THE PUBLIC'S RIGHT TO HEALTH: WHEN PATIENT RIGHTS THREATEN THE COMMONS

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ABSTRACT

This Article offers a contemporary examination of traditional public health objectives to address social problems not amenable to individual resolution. Taking the tradition a step further, it defines a "public health right" that may justify certain government actions that otherwise appear to impair individual rights. For example, lawmakers are considering whether current regulations on prescription drugs should be loosened to allow terminally ill patients to access drugs before they have been tested and approved for the general public. This Article concludes that expanding access to experimental drugs would violate the public health right to scientific knowledge and new drug development. The choice of a few patients to avail themselves of untested drugs depletes the "commons" of biomedical research. The Article concludes by briefly testing the public health right against other contemporary laws intended to promote public health and welfare, finding some but not all are justified.

TABLE OF CONTENTS

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I. INTRODUCTION

Most people, and most courts, accept that individuals have a right of personal autonomy and control over what is done to their bodies. The right is firmly rooted in common law doctrines, including the tort of battery,[1] self-defense privilege,[2] and informed-consent standards,[3] and recognized in constitutional rights to refuse medical treatment[4] and obtain an abortion.[5] At the same time, most people and most courts accept that individual rights may have to yield, at times, to the greater good of society.[6] For example, most states have well-established mandatory vaccination laws to prevent the spread of infectious diseases.[7] Most states

1. *See, e.g.*, Garratt v. Dailey, 279 P.2d 1091 (Wash. 1955); Vosburg v. Putney, 50 N.W. 403 (Wis. 1891). Even a slight touching, without harm, may constitute a battery. *See* Mahaise v. United States, 722 A.2d 29, 30 (D.C. 1998).

2. *See, e.g.*, People v. Pignatoro, 136 N.Y.S. 155, 160 (Magis. Ct. 1911) (describing self-defense as "an inherent right of man, older than states or Constitutions"); Courvoisier v. Raymond, 47 P. 284 (Colo. 1896); MODEL PENAL CODE § 3.04 (1962).

3. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972); Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . .").

4. *See* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990) (recognizing 14th Amendment liberty interest in refusing life-sustaining treatment).

5. *See* Roe v. Wade, 410 U.S. 113 (1973); *see also* Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992).

6. *See* Richard A. Epstein, *In Defense of the "Old" Public Health*, 69 BROOK. L. REV. 1421, 1422–23 (2004) (asserting that "[m]ost people start with the naive assumption that when matters of public health are on the table, claims for individual liberty normally must give way," but defending "traditional" role of public health in "containing epidemics, contagion, and nuisances, which . . . do not lend themselves effectively to either market solutions or private actions in tort").

7. Modern mandatory vaccination laws are usually imposed as conditions of public school attendance. *See* Jacobson v. Massachusetts, 197 U.S. 11, 31–32 (1905) ("And the principle of vaccination as a means to prevent the spread of smallpox has been enforced in many States by statutes

also have long required individuals to wear seat belts and motorcycle helmets, despite these types of laws' intrusions on liberty interests—such as not being pricked with a needle or traveling in one's personal vehicle unencumbered by straps and buckles.[8] Although not without controversy, many states and localities prohibit smoking in public places.[9] Such laws have been repeatedly justified and upheld in the interest of public health.[10]

But would most people, or most courts, as readily agree that individuals should be prohibited from ingesting certain substances into their bodies, selling substances to desirous consumers, restricted in handgun ownership, or required to buy health insurance in the interest of public health? Recent cases and policy debates raise those challenging questions. The United States Court of Appeals for the District of Columbia recently declined to recognize an individual right to take experimental

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making the vaccination of children a condition of their right to enter or remain in public schools.") (citing cases); Zucht v. King, 260 U.S. 174 (1922) (excluding from the public schools or other places of education children or other persons not having a certificate of vaccination); PUBLIC HEALTH LAW AND ETHICS: A READER 379 & 380 tbl.6 (Lawrence O. Gostin ed., 2002) (noting that "[a]ll states, as a condition of school entry, require proof of vaccination against a number of diseases on the immunization schedule" and cataloguing state laws); Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, *in* LAW IN PUBLIC HEALTH PRACTICE 262, 269–70 (Richard A. Goodman et al. eds., 2003) (tracing history of laws and noting that as of 1981, all fifty states had school vaccination laws, with all but four states requiring vaccination for all primary and secondary grades by 1999).

8. *See, e.g.*, Linda Geller Dubinsky, *The Minnesota Mandatory Seat Belt Law: No Right to Be Reckless?*, 10 HAMLINE L. REV. 229, 229 (1987); Anthony P. Polito, *Constitutional Law: Seatbelt Laws and the Right to Privacy*, 10 HARV. J.L. & PUB. POL'Y 752, 757 (1987) (describing debate between right to be free from government intrusion and government interest in preventing injuries); Kenneth M. Royalty, *Motorcycle Helmets and the Constitutionality of Self-Protective Legislation*, 30 OHIO ST. L.J. 355 (1969); Jeffery L. Thomas, *Freedom to Be Foolish? L.B. 496: The Mandatory Seatbelt Law*, 19 CREIGHTON L. REV. 743, 743 (1986).

9. *See, e.g.*, Jean C. O'Connor et al., *Preemption of Local Smoke-Free Air Ordinances: The Implications of Judicial Opinions for Meeting National Health Objectives*, 36 J.L. MED. & ETHICS 403, 403 (2008) (noting ongoing challenges to tobacco-related public health concerns, but, as of 2007, all but sixteen states adopted some form of law regulating indoor smoking); *see generally* James R. Davis & Ross C. Brownson, *A Policy for Clean Indoor Air in Missouri: History and Lessons Learned*, 13 ST. LOUIS U. PUB. L. REV. 749 (1994) (describing clean indoor air debate); Action on Smoking and Health, State Smokefree Air Laws At-A-Glance, http://www.ash.org/smokingbans.html (last visited May 9, 2009) (listing states and types of bans). *But cf. German Court Rejects Smoking Bans*, BBC NEWS, July 30, 2008, *available at* http://news.bbc.co.uk/2/hi/europe/7533132.stm (responding to challenge by bar owners).

10. *See, e.g.*, ARK. CODE ANN. § 27-37-702(a) (2008) (mandatory seat belt law); D.C. CODE § 50-1802(a) (2001) (same); HAW. REV. STAT. § 291-11.6(a)(1) (2006) (same); N.C. GEN. STAT. § 20-135.2A(a) (2007) (same); OKLA. STAT. tit. 47, § 12-417A (2007) (same); S.C. CODE ANN. § 56-5-6520 (2006) (same); *Jacobson*, 197 U.S. at 27 ("[A] community has the right to protect itself against an epidemic of disease which threatens the safety of its members."); Picou v. Gillum, 874 F.2d 1519 (11th Cir. 1989) (upholding Florida's motorcycle helmet law); Benning v. State, 641 A.2d 757 (Vt. 1994) (noting that most states rejected challenges to helmet laws, listing cases).

drugs.[11] One state and several localities have prohibited restaurants from selling certain foods believed to cause obesity.[12] Last term, four United States Supreme Court Justices and several commentators argued in support of handgun restrictions, partially on public health grounds.[13] In addition, state policy makers and U.S. presidential candidates propose to address the problem of health insurance coverage by requiring individuals to purchase health insurance.[14] Those examples suggest the emergence, or

11. *See* Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007).

12. *See* Charisse Jones & Nanci Hellmich, *NYC Bans Trans Fats in Restaurants; Landmark Rules Take Effect July 1*, USA TODAY, Dec. 6, 2006, at 1A; *For Your Own Good*, N.Y. TIMES, Aug. 3, 2008, at WK2 (noting California's new law, among others); Jennifer Steinhauer, *California Bars Restaurant Use of Trans Fats*, N.Y. TIMES, July 26, 2008, at A1. N.Y. City Dep't of Health & Mental Hygiene, Cardiovascular Disease Prevention: Healthy Heart—Avoid Trans Fat, http://www.nyc.gov/html/doh/html/cardio/cardio-transfat.shtml (last visited May 9, 2009) (announcing final trans fat regulation and providing links to Health Code amendments).

13. *See* District of Columbia v. Heller, 128 S. Ct. 2783, 2854–61 (2008) (Breyer, J., dissenting) (noting that, "[n]o one doubts the constitutional importance of the statute's basic objective, saving lives," and evaluating evidence from public health authorities, pediatricians, and other experts on violence prevention); Brief for the American Public Health Association et al. as Amici Curiae Supporting Petitioners at 3, 21, *Heller*, 128 S. Ct. 2783 (No. 07-290) ("Firearms have a profound effect on the public's health in the United States. . . . In this context, the District of Columbia's decision to focus its firearms regulations on handguns makes public health sense."); Brief of the American Academy of Pediatrics et al. as Amici Curiae Supporting Petitioners at 4, *Heller*, 128 S. Ct. 2783 (No. 07-290) ("Handgun-related injuries and fatalities to children are significant public health problems in terms of both impact on children's physical and mental health, and impact on the cost to the public health system."); Jeffery M. Drazen et al., *Guns and Health*, NEW ENG. J. MED. 517, 517–18 (2008) (citing medical literature demonstrating that closer regulation of guns promotes public health by reducing suicide and homicide, and describing *Heller*: "The Supreme Court has launched the country on a risky epidemiologic experiment."); *see also* Mark Tushnet, *Interpreting the Right to Bear Arms: Gun Regulation and Constitutional Law*, 10 NEW ENG. J. MED. 1424, 1425 (2008) (suggesting that case is "too close to call" but that the "gun-control side has a slightly better argument").

14. *See, e.g.*, Massachusetts Health Care Reform Act of 2006, MASS. GEN. LAWS ch. 111M, § 2(a) (2006) (requirement that all residents over age 18 maintain a minimum level of health insurance); Sonya Geis & Christopher Lee, *Schwarzenegger Proposes Universal Health Coverage*, WASH. POST, Jan. 9, 2007, at A3 (describing proposed California reforms, including individual health insurance mandate). Barack Obama's "Plan for a Healthy America" provides that "Obama will require that all children have health care coverage." BARACK OBAMA'S PLAN FOR A HEALTHY AMERICA, *available at* http://www.barackobama.com/pdf/HealthPlanFull.pdf (last visited May 9, 2009); *see also* Walter Shapiro, *The Quest for Universal Healthcare*, SALON.COM, Feb. 21, 2008, http://www.salon.com/news/feature/2008/02/21/healthcare/index.html (Hillary Clinton's plan required individuals "to get and keep insurance in a system where insurance is affordable and accessible"); Michael Luo, *On Health Care, Affordability and Comprehensiveness*, N.Y. TIMES ONLINE, Feb. 22, 2008, http://www.nytimes.com/ 2008/02/22/us/politics/22check.html (quoting Sen. Obama: "Senator Clinton believes the only way to achieve universal health care is to force everybody to purchase it"); Kevin Sack, *Comparing the Democratic Candidates' Health Care Plans*, INT'L HERALD TRIB., Feb. 22, 2008, *available at* http://www.nytimes.com/2008/02/22/world/americas/22iht-23health.10317717.html?_r=1 (describing Clinton's view that the only way to achieve universal health coverage is to require everyone to have it); Editorial, *Health Care; No Miracle Cures*, PHILADELPHIA INQUIRER, Aug. 3, 2008, at C4 ("[Obama's] plan could flop because it lacks a mandate that the uninsured actually purchase those newly affordable health plans."). *But cf.* Richard E. Ralston, *Mandatory Health*

reemergence, of a "public health right" that trumps otherwise strongly protected individual liberty, autonomy, privacy, and property rights.

This Article offers a contemporary view on the "public health right" and its relevance in recent policy debates. The public health right defended herein is conspicuously distinct from the "right to health," meaning an affirmative individual right to health or health care.[15] Neither does the public health right derive from the so-called new public health, which extends government intervention into a wide range of private choices and concerns.[16] Rather, the public health right is grounded in the core mission of public health to reduce "public bads" and protect "public goods."[17] The concept is also distinct from notions of the commonweal or common good,

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Insurance: Health Care By Force, CAPITALISM MAGAZINE, July 30, 2006, http://www.capmag.com/article.asp?ID=4753; Glen Whitman, *Hazards of the Individual Health Care Mandate*, CATO POLICY REPORT, Sept./Oct. 2007, at 1, *available at* http://www.cato.org/pubs/policy_report/v29n5/cpr29n5.pdf (criticizing individual mandate).

15. The concept of an affirmative right to health, health care, or a healthy environment is often tied to international human rights aspirational standards. *See* Eleanor D. Kinney, *Recognition of the International Human Right to Health and Health Care in the United States*, 60 RUTGERS L. REV. 335, 353–56, 363–64 (2008) (discussing "right to health" under Universal Declaration of Human Rights and other international declarations, as well as U.S. Constitution and state laws); Benjamin Mason Meier & Larisa M. Mori, *The Highest Attainable Standard: Advancing a Collective Human Right to Public Health*, 37 COLUM. HUM. RTS. L. REV. 101, 112–15, 121–24 (2005) (distinguishing "health" and "public health" rights); Jennifer Prah Ruger, *Governing Health*, 121 HARV. L. REV. F. 43, 43–44 (2008) (supporting "right to health and health care" as "ethical demand," realized through "public moral norms" in context of *Abigail Alliance* decision); George P. Smith, II, *Human Rights and Bioethics: Formulating a Universal Right to Health, Health Care, or Health Protection?*, 38 VAND. J. TRANSNAT'L L. 1295, 1313–17, 1319 (2005) (defining "right to health, health care, or health protection" in the global context); *see also* Mark Earnest & Dayna Bowen Matthew, *A Property Right to Medical Care*, 29 J. LEGAL MED. 65 (2008); Alan Jenkins & Sabrineh Ardalan, *Positive Health: The Human Right to Health Care Under the New York State Constitution*, 35 FORDHAM URB. L.J. 479 (2008).

16. *See* Epstein, *supra* note 6, at 1423 (distinguishing "old" and "new" public health and listing examples of inspection, quarantine, and vaccination for the former, and tort reform, access to health care, and relieving wealth disparity for the latter); *see, e.g.*, THEODORE H. TULCHINKSKY & ELENA A. VARAVIKOVA, THE NEW PUBLIC HEALTH 107–09 (2000) (citing World Health Organization definition of the "New Public Health (NPH)" as "[A] philosophy which endeavors to broaden the older understanding of public health so that, for example, it includes the health of the individual in addition to the health of populations, and seeks to address such contemporary health issues as are concerned with equitable access to health services, the environment, political governance and social and economic development."); Lawrence O. Gostin & M. Gregg Bloche, *The Politics of Public Health: A Response to Epstein*, 46 PERSP. BIOLOGY & MED. S160, S162, S172 (2003) (responding to Epstein's and other conservatives' attacks on public health but agreeing that "there is a 'new' public health, broader in its reach than . . . control of infectious disease"); Meier & Mori, *supra* note 15, at 119 ("[M]odern public health programs can be framed expansively as part of a social justice movement . . . ."); *id.* at 129 ("[T]he new public health considers that both disease and society are so interconnected that both must be considered dynamic.") (quoting Jonathan M. Mann).

17. *See* MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS (1971); R. H. Coase, *The Lighthouse in Economics*, 17 J.L. & ECON. 357 (1974) (defining public goods as non-exclusive, non-excludable goods, such as a lighthouse beacon).

whereby protecting the rights of many may justify intruding on the rights of one or a few.[18] The simple utilitarian calculus of saving several by killing one fails to provide a satisfying justification for the public health right.[19] Rather, this Article urges that the public, as a body (the "body politic") has a right to government protection and promotion.[20] The discussion begins by framing public health and individual rights in historical context, focusing on the traditional core functions of public health, such as sanitation and vaccination.

To develop the modern public health right in context, this Article examines the asserted right to experimental treatment. At least one court[21] and numerous commentators staunchly defended the fundamental, constitutional right of terminally ill patients to access experimental drugs that have not yet received regulatory approval as a right of medical self-defense,[22] right to make treatment decisions,[23] or right to life.[24] The last judicial word on that question concluded that no such fundamental right exists. This Article supports the court's final decision but offers the public health right as a stronger, ultimately more satisfying, rationale for the conclusion. This Article concludes with a general defense of a public health right and considers its application into other contemporary contexts.

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18. *See* Philip Cole, *The Moral Bases for Public Health Interventions*, 6 EPIDEMIOLOGY 78, 81 (1995) (discussing "commonweal" rationale for public health, which "lies in the reality that the protection of the rights of a larger number of people sometimes requires the abrogation of the rights of a smaller number").

19. *See, e.g.*, R v. Dudley and Stephens, (1884) 14 Q.B.D. 273 (holding defendants liable for murdering one cast-away, rejecting claim that it was necessary to save three others).

20. *See* Dan E. Beauchamp, *Community: The Neglected Tradition of Public Health*, 15 HASTINGS CENTER REP. 28, 29 (1985) ("[T]he 'body politic' or the 'commonwealth' as it was termed in the early days of the American Republic [referred to the public's] interest, held in common, in self-protection or preservation from threats of all kinds to their welfare."); *see also* Nancy M. Baum et al., *Looking Ahead: Addressing Ethical Challenges in Public Health Practice*, J.L. MED. & ETHICS 657, 658–59 (2007) (distinguishing "public health from individually oriented health care" and urging that "inadequacy of an autonomy-focused approach . . . suggest[s] that public health ethics is a field of inquiry in its own right"); Epstein, *supra* note 6, at 1427 (quoting the Latin maxim, "[t]he well being of the public is the supreme law," as having "powerful roots even in the American political tradition").

21. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006).

22. Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007).

23. B. Jessie Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 313–14 (2008).

24. Randy E. Barnett, *In Re: Life or Death*, WALL ST. J., Dec. 9, 2006, at A9 (discussing pending en banc review and asserting: "At stake is the right to life."); Steven Walker, *A Different "Right to Life,"* WALL ST. J., Jan. 11, 2008, at A10 (cofounder of the Abigail Alliance for Better Access to Developmental Drugs on pending petition for certiorari).

II. BACKGROUND

Before defining the modern public health right, it is helpful first to understand the tradition of public health and justifications for government action that may impair individual rights. This Part begins with an exposition on the "old" public health, and then describes various ethical justifications for government intrusions on individual rights. This background frames the discussion that follows.[25]

A. Public Health Objectives

The Institute of Medicine articulated a classic conception of public health: "Public health is what we, as a society, do collectively to assure the conditions for people to be healthy."[26] As that definition suggests, public health goals typically cannot be achieved through individual action, but require collective, coordinated interventions.[27] Often, that "we," the organizer of public health efforts, is the government.[28] In addition, the benefits accrue to the people—the community, the body politic, the public. "The government's concern . . . is not . . . for *this* or *that* individual but . . . for all individuals[,] . . . the welfare of the community."[29] Collective action and public benefit are hallmarks of public health interventions.

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25. *See infra* Part IV (making case for "public health right").

26. COMM. FOR THE STUDY OF THE FUTURE OF PUBLIC HEALTH, INSTITUTE OF MEDICINE, THE FUTURE OF PUBLIC HEALTH 19 (1988); *see also* PUBLIC HEALTH LAW AND ETHICS: A READER, *supra* note 7, at 2 (quoting same); PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 180 (1982) ("[P]ublic health [is] 'the science and art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community efforts . . . and the development of the social machinery which will ensure to every individual in the community a standard of living adequate for the maintenance of health.'") (quoting Yale professor of public health in 1920).

27. *See* MICHAEL WALZER, *Security and Welfare*, *in* SPHERES OF JUSTICE: A DEFENSE OF PLURALISM AND EQUALITY (1983), *reprinted in* PUBLIC HEALTH LAW AND ETHICS: A READER, *supra* note 7, at 69, 75 ("Dealing with tuberculosis, cancer, or heart failure, however, requires a common effort. Medical research is expensive, and the treatment of many particular diseases lies far beyond the resources of ordinary citizens. So the community must step in . . . .").

28. *Id.* (identifying "the role of the American government (or governments, for much of the activity is at the state and local levels)" in various public health interventions); *see also* Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 203 (1824) (regarding state powers to enact "[i]nspection laws, quarantine laws, health laws of every description").

29. Beauchamp, *supra* note 20, at 29 (quoting JOSEPH TUSSMAN, OBLIGATIONS AND THE BODY POLITIC 27–28 (1996)) (alteration and emphasis omitted); *see also* Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 HASTINGS CONST. L.Q. 267, 278–81 (1993) (describing role of government in public health).

For example, think of city sanitation[30]: I alone, or even with my neighbors, may decide to refrain from tossing our garbage, kitchen scraps, and human waste in the streets. That noble effort may make our immediate environment more pleasant and sanitary, but it does nothing to stop the flow of filth into our gutters, streams, and drinking water from other residents and businesses up the street and across town.[31] Despite our neighborhood efforts, we nevertheless may be exposed to unsightly, unpleasant, and disease-carrying sewage. We might try to spread the gospel of clean streets beyond our neighborhood through word of mouth, flyers, or billboards, or even try to pay others to stop dumping, if it is important enough to us. But those are logistically and monetarily difficult propositions. Even if we could identify all of the polluters, the transaction costs of negotiating with each individually would be staggering. The payment option, in particular, risks the hold-out problem of the last few people in town demanding inordinate sums to give up their individual trash-dumping rights.[32]

Moreover, even those who voluntarily agree to join our effort may lapse or otherwise decide to return to dumping their garbage in the gutters. We, as individuals or in small groups, are powerless to bring the violators back into compliance, save sanctions such as withholding any agreed payments, shaming, boycotts, or the like.[33] Even if the law assigns us the

30. Sanitation was one of the earliest public health objectives. *See* STARR, *supra* note 26, at 181 ("In mid-nineteenth-century America, public health was mainly concerned with sanitary reform and affiliated more closely with engineering than with medicine."); Elizabeth Fee, *The Origins and Development of Public Health in the United States*, *in* OXFORD TEXTBOOK OF PUBLIC HEALTH: THE SCOPE OF PUBLIC HEALTH (Roger Detels et al. eds., 3d ed. 1997), *reprinted in* PUBLIC HEALTH LAW AND ETHICS: A READER, *supra* note 7, at 27, 28 ("In the colonies, public health consisted of activities deemed necessary to protect the population from the spread of epidemic diseases, by the enactment of sanitary laws and regulations governing such matters as the construction of toilets, the disposal of wastes, and the disposition of dead animals."); Parmet, *supra* note 29, at 290 (noting that "public sanitation regulations in Massachusetts go back as far as 1634").

31. This discussion presumes that my neighbors and I do not live in isolation but as part of a community. The stated problem is city sanitation, thereby assuming a densely populated, organized environment. In isolation, a single individual could perhaps maintain optimal sanitary enjoyment without the neighborhood effects of others' conduct. *See* Lemuel Shattuck, *Introduction and Private Rights and Liberties*, *in* REPORT OF THE SANITARY COMMISSION OF MASSACHUSETTS (Harvard Univ. Press 1948) (1850), *reprinted in* PUBLIC HEALTH LAW AND ETHICS: A READER, *supra* note 7, at 25; *cf.* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 270 (7th ed. 2007) (noting that "[n]eighborliness and other forms of selflessness reduce external costs and increase external benefits," hence "externalities" are sometimes called "neighborhood effects"). The problem of *public* health applies to societies, not individuals living alone in the state of nature.

32. *See* POSNER, *supra* note 31, at 56 (noting that "people owning land in the path of the advancing line will be tempted to hold out for a very high price"); *id.* at 72–72 (describing holdouts and problems of incompatible land use).

33. *See* ROBERT C. ELLICKSON, ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES 127, 213–19 (1991) (listing gradual escalation of sanctions against social norms violators); Robert D.

initial right to be free from pollution, instead of a right to pollute, we face practical obstacles to enforcing our right. With thousands of potential polluter-defendants, whom should we sue and for how much? Could we convincingly prove who caused what harm to whom and that it was not an act of God? Can we track down the polluters and, once we do, will they have the means to compensate our harm?[34]

Thus, the goal of clean, sanitary streets necessitates collective action, along with a central enforcement mechanism (i.e., government). Similar analysis could apply to any number of other societal objectives, such as preventing spread of contagious diseases, protecting clean air and water, promoting temperance and reducing violence, ending child labor and ensuring workplace safety, and defending against terrorist attack.[35] Individually, one person cannot achieve those broad aims, even if she gets vaccinated, stops drinking, refuses to hire minors, limits use of her car, and builds a bomb shelter in her backyard. But government, by implementing and enforcing laws, can bring about collective action and societal benefit.[36]

At the same time, public health cannot achieve those goals "without, sooner or later, violating private beliefs or private property or the prerogatives of other institutions," including religious groups, business interests, medical professionals, and others.[37] Having clean streets means

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Cooter, *Decentralized Law for a Complex Economy: The Structural Approach to Adjudicating the New Law Merchant*, 144 U. PA. L. REV. 1643, 1668–69 (1996) (describing informal sanctions); Dan M. Kahan, *What Do Alternative Sanctions Mean?*, 63 U. CHI. L. REV. 591, 631–49 (1996) (listing and discussing various shaming penalties); Richard A. Posner & Eric B. Rasmusen, *Creating and Enforcing Norms, with Special Reference to Sanctions*, 19 INT'L REV. L. & ECON. 369, 370–72 (1999).

34. *See* Epstein, *supra* note 6, at 1443–45 (arguing similarly regarding control of communicable disease, that "massive breakdown in both the theory and practice of private rights makes public remedies instantly attractive"); Richard A. Epstein, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL'Y L. & ETHICS 741, 749 (2005) ("Private injunctions . . . falter when pollution from multiple sources damages many separate individuals. At this point the sensible approach has the state intervene as the agent for the aggrieved parties.").

35. *See* Baum et al., *supra* note 20, at 658–59 ("Communally shared health goals, such as herd immunity gained through mass vaccination, clean water, or protection from bioterrorist threats, are more than simply the aggregation of individual health goals: they are goods held in common."); Beauchamp, *supra* note 20, at 32 (articulating public health justification for temperance movement, beyond paternalistic protection of drinkers themselves, based on concerns that saloons "were often dirty and rowdy drinking halls that exploited the working class and the poor"); *id.* at 35 (suggesting public health justification for regulating steel, coal, alcohol, and cigarette industries).

36. *See* Parmet, *supra* note 29, at 335 (discussing U.S. constitutional law as illuminating "the very reasons for having governments and law: to care for and protect each other, as best we can"); James A. Tobey, *Public Health and the Police Power*, 4 N.Y.U. L. REV. 126, 126 (1927) (suggesting that government is "organized for the express purpose, among others, of conserving the public health").

37. STARR, *supra* note 26, at 180–81 (listing business, religious, and other sources of opposition to public health efforts); *see* Jacobson v. Massachusetts, 197 U.S. 11, 29 (1905) ("[I]n every well-

that I cannot dump my trash wherever I wish.[38] Clean air may require minimizing vehicle and industrial emissions by altering driving habits or installing emission-control devices. Avoiding contagious disease may mean having inoculations that are painful and risky. Safe workplace standards like minimum age and wage and maximum hours laws cost businesses money. The government, through courts, regulators, prosecutors, and lawmakers, serves as referee of these conflicts among members of society. In public health, the conflict is often not simply one individual versus another, but individual interests versus the public or common good.[39]

B. Public Health and Individual Rights

Individual rights seem inherently at odds with the collective, population-based perspective central to public health. "Health care" focuses on individual wellness or freedom from pathology, while "public health" is concerned with promoting optimal health of the population as a whole.[40] Public health seeks not merely the aggregation of individual

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ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand."); Beauchamp, *supra* note 20, at 30 ("It is the private sphere that is problematic for public health. Public health sometimes intrudes into this private sphere in the interest of the health and safety of the community.").

38. *See* Shattuck, *supra* note 31, at 25 ("It may be said, 'Sanitary measures will interfere with private matters. If a child is born, if a marriage takes place, or if a person dies . . . what business is it to the public? . . . . "Men who object and reason in this manner have very inadequate conceptions of the obligations they owe to themselves or to others.") (alteration omitted).

39. *See, e.g.*, Beauchamp, *supra* note 20, at 29 ("Public health and safety are community or group interests . . . that can transcend and take priority over private interests if the legislature so chooses.").

40. *See* Scott Burris, *The Invisibility of Public Health: Population-Level Measures in a Politics of Market Individualism*, 87 AM. J. PUB. HEALTH 1607, 1608 (1997) (defining "health" as a "personal, medical matter, a state of freedom from pathology achieved by an individual through the mediation of a doctor" and characterizing "[p]ublic health, by contrast . . . as an attribute of communities in social and physical environments"); Andrew W. Siegel, *The Jurisprudence of Public Health: Reflections on Lawrence O. Gostin's* Public Health Law, 18 J. CONTEMP. HEALTH L. & POL'Y 359, 361–62 (2001) (quoting LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 15 (2000) ("Public health law is concerned with the state's role in advancing the health of the community, whereas health care law is concerned with the 'microrelationships between health care providers and patients.'").

satisfaction but, rather, the common good.[41] Accordingly, individual rights are constantly in tension with communitarian interests.[42]

For example, Garrett Hardin's classic essay *The Tragedy of the Commons* describes the challenges of respecting individual interests while promoting social good.[43] In a ranch community with a common pasture, the interest of each cattle owner individually is to add cattle to the commons to increase his or her individual productivity. As the commons become more crowded, the yield of each animal decreases, requiring ranchers to add more cattle to produce the same level of individual benefit, and so the cycle continues. Eventually the commons is depleted and can be protected only through external controls, by restricting individual rights in favor of the collective good.[44]

This tension underlies many public health interventions. For example, an individual may prefer not to be vaccinated based on religious, philosophical, or personal objections, even if utterly irrational, or to avoid medical risks, even if infinitesimally small, associated with the vaccine.[45] Rights of individual autonomy, dignity, and bodily integrity would seem to allow an individual to refuse vaccination for even foolish reasons or slight probabilities. But one individual's decision, and all who follow his lead, depletes the "commons" of a disease-free society by increasing the number of unprotected people in the population.[46] The recent trend of parents opting out of mandatory vaccination for their children—sometimes for health or religious grounds, sometimes just for convenience—

41. Lawrence O. Gostin, *Health of the People: The Highest Law?*, 32 J.L. MED. & ETHICS 509, 510 (2004) ("The field of public health would profit from a vibrant conception of 'the common' that sees public interests as more than the aggregation of individual interests."); Baum et al., *supra* note 20, at 657 (noting "public health's emphasis on population health rather than issues of individual health").

42. *But see* Wendy E. Parmet, *Public Health and Constitutional Law: Recognizing the Relationship* 10 J. HEALTH CARE L. & POL'Y 13, 24 (2007) ("[T]he lessons for constitutional law are not necessarily that individual rights need to be overridden in the name of public health, or that individuals stand in opposition to public health, but that respect for individual rights may, at least at times, be a necessary prerequisite for improving public health . . . ."); Epstein, *supra* note 6, at 1422 (noting popular attitude that public health requires compromising individual rights).

43. Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243, 1244 (1968); *see also* Malone & Hinman, *supra* note 7, at 262–63 (describing Hardin's essay); *cf.* Carol M. Rose, *Rethinking Environmental Controls: Management Strategies for Common Resources*, 1991 DUKE L.J. 1, 2–5 (describing the environment as a commons problem).

44. Hardin, *supra* note 43, at 1245; *see also* Malone & Hinman, *supra* note 7, at 263.

45. *See* Jacobson v. Massachusetts, 197 U.S. 11, 39 (1905) (affirming prosecution for refusing vaccination, with no evidence of health contraindication or other justification); Malone & Hinman, *supra* note 7, at 273–74 (describing exemptions, including health risks, recognized in all states, and religious and philosophical objections, recognized in many states).

46. *See* Malone & Hinman, *supra* note 7, at 263 ("As more and more individuals choose to do what is in their 'best' individual interest, the common eventually fails as herd immunity disappears and disease outbreaks occur.").

demonstrates the accuracy of the "tragedy of the commons" model. Infection rates of diseases like polio, measles, mumps, and whopping cough that were virtually eradicated have reappeared in some communities.[47]

The "commons" rationale for mandatory vaccination depends on the scientific understanding that no vaccine is one hundred percent effective and that diseases, even if eradicated, can later mutate and reemerge.[48] For example, tuberculosis, nearly eradicated a generation ago, recently reemerged with new, more resistant strains.[49] Therefore, even those who become vaccinated remain at risk. If the science were otherwise—that is, if vaccination provided one hundred percent protection—then we might leave the matter to individual choice.[50] My neighbors and I might decide that good chances of avoiding the disease by being vaccinated far outweigh the small risk of harm from the vaccine itself. Other, risk-preferring members of society might opt to avoid vaccination and risk getting the disease. As long as the risk-preferrers endanger only themselves, there does not seem to be a public interest in requiring vaccination. Similarly, if I choose to wear sunscreen to reduce the risk of skin cancer, the fact that others prefer not to wear sunscreen in no way increases my risk of sunburn and cancer. Likewise, my neighbor's junk-food diet does not increase my risk of heart disease. Skin cancer and obesity, however, are not analogous to infectious disease. The risk of contracting infectious disease cannot be controlled by individual choice. It

47. *See* Donald G. McNeil, Jr., *When Parents Say No to Child Vaccinations*, N.Y. TIMES, Nov. 30, 2002, at A1; Saad B. Omer et al., *Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence*, 296 JAMA 1757, 1757 (2006); Jennifer Steinhauer, *Rising Public Health Risk Seen as More Parents Reject Vaccines*, N.Y. TIMES, Mar. 21, 2008, at A1.

48. *See Jacobson*, 197 U.S. at 32 n.1 (discussing history and effectiveness of smallpox vaccination, noting rates of infection considerably lower in vaccinated population); Malone & Hinman, *supra* note 7, at 263; *see also* Ben Kleifgen, Vaccination Requirements and Exemptions, Univ. of Penn. Center for Bioethics, http://www.vaccineethics.org/issue_briefs/requirements.php (last visited May 9, 2009).

49. *See* Thomas R. Frieden et al., *The Emergence of Drug-Resistant Tuberculosis in New York City*, 328 NEW ENG. J. MED. 521, 521 (1993); John D.H. Porter & Keith P.W.J. McAdam, *The Re-Emergence of Tuberculosis*, 15 ANN. REV. PUB. HEALTH 303 (1994); John M. Watson, *Tuberculosis in Britain Today: Notifications Are No Longer Falling*, 306 BRIT. MED. J. 221 (1993).

50. *See* Cole, *supra* note 18, at 81 ("It is difficult to find a moral basis for compelling adults to be immunized [if] the only person to endure the consequences of denying himself an immunization is the individual himself."); Epstein, *supra* note 6, at 1453–54 (suggesting that if "individuals could obtain *absolute* immunity from smallpox by taking the vaccine themselves," government action would not be justified, but acknowledging *Jacobson* Court's conclusion that smallpox vaccine "was less than perfect").

is a nonexcludable, nonexclusive "public bad" that cannot be spread upon some without being spread on all.[51]

Public health is grounded in the social contract whereby individuals leave the state of nature in order to join society.[52] Joining society means giving up certain individual rights in the interest of the greater good. In exchange for giving up those rights, individuals gain protection of social order and laws, considered superior to the state of nature.[53] For example, the law of battery protects the individual right to be free from offensive or nonconsensual touching, even if the touching might benefit the individual herself or society at large.[54] There are, however, limits on liberty or bodily integrity rights.[55] The seminal case of *Jacobson v. Massachusetts* held that the state's interest in providing sanitation and other public health measures operates as a limit on individual rights consistent with the social contract.[56]

Under the social contract, potential polluters may decide that the benefits gained from joining society outweigh the freedom to toss their trash where they like. At the same time, my neighbors and I, who have also given up other liberties to enter society, may have an easier time achieving a pollution-free environment because laws protect our interests and ability to obtain enforceable contracts and judgments. Whether the initial "right" is assigned to the clean-street proponents or the polluters, we can either sue to enforce our right or contract to reassign it.[57] Laws provide

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51. *See* Epstein, *supra* note 6, at 1426 (listing communicable disease and pollution as "public bads" and distinguishing "obesity and genetic disease").

52. JOHN LOCKE, THE SECOND TREATISE OF GOVERNMENT 8–9 (J.W. Gough ed., Basil Blackwell 3d ed. reprint 1976) (1690); THOMAS HOBBES, MAN AND CITIZEN 112 (Bernard Gert ed., Charles T. Wood et al. trans., Hackett Publishing Co. 1991) (1651); Parmet, *supra* note 29, at 308–11 (discussing social contract theory's relevance to Constitution's framing and public health).

53. LOCKE, *supra* note 52, at 8–10; HOBBES, *supra* note 52, at 112.

54. *See* O'Brien v. Cunard S.S. Co., 28 N.E. 266, 266 (Mass. 1891) (recognizing potential battery for vaccination but holding that plaintiff objectively manifested consent by holding out arm to doctor).

55. *See* Malone & Hinman, *supra* note 7, at 271–73 (discussing *Jacobson* and the constitutional basis for mandatory vaccination laws); Parmet, *supra* note 42, at 23 (citing Jacobson v. Massachusetts, 197 U.S. 11, 26, 39 (1905)).

56. *Jacobson*, 197 U.S. 11. As the Court noted:

> The possession and enjoyment of all rights are subject to such reasonable conditions as may be deemed by the governing authority of the country essential to the safety, health, peace, good order and morals of the community. Even liberty itself, the greatest of all rights, is not unrestricted license to act according to one's own will.

Id. at 26–27 (quoting Crowley v. Christensen, 137 U.S. 86, 89 (1890)). The Court also recognized "the social compact" in the Massachusetts Constitution. *Id.* at 27.

57. *See* R. H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1 (1960) (postulating that despite initial assignment of legal rights, parties will freely bargain for the most productive use, based on relative values assigned to competing uses); *see also* POSNER, *supra* note 31, at 7, 50–53 (defining Coase Theorem).

security and protection from wanton polluters and reinforce our loyalty to the society we have joined.

Public health interventions, especially safety regulations such as helmet and seat belt laws, seem starkly at odds with individual interests.[58] One justification for those laws is paternalism: protecting people from their own bad judgment and requiring them to protect themselves, despite their free will to disregard their own safety.[59] Safety regulations also purport to benefit society in a utilitarian sense by mitigating the extent of injuries resulting from inevitable accidents.[60] The lost productivity and medical expenses associated with avoidable injuries impose costs on the rest of society.[61] This "conserving common resources" rationale for public health regulations depends on the presumption that society will provide for the injured person through government welfare programs or the private health care system.[62] Otherwise, there would be no public harm resulting from one person's choice not to wear safety devices (or sunscreen).

Other antilibertarian laws, such as criminal prohibitions on prostitution or illicit drugs, paternalistically protect individuals from engaging in unsafe conduct, express moral condemnation, and aim to reduce

58. *See* JOHN STUART MILL, *On Liberty*, *reprinted in* ON LIBERTY AND OTHER ESSAYS 14 (John Gray ed., Oxford Univ. Press 1998) ("[T]he only purpose for which power can be rightfully exercised over any member of a civilized society, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant."); Beauchamp, *supra* note 20, at 29 ("In one version of democratic theory, the state has no legitimate role in restricting personal conduct that is substantially voluntary and that has little or no direct consequence for anyone other than the individual.") (attributing to John Stuart Mill); Cole, *supra* note 18, at 80–81 ("[P]aternalism is immoral as a basis for attempting to dictate the behavior of a competent adult.").

59. *See* Stephen P. Teret & Tom Christoffel, *Injury Prevention and the Law*, *reprinted in* LAW IN PUBLIC HEALTH PRACTICE, *supra* note 7, at 403 (noting "bitter debate over the propriety of [mandatory motorcycle helmet] laws [, which] are condemned by some as paternalistic deprivations of highly valued personal freedoms").

60. *See supra* notes 8, 10 and accompanying text (citing cases and commentary on mandatory motorcycle and seatbelt laws).

61. *See* John Leland, *The Superstar Athlete Is Paid to Take Risks, Right?*, N.Y. TIMES, June 18, 2006, at 3 (commenting on the motorcycle crash of Pittsburgh Steelers quarterback Ben Roethlisberger, riding without a helmet, and noting that "[p]olicy debates over seatbelt laws, cigarettes, gun locks, steroids, environmental safeguards, employee savings plans and storm evacuation orders" arise from the fact that "society—or a football team—has an interest in managing risk, trying to maximize individual liberty while minimizing the harm to others when one person's gamble doesn't pay off").

62. *See* Cole, *supra* note 18, at 81 ("[The] 'common resources' [rationale] . . . is gaining popularity in the USA. The reasoning behind this justification is that there is a pool of common resources (usually money) held by the government to meet claims that may be made by individuals."); Epstein, *supra* note 6, at 1463 ("[T]he major argument for extensive regulation of individual health practices comes from the government's role as the insurer of (first and) last resort . . . ."); Gostin, *supra* note 41, at 510 ("Laws designed to promote the common good may sometimes constrain individual actions (smoking in public places, riding a motorcycle without a helmet, etc.).").

"neighborhood effects."[63] But those laws, like safety regulations, restrict individual freedom to engage in certain professions or activities. Recent "new" public health measures, such as New York City's and California's restaurant bans on trans fats,[64] might be justified on paternalistic or "conserving common resources" grounds. Government may seek to protect people from becoming obese due to their own bad food choices by simply making bad foods unavailable. On different ground, government may seek to ensure that people do not become obese and incur greater health-care costs, which ultimately fall on society.[65] But those laws are difficult to square with traditional public health objectives.

III. PUBLIC HEALTH AND EXPERIMENTAL TREATMENT

Do terminally ill patients who have exhausted all other available, government-approved treatment options have a constitutional right to experimental treatment that may prolong their lives? On May 2, 2006, a divided panel of the U.S. Court of Appeals for the District of Columbia, in a startling opinion, *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, held that they do.[66] The plaintiffs, Abigail Alliance for Better Access to Developmental Drugs ("Abigail Alliance") and Washington Legal Foundation, sought to enjoin the Food and Drug Administration (FDA) from refusing to allow the sale of investigational new drugs.[67] The terminally ill plaintiffs contended that they quite literally could not wait for the drugs.[68] With no other treatment options available, the plaintiffs asserted a fundamental right to take potentially life-saving or life-prolonging drugs, even though the drugs could not be legally marketed to the public.[69] The plaintiffs framed the issue as a substantive due process to right "to decide, without FDA interference, whether to assume the risks of using potentially life-saving investigational new drugs."[70]

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63. MILTON FRIEDMAN, CAPITALISM AND FREEDOM 30–34 (1962) (offering rationale for paternalistic laws).

64. *See supra* note 12 and accompanying text (regarding New York City and California trans fats bans).

65. *See* Adam Benforado et al., *Broken Scales: Obesity and Justice in America*, 53 EMORY L.J. 1645, 1649–52 (2004) (describing "hidden costs" of obesity, including government health care program costs, private insurance premiums, lost productivity, more sick time for companies, and negative stereotypes, concluding: "In short, the Supersizing of America hurts us all.").

66. 445 F.3d 470 (D.C. Cir. 2006).

67. *Id*. at 471–72.

68. *Id*. at 474 (illustrating allegation in complaint with examples of four deaths of terminally ill patients).

69. *Id*. (describing plaintiffs' complaint).

70. *Id*. at 472; *see* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 331 (1990) (Stevens, J.,

The *Abigail Alliance* decision generated considerable interest from various constituencies. On one side, libertarian, free-market proponents supported the strong recognition of individual rights.[71] On the other side, public health and consumer safety advocates urged a more paternalistic or proregulatory stance on new drug development.[72] Meanwhile, in step with the panel decision, the FDA proposed amendments to regulations governing premarket access to experimental drugs, beyond the agency's existing "compassionate use" and "emergency use" case-by-case exceptions.[73] In addition, both sides of the aisle in Congress supported more liberal access.[74]

On rehearing, the en banc D.C. Circuit Court reversed the panel's decision. The en banc court reframed the issue not as a right to decide whether to take potentially life-saving drugs, but as "a right of access to experimental drugs that have passed limited safety trials but have not been proven safe and effective."[75] On that question, the court held that the purported right was not fundamental or "deeply rooted in this Nation's

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dissenting) (faulting the Court for allowing "the State's abstract, undifferentiated interests in the preservation of life to overwhelm the best interests of Nancy Beth Cruzan"); *see also* Hill, *supra* note 23, at 330–32 (urging Court to adopt consistent approach to balancing individual patients' rights and public health); Volokh, *supra* note 22, at 1815–16 (analogizing access to experimental drugs and payment for organs to "lethal self-defense").

71. *See, e.g.*, Brief for John E. Calfee et al. as Amici Curiae Supporting Appellants, Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007) (No. 04-5350), *available at* http://www.aei-brookings.org/admin/authorpdfs/page.php?id=1352; Volokh, *supra* note 22, at 1814–16.

72. *See, e.g.*, Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of* Abigail Alliance v. Von Eschenbach, 297 JAMA 205, 205 (2007); *see also* Beryl Lieff Benderly, *Experimental Drugs on Trial*, SCI. AM., Oct. 2007, at 93; Jerome Groopman, *The Right to a Trial; Should Dying Patients Have Access to Experimental Drugs*?, NEW YORKER, Dec. 18, 2006, at 40.

73. 21 C.F.R. §§ 312.34 ("Treatment use"), 314.36 ("Emergency use") (2008); Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147 (Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312); *see* Sheila R. Shulman & Jeffrey S. Brown, *The Food and Drug Administration's Early Access and Fast-Track Approval Initiatives: How Have They Worked?*, 50 FOOD & DRUG L.J. 503, 505 (1995); Meghan K. Talbott, *The Implications of Expanding Access to Unapproved Drugs*, 35 J.L. MED. & ETHICS 316 (2007) (critiquing the FDA's proposed changes).

74. *See, e.g.*, Access, Compassion, Care and Ethics for Seriously Ill Patients ("ACCESS") Act, S. 1956, 109th Cong. (2005); Press Release, Sam Brownback, U.S. Senate, Legislation Will Ensure Terminally-Ill Patients Get Treatment (Nov. 3, 2005) (announcing ACCESS Act), *available at* http://brownback.senate.gov/pressapp/record.cfm?id=248248; *see also* Geeta Anand, *Saying No to Penelope: Father Seeks Experimental Cancer Drug, But a Biotech Firm Says Risk Is Too High*, WALL ST. J., May 1, 2007, at A1 ("Urged on by [Penelope's] family, patient groups and politicians, including the staff of House Speaker Pelosi and [Democratic] Pennsylvania Gov. Edward Rendell, lobbied on behalf of giving the drug to the child.").

75. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 697 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

history and tradition."[76] In the wake of the reversal, congressional proposals have been renewed,[77] and the FDA's expanded guidelines are still forthcoming.[78] The *Abigail Alliance* plaintiffs sought U.S. Supreme Court review, which the Court denied summarily.[79]

Perhaps motivated by overwhelming compassion for terminally ill patients or strong adherence to protection of individual rights, proponents of expanding access to experimental drugs fail to consider the public health right. In particular, allowing patients to try unproven treatments outside of controlled clinical trials risks both the validity of the scientific study and the health of other patients who might benefit from the deliberate, careful process of new drug approval.[80] In a remarkable decision, the D.C. Circuit panel identified a new fundamental constitutional right.[81] The en banc court framed the asserted right differently and, accordingly, reached the opposite conclusion, restoring the state of the law to the place that most of us thought it did (and should) occupy.[82] Now that the U.S. Supreme Court has declined the case, the en banc decision is the last judicial word on the matter.[83] Unfortunately, the opinion fails to provide a satisfying rationale for its holding. The concept

76. *Id.* at 697 (citing Washington v. Glucksberg, 521 U.S. 702, 720–21 (1997)).

77. ACCESS Act, H.R. 6270, 110th Cong. (2008) (introduced June 12, 2008, by Rep. Diane Watson); ACCESS Act, S. 3046, 110th Cong. (2008); Press Release, Sam Brownback, U.S. Senate, Brownback Introduces Access, Compassion, Love, and Ethics for Seriously Ill Patients Act (May 21, 2008) (reintroducing ACCESS Act), http://brownback.senate.gov/pressapp/record.cfm?id=298216.

78. Expanded Access to Investigated Drugs for Treatment Use, 71 Fed. Reg. 75,147, 75,156 (Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312).

79. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 128 S. Ct. 1069 (2008) (mem.); *see also* David G. Savage, *Justices Uphold Ban on Test Drugs for the Dying*, L.A. TIMES, Jan. 15, 2008; *Court Declines Experimental Drugs Case*, HOUSTON CHRON., Jan. 14, 2008; Walker, *supra* note 24 (Abigail Alliance cofounder commenting on petition for certiorari).

80. *See generally* Jennifer Kulynych, *Will FDA Relinquish the "Gold Standard" for New Drug Approval? Redefining "Substantial Evidence" in the FDA Modernization Act of 1997*, 54 FOOD & DRUG L.J. 127, 129–30 (1999) (defining the FDA's "gold standard"); Benderly, *supra* note 72, at 93–99 (suggesting that current FDA new drug approval process may take over eight years but is the "gold standard"); Colin B. Begg et al., *Marketing Drugs Too Early in Testing*, 312 SCI. 195 (2006) (letter to the editor opposing ACCESS Act); Society for Clinical Trials Board of Directors, *The Society for Clinical Trials Opposes US Legislation to Permit Marketing of Unproven Medical Therapies for Seriously Ill Patients*, 3 CLINICAL TRIALS 154, 155–56 (2006) [hereinafter Society for Clinical Trials], *available at* http://www.sctweb.org/positionpapers/S.1956-clinical-trials.pdf (opposing ACCESS Act based on need for rigorous scientific testing for drug approval).

81. Benderly, *supra* note 72, at 93 (describing the potential of *Abigail Alliance* to be "one of the most important court decisions ever to affect medical science"); Hill, *supra* note 23, at 314 (panel decision "surprised many commentators"); Jacobson & Parmet, *supra* note 72, at 205 (describing case as "troubling" and having potential to "reshape the regulation and sale of pharmaceuticals").

82. *See supra* notes 1–5 and accompanying text (regarding long-standing personal autonomy right).

83. *Abigail Alliance*, 128 S. Ct. at 1069.

of a public health right offers an alternative rubric for resolving difficult public policy questions.

A. The Players

The issue of access to experimental drugs has drawn attention from a range of constituents with conflicting interests, in some cases, even among members of the same group. Terminally ill patients, pharmaceutical companies, government regulators, physicians, and the public all have reasons to care about the potentially dramatic change in pharmaceutical product testing and marketing.

1. Patients

First (and foremost, according to the *Abigail Alliance* plaintiffs), terminally ill patients express a compelling interest in controlling their own bodies and ingesting potentially dangerous, or possibly useless and costly, substances. Their arguments and interests relating to experimental drugs are fully discussed in the opinions, briefs, and supporting materials in the case.[84] A threshold question is: if we truly value bodily autonomy and patient self-determination, why limit the inquiry to terminally ill patients? Why not recognize any person's interest in ingesting potentially palliative, curative, or harmful drugs, free from government interference? On autonomy grounds alone, there does not appear to be a basis for the distinction.

2. Pharmaceutical Companies

Next are companies that manufacture and sell pharmaceutical products. Their interests may be aligned with patients' if their goals are to generate profits by increasing sales of their products. But manufacturers' interests may be opposed to patients', in terms of avoiding liability for marketing unsafe or unproven products. At first blush, broader availability of investigational drugs would seem a boon for drug companies. If they can market these inchoate products to terminally ill patients before incurring the cost of conducting clinical trials, why not? But there are countervailing concerns. Early access to drugs, outside of controlled trials, could undermine pharmaceutical companies' ultimate goal of full FDA approval, if unexplainable adverse reactions to the drug occur and are considered

84. *See discussion infra* Part III.B (regarding the *Abigail Alliance* opinions).

like trial results.[85] Moreover, scientific validity of trials could be compromised if patients are unwilling to enroll because they can obtain the drugs though the free market.[86] Also, investigational drugs are costly, and smaller companies may lack capacity to meet the expanded demand for their products.[87]

Public relations considerations cut both ways for pharmaceutical companies. Denying access gives the impression that such companies are greedy, motivated by fear of liability and loss of market share, and lacking in compassion for dying patients. Allowing access appears opportunistic, akin to "snake oil" vendors offering the vain hope of a cure to dying patients.[88] Indeed, no interested parties ever claimed a right to free drugs. The legislative and administrative proposals contain express provisions on payment.[89] But opening a pay window to investigational drugs could create an ethically questionable and harmful two-tiered market.[90]

Liability exposure is also a double-edged sword: Manufacturers face product liability suits for marketing allegedly dangerous or defective products, as well as suits under failure to warn, negligence, and fraud theories.[91] Congressional proposals to expand access to experimental

85. Safety and other concerns may motivate pharmaceutical companies to halt clinical trials before they are completed. *See, e.g.*, Abney v. Amgen, Inc., 443 F.3d 540, 544 (6th Cir. 2006) (describing Amgen's decision to terminate all clinical trials of Parkinson's drug "GDNF" based on two scientific concerns); George J. Annas, *Faith (Healing), Hope and Charity at the FDA: The Politics of AIDS Drug Trials*, 34 VILL. L. REV. 771, 785 & n.51 (1989) (demand for experimental drugs can undermine clinical results, citing DuPont AIDS drug Ampligen as an example); Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experimental Data to Promote Patient Welfare*, 49 CATH. U. L. REV. 449 (2000).

86. *See infra* notes 126–44 and accompanying text (listing examples of distortions in drug trials).

87. *See* Charging for Investigational Drugs, 71 Fed. Reg. 75,168, 75,170 (Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312) ("[M]aking investigational drugs available for expanded access for treatment use is potentially costly, especially when many patients are involved."); Anand, *supra* note 74 (describing experience of small biotech firm Netropix, Inc., noting that "in a small company with limited financial resources and a high risk profile, you really have to reduce the risks to drug development"); Susan Okie, *Access Before Approval—A Right to Take Experimental Drugs?*, 5 NEW ENG. J. MED. 355, 440 (2006) ("One of the biggest limitations [on access to experimental drugs] is manufacturing capacity."); Talbott, *supra* note 73, at 318 (noting cost concerns).

88. *E.g.*, United States v. Rutherford, 442 U.S. 544, 558 (1979) ("Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and 'Fountain of Youth' mixtures of spices, oil, and suet."); Benforado et al., *supra* note 65, at 1787 (quoting then-FDA Commissioner Mark McClellan on the FDA's role in "rooting out modern purveyors of snake oil").

89. ACCESS Act, H.R. 6270, 110th Cong. § 3(a)(10) (2008) ("A sponsor or investigator may charge for a . . . drug without notifying the Secretary or seeking or obtaining prior approval of the amount charged."); ACCESS Act S. 3046, 110th Cong., § 3(a)(10) (2008) (same); Charging for Investigational Drugs, 71 Fed. Reg. at 75,168.

90. *See infra* notes 131–38 and accompanying text (describing harm from financial incentives).

91. *See* Talbott, *supra* note 73, at 318 (identifying sponsor liability exposure).

drugs would provide immunity from liability to pharmaceutical manufacturers,[92] denying compensation to injured patients but shielding manufacturers from some concerns with marketing untested products. But there are litigation risks with denying access, too. For example, the *Abigail Alliance* case demonstrates that companies face constitutional, contractual, and other legal challenges if they deny access to drugs.[93]

3. Government Regulators

Government regulators, namely the FDA, also have a stake in the outcome of this debate. If the government's authority to restrict access to certain products is effectively eliminated by recognition of patients' fundamental right to drugs, what remains of the FDA's legitimate role and function? As noted above, if terminally ill patients have a right to experimental drugs, it is hard to see why any patient who wants to take non-FDA-approved drugs would not have the same right.[94] Nothing suggests that the FDA's authority to regulate drugs for terminal illnesses is any different than for other conditions. Indeed, the U.S. Supreme Court explicitly recognized, in a case involving the experimental cancer drug Laetrile, just that proposition: the FDA's authority to regulate drug safety is no different with respect to dying patients as nonterminal patients.[95] Although Laetrile was available in other countries, the FDA resisted

92. *See* H.R. 6270, § 3(a)(12) (prohibiting state and federal "claims of property, personal injury, or death caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispersing, prescribing, administration, efficacy, or use of a drug, biological product, or device" subject to the Act); S. 3046, § 3(a)(12) (same).

93. *See* Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006) (finding constitutional Due Process right to access). *But see* Abney v. Amgen, Inc., 443 F.3d 540, 553 (rejecting patients' state law claims for injunction compelling pharmaceutical company to continue supplying experimental drugs).

94. *See supra* Part III.A.1; Leif N. Furmansky, *Just Say No to Drugs: The Abigail Alliance and the Attempted Abolition of The Food and Drug Administration*, 26 BIOTECHNOLOGY. L. REP. 108 (2007); Jacobson & Parmet, *supra* note 72, at 207 (noting the panel decision would subject "the FDA's regulatory authority . . . to further erosion"); Stephen R. Kovatis, *The Right to Live: Do the Terminally Ill Have a Constitutional Right to use Experimental Drugs?*, 26 TEMPLE J. SCI. TECH. & ENVT'L L. 149, 163 (2007) (noting that panel identified "history and tradition" supporting "a broad right 'to act in order to save one's own life'" but "nowhere articulated why that right should only apply to the terminally ill"); *cf.* Hill, *supra* note 23, at 278–312 (urging consistent recognition of "a constitutional right to protect one's health" and discussing *Abigail*, medical marijuana, therapeutic abortion, and other cases).

95. *See* United States v. Rutherford, 442 U.S. 544, 551 (1979) ("The Federal Food, Drug, and Cosmetic Act makes no special provision for drugs used to treat terminally ill patients."); Annas, *supra* note 85, at 789–92 (postulating that "the FDA was correct on laetrile and should continue to insist on a scientifically valid randomized clinical trial before certifying drugs as safe and effective" for both terminal and non-terminal patients).

making it available in the United States for even terminal patients, because "there were no adequate, well-controlled scientific studies of Laetrile's safety or effectiveness."[96] So far, case law and agency policy do not support a distinction between terminal and nonterminal patients with respect to government regulation of experimental drugs. Therefore, the right of dying patients to access not-yet-FDA-approved drugs potentially undermines the FDA's legitimacy and existence.

Regulatory interests come from two angles, however. Scientists and medical researchers view the FDA's new drug approval process, characterized by rigorous scientific standards and double-blind, controlled trials, as the "gold standard" of scientific method.[97] As researchers themselves suggest: "[FDA's] long history of drug testing provides overwhelming evidence that the most reliable data for assessing efficacy is that obtained from prospective randomized clinical trials that are sufficiently large to establish efficacy at levels of conclusiveness that are broadly accepted by the scientific community."[98] Regulators and the research community claim a strong interest in the scientific process, an interest distinct from the health of individual patients participating in the studies.

The current push to ease access to experimental drugs is not the first incarnation. The 1980s AIDS crisis gave rise to a similar debate and ultimately the "compassionate use" exception.[99] Then, as now, "the major source of controversy surrounding drug trials for experimental AIDS drugs is that the investigators see these trials as *research* designed to provide

96. *Rutherford*, 442 U.S. at 549.

97. *See* Annas, *supra* note 85, at 789 (quoting R. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 211 (2d ed. 1986)); Benderly, *supra* note 72, at 94 ("The 'gold standard' of drug testing, the double-blind controlled clinical trial, compares an experimental drug against the best standard treatment or, sometimes, against an inactive placebo."); Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941, 964 (2007) ("Long-term clinical tests provide the best evidence about the safety risks of drugs for chronic use, as the history of Vioxx indicates."); Jacobson & Parmet, *supra* note 72, at 207 ("[T]he panel's opinion usurped the FDA's responsibility to balance the risks and benefits of new drugs and strikes at the core of the FDA's raison d'etre."); Kulynych, *supra* note 80, at 131 ("In short, the properly conducted RCT [random clinical trial] permits an accurate, objective, and scientific assessment of whether a treatment works—and if so, how effective it is.").

98. Society for Clinical Trials, *supra* note 80, at 155.

99. *See* Groopman, *supra* note 72, at 42 (describing ACT-UP and other AIDS activists' campaign, including staging "die-ins," to encourage the FDA to relax its experimental drugs policy); Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 295, 308–27 (2000) (discussing "AIDS, Activism, and Pressure for Change"); Linda Katherine Leibfarth, Note, *Giving the Terminally Ill Their Due (Process): A Case for Expanded Access to Experimental Drugs Through the Political Process*, 61 VAND. L. REV. 1281, 1288–89 (2008) (describing impact of AIDS on FDA changes in 1980s).

generalizable knowledge that may help others, while most individuals suffering with AIDS see these trials as *therapy* designed to benefit them."[100] That hope of treatment or cure motivates participants to enroll, but the researchers' objective is "answering scientific questions about safety and efficacy rather than providing therapy for individual participants."[101] In that view, the government's role in regulating new drug approval is principally to ensure the production of scientifically valid results, not treating patients.

Eliminating control groups and requiring researchers to expand qualifications for research participants, as congressional proposals suggest,[102] could undermine reliability of results and compromise patient safety. The FDA faces considerable criticism that its processes are too slow and deliberate, depriving patients of potentially beneficial, life-saving products.[103] But past and recent episodes with approved products, such as the recent controversies involving Vioxx and Vytorin, suggest that the FDA's standards may not be rigorous enough.[104] As much as the public is outraged when the FDA withholds potentially life-saving drugs from dying patients,[105] it is just as angry when dangerous or disappointing drugs

100. Annas, *supra* note 85, at 773 (footnote omitted); *see also* Greenberg, *supra* note 99, at 331 (describing "direct conflict between medical treatment and the clinical trial process"); Benderly, *supra* note 72, at 94 (discussing patients' "therapeutic misconception" that trials aim to cure and offer a good chance of helping, despite being informed of purpose and statistical likelihood to the contrary).

101. Benderly, *supra* note 72, at 94.

102. *See* Press Release, Sam Brownback, *supra* note 74 ("This legislation . . . would also ensure that dying patients will not be forced to participate in a clinical trial and be given a placebo or sugar pill if another reasonable treatment exists.").

103. *See, e.g.*, George J. Annas, *Cancer and the Constitution—Choice at Life's End*, 4 NEW ENG. J. MED. 357, 408 (2007) ("Frustration with the methods and slow progress of mainstream medical research has helped fuel a resistance movement that distrusts both conventional medicine and government," leading to terminally ill patients' demands for increased access to experimental drugs).

104. *See* INST. OF MED. OF THE NAT'L ACADEMIES, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE PUBLIC HEALTH (Alina Baciu et al. eds., 2006) (study and recommendations requested in aftermath of Vioxx concerns); Gilhooley, *supra* note 97, at 956–58 (calling for increasing rigor in testing procedures); Justin Blum, *FDA Accepted 19 Drugs in '07, Fewest It Has OK'd Since '83*, ARIZONA DAILY STAR, Jan. 10, 2008 ("FDA has faced pressure from members of Congress for more strict oversight of drug safety since Merck & Co. withdrew painkiller Vioxx in 2004 because of increased heart risks."). *But see* Epstein, *supra* note 34, at 746 (noting the "controversy over the usage of dangerous drugs has now reached a fever-pitch" and outlining a "coherent framework" for deciding which drugs should get to the market). The controversy surrounding Vytorin was not safety so much as efficacy, based on evidence that the combination drug performed no better than the cheaper component. *See* Alex Berenson, *Study Reveals Doubt on Drug for Cholesterol*, N.Y. TIMES, Jan. 15, 2008, at A1; Alice Park, *Is Vytorin a Failure?*, TIME, Jan. 15, 2008, *available at* http://www.time.com/time/health/article/0,8599,1703827,00.html (describing study demonstrating that drug was less effective at lowering bad cholesterol than results presented to the FDA).

105. *See, e.g.*, Peter Huber, *FDA Caution Can Be Deadly, Too*, WALL ST. J., July 24, 1998, at A14; Leibfarth, *supra* note 99, at 1286–89 (summarizing criticism of "FDA's Gold Standard," including expense, delay, and interference with both personal autonomy and physician-patient

reach the market.[106] Thus, the FDA faces contradictory pressures to both speed access and better ensure safety and efficacy.[107]

4. Physicians

The drugs at issue are available only after FDA approval and with a physician's prescription. Thus, physicians' interests matter, too. The *Abigail Alliance* opinions assumed the existence of physicians willing to prescribe and administer experimental drugs to dying patients. But physicians may have good reasons for reluctance to serve as intermediaries between patients wanting to take experimental drugs and pharmaceutical companies wanting to sell them. As pharmaceutical companies increasingly market prescription drugs directly to consumers, patients have become active consumers—asking their doctors to prescribe new drugs that they hear about rather than waiting for doctors to tell them.[108] The Abigail Alliance and other patients' rights organizations are well informed about clinical trials and other developments in the treatment of their conditions, often by compiling Internet resources and other databases of ongoing trials and enrollment procedures.[109]

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relationship); Clifton Leaf, *Deadly Caution: How Our National Obsession with Drug Safety is Killing People—And What We Can Do About It*, CNNMONEY.COM, Feb. 9, 2006, http://money.cnn.com/magazines/fortune/fortune_archive/2006/02/20/8369155/index.htm ("The approval process is broken—but not in the way most people think. It is in thrall to a well-intentioned but ultimately misguided national obsession: the quest for certainty about drug safety and efficacy."); *see also Implants and Science*, WALL ST. J., Nov. 20, 2006, at A16 (applauding the FDA's decision to lift ban on silicone breast implants as victory of science over politics: "Women will at last be allowed to make their own decisions about cosmetic surgery. This is especially welcome news for mastectomy patients.").

106. *See, e.g.*, Epstein, *supra* note 34, at 741–45 (describing public pressure to pull drugs from the market and increase regulatory oversight); Groopman, *supra* note 72, at 47 (describing concerns of "critics who believe that the F.D.A. needs stricter drug regulations").

107. Rochelle Sharpe, *FDA Tries to Find Right Balance on Drug Approvals*, WALL ST. J., Apr. 20, 1999, at A24 ("The [FDA] is caught in pincers between two intense political pressures: demands from the industry and the political right to move faster and faster in approving drugs, and rising insistence from consumer groups and the left to show more caution.").

108. *See generally* U.S. GENERAL ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS (2002); Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135, 1170–79.

109. *E.g.*, Center Watch, Search Clinical Trials, http://www.centerwatch.com/clinical-trials/listings (last visited May 9, 2009) (listing "[i]ndustry sponsors [that] are actively recruiting patients for clinical trials"); Novartis, Clinical Trial and Medical Research Information, http://www.novartisclinicaltrials.com/webapp/etrials/home.do (last visited May 9, 2009) (providing information for patients and caregivers); Annas, *supra* note 103, at 408 ("Today, families search the Internet for clinical trials, and even untested chemicals . . . that seem to offer some hope."); Greenberg, *supra* note 99, at 312 (describing AIDS activists efforts to promote access to new treatments through "alternative, gray market channels").

Physicians face ethical and liability concerns. On one hand, the "learned intermediary" doctrine of products liability law exposes physicians to potential liability for dispensing dangerous drugs without adequately warning of their risks, instead of strict liability passing through to the manufacturer for failure to directly warn the patient.[110] On the other hand, physicians may fear liability if they refuse to prescribe experimental drugs, since they are held to the standard of care of the profession.[111] Accordingly, if enough oncologists (or other comparable specialists) prescribe experimental drugs and that treatment becomes the standard of care, a physician who refuses may be liable for medical malpractice.[112]

5. The Public

In addition to patients currently suffering from terminal conditions, future patients with serious illnesses may be adversely impacted if the market for experimental drugs opens. Why would a patient who desperately wants a drug enroll in a traditional "gold standard" clinical trial and risk being assigned to a placebo or control group, rather than buy the drug upfront? Congressional proposals would allow patients to access such drugs directly, without enrolling in clinical trials and facing that very risk.[113] Manufacturers could sell drugs without the expense, effort, and risk of failure associated with conducting full trials. The combined effect of fewer patients enrolling and decreased incentive for manufacturers to conduct full trials could seriously hamper scientific research and

110. *E.g.*, Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 591–92 (Tex. 1986); Terhune v. A.H. Robins Co., 577 P.2d 975, 977–78 (Wash. 1978) (citing cases); *see also In re* Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374 (5th Cir. 1999) (applying doctrine even to prescription drugs advertised directly to patients).

111. *E.g.*, Robbins v. Footer, 553 F.2d 123, 126 (D.C. Cir. 1977) ("Whether a defendant has or has not conformed his conduct to a customary practice is generally only evidence of whether he has acted as a reasonably prudent person. In a malpractice case, however, the question of whether the defendant acted in conformity with the common practice within his profession is the heart of the suit." (citations omitted)).

112. *See* Peter D. Jacobson et al., *Litigating the Science of Breast Cancer Treatment*, 32 J. HEALTH POL. POL'Y & L. 785, 799 (2007) (discussing routine use of HDC/ABMT among oncologists, resulting in judges finding the treatment within the standard of care, despite experimental status); Francis C. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 438 (2002) (describing pressure on physicians to prescribe advertised drugs and strain on professional responsibility to patient and practice standards).

113. *See* Press Release, Sam Brownback, *supra* note 74 (describing ACCESS Act); Press Release, Sam Brownback, *supra* note 77 (same); Society for Clinical Trials, *supra* note 80, at 155 ("[T]he [Act] prohibits the use of placebo-only or no-treatment-only concurrent controls in any clinical investigations conducted under [the Act].").

undermine drug innovation.[114] As one commentator summarized: "[T]he premature introduction of new drugs may create additional problems in the form of ambiguity surrounding the comparative efficacy of different treatments, or a reduction in the pool of individuals willing to participate as subjects in double-blind clinical trials."[115] Several scenarios illustrate the validity of those concerns.

First, diethylstilbestrol ("DES"), a synthetic version of estrogen, was widely prescribed—initially to women with risks of miscarriage, later to pregnant women in general—like a prenatal vitamin, to promote healthier babies.[116] DES reached the U.S. market in the 1930s, free of patent restrictions and only nominal, on-paper statements about the drug's purpose and apparent safety, under the FDA's brand-new drug approval requirements.[117] Accordingly, DES was never systematically tested through controlled clinical trials in the U.S.; tragically, the drug was later revealed to cause a rare form of cancer in treated women's young-adult daughters.[118] It was especially difficult to assess cancer risks of DES for the public at large because patients who took the drug tended to be upper-class white women who had access to gynecological care.[119] Variables particular to that subgroup could not be isolated or identified, nor could

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114. *See* Annas, *supra* note 103, at 412 ("The drug companies are right to worry that the approaches of the judiciary, Congress, and the FDA will probably make clinical trials more difficult to conduct, because few seriously ill patients who have exhausted conventional treatments would rather be randomly assigned to an investigational drug than have a guarantee that they will receive the investigational drug their physician recommends for them."); Furmansky, *supra* note 94, at 113 (describing effect on clinical trials if early access is granted and patients no longer volunteer for double-blind trials); Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. ON REG. 401, 436–38 (1994) (describing randomized, double-blind, placebo-controlled experiments as "undoubtably the most scientifically sound means" producing statistically significant data on safety and effectiveness, although arguing for more open access and value of other information sources); Kevin M. Hill et al., *The ADVANTAGE Seeding Trial: A Review of Internal Documents*, 149 ANNALS INTERNAL MED. 251, 256 (2008) (suggesting that "seeding trials," designed to promote pharmaceutical companies' new products, are "harmful to science and society" because of lower patient enrollment and quality control "when marketing is the primary purpose of the study").

115. Greenberg, *supra* note 99, at 297.

116. Anita Bernstein, Hymowitz v. Eli Lilly and Co.*: Markets of Mothers*, *in* TORT STORIES 151, 154 (Robert L. Rabin & Stephen D. Sugarman eds., 2003).

117. In the 1930s, the FDA's new drug application required minimal evidence of the drug's safety; the efficacy requirement was not added until 1962. *See* Bernstein, *supra* note 116, at 153 & n.9, 155; *see infra* note 170 (citing additional sources on history of the FDA new drug approval process).

118. W. J. Dieckmann et al., *Does the Administration of Diethylstibestrol During Pregnancy Have Therapeutic Value?*, 66 AM. J. OBSTETRICS & GYNECOLOGY 1062 (1953) (describing nonrandomized DES trials); Bernstein, *supra* note 116, at 153 & n.9.

119. *See* Bernstein, *supra* note 116, at 155 (describing how DES was made available to the public without undergoing randomized, controlled clinical trials, and that the "exposed population was mostly white, upper-income, and reasonably well educated").

the affects be generalized for a whole population. Had DES been systematically tested in accordance with accepted scientific methods, the tragic results to prospective patients might have been avoided.

Another scenario involved Autologous Bone Marrow Transplant with High Dose Chemotherapy (ABMT/HDC), a novel treatment for certain cancers; the treatment was accepted for leukemia and Hodgkin's disease and showed early promise for breast and ovarian cancers.[120] Based on initial clinical results, physicians began recommending ABMT/HDC for other cancers; accordingly, patients began asking their health insurers to cover it. But insurers refused to cover the treatment, citing "experimental" or "not medically necessary" insurance contract exclusions.[121] Patients rallied, and a number of courts ruled against the insurers, requiring them to pay.[122] Eventually, complete clinical trials demonstrated that ABMT/HDC was no more effective than traditional treatments.[123] The public pressure to make the treatment available (as a practical matter) under insurance coverage accelerated its clinical application, despite lack of complete scientific information about its effectiveness, to painful and unnecessary results.[124] Those and many other cases illustrate the risks of allowing access to potential "miracle drugs" before they have been fully tested.[125]

The risks of underenrollment and clinical trial disruption are demonstrated by the AIDS drug trials in the late 1980s. Clinical trials of azidothymidine (AZT) on HIV-positive people (who had not yet

120. *See* Lubeznik v. HealthChicago, Inc., 644 N.E.2d 777 (Ill. App. Ct. 1994) (describing treatment history).

121. Jacobson et al., *supra* note 112, at 786–87 (describing litigation).

122. *See, e.g.*, *id*. *But see* Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405 (7th Cir. 1994) (denying coverage); Harris v. Mutual of Omaha Cos., 992 F.2d 706 (7th Cir. 1993) (same).

123. *See* E. Haavi Morreim, *From the Clinics to the Courts: The Role Evidence Should Play in Litigating Medical Care*, 26 J. HEALTH POL. POL'Y & L. 409, 411–13 (2001); Karen H. Antman et al., *High Dose Chemotherapy for Breast Cancer*, 282 JAMA 1701 (1999); Leaf, *supra* note 105 ("Clinical trials revealed that high-dose chemotherapy followed by a bone-marrow transplant, a once-common, brutal, and often deadly therapy for breast cancer, wasn't necessary.").

124. *See* RICHARD A. RETTIG ET AL., FALSE HOPE: BONE MARROW TRANSPLANTATION FOR BREAST CANCER (2007) (describing how providers' and insurers' enthusiasm for experimental HDC/ABMT to treat metastatic breast cancer made it difficult to enroll patients in randomized controlled trials, which eventually showed the procedure was much less effective than believed); Benderly, *supra* note 72, at 99 (regarding HDC/ABMT: "Thousands of women underwent, and some died from, this excruciating and costly experimental procedure after a lawsuit forced insurers to pay but before clinical trials finally proved it no more effective than standard therapy.").

125. *See* Okie, *supra* note 87, at 440 (Quoting pharmaceutical industry executive: "[T]he whole purpose of large clinical trials is to fully evaluate benefits and risks . . . and short-changing that is not in patients' best interests."); Society for Clinical Trials, *supra* note 80, at 156 (listing numerous examples, including drugs for heart disease and Lou Gehrig's disease that showed initial promise but ultimately harmful effects, evident only after placebo-controlled randomized trials).

developed AIDS) were seriously undermined by underenrollment.[126] In New York City, after five months of trying, researchers enrolled only 244 volunteers, out of a population of 200,000 HIV-infected individuals, in one of the most important AIDS trials to date.[127] Reasons for low enrollment included hostility to the FDA's slow pace of new drug approval, concerns about being relegated to placebos, and ability to obtain AZT and other drugs through gray markets.[128] Most patients, in consultation with their doctors, opted instead to take unproven drugs, rather than enroll in randomized, controlled trials.[129] The results were further undermined by research subjects who, fearing they were receiving the placebo, cheated by taking supplemental drugs without informing research sponsors.[130]

Moreover, allowing patients to purchase experimental drugs could create a two-tiered system for experimental drugs. Patients with financial means to purchase the drugs and resources to inform themselves about the drugs' availability might choose that option. Meanwhile, patients who cannot afford to purchase drugs or are less well-informed would be relegated to traditional trials. Typically, there is no charge for drugs provided to clinical trial participants.[131] Outside of controlled trials, pharmaceutical companies could charge patients because Congress and the FDA would expressly allow it.[132] The preamble to the FDA's proposed amendments allowing drug companies to charge for investigational drugs explained:

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126. *See* Gina Kolata, *Recruiting Problems in New York Slowing U.S. Trials of AIDS Drugs*, N.Y. TIMES, Dec. 18, 1988, at 1; Annas, *supra* note 85, at 786–87 (describing same); Greenberg, *supra* note 99, at 314 (noting that research subjects may "modify or supplement treatment in order to optimize a personal assessment of welfare").

127. *See* Kolata, *supra* note 126.

128. *Id.*

129. *Id.*

130. Annas, *supra* note 85, at 786–87 (noting that patients' taking drugs outside the trials "on the sly" further undermined results); Kolata, *supra* note 126 (quoting chairman of national study: "We're worried about cheating all the time.").

131. 21 C.F.R. § 312.7(d) (2008) (providing that "[c]harging for an investigational drug in a clinical trial under an IND is not permitted without the prior written approval of FDA"). *But see* Annas, *supra* note 85, at 779 ("[R]esearch drugs are no longer universally delivered free . . . [which] makes it even more difficult for patients suffering from disease to distinguish recognized therapy from early experimentation . . . .").

132. ACCESS Act, H.R. 6270, 110th Cong. § 3(a)(10) (2008) ("A sponsor or investigator may charge for a Compassionate Investigational Access drug without notifying the Secretary or seeking or obtaining prior approval of the amount charged."); S. 3046, 110th Cong., § 3(a)(10) (2008) (same); Charging for Investigational Drugs, 71 Fed. Reg. 75,168 (Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312).

> Charging for the cost of an investigational drug for expanded access for treatment use is a very different situation from charging for a drug in a clinical trial. Treatment use is not a necessary part of the drug development process and does not benefit the pharmaceutical companies by leading to systematic accumulation of data intended to support marketing authorization. Rather, treatment use is primarily intended to benefit very sick patients by permitting them to receive investigational drugs to treat their diseases and conditions, with collection of information about the drug being incident to the intent to treat.[133]

The agency further expressed a desire "to encourage sponsors to make investigational drugs available" but recognized that "making investigational drugs available . . . for treatment use is potentially costly"; thus, sponsors should be permitted to charge for them.[134] That discussion further supports the concerns about conflicting interests of research and therapy.[135] When conducting trials, companies are primarily concerned with science; when providing drugs outside of trials, costs become a significant motivator.

These concerns are exacerbated by private health insurers and government health care programs that do not cover experimental treatment on the grounds that it is not "medically necessary" because approved, traditional treatment options exist.[136] A two-tiered system, with patients who lack resources enrolling in traditional trials and patients with

133. Charging for Investigational Drugs, 71 Fed. Reg. at 75,170.

134. *Id.*

135. *See supra* notes 97–101 and accompanying text (describing dissonance between researchers' and patients' objectives in clinical trials).

136. *See* RAND E. ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 211, 242–45 (1997) (discussing insurance contract exclusions based on medical necessity or experimental status); Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1677–79 (1992) (regarding courts' interpretation of medical necessity of experimental treatment, citing ABMT example); Jacobson et al., *supra* note 112, at 797 (discussing coverage determinations and application of "medical necessity" provisions to HDC/ABMT); *see, e.g.*, Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405 (7th Cir. 1994) (denying coverage for HDC/ABMT); *see also* 42 U.S.C. § 1395y(a)(1)(B) (2000) (excluding coverage for items or services "not reasonable and necessary for the prevention of illness"). Federal and state reforms expanded coverage for experimental treatment. *See* Memorandum on Increasing Participation of Medicare Beneficiaries in Clinical Trials, 1 PUB. PAPERS 1107 (June 7, 2000) (providing that Medicare covers "routine costs" for patients enrolled in clinical trials, but not all expenses, including complications and injuries, associated with participation), *adopted in* DEP'T OF HEALTH AND HUMAN SERVICES, CMS PUB. NO. 100–06, MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL § 310.1 (2007); National Cancer Institute, States that Require Health Plans to Cover Patient Care Costs in Clinical Trials, http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs (last visited May 9, 2009) (map of states).

resources purchasing experimental drugs on the free market, is not only morally offensive, but also a threat to the validity of clinical trials.[137] Recent reports on the growing market for paid clinical trial participants suggest that this outcome is not far-fetched.[138]

In addition, failing to enroll or allowing an entire cohort of research subjects to opt out of trials, based on socioeconomic or other potentially significant differences, could undermine results, as the DES case illustrated.[139] The DES results were revealing for only upper-class white women and failed to account for other variables or provide generalizable data. Another example of distortions in the testing cohort is the drug BiDil, which was touted as the first drug developed specifically to treat heart disease in African Americans.[140] Seeing a potentially lucrative market for "race-specific drugs," the clinical trials enrolled only African Americans.[141] Other flaws in the research methodology and data interpretation produced results that could not reliably suggest any racial difference in the etiology or treatment of heart disease.[142] Moreover, the research failed to produce any evidence helpful for determining whether

137. *See, e.g.*, Carl Elliott & Roberto Abadie, *Exploiting a Research Underclass in Phase 1 Clinical Trials*, 358 NEW ENG. J. MED. 2316, 2316–17 (2008) (noting financial and other pressures on poor people to enroll as research subjects and incentives to falsify medical histories); Carl Elliott, *Guinea-Pigging*, NEW YORKER, Jan. 7, 2008, at 36 (discussing subjects' noncompliance with diet and other restrictions during testing and reluctance to report adverse reactions or other discomfort for fear of being excluded from future trials).

138. *See* Laurie P. Cohen, *To Screen New Drugs for Safety, Lilly Pays Homeless Alcoholics*, WALL ST. J., Nov. 14, 1996, at A1 (exposé on Lilly's practices at Indianapolis testing facility); Elliott & Abadie, *supra* note 137, at 2316 (discussing research industry's "'shadow economy' of paid human subjects"); Elliott & Abadie, *supra* note 137 (quoting Alan Milstein, attorney for Jesse Gelsinger, teenager who died in the notorious University of Pennsylvania gene-therapy clinical trial: "This is not something you or I do. . . . This is something the poor do so that the rich can get better drugs.").

139. *See, e.g.*, Bernstein, *supra* note 116, at 153 & n.9, 155 (noting that DES was made available to the public without undergoing randomized, controlled clinical trials and "exposed population was mostly white, upper-income, and reasonably well educated"); *See also* Dieckmann et al., *supra* note 118, at 1062–81 (describing nonrandomized DES trials).

140. Jonathan Kahn, *Letter to the Editor, Misreading Race and Genomics After BiDil*, 37 NATURE GENETICS 655, 655 (2005) ("BiDil is noteworthy because it may become the first race-specific drug ever approved by the FDA."); *see also* Ron Chepesiuk, *Are Race-Specific Drugs Unethical?*, BLACK ENTERPRISE, Nov. 1, 2005, http://www.blackenterprise.com/magazine/2005/11/01/are-race-specific-drugs-unethical/.

141. Kahn, *supra* note 140, at 655 (noting "dynamic relation between markets and the skewed interpretation of clinical trial data"); Robert Temple & Norman L. Stockbridge, *BiDil for Heart Failure in Black Patients: The U.S. Food and Drug Administration Perspective*, 146 ANNALS INTERNAL MED. 57, 57 (2007) (noting "entirely black patient population" in critical clinical trial of BiDil).

142. Chepesiuk, *supra* note 140 (questioning clinical basis and results); Kahn, *supra* note 140, at 655 (same). *But see* Temple & Stockbridge, *supra* note 141, at 57–61 (defending FDA approval of BiDil, despite criticism).

non-African American patients could benefit equally from the drug.[143] Similarly, initial trials of AZT were conducted almost exclusively on gay white males and were later considered questionable in terms of predicting efficacy in the general population.[144] These examples illustrate that the push for access to experimental drugs may undermine the scientific validity of studies and also compromise other and future patients' health and safety.

Accordingly, the public's interest in restricting access to experimental drugs aligns with the government's interest in maintaining the FDA's role,[145] but may be opposed to individual rights. This tension is a classic public health law dilemma: how to ensure the health of a population while recognizing the rights of individuals.[146] Mandatory vaccination benefits the public greatly by reducing the risk of infectious diseases, but liberty and autonomy interests of some individuals are necessarily infringed.[147] Similarly, the public interest in scientifically sound clinical trials may benefit the public greatly, while impairing individuals' interests in obtaining the drugs before they are approved.[148]

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143. *See* Kahn, *supra* note 140, at 655–56 (2005) (describing drug developed and marketed to African American population and noting that clinical trails expressly "enrolled only 'self-identified' African Americans; there was no comparison population" and "skewed interpretation of clinical data"); Temple & Stockbridge, supra note 141, at 59 (discussing concerns about "inadequate representation of women, elderly people, black people, and other groups in the drug development process" leading to "incorrect conclusions for those groups about benefits or adverse effects of treatments"); *see also* Chepesiuk, *supra* note 140.

144. *See* Greenberg, *supra* note 99, at 313.

145. *See* Okie, *supra* note 87, at 440 (Quoting pharmaceutical industry executive: "[T]he whole purpose of large clinical trials is to fully evaluate benefits and risks . . . and short-changing that is not in patients' best interests."); O. Carter Snead, *Unenumerated Rights and the Limits of Analogy: A Critique of the Right to Medical Self-Defense*, 121 HARV. L. REV. F. 1–2 (2007) (responding to Volokh, *supra* note 22, and noting: "FDA restricts access to unapproved drugs . . . to maintain a functional clinical trial system (the chief mechanism of bringing safe and effective drugs to the market).").

146. *See, e.g.*, PUBLIC HEALTH LAW AND ETHICS: A READER, *supra* note 7, at 23–24 (noting public health's "emphasis on the well-being of the population as opposed to clinical benefits for individuals"); Baum et al., *supra* note 20, at 657, 658 & n.1 (noting "public health ethics also tend to emphasize the role of social justice compared to the predominance of autonomy" and citing sources); Shattuck, *supra* note 31, at 25–27 (responding to concern that public health measures may interfere with private matters: "No family, no person liveth to himself alone. Every person has a direct or indirect interest in every other person."); Elizabeth A. Weeks, *Beyond Compensation: Using Torts to Promote Public Health*, 10 J. HEALTH CARE L. & POL'Y 27, 33–34 (2007) (describing and giving examples of public health tension with individual rights).

147. *See supra* notes 43–51 (describing mandatory vaccination debate and "commons" analogy).

148. *See* Rutherford v. United States, 616 F.2d 455, 457 (1980) (noting the FDA's authority to restrict access to experimental drugs "is within the area of governmental interest in protecting public health"); Furmansky, *supra* note 94, at 114 ("In this case, the good of the many must certainly outweigh the potential, (though not certain), good of the few."); Snead, *supra* note 145, at 1–2 ("The FDA restricts access to unapproved drugs (subject to certain exceptions) in the interest of public

B. The Opinions

During the brief sixteen-month period that the *Abigail Alliance* panel decision was on the books as good law, it generated considerable interest.[149] After the surprising panel decision, the government requested rehearing; the three-judge panel denied the request,[150] but the full court granted en banc review.[151] On March 1, 2007, the en banc court heard the case and, on August 7, 2008, reversed the panel and affirmed the district court, which had declined to recognize a right to experimental treatment.[152] In January 2008, the Supreme Court denied certiorari.[153] The various attempts to articulate the purported right in question clarifies the true interest at stake—the public's.

1. Panel Decision

On May 2, 2006, a divided panel of the D.C. Circuit recognized a fundamental constitutional right for terminally ill patients to take drugs that the FDA has not yet approved for marketing.[154] The panel then remanded the case back to the district court to determine, on the merits, whether the FDA violated that interest.[155] The plaintiffs were the Abigail Alliance, a patient advocacy organization, and Washington Legal Foundation, a consumer rights activist organization.[156] In 2001, Frank

health, that is, to prevent patient exposure to unsafe or ineffective drugs and to maintain a functional clinical trial system.").

149. *See, e.g.*, Furmansky, *supra* note 94, at 117 ("Desperately ill terminal patients should not be allowed to take so many other lives into their own hands . . . ."); Jacobson & Parmet, *supra* note 72, at 207–08 (urging the full court to reexamine the "panel's aggressively individualistic view, one that breathtakingly slights the public's interest in drug safety"); *see also* Hill, *supra* note 23, at 277; Volokh, *supra* note 22, at 1828–32.

150. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 469 F.3d 129, 138 (D.C. Cir. 2006) (rejecting the FDA's challenge to Abigail Alliance's standing to bring the constitutional challenge and denying motion for rehearing).

151. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006).

152. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008); Abigail Alliance for Better Access to Developmental Drugs v. McClellan, No. 03-1601, 2004 WL 3777340 (D.D.C. Aug. 30, 2004) (district court dismissal under Rule 12(b)(6) for failure to state a claim, suing in the name of former FDA Commissioner, Mark McClellan).

153. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 128 S. Ct. 1069 (2008).

154. *Abigail Alliance*, 445 F.3d at 472.

155. *Id.* at 486 (district court erred in dismissing for failure to state a claim and for refusing to recognize asserted fundamental right).

156. For information on Abigail Alliance, see Abigail Alliance for Better Access to Developmental Drugs, http://abigail-alliance.org/ (last visited May 9, 2009). For information on

Burroughs founded the Abigail Alliance. His daughter, Abigail, was diagnosed at age nineteen with squamous cell carcinoma in her neck and lungs. Her oncologist recommended her for clinical trials of two investigational drugs, but she did not qualify because she had a different type of cancer. As her father summarized, "she had the right type of cancer cells . . . in the wrong place." After Abigail died at age twenty-one, Burroughs and Steven Walker, whose terminally ill wife had been similarly excluded from trials, co-founded the Abigail Alliance.[157]

The defendants were FDA Commissioner Andrew von Eschenbach and U.S. Department of Health and Human Services (HHS) Secretary Michael Leavitt.[158] The litigation operated from several assumptions: that drug companies would willingly provide their preapproved products to dying patients; that patients would willingly pay for the drugs; and that doctors would willingly prescribe the drugs. Thus, Abigail's only obstacle to a possible cure or treatment was government regulators "interfering" with her right to decide whether to assume the risks of using potentially life-saving, investigational new drugs.[159] The complaint framed the issue as whether terminally ill patients who have exhausted all other government-approved treatment options have a constitutional due process right to pre-FDA-approved, experimental drugs that may prolong their lives.[160] The district court, after rejecting the defendants' ripeness, finality, and exhaustion arguments,[161] held that the plaintiffs failed to state a recognized due process claim on which relief could be granted and dismissed the complaint.[162]

On appeal, the *Abigail Alliance* panel held, two to one, that the plaintiffs stated a claim on their asserted constitutional right to

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Washington Legal Foundation, see Washington Legal Foundation, http://wlf.org/ (last visited May 9, 2009).

157. *See* Sue Kovach, *The Abigail Alliance: Motivated by Tragic Circumstances, Families Battle an Uncaring Bureaucracy*, LIFE EXTENSION, Sept. 2007, at 25, *available at* http://abigail-alliance.org/LEMSEP07pAbigailLR.pdf.

158. When the case was filed, Mark McClellan was FDA Commissioner and Tommy Thompson was Secretary of HHS. *See* Abigail Alliance for Better Access to Developmental Drugs v. McClellan, No. 03-1601, 2004 WL 3777340 (D.D.C. Aug. 30, 2004).

159. *See* Robert A. Bohrer, *The Abigail Alliance and the Role of the FDA*, 26 BIOTECHNOLOGY L. REP. 107, 107 ("The notion that the FDA is impermissibly interfering with the rights of terminally ill patients and drug companies to choose freely for themselves the terms of their agreements seems to be a necessary underpinning of the *Abigail Alliance* court's right to access experimental treatments.").

160. *Abigail Alliance*, 445 F.3d at 472 ("[T]he right at issue, carefully described, is the right of a mentally competent, terminally ill adult patient to access potentially life-saving post-Phase I investigational new drugs, upon a doctor's advice, even where that medication carries risks for the patient.").

161. 2004 WL 3777340, at *2–8.

162. *Id.* at *9–11.

experimental drugs.[163] The court recognized not just any constitutional right, but a *fundamental* right—the type to which we give the most constitutional protection. The court guised the new right in liberty and privacy, likening it to previously recognized constitutional rights to use contraceptives,[164] have abortions,[165] refuse medical treatment,[166] and engage in intimate association.[167] Specifically, the panel held that the Due Process Clause of the Constitution protects the right of a terminally ill patient to make an informed decision to use potentially life-saving drugs that the FDA has not yet approved for commercial marketing.[168]

The court limited its holding in several significant respects. First, the right extended only to terminally ill, mentally competent patients. Also, the patients must have exhausted all other options, and they must consult with their doctors. In addition, the right extended only to drugs approved for human clinical trials and passed Phase I of the FDA's new drug approval process. The two-judge majority and some commentators relied heavily on the erroneous assertion that Phase I conclusively settles the question of drug safety.[169] In fact, Phase I merely establishes preliminary dosage ranges and demonstrates that the drugs are not toxic or poisonous to humans. In Phase I, the drug is tested on small numbers of subjects, typically twenty to eighty, who may or may not have the disease for which the drug is indicated.[170] If a drug passes Phase I, researchers still do not

163. *Abigail Alliance*, 445 F.3d at 486.

164. Griswold v. Connecticut, 381 U.S. 479 (1965) (holding that Connecticut law forbidding use of contraceptives unconstitutionally intrudes upon the right of marital privacy); *see also* Eisenstadt v. Baird, 405 U.S. 438, 443 (1972) (holding that law allowing distribution of contraceptives to married but not single people violated equal protection).

165. Roe v. Wade, 410 U.S. 113 (1973) (holding that constitutional right of privacy is broad enough to encompass woman's decision whether or not to terminate her pregnancy but that state may have compelling justifications for limiting right); *see also* Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 837 (1992) (affirming *Roe* but replacing trimester approach with "undue burden" test).

166. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990) (recognizing Fourteenth Amendment liberty interest in refusing life-sustaining treatment).

167. Lawrence v. Texas, 539 U.S. 558 (2003) (Texas statute making it a crime for two persons of the same sex to engage in certain intimate sexual conduct impinged on Fourteenth Amendment liberty interests).

168. *Abigail Alliance*, 445 F.3d at 484 (discussing *Cruzan* and noting that "similar analysis leads to the conclusion that the Due Process Clause protects the liberty interest claimed by the Alliance for its terminally ill members").

169. *Id.* at 472–75; *see, e.g.*, Volokh, *supra* note 22, at 1830 & n.79 ("The insufficiency of such government interests should be especially clear when the drugs have passed Phase I . . . but it should be so even if the drugs have not been tested for safety.").

170. *See* 21 C.F.R. § 312.21(a) (2008) (describing Phase I, including fact that "studies may be conducted in patients or normal volunteer subjects"); *Abigail Alliance*, 445 F.3d at 473; Okie, *supra* note 87, at 438–49 (describing Phases and noting that Phase I provides "preliminary information about safety"); *see also* PETER BARTON HUTT & RICHARD A. MERRILL, FOOD & DRUG LAW 514–16 (2d ed.

know whether it will work as indicated or whether the benefits will outweigh the risks—they merely know that humans will not immediately suffer harm or death by taking it. As Judge Griffith (the panel dissenter) noted, both the remaining Phases and post-approval reporting continue to establish not only efficacy but also safety.[171]

Aside from misunderstanding the FDA's new drug approval process, the panel majority's reliance on Phase I awkwardly derives a fundamental, constitutional right from a federal administrative agency's regulatory scheme. The very agency whose validity and purpose is thrown into question by recognizing the right provides the rules that define its recognition.[172] If the FDA changes the rules, redefines the Phases, or otherwise alters the regulatory playing field, would the recognized fundamental right still exist? Tying the purported right to agency rules seems tenuous at best—hardly a fundamental constitutional right. Even if the court's operating presumption about the Phase I were correct, the only imaginable justification for prohibiting access to unsafe (i.e., pre-Phase I) drugs while allowing access to ineffective (i.e., post-Phase I) drugs, seems to be paternalism—and limited paternalism, at that, to protect patients from bodily harm but not monetary loss or consumer fraud to which they may be exposed by purchasing costly, ineffective products.

Perhaps the real explanation for the panel's limiting of the *Abigail Alliance* right to drugs approved through Phase I was the need to maneuver around Supreme Court precedent. In *United States v. Rutherford*,[173] the Court held that terminal cancer patients could not access Laetrile, an experimental drug that had not yet passed Phase I.[174] Laetrile,

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1991) (describing the FDA's process for approving new drugs and three Phases); Benderly, *supra* note 72, at 95 (describing Phases); Greenberg, *supra* note 99, at 304–06 (describing Phases). As discussed above, Phase I trials may include paid research subjects who do not suffer from the condition being tested. *See supra* note 138 and accompanying text.

171. *Abigail Alliance*, 445 F.3d at 488–89 (Griffith, J., dissenting) ("The majority and I differ in our understanding of the importance of the testing that occurs after Phase I. . . . Contrary to the majority's suggestion, all phases of the FDA's testing process for new drugs involve testing for safety."); *see* Postmarketing Reporting of Adverse Drug Experiences, 21 C.F.R. § 314.80 (2008); *see also* Epstein, *supra* note 34, at 756 (noting relevance of safety and effectiveness in all three Phases); Jacobson & Parmet, *supra* note 72, at 206 (noting safety concerns revealed throughout all Phases); Donald Kennedy, Editorial, *Health Roundup*, 312 SCI. 1105, 1105 (2006) (noting *Abigail Alliance* court's error in that "Phase I testing simply seeks to determine appropriate dosage ranges; it does not establish safety").

172. *See supra* Part III.A.3 (suggesting that expanded access to experimental drugs threatens the FDA's existence).

173. 442 U.S. 544 (1979).

174. *Id.* at 546–49 (noting that Laetrile was a "new drug," having not been determined as safe or effective by the FDA); *see* HUTT & MERRILL, *supra* note 170, at 557–58 (describing FDA enforcement against unproven cancer treatments and Laetrile issue); Furmansky, *supra* note 94, at 109–10

a drug derived from apricot pits and available in Mexico and Canada, where cancer patients by the thousands traveled to obtain it, was not even in experimental trials in the United States.[175] The drugs that the Abigail Alliance sought, by contrast, had been approved at least through Phase I. That distinction made all the difference to the *Abigail Alliance* panel majority.[176] According to the court, by not seeking access to pre–Phase I drugs, the Abigail Alliance demonstrated that they were not seeking an "unfettered right of access,"[177] thus distinguishing their claim from *Rutherford*. But the court's myopic focus on, and misunderstanding of, Phase I, caused them to miss the issue: whether the Constitution mandates access to possibly dangerous, ineffective experimental drugs, *even outside of* the controls that Congress and the FDA have in place.[178]

The panel also limited patients' access to experimental drugs "upon a doctor's advice," again muddling the analysis. Like the Phase I limit on the right, the "doctor's advice" limit ties the constitutional right to the FDA's regulatory scheme.[179] The FDA separately regulates prescription and over-the-counter ("OTC") drugs.[180] Drugs requiring a physician's advice or prescription typically are perceived to carry greater risks to and potential for abuse by patients. Mere labeling cannot adequately protect patients.[181] Drugs approved for OTC sale, by contrast, are deemed sufficiently safe for direct sale to patients, without an intermediary, as long

(discussing *Rutherford* Court's "holding that the same standards that apply to the general population of patients apply with equal force to terminal patients").

175. *See* Annas, *supra* note 85, at 779–80.

176. *Abigail Alliance*, 445 F.3d at 486 (noting that "the government's interest in *Rutherford* might well have been sufficiently compelling to warrant restricting access to the drug" but may be weaker in this case "because the Alliance seeks only access to investigational new drugs that the FDA, after Phase I human trials, has deemed sufficiently safe for human testing on a substantial number of human beings").

177. *Id.* at 478.

178. *Id.* at 490–91 (Griffith, J., dissenting).

179. *Id.* at 472, 478.

180. *See* 21 C.F.R. §§ 201.100 (2008) ("Prescription drugs for human use"), 201.66 (2008) (labeling requirements for OTC drugs); 21 C.F.R. §§ 330.1 (general requirements), 330.10 (2008) ("Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded. . . ."); *see also* Linda R. Horton, *Over-the-Counter Drug Authority Issues: Selected Topics*, 48 FOOD & DRUG L.J. 545, 550–51 (1993) (suggesting that the FDA's "new drug authority applies equally to prescription and OTC new drugs" but that "legislators periodically have singled out prescription drugs for different attention: . . . for labeling and dispensing, advertising, inspection, marketing controls, and additional user charges"); *see generally* HUTT & MERRILL, *supra* note 170, at 588–99 (describing OTC drug regulation).

181. *See* Peter Barton Hutt, *A Legal Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status*, 37 FOOD DRUG COSM. L.J. 427 (1982) (describing the FDA's justifications for prescription drug status but noting inconsistencies); Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & ECON. 91, 98–99 (1979) (discussing presumptions underlying 1938 Act regarding consumers' abilities to understand drug ingredients and labeling).

as warnings and labels meet FDA requirements.[182] Limiting the right of access to experimental drugs to those available on a doctor's advice, again, grounds the right in FDA rules. As with the Phase I limit, the recognized constitutional right could be altered or eliminated if the FDA alters its prescription or OTC regulatory scheme. More fundamentally, it is difficult to understand why the court would continue to insist on a physician intermediary to access the drugs when obstacles between the willing drug manufacturer and willing patient were precisely the Alliance's complaint—unless the court aims to protect patients from their own dangerous choices.

Despite the panel's attempts to carefully contain the recognized right, its holding cannot be defended, as the en banc court ultimately concluded. Attempts to characterize the right varied throughout the opinion, belying the panel's apparent certainty in its conclusion. Initially, the court conceptualized a "right of control over one's body," analogizing to *Cruzan*,[183] and later to *Eisenstadt*, *Roe*, and *Casey*.[184] The court buttressed the constitutional argument with reference to common-law privileges of self-defense, self-preservation, and private necessity.[185] In framing its opinion, the court characterized a "right to access potentially life-sustaining medication,"[186] a "right to make the decision about her life free from government interference,"[187] a "right . . . to make an informed decision that may prolong life,"[188] a "right . . . to choose to use [certain] drugs,"[189] or an "individual right of self-determination."[190] Each of those definitions fails to carefully, accurately frame the issue, as required by

182. *See* Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 365–66 (2006) (explaining that "virtually all" new drugs are available by prescription only and switched to OTC only after having "survived not only [FDA's] rigorous premarket review process for new chemical entities but also the test of time and a second round of FDA scrutiny").

183. *Abigail Alliance*, 445 F.3d at 480*; see also id*. at 484 ("'[N]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person'") (quoting Cruzan v. Dir., Mo. Dep't of Health, 496 U.S. 261, 269 (1990)).

184. *Id.* at 476, 481 n.12, 485 (citing Eisenstadt v. Baird, 405 U.S. 438 (1972)) (citing *Casey*'s recognition that "the Court has discerned the existence of fundamental rights by probing what 'personal dignity and autonomy' demand"; "[T]he right to be free from unwarranted government intrusion"); Volokh, *supra* note 22, at 1824–27 (discussing right to medical self-defense and comparing *Roe* and *Casey* to *Abigail Alliance*).

185. *Abigail Alliance*, 445 F.3d at 480.

186. *Id.* at 472.

187. *Id.* at 472, 485 ("right of access" recognized "in light of the explicit protection accorded to 'life'").

188. *Id.* at 477.

189. *Id.* at 484.

190. *Id.*

Supreme Court precedent, and moreover fails to take into account other interests affected by recognizing the patients' asserted right.

The Supreme Court's established test for identifying a derived fundamental right begins with a "careful description" requirement.[191] In *Washington v. Glucksberg*, the Court articulated a three-part test.[192] The right must be "deeply rooted in this Nation's history and tradition," "implicit in the concept of ordered liberty," and carefully described.[193] The "careful description" requirement tends to direct the analysis of the other two requirements because one conceptualization of a right may be consistent with the "[n]ation's history and tradition" and "implicit in the concept of ordered liberty" while another would not. For example, a constitutional challenge to laws prohibiting the use of medical marijuana, described as a "right to use cannabis for medical purposes," seems unlikely to be considered fundamental, whereas describing the right as a "right to preserve one's life or control one's body" *does* seem fundamental.[194] Some critics suggest that the courts have morphed *Glucksberg*'s "careful description" requirement into a "narrow description" requirement, with the effect (and arguably, purpose) of making it very difficult to recognize new fundamental rights.[195] Regardless, the "careful description" makes all the difference to the court's recognition of a fundamental right, as the opinions and discussion demonstrate.[196]

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191. Washington v. Glucksberg, 521 U.S. 702, 721 (1997) (citing cases); Randy E. Barnett, *Scrutiny Land*, 106 MICH. L. REV. 1479, 1489 (2008) (noting that "a right must be 'carefully defined' before a court can decide whether it is 'deeply rooted'").

192. *Glucksberg*, 521 U.S. at 720–21; *Abigail Alliance*, 445 F.3d at 476–77 (discussing *Glucksberg* fundamental rights analysis).

193. *Glucksberg*, 521 U.S. at 720–21 (quotations omitted).

194. *Compare* United States v. Cannabis Cultivator's Club, No. C 98-00085 CRB, 1999 WL 111893, at *1 (N.D. Cal. Feb 25, 1999) (declining to find "fundamental right 'to be free from governmental interdiction of their personal, self-funded medical choice, in consultation with their personal physician, to alleviate suffering through the only effective treatment available for them'"), *and* Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980) (rejecting constitutional right to obtain medication "free of the lawful exercise of the government's police powers"), *with* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 279 (1990) ("But for purposes of this case, we assume that the United States Constitution would grant a competent person a constitutionally protected right to refuse lifesaving hydration and nutrition."), *and* Union Pacific Ry. v. Botsford, 141 U.S. 250, 251 (1891) (recognizing "right of every individual to the possession and control of his own person, free from all restraint or interference of others").

195. *See* Barnett, *supra* note 191, at 1488–93 (describing difficulty of rights being recognized as fundamental under *Glucksberg* test); Randy Barnett, *Reefer Madness*, WALL ST. J., Mar. 16, 2007, at A13 (discussing Ninth Circuit medical marijuana decision).

196. *See infra* Part IV.A (evaluating various formulations of right).

Another line of reasoning with which the panel grappled unconvincingly was the relevance of FDA drug regulation in the second two prongs of the *Glucksberg* analysis: "deeply rooted" and "implicit in the concept of ordered liberty." To rebut the plaintiff's assertion that a right to take drugs free from government interference was firmly rooted in the nation's traditions and history, the government pointed out the long-standing history of FDA regulation.[197] The panel noted, however, that the FDA has been in existence only since 1906, regulated drug safety only since 1938, and regulated drug efficacy only since 1962.[198] According to the court, the right to *unrestricted* access to drugs is longer standing than government regulation of drugs.[199] The court further found that the Abigail Alliance's claimed right "also falls squarely within the realm of rights the Supreme Court has held are 'implicit in the concept of ordered liberty.'"[200] The court therefore held that "a terminally ill, mentally competent adult patient's informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Clause."[201] The majority failed to acknowledge the awkwardness of simultaneously denying the relevance of FDA regulation when it came to the *Glucksberg* analysis, but then explicitly incorporating FDA regulatory requirements into the definition of the right.

Having recognized a fundamental right, the panel remanded to the district court to apply the Due Process balancing test. On remand, the government would have had to meet a strict scrutiny standard, because of the fundamental nature of the right at issue, in establishing that "FDA's policy barring access to post-Phase I investigational new drugs by terminally ill patients is narrowly tailored to serve a compelling

197. *Abigail Alliance*, 445 F.3d at 480 (quoting appellee's brief).

198. *Id.* at 481–83 (discussing history of FDA authority to regulate new drugs); *see also* Furmansky, *supra* note 94, at 109–10 (describing history and regulations of the FDA); Greenberg, *supra* note 99, at 302–05 (describing evolution of FDA regulation, with changes prompted by drug-related public health crises, including elixir sulfanilamide, in 1938, and thalidomide, in early 1960s); Salbu, *supra* note 114, at 406–08 (noting same, and compassionate use exceptions prompted by 1980s AIDS crisis).

199. *Abigail Alliance*, 445 F.3d at 483 (quoting Brief for Appellee at 19, *Abigail Alliance*, 445 F.3d 470 (No. 04-5350)) ("Despite the FDA's claim to the contrary, therefore, it cannot be said that government control of access to potentially life-saving medication 'is now firmly ingrained in our understanding of the appropriate role of government.'"). *But see id.* at 494–95 (Griffith, J., dissenting) (discussing nation's longstanding history of drug regulation).

200. *Id.* at 483–84.

201. *Id.* at 486.

governmental interest."[202] The case never reached the district court for reconsideration, however, because the en banc court reversed.

2. En Banc Decision

The en banc opinion, authored by Judge Griffith, the panel dissenter, reframed the issue, not as a personal autonomy right to control one's body, but as a right to access something currently inaccessible—drugs that the FDA has not approved for marketing.[203] "This case presents the question whether the Constitution provides terminally ill patients a right of access to experimental drugs that have passed limited safety trials but have not been proven safe and effective."[204] On that question, the court concluded that "the Alliance has not provided evidence of a right to procure and use experimental drugs that is deeply rooted in our Nation's history and traditions."[205] The court rejected the Abigail Alliance's suggestion that the only question was drug efficacy, not safety, noting that all three (and sometimes four) Phases of FDA new drug approval address safety.[206]

The ongoing relevance of safety testing, even after Phase I, supported the en banc court's conclusion that unregulated access to experimental drugs was not firmly rooted in the nation's history and tradition. The FDA's regulation of drug safety, in particular, has been in place at least thirty years longer than regulation of drug efficacy.[207] In any event, although the FDA may be a relatively new federal agency, state and federal regulation of drugs dated back to the colonies.[208] Moreover, the court acknowledged the difficulty of defining a fundamental right based on a regulatory scheme, when Congress or the FDA at any time could

202. *Id.*

203. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 697 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008).

204. *Id.* (describing plaintiff's issue).

205. *Id.* at 711.

206. *Id.* at 698 & n.2 ("Clinical testing for safety and effectiveness requires three or sometimes four phases," including Phase IV, sometimes conducted to develop "additional information about the drug's risks, benefits, and optimal use.") (quotations omitted); *id.* at 708 ("The Alliance seeks access to drugs that are experimental and have not been shown to be safe, let alone effective at . . . prolonging life.").

207. *Id.* at 703 ("The Alliance's efforts to focus on efficacy regulation ignored one simple fact: it is unlawful for the Alliance to procure experimental drugs not only because they have not been proven effective, but because they have not been proven safe.").

208. *Id.* at 703–06 (beginning with the Colony of Virginia's 1736 act addressing "dispensing of more drugs than was 'necessary or useful' because that practice had become 'dangerous and intolerable'") (citation omitted).

amend the statute or rules, just as the FDA recently proposed in liberalizing access to experimental drugs:

> How can a constitutional right be defined by an administrative regulation that is subject to change? . . . [W]e find it difficult to imagine how a right inextricably entangled with the details of shifting administrative regulations could be "deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty."[209]

Specifically, the court rejected the Abigail Alliance's attempt to distinguish an asserted constitutional right to drugs deemed "safe" but not necessarily effective, from a right to access drugs that may not be safe—that is, drugs that have not passed Phase I.[210] The long history of government activity in medical and drug regulation[211] undermined the Abigail Alliance's contention that "the government never interfered with the judgment of individual doctors about the medical efficacy of particular drugs until 1962."[212] The court further noted consistent rejection of similar challenges to the FDA's authority to regulate access to drugs, including *Rutherford* in 1979 and recent medical marijuana cases.[213] Moreover, no circuit courts have recognized an "affirmative access claim" to particular medical treatments that the government restricts or regulates.[214]

The en banc court also rejected the Alliance's reliance on common law doctrines of necessity, intentional interference with rescue, and self-defense to support the claim of a fundamental right. Unable to deny the long-standing recognition of those judicial doctrines, the court noted

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209. *Id.* at 702 n.6 (quoting Washington v. Glucksberg, 521 U.S. 702, 721 (1997)) (quotations omitted); *see also id.* at 710 n.17 (discussing FDA regulation, prior judicial challenges, and suggesting that political branches are better suited than courts to address the Abigail Alliance's concerns); *see, e.g.*, 21 C.F.R. §§ 312.34 ("Treatment use"), 314.36 ("Emergency use") (2008); Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147 (Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312).

210. *Abigail Alliance*, 495 F.3d at 703.

211. *Id.* at 703 n.7, 704 (tracing history of drug regulation in England, beginning in 1447); *id.* at 706 & n.12 (discussing history of government regulation of scientific, mathematical, and medical advances).

212. *Id.* at 703 (citation and emphasis omitted).

213. *See id.* at 708–10 (citing cases rejecting statutory, if not constitutional, challenges to the FDA's authority); *see* Gonzales v. Raich, 545 U.S. 1 (2005) (upholding constitutionality of federal Controlled Substances Act (CSA) over challenge by California marijuana users and makers); United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483 (2001) (rejecting claimed implied medical necessity exception to federal CSA).

214. *Abigail Alliance*, 495 F.3d at 710 n.18; *see* Hill, *supra* note 23, at 303–04 (discussing *Rutherford*, *Whalen v. Roe*, and other cases examining right to make medical treatment decisions).

multiple exceptions and limitations on their application.[215] The necessity defense failed to override the government's interest in regulating marijuana under the Controlled Substances Act.[216] The interference with rescue claim requires proof that a third party was prevented from giving *necessary* assistance to the victim. According to the court, the "necessity" element was not met on the *Abigail Alliance* facts because the patients had not demonstrated that experimental drugs were safe, much less effective, in prolonging their lives.[217] Therefore, there was no interference with "necessary" rescue. The self-defense claim was not apt because patients' taking of experimental drugs was not analogous to their using reasonable force against an aggressor to defend themselves from immediate bodily harm.[218] Accordingly, none of the common law claims supported the claimed fundamental right.[219]

The panel majority, Chief Judge Ginsburg and Judge Rogers, now writing the en banc dissent, faulted the court's opinion for "reflect[ing] a flawed conception of the right."[220] Judges Ginsburg and Rogers here framed the purported right even more broadly than in their panel opinion. They described the Abigail Alliance's argument as not merely the right to use, obtain, decide, or self-determine, but the "right of a person to save her own life," which they concluded is certainly firmly rooted in the nation's history and tradition—beginning with Samuel Adams, Blackstone, and others who recognized the right of self-preservation as the "first law of nature" or "principal or primary" rights.[221] So framed, it is much harder to argue that the right is not firmly rooted or implicit in the concept of ordered liberty. But the dissent's description is certainly not "narrow" and arguably not "careful." More accurately, the Abigail Alliance asked the court to recognize a right to obtain, from a third party who may or may not be willing to provide, through at least two additional layers of regulatory oversight, a drug that suggests some hope but no promise of alleviating symptoms and of prolonging or saving their lives.

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215. *Abigail Alliance*, 495 F.3d at 707.

216. 21 U.S.C. § 801 (2006); *see Abigail Alliance*, 495 F.3d at 708 (discussing *Oakland Cannabis Buyers' Coop.*, 532 U.S. at 490–91).

217. *Abigail* Alliance, 495 F.3d at 708–09.

218. *Id.* at 709–10. The court distinguished Abigail Alliance's claim from abortion to save the life of the mother, a better example of medical self-defense. *See also* Volokh, *supra* note 22, at 1824–28 (discussing analogies). *But see* Snead, *supra* note 145, at 1 (refuting abortion and self-defense analogies).

219. *Abigail Alliance*, 495 F.3d at 711.

220. *Id.* at 714 (Rogers & Ginsburg, JJ., dissenting).

221. *Id.* at 714, 717; *see id.* at 701 n.5 (suggesting that "dissent has recast the Alliance's proposed right . . . into a right 'to try to save one's life'").

With respect to the common law doctrines, the dissent properly criticized the court for prematurely delving into the issue of the government's justification for interfering with the right, fundamental or otherwise. That balancing test would be the issue on remand to the district court, had the panel decision stood.[222] The court should not have reached that issue without first clearly resolving the threshold question of whether the fundamental right exists in the first place.[223] Indeed, the majority conflated its consideration of the common law theories by asserting that the government could limit those rights, with proper justification.[224] That common law privileges or protections for personal autonomy are not absolute and subject to exceptions does not disprove their existence as rights.[225] The en banc's approach is the easy way out. It is not difficult to recognize that, in many cases, the FDA has good reasons for limiting individual rights and restricting access to drugs that may not be safe or effective. But the government's justification was not yet ripe before the D.C. Circuit.[226] Even under strict scrutiny, the FDA's new drug approval process and restrictions on access to particular medical treatments likely would be upheld, as they had been under other challenges.[227]

In its petition for certiorari, the Abigail Alliance sought due process recognition of "the right of a terminally ill patient . . . to attempt to save her own life by deciding . . . whether to seek access to" experimental drugs that the FDA deems "safe and promising enough for substantial human testing."[228] The government's brief in opposition framed the issue as "[w]hether terminally ill patients who lack alternative treatment options have a constitutional right to purchase unapproved investigational drugs that have not been shown to be safe or effective and that have not been authorized for treatment uses by the Food and Drug Administration."[229]

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222. *See supra* text accompanying note 202 (citing panel's instructions on remand).

223. *See Abigail Alliance*, 495 F.3d at 714.

224. *See id.* at 707.

225. *See id.* at 708–10; *see also* Snead, *supra* note 145, at 1 (rejecting analogies, in part, because "the government [has] routinely restrict[ed] the instrumentalities of self-help in the name of avoiding what it takes to be more significant harms").

226. *See* Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470, 486 (2006) (remanding to district court); *id.* at 477 (describing strict scrutiny test); *see also* Washington v. Glucksberg, 521 U.S. 702, 721 (1997); Reno v. Flores, 507 U.S. 292, 301–02 (1993); Volokh, *supra* note 22, at 1837 (acknowledging that medical self-defense right may have limits and noting remand to determine "whether the FDA rules were narrowly tailored to some compelling government interest").

227. *See, e.g.*, *Abigail Alliance*, 495 F.3d at 710–11 n.18 (citing cases).

228. Petition for a Writ of Certiorari at 3, Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 128 S. Ct. 1069 (2008) (Mem.) (No. 07-444), 2007 WL 2846053, at *i.

229. Brief for the Respondents in Opposition at 3, *Abigail Alliance*, 128 S. Ct. 1069 (No. 07-444),

The Supreme Court summarily denied review, letting the en banc decision stand.[230] Unless other litigants renew the claim on new facts—likely before the D.C. Circuit, where the issue has been amply considered and reconsidered—the en banc decision remains the final judicial word on the proposed fundamental, constitutional right of access to experimental treatment.

So, what next? Bills are pending in both the U.S. House of Representatives and Senate. The FDA's proposed rules are still forthcoming. Public pressure to expand access to experimental drugs continues to mount. What is the "right" at stake, if not a fundamental, constitutional right for patients? The next Part considers other, possible ways of thinking about the rights implicated, urging that the public health right should take precedence. Brief consideration of the public health right in relation to other recent policy debates concludes this Article.

IV. THE PUBLIC HEALTH RIGHT

After the *Abigail Alliance* dust settled, we are left with the correct decision and unremarkable declaration that there is no fundamental, constitutional, substantive due process right for terminally ill patients to obtain drugs that have passed only Phase I of the FDA's new drug approval process. But the court's reasoning is less than satisfying. Reframing the issue and considering the various players' interests points to the public health right as a better way to support the conclusion. Whether the public health right can rationally be invoked to justify other recent regulations that impinge on individual rights remains ripe for discussion.

A. Redefining the Right

The en banc court ultimately declined to recognize a "right of access" to drugs that have begun the FDA's new drug approval process but are not yet deemed safe and effective. The panel recognized a "right to control one's body," relying on *Cruzan* and *Casey*.[231] But *Cruzan* is inapposite because freedom *from* having things done to one's body is not the same as an affirmative right *to* ingest something into one's body. A negative right to be free from government interference is distinct from an affirmative

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2007 WL 4458896, at *1.

230. *Abigail Alliance*, 128 S. Ct. 1069.

231. *Abigail Alliance*, 445 F.3d at 472, 476, 479, 484.

right to property, privileges, and protection from the government.[232] Similarly, saying that government cannot do things that cause injury or inflict harm on individual members of society is not the same as saying that government must ensure a healthy state of being or access to health care.[233]

It may be difficult to deny the right of an individual to ingest ineffective, even harmful drugs, other than on paternalistic grounds of preventing harm to the individual. If we respect people's liberty to know what is in their own best interest, then surely they should be allowed to take the drug.[234] When the person is dying and has nothing to lose, the claim seems even harder to deny.[235] Indeed, the panel drew just that distinction, limiting the recognized right to terminally ill patients who had exhausted all other options. But the court did not explain the distinction. Why should patients who seek access to potentially life-saving drugs have any greater right than patients who seek access to potentially life-enhancing drugs? Why should nonterminal patients not be given the same freedom to control their bodies? If anything, it seems that dying patients warrant greater government protection, given their desperate state and potential for impaired judgment and improper influence.[236]

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232. *See* Parmet, *supra* note 29, at 271–77, 304–06 (questioning conventional assumption that U.S. constitutional law primarily supports negative—not positive—rights, and discussing implications for public health).

233. *See* DeShaney v. Winnebago County Dep't of Soc. Servs., 489 U.S. 189, 195 (1989) (holding no substantive due process violation for harm to a foster child by foster parent because "nothing in the language of the Due Process Clause itself requires the State to protect the life, liberty, and property of its citizens against invasion by private actors"); *see also supra* note 15 and accompanying text (distinguishing "right to health" and "public health right").

234. *See* Epstein, *supra* note 34, at 758–59 ("The presumptions here should be set strongly in favor of allowing individuals to continue to take those drugs of choice even as other individuals, quite properly, decide to follow the opposite course of action."); Furmansky, *supra* note 94, at 108 (beginning with popular view, but ultimately debunking it: "The appeal of this view is obvious. Why shouldn't someone who is dying anyway be given the choice to assume the responsibility and risk of making the decision to try a drug that has not passed extensive testing in humans?"); *see also* Brief for the Respondent's at 42–43, United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483 (2001) (No. 00-151), 2001 WL 173541, at *42–43 ("[T]hese patients have a fundamental right to be free from government interdiction of their personal self-funded medical decision, in consultation with their physician, to alleviate their suffering through the only alternative available to them."). *But see* Volokh, *supra* note 22, at 1828–29 (suggesting that terminally ill patients should have a "right to ingest potentially lifesaving medicines without threatening anyone else's life" but that "[t]his is not a general autonomy argument, premised on the theory that all people should be free to put whatever they choose into their bodies," and offering medical self-defense as alternate rationale).

235. *See* Annas, *supra* note 103, at 408 (quoting National Cancer Institute spokesperson about calls to hotline, pleading access to drugs: "What the callers are saying is, 'Our mother, our brother, our sister is dying at this very moment. We have nothing to lose.'").

236. *See* United States v. Rutherford, 442 U.S. 544, 558 (1979) (rejecting suggestion that "Congress could reasonably have determined to protect the terminally ill, no less than other patients,

At the same time, the panel bought into certain patient-protective controls, even for dying patients, under the FDA's regulatory scheme.[237] First, the court allowed access only to drugs that passed Phase I, which the panel took to be conclusively safe. Apparently dying patients may incur the risks of drugs that might not work effectively, but not drugs that might harm or kill them. Second, the court required a physician intermediary between the patient and pharmaceutical company. The court trusted patients to know their own best interests—to a point. They may access investigational drugs only after a conversation with their doctors. Why not allow OTC access to investigational drugs? If the issue was that the FDA alone was standing in the way of patients' fundamental right to life, then it is hard to accept the panel's insistence on leaving some FDA paternalistic controls in place.[238]

Another difficulty with the "right to use" or "right of control over one's body" line of reasoning is that the patients asserted a right to ingest substances not in their possession or publicly available. They could not grow the drugs themselves, like they could marijuana, or otherwise possess or obtain them without involving another party.[239] Rather, the

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from the vast range of self-styled panaceas that inventive minds can devise"); Jacobson & Parmet, *supra* note 72, at 207 ("As the government argued to the panel, terminally ill patients are particularly vulnerable to promises that unproven treatments will be effective.").

237. As discussed above, precedent compelled the court to conclude that the FDA's authority was no different for terminal and nonterminal patients. *See supra* notes 94–96; *see also Rutherford*, 442 U.S. at 553.

238. *See* Epstein, *supra* note 34, at 747–48 (concluding that the FDA's "entire effort to make better judgments on what treatments should be used and why smacks of an unthinking paternalism," instead urging "downstream, not upstream" controls by allowing products to reach the market and individual users to decide); Leaf, *supra* note 105 (discussing "how our national obsession with drug safety is killing people"); Henry I. Miller, *Paternalism Costs Lives*, WALL ST. J., Mar. 2, 2006, at A14.

One commentator distinguishes "hard" and "soft" paternalism in public health. "Hard" paternalism leaves the individual with no choice at all about engaging in risky conduct, for example, mandatory helmet laws. "Soft paternalism legitimizes intervention . . . where the individual's decision to engage in that conduct is not factually informed, not adequately understood, coerced, or otherwise substantially cognitively or volitionally impaired." Requiring prescriptions for drugs is "soft" paternalism because the patient lacks information to make a fully autonomous decision. *See* Thaddeus Mason Pope, *Is Public Health Paternalism Really Never Justified? A Response to Joel Feinberg*, 30 OKLA. CITY U. L. REV. 121, 122–23 & n.3 (2005) (analyzing JOEL FEINBERG, HARM TO SELF: THE MORAL LIMITS OF THE CRIMINAL LAW (1986)).

239. The court made a similar observation in *Carnohan*, regarding Laetrile. *See* Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980) ("We need not decide whether Carnohan has a constitutional right to treat himself with home remedies of his own confection."); United States v. Cannabis Cultivator's Club, No. C 98-00085 CRB, 1999 WL 111893, at *1 (N.D. Cal. Feb 25, 1999) (not deciding whether patients "have a right to treat themselves with marijuana which they themselves grow" because *Carnohan* holds no right to obtain); *see also* Mugler v. Kansas, 123 U.S. 623 (1887) (rejecting argument that police power does not extend to regulating citizen's manufacturing beer for his own use because public health, public morals, and public safety nevertheless may be endangered).

drugs they wanted to take were developed under patent protection by pharmaceutical companies. In order to exercise the personal autonomy right, a patient would necessarily have to involve a third party—the drug company.

Accordingly, the panel dissent and en banc court conceived of a "right to access" or "right to obtain" the drugs that is arguably more accurate.[240] As Judge Griffith urged: "[A] tradition [of] protecting individual *freedom* from life-saving, but forced, medical treatment does not evidence a constitutional tradition of providing affirmative *access* to a potentially harmful, and even fatal, commercial good."[241] The panel simplified the question by assuming a willing drug company, willing patient, and willing physician. Accordingly, there was no issue of compelling or requiring access to the drug. But what if the manufacturer did not want to sell its experimental drug or lacked production capacity to meet demands? As a necessary corollary of the right to access or obtain drugs, would the government require drug companies to sell their investigational drugs to terminally ill patients? One might counter that recognizing a right to abortion does not compel a doctor to perform the procedure,[242] a pharmacist to prescribe the morning-after pill,[243] or the government to pay for abortions.[244] But those examples are distinguishable, as long as there is another avenue for exercising the right.[245] With experimental drugs, there usually is no other way to get the drugs.

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240. *See generally Carnohan*, 616 F.2d 1120; *Cannabis Cultivator's Club*, No. C 98-00085 CRB, 1999 WL 111893.

241. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470, 495 (2006) (Carth, J., dissenting).

242. *See, e.g.*, 42 U.S.C. § 300a-7 (2000) (providing that receipt of certain federal funds does not require "such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions"); GA. CODE ANN. § 16-12-142 (2007) ("[A]ny person who states in writing an objection to any abortion or all abortions on moral or religious grounds shall not be required to participate in procedures which will result in such abortion; and the refusal of the person to participate therein shall not form the basis of any claim for damages on account of such refusal or for any disciplinary or recriminatory action against the person.").

243. *See* Tom C. W. Lin, *Treating an Unhealthy Conscience: A Prescription for Medical Conscience Clauses*, 31 VT. L. REV. 105 (2006); Jennifer E. Spreng, *Pharmacists and the "Duty" to Dispense Emergency Contraceptives*, 23 ISSUES L. & MED. 215 (2008); Julie Cantor & Ken Baum, *The Limits of Conscientious Objection—May Pharmacists Refuse to Fill Prescriptions for Emergency Contraception?*, 351 NEW ENG. J. MED. 2008, 2009 (2004).

244. *See* Harris v. McRae, 448 U.S. 297 (1980) (state Medicaid programs are not required to pay for abortions); *see also* Maher v. Roe, 432 U.S. 464 (1977); Beal v. Doe, 432 U.S. 438 (1977).

245. *See, e.g.*, Webster v. Reprod. Health Servs., 492 U.S. 490 (1989) (state ban on abortions in public hospitals was not unconstitutional because patients could still obtain abortions from private providers).

Experimental drugs, by regulatory design, are in the sole, patented protection of the company that develops them.[246] If that company's drug is the one that a patient wants, the one to which she has a fundamental constitutional right, how else can she exercise the right except by compelling the company to hand it over? Perhaps the patient could obtain an injunction, requiring the company to give or sell the drug. Or perhaps the government would exercise some form of personal property eminent domain to seize the drugs for the benefit of terminally ill patients. In the real property context, the Court has upheld a compelled transfer from one private party to another when it benefited the public.[247] At least one court, however, expressly rejected chronically ill patients' claim to compel a drug company to provide them with investigational drugs.

A Sixth Circuit case, *Abney v. Amgen*,[248] involved Parkinson's drug trials, which the manufacturer and trials sponsor, Amgen, called off before they were completed. Patients enrolled in the trials, who believed they had experienced marked improvement from the investigational drugs, sued Amgen on state law theories, including breach of contract, breach of fiduciary duty, and detrimental reliance, to compel access to the drugs.[249] Amgen claimed that it ceased the trials because of safety concerns.[250] The patients suspected that they stopped because the product would not be lucrative.[251] If we respect the pharmaceutical company's fundamental property rights, its reasons for ceasing the trials should not be relevant to the analysis.[252] The court rejected all of the plaintiffs' common law claims, finding no contractual or other binding obligation on the drug company—in other words, no "right" for the patients to obtain the drugs against the manufacturer's willingness to provide or sell them.[253] Any other result

246. *See* Richard A. Epstein, *Justified Monopolies: Regulating Pharmaceuticals and Telecommunications*, 56 CASE W. RES. L. REV. 103, 109–25 (2005) (making case for pharmaceutical patents); Sheila Kadura, Note, *Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements Between Branded- and Generic-Pharmaceutical Companies?*, 86 TEX. L. REV. 647, 648–50 (2008) (suggesting that only 40% of pharmaceutical inventions would be developed without patent protection, compared to 86% for inventions in general, and describing operation of and incentives underlying U.S. patent system for pharmaceuticals).

247. *See* Kelo v. City of New London, 545 U.S. 469 (2005).

248. 443 F.3d 540 (2006).

249. *See id.* at 545 (listing claims); *see also* Epstein, *supra* note 34, at 757 (describing scenario and "howls of protests from unhappy patients").

250. *Abney*, 443 F.3d at 544.

251. *See id.* at 545.

252. *See* Epstein, *supra* note 34, at 758 ("And there is, in my view, no duty for [Amgen] to invest further in a drug that may promise them the unhappy trifecta of small markets, lagging profitability, and high liability exposure."). *But see* Anand, *supra* note 74 (describing outrage that drug company failed to provide drugs to dying children, believing profit motivations).

253. *Abney*, 443 F.3d at 553 (affirming district court's denial of preliminary injunction).

would seem to violate the manufacturer's right to exclusive enjoyment of its intellectual and personal property.[254]

Maybe the patients' right to obtain drugs could be justified on a hierarchy of rights, according to which the right to life trumps the right to property. Who could argue that the "greedy" pharmaceutical company's interests are more important than patients' right to obtain potentially life-prolonging treatment?[255] There is support for the argument that life trumps property in common law self-defense[256] and necessity doctrines.[257] The question becomes more complicated when the pharmaceutical company acts out of concern for safety, pulling the drugs based on adverse events. The debate is no longer over life versus property, but relative degrees of risk and safety and who decides whether patients should be permitted to encounter the risks.[258]

That debate suggests another way to reframe the issue. Maybe the balance is not life versus property, but life versus *lives*. Does the possibility of saving the life of one, or a few, terminally ill patients, by giving them access to an experimental drug now, outweigh the interests of countless future lives potentially saved or enhanced if the drug undergoes all three phases of "gold standard" clinical trials before it is made available to the public? The examples discussed above—nonexistent, rushed, abbreviated, incomplete, and nonrandomized clinical trials[259]—demonstrate the value of the scientific method and rigorous new drug approval process, for both current and future patients who may take the drug. Even clinical trials on drugs that are denied approval or are pulled

254. Patent law grants an innovator "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited term of years. 35 U.S.C. § 154(a) (2006); *see* Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (indicating that a patent gives the inventor the right to exclude others from profit from that invention, and citing cases).

255. *See* Furmansky, *supra* note 94, at 108 ("Ask any ten people in the street whether terminal patients, destined to die . . . should be allowed access to investigational drugs . . . . An overwhelming majority will say yes."); *see also* Sheryl Gay Stolberg & Jeff Gerth, *How Companies Stall Generics And Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at 1 (quoting Hatch-Waxman Act drafter on pharmaceutical companies' delay tactics to extend patent protection: "It's the evolution of greed versus need.").

256. *See, e.g.*, Katko v. Briney, 183 N.W.2d 657 (Iowa 1971) (denying self-defense claim for use of deadly force by spring-loaded gun to defend unoccupied building and antique mason jars).

257. *See, e.g.*, Putnam v. Ploof, 71 A. 188 (Vt. 1908) (holding property owner liable for damage to boat, where owner moored out of necessity without permission during sudden tempest).

258. *Compare* Epstein, *supra* note 34, at 757 (suggesting that patients should choose), *with* Annas, *supra* note 85, at 792 (suggesting that the FDA should choose).

259. *See supra* notes 116–48 and accompanying text (describing scenarios involving DES, ABMT/HDC, AZT, BiDil, and other drugs).

before all three Phases are completed—as most are[260]—may produce scientific data useful for developing other treatments. The research subject enrollment and random sampling problems would be exacerbated if patients could obtain potentially life-saving drugs without enrolling in trials and risking placebos or conventional treatment. Who would be left in the trials?[261]

It is disingenuous to argue that some risk-adverse patients might prefer to wait for drugs to be fully tested before taking them when that was precisely the complaint of the terminally ill plaintiffs in *Abigail Alliance*: they would literally die waiting.[262] Therefore, preapproval marketing removes a potentially significant set of data from the safety and efficacy trials, undermining the whole process.[263] How can we justify allowing the rights of a few dying patients to deny the rights of countless others who also have the disease, or may develop it sometime in the future, to benefit from the scientific knowledge gained by studying the drugs? That

260. Thirty percent of drugs are deemed too dangerous to pass beyond Phase I, and only one-third of drugs that pass Phase I complete Phase III. *See* Furmansky, *supra* note 94, at 110. For cancer drugs, only five percent of drugs approved for human trials are approved for patient use. *See* Jacobson & Parmet, *supra* note 72, at 206 (listing safety, efficacy, and financial concerns as reasons for abandonment).

261. *See* Kovatis, *supra* note 94, at 166 ("It would also be difficult to recruit patients for clinical trials if they can obtain the drugs from their own doctors without the restrictions and red tape of a clinical trial."); Groopman, *supra* note 72, at 47 (noting that expanded access would make it difficult to recruit patients for trials, for "what patient would want to risk receiving the standard treatment in a trial when he could get the experimental drug directly from his doctor?"). Real-world evidence, especially AZT trials, refutes hypothetical speculation that sufficient numbers of patients will nevertheless enroll and that, therefore, the "need-to-test" does not justify stripping the individual's right of medical self-defense. *See supra* notes 126–30 and accompanying text; Volokh, *supra* note 22, at 1829–30 (refuting "need-to-test" argument).

262. One commentator's response to the concern that no patients would enroll in clinical trials notes theoretically that "variance in risk assessment," "hope or faith," and "altruism" may influence some patients to enroll. Salbu, *supra* note 114, at 433. That argument is also unconvincing given the overwhelming anecdotal descriptions of terminally ill patients' desperate situations. Salbu, *supra* note 114, at 427–33. "Variance in financial resources" and financial incentives for clinical trial participation is offered as another way to ensure enrollment. *Id.* at 433–34. Paid research subjects and variance in financial resources only exacerbate the public health harms. *See supra* notes 137–38.

263. *See* Soc'y of Clinical Trials, *supra* note 80, at 155 (noting that "the most reliable data . . . is that obtained from prospective randomized clinical trials"); Jacobson & Parmet, *supra* note 72, at 206–07 ("Without random assignment of patients to receive either the new drug or a placebo or comparator drug, the true efficacy and adverse-event profile of an investigational drug will be unknown."). Some commentators argue that usable information about drugs could be obtained from expanded access to drugs, outside of controlled clinical trials. *See* Salbu, *supra* note 114, at 432 (suggesting "informal observations" and word of mouth will enhance information gathering because "drugs will be consumed more quickly"); Leibfarth, *supra* note 99, at 1306 ("Although feedback from individual patients may not provide quantitative data, it may produce both research strategies and hypotheses for further study.").

conception of the *Abigail Alliance* issue approaches the concept of the public health right, as explained more fully in the next Part.

B. The Public Health Right

The public health right contemplates that the public, as a body, merits protection from interference by individual members of society. In the case of access to experimental drugs, the potential harm to so many other patients who also await the promise of a cure or benefit from scientific developments, justifies the decision to deny access to experimental drugs to currently terminally ill patients. The *public* health right, as used here, is distinct from the "right to health" because it does not aim to ensure an affirmative right to access health-care services, health protection, or aspirational standards of health for individuals.[264] The public health right is grounded in the "old" public health, which aims at collective action problems, not the "new" public health, which aims broadly to ensure the "underlying determinants" for people to be healthy.[265]

Rather, the public health right, like the individual autonomy right relied on by the *Abigail Alliance* plaintiffs and the panel, is a negative right to be protected from interference by the exercise of others' rights. The competing uses are not one individual versus another, but select individuals versus the body politic. As in any other unresolvable competing uses conflict, the government typically referees the dispute and decides which right prevails.[266] Here, the en banc D.C. Circuit, without using these terms, ruled in favor of the public against the individual patients. Strong emphasis should be placed on the qualifying word "unresolvable" because the dispute between patients' interest in taking experimental drugs and the public's interest in pharmaceutical research is not amenable to private resolution.[267] Accepting the en banc court's

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264. *See supra* note 15 and accompanying text (distinguishing "public health right" and "right to health"). Accordingly, this Article's reference to the "public health right" must be distinguished from the term's use by other commentators who begin with the assumption that there is an *individual* right to health and propose the "public health right" as a way to collectively ensure the individual right. *See, e.g.*, Meier & Mori, *supra* note 15, at 137 ("If individuals are bearers of a human right to health, societies then become the only possible bearers of a collective right to public health, with the collective right necessary to fulfill the individual right."); Ruger, *supra* note 15, at 44, 48 (describing the "right to health as an ethical demand for equity in health," depending on "societal obligations, both State and non-state, for progressive realization of this right").

265. Meier & Mori, *supra* note 15, at 123 (citing Lawrence Gostin).

266. *See, e.g.*, *supra* notes 30–38 and accompanying text (discussing city sanitation example).

267. *See* Epstein, *supra* note 6, at 1423 (traditional public health interventions justified for problems that "do not lend themselves effectively to either market solutions or to private actions in

decision denying their right, the patients have already shown that litigation is ineffective. Their case remains dismissed for failing to identify an enforceable legal right. Likewise, market solutions do not seem to help them secure their asserted right, short of buying experimental drugs on the gray market, like many AIDS patients in the past.[268] And it is hard to envision what contract they could offer to the public to give up *its* public health right.

To return to the familiar analogy, allowing access to drugs before full clinical trials depletes the "commons" of the scientific process for developing new drugs by allowing "overgrazing" by a few justifiably desperate and terminally ill patients.[269] As discussed, one individual's decision to ingest a particular drug affects far greater interests than his or her own bodily integrity.[270] Taking an experimental drug is more akin to avoiding vaccination than avoiding sunscreen.[271] Unlike the sunscreen analogy, whereby one sunbather's decision to go bare leaves another person's choice to wear sun block unimpaired, Abigail's decision to expose herself to the risk of untested drugs imposes harm on the public's interest in having drugs scientifically studied. One individual's decision to avoid vaccination might have a negligible effect on public health, but the cumulative effect of more and more people opting out of vaccinations undermines "herd immunity" and erodes the commons of a disease-free society.[272] Similarly, the cumulative effect of more and more people opting in for early access to investigational drugs erodes the commons of "scientific research on the efficacy of pharmaceuticals."[273] Scientific knowledge and medical research is a public good in the sense that no individual has the capacity to produce it without collective action, just as my neighbors and I cannot secure a sanitary city on our own.[274] Moreover, the benefits of scientific research inure not just to me but to the public (the body politic). In other words, expanded access to experimental drugs is a

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tort"); Annas, *supra* note 85, at 795 ("Experimental drugs are not a consumer good appropriately governed by the free market.").

268. *See supra* notes 109, 128 (describing patients' resourcefulness in securing drugs).

269. *See* Ruger, *supra* note 15, at 50.

270. *But see* Epstein, *supra* note 34, at 758–59 ("The decision to ingest a given drug is the polar opposite of any public goods or collective action problem that might call for state intervention.").

271. *See supra* notes 48–51 (drawing analogies).

272. *See supra* notes 43–47 (describing "Tragedy of the Commons" concept and vaccine analogy).

273. *See supra* note 47 (discussing recent trend of parents opting out of mandatory vaccination).

274. *See* Ruger, *supra* note 15, at 50; *see also* Epstein, *supra* note 6, at 1434 (defining public good as "a good which has to be supplied to all if it is to be supplied to even one"). The public good at issue is deliberately identified as scientific knowledge and research, not the pharmaceutical products themselves, which are expressly protected as private monopolies under patents. *See supra* notes 246, 254 (regarding pharmaceutical patent laws).

"public bad" in the sense that the public is deprived of its choice to investigate drugs fully.[275]

Restricting access to experimental drugs for terminally ill patients is justified by the public health right, but not on the paternalistic grounds that many suggest is the basis for the FDA's regulatory authority.[276] The public health right recognizes an interest in fully testing pharmaceutical products, beyond preventing patients from wasting money and endangering their health by purchasing "snake oils." The objective is not merely protecting patients from their own bad decision to consume potentially harmful, or merely expensive and useless, drugs. Nor is it simply a matter of the *Abigail Alliance* plaintiffs hypothetically preferring to risk skin cancer while leaving the public free to apply sunscreen before going outside. As a practical matter, the public cannot secure its right without restricting access to experimental drugs.[277]

Does the public health right really justify relegating dying patients to the status of research guinea pigs so that the public might possibly enjoy some medical benefit in the future? Does the public's interest in cold science outweigh human compassion for dying patients? We must conclude: Yes. There is no suggestion that the principle goal of the FDA new drug approval process or of accepted clinical research standards is treatment rather than science.[278] The response is not as draconian as suggested; the FDA does allow access to experimental drugs under narrow "compassionate use" and "emergency" exceptions.[279] Moreover, well-

275. *See* Epstein, *supra* note 6, at 1426 ("In contrast to public goods, public bads are inflicted upon others without their consent, as are communicable diseases and pollution, but not obesity or genetic diseases.").

276. *See, e.g.*, Annas, *supra* note 85, at 792 (justifying the FDA new drug approval process because "the public is in no position to judge the value or usefulness of many medications"); Salbu, *supra* note 114, at 418–20 (critiquing the FDA's "paternalistic model" of drug testing and approval). *See generally* Epstein, *supra* note 34; Cole, *supra* note 18, at 80–81 (describing paternalistic justification for public health interventions); Pope, *supra* note 238, at 121 (evaluating same).

277. *See* Cole, *supra* note 18, at 81 (suggesting that "correct justification" for immunization is paternalism unless "immunization of one person will protect others who cannot, as a practical matter, protect themselves").

278. *See supra* notes 97–101 and accompanying text (noting patients' and researchers' competing objectives); Annas, *supra* note 85, at 773 ("Perhaps the major source of controversy surrounding [AIDS drug trials] is that the investigators see these trials as *research* designed to provide generalizable knowledge that may help others, while most individuals suffering with AIDS see these trials as *therapy* designed to benefit them.").

279. *See* 21 C.F.R. §§ 312.34 ("Treatment use"), 314.36 ("Emergency use") (2008); Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147 (Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312).

developed ethical rules and guidelines protect human subjects in clinical research.[280]

The outcome still may seem harsh. Under the social contract model, do the benefits of joining society really outweigh the price of being denied access to potentially life-saving treatment and being "used" for scientific study? Choosing to remain a member of society and enjoying its other protections may require compromising some individual interests,[281] but is this too much? The question is a straw man because there is no natural "right" to experimental drugs with which government is interfering. The patients seek more than simply a self-executing "right to life," right to avoid having something done to one's body like *Cruzan*, or "right to be left alone."[282] Rather, they seek access to something that they cannot produce themselves and that belongs to other members of society. Having already distinguished the individual right to health from the public health right, the argument that joining society affirmatively entitles members to health, health care, and access to investigational drugs is unavailing.

The public health right also is not based on the "conserving common resources" rationale that may sometimes support seat belt, helmet, and hypothetical obesity or mandatory sunscreen laws.[283] Under that view, the individual choice to avoid wearing a safety device, eat unhealthy foods containing trans fats, or go out without sun block imposes costs on the rest of society by increasing overall health care expenditures. That argument assumes that society will care for the brain injury, melanoma, diabetes, heart disease, or broken limbs. Otherwise, no cost is imposed on society from those individual bad choices. The case of experimental drugs is different. Allowing patients to access drugs before full approval does not require spending common resources on those patients as a result of their risky choice. Indeed, the *Abigail Alliance* litigation, as well as congressional and administrative proposals, all contemplate that patients will pay for the drugs, most likely out of pocket. Health insurers rarely cover experimental treatment, and Medicare may cover patient care costs

280. *See generally* 21 C.F.R. pts. 50, 56 (2008) (regulations for "Protection of Human Subject"). This is the FDA's codification of the "Common Rule." CARL H. COLEMAN ET AL., THE ETHICS OF REGULATION OF RESEARCH WITH HUMAN SUBJECTS 106–24, 143 (2005).

281. *See* Jacobson v. Massachusetts, 197 U.S. 11, 38 (1905) (rejecting individual privilege to avoid vaccination because "the spectacle would be presented of the welfare and safety of an entire population being subordinated to the notions of a single individual who chooses to remain a part of that population").

282. *See supra* Part III.B (describing court opinions' attempts to frame relevant interest); *see also* Picou v. Gillum, 874 F.2d 1519, 1521 (11th Cir. 1989) ("[T]here is no broad legal or constitutional 'right to be let alone.'").

283. *See supra* notes 58–65 and accompanying text (describing theory and examples).

for clinical trials participants but not access to drugs outside of trials.[284] Rather, the "cost" imposed on the public, if access to experimental drugs is expanded, is the distortion of clinical trials and the scientific process. In that sense, denying access to experimental drugs could fit within the conserving common resources rationale. But the commons or public goods rationale for the public health right is more defensible than paternalistic, social contract, or common resources justifications. The concept of a public health right upholds individual choices to expose oneself to risks, as long as public goods (or bads) are not implicated.

Despite baseline deference to individual rights under the public health right, the asserted individual right to experimental drugs cannot stand. Under this new rubric, the panel's self-defense analogy and commentators' medical self-defense theories fail. Self-defense does not allow a person to kill or harm people not threatening her with immediate bodily harm.[285] Nor does self-defense allow a person who fears grave injury to strike wildly and indiscriminately, taking down anyone in his path who threatens possible harm. Accepting the public as the "body" harmed by the Abigail Alliance's alliance, there is no self-defense claim. That body is not threatening the patients with serious bodily injury or death; therefore, there is no justification for lashing out at the public anymore than there was justification for three starving shipwrecked passengers to kill and eat the cabin boy.[286]

For similar reasons, the therapeutic abortion analogy fails,[287] unless the "fetus" is again the body politic that must be sacrificed to save the life of the "mother," the terminally ill patients. Arguably, the claimed right to experimental drugs is an even easier case than traditional self-defense or therapeutic abortion examples because no other life—merely dangerous cancer cells—are being sacrificed to save the individual.[288] But others'

284. *See supra* notes 131–36 and accompanying text (discussing insurance and government coverage for experimental treatment).

285. *See* Abigail Alliance for Better Access to Development Drugs v. Von Eschenbach, 495 F.3d 695, 709–10 (D.C. Cir. 2007) (en banc) (rejecting self-defense analogy because patients were not facing threat of harm from anyone); Volokh, *supra* note 22, at 1821 (acknowledging that self-defense "doesn't include the right to injure the life, liberty, or property of people who aren't the source of the threat"); *see also* Richard M. Cooper, *Response*, 121 HARV. L. REV. F. 31, 32 (2008) (responding to Volokh: "The 'right' of self-defense is not a claim against anyone else, merely a defense against others' charges or claims.").

286. *See* R v. Dudley and Stephens, (1884) 14 Q.B.D. 273.

287. *Abigail Alliance*, 495 F.3d at 709 (discussing plaintiffs' *Roe* and abortion analogy); Volokh, *supra* note 22, at 1824–27 (comparing *Roe* and *Casey* to *Abigail Alliance*).

288. *See* Volokh, *supra* note 22, at 1828 (suggesting that a patient "should have at least an equal right to ingest potentially lifesaving medicines without threatening anyone else's life").

lives, many other lives, *are* being threatened and sacrificed by allowing individuals to exercise the purported right to abort biomedical testing.

The emphasis on "lives" in this explication of the public health right should not be taken to mean that the right turns on a simple utilitarian calculus, justifiably invoked only when the number of lives saved by prohibiting access to experimental drugs outweighs the number of lives saved by expanding access.[289] To rely on that justification would require impossible and unnecessary calculations. Even if those calculations were possible with respect to a particular drug, targeted for a particular illness (for example, Erbitux for head and neck cancer[290]), the task would be made more challenging by the fact that once approved, drugs are often prescribed by physicians for other indications.[291] Moreover, even if the numbers of patients benefiting from a drug could be ascertained, the speculation on lives saved versus lives lost does not stop there. Drug development is a continuous interactive process. A drug that initially appears promising for treating one condition may be abandoned before clinical trials are completed. But research, even if unsuccessful for that study, may hold lessons for future drug development of improved or different products.[292] Those additional lives saved would have to be factored into the utilitarian calculus as well. Even more fundamentally, lives and life expectancies are not commensurable. Simply comparing "lives saved" does not lead to sound policy or regulation.[293]

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289. *See generally* Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533 (1996) (discussing difficulty assessing risks and challenges of comparing lives saved by various, uncoordinated regulatory interventions).

290. *See supra* note 157 (describing underlying facts of *Abigail Alliance*).

291. Although drug companies cannot promote approved drugs for off-label uses without FDA approval for the new use, the FDA has no authority to regulate the practice of medicine. *See* Elizabeth A. Weeks, *Is It Worth the Trouble? The New Policy on Dissemination of Information on Off-Label Drug Use Under the Food and Drug Administration Modernization Act of 1997*, 54 FOOD & DRUG L.J. 645, 647 (1999) (discussing off-label promotion and prescribing). Section 401 of the Food and Drug Administration Modernization Act, discussed in that article, was allowed to sunset on September 30, 2006; the FDA recently proposed new guidance on off-label promotion using peer reviewed articles. Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices; Availability, 73 Fed. Reg. 9,342 (Feb. 20, 2008).

292. *See generally* BARRY WERTH, THE BILLION-DOLLAR MOLECULE (1995) (describing saga of biotech company start-up, pharmaceutical researcher, and academic rivalry to isolate crucial immune system molecule); U.S. FOOD & DRUG ADMINISTRATION, INNOVATION OR STAGNATION? CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS (2004) (describing strategies for increasing new product pharmaceutical product development); Richard Li-dar Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J.L. & TECH. 251 (2008) (identifying incentives for opening research community).

293. *See* Sunstein, *supra* note 289, at 1552 ("We do not reason well if we think that two lives

More importantly, recognizing the public health right does not, and need not, depend on scientific certainty. As the Court recognized in *Jacobson*, Massachusetts's authority to mandate smallpox vaccination did not turn on dispositive proof of guaranteed immunizing effect of the vaccine.[294] It was enough for the Court that the legislature had a rational basis for its belief in the value of its public health intervention.[295] Public health measures often aim at prevention before harm becomes manifest,[296] necessarily involving some degree of risk prediction.[297] Mandatory vaccination is a prime example. The government requires an individual to be vaccinated not because that person is actually sick and known to infect others. At that point, vaccination would be ineffective, and quarantine alone would be the appropriate intervention.[298] Mandatory vaccination, by contrast, aims to prevent individuals from getting sick and infecting the rest of the population in the first place. No individual showing of risk is required to justify the government's intrusion on the right of bodily autonomy.[299]

Risk prediction is inherently imprecise. Government may stop activities that turn out to be harmless or allow activities that turn out to be

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should always be traded for, say, two and a half lives. A great deal depends on the context in which those statistical lives are put at risk (and on what those lives would be like).").

294. Jacobson v. Massachusetts, 197 U.S. 11, 34–35 (1905) ("While we do not decide and cannot decide that vaccination is a preventive of smallpox," the mandatory vaccination law is "enacted in a reasonable and proper exercise of the police power").

295. *Id.* (noting near-universal belief of medical profession, legislatures, and the people in value of vaccination); *see also* Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst. (*Benzene Case*), 448 U.S. 607, 652–55 (1980) (given agency's authority to "promulgate health and safety standards only where a significant risk of harm exists, the critical issue becomes how to define and allocate the burden of proving the significance of the risk in a case such as this, where scientific knowledge is imperfect and the precise quantification of risks is therefore impossible"; concluding that "requirement that a 'significant' risk be identified is not a mathematical straitjacket").

296. *See Benzene Case*, 448 U.S. at 656 (describing challenges of risk prediction and giving "OSHA some leeway where its findings must be made on the frontiers of scientific knowledge"); Beauchamp, *supra* note 20, at 31 (describing government interest in addressing potential harms to community interests); Cole, *supra* note 18, at 78 (discussing moral justifications for "preventive intervention"); *see, e.g.*, Commonwealth v. Alger, 61 Mass. (7 Cush.) 53, 96 (1851) (broadening police power to address not only existing but also prospective harms from private property use, "making them punishable, because they *tend to* injurious consequences") (emphasis added).

297. *See generally* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 3 (1993) (discussing challenges of risk assessment: "Regulators try to make our lives safer by eliminating or reducing our exposure to certain potentially risky substance or even persons (unsafe food additives, dangerous chemicals, unqualified doctors).").

298. *See, e.g.*, Kirk v. Wyman, 65 S.E. 387 (S.C. 1909) (accepting challenge to manner, but not fact, of quarantined elderly woman infected with leprosy, deemed dangerous and contagious).

299. *See Jacobson*, 197 U.S. at 37–38 (upholding "system of general vaccination" without individual exceptions).

deadly.[300] The current law, as affirmed by the *Abigail Alliance* en banc decision, requires new drugs to undergo an extensive, arduous testing process before they are marketed to the public, with a few narrow exceptions. That seemingly uncompassionate approach may harm some terminally ill patients who hold some hope of benefitting from early access to experimental drugs outside of clinical trials. Legislative or administrative changes may yet change the law and allow expanded access in order to alleviate the immediate, present, and highly salient suffering of terminally ill patients like Abigail.[301] That approach may produce seemingly abstract, unspecified harm to the public by short-circuiting the scientific process. The resulting harm from either approach cannot be known with any degree of certainty. "In public health, the perils of moving too rapidly are often as great as those of moving too slowly. There is no refuge, either way, from the risks of uncertainty."[302] The rush to try to save lives now should not obscure the potential benefit to the public now and in the future. The public health right is not about a special concern for this or that individual in particular but concern for all: the public health. The current approach to drug approval and testing embodies that concern.

C. The Public Health Right in Context

Having identified the public health right and explained its relevance to the issue of access to experimental drugs, it is helpful to test the concept in other contexts. Full, careful analysis of these examples is left for future scholarship, but brief consideration here clarifies the scope of the right and returns the reader to the issues raised at the beginning of this Article.[303] Does the new "old" public health right support other government curtailments of individual rights, such as smoking bans, obesity laws, mandatory health insurance, and handgun control?

Smoking bans are consistent with traditional public health interventions, like sanitation and vaccination, and with the public health right because smoking in public is a "public bad." Its effects are imposed

300. *See* Epstein, *supra* note 6, at 1458–59 (describing public health interventions and risks to individual liberties with risk prediction).

301. *See* CASS R. SUNSTEIN, BEHAVIORAL LAW & ECONOMICS 5 (2000) (describing "availability" heuristic whereby "[p]eople tend to think that risks are more serious when an incident is immediately called to mind or 'available'"); *see also* BREYER, *supra* note 297, at 35 (describing judgment errors in risk assessment, including "prominence," meaning that "[p]eople react more strongly, and give greater importance, to events that stand out from the background").

302. Epstein, *supra* note 6, at 1465–66.

303. *See supra* notes 11–14 (listing examples).

broadly on others, without their consent. Smoking bans aim to protect the public (i.e., nonsmokers) from the effects of second-hand smoke. Cigarette smoke is a tangible, visible externality in the form of puffs of smoke that nonsmokers have no choice but to inhale and against which they cannot adequately protect themselves. Although nonsmokers may have a choice to avoid encountering smoke in private homes or outdoors, it is much harder to suggest that they should simply avoid going into indoor public spaces if they want to avoid the risks. That the effects of second-hand smoke are uncertain and subject to debate does not undermine the public health right to restrictions, for the same reasons that perfect risk prediction is not required in the experimental drugs context.[304]

Also, the same practical problems with potential private law solutions that arose in the pollution context apply to second-hand smoke. It would be nearly impossible to indentify every smoker in whose presence a sick individual has breathed, prove those ill health effects were caused by said smoker, and collect judgments. Prospective solutions, such as contracts or injunctions, would be similarly difficult, in the same terms of identifying smokers, negotiating agreements, and enforcing breaches. Therefore, the restriction on individual rights in smoking bans seems consistent with the public health right.

As suggested above, obesity laws that aim to reduce availability of unhealthy foods in restaurants, schools, and grocery stores seem to intrude on individual rights with no countervailing public benefit, in the sense of the public health right. Trans fat bans seem justified only on paternalistic or "common resources" grounds because they prohibit restaurants from selling, and thereby consumers from purchasing, food containing that ingredient. Obesity is not a communicable disease and healthy people are not exposed to greater risk of obesity if more and more of their neighbors "overgraze."[305] Junk food does have a tendency to make people fat, and obesity does tend to cause myriad serious health problems. But for the fact that we, as a society, have made a choice to provide medical care for people with those health problems, there would be no public harm.[306]

304. *See* O'Connor et al., *supra* note 9, at 403 (citing "convincing scientific data that laws against indoor smoking protect people from the negative health effects of cigarette smoke"); Damon K. Nagami, Note, *Enforcement Methods Used in Applying the California Smoke-Free Workplace Act to Bars and Taverns*, 7 HASTINGS W.-NW. J. ENVT'L L. & POL'Y 159, 160–61 (2001) (describing reports and scientific studies linking second-hand smoke to health problems).

305. *See* Epstein, *supra* note 6, at 1462.

306. *See* Benforado et al., *supra* note 65, at 1649–51 (describing health effects of obesity and costs to the U.S. health-care system as well as lost productivity to businesses).

Accordingly, obesity regulation seems outside the scope of the public health right.

Handgun regulation comes closer, however. There are considerable, undisputed data on handgun-related deaths and injuries, especially to children and adolescents.[307] In addition, there is good indication that restricting access to handguns reduces those numbers.[308] Although the data and correlation between handgun regulation and violence reduction are subject to dispute,[309] the public health right, again, does not depend on scientific or mathematical certainty. The devices at issue, quite literally, can be characterized as "public bads," imposing serious and sometimes fatal harm on other, nonconsenting members of society. Admittedly, there are legitimate private uses of handguns that do not directly impose harm on others. Individuals may choose not to own firearms, but the evidence suggests this does not effectively insulate them from risk of harm. Thus, regulations that restrict and regulate ownership, perhaps just to certain persons and places, seem justified in the "old" public health sense.[310] Moreover, private law responses, including victims' tort actions, criminal prosecution for crimes involving handguns, and products liability litigation against gun manufacturers[311] have proved unsuccessful in reducing violence. Without intervention at the collective level, it is hard to envision how individuals could secure themselves from handgun violence. Therefore, those regulations appear consistent with the public health right.

The individual health insurance mandate smacks of paternalism[312] and seems hard to justify as a public health right. Sickness and disability cause

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307. *See* District of Columbia v. Heller, 128 S. Ct. 2783, 2854–61 (2008) (Breyer, J., dissenting) (discussing evidence); Brief for the American Public Health Association et al. as Amici Curiae Supporting Petitioners at 3, 21, *Heller*, 128 S. Ct. 2783 (No. 07-290); Brief of the American Academy of Pediatrics et al. as Amici Curiae Supporting Petitioners at 4, *Heller*, 128 S. Ct. 2783 (No. 07-290).

308. *See* Drazen et al., *supra* note 13, at 1 & n.4 (noting 25% decline in firearm-related homicides and suicides following 1976 D.C. handgun law and citing study).

309. *Heller*, 128 S. Ct. at 2854, 2857–58 (noting "considerable debate about whether the District's statute helps to achieve that objective" of saving lives and describing respondent's strong disagreement "with the District's *predictive judgment* that a ban on handguns will help solve the crime and accident problems that those figures disclose"). The Court, even in striking down the D.C. restrictions on handguns on Second Amendment grounds, acknowledged the "problem of handgun violence in this county and [took] seriously the concerns raised by the many *amici* who believe that prohibition of handgun ownership is a solution." *Id.* at 2822.

310. In *Heller*, the Court concluded that "the District of Columbia's" restrictions went too far. *Id.*

311. *See, e.g.*, Bloxham v. Glock Inc., 53 P.3d 196 (Ariz. Ct. App. 2002) (rejecting wrongful death claim against gun manufacturer for murder of child by third party); Hamilton v. Beretta U.S.A. Corp., 750 N.E.2d 1055, 1068 (N.Y. 2001) (overturning a jury verdict against multiple firearms manufacturers premised on negligent marketing theory).

312. *See, e.g.*, Ralston, *supra* note 14 ("How should we use the force of government to compel our fellow citizens to live their lives as the government thinks best?").

individual suffering that may be alleviated by medical treatment. But health care is expensive, and health-care costs can be financially devastating to individuals.[313] Requiring people to purchase health insurance may therefore protect them from physical and financial distress. But requiring healthy, risk-preferring individuals to purchase health insurance intrudes on individual autonomy and property rights. Much like sunscreen, one person's choice to "go bare" would not seem to restrict another's choice to be fully covered.

Mandates might be justified as "conserving common resources," starting from the baseline decision to provide medical care even to the uninsured.[314] Otherwise, the choice to be uninsured does not seem to impose any externalities and does not warrant interference. In order to cover the cost of uninsured care, health-care providers typically raise prices for privately and government-insured patients, effecting informal subsidization.[315] Requiring people to purchase health insurance is supposed to shift those costs back on the individuals, rather than government and the rest of society.[316] That argument works only to a point, however, because the insurance system itself is designed to pool risks, with the "good risks" subsidizing the "bad risks."[317] Therefore, the

313. *See* Melissa B. Jacoby, *Individual Health Insurance Mandates and Financial Distress: A Few Notes from the Debtor-Creditor Research and Debates*, 55 U. KAN. L. REV. 1247 (2007).

314. *See, e.g.*, Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1395(dd) (2000) (requiring all Medicare-participating hospitals to provide appropriate, nondiscriminatory medical screenings to all individuals presenting with emergency medical conditions, without regard to ability to pay, insurance status, or Medicare eligibility). EMTALA does not impose a broad duty on hospitals to treat beyond the emergency, much less a general duty on other providers, including physicians. Public hospitals, community health centers, charitable organizations, and government subsidies are some of the many ways that uninsured people receive care. *See also* Epstein, *supra* note 6, at 1463 ("Indeed today the major argument for extensive regulation of individual health practices comes from the government's role as the insurer of (first and) last resort"); Stephen J. Ware, *"Medical-Related Financial Distress" and Health Care Finance: A Reply to Professor Melissa Jacoby*, 55 U. KAN. L. REV. 1259, 1261 (2007) (suggesting that Jacoby's insight about shifting the insecurity "highlights an important truth that is too easily lost in discussions of medical care: the cost of providing such care has to be paid by somebody"). *See generally* ROSENBLATT ET AL., *supra* note 136, at 36–37 (Introduction to "Access to Care" chapter, listing topics).

315. *See* DAVID DRANOVE, THE ECONOMIC EVOLUTION OF AMERICAN HEALTH CARE 25 (2000) ("The idea that hospitals could raise prices to their privately insured patients to generate the revenues necessary to pursue their [nonprofit] mission became known as 'cost-shifting.'"); SHERMAN FOLLAND ET AL., THE ECONOMICS OF HEALTH AND HEALTH CARE 14 (2001) (discussing uncompensated care costs and cost-shifting).

316. *See* Whitman, *supra* note 14 ("the justification of the individual mandate was to reduce cost-shifting" and suggesting "subsidy to higher risk patients generates a political incentive to regulate personal lifestyles").

317. *See generally* Tom Baker, *Containing the Promise of Insurance: Adverse Selection and Risk Classification*, 9 CONN. INS. L.J. 371, 376–78 (2003).

individual mandate does not really eliminate the subsidy but merely spreads it more broadly.[318] Moreover, that justification inaccurately equates uninsured with indigent. There may be, of course, some uninsured patients who simply choose to pay for medical care as they need it, out of their own pockets, and do not require subsidization.

Initial assessment of the individual insurance mandate, therefore, does not seem to comport with the public health right. The fact that some members of society choose to finance health care through other methods (or not at all) exposing themselves to the risk of physical suffering and financial catastrophe, does not prevent others from allocating a portion of their private resources to purchase health insurance. Moreover, the fact that some people are deprived of the choice to purchase health insurance because they cannot afford it is not a justification for intervention, in the "old" sense of the public health right. Addressing socioeconomic inequalities and guaranteeing a right to health or access to health care, by contrast, are goals of the "new" public health and proponents of the individual right to health.[319] Surely, the challenges of health care and the uninsured warrant the public's attention and concern. Perhaps other rationales for a health insurance mandate can be offered, but the intrusion on individual property and liberty rights does not seem to be justified as a public health right.

V. CONCLUSION

This Article offers a contemporary examination of traditional public health objectives to address social problems not amenable to individual resolution. Taking the tradition a step further, it defines a new "public health right" that justifies certain government actions that otherwise appear to impair individual rights. For example, law and policy makers are considering whether current regulations on prescription drugs should be loosened to allow terminally ill patients to access the drugs before they have been tested and approved for the general public. This Article suggests that access to experimental drugs should not be expanded because the change would violate the public health right to scientific knowledge and new drug development. The "new" public health right is limited along the

318. *See* Jacoby, *supra* note 313, at 1250–51 (noting that by "requiring greater out-of-pocket outlays from citizens through the individual mandate . . . Massachusetts does not necessarily make its citizens more financially secure; it might just be shifting around the insecurity").

319. *See supra* notes 15–16 and accompanying text (discussing individual "right to health" and broad goals of "new" public health, including wealth redistribution).

same lines as the "old" public health, and supports some, but not all, approaches to current social and health problems. This Article's articulation and defense of a public health right, which may trump even strongly protected, assertedly fundamental individual rights, provides a rubric for future policy making, in a variety of contexts.