm. v. Pawtucket Teachers' Alliance Local 930, No. 87-0713, 1987 R.I. Super. LEXIS 3 (R.I. Super. May 21, 1987): The Rhode Island Superior Court held that a school committee could not unilaterally institute a school-wide prohibition on smoking pursuant to the Rhode Island Workplace Smoking Pollution Act without the arbitration contracted for in a union's collective bargaining agreement. The court denied the school committee's request for a preliminary injunction staying arbitration proceedings, finding that the implementation of the smoking ban brought about a change in working conditions that, according to the contract that the parties voluntarily entered into, was amenable to arbitration.

Statutes

Public Places

R.I. GEN. LAWS §§ 23-20.6-2(a), 23-20.6-2(c)-(e) (2002): Smoking is prohibited in any of the following places used by or open to the public: the state house, elevators, indoor movie theaters, libraries, art galleries, museums, concert halls, auditoriums, buses, schools, colleges, universities, public hallways in court buildings, hallways of elderly housing complexes, supermarkets, medical offices, public laundries, hospitals, health care facilities other than hospitals, and assisted living facilities. Smoking may be permitted in these spaces if it is confined to identified areas and areas separated from those used by the general public. Eating facilities with a seating capacity of fifty or more persons shall have separate seating for non-smokers and smokers. Bars, nightclubs, lounges, dance clubs, and privately sponsored social affairs are exempt from this requirement.

Child Care Facilities

R.I. GEN. LAWS § 23-28.15-23 (2002): No person shall smoke in the buildings or outdoor play areas of a licensed child day care center, or in any vehicle used by the center for transporting children. Smoking is not permitted in outside areas of the premises within twenty-five feet of buildings or outdoor play areas. Smoking in permitted areas shall not occur within view of children. No person shall smoke within the household or outdoor play area of a family or group family day care home, or in outside areas on the premises within twenty-five feet of the home or outdoor play areas. Smoking shall not occur on the premises within view of children when individuals receiving day care services are present. Smoking is permitted when recipients of day care services are not present, so long as the provider notifies all parents that smoking occurs during those times.

Health Care Facilities

R.I. GEN. LAWS § 23-17.5-26 (2002): All persons other than nursing home residents are prohibited from smoking in nursing homes. Residents may smoke only in smoking rooms, private rooms, and semi-private rooms where all occupants smoke.

Schools

R.I. GEN. LAWS §§ 23-20.9-5 to 23-20.9-9 (2002): The governing body of each school in Rhode Island is responsible for developing and enforcing prohibitions against the use of tobacco products by any person utilizing school facilities. The prohibitions against smoking in school facilities shall not apply to the use of a tobacco product if used as part of a limited classroom demonstration to show the health hazards of tobacco.

Workplace

R.I. GEN. LAWS §§ 23-20.7-5 to 23-20.7-6 (2002): An employer may prohibit smoking in the workplace. If smoking is permitted, the employer must make reasonable accommodations to protect the health and atmospheric environment of non-smoking employees and to ensure a comfortable environment for all employees. These provisions do not apply to smoking in private homes that serve as workplaces, office spaces leased or rented by independent contractors for their own use, or private enclosed workspaces occupied exclusively by smokers.

SOUTH CAROLINA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

S.C. CODE ANN. § 44-95-20 (Law. Co-op. 2002): Smoking is prohibited in public schools and preschools, except in private offices and lounges that are not adjacent to classrooms or libraries. However, more stringent local regulation of smoking in such private offices and lounges is not preempted. Smoking is also prohibited in all indoor facilities providing children's services, to the extent proscribed by federal law, and in all other child day care facilities; in health care facilities, except where smoking areas are designated in employee break areas (a health care facility may be declared smoke-free); in government buildings, except in private offices and designated employee break areas; in elevators; and in public transportation vehicles, except taxicabs. Smoking is prohibited in arenas and auditoriums of public theaters or performing art centers, but smoking areas may be designated in foyers, lobbies, or other common areas. Smoking is permitted in arenas and auditoriums as part of a legitimate theatrical performance.

Schools

S.C. CODE ANN. § 59-67-150 (Law. Co-op. 2002): Smoking is prohibited on school buses.

SOUTH DAKOTA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes***Public Places***

S.D. CODIFIED LAWS § 22-36-2 (Michie 2002): No person may smoke tobacco or carry any lighted tobacco product in any public place or place of employment. The prohibition does not apply to any sleeping room in a lodging establishment, on-sale licensee, licensed video lottery establishment, licensed gaming establishment, or tobacco or packaged liquor store if the store is primarily used for the sale of tobacco or alcoholic beverages or both.

S.D. CODIFIED LAWS § 22-36-3 (Michie 2002): A public place is any enclosed indoor area to which the public is invited or permitted, including hospitals and medical and dental facilities; nursing facilities; public libraries, museums, theaters, and concert halls; elementary and secondary school buildings; public conveyances; jury rooms; elevators; reception areas; restaurants; retail service establishments; retail stores; and registered and unregistered day care programs, day care centers, day care cooperatives, and family day care homes when children who are not family members of the provider are receiving care. A private residence is a public place only when used for day care.

Workplace

S.D. CODIFIED LAWS § 22-36-4 (Michie 2002): As used in S.D. CODIFIED LAWS § 22-36-2, a place of employment is an enclosed indoor area controlled by a public or private employer and includes work areas, employee lounges and restrooms, conference rooms and classrooms, employee cafeterias, and hallways.

TENNESSEE***Case Law***

No cases dealing with the regulation of smoking in public places were found.

Statutes***Public Places***

TENN. CODE ANN. § 39-17-1604 (2002): Smoking is prohibited in the following places: child care centers, except in designated child-inaccessible areas for adult staff and in private homes that provide child care; any room or area in a community center while being used for children's activities; group care facilities except by adult staff in adult staff residential quarters outside the presence of child clients of the home; health care facilities, except in nursing home facilities and in designated smoking areas for adult staff or outside the facility; museums, except at

private functions not attended by children after normal operating hours and in designated child-inaccessible areas for adult staff; all public and private kindergartens, and elementary and secondary schools except in fully enclosed adult staff residential quarters outside of the presence of students and not within fifty feet of any entrance to any building; residential treatment facilities for children and youth; youth development centers and facilities; and zoos, except in designated child-inaccessible areas where adult staff may smoke. On school grounds, adults may smoke after regular school hours in public restrooms or on property surrounding the school not blocking any entrance and not in public seating areas, such as bleachers used for sporting events.

State Buildings

TENN. CODE ANN. § 4-4-121 (2002): The administrative head of each state department, agency, board, commission, or other entity of the state and the administrative head of each public institution may establish a policy on smoking in buildings under such administrative head's control or supervision. Such a policy shall protect the rights of smokers and non-smokers and shall provide at least one area indoors where smokers are permitted to smoke. If a policy allows smoking in the workplace, then such policy must also provide a non-smoking area in the workplace.

TEXAS

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

TEX. PENAL CODE ANN. § 48.01 (Vernon 2002): Smoking is prohibited in public schools, elevators, enclosed theaters, libraries, museums, hospitals, public buses, trains, and airplanes. People may smoke in these areas if done as part of an authorized theatrical performance or exclusively within designated smoking areas.

TEX. GOV'T CODE ANN. § 494.010 (Vernon 2002): Employees of the Texas Department of Corrections may smoke during work at designated times and locations, provided that the smoking does not negatively affect the comfort or safety of any employee or inmate.

Schools

TEX. EDUC. CODE ANN. § 38.006 (Vernon 2002): The use of tobacco products is prohibited at school-related or school-sanctioned activities taking place either on or off school property.

UTAH

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes*Public Places*

UTAH CODE ANN. §§ 26-38-2 to 26-38-3 (2002): Smoking is prohibited in all enclosed indoor public places and publicly owned buildings, including buildings, offices, shops, elevators, and restrooms; means of transportation or common carrier waiting rooms; restaurants, cafes, or cafeterias; taverns or cabarets; shopping malls, retail stores, grocery stores, or arcades; libraries, theaters, concert halls, museums, art galleries, planetariums, historical sites, auditoriums, or arenas; barber shops, hair salons, or laundromats; sports or fitness facilities; common areas of nursing homes, hospitals, resorts, hotels, motels, bed and breakfast facilities, and other similar lodging facilities, including the lobbies, hallways, elevators, restrooms, restaurants, cafeterias, and other designated dining areas of these facilities; any child care facility; public or private school buildings and their property, but adults may smoke in designated smoking areas in private schools or on the grounds of private schools during non-school hours; and any posted non-smoking area. Smoking prohibitions do not apply to any building owned or used by a social, fraternal, or religious organization, or any facility used for private functions where the arrangements are under the control of the function sponsor; workplace smoking areas; areas not open to the public of owner-operated businesses having no employees other than the owner-operator; guests rooms in hotels, motels, and bed and breakfast facilities (but smoking is prohibited in common areas of these facilities); taverns; private clubs; and separate, enclosed smoking areas satisfying ventilation requirements in passenger terminals of an international airport.

UTAH CODE ANN. § 26-38-3.5 (2002): The smoking prohibition does not apply to American Indians smoking tobacco from a traditional pipe as part of a ceremony.

UTAH CODE ANN. § 26-38-4 (2002): Smoking is prohibited in public places that are adjoined to and share air space with private clubs that allow smoking, if the adjoining public place was in operation or under construction as of January 1, 1995. If a place of public access was not in operation or under construction as of January 1, 1995, it may not adjoin a private club that allows smoking unless it is separated from the adjoining private club by a continuous physical barrier, does not share air space with the private club, and has ventilation completely separate from that of the private club.

Housing

UTAH CODE ANN. § 57-8-16 (2002): Residential unit rental and purchase agreements for condominiums may prohibit smoking.

Public Transportation

UTAH CODE ANN. § 76-10-1506 (2002): Smoking on any bus except a chartered bus is a class C misdemeanor.

VERMONT

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

VT. STAT. ANN. tit. 18, § 1742 (2002): Smoking is prohibited in the common areas of all enclosed indoor places of public access and publicly owned buildings and offices.

VT. STAT. ANN. tit. 18, §§ 1743-1744 (2002): The restrictions in VT. STAT. ANN. tit. 18, § 1742 do not apply to buildings owned and operated by social, fraternal, or religious organizations when used by the membership of the organization, their guests, or their families; areas of owner-operated businesses with no employees that are not commonly open to the public; businesses operating with cabaret licenses; or designated workplace smoking areas.

Schools

VT. STAT. ANN. tit. 16, § 140 (2002): Smoking is prohibited on public school grounds, and no students can use tobacco at school-sponsored functions. Each public school board must adopt policies prohibiting possession and use of tobacco products by students at all times while under staff supervision.

Workplace

VT. STAT. ANN. tit. 18, §§ 1421-1422 (2002): Each employer shall establish, or shall negotiate through the collective bargaining process, a written smoking policy. The policy must prohibit smoking throughout the workplace or restrict smoking to designated enclosed smoking areas. Designated smoking areas may not occupy more than thirty percent of an employee cafeteria or lounge.

VIRGINIA

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

VA. CODE ANN. § 15.2-2801 (Michie 2002): The state and every locality shall provide reasonable non-smoking areas. The requirement does not apply to areas of the Department of Corrections not accessible to the general public in the normal course of business. Smoking is prohibited in the following places: elevators, except in any open, material hoist elevator not intended for use by the public; public school buses; the interior of any public elementary, intermediate, or secondary school; hospital emergency rooms; local or district health departments; polling rooms; indoor service lines and cashier lines; public restrooms in any building owned or leased by the state or its agencies; the interior of any child care center that is not also used for residential purposes; and public restrooms of health care facilities. The proprietor or other person in charge of an educational facility, except any public elementary, intermediate, or secondary school; health facility; or retail establishment of at least 15,000 square feet serving the general public shall designate reasonable non-smoking areas. Tobacco retail stores, warehouses, and manufacturing facilities are governed by separate laws. Any restaurant having a seating capacity for fifty or more persons shall have a designated non-smoking area sufficient to meet customer demand. Seating capacity does not include seats in any bar or lounge area, or seats in a separate room or section that is used exclusively for private functions.

VA. CODE ANN. § 15.2-2802 (Michie 2002): The proprietor or person who manages or otherwise controls any building or structure governed by state smoking regulations must provide reasonable non-smoking areas. Designated smoking areas must be separate to the extent reasonably practicable from those areas normally accessed by the public, while ventilation systems and existing physical barriers must be used in designated smoking areas when reasonably practicable to minimize the permeation of smoke into non-smoking areas.

Local Power To Restrict Smoking

VA. CODE ANN. § 15.2-2803 (Michie 2002): Local ordinances enacted prior to January 1, 1990 are not invalid or unenforceable because of lack of consistency with existing provisions. Unless specifically authorized, ordinances adopted after January 1, 1990 cannot contain provisions or standards that exceed those established by state law.

VA. CODE ANN. § 15.2-2804 (Michie 2002): Any ordinance shall provide that it is unlawful for a person to smoke in the following places: elevators; the interior of any public elementary, intermediate, or secondary school; common areas in an educational facility; any part of a restaurant designated as non-smoking pursuant to the Virginia Clean Indoor Air Act; indoor service lines and cashier areas; school buses; and public conveyances.

VA. CODE ANN. § 15.2-2805 (Michie 2002): Any ordinance may provide that management must designate reasonable non-smoking areas in the following

places: retail and service establishments of at least 15,000 square feet serving the general public; rooms in which a public hearing is being held; places of entertainment and cultural facilities, including but not limited to theaters, concert halls, gymnasiums, auditoriums, other enclosed arenas, art galleries, libraries, and museums; indoor facilities used for recreational purposes; and other public places. Any restaurant having a seating capacity of fifty or more must designate a non-smoking area sufficient to meet customer demand.

VA. CODE ANN. § 15.2-2806 (Michie 2002): Ordinances cannot regulate smoking in bars and lounge areas; retail tobacco stores; restaurants, conference or meeting rooms, and public and private assembly rooms while these places are used for private functions; office or work areas that are not accessed by the general public in the normal course of business or use of the premises; areas of enclosed shopping centers or malls that are external to the retail stores therein, that are used by customers to travel from one store to another, and that consist primarily of walkways and seating arrangements; and lobby areas of hotels, motels, and other public overnight establishments.

VA. CODE ANN. § 15.2-2807 (Michie 2002): Ordinances may allow employers to regulate smoking in private workplaces if the designation of smoking and non-smoking areas is subject to a written agreement between the employer and his or her employees. Also, a total ban on smoking in any workplace shall only be enforced by the employer upon an affirmative vote of the majority of the affected employees, unless such ban is the subject of an employment contract between the employer and employees as a prior condition of employment. No ordinance shall affect non-smoking policies established by employers prior to the adoption of such ordinance.

WASHINGTON

Case Law

No cases dealing with the regulation of smoking in public places were found.

Statutes

Public Places

WASH. REV. CODE ANN. § 70.160.030 (West 2002): No person may smoke in a public place except in designated smoking areas.

WASH. REV. CODE ANN. § 70.160.020 (West 2002): Public places include, but are not limited to elevators, public conveyances or transportation facilities, museums, concert halls, theaters, auditoriums, exhibition halls, indoor sports arenas, hospitals, nursing homes, health care facilities, enclosed shopping centers, retail stores, retail service establishments, financial institutions, educational facilities, ticket areas, public hearing facilities, state legislative chambers and

immediately adjacent hallways, public restrooms, libraries, restaurants, waiting areas, lobbies, and reception areas.

WASH. REV. CODE ANN. § 70.160.040 (West 2002): A smoking area may be designated in a public place except in elevators; buses; streetcars; taxis; public areas of retail stores and lobbies of financial institutions; office reception areas and waiting rooms of any building owned or leased by the government; museums; public meetings or hearings; classrooms; seating areas and lobbies of concert halls, theaters, and indoor sports arenas; and hallways of health care facilities except for nursing homes. No public places other than bars, taverns, bowling alleys, tobacco shops, or restaurants may be designated as smoking areas in their entirety.

Child Care Facilities

WASH. ADMIN. CODE § 388-155-430 (2002): Smoking must be prohibited in all child care facilities in areas used by children during the hours of operation and in all vehicles in which a child is being transported.

Schools

WASH. REV. CODE ANN. § 28A.210.310 (West 2002): Each school district board of directors shall issue a written policy prohibiting the use of all tobacco products on school property.

Workplace

WASH. REV. CODE ANN. § 70.160.060 (West 2002): Smoking prohibitions do not apply to private enclosed workplaces.

WASH. ADMIN. CODE § 296-307-59005 (2002): Smoking must be prohibited entirely in the work environment, or must be restricted to marked and designated enclosed smoking rooms that are not in common areas. Smoking rooms must meet ventilation requirements.

WEST VIRGINIA

Case Law

Bd. of Educ. v. Johnson, 497 S.E.2d 778 (W. Va. 1997): A school bus operator was fired by the Wood County Board of Education for allegedly smoking while transporting children. The Education and State Employees Grievance Board found that the charge had not been proven. The circuit court substituted its own findings for those of the grievance board, prompting the Supreme Court of Appeals to reverse.

Statutes

Public Places

W. VA. CODE ANN. § 16-38-4 (Michie 2002): Smoking is prohibited in tattoo studio workrooms.

W. VA. CODE ANN. § 47-20-28a (Michie 2002): Bingo operators distributing more than one hundred bingo cards shall provide a non-smoking and a smoking section, if smoking is permitted.

W. VA. CODE ANN. § 31-20-5b (Michie 2002): Prisoners cannot smoke in any facility operated solely by the West Virginia Regional Jail Authority.

Public Transportation

W. VA. CODE ANN. § 8-27-10a (Michie 2002): Smoking is prohibited on public vehicles designed for transporting more than seven passengers. The prohibition does not apply to any vehicle operated in interstate commerce or chartered vehicles, except that smoking is prohibited in posted non-smoking areas.

Schools

W. VA. CODE § 16-9A-4 (2002): Smoking is prohibited in school buildings or on school grounds while school is in session. The prohibition does not apply to faculty lounges or offices, or other areas that are not used for instructional purposes and to which students do not have access.

WISCONSIN

Case Law

Rossie v. State / Dept. of Revenue, 133 Wis. 2d 341 (Wis. Ct. App. 1986): Appellant, the Department of Revenue (DOR) challenged the circuit court's judgment that permanently enjoined the DOR from using its internal disciplinary system to enforce two administrative directives that banned smoking in all DOR facilities. Respondent, a DOR employee, cross-appealed the portion of the judgment that declared the directives valid. The court reversed the enjoinder and affirmed the validity of the DOR directives, holding that the directives did not affect a private right or interest, and that state laws do not limit the DOR's authority to issue internal work rules that regulated smoking. The court also rejected the employee's constitutional claims that state tobacco laws violated the employee's right to equal protection and interfered with his right to contract.

Statutes

Public Places

WIS. STAT. § 101.123 (2002): Smoking is completely prohibited in the following places: buses; hospitals, except for adult patients of mental health units with a physician's permission; physicians' offices; the state capitol building and its immediate vicinity; the premises, indoors and outdoors, of day care centers when children who are receiving services are present; and certain correctional facilities. With limited exceptions, smoking is prohibited in the following places: public conveyances, educational facilities, inpatient health care facilities, indoor movie

theaters, offices, passenger elevators, restaurants, retail establishments, public waiting rooms, and indoor areas of state, county, city, village, or town buildings. Exceptions from these prohibitions include rooms in which the main occupants are smokers, even if non-smokers are periodically present in the office or room; entire rooms or halls used for private functions, if the arrangements for the function are under the control of the sponsor of the function; restaurants holding certain liquor licenses if alcoholic beverages account for more than fifty percent of the restaurants' receipts; areas of facilities used principally to manufacture or assemble goods, products, or merchandise for sale; and areas specifically designated for smoking.

Schools

WIS. STAT. § 120.12 (2002): School boards must prohibit the use of any tobacco products on premises owned, rented, or controlled by a school board, except that the school board may allow the use of tobacco products on premises owned by the school district and rented to another party for non-educational purposes.

WYOMING

Case Law

No court cases dealing with the regulation of smoking in public places were found.

Statutes

No statutes dealing with the regulation of smoking in public places were found.

BOOK NOTES

***The Economic Evolution of American Health Care: From Marcus Welby to Managed Care.* By David Dranove. Princeton: Princeton University Press, 2002. Pp. 224.**

Dranove explores the transformational effect of managed care organizations (MCOs) on physician behavior in the American health care system. While most observers believe that MCOs have had a negative impact on health, Dranove alternatively suggests that these free market enterprises possess the capacity to improve the quality of care for patients. The book recommends that MCOs improve their ways of measuring provider performance, make medical records complete and accessible, and enable patients to seek the best available care.

***Safe Food: Bacteria, Biotechnology, and Bioterrorism.* By Marion Nestle. Berkeley: The University of California Press, 2003. Pp. 356.**

This book attempts to answer the questions, "Who decides when a food is safe?" Nestle reveals how the powerful food industry lobby has fought against safety regulations, denied accountability for tragic mishaps, and blamed consumers. Magnifying the problem, government regulations in this area have been largely ineffective. In the end, consumers are left vulnerable to wide-scale food poisonings, genetically engineered "Frankenfoods" with long-term health consequences, and susceptibility to terrorist attacks on food and water supplies.

***Death Is That Man Taking Names: Intersections of American Medicine, Law, and Culture.* By Robert A. Burt. Berkeley: The University of California Press, 2002. Pp. 232.**

This book examines the psychological and social forces underlying American cultural attitudes and policymaking on the issue of death. Burt claims that the post-1970's prevailing notion of a "right to die" and patient autonomy rests on two fundamental assumptions: death benefits the individual for whom pain has become intolerable and death is inevitable and therefore a morally neutral biological event. This ethical position has been translated into public policy through landmark judicial decisions on abortion and capital punishment. Burt raises concerns, however, that the current ethical regime suppresses a powerful undercurrent of ambivalence and moral opposition towards death, which in turn, could ultimately erode the progressive reforms made in the system.

***Pathologies of Power: Health, Human Rights, and the New War on the Poor.* By Paul Farmer. Berkeley: The University of California Press, 2003. Pp. 420.**

Farmer, a Professor of Medical Anthropology at Harvard Medical School and Founding Director of Partners in Health, draws on over twenty years of international medical experience in Haiti, Peru, and Russia to illustrate the link between poverty and health. He exposes the structural elements of politics and economics that contribute to powerlessness and illness among the general population in underdeveloped countries.

***Ethical Issues in Maternal-Fetal Medicine.* By Donna L. Dickenson. London: Cambridge University Press, 2002. Pp. 366.**

This book provides a revealing inspection of the many ethical and social problems linked to maternal-fetal medicine. Experts from reproductive medicine, medical ethics, and law explore topics such as: the balance of power in the doctor-patient relationship; the justifiable limits of paternalism and autonomy; the impact of new technologies and new diseases; and disability and enhancement. A focal theme is uniting analytic philosophy with actual practice.

***Manual for Research Ethics Committees.* By Sue Eckstein. London: Cambridge University Press, 2003. Pp. 624.**

The sixth edition of the Manual for Research Ethics Committees incorporates the key legal and ethical guidelines on major topics in bioethics. Written by leading academicians, practitioners, pharmaceutical industry associations, and professional bodies, the manual presents chapters covering key issues from participation in clinical trials to cloning.

***Self-Trust and Reproductive Autonomy.* By Carolyn McLeod. Cambridge: MIT Press, 2002. Pp. 215.**

A woman's ability to trust herself in making decisions regarding her reproductive health can be affected by new technology, cultural authority of physicians, and patient-physician relationship. Catherine McLeod brings new insight on ways that a woman's self-trust in reproductive health care can be undermined. The book takes a feminist approach in looking at philosophical moral psychology to reproductive and health care ethics. McLeod promotes patient autonomy and provides recommendations to providers on increasing women's self-trust on reproductive health issues.