

TABLE OF CONTENTS

ARTICLES

- 209 ***PLIVA v. Mensing: Generic Consumers' Unfortunate Hand***
Stacey B. Lee
- 264 **The Right to Be Fat**
Yofi Tirosh

NOTES

- 336 **Tipping the Scale: A Place for Childhood Obesity in the Evolving Legal Framework of Child Abuse and Neglect**
Shauneen M. Garrahan & Andrew W. Eichner
- 371 **The Devil (and Drugs) in the Details: Portugal's Focus on Public Health as a Model for Decriminalization of Drugs in Mexico**
Kellen Russoniello

YALE JOURNAL OF HEALTH POLICY, LAW, AND ETHICS

VOLUME XII

SUMMER 2012

EXECUTIVE EDITORIAL BOARD

Editors-in-Chief

Jamie Brooks
Laura E. Raposo

Executive Editors

Carolyn E. Brokowski
Anna Shabalov

Managing Editor

Laura Keay

SENIOR EDITORIAL BOARD

Article Editors

Benjamin Himes
Michelle Lu
Anjali Motgi (Note)
Danielle B. Rosenthal (Note)

Submissions Editors

Sarah Caruana
Garth Strohbehn
Jane Tucker, *Notes*

Webmaster

Laura Keay

YALE JOURNAL OF HEALTH POLICY, LAW, AND ETHICS

VOLUME XII**SUMMER 2012**

STAFF EDITORS

Danny Bousquet
Willa Campbell
Gwen Cassidy
Asiri Ediriwickrema
Kate Gendreau
Paul Guillod
Mona Guo
Samar Post Jamali
Leora Katz
Ike Lee
Julius Oatts
Psyche Philips

Kyle Ragins
Kaitlyn Rechenberg
Alix Rogers
Dionne Rudison
Gabe Scheffler
Surabhi Srivastava
Janine Sun
Chung-sang Tse
Andrew Tutt
Nicole West
Lacey Wright
Anna Zonderman

ADVISORY BOARD

- Henry J. Aaron, Ph.D., *Senior Fellow, Brookings Institution*
- Lori B. Andrews, J.D., *Professor, Chicago-Kent College of Law*
- George J. Annas, J.D., M.P.H., *Professor, Boston University Schools of Law, Medicine, and Public Health*
- John D. Arras, Ph.D., *Porterfield Professor of Biomedical Ethics, University of Virginia*
- M. Gregg Bloche, M.D., J.D., *Professor of Law, Georgetown University, and Co-Director, Georgetown-Johns Hopkins Joint Program in Law & Public Health*
- Troyen A. Brennan, M.A., M.D., J.D., M.P.H., *Executive Vice President and Chief Medical Officer, CVS Caremark*
- Scott Burris, J.D., *Professor, Temple University School of Law*
- Robert A. Burt, J.D., *Alexander M. Bickel Professor of Law, Yale Law School*
- James F. Childress, Ph.D., *Professor, University of Virginia*
- Paul D. Cleary, Ph.D., *Dean and C.E.A. Winslow Professor of Epidemiology and Public Health, Yale University School of Public Health*
- Ruth R. Faden, Ph.D., M.P.H., *Philip Franklin Wagley Professor of Biomedical Ethics and Director, The Phoebe R. Berman Bioethics Institute, Johns Hopkins University*
- John C. Fletcher, Ph.D., *Professor Emeritus, University of Virginia School of Medicine*
- Lawrence O. Gostin, J.D., L.L.D., *Professor and Director, Center for Law and the Public's Health, Georgetown and Johns Hopkins Universities*
- Christine Grady, R.N., Ph.D., *Head, Section of Human Subjects Research, Department of Clinical Bioethics, National Institutes of Health*
- Dean M. Hashimoto, M.D., J.D., M.P.H., *Associate Professor of Law, Boston College, and Chief of Occupational and Environmental Medicine, Massachusetts General Hospital and the Brigham and Women's Hospital*
- Timothy S. Jost, J.D., *Robert L. Willett Family Professor of Law, Washington and Lee University School of Law*
- Ruth Katz, J.D., M.P.H., *Dean and Walter G. Ross Professor of Health Policy, George Washington University School of Public Health and Health Services*
- David Kessler, M.D., J.D., *Dean, University of California, San Francisco School of Medicine, and Former Commissioner of the U.S. Food and Drug Administration*
- Alvin K. Klevorick, Ph.D., *John Thomas Smith Professor of Law and Professor of Economics, Yale Law School and Yale University Department of Economics*
- C. Everett Koop, M.D., Sc.D., *Senior Scholar, C. Everett Koop Institute at Dartmouth College and Former Surgeon General of the United States*
- Stephen R. Latham, J.D., Ph.D., *Deputy Director, Yale's Interdisciplinary Center on Bioethics*
- Jerold R. Mande, M.P.H., *Director of Policy Programs, Yale University School of Medicine*
- Theodore R. Marmor, Ph.D., *Professor, Yale University School of Management and Yale Law School*
- Leslie Meltzer, J.D., M.Sc., *Greenwall Fellow in Bioethics and Health Policy, Georgetown University Law Center and the Johns Hopkins Bloomberg School of Public Health*
- Theodore W. Ruger, J.D., *Professor, University of Pennsylvania Law School*
- Elyn R. Saks, M.Litt., J.D., *Orrin B. Evans Professor of Law, Psychology, and Psychiatry and the Behavioral Sciences, University of Southern California Gould School of Law*

ARTICLES

***PLIVA v. Mensing*: Generic Consumers' Unfortunate Hand**

Stacey B. Lee*

INTRODUCTION.....	211
I. DRUG APPROVAL PROCESS.....	214
A. BRAND-NAME DRUG APPROVAL AND LABELING PROCESS	214
1. PRE-APPROVAL.....	214
2. POST-APPROVAL.....	215
B. GENERIC DRUG APPROVAL AND LABELING PROCESS.....	219
1. PRE-APPROVAL.....	219
2. POST-APPROVAL.....	221
II. THE FEDERAL PREEMPTION DEBATE'S EFFECT ON THE GENERIC- LABELING FRAMEWORK	228
A. GENERIC MANUFACTURERS' REGULATORY FRAMEWORK BEFORE PLIVA V. MENSING: WYETH V. LEVINE AND THE SUBSEQUENT CIRCUIT SPLIT	228
B. PLIVA V. MENSING PROCEEDINGS BELOW	231
C. PLIVA V. MENSING	235
D. IMPLICATIONS FOR CONSUMERS, HEALTHCARE PROVIDERS, AND STATES	237
III. THE NEED FOR A NEW FRAMEWORK.....	245
A. INADEQUACIES OF THE CURRENT FRAMEWORK	245
1. GENERIC MANUFACTURERS' LACK OF DATA.....	245

* Assistant Professor, Johns Hopkins Carey Business School; J.D., University of Maryland School of Law. This piece was selected for the 2010 Health Law Scholars Workshop, sponsored by the Saint Louis University Center for Health Law Studies and the American Society of Law, Medicine & Ethics. Thank you to my reviewers: Professors Peter Jacobson, Judith Darr, Nicholas Terry, Efthimi Parasidis, and Robert Gatter.

2. LACK OF APPROPRIATE MECHANISMS FOR GENERIC MANUFACTURERS TO CHANGE A DRUG'S LABEL	249
3. THE FDA'S CONSTRAINTS PREVENT ADEQUATE POSTMARKET MONITORING OF GENERIC DRUGS TO ENSURE CONSUMER SAFETY	250
B. THE NEW FRAMEWORK	252
1. NECESSARY TOOLS FOR GENERIC MANUFACTURERS	252
2. ADDRESSING ANTICIPATED CRITICISMS.....	259
3. RECONCILING THE PROPOSED FRAMEWORK WITH THE INTENT OF THE HATCH-WAXMAN ACT	261
CONCLUSION	262

INTRODUCTION

The United States Supreme Court held in *PLIVA v. Mensing* that federal preemption immunizes generic drug manufacturers from liability for state law failure-to-warn claims.¹ As a result, consumers harmed by a mislabeled generic drug will be unable to bring actions against generic manufacturers under state law. The Court confessed that the resulting federal drug-labeling scheme dealt consumers an “unfortunate hand.”² By removing generic manufacturers’ duty to improve the adequacy of their products’ warning labels, the Supreme Court calls into question the safety of generic drugs.

This Article explores the unfortunate hand that *PLIVA* dealt generic drug consumers and proposes a framework to increase the odds that generic drug consumers are provided with safe, effective, and adequately labeled generic drugs. To fully understand how *PLIVA* recasts the generic manufacturers’ safety obligations to consumers, this Article begins with a discussion about the approval process for brand-name and generic drugs and the corresponding manufacturer responsibilities. In particular, this Article focuses on manufacturers’ post-approval responsibilities. Next, the discussion examines how *PLIVA* substantively alters generic manufacturers’ post-approval responsibilities and weakens the safety provisions in the drug-labeling framework. This Article then explores the implications this compromised framework could have on consumers, patients, physicians, pharmacists, and states. This Article offers a regulatory framework to remedy the deficiencies created by *PLIVA*. In doing so, the argument addresses anticipated criticisms and illustrates how the proposed framework fulfills the Hatch-Waxman Act’s goal of providing consumers with safe generic drugs.

Changes to the generic drug-labeling framework were instantiated after the Supreme Court determined the validity of the impossibility defense asserted by generic manufacturers to consumer state law failure-to-warn claims. Specifically, the *PLIVA* Court focused its preemptive lens on the regulatory requirements that govern generic manufacturers’ post-approval labeling responsibilities.³ This scrutiny assessed whether the federal regulations imposing a duty on generic manufacturers to maintain warning labels identical to their branded counterparts conflicted with, and therefore preempted, the state law duty to continuously change their warnings in order to produce increasingly safe labels.⁴ The Court concluded that the structure of the federal regulatory requirements rendered it impossible for generic manufacturers to comply with both.⁵

1. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577-78 (2011).

2. *Id.* at 2581.

3. *Id.* at 2575-77.

4. *Id.* at 2577.

5. *Id.*

By finding preemption grounded in “impossibility,” the Court settled much of the debate over the validity of generic manufacturers’ preemption defense. This debate touched on several important legal and moral issues: the appropriate level of judicial deference to agency pronouncements, the scope of State authority to protect citizens through the availability of product liability lawsuits,⁶ and the existence of factual predicates for drug manufacturers to claim preemption.⁷ In this respect, *PLIVA* resolved the question regarding the right of consumers to bring state-level failure-to-warn claims against generic drug manufacturers.

PLIVA exposes, but leaves unresolved, a more fundamental regulatory concern. A central premise of the federal drug regulatory framework is that “the manufacturer bears responsibility for the content of its label at all times.”⁸ Inherent in this responsibility is the federal requirement that generic manufacturers monitor the safety of their products.⁹ Nevertheless, generic manufacturers’ labeling requirements are bound by a regulatory scheme that is devoid of any formal requirements setting forth generic manufacturers’ duty to initiate a label change to warn consumers.¹⁰ The regulations also fail to articulate a label-changing process if a generic manufacturer wants to provide consumers with more accurate and timely product-labeling information.¹¹ Against this backdrop, *PLIVA* further erodes generic manufacturers’ nebulous labeling duties, by inoculating them against liability in situations in which they do not take steps to comply with state law requirements to strengthen their drugs’ safety labels.

While the need to address the inadequacies of the regulations governing generic manufacturers’ post-approval duties is exacerbated by the Court’s holding in *PLIVA*, fissures in the generic-labeling framework are longstanding. Prior to *PLIVA*, consumers faced divergent federal court interpretations regarding generic manufacturers’ obligation to comply with state law duty-to-warn requirements.¹² The split among the circuits intensified after the Supreme Court’s holding in *Wyeth v. Levine*. This decision seemingly sounded the death knell for brand-name manufacturers’ preemption defense to state law failure-to-warn claims when it rejected a similar preemption argument on behalf of brand-name manufacturers.¹³ Although the case did not directly reference generic

6. James M. Beck, *Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are and Where We Might Be Headed*, 32 HAMLINE L. REV. 657, 684-87 (2009); Margaret Gilhooly, *Drug Preemption and the Need To Reform the FDA Consultation Process*, 34 AM. J.L. & MED. 535, 536 (2008).

7. Lesley A. Stout, *Making Changes: Generic Drug Labeling and the Case Against Federal Preemption*, 98 KY. L.J. 623, 636-44 (2010).

8. *PLIVA*, 131 S. Ct. at 2576 (quoting *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009)).

9. *Id.* at 2586 (Sotomayor, J., dissenting).

10. *Id.* at 2582 (majority opinion).

11. *Id.*

12. See discussion *infra* Section II.A.

13. *Wyeth*, 555 U.S. 555.

manufacturers, a majority of circuits extended the Court's preemption exclusion to generic manufacturers.¹⁴

In *PLIVA*, the Supreme Court distinguished the error in such an application. The Court explained that “the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers.”¹⁵ As articulated by the FDA, the Supreme Court held that tools permitting brand-name manufacturers to change unilaterally their labels are not available to generic manufacturers.¹⁶ The practical effect of such a determination is twofold. First, generic manufacturers are prohibited statutorily from preventing consumer injury by independently strengthening inadequate warning labels on their products. Second, the ability of an injured consumer to bring a failure-to-warn claim against a drug manufacturer turns on “the happenstance” of whether the consumer's pharmacist dispensed the brand-name or generic version of the drug.¹⁷ The Court conceded that such a finding results in a federal drug scheme that deals generic consumers an “unfortunate hand.”¹⁸ After this acknowledgement, however, the opinion ends.

This Article picks up where the Supreme Court's decision left off, by exploring the implications of *PLIVA* for individual consumers and drug safety in general. Specifically, the Court's opinion creates a schism in the complementary federal and state regulatory schemes. This may lead to situations in which no manufacturer has the legal responsibility or ability to make the necessary changes to improve warnings; such manufacturers also may not be able to warn consumers and healthcare providers. Moreover, *PLIVA* reinforces regulatory deficiencies that dramatically reduce the awareness of the FDA and drug manufacturers of adverse consumer reactions to generic and brand-name medications. Further, the Court's opinion may have the chilling effect of diminishing consumer confidence in the safety and effectiveness of generic drugs. In refusing to concede the finality of this decision, this Article proposes a regulatory framework that enables generic manufacturers to meet unilaterally their primary responsibility to provide safe and effective drugs to consumers by equipping them with the tools necessary to address labeling concerns.

Part I provides an overview of the drug approval process. Section A of this Part examines the regulatory framework that defines the pre- and post-approval processes for brand-name drugs. Section B provides similar background about the approval procedures for generic drugs. Part II offers a focused analysis of the regulatory framework that defines generic manufacturers' post-approval labeling

14. See *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225 (9th Cir. 2011); *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

15. *PLIVA*, 131 S. Ct. at 2582.

16. *Id.* at 2575.

17. *Id.* at 2583.

18. *Id.* at 2581.

responsibilities, explores the duties of generic manufacturers in the wake of *PLIVA*, and examines the probable implications that truncated regulatory requirements will have on consumers, healthcare providers, and states. Section A of Part III highlights problems in the current regulatory framework by explaining how, at critical junctures of the generic drug's pre- and post-approval life cycle, manufacturers are denied data, consultation opportunities, and adequate access to compliance mechanisms. Finally, Section B articulates a practical framework in which generic manufacturers will have the necessary tools to fulfill their responsibility to provide consumers and the medical community with current and accurate labeling instructions for their products.

I. DRUG APPROVAL PROCESS

To appreciate the need for a more responsive legal and regulatory framework for generic drug manufacturers, it is necessary to explore the current drug approval process and how it incorporates generic drugs. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA).¹⁹ This Act granted the FDA exclusive authority to regulate the prescription drug industry.²⁰ Accordingly, it is the FDA's responsibility to ensure that drugs are safe, effective,²¹ and not mislabeled.²² To this end, the FDA is the principal governmental authority that establishes the regulations governing the manufacture, sale, and labeling of prescription drugs.²³

A. Brand-Name Drug Approval and Labeling Process

1. Pre-approval

Pursuant to the FDCA, all drug manufacturers must receive FDA approval before they introduce a new drug on the market.²⁴ For brand-name drugs, this requires the manufacturer to submit a new drug application (NDA) to the FDA. The NDA must contain information about the drug's safety and efficacy, which must be supported by data from clinical trials.²⁵ The manufacturer must also provide proposed labeling that reflects the appropriate drug use and warns about potential dangers and adverse reactions associated with the drug.²⁶

19. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-399D (1938)).

20. 21 U.S.C. § 355(a) (2006).

21. *Id.*

22. *Id.* § 355(d).

23. *Id.* §§ 321(n), 331(a)-(b), (k), 352, 355, 393(b)(2)(B).

24. *Id.* § 355(a).

25. *Id.* § 355(a)-(b), (d).

26. *Id.* § 355(b)(1)(F). See also 21 C.F.R. § 201.80 (2009) for detailed specifications about a drug's labeling.

Under the FDCA, labeling comprises “all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”²⁷ Also, courts have interpreted labeling to include product advertising attendant to the product.²⁸ A drug label that contains false, misleading, or inadequate information will be rejected by the FDA on the basis that the drug is mislabeled.²⁹

To avoid rejection, brand-name manufacturers work closely with the FDA during the NDA approval process to determine the appropriate labeling for the drug.³⁰ Side effects, contraindications, and relevant hazards are extensively discussed between the manufacturer and the FDA in order to satisfy its requirement that the label includes warnings of known risks based on scientific evidence.³¹ During this process, the FDA takes careful steps to omit risks that are inadequately supported by the scientific research.³² Ultimately, the FDA determines what information is included in the labeling and the exact final version of the instructions.³³ Because drug labeling provides doctors and other medical professionals with information needed to make informed prescription decisions, the FDA’s review of new drugs and their labels typically takes years.³⁴ Under federal law, therefore, the evaluation of a drug’s safety and effectiveness is inextricably linked with the drug’s labeling.³⁵

2. Post-approval

Scrutiny of a drug’s labeling does not end with FDA approval of the NDA. Drug manufacturers have a continued responsibility to maintain accurate labeling information.³⁶ This ongoing responsibility is rooted in several factors. During the pre-approval phase, the drug is tested on relatively small cohorts—generally, between six hundred and three thousand research subjects—and only for a

27. 21 U.S.C. § 321(m).

28. *Kordel v. United States*, 335 U.S. 345, 350 (1948).

29. 21 U.S.C. § 352(a), (f).

30. Brief for Amicus Curiae The United States of America at 5, *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-5500), 2006 WL 1724170 [hereinafter *Colacicco Amicus*] (noting that drug manufacturers and the FDA collaborate extensively when deciding about the content of proposed drug labeling).

31. See 21 C.F.R. §§ 201.56(a), 201.57(c).

32. See *Colacicco Amicus*, *supra* note 30, at 7-8.

33. See 21 C.F.R. §§ 201.56(a), 201.57(c).

34. Michael Dickson & Jean Paul Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 NATURE REVIEWS 417, 418 (2004) (estimating that research, development, testing, FDA review, and approval of a new drug take a minimum of three years).

35. See New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985) (“Drug labeling serves as the standard under which FDA determines whether a product is safe and effective.”).

36. 21 U.S.C. § 331(a)-(b), (k) (2006).

limited time period that is rarely in excess of two years.³⁷ As a result, pre-approval testing cannot readily detect adverse effects that occur infrequently, have long latency periods, or affect populations that are underrepresented.³⁸ Further, because underrepresented subgroups rarely provide sufficient data to permit refined analysis, the FDA's assessment of a drug's risks is performed on a population-wide, rather than on a subgroup-by-subgroup, basis.³⁹ In light of these limitations, the resulting FDA-approved labels cannot guarantee that a drug will not cause serious, unexpected adverse effects, even if properly used for the approved purposes.⁴⁰ To monitor the unanticipated adverse events, the FDA requires all manufacturers to submit adverse event reports to it.⁴¹

In the premarketing phase, the FDA is the exclusive authority for determining the adequacy and approval of the drug's label.⁴² The FDA's authority rests in part on its expertise in evaluating the studies provided by the manufacturer.⁴³ However, in the postmarket world, the burden rests squarely on the manufacturer to ensure that its labeling is adequate. In part, this shift in responsibility reflects the decreased data that the FDA receives regarding postmarket drug testing. For example, manufacturers are not required to provide the FDA with evaluations of the drug's performance in the market or assessments of the drug's safety profile after approval.⁴⁴ Even if such an ongoing obligation were to exist, the FDA might still lack sufficient manpower to make meaningful use of these data, in light of chronic resource constraints.⁴⁵

37. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 471 (2008).

38. INST. MED. NAT'L ACAD., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 37-38 (Alina Baciú et al. eds., 2006).

39. Most clinical studies can detect drug-related injuries that occur at a rate between 1 in 500 and 1 in 1000. "Yet, if the drug is used by 200,000 people . . . a serious adverse event appearing in as few as one in 10,000 people is very significant, since it would occur 20 times. These rare reactions can be identified only after a drug has been widely used." William B. Schultz, *How To Improve Drug Safety*, WASH. POST, Dec. 2, 2004, <http://washingtonpost.com/wp-dyn/articles/A26865-2004Dec1.html>.

40. Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta Analysis of Prospective Studies*, 279 JAMA 1200, 1202 (1998) (explaining that the FDA recognizes that even the most up-to-date, informative labels cannot avert adverse reactions); Kessler & Vladeck, *supra* note 37, at 471-72.

41. 21 C.F.R. § 314.80(b) (2011) (discussing postmarketing reporting obligations for NDA applicants); *id.* § 314.98 (discussing postmarketing reporting obligations for ANDA applicants).

42. 21 U.S.C. § 355(n) (2006). The day of approval is when the FDA is in the best position to comment on the drug's safety and efficacy. During the approval process, the FDA has had access to, and has invested considerable resources in, reviewing all available health and safety data pertaining to the drug.

43. *Id.* § 355(b)(1).

44. Kessler & Vladeck, *supra* note 37, at 492.

45. For example, the FDA's Office of Drug Safety—the unit responsible for monitoring adverse events that arise with the three thousand prescription, and approximately eight thousand over-the-counter, drugs that the FDA has approved—is staffed with one hundred professional employees. *FDA's Drug Approval Process: Up to the Challenge? Hearing Before the S. Comm. on*

As the maker and seller of the product, the primary responsibility to ensure that the drug is safe and effective is rightly placed on the manufacturer.⁴⁶ To this end, there are detailed procedures that regulate postmarket modifications to a drug's labeling.⁴⁷ For example, the brand-name manufacturer is required to conduct extensive postmarketing surveillance.⁴⁸ This includes review and analysis of reported adverse events and published medical and scientific literature.⁴⁹ The FDA requires brand-name manufacturers to disclose any relevant information discovered through this process—including information contained in the adverse reports regarding any version of their product.⁵⁰ In addition, the FDA commonly requires brand-name manufacturers to conduct follow-up phase IV clinical studies after selling their product.⁵¹ This analysis is conducted against the backdrop of the knowledge the manufacturer obtained during the clinical trials and other research conducted throughout the NDA approval process.⁵²

a. Mechanisms for Postmarket Modifications: Prior Approval Supplement

FDA regulations require brand-name manufacturers to provide additional warning labels “as soon as there is reasonable evidence of a causal association”⁵³ between the drug and the clinically significant hazard. The procedure for making these changes is set forth in 21 C.F.R. § 314.70⁵⁴ and includes the Prior Approval Supplement (PAS) and Changes Being Effectuated (CBE) mechanisms.⁵⁵ The PAS

Health, Educ., Labor and Pensions, 109th Cong. 11 tbl. (2005). In contrast, more than one thousand employees in the FDA's Office of New Drugs are involved in the review of a few dozen NDAs a year. *Ensuring Drug Safety: Where Do We Go From Here?: Hearing Before the S. Comm. on Health, Educ., Labor and Pensions*, 109th Cong. 42 (2005) (statement of Dr. Bruce S. Patsy).

46. Brent R. Gibson et al., *The U.S. Drug Safety System: Role of the Pharmaceutical Industry*, 17 PHARMACOEPIDEMIOL & DRUG SAFETY 110, 110-14 (2008).

47. Federal law requires brand-name manufacturers to file “postmarketing reports” with the FDA, notifying it of any serious and unexpected adverse incidents suffered by a user of the drug. See 21 C.F.R. § 314.80 (2009). In addition, manufacturers are required to submit annual reports detailing any other significant new information that might affect the safety, effectiveness, or labeling of the product. *Id.* § 314.81.

48. *Id.* § 314.80(b) (2011).

49. 21 U.S.C. § 355(k) (2006); 21 C.F.R. § 314.80.

50. 21 U.S.C. § 355(k); see also 21 C.F.R. § 314.80(b).

51. 21 C.F.R. § 314.510; FDA, CTR. FOR DRUG EVALUATION & RES. (CDER), CTR. FOR BIOLOGICS EVALUATION & RES., GUIDANCE FOR INDUSTRY: POSTMARKETING STUDIES AND CLINICAL TRIALS - IMPLEMENTATION OF SECTION 505(O)(3) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 3, nn.8-9 (2011), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf> [hereinafter *Clinical Trials Guidance*].

52. 21 C.F.R. § 314.510 (2011). During the period of market exclusivity, the brand-name manufacturer effectively has a monopoly not only on the market for the drug, but also on the accumulated data.

53. *Id.* § 201.57(c)(6)(i) (2006).

54. *Id.* § 314.70 (2011).

55. *Id.* § 314.70(b).

mechanism applies to “major changes” to an approved drug and requires manufacturers to submit a supplemental application to the FDA for approval prior to making significant changes to the approved product.⁵⁶ While PAS provisions enable certain labeling modifications, they expressly exclude labeling changes to “add or strengthen a contraindication, warning, precaution, or adverse reaction.”⁵⁷ Accordingly, manufacturers may not use the PAS mechanism to propose new warnings. Instead, the PAS strictly limits labeling changes to those that are necessitated by post-approval modifications, such as “qualitative or quantitative formulation of the drug product, including inactive ingredients”⁵⁸ that were listed on the original labeling.

b. Mechanisms for Postmarket Modifications: Changes Being Effected

The CBE mechanism also allows brand-name manufacturers to make postmarket modifications to their products’ labeling.⁵⁹ This provision gives brand-name manufacturers the ability to delete from any label “false, misleading, or unsupported indications”⁶⁰ about the drug’s use or effectiveness. Upon learning of a clinically significant hazard, a drug manufacturer can also unilaterally “add or strengthen a contraindication, warning, precaution, or adverse reaction,”⁶¹ without first obtaining FDA approval. This safety valve mechanism enables drug manufacturers to make post-approval label changes immediately to inadequately labeled products and inform doctors and patients about the new information.⁶² Through the CBE process, brand-name manufacturers may independently incorporate the latest safety information into their labels and quickly apprise the public of product changes.

c. Mechanisms for Postmarket Modifications: “Dear Doctor” Letters

A third way branded manufacturers can provide updated warnings about their products is through direct mailings to healthcare providers, commonly referred to as “Dear Doctor” letters.⁶³ These letters constitute a regulated

56. *Id.*

57. *Id.* § 314.70(c)(6)(iii)(A).

58. *Id.* § 314.70(b)(2)(i).

59. *Id.* § 314.70(c)(3).

60. *Id.* § 516.161(b)(1)(B) (2008).

61. *Id.* § 314.70(c)(6)(iii)(A).

62. The regulations, however, require the manufacturer to inform the FDA immediately of the change and to file a Supplemental New Drug Application at least thirty days prior to distributing the drug with the labeling changes.

63. 21 C.F.R. § 200.5 (2001); Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979) (codified at 21 C.F.R. pts. 201, 202); see FDA, CTR. FOR DRUG EVALUATION & RES., OFFICE OF NEW DRUGS, MANUAL OF POLICIES AND PROCEDURES (MAPP) 6020.10: NDAs: “DEAR HEALTH

“labeling” under the statute and case law.⁶⁴ Accordingly, they are subject to the same standards that govern all labeling, including the “misbranding” label provisions.

B. Generic Drug Approval and Labeling Process

1. Pre-approval

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act (the Hatch-Waxman Act), to aid generic drugs in coming to market as quickly as possible after the expiration of a brand-name patent.⁶⁵ This legislation created an abbreviated new drug application (ANDA) for generic drugs that eliminated the need for generic manufacturers to repeat the expensive and time-consuming clinical drug trials conducted by brand-name manufacturers.⁶⁶ The Hatch-Waxman Act permits ANDA applicants to rely on the FDA’s approval of the brand-name drug so long as the generic manufacturer establishes that the generic drug (1) is bioequivalent to its branded counterpart; (2) has the same route of administration, active ingredients, strength, and dosage form as the listed drug;⁶⁷ and (3) has the same labeling as that of the approved drug.⁶⁸ Because brand-name manufacturers hold their production processes as trade secrets, generic manufacturers demonstrate bioequivalence⁶⁹ through independent expertise. Accordingly, to formulate their drugs, generic manufacturers conduct both laboratory and clinical testing to ensure that their products are absorbed in the same manner as their branded counterparts.⁷⁰ They must also comply with the same elaborate chemical manufacturing controls as brand-name manufacturers. As a result, generic companies develop their own proprietary manufacturing processes.⁷¹ These clinical bioequivalence studies

CARE PROFESSIONAL” LETTERS 2 (2003), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm082012.pdf> (establishing protocols for FDA review of such correspondence).

64. 21 U.S.C. § 321(m) (2006); see also *Kordel v. United States*, 335 U.S. 345, 350 (1948); 21 C.F.R. § 202.1(a)(1)(2) (2011).

65. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355) (1984).

66. 21 U.S.C. § 355(j).

67. *Id.* § 355(j)(2)(A)(ii).

68. 21 C.F.R. § 314.94(a)(8) (2008); see *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 164 (4th Cir. 2000) (citing 21 U.S.C.A. § 355(j)(2)(A)(V)).

69. 21 C.F.R. § 320.1(e) (defining bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study”).

70. *Id.* §§ 210-11.

71. *Id.* §§ 314.50(d)(1), 314.94(a)(9).

require ANDA applicants to submit one or more bioequivalence studies in which human subjects are given the generic product, and drug concentrations in the blood are assessed statistically.⁷² The Hatch-Waxman Act, however, does not require applicants to submit clinical or nonclinical evidence to substantiate the safety and effectiveness of the active ingredients.

By requiring generic manufacturers only to prove bioequivalence and to maintain the same label as its branded counterpart, Congress intended a relatively inexpensive and streamlined approval process.⁷³ The resulting regulatory framework eliminated the need to conduct clinical trials because, as Congress noted, such trials would not only be “unnecessary and wasteful because the drug has already been determined to be safe and effective,”⁷⁴ but also would be “unethical because [trials] require[] that some sick patients take placebos and be denied treatment known to be effective.”⁷⁵

The 1992 regulations implementing the Hatch-Waxman Act’s ANDA requirements reiterated that labeling proposed for the generic must be “the same as”⁷⁶ the label of its branded counterpart.⁷⁷ This provision of the Hatch-Waxman Act illustrates the central premise of the ANDA process: that generic drugs are to be relied upon as the therapeutic equivalent of the listed drug.⁷⁸ The FDA places a high priority on ensuring consistency in labeling in order to minimize any cause for confusion among health care professionals and consumers and prevent a lack of confidence in the equivalency of generic versus brand-name products.⁷⁹

As part of the ANDA approval process, a generic manufacturer submits the following information: the proposed labeling for its product;⁸⁰ proof that the “conditions of use prescribed, recommended, or suggested”⁸¹ in the labeling of the generic drug have been previously approved for the brand-name drug; materials for a side-by-side comparison of the proposed labeling to the brand-name drug;⁸² and a statement affirming that the generic labeling is the same as

72. Barbara M. Davit et al., *Comparing Generic and Innovator Drugs: A Review of 12 years of Bioequivalence Data from the United States Food and Drug Administration*, 14 ANNALS PHARMACOTHERAPY 1583, 1584 (2009).

73. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355) (1984).

74. H.R. REP. NO. 98-857, pt. 1 (1984) (“The purpose of . . . the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs . . .”).

75. *Id.*

76. The FDA has defined “same as” to mean “identical.” 21 C.F.R. § 314.92(a)(1) (2008).

77. *Id.*

78. Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,884 (July 10, 1989) (explaining that the purpose of 21 U.S.C. § 355(j) “is to assure the marketing of generic drugs that are as safe and effective as their brand-name counterparts”).

79. See Division of Generic Drugs, FDA Policy and Procedure Guide 37 (1989); Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992).

80. 21 C.F.R. § 314.94(a)(8)(ii).

81. 21 U.S.C. § 355(j)(2)(A)(i).

82. 21 C.F.R. § 314.94(a)(8)(iv).

the labeling of the approved drug.⁸³ In contrast to the brand-name manufacturer's highly participatory role during the NDA approval process, the generic manufacturer's involvement in the ANDA process is restricted to establishing the extent of its identical nature to the branded counterpart. The scope of the FDA's labeling review of an ANDA is confined solely to whether the generic drug's labeling "is the same as the labeling approved for the [brand-name] drug."⁸⁴ In fact, the FDA rejects ANDAs that contain new warnings or safety precautions not present on the brand-name drug's label.⁸⁵

2. *Post-approval*

Once the ANDA is approved, the generic manufacturer's labeling responsibilities expand beyond merely demonstrating that its product's label is identical to that of the listed drug. As noted earlier, FDA labeling regulations reflect the reality that drug labels are subject to change.⁸⁶ In some cases, it is only after wide distribution and prolonged use that certain risks manifest.⁸⁷ Accordingly, after ANDA approval, FDA regulations charge generic manufacturers, as well as brand-name manufacturers, with the obligation to ensure that their products remain safe and effective as labeled.⁸⁸ All manufacturers must file annual reports that contain a "summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product"⁸⁹ and a "description of actions the applicant has taken or intends to take as a result of this new information."⁹⁰

All manufacturers have postmarket reporting duties. However, given the different regulatory frameworks that govern brand-name and generic manufacturers, their responsibilities are not the same. For example, the FDA does not require generic manufacturers to conduct post-approval clinical studies as a condition of ANDA approval,⁹¹ nor do FDA regulations require generic manufacturers to perform the same postmarketing surveillance, review, and data collection activities as brand-name manufacturers.⁹² Such manufacturers are required to review and analyze *all* reported adverse events.⁹³ This analysis is

83. *Id.* § 314.94(a)(8)(iii).

84. 21 U.S.C. § 355(j)(2)(A)(v).

85. Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,884 (July 10, 1989).

86. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 603 (8th Cir. 2011).

87. *Id.*

88. 21 U.S.C. § 355(k).

89. 21 C.F.R. § 314.81(b)(2)(i).

90. *Id.*

91. *See* 21 U.S.C. § 355(j)(2)(A) ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).").

92. 21 C.F.R. §§ 314.81(b)(2)(i), 314.98 (2009).

93. *Id.* § 314.80.

conducted based on the knowledge manufacturers obtain through the detailed clinical trials that they conduct, in order to obtain FDA approval of their branded drug. In contrast, generic manufacturers, who do not possess the underlying scientific data, are required only to forward to the FDA adverse event reports.⁹⁴ In addition, the duty to notify the FDA about a change in safety information for an approved drug differs depending on whether the manufacturer is an NDA or an ANDA holder. Under current regulations, generic manufacturers “should” notify the FDA about a change in safety information for an approved drug application.⁹⁵ Regulations governing brand-name manufacturers, however, state that they “must” notify the FDA about a change in safety information.⁹⁶

Similar to NDA holders, generic manufacturers are required to revise their product labels to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.⁹⁷ Failure to comply with these regulations could render the drug “misbranded” and in violation of the FDCA.⁹⁸ The regulatory mechanisms available for generic manufacturers to supplement and make other changes to an approved ANDA are contained in 21 C.F.R. § 314.97.⁹⁹ This section requires generic manufacturers to comply with 21 C.F.R. §§ 314.70¹⁰⁰ and 314.71,¹⁰¹ which address “major changes” and “moderate

94. *Id.* § 314.98(a) (requiring generic manufacturers to comply only with “the requirements of § 314.80 regarding the reporting and recordkeeping of adverse drug experiences,” rather than the review, scientific literature, and postmarketing provisions of § 314.80). Generic drug manufacturers receive far fewer of the reports than their branded counterparts and the FDA. *See* FDA, CTR. FOR DRUG EVALUATION & RES., OFFICE OF GENERIC DRUGS., MANUAL OF POLICIES AND PROCEDURES (MAPP) 5240.8: HANDLING OF ADVERSE EXPERIENCE REPORTS AND OTHER GENERIC DRUG POSTMARKETING REPORTS 1 (2005), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm079791.pdf> [hereinafter HANDLING OF ADVERSE EXPERIENCE REPORTS AND OTHER GENERIC DRUG POSTMARKETING REPORTS] (highlighting that the Office of Generic Drugs receives fewer adverse event reports, both because the reports frequently do not identify a generic manufacturer for the drug and the safety profile of a drug is well-known before the generic version is approved).

95. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992) (codified at 21 C.F.R. pts. 2, 5, 10, 310, 314, 320, 433).

96. 21 C.F.R. § 314.70(a) (2011).

97. *See id.* § 201.57(c)(6)(i) (2006) (NDA drugs after June 30, 2001); *id.* § 201.80(e) (NDA drugs before June 30, 2001).

98. A drug is considered misbranded when its labeling is false, misleading, or does not provide adequate instructions for use and adequate warnings. *See* 21 U.S.C.A. §§ 321(n), 331(a)-(b), (k), 352 (a), (f), (j), (n) (2006).

99. 21 C.F.R. § 314.97 (2012) (“The applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application.”).

100. *Id.* § 314.70. This section allows the manufacturer to supplement its application and propose changes to the drug or its labeling through Prior Approval Supplement (PAS), *see id.* § 314.70(b), or through the CBE supplement, *see id.* § 314.70(c). The applicability of these provisions to generic manufacturers is discussed *infra* in Subsection I.B.2.

101. *Id.* § 314.71 (2008) (detailing the requirements for making changes to supplements). This regulation states that the procedures are identical to those required for drugs submitted under 21

changes.”

a. Mechanisms for Postmarket Modifications: Prior Approval Supplement

Major changes comprise a large portion of labeling modifications.¹⁰² The procedure for effectuating a major change requires submission of a supplemental application that must be approved by the FDA prior to modifying the label.¹⁰³ For generic manufacturers, however, this prior approval supplement only allows generic manufacturers to use the Prior Approval Supplement (PAS) to revise their product to mirror major changes that their branded counterparts implement.¹⁰⁴ The overarching uniformity requirements contained in the regulations prohibit a generic manufacturer from initiating independent labeling changes.¹⁰⁵

Even if a generic manufacturer could propose a label change through the PAS process, it is questionable if a generic manufacturer would be in a position to evaluate the available data to determine whether or which types of labeling changes are potentially needed. As noted previously, brand-name manufacturers’ reporting requirements necessitate collecting and analyzing all adverse event information associated with their drugs.¹⁰⁶ From that information and the background knowledge acquired through the clinical trials and NDA approval process, brand-name manufacturers have the ability to assess the reported adverse events and discern the need for, and wording of, a major labeling change.¹⁰⁷ The regulatory framework that governs generic manufacturers recognizes that they lack the research base of brand-name manufacturers. Consequently, generic manufacturers submit to the FDA only adverse event reports they receive directly.¹⁰⁸ Given this limitation, the quality of their reports

C.F.R. § 314.50 (2008).

102. See generally *Revisions to 21 C.F.R. § 314.70: Supplement and Other Approved Changes to an Approved Application: PhRMA Perspective*, FDA Public Meeting, PhRMA, 6-10 (Feb. 7, 2007), available at <http://www.fda.gov/OHRMS/DOCKETS/DOCKETS/06n0525/06n-0525-ts00009-LLucisano.pdf>.

103. 21 U.S.C. § 356a(c)(1); 21 C.F.R. § 314.70(b)(2)(v)(A).

104. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082 (proposed Dec. 22, 2000).

105. See 21 C.F.R. § 314.94(a)(8)(iii)-(iv); Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,960 (Apr. 28, 1992) (“After ANDA approval, FDA tracks the labeling status of the pioneer drug product and, if necessary, notifies ANDA holders when and how they must revise their labeling.”).

106. 21 U.S.C. § 355(k); 21 C.F.R. § 314.80.

107. 21 C.F.R. § 314.510 (discussing that post-approval requirements of the FDA typically include conducting additional clinical trials to support new drug indications or formulations, and satisfying safety and efficacy concerns that arise.); see also *Clinical Trials Guidance*, *supra* note 51, at 4.

108. 21 C.F.R. § 314.94.

and any resulting major change request could be compromised by the lack of data from clinical trials. FDA Deputy Commissioner Mark Novitch echoed this concern when he stated, “[I]f adverse reaction reports were received by firms unfamiliar with the clinical trials, and, because of the nature of their business, lacking ties with the research community, we are concerned about the adequacy of the reports we would receive.”¹⁰⁹

b. Mechanisms for Postmarket Modifications: Changes Being Effected

While major changes require prior FDA approval, moderate changes as specified in 21 C.F.R. § 314.71 do not. Moderate changes to an approved label include alterations to “add or strengthen a contraindication, warning, precaution or adverse reaction.”¹¹⁰ Such changes are brought to the FDA’s attention through the CBE process.¹¹¹ The flashpoint in the preemption debate that *PLIVA* settled was whether this process would be available to generic manufacturers. On one side of the debate were those who argued that when the FDA adopted the regulations implementing Hatch-Waxman, the FDA included a provision that required generic manufacturers to “comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application.”¹¹² Read in isolation, these regulations appear to give generic manufacturers the ability to use the CBE process unilaterally to make changes to their approved labels.¹¹³ On the other side of the debate were those, including the FDA and the Eighth Circuit, who concluded that supplements and changes identified in 21 C.F.R. § 314.94 are subject to the substantive standards governing ANDA “applicants,” the person submitting an original ANDA, an amendment, or a supplement and any person who owns an approved ANDA.¹¹⁴ These pre-approval regulations specify that an ANDA application will not be approved unless the generic drug’s proposed

109. Reply Brief of Petitioners *PLIVA, Inc., et al.* on Petition for Writ of Certiorari at 7, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (No. 09-993).

110. 21 C.F.R. § 314.70(A).

111. *Id.*

112. 21 C.F.R. § 314.97; *see, e.g.*, *Stacel v. Teva Pharms., USA*, 620 F. Supp. 2d 899 (N.D. Ill. 2009); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262 (W.D. Okla. 2009); *Kellogg v. Wyeth*, 612 F. Supp. 2d 421 (D. Vt. 2008).

113. *See, e.g.*, *Stacel*, 620 F. Supp. 2d at 905 (“In other words, the regulations affecting generic drug applications state explicitly that the CBE provisions apply to generic drug manufacturers just as they do to name-brand manufacturers.”); *Bartlett v. Mutual Pharm. Co.*, 659 F. Supp. 2d 279, 296 (D.N.H. 2009) (“Just as nothing in the text of the Hatch-Waxman Amendments forbids a generic manufacturer from changing its label from the listed version’s post-approval, nothing in the text of the CBE regulation forbids a generic manufacturer from using the CBE process to do so.”).

114. *See* Brief for the United States as Amicus Curiae Supporting Respondents at 17-18, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 741927, at *17-*18.

labeling is the “same as” that of the brand-name drug¹¹⁵ and that approval will be withdrawn unless the generic labeling *stays* the “same as” its branded counterpart.¹¹⁶ Accordingly, under this interpretation, generic manufacturers cannot use the CBE process to change unilaterally their products’ labeling from wording used by their branded counterparts. The centrality of the CBE process in defining the post-approval responsibilities of generic manufacturers necessitates a closer look at the FDA’s position.

The FDA has long stressed that generic drugs’ labels should be the same as their branded counterpart.¹¹⁷ In response to FDA-proposed regulations implementing the labeling requirements of the Hatch-Waxman Act, several comments addressed whether a generic manufacturer could include warnings or precautions in addition to those listed on the branded drug.¹¹⁸ The FDA summarily rejected each suggestion.¹¹⁹ One comment, specifically addressing the labeling requirements of 21 C.F.R. § 314.94(a)(8), proposed that labeling provisions be “revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions, and other safety-related information.”¹²⁰ In rejecting the suggested change, the FDA insisted that generic drugs labels “must be the same as the listed drug product’s labeling because the listed drug product is the basis for ANDA approval.”¹²¹

Another comment suggested that the “FDA accept ANDAs with warnings or precautions in addition to those on the reference listed drug’s label, provided that such information was not indicative of diminished safety or effectiveness of the generic drug product.”¹²² Again, the FDA rejected the proposed change and reiterated that Section 505(j)(3)(G) of Hatch-Waxman “requires the applicant’s

115. 21 C.F.R. § 314.94(a)(8)(iii); *see* 21 U.S.C. § 355(j)(4)(g) (2006); 21 C.F.R. § 314.150(b)(10) (providing that the FDA may withdraw approval of an ANDA for a generic drug if it finds that the labeling for such a drug is “no longer consistent with that for the listed drug”).

116. 21 U.S.C. § 355(j)(4)(g); 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10).

117. The FDA has reiterated this position several times in the 1992 Final Rule, 21 C.F.R. §§ 314.94(a), 314.94(a)(8), 314.127(a)(7), and public comments to the 1992 final rule, *see, e.g.*, 57 Fed. Reg. 17,961, cmt. 40 (“FDA disagrees with the comments [that] the labeling provisions should be revised to permit ANDA applicants to deviate from labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions, and other safety-related information . . . [and that] ANDA applicants should be allowed to delete some of the indications contained in the labeling for the reference listed drug Except for labeling differences due to exclusivity or a patent and differences under section 505(j)(2)(v) of the act, the ANDA’s product labeling must be the same as the listed drug product’s labeling because the listed drug is the basis for ANDA approval.”).

118. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992) (codified at 21 C.F.R. § 314).

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.* at 17,953.

proposed labeling be the same as that of the reference listed drug”¹²³ and that “the exceptions in section 505(j)(2)(A)(v) and (j)(3)(G) of the [Hatch-Waxman Act] are limited.”¹²⁴ Similarly, the FDA disagreed with a suggestion that it accept petitions under Section 355(j)(2)(C) to submit an ANDA for a product whose labeling differs from its branded counterpart by being “more clear or offer[ing] better directions regarding how the drugs should be taken.”¹²⁵ The FDA admonished that “labeling differences, therefore, are not proper subjects for a suitability petition”¹²⁶ and “reminds applicants that the labeling for an ANDA product must be the same as the labeling for the listed drug product except for differences due to different manufacturers, exclusivity, etc.”¹²⁷

Shortly after the adoption of the Hatch-Waxman Act, the FDA issued a Policy and Procedure Guide. In the Guide, the FDA made it clear that, ultimately, it controls the labeling of generic drugs.¹²⁸ The Guide reiterates that generic manufacturers cannot unilaterally revise their product labels’ warnings, but instead must await FDA instructions before making any changes.¹²⁹ Part of the FDA’s rationale for this approach could be grounded in the recognition of the fragmented nature of the market for generic drugs. There are multiple generic competitors, each possessing only a portion of the accumulated safety data for a given drug. As a result, the FDA reasoned that generic drug manufacturers making unilateral changes could be both impractical and counterproductive¹³⁰:

[E]ach time there is a change in the innovator’s labeling, it could necessitate similar changes in the labeling of as many as 20 or 30 generic products. A change in any section of the package insert of the innovator’s product, particularly an important change, e.g., in WARNINGS, PRECAUTIONS, CONTRAINDICATIONS OR DOSAGE ADMINISTRATION, triggers action by the Labeling Review Branch to request submission from all generic manufacturers of that product. Prompt accomplishment of the revision process is important to assure that consistency is found in the labeling of all similar drug products.¹³¹

123. *Id.*

124. *Id.*

125. *Id.* at 17,957.

126. *Id.*

127. *Id.*

128. FDA, CTR. FOR DRUG EVALUATION & RES., GUIDANCE FOR INDUSTRY: CHANGES TO AN APPROVED NDA OR ANDA: QUESTIONS AND ANSWERS (1999).

129. FDA, CTR. FOR DRUG EVALUATION & RES., DIVISION OF GENERIC DRUGS, CHANGES IN THE LABELING OF ANDAS SUBSEQUENT TO REVISION OF INNOVATOR LABELING, POLICY AND PROCEDURES GUIDE NO. 8-89 (1989) [hereinafter POLICY AND PROCEDURES GUIDE NO. 8-89].

130. In general, generic manufacturers only possess data required by 21 C.F.R. § 314.98 (ANDA post-approval requirements).

131. POLICY AND PROCEDURES GUIDE NO. 8-89, *supra* note 129, at 1.

By limiting the ability of brand-name manufacturers to implement changes unilaterally, and by requiring generic product's labeling to be the same as its listed drug, the FDA made clear the premium it places on uniformity (perhaps at the expense of safety).¹³²

In 2008, the FDA once again affirmed its position regarding the availability of the CBE process for generic manufacturers and stated, specifically, that CBE modifications are not available for generic drugs approved under an ANDA. To the contrary, the proposed rule indicated that generic manufacturers' ability to change a label unilaterally is confined to reflect "differences in expiration date . . . or omission of an indication or other aspect of labeling protected by patent."¹³³

To the extent that generic manufacturers may use the CBE mechanism to propose or effectuate certain labeling changes, the FDA consistently has held that such actions may be taken only to "conform" their product labeling to that of their branded counterpart.¹³⁴ In short, the FDA always has made clear that generic manufacturers may not use the CBE process to craft their own warning labels independently.¹³⁵

As discussed in the next Part, prior to *PLIVA*, the majority of courts interpreted the regulatory framework as providing a sufficient basis to reject generic manufacturers' preemption defense against state law failure-to-warn claims. Accordingly, generic manufacturers were forced to choose between compliance with FDA regulatory guidance or possible liability under state failure-to-warn laws. With that specter of liability now removed, Part II examines the FDA's position on generic manufacturers' labeling responsibilities as articulated in *PLIVA* and the Supreme Court's incorporation of that position into

132. See *supra* Subsection I.B.2; see also POLICY AND PROCEDURES GUIDE No. 8-89, *supra* note 129, at 1.

133. 21 C.F.R. § 314.94(a)(8); see also Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,953, 17,961 n.1 (Apr. 28, 1992). The FDA issued its Final Rule on August 22, 2008. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices - Final Rule, 73 Fed. Reg. 49,603 (Aug. 22, 2008).

134. FDA, CTR. FOR DRUG EVALUATION & RES. (CDER), GUIDANCE FOR INDUSTRY: REVISING ANDA LABELING FOLLOWING REVISION OF THE RLD LABELING 5 (2000), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072891.pdf> ("The sponsor of an ANDA is now responsible for ensuring that the labeling contained in its application is *the same as* the currently approved labeling of the [branded drug].").

135. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,955 ("[T]he agency wishes to remind ANDA applicants that . . . the labeling for an ANDA product must, with few exceptions, correspond to that for the reference listed drug."); see also *id.* at 17,961 ("After ANDA approval, FDA tracks the labeling status of the pioneer drug product and, if necessary, notifies ANDA holders when and how they must revise their labeling."); CTR. FOR DRUG EVALUATION & RES. (CDER), GUIDANCE FOR INDUSTRY: CHANGES TO AN APPROVED NDA OR ANDA 24 (2004), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm077097.pdf> ("All labeling changes for ANDA drug products must be consistent with section 505(j) the Act.").

its holding. Next, this Part focuses on the implications of a framework that immunizes generic manufacturers from failure-to-warn claims and exposes consumers to potential harm from mislabeled medications.

II. THE FEDERAL PREEMPTION DEBATE'S EFFECT ON THE GENERIC-LABELING FRAMEWORK

The preemption debate serves as a lens with which to examine the inadequacies of the regulatory framework that prescribes generic manufacturers' labeling responsibilities. While *PLIVA* recently has thrust the issue into the limelight, consumers' tenuous ability to seek redress against generic manufacturers long has rested on courts' varied interpretations of the FDA regulations. Until *Wyeth v. Levine*, a majority of drug manufacturers had successfully avoided failure-to-warn liability by arguing that the federal regulatory framework preempted labeling changes prescribed by state law, because it was impossible for manufacturers to comply with both.¹³⁶ In addition, a number of courts had held that state law attempts to hold manufacturers liable for failing to strengthen warning labels on their products posed an impermissible obstacle to the effectiveness of federal regulations, and, thus, were preempted.¹³⁷ In 2009, the Supreme Court's decision in *Wyeth v. Levine* extinguished these defenses for brand-name manufacturers. Relying on the Supreme Court's analysis, several circuits extended the *Wyeth* rationale to generic manufacturers by holding that the existing regulatory labeling framework did, in fact, permit generic manufacturers to comply with state law failure-to-warn laws. Two years later in *PLIVA v. Mensing*, a consolidated appeal from the Fifth and Eighth Circuits, the Supreme Court ruled on the soundness of their interpretation.

A. Generic Manufacturers' Regulatory Framework Before PLIVA v. Mensing: Wyeth v. Levine and the Subsequent Circuit Split

The Supreme Court's decision in *Wyeth* called into question the viability of generic manufacturers' preemption defense and set the stage for *PLIVA*. The *Wyeth* decision, however, did not involve, or even reference, generic manufacturers, the Hatch-Waxman Act, ANDAs, or specific labeling

136. See, e.g., *Horne v. Novartis Pharm. Corp.*, 541 F. Supp. 2d 768 (W.D.N.C. 2008); see also *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009).

137. *Mason v. Smithkline Beecham Corp.*, 546 F. Supp. 2d 618, 625 (C.D. Ill. 2008); *Dobbs v. Wyeth Pharm.*, 530 F. Supp. 2d 1275, 1279-82, 1288-89 (W.D. Okla. 2008); *In re Bextra*, No. M: 05-1699 CRB, 2006 WL 2374742, at *6-*9 (N.D. Cal. Aug. 16, 2006); *Conte v. Wyeth, Inc.*, No. CGC-04-437382, 2006 WL 2692469, at *4-*6 (Cal. Super. Sept. 14, 2006); *Gourdine v. Crews*, No. CAL 05-00480, 2006 WL 5277412 (Md. Cir. June 28, 2006), *aff'd*, 955 A.2d 766 (Md. 2008).

regulations.¹³⁸ Nevertheless, it is impossible to discuss the adequacy and contours of the labeling regulatory framework that governs generic manufacturers without starting with *Wyeth*.

In 2001, Diane Levine sued Wyeth for injuries she suffered after receiving a direct intravenous injection of Wyeth's nausea medication, Phenergan.¹³⁹ Using a procedure known as IV push, the drug was inadvertently injected into her artery instead of her vein, resulting in gangrene and the eventual amputation of her arm.¹⁴⁰ Levine filed failure-to-warn claims against Wyeth, the manufacturer of the product. She alleged that the FDA-approved label was inadequate because it failed to warn healthcare professionals of the risk that an improper IV push could cause injuries like those she suffered.¹⁴¹ Wyeth maintained that Levine's failure-to-warn claims were preempted by federal law because the FDA had approved Phenergan for direct IV injection and had approved the labeling that warned of its risks.¹⁴²

In March 2009, the Supreme Court held that Levine's failure-to-warn claims were not preempted against brand-name manufacturers.¹⁴³ The Court considered and rejected Wyeth's preemption arguments that (1) it would have been impossible for Wyeth to alter existing FDA-approved labeling to comply with the state law in question without violating federal law ("impossibility preemption"), and (2) Levine's state law failure-to-warn claims interfered with the congressional objectives by substituting a lay jury's decision of the adequacy of a drug's labeling for the expert judgment of the FDA ("obstacle preemption").¹⁴⁴

According to the *Wyeth* Court, the manufacturer, and not the FDA, bears responsibility for the content of its label at all times.¹⁴⁵ The Court underscored this point by noting that the FDA did not even possess the authority to require a drug manufacturer to alter its label until 2007.¹⁴⁶ Despite key differences in the regulatory frameworks that govern brand-name and generic drugs, courts increasingly relied on *Wyeth*'s reasoning to reinterpret the requirements of the regulatory framework governing generic manufacturers.

For example, in *Schrock v. Wyeth*,¹⁴⁷ an Oklahoma district court interpreted *Wyeth v. Levine* broadly, holding that "the United States Supreme Court has clearly concluded that Congress did not intend [to] preempt state-law failure-to-

138. *Wyeth v. Levine*, 555 U.S. 555 (2009).

139. *Id.* at 559.

140. *Id.*

141. *See id.*

142. *Id.*

143. *Id.* at 581. Justice Stevens wrote for the majority and was joined by Justices Kennedy, Souter, Ginsburg, and Breyer. Justice Thomas concurred in judgment, but wrote a separate opinion. Chief Justice Roberts and Justices Scalia and Alito dissented.

144. *Id.* at 569-71.

145. *Id.* at 570-71.

146. *Id.*

147. 601 F. Supp. 2d 1262 (W.D. Okla. 2009).

warn actions.”¹⁴⁸ In denying the generic manufacturer’s motion to dismiss, the court applied *Wyeth* without considering the regulatory differences between brand-name and generic manufacturers. The *Schrock* court quoted *Wyeth*’s analysis of congressional intent regarding a drug manufacturer’s responsibility to maintain adequate drug labeling, stating, “With respect to a change in drug labels based upon safety information which becomes available after a drug’s initial approval, Congress ‘adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels.’”¹⁴⁹ The court reiterated *Wyeth*’s analysis that unless a manufacturer makes a clear showing that the FDA would reject a label change, making such a change is not impossible.¹⁵⁰

In *Stacel v. Teva Pharmaceuticals, USA*, an Illinois district court cited *Wyeth* and its interpretation of the Code of Federal Regulations as the basis for denying the generic manufacturer’s preemption defense.¹⁵¹ Unlike *Schrock*, the *Stacel* court acknowledged the regulatory differences between brand-name and generic manufacturers. Nevertheless, after considering these differences and engaging in its own analysis of regulations applicable to generic manufacturers, the court concluded not only that the congressional objectives for generic drug labeling are the same as those for brand-name drug labeling, but also that the CBE process is available to both brand-name and generic manufacturers.¹⁵² The court further reasoned that “if the generic manufacturers can utilize the CBE, then the logic of *Wyeth* is directly applicable.”¹⁵³ In considering the *Wyeth* Court’s observation that Congress utilizes state tort actions to help regulate brand-name drugs, the court reasoned that Congress could not take a different position with respect to generic drugs.¹⁵⁴ The court noted that, while generic drugs must have the same labels as their branded counterparts during the application process, the Hatch-Waxman Act does not require the labels to remain the same after approval.¹⁵⁵ Accordingly, the court concluded that, because labeling is a manufacturer’s responsibility and the statute does not require identical labeling post-approval, state law consumer protection duties do not conflict with congressional objectives.¹⁵⁶

Finally, in *Gaeta v. Perrigo Pharmaceuticals Co.*, the Ninth Circuit relied in part on *Wyeth* to elevate generic manufacturers’ labeling responsibilities to that of their branded counterparts and, thus, to reject the generic manufacturer’s

148. *Id.* at 1264.

149. *Id.*

150. *Id.* (citing *Wyeth*, 555 U.S. at 564).

151. 620 F. Supp. 2d 899, 905-07 (N.D. Ill. 2009).

152. *Id.* at 905.

153. *Id.*

154. *See id.* at 907.

155. *Id.*

156. *Id.*

preemption argument.¹⁵⁷ The court justified its elevation of generic manufacturers' responsibilities by referencing the *Wyeth* conclusion that, "because manufacturers have 'superior access to information' about their drugs than does the FDA, especially in the post-marketing phase as new risks emerge, they 'bear primary responsibility for their drug labeling at all times.'"¹⁵⁸ As demonstrated by the legal analysis that formed *PLIVA* appeal, the Fifth and Eighth Circuits similarly relied on *Wyeth* to reject generic drug manufacturers' preemption defense.

B. *PLIVA v. Mensing Proceedings Below*

In 2001, Gladys Mensing's doctor prescribed her Reglan to treat her diabetic gastroparesis, a paralysis that prevents the emptying of the stomach.¹⁵⁹ A year later, Julie Demahy's doctor prescribed her Reglan to treat her gastroesophageal reflux disorder, a condition that prohibits contractions of the esophagus, stomach, and intestines.¹⁶⁰ Pursuant to their states' generic substitution laws, Mensing's and Demahy's pharmacists filled their prescriptions with generic versions of Reglan.¹⁶¹ Mensing and Demahy took the drug as prescribed for approximately four years.¹⁶² Subsequently, both women developed tardive dyskinesia, a severe neurological disorder.¹⁶³ In separate state court actions, Mensing and Demahy sued the generic manufacturers, Wyeth, Inc. and Actavis, Inc. respectively, over the medications.¹⁶⁴ Both state law complaints alleged that "despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than indicated on the label,"¹⁶⁵ the generic manufacturers took no steps to meet their state law obligations to modify their labels to warn of the risks.¹⁶⁶ In response, the generic manufacturers in both cases argued that the plaintiffs' state law tort claims were preempted by federal statutes and FDA regulations.

In *Mensing v. Wyeth*, the federal district court in Minnesota granted the generic drug manufacturer's motion to dismiss, holding that the Hatch-Waxman Act preempted state law failure-to-warn claims.¹⁶⁷ On appeal, the Eighth Circuit

157. *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1127 (9th Cir. 2011).

158. *Id.* at 1230 (quoting *Wyeth v. Levine*, 555 U.S. 555, 578 (2009)).

159. Brief for Respondents Gladys Mensing and Julie Demahy at 4, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 686400, at *4.

160. *Id.*

161. *Id.* at *4-*5.

162. *Id.* at *5.

163. *PLIVA*, 131 S. Ct. at 2573.

164. *Id.*

165. *Id.* at 2573 (quoting *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009)).

166. *See, e.g., id.*

167. *Mensing*, 588 F.3d at 605.

reversed, citing the Supreme Court's decision in *Wyeth v. Levine*.¹⁶⁸ The Eighth Circuit acknowledged that "generic labels must be substantively identical to the name brand label even after they enter the market."¹⁶⁹ Nevertheless, the *Mensing* court rejected Wyeth's preemption defense by concluding that federal law would have at least allowed them to propose "a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved."¹⁷⁰

The Eighth Circuit supported its holding by stating that 21 C.F.R. § 201.57(e) requires a generic manufacturer to "take steps to warn its customers when it learns it may be marketing an unsafe drug."¹⁷¹ The court disagreed with the argument that generic manufacturers comply with the regulation simply by ensuring that their labels are identical to their branded counterpart.¹⁷² In the court's view, generic manufacturers are not "passively to accept the inadequacy of their drug's label as they market and profit from it."¹⁷³

Building on its interpretation that the regulations prohibit generic manufacturer passivity, the Eighth Circuit made short work of the generic manufacturer's impossibility defense.¹⁷⁴ Specifically, Wyeth argued that federal regulations requiring generic manufacturers to maintain warning labels identical to their branded counterparts prohibited these manufacturers from altering their labels to comply with stronger state law requirements through use of the CBE process.¹⁷⁵ In an interesting piece of legal draftsmanship, the court declined to address Wyeth's CBE argument directly. Instead, the court returned to its "steps could have been taken" refrain to render Wyeth's defense moot, stating, "In this case we need not decide whether generic manufacturers may unilaterally enhance a label warning through the CBE procedure because the generic defendants could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved."¹⁷⁶ The court also noted that the manufacturer "'may seek to add safety information to a drug label' through the prior approval process or by requesting that the FDA send 'Dear Health Care Professional' letters."¹⁷⁷ The Eighth Circuit acknowledged that "Congress did not intend that generic manufacturers send out 'Dear Healthcare Provider' letters uncoordinated with other manufacturers of the drug."¹⁷⁸ Nevertheless, the court maintained that the generic manufacturer "could have suggested that the FDA send out [such] a warning letter to health care

168. *Id.* at 607-08 (discussing *Wyeth v. Levine*, 555 U.S. 555 (2009)).

169. *Id.* at 608.

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.* at 609.

174. *Id.* at 608.

175. *Id.*

176. *Id.*

177. *Id.* at 610.

178. *Id.*

professionals.”¹⁷⁹

In refusing to decide definitively on the applicability of the CBE process, the court appeared at least to entertain the notion that the regulatory framework does not provide a mechanism for generic manufacturers to change their labels unilaterally. Rather than concede impossibility, however, the Eighth Circuit offered a solution, namely, that generic manufacturers always have the option of not selling their product: “The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product.”¹⁸⁰

In *Demahy v. Actavis*, a federal district court in Louisiana similarly denied a motion to dismiss filed by the generic manufacturer.¹⁸¹ The Fifth Circuit affirmed, holding that Demahy’s state law claims were not preempted, based in large part on its reliance on *Wyeth*.¹⁸² Notwithstanding its broad reliance on *Wyeth*, the court offered several novel regulatory interpretations that are worth discussing.

In contrast to *Mensing*, where the Eight Circuit chose not to address directly the applicability of the CBE process, in *Demahy*, the Fifth Circuit opted for a different approach. After a detailed review of FDA statements and regulations, the court determined that the statutory scheme was silent about the manufacturer’s obligations after the ANDA is granted.¹⁸³ From that silence, the court deduced that the FDA does not expressly prohibit generic manufacturers from using the CBE process.¹⁸⁴ As a result, the court stated, “[w]ithout explicit reference to the use of the CBE process by generic manufacturers, we decline to read in a bar to its use.”¹⁸⁵ The court applied this same “no specific prohibition” logic to its conclusion with respect to the availability of Dear Doctor letters.¹⁸⁶ The court conceded that, while these letters require pre-approval by the FDA, nothing in the regulations specifically prohibits generic manufacturers from at least proposing that the FDA send them out on their behalf.¹⁸⁷

When presented with arguments that inherent deficiencies in the regulatory framework made meeting both federal and state labeling requirements impossible, the court was unmoved. In particular, under the current regulatory scheme, if a generic manufacturer attempted to change its label, Actavis argued that the FDA could withdraw approval for the drug upon finding “a lack of

179. *Id.* at 611.

180. *Id.*

181. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010).

182. *See also id.* at 430, 434-35, 446, 449 (“*Levine* is not the case before us.”).

183. *Id.* at 426, 436.

184. *Id.* at 442.

185. *Id.* at 444.

186. *Id.* at 444-45.

187. *Id.* at 445.

substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.”¹⁸⁸ Actavis further asserted that changing the label makes it no longer consistent with its branded counterpart and could also prompt the FDA to initiate withdrawal of approval proceedings.¹⁸⁹ Again relying on *Wyeth*, the Fifth Circuit responded it would be “difficult to accept” that the FDA would take punitive action against a manufacturer for strengthening a warning.¹⁹⁰ Instead, once additional risks to the drug emerge, federal law does not preclude the generic manufacturer from taking steps to change the label to provide adequate warnings.¹⁹¹ According to the court, the regulatory framework allows a generic manufacturer to comply with both FDA regulations *and* state law by updating its labeling, proposing to update its labeling, or warning healthcare providers directly.¹⁹²

The *Demahy* court also asserted that the regulatory framework requires all drug manufacturers to revise their products’ labeling as soon “as there is reasonable evidence of an association of a serious hazard with a drug.”¹⁹³ This assertion mischaracterizes the regulatory framework. As a threshold matter, 21 C.F.R. § 201.80(e) does not require generic manufacturers to revise their labels before their branded counterparts.¹⁹⁴ As *Wyeth* recognized, that regulation obligates the brand-name manufacturer “both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.”¹⁹⁵ The rationale for this requirement is the fact that brand-name companies conduct the original clinical studies, form postmarket studies, and are subject to extensive post-approval surveillance obligations.¹⁹⁶ As such, companies are able to place information they acquire in context, review it, analyze its significance, and craft the suitable labeling change based on “sufficient evidence” of the standards for which changes are met.¹⁹⁷ By contrast, generic manufacturers lack the comprehensive data possessed by brand-name manufacturers and lack the context to assess properly the limited post-approval information they received.¹⁹⁸ In recognition of this, the FDA interprets 21 C.F.R.

188. *Id.* at 438.

189. *Id.*

190. *Id.* at 439 (quoting *Wyeth v. Levine*, 555 U.S. 555, 570 (2009)).

191. *Id.*

192. *Id.* at 439, 444.

193. *Id.* at 437.

194. 21 C.F.R. § 201.80(e).

195. *Demahy*, 593 F.3d at 437 (quoting *Wyeth*, 555 U.S. at 571 and citing 21 C.F.R. §§ 201.80(e) and 314.80(b)).

196. 21 C.F.R. § 314.80(b) (discussing postmarketing reporting obligations for NDA applicants).

197. See Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices – Final Rule, 73 Fed. Reg. 49,603, 49,603-605 (Aug. 22, 2008).

198. See, e.g., *id.* at 49,604 (“[T]he causal relationship between a product and an adverse

§ 201.80(e) as requiring generic manufacturers to conform their labeling to that of the brand-name manufacturer in a timely manner. Nevertheless, the Eighth Circuit's regulatory interpretation allowed it to hold that Demahy's state law failure-to-warn claims were not preempted. The generic manufacturers appealed. The Supreme Court granted their petitions for certiorari and consolidated the cases for review.¹⁹⁹ The issue on appeal was whether the duties imposed on generic manufacturers by federal regulations conflicted with, and therefore preempted, the state law duties that would have required a different label.²⁰⁰

C. PLIVA v. Mensing

Similar to their arguments in the proceedings below, Mensing and Demahy argued before the Supreme Court that the generic manufacturers could have, and should have, used the CBE process to modify their labels unilaterally to warn consumers of the true risks of the generic drug. They maintained that the CBE process is an effective way for generic manufacturers "to bring evidence of the need for a new warning to [the] FDA's attention and initiate consideration of whether the labels for both the [brand-name] and generic drugs should be changed."²⁰¹ Under their interpretation of the regulations, if the FDA ultimately were to approve the changes suggested by a generic manufacturer under the CBE process, the FDA then would require that the same change take place on the brand-name label.²⁰² Accordingly, plaintiffs reasoned that a temporary departure in the identical labeling between a generic and brand-name manufacturer "reflects [the] FDA's determination that such temporary differences are justified in the interest of drug safety."²⁰³ Plaintiffs further alleged that generic manufacturers also could have sent a Dear Doctor letter warning healthcare providers of the adverse risks associated with their product.²⁰⁴

The Solicitor General's amicus brief provided a different interpretation. In the FDA's view, federal regulations do not permit generic manufacturers to alter their labels unilaterally, because of the overriding statutory and regulatory requirements that generic drugs mirror the labels of their branded counterparts.²⁰⁵ Accordingly, the federal labeling scheme for generic manufacturers precludes

effect is often difficult to establish and may require large trials, often specifically designed to assess the risk."); *see also Wyeth*, 555 U.S. at 569 (noting that "risk information accumulates over time" and that subsequent developments might have meaning only in light of "reports previously submitted to FDA") (quoting 73 Fed. Reg. at 49,607).

199. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573 (2011).

200. *Id.* at 2572.

201. Brief for Respondents Gladys Mensing and Julie Demahy, *supra* note 159, at *34.

202. *Id.*

203. *Id.* at *35.

204. *PLIVA*, 131 S. Ct. at 2576.

205. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 114, at *15.

them from changing their labels, even under the CBE process.²⁰⁶ The Solicitor General explained further that use of a Dear Doctor letter is similarly unavailable to generic manufacturers.²⁰⁷ While the FDA conceded that no regulation precludes generic manufacturers from sending these letters, it maintained that such a letter “would only be appropriate in tandem with a corresponding change to the [brand-name] drug’s approved labeling.”²⁰⁸ Further, because a generic manufacturer cannot take advantage of the CBE process, the appearance of new risk information in a Dear Doctor letter would be contrary to FDA-approved labeling.²⁰⁹

The majority deferred to the FDA’s interpretations of the regulations regarding the CBE and Dear Doctor processes. In a consummate application of administrative deference, the Court concluded that the FDA’s views were “controlling unless plainly erroneous or inconsistent with the regulation[s].”²¹⁰ As a result, the Supreme Court chose not even to address the regulatory interpretations offered by either of the parties. Consequently, the Court adopted the FDA’s argument that generic manufacturers are prohibited from unilaterally changing their labeling under the CBE process, unilaterally issuing Dear Doctor letters or using the PAS process. Interestingly, however, this is where the Court’s blanket deference to the FDA’s regulatory interpretation ended.

The FDA maintained that, despite an inability to act unilaterally via the CBE process or through a Dear Doctor letter, generic manufacturers had various opportunities to inform the FDA about adverse reactions and risks caused by their products and seek permission to revise their label.²¹¹ After notification from the generic manufacturer of possible adverse health risks caused by the approved drug, the Solicitor General asserted that the FDA could evaluate the risks, and, if necessary, request that the brand-name manufacturer change its label or withdraw the drug’s approval.²¹² As support, the FDA referenced the final rule implementing the ANDA process, which directs a generic manufacturer to contact the FDA if it believes new safety information should be added to its labeling.²¹³ The FDA also noted that ANDA holders could contact the Office of Generic Drugs (OGD) with concerns regarding their products. According to the FDA, the OGD gives high priority to “ANDAs with possible serious safety

206. *Id.*

207. *Id.* at *18-*19 (citing 21 C.F.R. § 201.100(d)(1)).

208. *Id.* at *18.

209. *Id.* at *19 (citing 21 C.F.R. § 201.100(d)(1)).

210. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011) (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997)).

211. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 114, at *20-*35.

212. *Id.* at *21-*22 (citing 21 U.S.C. § 355(e); 21 C.F.R. §§ 314.70, 314.150(a)(2)).

213. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 114, at *20 (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992)).

concerns.”²¹⁴ From this process, the FDA reasoned that generic manufacturers were not powerless to set in motion a process that could lead to safety-enhancing label changes or product removal, both of which could be consistent with state law duties. The FDA maintained that, before a generic manufacturer could claim the affirmative defense of preemption, it must show that (1) the manufacturer proposed to the FDA a label change that could have prevented plaintiffs’ injuries, and, (2) the FDA would have denied any request for that label change.²¹⁵ According to the Solicitor General, only after the manufacturers had asked the FDA for a stronger warning when learning about the link between their product and tardive dyskinesia, and the FDA had rejected a label change, could the manufacturers claim that compliance with the state law duty to warn was truly impossible.

The Supreme Court rejected this regulatory interpretation. In the Court’s view, preemption was proper because there were no steps that the generic manufacturers could have taken independently to comply with both state and federal requirements. In doing so, the Court shed light on why the FDA’s no-preemption position and the “steps could have taken” approach affirmed by the Fifth and Eighth Circuits were unpersuasive. The majority pointed out that the state law’s duty is satisfied only by securing a safer label, not by communicating with the FDA about the possibility of a safer label.²¹⁶ The Court reasoned that had the generic manufacturers alerted the FDA to the increased risk, rather than satisfied their state tort law duties, they would have done no more than “started a Mouse Trap game that eventually [could have led] to a better label on generic metoclopramide.”²¹⁷ In the Court’s view, the Mouse Trap game is not enough to avoid preemption. Rather, the test to overcome preemption is “whether the private party could independently do under federal law what state law requires of it.”²¹⁸ Because “asking the FDA for help” in changing the label, and not changing label on their own, was the only action generic manufacturers could independently take, the Court concluded that plaintiffs’ failure-to-warn claims were preempted.²¹⁹

D. Implications for Consumers, Healthcare Providers, and States

To understand the far-reaching effects that *PLIVA* could have on patient health and safety requires an examination of the dominant role that generic drugs play in today’s healthcare industry. Since passage of the Hatch-Waxman Act, the

214. *Id.* at *21 (quoting CENTER FOR DRUG EVALUATION AND RES., MANUAL OF POLICIES AND PROCEDURES 5200.6, at 3 (May 9, 2001)).

215. *PLIVA*, 131 S. Ct. at 2578.

216. *Id.*

217. *Id.*

218. *Id.*

219. *Id.* at 2580.

impact of generic competition on overall drug prices has been dramatic. Approximately seventy-five percent of all drugs prescribed in 2009 were generic.²²⁰ As a result of concerted efforts by Congress, states, insurers, generic drug companies, physicians, and pharmacists, generic drugs fill nearly 2.6 billion prescriptions a year.²²¹ The Congressional Budget Office reported that generic drug use in 2007 saved senior citizens and the federal government thirty-three billion dollars just on Medicare Part D prescriptions alone.²²² Another recent study reported that dispensing generic versions of brand-name drugs saved the American healthcare system more than \$824 billion over approximately the past decade (2000-2009) and \$139.6 billion in 2009 alone.²²³ Today, the average generic drug costs barely a quarter of its branded counterpart.²²⁴ A 2009 IMS National Prescription Audit illustrated this saving by comparing the typical insurance or government formulary charges: \$6 for generic medications; \$29 for preferred brand-name drugs; and \$40 or more for non-preferred brand-name drugs.²²⁵ The natural effect of the affordability of generic drug alternatives is a dramatic increase in their use.

Adding to the pervasive use of generics are state substitution laws. These laws permit or require pharmacists who receive prescriptions for brand-name drugs to fill them with the drugs' generic equivalent.²²⁶ In addition, even in those states where pharmacists are only permitted (not required) to substitute generics for brand-name drugs, consumers tend to opt for generics because insurance companies often charge higher co-pays for a brand-name drug when a generic is available.²²⁷ State policies favoring generic substitution also receive extra force in the context of publicly funded programs such as Medicare, Medicaid, and the

220. *Id.* at 2884 (Sotomayor, J., dissenting).

221. *Facts at a Glance*, GENERIC PHARM. ASS'N (Mar. 10, 2012), <http://www.gphaonline.org/about-gpha/about-generics/facts> (noting that, overall, only eight out of the fifty most popular drugs are still brand names, compared to twenty in 2003).

222. CONGR. BUDGET OFFICE, EFFECTS OF USING GENERIC DRUGS ON MEDICARE'S PRESCRIPTION DRUG SPENDING vii (2010), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf> [hereinafter CBO 2010].

223. *Press Release, Generic Medicines Saved U.S. Health Care System \$139.6 Billion in 2009; \$824 Billion Saved Over the Last Decade*, GENERIC PHARM. ASS'N, July 26, 2010, <http://www.gphaonline.org/media/press-releases/2010/generic-medicines-saved-us-health-care-system-1396-billion-2009-824-billion>.

224. CBO 2010, *supra* note 222, at 8-9.

225. Murray Aitken et al., *Prescription Spending Trends in the United States: Looking Beyond the Turning Point*, 28 HEALTH AFFAIRS w151, w151-60 (2009).

226. William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFFAIRS 1383, 1386 (2010).

227. Experts Brief, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 794111, at *19-*20 (citing Geoffrey F. Joyce et al., *Employer Drug Benefit Plans and Spending on Prescription Drugs*, 288 JAMA 1733 (2002)); Haiden A. Huskamp et al., *The Effective Incentive-based Formularies on Prescription-Drug Utilization and Spending*, 349 NEW ENG. J. MED. 2224, 2225 (2003).

State Children's Health Insurance Program.²²⁸ Many states require the prescriptions for patients, whose drug expenses are covered by those programs, to be filled with generic drugs.

In addition to state substitution laws, pharmacies have incentives to substitute generic drugs when possible. The federal reimbursement rules in industry pricing structures typically mean that pharmacies can earn a higher markup on the generic option than the branded one.²²⁹ Insurers in the private market may offer direct incentives to pharmacies to substitute cheaper generic drugs for the more expensive branded ones.²³⁰

These features combine to help generic manufacturers earn above-average profit margins. In 2007, profit margins for the top fifty industries in the United States averaged 7.4%.²³¹ Several of the top generic manufacturers saw profits of 12% to 25%—some of which even top the pharmaceutical industry's 15.8% profit margin—without incurring the risk undertaken by brand-name manufacturers in researching potential new drugs that may never come to market.²³² The above facts indicate that, as regulatory and institutional factors have enabled them to obtain an increasing share of the prescription market, generic manufacturers have enjoyed considerable growth in revenue and profits.

Going forward, a number of factors will further increase the growth of generic drugs. The implementation of various provisions of the Affordable Care Act (ACA) will increase Americans' access to care and prescriptions. Specifically, the ACA provides significant expansion of coverage to the uninsured through a Medicaid expansion, an individual requirement to obtain health insurance, and subsidies to help low- and middle-income individuals buy coverage through newly established Health Benefit Exchanges.²³³ Under the terms of this Act, prescription drugs are one of the "essential health benefits" that

228. See, e.g., IND. CODE § 1396b(z)(2)(E); Office of Inspector General, Department of Health and Human Services, *Generic Drug Utilization and State Medicaid Programs*, Jul. 2006, at i, available at <http://oig.hhs.gov/oei/reports/oei-05-05-00360.pdf> ("The Centers for Medicare & Medicaid Services (CMS) has encouraged generic drug substitution (i.e., substituting a generic drug for its brand name equivalent) as a safe and effective way for states to increase drug utilization and reduce costs.").

229. See S.P. Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs*, at 4 (2004).

230. Helene L. Lipton et al., *Pharmacy Benefit Management Companies: Dimensions of Performance*, 20 ANN. REV. PUB. HEALTH 361, 370-96 (1999).

231. *Top Industries: Most Profitable*, CNNMONEY, <http://money.cnn.com/magazines/fortune/fortune500/2008/performers/industries/profits> (last visited July 31, 2012).

232. See PLIVA, ANNUAL REPORT 2007, at 4 (2008); see TEVA PHARMACEUTICAL INDUSTRIES LIMITED, 2009 ANNUAL REPORT; Ben Hirschler & Quentin Webb, Actavis Sees Record Year, No Rush to Sell, Sept. 30, 2010; Wockhardt Unlimited, Annual Report 2009-10, at 73 (2010).

233. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 1501(b), 10106(b), 124 Stat. 119, 244-49, 909-10 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, §§ 1002, 1004, 124 Stat. 1029, 1032-34 (2010) (to be codified at 26 U.S.C. § 5000A).

must be included in health plans.²³⁴

Between now and 2014, the patents of seven of the world's twenty best-selling drugs will expire.²³⁵ The loss of patent protection for these blockbuster drugs will invite competition from generic manufacturers. The ability of generic drug manufacturers to capture significant portions of the market share after a brand-name drug loses its patent is increasing. For example, between 1991 and 1993, generic drugs represented 44% of a market after one year.²³⁶ By 2008, generic drugs controlled as much as 86% to 97% of a market within the first month of entry.²³⁷

It is against this backdrop that the Supreme Court held that generic manufacturers are prohibited from unilaterally taking any steps to ensure the safety and accuracy of their products' warning labels.²³⁸ The following are barred: altering warning labels through the CBE process to reflect the most up-to-date warnings; issuing additional warnings to healthcare providers through Dear Doctor letters; and publicly disseminating any additional warnings on their own.²³⁹ Further, the Court held that consumer state law failure-to-warn claims based on these inadequately labeled products are preempted as a matter of law.²⁴⁰

Of the possible harms that can result from *PLIVA*, the most serious is the extent to which it jeopardizes the health of the growing number of consumers taking generic drugs. As noted previously, once a brand-name manufacturer loses patent protection, generics quickly capture large portions of the market.²⁴¹ While a generic drug's branded counterpart is still on the market, the regulatory framework requires brand-name manufacturers to uncover safety risks. Brand-name manufacturers, however, often leave the market once generic versions are approved. According to IMS Health, a leading aggregator of prescription and pharmaceutical sales, out of 4,318 unique drug molecules with active sales, nearly one-third are available exclusively in generic form.²⁴² In other words, the only version of the prescribed drug is one that is subject to ANDA regulations.

234. *Id.*

235. MEDCO, *Estimated Dates of Possible First Time Generic/Rx-to-OTC Market Entry* (Jan. 2012), http://www.medcohealth.com/art/corporate/anticipatedfirsttime_generics.pdf.

236. CONG. BUDGET OFFICE, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY*, at 28 (Jul. 1998), *available at* <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf>.

237. *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the H. Subcomm. on Commerce, Trade and Consumer Protection, of the Comm. on Energy and Commerce*, 111th Cong. 8 (2009) (statement of Diane E. Bieri, Exec. VP and Gen. Counsel, Pharm. Res. & Mfrs. of Am.).

238. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

239. *Id.* at 2575-76.

240. *Id.* at 2577-78.

241. *Id.* at 2584 (Sotomayor, J., dissenting).

242. GENERIC PHARM. ASS'N, *SAVINGS ACHIEVED THROUGH THE USE OF GENERIC PHARMACEUTICALS 2000-2009*, 7 (2010) *available at* http://www.prescriptionaccess.com/2010_Report_Generic_Savings_GPhA.pdf.

This highlights a common practice in the pharmaceutical industry. A brand-name manufacturer monitors its product only for as long as it has a financial incentive and legal obligation to do so. Once a manufacturer loses its exclusivity, it also loses its revenue stream.²⁴³ As a result, it is not unusual for the brand maker to simply stop selling the drug when facing a dramatic reduction in profits.²⁴⁴ In these situations, there is no manufacturer with the legal responsibility or ability to uncover inadequate label warnings—or even warn consumers and healthcare providers.

Compounding this safety concern is the fact that many long-term risks do not emerge until after a drug is sold as a generic. Often brand-name drugs are approved after short-term safety studies and the long-term effects of a drug are not known for years. Continual monitoring of possible side effects is critical to ensure safety, even in drugs that have lost their patent protections. For example, Metoclopramide, first marketed as Reglan, was approved by the FDA in 1980.²⁴⁵ The drug was available in generic form by the mid-1980s.²⁴⁶ New risk information about the safety of the drug emerged in 2004 and again in 2009.²⁴⁷ Both times, the information resulted in significant label changes. As *PLIVA* makes clear, under the regulatory system, the FDA and brand-name manufacturers are solely responsible for developing drugs, crafting labeling changes, and communicating labeling revisions to healthcare providers and consumers.²⁴⁸ While the Court acknowledges that generic manufacturers have a duty to monitor the ongoing safety of their products and ensure the adequacy of their product labels, these duties are in large part passive.²⁴⁹ The Court sidesteps the issue of holding that generic manufactures have an affirmative duty to take steps to revise by alerting the FDA and providing information about product risks.²⁵⁰ Further, patients have no recourse against generic manufacturers who fail to take these steps.²⁵¹

This absence of generic manufacturer oversight may reasonably diminish consumer confidence in the safety and effectiveness of generic drugs. Since the passage of the Hatch-Waxman Act and the resultant proliferation of generic

243. Cf. Martin A. Ramey, Conte v. Wyeth: *Caveat Innovator and the Case for Perpetual Liability in Drug Labeling*, 4 PITT. J. ENVTL. PUB. HEALTH L. 73, 87 (2010) (noting that generics quickly capture the majority of market share for drug).

244. Brief for Marc T. Law et al. as Amici Curiae in Support of Respondents at 18, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 794111.

245. *Id.* at 15.

246. *Id.*

247. Brief of the American Medical Association et al. as Amici Curiae in Support of Respondents at 15-16, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 794118 [hereinafter *AMA Brief*].

248. *PLIVA*, 131 S. Ct. at 2574.

249. *Id.* at 2584-85.

250. *Id.*

251. *Id.* at 2581.

drugs, Congress and the FDA have gone to great lengths to assure consumers that generic drugs are “just as safe and effective” as brand-name drugs.²⁵² For many, these assurances imply that brand-name and generic manufacturers are bound by the same requirements to actively monitor and ensure the safety of their products that are prescribed to consumers. Echoing an expectation reinforced through products liability case law, many also might presume that, if there is a defect in a product, then both generic and brand-name manufacturers have a responsibility to correct the problem, or, at a minimum, to alert the public. Given these assumptions, consumers may rightly balk at the divergent responsibilities and liability rules to which they can hold manufacturers of seemingly identical products.

In addressing this strange statutory result, the dissent in *PLIVA* contends that, as a result of the Court’s holding, a drug consumer’s right to seek redress for inadequate warnings turns solely on the “happenstance” of whether her pharmacist fills her prescription with the brand-name or a generic.²⁵³ The incongruity of the current framework is made more absurd by the fact that “brand name manufacturers may elect to manufacture and distribute a generic version of their own brand name drug—as Wyeth has done with Reglan—once the brand name drug loses patent protection.”²⁵⁴ In such a situation, injured consumers using the same drug, manufactured by the same company, would be treated differently under the law based solely on fortuity.

In defining the manufacturer’s duties in *PLIVA*, the Court established a hierarchical distinction between brand-name and generic drugs. By mandating substantially stricter safety monitoring requirements for brand-name drugs than generic drugs, the Court undercut the congressional goal of promoting generics as brand-name equivalents. *PLIVA* further deepened this divide by creating a system where consumers of brand-name drugs can sue manufacturers for inadequate warnings, but consumers of generic drugs cannot. This divergent treatment results in two separate, but equally significant, categories of harm. First, it robs individual plaintiffs of their right to be compensated for harm incurred. Second, it eliminates legal incentives for generic drug manufacturers to strive for safety, because they no longer have to worry about state failure-to-warn claims.

Foreclosing consumer state failure-to-warn claims creates a schism in the complementary federal and state regulatory schemes. The contributions of tort law to product safety are well recognized. As the Supreme Court noted in *Wyeth*, “[s]tate tort suits uncover unknown drug hazards and provide incentives for drug

252. *Facts About Generic Drugs*, FDA (Jul. 1, 2012, 11:31 PM), <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm>.

253. *PLIVA*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting).

254. *Kellogg v. Wyeth*, 612 F. Supp. 2d 437, 441 (D. Vt. 2009).

manufacturers to disclose safety risks promptly.”²⁵⁵ In this regard, courts have relied on state law as an important “layer of consumer protection that complements FDA regulation.”²⁵⁶ *PLIVA* eviscerates that traditional state law incentive for generic manufacturers in terms of monitoring and disclosing safety risks. Failure to hold generic manufacturers accountable for nondisclosure of known risks associated with their products also could create a schism between branded and generic drugs that likely would be exploited in marketing campaigns, and, ultimately, result in a turning away from generics by physicians and consumers.

Generic manufacturers need to be incentivized beyond the federal regulatory system to report known safety risks of their products. State tort suits aid in protecting consumers when harmful consequences become evident in drugs already approved by the FDA.²⁵⁷ When such information becomes apparent, manufacturers may not take appropriate action. The practical reality is that manufacturers often continue to sell their products for many years, while denying serious safety risks or downplaying emerging safety concerns.²⁵⁸ The potential damage awards from state failure-to-warn litigation provides drug manufacturers with incentives to quickly provide full and clear information to physicians and the FDA that otherwise may not come to light. Without such a mechanism, generic manufacturers may be motivated to act merely in their immediate financial interest, and, subsequently, become less forthcoming in providing safety-related data.

Litigation brought by individual patients helps to uncover previously unavailable data on adverse effects, questionable practices by manufacturers, and flaws in a regulatory system.²⁵⁹ *PLIVA* has the potential to dramatically reduce the awareness of both the FDA and manufacturers of adverse consumer reactions to generic and brand-name medications. In some cases, it is only when consumers file failure-to-warn lawsuits that the harmful effects of drugs are revealed. In fact, the Supreme Court noted that a benefit of the state law regulatory scheme was that it “motivates injured persons to come forward with

255. *Wyeth v. Levine*, 555 U.S. 555, 579 (2009).

256. *Id.* For example, the Medicaid program provides medical assistance to persons who cannot afford to pay their own medical costs and is funded in significant part by the states. Under the program’s third party liability provisions, states can recoup Medicaid payments from the medical costs portions of tort judgments and settlements. *Arkansas Dept. of Health & Human Servs. v. Ahlborn*, 547 U.S. 268 (2006).

257. *Wyeth*, 555 U.S. at 579.

258. Bruce M. Psaty & Richard A. Konmal, *Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment: A Case Study Based on Documents from Rofecoxib Litigation*, 299 JAMA 1813, 1813-17 (2008); Bruce M. Psaty et al., *Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: Use of Cerivastatin and Risk of Rhabdomyolysis*, 292 JAMA 2622, 2626-30 (2004).

259. See Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 308-11 (2007).

information.”²⁶⁰ By preempting future state law failure-to-warn claims, the Supreme Court virtually eliminated this valuable conduit of information.

The current regulatory framework also could have far reaching implications for states. The *PLIVA* Court’s holding has, in effect, made the states financially responsible for injuries caused by the negligence of a class of for-profit corporations. By immunizing manufacturers from costs that their negligence imposes on the healthcare system, injuries to consumers will go uncompensated by the wrongdoer.²⁶¹ Many of the costs of providing medical care, rehabilitation, and family support services will now be borne by state-funded programs.²⁶² In addition, states no longer can recoup Medicaid payments from the medical costs portion of tort judgments and settlements through Medicaid’s third party liability provisions.²⁶³ This may lead some state legislatures to rethink their support for generic drugs through state substitution laws. Moreover, providing immunity for generic manufacturers seems at odds with a state’s roles as both principal protector of its citizens’ health, safety, and welfare²⁶⁴ and regulator of its health professionals.²⁶⁵

Finally, the Court’s opinion could also adversely affect physician drug-prescribing behavior. As noted by the American Medical Association (AMA), physicians consider many factors in making healthcare decisions.²⁶⁶ Without question, their first priority is patient safety. Nevertheless, in the current healthcare environment, physicians are also under continual pressure to control costs. As such, physicians should be able to prescribe an “equivalent” generic drug with assurance that it is truly the same as the brand-name drug, not only on the date of its approval, but during its lifetime on the market.²⁶⁷ In fact, the AMA recognizes the benefits of generic drugs and supports the right of physicians to prescribe generic equivalents.²⁶⁸ To determine the optimal drug to prescribe, frequently physicians rely on a benefit-risk profile.²⁶⁹ These profiles encompass the most current product safety information from brand-name manufacturers under comprehensive regulatory requirements, not uncertain or unreliable safety data. Divergent labeling responsibilities and liability rules for brand-name and generic manufacturers, however, may now influence that assessment.²⁷⁰ When a

260. *Wyeth*, 555 U.S. at 579.

261. Brief for Nat’l Conf. of State Legislatures as Amici Curiae in Support of Respondents at 18, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 794119.

262. *Id.*

263. *Arkansas Dep’t of Health & Hum. Servs. v. Ahlborn*, 547 U.S. 268, 280-92 (2006).

264. *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 532 (1949).

265. *Barsky v. Bd. of Regents*, 347 U.S. 442, 470 (1954).

266. See *AMA Brief*, *supra* note 247, at 28.

267. *Id.*

268. See *id.* at 29.

269. *Id.* at 5, 21.

270. *Id.* at 29.

physician specifies a prescription to be filled with the brand-name drug, he or she has an assurance that the drug company is monitoring the safety of that drug. In contrast, if the generic drug is prescribed, there can be no guarantee that the product safety information accompanying the generic drug is current or reliable. As noted by Justice Sotomayor, this poses an ethical dilemma for prescribing physicians and may cause them to question the substitution of a generic for a brand-name drug.²⁷¹

III. THE NEED FOR A NEW FRAMEWORK

A. Inadequacies of the Current Framework

1. Generic Manufacturers' Lack of Data

To market a brand-name drug, the current regulatory framework requires manufacturers to conduct the original clinical studies, perform postmarketing studies, and adhere to extensive post-approval surveillance requirements.²⁷² Complying with these duties affords the brand-name manufacturer access to (1) virtually all clinical data on the branded and the generic versions of the drug, (2) all world literature regarding the product, and (3) years of adverse reports from all sources since the drug's approval.²⁷³

By design, the FDA deters generic manufacturers' access to comprehensive data that are readily available to brand-name manufacturers.²⁷⁴ This exclusion begins during the initial ANDA submission to the FDA and persists throughout the post-surveillance requirements.²⁷⁵ In establishing bioequivalence as part of the ANDA process, generic manufacturers cannot access directly any information contained in the brand-name manufacturers' NDA, including clinical data. Rather, generic manufacturers are forced to rely on publicly available literature and the FDA's prior findings of safety and effectiveness of an approved medication.²⁷⁶

271. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2593 (2011).

272. See *supra* Part I for a discussion of the brand-name drug approval process.

273. *Id.*

274. See pre- and post-approval processes discussed *supra* Section I.B.

275. Jane A. Fisher, *Disclosure of Safety and Effectiveness Data Under the Drug Price Competition and Patent Term Restoration Act*, 41 FOOD, DRUG COSM. L.J. 268, 270 (1986) (setting down the historical basis of FDA's interpretation and implementation of the trade secrets doctrine to data).

276. Some innovator manufacturers have filed citizen petitions against the use of the FDA's prior findings. These findings often are based on data from studies submitted as part of an approved NDA. While published literature is available in the public domain, data from NDA submissions remain proprietary. Although the statutory language clearly allows for full NDA applications that rely on data to which the applicant does not have right of reference, language does not clearly specify whether this information can extend beyond published literature. Some pharmaceutical manufacturers have argued that the intent of Section 505(b)(2) was to allow referencing only of

Before a manufacturer submits an NDA for FDA approval, the FDA's Center for Drug Evaluation and Research offers a consulting program to foster early communications between the manufacturer and the FDA. Through this program, brand-name manufacturers receive guidance on the data necessary for submission as well as the regulatory requirements for demonstrating safety and efficacy.²⁷⁷ During the NDA review, the brand-name manufacturer and FDA work together on the drug's warnings and package insert. By the time the drug is ready for marketing, its labeling reflects both the joint efforts of the FDA's years of experience reviewing drugs and drafting warnings and the brand-name manufacturers' firsthand knowledge of the clinical trial results.²⁷⁸

Once introduced into the market, the FDA cannot implement subsequent labeling revisions without first negotiating these changes with the drug brand manufacturer.²⁷⁹ Generic manufacturers are not included in these negotiations. Data and knowledge exchanged here are beyond the reach of the generic manufacturer. In fact, the FDA notifies the generic manufacturer of its proposed changes only if the brand-name manufacturer is no longer marketing the product.²⁸⁰ Similarly, generic manufacturers cannot access the results of phase IV clinical trials that brand-name manufacturers conduct at the FDA's request.²⁸¹ Perhaps it is in light of this systematized restriction from data that the FDA limited the responsibility of generic manufacturers to ensuring that their products were the same as those of the branded counterparts. This rationale for the FDA's approach gains even more traction when one examines the quality of the information that the generic manufacturer receives.

As noted previously, the FDA keeps current on postmarket surveillance by requiring both generic and brand-name manufacturers to submit adverse events. The generic manufacturer's responsibility is limited to submitting only those adverse events that it receives directly.²⁸² While, theoretically, this would appear to give generic manufacturers a knowledge base to suggest labeling changes, in reality, it does not. As observed by the FDA, generic manufacturers rarely receive adverse reports, since most are submitted to the brand-name manufacturer or the FDA directly.²⁸³ In fact, adverse reports often fail to specify

portions of an NDA application available in the published literature, not proprietary portions of data. The FDA has upheld its position that Section 505(b)(2) permits reliance on previous FDA findings of safety and efficacy.

277. See *Colacicco Amicus*, *supra* note 30, at 4-5.

278. *Id.*

279. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, tit. IX § 901(a), 121 Stat. 823 (2007) (codified as amended in sections of 21 U.S.C.).

280. 21 U.S.C. §§ 355(o), 255-1(g), 333(f).

281. *Id.*

282. 21 C.F.R. § 314.98.

283. HANDLING OF ADVERSE EXPERIENCE REPORTS AND OTHER GENERIC DRUG POSTMARKETING REPORTS, *supra* note 94 ("Generally, OGD [FDA's Office of Generic Drugs] receives few [adverse event reports] or similar reports since the reports may not specify a generic

generic manufacturers of the products entirely.²⁸⁴ While brand-name manufacturers are required to submit all adverse reports to the FDA, they are not required to share such information with the generic manufacturers of their product.²⁸⁵ It is ultimately up to the FDA to determine what and how information will be displayed to the public.²⁸⁶

To this end, the FDA requests that manufacturers not submit adverse reports unless there is (1) an identifiable patient and reporter, (2) a suspect drug, and (3) an adverse event or fatal outcome.²⁸⁷ The FDA is of the opinion that “reports without such information make interpretation of their significance difficult, at best, and impossible, in most instances.”²⁸⁸ It even has gone so far as to encourage “manufacturers to submit requests to the Agency . . . to waive the requirement to submit [forms] to the FDA for each adverse experience that is determined to be both nonserious and labeled.”²⁸⁹ Given these constraints and the current data vacuum in which generic manufacturers operate, it is hard to premise wholesale labeling revisions based on one or two adverse reports, generated years after approval.²⁹⁰

Another complication of the regulatory scheme is that once brand-name manufacturers remove their products from the market in favor of generics, there is typically no listing for either the brand-name drug or its generic equivalents in the Physician’s Desk Reference on prescription drugs. Without such listings and with the generic manufacturers’ inability to communicate independently with the physicians, it seems almost impossible for physicians to communicate up-to-date information regarding adverse affects to the manufacturer.

In 2007, Congress passed the Food and Drug Administration Amendments Act, which strengthened the FDA’s authority to compel labeling changes and identify postmarket risks.²⁹¹ Specifically, 21 U.S.C. § 355(j)(2)(A) authorizes the

manufacturer for the drug product.”).

284. *Id.*

285. 21 C.F.R. § 314.80(b).

286. See FDA, Adverse Drug Reaction Reporting Regulations Working Group, Center for Drug Evaluation & Research, *Guidance for Industry, Post-marketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report 1-2* (1997), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071981.pdf>.

287. *Id.*

288. *Id.* at 3.

289. *Id.* at 4.

290. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices - Final Rule, 73 Fed. Reg. 49,603, 49,604 (Aug. 22, 2008) (“[T]he causal relationship between a product and an adverse effect is often difficult to establish and may require large trials, often specifically designed to assess the risk.”); *id.* at 49,607 (noting that risk information accumulates and reasoning that subsequent developments may only be relevant in light of “reports previously submitted to FDA”).

291. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in sections of 21 U.S.C.).

FDA to require manufacturers to make certain labeling changes. Yet, as illustrated by the FDA in the *PLIVA* facts, some generic manufacturers are excluded from receiving FDA warning revisions.²⁹² Specifically, the FDA did not send letters to all metoclopramide manufacturers. Only brand-name and generic manufacturers, with product labels identical to that of the brand-name product that was on the market, were contacted.²⁹³

The data vacuum that the framework creates has taken on added significance for consumers in the post-*PLIVA* world. The FDA maintains, and the Supreme Court assumes, without deciding, that federal law requires generic manufacturers to propose stronger labels.²⁹⁴ The regulatory framework, however, does little to facilitate carrying out such a duty. As discussed in more detail in the following Section, generic manufacturers' access to meaningful data, upon which they could make such recommendations, is severely curtailed. For example, in the *PLIVA* facts, the only information available to the generic manufacturer that might have motivated the manufacturers to approach the FDA for a recommended change was restricted to a handful of adverse reports and publicly available information. In contrast, the FDA and the brand-name manufacturer could rely on the original clinical data, all the world literature regarding the drug, and twenty-nine years of data from adverse reports submitted by all brand-name and generic manufacturers of the drug since it was approved. The harm in such a framework is twofold. First, it essentially requires a generic manufacturer to carry out its duty to monitor the safety of its drugs with one hand tied behind its back. Second, thanks to *PLIVA*, it requires consumers to rely on a regulatory framework that immunizes generic manufacturers against state law claims that would flow from their failure to carry out their duty to continually monitor their products' safety and propose stronger labels to the FDA. To support a warning label revision, a generic manufacturer needs to demonstrate a change in the product's risk-benefit analysis. This type of substantiation necessitates that a generic manufacturer either produce or have access to clinical trial data. The time and expense necessary to generate such data effectively deprive the Hatch-Waxman Act's overriding purpose of providing American consumers and state and federal governments with low-cost generic drugs. Consequently, regulatory changes are needed to ensure that other options are available.²⁹⁵

292. 21 U.S.C. § 355(j)(2)(A) (2006).

293. Brief of Petitioners Actavis Inc. and Actavis Elizabeth LLC, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 288895, at *10.

294. *PLIVA*, 131 S. Ct. at 2576.

295. *Drug Legislation: Hearings on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health and the Env't of the H. Comm. on Energy and Commerce*, 98th Cong. (1983) [hereinafter *Hearings on H.R. 1554 and H.R. 3605*].

2. *Lack of Appropriate Mechanisms for Generic Manufacturers To Change a Drug's Label*

In *PLIVA*, the Supreme Court departed from its deference to all of the FDA's ultimate conclusions over the issue of impossibility. As previously noted, the FDA claimed that generic manufacturers had several mechanisms available to them to advise the FDA about products' risks and adverse events. In describing how generic manufacturers should meet their duty to provide adequate warnings, the FDA referenced the preamble to the final rule implementing the ANDA application process²⁹⁶:

If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.²⁹⁷

In the twenty-three years since implementing the ANDA process, the FDA has failed to promulgate any regulations to govern this procedure.²⁹⁸ Should a generic manufacturer want to raise a safety issue, it is forced to flounder about in an ill-defined process of contacting various members within the FDA's OGD. The FDA provides no timeline for review, contact names for follow-up, specifications of what a concerned manufacturer should submit, or description regarding what happens after the proposed change is submitted. The only vague reference about which type of investigation the FDA conducts after receipt is that "some labeling reviews" will require the OGD to consult with various FDA components before any change can be made.²⁹⁹ To date, the FDA has not identified which labeling reviews trigger this type of consultation, nor has it identified the other components within the FDA that participate in examining these requests. The FDA justifies this haphazard approach by stating that such instances arise infrequently.³⁰⁰ The Supreme Court found this "solution" insufficient for preemption purposes. This Article draws an additional conclusion from the absence of procedures to improve drug labeling.

The need for regulatory reform to ensure that generic drugs are properly

296. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992).

297. *Id.*

298. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 114, at 16.

299. *Id.* at 21.

300. *Id.*

labeled is evidenced by the inadequate FDA procedures that remain when a brand-name manufacturer withdraws its product from the market. While the FDA designates one of the remaining generic companies to serve as the new reference drug, the generic manufacturer is still prohibited from using the CBE process to change the label. Arguably, ensuring consumer confidence and avoiding confusion requires brand-name and generic drug warning labels to be identical when both drugs remain on the market. Perhaps it even justifies limiting a generic manufacturer's postmarketing labeling duty to that of merely mirroring its branded counterpart. This argument, however, ceases to be sound once the brand-name drug exits that market. Nevertheless, the FDA, not the generic manufacturer, is responsible for updating the product warnings. If the FDA determines that labeling for the product should be revised to meet current standards, it will advise the generic manufacturers to submit such labeling.³⁰¹ This seems to defy logic. As Congress has noted, "Clearly, the resources of the drug industry to collect and analyze postmarket safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does."³⁰² Given this reality, the duty and ability to provide adequate warning labels should reside with the generic manufacturer.

3. The FDA's Constraints Prevent Adequate Postmarket Monitoring of Generic Drugs To Ensure Consumer Safety

By immunizing generic manufacturers and essentially removing the crucial role the tort system has played in uncovering critical safety information, the courts have placed total reliance on brand-name manufacturers and the FDA to protect the public against pharmaceutical risks. At present, the FDA regulates products constituting twenty-five percent of the U.S. GDP.³⁰³ The FDA approves several hundred new and generic drugs each year, and it analyzes hundreds more.³⁰⁴ Over the past six years, the number of ANDAs submitted to the FDA has more than doubled. During the same period, staffing levels have only increased by twenty percent.³⁰⁵ What is more, after the drug is approved, the FDA's responsibility for monitoring drug safety increases. The FDA received

301. Determination That Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 72 Fed. Reg. 39,629, 39,630 (July 19, 2007).

302. 153 CONG. REC. S11832 (daily ed. Sept. 20, 2007) (statement of Sen. Kennedy).

303. Bruce M. Psaty & R. Alta Charo, *FDA Responds to Institute of Medicine Drug Safety Recommendations – In Part*, 297 JAMA 1917, 1917-19 (2007).

304. FDA, FY 2010 PERFORMANCE REPORT TO THE PRESIDENT AND CONGRESS FOR THE PRESCRIPTION DRUG USER FEE ACT at 103 (2010), available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/UCM243358.pdf>.

305. *Id.* at 6, 82, 92.

over 524,000 adverse event reports in 2010.³⁰⁶ As reflected in three recent analyses of drug safety oversight, under these constraints, the FDA simply does not have sufficient resources for responding promptly to safety problems that are discovered after marketing approval.³⁰⁷ It also lacks adequate procedures for quickly and effectively communicating appropriate risk information to the public.³⁰⁸

Moreover, the FDA does not have the necessary competencies to interpret the data it receives. Its own Science Board found that the FDA lacks sufficient expertise in quantitative methods, such as statistics and biomathematics, to assess the products it regulates or to guide sponsors to design valid and informative studies.³⁰⁹ The GAO recently has placed the FDA's drug safety program on its watch list of high-risk areas requiring attention by Congress and the executive branch:

Although improvements have been made, long-standing concerns remain regarding the effectiveness of the FDA's post-market oversight. FDA staff have expressed concern about their ability to meet the growing postmarket workload, with some maintaining that their premarket responsibilities are considered a higher priority. FDA is also encountering technological and staffing issues that limit its capacity to conduct drug safety studies.³¹⁰

These deficiencies reflect an agency that is ill equipped to fulfill its vital role in protecting the public from harm caused by inaccurately or inadequately labeled generic drugs. Ensuring the public's safety necessitates the addition of two critical components: (1) a regulatory framework that provides generic manufacturers with the tools necessary to fulfill the Supreme Court's charge that manufacturers bear responsibility for the labeling of their product at all times, and (2) a framework that can work in conjunction with state tort systems to

306. *AERS Patient Outcomes by Year*, FDA, (July 1, 2012, 4:28 P.M.), <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugs/ucm070461.htm> (reporting 471,291 "serious outcomes" and 82,724 reports of death).

307. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-278, HIGH-RISK SERIES: AN UPDATE 116-17 (Feb. 2011), *available at* <http://www.gao.gov/new.items/d11278.pdf> [hereinafter HIGH-RISK SERIES: AN UPDATE]; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-68, DRUG SAFETY: FDA HAS BEGUN EFFORTS TO ENHANCE POSTMARKET SAFETY, BUT ADDITIONAL ACTIONS ARE NEEDED 34 n.75 (Nov. 2009), *available at* <http://www.gao.gov/assets/300/298135.pdf>; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 18 (Mar. 2006), *available at* <http://www.gao.gov/new.items/d06402.pdf>.

308. See INST. MED. NAT'L ACAD., *supra* note 38.

309. FDA, SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY 31-35 (Nov. 2007), *available at* http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf.

310. HIGH-RISK SERIES: AN UPDATE, *supra* note 307, at 116-17.

incentivize generic manufacturers to monitor their products and disclose adverse drug effects through the risk of adverse verdicts and the cost of resulting damage awards.

B. The New Framework

1. Necessary Tools for Generic Manufacturers

The framework providing generic manufacturers with the ability to label their products adequately requires access to all relevant data and the unambiguous authority to transform that information into adequate warnings. While the issue in *PLIVA* focused on the availability of post-approval mechanisms, a broader scope is needed. This Article suggests a framework that seeks to remedy the unfortunate hand that generic drug consumers were dealt in *PLIVA*, while preserving the Hatch-Waxman Act's policy objectives of "getting safe and effective generics quickly to the market" without sacrificing the Act's cost-saving aims.³¹¹

For generic manufacturers to possess the necessary data to make meaningful labeling suggestions, they need complete access to the clinical, animal, and bioequivalence data submitted in the brand-name manufacturer's NDA.³¹² The implementing language of the Hatch-Waxman Act allows generic manufacturers to use brand-name drugs still under patent to obtain bioequivalence data.³¹³ Hatch-Waxman also allows generic manufacturers to use FDA safety and effectiveness findings, and publicly available literature, to reverse engineer the components of the referenced drug.³¹⁴ When it approves a generic equivalent developed through these indirect methods, the FDA does not render final judgment that the drug is safe. Rather, the FDA is merely concluding that the generic drug does not differ significantly in the rate of absorption when administered in the same dose as its branded counterpart.³¹⁵ Giving generic manufacturers access to the actual clinical results submitted in NDAs provides them a more complete clinical base with which to evaluate the current and future performance of their product.

This Article proposes another fundamental shift in the current framework in terms of generic manufacturers' post-approval responsibilities and access to data. All manufacturers bear the responsibility for the adequacy of their labeling. To

311. H.R. REP. NO. 98-857, pt. 2, at 9 (1984).

312. 21 U.S.C. § 355(j) (2006) (describing the components necessary to constitute bioequivalency for ANDA approval).

313. 35 U.S.C. § 271(e)(1) (2006).

314. 21 C.F.R. § 314(g)(ii) (2011). FDA's safety and effectiveness findings are contained in the "Summary Basis of Approval" that the Agency prepares and makes publicly available. This document is prepared in compliance with the safeguards against public disclosure of proprietary and confidential information contained in 21 C.F.R. § 210.

315. 21 U.S.C. § 355(j)(8)(B).

this end, crafting adequate warning labels necessitates that generic manufacturers' possessing "superior" access to information about their drugs.³¹⁶ As noted by the Supreme Court, this need is particularly important in the post-marketing phase. As new risks emerge, compliance with FDA post-approval reporting requirements should provide generic manufacturers with sufficient data to discern the need for adequate labeling improvements. Currently, they do not. To close that gap, generic manufacturer post-approval labeling regulations should be the same as the regulations for brand-name manufacturers. Accordingly, the proposed framework requires generic manufacturers to have access to and analyze: (1) post-approval safety activities, (2) reports to worldwide regulators, (3) safety-focused epidemiologic activities, (4) activities required for safety-related labeling changes, (5) literature review for adverse-event information, and (6) safety information provided to healthcare professionals.³¹⁷

A primary reason for the low cost of generic drugs is that the FDA does not require generic manufacturers to replicate costly clinical trials for approval.³¹⁸ The proposed framework does not suggest altering this core cost-saving tenet. Currently, brand-name manufacturers conduct and pay for the majority of post-approval safety analyses.³¹⁹ As with data generated in the NDA process, generic manufacturers should have access to those data. Post-approval studies could continue to be conducted by the brand-name manufacturer or through a contracted laboratory.³²⁰ Regardless of how they are performed, the results would be distributed to all manufacturers of the product. A critical distinction between generic manufacturers' access to NDA information and access to the post-approval information is that generic manufacturers would share in the costs of generating the data.³²¹ Congress could mandate an "accessing data fee" that

316. *Wyeth v. Levine*, 555 U.S. 555, 578 (2009).

317. David B. Ridley et al., *Spending on Post-approval Drug Safety*, HEALTH AFF. 429, 430-31, 436 (2006). Other information could include "summary report production of aggregate post-approval adverse-event information[,] . . . safety surveillance activities, including those related to post-approval risk management, safety-related product quality complaints, including product recall for safety reasons, [and] responses to safety questions from worldwide regulators." *Id.* at 430-31.

318. H.R. REP. NO. 98-857, pt. 2, at 3 (1984).

319. Ridley et al., *supra* note 317, at 429 ("We surveyed drug manufacturers regarding safety efforts. Mean spending on postapproval safety per company in 2003 was \$56 million (0.3 percent of sales). Assuming a constant safety-to-sales ratio, we estimated that total spending on post-approval safety by the top twenty drug manufacturers was \$800 million in 2003.").

320. Contract laboratories can perform preclinical and clinical testing, post-approval studies, and pharmacovigilance aimed at identifying safety signals from all sources. The benefits of contract laboratories are that some generic manufacturers may not have laboratories or the resources within their existing laboratories to perform the necessary studies and the contract laboratory may have expertise that the generic manufacturer lacks. Donald Singer et al., *Contract Laboratory Partnerships: How To Make a Partnership Work With a Contract Pharmaceutical Testing Laboratory*, CONTRACT PHARMA (June 6, 2011), http://www.contractpharma.com/issues/2011-06/view_features/contract-laboratory-partnerships; see also 21 C.F.R. § 312.3(b) (2008).

321. The lack of patent protection in the post-approval world increases brand-name manufacturer concerns of free riding. Implementing a fee structure for post-approval studies would

keeps the costs of generic drugs low, compensates brand-name manufacturers for their data, and prevents generic manufacturers from getting a “free ride.” This fee should not prevent generic manufacturers from offering their products at a lower cost.

During the pre-approval and post-approval marketing of NDA products, the brand-name manufacturer and the FDA engage in ongoing conversations and negotiations regarding safety and labeling. Once the brand-name drug’s patent expires, the regulatory framework should include generic manufacturers in these discussions. Currently, no process exists for joint consultation and dialogue among the FDA, the brand-name manufacturer, and generic manufacturers to discuss appropriate steps or labeling revisions raised in adverse events or post-approval study results. In the absence of such communications, one questions the appropriateness of the resulting labeling changes. Generic manufacturers possess unique insight about the performance of their products and should contribute to the negotiations with the FDA and brand-name manufacturers regarding all post-approval labeling changes. Generic manufacturers also should be invited to consult with the FDA at critical junctures in the ANDA approval process and in response to adverse event reports.³²² These manufacturers are often in the best position to discover, assess, and take early action to address risks that come to light after the brand-name drugs patent exclusivity ends, because once generics become available, generic drug manufacturers often have the majority market share for the drug.

In addition to direct access to brand-name manufacturers’ data, the proposed framework allows for increased transparency and communication between the FDA and generic manufacturers. All proposed labeling changes should be sent to all manufacturers of the product. It is not anticipated that generic manufacturers merely would be the recipients of increased information. Similar to their branded counterparts, generic manufacturers should have post-approval responsibilities requiring them to conduct worldwide literature searches of their product.

It was not Congress’ intent for the FDA to carry the burden of ensuring safety and effectiveness of the pharmaceutical industry alone.³²³ The current resource constraints of the FDA only underscore the importance of generic manufacturers embracing their responsibility to ensure the adequacy of their products. More transparency in data will allow them to meet the elevated responsibility, which the Supreme Court assumes belongs to all manufacturers.

These proposals actually align with generic manufacturers’ characterization of their recognized responsibilities. After hearings on the Hatch-Waxman Act, representatives of the generic drug industry commented on their continuing

alleviate some of these concerns.

322. For a description of bioequivalence studies conducted for ANDA review, see *supra* Subsection I.B.1.

323. *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009).

responsibility after their products' approval. For example, Kenneth Larson, the Chairman of the Generic Pharmaceutical Industry Association, asserted that generic drug companies were "sensitive to the importance of looking at adverse reactions."³²⁴ He further stated, "generic manufacturers of today will respond to those needs . . . [I]f it demands a higher level of knowledge on our part, we are prepared to meet and respond to the need."³²⁵ In response to the question about whether the brand-name manufacturers are better able to correct problems than generic companies, Mr. Larson stated:

I can state for my company as well as I think I can state for the other generic companies that produce these products, that we will do and provide whatever is required to be performed to meet the regulatory requirement to provide for the safety and well-being of those that are using the drug, this is our role and responsibility. This is an obligation to be in the business.³²⁶

Once brand-name and generic manufacturers are on an equal footing regarding access to information, the next concern is which mechanisms should be available to the generic manufacturers to promote changes that will improve the safety of their labeling. Generic manufacturers require the clear and unequivocal access to the CBE and Dear Doctor letters processes that are afforded their brand-name counterparts. For example, brand-name manufacturers typically meet and discuss proposed warning label changes with the FDA before implementing them through the CBE process. Generic manufacturers should have a similar opportunity to not only use the CBE process, but also to discuss proposed warning labels with the FDA beforehand. The CBE regulation was enacted because the FDA wanted to provide a mechanism for manufacturers to amend their labels with new safety information that "required prompt corrective action" without forcing the products off the market until the FDA approved or rejected the amended label.³²⁷ The intent then was to protect patients.

The Supreme Court reiterated this same goal in *Wyeth*.³²⁸ Accordingly, consumers and their doctors need the most up-to-date information available. There is no reason why this same mechanism should not be made available to generic manufacturers. While generic drugs were not directly referenced in the

324. *Hearings on H.R. 1554 and H.R. 3605, supra* note 295, at 45.

325. *Id.*

326. *Id.* at 47-48; *see also id.* at 50-51 (statement of Bill Haddad, Executive Officer and President of the Generic Pharmaceutical Industry Association) ("We [generic drug companies] also put our money into research. Every single generic drug company that I know has a large research staff. It not only researches the drug that they are copying, or bringing into the market but it researches new drugs, researches adverse reactions.").

327. New Drug and Antibiotic Regulations, 47 Fed. Reg. 46,622, 46,635 (Oct. 19, 1982) (proposed rule).

328. *Wyeth v. Levine*, 555 U.S. 555, 568 (summarizing the intent of 21 C.F.R. § 314.70(c)(6)(iii)(A), (C)).

CBE process, this is only because the CBE regulations were first proposed in 1982,³²⁹ two years before the enactment of the Hatch-Waxman Act revolutionized the approval, marketing, and affordability of generic drugs. Therefore, it makes sense to interpret the absence of robust amendment procedures for generic drug labels as reflecting nothing more than a lack of foresight.³³⁰

Furthermore, despite the truncated nature of generic manufacturers' responsibilities, there is a strong argument that the regulatory basis for extending the applicability of the CBE process to generics already exists. Both brand-name and generic manufacturers are required to comply with regulations designed to ensure the post-approval safety of their drugs. They must "promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological surveillance studies, reports in the scientific literature, and unpublished scientific papers."³³¹ All reports of a "serious and unexpected" drug experience must be reported to the FDA within fifteen days and must be investigated promptly by the manufacturer.³³² Manufacturers are also obligated to submit quarterly adverse reports for the initial three years after their application (ANDA or NDA) is accepted.³³³ These regulatory requirements demonstrate an expectation that generic manufacturers, similar to their branded counterparts, are to actively participate in postmarket surveillance and take an active role in enhancing patient safety. The availability of the CBE process and Dear Doctor letters are vital to accomplishing this goal.

Notwithstanding the articulated tools above, it would be naïve to think that merely creating a regulatory framework that provides generic manufacturers with the ability to use the CBE process and send Dear Doctor Letters would dramatically increase the accuracy and adequacy of generic drug warning labels. For these measures to have real effect, generic manufacturers must also have an incentive to use them. As a result of *PLIVA*, generic manufacturers have no motivation to ensure that their labels accurately reflect the risks associated with a given treatment, because they cannot be held accountable if their drugs do not. Patient safety and generic drug integrity require that generic manufacturers be saddled with a more robust duty than just to maintain identical warnings labels to their branded counterpart. To promote accurate labeling, manufacturers must expeditiously provide full and clear information to physicians and the FDA about

329. *Id.*; see also New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7498 (Feb. 22, 1985) (final rule).

330. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355) (1984).

331. 21 C.F.R. § 314.80(b) (made applicable to ANDA holders by 21 C.F.R. § 98(a)).

332. *Id.* § 314.80(c)(1)(i)-(ii).

333. *Id.* § 314.80(c)(2)(i).

a drug's properties and adverse effects.

State tort liability can provide generic manufacturers the necessary incentive to fuel the federal regulatory machinery. It also forces generic manufacturers to produce known safety risk information under the microscope of the adversarial system. State tort trials help to uncover previously unavailable data on adverse events, questionable practices by manufacturers, and flaws in regulatory systems.³³⁴ These suits also serve to facilitate the rapid transmission of information regarding drug properties. Failure-to-warn suits also provide lawyers economic incentive to gather information about safety risks that may have been known to drug manufacturers, but which have not yet been acted on by national regulatory bodies. Without such litigation, the potential cost to generic manufacturers of concealing information, which is none, could encourage them to withhold critical safety information. As noted in literature that traces the social welfare benefits of dual regulation of risky technologies,³³⁵ “[t]he common law system’s independence and private incentives to challenge the status quo are particularly valuable antidotes to complacency and ineffective regulation.”³³⁶ Given the FDA’s limited capacity to analyze the safety data it receives, state failure-to-warn suits are critical to support the FDA’s regulatory mission. Simply put, generic manufacturers have sufficient scientific and financial resources to fulfill the reasonable demands of product liability law and state courts. Maintaining tort liability is essential to preserving the alignment of manufacturers’ and consumers’ interest in full disclosure of evolving risk information.

The articulation of this framework raises the question, “What about *PLIVA*?” Specifically, how does one address the Court’s elimination of any generic manufacturer duty or ability to change its product labeling to protect consumers against inadequate warnings? Similarly, how could such a framework be integrated into the Court’s elimination of state tort failure-to-warn remedies for injured consumers harmed by those products? One solution is for the FDA to amend its labeling rules to eliminate the impossibility identified by the Supreme Court. In other words, if the FDA were to amend its rules to authorize generic drug manufacturers to use the CBE regulation in the same manner as brand-name manufacturers, the federal regulatory basis upon which the Court rested its impossibility finding would cease to exist. This amendment would eliminate the bizarre consequences of having inconsistent state law duties for brand-name and generic manufacturers. Admittedly, however, this could produce a situation

334. Kesselheim & Avorn, *supra* note 259, at 308-11.

335. See generally C.F. LARRY HEIMANN, *ACCEPTABLE RISKS: POLITICS, POLICY, AND RISKY TECHNOLOGIES* (1997); Michael M. Ting, *A Strategic Theory of Bureaucratic Redundancy*, 47 AM. J. POL. SCI. 274 (2003).

336. William M. Buzbee, *Asymmetrical Regulation: Risk, Preemption and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547 (2007).

where consumers are offered multiple labels containing varying safety requirements for the same product. While this is a departure from the FDA's desire for uniformity in labels, this approach bolsters consumer safety by establishing uniformity of manufacturer responsibility. In effect, this places the responsibility to ensure the safety of a product on its manufacturer. The viability of bringing a failure-to-warn lawsuit no longer would hinge on the happenstance of whether the drug was produced by a brand-name or generic manufacturer. Rather, this approach directly attaches culpability to the manufacturer. Therefore, the generic or brand-name manufacturer that provides inferior labeling will be a viable target for a tort claim, precisely because it failed to provide the safest warning it could have.

Alternatively, Congress could decide to overrule *PLIVA* by amending the FDCA to state that neither the Act nor its regulations are intended to preempt state law. In this regard, the Supreme Court's observations in *Wyeth v. Levine* are instructive. The Court noted that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.³³⁷ In particular, Congress "determined that widely available state rights of action provided appropriate relief for injured [drug] consumers"³³⁸ and that "state-law remedies further consumer protection by motivating manufacturers . . . to give adequate warnings."³³⁹ Congress could enact legislation making explicit that it considers "state tort law as complementing, not obstructing, the goals of the FDCA."³⁴⁰ Given that Congress can expressly regulate the dividing line between state and federal law, and that Congress frequently has invoked such regulatory power in the past, this could be a viable approach.

It remains an open question which of these two options would be the more effective route. If the past is any indicator, the FDA alternative may prove to be more expeditious. Following the Supreme Court's 2008 decision in *Riegel v. Medtronic*,³⁴¹ in which the Supreme Court held that certain state laws against medical device manufacturers were expressly preempted by the 1976 Medical Device Amendments, Congress introduced the Medical Device Safety Act in an effort to nullify *Riegel*'s effects. To date, however, this legislation has yet to take effect. Accordingly, if Congress decided to overturn *PLIVA*, a bill likely would take years to work its way through the legislative process. Regardless of whether the solution comes from Congress or the FDA, it is clear that, after *PLIVA*, some kind of change is necessary in order to ensure patient safety and the integrity of generic drug warnings.

337. *Wyeth v. Levine*, 555 U.S. 555, 574 (2009).

338. *Id.*

339. *Id.*

340. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612 (8th Cir. 2009).

341. 552 U.S. 312 (2008).

2. Addressing Anticipated Criticisms

One may anticipate several criticisms of the proposed framework. Under the current regulatory scheme, it is not unusual for brand-name manufacturers to file infringement challenges to prevent public disclosure of their NDA data.³⁴² The proposed framework's call to provide generic manufacturers with direct access to NDA information and the results from ongoing clinical trials will trigger additional proprietary and intellectual property issues that are beyond the scope of this Article.³⁴³ An argument can be made, however, that the proposed disclosures are in keeping with the intent of the Hatch-Waxman Act. Section 505 of the FDCA provides that NDA "safety and effectiveness data and information which has been submitted in an application . . . *shall be made available to the public, upon request.*"³⁴⁴ From this provision, it seems that Congress did not aim to bar the public from safety and effectiveness data.³⁴⁵ The proposed framework furthers congressional intent to foster one of Hatch-Waxman's goals of ensuring the availability of safe and effective generic drugs.³⁴⁶

In response to reinstating tort liability, the Generic Pharmaceutical Association of American (GPhA) has asserted that increased responsibilities to monitor the safety of their products would "wipe out" more than one hundred billion dollars per year in savings under the Hatch-Waxman scheme.³⁴⁷ In making this argument to the Supreme Court, however, GPhA offered no support to substantiate the actual costs to generic manufacturers for reporting known health risks or monitoring widely available public information about a drug. Similarly, GPhA offered no explanation as to why such responsibilities would be so costly

342. LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 339 (Robert C. Clark et al. eds., 2d ed. 2007).

343. For a competent summary, see Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51 (2003), which explains the purpose of the Hatch-Waxman Act as an attempt to correct the perceived imbalances between brand-name manufacturers and generics, while decrying the abilities of both sides to bypass strictures. See also Mustafa Ünlü, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, 16 MICH. TELECOMM. TECH. L. REV. 511 (2010), available at <http://www.mttl.org/volsixteen/unlu.pdf>.

344. 21 U.S.C. § 355(f)(1)(2006) (emphasis added).

345. In practice, brand-name manufacturers have successfully used the last minute addition of Section 505's tempering "unless extraordinary circumstances are shown" provision to curtail the release of research data. James T. O'Reilly, *Knowledge Is Power: Legislative Control of Drug Industry Trade Secrets*, 54 U. CIN. L. REV. 1, 6 (1985) ("Advocates of drug data disclosure acted quietly in attaching a full disclosure provision, buried amidst many unrelated and controversial provisions, to the pending legislation."); *id.* at 18 ("Maneuvering in a minefield of ambiguity and mutual mistrust, the drafters of the 1984 Act settled upon the term 'extraordinary circumstances' on the false impression that it represented current FDA policy on data disclosure of live data.").

346. H.R. REP. NO. 98-857, pt. 2, at 9 (1984).

347. Brief of the Generic Pharmaceutical Association as Amicus Curiae in Support of Petitioners at 3, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 343069.

as to undermine significantly the current level of savings consumers receive from the use of generic rather than brand-name drugs.³⁴⁸

Critics may argue that *PLIVA* merely returns individuals to their pre-*Wyeth* position, when the majority of courts held that state law failure-to-warn claims were preempted. Yet significant changes in the healthcare landscape render these *PLIVA* implications far more significant for consumers. Another probable criticism is that allowing generic manufacturers the ability to strengthen their labels independently erodes the FDA's mandate of uniformity across brand-name and generic drugs. Because this uniformity is crucial for public confidence in the safety and effectiveness of generic drugs, increasing the number of manufacturers who can unilaterally change their products would undermine the intent of the Hatch-Waxman Act.³⁴⁹

The issue of uniformity must be re-examined in the wake of *PLIVA*. The congressional intent of the Hatch-Waxman Act was to create a market of generic drugs equivalent in value to their branded counterparts.³⁵⁰ Holding brand-name and generic manufacturers to the same state law standards directly serves that aim. For generics to succeed, they must have equal value to branded drugs. In economic terms, they must be perfect substitutes, and, in safety terms, this requires a duty to disclose risks equal to that of its branded drug. A critical component of the value equation for any product is a consumer's recourse in the event the product is defective. Products sold "as is" are less valuable than one sold with an implied warranty of fitness and merchantability. Similarly, a product sold without a preemption of state law tort claim is more valuable than one sold with such a preemption. Barring a consumer from pursuing a product liability claim against a generic manufacturer, but not a brand-name manufacturer, undermines the goal of uniform value between generic and brand-name drugs.³⁵¹

A basic economic tenant is that the cost of accidents is lessened when society imposes such costs on "the 'cheapest cost avoider' or [the actor] who is in the best position to make the cost-benefit analysis between accident costs and accident avoidance costs and to act on that decision once it is made."³⁵² The Supreme Court endorsed this finding in *Wyeth v. Levine*, by holding that pharmaceutical manufacturers "have superior access to information about their

348. *Id.*

349. See, e.g., *Facts and Myths About Generic Drugs*, FDA (last updated June 22, 2012) <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm>.

350. See Brief of Rep. Henry A. Waxman as Amicus Curiae in Support of Respondents Urging Affirmance at 8, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 794113.

351. *Id.*

352. *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 548 (N.J. 1982) (citing Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055 (1972)).

drugs, especially in the post-marketing phase as new risks emerge,”³⁵³ and that “state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.”³⁵⁴ Uniformity necessitates this same standard be applied to generic manufacturers.

Under the current regulatory scheme, generic manufacturers do not make label modifications until the FDA approves the proposed label (whether through the CBE or some other process).³⁵⁵ As previously mentioned, it is a common practice for brand-name manufacturers to consult with the FDA prior to making these proposed changes.³⁵⁶ Giving generic manufacturers access to the same CBE change consultation process, and not requiring any industry-wide change in the generic or brand-name drug until the FDA approves the change, addresses many of the uniformity and consumer confidence concerns that critics may raise.³⁵⁷ Essentially, the proposed framework expands the process the FDA uses to notify generic manufacturers of changes made to their branded counterpart to now include notifying the brand-name manufacturer of required changes originally proposed by their generic counterpart. To be clear, it is not the intent of this Article to take exception to the Supreme Court’s preemption and validity of the impossibility defense analysis. Rather, this Article addresses the adequacy of a regulatory framework that contributed to the Supreme Court’s ruling and the resultant safety implications for consumers.

3. Reconciling the Proposed Framework with the Intent of the Hatch-Waxman Act

A major challenge to the proposed framework is balancing two of the Hatch-Waxman Act’s primary goals: increasing the availability of quality medical care and lowering the cost of generic drugs.³⁵⁸ In determining how that balance should be struck, Hatch-Waxman must be read in the context of the FDCA, which it amends. The purpose of the FDCA is to protect the public health and “assure the safety, effectiveness, and reliability of drugs.”³⁵⁹ As the Supreme Court succinctly noted, “Congress enacted the FDCA to bolster consumer protection against harmful products.”³⁶⁰ Nothing in the Hatch-Waxman Act suggests that Congress intended to abandon that position. Similarly, there is no evidence that, when Congress passed Hatch-Waxman, “it intended the goal of delivering low-

353. *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009).

354. *Id.* at 574.

355. *See infra* Subsection I.B.2.

356. Gilhooley, *supra* note 6, at 551.

357. The FDA could even consider expanding these pre-CBE change consultations to include both generic and brand-name manufacturers.

358. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355) (1984).

359. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

360. *Wyeth v. Levine*, 555 U.S. 555, 574 (2009).

cost generic drugs to supplant the FDCA's overall goal of providing consumers with safe and effective drugs."³⁶¹ Accordingly, while Hatch-Waxman sought to quickly make low-cost generic drugs more accessible, it did not pursue this goal at all costs.³⁶² To impute such a single-minded cost focus into Hatch-Waxman would give short shrift to Congress' purpose of consumer safety.³⁶³ Isolating the Hatch-Waxman Act from the entirety of FDCA would violate the basic principle that statutes should be read as a whole. The Hatch-Waxman Act's success rests in large part on the assurance of "sameness" between brand-name and generic drugs. The ANDA system, which streamlined the process for initially bringing generic drugs to market, is premised on this very idea. This "sameness" principle however, does not mean that generics are to be sold without regard for whether consumers are properly warned about serious risks.³⁶⁴ Rather, this core "sameness" principle requires generic and brand-name manufacturers to be held to the same post-approval standards. For example, brand-name and generic manufacturers often receive important safety information once their drugs are on the market. They should be treated the same with respect to their responsibility to bring that relevant data to the FDA's attention. They also should have the same access to regulatory mechanisms to strengthen their products' warning labels to ensure patient safety. Finally, any violation of the standards should be addressed with the same tort liability.

Simply put, requiring generic and brand-name manufacturers to bear the same level of responsibility for ensuring the safety of their products is directly in line with the intent of Hatch-Waxman Act. The solution proposed by this framework embraces the spirit of Hatch-Waxman disclosure provisions by providing generic manufacturers with direct access to the data necessary to craft adequate labeling changes.

CONCLUSION

The issue of whether the current regulatory framework adequately promotes safe and effective generic drugs has gotten lost amid state law failure-to-warn litigation. *PLIVA* effectively called a halt to circuits shoehorning generic manufacturers' regulatory responsibilities into a *Wyeth* analysis. In doing so, the Supreme Court clarified, for courts and consumers alike, "that federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully

361. *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1395 (9th Cir. 2011).

362. H.R. REP. NO. 98-857, pt. 1, at 14 (1984).

363. See 130 CONG. REC. 15847 (June 12, 1984) (statement of Sen. Hatch) ("This is a good bill. *Without compromising the public safety or welfare in the least* it will significantly lower the price of off-patent drugs, by many times in some cases, through increased generic competition.") (emphasis added).

364. See *State Consumer Education Efforts*, GENERIC PHARM. ASS'N (GPHA), <http://www.gphaonline.org/issues/state-consumer-education-efforts> (last visited Aug. 1, 2012).

different than those that apply to generic drug manufacturers.”³⁶⁵ According to the Court, these differences have divergent safety and legal implications for consumers. For example, these differences preempt the ability of generic drug consumers to sue generic manufactures for failure to warn. They also prohibit generic manufacturers from taking any steps to strengthen inadequate warning labels unilaterally or to disseminate publicly additional warnings on their own. Given that generic drugs constitute seventy-five percent of all prescriptions in the United States, the Court’s ruling has broad implications. By immunizing generic manufacturers against state law failure-to-warn claims, the Court arguably has reduced the incentive of generic manufacturers to provide comprehensive information about their products’ properties and associated risks. Generic manufacturers also may have less incentive to fulfill their duty to propose label changes under FDA regulations. All of these responsibilities are necessary components in ensuring that labels accurately reflect the risks associated with them. Without these controls, consumers may lose confidence in generic drugs and physicians may be reluctant to prescribe them. Additionally, as protectors of the health and welfare of their citizenry, states may reassess substitution laws.

Despite key differences between the labeling frameworks for brand-name and generic manufacturers, the *PLIVA* analysis loses sight of the most essential function of drug regulation: consumer safety. In the Court’s finding of “impossibility,” it essentially abandons a central premise of drug regulations. The framework advanced by this Article addresses what *PLIVA* neglected. While incorporating the unique role generic drugs play in the American healthcare system, this Article advances a framework that remains committed to Hatch-Waxman’s goals of providing safe, but less expensive, generic drugs. This is achieved through regulations that provide all manufacturers with increased access to data pertaining to the safety of their drugs. It also offers a structure for open communication among generic manufacturers, their branded counterparts, and the FDA. Finally, the framework grants generic manufacturers unambiguous access to label-changing mechanisms that are available to brand-name manufacturers.

365. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011).

The Right to Be Fat

Yofi Tirosh *

INTRODUCTION.....	266
I. FAT MANIFESTATIONS IN LAW	272
A. LEGAL MANIFESTATIONS OF BODY SIZE: AN OVERVIEW	273
B. THREE PRELIMINARY REMARKS	279
1. FATNESS HAS BECOME ASSOCIATED WITH A DISTINCT SET OF CHARACTERISTICS	279
2. THE MEDICAL FRAMEWORK’S MONOPOLY ON LEGAL DISCOURSE.....	281
3. “BUT NO ONE VIOLATES THE RIGHT TO BE FAT!”	283
II. THE CONTENTIOUS SCIENCE ON FAT.....	284
A. THE IMMUTABILITY OF BODILY WEIGHT	285
B. WEIGHT AND HEALTH	288
C. UTILITARIAN ARGUMENTS.....	291
III. THE PHILOSOPHICAL GROUNDING OF THE ARGUMENT FROM LIBERTY.....	294
A. A BRIEF OVERVIEW OF MIND-BODY DUALISM	295
1. THE CONTEMPORARY CRITIQUE OF MIND-BODY DUALISM.....	297
2. THE BODY TURN IN LAW	299
B. FATNESS AS A FUTURE-GROUNDED IDENTITY	301
C. PHENOMENOLOGICAL ACCOUNTS OF FATNESS	304
2. THE RICH MEANINGS OF FOOD AND EATING.....	308

* Assistant Professor, Tel Aviv University Faculty of Law. I am grateful to Susanne Baer, Yael Braudo, Michael Birnhack, Moshe Cohen-Eliya, Hanoach Dagan, Ronit Donyetz Kedar, Yair Eldan, Talia Fisher, Aeyal Gross, Tal Kohavi, Zohar Kohavi, Kevin Kolben, Shai Lavi, Menny Mautner, Sagit Mor, Tzili Paz-Wolk, Ariel Porat, Tali Scheafer, Hila Shamir, Sara Rushing, Rachel Wizner, Stephen Wizner, and Kenji Yoshino for illuminating conversations and helpful comments on earlier drafts. Hagai Kalai, Roni Liberson, Gal Sagi, and Tami Yakira provided outstanding research assistance. Finally, the suggestions of the editorial board of the *Yale Journal of Health Policy, Law, and Ethics* and its two anonymous peer reviewers have improved this Article significantly.

3. AFFIRMATIVE ACCOUNTS OF THE FAT BODY	310
IV. THE RIGHT TO BE FAT	312
A. THE BASIC CONTOURS OF THE RIGHT TO BE FAT	312
B. A NOTE ABOUT THE BEARERS OF THE RIGHT	319
C. NORMATIVE IMPLICATIONS: SOME HARD QUESTIONS.....	320
1. MAY THE GOVERNMENT STILL INTRODUCE WEIGHT-RELATED POLICIES?	320
2. AIRPLANE TICKETS AND HEALTH INSURANCE PREMIUMS	322
3. EMPLOYMENT DISCRIMINATION	326
4. SMOKING, SKYDIVING, AND OTHER DANGEROUS AND IDIOSYNCRATIC BEHAVIORS.....	332
CONCLUSION	334

INTRODUCTION

Why say “Inside every fat person there is a thin person waiting to get out.”
For me, it’s more like “Inside every fat person there is an even fatter person
waiting get out.”¹

In its now famous paragraph from *Planned Parenthood of Southeastern Pennsylvania v. Casey*,² the Supreme Court tried to delineate the scope of liberty that the Constitution guarantees:

Our law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education. . . . These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. At the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State³

As one would expect from a text that takes on the considerable task of outlining the scope of liberty, the Court’s words are emotive. They seem to convey a sense of the core dimensions of being and the amalgam of perspectives, choices, and practices that make individuals who they are. These are components so personal and vulnerable that the government should refrain from interfering with them. The Court’s conceptual framework concerning abortion here is useful when we try to determine the scope of constitutionally protected liberty, because it invokes an intuition about the most basic and private aspects of our lives—those aspects that are most one’s own and should not require any explanation or be subjected to any State intervention. What else in life, like the decision about whether to have an abortion, lies at the heart of liberty in that it defines one’s concept of existence, of meaning, and of the mystery of human lives? What other views, choices, and ways of living should not be “formed under compulsion of the state?” While some rights, such as free speech or religious freedom, clearly fall within this protected realm, there are territories of human existence that also lie at the heart of our liberty and define how we live, but are yet to be recognized as such by constitutional theory.

In this Article, I visit one such uncharted territory and argue that American law should recognize a new realm of liberty: the realm of body size. Recognizing

1. Thanks to Kenji Yoshino for sharing this quote (from a friend).

2. 505 U.S. 833 (1992).

3. *Id.* at 851 (citation omitted).

the right to be any body size as part of the general principle of liberty (and, more specifically, as part of autonomy and dignity) would entail that we cautiously scrutinize governmental policies aiming to create incentives for losing weight or deterrence against gaining weight, as well as some acts by private actors, and balance them vis-à-vis their potential infringement of the right. My principal contention is that the law has been blind to body size and shape, eating habits, and movement and exercise practices, due to a dualistic understanding of the relationship between mind and body.⁴ However, decisions pertaining to these domains of experience lie at the core of human existence, no less so than questions such as whether to become a parent, which church to join, or what views to hold and express. Due to economic, technological, and cultural changes, body size and the practices associated with it (such as dieting, exercising, and surgery) have become more meaningful in the lives of American legal subjects than ever before. Body size plays a role in shaping individual and social identity,⁵ but also it has become a central arena for policymakers, who routinely recruit the law in creating regulative instruments to encourage the slimming down of the U.S. population.

From the perspective of constitutional theory, legal instruments that encourage weight control are today construed as benign. To date, no legal scholar has argued that either legally mandated measures, such as regularly weighing school pupils to document their weight and recommend dietary and exercise measures, or the absence of body weight as a suspect category in antidiscrimination law constitutes an illegitimate violation of liberty.⁶ Typically, legal measures of this nature are not discussed in the context of liberty, as they seem harmless and even welcomed in “the war against obesity.”

4. Dualistic approaches view the body and the mind as distinct substances. For an elaboration see *infra* Section III.A.

5. There are important gendered aspects to the social meaning of body size. Since women’s physical appearance is more critically scrutinized in western culture, women are more susceptible to social sanctions for body sizes that deviate from conventions of the ideal body. This Article consciously employs a nongendered, general approach in conceptualizing the right to any body size, as it should be a right enjoyed both by men and women. However, there is undoubtedly room for further research on the different impact of weight-centered legal policies on men and women. Some classic accounts of the importance of body image and size, eating practices, and identity for women include SUSAN BORDO, *UNBEARABLE WEIGHT* (1993); KIM CHERNIN, *THE HUNGRY SELF: WOMEN, EATING, AND IDENTITY* (1994); and SUSIE ORBACH, *FAT IS A FEMINIST ISSUE* (2010). See also MICHAEL GARD & JAN WRIGHT, *THE OBESITY EPIDEMIC: SCIENCE, MORALITY, AND IDEOLOGY* 153-67 (2005); Yofi Tirosh, *Weighty Speech: Addressing Body Size in the Classroom*, 28 REV. EDUC. PEDAGOGY & CULTURAL STUD. 267 (2006). For empirical evidence demonstrating that women’s wages are more adversely impacted due to their “overweight” than men’s wages, see the sources cited in Jennifer Bennett Shinall, *Legal Largesse or Big Fat Failure: Do Weight-Discrimination Laws Improve Employment Outcomes for the Obese?* 31 N.Y.U. J. L. & PUB. INT. 14 (Jan. 14, 2011) (unpublished manuscript), available at ssrn.com/sol3/papers.cfm?abstract_id=1985371.

6. On “fat people’s liminal position outside civil rights protections,” see Anna Kirkland, *Think of the Hippopotamus: Rights Consciousness in the Fat Acceptance*, 42 LAW & SOC’Y REV. 397, 425 (2008).

Indeed, as I will show below, it is unsurprising that we have not yet recognized weight-related laws and policies as raising questions pertaining to liberty, since our jurisprudence has developed within the Western tradition of negating the body as secondary and inferior to the mind. This tradition has rendered it difficult for the law to identify the body as a domain of rights. However, it is time to take the body, and particularly body size, seriously as a subject of rights and as a domain that should be free from governmental (and in certain cases also societal) interference.

Thus far, weight has been discussed in legal scholarship mainly through the framework of discrimination.⁷ In the past decade, the debate about whether weight should be a protected category of antidiscrimination law has become increasingly vibrant. Scholarly legal commentators who argue that weight should be a protected category, either in itself or as part of disability discrimination, have based their argument on two main strategies: questioning the rooted belief that weight is a voluntary and mutable characteristic⁸ and critically examining the

7. See ANNA KIRKLAND, *FAT RIGHTS: DILEMMAS OF DIFFERENCE AND PERSONHOOD* 6 (2008) (mapping the possibilities of protecting weight discrimination under prevailing antidiscrimination law by “[e]xamining antidiscrimination law from both the center and the edges”); DEBORAH L. RHODE, *THE BEAUTY BIAS: THE INJUSTICE OF APPEARANCE IN LIFE AND LAW* 102 (2010) (arguing that weight-based discrimination is the most common form of appearance discrimination and that the law should take part in preventing it); SONDR A SOLOVAY, *TIPPING THE SCALES OF JUSTICE: FIGHTING WEIGHT-BASED DISCRIMINATION* 233-38 (2000) (using the lens of discrimination to analyze legally various manifestations of fat oppression); Jane Byeff Korn, *Fat*, 77 B.U. L. REV. 25, 50-68 (1997) [hereinafter Korn, *Fat*] (arguing that obesity should be recognized as a disability under the Americans With Disabilities Act’s antidiscrimination protections); Jane Korn, *Too Fat*, 17 VA. J. SOC. POL’Y & LAW 209, 242-44 (2011) [hereinafter Korn, *Too Fat*] (suggesting that the 2009 amendment to the ADA, the ADAAMA, may not provide sufficient protection for weight discrimination); Karen M. Kramer & Arlene B. Mayerson, *Obesity Discrimination in the Workplace: Protection Through a Perceived Disability Claim Under the Rehabilitation Act and the Americans with Disabilities Act*, 31 CAL. W. L. REV. 41, 52-64 (1994); Elizabeth E. Theran, “Free To Be Arbitrary and . . . Capricious”: *Weight-Based Discrimination and the Logic of American Antidiscrimination Law*, 11 CORNELL J.L. & PUB. POL’Y 113, 148-53 (2001); Donald L. Bierman, Jr., Comment, *Employment Discrimination Against Overweight Individuals: Should Obesity Be a Protected Classification?*, 30 SANTA CLARA L. REV. 951, 958-59, 971-75 (1990); Brenda K. DeVries, Note, *Health Should Not Be a Determinative Factor of Whether One Will Be a Suitable Adoptive Parent*, 6 IND. HEALTH L. REV. 137 (2009) (arguing that obesity should not disqualify potential adopting parents from eligibility to adopt); Elizabeth Kristen, Comment, *Addressing the Problem of Weight Discrimination in Employment*, 90 CAL. L. REV. 57, 71-100 (2002); Karol V. Mason, Note, *Employment Discrimination Against the Overweight*, 15 U. MICH. J.L. REFORM 337, 355-61 (1982); Bruce I. Shapiro, Comment, *The Heavy Burden of Establishing Weight as a Handicap Under Anti-Discrimination Statutes*, 18 W. ST. U. L. REV. 565, 575-77 (1991); William C. Taussig, Comment, *Weighing in Against Obesity Discrimination: Cook v. Rhode Island, Department of Mental Health, Retardation, and Hospitals and the Recognition of Obesity as a Disability Under the Rehabilitation Act and the Americans with Disabilities Act*, 35 B.C. L. REV. 927, 956-63 (1994).

8. See RHODE, *supra* note 7, at 104-05 (discussing the low success rates of diets); *id.* at 39-41 (presenting the health risks associated with dieting); SOLOVAY, *supra* note 7, at 190-209 (discussing the immutability of weight and the dangers of dieting); Korn, *Fat*, *supra* note 7, at 44-48 (citing

seemingly well-known linkage between fat and health risks.⁹ These lines of arguments are good strategies in the antidiscrimination context. Since suspect classifications in antidiscrimination law are usually of immutable traits, demonstrating that weight is not as changeable as is frequently assumed supports the claim that it should be a forbidden ground for discrimination. Similarly, if a large body is not as unhealthy as is commonly thought, then the number of cases in which body weight constitutes a relevant difference is significantly reduced. While discussing body size in the context of antidiscrimination law is important, this Article maintains that the antidiscrimination framework is insufficient. Body size raises challenges beyond the question of preventing discriminatory treatment because it is intrinsically worthy of protection in and of itself and not merely as a suspect classification. The size of one's body is an intimate feature of human experience. It touches the core of one's person, much like speech or religious faith. It thus merits more than what the antidiscrimination framework provides, which is the duty to be tolerant to certain differences. The law must develop a vocabulary that will enable respecting the sphere of body size and will restrict direct and indirect regulation to the necessary minimum. Thus, this Article takes an innovative approach: rather than relying on empirical data about the causes and effects of fat, it addresses the question of individual weight from a rights perspective and asks whether weight can and should be understood as a matter of liberty, alongside other deontologically based¹⁰ fundamental rights. This inquiry

sources that challenge the socially pervasive belief that weight is a matter of willpower and self control). *But see* Kramer & Mayerson, *supra* note 7, at 65-67 (reviewing scientific evidence that obesity is not a voluntary condition); Bierman, *supra* note 7, at 957 (citing medical and psychological causes for obesity, which are beyond the individual's control); DeVries, *supra* note 7, at 150-53 (reviewing the nature-nurture debate on obesity factors); Kristen, *supra* note 7, at 69 (surveying medical data indicating that "it is not clear that fat people can do anything about their size"); Mason, *supra* note 7, at 346 ("In most cases, [weight] losses are only short term, despite the claims of weight-loss clinics, diet books, and drug producers."); Taussig, *supra* note 7, at 930-32 (reviewing medical research on the genetic causes of obesity); Lucy Wang, Note, *Weight Discrimination: One Size Fits All Remedy?*, 117 YALE L.J. 1900, 1906-08 (2008) (discussing the role of genetics in obesity); Tali Schaefer, *Off Their Fat Backs!* 25-28 (May 25, 2010) (unpublished manuscript) (on file with author) (noting that "genetics are the most important cause of obesity, likely accounting for as much as forty to seventy percent of the variation in weight" and reviewing the research supporting this conclusion).

9. *See* RHODE, *supra* note 7, at 41 ("[F]rom a health perspective, the current obsession with weight is misdirected."); Kramer & Mayerson, *supra* note 7, at 70 ("[M]odern research shows that [it] is actually the effect of the diet cycle on the body, not extra pounds, that leads to health problems."); Theran, *supra* note 7, at 148-53 (referring to the complex and mixed medical evidence about the physiological causes and effects of fat); Bierman, *supra* note 7, at 958 ("[A]mbiguities remain whether a causal relationship exists between the obesity and the medical condition."); DeVries, *supra* note 7, at 154-55 ("[I]t is important to recognize that not all overweight people are unhealthy."); Kristen, *supra* note 7, at 67-69 ("Despite popular conceptions that being fat is dangerously unhealthy, the picture painted by the medical literature is not so clear."); Schaefer, *supra* note 8, at 33-50 (arguing that many of the assumptions about the benefit of weight loss and about the psychological and physiological harm of fat are flawed).

10. By saying that the philosophical basis of the right to be fat will be deontological, I mean

will lead to the conclusion that we should answer this question with an unequivocal “yes.”

The debate about the meaning of empirical data on obesity serves primarily utilitarian, instrumentalist arguments. Therefore, suspending the effects of these debates is important for addressing the question of liberty as “purely” as possible in developing a deontological basis for the right to be fat. Hence, I will assume, for the sake of argument and despite compelling data to the contrary, that weight is indeed a characteristic within the control of the person—a matter of willpower, discipline, and chosen lifestyle. I will further assume that being fat¹¹ is damaging to one’s health, although there is also a growing vein of critique of this view. In other words, I will assume that being fat is, from a health perspective, not an optimal lifestyle choice. And yet, mutability and health risks notwithstanding, I will argue for the freedom to occupy a body of any size by re-conceptualizing it within the domain of personhood—a domain in which a jurisprudence based on basic liberties in the classic liberal tradition would dictate that government and fellow citizens should not intervene.

The gist of my argument is that the dominant response to growing obesity rates has been to seek a solution to the obesity epidemic in getting people to lose weight or refrain from gaining it. But a complementary response must be to re-examine our biases concerning weight and our difficulty in recognizing the importance of corporeal existence. The necessary change is located as much on a social, political, legal, and ethical level as it is on a physiological level.

that the justification of the right should be rooted in the right’s intrinsic value and should not depend on establishing that protecting this right will promote some independent account of welfare. Sometimes, choices or rules that will bring about good results are still morally wrong and should be rejected. For deontologists, as opposed to consequentialists, “what makes a choice right is its conformity with a moral norm,” and the right has a priority over the good. Larry Alexander & Michael Moore, *Deontological Ethics*, THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Nov. 11, 2007), <http://plato.stanford.edu/archives/fall2008/entries/ethics-deontological/>. Making a deontological argument to justify the right to be fat means that we should examine whether it is justifiable to limit people’s freedom to be fat notwithstanding the positive outcomes that might result from such a policy (although *infra* Section II.C argues that making a utilitarian argument to justify pro-thinness policies is not as easy a task as it may seem).

11. Throughout this Article I prefer the term “fat” to “overweight,” “obese,” or “morbidly obese.” The terms I reject rest on the medical understanding of fatness, an understanding that, for reasons I will explain in this Article, I believe should be treated with caution. Indeed, “fat” is currently a derogative term in our culture, and I imagine that for many readers using this word in a law review article sounds inappropriately blunt. As prominent “fat advocate” Marilyn Wann puts it, fat is the new F-word. Marilyn Wann, *Fat Studies: An Invitation to Revolution, Forward to THE FAT STUDIES READER*, at ix, xii (Esther Rothblum & Sondra Solovay eds., 2009). Yet “fat” is the term used by identity politics groups who seek to empower and reaffirm big-bodied people and inject the term with positive meaning. See, e.g., NAAFA—NATIONAL ASSOCIATION TO ADVANCE FAT ACCEPTANCE, <http://www.naafaonline.com/dev2> (last visited Aug. 1, 2011). The growing academic field of fat studies chose to use “fat” and not “obese,” “big,” or “heavy” as its main signifier, in order to convey its critical standpoint regarding the pejoration of this term. See, e.g., Wann, *supra*, at xii; FAT!SO?, <http://www.fatso.com/> (last visited Aug. 1, 2011).

To many, being fat might seem unhealthy, aesthetically unappealing, costly to the individual and to society, and even immoral. Yet the law should not serve as an instrument for limiting fat people's access to basic liberties and to equal opportunities as it currently does—by creating incentives for weight loss and allowing private actors to express preferences not to employ fat persons, or by refusing to sell them health insurance or an airline ticket. In serving as an instrument to limit fat persons' access to rights and opportunities, American law reaches the most intimate areas of personal experience in ways that contradict the basic tenants of its commitment to liberty. Why, what, and with whom we eat, and how we exercise are such personal aspects of our existence that we should not be required to give account of them—neither to the government nor to fellow citizens.

Part I of this Article provides an inventory of the ways in which the law intervenes in the body size of its subjects. This review will demonstrate that fatness has become, in our culture and our law, a marker of a coherent set of personality traits. This Part also explains what I mean when I say that today there is no legal recognition of the right to be fat and how the legal discourse on weight is governed by the medical understanding of obesity. Part II reviews current research that challenges the predominant scientific and popular convictions that weight is within an individual's control and that being fat is counterproductive to one's health. This Part also temporarily abandons the *a priori* justification of the right to be fat and maps the utilitarian justifications for this right.

Part III provides the theoretical background to the argument that weight should be included in the scope of liberty by discussing the philosophical tradition of mind-body dualism, its contemporary deconstructions, and one of its alternatives, namely, the philosophical tradition of phenomenology. Rather than seeing fatness as an identity that is grounded in an imagined future and a lamented past with no possibility for a fat present, phenomenological accounts allow positive conceptions of the fat body as, among other things, a body that can be a subject of rights.

Part IV outlines the contours of the right to be fat and applies it to concrete legal issues. For example, it considers what legitimate policies the government can still promote in light of the right to be fat, whether it should be permissible for airlines to charge fat people for two seats, and whether weight should be a protected category under employment discrimination law. This Part also addresses the implication of my arguments for the legal regulation of dangerous behaviors and expensive tastes such as smoking or skydiving.

I. FAT MANIFESTATIONS IN LAW

[T]he body is uniquely “personal and political.”¹²

Discussions of the “obesity epidemic”¹³ have become ubiquitous. The media covers this issue extensively. The public is constantly warned by medical and nutritional experts, economists, and educators that we are becoming heavier, that overweight kills, and that something must be done immediately.¹⁴ We are told that growing obesity rates threaten to cast an unbearable burden on medical costs, to reduce the productivity of sedentary workers who suffer from lack of willpower and self-control, and even to diminish the ethics of the social body, which has lost its disciplined character by surrendering to gluttony and laziness.¹⁵

The anti-fat craze does not remain on the policy level, but infiltrates both culture and law. Culturally, fat people are represented in the media as laughable and miserable figures.¹⁶ They are socially marked as deviant and they experience prejudice and harassment. The preconceptions they encounter might be internalized, shaping their self-esteem such that it often reaches the core of their identity.¹⁷ As for the law, I present examples below illustrating how body size

12. Gowri Ramachandran, *Against the Right to Bodily Integrity: Of Cyborgs and Human Rights*, 87 DENVER U. L. REV. 1, 4 (2009) (citation omitted).

13. For an account of the development of the notion of an “obesity epidemic” in America, see J. ERIC OLIVER, *FAT POLITICS: THE REAL STORY BEHIND AMERICA’S OBESITY EPIDEMIC* 36-59 (2006).

14. A recent prominent example is First Lady Michelle Obama’s initiatives to fight childhood obesity, which include starting a vegetable garden at the White House, setting up exercise programs for children, and lecturing restaurants on how to reduce fat content in their servings. Notwithstanding this campaign, Ms. Obama herself stated that she never talks about her daughters’ weight in their presence, for fear of causing problems with their diet. See Mail Foreign Service, *Now First Lady Lectures Restaurants on Food Choice as She Steps Up Campaign Against Childhood Obesity*, MAILONLINE, Sept. 15, 2010, <http://www.dailymail.co.uk/news/article-1311902/Michelle-Obama-lectures-US-restaurants-steps-childhood-obesity-campaign.html>.

15. Sander Gilman discusses the link between citizens’ weight and the health of the nation in the past century: “Dieting . . . [has become] a way to halt the obesity epidemic, to intervene so as to improve the private life of the individual and thus the health of the nation. . . . There were claims that morbid obesity impacted on the health of the mother and child, and thus weakened the state.” SANDER L. GILMAN, *FAT: A CULTURAL HISTORY OF OBESITY* 4 (2008); see also SOLOVAY, *supra* note 7, at 78-85 (discussing the prevalence of verbal abuse towards fat people in personal, public, and professional settings).

16. See, e.g., Bradley S. Greenberg et al., *Portrayals of Overweight and Obese Individuals on Commercial Television*, 93 AM. J. PUB. HEALTH 1342, 1346-47 (2003) (sampling episodes from top prime-time fiction television and finding that fat individuals are under-represented by more than half their percentage in the general population and that they are less likely to have positive personality attributes); Susan M. Himes & J. Kevin Thompson, *Fat Stigmatization in Television Shows and Movies: A Content Analysis*, 15 OBESITY 712, 715-16 (2007) (noting that fat stigmatization is often presented in the form of commentary and humor through entertainment media).

17. This is especially so in the case of women and girls. See generally JOAN JACOBS BRUMBERG, *THE BODY PROJECT: AN INTIMATE HISTORY OF AMERICAN GIRLS* (1997) (arguing that

has become a relevant category in various areas. Weight plays a role in determining access to employment opportunities, health services, and education, and may impact the possibility of serving on juries. Weight also jeopardizes the ability of fat people to sustain a sense of self-worth and entitlement to participate in the full scope of civic and personal life.

A. Legal Manifestations of Body Size: An Overview

One way of characterizing the relationship between weight and the law is by distinguishing between *direct state interventions* that burden the right to be fat, and *failures of the State to intervene* in actions of private individuals or institutions that burden the right to be fat. In the first category of positive, active State intervention, I include features of the “war against obesity” that facilitate various regimes meant to regulate weight and create legal instruments that provide means for fighting the “obesity epidemic.” In the second category, the law is silent about weight even when it has become an insidious classification that might merit legal attention.

Usually in the first category, the legal intervention arises after other professional fields define a problem related to body weight and recruit the law to enforce policy. For example, the medical profession points to a fat-related risk. This risk is then echoed by public health officials, educators, or insurance companies. Finally, after these sectors have developed schemes of action to respond to the problem they named, we often find legal instruments are recruited to execute policies by creating legal authorizations and institutional, bureaucratized regulatory schemes.

Examples of State intervention include the following:

- 1) Laws mandating that schools weigh students on a regular basis and send report cards to their parents, along with dietary and exercise recommendations.¹⁸
- 2) Designing, via case law, parental neglect standards that are related to children’s weight. Courts may mandate that welfare authorities remove extremely fat children from the custody of their parents. The child’s weight is considered a

for American girls, shaping the body is a central site for shaping one’s selfhood).

18. For a recent weighing policy in an Arizona school district see *Flagstaff Schools Send Home Warnings About Overweight Students*, THE DAILY COURIER, Nov. 14, 2010, <http://www.dcourier.com/main.asp?SectionID=1&SubsectionID=1&ArticleID=87494>. For a report on the pros and cons of such a program in the U.K. see Frances Elliot, *Parents of Fat Children To Be Given a Warning*, TIMESONLINE, Oct. 22, 2007, <http://www.thetimes.co.uk/tto/health/article1880936.ece>. For a critique of such programs, see Daniel Engber, *Leave the Fat Kids Alone*, SLATE, Mar., 10, 2011, <http://hive.slate.com/hive/time-to-trim/article/leave-the-fat-kids-alone> (“Tell a little kid he’s fat (or *obese*, or *at elevated risk of obesity*, or whatever clinical spin you put on it) and you might help him to eat his fruits and veggies—but watch what happens to his bendy little brain. Get in there early enough, and even the best intentions can metastasize into a deep-seated anxiety. What happens in the mind of an adolescent could be inscribed there for years to come.”).

primary indication of parental neglect and abuse, often overriding contrary evidence of improvement in a child's health and lifestyle, such as lower blood sugar and blood pressure.¹⁹

3) Denial of entitlements such as the right to graduate from college even if one has successfully completed one's academic requirements. In late 2009, the media reported a practice by Lincoln University in Pennsylvania, a state-related university, which denied fat students the right to graduate after completing their academic requirements unless they completed a fitness class (commonly referred to as "the fat course") that met three times a week.²⁰ After the media exposure, the school retreated, noting that this policy violated its commitment to equal treatment. The class would now only be offered as an elective to relevant students.²¹

4) Initiatives that are aimed at a specific segment of the population, identified as one with high rates of obesity, to make it costly for them to buy junk food or maintain other practices that are assumed to be in correlation with fatness. New York City's Mayor Michael Bloomberg, for example, has been promoting a ban on using food stamps to buy sugared soft drinks.²² As I explain

19. See Schaefer, *supra* note 8, at 36 ("The legal system sees weight and nothing else. So much so, that courts *ignore the actual health improvement* that some of the children experience when their diet and exercise habits change and *see the parents as failing* where they succeed in ensuring a healthier—but not thinner—lifestyle for their children.") (second emphasis added); see also SOLOVAY, *supra* note 7, at 64-77 (discussing removal of children from their parents' custody due to children's weight); Theran, *supra* note 7, at 170-71 (reviewing weight-based discrimination in family law and child custody). Obesity is also becoming a factor in custody cases. See Shauneen M. Garrahan & Andrew W. Eichner, *Tipping the Scale: A Place for Childhood Obesity in the Evolving Legal Framework of Child Abuse and Neglect*, 12 YALE J. HEALTH POL'Y L. & ETHICS 336 (2012); Ashby Jones & Shirley S. Wang, *Obesity Fuels Custody Fights*, WALL ST. J., Oct. 29, 2011, <http://online.wsj.com/article/SB10001424052970204294504576613100908629810.html>.

20. Kate Harding, *You Must Be This Thin To Graduate*, SALON.COM, Dec. 1, 2009, http://www.salon.com/life/broadsheet/feature/2009/12/01/lincoln_university. Whether a university is public or private will change the above classification of such a policy as a State act or a private act. For further discussion of the divide between the government duty to respect the right to be fat and the duty of private actors, see *infra* note 216.

21. AP, *Pa. School Drops Required Fitness Class for Obese*, FOX NEWS, Dec. 6, 2009, <http://www.foxnews.com/story/0,2933,579577,00.html>. For a critique of the college practice, see Susan Albers, *Weighing College Students: Helpful or Harmful?*, PSYCHOL. TODAY, Nov. 21, 2009, <http://www.psychologytoday.com/blog/comfort-cravings/200911/weighing-college-students-helpful-or-harmful> (claiming the Lincoln University initiative did more harm than good, since it created weight discrimination by suggesting that students with BMI over thirty are unhealthy in comparison to thinner ones, an assumption that is incorrect). For data on the bias of instructors against fat students, and on its negative effects on students' achievements, see Rebecca M. Puhl & Chelsea A. Heuer, *The Stigma of Obesity: A Review and Update*, 17 OBESITY 941, 949-50 (2009).

22. See Anemona Hartocollis, *New York Asks To Bar Use of Food Stamps To Buy Sodas*, N.Y. TIMES, Oct. 6, 2010, <http://www.nytimes.com/2010/10/07/nyregion/07stamps.html>. One reader response to this article reads: "There is something very warped about the richest person in NYC trying to prevent the poorest from drinking soda pop. The one who could, if he so desired, drink the most expensive champagne instead of water, fixated on making sure the little people can't get their hands on an Orange Crush." Dave, Comment to *New York Asks To Bar Use of Food Stamps To Buy*

below,²³ in light of the right to be fat we should question the legitimacy of such initiatives, which directly target fat people. The picture is different, however, with regard to initiatives aimed at the entire population, such as First Lady Michelle Obama's bill setting more restrictions on what school cafeterias can serve and offering them additional funding for serving healthier food.²⁴ This bill, and other general measures, such as food labeling regulations requiring that fast food restaurants specify the nutritional value of their products,²⁵ are not problematic because they do not suggest that the problem is one of individual failure of fat persons. Rather, these measures offer structural solutions to promote the health of the entire population.

In the second category, the law's failure to intervene when necessary, we find instances in which fat persons' access to opportunities, goods, and services provided by private actors are strongly and adversely determined by their weight; yet the law is silent about such weight-based distinctions. Here are some illustrations:

1) Body weight is absent from the list of suspect classes in antidiscrimination provisions, such as the Equal Protection Clause and Titles IX and VII of the Civil Rights Act. I will focus on employment discrimination because it is the field with the most empirical data and scholarly legal discussion. Despite significant evidence of a connection between fatness and employment discrimination, weight-based employment discrimination continues to be permitted.²⁶ There are a few recent exceptions of state and local employment discrimination rules that enumerate weight or appearance as forbidden grounds

Sodas (Oct. 7, 2010, 7:49 AM), <http://community.nytimes.com/comments/www.nytimes.com/2010/10/07/nyregion/07stamps.html>. A similar 2004 scheme by Minnesota was rejected by the Department of Agriculture, which must authorize such limitations on food stamps, with the reasoning that such a scheme "was based on questionable merits and would 'perpetuate the myth' that food-stamp users made poor shopping decisions." Hartocollis, *supra*.

23. See *infra* Subsection IV.C.1.

24. See Mary Clare Jalonick, *Obama Signs Historic School Lunch Nutrition Bill*, SALON.COM, Dec. 13, 2010, http://www.salon.com/food/feature/2010/12/13/us_obama_child_nutrition. I agree with Professor Paul Campos' critique of this initiative as one that focuses on "getting rid of fat kids." Paul Campos, *Childhood Shmomesity*, NEW REPUBLIC, Feb. 11, 2010, <http://www.tnr.com/article/politics/childhood-shmomesity>. Campos maintains that goals such as improving the nutritional value of school meals, helping children become more active by making urban areas amenable to physical activity, or improving labels on food products are laudable goals, but they should not be achieved by focusing on the slimming down of children, as this goal is neither achievable nor relevant for improving children's health and is bound to increase the social stigma against fat children. See *id.*

25. See Sewell Chan, *Court Upholds the City's Rule Requiring Some Restaurants To Post Calorie Counts*, N.Y. TIMES, Feb. 18, 2009, <http://www.nytimes.com/2009/02/18/nyregion/18calorie.html> (reporting on the rejected appeal by the New York State Restaurant Association against a 2007 New York City initiative requiring most major fast-food and chain restaurants to display calorie information on their menus).

26. On the empirical evidence of weight-based employment discrimination see *infra* Subsection IV.C.3.a.

for discrimination.²⁷ But in most U.S. jurisdictions, the law does not forbid rejecting a job candidate because of his weight. Exceptions also include circumstances wherein the candidate has a disability discrimination claim, but this would not be a claim of weight-based discrimination per se.²⁸ Whether it is a good idea to introduce weight as a suspect class in employment discrimination law is a question I will discuss later in this Article.²⁹ For this early stage of the exploration, I simply wish to note that weight is significant in access to jobs, promotions, salaries and other employment-related resources, and that the law does not recognize this form of discrimination as worthy of remedy.

2) Current law also does not forbid various forms of price distinction, such as double-charging fat air travelers³⁰ and setting a higher health insurance premium for heavier persons, which would be considered price discrimination if we were to conclude that these are unjust pricing practices.³¹ There are other forms of price differentiation that might amount to discrimination. Anecdotal examples that have made it to the mass media include charging more for a manicure performed on a fat woman, explaining that she might cause damage to the salon chair,³² or charging a bereaved family extra burial services by claiming that it would require extra effort to carry the corpse of a heavy person.³³ Indeed, a recent study found that fat women pay consistently more for services and

27. The State of Michigan prohibits employers from discriminating on the basis of “religion, race, color, national origin, age sex, height, weight, or marital status.” MICH. COMP. LAWS ANN. § 37.2202(1)(a) (2012). Washington, D.C. prohibits any kind of discrimination based on “race, color, religion, national origin, sex, age, marital status, personal appearance . . . of any individual.” D.C. CODE ANN. § 2-1401.01 (2012). Interestingly, these advanced laws have produced very little litigation, for reasons I will discuss below. *See infra* Subsection III.C.2.

28. For scholarly accounts of weight-related disability claims *see infra* note 244.

29. *See infra* Subsection IV.C.3.

30. *See* Brian Bolton, *The Battle for the Armrest Reaches New Heights: The Air Carriers Access Act and the Issues Surrounding the Airlines’ Policy of Requiring Obese Passengers To Purchase Additional Tickets*, 69 J. AIR. L. & COM. 803, 813-16, 828-31 (2004) (examining whether it is appropriate to interpret the Air Carriers Access Act as covering obese passengers); Scott Mayerowitz, *How Fat Is Too Fat To Fly?*, ABC NEWS, Dec. 2, 2009, <http://abcnews.go.com/Travel/BusinessTraveler/obese-passengers-fat-fat-fly-us-airline/story?id=9227535> (reporting American Airlines’ policy for “larger passengers”); Rob Goldstone, *The Tricks and Trials of Traveling While Fat*, N.Y. TIMES, Oct. 20, 2010, <http://travel.nytimes.com/2010/10/24/travel/24journeys.html> (reporting a “plus size” passenger’s unpleasant traveling experience).

31. *See* Theran, *supra* note 7, at 162-65 (reviewing evidence for discrimination in provision of goods and services).

32. *See* Emily Friedman, *Salon Charges Customer Extra Five Dollars Because She’s Fat*, ABC NEWS, Aug. 23, 2010, <http://abcnews.go.com/US/michelle-fonville-charged-extra-georgia-salon-shes-fat/story?id=11461062>. For other problems of accommodation of goods and services encountered by fat clients *see* Korn, *Too Fat*, *supra* note 7, at 20 n.121, which cites cases dealing with incidents such as ejecting an obese woman from a bus, or not allowing an obese woman to bring her own chair to theater.

33. This incident was reported in the Israeli media. Amir Shuan & Shachar Genosar, *Herein Lies the Money*, YEDIOT ACHARONOT, July 3, 2009, at 20.

goods.³⁴

3) Fashion brands such as Old Navy or H&M practice what might be dubbed “service differentiation,”³⁵ by selling their large size items only online, to avoid the damage to the fashionable image of the brand in the eyes of “regular” size customers. Being able to buy a product only via the Internet is not a trivial technicality, but may be considered both a symbolic and a literal exclusion of fat consumers from the marketplace.³⁶

4) Fatness sneaks into litigation as well, often indirectly. For example, one case revealed a prenuptial agreement in which one of the conditions of marriage was that the wife “would not get fat.”³⁷ Since prenuptial agreements are at the private end of the public/private axis of contracts, I am not going to make a claim that the law should limit contractual freedom if it interferes with the liberty-based right to be fat. I am providing this example as an anecdotal illustration of how cultural values about weight surface in legal documents. The spouse’s weight emerges from this agreement as such a fundamental change in the spouse that it might be a cause of breaking the marriage bond.

Jury selection cases provide another example, whereby the “overweight” of a potential juror is cited as a legitimate reason for a peremptory challenge. In one case, the prosecutor explained why he struck two jurors:

[I]n his experience, this type of person had been picked on and made fun of by others . . . [and] they might feel sorry for the defendants because defendants also have the characteristic of having been picked on by the police or being deprived of the

34. See generally Avi Dor et al., *A Heavy Burden: The Individual Costs of Being Overweight and Obese in the United States*, GEO. WASH. U. SCH. PUB. HEALTH & HEALTH SERVS. 9 (Sept. 21, 2010), http://www.gwumc.edu/sphhs/departments/healthpolicy/dhp_publications/pub_uploads/dhpPublication_35308C47-5056-9D20-3DB157B39AC53093.pdf. Sometimes price or service discrimination is justified on efficiency considerations, at least short-term ones. See, e.g., Ian Ayres et al., *To Insure Prejudice: Racial Disparities in Taxicab Tipping*, 114 YALE L.J. 1613, 1653-56 (showing that taxi drivers might be justified in preferring white costumers because they leave better tips, but arguing, in a vein similar to mine, that this is a circular, somewhat tragic, effect of the market, that structural policy changes might appease).

35. Kay Jones, *Old Navy Removes Plus Size Clothes from Stores*, ASSOCIATED CONTENT (May 6, 2007), http://www.associatedcontent.com/article/235870/old_navy_removes_plus_size_line_from.html; *Good News and Bad News About H&M’s Plus Size Collection*, JEZEBEL, Jan. 26, 2011, <http://jezebel.com/5743168/good-news--bad-news-about-spring-plus+size-fashion-from-hm>.

36. See Hila Keren, *Equality Within Contract Law: A Feminist Call*, 31 MISHPATIM 269 (2000) (connecting the dots between exclusion of certain groups from private spaces). In the era of late capitalism, commerce areas such as stores and malls are the current town square. They shape people’s understanding of their community and serve as arenas for political and cultural exchange. I am grateful to my student, Guy Sadaka, for drawing my attention to this last point.

37. *Dewberry v. George*, 62 P.3d 525, 526 (Wash. 2003). I learned about this case from a paper by Martha Ertman, *Food R Us: The Primal Deal, Families, and Family Laws* (June 12, 2011) (unpublished manuscript) (on file with author).

advantages that others have.³⁸

The defendant challenged this reasoning, arguing that since they were both black, this was a racially discriminatory decision. However, two courts (a district court and a court of appeals) were satisfied with the prosecutor's explanation that "his ten years experience showed him that he did not relate well to overweight people, and he thought they tended to identify with defendants."³⁹ Besides, noted the Court of Appeals, this prosecutor struck down three more white jurors for the same reason. I am not interested in whether this was indeed a racially motivated jury selection decision, but instead am concerned about both the matter-of-factness with which certain personal characteristics are attributed to potential jurors based on their body size and the unbearable lightness of judicial affirmation of this "common wisdom" about fat people.

In another jury selection case, the prosecutor struck down "Juror 7920," the only black prospective juror on the panel.⁴⁰ In explaining why his decision was not racially motivated, the prosecutor declared:

Your honor, as far as people who are overweight, women who are overweight, I feel that people who do not take care of themselves cause[] me a concern as far as being able to sit on a jury, and evaluate the testimony and credibility of the witnesses. And I exercised my peremptory against Juror 8218 [who was not black] and the same reason for Juror 7920, as well. I think that people who do not take care of themselves to the point of obesity concern[] me, as far as being on a jury.⁴¹

In finding the reasoning of the prosecutor acceptable, the trial court noted that both jurors mentioned by the prosecutor were indeed "noticeably and markedly overweight."⁴² The California Court of Appeal found this reasoning acceptable:

We need not evaluate the reasonableness of the prosecutor's view of obesity to conclude as we conclude, based on the record as a whole, that the record supports the prosecutor's explanation that he challenged juror number 7920 because she was overweight and not because she was African-American, that the

38. *Davis v. Texas*, 1992 WL 86692, at *3 (Tex. Ct. App. 1992).

39. *Id.*

40. Since the prosecutor is not a private actor but a public servant, I could have classified this example under the first group of instances, as an illustration of State action towards citizens based on their weight. I classify it in the second group of examples because I want to emphasize the failure of jury selection doctrine to recognize that weight should not be a legitimate basis for attributing personality traits.

41. *People v. Wynn*, 2004 WL 417221, at *2 (Cal. Ct. App. 2004).

42. *Id.* at *4.

explanation is not inherently implausible, and that the trial court did not err in denying Wynn's motion for a new jury venire.⁴³

Given the current doctrine, it is unsurprising that the court focuses its concern on whether the challenge to the juror was racially motivated. Nonetheless, this decision illustrates how judicial reasoning can discursively normalize the negative characteristics associated with fatness even when it formally attempts to leave weight issues out of the law.

B. Three Preliminary Remarks

1. Fatness Has Become Associated with a Distinct Set of Characteristics

The prenuptial agreement case and the jury cases just discussed clearly demonstrate how fatness is emerging in culture and in the legal discourse as an identity with distinct personality attributes. The wife and the jurors' weight are understood as stable signifiers of a certain set of characteristics. From the viewpoint of the husband or the lawyer, the fat body marks not just a physical state, but also a persona.

The abundance of expert knowledge on fatness, and the multiple regulative schemes to monitor and correct it, render the fat body as a body that should be thoroughly monitored, deciphered, and treated. Fatness is becoming a status. It functions as an indicator of a set of traits that make up a certain character, or more accurately, for a general failure of character.⁴⁴ Fat, writes Sander Gilman, "has taken on a new and rather sinister quality over the past century."⁴⁵ The expansive waistline, Gilman continues, has new meanings now firmly attached to it.⁴⁶ It is an index for laziness, lack of self-control, illness, contamination, and even irrationality and feebleness of mind.⁴⁷

43. *Id.* For a discussion of other weight-related jury selection cases see SOLOVAY, *supra* note 7, at 90-98. For other concerns of fat bias in criminal procedure, see Valena Beety, *Criminal Justice and Corpulence: The Unsung Role of Fatism in the Courtroom* (Aug. 27, 2010), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1667136 (discussing weight-based discrimination of, among others, jurors and defendants); Theran, *supra* note 7, at 168-70 (reviewing discrimination against the overweight in juries and in prisons).

44. I have often been asked why I do not write on ugliness in general, but instead focus on weight. The answer is that these are different cases. Ugliness indeed prompts discrimination and bias, *see, e.g.*, NANCY ETCOFF, *SURVIVAL OF THE PRETTIEST: THE SCIENCE OF BEAUTY* (2000) (providing empirical evidence, grounded in evolutionary biology, of the preferred treatment society accords to beautiful people), but ugliness, unlike fat, is not subjected to the medical paradigm for explaining it, has not become associated with a set of characteristics, and is not assumed to be in the control of the individual (at least not to the extent that fat is).

45. GILMAN, *supra* note 15, at 3.

46. *See id.*; *see also* Beety, *supra* note 43, at 12 (noting that "lawyers and jurors . . . may infer or presume that the defendant's body provides insight into the crime and the defendant").

47. *See, e.g.*, Le'a Kent, *Fighting Abjection: Representing Fat Women*, in *BODIES OUT OF BOUNDS: FATNESS AS TRANSGRESSION* 130, 134 (Jana Evans Braziel & Kathleen LeBesco eds.,

We may be witnessing what might be called “a Foucauldian turn” with regard to fat identity. In volume I of *The History of Sexuality*, Michel Foucault famously observes that at a certain point in the nineteenth century, homosexual practices ceased to be perceived merely as forbidden acts, but took on a personality. It became an organizing category marking a fundamental quality that lay at the core of those who practiced homosexual acts.⁴⁸

As defined by ancient civil or canonical codes, sodomy was a category of forbidden acts; their perpetrator was nothing more than the juridical subject of them. The nineteenth-century homosexual became a personage, a past, a case history, and a childhood, in addition to being a type of life, a life norm, and a morphology with an indiscreet anatomy and possibly a mysterious psychology. Nothing that went into his total composition was unaffected by his sexuality. . . . We must not forget that the psychological, psychiatric, medical category of homosexuality was constituted from the moment it was characterized. . . . [T]he homosexual was now a species.⁴⁹

For Foucault, sexuality as a meaningful category in understanding the human subject emerged as a result of a new discourse about sexuality—discourse produced by disciplines such as medicine, law, education, and theology. It is the very thriving of the discourse on sexuality that constituted it and regulated it as a meaningful prism through which to “decipher” human subjects.

As with sexuality, fatness emerges as a trait that allegedly reveals much more about the individual than medical information such as body mass index or fats in blood. The new category of fatness pathologizes excessive weight and paves the way for many kinds of social control mechanisms aimed to supervise this perversion. As sociologists Abigail Saguy and Anna Ward note, “People who cannot buy health insurance, clothing in offline stores, or are forced to buy two airplane seats because of their body size unquestionably fall into a category that carries social costs. Such incidents provide frequent reminders that their body size makes them a second-class citizen.”⁵⁰ But these forms of direct and covert oppression also simultaneously enable the emergence of a counter-discourse that

2001) (discussing media representations of the fat body as signifying “lack of self-control, leading to disease”); Korn, *Too Fat*, *supra* note 7, at 222 (“Those who are obese are perceived as dishonest, sloppy, ugly, socially unattractive, less productive, lazy, stupid, and worthless.” (citation omitted)); Samantha Murray, *(Un)Be)Coming Out? Rethinking Fat Politics*, 15 *SOCIAL SEMIOTICS* 153, 154 (2005) (“[J]ust some of the characteristics we have come to assume define fatness are laziness, gluttony, poor personal hygiene, and a lack of fortitude.”).

48. MICHEL FOUCAULT, I *THE HISTORY OF SEXUALITY* 43 (Robert Hurley trans., Vintage Books 1990) (1976).

49. *Id.*

50. Abigail Saguy & Anna Ward, *Coming Out as Fat: Rethinking Stigma*, 74 *SOC. PSYCHOL. Q.* 53, 71 (2011).

resists labeling large bodies as deviating and turns to paradigms such as pride and politics of identity. In this context, it is significant to note the rise of a counter, fat-affirming, discourse that rejects the dominant negation of fatness and aspires to create room for an alternative discourse of a positive, visible, and vocal fat presence.⁵¹

As we have seen in the above survey of fat manifestations in law, the law plays a significant role in creating and protecting fat as a meaningful identity category.⁵² The Foucauldian framework acknowledges the interrelations between oppressive, normalizing power on the one hand, and resistance on the other hand, but expresses ambivalence towards this dynamic. This Article's argument, that body size should be conceptualized as part of liberty, is offered with similar ambivalence: wouldn't promoting recognition of body size as a new category only serve to further reify the importance of weight? Still, I believe that grounding the right to be fat within the conceptual framework of liberty, rather than within the framework of antidiscrimination, would mitigate many of the normalizing effects that are associated with the power of law. I elaborate on this point below.⁵³

2. *The Medical Framework's Monopoly on Legal Discourse*

In the legal manifestations of fatness reviewed above, fatness is almost exclusively discussed through the medical lens: by referring to accurate scientific measurements, such as weight, height, and BMI, or by examining medical causes of weight that might excuse one from responsibility for being fat. This point is stressed here because later in this Article, alternatives to the medical approach will be presented and advocated.⁵⁴

As early as 1977, a sex discrimination case challenged an airline for establishing maximum weight standards for its female flight attendants that were stricter than those for male flight attendants of the same height.⁵⁵ Flight attendants were subject to meticulous and elaborate supervision of their weight. At different stages, the airlines prescribed a desired rate of weight loss (between half a pound to two pounds per week) and issued various administrative rules, such as requirements that a flight attendant should not be weighed during her menstrual period.⁵⁶

A federal district court accepted as legitimate the medicalized height-weight tables in use, indicating that "the weight control program was implemented with

51. On the fat-affirming identity politics groups, see *infra* Subsection III.C.2.

52. The law does not, however, operate alone, but draws from, and feeds back into, other disciplines of knowledge that participate in the discursive constitution of the fat persona.

53. See *infra* Section IV.A.

54. See *infra* Section III.C.

55. *Jarrell v. Eastern Air Lines, Inc.*, 430 F. Supp. 884 (E.D. Va. 1977).

56. *Id.* at 888.

the approval of [the airline's] medical department."⁵⁷ The court found that "[t]he application of [the airline's] weight tables to the general population of the United States between the ages of 25 and 31 would find a greater percentage of women than percentage of men to be in noncompliance."⁵⁸ Despite these findings, the court rejected the sex discrimination claim and was satisfied by the medical testimony submitted at trial "that weight is a characteristic which, within reasonable limits, is controllable by an individual."⁵⁹ The court granted further credence to the medical discourse by noting that "[t]he standards adopted for both sexes are consistent with accepted medical notions of good health and may be complied with without imposing a health hazard. For those flight attendants who are medically unable to meet their chart weight, exemptions are available."⁶⁰ In another case, the court held that it passed muster to permit an employer's physician to determine whether an employee's weight was acceptable by consulting "a weight chart, which he had clipped out of a newspaper and which he believed conformed to an insurance company's actuarial tables."⁶¹

That this approach is not a relic of bygone judicial stances is evidenced by recent cases that still readily adopt the medical perspective on weight. In a 2007 case that turned on the question of the evidence required to establish a disability discrimination claim under the Americans with Disabilities Act (ADA) and an analogous state law, plaintiff's weight grew beyond the limit set for employees in his role on a team that was responsible for installation and maintenance of telephone services.⁶² The employing company hired another company to supervise the employees' weight, and plaintiff was informed that he would have to lose weight in order to continue his employment. The plaintiff was introduced with a timetable under which he was required to lose fifty pounds over a period of twenty-five weeks⁶³ and was terminated when he failed to lose the required weight.⁶⁴ Analyzing the problematic doctrine of ADA interpretation illustrated in this case is beyond the scope of this Article. What I wish to emphasize here is the face-value priority given to the medical gaze on the plaintiff's body, treating the body mechanically, as a simple object, easily susceptible to weight reduction or increase according to dictated and preset goals, while ignoring the plaintiff's own account that previous repeated attempts to lose weight caused him various types of distressing symptoms such as insomnia, a sense of sting in his hands and feet,

57. *Id.*

58. *Id.* at 889.

59. *Id.* at 890.

60. *Id.* at 893.

61. *Or. State Corr. Inst. v. Bureau of Labor & Indus.*, 780 P.2d 743, 744 (Or. App. 1989).

62. *Greenberg v. BellSouth Telecomm., Inc.*, 498 F.3d 1258 (11th Cir. 2007).

63. *Id.* at 1260.

64. *Id.* The company offered to help place the plaintiff in another job within the company before terminating him.

fainting spells, and more.⁶⁵

3. “*But No One Violates the Right To Be Fat!*”

One might object to the aim of this project that it makes no sense to protect a right to be fat because no one is denying fat persons the possibility of being fat. Indeed, in the above review of the manifestations of fat in contemporary law, nowhere can we find a government official who chases fat people with teeth wires (one of the more hideous and inhumane diet techniques—wiring the jaws so that no solid food can go through the mouth),⁶⁶ or threatens to throw fat people into jail unless they lose weight. But current legal arrangements do sometimes punish fat children and infringe the autonomy of their parents by mandating that obese children are removed from their parents’ custody to placements in which they are closely supervised so that they will not gain weight.⁶⁷ Current law also permits fining fat people for their weight (by allowing private actors to charge more for goods and services sold to fat people),⁶⁸ and limiting their freedom of opportunity (by striking fat people out of jury panels and by allowing weight-based employment discrimination).

What the above review demonstrates is the existence of an amalgam of legal arrangements (or lack thereof) that creates a legal climate in which being fat means being a second-class citizen. Our law sends repeated messages that fat people’s bodies are inferior. These messages also implicate the personality to which this body supposedly attests. They jeopardize the fat person’s sense of self-trust in his or her body and the sense of self-efficacy as an agent. Such legal arrangements hamper fat people’s ability to participate fully and equally in various domains from the family to the market. The law has an expressive role that is no less significant than its legal directives.⁶⁹ Recognizing the expressive role of the law enables us to realize the importance of the message sent by contemporary law—a message that life as a fat person is less valuable in many respects and merits less effort to create conditions for full realization of its potential.

65. *Id.*

66. See, e.g., Pietro Castelnovo-Tedesco et al., *Jaw-Wiring for Obesity*, 2 GENERAL HOSPITAL PSYCHIATRY 156 (1980) (reporting a clinical study that found that jaw wiring was an ineffective means for controlling weight).

67. See sources cited *supra* note 19.

68. See *supra* text accompanying note 30.

69. On the expressive role of law, see, for example, Alex Geisinger & Michael Ashley Stein, *A Theory of Expressive International Law*, 60 VAND. L. REV. 77, 81 (2007) (“By expressive law, we mean the impact that law and legal process have on individual behavior . . . by affecting the social, or normative, meaning of that behavior.” (footnotes omitted)).

II. THE CONTENTIOUS SCIENCE ON FAT

As with the blacks and the poor, fat people are thought to violate some of the most fundamental tenets in American political culture: that all people are fundamentally responsible for their own welfare; that self-control and restraint are the hallmarks of virtue; and that all Americans are obliged to work at improving themselves.⁷⁰

[L]ives are lived in the context of a range of competing priorities, such as cultural tradition, interpersonal relationships, physical pleasure and economic resources. While the case for making overweight and obesity our number one health concern may seem obvious to obesity scientists, perhaps outside in the wider world life is seen as more complex and more prone to compromise.⁷¹

In the discussion throughout this Article, I will assume, for the sake of argument, and despite evidence to the contrary, that weight is mutable. That is, I will assume that changes in lifestyle through diets and exercise, or more radical interventions such as surgery, can lead to a long-term weight loss. I will also assume that fatness is generally not conducive to good health, in that it is either a factor in, or a cause of, conditions such as diabetes, heart disease, cancer, and high blood pressure. Excess fat might decrease life expectancy and life quality.

Making these presuppositions renders the challenge of arguing for the right to be fat more difficult. If fatness can be changed and leads to a shorter and worse life, why should we worry about protecting a right to remain fat, instead of encouraging fat people with both sticks and carrots to lose weight and to lead a lifestyle that prevents weight gain?⁷²

Before embarking on the main argument, however, it is worth sketching the findings and claims regarding why fat is *not* as mutable and unhealthy as the medical establishment, the diet industry, and popular culture prompt us to believe. The following discussion is not offered as an exhaustive review of the literature, but rather as an outline of its main trajectories.

70. OLIVER, *supra* note 13, at 73.

71. GARD & WRIGHT, *supra* note 5, at 187-88.

72. The suspect categories enumerated in Title VII of The Civil Rights Act of 1964 are mostly immutable categories, such as race, sex, or nationality. This is also true for age. *See* The Age Discrimination in Employment Act of 1967, 29 U.S.C. §§ 621-34 (1967). The changeable categories, such as religion, are ones that it would seem too invasive for liberty and autonomy to require that one changes in order to avoid discrimination. For a pioneering study showing that traits (including weight) considered controllable by the individual are perceived as less worthy of protection from discrimination, see Tami Kricheli-Katz, *Choice Based Discrimination: Labor Force Type Discrimination Against Gay Men, the Obese and Mothers* (unpublished manuscript) (on file with author).

A. The Immutability of Bodily Weight

Constant advertisements for diets or fitness regimes, and the public health discourse about the need to slim down the population, emphasize personal accountability and self-control as the keys to “normal” weight. However, data increasingly indicate that hormonal factors, metabolism, and genetics⁷³ are all factors that predetermine one’s weight and impede attempts to lose it. Long-term, significant weight loss is still a challenging enigma to science and medicine. Rosenbaum and his colleagues, for example, found that after weight loss, brain regions associated with reward were more active than the parts associated with self-control, leading to fast regain of the lost pounds.⁷⁴ According to a 2001 survey of weight loss studies, five years after a weight loss subjects gained back almost eighty percent of their lost weight.⁷⁵ A 2007 extensive literature review found even more conclusive evidence that “dieters are not able to maintain their weight losses in the long term.”⁷⁶ Studies also find that the more weight is reduced, the smaller the chances of sustaining the new weight.⁷⁷ In other words, most weight losses (through diets, exercise, or surgery) end in regaining the pounds lost and adding to them more weight within five years.⁷⁸ Cynically

73. See, e.g., OLIVER, *supra* note 13, at 100-21 (surveying the research on physiological reasons for obesity and on its immutability); Elizabeth K. Speliotes et al., *Association Analysis of 249,796 Individuals Reveal 18 New Loci Associated with Body Mass Index*, 42 NATURE GENETICS 937 (2010) (thirty-two distinct genetic variations have so far been identified as related to body mass index or to obesity); Joanne E. Cecil et al., *Variants of the Peroxisome Proliferator-Activated Receptor γ - and β -Adrenergic Receptor Genes Are Associated with Measures of Compensatory Eating Behaviors in Young Children*, 86 AM. J. CLIN. NUTR. 167, 171-72 (2007) (finding correlation between genetic makeup and eating behaviors of children); Anthony G. Comuzzie & David B. Allison, *The Search for Human Obesity Gene*, 280 SCIENCE 1374 (1998) (indicating that by some estimates, between forty and seventy percent of human obesity is heritable); A. Marti et al., *Genes, Lifestyles, and Obesity*, 28 INT’L J. OBESITY S29, S36 (2004) (finding that it is difficult to separate the roles of genetic makeup from that of environmental factors such as “cultural and social mediated food intake and reduced domestic and living work activities”). But see James O. Hill & Edward L. Melanson, *Overview of the Determinants of Overweight and Obesity: Current Evidence and Research Issues*, 31 MED. & SCI. IN SPORTS & EXERCISE s515, s520 (1999) (arguing that genes play little if any role in obesity, and that the major factor in the increased rates of obesity is the decrease in physical activity).

74. Michael Rosenbaum et al., *Leptin Reverses Weight Loss-Induced Changes in Regional Neural Activity Responses to Visual Food Stimuli*, 118 J. CLIN. INVEST. 2583, 2588 (2008).

75. James W. Anderson et al., *Long-Term Weight-Loss Maintenance: A Meta-Analysis of US Studies*, 74 AM. J. CLINICAL NUTRITION 579, 582 (2001).

76. Traci Mann et al., *Medicare’s Search for Effective Obesity Treatment: Diets Are Not the Answer*, 62 AM. PSYCHOLOGIST 220, 230 (2007).

77. Anderson et al., *supra* note 75, at 583. Although subjects who exercised regularly had a better chance of keeping their new weight, even their success was limited. See *id.* at 582.

78. Glenn Gaesser, *Is “Permanent Weight Loss” an Oxymoron? The Statistics on Weight Loss and the National Weight Control Registry*, in THE FAT STUDIES READER, *supra* note 11, at 37-40 (indicating that solid data about weight loss success is hard to find, and that the 90-95% figure of failure in long term weight loss “may not be far from the truth”). Gaesser also points to a direct correlation between weight loss attempts in U.S. population and weight gain of this population. *Id.*

phrased, the available data indicate that good strategy for *gaining* weight is embarking on a weight loss program.⁷⁹

Mainstream science promoting the notion that weight is mutable employs, according to critics, problematic methodologies, such as keeping track of the weight of research subjects for too short a time (thus boosting the data on the success of weight loss and failing to isolate the benefits of weight loss from other factors such as “exercise, sodium/alcohol reduction, or even antihypertensive medication use”⁸⁰). Critics also maintain that weight loss studies fail to address the health consequences of weight regain, which occurs in most dieters within five years of their weight loss.⁸¹

Another factor that weakens the individualistic personal-choice explanations for weight gain is the tight nexus between weight and socioeconomic factors. Income and home location determine one’s ability to access fresh produce and fiber-rich foods.⁸² Race and ethnicity are also strong predictors of weight in the United States—partly because of their correlation with poverty⁸³ and the lived environment that encourages a sedentary lifestyle,⁸⁴ but also due to genetics.⁸⁵

79. See LINDA BACON, *HEALTH AT EVERY SIZE: THE SURPRISING TRUTH ABOUT YOUR WEIGHT* 47-50 (2008).

80. Mann, *supra* note 76, at 229.

81. *Id.* at 230.

82. See, e.g., Paul Ernsberger & Richard J Koletsky, *Biomedical Rationale for a Wellness Approach to Obesity: An Alternative to a Focus on Weight Loss*, 55 J. SOCIAL ISSUES 221, 244 (1999) (analyzing the evidence that fat people are significantly more likely to be poor and uneducated). For low-income families, it is often a rational choice to eat three meals a day in cheap fast food restaurants rather than buy basic ingredients and prepare them at home.

83. See OLIVER, *supra* note 13, at 75 (surveying data that demonstrate that “America’s poor and minorities are much fatter, on average, than its middle class, whites” (citation omitted)); RHODE, *supra* note 7, at 42-43; Kylie Ball & David Crawford, *Socioeconomic Status and Weight Change in Adults: A Review*, 60 SOC. SCI. & MED. 1987, 2007 (2004) (finding an inverse correlation between occupation status and obesity among non-blacks in developed countries); Sirin Yaemsiri et al., *Food Concern and Its Associations with Obesity and Diabetes Among Lower-Income New Yorkers*, 15 PUB. HEALTH NUTRITION 39 (2011) (finding a correlation between being concerned about the availability of sufficient food to one’s family and obesity rates among whites and some sub-groups of blacks in New York). Women’s body size is particularly susceptible to poverty, probably due to gendered expectations that women prioritize the healthful nutrition of other family members. See, e.g., Molly A. Martin & Adam M. Lippert, *Feeding Her Children, But Risking Her Health: The Intersection of Gender, Household Food Insecurity, and Obesity*, 74 SOC. SCI. & MED. 1754 (forthcoming 2012), available at <http://dx.doi.org/10.1016/j.socscimed.2011.11.013>.

84. There is often a correlation between race, poverty, and environmental measures that encourage outdoor physical activity, such as the availability of streetlights and sidewalks, recreational facilities, and trust of neighbors. See, e.g., Charyl L. Addy et al., *Association of Perceived Social and Physical Environmental Support with Physical Activity and Walking Behavior*, 94 AM. J. PUB. HEALTH 440 (2004) (finding correlation between the perceived social and physical environment and tendency for walking and other physical activity).

85. See John P. Block et al., *Fast Food, Race/Ethnicity, and Income: A Geographic Analysis*, 27 AM. J. PREVENTATIVE MED. 211 (2004) (finding a higher availability of fast food restaurants in predominantly black neighborhoods); Mason, *supra* note 7, at 344-45 (reviewing data on the

The immutability of weight is relevant to the debate about weight-based discrimination because it has implications for questions of distributive justice. It would seem unfair, for instance, to tell a young man applying for a job that, because he grew up in an inner-city neighborhood where the available food was processed, rich in simple carbohydrates, and poor in fiber—facts that prompted his high body weight—now he will not receive a fair, merit-based chance of employment because he is too fat. Such limitations on one's opportunities due to one's background would go against the principles of freedom of opportunity and of meritocracy.

As these data suggest, even those who view obesity as a problem that should be prevented (and I am not among them) should neglect the individualistic “willpower” understanding of obesity and realize that the appropriate way to comprehend “the obesity epidemic” is as a collective and structural phenomenon.⁸⁶ The structure of the food market is not a natural fact, but a result of large-scale governmental policies that would be changeable, given the right political conviction.⁸⁷ It would be both more effective and more just to redirect government subsidies from corn and meat to fruit, vegetables, and whole grains and legumes than to target obesity as the means to promote public health. Similarly, attention should be directed at discouraging consumption of processed food and fast food, which are often cheaper than raw ingredients. This has to do not only with price schemes, but also with other factors that determine how Americans prepare and consume their food. The structure of the labor market, which may require that both parents work full time in order to sustain a family, makes it hard for parents to shop for basic ingredients and cook at home, rather than shop for TV dinners or to dine in fast food venues.⁸⁸ The ever more

unequal affliction of obesity among social groups).

86. See, e.g., Robert Paarlberg, *The Politics of Obesity*, in *FOOD POLITICS: WHAT EVERYONE NEEDS TO KNOW* 81-94 (2010) (anchoring the causes for obesity in structural reasons such as fast food and the food industry, and failure of governmental intervention); J. C. Peters et al., *From Instinct to Intellect: The Challenge of Maintaining Health Weight in the Modern World*, 3 *OBSIDITY* 69, 72 (2002) (stressing the recognition that “obesity is not a problem of defective physiological regulation, but is an environmental and societal problem and therefore must be approached through environmental and social solutions”).

87. For a detailed account of a different structure of food subsidies, and other original measures such as replacing soda vending machines with carrots and grapes machines, see Mark Bittman, *Bad Food? Tax It, and Subsidize Vegetables*, *N.Y. TIMES*, July 23, 2011, <http://www.nytimes.com/2011/07/24/opinion/sunday/24bittman.html?pagewanted=all>.

88. See Roberto De Vogli et al., “Globesization”: *Ecological Evidence on the Relationship Between Fast Food Outlets and Obesity Among 26 Advanced Economies*, 21 *CRITICAL PUB. H.* 395 (2011) (finding correlation between the prevalence of fast food change and obesity rates). In an interview, this study's leader stressed that “the public debate is too much focused on individual genetics and other individual factors, and overlooks the global forces in society that are shaping behaviors worldwide.” Jeannine Stein, *Wealthy Nations with a Lot of Fast Food: Destined To Be Obese?*, *L.A. TIMES BOOSTER SHOTS BLOG* (Dec. 22, 2011), <http://articles.latimes.com/2011/dec/22/news/La-heb-obesity-fast-food-20111222> (quoting study author Roberto De Vogli). Another study found that the prevalence of obesity was lower in areas with supermarkets and

demanding and stressful corporate culture dictates that employees eat lunch at their desk, and often they do not even move their bodies to go out and shop for it.

I discuss the accessibility of healthy food and of constructive eating habits because they likely play a role in obesity rates (alongside other factors such as genetic makeup). But I should clarify that, while I maintain that the law should protect the right to be of any body size, this Article is not meant as a vindication of the food industry, waiving it of its responsibility to the population's health. This Article does not object to governmental policies that would promote citizens' health. It does, however, strongly object to policies that target weight and aim to enhance weight loss with sticks or carrots. As my review of the ways in which fat manifests in law demonstrates,⁸⁹ the law mostly treats fatness as an *individual* fault that is in the control of each legal subject alone. All that is allegedly needed is a stronger willpower, and the extra pounds will fall off. This privatization of the issue is unconvincing and ineffective.

For the sake of analytical clarity, let me emphasize that, although I think that there is much that should be done to improve access to healthier eating and more active lifestyles, I do not believe this should undermine the right to be fat. Policymakers should focus on measures that would improve the quality of life rather than ones that would promote weight loss. I would argue for the right to be of any body size, including the right to be fat, even if we were to assume a utopian world in which everyone would have access to healthy food and active lifestyles, and even if there were no linkage between weight and poverty or weight and race.⁹⁰ The right to be fat would still be viable under such hypothetical conditions because, as I will show below, body size is a factor in human experience that has intimate and diverse meanings—meanings that are far wider than its narrow medical understanding conveys and that are derived from one's identity, community, culture, and psychology.

B. Weight and Health

A growing body of research suggests that the correlation between fatness and illness is much more complex than is popularly assumed and that the prevailing argument that obesity leads to health risks stands on unstable ground.⁹¹

higher in areas that had fast food restaurants and small grocery stores. See Kimberly B. Morland & Kelly R. Evenson, *Obesity Prevalence and the Local Food Environment*, 15 HEALTH & PLACE 491, 493 (2009).

89. See *supra* Section I.A.

90. Still, the grave contemporary state of eating habits and bodily practices and the increasing weight of the population are of course a significant catalyst in writing this Article. It is likely that had obesity not become a central issue of public policy, and had fatness not become associated with a distinct character, see *supra* Subsection I.B.1, there would not have been a need for an article about the right to be fat, for fat people would not have become a stigmatized social and legal category.

91. See, e.g., sources cited *supra* note 88.

A salient example is provided by Paul Campos' *The Diet Myth*,⁹² which constructs a powerful critique of the economic interests of pharmaceutical companies, physicians, and insurance companies to convince policymakers and the public that weight is a central factor of disease.⁹³ Research demonstrates that the weight-height charts used by health insurers and employers are skewed and finds that some people who are considered overweight by such charts actually live longer than those at a "normal" weight.⁹⁴

There are strong indications that data on the health risks involved in weight might be inflated and skewed.⁹⁵ Research indicates, for example, that fat but physically fit obese people are healthier than thin and sedentary persons.⁹⁶ In some disease, such as cancer and heart disease, higher BMI is actually associated with lower rates of disease.⁹⁷ Furthermore, evidence suggests that the pressure by the medical establishment to lose weight is itself a risk factor: frequent attempts to lose weight and yo-yo dieting cause damage to physical and mental health by increasing cardiovascular disease, mortality, and damaging self-confidence and

92. PAUL CAMPOS, *THE DIET MYTH: WHY AMERICA'S OBSESSION WITH WEIGHT IS HAZARDOUS TO YOUR HEALTH* (2005) (arguing that financial and political interests distort public health policy regarding obesity); see also SOLOVAY, *supra* note 7, at 171-88 (discussing the interests of the diet industry in portraying obesity a pressing medical and moral issue).

93. Such interests contribute to scientific accounts that are biased and falsely amplify the problem, enhance the sense of public moral panic, and prompt the demonization of people who are considered overweight. When assessing the benefits of weight loss surgeries, for example, many researchers measure and document only the success, such as the decrease in blood pressure, but not the risks from anesthesia, infection, or other surgery side effects. Cf. Jeanine C. Cogan, *Re-evaluating the Weight-Centered Approach Toward Health: The Need for a Paradigm Shift*, in *INTERPRETING WEIGHT: THE SOCIAL MANAGEMENT OF FATNESS AND THINNESS* 229 (Jeffery Sobal & Donna Maurer eds., 1999) (reviewing evidence on the distortion of medical research data that is affected by what a thinness bias). Some studies also exclude participants with physical health problems, and thus are not able to examine whether weight loss actually improves health conditions. See Esther D. Rothblum, *Contradictions and Confounds in Coverage of Obesity: Psychology Journals, Textbooks, and the Media*, 55 J. SOC. ISSUES 355, 359 (1999) (noting the inherently problematic nature of weight-loss studies in psychology journals and how they are misinterpreted by the media).

94. See, e.g., CAMPOS, *supra* note 92, at 5-40; Katherine M. Flegal et al., *Aim for a Healthy Weight: What Is the Target?*, 131 J. NUTRITION 440S, 449S (2001) ("[W]eights outside the healthy weight range may be healthy and . . . weights inside the healthy weight range may not be healthy.").

95. See generally GARD & WRIGHT, *supra* note 5 (arguing that the current science on obesity is "confused and replete with flawed and misleading assumptions" and that the inflated rhetoric of risks associated with obesity is harmful); MICHAEL GARD, *THE END OF THE OBESITY EPIDEMIC* 12 (2011) (arguing that "there is now consistent evidence that obesity rates are leveling off" and providing a helpful review of the arguments against the seeming scientific consensus on the causes, scope, and solutions to obesity).

96. See, e.g., Xuemei Sui et al., *Cardiorespiratory Fitness and Adiposity as Mortality Predictors in Older Adults*, 298 JAMA 2507, 2515 (2007) (finding that in adults sixty years old and older, lack of fitness was a better predictor of mortality than BMI, waistline, and other measures of obesity).

97. See OLIVER, *supra* note 13, at 26.

emotional well-being.⁹⁸

Another factor undermining the conviction that weight itself is risky to one's health is the bad healthcare provided to fat people. Physicians—operating from the paradigm that fat is unhealthy—tend to focus on what they see as the patient's imperative to lose weight while withholding treatment for other symptoms and ailments.⁹⁹ Many fat patients leave the doctor's office with no treatment for their ear infection or joint problem—but with the sole instruction to lose weight.¹⁰⁰ Many do not return to the clinic, deterred by the focus on their being a failure and the lack of responsiveness to their physical distress.¹⁰¹ There are also accessibility and accommodation problems: treatment beds, for example, are often too narrow or not stable enough for very fat patients, which is another reason that fat persons do not seek appropriate medical care.¹⁰² These obstacles to medical care frame the grim data about the bad health of fat persons in a different light. The unaccommodating and often hostile medical institution significantly contributes to their deteriorating health.¹⁰³

There is also a problem of causality in linking weight to bad health. Science has thus far succeeded in finding a linkage between high weight and disease, but it

98. See, e.g., Frances M. Berg, *Health Risks Associated with Weight Loss and Obesity Treatment Programs*, 55 J. SOC. ISSUES 277, 279, 282-84, 287-89 (1999) (examining the unhealthy influence of diet techniques such as pills and surgeries); Jerome P. Kassirer & Marcia Angell, *Losing Weight—An Ill-Fated New Year's Resolution*, 338 N. ENGL. J. MED. 52, 52 (1998) (noting that failed attempts to lose weight often create guilt and self-hatred, and that anti-obesity and weight-loss drugs are linked to medical problems, such as a loss of essential nutrients). Metabolic activity in bodies that lose and regain weight slows down, as the body reacts by slowing fat burn due to evolutionary survival programming. See, e.g., Gretchen Voss, *When You Lose Weight—And Gain It All Back*, MSNBC, June 6, 2010, <http://www.msnbc.msn.com/id/36716808/#.T52RO-lytYs>. The sense of failure and self-unworthiness that accompanies weight regain impairs both physical and psychological quality of life. *Id.* at 189-90.

99. See Kelly D. Brownell & Rebecca M. Puhl, *Stigma and Discrimination in Weight Management and Obesity*, 7 PERMANENTE J. 21, 21-22 (2003) (reviewing studies that find pervasive implicit bias against the obese even among medical professionals who specialize in obesity treatment, and that such negative attitudes lead obese persons to avoid seeking medical care, including routine preventative checkups such as pelvic exams or breast exams); Puhl & Heuer, *supra* note 21 at 947 (“[R]ecent studies confirm that obese patients encounter prejudice, ambivalence, and oftentimes unsatisfactory treatment in health care.”).

100. Cf. Marlene B. Schwartz et al., *Weight Bias Among Health Professionals Specializing in Obesity*, 11 OBESITY RES. 1033, 1037-39 (2003); SOLOVAY, *supra* note 7, at 218-28 (discussing the inadequate medical treatment given to obese patients).

101. For personal accounts of never returning to doctors who focus on the patient's weight regardless of the patient's complaint see KATE HARDING & MARIANNE KIRBY, LESSONS FROM THE FAT-O-SPHERE: QUIT DIETING AND DECLARE A TRUCE WITH YOUR BODY 49-63 (2009).

102. Cogan and Ernsberger dub this a “weight-centered approach toward health.” Cogan & Ernsberger, *supra* note 98, at 188; see also Susan Trossman, *Obesity on the Rise Leads to Workplace Challenges, Patient Concerns*, REDORBIT (May 11, 2005), http://www.redorbit.com/news/health/149270/obesity_on_the_rise_leads_to_workplace_challenges_patient_concerns/ (noting that in American hospitals rooms are too small for obese patients, beds are too narrow, chairs have arms, and even larger blood pressure cuffs tend not to fit).

103. See OLIVER, *supra* note 13, at 108 (discussing the health damages of diets).

has yet to establish the causal direction between the two. It is unclear, for example, whether high weight leads to high blood pressure or to diabetes, or whether high blood pressure and diabetes prompt weight increase.¹⁰⁴ In addition, the monetary burden that high rates of obesity cast on the public budget is often inflated and miscalculated, for example, by failing to include in the calculations the millions of dollars spent on useless and even harmful diet products.¹⁰⁵

Data also indicate that perhaps the growing social problem is not the increasing rate of growth of the fat population, but instead is the increasing and ever more radical pursuit of thinness.¹⁰⁶ In our contemporary sociolegal atmosphere, not only is there no right to be fat, but there is also a duty to be thin. Having reviewed substantial data undermining the predominant belief that weight is both unhealthy and mutable, I will nonetheless presume, as a preliminary matter for the rest of my argument, that the majority is correct in its conviction that weight is changeable and hampers good health.

C. Utilitarian Arguments

The main line of argument in this Article develops a deontological justification for a right to be fat. Yet the predominant debate about weight employs a utilitarian framework, emphasizing the allegedly high social cost of fatness and the urgency in lowering this cost. Although I have deep reservations about anchoring the right to be fat in utilitarian justifications, I provide the following discussion to demonstrate that this right could also be instrumentally justified. This Section challenges the prevailing view that policies that create incentives to lose weight or to avoid gaining it promote overall utility. I will briefly demonstrate that the current formulation of the utilitarian calculations misses important components due to anti-fat bias. Furthermore, recognizing the right to be fat might not be as expensive as we tend to assume, and, in fact, acknowledging it might even produce more efficient outcomes.

104. See GARD & WRIGHT, *supra* note 5, at 102 (claiming that the available studies “provide little or no information about the impact of fatness and changing levels of fat on the health of individuals” and that there is no direct evidence tying excess fat tissue to diabetes or heart disease); OLIVER, *supra* note 13, at 118 (noting that the prevailing view that losing weight is the way to prevent diabetes, heart disease, and other conditions is based on data that prove association between certain conditions and obesity, but not the causal direction).

105. For more problems with the calculation of the benefits and costs of obesity see *infra* Section II.C.

106. One extensive study found that a high discrepancy between participants’ actual and ideal weight was a better predictor of poorer mental and physical health than actual BMI. See Peter Muennig et al., *I Think Therefore I Am: Perceived Ideal Weight as a Determinant of Health*, 98 AM. J. PUB. HEALTH 501, 504 (2008) (“[P]ercentage of desired weight loss was a much stronger predictor of unhealthy days than was BMI.”). Describing the study, the authors state, “The number of unhealthy days increased as participants became increasingly dissatisfied with their weight. . . . [P]sychological stress associated with a negative body image explains some of the morbidity commonly associated with being obese.” *Id.* at 503-04.

Cost-benefit analysis is central in prevailing discourse about obesity: The argument is that the increase in the population's weight causes an overall deterioration in the population's health, which in turn leads to ever-growing medical costs, decreases in workers' productivity, etc.¹⁰⁷ But such calculations of the effect of obesity on overall welfare usually neglect the significant benefits that fat people would draw from operating in conditions of autonomy and dignity in whatever body size.¹⁰⁸ If welfarist approaches are to produce a convincing argument that it is best to continue fighting obesity by targeting fat people and creating direct and indirect incentives for them to lose weight, or refrain from gaining it, then their calculus must take more costs into account.¹⁰⁹

The utility calculus must include the public money invested in convincing fat people that their body needs to change. In addition to the burden these costs present to the public budget, we must be aware that funds that are currently invested in obesity-focused policies divert resources from alternative measures that could benefit the health of the entire population, weight notwithstanding (e.g., investing in subsidizing healthful food, decreasing pollution, designing neighborhoods that facilitate walking rather than driving).

The health risks associated with frequent attempts to lose weight should be taken into account. To the extent that they are effective in convincing the public it should try to lose weight, public campaigns and other policies designed to create incentives for weight loss damage public health. As demonstrated earlier, long-term weight loss is virtually impossible for most, and repetitive attempts to lose weight may be harmful for both physical and mental health. In calculating the utility of weight-loss promoting policies, therefore, we should take into account the damage to health by yo-yo dieting or crash diets, the complication risks of weight-loss surgery, and the stress and decrease in self-esteem caused by failing to lose weight and being labeled as unhealthy, not pretty, and of a weak personality. As we know, stress is a significant health risk factor, so the mental effects of dieting feed back to the physical ones. In other words, any argument from utility that supports casting heavier burdens on fat people as a way to

107. See, e.g., Tomas Philipson & Richard Posner, *Is the Obesity Epidemic a Public Health Problem? A Review of Zoltan J. Acs and Alan Lyles's Obesity, Business and Public Policy*, 46 J. ECON. LITERATURE 974, 974 (2008). The authors offer utilitarian arguments such as: "The problem is not that disadvantaged persons cannot read labels and are unaware that obesity is bad for their health, but that uneducated persons have less of an incentive to invest in their health because their longevity and their utility from living are below average," thus stressing that the life of the obese is a life of lesser worth. *Id.* at 979.

108. See generally RONALD DWORKIN, *TAKING RIGHTS SERIOUSLY* (1977) (discussing the distinction between the intrinsic value of rights and utilitarian justifications for rights).

109. Because the utility arguments are inherently based on empirical data about obesity rates, health costs, etc., in this Part, I abandon the assumptions employed throughout the main part of this Article (i.e., that weight is mutable and that it is unhealthy), and return to a fact-based analysis, which takes into account the prevalence of failure in losing weight and the indications that weight is not as unhealthy as is commonly assumed.

compensate for the externalities their weight casts on society (e.g., by charging a higher health insurance premium, or by allowing weight-based employment discrimination) must also take into account the thus-far glaringly low success rates of such policies and assess them vis-à-vis the cost of stigma, guilt, low self-esteem, and disempowerment that would be associated with such burdens.

The monetary costs of largely futile weight-loss attempts should not be ignored. In addition to the health risks created by repeated efforts to lose weight, a cost-benefit analysis of the best policy regarding weight should incorporate the costs of the billions of dollars spent on diet products, diet food, diet groups, etc.¹¹⁰

An assessment of the cost of fatness must additionally consider the reverse behavioral effects of fat bias. The public campaigns discussed here may not even be efficient in changing behavior. Telling people that they should lose weight does not prompt them to a constructive behavior associated with weight loss, probably because such messages create psychological burden such as low self-esteem and a sense of inadequacy. Recent studies demonstrate that the more fat people internalize the stigma associated with their weight, and the more they are subject to teasing about their weight, the more likely they are to binge-eat, and the less likely they are to exercise.¹¹¹

Finally, law professor Gowri Ramachandran anchors body-related rights not in dignity, autonomy, and other deontological grounds, but rather in the potential of subversive bodily practices “to engage in making culture,” to resist conventional bodily norms, to engage in culture wars, and to “[move] culture in radical ways”¹¹² (a function she dubs “cultural velocity”). Following this work, utilitarian accounts of the desirability of regulating obesity should add to their calculus the damage in halting Ramachandran’s cultural velocity by superimposing a narrow notion of the normal body size. Weight-control policies suppress the potential for subversive and destabilizing bodily practices of fat people (such as fully participating in activities like dancing or swimming which

110. A common figure in the literature is that the diet industry is a forty billion dollar per year industry in the United States. See, e.g., Eric A. Finkelstein et al., *Economic Causes and Consequences of Obesity*, 26 ANN. REV. PUB. HEALTH 239, 252 (2005).

111. Rebecca M. Puhl & Chelsea A. Heuer, *Obesity Stigma: Important Considerations for Public Health*, 100 AM. J. PUB. HEALTH 1019, 1024 (2010) (finding that stigmatizing fat individuals threatens health and interferes with effective prevention efforts); Puhl & Heuer, *supra* note 21, at 956 (“[T]he existing evidence is sufficient to challenge common perceptions that stigma may motivate healthy eating behaviors, and instead suggests that bias may increase maladaptive eating behaviors, exercise avoidance, and in some cases reduce motivation to lose weight.”); see also RHODE, *supra* note 4, at 42 (surveying data that demonstrates that bias against fat people is counterproductive); Douglas Degher & Gerald Hughes, *The Adoption and Management of “Fat” Identity*, in INTERPRETING WEIGHT: THE SOCIAL MANAGEMENT OF FATNESS AND THINNESS, *supra* note 93, at 11, 20-21.

112. See Ramachandran, *supra* note 12, at 30-31.

many fat individuals prefer to avoid)¹¹³ and neglect law's potential in "[carving] out [a] space for individuals, subcultures, families, and other groups to form different, challenging identities, and even reform them, yet still have a job, shelter, and other needs met that would permit participation in the broader culture."¹¹⁴

The items on the list above are consistently omitted by the prevailing welfarist policy discourse that advocates the pressing need to slim down the population. It is only after incorporating these items into the utility calculus that welfarist calls to take measures in "the war against obesity" can be made convincingly. Including the above-mentioned components might lead to the conclusion that the right to be fat is defensible in instrumentalist, utilitarian terms as well.

III. THE PHILOSOPHICAL GROUNDING OF THE ARGUMENT FROM LIBERTY

Human beings are creatures of the flesh. What we can experience and how we make sense of what we experience depend on the kinds of bodies we have and on the ways we interact with the various environments we inhabit. It is through our embodied interactions that we inhabit a world, and it is through our bodies that we are able to understand and act within this world with varying degrees of success.¹¹⁵

Liberty is a basic tenet of modern liberal legal regimes. But liberty is an open-ended and abstract concept, and the content that has been associated with it throughout its existence in political and legal thought has been ever changing depending on place, time, and context. I would like to argue here that the modern legal understanding of liberty, as well as the related rights of autonomy and dignity, have been based on a disembodied, mind-focused understanding of human experience. This "trouble with the body" is to a great extent responsible for our failure to recognize legal regulation of weight as infringing on liberty. Our concept of liberty should be broadened to include an appreciation of body size (along with certain other bodily traits and experiences), as an important locus of freedom, autonomy, and dignity. This Part will lay down the philosophical foundations for my argument that, even if weight is mutable and

113. See, e.g., Degher & Hughes, *supra* note 111, at 19-20.

114. See Ramachandran, *supra* note 12, at 31, 39 ("Due to the embodied nature of subjectivity, control of a person's body may in fact become control of that person's very subjectivity, directing the identity, thoughts, and beliefs of the person being controlled."). Like Ramachandran, I stress that my argument for the right to be fat is not universal: It is contingent on the unique ways in which fat is understood in twenty-first century U.S. society, culture, and law. In a society in which fatness has *not* become associated with a set of distinct characteristics, see *supra* Subsection I.B.1, there would probably be no room for this right, and it would be rendered meaningless.

115. Mark L. Johnson, *Embodied Reason*, in PERSPECTIVES ON EMBODIMENT: THE INTERSECTIONS OF NATURE AND CULTURE 81, 81 (Gail Weiss & Honi Fern Haber eds., 1999) [hereinafter PERSPECTIVES ON EMBODIMENT].

harmful to one's health, body size should be guarded from governmental regulation and also be partly protected in the private sphere, because, like speech or the right to have an abortion, body size is an intimate and fundamental area of personhood. This conclusion dictates that body size must be handled with the same respect and care apportioned for speech, even speech with which we vehemently disagree, or for abortion, even an abortion decision that we believe to be ill-informed and mistaken.

A. A Brief Overview of Mind-Body Dualism

Rene Descartes, arguably the founder of modern philosophy, maintained that, in order to find certain truth, one must disregard information attained through the senses, which sometimes mislead, and instead rely instead on the mind. Descartes wrote, "I shall consider myself as not having hands or eyes, or flesh, or blood or senses, but as falsely believing that I have all these things."¹¹⁶ Descartes reached the well-known maxim *cogito ergo sum* (I think, therefore I am)¹¹⁷ and launched a bold intellectual experiment negating the importance of the body. In Descartes' view, the body, unlike the soul, is a machine, "devoid of subjectivity and intention."¹¹⁸ Descartes played a crucial role in our tradition, both in conceptually separating the soul from the body and in privileging the mind over the body by identifying it as the residence of our souls, and consequently, our true selves.¹¹⁹ This perspective has invited a view of the body as something that could be reshaped in a limitless fashion by science, medicine, and by the choice of the soul that occupies it.

The idea that it is possible, and even desirable, to conceptually separate oneself from all bodily and sensory experience, has managed to keep a tight grip on the West's imagination—so much so that it is possible to posit that in the centuries since Descartes' dualistic framework, our ability to relate to our body as a meaningful site of our being has been numbed. The right to be fat is a good example. We can easily recognize the harm in limiting speech or intervening in

116. DESCARTES, *Meditations on First Philosophy*, in DESCARTES SELECTED PHILOSOPHICAL WRITINGS 73, 77 (John Cottingham et al. trans., 1998).

117. *Id.* at 80.

118. Drew Leder, *A Tale of Two Bodies: The Cartesian Corpse and the Lived Body*, in THE BODY IN MEDICAL THOUGHT AND PRACTICE 17, 20 (Drew Leder ed., 1992).

119. This shift could be traced back to other origins, such as to the Judeo-Christian tradition, which separates body and soul, or to Plato, who was infatuated with knowledge that is based on neither the senses nor concrete material existence. In Plato's view, because the soul is eternal, it has privileged access to the truth compared to the finite body. Since the center of my project is not intellectual history, I focus on Descartes' ideas and their aftermath because they occupy the scholarly critique of the denial of the body in modern sensibility. I could have delved, however, into sources of the mind-body separation, from Plato, through Christianity, to Kant. For a discussion of the history and philosophical origins of mind-body dualism, see Howard Robinson, *Dualism*, in THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY, pt. 1 (Edward N. Zalta ed., 2003), <http://plato.stanford.edu/archives/fall2003/entries/dualism/>.

one's religious faith, but most people simply do not appreciate what is so shocking or wrong about sending a message to a growing segment of the population that their bodies are deformed, inferior, and in urgent need of change. We treat the body instrumentally, essentially as a vessel for our mind, emotions, and other faculties that are considered abstract. But changing one's body size is not nearly a technical thing or something that is external to the self (as Descartes would have it). Losing weight affects the intimate corporeal experience. It affects one's pace of walking and of breathing, the texture of one's skin, and the extent to which the body's contours are rounded or straight angled. As the famous Gershwin song goes, it affects "the way you wear your hat/ the way you drink your tea."¹²⁰ It affects the most basic gestures, the most fundamental aspects of what it means to be a person. And yet, largely due to Cartesian tradition, mind-body dualism had a decisive influence on modern legal thought, and this influence has had a significant role in contemporary law's obliviousness toward the body in general, and body-size in particular, as important sites of rights. Thinking purely, without dependence on the body, is perceived as a superior activity. The body remains in this tradition opaque, misleading, and insignificant.¹²¹ Our law, therefore, sees body size through a mechanistic lens, as if asking legal subjects to lose weight is no more cumbersome than requiring them to get their car fixed by a mechanic.

American constitutional law has recognized rights related to bodily practices, such as the right to abortion, contraceptive rights, the fundamental right to intimate consensual sexual conduct, or the right to refuse medical treatment. These rights are distinct from the problem of bodily weight, however, in at least two ways that contributed to their recognition as worthy of legal protection. First, they are concerned with something the body does, or something that is done to the body directly. The right to any body size lacks a concrete moment in which one can take, or refrain from taking, specific actions. One's body size is determined by myriad daily practices. This Article's argument is crucially related to this fact: Regulating body size essentially involves regulating one's everyday practices and habits, in a way that is disturbing when examined from the prism of liberty interests. Second, the courts grounded the bodily rights mentioned above in easily recognizable underlying interests that were not essentially about the body. Abortion rights, for example, have been theorized as part of the right to privacy. Sex rights have been explained as pertaining to the right to personal autonomy. In the present case, by contrast, it is difficult to generalize and

120. Fred Astaire, *They Can't Take That Away from Me*, on SHALL WE DANCE? (RKO Radio Pictures 1937).

121. See, e.g., BORDO, *supra* note 5, at 1-3 (2004) (analyzing the poem "The Heavy Bear," by twentieth century American poet Delmore Schwartz, in which the body is represented as with me but not "me," lacking intelligence or intentionality, clumsy, gross, disgusting and capable of aggression, an obstacle to self expression, and a "prison of the soul and confounder of its projects").

represent through conceptual language the experience of “being of a certain body size”¹²² and, therefore, it is more difficult to recognize the precise interests that are derived from one’s body size. As a result, this Article suggests anchoring the right to be fat in the right to liberty, rather than in more specific rights such as privacy or free speech.

1. The Contemporary Critique of Mind-Body Dualism

The last four decades have seen a flourishing of scholarship that positions the body as a central and essential site of human existence. Such critical strands emerged from a sense of unease regarding the omission of the body in understanding culture, psychology, history, and politics.¹²³ Scholars have begun to point out that the erasure of the body not only is unconvincing, but that it also fails to address the role that judgments about bodies play in sustaining the exclusion of marginalized groups such as people of color, women, Jews, the LGBT community, or people with disabilities.¹²⁴ Stigma and prejudice toward such groups have been in large part directed at their bodily features in two significant ways.

First, the “essence” of members of marginalized groups has been characterized as more bodily and thus less capable of rational thinking, abstract scientific inquiry, or artistic, ethical, and spiritual achievements.¹²⁵ Women, for example, who are distinct from men in their body and its natural procreative functions, have been associated with an emotional and irrational nature, and thus viewed as secondary, and even dangerous, to the development of human civilization.¹²⁶ Similarly, in American culture, past portrayals of black people as

122. On the ways in which the body is resistant to representation through language, see Yofi Tirosh, *Adjudicating Appearance: From Identity to Personhood*, 19 YALE J.L. & FEMINISM 49, 104-08 (2007). For a discussion of conceptual language and its limitations in general, see JAMES BOYD WHITE, JUSTICE AS TRANSLATION 22-45 (1990).

123. See, for example, Seyla Benhabib’s critique of social contract theories, which argues that Thomas Hobbes’ account that a “vision of men as mushrooms is an ultimate picture of autonomy” erases the role of maternal pregnancy and care from our understanding of the human condition. SEYLA BENHABIB, SITUATING THE SELF: GENDER, COMMUNITY, AND POSTMODERNISM IN CONTEMPORARY ETHICS 156-58 (1992) (citing THOMAS HOBBS, PHILOSOPHICAL RUDIMENTS CONCERNING GOVERNMENT AND SOCIETY 109 (W. Molesworth ed., Wissenschaftliche Buchgesellschaft 1966) (1651)).

124. See, e.g., IRIS MARION YOUNG, JUSTICE AND THE POLITICS OF DIFFERENCE 11 (1990) (“In the last twenty years feminists, Black liberation activists, American Indians, disabled people, and other groups oppressed by being marked as fearful bodies have asserted such images of positive difference.”)

125. See DREW LEDER, THE ABSENT BODY 4 (1990) (discussing the far reaching social effects of the mind-body dualism, as used to sustain projects of oppression of “women, animals, nature, and other ‘Others’”).

126. See Sherry B. Ortner, *Is Female to Male As Nature Is to Culture?*, in WOMAN, CULTURE AND SOCIETY 67 (1974) (arguing that the identification of women with nature leads to their devaluation across all cultures).

sub-human were rooted in a perception that they had amplified sexual potency and animal-like body features. These characterizations were thought to capture fundamental bodily differences between black people and “normal” (white) humans.¹²⁷

Second, not only were marginalized groups considered more bodily, but their bodies were viewed as deviant, disgusting, and dangerous. Contemporary research has documented how moral imperatives, gender conventions, and class and race distinctions are “engraved” and “inscribed” on the body.¹²⁸ The emerging account of the human body suggests that these distinctions are far from a natural, biological fact. Rather, it is constructed by socio-cultural requirements, norms, and habits.¹²⁹ Judith Butler famously observed, for example, that one’s sex, gender, or sexual orientation involve constant acts of reiteration, citation, and “performative repetition” of norms associated with one’s gender.¹³⁰ Kendall Thomas made a similar point about race, maintaining that “‘race’ is a verb, that we are ‘raced’ through a constellation of practices that construct and control racial subjectivities.”¹³¹

127. See Frank Rudy Cooper, *Against Bipolar Black Masculinity: Intersectionality, Assimilation, Identity Performance, and Hierarchy*, 39 U.C. DAVIS L. REV. 853, 876-79 (2006); N. Jeremi Duru, *The Central Park Five, the Scottsboro Boys, and the Myth of the Bestial Black Man*, 25 CARDOZO L. REV. 1315, 1321-22 (2004); D. Marvin Jones, “We’re All Stuck Here for a While”: *Law and the Social Construction of the Black Male*, 24 J. CONTEMP. L. 35, 71-77 (1998).

128. See, e.g., PIERRE BOURDIEU, *DISTINCTION: A SOCIAL CRITIQUE OF THE JUDGEMENT OF TASTE* (Richard Nice trans., Harvard University Press 1984) (1979) (connecting class differences to bodily practices such as how people eat, what they wear, and how they move about); MICHEL FOUCAULT, *DISCIPLINE AND PUNISH: THE BIRTH OF THE PRISON* (Alan Sheridan trans., Vintage Books 2d ed. 1995) (1977) (discussing the evolution of punishment and how different disciplinary practices mark the convict’s body with his crime); IRIS MARION YOUNG, *ON FEMALE BODY EXPERIENCE: “THROWING LIKE A GIRL” AND OTHER ESSAYS* (2005) (exploring women’s embodied experiences as a way to understand the social meaning of gender).

129. See, e.g., Seyla Benhabib, *The Generalized and the Concrete Other: The Kohlberg-Gilligan Controversy and Feminist Theory*, 4 PRAXIS INT’L 402, 413 (1985) (“Identity does not refer to my potential for choice alone, but to the actuality of my choices, namely, to how I as a finite, concrete, embodied individual shape and fashion the circumstances of my birth and family, linguistic, cultural, and gender identity into a coherent narrative that stands as my life’s story.”); see also CAROLE PATEMAN, *THE SEXUAL CONTRACT* 206-07 (1988) (arguing that the body is integrally related to the self, therefore prostitution and surrogacy are unlike regular labor, where the employer is interested not in the employee’s body but in her work).

130. See JUDITH BUTLER, *GENDER TROUBLE: FEMINISM AND THE SUBVERSION OF IDENTITY*, at xiv-xv (2d prtg. 1999) (1990). But cf. Seyla Benhabib, *Feminism and Postmodernism: An Uneasy Alliance*, in *FEMINIST CONTENTIONS: A PHILOSOPHICAL EXCHANGE* 17, 21-30 (Seyla Benhabib et al. eds., 1995) (doubting Butler’s notion that there is no self behind the mask of its representation, for it debunks women’s fragile autonomy as well as any possibility for new ethics, politics, or aesthetics); Kelly Oliver, *What Is Transformative About the Performative? From Repetition to Working-Through*, in *CONTINENTAL FEMINISM READER* 168, 168-90 (Ann J. Cahill & Jennifer Hansen eds., 2003) (arguing that Butler’s proposal “that a theory of performative agency better serves political theory than a theory of sovereign agency” is insufficient and needs supplementing through critical self-analysis and interpretation).

131. Kendall Thomas, *The Eclipse of Reason: A Rhetorical Reading of Bowers v. Hardwick*,

Shifting the research focus to embodied experience, then, was an intellectual move with potentially important implications for promoting equality and universal humanness.¹³² This new attention to the body has been dubbed “the body turn,” “the embodiment turn,” or “the corporeal turn.”¹³³ Scholarly attention to the body has not stopped at research related to stigmatized groups. Today it engages studies of “unmarked” hegemonic groups as well, a shift illustrated by the development of fields such as masculinity studies and whiteness studies.¹³⁴ Another vein of recent scholarship is located outside of the identity paradigm (blackness-whiteness, masculinity-femininity, etc.) but rather explores embodied meanings in themes and fields that vary from modern dance¹³⁵ to geography.¹³⁶ Such accounts relate to the body not merely as a physical fact or as inanimate matter in which the mind is clothed, but as an important site of meaning-making, crucial for understanding human experience. They recognize the body as a site through which the self is constituted and maintained, and through which the powers of culture, language and society are manifested and negotiated.

2. *The Body Turn in Law*

The intellectual developments emanating from the critique of mind-body

79 VA. L. REV. 1805, 1806-07 (1993).

132. See, e.g., MARTHA C. NUSSBAUM, HIDING FROM HUMANITY: DISGUST, SHAME, AND THE LAW 71-123 (2004).

133. See, e.g., Martine Abramovici, *The Sensual Embodiment of Italian Women*, in TOURISM & GENDER: EMBODIMENT, SENSUALITY AND EXPERIENCE 107, 110 (Annette Pritchard et al. eds., 2007) (discussing the “embodiment and corporeal turn in tourism studies” as an intellectual shift that enables understanding touristic experience as sensory, and as one that goes beyond “the passivity of the ‘tourist gaze’”); Barbara Kirshenblatt-Gimblett, *The Corporeal Turn*, 95 JEWISH QUARTERLY REV. 447, 447-53 (2005) (discussing the corporeal turn in Judaic studies); Shoji Nagataki & Satoru Hirose, *Phenomenology and the Third Generation of Cognitive Science: Towards a Cognitive Phenomenology of the Body*, 30 HUMAN STUD. 219, 224 (2007) (referring to “the embodiment turn” in the history of philosophy as a counter to Richard Rorty’s “linguistic turn”).

134. See, e.g., CRITICAL WHITE STUDIES: LOOKING BEHIND THE MIRROR (Richard Delgado & Jean Stefancic eds., 1997) (featuring articles such as “Growing Up (What) in America?” and “The End of the Great White Male”); RICHARD DYER, WHITE (1997) (a cultural analysis of the representation of whiteness in white Western literature, cinema, art, and popular culture); THE MASCULINITY STUDIES READER (Rachel Adams & David Savran eds., 2002) (exploring themes such as the macho, sex differences, and honor and shame); MASCULINITY STUDIES AND FEMINIST THEORY: NEW DIRECTIONS (Judith Kegan Gardiner ed., 2002) (mapping both the productive and the tensed intersections between masculinity studies and feminist theory).

135. See, e.g., TAL KOHAVI, BETWEEN DANCE AND ANTHROPOLOGY (forthcoming 2012) (on file with author) (arguing that the body in itself is a site of meaning production and outlining ways to access these meanings).

136. See, e.g., Robyn Longhurst, *VIEWPOINT: The Body and Geography*, 2 GENDER, PLACE AND CULTURE 97, 99 (1995) (observing that the body is portrayed in geography as the passive and weak partner of the dominant and potent mind).

dualism have not skipped over legal studies.¹³⁷ Legal theory dealing with underrepresented, stigmatized, or underprivileged groups (feminist jurisprudence, Critical Race Theory, Queer Legal Theory, and Disability Legal Studies) explicitly sought to deconstruct the mind-body dualism and to understand the ways in which bodily differences constitute identities and play a central role in the legal subject's life. Moreover, physical appearance itself has been the subject of a wide range of scholarship in the areas of discrimination¹³⁸ and of basic liberties.¹³⁹ A consistent vein in the legal scholarship on appearance is a refusal to accept the hierarchical distinction, prevalent in Western philosophy, between "inner" identity and "outer" appearance (or, more generally, between status and conduct).

While studies have demonstrated convincingly that bodily practices, including grooming and dress, do not merely represent the "real" person behind them, but are part of bidirectional dynamics in which how one looks and is socially perceived shapes who one is, the theoretical shift in legal thought towards the body has yet to include body size in its account of the interplay between body and law. In what ways does the thin or fat body constitute us as persons and as legal subjects? What are the personal, psychological, social, and cultural meanings of fatness, and to what extent should our legal arrangements regarding body size be shaped by such meanings? Descartes' devaluation of the body renders it unsurprising that we lack the vocabulary and the conceptual toolbox to talk and think about the body as a subject of the law. This Article establishes the theoretical foundations to begin filling this gap.

137. See generally ALAN HYDE, *BODIES OF LAW* (1997) (analyzing manifestations of the body in different legal contexts and depicting the conceptual challenges that the body presents for legal analysis).

138. See, e.g., Devon W. Carbado & Mitu Gulati, *Working Identity*, 85 CORNELL L. REV. 1259, 1279-99 (2000) (pointing to the extra "identity work" that outsiders such as women and minorities seem pressured to do in the workplace because of negative views on their identity); Camille Gear Rich, *Performing Racial and Ethnic Identity: Discrimination by Proxy and the Future of Title VII*, 79 N.Y.U. L. REV. 1134, 1230-44 (2004) (arguing that voluntary behavior, such as hairstyle, of minority employees should be of concern to judges in discrimination cases); Patrick S. Shin, *Vive La Difference? A Critical Analysis of the Justification of Sex-Dependent Workplace Restrictions on Dress and Grooming*, 14 DUKE J. GENDER L. & POL'Y 491, 493-95 (2007) (questioning the exclusion by employment antidiscrimination law of sex-specific workplace dress and appearance codes).

139. KENJI YOSHINO, *COVERING: THE HIDDEN ASSAULT ON OUR CIVIL RIGHTS* 74-176 (2007) (arguing that the burden on minorities to assimilate through their behavior and appearance contradicts basic liberties); Gowry Ramachandran, *Freedom of Dress: State and Private Regulation of Clothing, Hairstyle, Jewelry, Makeup, Tattoos and Piercing*, 66 MD. L. REV. 11, 30-60 (2006) (proposing a legal right to dress as a liberty-based right); Tirosh, *supra* note 124, at 99-104, 113-19 (arguing that the identity paradigm for protecting appearance claims is insufficient, and proposing personhood as the alternative organizing concept).

B. Fatness as a Future-Grounded Identity

In the previous Section, I argued that the body turn in law has yet to include body size as part of its comprehension of the interrelation between body and law. In the following Sections, I will explore what it would mean for legal discourse to decipher the meaning of body size. While the present Section focuses on the negative meaning of fat and asks why, in light of this negative meaning, a defense of a right to be fat is warranted, Section C lays the foundations for positive accounts of fatness.

Most people perceiving themselves as fat experience the center of gravity of their identity in their imagined, post-transformation future.¹⁴⁰ Often, they experience the present as a limbo between a thinner past in which things were right and a future that will restore this longed-for past. Or, if they were fat for as long as they can remember, the leap is from a past that should be carefully analyzed to trace the reasons that brought about their fatness, to a future of miraculous metamorphosis into thinness. Weight loss is conceived as an act of restoring or finally finding the true self, whose emergence will bring with it confidence and happiness that are deficient for many fat people.¹⁴¹

The discourse around fat people is, then, past-centered and future-centered, while neglecting the present. It leaps from the paradise lost onto the idealized post-diet transformation. A full experience of oneself and one's body in the present, with its various characteristics, both desired and unwelcome, is denied and unattended to. Diets are often a way to suspend dealing with current issues and challenges in a fat person's life, such as a career or relationship. As clinical psychologist Deb Burgard told *The New York Times*, for many dieters "the pursuit of thinness as a dream is a place holder. . . . It gets in the way of asking, 'What is it I am dreaming of?'" Burgard further said that a dieter may think: "'If I could just lose weight, all that will take care of itself,' so they don't invest in getting what they want, [but instead] they invest in weight loss."¹⁴² Cultural studies scholar, Samantha Murray, describes the experience of her fat body as one in which "there is a sense of suspension, of deferral, of hiatus. One is waiting to become 'thin', to become 'sexual', waiting to *become*."¹⁴³

People undergoing weight-loss surgery often relate to the surgery day as a "re-birth date," as an opportunity to be reborn, or as a "take two" of their life. This narrative of dramatic transformation and of an opportunity for a fresh start is

140. See, e.g., Kent, *supra* note 48, at 131 (discussing fat women's experience of their bodies "as the 'before' picture"); Samantha Murray, *supra* note 48, at 154-55 (noting that "the fat body is discursively constructed as a failed body project").

141. See Karen Throsby, *Happy Re-Birthday: Weight Loss Surgery and the 'New Me'*, 14 BODY & SOCIETY 117, 122 (2008).

142. Mandy Katz, *Tossing Out the Diet and Embracing the Fat*, N.Y. TIMES, Jul. 15, 2009, <http://www.nytimes.com/2009/07/16/health/nutrition/16skin.html>.

143. Murray, *supra* note 47, at 155.

also manifested in the ritualistic practice of “before and after” photographs, illustrating the dramatic change, sometimes to the point at which it is hard to recognize that the two photos are of the same person.¹⁴⁴ The structure of weight-loss narratives, then, portrays bodily fat as an obstacle to a full and authentic expression of one’s true self, which is always thin, currently trapped within the layers of fat that require removal.¹⁴⁵

This present-denying temporal characteristic of fat identity poses difficulty for the argument that fatness should be conceptualized as a right. If all that fat people want is to become thin, and both fat and thin people believe that everyone should be thin, then who needs a right to be fat?¹⁴⁶ My answer to this question is twofold. First, recognizing the right to be fat entails recognizing the right to be of any body size. That is, the right to be fat does not negate or contradict people’s will *not* to be fat, just like the right to religious freedom entails both the right to be free *from* religion and the freedom to practice any religion or none at all. Second, in recognizing the right to be fat, it is important to be aware of the dynamic interplay between law and life. Legal change often precipitates social change. Therefore, protecting the right to be fat is justifiable even when fatness is mostly experienced through its negation and temporariness. In Section III.C below, I will describe the thriving of alternative voices in current public discourse, involving grassroots activists, medical, legal, and policy professionals, as well as scholars, who posit an alternative, affirmative approach to fatness. They claim that it is both unproductive and unjust to frame the lives of so many people as lives that would only gain value when the longed-for, permanent weight loss finally happens.

These increasingly loud voices serve as a reminder that the commonsense understanding of “good” or “bad” identities and bodies is constantly evolving. As recently as four decades ago, many gay individuals would have preferred to be able to “correct” their sexual orientation and transform “back” to straightness. Here, “back” signifies that heterosexuality was considered the default sexual orientation, just like “normal” BMI is considered default body size today.¹⁴⁷ The notion that, for example, gay identity would be claimed and affirmed through

144. Throsby, *supra* note 141, at 118. Moreover, “the pre-transformation body [is conceived] as discordant with the true self.” *Id.* at 119.

145. The quest of the dieting person is to find “the thin person hiding inside you.” *Id.* at 119; see also Donald Moss, *Obesity, Objectification, and Identity: The Encounter with the Body as an Object in Obesity*, in *THE BODY IN MEDICAL THOUGHT AND PRACTICE*, *supra* note 118, at 179, 190 (finding obese women often feel that “this body that you see is never me, I am always the beautiful personality that resides invisibly within”).

146. Cf. Kevin Kolben, *The Right Not To Be Fat* (unpublished manuscript) (on file with author) (claiming that current food policy in the United States ignores the will of most Americans to be thin).

147. Homosexuality was removed from the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders only in 1973. See RONALD BAYER, *HOMOSEXUALITY AND AMERICAN PSYCHIATRY: THE POLITICS OF DIAGNOSIS* 40 (1987).

concepts such as pride seemed then not only unrealistic, but also unnecessary and even unwelcomed. Straight was normal and good; gay was a psychiatric pathology and a threat to the health of the individual, the family, and society as a whole.

We might be witnessing the emergence of a similar development regarding fat identity. It is plausible that fifty years from now, people might look back at our time and sigh uncomfortably about how crassly wrong we were in our expectation that fat people must correct themselves (or at least signal that they know that they are abnormal and need to change).¹⁴⁸ In advocating for the right to be fat, then, my legal argument echoes and picks up on the radical new interpretations of fatness by certain strands in science and culture. The bidirectional movement between law and life suggests that recognizing the right to be of any body size might have expressive and constitutive effects of enabling more people to unapologetically define themselves as its bearers.

Indeed, the case of the fat body provides a powerful demonstration that bodies “can be shown to have been lived differently historically . . . or to be lived differently culturally.”¹⁴⁹ Fat bodies were considered healthy and beautiful in the Middle Ages, for example, as they signified wealth (manifested by abundant access to food)¹⁵⁰ and freedom from the need for physical labor. There are also contemporary examples of cultures and sub-cultures that challenge the prevailing aversion toward fat bodies. Some rappers aim to achieve a “phat” sound through effects such as delay, echo, and double voice, but the positive characteristics of largeness do not end with sound: they also manifest in attitude toward body size. As Joan Gross documents, black male rappers view heavy physical weight as symbolizing wealth, authority, and virility.¹⁵¹ As another example, although male gay culture generally demonstrates harsh attitudes toward fat, and privileges bodies that are considered fit, there is also a cultural vein of admiring “bears”: big, hairy men, who are considered sexy and desirable.¹⁵² As much as the current prevailing negative meanings of fatness seem to most of us so natural and self-

148. Signaling that one needs to lose weight has been theorized as an act of coming out of the fat closet. See discussion *infra* Subsection III.C.2.

149. David Couzens Hoy, *Critical Resistance: Foucault and Bourdieu*, in PERSPECTIVES ON EMBODIMENT, *supra* note 115, at 3, 8.

150. See Richard Klein, *Fat Beauty*, in BODIES OUT OF BOUNDS: FATNESS AS TRANSGRESSION, *supra* note 44, at 19, 24.

151. See Joan Gross, *Phat*, in FAT: AN ANTHROPOLOGY OF AN OBSESSION 63 (Don Kulick & Anne Meneley eds., 2005).

152. See Les Wright, *Introduction: Theoretical Bears*, in THE BEAR BOOK: READINGS IN THE HISTORY AND EVOLUTION OF A GAY MALE SUBCULTURE 1-20 (Les Wright ed., 1997). Wright's examination of how women in Niger aspire for as much body fat as possible provides an opportunity for re-examining Western axioms about weight. These women try to gain a lot of weight to make themselves attractive before they marry; these women also seek to achieve stretch marks on their stomachs, arms, and thighs. See Rebecca Popenoe, *Ideal*, in FAT: AN ANTHROPOLOGY OF AN OBSESSION, *supra* note 151, at 9.

evident that it is impossible to contest, I believe that such resistance is not only theoretically possible, but also empirically around the corner.¹⁵³ On the possibility of resisting seemingly natural and universal truths about the body, one author writes that by exposing contrasting meanings given to the body across time and space, “[w]e will not be able to go back to the past or to step out of our culture entirely, but we may be able to find the resources in ourselves to save ourselves from the destructive tendencies that the contrast reveals.”¹⁵⁴

C. Phenomenological Accounts of Fatness

If, as I proposed in the last Section, the fat body is experienced through its present negation, and is mainly located in a longed-for past and an imagined future, then what would an alternative to this conceptual schema look like? How would it be possible to think about the fat body in the present? The philosophical stream of phenomenology provides appealing alternatives to the prevailing medicalized understanding of the fat body, which sustains the dualistic conception of the body as an object¹⁵⁵ and of the fat body as essentially negative and under a pressing imperative to change. Developed by such continental philosophers as Husserl, Heidegger, and Merleau-Ponty, phenomenology evolved, to a great extent, due to a sense of unease with the dualistic view of mind and body.¹⁵⁶ It objected to a view that treats the body as an object for scientific accounts of human experience, which often “have objectified human behavior, separated the senses from one another, and have failed to grasp the subject as a holistic manner.”¹⁵⁷ Phenomenological analysis of the body emphasizes understanding the body not as an object, but as a “lived body,” as a meaningful site of experience, and as a body of one’s own.¹⁵⁸

As Merleau-Ponty poignantly writes, “we are *condemned to meaning*.”¹⁵⁹

153. See Klein’s interesting thesis, speculating that it is either the global food crisis or simply the pendulum movement of fashion that will bring fat back to fashion. Klein, *supra* note 150, at 20–21.

154. Hoy, *supra* note 151, at 8. There are two more answers to the question I posited in this Section (namely, who needs the right to be fat when fatness is a negated identity). First, even if one thinks that fat people should aspire to lose weight, this does not mean that until they do, they should be denied equal access to opportunities, to conditions that enable self-respect and dignity, and to other social goods. And second (as I argued *supra* in Section II.C), even from a utilitarian perspective that rejects the deontological basis for the right to be fat, there are some strong indications to suggest that enabling fat people to lead a life in which they accept their body size would be instrumental for enhancing the health of the overall population.

155. Mind-body dualism is discussed *supra* in Section III.A.

156. *See id.*

157. DERMUT MORAN, INTRODUCTION TO PHENOMENOLOGY 420 (2000); *see also id.* at 422 (discussing Merleau-Ponty’s aspiration “to rethink our traditional dualism of soul and body, mind and body, consciousness and body”).

158. *See* THE ABSENT BODY, *supra* note 125, at 5 (discussing the problematic distinction between the physical body and the living body).

159. MAURICE MERLEAU-PONTY, PHENOMENOLOGY OF PERCEPTION, at xxii (Colin Smith trans.,

Phenomenology rejects as unsatisfactory the traditional view of the body as a thing, a derivative phenomenon that should be mainly scientifically examined. As Dermut Moran noted, "The lived body is the body as immediately experienced, that is, as an organ for action in the world, and as a vital relation to the world. . . . [T]he body is that through which [a person] moves through the field of daily life."¹⁶⁰ It is clear why, from this understanding, the body does not have merely a passive role in its bearer's life, but rather an active role of constituting one's sense of self and of shaping one's relationship to objects and to other humans.¹⁶¹

The phenomenological critique points to the limiting reductionism that typifies current scientific accounts of human life. In order to count as a valid scientific statement, data must be quantifiable, generalizable, and measurable, as well as produced and presented from an external point of view. In contrast, the phenomenological approach "holds that the body of a living being has an essential structure of its own which cannot be captured by the language and concepts used to explain inanimate nature."¹⁶² Living things cannot be explained and observed only in terms of material parts and processes. Living organisms, even when viewed through their biology, should be understood as more than "highly complex physical mechanisms constituted only by their distinct material parts."¹⁶³ This entails employing a perspective "from within," seeking the voice of the embodied subject and his or her embodied experience.

Being attuned to the lived body involves not only noticing how we carry ourselves in the world, but also how the world comes to be for us. In other words, the body has a role in constituting the way we perceive and experience our environment. The body has a significant part in creating our environment and in the formation of meaning, relationship, and sense of self.

Importantly, phenomenology does not deny the material aspects of the body or the ways in which it is an object or a thing. It is, however, a view that maintains that not only is the body matter, but that the body also has subjective aspects and that it is an intentional entity. Different body sizes would, therefore, produce different experiences of ourselves and of the world around us. As Mark Johnson stresses, "If our bodies were different, and if we therefore had different bodily experiences and different kinds of interactions with our multiple and multidimensional environments, then we would have a different sense of self and

Routledge 2002) (1945).

160. Moss, *supra* note 145, at 181. Moss notes that Husserl describes the body as that by which humans hold sway in the world. *Id.*

161. See MORAN, *supra* note 157, at 426 (explaining Merleau-Ponty's understanding of bodily inhabitation of space).

162. Leder, *supra* note 118, at 25.

163. Chris Oleson, *Remembering the Phenomenon of Life*, THE WESTCHESTER INSTITUTE, http://www.westchesterinstitute.net/index.php?option=com_content&view=article&id=372 (last visited Apr. 9, 2012) (reviewing HANS JONAS, *THE PHENOMENON OF LIFE: TOWARDS A PHILOSOPHICAL BIOLOGY* (2001)).

different ways of understanding and reasoning.”¹⁶⁴

Beyond the quantitative means for understanding personal physique, health and disease should also be understood via “qualitative differences in the individual’s relations to the physical environment, in personal temporality and spatiality, in relationships to the family and social world, and in the struggle for identity.”¹⁶⁵ According to this approach, weight gain and weight loss would be understood as “never merely a phenomenon of the *physical* body. . . . They are always also an event of the *human* body”¹⁶⁶ and as such are both an expression of one’s relations to the world and play a role in transforming these relations.

In the medical context, philosopher of medicine Drew Leder proposes replacing the mechanical approach to illness with a phenomenological approach, which considers the “lived body” as a central factor in understanding the patient’s condition. Thus, from a phenomenological perspective, one’s bodily weight would not only (and not mainly) be seen as a biological fact, measured and explained by factors such as BMI, body fat percentage, or blood lipids. Understanding the fat body would entail looking beyond such medical measures.¹⁶⁷ As Donald Moss explains, “The physician and the clinic produce a context of vocabulary, concepts, images, and interventions which permeate the everyday life of the obese individual.”¹⁶⁸ The fat body would need to be understood in legal theory through social practices associated with it, and through the individual’s personal experience of his or her body.¹⁶⁹

From a phenomenological perspective, then, foundational notions such as liberty, autonomy, freedom, experience, and agency would be impossible to explore without tracing their bodily dimensions and manifestations.¹⁷⁰ From this

164. Johnson, *supra* note 115, at 99.

165. Moss, *supra* note 145, at 179.

166. *Id.* at 181 (emphasis added) (quoting and translating MEDARD BOSS, *GRUNDRISSE DER MEDIZIN UND DER PSYCHOLOGIE* (Switzerland, Verlag Hans Huber 1975)).

167. Leder, *supra* note 118, at 25.

168. Moss, *supra* note 147, at 182; *see also id.* at 188-89 (describing the “identity-depleting battle” in an environment where “from infancy she is immersed within a total cultural milieu, permeated by the concepts and language of a medicine which serves to define her body and its size, in its many meanings, from her earliest self-awareness as a young woman with a body”).

169. Critics point to several shortcomings of phenomenology as a comprehensive theory for understanding the human condition in general, and embodied experience in particular. An extended discussion of these critiques is unnecessary for the present context, both because of the very specific application of phenomenology that this Article employs—phenomenology as an account that can fill the gap of thinking about the fat body in the present—and because many of the criticisms against phenomenology are, in my view, pointed at its earlier versions, while contemporary phenomenological accounts correct for many of the shortcomings that critics noted. Thus, for example, one criticism was that phenomenological accounts of the body tend to be a-historical and lack social contexts about power relations. Today, however, it seems nearly impossible to produce phenomenological work without incorporating critical lenses such as Bourdieu’s *habitus* and Foucault’s *bio power* and disciplinary knowledge.

170. Legal scholars have also attempted to develop phenomenological accounts from other perspectives, such as that of judges. *See, e.g.*, WILLIAM E. CONKLIN, *THE PHENOMENOLOGY OF*

theoretical standpoint, by which “the mind is incarnated in the body,”¹⁷¹ it would simply be impossible to produce value judgments about the fat body as disconnected from the experience of its bearer or treat the fat body as an object that the mind can discipline or tame.

The phenomenological approach to the body demonstrates that legal regulation of body size reaches far beyond the technical aspects of weight, such as calories consumed and energy burned. Rather, legal policies pertaining to body weight entail changing behaviors, emotional patterns, and personal characteristics. Such regulation amounts to heavy-handed intrusion into intimate areas of personal existence, which are often hard to put into words because, as Merleau-Ponty sees it, they “arise out of a more primordial, less articulated form of experience.”¹⁷² In a legal system that respects personal autonomy in other contexts, such as religious belief or freedom of conscience, such mechanistic interruptions to the person should be considered illegitimate.

The meanings of being of a large body extend far beyond the medical meaning of fatness. A phenomenological approach would go beyond the “inadequacy of contemporary empiricist and scientific accounts of human experience,” which “failed to grasp the subject in a holistic manner,”¹⁷³ and would stress that “[w]hat we need to look for are not causes but *reasons* motivating the behaviour of the patient.”¹⁷⁴ For example, being heavy can enhance one’s sense of groundedness and stability in an ever-more unstable and dynamic world. Or consider the argument that the fat body has positive sexy and sexual qualities, as articulated by Hanne Blank: “[F]at bodies are really sexy and sensual. There are a lot of textures and there’s a lot of skin and surface area, and a lot of sensory nerves. Everything that you’ve got on a thin body you’ve just got more of on a fat body.”¹⁷⁵

As another example, survivors of sexual abuse sometimes don extra pounds, deliberately or unwittingly, in an attempt to avoid objectifying and sexualizing gazes.¹⁷⁶ Legal arrangements with regard to body size must recognize that the

MODERN LEGAL DISCOURSE: THE JURIDICAL PRODUCTION AND THE DISCLOSURE OF SUFFERING 135-68 (1998) (analyzing *Brown v. Board of Education* from the perspective of Justice Holmes’ lived world).

171. MORAN, *supra* note 157, at 425.

172. *Id.* at 418. For a beautiful treatment of the moral recognition worthy of “unalterable” individual qualities such as the way one laughs or moves about, see Martha C. Nussbaum, *Love and the Individual: Romantic Rightness and Platonic Aspiration*, in LOVE’S KNOWLEDGE 314 (1990).

173. MORAN, *supra* note 157, at 420 (citations omitted).

174. *Id.*

175. Tracy Clark-Flory, *The Joy of Fat Sex*, SALON.COM, Sept. 24, 2011, http://www.salon.com/2011/09/24/fat_sex/ (an interview with the author of HANNE BLANK, *BIG BIG LOVE* (2011)).

176. See, e.g., T. B. Gustafson & D. B. Sarwer, *Childhood Sexual Abuse and Obesity*, 5 OBESITY REVIEWS 129, 132-33 (2004) (reviewing the available studies on the link between obesity and childhood sexual abuse); Jennie G. Noll et al., *Obesity Risk for Female Victims of Childhood*

contours of a body are the outcome of intimate, not always explicable, pasts and practices. Prompting people to change their body size is prompting them to change the way it feels when they breathe, walk, and encounter others—it is changing fundamental axes of who they are and how they experience themselves and the world.

From a phenomenological perspective, such examples are important because they provide an alternative story about the meaning that weight can have for certain people; a meaning that is different from the narrow medical one that usually monopolizes the legal discourse. Such accounts of the meaning of the fat body bolster the position that a law's requirement that individuals lose weight or refrain from gaining it as a precondition for equal opportunity or access to rights and liberties is far from a mere technical requirement. This mandate requires more than changing caloric consumption or increasing physical activity; it has to do with deeply personal aspects of one's being.

This perspective is all but completely absent from the existing discourse on the appropriate legal approaches to fat prevention. The law relies almost exclusively on the medical paradigm in comprehending the fat body.¹⁷⁷ A legal system that fails both to appreciate the uniqueness of literally every body and to allow its subjects the freedom to live their lives with their own, special, intimate bodily texture (which is both a product of who they are and makes them who they are) is a legal system that cannot claim to be based on the liberal premise of respect for basic liberty, autonomy, and dignity.

2. *The Rich Meanings of Food and Eating*

Eating habits—alongside other factors like physical activity, genetic

Sexual Abuse: A Prospective Study, 120 PEDIATRICS e61, e65-66 (2007) (finding that young adults females who were subject to sexual abuse in childhood were more than twice as likely to be obese compared to a demographically similar control group of nonabused women). The more severe the sexual offense (e.g., offenses that include penetration), the more prevalent the obesity rates. See Gustafson & Sarwer, *supra*, at 131 (indicating that sexual abuse that involved any type of penetration was associated with an increased risk of obesity); see also D. F. Williamson et al., *Body Weight and Obesity in Adults and Self Reported Abuse in Childhood*, 26 INT'L J. OBESITY 1075, 1079 (2002) (finding that obesity rates among adults increased the more severe and frequent the abuse as children). Findings from these studies, however, should be read with caution, however. Many obese people are not survivors of abuse, and fat is not protective of abuse, although it does make reporting abuse much harder. Still, to appreciate the diverse meaning of weight for different people, it is noteworthy that according to one study, among groups of obese people, survivors of sexual abuse were the only ones to express positive stances towards their weight and expressed less body dissatisfaction among obese adults. See Gustafson & Sarwer, *supra*, at 132-32. When asked to indicate their ideal weight, the only ones whose ideal weight fell within the medical definitions of obesity (rather than "normal" weight) were sexual abuse survivors. Among weight reduction groups, victims of childhood sexual abuse lost significantly less weight and had higher likelihood of regaining their weight within eighteen months. *Id.* at 133.

177. See *infra* Subsection I.B.2.

makeup, and medical condition—determine body size. But eating is not like fueling a car or charging a battery. Yet this is how they are most often discussed by the prevailing medical discourse, which has been dominating the legal discourse on weight. What we eat, how we shop for our food and prepare it, and when, where, and with whom we eat are matters that have strong social, financial, political, and emotional aspects.¹⁷⁸ As many scholars have argued, food has symbolic value, functioning in our lives as a system rich with meaning.¹⁷⁹ For most Americans it would be unacceptable to measure the value of the turkey eaten at the Thanksgiving dinner merely through the lens of its caloric and nutritional values; turkey has a meaning special to national identity, family tradition, childhood memories, and household rituals of preparation. (Mother's secret stuffing recipe will never be the same if replaced by a low-calorie substitute.) Similarly, for immigrant and indigenous communities, certain foods and particular ways of consuming them connote the cherished past and are significant in sustaining their affinity with their native or old homeland's culture.

Food writer Michael Pollan coined the term “nutritionism”¹⁸⁰ to describe the growing tendency in America to view food and eating from the scientific lens alone, in which food is assessed through its nutrients, such as fat percentage, carbohydrates and protein content, and calories. Nutritionism is also how food is treated in the legal discourse: Eat *X* calories to correct your body, and do not bother us with the cultural and personal meaning of your ways of eating. To employ a famous literary example, it is not the nutritional content of the madeleine cookie that raised in Marcel Proust a powerful childhood memory.¹⁸¹ Using the exact same amount of sugar, butter, or daily percentage value of protein and carbohydrates needed for a madeleine to bake another cookie—different in shape (a shape that, according to Proust, “look[s] as though [it] had been molded in the fluted scallop of a pilgrim's shell,”¹⁸²) or different in density than the madeleine, would not have produced the same strong memory in the adult Proust. The craving for a particular cookie as a vehicle for a faint childhood memory cannot be summarized by the pseudomedical phrase (so commonly

178. See MICHAEL S. CAROLAN, *EMBODIED FOOD POLITICS* 130-33 (2011) (discussing a phenomenological account of the embodied experience of food and eating, and on the changing relations to food when one grows it in programs such as Community Supported Agriculture). See generally SIDNEY W. MINTZ, *TASTING FOOD, TASTING FREEDOM: EXCURSIONS INTO EATING, CULTURE, AND THE PAST* 69 (1996).

179. See, e.g., Mary Douglass, *Deciphering a Meal*, 101 *DAEDALUS* 61-68 (1972); see also Claude Lévi-Strauss, *The Culinary Triangle*, 22 *NEW SOC'Y* 937-40 (1966).

180. MICHAEL POLLAN, *IN DEFENSE OF FOOD: AN EATER'S MANIFESTO* 28-29 (2008) (lamenting the prevalence of the ideology for which “[f]oods are the sum of their nutrient parts” rather than an approach to food that is not reliant on expert knowledge but on tradition, culture, taste, pleasure, and identity).

181. MARCEL PROUST, *REMEMBRANCE OF THINGS PAST PART ONE: SWANN'S WAY* 58 (Charles Kenneth Scott Moncrieff trans., 1922).

182. *Id.*

heard these days) “my blood sugar dropped, I need something sweet.” The drop in blood sugar certainly might play a part in our craving for certain foods, but it fails to reflect the whole story. Often, the food we eat is an extension of ourselves and our tradition, culture, community, memory, esthetic upbringing, and more.

I could go on with numerous examples of the rich meanings of particular foods and specific ways of eating, but I presume the point is clear: our body size, which, to a significant extent, is a product of the food we eat and of how we eat (alongside other factors such as genetic makeup or physical activity), reflects an array of often personal motivations that are sometimes hard to put to words. These reasons for what we eat and how we eat are richer than a summary of caloric consumption and energy burn measures can explain. Such reasons have to do with who we are as humans, not merely as living organisms; they are related to axes of our identity that involve race, religion, socioeconomic class, gender, and more. Our body size reflects a subtle everyday internal dialogue (often in the form of negotiation) about how we live in the world. Hence, when law or society sends a message to people that they should lose weight, this imperative is far from being a technical demand about reducing caloric consumption and increasing physical activity. It is a requirement that penetrates areas of personhood that we feel certain, in other contexts, both law and fellow humans should stay out of. Thus, body size, like speech, thought, religion, and other areas of liberty, should be protected from interventions by both the law and other social actors.

3. Affirmative Accounts of the Fat Body

Since the 1960s there have been alternative voices, mainly from grassroot activists, that have been trying to formulate and advocate for an understanding of fat identity that is grounded in the present and rejects the focus on the fantasized post-diet future.¹⁸³ In the past decade, these voices have been growing in prominence and visibility. Fat activism seems to draw more constituencies with the thriving of fat affirmative blogs,¹⁸⁴ books, and conferences. In addition, more scientists, dieticians, and physicians are ready to question the almost axiomatic medical conviction that obesity is a pressing problem. These developments have drawn the attention of humanities and social science scholars, marking the emergence of a new field of study: Fat Studies.¹⁸⁵ These new discourses do not

183. See generally Jeffery Sobal, *The Size Acceptance Movement and the Social Construction of Body Weight*, in *WEIGHTY ISSUES: FATNESS AND THINNESS AS SOCIAL PROBLEMS* 231 (Jeffery Sobal & Donna Maurer eds., 1999).

184. See, e.g., BIG FAT BLOG, <http://bigfatblog.com/> (last visited Apr. 4, 2012); Marianne Kirby, THE ROTUND, <http://www.therotund.com/> (last visited Apr. 4, 2012); Joy Nash, FAT RANT BLOG, <http://fatrantblog.wordpress.com/> (last visited Apr. 4, 2012).

185. The publication of *The Fat Studies Reader*, *supra* note 9, and the forthcoming new journal, *Fat Studies*, to be published by Routledge/Taylor & Francis Group, are some indications of

stop at rejecting the dominant understanding of the fat body as a signifier of failure or disease, but instead take an extra step by developing positive accounts that affirm the fat body as a legitimate one—a body that is an object of desire, that can be healthy and productive, and that may rid itself of the ubiquitous and pressing requirements to change by slimming down.

One such affirmation that has received scholarly attention is the act of “coming out of the fat closet.”¹⁸⁶ At first, the notion of a fat closet may sound absurd, for body size is plainly visible.¹⁸⁷ But, as Eve Kosofsky Sedgwick observed, the idea of a fat closet makes sense because in contemporary culture, occupying a fat body is difficult, because it is a discursive taboo.¹⁸⁸ Until a fat person comes out of the closet as fat (that is, until he signifies that he is fully aware of his body size and claims a stable position within this body size), it is an untouchable topic of conversation. Before the topic is opened to conversation, there is little room for ambivalent or unstable meanings of the fat body. It is deciphered by the social environment along the prevailing codes of unhealthiness, lack of willpower, laziness, etc. As Saguy and Ward put it, “While coming out as fat . . . does not involve revealing a secret about one’s body size, it does reveal the surprising—and potentially subversive—attitude that being fat is acceptable.”¹⁸⁹ De-closeting oneself also means changing the temporal mode of the fat body. As Saguy and Ward note, “[C]oming out as fat involves a person who is easily recognized as fat affirming to herself and others her fatness as a nonnegotiable aspect of self, rather than as a temporary state to be remedied through weight loss.”¹⁹⁰

Such a spirit of living fully with one’s fat body provides the basis for a recent public health approach called Health at Every Size (HAES).¹⁹¹ The approach stems from research findings that active and well-nourished fat people can be healthier than sedentary and poorly nourished thin people and from the recognition that weight loss diets are generally unsuccessful and detrimental to

this new field. This development reaches law as well. At the May 2011 Law and Society Association’s Annual Meeting in San Francisco, there was a round table entitled “Legal Fat Studies: Directions, Promises, Challenges.”

186. For a study of “the migration of the coming out narrative from queer to fat politics,” see Saguy & Ward, *supra* note 50, at 61. See also Tirosh, *supra* note 5, at 274-75 (2006) (presenting Eve Kosowsky Sedgwick’s idea of a fat closet and applying it to a pedagogical challenge of teaching about weight).

187. Indeed, writes Samantha Murray, “[u]nlike the gay body, the fat body is always already out.” Murray, *supra* note 47, at 157.

188. EVE KOSOFSKY SEDGWICK, *EPISTEMOLOGY OF THE CLOSET* 45 (1990).

189. Saguy & Ward, *supra* note 50, at 66.

190. *Id.* at 65.

191. See generally BACON, *supra* note 79; Deb Burgard, *What Is “Health at Every Size”?*, in *THE FAT STUDIES READER*, *supra* note 11, at 41 (explaining the principles of this public health approach); ASDAH (ASSOCIATION FOR SIZE DIVERSITY AND HEALTH), <http://sizediversityandhealth.org> (last visited Apr. 29, 2012) (containing information and resources on HAES).

health.¹⁹² HEAS advocates recommend that fat people be physically active and eat healthful food, while abandoning their attempts to lose weight.¹⁹³ When Kate Harding and Marianne Kirby, veteran bloggers on fat acceptance, recommend adopting HAES,¹⁹⁴ they accompany their recommendation with several steps that stress living in the present, rather than in an imagined thin future. They recommend, for example, to avoid keeping clothes that do not fit as a motivator for losing weight¹⁹⁵ and to refrain from putting things off until one is thin.¹⁹⁶

The idea is, then, that in the interests of physical and mental health for all, our culture and law should open up the possibility for fat people to occupy the present, to be here now. Rather than suspending their potential for a full and prosperous life, fat people should claim the possibility to live fully in whatever size—to be physically active, outgoing, and outreaching and to be in touch with their present body, its needs, desires, and beauty. Such affirmative notions of the fat body pave the road for a new way to talk about the fat body in law and for theorizing the right to be fat.

IV. THE RIGHT TO BE FAT

[W]e should see [rights] as part of ongoing practices of social self-interpretation and negotiation.¹⁹⁷

A. The Basic Contours of the Right To Be Fat

Thus far I have argued that human experience of body size is imbued with meanings beyond what the medical, instrumentalist, and scientific paradigms can capture. These meanings stem from domains as intimate and intricate as

192. For evidence on these facts, see *supra* Section II.B.

193. Linda Bacon et al., *Size Acceptance and Intuitive Eating Improve Health for Obese, Female Chronic Dieters*, 105 J. AM. DIETETIC ASS'N 929, 935-36 (2005) (comparing women who underwent a diet program with women who were trained in the HAES program, and finding that the latter showed better results in health measures, physical activity, and self-esteem); Katz, *supra* note 142 (quoting Steven Blair, Professor of exercise science, epidemiology and biostatistics at the University of South Carolina, indicating that his research shows that “obese individuals who are fit have a death rate one half that of normal-weight people who are not fit”); Marcia Wood, *Health at Every Size: New Hope for Obese Americans*, 54 AGRIC. RES. 10, 11 (2006) (monitoring two groups of obese women—one following traditional diet and exercise advice, and the other following the HAES approach, and finding that two years later, the group of dieters regained their weight, and the HAES group maintained a stable weight for the entire time, and that the latter group lowered their cholesterol levels and systolic blood pressure for the entire duration of the study, as opposed to the dieted group, who did not lower their cholesterol at all, and reduced and then regained their blood pressure).

194. HARDING & KIRBY, *supra* note 101, at 13-18.

195. *Id.* at 158-61.

196. *Id.* at 213-21.

197. Leif Wenar, *Rights*, THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (FALL 2011 EDITION), <http://plato.stanford.edu/archives/fall2011/entries/rights> (last updated Jul. 2, 2011).

emotions, culture, identity, and personhood. Such an understanding of body size in the life of legal subjects must lead, in my view, to the realization that contemporary law should add to the list of legally recognized fundamental rights the right to be of any body size, including the right to be fat. This right derives from the right to liberty and is a concrete instance of the rights to autonomy and human dignity.¹⁹⁸

The right to be fat is the right to be free of governmental (and sometimes societal) intervention regarding one's weight, either by direct treatment or indirect impact.¹⁹⁹ It also means being equally entitled to social goods²⁰⁰ regardless of one's physical weight.²⁰¹ The legal framework of antidiscrimination, which, thus far, has prevailed in the scholarly treatments of the fat body in law, is important but insufficient, in my view, for fully reflecting the role of body size in human experience. Antidiscrimination law can indeed prevent disparate treatment of fat people on the basis of their weight, but it does not provide ways to understand fatness affirmatively.²⁰² The framework of antidiscrimination can protect a certain group from differential treatment while still sustaining the view that the protected group is inferior, worthy of pity, and better if changed. As the phenomenological accounts of fatness (discussed in

198. Whether the right to be fat should be conceptualized as located in the penumbra of other constitutional rights, such as the right to free speech or as part of due process, is certainly a point worth developing, but since this Article employs "thick brush strokes" to set the theoretical premise for establishing the right, it seems premature to enter such detailed doctrinal analysis at this stage.

199. In Hohfeldian terms, this is a privilege-right, as it creates a duty of non-interference by the government and by fellow citizens. However, as I show in the present discussion, the right to be fat has other aspects of Hohfeld's typology. For example, it creates claims against those who interfere with one's right to any body size. See Wesley N. Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YALE L.J. 16, 34-38 (1913).

200. John Rawls' enumeration of primary goods provides a helpful list for appreciating what I mean by social goods. See JOHN RAWLS, *A THEORY OF JUSTICE* 62 (1971).

201. There is myriad literature critiquing the usefulness of rights as indeterminate, individualistic in nature, rendering the legal discourse as monopolist and imperialist by numbing other, non-legal venues for social change. I am aware of this literature, and still believe in the power of using the language of rights, particularly with regards to thus-far neglected groups and causes. For a classical formulation of the critique of rights, see, for example, Morton J. Horowitz, *Rights*, 23 HARV. C.R.-C.L. L. REV. 393, 396-406 (1988); and Robin L. West, *Tragic Rights: The Rights Critique in the Age of Obama*, 53 WM. & MARY L. REV. 713, 719 (2011) ("[W]e need a critical way for thinking about rights that not only survives across generations but also adapts to the changing contours of rights."). But cf. Richard Delgado, *The Ethereal Scholar: Does Critical Legal Studies Have What Minorities Want?*, 22 HARV. C.R.-C.L. L. REV. 301, 301-15 (1987) (arguing that rights are still a useful concept for those who have been denied access to them, such as people of color); Mari J. Matsuda, *When the First Quail Calls: Multiple Consciousness as Jurisprudential Method*, 11 WOMEN'S RTS. L. REP. 297, 299 (1992) (arguing that using rights to promote change should not be construed as expressing naïve faith in the power of legal change to produce a structural revolution).

202. See generally Susanne Baer, *Dignity, Liberty, Equality: A Fundamental Rights Triangle of Constitutionalism*, 59 U. TORONTO L.J. 417 (2009) (developing a holistic account of liberty, equality, and dignity as mutually complementing fundamental rights).

Section III.C) demonstrate, one's body size is intrinsically worthy of protection, not just in comparison to how other bodies are treated, but due to its fundamental role in developing and sustaining a sense of identity and personhood. According to my suggested framework, it is the liberty to be fat that paves the way to protecting people against weight-based discrimination. As explained in Subsection IV.C.3 below, the antidiscrimination framework has additional disadvantages, such as a plaintiff's need to prove that his or her body is included in the protected group, and the reification of the medical categorization of body size that emanates from the antidiscrimination discourse.

Injecting notions of both liberty and equality into the justifications for the right to be fat would mean, for example, that individuals will be entitled to medical treatment that is not only unbiased against fat people, but also abandons the prevailing imperative to change the fat body and annihilate it to the extent possible. Such a principle shift necessitates, therefore, going beyond the paradigm of fairness and impartiality that underlines antidiscrimination law and a thick account of the nature and significance of the experience of body size. Such an account would appreciate the extent to which body size is an intimate sphere of existence and the extent to which bodies that are considered too large can have positive and enriching roles in the lives of their bearers. Conceptualizing body size as an aspect of liberty would similarly entail a more careful and critical assessment of parental capability in custody cases of fat children.

The central rationale behind the right to be fat is that sending a direct or an indirect message to a fat person that he or she needs to lose weight in order to gain access to various social goods, such as equal opportunity, dignity, and autonomy, is no less intrusive than telling a legal subject how to think, what to believe, or what to say. Limiting the extent of the body is, from the perspective of non-dualistic notions of personhood, as severe as limiting the scope of speech.

Regulating speech and regulating body size are indeed two radically different ways of infringing upon human freedom, but there are some aspects in which they are very similar. Liberal legal systems recognize that speech is one of those mysterious and idiosyncratic activities that sometimes emerge spontaneously, without a systematic premeditation.²⁰³ Thus one need not justify the usefulness or truthfulness of one's speech before one utters it. Additionally, because of the law's recognition of the fragile interplay between speech and thought, speech is left alone so as not to limit thought. Legal subjects are, therefore, allowed to produce the most bizarre, nonsensical, and even, to some extent, harmful speech.²⁰⁴ In the end, according to contemporary American

203. See, e.g., Robert Post, *Participatory Democracy and Free Speech*, 97 VA. L. REV. 477, 482-86 (2011) (anchoring the right to free speech in the interest of maintaining participatory democracy).

204. The right to free speech, like any right, is not unlimited. To invoke the familiar example, shouting "fire!" in a crowded theater would amount to an abuse of the right to free speech, and

constitutional law, individual freedom to think and speak is, in most instances, more important than the potential costs and damages of speech.

Similarly, as I have shown, bodily weight is related to our most intimate, vulnerable, and inexplicable inner worlds. Even in cases when the weight-related elements of our inner worlds *can* be explained, we should not be required to account for them.²⁰⁵ Bodily weight has to do with the emotional value of food, with communal and cultural aspects of eating, with one's gender,²⁰⁶ race, and class,²⁰⁷ with his or her self positioning on the spectrum of conventional beauty and body size norms. Limiting body weight is analogous to limiting speech in that both can be potentially intrusive. They invite society and government to enter areas in the life of persons that no liberal political philosophy views as legitimately accessible to others. Current legal arrangements deny a job applicant the job because he or she is too fat, or remove children from their parents' custody due to the children's or the parents' body sizes. For fat persons (and their guardians) these are requirements that they change not only their BMI, but also their psychological makeup, their idiosyncratic, fragmented, and intimate internal dialogues, and their basic understanding of themselves, of others, and of the human condition. Weight-related requirements, whether direct or indirect, are requirements that one modifies core aspects of one's existence. Thus weight should not be assessed merely through its alleged social cost, but respected as a domain of self that is as intimate to individual privacy and autonomy as faith, conscience, thought, or speech. Weight should be deontologically released from the socio-legal gaze. Even readers who are convinced that being fat without making efforts to lose weight is a bad lifestyle choice should endorse the right to be fat. They should view it as the right to make one's own mistakes in one's own way. This is how we think of ill-informed speech. As mistaken as it may be, it

would not be respected as part of this right. Indeed, the body also challenges the doctrine of free speech. As Amy Adler shows, the strong judicial fears and sexual panic that females dancers can evoke led the Supreme Court to produce a skewed doctrine of free speech. Amy Adler, *Girls! Girls! Girls!: The Supreme Court Confronts the G-String*, 80 N.Y.U. L. REV. 1108 (2005).

205. I developed a similar argument in a different context, in which I defended the need to rid legal subjects of the need to explain their hairstyle or grooming practices: Tirosh, *supra* note 122, at 83-89, 104-08.

206. There is abundant evidence that for women, weight is often a more critical site of their experience of self, and that women are socially sanctioned for much milder overweight than men. See, e.g., RHODE, *supra* note 5, at 30-31 (women are more penalized for perceived overweight); NAOMI WOLF, *THE BEAUTY MYTH* 179-217 (Anchor Books 1992) (1991) (discussing the worrying prevalence of anorexia nervosa among women and tying it to the increase in harsh and debilitating cultural expectations of women at the historical moment when women entered the public and thus far male dominated spheres); Korn, *Fat*, *supra* note 7, at 29-32 (discussing the unrealistic and unhealthy weight expectations American women face and some of the explanations for this phenomenon). My approach in this Article, however, is not gender-specific, for I believe that despite the significant gender disparities in the behavior of weight vis-à-vis liberty and equality infringements, the right to be fat would benefit both sexes.

207. On the correlation between body size and race and class, see *supra* Section II.A.

should still be protected, because the damage of limiting it and interfering with it would outweigh the benefits of such constraints.

Frances Kamm writes of the right to free speech, stating “The right to speak freely may simply be the only appropriate way to treat people with minds of their own and the capacity to use means to express it. . . . Not recognizing a person’s option of speaking is to fail to respect him.”²⁰⁸ This justification easily could be paraphrased to fit the right to be fat: The right to be fat may simply be the only appropriate way to treat people with bodies of their own and the capacity to use means to embody, or occupy it. Not recognizing a person’s option to live in whatever body size is to fail to respect him. This, then, is the rationale for the recognition of the right to be fat.

This right has both “negative” and “positive” aspects.²⁰⁹ It is derived from rights traditionally classified as negative, such as the right to autonomy, to dignity, and to liberty, because it essentially requires that the government or other societal actors refrain from intruding upon the lives of people when the basis for such intrusion is body size. A person’s body size, be it petite or voluptuous, should be irrelevant to the relationship between the citizen and the State.

Thus, legal subjects should be free of the requirement to lose weight in order to gain access to basic goods and opportunities, such as an equal opportunity to serve on juries,²¹⁰ equal taxes (so that it would be illegitimate to tax only poor people—who are generally fatter than more privileged groups—for unhealthful foods),²¹¹ or merit-based accreditation in public education (recall the example of the mandatory “fat class” in Lincoln college).²¹²

Acknowledging the right to be fat does not mean ignoring the complex

208. F.M. KAMM, *INTRICATE ETHICS: RIGHTS, RESPONSIBILITIES, AND PERMISSIBLE HARM* 247 (2007).

209. In their important book, Holmes and Sunstein convincingly show that the classification of rights as either negative or positive, as much as it resonates with intuition, is still false, because negative rights also have costs and require State action to sustain them (e.g., by financing the justice, enforcement, and correction systems, or by giving tax exemptions to organizations that work to protect rights such as the American Civil Liberties Union). STEPHEN HOLMES & CASS R. SUNSTEIN, *THE COST OF RIGHTS: WHY LIBERTY DEPENDS ON TAXES* 37-48 (1999). While I accept this argument, I still employ the negative/positive classification for the sake of ease of communication about the different aspects of the right.

210. *See supra* Section I.A.

211. *See id.* As I clarify in *infra* Subsection IV.C.1, I am not categorically opposed to taxing junk food. However, we should be mindful about the regressive effects of such a tax, as it would unequally limit the consumption patterns of poor people. When taking into account that there is significant correlation between poverty and rates of fatness, the reservations against junk food tax become even stronger, because this might be a policy against poor people disguised as neutral. Additionally, I believe it is insufficient and unjust to tax junk food without simultaneously increasing the affordability of healthful foods.

212. *See supra* Section I.A. Again, although I classify this aspect of the right as negative, we should be mindful that these aspects of the right have costs. For example, these rights have costs in holding effective legal proceedings that would provide remedies for infringements of this right. *See* Holmes & Sunstein, *supra* note 209, at 35-48.

health toll that fatness might charge.²¹³ Rather, it means recognizing that some practices merit a respectful distance despite the risks that they pose to one's longevity, or quality of life. Indeed, going back to the canonical articulation of liberalism, John Stuart Mill's *On Liberty* reminds us that this is what true respect for personal freedom entails. Mill gives the example of a man about to cross an unsafe bridge. It is permissible to stop him from crossing if there is no time to inform him of the danger, and this would not count as an infringement of his liberty, "for liberty consists in doing what one desires, and he does not desire to fall into the river."²¹⁴ Mill continues:

[W]hen there is not a certainty, but only a danger of mischief, no one but the person himself can judge of the sufficiency of the motive which may prompt him to incur the risk: in this case, therefore (unless he is a child, or delirious, or in some state of excitement or absorption incompatible with the full use of the reflecting faculty), he ought, I conceive, to be only warned of the danger; not forcibly prevented from exposing himself to it.²¹⁵

Protecting the liberty to be any body size should not be restricted to the scope of the relationship between citizens and the government. It also reaches the relationships among citizens, and contractual relationships in particular.²¹⁶ The right to be fat would cast a burden on private actors not to discriminate based on

213. Although these concerns may be much more limited than the prevailing account on weight and health indicates, and many of them have been used to justify stigmatization and discrimination. For a discussion of the contested relationship between health and weight see *supra* Section II.B.

214. JOHN STUART MILL, *On Liberty*, in THE BASIC WRITINGS OF JOHN STUART MILL 95, 100 (2002).

215. *Id.* Mill indeed permits warning against the danger. While some may argue that because obesity is not illegal, all that current law does is warn people against the dangers of obesity, I contend that many of the practices currently in place do much more than inform. They are sufficiently coercive that they are more like stopping a man than warning him.

216. Addressing the extent to which constitutional protections apply "horizontally" (between private actors) rather than "vertically" (between the government and its citizens) is beyond the scope of this Article. At this primary stage of conceptualizing the right to body size, I merely wish to indicate that the right might have implication for private actors, within the constraints of constitutional law. Indeed, the justification of the State action doctrine has been characterized as "one of the most important and hotly debated in comparative constitutional law." Stephen Gardbaum, *The "Horizontal Effect" of Constitutional Rights*, 102 MICH. L. REV. 387, 388 (2003). Gardbaum argues that the threshold search for State action in order to trigger a constitutional claim is misguided and unwarranted, because all law is subject to the Constitution. *Id.* at 414. For a critique of the way that State action doctrine preserves the status quo by portraying it as neutral, see CASS R. SUNSTEIN, *THE PARTIAL CONSTITUTION* 159-61 (1993). For a review of the ways in which the Supreme Court already recognized private actors' duty to refrain from violating constitutional rights, see Helen Hershkoff, *Horizontalities and the "Spooky" Doctrines of American Law*, 59 BUFF. L. REV. 455, 486-505 (2011). For an argument that the government has a duty to protect citizens from fellow citizens' attempt to infringe on their right to religious freedom, see HOLMES & SUNSTEIN, *supra* note 209, at 184.

body size (for example, in charging more for goods and services,²¹⁷ or in using weight as a factor in granting employment opportunities²¹⁸).

The right to be fat also has what is traditionally thought of as “positive” aspects. Guaranteeing the right to be fat entails that life activities and opportunities would be open to fat persons just as they are open to any other person. Physical spaces such as doctors’ beds or theater and airplane seats would need to be accommodating to various body sizes.²¹⁹ Fat people are often publicly shamed by when the passengers next to them on the airplane demand to be seated elsewhere, or when fat individuals are subjected to the “armrest test” to determine whether they can remain on the flight. Furthermore, fat airline passengers often leave a plane bruised from the seat’s armrests after sitting on two seats with an armrest in their back. Other times they are dehydrated from avoiding beverages prior to and during traveling, because they cannot use the airplane restrooms.²²⁰

Like any other right, the right to be fat is not absolute and might be withheld when it conflicts with other rights or interests.²²¹ Recognizing body size as a

217. I elaborate on this point *infra* Subsection IV.C.2.

218. For a discussion on weight-based employment discrimination, see *infra* Subsection IV.B.3.

219. The idea of setting a duty on private entities to provide physical accommodation has already been introduced to U.S. law in Title III of the Americans with Disabilities Act. I elaborate on airplane seats *infra* Subsection IV.C.2.

220. Many of these forms of accommodation are similar in character and scope to the accommodations of disabled people, and my approach draws significantly on disability legal studies (DLS). For a pioneering account on DLS see Sagit Mor, *Between Charity, Welfare, and Warfare: A Disability Legal Studies Analysis of Privilege and Neglect in Israeli Disability Policy*, 18 YALE J.L. & HUMAN. 63, 67-79 (2006).

221. The same is true for the right to be extremely thin. This Article was written with the case of “overweight” in mind, but the case of anorexia nervosa also raises, of course, questions regarding the legitimate scope for legal intervention in body size, because like the fat body, the anorexic body is considered on the extreme end of the spectrum of normative body size. As with fatness, there are competing cultural and biological, explanatory frameworks for the phenomenon. See ARTHUR KLEINMAN, *RETHINKING PSYCHIATRY: FROM CULTURAL CATEGORY TO PERSONAL EXPERIENCE* 34-76 (1988) (mapping the culture/biology debate with regards to schizophrenia, depression, and anxiety disorders in the context of both the mental and physical symptoms they produce and may be caused by). But fatness and anorexia are also different in significant ways. The threats to life and health (reproductive function, bone mass, blood makeup, immune system and more) posed by anorexia nervosa are much less contestable and much more immediate than the threats to life and health posed by heavy weight. See American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* 584 (4th ed. 2000) [hereinafter *DSM-IV-TR*] (discussing the menstrual abnormalities of anorectic patients); see also *id.* at 587-88 (indicating that the long-term mortality rate due to anorexia of individuals admitted to university hospitals is over ten percent); *id.* at 585 (noting that disorders associated with anorexia include depressive symptoms and obsessive compulsive features). Even those considered “morbidly obese” usually live for many more years and in much more productive and regular working and personal lives than anorexic patients in advanced stages of the illness. This difference suggests that it might be more legitimate to intervene in the short-term autonomy of the anorexic patient than in that of fat individuals. Another difference concerns age. Anorexia mostly bursts among teenagers, at an age at which

basic right would entail weighing it against other rights and interests, such as freedom of contract, the property rights of employers or insurers, or the utility and competitiveness of air carriers. This should be done with care similar to that taken when balancing traditionally recognized rights, such as freedom of speech or religious freedom, against competing state interests. I provide illustrations of such balancing in Section IV.C below.

B. A Note About the Bearers of the Right

In presenting this Article's argument, I am sometimes asked, "But what about those really huge people? You can't seriously include *them* in your defense of the right to be fat!" Many interlocutors, who are sympathetic to the idea that "moderately fat" people should have a weight range in which the law shall not interfere still feel that people who are clinically defined as "morbidly obese" present a fundamentally different challenge to law and policy.

My argument does not and cannot contain an internal distinction between different scales of fatness. The right to be fat extends even to cases wherein most people would agree that one's current weight is unhealthy. I do not see the difference between saying that it might be okay to be fat as long as you are not *really* fat or *too* fat and saying that it is okay to have freedom of speech as long as one does not say *extremely* silly things or make *absolutely* outrageous arguments.²²² Just as the real commitment to freedom of speech is tested at the extremes, so it is with the right to be of any body size. Principled recognition of body size autonomy means extending it to any body size.

In addition, I believe that the heaviest end of the weight spectrum is not where the real body-size drama takes place. The endless self-critique and societal judgment, the internal dialogues on dieting, calorie counting, and waist size also happen in the lives of people of more moderate sizes. For many average-weight women, for example, weighing as little as five pounds more than their desired weight makes all the difference in the world in their feelings about themselves.

patients are neither legally autonomous nor psychologically ripe to fully appreciate the implications of their condition. With fatness, people usually become fatter as they grow older. See LeAdelle Phelps et al., *Figure Preference, Body Dissatisfaction, and Body Distortion in Adolescence*, 8 J. ADOLESCENT RES. 297, 306-07 (1993) (finding that the highest rates of body distortion among girls are in their mid-teenage years); DSM-IV-TR, *supra*, at 587 ("Anorexia Nervosa typically begins in mid- to late adolescence (age 14-18 years).") Even when fat people were already fat in childhood, their childhood fat normally does not kill them (at least not nearly as much as anorexia kills young women), and so they live to be adults who can appreciate the implications of their body size more than teenagers can. I thank Tal Kohavi for pointing out this difference.

222. See, e.g., *United States v. Ballard*, 322 U.S. 78, 87 (1944) ("The First Amendment does not select any one group or any one type of religion for preferred treatment. It puts them all in that position."); *Collin v. Smith*, 578 F.2d 1197, 1203 (7th Cir. 1978) ("The asserted falseness of Nazi dogma, and, indeed, its general repudiation, simply do not justify its suppression."); *Collin*, at 1210 ("[I]f [First Amendment] rights are to remain vital for all, they must protect not only those society deems acceptable, but also those whose ideas it quite justifiably rejects and despises.").

These five pounds may determine whether they permit themselves to go on a job interview, on a blind date, or to the beach. Moreover, such a gap between present and desired weight defines whether they perceive themselves to be good, both as women and as persons. The borders of fat identity are very fluid. For most purposes they are not defined by medical indicators such as the lines drawn between obese and morbidly obese BMI, but by a personal sense and social perception of appropriateness of one's body size or the deviation therefrom. Potential jurors or employment candidates are disqualified because they are perceived as fat, regardless of their actual medical measurements such as BMI or body fat percentage. For the airline hostesses who, as described in *Gerdom v. Continental Airlines*,²²³ "were weighed once a month in full uniform including shoes" and required to lose two pounds a week if "excess" weight was found,²²⁴ fat was a significant factor in their lives even when they would have been considered thin by prevailing social standards.

In other words, the main locus of the right to be fat is not the "morbidly obese." This Article is as much about those defined as slightly overweight as it is about those at the extreme end of the weight spectrum.

C. Normative Implications: Some Hard Questions

What does a right to be fat look like? What is the meaning of this suggested new legal notion? In this Section, I outline normative implications of this right.

1. May the Government Still Introduce Weight-Related Policies?

Releasing bodily weight from law and society's regulative grip does not mean that the government may not introduce policies that educate and encourage all people to live a healthier life, richer in physical activity, and with nourishing, rather than inferior and nutritionally impoverished, foods. But in light of the right to be fat, such policies should be introduced without using weight as a proxy for singling out their audience.²²⁵ Defining fat people as the target of such programs would be counterproductive for fat people themselves, as the programs' humiliating and stigmatizing effects would likely hamper the chances of fat persons developing a healthy connection with their body.²²⁶ Rather, such

223. *Gerdom v. Continental Airlines, Inc.*, 692 F.2d 602 (9th Cir. 1982).

224. *Id.* at 603.

225. For a helpful review of possible legal instruments for encouraging healthful habits for all, see generally Jennifer L. Pomeranz et al., *Innovative Legal Approaches to Address Obesity*, 87 MILBANK Q. 185 (2009), which suggests measures such as compelling the food industry to expose the nutritional facts of its products, introducing government speech to do the same, using tort litigation as a regulatory mechanism, and more. See also Stephen D. Sugarman & Nirit Sandman, *Fighting Childhood Obesity Through Performance-Based Regulation of the Food Industry*, 56 DUKE L.J. 1403, 1411-29 (2007).

226. On stigma being counterproductive to weight loss, see *supra* note 111.

programs would probably lead to even greater alienation from the body and its needs. Additionally, people who are not fat would also significantly benefit from general health and education programs, because they have no less need for accessible healthful food and environments that encourage physical activity. Many people who are not considered fat by prevalent BMI guidelines or height/weight tables still consider themselves fat or are constantly worried that they might become fat and turn to extreme and unhealthy measures to control their weight.²²⁷ Therefore, they would also benefit from eliminating fat-phobic messages. An extensive study of almost a quarter million participants found that a wide gap between one's weight and one's desired weight is a better predictor of poor health than actual weight or BMI.²²⁸ These findings demonstrate the extent to which the public atmosphere that constantly stamps fat or seemingly fat bodies as inferior might pose a health risk no less serious than the purported health risks from fat itself.

The government can, for example, legitimately design a program to encourage all citizens to walk at least ten thousand steps a day (preferably while also creating conditions for such walks, through walking-friendly urban and suburban planning) or to buy fresh produce at the farmers' market supplied by sustainable farming, rather than the processed food industry. It is crucial, however, that these programs target everyone, not only fat people.²²⁹ It could even legitimately design a lifestyle program targeting the diabetic or high blood pressure patients, as long as it does not use weight as a proxy for tracing the recipients of such programs, for there are many fat people who do not suffer from diabetes or high blood pressure and many thin people who do. In contrast, a city-wide campaign that recruits the whole city to a goal of losing weight together to reach a total of such and such tons within a year would be problematic, because it focuses on weight and not on health. As a result, it would probably place social pressure on those who visibly "spoil" the city's chances to reach its goal.²³⁰

227. The stigma associated with fatness renders those who do not presently feel fat "to live in fear of getting fat." Marilyn Wann, *supra* note 11, at xi, xv (2009). A study on American teenagers found that if they considered themselves not the right weight (too thin or too fat—regardless of their actual BMI), they were significantly more likely to attempt suicide. Danice K. Eaton et al., *Associations of Body Mass Index and Perceived Weight with Suicide Ideation and Suicide Attempts Among US High School Students*, 159 ARCH. PEDIATR. & ADOLESC. MED. 513, 517 (2005). Another study found that teenagers who use conventional dieting practices, as well as teenagers who turn to unhealthy weight control behaviors, are *more* likely to gain weight compared to non-dieting teenagers within ten years. See Dianne Neumark-Szainer et al., *Dieting and Unhealthy Weight Control Behaviors During Adolescence: Associations with 10-Year Change in Body Mass Index*, 50 J. ADOLESC. HEALTH 80, 84-85 (2012).

228. See Muennig et al., *supra* note 106, at 504-05.

229. On the problematic ethical and factual aspects of the individualistic approach to obesity, see OLIVER, *supra* note 13, at 72-76.

230. Returning to the analogy to free speech, a governmental policy that targets certain body sizes would be subject to constitutional scrutiny similar to the scrutiny of governmental measures limiting free speech. In *Reynolds v. U.S.*, 98 U.S. 145, 162-65 (1878), the Court explained that the

2. *Airplane Tickets and Health Insurance Premiums*

Should air carriers be allowed to require a double ticket from very fat people who cannot fit into one airplane seat, or at least cannot fit while leaving enough free space for the passengers sitting next to them? And should health insurance providers be permitted to refuse insuring very fat people, refuse to cover gastric bypass surgery, or charge more from those whom they categorize as overweight? How would the right to be fat help determine these questions?

First, it is problematic to determine the prices of goods and services for individuals, based on statistical data about their group. The practice of health insurance companies to categorize insurance applicants based on their weight burdens the applicants' right to be of any body size. Including fat people in a group where certain ailments may be more prevalent is problematic because individual applicants do not necessarily exhibit these ailments.

Second, although airlines justify charging fat people a higher price by citing the additional costs that such passengers incur on the carrier, there are groups that the airlines do not single out for charging higher price, even when they result in higher costs for the airline when compared to other passengers. Religious customers provide such an example. On flights departing from or arriving in Israel, it is common for observant Jewish passengers to group at the rear of the airplane during prayer times. It is often highly inconvenient for both flight crew and other passengers wishing to use the bathroom or to have peace and quiet. Yet, religious needs do not serve as a basis for an extra "prayer charge" in flight tickets. Religious practices are, in our current sensibility, intimate enough to the self to justify refraining from price distinction. I contend that bodily weight should be too.

Both passengers in wheelchairs, who take up more space and add weight to the airplane, and older passengers, who need to be escorted from check-in to the gate, are not required to cover their extra costs. This might be due not only to company image interests, but also to legal bans on disability and age

Founding Fathers adopted the First Amendment in order to prevent the U.S. government from continuing the practice then rampant in the colonies of shaping the doctrines and precepts of the people by taxing or punishing them for failing to comport with the predominant belief. *See also* *Everson v. Board of Education*, 330 U.S. 1, 15-17 (1947) ("Neither a state nor the Federal Government can . . . pass laws which aid one religion, aid all religions, or prefer one religion over another. No person can be punished for entertaining or professing religious beliefs or disbeliefs"). Prohibiting the government from sanctioning or even disadvantaging citizens maintaining beliefs that society finds offensive or disagreeable is not a mere procedural technicality, but rather the bedrock principle motivating the enactment of the First Amendment. *See Texas v. Johnson*, 491 U.S. 397 (1989); *see also* *R.A.V. v. City of St. Paul*, 505 U.S. 377 (1992). The question of what degree of scrutiny should be applied in examining the constitutionality of different policies centered on body size is important, but it is premature in the context of this Article, whose main goal is to provide principled preliminary justifications for the right to be fat. However, there is undoubtedly room for future development of the intricate doctrinal framework of this right.

discrimination.²³¹ Indeed, it is likely that part of the reason that age and disability are socially and legally viewed as more worthy of accommodation than body size is because these traits are considered immutable. But another important aspect of airlines' decision to refrain from charging the disabled or the elderly more has to do, I believe, with dignity. Many consider it morally wrong to burden people because of their age or physical ability, due to the paradigm of universal egalitarian humanism. This paradigm, in turn, stresses our dignity and inherent value as human beings. Once weight is recognized not as a moral flaw or as a sign of weakness of character, but as a legitimate choice that belongs to one's intimate sphere in which no one should interfere, then it would be less legitimate to cast extra charges on fat people.

If insurers and airlines are not targeting many other groups that jeopardize their profitability, it is not only a case of inefficient market distortion, but also a testament to the (conscious or unconscious) fat-phobic bias that prompts such price distinctions. Here, bias might be dressed up as inaccurate efficiency considerations. If this is the case, then once contemporary legal systems have recognized the importance of being left alone regarding body size—once we recognize the right to be fat—there is room to conclude that these price distinctions are in fact illegitimate price discrimination against a stigmatized group. In sum, such price differentiations should be considered illegitimate because they are based on bias rather than on straightforward efficiency considerations, and also, because the personal characteristics that prompt this price distinction are aspects of personhood that should be respected by society, including private contracting parties.²³²

Third, fat bodies are considered a costly burden often as a result of the absence of a more imaginative, inclusive social vision. This sentiment is an expression of the ways in which social and physical design is based on some problematic ideal notion of a "normal body." The theory and doctrinal directions emanating from the field of Disability Legal Studies (DLS) have illuminating potential for the present discussion.²³³ The DLS analysis reveals how public buildings, restaurants, and workplaces are inaccessible not as a natural fact of life, but due to ableist assumptions about average or normal bodies.²³⁴ A ramp

231. The extent to which age or disability discrimination is legally forbidden in the private goods and services sectors is a complex question, which is not the focus of the current discussion. See *supra* note 218.

232. Evidence from other stigmatized groups, such as racial minorities, reinforce the concern that insurers' decisions are not solely based on efficiency considerations. See, e.g., Ana E. Balsa & Thomas G. McGuire, *Statistical Discrimination in Health Care*, 20 J. HEALTH & ECON. 881, 901-03 (2001).

233. Some weight-based discrimination cases are litigated under the Americans with Disabilities Act, but protection under the disability framework is off the mark for the present discussion because fatness is not discussed here as a disability.

234. See generally Arlene S. Kanter, *The Globalization of Disability Rights Law*, 30 SYRACUSE J. INT'L L. & COM. 241, 247-48 (2003) (presenting the human rights model for

instead of a staircase could easily render a venue accessible to more people. But DLS delves deeper by addressing areas that require even more imagination and accommodation effort, such as employers using text-based communication for the hearing impaired or schools changing the pace and methods of studying and testing to cater to those who have difficulty concentrating or reading and writing.

Realizing that there is nothing natural or immanent in the way buildings, airplanes, or insurance policies are designed prompts new questions about the way fat bodies are spatially and symbolically positioned as abnormal and unfitting. Just as a ramp can unmark the person on a wheel chair, so might a different design of the airplane rid fat people from the need to pay double for a ticket. Also, we should be mindful that fat people who pay for two seats get more space, but they do not receive what thin people do: a seat that fits. They get a seat with an armrest in their back that might present a safety hazard in case of an accident. Additionally, although they pay twice as much, they only get one set of frequent flyers miles. What if rather than the uniform seat size in the economy class of the plane, there would be rows with different seat sizes? Or, even better, what if seat width was changeable by horizontally shifting the hand rests? This would not only be an inclusive adjustment that would cater to fat people, but it would also represent a more accurate and efficient pricing system. Today, thin or short people enjoy extra arm and leg space without paying for it, as they free ride on the design that assumes a normal body that is wider or taller than theirs.

Once we start looking at thin people in airplanes (thus doing away with our treatment of their bodies as unremarkable and natural), different directions for solutions open up. The cost of redesigning adjustable seats might be lower than the profits stemming from the airline's ability to offer each passenger a seat fit for their size, thereby saving the space that is currently wasted on thin and short people.

I am not suggesting that price differentiation based on body size would never be legitimate. I am arguing that once the right to be of any body size, including fat, is recognized as part of personhood and as a matter that concerns autonomy, dignity, and liberty, then price distinction schemes will need to be much more carefully crafted than they are today. Factual assumptions about the efficiency of a fat premium would need to be scrutinized in light of these dignity-based costs and carefully balanced vis-à-vis the right to be of any body size. Furthermore, pricing schemes would need to be considered in light of the effect of price distinction on creating false notions of a normal body.²³⁵ Just as with other basic

disability); Sagit Mor, *Between Hope and Evil: Reframing Disability Allowance* 7-14 (2009) (unpublished manuscript), available at http://works.bepress.com/sagit_mor/ (challenging the seemingly immanent relationship between disability and poverty).

235. As already mentioned, I am deliberately refraining from conducting a detailed discussion on the exact constitutional formulation of the right. For discussions on balancing public rights against private interests see, for example, Erwin Chemerinsky, *Rethinking State Action*, 80 Nw. L. REV. 503, 506 (1985).

liberties that are sometimes protected despite the cost of this protection, we should expect that, at times, the interest of protecting the right to be fat would override efficiency considerations.²³⁶

Fourth, the empirical assumptions that underlie price distinctions should be carefully scrutinized, for there are reasons to suspect that the difference in pricing is not based on actual relevant differences of the fat body, but on perceived differences resulting from fat bias.²³⁷ Both air carriers and health insurers base their price distinction on the assumption that fat people would be more costly to them than other groups, but these assumptions might be based on cognitive biases, which do not promote market efficiency.²³⁸

Consider the characteristics of other customers that airlines and insurers should target from an efficiency perspective, and yet they refrain from doing so. Life insurance providers ask applicants about their weight in order to determine their admissibility and their premium, but as far as I can tell, they do not ask whether the insurance applicant has a high-stress job. Stress has been known to have adverse effects on health and longevity that are probably no less severe than what is often argued about weight,²³⁹ but perhaps it is cognitively harder to identify that esteemed and high-earning members of society are casting a burden on the insurer's pocket. It may be also harder in terms of the insurance company's image to charge higher premiums and attach labels to clients from a prominent and esteemed professional segment of society. Fat people, on the other hand, internalize their inferiority and blame themselves for their unworthy bodies, thus making it easier for their high premium to pass muster.²⁴⁰ Fat people

236. See Daphne Barak-Erez & Aeyal M Gross, *Introduction* to EXPLORING SOCIAL RIGHTS: BETWEEN THEORY AND PRACTICE 5-6 (Daphne Barak-Erez & Aeyal M Gross eds., 2007) (noting that both traditional civil liberties and newer social rights often cost money); see also HOLMES & SUNSTEIN, *supra* note 207, at 35-45 (claiming that all rights are positive, in the sense that they cast a monetary burden on the government in enforcing them); *id.* at 20-21 ("The individual rights of Americans . . . are generally funded by taxes, not by fees. This all-important funding formula signals that, under American law, individual rights are public not private goods." (citations omitted)).

237. Excellent accounts are available on biased inefficient price discrimination based on race and ethnicity in the business sector. See, e.g., John Yinger, *Evidence on Discrimination in Consumer Markets*, 12 J. ECON. PERSP. 23, 38 (1998); see also John J. Donohue, *Antidiscrimination Law*, in 2 HANDBOOK OF LAW AND ECONOMICS 1387 (A. Mitchell Polinsky & Steven Shavell eds., 2007) (assessing the extent to which discrimination is based on bias from an experimental economic perspective).

238. For evidence that health costs and insurance premiums did not go up due to laws mandating health insurers cover obese people and fund surgery, see Wang, *supra* note 8, at 1941-42.

239. On stress as a health risk factor, see, for example, Anita DeLongis et al., *The Impact of Daily Stress on Health and Mood: Psychological and Social Resources as Mediators*, 54 J. PERSONALITY & SOC. PSYCHOL. 486, 492-94 (1988) (finding significant relationship between daily stress and health problems); and Stanislav V. Kasl, *Stress and Health*, 5 ANN. REV. PUB. HEALTH 319, 327-35 (1984) (reviewing evidence for the correlation between stress and health risks).

240. There are myriad illustrations of such cognitive biases in business and in public mores.

are also likely to be generally poorer than people in professional high stress jobs,²⁴¹ and thus it is probably easier to give up on them as customers.

3. Employment Discrimination

Fat people are clearly subjected to adverse treatment and lack of equal opportunity in the workplace.²⁴² The animosity against fat employees includes verbal harassment²⁴³ and discrimination in hiring, wages, and promotion.²⁴⁴ Fat people must often also face demeaning work practices such as periodical weighing of employees²⁴⁵ or the recent growing phenomenon of mandatory wellness programs sponsored by the employer, which frequently involve “aggressive” policies such as “charging higher health insurance premiums or deductibles to those employees who do not participate in the wellness program, or who engage in unhealthy behavior.”²⁴⁶ Such policies send a repeated message

See, e.g., PAUL FUSSELL, *CLASS: A GUIDE THROUGH THE AMERICAN STATUS SYSTEM* 25-26 (1983) (discussing the double standards by which the media reports on working class accidents versus the outcry that would occur if a similar number of corporate executives were killed at work).

241. For the correlation between weight and socioeconomic status, see *supra* Section II.A.

242. See, e.g., SOLOVAY, *supra* note 7, at 99-121 (discussing the evidence and the law of weight-based employment discrimination); Dor et al., *supra* note 34, at 10 (noting that female employees who are obese earn \$1,855 less annually compared to female employees who are not obese (and 6% lower than the median women annual wage)); Kari Horner, *A Growing Problem: Why the Federal Government Needs To Shoulder the Burden in Protecting Workers from Weight Discrimination*, 54 CATH. U. L. REV. 589 (2005) (reviewing and assessing the available legal paths to claim weight-based discrimination at work, and arguing for federal legislation to protect against such discrimination); Rebecca Puhl & Kelly D. Brownell, *Bias, Discrimination, and Obesity*, 9 OBESITY RES. 788, 789-90 (2001) (noting that the obese tend to earn lower wages for the same job performed by non-obese counterparts and may be at a substantial disadvantage even before the interview process begins, as they are assumed to lack self-discipline, be lazy, sloppy, and so on); Mark Roehling, *Weight-Based Discrimination in Employment: Psychological and Legal Aspects*, 52 PERSONNEL PSYCHOL. 969, 971-88 (1999) (reviewing the available empirical evidence on weight-based discrimination in the workplace); Esther D. Rothblum et al., *The Relationship Between Obesity, Employment Discrimination, and Employment-Related Victimization*, 37 J. VOCATIONAL BEHAV. 251, 260 (1990) (noting that very obese subjects reported more types of employment discrimination than did non-obese subjects); Theran, *supra* note 7, at 153-62 (reviewing evidence of weight-based discrimination in employment).

243. See, e.g., *Figgins v. Advance Am. Cash Advance Ctr. of Mich., Inc.*, 476 F. Supp. 2d 675, 680 (E.D. Mich. 2007) (describing plaintiff's manager's questioning her on whether she made sure she got diet soda, and documenting other similar remarks).

244. Puhl & Heuer, *supra* note 21, at 941-43 (reviewing recent research findings that point to consistently prevalent weight discrimination in hiring, promotion, and wages).

245. See, e.g., *Frank v. United Airlines, Inc.*, 216 F.3d 845, 848 (9th Cir. 2000) (indicating that plaintiffs, all female flight attendants working for the defendant, “attempted to lose weight by various means, including severely restricting their caloric intake, using diuretics, and purging” in order to comply with the defendant's weight requirements); see also RHODE, *supra* note 5, at 106 (describing contemporary weighing practices by employers).

246. Ann Hendrix & Josh Buck, Comment, *Employer Sponsored Wellness Programs: Should Your Employer Be the Boss of More Than Your Work?*, 38 SW. L. REV. 465, 469 (2009); see also *id.* at 470 (describing an Arkansas program under which “government employees receive a heavily

that being fat is bad and that employees must reduce their size once their body transgresses its prescribed bounds.²⁴⁷ Therefore, these policies infringe the right to body size. Under the current legal framework, some cases of weight-based employment discrimination can be remedied under disability antidiscrimination law—where a fat plaintiff successfully demonstrates that his weight is limiting major life activities, or when he demonstrates that he was regarded as disabled because of his weight.²⁴⁸ Fat plaintiffs can also argue that their employer used weight as a proxy to discriminate on the basis of a recognized suspect category, such as sex²⁴⁹ or race.²⁵⁰ But framing fat discrimination as disability discrimination or as sex or race discrimination would undermine the underlying rationale of the present project, because, as this Article stresses, fat often serves as an independent cause for limiting employment opportunities.²⁵¹ Should there

reduced deductible for having a low height-to-weight ratio, measured at on-site annual physicals”).

247. Indeed, in other liberty-based rights, such as the right to abortion, applying aggressive policies against the right (such as the duty to undergo ultrasound) is not unconstitutional as long as the fundamental right is not unduly burdened. But the right to be fat is different from the right to abortion. Most women undergoing abortion would not view abortion as a positive or welcomed experience in itself. Fatness, as argued above, should be conceived as an experience that can be inherently positive, a productive locus of meaning for the individual. Thus the right to be fat is more similar to religious freedom. Employers cannot subject employees to a religion class, nor demand their employees to declare their religion. Similarly, employers should not be permitted to monitor employees’ weight or to encourage them to lose it.

248. Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. § 12102(1)(A) (2006). For scholarly treatments of the possibility to protect weight discrimination under the ADA and similar discrimination acts, see KIRKLAND, *supra* note 5, at 126-46, which observes that identification as disabled will result in fat accommodation, but at the same time hamper the political solidarity needed for forging a positive group identity; and SOLOVAY, *supra* note 7, at 122-27. *See also* Korn, *Fat*, *supra* note 7 (arguing that the ADA should protect obesity as either an actual or perceived disability); *id.*, *Too Fat*, *supra* note 7, at 3 (“While the [2009 Americans With Disabilities Act Amendments Act] appears to provide more protection for most people with disabilities, this amendment will probably not protect people who are obese absent a significant change in our thinking about obesity.”); Kramer & Mayerson, *supra* note 7, at 210 (“Specific features of obesity and common reactions to the condition make it especially suited for protection under a perceived disability theory [under the ADA].”).

249. *See, e.g.*, *Gerdom v. Cont’l Airlines, Inc.*, 692 F.2d 602 (9th Cir. 1982) (accepting a claim that different weight requirements for female employees amounted to a violation of Title VII’s ban on sex discrimination). The airline cases demonstrate that sometimes the plaintiffs would not be considered fat by conventional standards, but the employer sets a weight standard that only fits thin employees.

250. *See, e.g.*, *Murray v. John D. Archbold Mem’l Hosp., Inc.*, 50 F. Supp. 2d 1368 (M.D. Ga. 1999) (rejecting the plaintiffs’ argument that employer’s weight requirements amounted, among other things, to race discrimination in violation of Title VII of the Civil Rights Act, because it disparately impacted black applicants).

251. An analogous debate on whether disability law should be the recourse exists in the literature on transgender people. *See, e.g.*, Jennifer L. Levi & Bennett H. Klein, *Pursuing Protection for Transgender People Through Disability Laws*, in *TRANSGENDER RIGHTS* 74-77 (Paisley Currah et al. eds., 2006) (arguing that while the fear of stereotyping transgender people as abnormal or inferior is understandable, the transgender community should not shy away from coverage by disability laws, for the contemporary disability movement had instilled new positive

be, then, a distinct category for weight in antidiscrimination clauses?²⁵² Should such language enter Title VII and similar state and local employment discrimination rules? The answer to this question is not simple, and it merits examination in a separate article. Here I will only briefly map the key arguments for and against such antidiscrimination legislation.

It is important to stress that unlike previous scholarly treatments of this question, my answer is informed by my liberty-centered approach to body size, and, therefore, contains serious reservations about including weight in the antidiscrimination legal framework.

a. Arguments in Support of Banning Weight-Based Employment Discrimination

First, as already mentioned, there is consistent empirical evidence suggesting that fat people pay in opportunities and income because of their weight. Fat people are often judged not on their merits (i.e. their education, skills, or experience) but on the assumed meanings of their size. This is not only unjust, but also inefficient for employers, because by focusing on weight they might miss qualified employees.²⁵³ Fat people are also frequently subjected to hostile environments where co-workers and managers peck at them for eating certain foods or make humiliating remarks.²⁵⁴

Second, it is legitimate to interfere with the contractual freedom of employers in this context even if we stick with one of this Article's preliminary assumptions—that weight is a mutable characteristic within the person's control. Antidiscrimination clauses contain not only immutable traits (such as race, sex, age, or nationality), but also traits that are within the control of the individual, such as religion or marital and parental status. The rationale for marking the latter characteristics as suspect categories is that they concern matters so central to the core of personhood that people should not be required to change them in order to gain access to equal employment opportunities. According to the theoretical

and critical meanings to disability).

252. A small number of states and municipalities did introduce "weight," "appearance," and similar phrases as forbidden grounds in their employment discrimination law. *See, e.g.*, District of Columbia Human Rights Act, D.C. CODE ANN. § 2-1402.11 (2002); Elliott-Larson Civil Rights Act, MICH. COMP. LAWS § 37.2101-2804 (1976) (a Michigan law prohibiting an employer from discriminating on the basis of, *inter alia*, weight). Litigation is, however, still too scant to allow for assessing the effects of such laws.

253. *See, e.g.*, RHODE, *supra* note 7 (providing ample evidence for appearance-based employment discrimination and suggesting legal reform to prevent such discrimination). *But cf.* William R. Corbett, *The Ugly Truth About Appearance Discrimination and the Beauty of Our Employment Discrimination Law*, 14 DUKE J. GENDER L. & POL'Y 153, 178 (2007) (arguing that the logic of U.S. antidiscrimination law does not extend to banning appearance-based discrimination).

254. *See, e.g.*, Leanne Joannis & Anthony Synnott, *Fighting Back: Reactions and Resistance to the Stigma of Obesity*, in *WEIGHTY ISSUES: FATNESS AND THINNESS AS SOCIAL PROBLEMS*, *supra* note 185, at 49, 56.

framework developed in this Article, weight is a core part of personhood and, therefore, should be free of societal intervention. As such, it is similar to religious freedom or family status, with which, in general, employers cannot interfere.

Questions of merit-based hiring and promotion are always complicated, and the area of body size is no exception. In what jobs would employers be permitted to consider damage to company image caused by a service giver who is “unaesthetic,” for example? Should they be allowed to consider the health insurance costs of fat employees? These questions should be determined by drawing from analogies found in the existing tools of employment discrimination doctrine.²⁵⁵ What is clear, however, is that many assumptions about skills, professionalism, and performance of fat people are shaped by bias rather than evidence. Indeed, in certain occupations, there might be bona fide occupational qualifications to justify excluding many fat candidates, but the criterion used for assessment should not be the candidate’s weight per se, but the candidate’s abilities. For example, police officers should be agile and able to operate quickly. While many fat people might not meet this job requirement, some fat people might be fit enough to qualify, and many thin people would not qualify as well. Additionally, since the right to be fat also has positive aspects, recognizing it would create duties for employers to create reasonable accommodations, similar to their duties under disability law.²⁵⁶ For example, employers would have the duty to provide office furniture that would fit their employees’ sizes, or a big enough sitting space in the bus or truck that they would drive.

*b. Arguments Against a Legal Ban on Weight-Based Employment
Discrimination*

First, the most disconcerting potential consequence of introducing weight to the list of suspect categories in employment antidiscrimination laws is that such laws would pave the way for a whole new spectrum of oppressive legal discourse about the fat body. Despite good intentions to protect fat people from discrimination, the legal gaze at fat plaintiffs’ bodies might produce more humiliating outcomes than the harm of discrimination itself. The concern here is that the legal discourse on weight would normalize the medical framework for

255. For example, courts have been very careful not to construe customer preferences as Bona Fide Occupational Qualifications, and this principle should apply to the case of body size as well. See, e.g., Kimberly A. Yuracko, *Private Nurses and Playboy Bunnies: Explaining Permissible Sex Discrimination*, 92 CALIF. L. REV. 147, 196-201 (2004) (analyzing the cases in which courts do permit recognizing customer preferences as BFOQ). For an excellent account of the extent to which antidiscrimination law can remedy weight-based discrimination, see generally KIRKLAND, *supra* note 6.

256. See generally Jeffry O. Cooper, Comment, *Overcoming Barriers to Employment: The Meaning of Reasonable Accommodation and Undue Hardship in the Americans with Disabilities Act*, 139 U. PA. L. REV. 1423 (1991) (discussing the scope of the employer’s duty to provide accommodation under the ADA).

talking about the fat body. The law would thereby partake in disciplining it, rather than assisting in its liberation. This, in my view, is a central weakness of antidiscrimination discourse: While it focuses on equalizing the treatment of the protected group to that of others, there are no internal mechanisms within this discourse to guarantee that the protected group will not still be portrayed by this discourse as inferior and pitiful, albeit worthy of tolerance. This is why, as I argue here, a liberty-based protection of body size should underlie any weight-based antidiscrimination rule.²⁵⁷

In reading existing weight discrimination cases, we can witness the emergence of discursive conventions, or trends in speech, that tell the story of the fat body in a vocabulary that is governed by the medical understanding of the fat body, finding no trace of, and leaving no room for, competing meanings of corpulence. Figures, measurements, body organs and physical functions such as glandular activity, genetic makeup, and various metabolites are all meant to establish a seemingly objective viewpoint on which the legal gaze can comfortably rely in assessing the legitimacy of the fat body. To illustrate, consider this statement, from a case arguing, among other things, weight-based discrimination: “[A]t the time her employment was terminated, she was fifty-five years old, 5’7” tall and weighed about 240 pounds and . . . previously, she had weighed as much as 311 pounds.”²⁵⁸

As another example, we read that the plaintiff did not present evidence to show that his weight was a result of a genetic or metabolic condition.²⁵⁹ Sometimes, such medicalized measurements of bodies in the workplace do not stop at describing the plaintiff’s body, but spread to descriptions of the bodies of colleagues and supervisors.²⁶⁰ As should be clear by now, I find this way of talking and writing about the fat body to be reductive as it provides a partial and non-humanist account of the body as a machine devoid of complex meanings and multiple motivations.²⁶¹

257. For a discussion of the impact of disability movements on identity politics, see generally Martha Minow, *Not Only for Myself: Identity, Politics, and Law*, 75 OR. L. REV. 647 (1996).

258. *Lamoria v. Health Care & Retirement Corp.*, 584 N.W.2d 589, 589 (Mich. Ct. App. 1998). Other examples abound. See, e.g., *Phil. Elec. Co. v. Commonwealth*, 448 A.2d 701, 214 (Pa. Commw. Ct. 1982) (“On the date in question, [Petitioner] was 27 years old, 5’ 8” tall and weighed 341 pounds. There is no question that on April 26, 1977 [Petitioner] was morbidly obese.”). On the normalization of the discourse on fat, see KIRKLAND, *supra* note 7, at 112-14. See also *id.* at 112 (“[M]ore and more concerns about fat are expressed with demographics, Body Mass Index (BMI) ranges, and cost projections.”).

259. See, e.g., *Delta Air Lines v. N.Y. State Div. Human Rights*, 689 N.E.2d 898, 91 N.Y.2d 65, 73 (1997) (“Appellants did not proffer evidence or make a record establishing that they are medically incapable of meeting Delta’s weight requirements due to some cognizable medical condition.”).

260. See, e.g., *Figgins v. Advance Am. Cash Advance Ctrs. of Mich., Inc.*, 476 F. Supp. 2d 675, 679 (E.D. Mich. 2007) (describing the weights of the plaintiff’s area manager, regional director of operations, and assistant manager).

261. These concerns are raised by the critical disability literature as well, which stresses the

Indeed, similar problems, concerning the normalizing effects of the legal discourse, have been addressed by scholars with regard to subjecting sex, race, or sexuality to the gaze of antidiscrimination law. I suspect, however, that the damage in the case of weight might be even more severe, since being a woman or a person of color are statuses that do not require as intrusive and clinical of an inquiry into whether or not they fall into the protected category as weight does, and do not burden the plaintiffs with a detailed depiction of their “condition.”²⁶² The antidiscrimination framework entails that a plaintiff classify his or her specific body size according to a ready-made legal categorization of bodies. This is bound to come with the price of reifying the medical taxonomy of body size, thereby stifling competing perspectives on body size and its role in human experience.

If protecting fat people from discrimination would require subjecting plaintiffs to a legal inquiry about their weight, metabolic function, genetic makeup and lifestyle, then perhaps antidiscrimination law is not the appropriate means for protecting fat people against discrimination. An alternative dignity- or liberty-based legal framework for providing remedies for workplace infringements might be better suited in this context, in that it might rid litigation of the need to require plaintiffs to define their identity and fit it into the protected category.²⁶³ Liberty or dignity claims do not require that the plaintiff prove that he or she belongs to a certain protected group. Rather, they are based on a conception of universal humanness, thus avoiding the need to meticulously examine the weight of the plaintiff or the reasons that brought about his or her body size. It is precisely because weight is extremely meaningful to individuals—imbued with meanings that often resist representation in language

need to differentiate between impairment (referring to the physical limitation) and disability (referring to the social exclusion, which is not a necessary outcome of impairment, but a result of social organization that takes little or no account of people who have physical impairment and, thus, excludes them from participation in the mainstream of social activities). See UNION OF THE PHYSICALLY IMPAIRED AGAINST SEGREGATION, FUNDAMENTAL PRINCIPLES OF DISABILITY 20 (1975). However, I think the question of body size presents an even bigger challenge to the dilemma of whether to surrender the body to representation in language, because there is something about the status of weight in our culture that is so loaded with shame and negative judgment that it is virtually impossible to surrender it to language without oppressive and normalizing outcomes. I explored this question in Tirosh, *supra* note 5. I am therefore much more reserved about introducing weight to the antidiscrimination framework than I am about disability.

262. The experience of transgender people seeking legal recognition of their transition can provide an analogy to the level of intrusiveness of the judicial gaze. See Taylor Flynn, *The Ties That (Don't) Bind: Transgender Family Law and the Unmaking of Families*, in TRANSGENDER RIGHTS, *supra* note 251, at 32, 35-39 (arguing that judicial concern for the privacy of litigants disappears when it comes to transgender and transsexual litigants, whose body, medical history, and sex lives are subject to detailed scrutiny).

263. See generally Tirosh, *supra* note 122 (developing the argument about the advantage of liberty-based justifications over discrimination-based protections in the context of appearance claims).

and that challenge the mainstream negation of fatness—that one’s weight should not be subjected to inquiries into whether it falls within the legal rubric of a protected class.

Second, some jurisdictions, such as the State of Michigan, Washington D.C., or Santa Cruz, California, have already introduced appearance or weight as forbidden grounds for discrimination. In the decade since introducing those laws, we find surprisingly little litigation because plaintiffs do not file claims about their weight-based discrimination.²⁶⁴ One likely reason for this failure to use the law to mobilize fat rights is that fat plaintiffs are hesitant to expose themselves publicly as fat. For example, if they file a weight discrimination claim, a simple online search of their name would expose this fact, thus marking them publically as fat. Perhaps potential fat plaintiffs are not ready to stably occupy the position of people who have been wronged due to their weight. Perhaps they are not ready to come out of the fat closet,²⁶⁵ a move that would entail claiming with conviction that they are entitled to equal opportunity. This hypothesis is supported by Solovay and Vade’s observation that plaintiffs in employment discrimination cases who are unapologetic about their weight fare worse than plaintiffs who tell the court that they know something is wrong about their body, and they have tried every possible method for weight loss.²⁶⁶

Another possible reason for the scant number of weight discrimination lawsuits is that potential plaintiffs are unable to admit to themselves that they are going to remain fat (that is, they internalize the future-grounded understanding of fat identity as one that is only pending metamorphosis). The legal venue, then, has thus far not proven to be effective or significant in preventing weight-based discrimination. This Article takes a liberty-based approach to weight because it does not raise the problems associated with employment discrimination approaches.

4. *Smoking, Skydiving, and Other Dangerous and Idiosyncratic Behaviors*

My argument has normative implications for other behaviors that can be categorized as body-centered and as dangerous to one’s health, such as smoking

264. See Kristen, *supra* note 7, at 101 (indicating that “only eight to ten cases of weight-related discrimination had been pursued” since the law reform in Michigan); see also RHODE, *supra* note 7, at 126 (“No jurisdiction [that explicitly prohibits appearance or weight discrimination] has experienced the flood of frivolous litigation and business backlash that critics have predicted.”); Kristen, *supra* note 7, at 105-08 (indicating that no cases were litigated under Santa Cruz and San Francisco’s explicit ban on weight discrimination). For a recent statistical analysis of the little change that obesity antidiscrimination laws made in the lives of fat legal subjects see Shinall, *supra* note 5, at 20-30.

265. For a discussion of the fat closet, see *infra* Subsection III.C.2.

266. Sondra Solovay & Dylan Vade, *No Apology: Shared Struggles in Fat and Transgender Law*, in THE FAT STUDIES READER, *supra* note 11, 167, 167-69 (noting that for obesity, there is a sense of moral failure that prevents accepting it as primarily a physiological disorder).

or engaging in extreme sports.²⁶⁷ These behaviors, which are sometimes dubbed “expensive tastes,”²⁶⁸ are controllable and unhealthy. Perhaps due to the cultural grip of the dualistic approach to body and mind discussed above,²⁶⁹ the law generally does not tend to protect physical behaviors that might be considered eccentric or peculiar, while recognizing and protecting eccentric activities more associated with the mind, such as speech or thought. I believe the account provided here about the intimate and non-generalizable nature of embodied experience can contribute to our understanding of the law’s approach to such practices. Smokers are attached to the sense of peace, pause, and release that a cigarette provides. They often feel that their cigarette smoking time is a cherished time and that there are no equivalent replacements for the feelings that smoking provides for them.

Indeed, one of the implications of my argument is that we should begin to develop a set of criteria for determining which activities or lifestyle choices merit legal recognition and protection. These criteria will attempt to rate the extent to which a certain bodily habit is close to the core of our person. Smoking, for example, is different from eating in that it is not essential for survival. We cannot completely abolish eating from our lives, and in that sense, regulation of smoking would be ranked as farther from the core of our person than regulation of eating—an activity inherent to human existence. Additionally, “the individual makes the initial decision on whether to pick up the cigarette, [but a] person struggling with obesity has often been dealing with weight issues since childhood and did not really make the choice to become obese.”²⁷⁰ Furthermore, smoking poses direct damages to others in the proximity of the smoker, unlike being fat.

Another criterion would be the extent to which such bodily aspects of experience define our sense of who we are, both “from the inside out” (for ourselves) and “from the outside in” (by society’s gaze). I mentioned earlier²⁷¹ that being fat today entails a persona; an entire set of characteristics that seemingly emanate from body size. It reflects substantial qualities in the fat person such as lack of self-control or laziness, but also perhaps a sense of humor and ability to enjoy life.²⁷² We are not there with regard to smoking or with

267. Like smoking, fat is sometimes theorized as contagious. See, e.g., Nicholas A. Christakis & James H. Fowler, *The Spread of Obesity in a Large Social Network over 32 Years*, 357 N. ENG. J. MED. 370 (2007); Gina Kolata, *Find Yourself Packing It On? Blame Friends*, N.Y. TIMES, July 26, 2007, <http://www.nytimes.com/2007/07/26/health/26fat.html>.

268. On expensive tastes, see, for example, John Rawls, *Social Unity and Primary Goods*, in UTILITARIANISM AND BEYOND 159, 168-69 (Amaryta Sen & Bernard Williams eds., 1982); and Simon Keller, *Expensive Tastes and Distributive Justice*, 28 SOC. THEORY & PRAC. 529, 529-32 (2002).

269. See *supra* Section III.A.

270. DeVries, *supra* note 7, at 165.

271. See *supra* Section I.A.

272. Even ascriptions of traits that seem positive still stereotype and lock fat people within a particular social role. See, e.g., Gina Cordell & Carol Rambo Ronai, *Identity Management Among*

extreme sports. Indeed smokers in the United States are today viewed as lacking self-control, risking harm to themselves and others, and casting a burden on the public budget with their expected illnesses. However, these attributes do not amount to a sense that smokers are primarily defined by their smoking. There are exceptions, but we usually say “his profession is *X*, he is age *Y*, and he is a smoker.” With fat people, their size comes earlier in our perceiving and talking about them. This is another reason that there should not be an automatic leap from the right to be fat to a right to smoke or to skydive.

In sum, it is certainly expected that the set of tools that would hopefully develop in the process of broadening and applying the right to be fat could be extrapolated to our way of thinking about other volitional bodily practices. Determining whether the legal anchoring of a right to be fat should be extended to other self-risking behaviors would depend on the extent to which the practice in question is in close proximity to the core of the person and to one’s sense of self.

CONCLUSION

[W]e need to make our bodies just as central to our moral theorizing as they are in our moral practices.²⁷³

This Article has argued that American law’s current constitutional commitments to liberty, autonomy, and human dignity entail that it legally recognize the right to be of any body size, including the right to be fat. This analysis has traced the tradition of mind-body dualism as a central cause for our ongoing neglect of body size as a significant domain of rights and presented affirmative approaches to the fat body as an alternative to its prevalent negation. Recognizing the recent critique of this dualism, and the potential contribution of phenomenological accounts of body size, this Article has argued that we can no longer omit the realm of bodily existence—of eating, moving and generally existing corporeally—from the rights framework.²⁷⁴

Being directly or indirectly targeted by laws and regulations that mark the fat body as a body that merits correction makes it difficult for fat persons to maintain a sense of dignity and of self worth. Current legal arrangements deprive fat

Overweight Women, in INTERPRETING WEIGHT: THE SOCIAL MANAGEMENT OF FATNESS AND THINNESS, *supra* note 93, at 29, 35-40 (providing a sociological account of resistance to the notion that fat people are jolly or funny).

273. GAIL WEISS, BODY IMAGES: EMBODIMENT AS INTERCORPOREALITY 5 (1999).

274. Indeed, there are other aspects of embodied experience that such recognition would render worthy of renewed consideration, such as nudity or dress style. The latter topic has been the subject of legal scholarship in recent years. *See, e.g.*, sources cited *supra* note 138-139. As I maintained throughout this Article, focusing on weight is particularly timely and important because recently it has become the focus of extensive and innovative legal regulation and because it is a central axis of meaning in the lives of many individuals in American society.

persons of a sense of equal entitlement to take part in the social, political, and economical realms. Body size is intrinsically valuable both for one's sense of personhood and for one's interactions with the physical and social world. The antidiscrimination framework does not fully and accurately capture what is being denied to fat people when their body size is targeted. Because embodied existence is an important locus of human experience, liberty is a more appropriate basis for the right to any body size. The legal protections that would derive from liberty have the power to guard individuals against legal and social interference with the intimate domain of body size and the practices associated with it.

Indeed, the argument that our contemporary map of basic rights should open up to include rights related to bodily practices in general and to body size in particular is far from conceptually trivial or simple to apply. The implications of a legal recognition of the right to be fat will unfold if and when such a right is recognized. Until then, my hope is that it would no longer be possible to offhandedly recruit the law to "the war against obesity." Every time the law is invited to take part, whether directly or indirectly, in narrowing the scope of liberties or in limiting the opportunities of fat people, lawmakers should pause to consider fatness not merely through the reductive and impoverished medical and instrumental vocabularies, but also through a humanist framework that recognizes the potential richness and uniqueness of experiences of every body size.

Tipping the Scale: A Place for Childhood Obesity in the Evolving Legal Framework of Child Abuse and Neglect

Shauneen M. Garrahan* & Andrew W. Eichner**

INTRODUCTION.....	338
I. HISTORICAL AND SCIENTIFIC PERSPECTIVES ON CHILDHOOD OBESITY.....	339
A. DEFINING OBESITY IN THE MEDICAL FIELD	340
B. ORIGINS OF THE CHILDHOOD OBESITY EPIDEMIC.....	340
C. CAUSES OF CHILDHOOD OBESITY	342
1. FACTORS WITHIN PARENTAL CONTROL LINKED TO CHILDHOOD OBESITY.....	342
i. THE ROLE OF HEREDITY AND GENETIC SUSCEPTIBILITY	345
ii. THE ROLE OF CHEMICAL FACTORS	347
II. CHILD PROTECTION IN THE LEGAL SYSTEM AND THE BALANCING OF PARENTAL RIGHTS	348
A. THE HISTORICAL DEVELOPMENT OF CHILD PROTECTION LAWS.....	349
B. SAVING CHILDREN FROM ABUSE AND NEGLECT IN THE PRESENT DAY...	351
C. RELEVANT PARENTAL RIGHTS AND DUTIES TO CHILDREN.....	354
III. CHILDHOOD OBESITY IN THE COURTS.....	356
IV. THE FUTURE DIRECTION OF THE LEGAL FRAMEWORK FOR CHILDHOOD OBESITY.....	364
A. DEVELOPING A JUDICIAL AND LEGISLATIVE STRUCTURE TO ADDRESS CHILDHOOD OBESITY.....	364
1. SUGGESTIONS FOR FUTURE DEVELOPMENTS IN JUDICIAL INTERPRETATION.....	364

* J.D., The University of Texas School of Law, 2012. B.A., Amherst College, 2007.

** J.D., The University of Texas School of Law, 2012. B.A., Boston University, 2009. The authors would like to thank Professor Allison Benesch for her guidance, instruction, and expertise.

2. SUGGESTIONS FOR FUTURE LEGISLATIVE DEVELOPMENTS	365
B. CHILDHOOD OBESITY AND CHILD PROTECTION POLICY	
RECOMMENDATIONS	366
CONCLUSION	369

INTRODUCTION

In 2009, a South Carolina mother named Jerri Gray was charged with criminally neglecting her fourteen-year-old son, Alexander Draper.¹ The State removed her son from her custody and placed him in foster care.² Even as of August 2011, two years later, Gray's charges were still pending and Draper remained with his aunt.³

It is a well-known and sobering reality that child protective systems across the United States often must separate children from their abusive or neglectful parents in order to protect them from the harm inevitably caused by this type of home environment. Yet, in Ms. Gray's case, her negligent behavior was not of a kind traditionally associated with child neglect. When removed from his mother's custody, Alexander Draper weighed 555 pounds⁴—well beyond a healthy weight for his age. Ms. Gray's arrest came shortly after she missed a custody hearing, which was scheduled after doctors had expressed concerns to social services about her son's weight.⁵

Though the story of Jerri Gray and her son may seem unusual, it is not the only one of its kind. Numerous state agencies around the country have begun to remove obese children from their parents' custody.⁶ As concerns about childhood obesity continue to grow, courts across the nation will have to struggle with the difficult legal and moral questions that arise in these scenarios. The idea that the government can reach into the traditionally private sphere of the family and remove a child merely on the grounds that the child is overweight is difficult to justify and the lack of a consistent legal framework further complicates the matter.

This Note considers the increasing need for state courts to apply child abuse and neglect laws to issues of childhood obesity and proposes practical reforms that will resolve the legal ambiguities that currently exist in the system. The system that we propose suggests state intervention in cases where parents negligently fail to address the medical needs of their morbidly obese children. In Part I, we examine historical and scientific perspectives on childhood obesity.

1. See Ron Barnett, *S.C. Case Looks on Child Obesity as Child Abuse. But Is It?*, USA TODAY, July 23, 2009, http://www.usatoday.com/news/health/weightloss/2009-07-20-obesityboy_N.htm.

2. *Id.*

3. Julianne Hing, *Jezebels, Welfare Queens—And Now, Criminally Bad Black Moms*, COLORLINES, Aug. 8, 2011, http://colorlines.com/archives/2011/08/the_criminal_justice_systems_hit_and_run_of_black_moms_in_the_us.html.

4. Gaëlle Faure, *Should Parents of Obese Kids Lose Custody?*, TIME, Oct. 16, 2009, <http://www.time.com/time/health/article/0,8599,1930772,00.html>.

5. *Id.*

6. See Barnett, *supra* note 1 (“State courts in Texas, Pennsylvania, New York, New Mexico, Indiana and California have grappled with the question in recent years.”); Faure, *supra* note 4 (“Several other cases in recent years — in California, New Mexico, Texas and New York, as well as Canada — have garnered attention because a child's obesity resulted in loss of custody.”).

Considering the historic roots of childhood obesity in the United States and exploring the internal and external causes of obesity, we isolate those fundamental causes of childhood obesity that are within parental control. By identifying which of these causes are within parental control, we hope to provide clarity necessary to develop an effective legal standard that can serve as a guideline for legislatures to adopt and courts to enforce.

Part II describes the development of child protection laws in the United States and provides the framework for comparing childhood obesity to child abuse and neglect. The history of child abuse laws in the United States indicates a general progression towards greater government involvement in the family sphere when negligent parental actions put the health of a child at risk. The development of child protection laws nationwide indicates a trend towards earlier and more aggressive intervention.

With this understanding of the current law, Part III presents recent court cases that have examined the question of whether removal is warranted by a child's obesity and evaluates the circumstances surrounding those decisions in order to determine the likely future direction of judicial treatment of this issue. We argue that the courts should employ the same legal standard in childhood obesity cases that they use for determining medical neglect.

Finally, Part IV proposes recommendations for future developments in child protection law and policy relating to childhood obesity. These suggestions include modifying the law to encompass morbid childhood obesity as part of medical neglect and permitting child protection services (CPS) to intervene earlier in morbid childhood obesity cases as a means of reducing the need for later removal. While these reforms would increase the government's role in regulating the sphere of the family, they are intended to protect morbidly obese children, not to infringe the natural rights of responsible parents. The ultimate goal in all proposed reforms is to protect the sanctity of the family by informing parents of the dangers of childhood obesity well before the State must take drastic action.

I. HISTORICAL AND SCIENTIFIC PERSPECTIVES ON CHILDHOOD OBESITY

This Part explores the history of childhood obesity and examines some of the leading scientific perspectives regarding the causes of the current childhood obesity epidemic. This information provides useful background for the later discussion of the legal issues addressed in this Note. It also contextualizes the recommendations for future development of child obesity protection measures across the United States. It is important to understand this background because it has complicated courts' analyses as to whether obesity is a result of parental neglect or, alternatively, factors beyond parental control.

A. Defining Obesity in the Medical Field

Body Mass Index (BMI) is the focal point for defining obesity in children. Unlike adults, whose weight status is determined by specifically set BMI categories,⁷ the weight status of children is determined by using an age- and sex-specific percentile for BMI to reflect the fact that children's body composition varies with both age and gender.⁸

Children with abnormally high BMI levels fall into one of three categories. An "overweight" child has "a BMI at or above the 85th percentile and lower than the 95th percentile for children of the same age and sex."⁹ An "obese" child has "a BMI at or above the 95th percentile."¹⁰ Finally, a "morbidly obese" child has a BMI over the 99th percentile.¹¹

This Note's legal discussion centers primarily on morbidly obese children. All parents would benefit from knowing about the importance of healthy eating and the responsibilities parents have to attend to the weight of their children well before their children become morbidly obese. However, in the interest of protecting the private family sphere and preserving limited state resources, intervention should focus on cases involving morbidly obese children, whose health is most significantly at risk. The court cases discussed in Part III focus entirely on this bracket of the epidemic, and the policy recommendations that we promote in Part IV are also largely intended to prevent children from becoming morbidly obese and to take legal action to protect those that already are.

B. Origins of the Childhood Obesity Epidemic

In order to understand the severity of the modern obesity epidemic, it is helpful to discuss the development of the problem. Morbid childhood obesity is a modern phenomenon that justifies greater state intervention. Until the last decades of the nineteenth century, the primary nutritional concerns relating to children's health were not about food excess but rather about food scarcity and childhood malnutrition.¹² Hopes of improving chances of survival and productivity greatly incentivized parents to increase BMI for children in the underweight range.¹³

By the early years of the twentieth century, federal, state, and local

7. *Basics About Childhood Obesity*, CDC, <http://www.cdc.gov/obesity/childhood/basics.html> (last updated Apr. 26, 2011).

8. *Id.*

9. *Id.*

10. *Id.*

11. See Lindsey Murtagh & David S. Ludwig, *State Intervention in Life-Threatening Childhood Obesity*, 306 JAMA 206, 206 (2011) ("Severe obesity . . . [is] characterized by a body mass index (BMI) at or beyond the 99th percentile . . .").

12. See Benjamin Cabellero, *The Global Epidemic of Obesity: An Overview*, 29 EPIDEMIOLOGICAL REV. 1, 1 (2007) ("Until the last decades of the 19th century, developed countries were still struggling with poverty, malnutrition, and communicable diseases.").

13. See *id.* ("Moving the body mass index (BMI) distribution of the population from the underweight range toward normality had an important impact on survival and productivity . . .").

intervention in the form of government-subsidized, nutritional school lunches to fight malnutrition became justifiable on the grounds that childhood malnutrition was a serious, though avoidable, trouble.¹⁴ Additionally, with industrialization and the increased availability of commercial food products, malnutrition became less prevalent.¹⁵ However, many parents still acted as though food might not always be available and overfeeding became increasingly common. In regards to early feeding in infancy, doctors observed that it was “very difficult to convince the lay mind that rosy cheeks and a fine weight record can be of unfavorable augury.”¹⁶

By the 1930s, there were indications that the health risks associated with obesity were more widely recognized; for example, during this time life insurance companies were using body weight data to determine premiums, due to the relationship between excess weight and premature death.¹⁷ Levels of obesity continued to rise, and by the early 1950s the direct link between the increasing prevalence of obesity and increasing rates of cardiovascular disease was well established.¹⁸

During the 1970s and 1980s, obesity among six- to eleven-year-olds increased from 6% to 9% for boys and from 6% to 13% for girls.¹⁹ Since then, childhood obesity has continued to increase at an alarming rate. Among preschool children aged two to five, obesity increased from 5% to 10.4% between 1976 and 2008.²⁰ During this time, obesity also swelled from 6.5% to 19.5% among children aged six to eleven and from 5% to 18.1% of adolescents aged twelve to nineteen.²¹ Today, more than nine million American children and adolescents are obese.²²

Because obesity is associated with a number of adverse health outcomes, the

14. See generally GORDON W. GUNDERSON, *THE NATIONAL SCHOOL LUNCH PROGRAM: BACKGROUND AND DEVELOPMENT* 7–17 (2003) (describing examples of various state efforts to improve school lunches and fight against malnutrition).

15. Cabellero, *supra* note 12, at 1.

16. Ian G. Wickes, *Overfeeding in Early Infancy*, 1 BRIT. MED. J. 1178, 1179 (1952) (internal quotation marks omitted). Even today, many parents do not see any harm in having an overweight child. See NAT’L ASS’N TO ADVANCE FAT ACCEPTANCE, *CHILD ADVOCACY TOOLKIT* (2011), http://issuu.com/naafa/docs/naafa_childadvocacy2011combined_v04?viewMode=magazine&mode=embed.

17. Lester Breslow, *Public Health Aspects of Weight Control*, 42 AM. J. PUB. HEALTH 1116, 1118 (1952).

18. *Id.* at 1117.

19. Sara Gable & Susan Lutz, *Household, Parent, and Child Contributions to Childhood Obesity*, 49 FAM. REL. 293, 293 (2000). For an indication as to why obesity levels might be higher amongst girls than boys, see *Active Healthy Living: Prevention of Childhood Obesity Through Increased Physical Activity*, 117 PEDIATRICS 1834, 1835 (2006) (“According to a meta-analysis, boys were approximately 20% more active than girls.”).

20. Cynthia Ogden & Margaret Carroll, *Prevalence of Obesity Among Children and Adolescents: United States, Trends 1963–1965 Through 2007–2008*, NAT’L CTR. FOR HEALTH STATISTICS, CDC 1 (June 2010), http://www.cdc.gov/nchs/data/hestat/obesity_child_07_08/obesity_child_07_08.pdf.

21. *Id.*

22. *Id.*

growing incidence of this condition among children is a serious concern.²³ Obese children are at an increased risk for developing glucose intolerance, high blood pressure and abnormal lipid profiles, as well as chronic illnesses like type 2 diabetes and cardiovascular disease.²⁴ As a result, obesity-related annual hospital costs for children total more than \$121 million each year, over triple the amount from 1979.²⁵

Despite the fact that overnourishment is a large issue in the United States, parents seem to instinctively worry about underfeeding their children. As we will argue in Parts III and IV, state intervention holding parents equally responsible for both over- and undernourishing is the most effective way to combat this misguided instinct. Understanding the similarities between under- and overfeeding provides the background to appreciate why the courts should treat both kinds of neglect as equivalent.

C. Causes of Childhood Obesity

Difficulties in combating childhood obesity, both medically and through the legal system, may be partially explained by the wide variety of factors that directly contribute to the development of the condition.²⁶ In addition to internal factors like hereditary traits and a variety of chemical factors, external factors such as the cultural environment and a lack of parental supervision over children's eating habits may also perpetuate obesity. Thus, the cause of a child's morbid obesity can be difficult for courts to determine. While parental care cannot influence hereditary or chemical factors, it can have an impact on environmental factors such as eating habits. This Section provides a general overview of potential sources of childhood obesity and considers their respective roles in the obesity epidemic.

1. Factors Within Parental Control Linked to Childhood Obesity

Certain external factors have been noted as important in the debate over causes of childhood obesity. When evaluating the possible sources of the obesity epidemic, the impact of raising children in an obesogenic environment²⁷ is not to be understated. Some scientists even believe that, given the short timeframe in which population-level changes in body weight have occurred across the globe, it is almost certain that the causes are environmental and behavioral rather than biological.²⁸ This Subsection presents some of the primary environmental factors

23. Gable & Lutz, *supra* note 19, at 293.

24. *Basics About Childhood Obesity*, *supra* note 7.

25. *Id.*

26. Body weight is thought to be "the result of a combination of genetic, metabolic, behavioral, environmental, cultural, and socioeconomic influences." Office of the Surgeon Gen., *The Facts About Overweight and Obesity*, in *CHILDHOOD OBESITY IN THE UNITED STATES* 123, 127 (Marie K. Frugier ed., 2004).

²⁷ See *infra* note 55.

28. Jennifer A. Linde & Robert W. Jeffery, *Evolving Environmental Factors in the Obesity Epidemic*, in *OBESITY EPIDEMIOLOGY: FROM AETIOLOGY TO PUBLIC HEALTH* 119 (David Crawford

attributed to the development of childhood obesity, specifically the role of parents, the evolution of the obesogenic environment, and the impact of sociocultural and socioeconomic status.

i. The Impact of Parents on Childhood Obesity

Because parents directly influence their children's eating habits and weight in a variety of ways, the legal system must recognize parental accountability for childhood obesity. One such influence involves the type of food that parents choose to have in the house. Not surprisingly, children are more likely to be obese if they live in a household where prepared food items high in fat and sodium are frequently served.²⁹ One study also showed that between 1977 and 1998, parents substantially increased the size of portions they served to their children.³⁰ Generally speaking, today's children consume approximately 350 more calories per day than children did in the 1970s.³¹ This problematic trend increases the risk of childhood obesity.

Parents also have the ability to influence their children's eating habits by modeling an unhealthy lifestyle for their children. Children born to obese parents are much more likely to be obese.³² A few long-term studies have shown that the daughter of an overweight mother is ten times more likely to be obese by the time she reaches the age of eight than a daughter born to a slim mother.³³ Likewise, according to one group of researchers, the son of an obese male is six times more likely to be overweight.³⁴ According to the Early Bird Diabetes Project, overeating behavior learned from parents, rather than genetics, is the primary cause of childhood obesity.³⁵ Although scholars often cite lack of physical activity as a major cause of childhood obesity, according to one study "physical activity does not lead to obesity, but rather obesity to inactivity, suggesting that the primary cause of childhood obesity is overnutrition."³⁶ The inactivity of parents may also negatively inspire children to behave in

et al. eds., 2d ed. 2010).

29. Gable & Lutz, *supra* note 19, at 293.

30. See generally Samara Nielsen & Barry Popkin, *Patterns and Trends in Food Portion Sizes, 1977-1998*, 289 JAMA 450 (2003) (describing the trends of parents feeding their children from 1977 to 1998). For example, the average number of calories in a portion of salty snacks increased from 132 to 225 and hamburger portions increased from 389 to 486 calories. *Id.* at 452 tbl.2.

31. *Today's Kids Are Fat. Why? They Eat More*, U.S. NEWS, May 11, 2009, <http://health.usnews.com/health-news/blogs/on-parenting/2009/05/11/todays-kids-are-fat-why-they-eat-more>.

32. Debra Kibbe & Richard Offner, *Childhood Obesity-Advancing Effective Prevention and Treatment: An Overview for Health Professionals*, NAT'L INST. FOR HEALTH CARE MGMT. FOUND. 5 (Apr. 9, 2003), <http://www.nihcm.org/pdf/ChildObesityOverview.pdf>.

33. Christopher Hope, *Fat Parents to Blame for Childhood Obesity Epidemic by Over-Feeding Under-Fives, Study Finds*, THE TELEGRAPH, Jan. 31, 2010, <http://www.telegraph.co.uk/news/uknews/7103587/Fat-parents-to-blame-for-childhood-obesity-epidemic-by-over-feeding-under-fives-study-finds.html>.

34. *Id.*

35. *Id.*

36. *Id.*

unproductive and unhealthy ways by influencing children to choose a sedentary lifestyle early on.³⁷ Because these parental factors are controllable, the courts should carefully consider these influences when allocating responsibility in cases of morbid childhood obesity.

ii. The Impact of Sociological, Economic, and Cultural Factors on Childhood Obesity

Many scientists believe that there are also a number of sociological, economic, and cultural factors that directly impact the obesity epidemic, complicating the attribution of fault for a child's obesity. The years of the obesity epidemic have been a period of considerable change in the ethnic and cultural mix of many developed countries. The United States, long considered a cultural melting pot,³⁸ has become increasingly diverse, with minority groups making up a growing percentage of the population in every state except for West Virginia.³⁹ The changing ethnocultural atmosphere in the United States relates to ethnic disparities in obesity prevalence amongst American children.⁴⁰ As of 2008, 26.8% of Mexican-American male youths were obese compared with 16.7% of non-Hispanic white male youths.⁴¹ In addition, a staggering 29.2% of non-Hispanic black female youths were obese, compared to 14.5% of non-Hispanic white female youths.⁴² Considering these racial dividing lines, differences in weight appear at least partially attributable to ethnocultural variation.⁴³

Economic disparities may also in part account for high rates of childhood obesity amongst certain social groups. Studies have indicated that there is a socioeconomic gradient in diet in which persons in higher socioeconomic groups tend to have a healthier diet, characterized by greater consumption of fruit, vegetables, and lower-fat milk, as well as a lower intake of fats.⁴⁴ This disparity may be a reflection of an individual's economic capacity to purchase healthy foods, which are more expensive than less nutritious food items.⁴⁵ The living conditions that lower socioeconomic classes face also may contribute to the

37. See generally Lynn L. Moore et al., *Influence of Parents' Physical Activity Levels on Activity Levels of Young Children*, 118 J. PEDIATRICS 215 (1991) (describing the influence of parental activity levels on the activity levels of their children).

38. See, e.g., 'Melting Pot' America, BBC, May 12, 2006, <http://news.bbc.co.uk/2/hi/americas/4931534.stm>.

39. Report: *Diversity Growing in Nearly Every State*, MSNBC Aug. 17, 2006, http://www.msnbc.msn.com/id/14348539/ns/us_news-life/t/report-diversity-growing-nearly-every-state/#.TovN_3GQ324.

40. Ogden & Carroll, *supra* note 20, at 1–2.

41. *Id.* at 2.

42. *Id.*

43. For a comprehensive discussion of the ethnic differences between groups which may contribute to obesity patterns, see generally Patricia B. Crawford et al., *Ethnic Issues in the Epidemiology of Childhood Obesity*, 48 PEDIATRIC CLINICS N. AM. 855 (2001).

44. Lindsay McLaren, *Socioeconomic Status and Obesity*, 29 EPIDEMIOLOGIC REV. 29, 35 (2007).

45. *Id.*

childhood obesity problem among these groups. Living in disadvantaged neighborhoods can present many obstacles for children's weight, including "less access to healthy foods and more unhealthy fast-food outlets."⁴⁶ Children living in these neighborhoods also often lack safe places to play outdoors, reducing opportunities for energy expenditure through physical activity.⁴⁷

Though the relative contribution of each of these causes to childhood obesity is unknown, the combination of social, economic and cultural factors is clearly important in future efforts to understand and ultimately resolve the problem of childhood obesity. Though representatives from child protective services should be aware of these factors, courts should refrain from mitigating parental responsibility on the basis of culture or socioeconomic status. Also, while there is debate over whether the legal system should be more lenient towards parents who are stuck in "food deserts" without safe places for exercise, it is important that the child's health be given first consideration. Cases will only be resolved in a satisfactory manner if the courts do not treat socioeconomic factors as excuses, but only as mitigating factors in a comprehensive analysis of the causes of a child's morbid obesity. While child protection services must vigilantly guard against drawing inferences about parental practices based on unreliable and prejudicial socioeconomic factors alone, by continuing to study and acknowledge these factors, health advocates may learn to target the specific practices that lead to the disproportionate prevalence of obesity in these groups.

2. Internal Factors Linked to Childhood Obesity

Heredity and chemical factors are the two internal variables most commonly linked to childhood obesity. To understand the actual impact of these traits on the childhood obesity epidemic and the role that they should, therefore, play in evaluating whether parents should be held responsible, it is important to consider their importance and biological connection to obesity.

i. The Role of Heredity and Genetic Susceptibility

Scientists and nutritionists commonly document heredity's role in creating genetic susceptibility to obesity for both children and adults.⁴⁸ A twin study

46 *Childhood Obesity Linked to Neighborhood Social and Economic Status*, GROUP HEALTH RES. INST. (June 11, 2010), <http://www.grouphealthresearch.org/newsroom/newsrel/2010/100611.html>. But see Sarah Kliff, *Don't Blame Food Deserts for Obesity*, WASH. POST, Mar. 7, 2012, http://www.washingtonpost.com/blogs/ezra-klein/post/dont-blame-food-deserts-for-obesity/2012/03/06/gIQAwoEUvR_blog.html.

47. *Childhood Obesity Linked to Neighborhood Social and Economic Status*, *supra* note 46.

48. See, e.g., Jane Wardle et al., *Evidence for a Strong Genetic Influence on Childhood Adiposity Despite the Force of the Obesogenic Environment*, 87 AM. J. CLIN. NUTRITION 398, 398 (2008) ("If genetic influence is important, monozygotic twins must be more similar than dizygotic twins."). Specifically, "[t]win studies can . . . estimate the extent to which the family environment makes family members more similar than would be expected from their genetic relatedness . . . [and] can go beyond pitting nature against nurture to consider interactions between genes and environment." *Id.*

published in 2008 in the *American Journal of Clinical Nutrition* examined over five thousand families with twins born between 1994 and 1996.⁴⁹ The results of the study were surprising: the authors calculated that 77% of the BMI variation between children was attributable to genetic differences.⁵⁰ The authors of the study urged that excessive weight gain in children should be more greatly attributed to genetics than to parental neglect.⁵¹

Similarly, in formulating parental advice, some nutritionists have focused their attention on the role of genetics in weight gain. In exploring the idea of personalized dietary advice based on a person's DNA, some nutritionists have argued that "genetic testing . . . might be used to predict . . . [an individual's] susceptibility to certain dietary-related conditions."⁵² By focusing on a person's genetic predisposition towards obesity instead of blaming parents, nutritionists can better target the individual's nutritional needs before obesity sets in and can "direct[] more intensive lifestyle interventions to [identified] high-risk groups."⁵³

These studies indicate that genetic research should continue to play a role in society's exploration of possible means of battling childhood obesity and genes should be a factor that the legal system considers in determining the responsibility of parents for the obesity of their children. Though changes in a population's genetic makeup occur too slowly to be responsible for the rapid rise in obesity, genes do play a role in the development of obesity⁵⁴ and, therefore, are an important consideration in constructing a comprehensive picture of the causes of childhood obesity. The relationship between genetics and the modern obesogenic environment⁵⁵ is only beginning to be understood and continued attention must be paid to the subject by those looking to mitigate the dangers of childhood obesity.

49. *Id.* at 399. The total sample group was composed of 5,902 families. The twins were all between ages eight and eleven at the time of the study. *Id.*

50. William Saletan, *Fat Chance: Obesity, Genetics, and Responsibility*, SLATE, Feb. 15, 2008, http://www.slate.com/articles/health_and_science/human_nature/2008/02/fat_chance.html; see Wardle et al., *supra* note 48, at 401 ("These results indicate that adiposity in preadolescent children born since the onset of the obesity epidemic is highly heritable.").

51. See Wardle et al., *supra* note 48, at 403 ("What is important is this finding means that 'blaming' parents is wrong.").

52. See Michiel Korthals, *Three Main Areas of Concern, Four Trends in Genomics and Existing Deficiencies in Academic Ethics*, in GENOMICS, OBESITY AND THE STRUGGLE OVER RESPONSIBILITIES 59, 65–66 (Michiel Korthals ed., 2011).

53. *Genomics and Health: Obesity and Genomics*, CDC, <http://www.cdc.gov/genomics/resources/diseases/obesity/obesedit.htm> (last updated Apr. 20, 2010).

54. *Obesity & Genetics*, CDC, <http://www.cdc.gov/Features/Obesity/> (last updated Jan. 19, 2010).

55. An "obesogenic environment" is defined as an environment promoting weight gain and which is not conducive to weight loss—in other words, an environment that contributes to obesity. See generally Pamela Powell et al., *What Is Obesogenic Environment?*, U. NEV. COOPERATIVE EXTENSION (2010), <http://www.unce.unr.edu/publications/files/hn/2010/fs1011.pdf> (describing the obesogenic environment and how it contributes to obesity).

ii. *The Role of Chemical Factors*

In addition to each individual's hereditary design, chemical factors are other immutable variables that influence a person's weight. Two notable examples of chemical involvement in the obesity epidemic are the hormone leptin and the interference of chemicals known as endocrine-disrupting chemicals (EDCs), or what are more commonly referred to as obesogens.⁵⁶

In the mid-1990s, scientists discovered leptin, which is "an appetite-suppressing hormone secreted by fat tissue."⁵⁷ In the years since, scientists have continued to study the hormone, discovering that it plays a critical role in controlling the eating habits of humans. Humans have developed a complex physiological system for optimally regulating fuel stores and energy balance, in which leptin and its receptor signal nutritional status to other physiological systems.⁵⁸ Leptin deficiency has been shown to result in excessive obesity in children,⁵⁹ particularly in children who suffer from other genetic diseases, such as Down syndrome.⁶⁰ Though genetically based leptin deficiency is beyond parental control, knowledge of a child's condition could help a parent determine what needs to be done to maintain a healthy weight.

As medical science has advanced, scientists have continued to research ways to address leptin deficiency for both children and adults. Experimentation has shown that daily subcutaneous injections of leptin can drastically and beneficially reduce fat mass and body weight.⁶¹ However, treatments for leptin deficiency remain imperfect; many individuals undergoing leptin supplementation rebound back after a temporary period of weight loss.⁶² The tendency of obese individuals to have increased leptin resistance also complicates matters,⁶³ leaving scientists

56. Stephen Perrine & Heather Hurlock, *Fat Epidemic Linked to Chemicals Run Amok*, MSNBC, Mar. 8, 2010, http://www.msnbc.msn.com/id/35315651/ns/health-diet_and_nutrition/t/fat-epidemic-linked-chemicals-run-amok/#.ToaPe0_aFKE.

57. *Obesity: Reviving the Promise of Leptin*, SCIENCE DAILY, Jan. 6, 2009, <http://www.sciencedaily.com/releases/2009/01/090106144937.htm>.

58. Jeffrey M. Friedman & Jeffrey L. Halaas, *Leptin and the Regulation of Body Weight in Mammals*, 395 NATURE 763, 763 (1998).

59. See I. Sadaf Farooqi, *Genes and Obesity*, in CLINICAL OBESITY IN ADULTS AND CHILDREN 81, 86 (Peter G. Kopelman et al. eds., 2d ed. 2005) (discussing the impact of leptin deficiency on the weight of children).

60. See *Obesity-Related Hormone Is Higher in Children with Down Syndrome*, SCIENCE DAILY, Oct. 26, 2007, <http://www.sciencedaily.com/releases/2007/10/071026124010.htm> ("The hormone, leptin, may contribute to the known higher risk of obesity among children and adults with Down syndrome.").

61. Stephen O'Rahilly & I. Sadaf Farooqi, *Genetics of Obesity*, 361 PHIL. TRANS. R. SOC. B 1095, 1101 (2006).

62. See *Obesity: Reviving the Promise of Leptin*, *supra* note 57 ("Unfortunately, when obese humans took the hormone [leptin], they lost weight only temporarily – then rebounded back."). This is not to say that the control of leptin deficiency has been totally ineffective. At least one scientist has reported success with weight management through leptin injections with children. See Farooqi, *supra* note 59, at 87 ("Thus far, we have been able to regain control of weight loss by increasing the dose of leptin.").

63. See *Obesity: Reviving the Promise of Leptin*, *supra* note 57 ("Most humans who are obese

and doctors with the question of how to resolve leptin deficiency appropriately, while circumventing a person's heightened resistance to the hormone.⁶⁴

In addition to struggling with leptin deficiency, scientists must also resolve difficulties caused by other chemical factors, such as obesogens. These chemicals disrupt the function of hormonal systems and are believed to "lead to weight gain and, in turn, numerous diseases that curse the American populace."⁶⁵ Obesogens can enter our bodies from a variety of sources: natural hormones found in soy products, hormones administered to animals, plastics in some food and drink packaging, ingredients added to processed foods, and pesticides used on produce.⁶⁶ Once internalized by an individual, obesogens can act in a variety of ways, including mimicking human hormones, misprogramming stem cells, and altering gene function.⁶⁷

Recent studies have indicated that obesogens may also be an underlying cause of obesity.⁶⁸ This possibility is an especially worrisome prospect for fetuses and newborns, for whom obesogens are thought to "act on genes . . . to turn more precursor cells into fat cells, which stay with you for life[, a]nd . . . may alter metabolic rate[] so that the body hoards calories rather than burning them, like a physiological Scrooge."⁶⁹ Unfortunately, it seems that scientists understand the exact connection between obesity and obesogens even less than the genetics behind leptin deficiency.⁷⁰

In the debate over the contribution of different variables to the childhood obesity epidemic, chemical factors, whether internal since birth or later introduced into the body from an external source, are much like genetics. Both are immutable physiological factors that can contribute to obesity in certain individuals, but cannot be identified as the sole cause of excessive weight gain.

II. CHILD PROTECTION IN THE LEGAL SYSTEM AND THE BALANCING OF PARENTAL RIGHTS

After decades of development, today the United States provides a fairly robust system of child protection laws. This Part will recount the evolution of the legal framework that has led to the current standards for both child and parental rights, as well as the place for childhood obesity within the existing system.

have leptin resistance." (internal quotation marks omitted)).

64 *Id.* ("For years, industry and academic laboratories have been searching for a drug to make peoples' brains sensitive to leptin again, without success.").

65. Perrine & Hurlock, *supra* note 56.

66. *Id.*

67. *Id.*

68. *Id.*

69. Sharon Begley, *Born To Be Big*, THE DAILY BEAST, Sept. 10, 2009, <http://www.thedailybeast.com/newsweek/2009/09/10/born-to-be-big.html>.

70. Considering "the ubiquity of obesogens, traces of which are found in the blood or tissue of virtually every American," it is unclear why the chemicals do not have an equally drastic affect on the weight of all individuals; "[f]or now, all scientists can say is that even a slight variation in the amounts and timing of exposures might matter, as could individual differences in physiology." *Id.*

A. The Historical Development of Child Protection Laws

Over the course of U.S. history, child protection laws have “evolved according to changing beliefs and attitudes about what role government should play in the protection and care of abused and neglected children.”⁷¹ The result is a system that has increased protections for children by enlarging government involvement in American family life.

At the time of the nation’s founding, there were no real governmental protective measures for abused or neglected children.⁷² In the nineteenth century, the legal system still did little to address the need for child protection reforms.⁷³ In 1899, the United States first established juvenile courts, which “were not focused on protecting maltreated children as much as they were concerned with keeping the streets free of poor and vagrant children.”⁷⁴

During the twentieth century, public concerns over child protection increased dramatically and, in response, both state and federal governments became far more involved in efforts to protect children. The early 1900s saw the genesis of a wave of new organizations designed to protect children and their rights.⁷⁵ In 1932, the Supreme Court, in *Powell v. Alabama*, expressly held that children have constitutional rights⁷⁶ when it declared that Alabama had denied the child defendants—“young, ignorant, illiterate, [and] surrounded by hostile sentiment”⁷⁷—their constitutional right to counsel in violation of the Fourteenth Amendment.⁷⁸ The Court’s dicta has been interpreted as declaring that “children clearly had certain fundamental constitutional rights such as a Thirteenth Amendment right not to be enslaved and rights under the Due Process Clause not to be deprived arbitrarily of life or liberty,”⁷⁹ providing constitutional justification for modern child protection laws.

Three years later, Congress passed the Social Security Act of 1935 (SSA), a monumental piece of New Deal legislation that introduced child protection

71. Kasia O’Neill Murray & Sarah Gesiriech, *A Brief Legislative History of the Child Welfare System*, PEW CHARITABLE TRUSTS 1 (2004), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Foster_care_reform/LegislativeHistory2004.pdf.

72. *Id.*

73. Most of the efforts to help children at this time were undertaken by private actors. In the early 1800s private religious and charitable organizations had established the first orphanages and by the latter half of the nineteenth century private agencies had begun to place orphans with foster families “out of concern about the effects of growing up in orphanages.” *Id.* In these early foster family appointments, however, prospective families were rarely screened and agencies seldom monitored placements. *Id.*

74. *Child Maltreatment*, NAT’L ASS’N COUNS. FOR CHILD., <http://www.naccchildlaw.org/?page=ChildMaltreatment> (last visited Apr. 10, 2012).

75. *Id.*

76. Anne C. Dailey, *Children’s Constitutional Rights*, 95 MINN. L. REV. 2099, 2099–100 (2011).

77. *Powell v. Alabama*, 287 U.S. 45, 57–58 (1932).

78. *Id.* at 58 (“Under the circumstances disclosed, we hold that defendants were not accorded the right of counsel in any substantial sense.”).

79. Dailey, *supra* note 76, at 2100.

provisions. The SSA's Aid to Dependent Children (ADC) provision⁸⁰ authorized the first federal grant for child welfare services,⁸¹ which served as an impetus for states to establish their own child protection measures through child welfare agencies and local programs that deliver child welfare services.⁸² In 1961, legislative amendments to the SSA created mandatory ADC requirements stating that states could not ignore the needs of children in unsuitable living situations. Specifically, it has been interpreted as demanding that the states provide appropriate services to make the child's current house suitable or otherwise relocate the child to a more suitable living situation while providing financial support on behalf of the child.⁸³ In the following year, an additional set of changes, collectively titled the Public Welfare Amendments, required state agencies to report to the court system those "families whose children were identified as candidates for removal."⁸⁴ This led to a growing number of out-of-home placements of children in the mid- to late-1960s.⁸⁵

After the child welfare provisions of the SSA, the 1974 Child Abuse Prevention and Treatment Act (CAPTA) is the second most significant piece of federal child protection legislation.⁸⁶ CAPTA was the first major federal legislation to address child abuse and neglect.⁸⁷ Congress designed CAPTA primarily to focus on physical abuse cases by providing states with federal funding for the investigation and prevention of child maltreatment⁸⁸ conditioned on the states' adoption of mandatory reporting laws with reporter immunity, confidentiality, and the appointment of guardians ad litem for children.⁸⁹ In recent decades, there have been numerous other state and federal legislative

80. In 1962, the program's name was changed to Aid to Families with Dependent Children (AFDC). See Murray & Gesiriech, *supra* note 71, at 2.

81. *Id.* at 1.

82. *Id.*

83. See *id.* at 2 (describing the legislative amendment introducing the Flemming Rule into the Act, which demands that "states could not simply ignore the needs of children living in households deemed to be unsuitable[, but] [i]nstead, . . . required states to either (1) provide appropriate services to make the home suitable, or (2) move the child to a suitable placement while continuing to provide financial support on behalf of the child").

84. *Id.*

85. *Id.*

86. At the time of its passage, CAPTA was criticized for infringing upon federalism. See Caroline T. Trost, Note, *Chilling Child Abuse Reporting: Rethinking the CAPTA Amendments*, 51 VAND. L. REV. 183, 194 (1998) (citation omitted) ("[CAPTA] was still criticized both for not providing enough funding and for involving the federal government in an area that had thus far been reserved entirely to the states." (citation omitted)). The changes we propose in this Note are focused on state-level reforms and respect the boundaries of the Tenth Amendment.

87. *Id.*

88. *Child Maltreatment*, *supra* note 74; see 42 U.S.C. § 5106c (2010) (describing CAPTA-based grants to states for programs designed to curb child abuse and neglect).

89. See *Major Federal Legislation Concerned with Child Protection, Child Welfare, and Adoption*, U.S. DEP'T OF HEALTH & HUMAN SERVS. 2 (Apr. 2011), www.childwelfare.gov/pubs/otherpubs/majorfedlegis.pdf ("[CAPTA] also prompts responses at the State level, including enactment of State legislation, development or revision of State agency policy and regulations, and implementation of new programs.").

pushes to improve the safety of children by protecting them from abuse and neglect.⁹⁰ While one could devote an entire article to exploring these legislative actions and their effects, the underlying point is nevertheless clear: the government has come to recognize the importance of protecting children from harmful living situations and has come to demand that the State intervene in the family sphere when parents have failed to supply suitable care. Just as the State has a strong interest in ensuring justice for children who suffer abuse from strangers, government intervention is also necessary to protect children from irreparable harm caused by a family member. The legal system focuses on the fact that an unjustifiable harm has occurred, regardless of its origin.

B. Saving Children from Abuse and Neglect in the Present Day

This Section will attempt to present a coherent framework for understanding the current status of abuse and neglect within the American legal system. Evaluating the practice of child protection in the modern legal system⁹¹ involves first examining and defining the key legal terms used to identify child maltreatment: “child abuse” and “neglect.” Because the laws regarding child abuse and neglect vary from state to state, there is no single national definition for these terms.⁹² Commonalities, however, run through various states’ definitions of child mistreatment. In almost every state, the concept of child maltreatment encompasses physical abuse, sexual abuse, neglect, and emotional

90. See generally Murray & Gesiriech, *supra* note 71 (detailing legislative acts and reforms that have been designed to benefit and protect children). For an example of another important piece of legislation, see Marygold S. Melli, *Protecting Children in Child Abuse and Neglect Proceedings*, PARENTHOOD IN AMERICA (1998), <http://parenthood.library.wisc.edu/Melli/Melli.html>. The author writes:

The Adoption Assistance and Child Welfare Act of 1980 required states as a condition for receiving federal reimbursement for foster care to create social programs to help the family before a child is at risk and to prevent the need for removal. These services include, for example, temporary child care and counseling services.

Id.

91. Today, as during the early years of child protection laws, “[t]he primary responsibility for child welfare services rests with the States, and each State has its own legal and administrative structures and programs that address the needs of children and families.” *Major Federal Legislation Concerned with Child Protection, Child Welfare, and Adoption*, U.S. DEP’T OF HEALTH & HUMAN SERVS. 1 (Apr. 2011), <http://www.childwelfare.gov/pubs/otherpubs/majorfedlegis.pdf>. The federal government still plays an important role in this system, as states must comply with specific Federal requirements and guidelines in order to be eligible for Federal funding. *Id.* The combined efforts of these multiple levels of government involvement help to achieve more effective protection for children.

92. See *Child Maltreatment*, *supra* note 74 (“Each state provides its own definition of child abuse and neglect.”). See generally *Definitions of Child Abuse and Neglect*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (Feb. 2011), http://www.childwelfare.gov/systemwide/laws_policies/statutes/define.pdf (showing differences between states by providing a state-by-state list of child abuse and neglect laws).

abuse.⁹³ The dividing lines between these four categories of maltreatment are not always clear and it is common for children to be subjected to more than one type of abuse, particularly when emotional abuse is involved. It has been estimated that less than 5% of cases involve only one type of abuse.⁹⁴ This Section will focus on the categories most relevant to childhood morbid obesity: physical abuse and medical neglect.

Physical abuse of a child is one of the most difficult categories of maltreatment to properly define because its origin may be difficult to prove and the intent of the abuser is often hard to discern. The absence of a universally accepted definition for physical abuse complicates the task of understanding the epidemiology of child abuse in all of its forms.⁹⁵ A very simplistic definition of physical abuse is “[n]on-accidental physical injury as a result of caretaker acts,”⁹⁶ which includes, for example, “shaking, slapping, punching, beating, kicking, biting and burning.”⁹⁷

While this broad definition provides some general guidance to the courts as to the types of behavior that constitute physical abuse,⁹⁸ it erroneously focuses on the injurious act rather than on whether the intent of the actor is justified or unjustified. The term “injury” implies some sort of observable physical malady such as a bruise, a cut, or a broken bone. Yet, a test requiring one to identify a physical injury of this kind may lead the court to altogether miss the problem.⁹⁹ Consider the following example: a child and a parent are walking outside and suddenly the parent shoves the child to the ground, breaking his nose on impact. While an injury has obviously been sustained, whether abuse occurred cannot be discerned until the intent of the actor is discovered. If the parent was acting out of the malicious intent, then it is clear that an abusive act has occurred. Alternatively, if the parent pushed the child in order to prevent him from being hit by an oncoming speeding car, then the act was justified and not abusive. An analogous approach to morbid childhood obesity cases would similarly seek to determine the underlying causes of a child’s morbid obesity and whether a parent’s response is reasonable and justified.

It is also extremely difficult to clearly define neglect due to the large number of forms this kind of maltreatment can take. Under state law, neglect is often defined as “the failure of a parent or other person with responsibility for the child to provide needed food, clothing, shelter, medical care, or supervision to the degree that the child’s health, safety, and well-being are threatened with

93. *Id.*; see R. KIM OATES, THE SPECTRUM OF CHILD ABUSE 2 (1996) (“Child abuse can be divided into four broad areas: [p]hysical abuse[,] [s]exual abuse[,] [n]eglect and nonorganic failure to thrive, and [e]motional abuse.”).

94. OATES, *supra* note 93, at 2 (citing P. Ney et al., *The Worst Combination of Child Abuse and Neglect*, 18 CHILD ABUSE & NEGLECT 705 (1994)).

95. *Id.* at 3.

96. *Child Maltreatment*, *supra* note 74 (emphasis omitted) (citing OATES, *supra* note 93).

97. *Id.* (internal citation omitted).

98. See OATES, *supra* note 93, at 2 (noting the advantages of definitions that “recogniz[e] the vulnerability of the child and . . . plac[e] responsibility on the child’s caretaker”).

99. *Id.* at 3.

harm.”¹⁰⁰

Neglect is also considerably more difficult for observers to detect than physical abuse because the changes in the neglected child’s body and behavior are slower to develop and more easily mistaken for symptoms of poor health or a shy personality.¹⁰¹ In some ways, neglect may actually be more injurious to a child than physical abuse. Research shows that neglect can have deeper and longer lasting consequences than physical abuse.¹⁰² Because “[t]he neglected child is treated more as if he were not there, or as if his parents wished he were not there, . . . this insidious and fundamental rejection can inflict deep psychological wounds”¹⁰³ that have the potential for a lifelong negative impact on a child’s mental state. Physically abused children “frequently are cared for in other ways by their abusers,” often receiving “food, clothing, playthings, and even enjoy[ing] good times with others in the family.”¹⁰⁴ By contrast, neglected children are denied many (if not all) of these benefits.

While the level of neglect warranting removal is traditionally associated with a failure to provide food,¹⁰⁵ some courts have begun to acknowledge that neglect could also come in the form of a failure to care for those aspects of the child’s physical well-being that are related to obesity. Most courts that have examined this issue have categorized this failure as a form of medical neglect.¹⁰⁶ Like neglect generally, the definition of medical neglect varies from state to state. For example, seven states define medical neglect as “failing to provide any special medical treatment or mental health care needed by the child,”¹⁰⁷ while four other states define it as “the withholding of medical treatment or nutrition from disabled infants with life-threatening conditions.”¹⁰⁸ Notably, as of February 2011, the other thirty-nine states and the District of Columbia had not provided a specific statutory definition of medical neglect.¹⁰⁹ The absence of a definition in most jurisdictions may complicate the task of courts attempting to apply the legal

100. *Definitions of Child Abuse and Neglect*, *supra* note 92, at 3.

101. Patrick Fagan, *The Child Abuse Crisis: The Disintegration of Marriage, Family, and the American Community*, 1115 HERITAGE FOUND. BACKGROUNDER 1, 3–4 (1997), available at <http://www.heritage.org/research/reports/1997/05/bg1115-the-child-abuse-crisis>.

102. *Id.* at 4.

103. *Id.*

104. *Id.*

105. See generally DIANNE DEPANFILIS, U.S. DEP’T HEALTH & HUMAN SERVS., CHILD NEGLECT: A GUIDE FOR PREVENTION, ASSESSMENT, AND INTERVENTION 89 (2006), available at <http://www.childwelfare.gov/pubs/usermanuals/neglect/neglect.pdf> (“Physical neglect can include not providing adequate food or clothing.”).

106. For examples of courts that have relied on medical factors to justify their findings of neglect see *In re L.T.*, 494 N.W.2d 450, 452–53 (Iowa Ct. App. 1992); *In re D.K.*, 58 Pa. D. & C.4th 353, 356 (Com. Pl. 2002); and *In re G.C.*, 66 S.W.3d 517, 520 (Tex. Ct. App. 2002).

107. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 92, at 3 (definition used in Mississippi, North Dakota, Ohio, Oklahoma, Tennessee, Texas, and West Virginia).

108. *Id.* (definition used in Indiana, Kansas, Minnesota, and Montana).

109. See *Medical Neglect Specifically Defined in Statute*, CASEY FAMILY PROGRAMS (Feb. 2011), <http://www.childwelfarepolicy.org/maps/single?id=144> (providing a comprehensive list of state statutes on medical neglect).

standards for medical neglect to obesity cases.

In sum, it is difficult to determine how exactly childhood obesity fits within the multitiered and complex system of standards grouped under the terms abuse and neglect. This difficulty highlights the need for legislation defining the legal standards for those cases of childhood obesity that ought to be characterized as maltreatment. We will explore this concern in greater depth through the lens of state judicial systems in Part III, where we analyze obesity cases in the state judicial system, and in Part IV, where we present our policy recommendations.

C. Relevant Parental Rights and Duties to Children

Another relevant debate about how childhood obesity fits into the doctrines of child abuse and neglect involves the question of how much control parents should be allowed to exert over their children's lives. This Section examines the roots of parental control within the legal system and explains why parental rights are a double-edged sword. After this analysis, we conclude that while parents should continue to be afforded the *prima facie* right to decide how to feed their children, this right is limited by the responsibility to ensure that their actions do not cause their children irreparable harm.

The historical jurisprudence of parental rights comes from three primary Supreme Court decisions: *Meyer v. Nebraska*,¹¹⁰ *Pierce v. Society of Sisters*,¹¹¹ and *Prince v. Massachusetts*.¹¹² These cases acknowledged that parents have a due process liberty right¹¹³ to control the methods and choices involved in child rearing.¹¹⁴ In identifying the fundamental right of a legal parent over his or her

110. *Meyer v. Nebraska*, 262 U.S. 390 (1923).

111. *Pierce v. Soc'y of Sisters*, 268 U.S. 510 (1925).

112. *Prince v. Massachusetts*, 321 U.S. 158 (1944); see Jessica Dixon Weaver, *The Principle of Subsidiarity Applied: Reforming the Legal Framework To Capture the Psychological Abuse of Children*, 18 VA. J. SOC. POL'Y & L. 247, 270 (2011) ("These three cases form the basis of the legal relationship between parents, children, and the state.").

113. Due process guarantees against the State are derived from the Fourteenth Amendment, which guarantees that "[n]o State . . . shall deprive any person of life, liberty, or property, without due process of law." U.S. CONST. amend. XIV, § 1.

114. See Weaver, *supra* note 112, at 270 nn.127–29. *Meyer v. Nebraska* also held that "a state statute forbidding the teaching of subjects in foreign languages impermissibly interferes with the parents' right to control the education of their children." *Id.* at 270 n.127; see also *Meyer*, 262 U.S. at 402 ("The desire of the Legislature to foster a homogeneous people with American ideals prepared readily to understand current discussions of civic matters is easy to appreciate. Unfortunate experiences during the late war and aversion toward every character of truculent adversaries were certainly enough to quicken that aspiration. But the means adopted, we think, exceed the limitations upon the power of the state and conflict with rights assured to plaintiff in error."). *Pierce v. Society of Sisters* held that "an Oregon statute requiring all children to attend public schools was invalid because it unreasonably interfered with the liberty of parents and guardians to direct the upbringing and education of children under their control." Weaver, *supra* note 112, at 270 n.128; *Pierce*, 268 U.S. at 535 ("The fundamental theory of liberty upon which all governments in this Union repose excludes any general power of the state to standardize its children by forcing them to accept instruction from public teachers only."). *Prince v. Massachusetts* "recogniz[ed] that parents have the right to provide a child with religious training but, when

child, the Court found support for the “parental rights doctrine” through various cases defining the sphere of rights derived from the privacy of the family.¹¹⁵ Parental rights are afforded strict scrutiny within the legal system and “[a] state may infringe on these rights only for a compelling reason and only insofar as that infringement is necessary to protect the state’s interest.”¹¹⁶

Though parental rights play a valuable role in protecting certain family liberties from governmental intervention, these rights are not plenary and may be infringed by the State in certain circumstances.¹¹⁷ In the 1944 case *Prince v. Massachusetts*, Justice Rutledge, writing for the majority, asserted as part of his reasoning that “[a] democratic society rests, for its continuance, upon the healthy, well-rounded growth of young people into full maturity as citizens, with all that implies.”¹¹⁸ According to Justice Rutledge, a state “may secure [this healthy growth] against impeding restraints and dangers”¹¹⁹ by asserting governmental powers, including the power to stop a parent from putting their children under threat of physical danger or either emotional or psychological harm.¹²⁰

When parents threaten the State’s compelling interest in promoting the health of children, through their actions—or, in the case of neglect, inaction—the State reserves the authority to restrict or burden the parental right in order to protect its interests in the welfare of children.¹²¹ Though no single, universal test

children may be harmed by their religious activities, the state has more authority over children.” Weaver, *supra* note 112, at 270 n.129; *Prince*, 321 U.S. at 166–67 (“The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.”).

115. Weaver, *supra* note 112, at 270–71; *see also* Stanley v. Illinois, 405 U.S. 645, 651 (1972) (“It is plain that the interest of a parent in the companionship, care, custody, and management of his or her children ‘come(s) to this Court with a momentum for respect lacking when appeal is made to liberties which derive merely from shifting economic arrangements.’” (quoting Kovacs v. Cooper, 336 U.S. 77, 95 (1949) (Frankfurter, J., concurring))).

116. Weaver, *supra* note 112, at 271; Stanley, 405 U.S. at 652 (“[R]emoving [a child] from the custody of his parents [is] only [acceptable] when his welfare or safety or the protection of the public cannot be adequately safeguarded without removal These are legitimate interests, well within the power of the State to implement. We do not question the assertion that neglectful parents may be separated from their children.” (citation omitted)).

117. *See* Weaver, *supra* note 112, at 271 (“*Prince* established that parental authority is not absolute and can be permissibly restricted, if doing so is in the interests of a child’s welfare.”).

118. *Prince*, 321 U.S. at 168.

119. *Id.*

120. *See id.* at 170 (“Other harmful possibilities could be stated, of emotional excitement and psychological or physical injury. Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.”).

121. *See* JILL GOLDMAN ET AL., A COORDINATED RESPONSE TO CHILD ABUSE AND NEGLECT: THE FOUNDATION FOR PRACTICE 51–52 (2003), *available at* www.childwelfare.gov/pubs/usermanuals/foundation/foundation.pdf. Describing the foundation for the State’s authority, the authors write: “The basis for intervention in child maltreatment is grounded in the concept of *parens patriae*—a legal term that asserts the government’s role in protecting the interests of children and intervening when parents fail to provide proper care.” *Id.* at 51. The authors also note that the “parent-child relationship grants certain rights, duties, and obligations to both parent and child . . . [and if] a parent . . . is unable or unwilling to meet this

determines when children must be removed from parental custody, many states mandate the following requirements before ordering removal: the State must (1) prove imminent danger to the physical health or safety of the child, (2) determine whether it is contrary to the welfare of the child to remain in the home, and (3) make reasonable efforts to prevent the removal of the child from his or her home.¹²²

As evidenced by the third requirement of the above test, states always view the separation of children from their parents as a last resort and will make reasonable efforts to avoid separating a family.¹²³ The State, however, will break apart a family if necessary to protect endangered children.¹²⁴ Though the definition of “reasonable efforts” varies from state to state,¹²⁵ such efforts can include drug rehabilitation, parenting classes, psychological or psychiatric counseling, education or job training, and therapy.¹²⁶

Judges must consider the constitutionally protected parental right against the relatively new threat that childhood obesity presents to the State’s interest in the protecting the children’s health. However, obesity cases would not present an unconstitutional challenge to the parental right if they were framed in terms of the existing standards of medical neglect, since courts have a long history of upholding restriction on the parental right in those situations. In Part III, we analyze judicial decisions that have handled the obesity issue and argue that courts should focus on incorporating the legal issue of childhood morbid obesity into existing standards of medical neglect.

III. CHILDHOOD OBESITY IN THE COURTS

Given the pervasive ambiguity of established child protection laws, it is not surprising that the courts that have begun to address the novel child obesity cases have taken inconsistent approaches.¹²⁷ Most courts have held that states may intervene only in the most extreme circumstances. For example, states may order medical treatment for a child contrary to a parent’s wishes when it is necessary to

responsibility, the State has the power and authority to take action to protect a child from significant harm.” *Id.* at 51–52.

122. See Weaver, *supra* note 112, at 269 (“Most states generally use a three-prong legal standard to determine whether a child should be removed from his or her parents’ home when there are allegations of child abuse and neglect.”).

123. See *id.* at 273 (citing 42 U.S.C.A. § 671(a)(15)(B) (West 2010)) (“If the state can prevent the child from being removed from his or her home, it must make reasonable efforts to do so.”).

124. See *id.* at 274 (“If the current risks or harm to the children cannot be controlled, the state removes the children and places them in foster care.”).

125. For a description of the “reasonable efforts” requirement and its variance from state to state, see *Reasonable Efforts To Preserve or Reunify Families and Achieve Permanency for Children: Summary of State Laws*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (2009), available at www.childwelfare.gov/systemwide/laws_policies/statutes/reunifyall.pdf.

126. Weaver, *supra* note 112, at 275.

127. Compare *In re D.K.*, 58 Pa. D. & C.4th 353, 358 (Com. Pl. 2002) (ordering removal based on classification as a “dependent child”), with *In re L.T.*, 494 N.W.2d 450, 451 (Iowa Ct. App. 1992) (ordering removal based on classification as a “child in need of assistance”).

save the child's life or to avoid serious physical, mental, or emotional harm.¹²⁸ Other courts, however, have used alternative standards for removing children, such as classifying them as "dependent children"¹²⁹ or "children in need of assistance."¹³⁰ Although states have the right to develop their own legal standards, the standards applied by the courts in the following cases are less than ideal. While this Part details the legal standards currently evolving in state courts, Part IV will address the benefits of adopting the predominant approach of applying the standard for medical neglect to these types of cases.

A Pennsylvania case, *In re D.K.*, involved a sixteen-year-old boy who suffered from morbid obesity, weighing 451 pounds despite his five-foot-three stature.¹³¹ Records showed that he had been overweight since infancy and that his parents had never taken him to see a dietician or any other specialist.¹³² In the year prior alone, he had gained one hundred pounds, putting his health in a "life threatening situation."¹³³ In addition to morbid obesity, he suffered from an enlarged liver, hypertension, respiratory problems requiring oxygen at night, insulin resistance, sleep apnea, knee pain, and a depressive disorder.¹³⁴

On the basis of a medical referral, the Northcumberland County Children and Youth Services Department (CYS) initially obtained a voluntary entrustment agreement from the boy's mother that placed D.K. in the custody of CYS as a dependent child.¹³⁵ Under Pennsylvania law, a dependent child is one who is "without proper parental care or control, subsistence, education as required by law, or other care or control necessary for his physical, mental, or emotional health, or morals."¹³⁶ After being under CYS's care for three months and receiving a physician-supervised diet and regular exercise, D.K. lost fifty pounds.¹³⁷ This indicated that D.K.'s weight problem was most likely due to irresponsible parental choices rather than hereditary or chemical factors. Both D.K. and his mother, however, challenged his designation as a "dependent child" and advocated for his return.¹³⁸

The court determined that D.K.'s mother was not capable of providing adequate care for his physical needs because she had failed to take any steps to address her child's morbid obesity, such as bringing D.K. to a dietician.¹³⁹ In support of the court's finding that D.K. was a dependent child, it noted:

128. Michael MacDonald et al., *Consent to Medical Treatment*, in *HEALTH CARE LAW: A PRACTICAL GUIDE* § 19.06 (2d ed. 2010).

129. *See D.K.*, 58 Pa. D. & C.4th at 354.

130. *See L.T.*, 494 N.W.2d at 451.

131. *D.K.*, 58 Pa. D. & C.4th at 354.

132. *Id.* at 354–55, 359.

133. *Id.* at 355.

134. *Id.*

135. *Id.*

136. *Id.* at 357 (quoting 42 PA. CONS. STAT. ANN. § 6302(1)).

137. *D.K.*, 58 Pa. D. & C.4th at 356.

138. *Id.*

139. *Id.* Though this appears to be an example of neglect, the court never explicitly uses that term.

If a child does not receive necessary medical care for a health problem, there is usually no difficulty in a court making a finding of dependency, and especially in the situation where a child was malnourished to the point of near starvation. . . . This situation here is on the other end of the nourishment spectrum, but it is no less dangerous to the child's physical and mental well-being.¹⁴⁰

This discussion illustrates the fairly recent acceptance that overfeeding is just as harmful as underfeeding. Furthermore, the court seemed to base its decision on the mother's own extreme obesity that rendered her homebound and unable to bring D.K. to medical appointments.¹⁴¹ The opinion noted that since she had not been able to address her own severe obesity problem, "it [was] highly unlikely that she will now be able to do so with regard to her son's identical problem."¹⁴² The court's reasoning in ordering the child's removal relied on an analogy to traditional medical neglect. After the court had determined that the mother could have taken measures to combat her son's obesity, it framed her failure to do so as a harm much like failing to provide medical treatment.

Though the court ordered D.K.'s removal, it acknowledged that D.K. could be reunited with his mother once his mother demonstrated her ability to address her son's morbid obesity.¹⁴³ By discussing how children should be separated from their families only in cases of clear necessity,¹⁴⁴ the court recognized the importance of trying to uphold parents' fundamental right to determine how to raise their children.

Other state courts have applied similar logic but different legal standards for removal. An Iowa case involved parents of a ten-year-old girl, Liza, who weighed 290 pounds.¹⁴⁵ Her obesity was so severe that a yeast infection, growing out of control in the skin creases on her abdomen and producing an extremely strong body odor, caused her to be hospitalized.¹⁴⁶ Upon her release from the hospital, the doctors recommended her placement in a residential treatment facility.¹⁴⁷ When her parents declined, the juvenile court intervened, determined that she was a "child in need of assistance" (CINA), and ordered her placement in residential treatment foster care.¹⁴⁸

Iowa law defines a CINA:

an unmarried child who is in need of medical treatment to cure or alleviate serious mental illness or disorder, or emotional

140. *Id.* at 358.

141. *Id.* at 359.

142. *Id.* at 360.

143. *Id.*

144. *Id.* at 358.

145. *In re L.T.*, 494 N.W.2d 450 (Iowa Ct. App. 1992).

146. *Id.* at 451.

147. *Id.*

148. *Id.* at 452.

damage as evidenced by severe anxiety, depression, withdrawal or untoward aggressive behavior toward self or others and whose parent, guardian, or custodian is unwilling or unable to provide such treatment.¹⁴⁹

Her mother appealed the juvenile court's determination that Liza was a CINA.¹⁵⁰

On appeal, the Iowa Court of Appeals noted evidence from psychologists that Liza suffered from severe depression, which contributed to her obesity by causing her to overeat.¹⁵¹ Evidence also showed that Liza's obesity was "a potentially life-threatening condition,"¹⁵² which would "likely result in a significantly increased risk of hypertension and a decreased life expectancy."¹⁵³ In addition, her severe obesity interfered with her ability "to develop physically, mentally, and emotionally."¹⁵⁴ Based on this evidence, Liza was at serious risk of developing lifelong conditions due to her weight and, therefore, fit the criteria for being a CINA.

The court also observed that Liza's mother exacerbated her child's obesity by encouraging her to overeat as a method of coping with stress. Specifically, she provided food as a reward and refused to allow Liza to enter residential treatment.¹⁵⁵ Therefore, the court affirmed the juvenile court's order, holding that the "best interests of the child" dictated her placement into the custody of the Department of Human Services so that she could enter the residential treatment for her morbid obesity.¹⁵⁶ The court in this case justified state intervention in part by employing definitions of what constitutes a CINA and by drawing connections to medical neglect. Nonetheless, the decision established a dangerous precedent by instituting the "best interests of the child" standard. Because this standard allows for a more subjective determination by the State of when intervention should be allowed as compared to the dependent child standard based on clear necessity used in *In re D.K.*, it opens the door to unjust government intrusion into the otherwise private family sphere.

In another case using the "best interests of the child" standard, the Court of Appeals in Michigan affirmed the trial court's termination of parental rights in a case involving a morbidly obese four-year-old named Jered.¹⁵⁷ The Family Independence Agency first became involved when Jered was almost three years old and weighed approximately 106 pounds.¹⁵⁸ Although the Agency offered numerous services to his mother, five months later Jered weighed 120 pounds

149. *Id.* (quoting IOWA CODE § 232.2(6)(f) (1991)).

150. *Id.* at 451.

151. *Id.* at 452.

152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.* at 453.

156. *Id.*

157. *In re Ostrander*, No. 247661, 2004 WL 515561, at *2 (Mich. Ct. App. Mar. 16, 2004).

158. *Id.*

and frequently used a wheelchair because he had trouble walking.¹⁵⁹ The Agency ruled out any alternative medical reasons for his weight.¹⁶⁰ Additionally, Jered had ten cavities, delayed physical and verbal skills, head lice, scabies, and infections from improper cleaning.¹⁶¹ Although the court removed him from his mother's care¹⁶² due to a combination of these factors, it is not clear whether his morbid obesity alone would have been enough to motivate the court to rule this way. Jered thrived in foster care and soon lost over sixty pounds.¹⁶³ Just as in *In re D.K.*, this type of recovery indicated that Jered's weight problem was most likely due to irresponsible parental choices. Under the standard of medical neglect that we will propose, however, Jered's obesity alone would have been sufficient to warrant removal because his parents had failed to address his serious medical needs.

The Agency eventually sought termination of all parental rights. At the termination trial, evidence introduced by the State showed that Jered's mother "had not truly accepted responsibility for Jered's obesity," had continued to feed him fast food during parenting time after completing nutritional education, had failed to attend Jered's occupational therapy appointments, and did not have a close bond with her son.¹⁶⁴ For these reasons, the trial court determined that terminating his mother's parental rights was in Jered's best interest.¹⁶⁵ On appeal, the appellate court affirmed, holding that the trial court "did not clearly err in finding that [termination of parental rights] was established by clear and convincing evidence."¹⁶⁶

It is not always evident which standard a court has used to determine if termination of parental rights is necessary. A California Court of Appeals did not invoke a clear standard when it affirmed the termination of parental rights in a case that involved a morbidly obese eleven-year-old boy, Jo.¹⁶⁷ The Los Angeles County Department of Children and Family Services originally became involved with Jo's family when Jo was four years old and weighed 160 pounds.¹⁶⁸ The Department determined Jo to be at high risk for diabetes, heart disease, and sleep apnea.¹⁶⁹ Although the Department helped arrange numerous appointments "for diagnosis, testing and treatment of Jo's condition," his parents failed to cooperate.¹⁷⁰ After a year, Jo's weight increased to 200 pounds.¹⁷¹ A physician explained that his obesity "was not the result of a genetic or endocrine disorder

159. *Id.*

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.* at *3.

164. *Id.* at *4.

165. *Id.* at *3.

166. *Id.*

167. *Jose G. v. Superior Court*, No. B208365, 2008 WL 4491681, at *8 (Cal. Ct. App. Oct. 8, 2008).

168. *Id.* at *1.

169. *Id.*

170. *Id.*

171. *Id.*

and was likely caused by behavioral and environmental factors,”¹⁷² thereby eliminating internal causes and shifting the blame onto the parents. For example, in order to quiet Jose down during his tantrums, his parents gave him food, and Department agents observed that “the family home lacked the structured environment necessary for Jo to lose weight and improve his behavior.”¹⁷³

As a result, Jo was declared a court dependent and sent to live in a group home.¹⁷⁴ After being away from his parents for eighteen months, his weight dropped to 150 pounds and his behavior improved.¹⁷⁵ Since the goal was still family reunification, the State returned Jo to his parents’ custody on the condition that they comply with the treatment plan.¹⁷⁶ By the time of the parental review hearing two months later, however, “Jo’s weight had ballooned to 213 pounds and he was reverting to aggressive behavior.”¹⁷⁷ Due to Jo’s pattern of losing weight during out-of-home care and gaining massive weight when returned to his parents’ custody, and his parents’ lack of response to numerous health-based services, the Department sought the termination of the parental rights.¹⁷⁸ The juvenile court granted the order under the standard that “the child is suffering severe emotional damage and there are no reasonable means to protect the child’s emotional health without removing the child from the physical custody of the parents.”¹⁷⁹ While the court did not explicitly invoke medical neglect,¹⁸⁰ the language of the decision implied that the court was relying on this standard when it noted that Jo’s mother and father “failed to ensure his proper care”¹⁸¹ and placed him “at risk of physical and emotional harm.”¹⁸² The appellate court upheld this decision.¹⁸³

In *In re Brittany T.*, a family court in Chemung County, New York, considered whether it was in the best interest of a morbidly obese eleven year-old girl to be removed from her parents because they consistently failed to address her severe medical condition and also failed to ensure her proper school attendance.¹⁸⁴ Following the best interests of the child standard,¹⁸⁵ the court ordered Brittany’s parents, who were under observation of the Chemung County

172. *Id.*

173. *Id.*

174. *Id.* at *2, *4.

175. *Id.* at *5.

176. *Id.* at *4.

177. *Id.*

178. *Id.* at *6.

179. *Id.* at *7.

180. In California, the standard of medical neglect is if “[t]he child has suffered, or there is a substantial risk that the child will suffer, serious physical harm or illness as a result of . . . the willful or negligent failure of the parent or guardian to provide the child with adequate . . . medical treatment.” CA. WELF. & INST. CODE § 300 (West 2006).

181. *Jose G.*, 2008 WL 4491681, at *8.

182. *Id.*

183. *In re Esperanza G.*, No. B217911, 2010 WL 1212414 (Cal. Ct. App. Mar. 30, 2010).

184. *In re Brittany T.*, 835 N.Y.S.2d 829, 831 (Fam. Ct. 2007), *rev’d*, 48 A.D.3d 995, 852 N.Y.S.2d 475 (App. Div. 2008).

185. *Id.* at 838.

Department of Social Services, to abide by certain enumerated conditions designed to facilitate improvement of Brittany's health and educational needs.¹⁸⁶ Her parents failed to comply, however, and the court placed Brittany in foster care.¹⁸⁷ During the time that she was in foster care and receiving treatment, Brittany lost about one to two pounds per month,¹⁸⁸ and she was eventually returned to her parents.¹⁸⁹

Within six months of returning home, however, Brittany's weight increased from 238 pounds to 263 pounds, an average weight gain of almost five pounds per month.¹⁹⁰ According to doctors, Brittany's morbid obesity was due to "excessive caloric intake and a sedentary lifestyle," rather than any genetic or psychiatric syndrome,¹⁹¹ indicating that her parents had the opportunity to control the causes of her weight gain. If she did not return to treatment and receive the necessary and proper attention for her morbid obesity, doctors predicted that Brittany would have continued gaining weight, resulting in further deterioration of her health.¹⁹² The doctors classified these medical concerns as "life-limiting."¹⁹³ As a result, the Department charged her parents with neglect and alleged that they had violated the court orders to address her obesity.¹⁹⁴

At trial, the Department alleged that Brittany's parents violated the terms of the court's dispositional order by "failing to take [Brittany] at least two to three times per week to the gym" and "failing to actively and honestly attend and participate in a nutrition education program."¹⁹⁵ Department witnesses also testified that despite receiving education on nutrition from the Department, Brittany's parents continued to feed her "lots of chicken nuggets, lots of pop tarts, hot dogs and pizza."¹⁹⁶ Furthermore, the State revealed that "Brittany suffer[ed] from a significant amount of emotional distress related to her excessive weight" and that her weight had "a detrimental effect on her physical and emotional well-being."¹⁹⁷

Under New York law, an alleged violation of a court order of supervision can be sustained if the court finds sufficient proof that the violation was performed "willfully and without just cause."¹⁹⁸ Here, the court determined that Brittany's parents' "unequivocally" met this standard by their "unwillingness to follow doctors' and others' advice," which "convincingly and patently had a very negative physical, emotional and mental impact on Brittany."¹⁹⁹

186. *Id.* at 831.

187. *Id.*

188. *Id.* at 834.

189. *Id.* at 831.

190. *Id.* at 834.

191. *Id.* at 833.

192. *Id.* at 834.

193. *Id.*

194. *Id.* at 831–32.

195. *Id.*

196. *Id.* at 834 (internal quotation marks omitted).

197. *Id.* at 835.

198. *Id.* at 836 (citing N.Y. FAM. CT. ACT § 1072).

199. *Id.* at 837.

According to New York statute, a child is neglected when his or her “physical, mental or emotional condition has been impaired as a result of the failure of his or her parent to exercise a minimum degree of care in supplying the child with adequate education or medical care though financially able to do so.”²⁰⁰ Here, the court held that Brittany’s parents’ behavior, in failing to take steps to address her obesity, “indicate[d] an unwillingness or inability to take the steps necessary to assume responsibility for [their] child[.]”²⁰¹ The court also reasoned that removal on the basis of morbid obesity was no less justified than removal for any other situation in which “a child is at risk of life-limiting consequences due to malnourishment, inadequate supervision or other heretofore well-established bases for removal.”²⁰² This comparison between overfeeding and malnourishment echoes the analysis of *In re D.K.*, in which the court considered the two symptoms to be analogous in the charging of neglect.

Unlike the other cases so far discussed, however, this decision was subsequently reversed by the Appellate Division of the Supreme Court of New York, which determined that the facts did not support a finding of the parent’s willful violation of the court’s order.²⁰³ Acknowledging that the parents’ care had been far from ideal,²⁰⁴ the court held that there was nevertheless no “clear and convincing evidence” that the parents exhibited a “‘continuous, willful and unjustifiable refusal’ to comply with the terms of th[e] order.”²⁰⁵

In support of the decision that Brittany’s parents were not willfully violating the terms of the court order, the appellate court found that by requiring their daughter to attend the gym at least once a week for twenty-seven of the thirty-one weeks, Brittany’s parents made a “good faith attempt” to fulfill their court-mandated obligation to take Brittany to the gym two or three times a week.²⁰⁶ Significantly, the court was not convinced that Brittany’s weight gain could be completely attributed to her parent’s neglect.²⁰⁷ The court noted that “[i]t is true that the child gained weight after being returned to respondents, but other factors outside of their control may well account for this increase.”²⁰⁸ The court’s decision acknowledges the difficulty in deciphering the cause of weight gain, holding that, despite findings that Brittany’s parents fed her an unhealthy diet and failed to consistently take her to the gym, it could not rule out the possibility that her morbid obesity was caused by factors beyond her parents’ control. The court noted that Brittany had an eating disorder and consumed inappropriate foods at school, when she was not under her parents’ direct supervision and control.²⁰⁹ The court’s reasoning recognized the existence of factors external to parental

200. *Id.* at 838 (quoting N.Y. FAM. CT. ACT § 1012(f) (internal quotation marks omitted)).

201. *Id.* at 836.

202. *Id.* at 839.

203. *In re Brittany T.*, 852 N.Y.S.2d 475, 477, 478 (App. Div. 2008).

204. *Id.* at 479.

205. *Id.* at 480 (quoting *In re Rachel A.*, 716 N.Y.S.2d 829, 830 (App. Div. 2000)).

206. *Id.* at 479.

207. *Id.* at 480.

208. *Id.*

209. *Id.*

care that may affect weight.²¹⁰ Because the court found it difficult to attribute responsibility primarily to the parents, the court was unwilling to take drastic action such as the termination of parental rights. Therefore, the lower court's order was reversed, and Brittany was returned to her parents.²¹¹

It can be gleaned from these cases that some state courts have begun to recognize that morbid childhood obesity can become sufficiently severe so as to trigger state action under child neglect laws. At the same time, courts appear to have carefully restricted state involvement and removal to only the most extreme instances, where the child greatly exceeds the medical standard for morbid obesity, where the child suffers from numerous serious health concerns, and where the parents have blatantly failed to address the child's obesity-related health needs. As the jurisprudence of childhood obesity continues to develop, it needs to reconcile its approach in these cases with the need for clearer standards and guidelines. In the next Part, we will argue that courts should apply the standard of medical neglect to instances of morbid childhood obesity.

IV. THE FUTURE DIRECTION OF THE LEGAL FRAMEWORK FOR CHILDHOOD OBESITY

It is clear, based on the court cases discussed in Part III, that the designation of childhood obesity as a form of child abuse or neglect is quickly becoming a legal reality in the United States. That said, the current framework is inadequate because it often gives too much power to judges in deciding when to terminate parental rights, thereby risking inconsistent application of legal standards. Furthermore, the existing framework does not distinguish between the different legal standards for intervention as opposed to removal. The legal standards currently governing state intervention in childhood morbid obesity cases are problematic because they are broad and imprecise. Moving forward, reforms are needed both in the judicial and legislative arenas. In this Part, we provide interpretative guidelines for courts and suggest legislative changes aimed at offering clearer guidance on the issue of childhood obesity.

A. Developing a Judicial and Legislative Structure To Address Childhood Obesity

1. Suggestions for Future Developments in Judicial Interpretation

There are various options for judicial interpretation that can be taken to improve the legal system's handling of morbid childhood obesity. The simplest approach might be for more courts to continue applying existing child abuse and neglect laws to situations involving morbid childhood obesity. This would allow judges to work within existing legal standards. However, courts' application of the law would likely continue to be inconsistent and the benefit of early

210. See *supra* Section I.C, discussing the numerous other factors that may affect an individual's weight, such as biological, chemical, or certain external factors.

211. *Brittany T.*, 852 N.Y.S.2d at 480.

intervention would never be realized. Similarly, following standards like the “best interest of the child” invites judges to act “in accord with their own personal child-rearing preferences,”²¹² which can lead to “discrimination against the poor, minorities, and other disfavored children.”²¹³ Imprecise statutory definitions “inexorably lead to often unpredictable and unjustified intervention into family life.”²¹⁴

Courts could also analogize overnourishment to undernourishment, which has a widespread and longstanding precedent of state intervention.²¹⁵ This would allow judges to perform an analysis similar to the one with which they are already familiar and could provide greater consistency in the legal system. Furthermore, malnourishment cases often warrant early intervention by the State, which would be a procedural step forward for morbid obesity cases. Morbid obesity is essentially nutritional neglect at the other end of the spectrum.²¹⁶ Since both extreme under- and overfeeding of children cause severe health consequences, it makes sense to treat both situations analogously under the law.

Some critics fear that any laws holding parents liable for childhood obesity would “place a tremendous burden on parents—and an unfair one.”²¹⁷ These people note that governments and companies that market unhealthy foods to children should also share the blame for obesity.²¹⁸ While it is certainly true that there are many causes of childhood obesity, this does not mean that legislatures and courts should avoid intervening where parents are at fault, especially in extreme instances of morbid obesity. Many of the factors that cause morbid obesity are directly within the control of parents and their contribution to the problem should not be minimized by shifting the blame to other causes.

2. Suggestions for Future Legislative Developments

One legislative solution that should be adopted is to add a subsection to existing child neglect laws specifying that a failure to follow medical advice to address childhood morbid obesity constitutes medical neglect. The more specific

212. Douglas J. Besharov, “*Doing Something*” About Child Abuse: The Need To Narrow the Grounds for State Intervention, 8 HARV. J.L. & PUB. POL’Y 539, 570 (1985).

213. *Id.* (quoting J. GOLDSTEIN ET AL., BEFORE THE BEST INTERESTS OF THE CHILD 15–17 (1980)).

214. *Id.* (citing Note, *In the Child’s Best Interest: Rights of the Natural Parents in Child Placement Proceedings*, 51 N.Y.U. L. REV. 446 (1975)).

215. See Jessica Pauline Ogilvie, *Pro/Con: Does Obesity Qualify as Child Abuse?*, L.A. TIMES, Aug. 29, 2011, <http://articles.latimes.com/2011/aug/29/health/la-he-childhood-obesity-custody-20110829> (“Morbid obesity is just another form of malnutrition. It doesn’t require new legislation or a change in the criteria for state intervention.”).

216. S. Romeo & P. Nicolás, *Morbid Obesity in Children and the Law*, GLOBAL FOOD SECURITY: ETHICAL AND LEGAL CHALLENGES 176, 181 (Carlos M. Romeo Casabona et al. eds., 2010).

217. Philip Yam, *Should Morbid Childhood Obesity Be Considered Child Abuse?*, SCI. AM, July 13, 2011, <http://blogs.scientificamerican.com/observations/2011/07/13/should-morbid-childhood-obesity-be-considered-child-abuse/>.

218. *Id.*

a legislature can be in crafting statutes for medical neglect in childhood morbid obesity cases, the less likely judges will be able to employ their own policy preferences about what ought to be the proper standard of removal. If the legislature were to expressly describe when child obesity *does* constitute neglect, it would reduce the risk of courts incorrectly interpreting the statute to encompass less severe instances in which children are merely overweight. The law could also refer to the medical definition of morbid obesity so that courts are not in the position to perform an arbitrary weight analysis that could lead to judicial disparity and the unjust termination of parental rights. Such a law should also include a provision safeguarding against situations where the child's morbid obesity is caused by an underlying genetic condition despite the parents' best efforts to follow medical advice and provide healthy nutrition.

Another strategy could be to revise child neglect laws to permit state involvement at a lower threshold than "imminent danger." While the threshold for removal should continue to use this high standard, the law should provide for earlier intervention whenever a child's condition is serious and threatening to his or her health or places him at an unreasonable risk of harm. Having a lower standard for intervention in those cases would allow state child protective services to intervene earlier to guide parents to the support they need, such as nutritionists, doctors, and personal trainers, in order to help prevent serious cases of childhood obesity from becoming life-threatening. While a state would be *allowed* to intervene and parents would benefit from accepting the State's services, the parents' fundamental and constitutional rights to rear their children would not be violated because they would not be required to accept this assistance. However, regardless of whether they accept these earlier offers of state assistance, parents would still be held to the same standards for potential removal. By making these involvements optional, the State would also ensure that its limited resources were allocated to the individuals who would likely take the best advantage of them. Addressing childhood obesity early also has the benefit of saving significant money for parents and taxpayers in the long run, since annual overweight- and obesity-attributable medical care spending is estimated to be approximately \$78.5 billion per year.²¹⁹

Following these proposals for legislative action would ensure that, to the fullest extent possible, parents maintain their rights to determine how to raise their children without unnecessary levels of government interference. Additional policy considerations can help solidify the new legal framework and balance the interests of parents with those of the State.

B. Childhood Obesity and Child Protection Policy Recommendations

This Section explores some of the major policy topics in this field, namely, the dilemma of how best to enforce new rules in this field and what sort of recommendations should be made to parents in order to help them avoid these

219. Eric A. Finkelstein et al., *National Medical Spending Attributable to Overweight and Obesity: How Much and Who's Paying?*, 22 HEALTH AFF. 219, 219 (2003).

troubling legal issues.

There is opposition to establishing a new system of laws in which children can be removed from their parents due to weight problems.²²⁰ Parents rebel against the idea that the government can get involved in the private choices of family life. In order to have the system function properly and to avoid widespread social opposition to such a legal framework, it is important that enforcement procedure be clearly defined and generally known. A well-defined system provides clarity to both those bound by the laws and those seeking to enforce them.

Ideally, the first step to the system should not involve state intervention but instead take the form of a consultation between parents and doctors at an early stage in a child's development of weight problems. This opportunity could be used to bolster public awareness about the causes and implications of childhood obesity. Parents should be informed of the potential ramifications of allowing excessive weight gain in their children, such as court interference with their family life²²¹ and, in the most extreme cases, the termination of parental rights.²²²

If a parent fails to heed a doctor's warnings about his or her child's weight and the child becomes morbidly obese, the doctor should then give an ultimatum to the parents wherein either the child becomes enrolled in a weight treatment program or, alternatively, the pediatrician notifies a court-based CPS worker of a parent's failure to successfully monitor his or her child's health.²²³ Mandatory reporter laws²²⁴ could lessen the risk of parents vilifying the medical professional when the doctor explains the latter option. Giving such an ultimatum may provide sufficient incentive to certain parents to become more proactive in the child's dietary and behavioral habits.

Where a parent refuses to take these necessary steps to reduce his or her child's weight, a CPS worker should become an active participant in the monitoring and handling of the child's weight. Unfortunately, there is a strong social stigma associated with the involvement of protective services in the life of

220. For a description of the "knee-jerk" reaction of many in opposition to such legal doctrine, see generally David Katz, *Should Obese Children Be Taken from Parents?*, HUFFINGTON POST, July 14, 2011, http://www.huffingtonpost.com/david-katz-md/children-obesity-parents_b_897667.html.

221. See, e.g., *Jose G. v. Superior Court*, No. B208365, 2008 WL 4491681, at *2 (Cal. Ct. App. Oct. 8, 2008) (describing the government-instituted involvement of counselors and nutritionists in the daily lives of the family members).

222. See generally *In re G.C.*, 66 S.W.3d 517 (Tex. Ct. App.) (affirming the termination of the appellant's parental rights on the grounds that she neglected her child's weight problem).

223. Although there is concern over patient-physician confidentiality, many states have already enacted mandatory reporting laws for child abuse amongst doctors. See generally U.S. DEP'T OF HEALTH & HUMAN SERVS., MANDATORY REPORTERS OF CHILD ABUSE AND NEGLECT: SUMMARY OF STATE LAWS (2010), http://www.childwelfare.gov/systemwide/laws_policies/statutes/manda.pdf. Morbid childhood obesity could be included as a reportable offense.

224. Murtagh & Ludwig, *supra* note 11, at 206 ("Nevertheless, mandated reporter laws may obligate physicians to contact child protective services in the cases of children for whom chronic parental neglect has resulted in severe weight-related health complications."). For a general description of mandatory reporter laws as they relate to child abuse and neglect, see U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 223.

a child.²²⁵ In many instances, however, this stigma is misguided: “[s]tate intervention ideally will support not just the child but the whole family.”²²⁶ In this sense, early involvement of child protection services is not about punishing parents but instead about educating them and returning the family to normalcy as quickly and efficiently as possible. Also, while there is a common perception that CPS involvement means that of children will be removed from their parents’ custody,²²⁷ this is only one possible tactic in a long list of techniques used by such services.²²⁸ Lesser types of intervention, such as recommendations for physical therapy or nutritional guidance, may be sufficient and preferable in many cases.²²⁹

If parents fail to follow the guidelines put in place by CPS while the child still remains with his or her family, the next step would be to temporarily remove the child from the parents’ custody in order to place him or her in a residential treatment center or with a foster family prepared to meet the child’s nutritional needs.²³⁰ This would be a necessary step where “support services may be insufficient to prevent severe harm.”²³¹ During the time apart, parents would be able to work towards regaining custody of their child by following guidelines established by CPS. They would also be able to continue their own education regarding how best to control the dietary habits of children.²³² The ultimate goal of this step would be to reunite the child with his or her family once the child becomes healthier, and to educate the parents as to the child’s needs.

If the parents are unwilling or unable to properly educate themselves regarding their child’s nutritional needs and the child faces severe imminent health risks to the extent of medical neglect, the final step of the process would be the termination of parental rights, which is done to uphold the State’s interest in protecting children.²³³ By removing children from parents who neglect to meet

225. See Jennifer Sykes, *Negotiating Stigma: Understanding Mothers’ Responses to Accusations of Child Neglect*, 33 CHILD. & YOUTH SERVICES REV. 448, 448 (2011) (“Mothers who undergo child protective service (CPS) investigations have this identity called into question and may wrestle with the profound stigma as a result.” (internal citation omitted)).

226. Associated Press, *Foster Care for Severely Obese Kids May Be Needed*, CBC NEWS, July 12, 2011, <http://www.cbc.ca/news/health/story/2011/07/12/obese-children-custody.html> (internal quotation marks omitted).

227. See, e.g., Nancy Schaefer, *The Corrupt Business of Child Protective Services*, HOW CHILD PROTECTION SERVICES BUYS AND SELLS OUR CHILDREN (Sept. 25, 2008), <http://protectingourchildrenfrombeingsold.wordpress.com/about/the-corrupt-business-of-child-protection-services/> (attacking CPS as a corrupt enterprise).

228. See Murtagh & Ludwig, *supra* note 11, at 207 (“Child protective services typically provide intermediate options such as in-home social supports, parenting training, counseling, and financial assistance, that may address underlying problems without resorting to removal.”).

229. *Id.*

230. *But see id.* (“Moreover, the quality of foster care varies greatly; removal from the home does not guarantee improved physical health, and substantial psychosocial morbidity may ensue.”).

231. *Id.*

232. The education of parents is an important part of most state-created programs designed to curb childhood obesity. See, e.g., *In re Brittany T.*, 852 N.Y.S. 2d 475, 480 (App. Div. 2008) (describing the nutrition program that both Brittany and her parents were required to attend).

233. See Murtagh & Ludwig, *supra* note 11, at 207.

their nutritional needs, the State also aims to improve the chances that the child will grow up and live a healthier lifestyle free from long-term weight-related illnesses such as type 2 diabetes. In a properly functioning legal system, termination of parental rights should be used only as a last resort—even in cases of morbid obesity, “state intervention would clearly not be desirable or practical, and probably not be legally justifiable, for most of the approximately two million children in the United States with a BMI at or beyond the 99th percentile.”²³⁴ There is a high social cost associated with removing children from their parents in all but the most extreme circumstances.²³⁵ Such intrusive actions should only be taken when there is a definitive risk of life-threatening health problems and the parents have made the personal choice to avoid their obligations.

Instituting a system of clearly defined steps in the legal system like those listed above would be a useful means of educating parents, providing clear explanations of the law, and plainly expressing the expectations of the State. Hopefully, as the laws governing childhood obesity and child abuse and neglect develop further in both the courts and legislative bodies, a system similar to the one described here will begin to emerge as a means of helpful guidance.

CONCLUSION

Childhood obesity is a growing concern that is putting the health of millions of children at risk. Several state courts have begun to consider whether childhood obesity warrants state intervention under child abuse and neglect laws. These courts have held that court-ordered services and removal are appropriate in extreme situations where parents have neglected to follow medical advice to address the dire health complications from their child’s morbid obesity.

Although all levels of obesity present health concerns, it is preferable for courts and legislatures to focus their efforts on morbidly obese children, rather than the merely obese or overweight. Because morbid obesity presents the most immediate and serious health complications, it demands rapid action that trumps the constitutional right otherwise belonging to parents to rear their own children. Enacting laws that specify when childhood morbid obesity falls within the definition of neglect provides greater clarity within the legal system and reduces the likelihood of judicial activism. By allowing intervention earlier in the process, our recommendations would likely decrease the need for removal in all but the most severe cases, where the parents chronically fail to make reasonable efforts to address the imminent danger to the child’s physical health.

Unless widespread efforts are undertaken to address the childhood obesity epidemic, the present generation of children will not live as long as their parents.²³⁶ By developing new standards that help ensure that children are

234. *Id.* (“An increasing proportion of US children are so severely obese as to be at immediate risk for life-threatening complications including type 2 diabetes.”).

235. *See generally* Besharov, *supra* note 212, at 561 (describing the high social cost of removing children from their parents).

236. Deena Patel, *Super-Sized Kids: Using the Law To Combat Morbid Obesity in Children*, 43 FAM. CT. REV. 164, 173 (2005).

protected against the negative nutritional influences of their parents, the United States' legal system will be able to ensure a healthier future for our youth.

The Devil (and Drugs) in the Details: Portugal’s Focus on Public Health as a Model for Decriminalization of Drugs in Mexico

Kellen Russoniello *

INTRODUCTION.....	373
I. PORTUGUESE DRUG POLICIES AND PROBLEMS, PRE- AND POST- DECRIMINALIZATION	375
A. PORTUGAL’S LEGAL FRAMEWORK AND DRUG POLICY PRIOR TO DECRIMINALIZATION	376
B. SOCIAL PROBLEMS ASSOCIATED WITH DRUG USE DURING THE MID-1980S AND THROUGHOUT THE 1990S	380
C. PORTUGAL’S DECRIMINALIZATION SCHEME	383
D. EFFECTS AND DEVELOPMENTS AFTER PORTUGUESE DECRIMINALIZATION	390
II. MEXICAN DRUG POLICIES AND PROBLEMS, PRE- AND POST- DECRIMINALIZATION	395
A. MEXICO’S LEGAL FRAMEWORK AND DRUG POLICY PRIOR TO DECRIMINALIZATION	395
B. SOCIAL PROBLEMS ASSOCIATED WITH DRUG USE IN THE NEW MILLENNIUM	399
C. MEXICO’S DECRIMINALIZATION SCHEME	404
D. EFFECTS AND DEVELOPMENTS AFTER MEXICAN DECRIMINALIZATION	408
III. ANALYSIS	411
A. ABANDONING THE CRIMINAL JUSTICE APPROACH FOR A PUBLIC HEALTH APPROACH	413

* JD/MPH Candidate, expected 2013, The George Washington University Law School/School of Public Health and Health Services; B.A. 2009, *summa cum laude*, Eastern Washington University; Member, Students for Sensible Drug Policy National Board of Directors. The author would like to thank his mom, Christine Carroll, dad, Carmen Russoniello, Valerie Chang, all his other family and friends, and all the great people involved with Students for Sensible Drug Policy.

B. IMPLEMENTING COMMISSIONS BASED ON THE PORTUGUESE MODEL 417

C. INCREASING THE MAXIMUM AMOUNTS OF DRUGS DEFINED AS PERSONAL
USE..... 420

D. POTENTIAL OBSTACLES TO IMPLEMENTING PORTUGUESE-STYLE
DECRIMINALIZATION 423

CONCLUSION 429

INTRODUCTION

It is a crisp morning in November of 2000, on the outskirts of the capital city.¹ A man sits on the side of the road with a needle in his hand. Several individuals nearby make their home on the street. Some lay unconscious on the cold ground, some prepare to inject themselves with drugs, and still others wait for the droves of customers to pour into the area for their supply. It is an area characterized by rampant drug use, crime, and disease. Many of the people wandering these streets are infected with HIV, hepatitis, or tuberculosis. Rundown shacks and used needles evince the extreme poverty, social exclusion, and drug addiction that have become the norm here. Located on the fringe of Lisbon, Portugal, this place is called Casal Ventoso, and is notorious throughout Europe for being the continent's largest open-air drug market. Here, one could purchase illegal drugs as easily as one might draw a breath, and could contract a disease with hardly more effort. The needle in the hand of the man on the street contains a dose of heroin, the predominant drug of use in the area. Looking around at this slum, one cannot help but wonder if the novel drug laws that take effect in July 2001 will provide any hope for this ravaged region.²

Nearly a decade later, across the Atlantic Ocean, a similar scene has developed.³ On a blistering summer day in the heart of a major tourist city, addicts search for their drug of choice. A man sits on the sidewalk and injects himself with a needle that may be filled with any of a number of substances—heroin, cocaine, and methamphetamine have all become common among drug-using populations in this area. Just as in Casal Ventoso, poverty and disease have become prevalent. Illicit drugs can be readily purchased from what have become known as “ice cream trucks.” Roving the main streets of the town in broad daylight, these vehicles provide a constant supply of nearly any drug a customer could want.

Yet there is more to the story here, in the northern Mexican town of Tijuana.⁴ Violence plagues the area and fear grips the citizens. Drug-trafficking

¹ This paragraph is based on information taken from Caitlin Elizabeth Hughes, *Overcoming Obstacles to Reform?: Making and Shaping Drug Policy in Contemporary Portugal and Australia* 85, 102 (Oct. 2006) (unpublished Ph.D. dissertation, University of Melbourne) (on file with Research Collection, University of Melbourne).

² See Decreto-Lei 30/2000 [Decree Law 30/2000], DIÁRIO DA REPÚBLICA de 29.11.2000 (Port.) [hereinafter Decree Law 30/2000].

³ This paragraph is based on information from Chris Hawley, *Drug Addiction Soars in Mexico*, USA TODAY, July 22, 2008, http://www.usatoday.com/news/world/2008-07-22-mexaddicts_N.htm; and Marc Lacey, *In Mexico, Ambivalence on a Drug Law*, N.Y. TIMES, Aug. 23, 2009, <http://www.nytimes.com/2009/08/24/world/americas/24mexico.html?pagewanted=1&r=1>.

⁴ This paragraph is based on information from Jason Beaubien, *As Drug War Turns into Quagmire, Fear Rules Mexico* (pt. 1), NPR, Aug. 2, 2010,

organizations battle both each other and the government in their struggle to transport and sell drugs to their number one customer, the United States, and increasingly to domestic consumers. This phenomenon has spread to several areas throughout the country. Midday firefights have become a common phenomenon in many Mexican towns. Amid the addiction, disease, and violence, a shift in drug policy in 2009 seeks to eliminate the source of these ills for the citizens of these towns.

In an effort to confront their escalating drug crises, both Portugal and Mexico determined that decriminalizing the possession of drugs would help to alleviate the problems in areas like Casal Ventoso and Tijuana.⁵ In 2001, Portugal decriminalized possession of all drugs for personal consumption and has since reported positive results in combating drug addiction, related health problems, and drug trafficking.⁶ Then, in 2009, Mexico became the most recent country to participate in this trend, occurring primarily in Latin America and Europe, to ease drug policies, when it passed a bill decriminalizing the possession of small amounts of drugs.⁷ Although both Portugal and Mexico decided to explore drug decriminalization, as a result of their divergent drug legislation, the systems in each country are remarkably different. Thus far, Mexico's decriminalization scheme has not seen many, if any, of the positive effects witnessed in Portugal.⁸

Although it is too soon to conduct a comprehensive assessment of the outcomes of the decriminalization scheme in Mexico, this Note argues that Mexico's 2009 law decriminalizing the possession of small amounts of drugs will not be able to achieve the same positive results as the Portuguese law. By increasing penalties for small-scale dealers, only referring offenders to treatment after a third offense, and continuing to process offenders through the court

<http://www.npr.org/templates/story/story.php?storyId=128804488>.

⁵ Decriminalization should be distinguished from legalization, as the two terms are often confused. For the purposes of this Note, decriminalization refers to the removal of criminal sanctions while retaining administrative penalties, whereas legalization is the removal of all sanctions including administrative penalties, making the action legal.

⁶ See *infra* Section I.D.

⁷ Decreto por el que se reforman, adicionan y derogan diversas disposiciones de la Ley General de Salud, del Código Penal Federal y del Código Federal de Procedimientos Penales [Decree Amending, Supplementing or Repealing Certain Provisions of the General Health Law, the Federal Criminal Code and Federal Code of Criminal Procedure], Diario Oficial de la Federación [DO], 20 de Agosto de 2009 (Mex.) [hereinafter *Narcomenudeo Law*]; see also Philip Smith, *Mexico and Argentina Enact Drug Decriminalization*, DRUG WAR CHRON., Aug. 28, 2009, http://stopthedrugwar.org/chronicle/2009/aug/28/feature_mexico_and_argentina_ena; Coletta A. Youngers & John M. Walsh, *Drug Decriminalization: A Trend Takes Shape*, AM. Q., Fall 2009, at 123, available at <http://www.americasquarterly.org/node/978/>.

⁸ See *infra* Section II.D.

system, the Mexican law focuses too much on criminal justice, at the expense of a more thorough public health approach.⁹ As a result, Mexican decriminalization fails to improve the ability of the government to address effectively drug use, drug-related disease, mortality, and the rights of the drug user. Though the current conflict in Mexico between law enforcement and drug-trafficking organizations creates a somewhat different landscape than the one in which Portugal enacted its decriminalization law,¹⁰ Mexico could nevertheless use Portugal's regime as a guide in developing a more public health-oriented approach to its drug problem. In doing so, Mexico would be able to enjoy reductions in many of the social ills that Portugal is currently experiencing.

This Note will begin in Part I by examining the evolution of drug policy in Portugal, the public health crisis that Portugal experienced in the mid-1980s through the 1990s, and the decriminalization law that was enacted in response to this crisis. It will also observe the positive developments that occurred after the enactment of Portugal's public health-oriented decriminalization law. Next, Part II will examine Mexican drug legislation before decriminalization and the violence, public health problems, and other social consequences associated with drug use and trafficking. It will then evaluate the recently enacted decriminalization law and its effects on Mexican society. This Note will proceed to argue, in Part III, that because of its misguided emphasis on criminal justice, Mexico's law as it currently stands will not be able to achieve the same progress against drug use and trafficking that Portugal's law has. It will propose that Mexico adopt a more explicitly public health-oriented approach to decriminalization, create administrative commissions to deal with drug possession offenses, and increase the maximum amount of drugs allowed to be possessed under decriminalization. Section III.D analyzes challenges to implementation, such as political obstacles, corruption, human rights abuses, violence, and shortages of resources, that may impede the success of Portuguese-style decriminalization in Mexico. These barriers, however, are not insurmountable, and Mexico should be able to follow Portugal's example and achieve similar favorable outcomes.

I. PORTUGUESE DRUG POLICIES AND PROBLEMS, PRE- AND POST-DECRIMINALIZATION

The legal approach to curbing personal consumption of illegal drugs in Portugal has varied considerably throughout the last century, ranging from a total

⁹ See Jorge Hernández Tinajero & Carlos Zamudio Angles, *Mexico: The Law Against Small-Scale Drug Dealing*, TRANSNAT'L INST. & WASH. OFFICE ON LATIN AM. 2 (2009), <http://www.tni.org/sites/www.tni.org/files/download/dlr3.pdf>.

¹⁰ See *infra* Section II.B.

absence of drug legislation to absolute statutory prohibition.¹¹ This Part will examine the evolution of Portuguese laws prior to decriminalization and the problems resulting from drug consumption that prompted the paradigm shift. Then it will describe Portugal's current drug policy, concluding with an observation about the effects of decriminalization on drug-associated problems.

A. Portugal's Legal Framework and Drug Policy Prior to Decriminalization

Use of specific drugs first became a penal offense in Portugal in 1970.¹² In 1974, when the totalitarian regime that had ruled since 1926 fell,¹³ illegal drug use became more visible.¹⁴ In response, the Portuguese government created a series of organizations whose main objectives were to study and reduce drug use.¹⁵ Portugal also enacted legislation aimed at decreasing illegal drug use and

¹¹ INEKE VAN BEUSEKOM ET AL., RAND EUROPE, GUIDELINES FOR IMPLEMENTING AND EVALUATING THE PORTUGUESE DRUG STRATEGY 7 (2002).

¹² *Id.*; see Decreto-Lei 420/70 [Decree Law 420/70], DIÁRIO DA REPÚBLICA de 3.9.1970 (Port.). However, drug trafficking was considered a penal offense before enactment of this decree. VAN BEUSEKOM ET AL., *supra* note 11, at 7. The criminalization of use most likely occurred in order to bring Portugal in line with the UN Single Convention on Narcotic Drugs of 1961. See *infra* notes 20-23 and accompanying text.

¹³ Following its liberation from dictatorship, Portugal enacted a new constitution that included a major focus on human rights. See CONSTITUIÇÃO DA REPÚBLICA PORTUGUESA Apr. 2, 1976, pmbl. (Port.). Under this constitution, the government has a duty to "[s]ecure the access of all citizens, regardless of their economic condition, to preventive as well as curative and rehabilitation medical care." *Id.* art. 64(3)(a). As one researcher pointed out, "[w]hile the Constitution does not guarantee the right to take drugs, it does guarantee to provide treatment for drug users." Hughes, *supra* note 1, at 95-96. For information on the totalitarian rule of Portugal from 1926 to 1974, see, for example, DAVID BIRMINGHAM, A CONCISE HISTORY OF PORTUGAL 161-84 (2d ed. 2003); and MALYN NEWITT, PORTUGAL IN EUROPEAN AND WORLD HISTORY 197-216 (2009).

¹⁴ VAN BEUSEKOM ET AL., *supra* note 11, at 7. Cannabis use among youths was the most visible. *Id.* Increased use rates may be attributable to the opening of relations between the people of Portugal and of other countries, which included the trading of ideas and attitudes regarding drugs. See José Manuel Gaspar de Almeida & Rosa Encarnação, *Building a Drug Treatment System in Postrevolutionary Portugal*, in DRUG TREATMENT SYSTEMS IN AN INTERNATIONAL PERSPECTIVE: DRUGS, DEMONS, AND DELINQUENTS 217, 217 (Harald Klingemann & Geoffrey Hunt eds., 1998). Other reasons include the return of exiles, colonial soldiers, and refugees to Portugal, and an influx of Brazilian students who brought with them new attitudes regarding drug use. *Id.* at 217-18.

¹⁵ In 1976, the Gabinete de Coordenação do Combate à Droga (Drug Fighting Coordination Office) was established and charged with collecting data on drugs and coordinating two other organizations: Centro de Estudo e Profilaxia da Droga (Drug Prophylaxis Studies Center), which was responsible for treatment and other demand reduction, and Centro de Investigação e Controle da Droga (Drug Control and Research

related problems, including a 1983 decree allowing for the suspension of punishment for some drug-related offenses as long as the offender agreed to enter a treatment program.¹⁶ In the late 1980s, government-operated anti-drug agencies also demonstrated dedication to approaches other than strict prohibition and incarceration.¹⁷ Although in 1993 new legislation increased penalties for trafficking drugs and diverting drugs from a legal source, it also made penalties for possession of substances for personal consumption more lenient.¹⁸ This law

Center), which was responsible for reducing the supply of illegal drugs. VAN BEUSEKOM ET AL., *supra* note 11, at 8. In 1982, the Drug Fighting Coordination Office was replaced by the Gabinete de Planeamento e de Coordenação do Combate à Droga (Drugs Planning and Coordination Office). *Id.* In 1987, Projecto VIDA—Vida Inteligente Droga Ausente (Project Life—Intelligent Life Without Drugs) was established. de Almeida & Encarnação, *supra* note 14, at 218-19.

¹⁶ Decreto-Lei 430/83 [Decree Law 430/83], arts. 25(2), 36, DIÁRIO DA REPÚBLICA de 13.12.1983 (Port.) [hereinafter Decree Law 430/83]; VAN BEUSEKOM ET AL., *supra* note 11, at 8. The preamble states that drug addiction creates many social costs, and that the causes of drug consumption must be identified and attacked. Decree Law 430/83, pmbl. It declares that the remedy is “education towards a healthy lifestyle where school, family and the whole environment helps the development of a balanced personality.” *Id.* It also states that the drug addict shall “not be considered as someone not in need of medical assistance,” and mandates that efforts must be made to treat and protect him. *Id.*

Possession of drugs was punishable by imprisonment of six to twelve years and a fine of PTE 50,000 to 5,000,000 (\$332 to \$33,252) unless the amount was a small quantity, meaning it did not exceed the necessary dose for individual consumption, in which case the penalty would have been one to four years’ imprisonment and a fine of PTE 20,000 to 1,500,000 (\$133 to \$9,976). Decree Law 430/83, arts. 23-24. However, if the drugs were intended for personal consumption, the penalty was up to one year of imprisonment and a fine of PTE 5,000 to 200,000 (\$33 to \$1,330). *Id.* art. 25.

PTE stands for Portuguese escudo, which was the currency of Portugal until it adopted the euro in 1999. PTE went out of circulation in 2002. Kalin Tasev, *Currency History – History of Portuguese Escudo*, CURRENCY HISTORY: INFORMATION ABOUT WORLD CURRENCIES AND THEIR DEVELOPMENT (Oct. 5, 2010, 11:44 PM), <http://currency-history.blogspot.com/2010/10/currency-history-history-of-portuguese.html>. All conversions from euros to U.S. dollars in this Note are calculated using a 1.40 conversion rate.

¹⁷ See VAN BEUSEKOM ET AL., *supra* note 11, at 8. Through Projecto VIDA, the government enacted thirty measures focused on prevention, treatment, reinsertion, and supply reduction. *Id.*

¹⁸ See Decreto-Lei 15/93 [Decree Law 15/93], arts. 21(2), 25(a), DIÁRIO DA REPÚBLICA de 22.1.1993 (Port.) [hereinafter Decree Law 15/93]. Compare Decree Law 15/93, art. 40, with Decree Law 430/83, arts. 23-25. The main objective of this law was to make sure that Portuguese domestic law was in compliance with the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, discussed *infra*. VAN BEUSEKOM ET AL., *supra* note 11, at 9. Decree Law 15/93 was amended in 1996, but the amendments within are not applicable to the current analysis. See Decreto-Lei 45/96 [Decree Law 45/96], DIÁRIO DA REPÚBLICA de 3.9.1996 (Port.).

continued to allow for suspension of sentences if the offender agreed to enter into drug addiction treatment.¹⁹

Portugal's domestic drug legislation has been in compliance with the three major United Nations treaties pertaining to drugs.²⁰ Under the Single Convention on Narcotic Drugs of 1961, which Portugal signed in 1961 and ratified in 1971, all signing countries "shall take such legislative and administrative measures as may be necessary . . . to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs."²¹ Article 33 of the treaty forbids parties from permitting the possession of drugs except under legal authority.²² Additionally, Article 36(a) ("Penal Provisions") requires:

[E]ach Party shall adopt such measures as will ensure that cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation and exportation of drugs contrary to the provisions of this Convention . . . shall be punishable offences when committed intentionally, and that serious offences shall be liable to adequate punishment particularly by imprisonment or other penalties of deprivation of

¹⁹ Decree Law 15/93, art. 44. If such a person fails to meet all of the obligations of the treatment program, then they may be found guilty of the criminal offense of failure to comply and may have their suspension revoked, possibly resulting in a prison sentence. *Id.* art. 44(2)-(3).

²⁰ United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances art. 3, Dec. 20, 1988, 1582 U.N.T.S. 95; Single Convention on Narcotic Drugs, 1961, as amended by the Protocol Amending the Single Convention on Narcotic Drugs, 1961 art. 4(a), Aug. 8, 1975, 18 U.S.T. 1407, 976 U.N.T.S. 105 [hereinafter *Single Convention on Narcotic Drugs*]; Convention on Psychotropic Substances art. 22, Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175. There are also several agreements regarding drugs and drug trafficking among countries of the European Union. *See* Resolução do Conselho de Ministros 46/99 [Resolution of the Council of Ministers 46/99], ch. I, § 7, DIÁRIO DA REPÚBLICA de 22.4.1999 (Port.) [hereinafter *Resolution of the Council of Ministers 46/99*]. For the most part, the strategies in these policies are the same as those of the international treaties described above. *See id.*

²¹ *Single Convention on Narcotic Drugs*, *supra* note 20, art. 4(c); *see also Single Convention on Narcotic Drugs, 1961*, UNITED NATIONS TREATY COLLECTION, http://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-15&chapter=6&lang=en (last visited Apr. 24, 2012). Although the treaty lists a number of substances in the Schedules, the main drugs targeted by this treaty are cannabis, cocaine, and opiates. *See Single Convention on Narcotic Drugs*, *supra* note 20, scheds. I-IV.

²² *Single Convention on Narcotic Drugs*, *supra* note 20, art. 33.

liberty.²³

The Convention of Psychotropic Substances of 1971 “extended control to a broad range of fabricated behavior and mood-altering substances that according to the [United Nations] could lead to harmful dependencies,” and requires ratifying nations to limit the use of psychotropic substances listed in the treaty to scientific and medical purposes.²⁴ Further, it requires:

[E]ach Party shall treat as a punishable offence, when committed intentionally, any action contrary to a law or regulation adopted in pursuance of its obligations under this Convention, and shall ensure that serious offences shall be liable to adequate punishment, particularly by imprisonment or other penalty of deprivation of liberty.²⁵

Finally, Article III of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 requires all parties to create criminal offenses for the manufacture and distribution of any narcotic drug or psychotropic substance listed in the two earlier treaties.²⁶ Furthermore, it states:

Subject to its constitutional principles and the basic concepts of its legal system, each Party shall adopt such measures as may be necessary to establish as a criminal offense under its domestic law, when committed intentionally, the possession, purchase or cultivation of narcotic drugs or psychotropic substances for

²³ *Id.* art. 36(1)(a). It is important to note that the title of Article 36 is Penal Provisions. *Id.* Although possession is present in this list, this Article merely commands that Parties shall not admit possession under legal authority. *See id.* This suggests that under the treaty, possession does not need to be treated as a criminal offense. The treaty also states that “[t]he Parties shall give special attention to and take all practicable measures for the prevention of abuse of drugs and for the early identification, treatment, education, after-care, rehabilitation and social reintegration of the persons involved” *Id.* art. 38(1).

²⁴ Convention on Psychotropic Substances, *supra* note 20, art. 5; DAVID R. BEWLEY-TAYLOR, THE UNITED STATES AND INTERNATIONAL DRUG CONTROL, 1909-1997, at 166-67 (1999). The 1961 treaty could not encompass these substances within its scope because they were not “liable to similar abuse and productive of similar ill effects as the drugs in Schedule I or Schedule II,” namely coca, opium, or cannabis. *See* Single Convention on Narcotic Drugs, *supra* note 20, art. 3(3)(iii). The psychotropic substances referred to in this treaty include MDMA (ecstasy), amphetamines, barbiturates, benzodiazepines, psilocybin, lysergic acid diethylamide (LSD), and mescaline, among others. *See* Convention on Psychotropic Substances, *supra* note 20, scheds. I-IV.

²⁵ Convention on Psychotropic Substances, *supra* note 20, art. 22(1)(a).

²⁶ United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, *supra* note 20, art. 3(1)(a)(i).

personal consumption²⁷

The remainder of the treaty is focused mainly on combating organized crime and controlling precursors to illicit drug use and trafficking.²⁸

Not only did Portugal change from having no drug regulation to enacting a criminalization regime, but it also entered into a system that constrained the types of regulation it was permitted to adopt. Despite added penalties, these policies did not prevent a rise in certain social problems related to drug use.

B. Social Problems Associated with Drug Use During the Mid-1980s and Throughout the 1990s

Portugal is the closest country in Western Europe to Latin America, and this proximity, coupled with its historical ties to this region, established it as an

²⁷ *Id.* art. 3(2). The possession or purchase of any narcotic drug or psychotropic substance for the purposes of manufacture or distribution is also to be made a criminal offense. *Id.* art. 3(1)(a)(iii).

²⁸ *See id.* arts. 5 (confiscation, including bank, financial, and commercial records), 6 (extradition), 7 (mutual legal assistance), 9 (other forms of cooperation and training), 10 (international cooperation and assistance for transit States), 12 (addressing precursors), 17 (illicit traffic by sea), 18 (free trade zones and free ports), 19 (the use of mails). Implementation of the treaties is monitored by the Commission on Narcotic Drugs of the Council (Commission) and the International Narcotics Control Board (INCB). *See* United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, *supra* note 20, arts. 21-22; Single Convention on Narcotic Drugs, *supra* note 20, arts. 5, 8(c), 9(4), 14; Convention on Psychotropic Substances, *supra* note 20, arts. 17, 19. If the INCB finds a signatory to be noncompliant with the treaty requirements, the INCB may request that the government concerned open consultations or furnish an explanation. United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, *supra* note 20, art. 22(1)(a); Single Convention on Narcotic Drugs, *supra* note 20, art. 14(1)(a); Convention on Psychotropic Substances, *supra* note 20, art. 19(1)(a). If the INCB finds it necessary, it may then request that the government adopt remedial measures to ensure compliance with the treaties. United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, *supra* note 20, art. 22(1)(b)(i); Single Convention on Narcotic Drugs, *supra* note 20, art. 14(1)(b); Convention on Psychotropic Substances, *supra* note 20, art. 19(1)(b). The INCB may also call the matter to the attention of the Commission, the Economic and Social Council of the United Nations, and the other Parties to the treaty. United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, *supra* note 20, art. 22(1)(b)(iii); Single Convention on Narcotic Drugs, *supra* note 20, art. 14(1)(d); Convention on Psychotropic Substances, *supra* note 20, art. 19(1)(c). Should the INCB take this approach, it may also recommend that the Parties stop importing or exporting drugs from or to the noncompliant nation. Single Convention on Narcotic Drugs, *supra* note 20, art. 14(2); Convention on Psychotropic Substances, *supra* note 20, art. 19(2).

important trade route for drugs.²⁹ Cultural links to Brazil and access to the ocean make Portugal an attractive transshipment country.³⁰ Its location on the southwest border of Europe makes it a trafficking gateway to the rest of the continent.³¹ Cocaine comes into Portugal from Latin America (specifically Brazil and Mexico), heroin from Spain and the Middle East, hashish from Morocco, and herbal cannabis from southern Africa.³² Despite this, the percentage of the Portuguese population that claims to have used illegal drugs at least once has historically been low, indicating that these drugs are being exported to other countries in Europe.³³

During the 1990s, however, Portugal experienced a substantial influx of

²⁹ CAITLIN HUGHES & ALEX STEVENS, THE BECKLEY FOUND. DRUG POLICY PROGRAMME, THE EFFECTS OF DECRIMINALIZATION OF DRUG USE IN PORTUGAL 3 (2007).

³⁰ VAN BEUSEKOM ET AL., *supra* note 11, at 64. The assistant director of the Department of Narcotics Traffic of Portugal explained that “Portugal, and in a more general sense the Iberian Peninsula, is the big entry door for cocaine into Europe” Levi Fernandes, *Portugal Seen as European Gateway for Cocaine*, MAIL & GUARDIAN ONLINE, Feb. 12, 2011, <http://www.mg.co.za/article/2005-12-19-portugal-seen-as-european-gateway-for-cocaine>. Most of the cocaine entering Portugal originally comes from Colombia, but some is shipped through Brazil, a former Portuguese colony, Venezuela, which has a large Portuguese population, and Mexico. Caitlin Elizabeth Hughes & Alex Stevens, *What Can We Learn from the Portuguese Decriminalization of Illicit Drugs?*, 50 BRIT. J. CRIMINOLOGY 999, 1001 (2010). Easy access to other European Union countries and close ties to former Portuguese colonies in Northern Africa make Portugal an appealing transshipment point for traffickers. Fernandes, *supra*. In fact, about five percent of cocaine seized worldwide is in Portugal and Spain. *Id.*

³¹ Hughes & Stevens, *supra* note 30, at 1001. By the 1990s, “Portugal had developed a reputation as a gateway for drug trafficking, with more than three quarters of drugs seized destined for other European countries.” Matthew Hill, *Can Lessons Be Learned from Portugal’s Drug Laws?*, BBC, Oct. 2, 2010, <http://www.bbc.co.uk/news/uk-11454671>.

³² Hughes & Stevens, *supra* note 30, at 1001; Central Intelligence Agency, *The World Factbook: Field Listing—Illicit Drugs*, <https://www.cia.gov/library/publications/the-world-factbook/fields/2086.html> (last visited Apr. 24, 2012). “Since the 1970’s Latin America has been both the major producer and exporter of one of the main illegal drugs, cocaine Brazil is reckoned to be the major exporter of illegal drugs to Europe” Philip J. O’Brien, *Terrorism and the War Against Drugs*, in SOUTH AMERICA, CENTRAL AMERICA, AND THE CARIBBEAN 2003, at 28, 28 (Jacqueline West ed., 11th ed. 2002).

³³ Hughes & Stevens, *supra* note 30, at 1001. For example, in 2006, Portugal’s lifetime prevalence for cannabis use among adults aged fifty to sixty-four was 11.7%, compared to 40.6% in the United States, 30.1% in the United Kingdom, and 22.6% in the Netherlands. LOUISA DEGENHARDT ET AL., THE BECKLEY FOUND. DRUG POLICY PROGRAMME, COMPARING THE DRUG SITUATION ACROSS COUNTRIES: PROBLEMS, PITFALLS, AND POSSIBILITIES 4 (2009).

heroin, and with this increase came a rise in social problems related to its use.³⁴ The rate of injection drug-related AIDS cases rose from 0.1 per million persons in 1985 to 54.7 per million persons in 1998.³⁵ By 1999, Portugal had the highest rate of injection drug-related AIDS cases and the second-highest prevalence of HIV amongst injection drug users in the European Union.³⁶ In 2000, the prevalence of HIV among drug users who entered drug treatment in the public sector was fourteen percent.³⁷ Cases of tuberculosis and hepatitis B and C, common HIV co-infections, also skyrocketed during this period.³⁸ Additionally, the number of acute drug-related deaths in the country rose from about twenty in 1987 to almost four hundred in 1999.³⁹

Another consequence of the rise in use of heroin was an increase in the number of arrests for drug offenses—from 4,667 in 1991 to 11,395 in 1998.⁴⁰ Further, the number of treatment episodes in Portugal, the overwhelming majority of which were for the treatment of heroin addiction, rose from 56,438 in 1990 to 288,038 in 1999.⁴¹ Estimates for the late 1990s and early 2000s generally placed the number of drug addicts between fifty and sixty thousand out of a population of approximately ten million.⁴² Concerns of both the general public and the government over the social exclusion and marginalization of drug users grew.⁴³ Ultimately, this public health crisis became a turning point in the public's

³⁴ VAN BEUSEKOM ET AL., *supra* note 11, at 8.

³⁵ Mirjam van het Loo et al., *Decriminalization of Drug Use in Portugal: The Development of a Policy*, 582 ANNALS AM. ACAD. POL. & SOC. SCI. 49, 52 (2002).

³⁶ Hughes & Stevens, *supra* note 30, at 1001.

³⁷ Paula Vale de Andrade & Ludmila Carapinha, *Drug Decriminalisation in Portugal*, 341 BRIT. MED. J. 4554 (2010). Compare this number with the 0.6% HIV rate among the entire adult population of Portugal in 2009. See *Portugal*, HIV INSITE, <http://hivinsite.ucsf.edu/global?page=cr10-po-00> (last updated Sept. 2006).

³⁸ Hughes & Stevens, *supra* note 30, at 1001.

³⁹ van het Loo et al., *supra* note 35, at 53 fig.1.

⁴⁰ *Id.* at 52. In 1998, sixty-one percent of these arrests were for use or possession, and forty-five percent were heroin related. *Id.*

⁴¹ *Id.* at 53-54. Heroin users accounted for 95.4% of all drug users undergoing treatment in 1997. *Id.* at 54.

⁴² VAN BEUSEKOM ET AL., *supra* note 11, at 10. This is about 0.6% of the population. Comparatively, in the United States, "23.2 million persons (9.4 percent of the U.S. population) aged 12 or older needed treatment for an illicit drug or alcohol use problem in 2007." *InfoFacts: Treatment Approaches for Drug Addiction*, NAT'L INST. DRUG ABUSE 1 (Sept. 2009), http://www.drugabuse.gov/sites/default/files/if_treatment_approaches_2009_to_nida_92209.pdf.

⁴³ Social exclusion is "a process of progressive social rupture, detaching groups and individuals from social relations and institutions and preventing them from full participation in the normal activities of the society in which they live." HILARY SILVER, *SOCIAL EXCLUSION: COMPARATIVE ANALYSIS OF EUROPE AND MIDDLE EAST YOUTH* 15 (2007).

perception of the drug-using population, resulting in a shift away from seeing an addict as a criminal toward seeing him or her as an ill person.⁴⁴ Casal Ventoso, described in the Introduction, played a major role in facilitating this change in conceptualization by serving as a test site for experimentation with harm reduction approaches such as mobile syringe exchange, methadone treatment, and the provision of clothes, food, and medical support to users.⁴⁵

C. Portugal's Decriminalization Scheme

Toward the end of the last millennium, the citizens and government of Portugal came to view drug abuse and its accompanying problems as uncontrollable.⁴⁶ The greatest obstacles to addressing these issues were the draining of financial and human resources caused by the criminalization regime and barriers to drug addiction treatment, like stigma and fear of prosecution.⁴⁷ As

⁴⁴ Hughes, *supra* note 1, at 103.

⁴⁵ *Id.* at 103. Harm reduction in the context of drug use is a public health philosophy that recognizes that complete abstinence from drugs is not a realistic goal for many users and focuses instead on education, injury prevention, and treatment to minimize the harms associated with drug use. *See, e.g., Reducing Drug Harm*, DRUG POLICY ALLIANCE, <http://www.drugpolicy.org/issues/reducing-drug-harm> (last visited Mar. 4, 2012). It differs from supply reduction, which seeks to disrupt the production and supply of illicit drugs, and demand reduction, which seeks to prevent people from wanting and taking drugs, although all three strategies can be used in conjunction. CTR. FOR HARM REDUCTION, FACT SHEET: SUPPLY, DEMAND & HARM REDUCTION 1, 2 (2004). Because harm reduction focuses on the health of the user, it is regarded as a more public health-oriented approach to drug use, whereas prohibition is regarded as a criminal justice approach because of its focus on making use illegal. *Id.*

Syringe exchange programs provide a reliable way for injection drug users to get sterile syringes and dispose of used syringes at no cost, thus reducing the possibility that they will share or reuse syringes. *Syringe Exchange Programs*, CTRS. FOR DISEASE CONTROL AND PREVENTION 1 (Dec. 2005), http://www.cdc.gov/idu/facts/aed_idu_syr.pdf. In addition to lowering the risk of spreading blood-borne diseases, syringe exchanges provide a contact between injecting drug users and public health services, such as tuberculosis and sexually transmitted infection screening, condom distribution, and treatment providers. *Id.* at 2. Methadone is a synthetic opiate that blocks the receptor sites for heroin and other opiates, preventing the user from experiencing euphoric effects, reducing craving, preventing withdrawal, and allowing the user to function. *Methadone Maintenance Treatment*, CTRS. FOR DISEASE CONTROL AND PREVENTION 1 (Feb. 2002), <http://www.cdc.gov/idu/facts/MethadoneFin.pdf>.

⁴⁶ GLENN GREENWALD, CATO INST., DRUG DECRIMINALIZATION IN PORTUGAL: LESSONS FOR CREATING FAIR AND SUCCESSFUL DRUG POLICIES 6 (2009).

⁴⁷ *Id.* Criminal justice professionals also viewed the situation in this manner. Hughes, *supra* note 1, at 111. Many supported reform for two reasons: the belief that the drug trade in Portugal could never be halted and the belief that drug users could be better assisted through the health and social systems. This widely held belief led to a de facto

one commentator stated, “decriminalization was driven *not* by the perception that drug abuse was an insignificant problem, but rather by the consensus view that it was a highly significant problem, that criminalization was *exacerbating* the problem, and that only decriminalization could enable an effective government response.”⁴⁸ In fact, the decriminalization law was enacted only after an expert commission, known as the Comissão para a Estratégia Nacional de Combate à Droga (Commission for a National Drug Strategy, “CNDS”), conducted an extensive study of potential solutions to drug use and its related problems.⁴⁹ The CNDS issued a report recommending a drug strategy based on the principles of harm reduction, prevention, and reintegration of the drug user into society.⁵⁰ As one commentator noted, the “commission ultimately recommended decriminalization as the optimal strategy for combating Portugal’s growing abuse and addiction problems. The commission emphasized that the objective of its decriminalization strategy was to reduce drug abuse and usage.”⁵¹

In 1999, a newly elected Assembly of the Republic, Portugal’s primary Parliamentary body, took office and almost immediately began implementing the CNDS recommendations for national drug policy. The Assembly approved a strategy based heavily on the CNDS report,⁵² which takes the following view:

[D]rugs users are to be regarded as full members of society instead of cast out as criminals or other pariahs and . . . the strategy will not attempt to strive toward an unachievable perfection such as zero drug use but will instead try to make

decriminalization system in which the police would not enforce criminal penalties against users. *Id.* Instead, offenders could and were being sent to treatment or were not facing prosecution at all. LAURENCE ALLEN ET AL., THE BECKLEY FOUND. DRUG POLICY PROGRAMME, DECRIMINALISATION OF DRUGS IN PORTUGAL: A CURRENT OVERVIEW 2 (2004).

⁴⁸ GREENWALD, *supra* note 46, at 6; see COMISSÃO PARA A ESTRATÉGIA NACIONAL DE COMBATE À DROGA [COMMISSION FOR A NATIONAL DRUG STRATEGY], ESTRATÉGIA NACIONAL DE LUTA CONTRA DROGA [NATIONAL STRATEGY FOR THE FIGHT AGAINST DRUGS] 82 (1998) (Port.) [hereinafter COMMISSION FOR A NATIONAL DRUG STRATEGY].

⁴⁹ COMMISSION FOR A NATIONAL DRUG STRATEGY, *supra* note 48; GREENWALD, *supra* note 46, at 6. The panel consisted of leading academics and medical professionals, among others. See ALLEN ET AL., *supra* note 47, at 2.

⁵⁰ *Id.*; see also COMMISSION FOR A NATIONAL DRUG STRATEGY, *supra* note 48.

⁵¹ GREENWALD, *supra* note 46, at 6-7 (emphasis omitted); see COMMISSION FOR A NATIONAL DRUG STRATEGY, *supra* note 48, at 82.

⁵² ALLEN ET AL., *supra* note 47, at 2; van het Loo et al., *supra* note 35, at 50; see Resolution of the Council of Ministers 46/99, *supra* note 20. Before the new Assembly took office, the recommendations of the CNDS had been ignored. Hughes, *supra* note 1, at 117.

things better for all segments of society.⁵³

It also stresses thirteen strategic options, including the decriminalization of drug use, the expansion of quality healthcare and access to treatment for addicts, the expansion of harm reduction policies including syringe exchange and substitution treatment, the guarantee of available voluntary treatment as a substitute for criminal penalties for drug addicts, and the reinforcement of the fight against drug trafficking and money laundering.⁵⁴ The strategy was approved later in 1999,⁵⁵ after which implementation efforts began in full force.

Decree Law 30/2000 was enacted in October 2000 and took effect on July 1, 2001.⁵⁶ This law decriminalizes the use and possession of drugs and establishes commission of these acts as an administrative offense, so long as the amount possessed or consumed does not exceed the quantity needed for average individual consumption over a period of ten days.⁵⁷ A ten-day supply would be one gram for heroin, ecstasy, and amphetamines, two grams for cocaine, and twenty-five grams for cannabis.⁵⁸ There is no distinction in the law between “hard” and “soft” drugs or between consumption and possession in public or private, as are sometimes made in the drug decriminalization schemes of other

⁵³ van het Loo et al., *supra* note 35, at 55. The report is based on eight structuring principles: international cooperation, prevention, humanism, pragmatism, security, coordination and rationalization of resources, subsidiarity, and participation. Resolution of the Council of Ministers 46/99, *supra* note 20, ch. II, § 5. “The principle of subsidiarity implies the distribution of responsibilities and competencies enabling decisions and actions to be entrusted to the level of Administration that is closest to the population . . .” *Id.* ch. II, § 5(7).

⁵⁴ Resolution of the Council of Ministers 46/99, *supra* note 20, ch. II, § 10(2), (4)-(5), (8), (12).

⁵⁵ See Resolution of the Council of Ministers 46/99, *supra* note 20.

⁵⁶ van het Loo et al., *supra* note 35, at 57. The decriminalization law was not enacted without opposition. Hughes, *supra* note 1, at 121. Conflicting ideologies, political developments, and fears that Portugal would become a drug paradise generated opposition to the passage of the law. *Id.* For a full account of the political tension leading up to the passage of Decree Law 30/2000, see *id.* at 120-25.

⁵⁷ Decree Law 30/2000, *supra* note 2, art. 2.

⁵⁸ See Portaria 94/96 [Ordinance 94/96], art. IV(9), map, DIÁRIO DA REPÚBLICA de 26.3.1996 (Port.). According to this ordinance, a daily average intake would be 0.1 grams of heroin, 0.1 grams of ecstasy, 0.1 grams of amphetamines, 0.2 grams of cocaine, and 2.5 grams of cannabis. *Id.* It is estimated that average heroin addicts use somewhere between 0.15 and 0.25 grams of heroin daily. *Heroin Statistics*, HEROIN ADDICTION, http://www.heroin-addiction.info/Heroin_Statistics.htm (last visited Apr. 3, 2012). Five grams of marijuana is enough to make three to five joints (marijuana cigarettes) and 0.5 grams of cocaine is the equivalent of three to eight “lines.” Drug Policy Alliance, *DPA Statement: Mexico’s Drug Decriminalization Law Effective Today*, YOUTUBE (Aug. 21, 2009), <http://www.drugpolicy.org/news/pressroom/pressrelease/pr082109a.cfm>.

countries.⁵⁹

Offenses committed under this law are not handled by the criminal justice system.⁶⁰ Instead, the law creates special committees, known as Comissões para a Dissuasão da Toxicodependência (Commissions for the Dissuasion of Drug Addiction, “CDTs”), which have the power to enforce the provisions of the law by imposing fines and alternative penalties.⁶¹ The police refer users to a CDT within seventy-two hours of the offense, but no arrests may be made.⁶² The primary goal of removing both the authority of police to make arrests and the requirement that the offender appear before a criminal court is to prevent users from incurring the stigma that is attached to criminal proceedings, thus eliminating a key barrier to treatment and alleviating the user’s fear of prosecution when seeking help.⁶³

Each CDT is comprised of three government-appointed civilians.⁶⁴ One of the members must be a legal expert appointed by the Ministry of Justice, but the other two are appointed by the Ministry of Health and may be chosen from the fields of medicine, psychology, sociology, social services, or other areas where expertise in drug addiction may be found.⁶⁵ The CDTs hear from the accused and gather information to assess his or her economic status, determine if he or she is addicted, and evaluate the circumstances surrounding the drug consumption, including the nature of the substances consumed and the place of use.⁶⁶ These

⁵⁹ van het Loo et al., *supra* note 35, at 58. For example, in some countries marijuana may be considered a soft drug while heroin would be categorized as a hard drug. *See, e.g.,* D. VAN DER GOUWE ET AL., TRIMBOS INST., DRUG POLICIES IN THE NETHERLANDS 5 (2009).

⁶⁰ VAN BEUSEKOM ET AL., *supra* note 11, at 15. This distinguishes Portugal from countries like Spain, where there is a de facto decriminalization system where the user will not be sentenced to criminal penalties but will still be processed through the criminal justice system, and the United States, where the user can enter treatment only after being convicted in a criminal court. *Id.*

⁶¹ Decree Law 30/2000, *supra* note 2, art. 5(1)-(2); HUGHES & STEVENS, *supra* note 29, at 1.

⁶² ALLEN ET AL., *supra* note 47, at 2. Although citation by the police is the main method by which consumers are introduced into the administrative system, they can also be reported by their doctors. *See* Decree Law 30/2000, *supra* note 2, art. 3(2). However, doctors feel repugnance toward reporting, which may breach their oath of confidentiality. VAN BEUSEKOM ET AL., *supra* note 11, at 15-16.

⁶³ VAN BEUSEKOM ET AL., *supra* note 11, at 26; GREENWALD, *supra* note 46, at 9.

⁶⁴ Decree Law 30/2000, *supra* note 2, art. 7(1).

⁶⁵ *Id.* art. 7(2); *see* Decreto-Lei 40/2010 [Decree Law 40/2010], DIÁRIO DA REPÚBLICA de 28.4.2010 (Port.) [hereinafter Decree Law 40/2010]. Originally, the Instituto da Droga e da Toxicodependência became the government’s coordinator of drug policy. *See infra* note 89. However, changes in the law occurring in 2010 gave this responsibility to the Minister of Health. *See* Decree Law 40/2010, art. 5.

⁶⁶ Decree Law 30/2000, *supra* note 2, art. 10(1). There are no set criteria for

commissions are designed to emphasize respect for the alleged offender at each step of the process and to encourage offender participation.⁶⁷ To facilitate this respectful setting, commissioners dress informally, sit on the same level as the alleged offender, and allow a therapist of the alleged offender's choice to take part in the proceeding.⁶⁸

If a user is found to have no prior offenses under the law and is not addicted, the CDT must provisionally suspend the proceedings.⁶⁹ If the CDT determines that the user is addicted, but the user has not committed a prior offense under the law, then the proceedings are provisionally suspended if the addict voluntarily agrees to undergo treatment.⁷⁰ The CDT also has discretion to provisionally suspend proceedings if the user is found to be an addict with prior offenses under the law but agrees to undergo treatment.⁷¹ If a non-addicted user does not repeat the offense, or in the case of an addicted user, completes treatment without interruption, then the proceedings may not be reopened.⁷² If the CDT decides to impose penalties against an addicted user, these may be suspended if the user voluntarily agrees to undergo treatment.⁷³

CDTs may assess a wide variety of sanctions for violations. For addicted users, the penalties can include: ineligibility for the practice of certain occupations requiring licenses; expulsion from certain places; prohibition on associating with certain people; restrictions on foreign travel; periodic presentation at a place indicated by the commission (usually for medical services); ineligibility for firearm licenses; seizure of objects that represent a risk to the consumer or the public or that would encourage the commission of a crime or other offense; termination of public benefits for subsidies or allowances; mandatory donation to a charitable organization; or required hours of community service.⁷⁴ Non-addicted users are subject to all of the same penalties, in addition

determining if a user is addicted and it is left to the judgment of the CDT. *See id.* However, the CDT may request that medical examinations be conducted in order to help make this determination. *Id.* art. 10(3).

⁶⁷ GREENWALD, *supra* note 46, at 6.

⁶⁸ *Id.* at 5-6. Alleged offenders are not represented by attorneys, further emphasizing that the proceeding is not criminal in nature. Alex Kreit, *The Decriminalization Option: Should States Consider Moving from a Criminal to a Civil Drug Court Model?*, 2010 U. CHI. LEGAL F. 299, 327 (2010).

⁶⁹ Decree Law 30/2000, *supra* note 2, art. 11(1). Suspensions of proceedings last for two years, unless the CDT decides on due grounds that it should last three years. *Id.* art. 13(1).

⁷⁰ *Id.* art. 11(2).

⁷¹ *Id.* art. 11(3).

⁷² *Id.* art. 13(2).

⁷³ *Id.* art. 14(1). The penalties may be suspended for up to three years, at which point the proceedings will be closed and the penalties will not apply. *Id.* art. 14(2)-(4).

⁷⁴ *Id.* art. 17(2)-(3); *see id.* art. 15(2). An example of a place that a person can be

to or in place of a fine between \$35 and the minimum national wage, which was \$792.16 per month in 2012.⁷⁵ CDTs also have the power to limit sanctions to a mere warning if it is determined, after consideration of the circumstances of the user, the type of consumption, and the substance consumed, that the user will abstain from future consumption.⁷⁶ The CDT decides which penalties to apply based on several factors so that each case is individualized.⁷⁷ These factors include: seriousness of the act; degree of fault; type of substance consumed; whether consumption was public or private; and, if public, the place where it occurred.⁷⁸ For non-addicted users, additional considerations include the occasional or habitual nature of use and the personal circumstances (mainly financial) of the user.⁷⁹ The national government has the power to enforce these penalties through its administrative offices in each district.⁸⁰

When this legislation was first adopted, Portugal recognized the possible tension between its decriminalization of possession and use of drugs and the international treaties with which it is obligated to comply, but ultimately decided that its policies were consistent with those treaties.⁸¹ The International Narcotics Control Board (INCB) initially stated in 1999 that removal of criminal sanctions for possession of drugs was not in line with the international treaties.⁸² In their 2004 report, however, the INCB stated the following about Portugal's policy:

[T]he acquisition, possession and abuse of drugs had remained prohibited. While the practice of exempting small quantities of drugs from criminal prosecution is consistent with the international drug control treaties, the Board emphasizes that the objective of the treaties is to prevent drug abuse and to limit the

prohibited from visiting would be a nightclub. GREENWALD, *supra* note 46, at 4. An example of the type of people that the user may be prohibited from associating with might be acquaintances with whom the user consumes substances.

⁷⁵ Decree Law 30/2000, *supra* note 2, arts. 15(1), 16(1); GREENWALD, *supra* note 46, at 3; *NMW - National Minimum Wage - Portugal*, DATOSMACRO.COM, <http://www.datosmacro.com/en/national-minimum-wage/portugal> (last visited Mar. 4, 2012). The law notes the figure of \$35 as PTE 5,000. See Decree Law 30/2000, *supra* note 2, art. 16(1).

⁷⁶ Decree Law 30/2000, *supra* note 2, art. 18(1).

⁷⁷ VAN BEUSEKOM ET AL., *supra* note 11, at 53.

⁷⁸ Decree Law 30/2000, *supra* note 2, art. 15(4).

⁷⁹ *Id.*

⁸⁰ *Id.* art. 5(2).

⁸¹ Resolution of the Council of Ministers 46/99, *supra* note 20, ch. IV, § 28.

⁸² INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 1999, at 56, ¶ 449, U.N. Doc. E/INCB/1999/1, U.N. Sales No. E.00.XI.1 (2000); Hughes, *supra* note 1, at 94. For more information on the INCB, see *supra* text accompanying note 27.

use of controlled substances to medical and scientific purposes.⁸³

To accompany the decriminalization law, the Portuguese government enacted a law establishing rules for the implementation of harm reduction measures.⁸⁴ Portugal's law sought as its main objective to "create programmes and social and health structures designed to raise awareness amongst drug users and to guide them towards treatment, as well as to prevent and reduce risk attitudes and to minimise the damage caused to individuals and society by drug addiction."⁸⁵ The law regulates the development of mobile centers for the prevention of infectious diseases, drug substitution programs, and syringe exchange schemes, among others.⁸⁶ Although the law sets a uniform framework for implementing these harm reduction measures, it does not command specific implementation of these measures by any enforcement entity.⁸⁷

Between 1998 and 2000, a new agency was established that would eventually become known as the Instituto da Droga e da Toxicodependência (Institute for Drugs and Drug Addiction, "IDT").⁸⁸ The purpose of creating the

⁸³ INT'L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2004, at 80, ¶ 538, U.N. Doc. E/INCB/2004/1, U.N. Sales No. E.05.XI.3 (2005) [hereinafter INCB Report for 2004].

⁸⁴ Decreto-Lei 183/2001 [Decree Law 183/2001], DIÁRIO DA REPÚBLICA de 21.6.2001 (Port.) [hereinafter Decree Law 183/2001]; see VAN BEUSEKOM ET AL., *supra* note 11, at 17.

⁸⁵ Decree Law 183/2001, *supra* note 84, ch. I, art. 1.

⁸⁶ *Id.* ch. I, art. 3. Specific criteria for the authorization and funding of these services were set forth in 2007. See Portaria 748/2007 [Administrative Rule 748/2007], DIÁRIO DA REPÚBLICA de 25.6.2007 (Port.); Portaria 749/2007 [Administrative Rule 749/2007], DIÁRIO DA REPÚBLICA de 25.6.2007 (Port.).

⁸⁷ VAN BEUSEKOM ET AL., *supra* note 11, at 17. For example, the law dictates the structure for programs of supervised drug use, but Portugal does not currently have any of these programs. See Decree Law 183/2001, *supra* note 84, ch. X. A reason for this may be that the United Nations has stated that supervised consumption sites violate international treaties. See *Safe Injection Site Breaks Treaties*, UN Agency Says, VANCOUVER SUN, Mar. 2, 2007, <http://www.canada.com/vancouvernews/story.html?id=f9922177-8a0b-4f2f-8323-8bec41ef2819&k=70372>.

⁸⁸ See Decreto-Lei 269-A/2002 [Decree Law 269-A/2002], DIÁRIO DA REPÚBLICA de 29.11.2002 (Port.) [hereinafter Decree Law 269-A/2002]; see also Decreto-Lei 31/99 [Decree Law 31/99], DIÁRIO DA REPÚBLICA de 5.2.1999 (Port.) [hereinafter Decree Law 31/99] (repealing Decreto-Lei 365/82 [Decree Law 365/82], DIÁRIO DA REPÚBLICA de 8.9.1982 (Port.) (establishing Gabinete de Planeamento e de Coordenação do Combate à Droga)); Decreto-Lei 418/85 [Decree Law 418/85], DIÁRIO DA REPÚBLICA de 21.10.1985 (Port.). Originally called the Instituto Português da Droga e da Toxicodependência (Portuguese Institute for Drugs and Drug Addiction), this agency combined with the Serviço de Prevenção e Tratamento da Toxicodependência (Service for the Prevention and Treatment of Drug Abuse) to form a single institution (Institute for Drugs and Drug Addiction), consolidating the evaluation and other responsibilities of the two

IDT was to consolidate resources; oversee the CDTs; appoint CDT members; and collect, process, and disseminate data in the area of drug use and addiction.⁸⁹ It has since issued regulations and guidelines for specific types of cases, created a central committee to provide advice to the CDTs, and developed a database of information about the individuals brought before the CDTs and the decisions rendered, to monitor effectiveness.⁹⁰ The IDT is also charged with promoting, planning, coordinating, and implementing the harm reduction programs in each geographic region, ensuring that none are duplicated, and evaluating the programs' effectiveness.⁹¹ Since the inception of the IDT, healthcare for drug users has been provided mainly through public network services.⁹²

D. Effects and Developments After Portuguese Decriminalization

Portugal has undergone several institutional changes in response to the decriminalization law, including establishing CDTs in every region of Portugal, increasing the provision of drug treatment and education, and refocusing police efforts on large-scale operations.⁹³ In 2009, there were 7,549 processes filed with the CDTs, 5,508 of which were resolved by the end of that year.⁹⁴ This represented both the highest number of processes filed and decisions rendered since decriminalization was implemented.⁹⁵ Of the commission rulings, eighty-five percent suspended the proceeding; fourteen percent imposed a sanction, and one percent resulted in absolution.⁹⁶ This distribution has remained constant since the law's enactment.⁹⁷ In order to facilitate these changes, drug policy

organizations. *See* Decree Law 269-A/2002, *supra*.

⁸⁹ Decree Law 269-A/2002, *supra* note 88, Annex art. 5; Resolution of the Council of Ministers 46/99, *supra* note 20, ch. I, § 1; *see* Decree Law 31/99, *supra* note 88, arts. 2, 3(a)-(b), 13; VAN BEUSEKOM ET AL., *supra* note 11, at 17.

⁹⁰ VAN BEUSEKOM ET AL., *supra* note 11, at 17.

⁹¹ Decree Law 269-A/2002, *supra* note 88, Annex art. 5; Decree Law 183/2001, *supra* note 84, ch. I, art. 5; *see, e.g.*, Decree Law 183/2001, *supra* note 84, ch. II, art. 13; *id.* ch. IV, art. 28. In 2010, Decree Law 40/2010 extended authority of the IDT to cover harmful use of alcohol. *See* Decreto-Lei 40/2010 [Decree Law 40/2010], DIÁRIO DA REPÚBLICA de 28.4.2010 (Port.).

⁹² INSTITUTO DA DROGA E DA TOXICODPENDENCIA [INST. FOR DRUGS & DRUG ADDICTION], 2010 NATIONAL REPORT (2009 DATA) TO THE EMCDDA 63 (2010), http://www.idt.pt/PT/IDT/Documents/Ponto_Focal/2010_NationalReport.pdf.

⁹³ HUGHES & STEVENS, *supra* note 29, at 2.

⁹⁴ INSTITUTO DA DROGA E DA TOXICODPENDENCIA, *supra* note 92, at 107.

⁹⁵ *See id.*

⁹⁶ *Id.*

⁹⁷ GREENWALD, *supra* note 46, at 6. Where sanctions were imposed, the majority were requirements that the offender periodically report to designated locales. *Id.* In 2002, ninety-one percent of commission rulings suspended the proceeding, six percent resulted in sanctions, and three percent resulted in absolution. ALLEN ET AL., *supra* note 47, at 2.

expenditures doubled between 1998 and 2004, and by 2008, spending had risen to \$77.5 million.⁹⁸

Decriminalization in Portugal has generally been seen as a success.⁹⁹ A comprehensive study by the CATO Institute noted that “[w]hile drug addiction, usage, and associated pathologies continue to skyrocket in many EU states, those problems—in virtually every relevant category—have been either contained or measurably improved within Portugal since 2001.”¹⁰⁰ Further, Portugal has outperformed the overwhelming majority of other nations in almost all categories of significance since decriminalization.¹⁰¹ Many categories of drug use, such as prevalence rates within certain age groups and problem drug use, have actually decreased in absolute terms, contrary to fears of the opposite effect, and usage in other categories has increased only slightly or mildly.¹⁰²

In 2005, eighty-three percent of commission rulings suspending the proceeding, fifteen percent imposed a sanction, and two percent resulted in absolution. GREENWALD, *supra* note 46, at 6. An added benefit of the commissions is that most cases are resolved in four to five weeks, whereas court decisions can take up to two years. ALLEN ET AL., *supra* note 47, at 3.

⁹⁸ DEGENHARDT ET AL., *supra* note 33, at 12; Hughes, *supra* note 1, at 120.

⁹⁹ See, e.g., Peter Beaumont et al., *Britain Looks at Portugal's Success Story over Decriminalising Personal Drug Use*, GUARDIAN.CO.UK, Sept. 5, 2010, <http://www.guardian.co.uk/politics/2010/sep/05/portugal-decriminalising-personal-drug-use>; Lauren Frayer, *Is Portugal's Liberal Drug Policy a Model for US?*, AOL NEWS, Aug. 14, 2010, <http://www.aolnews.com/2010/08/14/is-portugals-liberal-drug-policy-a-model-for-us/>; Keith O'Brien, *Drug Experiment*, BOSTON GLOBE, Jan. 16, 2011, http://www.boston.com/bostonglobe/ideas/articles/2011/01/16/drug_experiment/; *Portugal's Drug Policy: Treating, Not Punishing*, ECONOMIST, Aug. 27, 2009, <http://www.economist.com/node/14309861>; Michael Tracy & Neima Jahromi, *Importing the Portuguese Model of Drug Reform*, THE NATION, Dec. 15, 2010, <http://www.thenation.com/article/157124/importing-portuguese-model-drug-reform>; Brian Vastag, *5 Years After: Portugal's Drug Decriminalization Policy Shows Positive Results*, SCI. AM., Apr. 7, 2009, <http://www.scientificamerican.com/article.cfm?id=portugal-drug-decriminalization>. But see *Mixed Results for Portugal's Great Drug Experiment*, NAT'L PUB. RADIO, Jan. 20, 2011 (radio broadcast).

¹⁰⁰ GREENWALD, *supra* note 46, at 28.

¹⁰¹ *Id.* at 11.

¹⁰² *Id.* at 11-12. For thirteen- to fifteen-year-olds the rate of lifetime use dropped from 14.1% in 2001 to 10.6% in 2006 and for sixteen- to eighteen-year-olds the rate of lifetime use dropped from 27.6% in 2001 to 21.6% in 2006. *Id.* For those two groups, rate of use for virtually every drug has decreased since decriminalization. *Id.* “[S]ubsequent to decriminalization in Portugal, for almost every narcotic, the lifetime prevalence rates . . . [are] far lower in Portugal than in Europe generally.” *Id.* at 22; see also *supra* text accompanying note 33 (comparing drug usage rate in Portugal with other countries). “Problem drug use,” defined as long-term use or injecting opioids, cocaine, or amphetamines, is also much lower in Portugal than in some other countries. See DEGENHARDT ET AL., *supra* note 33, at 6. For example, in 2005 it was estimated that

Although syringe exchange has been in place since at least 1993, by 2008 the number of syringe exchange programs had reportedly increased to cover fifty percent of Portugal's territory.¹⁰³ The amount of people utilizing opioid substitution treatment, such as methadone replacement therapy, has also increased considerably since decriminalization.¹⁰⁴ In general, "treatment programs—both in terms of funding levels and the willingness of the population to seek them—have improved substantially."¹⁰⁵

With the increase in treatment and emphasis on public health, many improvements in the rates of disease associated with intravenous drug use have been recorded. For instance:

[T]he number of newly reported cases of HIV and AIDS among

Portugal had a prevalence rate of problem drug use between 4.3 and 7.4, whereas the United Kingdom's rate was 9.9. *Id.*; European Monitoring Center for Drugs and Drug Addiction, *Estimates of Prevalence of Problem Drug Use at National Level: Summary Table, 2004–2009, Rate Per 1000 Aged 15–64*, <http://www.emcdda.europa.eu/stats11/ptutabla> (last visited Mar. 4, 2012). Although lifetime prevalence of drug use in the general population has increased slightly, use rates among young and problem users have decreased. Hughes & Stevens, *supra* note 30, at 1008. About ninety-five percent of citations for drug offenses in Portugal are for Portuguese citizens. INSTITUTO DA DROGA E DA TOXICODPENDÊNCIA, *supra* note 92, at 109; GREENWALD, *supra* note 46, at 6.

¹⁰³ de Almeida & Encarnação, *supra* note 14, at 221; Dagmar Hedrich et al., Eur. Monitoring Centre for Drugs and Drug Addiction, *From Margin to Mainstream: The Evolution of Harm Reduction Responses to Problem Drug Use in Europe*, 15 DRUGS: EDUC., PREVENTION, & POL'Y 503, 508 (2008). In 2007, more than one hundred needles were exchanged per intravenous drug user in Portugal. Bradley M. Mathers et al., 2009 Reference Grp. to the U.N. on HIV and Injecting Drug Use, *HIV Prevention, Treatment, and Care Services for People Who Inject Drugs: A Systematic Review of Global, Regional, and National Coverage*, 375 LANCET 1014, 1018 (2010). In 2009, users exchanged 2,365,821 syringes. INSTITUTO DA DROGA E DA TOXICODPENDÊNCIA, *supra* note 92, at 88. For more information on syringe exchanges, see *supra* text accompanying note 45.

¹⁰⁴ GREENWALD, *supra* note 46, at 15. In 1999, there were 6,040 people utilizing substitution treatment, compared to 14,877 in 2003. *Id.* In 2007, the number had again increased to 17,780 people. Mathers et al., *supra* note 103, at 1018. "Substitution therapy . . . is defined as the administration under medical supervision of a prescribed psychoactive substance, pharmacologically related to the one producing dependence, to people with substance dependence, for achieving defined treatment aims." WHO ET AL., SUBSTITUTION MAINTENANCE THERAPY IN THE MANAGEMENT OF OPIOID DEPENDENCE AND HIV/AIDS PREVENTION: POSITION PAPER 12 (2004). "Substitution maintenance therapy is one of the most effective types of pharmacological therapy of opioid dependence." *Id.* at 13.

¹⁰⁵ GREENWALD, *supra* note 46, at 15. Between 1998 and 2008, the number of people seeking treatment for drug addiction increased from 23,654 to 38,532. Hughes & Stevens, *supra* note 30, at 1015.

drug addicts has declined substantially every year since 2001. The percentage of newly diagnosed HIV and AIDS patients who are drug addicts has steadily decreased over the same time. Likely for the same reasons, there has been, since 2000, a mild decrease in the rates of new hepatitis B and C infections nationwide, all of which are attributed by analysts to the enhanced treatment programs enabled by decriminalization.¹⁰⁶

This same study notes that there have been significant reductions in tuberculosis and HCV, the virus that causes hepatitis C.¹⁰⁷ Moreover, drug-related mortality has decreased since decriminalization, with the total number of drug-related deaths decreasing from almost 400 in 1999 to 290 in 2006.¹⁰⁸

In the first four years after decriminalization, the number of sentences for drug-trafficking offenses rose by eleven percent as compared to the four-year period leading up to decriminalization.¹⁰⁹ This may be attributed to a refocused effort against drug trafficking by police, an increase in trafficking in Portugal, or both.¹¹⁰ Since 2003, total convictions for drug trafficking has decreased.¹¹¹ Overall, the number of criminal offenses related to drugs decreased from 14,000 in 2000 to between 5,000 and 5,500 per year since decriminalization.¹¹²

Additionally, the amount of drugs seized in Portugal has increased considerably.¹¹³ In total, the amount seized for the period of 2000 to 2004

¹⁰⁶ GREENWALD, *supra* note 46, at 16 (footnotes omitted). Notifications of new drug-related HIV infections dropped by seventeen percent between 1999 and 2003. HUGHES & STEVENS, *supra* note 29, at 3. Between 2000 and 2008, the number of HIV cases among injection drug users decreased from 907 to 267, and the number of AIDS cases among injection drug users decreased from 506 to 108. Hughes & Stevens, *supra* note 30, at 1015.

¹⁰⁷ Hughes & Stevens, *supra* note 30, at 1014.

¹⁰⁸ GREENWALD, *supra* note 46, at 17. Decreases in deaths related to opiate use has been partially contributed to an increase in users entering substitution treatment. HUGHES & STEVENS, *supra* note 29, at 3 (citation omitted).

¹⁰⁹ HUGHES & STEVENS, *supra* note 29, at 4.

¹¹⁰ *Id.* “The data thus suggests that the Portuguese decriminalization may have increased efficiency of police or court operations as they became less crowded with drug offenders.” Hughes & Stevens, *supra* note 30, at 1009.

¹¹¹ GREENWALD, *supra* note 46, at 15.

¹¹² Hughes & Stevens, *supra* note 31, at 1008-09 (citation omitted). Arrests for drug consumption or possession also decreased significantly from 8,030 in 1999 to 4,998 in 2004. Hughes, *supra* note 1, at 192 (citation omitted). A person may still be arrested for possession if they possess an amount over the maximum allowed under decriminalization. Decreto-Lei 15/93 [Decree Law 15/93], arts. 21(1), 26(1), DIÁRIO DA REPÚBLICA de 22.1.1993 (Port.).

¹¹³ HUGHES & STEVENS, *supra* note 29, at 3 (“There were increases of more than 100 percent in the amount of heroin, cocaine, cannabis, and ecstasy seized between the four years 1995-1999 and the 2000-2004 period, even though the number of seizures

increased by nearly five hundred percent as compared to the amount seized for the period of 1995 to 1999.¹¹⁴ Commentators suggest that this increase in quantity seized is evidence of increased law enforcement effort to constrain drug trafficking, rather than an indication of an increase in the domestic market for drugs.¹¹⁵

Another positive consequence of this new legislation has been a reduction in Portugal's prison population.¹¹⁶ The number of offenses committed under the influence of drugs or to fund drug consumption has decreased from forty-four percent in 1999 to twenty-one percent in 2008.¹¹⁷ In total, between 2001 and 2005, the number of prisoners declined from 199 to 101.5 per 100 prison spaces.¹¹⁸ Portugal enjoyed a continued decline in the number of inmates throughout the first decade of the 2000s.¹¹⁹ Overall, the strategy has resulted in considerable financial savings for the court and prison systems.¹²⁰

Despite these benefits, some commentators have argued that the strategy of decriminalization with an emphasis on addiction treatment has not been implemented to its full potential.¹²¹ A major impediment to implementation has been the national government's failure to provide additional resources to the CDTs.¹²² For example, between 2003 and 2009, several CDTs were functioning without a quorum.¹²³ When all CDTs obtained full membership, the decision-making capacity increased beyond the level of previous years.¹²⁴ Setbacks in execution of the strategy may stem in part from political ideologies of the party in power at the time.¹²⁵ These criticisms, however, merely demonstrate that greater resources and political will should be devoted to the current strategy.

Portugal extended this strategy until January 2012,¹²⁶ when a change in the

decreased." (citation omitted)).

¹¹⁴ Hughes & Stevens, *supra* note 30, at 1011.

¹¹⁵ *Id.* (comparing seizure patterns of Portugal to Spain and Italy).

¹¹⁶ See HUGHES & STEVENS, *supra* note 29, at 5.

¹¹⁷ Hughes & Stevens, *supra* note 30, at 1010.

¹¹⁸ HUGHES & STEVENS, *supra* note 29, at 5.

¹¹⁹ See INSTITUTO DA DROGA E DA TOXICODPENDÊNCIA, *supra* note 92, at 115.

¹²⁰ ALLEN ET AL., *supra* note 47, at 4.

¹²¹ Hughes & Stevens, *supra* note 30, at 1005.

¹²² *Id.* Another noted problem is the lack of appropriate treatment for occasional drug users and for those addicted to drugs other than opiates. *Id.*

¹²³ INSTITUTO DA DROGA E DA TOXICODPENDÊNCIA, *supra* note 92, at 107 n.50.

¹²⁴ *Id.* at 106.

¹²⁵ See Hughes, *supra* note 1, at 205-08 (explaining that the Social Democratic Party (PSD), which had gained control of Parliament after decriminalization legislation was enacted, threatened to re-criminalize drug use and interfered with full implementation of the law).

¹²⁶ See generally INSTITUTO DA DROGA E DA TOXICODPENDÊNCIA [INST. FOR DRUGS & DRUG ADDICTION], NATIONAL PLAN AGAINST DRUGS AND DRUG ADDICTION 2005-

law significantly altered the scheme. On February 1, 2012, Decree Law 17/2012 transferred almost all of the duties of the IDT to a new organization called the Serviço de Intervenção nos Comportamentos Aditivos e nas Dependências (Service of Intervention in Addictive Behaviors and Addictions, “SICAD”) and made regional governmental authorities responsible for providing treatment and other services previously provided by the IDT.¹²⁷ Economic downturn and attempts to consolidate and conserve resources spurred this transition.¹²⁸ Treatment and harm reduction providers have become worried that this change will result in disrupted or discontinued funding and possible closure of services.¹²⁹ The effects that this shift in policy will have on rates of drug use, treatment uptake, drug-related disease, and other factors are as yet unknown and will have to be studied more thoroughly in later years. Portugal focused on public health when decriminalizing drugs, and the result has been an increase in treatment uptake and savings, and a decrease in drug-related disease rates and prison population. However, without the emphasis on public health, decriminalization can produce much different results.

II. MEXICAN DRUG POLICIES AND PROBLEMS, PRE- AND POST-DECRIMINALIZATION

Part II will focus first on the development of drug policy in Mexico prior to decriminalization. It will then address the social ills that were present before the recent law was enacted. Next, it will examine the provisions of the law against small-scale trafficking. Finally, it will identify the effects that the law has had since its implementation and will offer predictions about the effects that the law might have on Mexican society more broadly.

A. Mexico’s Legal Framework and Drug Policy Prior to Decriminalization

Throughout the nineteenth century, drug use in Mexico—primarily use of

2012 (2004).

¹²⁷ Decreto-Lei 17/2012 [Decree Law 17/2012], DIÁRIO DA REPÚBLICA de 26.1.2012 (Port.). The only duties now left to the IDT are the licensing of private healthcare providers in the area of drug addiction, the implementation of programs of local intervention, and monitoring trends in drug use and treatment. *Id.* art. 10.

¹²⁸ See *id.* pmb.; Alexandra Kirby-Lepesh, *In Times of Austerity, a Threat to Portugal’s Drug Policies*, OPEN SOCIETY FOUNDATIONS, Feb. 10, 2012, http://blog.soros.org/2012/02/in-times-of-austerity-a-threat-to-portugals-drug-policies/?utm_source=Open+Society+Institute&utm_campaign=43677f33f6-health-20120221&utm_medium=email.

¹²⁹ Kirby-Lepesh, *supra* note 128; *Instituto da Droga e Toxicoddependencia acaba hoje. Comunidades terapêuticas às escuras* [Institute for Drugs and Drug Addiction Ends Today. Health Communities in the Dark], RENASCENÇA, Jan. 31, 2012, http://rr.sapo.pt/informacao_detalhe.aspx?fid=31&did=48662.

marijuana, cocaine, and opiates—was legal and common.¹³⁰ People who were addicted to drugs were considered ill or sick, not criminal.¹³¹ This was recognized in legislation in 1940, when a reform to the Federal Criminal Code included a regulation declaring “the vice-ridden person should be conceived of more as a patient who must be cared for and cured than as a true criminal who should suffer a penalty.”¹³² After the United States outlawed these three drugs in the early twentieth century, the conditions for a lucrative trade in drugs illegal in the U.S. materialized south of the U.S.-Mexico border. Following the rise of the illegal drug trade between these two countries, Mexico began to enact penal provisions for drug offenses.¹³³

By the late 1960s, possession or distribution of a number of illicit drugs was punishable by three to twelve years of imprisonment.¹³⁴ It was not an offense, however, for an addicted individual to possess any drug if the amount possessed was for personal consumption.¹³⁵ This changed in the mid-1970s, when possession of marijuana or other illicit drugs (not including heroin or cocaine) for personal use became punishable by six months to three years of imprisonment.¹³⁶

¹³⁰ LUÍS ASTORGA, UNESCO, DRUG TRAFFICKING IN MEXICO: A FIRST GENERAL ASSESSMENT 11 (1999).

¹³¹ *Id.*

¹³² Ana Paula Hernández, *Drug Legislation and Prison Situation in Mexico*, in SYSTEMS OVERLOAD: DRUG LAWS AND PRISONS IN LATIN AMERICA 60, 60 (Pien Metaal & Coletta Youngers eds., 2011); see also Reglamento Federal de Toxicomanías [Federal Rules of Addiction], Diario Oficial de la Federación [DO], 17 de Febrero de 1940 (Mex.).

¹³³ ASTORGA, *supra* note 130, at 11. Mexico has supported opium cultivation since at least the early twentieth century. The practice was heavily concentrated in the Mexican states of Sinaloa, Durango, and Chihuahua. JOSÉ LUIS VELASCO, INSURGENCY, AUTHORITARIANISM, AND DRUG TRAFFICKING IN MEXICO’S “DEMOCRATIZATION” 97 (David Mares ed., 2005). Today, Mexico is the world’s third-largest producer of illegal opium. INT’L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2010, at 68, ¶ 416, U.N. Doc. E/INCB/2010/1, U.N. Sales No. E.11.XI.1 (2011) [hereinafter INCB Report for 2010].

¹³⁴ Decreto que reforma los Artículos 15, 85, 193, 194, 195, 196, 197, 198, 199, 201, 306, 309 y 387; modificación del nombre de Capítulo Primero, Título Séptimo, Libro Segundo; y adición del Artículo 164 Bis del Código Penal para el Distrito y Territorios Federales en materia de Fuero Común y para toda la República en materia de Fuero Federal [Decree Amending Articles 15, 85, 193, 194, 195, 196, 197, 198, 199, 201, 306, 309 and 387, Changes in the Name of Chapter One, Part Seven, Book Two, and Addition of Article 164 Bis Penal Code for the Federal District and Territories in Ordinary Matters and for the Entire Republic in Matters of Federal Jurisdiction], art. 195, Diario Oficial de la Federación [DO], 8 de Marzo de 1968 (Mex.).

¹³⁵ *Id.*

¹³⁶ Decreto de Reformas al Código Penal para Distrito Federal en materia de Fuero Común y para toda la República en materia de Fuero Federal; al Código Sanitario de los Estados Unidos Mexicanos, en relación con estupefacientes y psicotrópicos y al Artículo

Possession of a quantity of marijuana over the amount for personal consumption or possession of heroin or cocaine was punishable by five to twelve years of imprisonment.¹³⁷ However, the law still exempted addicts who were in possession of a small quantity of drugs for personal consumption only.¹³⁸

In 1976, the Ministry of Health was charged with developing a national program for the prevention and treatment of drug abuse and addiction and was given the broad mandate to “promulgate drug addiction control measures.”¹³⁹ More specifically, it was directed to issue general standards for treatment, provide medical care for drug addicts, give advice on the treatment of drug addicts, and create, promote, and expand services and establishments that provide care in this area.¹⁴⁰

Trafficking in Mexico became more prevalent throughout the twentieth century, especially during the 1980s and 1990s.¹⁴¹ By the mid-twentieth century,

41 del Primer Ordenamiento [Decree Amending the Penal Code for all Ordinary Offenses in the Federal District and for Federal Offenses Throughout the Republic; and the Health Code of the United Mexican States, in Respect of Narcotic Drugs and Psychotropic Substances, as Well as Article 41 of the First Ordinance], art. 195, *Diario Oficial de la Federación* [DO], 31 de Diciembre de 1974 (Mex.).

¹³⁷ *Id.* art. 198(I).

¹³⁸ *Id.* art. 198(V). However, drug addicts could be forced into confinement. *Id.* art. 24(3).

¹³⁹ Reglamento sobre estupefacientes y sustancias psicotrópicas [Regulations Concerning Narcotic Drugs and Psychotropic Substances], arts. 77, 79, *Diario Oficial de la Federación* [DO], 23 de Julio de 1976 (Mex.) [hereinafter Regulations Concerning Narcotic Drugs and Psychotropic Substances].

¹⁴⁰ *Id.* art. 88.

¹⁴¹ GUILHEM FABRE, CRIMINAL PROSPERITY: DRUG TRAFFICKING, MONEY LAUNDERING AND FINANCIAL CRISES AFTER THE COLD WAR 112 (RoutledgeCurzon 2003) (1999). “[I]t is incontestable that Mexico has become an important place for transiting, providing and laundering for the biggest drug market of the world [the United States].” *Id.* Contributing factors were the increase of law enforcement in the Caribbean, the collapse of the Colombian drug cartels, and the signing of the North American Free Trade Agreement (NAFTA). VELASCO, *supra* note 133, at 95; Colleen W. Cook, Congressional Research Service, *Mexico’s Drug Cartels, in COOPERATION WITH DRUG TRANSIT COUNTRIES OF ILLEGAL DRUGS* 39, 42 (Benjamin S. Rosen ed., 2009); J. Patrick Larue, *The “ILL-ICIT” Effects of NAFTA: Increased Drug Trafficking into the United States Through the Southwest Border*, 9 CURRENTS INT’L TRADE L.J. 38, 38 (2000); Luis Astorga & David A. Shirk, *Drug Trafficking Organizations and Counter-Drug Strategies in the U.S.-Mexican Context* 5 (Center for U.S.-Mexican Studies, Working Paper No. 10-01, 2010). For more information on the collapse of Colombian drug cartels, see RON CHEPESIUK, *THE BULLET OR THE BRIBE: TAKING DOWN COLOMBIA’S CALI DRUG CARTEL* (2003). For more information on how NAFTA influenced drug trafficking on the Mexican-U.S. border, see Larue, *supra*; and Taylor W. French, Note, *Free Trade and Illegal Drugs: Will NAFTA Transform the United States into the Netherlands?*, 38 VAND. J. TRANSNAT’L L. 501, 530-34 (2005).

the Federal Security Directorate, the Federal Judicial Police, and the national army had become the main institutions responsible for eliminating the drug trade. The 1980s saw a renewed effort to combat the escalation in drug trafficking and resulted in framing drug policy as a national security issue.¹⁴² Yet at the same time, reforms to the Federal Criminal Code in 1994 resulted in the removal of penalties for persons in possession of any drug who were not addicted, if this was their first offense, and if the amount possessed was for personal consumption only.¹⁴³ Additionally, an exemption remained in place in criminal legislation for possession of any drug for individual use by an addict.¹⁴⁴ Also during this period, Mexican drug legislation underwent reforms that focused law enforcement efforts on organized crime, but a disproportionate share of the arrests made during this time were for small-scale growers and traffickers.¹⁴⁵ Throughout the 1990s and 2000s, Mexico's federal anti-drug budget increased significantly. In 1991, the Mexican federal government allocated \$100 million to anti-drug

¹⁴² ASTORGA, *supra* note 130, at 14; MAUREEN MEYER, THE BECKLEY FOUND. DRUG POLICY PROGRAMME & WASH. OFFICE ON LATIN AM., AT A CROSSROADS: DRUG TRAFFICKING, VIOLENCE, AND THE MEXICAN STATE 4 (2007).

¹⁴³ Decreto que reforma, adiciona y deroga diversos articulos del Código Penal para el Distrito Federal en Materia de Fuero Común y para toda la República en Materia de Fuero Federal, del Código Federal de Procedimientos Penales, del Código de Procedimientos Penales para el Distrito Federal, de la Ley de Amparo Reglamentaria de los artículos 103 y 107 de la Constitución Política de los Estados Unidos Mexicanos, de la Ley de Extradición Internacional, del Código Civil para el Distrito Federal en Materia Común y para toda la República en Materia Federal, de la Ley Federal de Responsabilidades de los Servidores Públicos, de la Ley Orgánica del Tribunal Fiscal de la Federación, de la Ley del Tribunal de lo Contencioso Administrativo del Distrito Federal, de la Ley Federal para Prevenir y Sancionar la Tortura y de la Ley de Presupuesto, Contabilidad y Gasto Público Federal y de la Ley Orgánica del Poder Judicial de la Federación [Decree that Amends, Adds, and Repeals a Significant Number of Articles of the Criminal Code for the Federal District and for the Entire Country at the Federal Level, the Federal Code of Criminal Procedure, the Code of Criminal Procedure for the Federal District, the Law of Amparo Which Regulates Articles 103 and 107 of the Political Constitution of the United Mexican States, the Law of International Extradition, the Civil Code for the Federal District and for the Entire Country at the Federal Level, the Federal Law of Responsibilities of Public Servants, the Organic Law of the Fiscal Tribunal of the Federation, the Law of the Contentious Administrative Court of the Federal District, the Federal Law to Prevent and Sanction Torture, the Law of the Budget, Accounting, and Public Federal Expenses, and the Organic Law of the Judicial Power of the Federation], art. 195, Diario Oficial de la Federación [DO], 10 de Enero de 1994.

¹⁴⁴ *Id.* art. 199.

¹⁴⁵ VELASCO, *supra* note 133, at 110. In 1992, the Instituto Nacional para el Combate a las Drogas (National Institute to Combat Drugs) was formed and included representatives from the military, for the first time, in the drug policy decision-making process. MEYER, *supra* note 142, at 4. For more on how the military became an integral part of Mexican drug strategy, see *id.*

spending.¹⁴⁶ As of 2009, this number had risen to \$4.3 billion.¹⁴⁷

Mexico has also ratified the same three United Nations drug treaties to which Portugal is a signatory: the 1961 Single Convention on Narcotic Drugs, 1971 Convention on Psychotropic Substances, and 1988 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.¹⁴⁸ Accordingly, Mexico's domestic drug policies must comply with the provisions of these treaties.¹⁴⁹

B. Social Problems Associated with Drug Use in the New Millennium

At the beginning of the twenty-first century, the Institutional Revolutionary Party, which had been in power throughout most of the twentieth century, collapsed.¹⁵⁰ After the collapse, the protection that the party had offered to traffickers waned, resulting in a struggle amongst traffickers to maintain power, and increasing the conflict between law enforcement and traffickers.¹⁵¹ When President Vicente Fox was elected in December 2000, his administration utilized aggressive enforcement and militarization of drug policy to combat drug trafficking, and established institutional changes reflecting this agenda.¹⁵²

Despite this reorganization of anti-drug priorities and policy reform, Mexico did not realize a reduction in the volume of drug trade or violence; nevertheless, the militarization of police forces continued as the next administration took

¹⁴⁶ Astorga & Shirk, *supra* note 141, at 3 n.4.

¹⁴⁷ *Id.*

¹⁴⁸ United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, *supra* note 20; Single Convention on Narcotic Drugs, *supra* note 20; Convention on Psychotropic Substances, *supra* note 20.

¹⁴⁹ For more information about treaty requirements, see *supra* Section I.A.

¹⁵⁰ HAL BRANDS, STRATEGIC STUDIES INST., MEXICO'S NARCO-INSURGENCY AND U.S. COUNTERDRUG POLICY 6 (2009).

¹⁵¹ See LUIS ASTORGA, MEXICO: ITS DEMOCRATIC TRANSITION AND NARCO-TERRORISM 3-4 (2010), available at <http://www.yorku.ca/robarts/projects/canada-watch/obama/pdfs/Astorga>; BRANDS, *supra* note 150, at 6; Associated Press, *Voters End 71 Years of PRI Rule in Mexico*, DESERET NEWS, July 3, 2000, <http://www.deseretnews.com/article/769662/Voters-end-71-years-of-PRI-rule-in-Mexico.html>.

¹⁵² VELASCO, *supra* note 133, at 117, 119. This included the creation of a new cabinet position called the Ministry for Public Safety and Services to Justice, which controls the Federal Police, the creation of "a Special Deputy Attorney General Office Specialized in Organized Crime, the largest institution ever set up within the PGR (Mexico's attorney general office) for prosecuting organized crime and illegal drug activities," and the creation of the Federal Investigative Agency to replace the Federal Judicial Police because of widespread corruption that had infiltrated that agency. *Id.* at 117. It was also bolstered by the grant of authority by the Mexican Supreme Court to extradite Mexican nationals to the United States. *Id.*

control.¹⁵³ At the end of 2006, newly elected President Felipe Calderón launched an offensive against the nation's four largest drug-trafficking organizations, even going so far as to deploy 20,000 troops to patrol border cities.¹⁵⁴ Since the beginning of this attack on organized drug crimes in 2006, violence has escalated between government officials and the drug-trafficking organizations.¹⁵⁵ This drug-related violence has resulted in a total of at least 47,515 deaths, with 15,273 of those occurring in 2010 alone.¹⁵⁶ Within the first four years of Calderón's administration, the number of drug-related homicides—more than 35,000—was four times greater than the 8,901 such deaths during President Fox's term.¹⁵⁷ A related problem is the considerable corruption that pervades all sectors of the

¹⁵³ MEYER, *supra* note 142, at 7-8; VELASCO, *supra* note 133, at 118-19. In fact, both the amount of seizures and arrests decreased, while production increased between 2000 and 2002. VELASCO, *supra* note 133, at 118. The Defense Ministry has taken control over all drug eradication programs, and in 2007 a Special Support Force (Cuerpo Especial de Fuerzas de Apoyo del Ejército y la Fuerza Aérea Mexicana) composed of army and navy personnel was established to combat organized crime. MEYER, *supra* note 142, at 8.

¹⁵⁴ Hawley, *supra* note 3. By 2009, the number of Mexican soldiers combating drug-trafficking organizations had increased to 45,000. *Escalating Violence in Mexico and Southwest Border as a Result of the Illicit Drug Trade: Hearing Before the Subcomm. on Crime, Terrorism, & Homeland Security of the H. Comm. on the Judiciary*, 111th Cong. 7 (2009) (statement of Rep. Sheila Jackson Lee, Member, H. Subcomm. on Crime, Terrorism, & Homeland Security).

¹⁵⁵ Ken Ellingwood, *More Than 12,000 Killed in Mexican Drug War This Year, Officials Say*, L.A. TIMES, Dec. 16, 2010, <http://www.latimes.com/news/nationworld/world/la-fg-mexico-death-toll-20101217,0,3176872.story>. For more information on the Mexican drug-trafficking organizations, see, for example, GEORGE W. GRAYSON, MEXICO: NARCO-VIOLENCE AND A FAILED STATE? (2010); and Cook, *supra* note 141, at 39.

¹⁵⁶ VIRIDIANA RÍOS & DAVID A. SHIRK, TRANS-BORDER INST., DRUG VIOLENCE IN MEXICO: DATA AND ANALYSIS THROUGH 2010, at 8 (2011); Damien Cave, *Mexico Updates Death Toll in Drug War to 47,515, but Critics Dispute the Data*, N.Y. TIMES, Jan. 11, 2012, <http://www.nytimes.com/2012/01/12/world/americas/mexico-updates-drug-war-death-toll-but-critics-dispute-data.html>. Critics estimate a much greater number of homicides have occurred, including one estimate nearing 70,000. See Cave, *supra*. "[M]any of [the killings] are accompanied by beheadings, dismemberment, torture, and other acts of extraordinary cruelty." RÍOS & SHIRK, *supra*, at 13. These deaths include drug traffickers, law enforcement personnel, government officials, and innocent bystanders. VELASCO, *supra* note 133, at 101. There has also been an associated rise in kidnappings. *On the Trail of the Traffickers*, THE ECONOMIST, Mar. 5, 2009, <http://www.economist.com/node/13234157>. As a result of this violence, U.S. Attorney General Eric Holder stated in 2009 that the drug-trafficking organizations of Mexico posed a threat to national security. Randal C. Archibold, *U.S. Moves Against Top Mexican Drug Cartel*, N.Y. TIMES, Feb. 26, 2009, <http://www.nytimes.com/2009/02/26/us/26raids.html>.

¹⁵⁷ RÍOS & SHIRK, *supra* note 156, at 8.

Mexican government and continues to hinder efforts to reverse the rise in drug-related violence:¹⁵⁸

[C]orruption remains a significant impediment to counter narcotics efforts in Mexico. Cartels combine threats of violence with promises of financial gain . . . to influence law enforcement and government officials. Their influence is greatest among lower paid municipal and state police who have historically low hiring standards and fewer controls in place to check for corruption. This is a significant problem given that these police organizations represent roughly 90 percent of Mexico's total police force.¹⁵⁹

There is significant drug-related corruption among police agents, high-ranking police officials, members of the armed forces, the Attorney General's Office, and the political elite.¹⁶⁰ Evidence demonstrates that corruption is a systemic component of the drug problem.¹⁶¹ There have been several instances where local police forces have become so infested with corrupt officials that the federal government forced them to disband.¹⁶²

¹⁵⁸ See U.S. DEP'T OF STATE BUREAU OF INT'L NARCOTICS AND LAW ENFORCEMENT AFFAIRS, INTERNATIONAL NARCOTICS CONTROL STRATEGY REPORT 434-35 (2010). According to a recent study measuring perceptions about the extent of corruption in the public sectors of different countries, on a scale from zero to ten, with ten being not corrupt and zero being completely corrupt, Mexico received a 3.1. TRANSPARENCY INT'L., CORRUPTION PERCEPTIONS INDEX 2010, at 3 (2010).

¹⁵⁹ U.S. DEP'T OF STATE BUREAU OF INT'L NARCOTICS AND LAW ENFORCEMENT AFFAIRS, *supra* note 158, at 434-35. This method of corruption by the drug-trafficking organizations is known as "plata o plomo" ("money or lead"). BRANDS, *supra* note 150, at 16.

¹⁶⁰ VELASCO, *supra* note 133, at 100. Corruption in the military has resulted in defection to drug trafficking organizations, which has contributed to their militarization and increased violence. See Astorga & Shirk, *supra* note 141, at 29. Los Zetas is probably the most infamous example. For more information on Los Zetas, see, for example, Cook, *supra* note 141, at 47-49; and George W. Grayson, *Los Zetas: The Ruthless Army Spawned by a Mexican Drug Cartel*, FOREIGN POL. RES. INST. (May 2008), <http://www.fpri.org/enotes/200805.grayson.loszetas.html>.

¹⁶¹ VELASCO, *supra* note 133, at 101.

¹⁶² BRANDS, *supra* note 150, at 16. The Federal Investigative Authority created in 2001 was "widely criticized for corruption by 2005 and partially disbanded by 2009." STAFF OF S. COMM. ON FOREIGN REL., 111TH CONG., COMMON ENEMY, COMMON STRUGGLE: PROGRESS IN U.S.-MEXICAN EFFORTS TO DEFEAT ORGANIZED CRIME AND DRUG TRAFFICKING 10 (Comm. Print 2010). It was replaced with the Federal Ministerial Police, which has more investigative powers, but is also required to undergo more rigorous inspection for corruption. Astorga & Shirk, *supra* note 141, at 31. More recently, the Veracruz-Boca del Rio police force was disbanded as part of a campaign to root out

Compounding this problem, the Mexican judiciary has been inadequate in its administration of justice.¹⁶³ This results from “persistent and deeply engrained problems in the functioning of courts and penal institutions, which suffer from significant resource limitations and case backlogs.”¹⁶⁴ As a result, only about one in five reported crimes are investigated and one in one hundred result in conviction.¹⁶⁵ In addition, defendants are frequently held in pre-trial detention with restricted access to bail, even for minor offenses.¹⁶⁶

Furthermore, serious human rights violations committed by law enforcement, such as extrajudicial executions, forced disappearances, and torture, have increased since the late 1990s.¹⁶⁷ These abuses have mainly affected impoverished people and small-scale traffickers.¹⁶⁸ Human rights abuses are counterproductive, as they erode trust between the armed forces and the public, making citizens less likely to cooperate with law enforcement efforts.¹⁶⁹

In this climate, use rates for methamphetamine, cocaine, and heroin in Mexico have skyrocketed.¹⁷⁰ Addiction rates have also risen substantially,

corruption. *Mexico Disbands Veracruz-Boca del Rio Police Force*, BBC, Dec. 21, 2011, <http://www.bbc.co.uk/news/world-latin-america-16296273>.

¹⁶³ DAVID A. SHIRK, TRANS-BORDER INST., JUDICIAL REFORM IN MEXICO: CHANGE AND CHALLENGES IN THE JUSTICE SECTOR 6 (2010) (attributing the inadequacy of the judiciary to historical neglect and other factors that hindered democratic development, resulting in much more powerful legislative and executive branches).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 7.

¹⁶⁷ VELASCO, *supra* note 133, at 108. For information about how the prosecutorial system of Mexico may contribute to human rights abuses, see Ronald F. Wright, *Mexican Drug Violence and Adversarial Experiments*, 35 N.C.J. INT'L L. & COM. REG. 363, 371-74 (2010). There have also been reports of arbitrary detentions, illegal searches, theft, and sexual assaults. See BRANDS, *supra* note 150, at 17; MAUREEN MEYER & ROGER ATWOOD, WASH. OFF. ON LATIN AM., REFORMING THE RANKS: DRUG-RELATED VIOLENCE AND THE NEED FOR POLICE REFORM IN MEXICO 2 (2007); Steve Fainaru & William Booth, *Mexican Army Using Torture To Battle Drug Traffickers, Rights Groups Say*, WASH. POST, July 9, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/07/08/AR2009070804197.html>. Torture methods such as asphyxiation, electric shocks to the genitals, and submerging the individual's head in water are also used by law enforcement. Fainaru & Booth, *supra*.

¹⁶⁸ VELASCO, *supra* note 133, at 108.

¹⁶⁹ BRANDS, *supra* note 150, at 18. Although the United States can suspend funding to foreign militaries or police units if they are implicated in human rights violations, this power has rarely been invoked. See Coletta A. Youngers, *Executive Summary* of WASH. OFFICE ON LATIN AM., DRUGS AND DEMOCRACY IN LATIN AMERICA: THE IMPACT OF U.S. POLICY 8 (Coletta A. Youngers & Eileen Rosen eds., 2004).

¹⁷⁰ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-1018, *Drug Control: U.S. Assistance Has Helped Mexican Counternarcotics Efforts, but Tons of Illicit Drugs Continue To Flow into the United States*, in COOPERATION WITH DRUG TRANSIT

doubling between 2002 and 2008 to nearly half a million people (0.6% of the population).¹⁷¹ As a result of these increasing use rates, the number of new patients in Mexican drug treatment centers has more than quadrupled since 2000.¹⁷²

Moreover, the prevalence of HIV along the U.S.-Mexico border is rising and could impact rates in the rest of Mexico.¹⁷³ The co-occurrence of the drug and sex trades may be contributing to the increasing rates of HIV and other sexually transmitted infections.¹⁷⁴ A recent study in *The Lancet* estimated that 1 in every 116 persons in Tijuana aged fifteen to forty-nine years was infected with HIV in 2006.¹⁷⁵ High prevalence rates of hepatitis B and C have been reported among injection drug users, as well.¹⁷⁶

Until the mid-2000s, only one syringe exchange program existed in Mexico.¹⁷⁷ By 2010, syringe exchange had expanded and programs were established in nine of thirty-one Mexican states.¹⁷⁸ Additionally, mobile clinics funded by the government and offering syringe exchange have been established

COUNTRIES OF ILLEGAL DRUGS 91, 99 (Benjamin S. Rosen ed., 2009). The problem is particularly acute at regions near the U.S. border. MEYER, *supra* note 142, at 9. In Tijuana, a city with a population of 1.4 million, there were over 100,000 methamphetamine addicts. *Id.*

¹⁷¹ CONSEJO NACIONAL CONTRA LAS ADICCIONES [NATIONAL COUNCIL AGAINST ADDICTIONS], ENCUESTA NACIONAL DE ADICCIONES 2008 [NATIONAL SURVEY ON ADDICTIONS 2008], 89, 90 (2008) (Mex.) [hereinafter NATIONAL COUNCIL AGAINST ADDICTIONS]; Alexis Okeowo, *Drug Addiction Explodes in Mexico*, S.F. CHRON., Feb. 8, 2009, http://articles.sfgate.com/2009-02-08/news/17187173_1_drug-users-cartels-drug-prevention. A national survey totaled the number of people addicted to one or more illicit drugs at 428,819. NATIONAL COUNCIL AGAINST ADDICTIONS, *supra*, at 89-90.

¹⁷² Hawley, *supra* note 3.

¹⁷³ Steffanie A. Strathdee & Carlos Magis-Rodriguez, *Mexico's Evolving HIV Epidemic*, 300 JAMA 571, 571 (2008). The rate of those infected with HIV in Ciudad Juarez was reported at 2.1% among injection drug users in one recent study. See Joan P. Baumbach et al., *Seroprevalence of Select Bloodborne Pathogens and Associated Risk Behaviors Among Injection Drug Users in the Paso del Norte Region of the United States—Mexico border*, 5 HARM REDUCTION J. 1, 5 (2008).

¹⁷⁴ Strathdee & Magis-Rodriguez, *supra* note 173, at 571.

¹⁷⁵ See José Guadalupe Bustamante Moreno et al., *Tackling HIV and Drug Addiction in Mexico*, 376 LANCET 493, 493 (2010).

¹⁷⁶ Baumbach et al., *supra* note 173, at 1 (finding that hepatitis B was estimated at 88.3% and hepatitis C at 98.7% in injecting drug users in Ciudad Juarez).

¹⁷⁷ Strathdee & Magis-Rodriguez, *supra* note 173, at 572.

¹⁷⁸ Moreno et al., *supra* note 175, at 494. However, a recent study found that 85.3% of injecting drug users were unaware of needle exchange programs in the area of Ciudad Juarez, and 64.7% reported sharing a needle with another user. See Baumbach et al., *supra* note 173, at 7.

in some Mexican cities.¹⁷⁹ However, only one publicly funded methadone substitution program existed in 2008.¹⁸⁰ Furthermore, preventative and rehabilitation efforts are each distributed across several agencies.¹⁸¹ In an attempt to address drug use-related problems, a government program entitled “Limpiemos México” (Let’s Clean Mexico) has been established to create three hundred specialized units for the treatment of addiction throughout Mexico by 2012.¹⁸²

Although 58.5% of Mexicans believe that those addicted to drugs are sick and 60.4% believe that addicts are people in need of help,¹⁸³ incarceration rates continued to rise. The prison population in Mexico increased by almost 100,000 between 1998 and 2009.¹⁸⁴ Mexico now has the sixth largest prison population in the world.¹⁸⁵ It was estimated that in 2007 the cost of containing this many prisoners was \$775 million per year.¹⁸⁶ An analysis of the prison system in Mexico found that fifty percent of the prisoners who were detained for selling drugs had possessed an amount worth less than \$100, and twenty-five percent were detained for an amount worth \$18 or less.¹⁸⁷

C. Mexico’s Decriminalization Scheme

The United States has been a key factor in both the development and maintenance of militarized police forces in the Mexican drug war.¹⁸⁸ In fact, in

¹⁷⁹ Strathdee & Magis-Rodriguez, *supra* note 173, at 572.

¹⁸⁰ Mathers et al., *supra* note 103, at 1021; *see also supra* text accompanying notes 45, 104 (discussing methadone substitution treatment).

¹⁸¹ MEYER, *supra* note 142, at 9.

¹⁸² *Id.*

¹⁸³ NATIONAL COUNCIL AGAINST ADDICTIONS, *supra* note 171, at 71.

¹⁸⁴ *See* Hernández, *supra* note 132, at 64 (presenting data from the Ministry of Public Security showing that the total Mexican prison population rose from 128,902 in 1998 to 227,021 in 2009).

¹⁸⁵ *Id.* at 65.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *See* VELASCO, *supra* note 133, at 93, 94, 103, 119; Jorge Chabat, *Mexico’s War on Drugs: No Margin for Maneuver*, 582 ANNALS AM. ACAD. POL. & SOC. SCI. 134, 135 (2002). “[T]he United States has progressively increased its *de facto* role in the design and implementation of Mexico’s law enforcement policies.” Chabat, *supra*. One major reason that the United States has played such a large role in shaping drug policy in Mexico is because if it determines that Mexico has not demonstrated substantial efforts to adhere to international counter-narcotics agreements, the U.S. may suspend foreign assistance appropriations. *See* Narcotics Control Trade Act, 19 U.S.C.A. § 2492 (West 2011); LIANA SUN WYLER, CONG. RESEARCH SERV., RL 34543, INTERNATIONAL DRUG CONTROL POLICY 9 (2009); Chabat, *supra*, at 142-43. Mexico may also be subject to sanctions under NAFTA if the United States believes that these sanctions are in its

2006, Mexico's Congress approved a decriminalization bill that contained almost exactly the same provisions as the one that ultimately passed in 2009.¹⁸⁹ Then-President Fox, however, refused to sign the bill due to pressure from the U.S. government.¹⁹⁰

Three years later, the political dynamic had changed. There was little resistance from the United States to the passage of a bill introduced in 2008 by President Calderón that would decriminalize the possession of small amounts of illegal drugs, as well as increase penalties for traffickers.¹⁹¹ The change in pressure may reflect a difference in the approach to drug policy between the presidential administrations of George W. Bush and Barack Obama, a reconsideration of the confrontational approach to drug policy followed thus far in the United States, predictions that the law will have little effect on the street, and lack of publicity of the law.¹⁹² Both houses of the Mexican Congress passed

national security interests. See North American Free Trade Agreement art. 2102, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993); Joe Swanson, Note, *Drug Trafficking in the Americas: Reforming United States Trade Policy*, 38 GEO. WASH. INT'L L. REV. 779, 788, 795 (2006). Still further, in 2007, the United States and Mexico signed the Mérida Initiative, an aid package proposing \$1.4 billion in foreign aid to Mexico to help reduce drug trafficking. CLARE RIBANDO SEELKE, CONG. RESEARCH SERV., R 40135, MÉRIDA INITIATIVE FOR MEXICO AND CENTRAL AMERICA: FUNDING AND POLICY ISSUES 1 (2009); Colleen W. Cook & Clare Ribando Seelke, *Mérida Initiative: Proposed U.S. Anticrime and Counterdrug Assistance for Mexico and Central America*, in COOPERATION WITH DRUG TRANSIT COUNTRIES OF ILLEGAL DRUGS 61, 61 (Benjamin S. Rosen ed., 2009). For information on the Mérida Initiative, see generally Cook & Seelke, *supra*; and Steven E. Hendrix, *The Mérida Initiative for Mexico and Central America: The New Paradigm for Security Cooperation, Attacking Organized Crime, Corruption and Violence*, 5 LOY. U. CHI. INT'L L. REV. 107 (2008). For the argument that a new approach to Mérida is needed, see BRANDS, *supra* note 150; and Stephanie E. Brewer, *Rethinking the Mérida Initiative: Why the U.S. Must Change Course in its Approach to Mexico's Drug War*, 16 HUM. RTS. BR. 9 (2009).

¹⁸⁹ Ioan Grillo, *Mexico's New Drug Law May Set an Example*, TIME, Aug. 26, 2009, <http://www.time.com/time/world/article/0,8599,1918725,00.html>.

¹⁹⁰ *Id.* Officials from the U.S. State Department and Office of National Drug Control Policy expressed concern that decriminalization would encourage both drug use locally and drug tourism (visiting Mexico to use drugs). Danna Harman, *Debate Far from Over for Mexico's Drug Bill*, CHRISTIAN SCI. MONITOR, May 10, 2006, <http://www.csmonitor.com/2006/0510/p04s01-woam.html>.

¹⁹¹ Tinajero & Angles, *supra* note 9, at 1; Grillo, *supra* note 189.

¹⁹² Patrick Corcoran, *Decriminalization Fails To Alter Mexican Reality*, ALLVOICES, Jan. 15, 2010, <http://www.allvoices.com/contributed-news/5045291-decriminalization-fails-to-alter-mexican-reality>; Grillo, *supra* note 189; R. Gil Kerlikowske, *The Obama Administration's Public Health Approach to Drug Policy*, HUFFINGTON POST, Feb. 1, 2011, http://www.huffingtonpost.com/r-gil-kerlikowske/the-obama-administrations_1_b_816786.html (outlining the Obama administration's commitment to drug problems as a public health issue); Scott Michels, *Drug Czar Nominee: Renewed Focus on Prevention*,

the law in April 2009, and it officially came into effect on August 21, 2009.¹⁹³

The main objective of the law, which is known as the Ley de Narcomenudeo (Law Against Small-Scale Drug Dealing), was to allow counter-narcotics officials to focus their efforts on drug traffickers instead of drug users.¹⁹⁴ Secondary objectives included freeing up space in Mexican jails and emphasizing treatment and harm reduction instead of incarceration for users.¹⁹⁵ The law was not designed to protect drug users' rights or develop an effective public health system, but instead was constructed with the predominant mentality that criminalization and incarceration are the primary solutions to the drug problems in Mexico.¹⁹⁶

The law imposes no criminal penalties for possession of drugs if the quantity possessed is within the legal amount for personal consumption.¹⁹⁷ The amounts that are permitted for personal consumption are 50 milligrams of heroin, 5 grams of marijuana, 500 milligrams of cocaine, 0.015 milligrams of LSD, and 40 milligrams of MDMA (ecstasy) or methamphetamine or one pill weighing no more than 200 milligrams that contains MDMA or methamphetamine.¹⁹⁸ If a person is found to have been in possession of an amount of drugs within these limits, then they will be given a warning for the first two offenses.¹⁹⁹ The third

ABC NEWS, Apr. 2, 2009, <http://abcnews.go.com/Health/story?id=7233062&page=1>; Tracy Wilkinson, *Mexico Moves To Decriminalize Minor Drug Use*, L.A. TIMES, June 21, 2009, <http://articles.latimes.com/2009/jun/21/world/fg-mexico-decriminalize21>. The Obama administration has decided to take a "wait and see" approach to Mexico's decriminalization. See WYLER, *supra* note 188, at 34; Grillo, *supra* note 189. Another influencing factor may have been the release of a statement by a committee comprised of politicians, journalists, and scholars, including three former Latin American Presidents (César Gaviria Trujillo of Colombia, Ernesto Zedillo Ponce de Leon of Mexico, and Fernando Henrique Cardoso of Brazil), which advocated for a public health approach to drug policy and for the decriminalization of possession of cannabis for personal use. See LATIN AM. COMM. ON DRUGS AND DEMOCRACY, DRUGS AND DEMOCRACY: TOWARDS A PARADIGM SHIFT 8-10 (2009) ("Treating drug users as a matter of public health and promoting the reduction of drug consumption are actually the inescapable preconditions for focusing repressive action on two critical points: reduction of production and dismantling the networks of drug trafficking.").

¹⁹³ Tinajero & Angles, *supra* note 9, at 1.

¹⁹⁴ Hernández, *supra* note 132, at 63. The law does recognize and exempt ceremonial use of peyote and psychedelic mushrooms by indigenous populations. See Narcomenudeo Law, *supra* note 7, art. 195 BIS(II).

¹⁹⁵ WYLER, *supra* note 188, at 33-34; Tinajero & Angles, *supra* note 9, at 1.

¹⁹⁶ Hernández, *supra* note 132, at 63; Tinajero & Angles, *supra* note 9, at 2.

¹⁹⁷ Narcomenudeo Law, *supra* note 7, art. 478.

¹⁹⁸ *Id.* art. 479.

¹⁹⁹ *Id.* art. 193 BIS. Although the law explicitly defines consumer and addict as distinct, they are treated the same when apprehended for this offense. See *id.* arts. 473, 193 BIS.

offense of this type results in placement of the offender in mandatory drug addiction treatment.²⁰⁰ The judge is not empowered to make a decision based on factors such as social status, circumstances of the arrest, or number of offenses in determining whether the offender will be criminally charged because the sole decisive factor is the quantity possessed.²⁰¹

Although the law decriminalizes possession of drugs for personal consumption, its main features reflect a traditional criminal justice approach to drug use and trafficking. One important amendment is the increase in penalties for possession over the amount defined for personal use.²⁰² Should a person be found in excess of the maximum amount for personal use but less than one thousand times the maximum amount for personal use, they will be sentenced to three to six years of imprisonment if it is determined that the drugs were intended for distribution, or ten months to three years of imprisonment if it is determined that the drugs were not intended for distribution.²⁰³ Prison terms for sale of any drug above the maximum amount for personal use but below one thousand times that amount were increased to between four and eight years.²⁰⁴

The law further increases penalties for possession of large amounts of drugs. Possession of any substance in an amount equal to or greater than one thousand times the maximum amount for personal consumption warrants a sentence ranging from four years to seven years and six months if it is determined that the offender did not have intent to distribute the drugs.²⁰⁵ If the offender can be shown to have had intent to distribute, then the sentence increases to between five and fifteen years of imprisonment.²⁰⁶ These increased penalties demonstrate that Mexico was focused mainly on incarceration as the solution to problems associated with drug use.

Another novel approach set forth by these amendments is the ability of state and local authorities to apprehend drug users, an authority that until passage of these amendments was reserved only for federal officers.²⁰⁷ The rationale behind this change was to allow state and local law enforcement to focus on small-scale traffickers, while the federal government would have more resources to pursue

²⁰⁰ *Id.* art. 193 BIS. The law does not specify a penalty for noncompliance to enter treatment. Lacey, *supra* note 3.

²⁰¹ MARTIN JELSMA, TRANSNAT'L INST., TRENDS IN DRUG LAW REFORM IN EUROPE AND LATIN AMERICA 9 (2010).

²⁰² *See* Narcomenudeo Law, *supra* note 7, arts. 475-76.

²⁰³ *Id.* For example, possession of over 50 milligrams but less than 50 grams of heroin would be punishable by this sentence.

²⁰⁴ *Id.* art. 475. For example, sale of any amount of cocaine between 500 milligrams and 449 grams would earn this penalty.

²⁰⁵ *Id.* art. 195.

²⁰⁶ *Id.* art. 195 BIS.

²⁰⁷ *Id.* arts. 194, 195, 195 BIS, 474.

large drug-trafficking organizations.²⁰⁸ Federal police officers were also given authority to simulate drug buys to arrest offenders.²⁰⁹ By increasing the reach of law enforcement, Mexico further solidified its criminal justice approach to drug use.

It is important to note that persons found to be in possession of drugs, even if within the amount permitted for personal consumption, can still be taken into custody by the police and detained until the Public Ministry determines whether it will file charges.²¹⁰ In this sense, the user is treated as an offender until the prosecutor decides to release him.²¹¹ This contrasts with Portugal's policy, where police are not authorized to arrest users determined to possess an amount of drugs within the limits for personal consumption.²¹²

Mexico's criminal decree also commands the Ministry of Health to formulate a national program for addressing drug prevention and treatment.²¹³ It lays out broad mandates that the national program must contain for prevention and treatment programs, but contains limited substantive requirements.²¹⁴ The decree also requires the Ministry of Health to conduct research regarding effective treatment and prevention of drug use and methods of evaluation for these programs.²¹⁵ Despite these limited provisions, the main thrust of the law furthers the criminal justice approach as the solution to problems associated with drug use and traffic.

D. Effects and Developments After Mexican Decriminalization

Although, at the time of this writing, the criminal decree has been in effect for almost three years, problems associated with drug use and traffic have continued.²¹⁶ One journalist noted:

[C]ops, treatment counselors, government officials, researchers and addicts interviewed last month said there have been no discernible changes related to the new law. Police still arrest and

²⁰⁸ See Hernández, *supra* note 132, at 63.

²⁰⁹ Narcomenudeo Law, *supra* note 7, art. 180 BIS.

²¹⁰ Hernández, *supra* note 132, at 63.

²¹¹ *Id.* "The inefficiency or lack of investigation by the country's prosecutorial authorities often leads to a large number of persons being arrested before the authorities have pulled together the necessary evidence to be able to file charges or indict and convict them." *Id.* at 65.

²¹² See ALLEN ET AL., *supra* note 47, at 2.

²¹³ Narcomenudeo Law, *supra* note 7, art. 192.

²¹⁴ *Id.* arts. 192 TER, 192 QUÁTER, 192 SEXTUS.

²¹⁵ *Id.* art. 192 QUINTUS.

²¹⁶ Although there have not yet been comprehensive reviews performed of the law's effects, this Note argues that the way that the law is structured will most likely result in little or negative consequences.

incarcerate drug users. Americans have not flocked to dope parlors south of the border. Mexican narcotics abuse surges unabated, as does the flow of drugs and blood.²¹⁷

As noted previously, the death tolls have continued to rise, with 2011 being an especially violent year.²¹⁸

Some commentators have predicted that the law will actually exacerbate the problems that Mexico was experiencing before decriminalization.²¹⁹ One analyst observed that the quantities defined under the law as personal use are so small that prosecution may actually increase for simple possession.²²⁰ Because the amount defined as personal use is in fact lower than the amount at which most of the drugs on the street are sold, in reality, most personal use is not decriminalized.²²¹ For example, the law only allows for possession of half a gram of cocaine, despite the fact that cocaine is normally sold by the gram.²²² Portuguese law, by contrast, decriminalizes possession of up to two grams of cocaine.²²³ Mexico's policy has the danger of further increasing the prison population by incarcerating more low-level dealers and minor offenders.²²⁴

Although some commentators have noted that "the change takes the discretion of whether to throw drug users in jail away from police officers, who frequently shook down people by threatening them with arrest," this is most likely inaccurate.²²⁵ While the public prosecutor is ultimately responsible for determining whether the drugs possessed fall within the allowable quantity, police are still authorized to make arrests for drug possession.²²⁶ As a result, the use is still referred to the criminal justice system, and this may increase the burden on the Public Ministry's office.²²⁷ Furthermore, because number of arrests is a common metric used to ascertain the effectiveness of police efforts in drug policy, police may continue to make arrests without regard to the actual quantity of drugs possessed by the offender, in the hopes that the artificial inflation of their arrest count will make their department look more successful.²²⁸

²¹⁷ Dennis Wagner, *Drug Law Changes Little for Life in Mexico*, ARIZONA REPUBLIC, Jan. 10, 2010, http://www.azcentral.com/news/articles/2010/01/10/20100110_mex-drugs.html.

²¹⁸ See Cave, *supra* note 156.

²¹⁹ See, e.g., Hernández, *supra* note 132, at 63-64; Wagner, *supra* note 217.

²²⁰ Hernández, *supra* note 132, at 63-64.

²²¹ *Id.* at 64; Wagner, *supra* note 217.

²²² Hernández, *supra* note 132, at 64.

²²³ See *supra* note 58.

²²⁴ Hernández, *supra* note 132, at 65.

²²⁵ Lacey, *supra* note 3.

²²⁶ Tinajero & Angles, *supra* note 9, at 3.

²²⁷ *Id.*

²²⁸ *Id.* at 5-6.

There is a very real possibility that this law will actually increase corruption and extortion by police forces.²²⁹ Jurisdiction to enforce criminal penalties for small-scale trafficking has been extended to state and local police, believed to be the most corrupt segments of Mexican law enforcement.²³⁰ These agencies will in turn experience new pressure to pursue drug offenders, requiring them to obtain more resources and skills. This will be a difficult task because they are already lacking in professional staff and sufficient capital.²³¹ Extortion may also increase under this law because the low possession quantities that qualify as personal use under the amended laws could encourage state police forces to “shake down” addicts who possess an amount over the prescribed limit.²³²

Additionally, some fear that the law may distract enforcement authorities from pursuing more serious crimes, including large-scale drug-trafficking operations.²³³ This, in addition to a failure to focus on demand reduction,²³⁴ has prompted some observers to claim that the law will not significantly impact the market for drugs in Mexico.²³⁵ They note that the economic reality of the situation is that someone will rise to fill the shoes of the small-time trafficker who has been apprehended by the authorities.²³⁶ Under the current Mexican decriminalization regime, the inadequate emphasis on demand reduction does little to diminish the problems associated with drug use. Because demand reduction would require the government to focus on the user, public health, rather than criminal justice, is prioritized.

In 2009, Mexico had over three hundred government-funded drug treatment centers.²³⁷ However, most centers were staffed by personnel with limited training in drug counseling due to the inadequate resources allocated to demand reduction and the lack of comprehensive training programs for substance abuse professionals.²³⁸ Consequently, only 39,000 people received treatment that year,

²²⁹ *Id.* at 2; Wagner, *supra* note 217.

²³⁰ See Narcomenudeo Law, *supra* note 7, arts. 194, 195, 195 BIS, 474; U.S. DEP’T OF STATE BUREAU FOR INT’L NARCOTICS AND LAW ENFORCEMENT AFFAIRS, *supra* note 158, at 434-35.

²³¹ Tinajero & Angles, *supra* note 9, at 2. “Local and state law enforcement agencies, in particular, suffer a lack of institutional capacity Most Mexican police officers have had few opportunities for educational development, and lead lives that are terribly impoverished.” Astorga & Shirk, *supra* note 141, at 27.

²³² Tinajero & Angles, *supra* note 9, at 4.

²³³ *Id.* at 2.

²³⁴ Demand reduction is discussed *supra* in the text accompanying note 45.

²³⁵ Tinajero & Angles, *supra* note 9, at 2.

²³⁶ *Id.*

²³⁷ U.S. DEP’T OF STATE BUREAU FOR INT’L NARCOTICS AND LAW ENFORCEMENT AFFAIRS, *supra* note 158, at 436.

²³⁸ *Id.* Mexico began a program to train and accredit treatment providers in 2009. INCB Report for 2010, *supra* note 133, at 72, ¶ 442.

a small proportion of the nearly 430,000 estimated addicts.²³⁹ In 2010, a national action program for the prevention and treatment of addictions was launched, expanding the number of community-based centers offering basic services in addiction treatment.²⁴⁰ This was accompanied by a nationwide effort to expand opioid substitution treatment.²⁴¹

The international community has disputed whether the drug decriminalization legislation complies with international treaties. In 2009, the INCB indicated concern that the legislation in Mexico would send the wrong message.²⁴² It went on to state:

The Board would like to remind the Government [of Mexico] that article 3, paragraph 2, of the 1988 Convention [Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances] requires each party to that Convention to establish as a criminal offence under its domestic law, when committed intentionally, the possession, purchase or cultivation of narcotic drugs or psychotropic substances for personal consumption contrary to the provisions of the 1961 Convention, the 1961 Convention as amended by the 1972 Protocol or the 1971 Convention.²⁴³

However, the INCB report for 2010 did not mention decriminalization in Mexican legislation nor did it declare that Mexico was in violation of the treaties, and in its 2011 report, the INCB noted that Mexico was “firmly committed to the goals and objectives of [the UN] treaties.”²⁴⁴

III. ANALYSIS

Although Mexico now joins several other Latin American countries that have adopted some form of a decriminalization scheme,²⁴⁵ a comparison of

²³⁹ *Id.*; see *supra* text accompanying note 171.

²⁴⁰ INCB Report for 2010, *supra* note 133, at 71-72, ¶ 442.

²⁴¹ Moreno et al., *supra* note 175, at 494.

²⁴² INT’L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2009, at 68, ¶ 408, U.N. Doc. E/INCB/2009/1, U.N. Sales No. E.10.XI.1 (2010) [hereinafter INCB Report for 2009].

²⁴³ *Id.*

²⁴⁴ INT’L NARCOTICS CONTROL BD., REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2011, at 12, ¶ 87, U.N. Doc. E/INCB/2011/1, U.N. Sales No. E.12.XI.5 (2012) [hereinafter INCB Report for 2011]; see also INCB Report for 2010, *supra* note 133, at 65, ¶¶ 401-02.

²⁴⁵ See CONSTITUCIÓN POLÍTICA DE LA REPÚBLICA DE ECUADOR [C.P.] art. 364 (Ecuador); Lei No. 11.343, de 23 de Agosto de 2006, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 24.08.2006 (Braz.); Law No. 20.000, arts. 4, 50, Febrero 16, 2005, DIARIO OFICIAL [D.O.] (Chile); Law No. 1.340, *as amended*, art. 30, Noviembre 22, 1988,

Portugal and Mexico is especially appropriate for five reasons: First, both countries established decriminalization through the legislative process, rather than through judicial interpretation, as did Argentina, or through constitutional amendment, as did Ecuador.²⁴⁶ Second, both countries have decriminalized possession of all drugs, not merely soft drugs, which were the sole target of decriminalization in some other countries.²⁴⁷ Third, addiction treatment and harm reduction were motivating goals behind the implementation of both countries' laws, although Portuguese law emphasized these goals to a much greater extent.²⁴⁸ Fourth, in Mexico, the increasing rates of addiction and drug-related health outcomes, such as HIV infection, resemble the crisis that precipitated Portuguese decriminalization.²⁴⁹ Finally, both countries maintain significant drug export industries, and their decriminalization laws are intended to address their domestic drug trades and illicit international trafficking.²⁵⁰

This Part will address the different approaches to decriminalization in Portugal and Mexico and will ultimately argue that Mexico could achieve decreased rates of drug use and drug-related disease, a reduction in prison populations, and an increase in resources for enforcement against large-scale drug trafficking if Mexico were to adopt a model similar to the one in Portugal. More specifically, this Part will first suggest ways in which Mexico could adopt a more effective approach by replicating Portugal's focus on public health rather than measuring success in terms of criminal justice outcomes. Next, it will argue that the CDTs in Portugal could serve as a valuable model for Mexico and that implementation of these commissions in Mexico could result in a reduction in judicial backlog and governmental corruption. Another aspect of the Portuguese law that could provide a model for Mexico is the quantities of drugs the law defines as within the limits for personal use. An increase in the maximum allowable quantities would make available resources currently tied to the criminal justice system, and redirect those resources toward programs targeting

GACETA OFICIAL DE LA REPÚBLICA (Para.); CÓDIGO PENAL (Criminal Code), *as amended*, art. 299, Abril 3, 1991, DIARIO OFICIAL [D.O.] (Peru); Law No. 14.294, art. 31, Noviembre 11, 1974, DIARIO OFICIAL [D.O.] (Uru.); Corte Suprema de Justicia de la Nación [CSJN] [National Supreme Court of Justice], 25/8/2009, "Arriola, Sebastián y otros / recurso de hecho," Fallos (A. 891. XLIV) (Arg.) [hereinafter Arriola]; *see also supra* note 7.

²⁴⁶ *See* Narcomenudeo Law, *supra* note 7; Decree Law 30/2000, *supra* note 2; *see also* CONSTITUCIÓN POLÍTICA DE LA REPÚBLICA DE ECUADOR [C.P.] art. 364 (Ecuador); Arriola, *supra* note 245.

²⁴⁷ *See* Narcomenudeo Law, *supra* note 7, art. 478; van het Loo et al., *supra* note 35, at 58; *supra* text accompanying note 59.

²⁴⁸ *See* Decree Law 183/2001, *supra* note 84; WYLER, *supra* note 188, at 33-34; Tinajero & Angles, *supra* note 9, at 1.

²⁴⁹ *See supra* Sections I.B, II.B.

²⁵⁰ *See supra* Sections I.C, II.C.

users directly. Finally, this Part will address potential problems that Mexico may face should it choose to implement a strategy like Portugal's, including political hurdles, pervasive corruption and violence, and the availability of resources.

A. Abandoning the Criminal Justice Approach for a Public Health Approach

In Portugal, the rights of the addict and the impact of drug use on the country's growing public health problems were the driving factors behind decriminalization.²⁵¹ It is clear that decriminalization in Portugal was implemented as a means of reducing the disease and death that were associated with drug use and encouraging drug users to seek treatment by removing the stigma associated with the criminal justice system.²⁵² By contrast, in Mexico, the shift to decriminalization was driven by escalating drug trafficking and associated violence.²⁵³ This led Mexico to take a criminal justice approach to drug regulation, giving only a nod to public health concerns in its legislation. As discussed in Section I.D, Portugal's public health approach has significantly impacted the rates of drug use, the prevalence of associated disease and death, and the efficacy of law enforcement against drug trafficking.²⁵⁴ Given the recent rise in drug use, addiction, and drug-related health problems, such as HIV infection, Mexico should look to Portugal's program as an example of success in reducing these societal ills. Following the Portuguese model would also allow the Mexican government to more effectively focus on dismantling drug-trafficking organizations, which was the original purpose of Mexico's decriminalization legislation. By further decriminalizing drug possession, it is possible that Mexico could realize similar results to those observed in Portugal. First, however, it must restructure its law to target public health issues before criminal justice concerns. There are several ways that Mexico can use the development of decriminalization in Portugal as a model for how to create its own public health-oriented approach.

Mexico's focus on the violence of drug traffickers and its desire to increase enforcement against small-scale traffickers is misguided for three reasons: First, targeting small-scale traffickers will not reduce drug-related violence, since this violence is mostly produced by large drug-trafficking organizations. Second, the current system will most likely allow harms associated with drug use itself to persist at their current rate because the criminal justice system will operate as it did in the past and preoccupy itself with the frequent arrest and incarceration of addicts. This approach fails to appropriately consider the impacts of drug-related disease and mortality. Mexico, although caught in a violent standoff with drug-

²⁵¹ GREENWALD, *supra* note 46, at 6-7; *see also* Decree Law 183/2001, *supra* note 84, ch. I, art. 1; COMMISSION FOR A NATIONAL DRUG STRATEGY, *supra* note 48, at 82.

²⁵² *See* Decree Law 183/2001, *supra* note 84, ch. I, art. 1.

²⁵³ *See* Hernández, *supra* note 132, at 63; Tinajero & Angles, *supra* note 9, at 2.

²⁵⁴ *See supra* Section I.D.

trafficking organizations, must take account of other ills, namely the rising drug use and addiction rates and increasing HIV and hepatitis rates observed in high-drug-trafficking areas, before they spread to the rest of the country. Addressing these issues will also allow Mexico to devote greater resources to fighting drug trafficking and the violence it produces.

Third, stigma is frequently a barrier to treatment of addiction, and decriminalization can help to eliminate that barrier, thereby encouraging an uptake in treatment and a gradual decline in the rate of addiction.²⁵⁵ A key feature of Portugal's drug regime is the recognition that the imposition of criminal penalties on people who are addicted to drugs might discourage them from actively seeking help.²⁵⁶ By maintaining the primary objective of incarcerating those involved in the drug trade, Mexican policy continues to discourage addicts from openly entering treatment by stigmatizing their drug use as a moral failing. However, Mexico has a long history of identifying the addicted person as a sick individual, rather than as a criminal.²⁵⁷ A recent survey showed that the majority of Mexican citizens believe that an addict is ill and in need of professional medical help.²⁵⁸ Mexico can and should capitalize on this prevalent attitude by developing a public health-oriented approach to drug policy aimed at reducing stigma and increasing treatment uptake.²⁵⁹ Acknowledging that stigma is an impediment to receiving help is an important step in breaking down the barrier to treatment created by the fear that users may have of the criminal justice system, ultimately reducing addiction rates.²⁶⁰ A concrete

²⁵⁵ See *supra* Section I.C.

²⁵⁶ See GREENWALD, *supra* note 46, at 9; VAN BEUSEKOM ET AL., *supra* note 11, at 15-16.

²⁵⁷ See *supra* Section II.A.

²⁵⁸ See NATIONAL COUNCIL AGAINST ADDICTIONS, *supra* note 171, at 71.

²⁵⁹ See, e.g., Regulations Concerning Narcotic Drugs and Psychotropic Substances, *supra* note 139, art. 88 (commanding the Ministry of Health to provide medical care to addicts); Ana Paula Hernández, *Drug Legislation and Prison Situation in Mexico*, in SYSTEMS OVERLOAD: DRUG LAWS AND PRISONS IN LATIN AMERICA 60, 60 (Pien Metaal & Coletta Youngers eds., 2011) (noting that legislation enacted in 1940 regarded the addict as a sick person). Professionals vigorously debate how to characterize addiction. Two predominant and competing models describe addiction as either mental disease or a behavioral disorder. See, e.g., ADDICTION MEDICINE (Bankole A. Johnson ed., 2011). Under the disease model, a combination of substance use, environmental, genetic, and societal factors result in modification of brain function, causing the user to repeat use and eventually become addicted. Daniel Buchman & Peter B. Reiner, *Stigma and Addiction: Being and Becoming*, 9 AM. J. BIOETHICS-NEUROSCIENCE 18 (2009). Scientists and public health advocates have long argued that society should accept this view. *Id.* at 18-19. "Attributing neurobiological factors to addiction has the potential to reduce stigma (both perceived and experienced), blame and responsibility, and provide more effective treatment options for society." *Id.* at 19.

²⁶⁰ See James. D. Livingston et al., *The Effectiveness of Interventions for Reducing*

strategy for eliminating stigma based on the Portuguese model will be set forth in Section III.B.

Another means of strengthening the public health approach is the reorganization of agencies that are responsible for monitoring and reducing drug use and related problems. When Portugal enacted its decriminalization law, the multiple organizations charged with addressing drug use were replaced by the IDT.²⁶¹ The government's consolidation of a number of ineffective organizations into a single effective agency with a new mandate for research, evaluation, implementation, and oversight of drug treatment programs demonstrated a novel commitment to a public health approach to combating drug use. It also created a national standard for harm reduction programs and for the CDTs, so that all drug regulations would be uniform.²⁶² This consolidation is important not only because it exemplifies the government's perspective that drug use is a public health issue, but because it also allows one agency, instead of several, to coordinate efforts in reducing social ills associated with drug use, ensure programs are not duplicated and resources are not wasted, and evaluate existing efforts for effectiveness. Although the IDT was recently stripped of most of its power due to austerity measures, Mexico can look to the example that Portugal set in consolidating its resources into a unified agency.

Mexico should follow Portugal's approach in reorganizing the agencies that address drug use and related problems. Restructuring and consolidating the numerous government-run organizations that address drug use and harm reduction in Mexico would demonstrate a commitment to addressing serious drug problems through public health measures. It would also allow a central agency to create a uniform approach to drug issues, to appropriate resources to support programs in line with that approach, and to evaluate efforts already under way. Explicitly requiring the organization to complete these tasks, instead of only giving the vague command to institute drug addiction control measures, should foster the growth of addiction services and positively impact rates of drug use and associated harms.²⁶³ Further, reorganization may actually reduce corruption

Stigma Related to Substance Use Disorders: A Systematic Review, 107 ADDICTION 39, 40-41 (2011).

²⁶¹ See Decree Law 269-A/2002, *supra* note 88; Decree Law 31/99, *supra* note 88; *supra* text accompanying note 88.

²⁶² See Decree Law 269-A/2002, *supra* note 88, Annex art. 5; Decree Law 183/2001, *supra* note 84, ch. I, art. 5.

²⁶³ See Narcomenudeo Law, *supra* note 7, art. 192 (describing the Mexican Ministry of Health's obligations under the new law). Although the recent law includes a mandate for the Ministry of Health to create a national program for addressing drugs, the terms are broad and are similar to those it was charged with in 1976. *Compare id.*, with Regulations Concerning Narcotic Drugs and Psychotropic Substances, *supra* note 139, arts. 77, 79. The Ministry of Health would also be able to oversee the commissions, the implementation of which is argued for *infra* Section III.B.

in Mexico. By restructuring an agency, it is possible to root out officials who have been bought by drug-trafficking organizations, as has been attempted in the police forces.²⁶⁴ Mexico would need to develop procedures for detecting corruption in new applicants, as well as a system for evaluating the levels of current corruption. Overall, the introduction of a new agency will show that public health is a primary concern of the Mexican government, paving the way for the implementation of new measures designed to effectively address drug use.

The Portuguese experience demonstrates another means of prioritizing public health through a decriminalization scheme. Implementation of decriminalization in Portugal was accompanied by another decree that laid out the framework for establishing harm reduction service centers.²⁶⁵ This accompanying decree was important for three key reasons: First, it again demonstrated the government's dedication to addressing drug use as a public health problem by prioritizing the health of drug users and the prevalence of disease in society over incarceration of drug crime perpetrators. Second, it encouraged the creation of specific harm reduction programs that directly targeted the health-related dangers of drug use, such as shelters for homeless drug users and needle exchanges all over the country. Third, it provided uniform standards for the creation, implementation, and evaluation of these programs, guaranteeing equal services in regions where the programs exist.

A similar measure, if enacted in Mexico, would help redirect the focus of decriminalization to decreasing the levels of drug use, addiction, and related diseases. It would demonstrate that the government is concerned with the health of its population and is taking steps to remedy the current high drug use situation. It would also provide the organization in charge of drug prevention and treatment with clear guidelines for implementing services instead of the vague mandates with which Mexico's Ministry of Health must currently comply.

Finally, Mexico must act to increase the resources available to address the harms associated with drug use. The rising rates of addiction, HIV, and hepatitis in Mexico can only be quelled if services exist for their treatment. In Portugal, the significant increase in providers all over the country has resulted in reductions in drug use and drug-related mortality and disease.²⁶⁶ Although, in Mexico, the number of syringe exchanges increased substantially in the 2000s and programs have been established to increase the number of treatment providers, more services, especially opioid replacement therapy, are needed.²⁶⁷

²⁶⁴ See BRANDS, *supra* note 150, at 16.

²⁶⁵ See Decree Law 183/2001, *supra* note 84.

²⁶⁶ See GREENWALD, *supra* note 46, at 15-17; de Almeida & Encarnação, *supra* note 14, at 221; Hedrich et al., *supra* note 103, at 503, 508.

²⁶⁷ See MEYER, *supra* note 142, at 9; Mathers et al., *supra* note 103, at 1020, 1021 (noting that only one publicly funded methadone maintenance program existed in 2009); Moreno et al., *supra* note 175, at 494; INCB Report for 2010, *supra* note 133, at 71-72, ¶

Additionally, the lack of resources and training for existing providers must be addressed. Devoting resources to and encouraging the creation of these services could allow Mexico to realize some of the successes of Portugal's decriminalization scheme, while also cementing the notion that Mexico is committed to addressing drug use as a public health issue. The fact that Mexico has already begun to implement these measures demonstrates the government's desire to achieve the results that the criminal justice system has failed to produce.

Reframing its drug crisis in terms of public health would help Mexico achieve reductions in drug use, addiction, disease, and other related consequences. However, redefining objectives is not enough in itself. Mexico must also make concrete changes to its decriminalization structure. One of these needed alterations should be modeled after a cornerstone of Portugal's law: the CDTs.

B. Implementing Commissions Based on the Portuguese Model

The CDTs are arguably the most unique feature of decriminalization in Portugal. These bodies represent a marked departure from traditional law enforcement in addressing drug use. Mexican decriminalization could much more effectively reduce drug use, drug-related disease, and burdens on the criminal justice system if it were to adopt commissions like the CDTs of Portugal for two reasons: First, a diverse panel would be able to make offender-specific determinations and impose a variety of sanctions aimed at achieving the most effective outcomes. Second, the commission would be removed from the criminal justice system. This separation is likely to encourage users to seek treatment voluntarily; reduce the burden of drug use cases on the courts; decrease corruption, extortion, and human rights abuses; and refocus law enforcement efforts on large-scale drug trafficking.

An advantage of the Portuguese system is that experts in the field of drug addiction, and not judges with limited knowledge in this field, determine whether a drug possession offense has occurred and whether the offender is addicted.²⁶⁸ The creation of similar commissions in Mexico would allow for experts in the area of substance abuse to determine whether or not a user is addicted. This is preferable to having a judge perform this task, since the commission would likely be more familiar with the symptoms and presentation of addiction and would be able to more accurately decide whether a person is addicted. Additionally, removal of this decision-making power from the criminal justice system would help reduce the stigma associated with addiction, thus mitigating one barrier to treatment.

Currently, in Mexico, the decision to impose a sanction on a drug offender is

442.

²⁶⁸ See Decree Law 30/2000, *supra* note 2, art. 7(2).

made solely by the amount of the drug possessed and whether the offender had been apprehended twice before.²⁶⁹ This approach does not leave discretion to the sentencing body to take into account the circumstances of the offense or offender, or to tailor an individualized sanction that would encourage the offender to abstain from reoffending. Expert panels with the ability to consider all the facts, like the CDTs of Portugal, are more likely to produce results that reflect the best interests of both the individual user and of Mexican society. By encouraging offender participation in the proceedings, expert sentencing bodies would contribute to the visibility of both drug addicts as people in need of help and drug use as a public health problem. Both of these features of an expert commission would facilitate rehabilitation and improve treatment outcomes.

Moreover, compelled treatment for third-time offenders is the only penalty that can be imposed on those whose possession is within the decriminalized amount under the current regime in Mexico.²⁷⁰ This approach is both over- and under-inclusive. It is over-inclusive because a person who is a third-time offender but not an addict would still be subjected to the inappropriate, and most likely unhelpful, sentence of forced treatment. It is also under-inclusive because an addict in need of treatment will not be compelled to get help until his third offense. This will likely incur greater costs for the criminal justice system and for the individual's health because an addicted person will have to report to court three times before receiving treatment. This is another reason why discretion by the deciding body is important. As already noted, the experts on CDTs are better equipped than the judges in the criminal justice system to determine whether an alleged offender is addicted and to fashion the most appropriate sanction for an individual.

Further, the variety of sanctions available to the CDTs should serve as a model for Mexico. In Portugal, the penalties for drug offenses include prohibitions on visiting certain places or people, fines, suspension of professional licenses, or prohibition on travel.²⁷¹ Because the main purpose of imposing sanctions is to deter the offender from committing offenses in the future, a wide variety of penalties are needed to address the needs of the specific individual. Mexican law should empower commissions to impose a variety of sanctions, rather than only mandating treatment after the third offense, because allowing for personalized penalties would increase the probability that the individual will not reoffend.

The method of referrals to commissions is another opportunity to further a public health-oriented approach to drug use. Although in Portugal users are still referred to CDTs by police officers, this encounter represents the only contact

²⁶⁹ See *Narcomenudeo Law*, *supra* note 7, art. 193 BIS.

²⁷⁰ See *id.*

²⁷¹ See Decree Law 30/2000, *supra* note 2, arts. 11(1), 15-18.

between the user and the criminal justice system.²⁷² In contrast, users in Mexico can be arrested and held in pre-trial detention until a prosecutor determines whether the amount possessed is within the limit for personal use.²⁷³ Mexico's approach does not remove the user from the criminal justice system. As a result, the stigma of being considered a criminal is still present and functions as a barrier to treatment. This was an important consideration in Portugal's decision to remove the authority of police officers to arrest for drug possession.²⁷⁴ Since adopting this strategy, Portugal has seen a significant increase in the number of people seeking treatment for drug addiction.²⁷⁵ Removing the power of the police to make arrests for drug possession under the defined amount in Mexico would be a major step both in eliminating the stigma associated with the criminal justice system and in moving toward a public health approach. It would also likely result in less extortion because the corrupt state and local officials granted power under the current law to enforce drug offenses would not be able to leverage their arrest power over citizens to receive bribes.²⁷⁶ Although police officers may still demand a bribe to prevent them from issuing a referral to the commission, the removal of this process from the criminal justice system is likely to persuade more citizens to accept the referral than would have accepted arrest, thus increasing the likelihood that a user will receive treatment if needed.²⁷⁷ Pre-trial detention of offenders may decrease as well, which would conserve resources and prevent unwarranted confinement of minor offenders.

Establishing commissions like the Portuguese CDTs would complete the removal of minor drug possession offenses from the criminal justice system. In addition to reducing the stigma associated with a criminal charge and enabling users to openly seek treatment without fear of criminal penalties, a commission could have several other positive effects. First, it would reduce the burden on courts. In Mexico, this would mean removal of jurisdiction over several offenses from the resource-strapped and backlogged judiciary.²⁷⁸ Corruption could also be avoided, as the offender would not have to deal with judges or prosecutors, but

²⁷² See ALLEN ET AL., *supra* note 47, at 2.

²⁷³ See Narcomenudeo Law, *supra* note 7, art. 180 BIS; Hernández, *supra* note 132, at 63.

²⁷⁴ See GREENWALD, *supra* note 46, at 9; VAN BEUSEKOM ET AL., *supra* note 11, at 26.

²⁷⁵ See GREENWALD, *supra* note 46, at 15.

²⁷⁶ See Narcomenudeo Law, *supra* note 7, art. 474 BIS; U.S. DEP'T OF STATE BUREAU FOR INT'L NARCOTICS AND LAW ENFORCEMENT AFFAIRS, *supra* note 158, at 434-35.

²⁷⁷ For example, because users could no longer be placed in jail, the fear of having their freedom infringed and being removed from loved ones would no longer exist.

²⁷⁸ See SHIRK, *supra* note 163, at 6 (describing the shortage of resources in the Mexican judiciary).

would instead be sent to a newly formed commission that could implement new procedures for assuring that its members were not corrupt.²⁷⁹ Police officers and prosecutors would be able to focus more intensely on major drug-trafficking cases instead of having to deal with minor possession cases. As has been seen in Portugal, this refocused effort can produce significant increases in drug seizures.²⁸⁰ Human rights abuses such as illegal searches and detentions could also be curtailed by this new approach because police would be formally prohibited from targeting those populations suspected to be solely in possession of the quantity of drugs typical of personal use.

For these reasons, the adoption of a system of commissions and the removal of drug possession cases from the criminal justice system are imperative to implementing a public health approach. Although adoption of Portuguese-style CDTs is a crucial step toward achieving positive results through drug decriminalization, Mexico must also address the maximum amounts of drugs that it characterizes as personal use.

C. Increasing the Maximum Amounts of Drugs Defined as Personal Use

Under current Mexican law, the amount defined as personal use for most drugs is set quite low, at under a gram for all drugs except marijuana.²⁸¹ In contrast, the law in Portugal defines a ten-day supply of any drug as decriminalized, with one gram being the lowest of the maximums.²⁸² This stark difference again reflects the divergent legal approaches taken by the two countries. Mexico, focused on increasing penalties for small-scale trafficking instead of on directly improving the health of the drug user, designated the allowable limit at a very low threshold and increased penalties for possession of all amounts above that limit.²⁸³ This will not solve any of the problems that Mexico is currently facing, and in fact, may exacerbate them. In order for decriminalization to have a positive impact on its drug crisis, Mexico should follow Portugal's lead and increase the amounts defined as personal use.

What is striking about the current limits in Mexico is that they are below the amount in which most drugs are sold on the street.²⁸⁴ For example, the maximum limit for cocaine is five hundred milligrams, but most users buy their supply by

²⁷⁹ To fully achieve this change, programs to combat corruption would have to be developed.

²⁸⁰ See HUGHES & STEVENS, *supra* note 29, at 3.

²⁸¹ See Narcomenudeo Law, *supra* note 7, art. 479 BIS.

²⁸² See Decree Law 30/2000, *supra* note 2, art. 2; Portaria 94/96 [Ordinance 94/96], art. IV(9), mapa, DIÁRIO DA REPÚBLICA de 26.3.1996 (Port.); *supra* text accompanying note 58.

²⁸³ See Narcomenudeo Law, *supra* note 7, arts. 476-77; Hernández, *supra* note 132, at 63-64.

²⁸⁴ See Hernández, *supra* note 132, at 64.

the gram.²⁸⁵ This creates several problems: First, this will likely result in more addicts being imprisoned. Because many drug addicts may purchase and possess drugs in greater quantities than what is allowed, they could be designated as criminals within the legal regime, not as users in need of help. Because the law also increases penalties for possession over the defined limit, these addicts may end up spending a longer term in prison than they would have prior to decriminalization. Such an outcome is inconsistent with a public health approach to addressing a national drug crisis, because it incarcerates addicts instead of providing them with needed treatment. Increasing the maximum amount of non-criminalized possession would ensure that addicts are diverted from the criminal justice system into the administrative regime, where they can receive the appropriate sanctions to discourage recidivism. If Mexico adopted the CDT system, raising the maximum amounts would allow the commission members to consider the quantity possessed by users as a factor in determining an appropriate sanction. As a result, criminal penalties would not automatically apply to addicts in possession of slightly larger quantities of drugs than as defined for personal use.

A related negative consequence of Mexico's currently low thresholds is the stress they place on the already over-burdened prison system. Mexico has the sixth highest prison population in the world and overcrowding is pervasive in prisons throughout the country.²⁸⁶ Because the typical drug user will possess an amount over the decriminalized limit after purchasing drugs, most addicts are at risk of being incarcerated, not of being released or mandated to undergo treatment.²⁸⁷ Moreover, since Mexico has lengthened the prison sentences for possession over the stipulated amount it decriminalized, users caught possessing greater quantities than this will be imprisoned for longer periods, further exacerbating the problem of prison overcrowding.²⁸⁸ If Mexico were to follow Portugal's approach and increase the maximum limit to a more reasonable amount—one that more accurately reflects the known average purchase quantities of various drugs—then prison populations would likely decrease. This was one positive outcome experienced by Portugal in the years immediately following the adoption of its decriminalization legislation. The rate of drug-related offenders in prison decreased significantly and the total number of people

²⁸⁵ *Id.*

²⁸⁶ *See id.* at 64-65, 70.

²⁸⁷ There may be concern over whether there are treatment resources available for all offenders. In Portugal, even though treatment facilities are divided between inpatient and outpatient services, treatment is fully available for any drug user seeking treatment. *See Drug Treatment Overview for Portugal*, EMCDDA, <http://www.emcdda.europa.eu/data/treatment-overviews/Portugal> (last visited Mar. 6, 2012).

²⁸⁸ *See supra* Section II.B.

in prison also declined substantially.²⁸⁹ Raising the criminalized quantities under Mexican decriminalization should result in similar penal outcomes. Mexico would also experience considerable monetary savings in the prison system, which currently spends approximately \$775 million annually on the containment of inmates.²⁹⁰

Furthermore, increasing the quantity limits for possession might reduce the amount of extortion that occurs among law enforcement agencies. Under the current legal limits, it is actually more likely that extortion will increase than decrease. Because the penalties for those caught in possession over the limit have grown harsher, police will have greater leverage to extract payoffs from suspected offenders. Increasing the limits should discourage this extortion by cabining some of this police leverage. Assuming that arrest power for drug possession offenses has been removed, police officers will not be able to target users and addicts who possess amounts below the maximum—removing or limiting their ability to threaten offenders with incarceration if they fail to produce a bribe. In fact, without raising the limits, removing the arrest power for these offenses would do little to combat corruption, because in most cases the addict will possess drugs in quantities over the maximum. This is especially significant because state and local law enforcement in Mexico, empowered to enforce drug charges under the recent amendments, are widely regarded as the most corrupt of law enforcement officials.²⁹¹

A final benefit of increasing the limits would be that police could refocus their efforts on traffickers. Because the possession limits are currently set so low, police continue to expend substantial resources apprehending small-time users and addicts instead of pursuing high-level distributors.²⁹² In Portugal, setting the limits at a higher amount allowed police to shift their attention to combating trafficking, resulting in major increases in the amount of drugs seized.²⁹³ Mexican law enforcement officials could, therefore, benefit from increasing the maximum amount by concentrating on major drug-trafficking organizations and combating the violence that they produce, instead of incarcerating low-level dealers in possession of an amount worth less than \$100.²⁹⁴

²⁸⁹ See HUGHES & STEVENS, *supra* note 29, at 4; Hughes & Stevens, *supra* note 30, at 1010.

²⁹⁰ See Hernández, *supra* note 132, at 65.

²⁹¹ See Narcomenudeo Law, *supra* note 7, art. 474; U.S. DEP'T OF STATE BUREAU FOR INT'L NARCOTICS AND LAW ENFORCEMENT AFFAIRS, *supra* note 158, at 435.

²⁹² Wagner, *supra* note 217.

²⁹³ See Hughes & Stevens, *supra* note 31, at 1011.

²⁹⁴ See Hernández, *supra* note 132, at 65 (noting that fifty percent of those incarcerated for selling drugs were in possession of amounts worth \$100 or less); *supra* Section I.D (explaining how Portugal was able to refocus its efforts on trafficking after decriminalization).

The amount that Mexico should set as the maximum under its decriminalization scheme need not be exactly the same as Portugal's, but Portuguese limits would serve as an apt example because of the successes that Portugal's structure has produced. A ten-day supply allows an addict or user to possess an amount of the drug that falls within the normal quantity of drugs purchased by users, but still sets a threshold to differentiate users from traffickers. Conducting empirical research on the typical drug quantity purchased by users in Mexico may help to determine the most appropriate threshold. If the definitional limits for personal use under the current law were determined to be a one-day supply, then decriminalizing a ten-day supply may be too much. Instead, it may be best to consider not the abstract concept of a ten-day supply, but rather the concrete numerical amounts identified by the Portuguese law.

Implementation of the solutions described above could alleviate many of the problems that plague Mexico's drug crisis. Nevertheless, Mexico and Portugal are different countries, and execution of these objectives in Mexico may encounter several difficulties.

D. Potential Obstacles to Implementing Portuguese-Style Decriminalization

Although both are supply countries that have experienced (or in the case of Mexico, are still experiencing) similar public health problems related to drug use, Portugal and Mexico have different histories, governments, and relationships with foreign nations. Therefore, Mexico may face different challenges to implementation of decriminalization than did Portugal. Political pressure from the United States, the international community, and groups within Mexico may impede the adoption of these recommendations. Although implementing the strategies described in this Part may alleviate some corruption, human rights abuses, and extreme violence, these and other obstacles may still stand in the way of the strategies' full execution. Since these strategies will not be a cure-all for drug-related problems, obstacles will most likely persist on some level after the new policy is in place. Finally, Mexico must be willing and able to produce the needed resources for successful implementation of the program. This Section will address these potential issues and offer solutions where appropriate.

Unlike in Portugal, the development of drug policy in Mexico has always been heavily influenced by the United States.²⁹⁵ It is, therefore, highly likely that the United States would play a major role in Mexico's decision about whether to adopt the Portuguese model of decriminalization. In fact, Mexico experienced such intense pressure from the United States when it first attempted to implement its own style of decriminalization that it abandoned the effort.²⁹⁶ Mexican officials would most likely be wary of adopting a drug policy that the United

²⁹⁵ See VELASCO, *supra* note 133, at 93-94, 103, 119; Chabat, *supra* note 188, at 135.

²⁹⁶ See Grillo, *supra* note 189.

States would disfavor. Mexico's current approach is acceptable because it furthers the militarization method that the United States supports.²⁹⁷ Moving away from this attitude toward a public health approach may expose the Mexican government to significant additional pressure from the United States.

However, there are indications that the United States would accept such a paradigm shift in Mexico. Although the United States applied immense pressure against legislative change in 2006 when Mexico first attempted decriminalization, resistance to the 2009 changes was minimal.²⁹⁸ It is possible that the United States would oppose Mexico's adoption of the Portuguese model, but the recent public rhetoric and attitude in the United States suggest that it may be willing to accept this new structure in the drug regime of its southern neighbor.²⁹⁹ Arguing that implementing the Portuguese approach will allow Mexican police forces to focus on large-scale trafficking may help to persuade skeptical U.S. policymakers that this method is preferable, as Mexican drug-trafficking organizations are considered a major threat to U.S. national security.³⁰⁰ Additionally, changes to the Mexican law could still increase penalties for traffickers, reinforcing the objective of identifying and dismantling drug-trafficking organizations while providing more resources for drug users. Of course, the U.S. approach to drug policy is likely to vary significantly based on the political party in control, and changes in the presidential administration may cause policymakers' mindsets to again shift towards increased militarization.

The United States is not the only source of political pressure from the international community that Mexico must address. As a signatory to the three major United Nations drug treaties, Mexico is obligated to comply with their provisions or face international scrutiny.³⁰¹ Initially, the International Narcotics Control Board (INCB) suggested that the new approach in Mexico may violate these UN treaties.³⁰² However, they have more recently approved of Mexico's dedication to the treaties' goals and commitments.³⁰³ Furthermore, the INCB has approved the Portuguese model and has explicitly stated that the "practice of exempting small quantities of drugs from criminal prosecution is consistent with the international drug control treaties."³⁰⁴ In fact, by following the Portuguese precedent in adopting a model of sanctions administered by commissions, it is more likely that the international community would accept a revised Mexican decriminalization scheme. Under the Mexican structure, offenders are not

²⁹⁷ See *supra* Section II.C.

²⁹⁸ See Grillo, *supra* note 189.

²⁹⁹ See *id.*; *supra* text accompanying note 192.

³⁰⁰ See Archibold, *supra* note 156.

³⁰¹ See *supra* text accompanying note 27.

³⁰² See INCB Report for 2009, *supra* note 242, at 68, ¶ 408.

³⁰³ See INCB Report for 2011, *supra* note 244, at 12, ¶ 87.

³⁰⁴ INCB Report for 2004, *supra* note 83, at 80, ¶ 538.

sanctioned until their third offense.³⁰⁵ In Portugal, the CDTs can exercise discretion to apply a wide array of sanctions to offenders, within some limits.³⁰⁶ Although they must provisionally suspend the proceedings if they determine that the offender was not addicted and that this was the first offense, this suspension can be viewed as a form of probation, because the proceedings will resume if the user is caught reoffending.³⁰⁷ Therefore, if Mexico were to enact new legislation permitting greater discretion by sentencing officials among a wider variety of sanctions, the INCB would be more likely to accept the structure. Finally, the U.N. Convention identifies “the prevention of abuse of drugs and [] the early identification, treatment, education, after-care, rehabilitation and social reintegration of the persons involved” as imperative goals and require all signatories to “take all practicable measures” to further them.³⁰⁸ Under the Portuguese approach, these prevention and treatment objectives are paramount, and the significant reductions in drug-related disease and death as well as the recorded increases in treatment in Portugal after decriminalization lend credence to the notion that Mexico would be able to advance these aims by following Portugal’s lead.

Of course, Mexico is only one of the most recent countries to enact some form of drug decriminalization legislation. In fact, a trend toward this type of policy has been observed both in Europe and in Latin America.³⁰⁹ These countries are therefore likely to offer support for the adoption of the Portuguese model in Mexico, offsetting contrary political pressure.³¹⁰

Even if the international community would accept a shift from Mexico’s current scheme to a structure based on Portugal’s, there must be domestic political support for these changes. This domestic political support will depend heavily on the political party in power in Mexico. Officials must determine priorities and respond to their party’s objectives and the wishes of their constituencies. Given the current state of the drug crisis in Mexico, it does not

³⁰⁵ See *Narcomenudeo Law*, *supra* note 7, art. 193 BIS.

³⁰⁶ See *supra* Section I.C.

³⁰⁷ See Decree Law 30/2000, *supra* note 2.

³⁰⁸ Single Convention on Narcotic Drugs, *supra* note 20, art. 38(1); see also *supra* text accompanying note 23.

³⁰⁹ See Youngers & Walsh, *supra* note 7, at 123.

³¹⁰ Additionally, there is support for more public health-oriented approaches to drug policy from the Latin American Commission on Drugs and Democracy and the Global Commission on Drug Policy, a body comprised of important political figures from around the world, including former presidents. See GLOBAL COMM’N ON DRUG POLICY, REPORT OF THE GLOBAL COMMISSION ON DRUG POLICY (2011); *supra* text accompanying note 192. The President of Guatemala has also called for legalization of drugs as a solution to the problems that Latin American countries are facing. Catherine E. Schoichet, *Guatemalan President Leads Drug Legalization Debate*, CNN, Mar. 23, 2012, <http://www.cnn.com/2012/03/23/world/americas/guatemala-drug-legalization/index.html>.

seem that prioritizing the adoption of a more effective drug strategy would be a great hurdle for any political party. However, various parties' proposals for addressing drug use are likely to vary significantly. Mexico will elect a new president in the summer of 2012, and the three candidates each have unique views on whether a more liberal approach to drug policy should be taken.³¹¹ If the administration elected in 2012 were to view drug use as a criminal offense, it might even work to repeal the current decriminalization law or may exhibit a lack of vigor in its implementation. As seen in Portugal, execution of the decriminalization strategy can suffer if politicians fail to provide adequate resources.³¹² Since at least 1940, however, addicts in Mexico have been identified in legislation as sick persons in need of help, and not categorized as criminal offenders, so long as the amount possessed was for personal consumption.³¹³ Additionally, recent polls indicate that the majority of Mexican citizens view drug addiction as a sickness and believe that the addict is a person in need of help.³¹⁴ This history and context suggests that adopting a public health approach more similar to the drug legislation in Portugal might not meet an extraordinary amount of domestic opposition in Mexico.³¹⁵

Aside from political challenges, implementation of the Portuguese decriminalization regime presents other problems. The level of corruption that

³¹¹ Enrique Peña Nieto of the Institutional Revolutionary Party (PRI) is completely opposed to legalization and favors the currently prevailing approach of militarization. Josefina Vázquez Mota of the National Action Party (PAN) encourages debate on the topic of legalization, but contends that legalizing drug use would constitute a surrender to the drug-trafficking organizations. Andrés Manuel López Obrador of the Party of the Democratic Revolution has come closest to supporting legalization by proposing to submit the question of whether drugs should be legalized to a national debate. Katie Putnam, *The Week in Review: 3/5/2012*, MEXICO INST. ELECTIONS GUIDE (Mar. 5, 2012, 7:08 AM), <http://mexicoinstituteelections.wordpress.com/2012/03/05/the-week-in-review-352012/>. Unfortunately, little information is available on the candidates' views on the current policy of decriminalization.

³¹² See Hughes & Stevens, *supra* note 30, at 1005.

³¹³ See Regulations Concerning Narcotic Drugs and Psychotropic Substances, *supra* note 139 art. 88; Reglamento Federal de Toxicomanías [Federal Rules of Addiction], Diario Oficial de la Federación [DO], 17 de Febrero de 1940 (Mex.).

³¹⁴ See NATIONAL COUNCIL AGAINST ADDICTIONS, *supra* note 171, at 71.

³¹⁵ Domestic support for a public health-oriented approach to drug legislation is especially likely after the Mexican government's recent expansion and centralization of healthcare, which has been lauded by the international public health community. See Decreto por el que se reforma y adiciona la Ley General de Salud [Decree Amending and Adding to the General Health Law], Diario Oficial de la Federación [DO], 15 de Mayo de 2003 (Mex.); see also Felicia Marie Knaul et al., *Evidence Is Good for Your Health System: Policy Reform To Remedy Catastrophic and Impoverishing Health Spending in Mexico*, 368 LANCET 1828 (2006) (arguing that Mexico's health reform should serve as an example for other countries).

pervades the Mexican government is staggering and stands in the way of executing any real reform. An extensive reform of the justice system in Mexico is needed; Portuguese-style decriminalization will not be a panacea for the system—and may in fact suffer as a result. Should the members of the proposed CDT-style commissions be as corrupt as their existing law enforcement analogs, they may extort users diverted to them, and fail entirely to impose sanctions or refer addicts and users to treatment.

Yet the nature of what is at stake in these CDT commissions may actually decrease the chances that its members will be corrupt. Drug-trafficking organizations would not have as much to gain from bribing commission members as they would from bribing prosecutors or judges. Bribing CDT members would only protect users and addicts who come in contact with these commissions, not high-ranking individuals in trafficking organizations. Additionally, since users in possession below the raised maximum amounts would not be in danger of arrest, the police would have diminished leverage for extortion. Resources saved by diverting these offenders to an administrative system could also be refocused on battling larger-scale drug-trafficking organizations and on curbing corruption within the ranks of the Mexican government. Although far more extensive efforts will be needed to successfully address the widespread corruption among Mexican officials in all areas of government, implementing the Portuguese model of decriminalization may offer some relief at the law enforcement level.

Human rights abuses committed by Mexican police and military forces present another predicament. The Portuguese model of decriminalization may have some positive effects on the mistreatment of drug users. Although refocused efforts should decrease the amount of contact between addicts and the police, there still exists the initial contact where police cite the offenders and apprise them of their obligation to report to the commission. Present in this situation is the opportunity for an official to perform an illegal search, detention, or torture to procure information. The proposed reform would, however, grant less opportunity for this given that the contact between user and law enforcement is shorter and there is less incentive for such abuses since the end result will not be criminal sanctions. Although the potential for human rights abuses would be lessened under the Portuguese approach, serious reform of professional standards, training, and education for law enforcement agents are needed to address this problem.

The amount and extremity of violence has become perhaps the most visible aspect of the drug crisis in Mexico. This has been a major cause of the increase in militarization and aggression by Mexican law enforcement—which has, in turn, exacerbated the violent nature of the drug problem.³¹⁶ Because addressing violence is such a primary focus of the struggle in Mexico, its decriminalization

³¹⁶ See MEYER, *supra* note 142, at 8; RIOS & SHIRK, *supra* note 156, at 8.

policy continues to promote military involvement and increased penalties for those found in the drug trade. This approach may impede the implementation of the Portuguese model of decriminalization, which instead focuses on the public health issues associated with drug use. It may also lead to further violence and abuse by Mexican law enforcement. Although many drug strategists in Mexico have taken the militarization approach, a policy like that of Portugal should actually allow law enforcement to focus more on traffickers. Removing drug users and addicts from the criminal justice system should allow the concentration of resources and personnel on drug-trafficking organizations. In Portugal, where the amount of drugs seized has vastly increased, this has proven to be the case.³¹⁷ Mexican officials will likely be able to better focus on reducing violence once greater resources are free to target traffickers.

With a potential shift in focus toward large-scale illegal drug operations, a concern that may arise is that police officers may ignore those in possession of personal amounts of drugs and choose not to issue a citation compelling them to appear before a commission. Officers may no longer be concerned with the petty offender or may feel that referrals to the commissions are useless. The amended decriminalization regime may need to develop incentives to motivate police officers to issue citations to low-level offenders, if the CDT-style model is adopted.

A final difficulty of importing the Portuguese model of decriminalization to Mexico lies in the allocation of resources. In order to fully effectuate its strategy, Portugal increased overall funding for drug policy implementation, increased the number of public treatment and harm reduction facilities, and established CDTs in every region of the country.³¹⁸ In Mexico, public health measures focused on drug use have increased during the last decade, but needle exchange and opioid substitution programs are still not at the capacity reached in Portugal.³¹⁹ Furthermore, most of the staff in these treatment centers are undertrained as a result of inadequately funded and poorly managed training programs.³²⁰ Efforts to reduce drug-related health consequences must be supplemented by adequate resources; without the additional infusion of resources, such measures are destined to fail.

This resource problem is compounded by the fact that most police forces are already under-resourced and understaffed.³²¹ The Mexican government may be

³¹⁷ See HUGHES & STEVENS, *supra* note 29, at 3.

³¹⁸ See DEGENHARDT ET AL., *supra* note 33, at 12; GREENWALD, *supra* note 46, at 15; INSTITUTO DA DROGA E DA TOXICODÊPENDÊNCIA, *supra* note 92, at 106; Hughes, *supra* note 1, at 120.

³¹⁹ See INCB Report for 2010, *supra* note 133, at 71-72, ¶ 442.

³²⁰ See U.S. DEP'T OF STATE BUREAU FOR INT'L NARCOTICS AND LAW ENFORCEMENT AFFAIRS, *supra* note 158, at 436.

³²¹ See Tinajero & Angles, *supra* note 9, at 2; Astorga & Shirk, *supra* note 141, at 27.

reluctant to divert resources to public health measures that it feels might better be used in combating the drug-trafficking organizations. Yet, as noted earlier, the allocation of resources to such measures should actually increase the resources that are available in the criminal justice system to target traffickers, as removing low-level drug users from the criminal system could save both court costs and the costs of incarceration. These cost savings have already been realized in Portugal.³²² The criminal justice system is also likely to conserve resources as the reduction in addiction rates results, over time, in fewer addicts committing crimes either to support their habit or while intoxicated. Additionally, the associated reduction in disease, death, and addiction should reduce healthcare spending broadly. As low-level users come in contact with the public health system, they can begin to receive treatment for HIV, hepatitis, and tuberculosis. This, in turn, should reduce the prevalence of these diseases and associated death, a particularly significant effect given that these diseases are major drivers of national healthcare expenses.

Thus, in the long term, the adoption of a decriminalization scheme that shares the public health orientation of Portugal's drug regime could result in net savings for the Mexican government. But failure to adequately fund such a program from the outset could result in a corrupt system of commissions not significantly different from current law enforcement. Without sufficient resources, the members of these commissions may resort to soliciting bribes from offenders who come before them, either because commissioners might not have the time or ability to hear the volume of cases presented to them or because commissioners need to supplement their own insufficient salaries. In light of the impoverished status of most law enforcement agencies in Mexico, such grave concerns must inform the implementation of any new drug decriminalization policy.

Finally, it is worth noting that Mexico already expends an appreciably greater amount of money on its existing drug policies than does Portugal. While Portugal only spent \$77.5 million in 2008, Mexican drug policy expenditures totaled \$4.3 billion in 2009.³²³ Of course, the population of Mexico is about ten times that of Portugal, yet Mexico is still spending more than fifty-five times the amount that Portugal is on addressing its drug crisis. This suggests, in part, that it may be possible to achieve a reduction in public health problems and an increase in drug seizures through a lower-cost drug enforcement regime.

CONCLUSION

Today, the scene at Casal Ventoso has changed dramatically. No longer is

³²² See ALLEN ET AL., *supra* note 47, at 4.

³²³ See DEGENHARDT ET AL., *supra* note 33, at 12; Astorga & Shirk, *supra* note 141, at 3 n.4.

the area known across Europe as a scourge, an uncontrolled venue for the purchase of dangerous substances. No longer is a visitor to the area likely to spot a man on the side of the street with a syringe in his hand, casually administering an illegal drug. Fewer homeless individuals inhabit the region, and disease rates have dropped significantly. The effects of Portugal's new approach to drug policy have produced a noticeable impact on this once-dismal scene, and the outlook for continued improvements is positive.

On the other hand, the outlook is much bleaker in Tijuana than before. Dealers continue to roam the streets in "ice cream trucks," people still openly use their drug of choice, disease remains common, and violence is never far away. It is not easy to identify evidence of any positive outcomes of the new law decriminalizing possession of small amounts of drugs. Clearly, a new approach to drug policy is needed in Mexico. In order to achieve reductions in addiction and disease, public health must become a priority in the development of the national drug strategy. This, more than Mexico's current approach, will allow an increased focus on large-scale drug-trafficking organizations; for this reason, the structure in Portugal could serve as a groundbreaking new model for Mexico.

Developing an effective drug policy is a challenge that must take into account criminal justice, public health, and political concerns. Each country must adopt a strategy that conforms to its ideals of good government and individual rights. Certainly, different political pressures, governmental structures, and histories inform the conditions of drug-related law enforcement in Mexico and in Portugal. But the similar societal problems experienced in both countries as a result of escalating drug use, and the status of each country as a supplier nation, make comparison valuable and suggests that implementation of the Portuguese decriminalization scheme would be successful in Mexico.

If Mexico were to implement Portuguese-style decriminalization, it is likely to realize several positive effects. A new focus on public health could reduce the number of addicts and the rate of disease by increasing publically available harm reduction services and encouraging addicts to seek treatment. It could allow law enforcement to more effectively target large-scale traffickers and address other ancillary issues including corruption, human rights abuses, and violence. The prison population and backlog of casework in the criminal justice system are also likely to decrease; this, coupled with a reduction in spending on small-scale drug crimes, would free up resources to address other crimes.

Mexico may not be able to adopt the Portuguese model without opposition. The country is likely to experience adverse political pressure from several sources, including the very influential United States. Additionally, problems of local and national corruption, violence, and human rights abuses will persist. Implementing a decriminalization scheme as Portugal has done, however, should eventually abate the impact of these issues in Mexico, and would likely generate positive public health outcomes related to drugs, through increased treatment

uptake and reductions in drug-related disease. Such a legislative change is, therefore, a worthwhile objective that will better promote not only the well-being of drug users, but also the broader aims and efficacy of Mexico's criminal justice system, and the cohesion and health of Mexican society.

