The Ethical Issues behind Expanding the Right to Try Preapproval Drugs and Medical Devices

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ABSTRACT

This paper looks at the ethical issues behind the "right to try" movement, which supports giving terminal patients access to drugs that have yet to be approved fully by the FDA. Even as momentum builds and more states pass right-to-try legislation, the discussion to this point has mostly addressed the political aspects of the debate to the exclusion of the ethical aspects. In this paper, I examine the ethics of the right to try, focusing on the contrast between (1) the individual's right of freedom regarding his or her body and health (and the state's responsibility to support this) and (2) the state's duty to protect its citizens from unwarranted harm from dangerous substances and procedures. Based on the ethical analysis, the paper makes several proposals for reform and also considers the equity issues invoked by alternative methods of financing the use of unapproved drugs and devices.

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A paradox lies at the heart of health care in modern liberal societies. On the one hand, we value individual autonomy and regard each person's body to be his or her sovereign domain. On the other hand, we carefully regulate what individuals can do to or put into their bodies. One widely discussed example is the prohibition of controlled substances, which has led to a tragically costly "war on drugs." Another example is the FDA's decision about which drugs and procedures individuals can use to improve their health and, in some cases, attempt to save their lives. Advocates of both types of regulation justify them based primarily on the assertion that they reduce risk of individual harm. Opponents argue that people balance various risks with benefits every day in light of their unique, individual interests, and that they know more about those interests than policymakers do. Generally, given the intrinsically personal nature of healthcare decisions, opponents maintain that the government should grant individuals more autonomy, not less, to make them than to make other types of decisions (such as those regarding consumption or finances).

This debate is not merely a philosophical one; it is also a political debate at the state level. Reminiscent of the struggle of AIDS sufferers to gain access to preapproval medicines in the 1980s, a "right to try" movement has emerged, which supports legislation to allow terminally ill patients to use drugs and devices that have passed the first stage of FDA approval, which focuses on basic safety, not efficacy.[1] While this movement has had admirable success in just two years, achieving its legislative goal in almost half of the 50 states, questions nonetheless remain, such as why right to try is a subject of debate and what justifies the FDA's authority to limit access to such treatments for the terminally ill (and the nonterminally ill as well).

1. For an overview, see Darcy Olsen, *The Right to Try: How the Federal Government Prevents Americans from Getting the Lifesaving Treatments They Need* (New York: Harper, 2015).

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This paper will explore the arguments for and against government regulation of healthcare interventions, with particular attention given to experimental drugs and procedures that have not yet been approved by the FDA. Does the individual right to autonomy over one's body preclude any government intervention? If not, how do we as a society decide how far the government may go in protecting its citizens from harm from unapproved drugs and devices—and is the government in a position to control such decisions effectively, or should it limit itself to providing information on potential harm? Finally, if the right to try is expanded, what issues will it raise in terms of equity? Specifically, who will bear the costs of experimentation and who will have access to it?

CONTRASTING PRINCIPLES IN HEALTH POLICY AND REGULATION

There are many arguments for individual or personal autonomy, including natural rights, dignity, and personhood, as well as more practical epistemic concerns.[2] We need not rehearse them at length here because the issue with medical paternalism is not whether persons have the right to control their own bodies and what they do to them, but whether this right is absolute or allows exceptions that would open the door for state interference with individual choice.

If we do not hold the individual right to bodily autonomy to be absolute, actions taken to limit it nonetheless need to be justified on the basis of another principle or goal. One such principle is the autonomy of other people, which obligates a person to avoid wrongfully infringing on the rights and liberties of others. More relevant to the case of health interventions is the principle of beneficence, by which the government is held to have a responsibility or duty to increase the well-being, or at least prevent decreases

2. For a more comprehensive discussion, see Gerald Dworkin, *The Theory and Practice of Autonomy* (Cambridge: Cambridge University Press, 1988).

in the well-being, of its citizens (and perhaps noncitizens as well). For example, the first sentence of the US Constitution states that the people intend the government to, among other things, "promote the general Welfare," which can be interpreted to imply a responsibility on the part of the government to make its citizens better off. This is reflected in the FDA's mandate "to promote health" as laid out in the Federal Food, Drug, and Cosmetic Act,[3] as well as in a statement by bioethicist James F. Childress and his coauthors that "the government has a strong role in public health because of its responsibility, grounded in its police powers, to protect the public's health and welfare."[4]

While this interpretation of the constitutional language can be contested on libertarian grounds, it could be considered consistent with minimal government, depending on how the government is assumed to behave toward its citizens. Supporters of liberty and rights favor a system of limited, hands-off government that creates a level playing field on which individuals can pursue their own interests. By performing functions such as maintaining a court system and police force and by providing certain public goods in response to the democratic process, such a government promotes individuals' well-being indirectly: it lets citizens, who know their interests better than policymakers do, make decisions in those interests.[5] This is an explicitly passive approach to promoting well-being in that the government leaves it to the people to decide what makes them "better off," limiting their welfarist interventions to the defense of individual interests, in line with John Stuart Mill's famous "harm principle."[6] In terms of health regulation, the government would be limited to, at the most, assessing the safety of medical innovations such as drugs, devices, and procedures, and informing their citizens of the results, a role that can be considered both a public good and part of protecting citizens from each other (specifically, protecting medical consumers

3. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 9.

4. James F. Childress et al., "Public Health Ethics: Mapping the Terrain," *Journal of Law, Medicine & Ethics* 30, no. 2 (2002): 170–78. For more on the FDA's mandate, see Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton: Princeton University Press, 2010).

5. See, for instance, Richard A. Epstein, *The Classical Liberal Constitution: The Uncertain Quest for Limited Government* (Cambridge, MA: Harvard University Press, 2014); and Mark D. White, *The Illusion of Well-Being: Economic Policymaking Based on Respect and Responsiveness* (New York: Palgrave Macmillan, 2014).

6. "The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right." John Stuart Mill, *On Liberty* (London: Longman, Roberts & Green, 1869).

from negligent or careless medical suppliers).[7] Aside from this role, the government leaves it to individuals to make their own choices, in conjunction with doctors and family members, regarding whether or how to use medical innovations to further their own interests.

However, another view dominates health policy: according to this view, the government should take a more active approach to promote the well-being of citizens, one that goes beyond protecting some citizens from others by implementing policies that the government believes to be in people's best interests. This approach is explicitly paternalistic, involving a presumption on the part of government decision makers that they understand what their citizens' interests are. Typically, paternalists understand the relevant components of people's well-being to be common and general, such as wealth and health. Furthermore, based on psychological research on the imperfections of human decision-making, policymakers often believe that, left to their own devices, individuals will not make the best decisions in their own interests. Together, the assumptions of general interests and flawed decision-making motivate government intervention to improve people's choices in order to further those interests. Such interventions can take the form of openly coercive measures, such as taxes and bans, or more subtle measures, such as "nudges" that use behavioral insights to steer choices in the direction preferred by policymakers.[8]

We need not take issue here with the position that personal bodily autonomy can be outweighed by the government interest in its citizens' health. The focus of this paper is on assessing the practical case for health paternalism in order to find the proper balance between these competing principles. On a purely conceptual level, the arguments in favor of both principles are strong. In liberal societies individual autonomy is taken to be of central importance in general, and even more so in the area of bodily autonomy. Even those (typically on the Left) who would question the institution of property rights and the autonomy associated with them would assent to strong autonomy rights regarding one's body (as

7. A related issue regards the "public" in public health: whereas some argue that public health should be concerned with supraindividual health concerns such as contagious diseases, others argue that health in general is a public concern. For the former view, see Richard A. Epstein, "In Defense of the 'Old' Public Health: The Legal Framework for the Regulation of Public Health," *Brooklyn Law Review* 69 (2004): 1421–70; for the latter, see John Coggon, *What Makes Health Public? A Critical Evaluation of Moral, Legal, and Political Claims in Public Health* (Cambridge: Cambridge University Press, 2012), especially chap. 1–3.

8. On coercive paternalism, see Sarah Conly, *Against Autonomy: Justifying Coercive Paternalism* (Cambridge: Cambridge University Press, 2013); on nudge paternalism, see Richard H. Thaler and Cass R. Sunstein, *Nudge: Improving Decisions about Health, Wealth, and Happiness* (New Haven: Yale University Press, 2008).

seen in arguments in favor of sexual and reproductive freedom). The arguments for medical paternalism also acknowledge the importance of the individuals' bodies and do not overtly question their rights regarding them. At the same time, however, they emphasize that individuals may not have sufficient information or willpower to take proper care of their health, whether in terms of diet or exercise, or in adhering to scheduled checkups and drug regimes. In other words, it is *because* of the importance of bodily autonomy, as well as the importance of health to the pursuit of other personal goals, that the government feels it necessary to intervene in health choices.[9]

If there is no clear way to decide between autonomy and paternalism on a conceptual basis, more practical elements must be used to weigh these concepts against each other. In the following sections, I will survey several aspects of this debate, all of which, in the end, question the ability of the government to effectively increase individuals' well-being through regulation of medical interventions, especially preapproval drugs and devices. Instead, I recommend that, if the government is to take an interest in its citizens' healthcare decisions, the most effective way to do so is by providing information and education, which individuals can then combine with their own interests and the advice of their doctors and loved ones in order to make well-informed decisions that—in the individuals' own judgment—truly make them better off.

INTERESTS AND CHOICE

The most common justification for government intervention in private health choices, especially regarding unapproved drugs and devices, is that people may not be able to accurately assess the risks and costs relative to their medical and financial situation. Policymakers feel that people cannot be trusted to make the best decisions in their own interests owing to (1) a lack of information about medical risks and outcomes, as well as their financial implications, (2) well-documented cognitive difficulties in assessing risk, and (3) the emotionally fraught context in which many of these decisions are made. Indeed, in a position paper against the right to try, the Society for Clinical Trials asserted that an expanded

9. Along these lines, Thomas R. V. Nys argues that in some cases health paternalism can promote "deep autonomy," limiting some decisions in the interest of promoting health, thereby giving people a wider ranging of choices in other areas of life. "Paternalism in Public Health Care," *Public Health Ethics* 1, no. 1 (2008): 64–72. Jennifer Prah Ruger makes a similar argument in the context of capabilities theory. *Health and Social Justice* (Oxford: Oxford University Press, 2010).

process for allowing early use "is not in the best interests" of patients.[10] In this section, I will first address the more general issue of interests, and then turn to the particular aspects of decisions in the context of health.[11]

The problem with government policymakers' concern, however sincerely benevolent it may be, is that they have no way of knowing the true interests of individuals, including those struggling near the end of their lives with decisions regarding experimental drugs and procedures. Whatever simplistic interests that policymakers implicitly or explicitly assume on individuals' behalf—likely some rough combination of measures of health and quality of life (possibly also including costs)—they do not accurately represent people's true interests, which are multifaceted, complex, and subjective. They are multifaceted in that they incorporate a wide range of concerns, from self-interested and other-interested preferences to personal moral principles and societal ideals. They are complex in that these interests are combined and balanced in ways that change with each specific choice situation an individual faces. Furthermore, a person's true interests are inherently subjective and can only be known to that person (albeit imperfectly); absent revelation, they are unknown to the policymaker.

Policymakers could concede the nature of individuals' true interests as described above yet still argue that the interests in the choice situations under consideration here can safely be reduced to those relevant to health and finances. For instance, James Wilson argues in defense of health paternalism that "health has as strong a claim as any good to be an uncontroversial good for states to promote."[12] This argument is not unreasonable, but it fails to recognize that individuals' interests regarding health (and wealth) are themselves just as multifaceted, complex, and subjective as interests in general. As Jessica Flanigan writes, public health experts

> do not have extensive knowledge about how remaining healthy would balance against other values for a particular person. How health or safety is valued when it conflicts with other values, like

10. Society for Clinical Trials Board of Directors, "The Society for Clinical Trials Opposes US Legislation to Permit Marketing of Unproven Medical Therapies for Seriously Ill Patients," *Clinical Trials* 3, no. 2 (2006): 155.

11. For more on this, see Mark D. White, "Bad Medicine: Does the Unique Nature of Health Care Decisions Justify Nudges?," in *Nudging Health: Health Law and Behavioral Economics*, ed. I. Glenn Cohen, Holly Fernandez Lynch, and Christopher T. Robertson (Baltimore: Johns Hopkins University Press, 2016), 72–82; and "The Crucial Importance of Interests in Libertarian Paternalism," in *Nudging: Possibilities, Limitations and Applications in European Law and Economics*, ed. Klaus Mathis and Avishalom Tor (New York: Springer, 2016), 21–38.

12. James Wilson, "Why It's Time to Stop Worrying about Paternalism in Health Policy," *Public Health Ethics* 4, no. 3 (2011): 270.

> the pleasure of eating fatty foods or feeling the wind in one's hair, will vary from person to person.[13]

In terms of health and life, one person may be more concerned with quality than length, while another may have the opposite ranking, with the difference between them based on any number of other personal factors, including family and friends, life goals, and personal finances. With regard to the last, people with large fortunes may be willing to spend it to prolong their lives, while others may want to pass most of it on to relatives or donate it to charity. Even those with few resources will have a similar breadth of preferences regarding how they allocate those resources, either to their health or to other uses. There is no way for policymakers to know or account for these interests; they can only impose their own specific conception of health and wealth and their particular way of weighing them against each other.[14]

Furthermore, individuals' choices regarding their health can be considered more personal than other choices they make, and therefore they should receive special protection from government intervention. The ideal of liberal neutrality holds that people should be free to pursue their unique visions of the good life, provided they do not wrongfully interfere with others doing the same. This encompasses all the choices that people make in their lives, such as where to live, who to love, and what kind of work

"Individuals' choices regarding their health can be considered more personal than other choices they make, and therefore they should receive special protection from government intervention."

13. Jessica Flanigan, "The Perils of Public Health Regulation," *Society* 51, no. 3 (2014), 230. In another paper, Flanigan argues that the same presumption against paternalism in doctor-patient relationships should extend to policy. "Public Bioethics," *Public Health Ethics* 6, no. 2 (2013): 170–84. On doctor-patient relationships, see Allen Buchanan, "Medical Paternalism," *Philosophy & Public Affairs* 7 (1978): 370–90.
14. Some also argue that not all health decisions are important enough to be immune from paternalistic intervention; for instance, see Wilson, "Why It's Time to Stop Worrying," 275–76; Madison Powers, Ruth Faden, and Yashar Saghai, "Liberty, Mill and the Framework of Public Health Ethics," *Public Health Ethics* 5, no. 1 (2012): 6–15; and Conly, *Against Autonomy*, chap. 6. However, this distinction invokes the same external value judgment present in all arbitrary decisions regarding individuals' interests.

to do. The most essential of these choices are the ones people make regarding their bodies, including what substances they ingest, how they exercise, and what medical treatments they accept. Advocates of health paternalism (such as Wilson) are correct to point out the instrumental value of health to other life goals and ends, but they fail to acknowledge that this importance also implies a greater respect for autonomy concerning decisions about health.

Policymakers may acknowledge their ignorance of individuals' specific interests in health and wealth and then argue for general rules and standards that are designed to lead to improved outcomes overall, using a more welfarist decision-making procedure.[15] But this raises the question of how those outcomes will be assessed or measured without knowledge of individuals' true interests. Without such evidence, regulation promotes a vaguely defined conception of the public interest to the detriment of individual interests and the autonomy to make decisions in pursuit of them. At the very least, by limiting individual choice to use certain drugs and medical procedures in the interest of collective general outcomes, policymakers are blocking individuals' pursuit of their own interests—precisely those interests that are most intensely personal and should be protected even more strongly from usurpation.

Policymakers regularly question the ability of individuals to make informed and rational healthcare decisions, especially in circumstances such as those considered here. As described by experimental psychologists and behavioral economists, individuals are subject to a number of cognitive biases and dysfunctions that cause their decision-making to deviate from ideal rational models and lead them to develop heuristics that overcome some of these flaws but may introduce new irrationalities.[16] For instance, confirmation bias can lead us to focus on new information that corresponds with existing beliefs, such as when positive news regarding the health effects of one's favorite food is remembered and negative news about the same food is forgotten. Also, present bias causes us to undervalue future costs and make imprudent health decisions that have short-term benefits but long-term consequences. These cognitive

15. Mary Jean Walker, Wendy A. Rogers, and Vikki Entwistle, "Ethical Justifications for Access to Unapproved Medical Interventions: An Argument for (Limited) Patient Obligations," *American Journal of Bioethics* 14, no. 11 (2014): 4. On the slide from individualist paternalism to collective welfarism, see Russell Korobkin, "Libertarian Welfarism," *California Law Review* 97, no. 6 (2009): 1651–85.

16. For foundational work in this area, see Daniel Kahneman, Paul Slovic, and Amos Tversky, eds., *Judgment under Uncertainty: Heuristics and Biases* (Cambridge: Cambridge University Press, 1982); for overviews, see Dan Ariely, *Predictably Irrational, Revised and Expanded Edition: The Hidden Forces That Shape Our Decisions*, exp. ed. (New York: Harper Perennial, 2010); and Erik Angner, *A Course in Behavioral Economics*, 2nd ed. (New York: Palgrave Macmillan, 2016).

factors are particularly salient in the context of healthcare decisions, especially those that prompt consideration of unapproved drugs and procedures, given the elements of complex information, uncertainty and risk, and emotion that are in play.

One can acknowledge the importance of these factors and still deny the need for medical paternalism. To begin, patients do not make decisions in isolation. Medical professionals provide and interpret medical information and put risks into context. They can cooperate with friends and family to help the patient think calmly and clearly about the various issues involved. More essentially, questioning the rationality of general decision-making in such fraught contexts is not the same as knowing which specific decisions are or are not in an individual's interests, even if we restrict the interests considered to health and wealth alone. Since individuals have the best knowledge of their true interests, they are in the best position to know whether a decision supports those interests. A medical choice that may seem imprudent or irrational to an outsider—such as rejecting the course of action recommended by a physician, spending all one's wealth to extend life by a few months, or taking a risk on an unapproved medication or procedure—may well be in the decision maker's true interests as understood by the individual.

Medical professionals do have an essential role to play in *helping* individuals make the best decisions in their own interests, by providing technical information regarding alternative treatments as well as the risks and costs of each. This is complicated information, to be sure, and it is the medical professional's responsibility to break it down for the patient and his or her family so they can use the information to make the best decision in the patient's interests.[17] Ethical doctors would not make the decision for the patient or rule out certain options without the consent of the patient, because they lack knowledge of the complex and multifaceted interests on which these decisions will be made. Policymakers do, however, rule out options when they prevent patients from experimenting with unapproved medications and procedures. Basing decisions on even less information about individuals' interests than their doctors have, policymakers block the use of such options in an attempt to limit vague conceptions of risk and mortality but with unknown effects on individuals' true interests.

17. The issue of competence on the part of doctors is relevant here: most patients are not in a position to evaluate the quality of their doctors' advice, which is often taken as a matter of faith. (This may also be an issue of equity if the poor are more likely to see doctors with less expertise.) While this is an issue in all doctor-patient relationships, if more safeguards are deemed necessary in the case of right to try, the FDA could require second opinions or multiple prescriptions.

This external judgment of decisions is a problem in many healthcare contexts but particularly in the context of end-of-life decisions, when individuals' choices to try unapproved medications or procedures may seem to the policymaker or doctor to represent an unwarranted risk. They question the individuals' decision-making faculties and the way they balance the various costs and benefits involved against their own interests (including the risks the individuals consider acceptable). But policymakers and doctors cannot make such judgments without assuming particular interests on the part of individuals, which betrays a lack of respect at a time when those interests should be respected more, not less. In the case of terminally ill patients in particular, the revelant balance of interests is likely to be extraordinary: the benefits, in terms of extended length of life or enhanced quality of life, are greater, and the costs are lower than in normal health situations (especially if, without intervention, death is imminent). This realization is even more imperative if there is a high probability the patient will die while waiting for drugs to be approved.[18] Such cases illustrate very dramatically the folly of presuming general common interests on the part of patients and the imperative to be respectful of their choices, no matter what the policymaker or medical professional may think of them.

REFORMING THE SYSTEM

Under current law, the FDA has the power to grant exceptions to allow terminally ill patients to try preapproval medications and devices, and it does grant most such applications, but right-to-try advocates argue that the application procedure is too burdensome and lengthy to be truly effective.[19] If we think of this situation in terms of the contrasting principles of autonomy and beneficence, the FDA finds the balance between them to be much closer to the latter by default, moving in

18. See, for instance, Richard A. Epstein, "The Erosion of Individual Autonomy in Medical Decisionmaking: Of the FDA and IRBs," *Georgetown Law Journal* 96, no. 2 (2007): 579. Some disagree: in questioning the decision-making autonomy of terminally ill patients, Arthur L. Caplan writes, "There are things worse than death—being made to die fast, being made to die more miserably or having one's dying prolonged but with no appreciable increase in quality of life or functionality." Arthur L. Caplan, "Is It Sound Public Policy to Let the Terminally Ill Access Experimental Medical Innovations?," *American Journal of Bioethics* 7, no. 6 (2007): 3. Nonetheless, after being informed of all the possible consequences by doctors and after consultation with loved ones, there seems no reason to restrict or deny patient autonomy even in such circumstances. These consequences are dire and to a large extent unimaginable, but they are the patient's to weigh and decide on.

19. For details, see Walker, Rogers, and Entwistle, "Ethical Justifications for Access"; Rebecca Dresser, "The 'Right to Try' Investigational Drugs: Science and Stories in the Access Debate," *Texas Law Review* 93 (2015): 1631–57, esp. 1633–41; Mark Flatten, "Dead on Arrival: Federal 'Compassionate Use' Leaves Little Hope for Dying Patients," Goldwater Institute, 2016; and Olsen, *Right to Try*.

the direction of autonomy only at their discretion (a process which itself reflects a devaluation of autonomy). In general, the FDA position may be due to doubts about the ability of individuals to make sound choices in a complex and emotionally fraught context. However, if the arguments above regarding interests and choice are accepted, those concerns are exaggerated, and the number and type of exceptions granted by the FDA should be expanded and expedited significantly along several dimensions.

For instance, there is the question of whether patients should be required to seek exceptions from the FDA at all. Government officials have no knowledge of patients' interests, and have no information that patients' doctors do not have (or cannot be given). If some approval is deemed necessary, parallel authorities in other countries often approve new drugs and devices much more quickly than the FDA does. If, as I have argued, individuals are best placed to make prudent decisions in their own interests—with the advice of doctors acting on up-to-date information—then the approval of those same drugs or devices by other countries' testing agencies should make our domestic authorities more comfortable about "allowing" patients to try these medical innovations before FDA approval is completed.[20]

We can also ask why exceptions are limited to the terminally ill (or a small subset of them).[21] If dying individuals' right to take ownership of their healthcare choices regarding preapproval drugs and devices were affirmed, the FDA would need to justify withholding such choices from patients who are suffering but not terminally so, including those who linger in agony for years without being classified as terminal.[22] This touches on the issue of humane end-of-life care that is becoming increasingly important as the population ages, an issue not only of prolonging life but of improving its quality as well.[23] Individuals' rights to make decisions regarding their own health care should extend, not only to the treatment choices they make, but also to the reasons they make them, both of which are integral parts of their healthcare choices. Again, the FDA arbitrarily makes external judgments regarding which medical problems are severe enough to justify "exceptionally"

20. To this end, Daniel Klein and Alex Tabarrok advocate for international regulatory reciprocity in their section "Reform Options" at FDAReview.org (Independent Institute, 2016).
21. See, for instance, Denise Meyerson, "Is There a Right to Access Innovative Surgery?," *Bioethics* 29, no. 5 (2015): 351.
22. The definition of what states of illness are classified as terminal is a conceptual problem in itself, and one with clear practical ramifications in these cases; see Caplan, "Is It Sound Public Policy," 2.
23. Atul Gawande, *Being Mortal: Medicine and What Matters in the End* (New York: Metropolitan Books, 2014).

risky interventions (a value judgment in and of itself), but it is the patients' risk to assess and take, not the FDA's.[24]

A practical issue that is often cited by critics of an expanded right to try is the effect of such access on the validity of the clinical trial process that leads to approval of drugs for general usage.[25] They claim that early access will compromise the success of clinical trials by reducing the number of willing applicants for them, and it may also reduce the incentive for drug companies to invest in costly trials if they can sell drugs without full approval, resulting in the widespread marketing of medications with proven safety but without proven effectiveness. These are legitimate concerns but not necessarily dispositive ones, relying on empirical judgments such as the number of patients eligible for trials compared to the number of patients seeking preapproval access—as well as the number of patients ineligible for the trials who might seek access—and the number of patients willing and able to experiment with such treatments in general (which is relevant to the discussion of equity below).[26] Richard Epstein compares this problem

"Government officials have no knowledge of patients' interests, and have no information that patients' doctors do not have (or cannot be given)."

24. A similar debate is playing out in Europe with regard to euthanasia and whether it should be extended to people with a nonterminal illness as well as those suffering from mental illness (including depression). Without expressing any opinion on the proper scope of euthanasia, it would seem that extraordinary measures to try to improve or save a life would be more acceptable than those meant to end one. This contrast was clear in Governor Jerry Brown's back-to-back decisions in 2015 to sign one bill granting the Right to Die and veto another one that would allow the right to try. Naomi Lopez Bauman, "What Gov. Jerry Brown's Veto of 'Right to Try' Means for California's Terminally Ill Patients," *Ricochet*, November 10, 2015. For more, see Epstein, "Erosion of Individual Autonomy," 569; Meyerson, "Is There a Right to Access Innovative Surgery?," 344–46; and Olsen, *Right to Try*, chap. 9 ("If You Have the Right to Die, You Should Have the Right to Try").
25. Shira Bender, Lauren Flicker, and Rosamond Rhodes, "Access for the Terminally Ill to Experimental Medical Innovations: A Three-Pronged Threat," *American Journal of Bioethics* 7, no. 10 (2007): 3–6; Walker, Rogers, and Entwistle, "Ethical Justifications for Access," 10.
26. Eugene Volokh, "Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs," *Harvard Law Review* 120 (2007): 1830. Only 3 percent of patients are admitted into clinical trials (see Flatten, "Dead on Arrival"); nonetheless, to eliminate any negative effect on participation rates, some right-to-try laws restrict access to experimental drugs to patients not accepted into clinical trials.

to the prisoner's dilemma in game theory, in which mutual participation ensures gains for all while there are greater gains from defection.[27] He argues, however, that even if this is an accurate description of the current situation, collective action arguments such as these do not justify coercion or limitations on individual actions that are otherwise permissible and protected, such as the exercise of bodily autonomy.[28]

One way to address this concern is with a two-tiered approval process. Such a process could correspond to the current FDA approval system by which Stage I approval is based largely on safety while Stage II focuses on efficacy, with drugs and devices given a different degree of approval at each stage. For terminally ill patients willing to try anything, neither safety nor efficacy may be a significant concern; even if the government's interest in preserving life is acknowledged, it would require only that safety be assured, which would be achieved by demanding that innovations pass Stage I before the lesser degree of approval and access are granted. Patients besides the terminally ill may want access to such medications as well, even if they have not yet passed Stage II (and even if they fail to demonstrate efficacy at that stage). This could be allowed under a two-tiered system, alleviating the need to make a distinction between terminal and nonterminal cases.

It would be reasonable to expect treatments with unproven efficacy would be priced lower than drugs with proven efficacy, and physicians would be less likely to prescribe them. Nonetheless, some consumers may be willing to accept this trade-off in order to secure earlier or cheaper access to medications whose safety has been verified. Consumers willing to wait for medications with proven safety *and* efficacy—and willing to pay the higher price for them—can buy those medications with the higher level of approval following proper clinical trials, which may be more difficult to conduct but at the same time less important (at least at later stages of the process). Forcing all medications to pass the highest level of approval in order to be sold on the open market when only Stage I is necessary to satisfy concerns about safety places too high a burden—in terms of dollars and lives—on consumers and drug manufacturers alike, as well as on patient autonomy and the right to make one's own healthcare choices.

More generally, the FDA's drug approval process should shift its focus from banning drugs and devices to informing consumers of their risks. As Richard

27. Epstein, "Erosion of Individual Autonomy," 579–80.
28. Volokh ("Medical Self-Defense") defends this right, not on the basis of autonomy but on the basis of self-defense, likening taking preapproval medications to other lifesaving measures (such as taking a life) that are justified under law. See also Epstein, "Erosion of Individual Autonomy," 576–77.

Epstein argues, based on the agency's relatively permissive policy with respect to off-label uses of approved medications, they "should get out of the banning business and stay in the warning business," citing their ignorance of risks and benefits in individual cases.[29] A responsibility to provide information rather than block choice would be consistent with the government's interest in the health of its citizens, and at the same time it would allow consumers to make the decisions they feel would best further their interests. Consumers may sometimes make choices that government regulators would have chosen to restrict, but due to ignorance, regulators' choices are not always in the best interests of the regulated. Regulators should acknowledge this fact, respect individuals' choices, and use their medical knowledge to inform consumers regarding the safety and danger of various medical options. Consumers, together with their doctors and loved ones, can then use this information to make the best choices in their interest.

SOCIAL POLICY AND EQUITY

Besides the effect on individuals' autonomy and interests, there are also social issues at stake when considering early access programs. One example is the aforementioned effect of early access on clinical drug trials. A more general concern is the cost of experimental treatments and the implications for equity in health care. Because of the unique nature of health care in the market and society, as well as the trend toward universal health care, equity represents a serious problem, transcending the issues of beneficence and paternalism that motivate limitations on the right to try.

The default option in financing experimental treatments is to allow people to use preapproved drugs and devices as they wish, provided they bear the full costs. This would be the free-market option and, accordingly, the one that best aligns individuals' costs and benefits, but it also flies in the face of current trends in healthcare financing toward cost sharing and universalization. It would also render experimental lifesaving procedures more accessible to those with more resources, raising important equity issues, as demonstrated in medical tourism, where the wealthy effectively have more access than the poor to better and faster health care.[30]

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29. Epstein, "Erosion of Individual Autonomy," 574. See also Nicole E. Lombard, "Paternalism vs. Autonomy: Steps toward Resolving the Conflict over Experimental Drug Access between the Food and Drug Administration and the Terminally Ill," *Journal of Health & Biomedical Law* 3 (2007): 187–88. ("A practical alternative [to current FDA access procedures] would be to only require the substantial evidence requirement of the drug's safety, which remains a valid governmental concern.")
30. See, for instance, I. Glenn Cohen, *Patients with Passports: Medical Tourism, Law, and Ethics* (Oxford: Oxford University Press, 2014).

Another option is to rely on insurance companies to support preapproval treatments, which would be more equitable (contingent on the level of equity in the healthcare system as a whole), but also implies that the costs of experimentation would be shared among all policyholders. The size of the cost increases is impossible to know, as it would be based on the level of usage and any subsidization from the companies themselves, and policyholders could have personal objections to helping pay for unapproved procedures at all (in the same way they have objections to other types of care that conflict with moral and religious beliefs). At bottom, the issue here is the more general one of which procedures should be covered by insurance and therefore paid for by policyholders as a group (unless costs are segmented, which would represent a partial return to individual financing). Again, the current trend in healthcare finance is toward more insurance coverage, which would presumably include experimental treatments as well; any political issues that may arise owing to experimental treatments being covered by insurance would be issues with granting early access in general rather than with insurance coverage or equity itself.

In a market economy, most people accept that those with more resources can buy more or better goods and services. But health care is often held to be an exception to this, especially if it is considered a human right that should be guaranteed to all, in which case its provision becomes a matter of right and justice.[31] In a world of scarcity, however, health care must be limited and rationed somehow, and the choice between market-oriented and centralized healthcare systems comes down to who does the rationing. As philosopher Mary Jean Walker and her coauthors note,

> Where health care systems are structured around evidence of safety, efficacy, and cost-effectiveness, [special access programs] have the potential to open the door to costly and unproven interventions, thereby subverting attempts to contain costs based on sound reasoning and evidence.[32]

In a market system, "exceptions" to prohibitions of unapproved drugs and devices would be "granted" according to willingness and ability to pay rather than by FDA fiat, itself based on cost-effectiveness, albeit on an impersonal, sys-

31. There is extensive literature on health care and justice; for example, see Norman Daniels, *Just Health Care* (Cambridge: Cambridge University Press, 1985) and *Just Health: Meeting Health Needs Fairly* (Cambridge: Cambridge University Press: 2008); Coggon, *What Makes Health Public?*; and Ruger, *Health and Social Justice*.
32. Walker, Rogers, and Entwistle, "Ethical Justifications for Access," 10.

tem-wide level rather than on a personal, individual one. An insurance-based system may rule out such interventions for everyone on the basis of aggregate cost and statistical benefit, whereas a market system would allow those with access to resources, credit, or charity to make their own choices regarding personal costs and benefits based on personal interests.

The choice need not be this stark, though. Ideally, a centralized insurance system can guarantee that everybody receives a standard level of care, while greater care is available to those who can pay. Many countries with some form of universal health care, such as Canada and most European countries, have this kind of system. A system that allows those with adequate resources to purchase the use of experimental drugs and devices would not deny the standard level of care to the insured population, and it would resemble the provision of premium care in such universal healthcare systems. If the insurance system, for one reason or another, will not expand to cover experimental treatments, then it is difficult to see a reason why private citizens should not be able to spend their own resources to secure them, other than a basic appeal to "lowest common denominator" equity that would deny such treatments to everybody rather than allow them to some.

Given the integrally personal nature of healthcare decisions, it is preferable to limit governmental interference as much as possible so that patients, their loved ones, and the doctors who know their cases best can make the choices that best correspond to their interests and circumstances. It is possible that those with fewer resources could have expanded access to treatments, including experimental treatments, but given the imperative to minimize costs in a more centralized insurance-based system, there is no guarantee that this would happen.

CONCLUSION

While the government may have a strong interest in protecting the health of its citizens, it lacks the information about individual interests necessary to justify overriding their basic rights to make their own healthcare decisions, including decisions to try drugs and medical devices that have not successfully won full approval from the FDA. As Richard Epstein writes,

> The question is often whether the FDA will in its wisdom grant a compassionate use exemption for certain people in dire straits. Simply putting the question into this form shows just how deeply and powerfully the government has inserted itself into the lives

> of ordinary citizens regarding their life and death decisions. Citizens, as autonomous individuals, should be free to make these decisions for themselves.[33]

Given this solid foundation in the principle of autonomy and personal choice, concerns about the quality of clinical drug trials and distributional equity, while valid and significant, are not important enough to weigh decidedly against increased access to experimental medications and techniques. The dangers to the integrity of clinical trials is uncertain, being contingent on numerous factors, and the implications for equity are coincident with, but not distinct from, current debates over the provision of health care in this country.

The central issue in this debate is the value and importance that policymakers grant to individual choice and interests, and there is no area in life in which these factors are more personal or existentially valuable than a person's health, including end-of-life decisions. Patients should be given the maximum latitude to make these decisions for themselves, with the help of medical professionals and loved ones, at any stage of their adult lives—including the right to try preapproval drugs and devices that may extend their lives and allow them to control their destinies, even if only for a short time more.

33. Epstein, "Erosion of Individual Autonomy," 574.

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