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Everything Old Is New Again: The Re-emerging Public Health Right

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EVERYTHING OLD IS NEW AGAIN:
THE RE-EMERGING “PUBLIC HEALTH RIGHT”

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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 justified.

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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, self-defense privilege, and informed consent standards, and recognized in constitutional rights to refuse medical treatment and obtain an abortion. 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.

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2 See, e.g., MODEL PENAL CODE § 3.04; 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).

3 See, e.g., Cantebury v. Spence, 464 F.2d 772 (D.C. Cir. 1972); Schloendorff v. Society of N.Y. Hosp., 105 N.E. 92 (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”).


6 See Richard A. Epstein, In Defense of the “Old” Public Health, 69 BROOK. L. REV. 1421, 1422 – 23 (2004) (asserting that “Most people start with the naïve assumption that when matters of public health are on the table, claims for individual liberty must give way,” but defending “traditional” role of public health in “containing epidemics, contagion, and nuisance,” which do not lend themselves to market or private law
For example, most states have long-established mandatory vaccination laws to prevent spread of infectious diseases. Most states also have long required individuals to wear seatbelts and motorcycle helmets, despite those laws’ intrusions on liberty interests in not being exposed to a potentially dangerous disease, being pricked with a needle, or traveling in one’s personal vehicle, unencumbered by straps and buckles. Although not without controversy, many states and localities prohibit smoking in public places. Such laws have been repeatedly justified and upheld in the interest of public health.
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 drugs.\textsuperscript{11} One state and several localities have prohibited restaurants from selling certain foods believed to cause obesity. \textsuperscript{12} Last term, four United States Supreme Court justices and several commentators argued in support of handgun restrictions, in part, on public health grounds. \textsuperscript{13} In addition, state policymakers and U.S. Presidential candidates propose to address the problem of health insurance coverage by requiring individuals to purchase health insurance. \textsuperscript{14} Those examples suggest the emergence, or re-emergence, of a “public


\textsuperscript{13} See District of Columbia v. Heller, 128 S. Ct. 2783, 2854 – 61 (2008) (Breyer, Stevens, Souter, & Ginsburg, JJ., dissenting) (noting, “No 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. at 3, 21, District of Columbia v. Heller, 128 S. Ct. 1467 (2008) (No. 07-290) (asserting that “[f]irearms have a profound effect on the public’s health in the United States,” and “[i]n this context, the District of Columbia’s decision to focus its firearms regulations on handguns makes public health sense”); Brief for the American Academy of Pediatrics et al. at 4, District of Columbia v. Heller, 128 S. Ct. 1467 (2008) (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, Stephen Morrisey & Gregory Curfman, \textit{Guns and Health}, NEW ENG. J. MED., July 9, 2008, at 1 – 2 (citing medical literature demonstrating that closer regulation of guns promotes public health by reducing suicide and homicide, and describing \textit{Heller}: “The Supreme Court has launched the country on a risky epidemiological experiment.”); \textit{see also} Mark Tushnet, \textit{Interpreting the Right to Bear Arms – Gun Regulation and Constitutional Law}, 10 NEW ENG. J. MED., April 2, 2008, at 1425 – 26 (suggesting that case is a “too close to call” but that “gun-control side has a slightly better argument”).

\textsuperscript{14} See, \textit{e.g.}, Massachusetts Health Care Reform Act of 2006, MASS. GEN. LAWS ch. 111M § 2(a) (requirement that all residents over age 18 maintain a minimum level of health insurance); Sonya Geis &
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. Nor does the public health right derive from the so-called “new public health,” extending government intervention into a wide range of private choices and concerns. Rather, the public health right is grounded in the core mission of public

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16 See Epstein, supra note 6, at 1423 (distinguishing “old” and “new” public health and listing
health to reduce “public harms” and protect “public goods.” The concept is also distinct from notions of the commonweal or common good, whereby protecting the rights of many may justify intruding on the rights of one or a few. The simple utilitarian calculus of saving several by killing one fails to provide a satisfying justification for the public health right. Rather, the Article urges that the public, as a body – the “body politic” – has a right to government protection and promotion. The discussion begins by framing public health and individual rights in historical context, focusing the traditional, core function of public health, such as sanitation and vaccination.

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18 See Philip Cole, The Moral Bases for Public Health Interventions, Epidemiology, vol. 6, no. 1, Jan. 1995, at 78, 81 (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 abrogation of the rights of a smaller number”).

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

20 See Dan E. Beauchamp, Community: The Neglected Tradition of Public Health, The Hastings Center Report (Dec. 1985), at 29 (“the ‘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 autonomy-focused approach” suggests that “public health ethics is a field of inquiry in its own right”); Epstein, supra note 6, at 1428 (quoting Latin maxim, “The well being of the public is the supreme law,” as having “powerful roots in the American political tradition”).
To develop the modern public health right in context, the Article examines the asserted right to experimental treatment. At least one court\textsuperscript{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,\textsuperscript{22} right to make treatment decisions,\textsuperscript{23} or right to life.\textsuperscript{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. The Article concludes with a general defense of a public health right and considers its application into other contemporary contexts.

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 on individual rights. This Section begins with an exposition on the “old” public health. It then describes various ethical justifications for government intrusions on individual rights. This background frames the discussion that follows.\textsuperscript{25}

\textsuperscript{22} Eugene Volokh, Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs, 120 HARV. L. REV. 1813 (2007).
\textsuperscript{24} Randy E. Barnett, In Re: Life or Death, WALL ST. J., Dec. 9, 2006 (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 (co-founder of the Abigail Alliance for Better Access to Developmental Drugs on pending petition for certiorari).
\textsuperscript{25} See infra Section IV (making case for “public health right”).
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.”

As that definition suggests public health goals typically cannot be achieved through individual action, but require collective, coordinated interventions. Often, the “we,” the organizer of public health efforts, is the government. In addition, the benefits accrue to the “people,” meaning the community, the body politic, the public. The government’s concern is not for this or that particular individual or individuals, but all of us – the welfare of the community. Collective action and public benefit are hallmarks of public health interventions.

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26 COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, INST. OF MED., THE FUTURE OF PUBLIC HEALTH 19 (1988); see also GOSTIN, supra note 7, at 2 (quoting same). See also PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 180 (1982) (defining “public health as 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 public health professor in 1920)).

27 See Michael Walzer, Security and Welfare, reprinted in GOSTIN, supra note 7, at 69, 75 (from SPHERES OF JUSTICE: A DEFENSE OF PLURALISM AND EQUALITY (1983)) (“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 any individual citizens. So the community steps 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 (1824) (regarding state powers to enact “Inspection laws, quarantine laws, health laws of every description”).

Think, for example, of city sanitation: I alone, or even I and my neighbors, may agree 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. 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 difficult propositions, logistically and monetarily. Even if we could identify all of the polluters, the transactions 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.

Sanitation was one of the earliest public health objectives. See STARR, supra note 26, at 189 – 90 (“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, reprinted in GOSTIN, supra note 7, at 27, 28 (from Oxford Textbook of Public Health, vol. 1 (3d ed. 1997)) (“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, HASTINGS CONST. L.Q., supra note 29, at 290 (noting that “public sanitation regulations in Massachusetts go back as far as 1634”).

This discussion presumes that I and my neighbors 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, from Report of the Sanitary Commission of Massachusetts (1850), at 9 – 10, available at www.deltaomega.org/shattuck.pdf, reprinted in GOSTIN, at 25; cf. See RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 284 (1998) (noting that “neighborliness 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.

See POSNER, supra note 31, at 62 (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 hold-outs and problems of incompatible land use).
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 a 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 the initial right to be free from pollution to us, not a right to pollute to our upstream and cross-town residents, 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 insuring workplace safety, and defending against terrorist attack. 35

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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 749 (2005) (suggesting that 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, supra note 20, at 659 (“Communally shared 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
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, we can bring about collective action and societal benefit.\(^{36}\)

At the same time, however, 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 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, minimum age and wage, and maximum hours laws cost businesses money. The government, though courts, regulators, prosecutors, and lawmakers, serves as referee of these conflicts among 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, HASTINGS CONST. L.Q., 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 (1927) (suggesting that government is “organized for the express purpose, among others, of conserving the public health”).

\(^{37}\) See Jacobson v. Massachusetts, 197 U.S. 11, 29 (“In every well-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 subject to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand”); see 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.”); see also STARR, supra note 26, at 180 – 81 (listing business, religious, and other sources of opposition to public health efforts).

\(^{38}\) See Shattuck, supra note 31, at 25 (“It might 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.’\).
members of society. In public health, the conflict often is not as simply one individual versus another, but individual interests versus the public or common good.\textsuperscript{39}

\textbf{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, whereas “public health” is concerned with promoting optimal health of the population as a whole.\textsuperscript{40} Public health seeks more than the aggregation of individual satisfaction but rather the common good.\textsuperscript{41} Accordingly, individual rights are constantly in tension with communitarian interests.\textsuperscript{42}

For example, Garrett Hardin’s classic essay, \textit{The Tragedy of the Commons}, describes the challenges of respecting individual interests while promoting social good.\textsuperscript{43}

\textsuperscript{39}See, e.g., Beauchamp, \textit{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.”).


\textsuperscript{41}Baum, \textit{supra} note 20, at 657 (noting “public health’s emphasis on population health rather than issues of individual health”).

\textsuperscript{42}But see Wendy K. Parmet, \textit{Public Health and Constitutional Law: Defining the State’s Interest}, 10 J. HEALTH CARE L. & POL’Y 13, 24 (2007) (“individual rights need not 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, \textit{supra} note 6, at 1422 (noting popular attitude that public health requires compromising individual rights).

\textsuperscript{43}Garrett Hardin, \textit{The Tragedy of the Commons}, 162 SCIENCE 1243, 1244 (1968); see also Malone &
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, religious, or grounds, sometimes just convenience – demonstrates the accuracy of the “tragedy of the commons”


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.”).
model. Infection rates of diseases, like polio, measles, mumps, and whopping cough, that were virtually eradicated, have reappeared in some communities.\textsuperscript{47}

The “commons” rationale for mandatory vaccination depends on the scientific understanding that no vaccine is one-hundred percent effective, and diseases, even if eradicated, can later mutate and reemerge as new strains.\textsuperscript{48} For example, tuberculosis, nearly eradication a generation ago, recently reemerged with new, more resistant strains.\textsuperscript{49} Therefore, even those whom 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.\textsuperscript{50} I and my neighbors might decide that good chances of avoiding the disease by being vaccinated far outweighs 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 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


\textsuperscript{48} See Jacobson, 197 U.S. at 132 n.+ (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, Vaccine Requirements and Exemptions, Univ. of Penn. Center for Bioethics, vaccineethics.org, available at http://www.vaccineethics.org/issue_briefs/requirements.php


\textsuperscript{50} See Beauchamp, supra note 20, 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 contain 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”).
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 is a non-excludable, non-exclusive “public bad” that it cannot be spread upon some with 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 The law of battery, for example, 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 holds that the state’s interest in providing sanitation and other public health measures operate as a limit on individual rights, consistent with the social contract.56

51 See Epstein, supra note 6, at 1426 (listing communicable disease and pollution as “public bads” and distinguishing “obesity and genetic disease”).
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 (discussing Jacobson v. Massachusetts, 197 U.S. 11, 25-26, 39 (1905)).
56 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 unrestrained license to act according to one’s own will.
   Jacobson, 197 U.S. at 26-27 (quoting Commonwealth v. Alger, 61 Mass. (7 Cush.) 53, 84 (1851)). The Court also recognized “the social compact” in the Massachusetts constitution. Id. at 27.
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 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 the our right or contract to reassign it.\(^{57}\) Laws provide 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 seatbelt 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

\(^{57}\) See Ronald H. Coase, The Problem of Social Cost, 3 J. LAW & 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 8, 55 – 56 (defining Coase Theorem).

\(^{58}\) See JOHN STUART MILL, On Liberty, FRAZIER’S MAG. (1859), reprinted in On Liberty and Other Essays 14 (John Gray ed., Oxford University 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 view of democratic society, the state has no legitimate role in restricting personal conduct that is substantially voluntary and that had little or no direct consequence for anyone other than the individual,” attributing to Mill); Cole, supra note 18, at 80 – 81 (urging that “paternalism 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 proprietary of [mandatory motorcycle helmet] laws” and condemnation “by some as paternalistic deprivations of highly valued personal freedoms”).
injuries resulting from inevitable accidents.\textsuperscript{60} The lost productivity and medical expenses associated with avoidable injuries impose costs on the rest of society.\textsuperscript{61} This “conserving common resources” rationale for public health regulations depends on the presumption that society will provide for the injured person, through welfare programs or the health care system.\textsuperscript{62} Otherwise, there would be no public harm resulting from one person’s choice not to wear safety devices (or sunscreen).

Other anti-libertarian 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 “neighborhood effects.”\textsuperscript{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 the State of California’s restaurant bans on trans fats,\textsuperscript{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

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\item \textsuperscript{60} See supra note 10 and accompanying text (citing cases and commentary on mandatory motorcycle and seatbelt laws).
\item \textsuperscript{61} See John Leland, The Superstar Athlete Is Paid to Take Risks, Right?, N.Y. TIMES, June 18, 2006, § 4, 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”).
\item \textsuperscript{62} See Cole, supra note 18, at 81 (noting that “common resources” rationale is gaining popularity in the U.S. and “[t]he 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 (“the 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.).”)
\item \textsuperscript{63} MILTON FRIEDMAN, CAPITALISM AND FREEDOM 30 – 34 (offering rationale for paternalistic laws).
\item \textsuperscript{64} See supra note 12 and accompanying text (regarding New York City and State of California trans-fats bans).
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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. 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 “Yes.” 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. The terminally ill plaintiffs contended that they quite literally could not wait for the drugs. 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. 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.”

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65 See Adam Benforado et al., *Broken Scales: Obesity and Justice in America*, 53 EMORY L.J. 1648, 1649 – 52 (2004) (describing “hidden costs” of obesity, including government health care program costs, private insurance premiums, lost productivity and more sick time for companies, negative stereotypes, concluding, “In short, the Supersizing of America hurts us all.”).

66 Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006); panel rehearing denied, Nov. 21, 2006 (vacating opinion and granting en banc rehearing).

67 *Id.* at 472; see Cruzan v. Missouri Dir. of Health, 497 U.S. 261, 331 (1990) (Stevens, J., dissenting)
The Abigail Alliance decision generated considerable interest from various constituencies. On one side, libertarian, free market proponents supported the strong recognition of individual rights. On the other side, public health and consumer safety advocates urged a more paternalistic or pro-regulatory stance on new drug development. Meanwhile, in step with the panel decision, FDA proposed amendments to regulations governing pre-market access to experimental drugs, beyond the agency’s existing “compassionate use” and “emergency use” case-by-case exceptions. In addition, both sides of the aisle in Congress supported more liberal access.

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-

(faulting Court for allowing “the State’s abstract, undifferentiated interest in the preservation of life to overwhelm the best interest 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 experimental drugs and payment for organs to lethal self-defense).


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.” On that question, the court held that the purported right was not fundamental or “deeply rooted in this Nation’s history and tradition.” In the wake of the reversal, congressional proposals have been renewed, and FDA’s expanded guidelines are still forthcoming. The Abigail Alliance plaintiffs sought U.S. Supreme Court review, which the Court denied summarily.

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 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. In a remarkable decision, the D.C. Circuit panel

73 Id. at 697.
75 71 Fed. Reg. at 75156.
identified a new, fundamental constitutional right.\textsuperscript{78} The en banc court framed the asserted right differently and, accordingly, reached the opposite conclusion, restoring the state of the law to place that most of us thought it did (and should) occupy.\textsuperscript{79} Now that the U.S. Supreme Court has declined the case, the en banc decision is the last judicial word on the matter.\textsuperscript{80} Unfortunately, that opinion fails to provide a satisfying rationale for its holding. The concept 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 with terminal illnesses, 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 even

\textsuperscript{78} See, e.g., Benderly, \emph{supra} note 69, at 93 (describing \textit{Abigail Alliance} as “one of the most important court decisions ever to affect medical science”); Hill, \emph{supra} note 23, at 314 (noting panel decision “surprised many commentators”); Jacobson & Parmet, \emph{supra} note 69, at 205 (describing case as “troubling” and having potential to “reshape the regulation and sale of pharmaceuticals”).

\textsuperscript{79} See \emph{supra} notes 1 – 5 and accompanying text (regarding long-standing personal autonomy right).

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. A threshold question is: if we truly value bodily autonomy and patient self-determination, why limit the question 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 seem 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 drug companies’ ultimate goal of gaining full FDA approval because unexplainable, adverse reactions to the drug could be revealed. Moreover, scientific validity of trials could be compromised if patients are

81 See infra Section III.B (discussing the Abigail Alliance opinions).
82 Safety and other concerns may motivate pharmaceutical companies to halt clinical trials before they are completed. See, e.g., Abney v. Amgen, 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); see also 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 example) [hereinafter Annas, Faith (Healing)]; Barbara A. Noah,
unwilling to enroll, having already obtained the drugs though the free market.\textsuperscript{83} Also, investigational drugs are costly, and smaller companies may lack capacity to meet the expanded demand for their products.\textsuperscript{84}

Public relations considerations cut both ways for pharmaceutical companies: Denying access gives the impression that drug companies are greedy, motivated by fear of liability and loss of market share, and lack compassion for dying patients. Allowing access appears opportunistic, akin to “snake oil” vendors offering the vain hope of a cure to dying patients.\textsuperscript{85} Indeed, none of the interested parties ever claimed a right to drugs for free. The legislative and administrative proposals contain express provisions on payment.\textsuperscript{86} Opening a paid market for investigational drug exacerbates could create a ethnically questionable, harmful a two-tiered market.\textsuperscript{87}

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\textsuperscript{83} See infra notes 116 – 38 and accompanying text (listing examples of distortions in drug trials).

\textsuperscript{84} See 71 Fed. Reg. at 75170 (“making investigational drugs available for expanded access for treatment use is potentially costly, especially when many patients are involved”); Anand, supra note 71 (describing experience of small biotech firm, Netropix, Inc., and 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, \textit{Access Before Approval – A Right to Take Experimental Drugs?}, New Eng. J. Med., Aug. 3, 2006, at 437, 440 (quoting pharmaceutical industry, “One of the biggest limitations [to access to experimental drugs] is manufacturing capacity”); Talbott, supra note 70, at 318 (noting cost concerns).

\textsuperscript{85} See, 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, supra note 65, at 1786 – 87 (quoting then-FDA Commissioner Mark McClellan on FDA’s role in “rooting out modern purveyors of snake oil”).

\textsuperscript{86} 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”); S. 3046, 110th Cong., § 3(a)(10) (2008) (same); Dep’t of HHS, FDA, Proposed Rule, Charging for Investigational Drugs, 71 Fed. Reg. 75168 (Dec. 14, 2006).

\textsuperscript{87} See infra notes 124 – 31 and accompanying text (describing harm from financial incentives).
Liability exposure is also a double-edged sword: Manufacturers face products liability suits for marketing allegedly dangerous or defective products, as well as failure to warn, negligence, and fraud theories. Congressional proposals to expand access to experimental drugs would provide immunity from liability to drug manufacturers, denying compensation to injured patients but shielding manufacturers from some concerns with marketing untested products. There are litigation risks with denying access, too, however. The Abigail Alliance case itself demonstrate that companies face constitutional, contractual, and other legal challenges if they deny access to drugs.

3. Government Regulators

Government regulators, namely FDA, have a stake in the outcome of this debate, too. If the government’s authority to restrict access to certain products is effectively eliminated by recognition of patients’ fundamental right to the drugs, what remains of 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. Nothing suggests that FDA’s authority

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88 See Talbott, supra note 70, at 318 (identifying sponsor liability exposure).
89 See ACCESS Act, H.R. 6270, 110th Cong. § 3(a)(12) (2008) (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, 110th Cong., § 3(a)(12) (2008) (same).
90 See e.g., Abigail Alliance, 445 F.3d 470 (finding constitutional Due Process right to access). But see Abney, 443 F.3d at 553 (rejecting patients’ state law claims for injunction compelling pharmaceutical company to continue supplying experimental drugs).
91 See supra Section III.A.1; Robert A. Bohrer, The Abigail Alliance and the Role of the FDA, 26 BIOTECHNOLOGY L. REP. 107, 163 (April 2007) (noting that panel identified history and tradition supporting “a broad right to act in order to save one’s own life” but never “articulated why that right should apply only to the terminally ill”); Leif N. Furmansky, Just Say No to Drugs: The Abigail Alliance and the Attempted Abolition of The Food and Drug Administration, 26 BIOTECH. L. REP. 108 (2007)
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. FDA’s authority to regulate drug safety is no different with respect to dying patients as non-terminal patients.92 Although Laetrile was available in other countries, FDA resisted making it available in the United States, even for terminal patients, because “there were no adequate, well-controlled scientific studies of Laetrile’s safety or effectiveness.”93 So far case law and agency policy do not support a distinction between terminal and non-terminal patients with respect to government regulation of experimental drugs. Therefore, the right for dying patients to access not-yet-FDA-approved drugs potentially threatens the FDA’s legitimacy and existence.

Regulatory interests come from two angles, too, however. Scientists and medical researchers view FDA’s new drug approval process, characterized by rigorous scientific standards, double-blind, controlled trials, as the “gold standard” of scientific method.94

92 See United States v. Rutherford, 442 U.S. 544, 553 (1979) (“The Federal Food, Drug, and Cosmetic Act makes no special provision for drugs used to treat terminally ill patients.”); Annas, Faith (Healing), supra note 82, at 789 – 92 (concluding 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).
93 Rutherford, 442 U.S. at 549.
94 See Annas, Faith (Healing), supra note 82, at 789 (quoting R. Levine, Ethics and Regulation of Clinical Research 211 (2d ed. 1986)); Benderly, supra note 69, 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.”); Kulynych, supra note 77, at 131 (“in short, the properly conducted [random clinical trial] permits an accurate, objective, and scientific assessment of whether a treatment works – and if so, how effective is it.”); Jacobson & Parmet, supra note 69, at 207 (suggesting that “the 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”).
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.” Regulators and the research community claim a strong interest in the scientific process, apart from the health of individual patients participating in the studies.

The current push to ease access to experimental drugs is not the first go-round. The 1980s AIDS crisis gave rise to a similar debate and ultimately the “compassionate use” exceptions. 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 generalizable knowledge that may help others, while most individuals suffering with AIDS see these trials as therapy designed to benefit them.” 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.” 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.


97 See Annas, FAITH (HEALING), supra note 82, at 773; Greenberg, supra note 96, at 331 (describing “direct conflict between medical treatment and clinical trial process”); Benderly, supra note 69, 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).

98 Benderly, supra note 69, at 94.
Eliminating control groups and requiring researchers to expand qualifications for research participants, as congressional proposals suggest, could undermine reliability of results and compromise patient safety. FDA faces considerable criticism that its processes are too slow and deliberate, depriving patients of potentially beneficial, life-saving products. But past and recent episodes with approved products, for example, recent scenarios involving Vioxx and Vytorin, suggest that the FDA’s standards may not be rigorous enough. As much as the public is outraged when FDA withholds potentially life-saving drugs from dying patients, it is just as angry when dangerous or

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99 See Brownback, Press Release, supra note 71 (“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”).

100 See, e.g., George J. Annas, Cancer and the Constitution – Choice at Life’s End, NEW ENG. J. MED., July 26, 2007, at 408, 408 (“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).

101 See INST. OF MED. OF THE NAT’L ACADEMIES, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE PUBLIC HEALTH (Alina Baciu, Kathleen Stratton & Sheila P. Burke eds., 2006) (study and recommendations requested in aftermath of Vioxx concerns); Gilhooley, supra note 94, at 956 – 958 (calling for increasing rigor in testing procedures); Justin Blum, FDA Accepted 19 Drugs in ‘07, Fewest It Has OK’ed since 1983, ARIZONA DAILY STAR, Jan. 10, 2008 (noting that “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, Regulatory Paternalism, supra note 34, at 746 (noting that “controversy over the usage of dangerous drugs has now reached a fever-pitch” and outlining “coherent framework” for deciding which drugs should get to the market). The controversy surrounding Vytorin was not safety so much as efficacious, based on evidence that the combination drug performed no better than the separate, cheaper products. See Alex Berenson, Drug Has No Benefit in Trial, Makers Say, N.Y. TIMES, Jan. 14, 2008; Alice Park, Is Vytorin a Failure?, TIME, Jan. 15, 2008 (describing study demonstrating that drug was less effective at lowering bad cholesterol than results presented to FDA).

102 See, e.g., Peter Huber, FDA Caution Can be Deadly, Too, WALL ST. J., July 24, 1998, at A14; Leibfarth, supra note 96, at 1286 – 89 (summarizing criticism of “FDA’s Gold Standard,” including expense, delay, and interference with personal autonomy and physician-patient 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, available at 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 FDA’s decision to lift ban on silicone-breast implants as victory of science over politics, by which “Women will at last be allowed to make their own decisions about cosmetic surgery. This is especially welcome news for mastectomy patients.”).
disappointing drugs reach the market. Thus, FDA faces pressure to both speed access and better ensure safety and efficacy.

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 being reluctant to serve as intermediaries between patients wanting to take the drugs and drug 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. The Abigail Alliance and other patients’ rights organizations are well-informed about clinical trials and other developments in the treatment of their conditions, including compiling internet and other databases of ongoing trials and procedures for enrolling.

103 See, e.g., Epstein, Regulatory Paternalism, supra note 34, at 741 – 45 (describing public pressure to pull drugs from the market and increase regulatory oversight); Groopman, supra note 69, at 47 (describing concerns of “critics who believe that the FDA needs stricter drug regulations”).

104 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.”).


106 See, e.g., Center Watch, Clinical Trials Listing Service, Trial Listings by Medical Areas, available at http://www.centerwatch.com/patient/trials.html (providing “listing of industry-sponsored clinical trials that are actively recruiting patients”); Novartis, Clinical Trial Information, novartiscclinicaltrials.com, available at http://www.novartiscclinicaltrials.com/webapp/etrials/home.do (providing information for patients and caregivers); see also Annas, supra note 100, at 408 (“Today, families search the internet for
Physicians face ethical and liability concerns. Under the “learned intermediary” doctrine of products liability law, patients may sue physicians for dispensing dangerous drugs without adequately warning patients of the risks, rather than passing liability through to the manufacturer for failure to warn the patient directly. On the other hand, physicians may fear liability if they refuse to prescribe experimental drugs. Physicians are held to the standard of care of the profession. 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.

5. The Public

In addition to patients currently suffering from terminal conditions, future and other 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

107 See, e.g., Alm v. Aluminum Co. of America, 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 Products Litigation, 165 F.3d 374 (5th Cir. 1999) (applying doctrine even to prescription drugs advertised directly to patients).

108 See, 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)).

group, rather than buy the drug upfront? Congressional proposals would allow patients to access to drugs directly, without enrolling in clinical trials and facing that very risk. 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 undermine drug innovation. As one commentator summarized, identifying the “worst case” of allowing access to untested drugs: “[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.”

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 and, later, to pregnant women generally as a sort of “prenatal vitamin” to promote healthier babies. 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 brand-new federal agency’s (that

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110 See Brownback, Press Releases, supra notes 71 & 74, (describing ACCESS Act); Society for Clinical Trials, supra note 77, at 155 (describing ACCESS Act’s prohibition on “placebo-only or no-treatment-only concurrent controls in any clinical investigations” conducted under the Act).
111 See Annas, supra note 100, 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.”); Furmanksy, supra note 91, 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 (1994) (describing randomized, double-blind, placebo-controlled experiments as “undoubtedly 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).
112 Greenberg, supra note 96, at 297.
is, FDA’s) new drug approval requirements.113 Accordingly, DES was never systematically tested through controlled, clinical trials in U.S. market. Tragically, a generation later, the drug was revealed to cause a rare form of cancer in the treated women’s young-adult daughters.114 It was especially difficult to assess cancer risks of DES for the public because patients who took the drug tended to be white, upper-class women, who had access to gynecological care.115 Variables particular to that sub-group could not be isolated or identified, nor could the affects be generalized to whole population. Had DES been systematically tested, in accordance with accepted scientific methods, the tragic results to those and future patient 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.116 Based on initial clinical results, physicians began recommending ABMT/HDC for other cancers, and patients, accordingly, began asking their health insurers to cover it. But insurers refused to cover the treatment, citing “experimental” or “not medically necessary” insurance contract exclusions. Patients rallied, and a number

113 In the 1930s, FDA’s new drug application required minimal evidence of the drug’s safety. The efficacy requirement was not added until 1962. See Anita Bernstein, Hymowitz v. Eli Lilly and Co., in ROBERT L. RABIN & STEPHEN D. SUGARMAN, TORT STORIES 151, 153 & n. 9, 155 (2003); see infra note 160 (citing additional sources on history of FDA new drug approval process).


115 See Bernstein, supra note 113, at 155 (describing how 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”).

of courts ruled against the insurers, requiring them to pay.\textsuperscript{117} Eventually, complete clinical trials demonstrated that ABMT/HDC was no more effective than traditional treatments.\textsuperscript{118} The public pressure to make the treatment available, as a practical matter of insurance coverage, accelerated its clinical application, despite lack of complete scientific information about its effectiveness, to painful and unnecessary results.\textsuperscript{119} Those and many other cases illustrate the risks of allowing access to potential “miracle drugs” before they have been fully tested.\textsuperscript{120}

The risks of research subject under-enrollment and disruption of clinical trials are demonstrated by experience with AIDS drug trials in the late 1980s. Clinical trials of azidothymidine (“AZT”) to treat people who were HIV-positive but had not yet developed AIDS were seriously undermined by under-enrollment.\textsuperscript{121} AZT was FDA-approved for AIDS but not HIV. In New York City, after five months of trying, researchers enrolled only nine volunteers, out of a population of 200,000 infected

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\item \textsuperscript{117} See, e.g., id. But see Fuja v. Benefit Trust Life Insur. Co., 18 F.3d 1405 (7th Cir. 1994) (denying coverage); Harris v. Mutual of Omaha Cos., 992 F.2d 706 (7th Cir. 1993) (same).
\item \textsuperscript{118} 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 Antman, et al., High Dose Chemotherapy for Breast Cancer, 282 JAMA 1701 (1999); Leaf, supra note 102 (“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.”)
\item \textsuperscript{119} See RICHARD RETTIG ET AL., FALSE HOPE: BONE MARROW TRANSPLANTATION FOR BREAST CANCER (2007) (describing how providers’ and insurers’ enthusiasm for experimental, high-dose chemotherapy with ABMT to treat metastatic breast cancer made it difficult to enroll patients in randomized, controlled trials and that trial eventually showed procedure was much less effective than believed); Benderly, supra note 69, at 99 (regarding HDC/ABMT, noting that “Thousands of women underwent, and some died from, this exruciating and costly experimental procedure, after a lawsuit forced insurers to pay but before clinical trials finally proved it no more effective than standard therapy”).
\item \textsuperscript{120} See Okie, supra note 84, at 440 (quoting pharmaceutical industry executive, “the whole purpose of large clinical trials is to fully evaluate benefits and risks . . . and short-changing that is not in the patients’ best interest”); Society for Clinical Trials, supra note 77, 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).
\item \textsuperscript{121} See Gina Kolata, Recruiting Problems in New York Slowing U.S. Trials of AIDS Drugs, N.Y. TIMES, Dec. 18, 1988, at 11; Annas, Faith (Healing), supra note 82, at 786 – 87 (describing same).
\end{itemize}
individuals, in one of the most important AIDS trials to date. Reasons for low enrollment included hostility to FDA’s slow pace of new drug approval, concerns about being relegated to placebos, and ability to obtain AZT and other drugs through “grey” markets. Most patients, in consultation with their doctors, opted instead to take unproved drugs, rather than enroll in randomized, controlled trials. The results were further undermined by research subjects who feared they were receiving the placebo “cheating,” or taking supplemental drugs without informing research sponsors.

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 less well informed would be relegated to traditional trials. Typically, there is no charge for drugs provided to clinical trials research participants. But outside of controlled trials drug companies could charge patients, as Congress and FDA would expressly allow it. The preamble to FDA’s proposed amendments allowing drug companies to charge for investigational drugs explained:

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122 See Kolata, supra note 121, at 11.
123 Annas, Faith (Healing), supra note 82, at 786 – 87 (noting that patients’ taking drugs outside the trials “on the sly” further undermined results); Kolata, supra note 121, at 11 (quoting chairman of national study: “We’re worried about cheating all the time”).
124 21 C.F.R. § 312.7(d) (providing that “Charging for an investigational drug in a clinical trial under an IND is not permitted without the prior written approval or FDA”). But see Annas, Faith (Healing), supra note 82, at 779 (“research 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”).
Charging for the cost of an investigational drug for expanded access for treatment use is a very different 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 being incident to the intent to treat.\textsuperscript{126}

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.\textsuperscript{127} That discussion further supports the concerns about conflicting interests of research and therapy.\textsuperscript{128} When conducting trials, companies are primarily concerned with science; when providing drugs outside of trials, costs become a significant motivator.

The concerns are exacerbated by the fact that private health insurers and government health care programs usually do not cover experimental treatment, on grounds that it is not “medically necessary” because approved, traditional treatment

\textsuperscript{126} 71 Fed. Reg. at 75170.
\textsuperscript{127} \textit{Id.}
\textsuperscript{128} \textit{See supra} notes 94 – 98 and accompanying text (describing dissonance between researchers’ and patients’ objectives in clinical trials).
options exist. A two-tiered system, with patients who lack resources enrolling in
traditional trials, and patients with means purchasing experimental drugs on the free
market is not only morally offensive but also could further undermine the validity of
clinical trials. Recent reports on the growing market for paid clinical trial participants
suggest that the scenario is not far-fetched.

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. The DES results were revealing
only about upper-middle class, white women and failed to account for other variables or

129 See RAND E. ROSENBLATT, ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 211 – 15, 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. PENN. L.
treatment, citing ABMT example); Jacobson, supra note 109, at 797 (discussing coverage determinations
and application of “medical necessity” provisions to HDC/ABMT); see, e.g., Fuji 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)
(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 Clinical Trial Policy, issued
by Executive Order, June 7, 2000, 36 Weekly Comp. Pres. Doc. 1311, and adopted in Medicare National
Coverage Determinations Manual § 310.1 (CMS Pub. 100-06) (providing that Medicare covers “routine
costs” for patients enrolled in clinical trials, but not all expenses, including complications and injuries,
associated with participation); National Cancer Institute, States That Require Health Plans to Cover Patient
Care Costs in Clinical Trials, available at http://www.cancer.gov/clinicaltrials/developments/laws-about-
clinical-trial-costs (map of states).

130 See, e.g., Carl Elliott & Roberto Abidie, Exploiting a Research Underclass in Phase I Clinical
Trials, NEW ENG. J. MED., May 29, 2008, at 2316, 2316 – 17 (noting financial and other pressures on poor
people to enroll as research subjects and incentives to falsify medical histories); Carl Elliott, Guinea-
Pigging; Healthy Human Subjects for Drug-Safety Trials Are in Demand. But Is It A Living?, THE NEW
YORKER, Jan. 7, 2008 (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)
[hereinafter Elliot, Guinea-Pigging].

131 See Laurie P. Cohen, To Screen New Drugs for Safety, Lilly Pays Homeless Alcoholics, WALL ST.
J., Nov. 14, 1996, at A1, A10 (expose on Lilly’s practices at Indianapolis testing facility); Elliott & Abidie,
supra note 130, at 2316 (discussing “shadow economy” of paid research subjects); Elliott, Guinea-Pigging,
supra note 130 (quoting Alan Milstein, attorney for Jesse Gelsinger, teenager who died in 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.”).

132 See, e.g., Bernstein, supra note 113, 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”); Dieckmann, supra note 114, at 1062 – 81
(describing non-randomized DES trials).
provide generalizable data. Another example of distortions in the testing cohort is the drug, BiDil. BiDil was touted at the first drug developed specifically to treat heart disease in African Americans. Seeing a potentially lucrative market for “race-specific drugs,” the clinical trials enrolled only African Americans. 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. Moreover, the research failed to produce any evidence helpful for determining whether other, non-African-American patients, could similarly benefit from the drug.133 Similarly, initial trials of AZT were conducted almost exclusively on gay, white males and likewise were later considered questionable in terms of predicting efficacy in the general population.134 These examples illustrate that the push for access to experimental drugs may undermine the scientific validity of the studies and compromise other, including future, patients’ health and safety.

Accordingly, the public’s interest in restricting access to experimental drugs is aligned with government’s interest in maintaining the FDA’s role135 but may be opposed

133 See Jonathan Kahn, Letter to the Editor: Misreading Race and Genomics after BiDil, NATURE GENETICS, July 2005, at 655 – 56 (describing drug developed and marketed to African-American population and noting that clinical trials expressly “enrolled only ‘self-identified’ African Americans; there was no comparison population” and “skewed interpretation of clinical data”); Robert Temple & Norman L. Stockbridge, BiDil for Heart Failure in Black Patients: The U.S. Food and Drug Administration Perspective, ANNALS OF INTERNAL MED., Jan. 2, 2007, at 57, 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 Ron Chepesiuk, Are Race-Specific Drugs Unethical? With BiDil on the Market, Experts Weigh the Moral Implications, BLACK ENTERPRISE, Nov. 2005, available at http://findarticles.com/p/articles/mi_m1365/is_4_36/ai_n15890897.

134 See Greenberg, supra note 96, at 313.

135 See Okie, supra note 84, at 440 (quoting pharmaceutical industry representatives that “the 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 (2007) (responding to Volokh, supra note 22)
to individual rights. That tension is a classic public health law dilemma: How to ensure the health of a population while recognizing the rights of individuals.\(^{136}\) Mandatory vaccination benefits the public greatly by reducing the risk of infectious diseases, but liberty and autonomy interests of some individuals are necessarily infringed.\(^{137}\) 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.\(^{138}\)

### B. The Opinions

For the brief sixteen-month period that the Abigail Alliance panel decision was on the books as good law, it generated considerable interest.\(^ {139}\) After the surprising panel decision, the government requested rehearing. The three-judge panel denied the request,\(^ {140}\) but the full court granted en banc review.\(^ {141}\) On March 1, 2007, the en banc

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\(^{136}\) See, e.g., GOSTIN, supra note 7, at 23 (noting public health’s “emphasis on the well-being of the population as opposed to clinical benefits for individuals”); Baum, supra note 20, at 657, 658 & n.1 (noting that “public health ethics 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, 1 J. HEALTH CARE L. & POL’Y 27, 33 – 34 (2007) (describing and giving examples of public health tension with individual rights).

\(^{137}\) See supra notes 43 – 51 (describing mandatory vaccination debate and “commons” analogy).

\(^{138}\) See United States v. Rutherford, 442 U.S. 544, 547 (1979) (noting FDA’s authority to restrict access to experimental drugs “is within the area of governmental interest in protecting public health”); Furmansky, supra note 91, at 113 – 14 (“In this case, the good of the many must certainly outweigh the potential, (though not certain), good of the few.”); Snead, supra note 135, at 1 (“The FDA restricts access to unapproved drugs (subject to certain exceptions) in the interest of public health, that is, to prevent patient exposure to unsafe or ineffective drugs and to maintain a functional clinical trial system”).

\(^{139}\) See, e.g., Furmansky, supra note 91, at 117 (“Desperately ill terminal patients should not be allowed to take so many other lives into their own hands”); Jacobson & Parmet, supra note 69, at 207 – 08 (urging court to reexamine “panel’s aggressively individualistic view, one that breathtakingly slight the public’s interest in drug safety”); see also Hill, supra note 23, at 277; Volokh, supra note 22, at 1828 – 32.

\(^{140}\) Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 469 F.3d 129, 138 (D.C. Cir. 2006) (rejecting FDA’s challenge to Abigail Alliance’s standing to bring the constitutional
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.\footnote{Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695 (D.C. Cir. 2006); Abigail Alliance for Better Access to Developmental Drugs v. McClellan, 2004 WL 3777340 (D.D.C. Aug. 30, 2004) (No. 03-1601) (district court dismissal on F.R.C.P. 12(b)(6) failure to state a claim, suing in the name of former FDA Commissioner, Mark McClellan).} In January 2008, the Supreme Court denied certiorari.\footnote{Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 128 S. Ct. 1069 (U.S. Jan. 14, 2008).} The various attempts to articulate the purported right in question clarifies the true interest at stake – the public’s. Accordingly, a selective discussion of relevant arguments and reasoning in the opinions follows.

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 FDA has not yet approved for marketing.\footnote{Abigail Alliance, 445 F.3d at 472 (Ginsburg, C.J. & Rogers, J.).} The panel then remanded the case back to the district court to determine, on the merits, whether FDA violated that interest.\footnote{Id. at 486 (holding that district court erred in dismissing case for failure to state a claim and refusing to recognize asserted fundamental right).} The plaintiffs were the Abigail Alliance, a patient advocacy organization, and Washington Legal Foundation, a consumer rights activist organization.\footnote{For information on Abigail Alliance, see \url{http://abigail-alliance.org/}. For information on Washington Legal Foundation, see \url{http://www.wlf.org/}.} The Abigail Alliance was founded in 2001 by Frank Burroughs, whose daughter, Abigail, at age 21, suffered from squamous-cell carcinoma of head and neck. 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 cells in the wrong place.” After Abigail died, Burroughs, along with co-founder Steven Walker, whose terminally ill wife had also been excluded from trials, formed the Abigail Alliance.147

The defendants were FDA Commissioner Andrew von Eschenbach and U.S. Department of Health and Human Services (“HHS”) Secretary Michael Leavitt.148 The litigation operated from several assumptions: That drug companies would willingly provide their pre-approved 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.149 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.150 The district court, after rejecting the defendants’ ripeness, finality, and exhaustion arguments,151 held that the plaintiffs failed to state a recognized due process claim on which relief could be granted, and dismissed the complaint.152

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148 When the case was filed, Mark McClellan was FDA Commissioner and Tommy Thompson was Secretary of HHS. See 2004 WL 3777340 (D.D.C. Aug 30, 2004).
149 See Bohrer, supra note 91, at 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.”).
150 Abigail Alliance, 445 F.3d at 472 (noting that “the 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 the medication carries risks for the patient”).
152 Id. at *9 – *11.
On appeal, the *Abigail Alliance* panel held, two to one, that the plaintiffs stated a claim on their asserted constitutional right to experimental drugs.\textsuperscript{153} 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,\textsuperscript{154} have abortions,\textsuperscript{155} refuse medical treatment,\textsuperscript{156} and engage in intimate association.\textsuperscript{157} Specifically, the panel held that the Due Process clause of 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.\textsuperscript{158}

The holding was limited in several significant respects. First, the right extended only to terminally ill, mentally competent patients. Also, the patients also must have exhausted all other options. 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

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  \item \textsuperscript{153} 445 F.3d at 486.
  \item \textsuperscript{154} 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 (1972) (holding that law allowing distribution of contraceptives to married but not single people violated Equal Protection).
  \item \textsuperscript{155} 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 Casey v. Planned Parenthood of Southeastern Penn., 505 U.S. 833 (1992) (affirming *Casey* but replacing trimester approach with “undue burden” test).
  \item \textsuperscript{156} Cruzan v. Missouri Dir. of Health, 497 U.S. 261 (1990) (recognizing 14th Amendment liberty interest in refusing life-sustaining treatment).
  \item \textsuperscript{157} 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 14th Amendment liberty interests).
  \item \textsuperscript{158} *Abigail Alliance*, 445 F.3d at 484 (citing *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”).
\end{itemize}
drug safety.\textsuperscript{159} In fact, Phase I merely establishes preliminary human 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.\textsuperscript{160} If a drug passes Phase I, researchers still do not 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, the remaining Phases, as well as post-approval reporting, continue to establish not only efficacy but also safety.\textsuperscript{161}

Aside from misunderstanding the FDA new drug approval process, the panel’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 opinion provides the rules that define the recognized individual right.\textsuperscript{162} What if the FDA changes the rules, redefines the Phases,

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\textsuperscript{159} Id. at 472 – 75; see, e.g., Volokh, supra note 22, at 1830 & n.79 (suggesting that “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”).
\textsuperscript{160} 21 C.F.R. § 312.21(a) (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 84, 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. 1991) (describing FDA’s process for approving new drugs and three Phases); Benderly, supra note 69, at 95 (describing Phases); Greenberg, supra note 96, 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 131 and accompanying text.
\textsuperscript{161} Abigail Alliance, 445 F.3d at 488 – 89 (Griffith, J., dissenting) (noting that “[t]he majority and I differ in our understanding of the importance of the testing that occurs after Phase I” and that “Contrary to the majority’s suggestion, all phases of the FDA’s testing process for new drugs involve testing for safety.”); see 21 C.F.R. § 314.80 (“Postmarketing reporting of adverse drug experiences”); see also Epstein, Regulatory Paternalism, supra note 34, at 756 (noting relevance of safety and effectiveness in all three Phases); Jacobson & Parmet, supra note 69, at 206 (noting safety concerns revealed throughout all Phases); Donald Kennedy, Health Roundup (Editorial), SCIENCE, May 26, 2006, at 1105 (noting court’s error, in that “Phase I testing simply seeks to determine appropriate dosage ranges; it does not establish safety”).
\textsuperscript{162} See supra Section III.A.3 (suggesting that expanded access to experimental drugs threatens FDA’s
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, and hardly a first-order 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 useless, ineffective products.

Perhaps the real explanation for the panel’s limiting the Abigail Alliance right to drugs approved through Phase I was the need to maneuver around Supreme Court precedent. In United States v. Rutherford, the Court held that terminal cancer patients could not access Laetrile, an experimental drug that had not yet passed Phase I. Laetrile, 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. 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 majority. According to the court, by not seeking access to pre-Phase I drugs,

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163 Rutherford, 442 U.S. at 546 - 49 (noting that Laetrile was a “new drug,” having not been determined as safe or effective by FDA); see Hutt & Merrill, supra note 160, at 557 – 58 (describing FDA enforcement against unproven cancer treatments and Laetrile issue); Furmanksy, supra note 91, at 109 – 10 (discussing Rutherford Court’s “holding that the same standards that apply to the general population of patients apply with equal force to terminal patients”).

164 See Annas, Faith (Healing), supra note 82, at 779.

165 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”).
the Abigail Alliance demonstrated that they were not seeking an “unfettered right of access,” thus distinguishing their claim from Rutherford. But the court’s myopic focus on, and misunderstanding of Phase I, caused them to miss issue: Whether the Constitution mandates access to possibly dangerous, ineffective experimental drugs, even outside of the controls that Congress and FDA have in place.167

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 FDA’s regulatory scheme.168 The FDA separately regulates prescription and so-called over-the-counter (“OTC”) drugs.169 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.170 Drugs approved for OTC sale, by contrast, are deemed sufficiently safe for direct sale to patients, without an intermediary, as long as warnings and labels meet FDA requirements.171 Limiting the right of access to experimental drugs to those available on

166 Id. at 478
167 Id. at 490 – 91 (Griffith, J. dissenting).
168 Id. at 472, 478.
169 See 21 C.F.R. §§ 201.100 (prescription drugs for human use), 201.66 (labeling requirements for OTC drugs); 21 C.F.R. §§ 330.1 (general requirements), 330.10 (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 FDA’s “new drug authority applies equally to prescription and OTC drugs” but that “legislators have singled out prescription drugs for different attention” on labeling, dispensing, advertising, inspection, marketing, and user charges); see generally HUTT & MERRILL, supra note 160, at 588 – 99 (describing OTC drug regulation).
171 See Lars Noah, Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?, 19 HARV. J.L. & TECH. 359 (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”).
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 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 to control one’s own body,” analogizing to *Cruzan*, and *Roe* and *Casey*. The court buttressed the constitutional cases with reference to common-law privileges of self-defense, self-preservation, and private necessity. In other parts of the opinion, the court described a “right to access potentially life-saving . . . drugs,” a “right to make the decision about her life free from government interference,” a “right to make an informed decision that may prolong

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172 *Abigail Alliance*, 445 F.3d at 484 (citing *Cruzan*’s observation that “[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”).

173 Id. at 476 (citing *Casey*’s recognition that “the Court has discerned the existence of fundamental rights by probing what ‘personal dignity and autonomy’ demand”); Volokh, *supra* note 22, at 1824 – 27 (discussing right to medical-self defense and comparing *Roe* and *Casey* to *Abigail Alliance*).

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

175 Id. at 472, 478 (“right…to obtain potentially life-saving medication”); id. at 485 (“right of access” recognized “in light of the explicit protection accorded to ‘life’”).

176 Id. at 472, 478 (“the Alliance asks only that the decision to assume these known or unknown risks be left to the terminally ill patient and not the FDA”).
life,“" a “right to choose” to use certain drugs, or an “individual right of self-determination.” Each of those definitions fails to carefully, accurately frame the issue, as required by Supreme Court precedent, and moreover fails to take into account other interests are affected by recognizing the patients’ asserted right.

The Supreme Court’s established test for identifying a fundamental right begins with a “careful description” requirement. In Washington v. Glucksberg, the Court articulated a three-part test. The right must be “firmly rooted” in the nation’s history and traditions, “implicit in the concept of ordered liberty,” and carefully described. The “careful description” requirement tends to direct the analysis of the other two requirements inasmuch as one way of thinking of the right may be consistent with the “nation’s history and traditions” and “firmly rooted in the concept of ordered liberty,” while a different conception would not be. For example, a constitutional challenge to laws prohibiting the use of medical marijuana, describing 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. Some critics suggest that the courts have morphed Glucksberg’s “careful description”

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177 Id. at 477.
178 Id. at 484.
179 Id.
181 Glucksberg, 521 U.S. at 720 – 21.
182 Compare U.S. v. Cannabis Cultivator's Club, 1999 WL 111893 (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 (9th Cir. 1980) (rejecting constitutional right to obtain medication free from the lawful exercise of the government’s police powers) with Cruzan, 497 U.S. at 279 (“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 R. Co. 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”).
requirement into a “narrow description” requirement, with the effect – and, arguably, purpose – of making it very difficult to recognize new fundamental rights.\textsuperscript{183} Regardless, the “careful description” makes all the difference to the court’s recognition of a fundamental right, as the opinions and discussion demonstrate.\textsuperscript{184}

Another line of reasoning with which the panel grappled unconvincingly was the relevance of FDA drug regulation in the second two prongs of the \textit{Glucksberg} analysis: “firmly 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 long-standing history of FDA regulation. The panel noted, however, that FDA has been in existence only since 1906, regulated drug safety only since 1938, and regulated drug efficacy only since 1962.\textsuperscript{185} According to the court, the right to \textit{unrestricted} access to drugs is long-standing, indeed longer-standing than government regulation of drugs.\textsuperscript{186} Therefore, the Abigail Alliance’s claimed right “falls squarely within the realm of rights” that the Court has recognized as fundamental.\textsuperscript{187} 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

\textsuperscript{184} See infra Section IV.A (evaluating various formulations of right).
\textsuperscript{185} 445 F.3d at 481 – 83 (discussion history of FDA authority to regulate new drugs); see also Furmansky, \textit{supra} note 91, at 109 – 10 (describing history and regulations of FDA); Greenberg, \textit{supra} note 96, 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, \textit{supra} note 111, at 406 – 08 (noting same, and compassionate use exceptions prompted by 1980s AIDS crisis).
\textsuperscript{186} 445 F.3d at 483 (“Despite FDA’s claim to the contrary, therefore, it cannot be said that government control of access to potentially life-saving medication ‘is not firmly ingrained in our understanding of the appropriate role of government’” (quoting Appellee’s brief)). But see 445 F.3d at 494 – 95 (Griffith, J., dissenting) (discussing nation’s longstanding history of drug regulation).
\textsuperscript{187} \textit{Id.} at 483.
human trials warrants protection under the Due Process Clause.” ¹⁸⁸ 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, 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 governmental interest.” ¹⁸⁹ The case never reached the district court for reconsideration, however, after the en banc court reversal.

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 FDA has not approved for marketing. ¹⁹⁰ “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

¹⁸⁸ *Id.* at 486.
¹⁸⁹ *Id.*
¹⁹⁰ Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenback, 495 F.3d 695, 697 (D.C. Cir. 2007) (describing plaintiffs’ issue as “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”).
been proven safe and effective.” 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.” 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.

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. FDA’s regulation of drug safety, in particular, has been in place at least thirty years longer than regulation of drug efficacy. In any event, although FDA may be a relatively new federal agency, government regulation of drugs by states and the federal government dated back to the Colonies. Moreover, the court acknowledged the difficulty defining a fundamental right based on a regulatory scheme, when Congress or FDA at any time could amend the statute or rules, just as 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

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191 Id.
192 Id. at 711.
193 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”); 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.”).
194 Id. at 703 (“The Alliance’s 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.”).
195 Id. at 703 – 06 (beginning with Colony of Virginia’s 1736 act addressing “dispensing of more drugs than was ‘necessary or useful’ because that practice had become ‘dangerous and intolerable’”).
inextricably entangled with the detail of shifting administrative regulations
could be “deeply rooted in this Nation’s history and tradition and implicit
in the concept of ordered liberty.”

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, i.e., drugs that have not passed Phase I. The long
history of government regulation of medical and drug regulation undermined the
Abigail Alliance’s suggestion that “the government never interfered with the judgment of
individual doctors about the medical efficacy of particular drugs until 1962.” 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. Moreover, no courts have recognized an affirmative right of access to particular
medical treatments that the government restricts or regulates.

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

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196 Id. at 702, n.6 (quoting Glucksberg); 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 Abigail
Alliance’s concerns); see, e.g., supra note 70 (citing FDA Proposed Rules).
197 495 F.3d at 703.
198 Id. at 704 & n.7 (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).
199 Id. at 703.
200 Id. at 708 – 10 (citing cases rejecting statutory, if not constitutional, challenges to FDA’s authority);
see Gonzales v. Raich, 545 U.S. 1 (2005); United States v. Oakland Cannabis Buyer’ Coop., 532 U.S. 483
201 495 F.3d at 710, n.18; see Hill, supra note 23, at 303 – 04 (discussing Rutherford, Walen v. Roe, and
other cases examining right to make medical treatment decisions).
judicial doctrines, the court noted multiple exceptions and limitations on their application. The necessity defense failed to override the government’s interest in regulating marijuana under the Controlled Substances Act.\textsuperscript{202} The interference with rescue claim requires proof that a third party was prevented from giving \textit{necessary} assistance to the victim. According to the court, the “necessity” element was not met on the \textit{Abigail Alliance} facts because the patients had not demonstrated that experimental drugs were safe, much less effective, in prolonging their lives.\textsuperscript{203} Therefore, there was no interference with “necessary” rescue. The self-defense claim was not apt because patients’ taking experimental drugs was not analogous to their using reasonable force against an aggressor to defend themselves from immediate bodily harm.\textsuperscript{204} Accordingly, none of the common law claims supported the claimed fundamental right.\textsuperscript{205}

The en banc dissent, comprised of the panel majority, Chief Judge Ginsburg and Judge Rogers, faulted the en banc opinion as “reflect[ing] a flawed conception of the purported right.”\textsuperscript{206} 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.” That right, they concluded, certainly is firmly rooted in nation’s history and tradition, beginning with Samuel Adams, Blackstone, and others

\begin{itemize}
\item \textsuperscript{202} Id. at 708 (discussing \textit{Oakland Cannibis Buyers’ Coop.}).
\item \textsuperscript{203} Id. at 708 – 09.
\item \textsuperscript{204} Id. at 709 – 10. The court suggested that therapeutic abortion, justified to save the life of the mother, might be a closer analogy. \textit{See also} Volokh, \textit{supra} note 22, at 1824 – 28 (discussing analogies). \textit{But see} Snead, \textit{supra} note 135, at 1 (refuting abortion and self-defense analogies).
\item \textsuperscript{205} 495 F.3d at 411.
\item \textsuperscript{206} Id. at 714 (Rogers & Ginsburg, JJ., dissenting).
\end{itemize}
recognizing the right self-preservation as the “first law of nature” or “primary rights.”

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 which suggests some hope but no promise of alleviating symptoms, prolonging their lives, and perhaps – just perhaps – saving their lives.

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. The court should not have reached that issue without first clearly resolving the threshold question whether the fundamental right exists in the first place. Indeed, the majority conflated its consideration of the common law theories by asserting that the government could limit those rights, with proper justification. That common law privileges or protections for personal autonomy are not absolute and subject to exceptions does not disprove their existence as rights. The en banc’s approach is the easy way out. It is not difficult to recognize that, in many cases, FDA has good reasons for limiting individual rights and

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207 Id. at 714 – 15; 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’”).
208 See supra note 189 (citing panel’s instructions on remand).
209 Id. at 714.
210 Id. at 707.
211 Id. at 708 – 10; see Snead, supra note 135, at 1 (rejecting analogies, in part, because government has routinely restricted them “in the name of avoiding what it takes to be more significant harms”).
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.\textsuperscript{212} Even under strict scrutiny, the FDA’s new drug approval process and restrictions on access to particular medical treatments likely would be upheld, as the had been under other challenges.\textsuperscript{213}

In their petition for certiorari, the Abigail Alliance sought due process recognition of “the right of terminally ill patient . . . to attempt to save her own life . . . deciding whether to seek access to” experimental drugs that FDA deems “safe and promising enough for substantial human testing.”\textsuperscript{214} The government’s Brief in Opposition framed the issue as “whether 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.”\textsuperscript{215} The Supreme Court summarily denied review, letting the en banc decision stand.\textsuperscript{216} Unless other litigants renew the claim on new facts, which would likely again be heard in the District of Columbia Circuit where the issue has been amply considered and reconsidered, that decision remains the final judicial word on the proposed fundamental, constitutional right of access to experimental treatment.

\textsuperscript{212} See Abigail Alliance, 445 F.3d at 486 (remanding to district court); id. at 477 (describing strict scrutiny test); see also Glucksberg, 521 U.S. at 721; Reno v. Flores, 507 U.S. 292, 302 (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”).

\textsuperscript{213} See, e.g., 495 F.3d at 710, n.10 (citing cases).


\textsuperscript{216} 128 S. Ct. 1069 (Jan. 14, 2008).
So, what next? Bills are pending in both the House and Senate. 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 Section 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 the 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 FDA’s new drug approval process. The court’s reasoning, however, 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 be rationally 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 FDA’s new drug approval process but not yet deemed safe and effective.
The panel recognized a “right to control one’s body,” relying on *Cruzan* and *Roe*. But *Cruzan*, in particular, 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 right to property, privileges, and protection from the government.\(^{217}\) 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.\(^{218}\)

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 him or herself. 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.\(^{219}\) When the person is dying and has

\(^{217}\) See Parmet, HASTINGS CONST. L.Q., *supra* note 29, at 271 – 77, 304 – 06 (questioning conventional assumption that U.S. constitutional law primarily supports negative, not positive, rights, and implications for public health).

\(^{218}\) See DeShaney v. Winnebago Co. Dept. 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”).

\(^{219}\) See Epstein, *Regulatory Paternalism*, *supra* note 34, at 758 – 59 (“The presumption 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 91, 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 Respondents, at 43, Unite States v. Oakland Cannabis Buyers’ Coop., 532 U.S. 483 (2001) (No. 00-151), 2001 WL 173541 (arguing that “these 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 “this is not a general autonomy argument, premised on the theory that all people should be free to put whatever they choose into their bodies,” offering medical self-defense as alternate rationale).
nothing to lose, the claim seems even harder to deny.\textsuperscript{220} 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 non-terminal 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.\textsuperscript{221}

At the same time, the panel bought into certain patient-protective controls, even for dying patients, under FDA’s regulatory scheme.\textsuperscript{222} First, the court allowed access only to drugs that passed Phase I, which the panel took to mean 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 FDA alone was standing in the way of

\textsuperscript{220} See Annas, supra note 100, 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.’”).

\textsuperscript{221} See Jacobson & Parmet, supra note 69, at 207 (“As the government argued to the panel, terminally ill patients are particularly vulnerable to promises that unproved treatments will be effective.”)

\textsuperscript{222} As discussed above, notes 163 – 167, precedent compelled the Court to conclude that FDA’s authority was no different for terminal and non-terminal patients. See Rutherford, 442 U.S. at 553.
patients’ fundamental right to life, then it is hard to accept the panel’s insistence on leaving some FDA paternalistic controls in place.\textsuperscript{223}

Another difficulty with the “right to use” or “right to control 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 marijuana, or otherwise possess or obtain them without involving another party.\textsuperscript{224} Rather, the drugs they wanted to take were developed, under patent protection, by pharmaceutical companies. Therefore, in order to exercise the personal autonomy right, a patient would necessarily have to involve another party, namely, a drug company.

Accordingly, the panel dissent’s and en banc court’s concept of a “right to access” or “right to obtain” the drugs is arguably more accurate.\textsuperscript{225} As Judge Griffith urged: “[A] tradition [of] protecting individual freedom from life-saving, but forced, medical

\begin{itemize}
  \item \textsuperscript{223} See Epstein, \textit{Regulatory Paternalism, supra} note 34, at 747, 748 (concluding that 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, \textit{supra} note 102 (discussing “how our national obsession with drug safety is killing people”); Henry I. Miller, \textit{Paternalism Costs Lives}, WALL ST. J., March 2, 2006, at A15. 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, \textit{e.g.}, mandatory helmet laws. “Soft” paternalism “legitimizes intervention…when the individual 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. \textit{See} Thaddeus Mason Pope, \textit{Is Public Health Paternalism Really Never Justified? A Response to Joel Feinberg}, 30 OKLA. CITY U. L. REV. 121, 122 & n.3 (2005) (analyzing Feinberg’s, \textit{THE MORAL LIMITS OF CRIMINAL LAW: HARM TO SELF}).
  \item \textsuperscript{224} The court made a similar observation in \textit{Carnohan}, regarding Laetrile. \textit{Carnohan} v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980) (\textit{“We need not decide whether Carnohan has a constitutional right to treat himself with home remedies of his own confection.”}); U.S. v. Cannabis Cultivator’s Club, 1999 WL 111893 (N.D. Cal. Feb 25, 1999) (not deciding whether patients “have a right to treat themselves with marijuana which they themselves grow” because \textit{Carnohan} holds no right to obtain); \textit{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).
  \item \textsuperscript{225} \textit{See similarly} \textit{Carnohan}, 616 F.2d 1120; \textit{Cannabis Cultivator’s Club}, 1999 WL 111893.
\end{itemize}
treatment does not evidence a constitutional tradition of providing affirmative access to a potentially harmful, and even fatal, commercial good.” 226 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, 227 a pharmacist to prescribe the morning-after pill, 228 or the government to pay for abortions. 229 But those examples are distinguishable, as long as there is another avenue for exercising the right. 230 With experimental drugs, there usually is no other way to get the drugs.

227 See, e.g., 42 U.S.C.A. § 300a-7 (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 (“[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.”).
229 See Harris v. McRae, 448 U.S. 297 (1980) (holding that state Medicaid programs are not required to pay for abortions).
230 See, e.g., Webster v. Reproductive Health Services, 492 U.S. 490 (1989) (holding that 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. 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. 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, 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 improved on the investigational drugs, sued Amgen on state law breach of contract, breach of fiduciary duty, detrimental reliance, and similar theories, to compel access to the drugs. Amgen claimed that it ceased the trials because of safety concerns. The patients suspected that

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234 Id. at 545 (listing claims); see also Epstein, Regulatory Paternalism, supra note 34, at 757 (describing scenario and “howls of protests by unhappy patients”).

235 443 F.3d at 544.
they stopped because the product would not be lucrative.\textsuperscript{236} Of course, if we respect the pharmaceutical company’s fundamental property rights, its reasons for ceasing the trials should not be relevant to the analysis.\textsuperscript{237} 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.\textsuperscript{238} Any other result would seem to violate the manufacturer’s right to exclusive enjoyment of its intellectual and personal property.\textsuperscript{239}

Maybe the patients’ right to obtain 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 is more important patients’ right to obtain potentially life-prolonging treatment?\textsuperscript{240} There is support for the argument that life trumps property in common law self-defense\textsuperscript{241} and necessity doctrines.\textsuperscript{242} The question becomes more complicated, however, when the pharmaceutical company acts

\begin{footnotesize}
\textsuperscript{236}Id. at 545.
\textsuperscript{237}See Epstein, Regulatory Paternalism, supra note 34, at 757 (“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.”). \textit{But see} Anand, supra note 71, at A1 (describing outrage that drug company failed to provide drugs to dying children, believing profit motivations).

\textsuperscript{238}443 F.3d at 553 (affirming district court’s denial of preliminary injunction).
\textsuperscript{239}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); 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 (citing cases)).

\textsuperscript{240}See Furmansky, supra note 91, 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, Keeping Down the Competition; How Companies Stall Generics And Keep Themselves Healthy, N.Y. TIMES, July 24, 2000, § 1, at 1 (quoting Hatch-Waxman Act drafter on pharmaceutical companies’ delay tactics to extend patent protection: “It’s the evolution of greed versus need.”)

\textsuperscript{241}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).
\textsuperscript{242}See, e.g., Putnam v. Ploof, 71 A. 188 (Vt. 1908) (denying property owners trespass claim for for dock damage against boat owner who moored himself without permission during sudden tempest).
\end{footnotesize}
not out of “greed” but safety concerns, pulling the drugs based on adverse events. Then the question is not so much life versus property but relative degrees of risk and safety, and who decides whether the patients should be permitted to encounter the risks.243

That question 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 (and, in some cases, not-yet-countable) lives potentially saved or enhanced if the drugs undergo all three phases of “gold standard” clinical trials before they are made available to the public? The examples discussed above of nonexistent, rushed, abbreviated, incomplete, and non-randomized clinical trials demonstrate the value of the scientific method and rigorous new drug approval process, for not just current but also future patients who may take the drug.244 Even clinical trials on drugs that are denied approval or are pulled before all three Phases are completed – as most are245 – 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?246

243 Compare Epstein, Regulatory Paternalism, supra note 34, at 757 (suggesting that patients’ should choose) with Annas, Faith (Healing), supra note 82, at 792 (suggesting that FDA should).
244 See supra notes 113 – 38 and accompanying text (describing scenarios involving DES, ABMT-HDC, AZT, BiDil, and other drugs).
245 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 91, at 110 (citing Centers for Disease Control reports). For cancer drugs, only 5% of drugs approved for human trials are approved for patient use. See Jacobson & Parmet, supra note 69, at 206 (listing safety, efficacy, and financial concerns as reasons for abandonment).
246 See Bohrer, supra note 91, 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”);
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.\(^{247}\) Therefore, preapproval marketing removes a potentially significant set of data from the safety and efficacy trials, undermining the whole process.\(^{248}\) 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, and would benefit from the scientific knowledge gained by studying the drugs? That conception of the *Abigail Alliance* issue approaches the concept of the public health right, as explained more fully in the next Section.

\(^{247}\) One commentator’s response to the concern that no patients would enroll in clinical trials notes theoretically that “variance in risk assessment,” and “hope and faith” and “altruism” may influence some patients to enroll. See Salbu, *supra* note 111, at 403. That argument is also unconvincing given the overwhelming anecdotal descriptions, including his own, of terminally ill patients’ desperate situations. Salbu, *supra* note 11, at 432 – 33. “Variance in financial resources” and financial incentives for clinical trial participation is offered as another way to ensure enrollment. *Id.* Paid research subjects and variance in financial resources only exacerbate the public health harms. See *supra* notes 130 – 31.

\(^{248}\) See Greenberg, *supra* note 96, at 297 (noting that the “most reliable data . . . is that obtained from prospective randomized clinical trials”); Jacobson & Parmet, *supra* note 69, 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 111, at 432 (suggesting “informal observation” and “word of mouth” will enhance information-gathering because “drugs will be consumed more quickly”); Leibfarth, *supra* note 96, at 1306 (“Although feedback from individual patients may not provide quantitative data, it may produce both research strategies and hypotheses for further study.”).
B. The Public Health Right

The public health right contemplates that the public, as a body, merits protection from interference by other, individual members of society. In the case of access to experimental drugs, the potential harm to so many other patients whom also await the promise of a cure and benefit from scientific developments justifies the decision to deny access to experimental drugs to current, 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 access health care services, health protection, or aspirational standards of health for individuals.\(^{249}\) 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.\(^{250}\)

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 one or a few individuals versus the body politic. As in any other unresolvable competing uses conflict, the government typically referees the dispute and

\(^{249}\) 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 right to health and propose the “public health right” is a way of collectively ensuring 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 43 (describing “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”).

\(^{250}\) Meier & Mori, supra note 15, at 123 (citing Lawrence Gostin and Jonathan Mann).
decides which right prevails. Here, the en banc D.C. Circuit, although not articulated in these terms, ruled in favor of the public, against the individual patients. Strong emphasis should be placed on the qualifying word, “unresolvable” competing uses because the dispute between patients’ interest in taking experimental drugs and the public’s interest in pharmaceutical research is not amenable to private resolution. Accepting the en banc court’s 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 “grey” market, like many AIDS patients in the past. 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 the full clinical trials depletes the “commons” of the scientific process for developing new drugs by allowing “overgrazing” by a few, justifiably desperate, terminally ill patients. As discussed, one individual’s decision to ingest a particular drug affects far greater interests than his or her own bodily integrity. Taking an experimental drug is more akin to avoiding vaccination than avoiding sunscreen. Unlike the sunscreen analogy, whereby

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251 See, e.g., supra notes 30 – 38 and accompanying text (discussing city sanitation example).
252 See Epstein, supra note 6, at 1423 (traditional public health interventions justified for problems that “do not lend themselves to either market solutions or private actions in tort”); Annas, Faith (Healing), supra note 82, at 795 (“Experimental drugs are not a consumer good appropriately governed by the free market.”).
253 See supra note 106 (describing patients’ resourcefulness in securing drugs).
254 See Ruger, supra note 15, at 43.
255 But see Epstein, Regulatory Paternalism, 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.”)
256 See supra notes 48 – 51 (drawing analogies).
one sunbather’s decision to go bare leaves another person’s choice to wear sunblock 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.\textsuperscript{257} 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.”\textsuperscript{258} 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 I and my neighbors cannot secure a sanitary city on our own.\textsuperscript{259} 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 “public bad” in the sense that the public is deprived of its choice to investigate drugs fully.\textsuperscript{260}

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 as the basis for FDA’s regulatory authority.\textsuperscript{261} The public health right recognizes an interest in fully

\begin{footnotesize}
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\item[\textsuperscript{257}] See supra note 43 – 46 (describing “Tragedy of the Commons” concept and vaccine analogy).
\item[\textsuperscript{258}] See supra notes 47 (discussing recent trend of parents opting out of mandatory vaccination).
\item[\textsuperscript{259}] See Ruger, supra note 15, at 43; see also Epstein, supra at 1343 (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 231, 239 (regarding pharmaceutical patent laws).
\item[\textsuperscript{260}] 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 pollutants, but not obesity or genetic disorders.”)
\item[\textsuperscript{261}] See, e.g., Annas, Faith (Healing), supra note 82, at 792 (justifying FDA new drug approval process
\end{itemize}
\end{footnotesize}
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 preferring to risk skin cancer while leaving the public free to lotion up before going outside. As a practical matter, the public cannot secure its right without restricting access to experimental drugs.262

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 that the principle goal of the FDA new drug approval process or accepted clinical research standards is treatment, rather than science.263 The response is not as draconian as suggested; FDA does allow access to experimental drugs under narrow “compassionate use” and “emergency” exceptions.264 Moreover, well-developed ethical rules and guidelines protect human subjects in clinical research.265

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262 See supra note 111, at 401, 418 – 20 (critiquing FDA’s “paternalistic model” of drug testing and approval); see generally Epstein, Regulatory Paternalism, supra note 34; see generally Cole, supra note 18, at 80 – 81 (describing paternalistic justification for public health interventions); Pope, supra note 223, at 121 (evaluating same).

263 See supra note 70 (citing regulations).

264 See supra notes 94 – 98 and accompanying text (noting patients’ and researchers’ competing objectives); Annas, Faith (Healing), supra note 82, at 773 (discussing “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”).

265 See generally 21 C.F.R. part 50 (regulations for “Protection of Human Subject,” FDA’s codification
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, but is this too much? But 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,” or right to avoid having something done to one’s body, like *Cruzan*, or “right to be left alone.” 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 – or access investigational drugs – is unavailing.

The public health right also is not based on the “conserving common resources” rationale that may sometime support seatbelt, helmet, and obesity (and hypothetical mandatory sunscreen) laws. Under that view, the individual choice to avoid wearing a safety device, eat unhealthy foods containing trans fats, or go out without sunblock imposes costs on the rest of society by increasing overall health care expenditures. That

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of “Common Rule”); *Carl H. Coleman et al., The Ethics of Regulation of Research with Human Subjects* (2005).
266 See Jacobson, 197 U.S. at 38 (rejecting individual privilege to avoid vaccination because “the spectacle of an entire population being subordinated to the notions of a single individual who chooses to remain a part of that population”).
267 See supra Section III.B (describing court opinions’ attempts to frame relevant interest); see also Picou v. Gillum, 874 F.2d 1519, 1521 (11th Cir. 1989) (“there is no broad legal or constitutional ‘right to be let alone’”).
268 See supra notes 60 – 67 and accompanying text (describing theory and examples).
argument, however, 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 for clinical trials participants but not access to drugs outside of trials. 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, then, 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 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. Nor does self-defense allow a person who fears grave injury

\[\text{269 See supra notes 24 – 29 and accompanying text (discussing insurance and government coverage for experimental treatment).}\]

\[\text{270 See Abigail Alliance, 495 F.3d at 709 – 10 (en banc opinion, rejecting self-defense analogy because patients were not facing threat of harm from anyone); Volokh, supra note 22, at 1821 (acknowledging that}\]
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.  

For similar reasons, the therapeutic abortion analogy fails, 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. But others lives – many other lives – are being threatened and sacrificed by allowing individuals to exercise the purported right and aborting biomedical research.

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. To rely on that justification would

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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 (2008) (responding to Volokh) (noting that “[t]he ‘right’ of self-defense is not a claim against anyone else, merely a defense against others’ charges or claims”).


272 Abigail Alliance, 495 F.3d at 709 (discussing Roe and abortion analogy).

273 See Volokh, supra note 22, at 1828 – 29 (suggesting that patient “should have at least an equal right to ingest potentially lifesaving medicines without threatening anyone else’s life).”

require impossible and unnecessary calculations. Even if those calculations were possible with respect to a particular drug, targeted for a particular illness (say, Erbitux for head and neck cancer),\(^\text{275}\) the task would be made more challenging by the fact that drugs, once approved, are often prescribed by physicians for other indications.\(^\text{276}\) 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.\(^\text{277}\) Those additional lives saved would have to been 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.\(^\text{278}\)

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\(^{275}\) See supra note 147 (describing underlying facts of Abigail Alliance).

\(^{276}\) Although drug companies cannot promote approved drugs for off-label uses without FDA approval for the new use, 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 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 in September 2006. FDA recently proposed new guidance on off-label promotion using peer reviewed articles. Dept of HHS, FDA, Notice, Draft Guidance for Industry Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved Uses of Approved Drugs and Approved or Cleared Medical Devices; Availability, 73 Fed. Reg. 9342 (Feb. 20, 2008).


\(^{278}\) See Sunstein, supra note 274, at 1552 (“We do not reason well if we think that two lives 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).”)
More importantly, recognizing the public health right does not, and need not, depend on scientific certainty. As the Court recognized in Jacobson, the Massachusetts’s authority to mandate smallpox vaccination did not turn on dispositive proof of guaranteed immunizing effect of the vaccine.\textsuperscript{279} It was enough for the Court that the legislature had a rational basis for its belief in the value of its public health intervention.\textsuperscript{280} Public health measures often aim at prevention before harm becomes manifest,\textsuperscript{281} necessarily involving some degree of risk prediction.\textsuperscript{282} Mandatory vaccination is a prime example. The government requires an individual to be vaccination 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.\textsuperscript{283} Mandatory vaccination, by contrast, aims to prevent individuals from getting sick and thereby infecting the rest of

\textsuperscript{279} 197 U.S. at 34 – 35 (“While we do not decide, and cannot decide, that vaccination is a preventive of smallpox” but nevertheless holding that mandatory vaccination law as “enacted in a reasonable and proper exercise of the police power”).

\textsuperscript{280} Id. (noting near-universal belief of medical profession, legislatures, and the people in value of vaccination);\textit{ see also }Industrial Union Dep’t, AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 652 – 55 (1980) (“Benzene Case”) (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” and concluding that “requirement that a ‘significant’ risk be identified is not a mathematical straitjacket”).

\textsuperscript{281} \textit{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, \textit{supra} note 20, at 31 (describing government interest in addressing potential harms to community interests); Cole, \textit{supra} note 18, at 78 (discussing moral justifications for “prevention intervention”);\textit{ see, e.g., Commonwealth v. Alger, 61 Mass. 53 (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)).

\textsuperscript{282} \textit{See generally }STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 3 (1993) (discussing challenges of risk assessment and noting, “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.*”).

\textsuperscript{283} \textit{See, e.g., Kirk v. Wyman, 65 S.E. 387 (S.C. 1909) (accepting challenge to manner, but not fact, of quarantine of elderly woman infected with leprosy, deemed dangerous and communicable).}
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.\footnote{See Jacobson, 197 U.S. at 37 – 38 (upholding “system of general vaccination,” without individual exceptions).}

Risk prediction is inherently imprecise. Government may stop activities that turn out to be harmless or allow activities that turn out to be deadly.\footnote{See Epstein, supra note 6, at 1458 – 59 (describing public health interventions and risks to individual liberties with risk prediction).} 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, highly salient suffering of Abigail and other terminally ill patients.\footnote{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 similarly Breyer, supra note 282, 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”).} That approach may produce seemingly abstract, unspecified harm 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.”\footnote{Epstein, supra note 6, at 1465 – 66.} 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 the Article. 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 the public health right because smoking in public is a “public bad.” Its effects are imposed broadly on others, without their consent. Smoking bans aim to protect the public, i.e., non-smokers, from the effects of second-hand smokers. Cigarette smoke is a tangible, visible externality in the form of puffs of smoke that non-smokers have no choice but to inhale and against which they cannot adequately protect themselves. Although non-smokers may have a choice to avoid encountering smoke in private homes or other locations, it is much harder to suggest that they should simply avoid going out in public if they want to avoid the risks. Even though the effects of second-hand smoke are not certain and subject to debate does not defeat the public

288 See supra notes 11 – 14 (listing examples).
health right, here, for the same reasons that perfect risk prediction is not required in the experimental drugs context.\textsuperscript{289}

Also, the same practical problems with potential private law solutions that arose in the pollution context apply to second-hand smoke. It would be difficult to identify every smoker in whose presence a sick individual has been, prove that his ill health effects were caused by this or that smoker, and collect judgments. Prospective solutions, such as contracts or injunctions, would be similarly difficult, in terms of identifying the smokers, negotiating an agreement, and enforcing any breach. 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.”\textsuperscript{290} 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

\textsuperscript{289} See O’Connor et al., supra note 9, at 403 (citing “convincing scientific data that laws against indoor smoking protect people from negative health effects of cigarette smoke”); Damon K. Nagami, Comment, Enforcement Methods Used in Applying the California Smoke-Free Workplace Act to Bars and Taverns, 7 HASTINGS W.-N.W. J. ENVTL. L. & POL’Y 159, 160 – 61 (2001) (describing reports and scientific studies linking second-hand smoke to health problems).

\textsuperscript{290} See Epstein, supra note 6, at 1464.
made a choice to provide medical care for people with those health problems, there would be no public harm.\textsuperscript{291} Accordingly, obesity regulation seems outside the scope of the public health right.

Handgun regulation comes closer, however. There is considerable, undisputed data on handgun-related deaths and injuries, especially to children and adolescents.\textsuperscript{292} In addition, there is good indication that restricting access to handguns reduces those numbers.\textsuperscript{293} Although the data and correlation between handgun regulation and violence reduction are subject to dispute,\textsuperscript{294} 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 may be legitimate, private uses of handguns (target practice?) that do not directly impose harm on others. Individuals may choose not to own firearms, but the evidence suggests that that does not effectively insulate them from risk of harm. Thus, regulations that restrict ownership, perhaps just to

\begin{footnotes}
\textsuperscript{291} See Benforado, 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).
\textsuperscript{293} See Drazen, Morrisey & Curfman, supra note 13, at 1 & n.4 (noting 25% decline in firearm-related homicides and suicides following D.C. 1976 handgun law and citing study).
\textsuperscript{294} Heller, 128 S. Ct. at 2854, 2857 – 58 (noting “considerable debate about whether the District’s statute helps 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 2nd 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.” 128 S. Ct. at 2822.
\end{footnotes}
certain persons and places, seem justified in the “old” public health sense. Moreover, private law responses, including victims’ tort actions, criminal prosecution for crimes involving handguns, and products liability litigation against gun manufacturers 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 and seems hard to justify as a public health right. Sickness and disability cause individuals suffering that may be alleviated by medical treatment. But health care is expensive, and health care costs can be financially devastating to individuals. Requiring people to purchase health insurance, therefore, may 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 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. Otherwise, the choice

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295 In *Heller*, the Court concluded that D.C.’s restrictions went too far. 128 S. Ct. at 2822.
297 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?”).
299 See, e.g., Emergency Medical Treatment and Active Labor Act (“EMTALA”), 42 U.S.C.A. § 1395dd (requiring all Medicare-participating hospitals to provide appropriate, nondiscriminatory medical
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.\footnote{See \textit{DRA NOVE}, \textit{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.'"); \textit{SHERMAN FOLLAND ET AL.}, \textit{THE ECONOMICS OF HEALTH AND HEALTH CARE} 13 (2001) (discussing uncompensated care costs and cost-shifting).} Requiring people to purchase health insurance is supposed to shift those costs back on the individuals, rather than government and the rest of society.\footnote{See Whitman, supra note 14 ("the justification of the individual mandate was to reduce cost-shifting" and suggesting "subsidy to high risk patients generates a political incentive to regulate personal lifestyles").} 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.”\footnote{See generally \textit{Tom Baker, Containing the Promise of Insurance: Adverse Selection and Risk Classification}, 9 CONN. INS. L.J. 371, 376 – 78 (2002/2003).} Therefore, the individual mandate does not really eliminate the subsidy but merely spreads it more broadly.\footnote{See \textit{Jacob}, supra note 298, 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").} 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 does 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.304 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 policymakers are considering whether current regulations on prescription drugs should be loosened to allow terminally ill patients to access the drugs before they have

304 See supra notes 15 – 16 and accompanying text (discussing individual “right to health” and broad goals of “new” public health, including wealth redistribution).
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, however, in keeping with the “old” public health, and supports some, but not all, approaches to current social and health problems.