

The Right to Try and the Future of the FDA in the Age of Personalized Medicine

Adam Thierer

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Abstract

Do citizens have the right to determine their own courses of treatment and to use medicines and devices that they think could improve their health? And, to the extent regulators seek to restrict that freedom, what is the practicality and cost of doing so? These questions animate the debate over the so-called "right to try," a growing movement to allow terminally ill individuals to experiment with alternative medical treatments, therapies, and devices that are tightly controlled by the Food and Drug Administration (FDA). This essay argues that such an expansion of the right-to-try notion may be happening already as technological innovation decentralizes and democratizes medical decisions. This expansion does not mean that all FDA regulation will fade away, but it will necessitate a move away from the agency's command-and-control methods of the past and toward a new focus on patient empowerment through enhanced choice, improved risk education, and clearer consent mechanisms.

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Author Affiliation and Contact Information

Adam Thierer
Senior Research Fellow
Mercatus Center at George Mason University
athierer@mercatus.gmu.edu

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Adam Thierer

Do citizens have the right to determine their own courses of treatment and to use medicines and devices that they think could improve their health or the well-being of their families? And, to the extent that regulators seek to restrict people's freedom to determine their own treatments, what is the practicality and cost of doing so?

These are the central questions that animate the debate over the so-called right to try.¹ “Right to try” refers to the growing movement (especially at the state level in the United States) to allow terminally ill individuals to experiment with alternative medical treatments, therapies, and devices that are tightly restricted or even prohibited in some fashion by the Food and Drug Administration (FDA).²

As the modern computing and Internet revolution continues to spread to other fields—and software, sensors, networked technologies, and other digital devices and applications begin to influence the world of drugs and medical devices—technological innovation is starting to challenge the way traditional food and drug regulation works. This development presents policymakers with a stark choice: they can try to hold on to the past and the top-down regulatory regime that has governed drugs and medical devices for the past century, or they can embrace new technological realities and adapt to them to capture the benefits associated with such innovations.

¹ Y. Tony Yang, Brian Chen, and Charles Bennett, “‘Right-to-Try’ Legislation: Progress or Peril?,” *Journal of Clinical Oncology* 33 (2015).

² See Sam Adriance, “Fighting for the ‘Right To Try’ Unapproved Drugs: Law as Persuasion,” *Yale Law Journal* 148 (2014); Christina Corieri, “Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of Their Treatment,” *Goldwater Institute Policy Report* No. 266, February 11, 2014.

We can think of this choice as one between the opposing policy dispositions of the “precautionary principle” (seeking to preemptively eradicate every theoretical danger through regulation) and “permissionless innovation” (allowing trial-and-error experimentation without excessive prior restraint).³ If the right-to-try movement is to succeed and is potentially to be applied more broadly beyond end-of-life scenarios, it requires a fuller embrace of the latter disposition and a serious rethinking of the old precautionary approach, which is increasingly unwise and unworkable.⁴ This essay argues that such an expansion of the right-to-try notion may be happening already as technological innovation decentralizes and democratizes medical treatment decisions. This expansion does not mean all FDA regulation will fade away, but it will necessitate a move away from the agency’s command-and-control methods of the past and toward patient empowerment through enhanced choice, improved risk education, and clearer consent mechanisms.

Ethical Dimensions of the Right to Try

The debate over the nature and scope of the right-to-try experimental medical treatments raises profound ethical⁵ and legal questions.⁶ Those on opposing sides of the debate advance strong moral claims in favor of their respective positions.

³ Adam Thierer, *Permissionless Innovation: The Continuing Case for Comprehensive Technological Freedom* (Arlington, VA: Mercatus Center at George Mason University, 2014); Alex J. Adams, “Toward Permissionless Innovation in Health Care,” *Journal of the American Pharmacists Association* 55, no. 4 (July/August 2015): 359–63; Henry Chesbrough and Marshall Van Alstyne, “Permissionless Innovation: Seeking a Better Approach to Pharmaceutical Research and Development,” *Communications of the ACM* 58, no. 8 (August 2015): 24–26.

⁴ “Permissionless innovation greatly increases the speed of invention and allows the ecosystem to provide ideas its system designers never had. The pharmaceutical industry could benefit from this approach.” Chesbrough and Van Alstyne, “Permissionless Innovation,” 24.

⁵ Jonathan J. Darrow et al., “Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs,” *New England Journal of Medicine* (2015): 279–86.

⁶ The more notable cases involving access to experimental drugs for terminally ill patients generally found that no such right exists. See *United States v. Rutherford*, 442 U.S. 544 (1979); *Abigail Alliance v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

The heavy-handed approach of modern FDA regulation is rooted in the belief that citizens simply cannot be trusted to make important health-related decisions on their own because they will never be able to appreciate the relative risks involved.⁷ This attitude is based on the simple truth that people sometimes make rash or unwise decisions about their health, often because of a lack of quality information. As a result, policymakers have taken the right to make choices about treatments away from citizens altogether in many circumstances.

By extension, the right-to-try movement is viewed with suspicion by defenders of what economist Robert Graboyes of the Mercatus Center at George Mason University labels the “Fortress” mindset.⁸ “The Fortress is an institutional environment that aims to obviate risk and protect established producers (insiders) against competition from newcomers (outsiders),” he notes. What is needed instead, he argues, is an embrace of the Frontier spirit, which “tolerates risk and allows outsiders to compete against established insiders.”⁹

Unfortunately, current FDA regulation remains firmly rooted in a Fortress mentality.¹⁰ Studies have shown that the FDA’s regulatory review process is dramatically too conservative¹¹ and thwarts far too many life-enriching innovations.¹² When a little freedom is allowed by the agency—as is the case, for example, with off-label prescriptions, which are largely unregulated—the benefits have been substantial in improved quality and lower costs for

⁷ Clint Bolick, “The End of FDA Paternalism?,” Hoover Institution, *Defining Ideas*, August 14, 2014.

⁸ Adam Thierer, “Robert Graboyes on What the Internet Can Teach Us about Health Care Innovation,” *Technology Liberation Front*, November 10, 2014.

⁹ Robert Graboyes, “Fortress and Frontier in American Health Care” (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, October 2014), 4.

¹⁰ Richard Williams, “The FDA Is Showing Its Age,” *U.S. News & World Report*, February 1, 2016.

¹¹ Vahid Montazerhodjat and Andrew W. Lo, “Is the FDA Too Conservative or Too Aggressive? A Bayesian Decision Analysis of Clinical Trial Design” (NBER Working Paper No. 21499, National Bureau of Economic Research, Cambridge, MA, August 19, 2015).

¹² Joseph V. Gulfo, *Innovation Breakdown: How the FDA and Wall Street Cripple Medical Advances* (Franklin TN: Post Hill Press, 2014); Richard A. Epstein, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation* (New Haven, CT: Yale University Institute for Policy Innovation, 2006).

patients.¹³ The FDA’s overbearing regulatory stance results in a significant drag on timely release of new drugs. As Darcy Olsen notes,

In an age when the speed of technological innovation is accelerating in almost every aspect of our lives, the time it takes to bring a new drug from the laboratory to the pharmacy shelf has nearly doubled over the last five decades. It now takes, on average, nearly fifteen years to bring a new drug to market.¹⁴

While the agency is not quite as heavy-handed in its approach to medical devices, it also imposes a complicated and time-consuming process for those seeking approval.¹⁵ Many leading Internet companies and venture capitalists now actively avoid investing in advanced medical devices because they fear years of delay and potential disapproval in the long-run.¹⁶ “If it says ‘FDA approval needed’ in the business plan, I myself scream in fear and run away,” says Tim Chang, managing director at Mayfield Fund, a venture capital firm. Chang has never backed a company that needed to go through the FDA’s review process.¹⁷ Even major tech companies like Google, which could potentially absorb the significant costs associated with FDA review, still don’t want any part in it. “Generally, health is just so heavily regulated. It’s just a painful business to be in,” says Sergey Brin, one of Google’s founders. “I think the regulatory burden in the US is so high that . . . it would dissuade a lot of entrepreneurs.”¹⁸

¹³ “The largely unregulated system of off-label prescribing has large benefits and few costs. Off-label prescribing speeds medical innovations to patients, increases the number of drugs available to doctors, and lowers the costs of medical innovation. Because of these benefits, off-label prescribing is common in the United States today. The largely unregulated system of off-label prescribing is working well, and it should be extended.” Alexander T. Tabarrok, “Assessing the FDA via the Anomaly of Off-Label Drug Prescribing,” *The Independent Review* 5, no. 1, (Summer 2000): 25–53.

¹⁴ Darcy Olsen, *The Right to Try: How the Federal Government Prevents Americans from Getting the Life-Saving Treatments They Need* (New York: HarperCollins, 2015), 215.

¹⁵ Richard Williams, Robert Graboyes, and Adam Thierer, “US Medical Devices: Choices and Consequences” (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, October 2015).

¹⁶ “Due to ‘regulatory uncertainty’ . . . [and] the complete and utter capriciousness and unpredictability in the FDA review process of new medical products, venture capitalists are becoming less inclined to fund very early stage companies.” Gulfo, *Innovation Breakdown*, 45–6.

¹⁷ April Dembosky, “Play This Video Game and Call Me in the Morning,” *NPR*, August 17, 2015.

¹⁸ Vinod Khosla, “Fireside Chat with Google Co-founders, Larry Page and Sergey Brin,” *Khosla Adventures*, July 3, 2014.

Although the FDA has moved to streamline the approval process for access to “investigational drugs”¹⁹ in recent years, every stage of this process remains highly permissioned; it is a veritable “Mother, May I?” list of restrictions and requirements limited to patients who “have a serious or immediately life-threatening disease or condition.”²⁰ In other words, unless patients are literally on their deathbeds, the FDA is not willing to let citizens make the ultimate decisions about their own health and medical treatments. Instead, these decisions are primarily made by bureaucrats.

Though motivated by the best of intentions, this approach has always been excessively oppressive. The case for restricting patient choice when patients are facing end-of-life scenarios is quite weak, especially when regulators or legislators are imposing such restrictions in a rigid, top-down fashion. Such decisions are best left to patients and their loved ones, in consultation with their physicians and other caregivers, of course.²¹ While patients are not owed access to any specific drugs, devices, or other treatments, they should not be uniformly denied the freedom to pursue those treatments on the basis of paternalistic attitudes about what is in their best interests when they are terminally ill.

The more interesting question is whether citizens should possess a more general right to try, which would let them make their own health decisions in other circumstances and long before they are facing end-of-life scenarios. Again, strong moral claims can be made in defense

¹⁹ Some of the relevant FDA announcements since 2009 include the following: FDA, “Expanded Access to Investigational Drugs for Treatment Use,” 74 Fed. Reg. 155, 40900–943 (August 13, 2009); FDA, “Guidance for Industry: Expanded Access to Investigational Drugs for Treatment Use—Qs & As,” draft guidance document, May 2013; FDA, “Expanded Access to Investigational Drugs for Treatment Use,” *Code of Federal Regulations*, Title 21, Volume 5, April 1, 2014; FDA, “Individual Patient Expanded Access Applications: Form FDA 3926; Draft Guidance for Industry; Availability,” 80 Fed. Reg. 27 (February 10, 2015).

²⁰ See FDA, “Expanded Access to Investigational Drugs,” at 40943.

²¹ See Olsen, *Right to Try*.

of this position, which holds that citizens should be at liberty to determine their own course of treatment for what they ingest in their bodies or what medical devices they use.

Of course, if citizens are free to make more of their own health decisions they could, at times, be rolling the dice with their health and lives. But the better way to deal with the potential downsides associated with expanded freedom of medical choice is to educate citizens about the relative risks associated with various medical treatments and devices and not necessarily to forbid them from seeking such treatments altogether. That doesn't mean the FDA's regulatory powers evaporate entirely; the agency's drug and device approval authority will, no doubt, remain in place for some time to come. Practically speaking, however, the relevance of that process may shrink as citizens gain new technological capabilities and are able to take greater control over their health and treatment decisions.

The Costs of Control

This points to how the debate over right to try transcends ethics and various normative considerations. The practicality of regulatory control is also relevant. With each passing day it becomes increasingly difficult for governments to control information about—and even access to—various medical devices, drugs, and other alternative treatments or therapies.²² In turn, that significantly raises the costs of enforcement and raises the question of exactly how far the FDA or other regulators will go to slow or to stop the development or use of new medical technologies.

This question is more pertinent today because of the rise of a diverse array of technologies—most of which were spawned by the information revolution—that are converging

²² Adam Thierer, “When It Comes to Information Control, Everybody Has a Pet Issue and Everyone Will Be Disappointed,” *Technology Liberation Front*, April 29, 2011.

to create a new paradigm for medical care. In his recent book, *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care*, Eric Topol describes a taxonomy of the new technologies that are radically disrupting the practice of medicine.²³ They include information systems, imaging, genomics, wireless sensors, mobile connectivity and bandwidth, the Internet, social networking, and computing power and data universe. Topol argues that these technologies will usher in a Schumpeterian wave of creative destruction that will radically alter the practice of medicine. By extension, it will challenge the traditional command-and-control approach our government takes to the regulation of health technology.

We can think of this as the “cost of control” problem, and it should have a bearing on how policy is crafted going forward. When enforcement challenges and costs reach a certain threshold, the case for preemptive control gets weaker simply because of (1) the massive resources that regulators would have to pour into the task of crafting a workable enforcement regime and (2) the massive loss of liberty it would entail for society more generally to enforce those solutions. With the rise of the Internet of Things, wearable devices, mobile medical apps, and other networked health and fitness technologies, these considerations are going to become increasingly ripe for academic and policy consideration.²⁴

A Hypothetical Scenario: 3-D–Printed Prosthetics

To illustrate how these enforcement complexities might affect medical device or drug regulation in the future, consider a hypothetical case study involving the 3-D printing of prosthetics. 3-D

²³ Eric Topol, *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care* (New York: Basic Books, 2012), vii.

²⁴ Adam Thierer, “The Internet of Things and Wearable Technology: Addressing Privacy and Security Concerns without Derailing Innovation,” *Richmond Journal of Law and Technology* 21, no. 6 (2015).

printers let organizations or average citizens design and then manufacture a wide variety of products using plastics.²⁵ An estimated 67 percent of manufacturers are already using 3-D printing in some fashion.²⁶

3-D–printed prosthetics, which are being designed and printed by volunteer organizations that are helping individuals (especially children) with limb deficiencies, are already being widely distributed today.²⁷ Prosthetics are medical devices in a traditional regulatory sense, but few people are going to the FDA to ask permission for or a right to try new 3-D–printed limbs.²⁸ Instead, they are just going ahead and engaging in this sort of permissionless innovation.²⁹

What might regulators do if they really want to limit access to 3-D–printed prosthetics? It is unlikely they could ban 3-D printers outright because the technology is already too diffuse, growing too rapidly, and being used for so many alternative (and uncontroversial) purposes. According to Siemens, over the next five years, 3-D printing will become 50 percent cheaper and up to 400 percent faster.³⁰

Nor is it likely that regulators could ban the inputs used by 3-D printers—namely, plastics and glue—which are widely available. Banning 3-D printer blueprints (that is, the underlying design documents) would almost certainly violate the First Amendment of the US Constitution, and it would be extraordinarily difficult to suppress such blueprints anyway because they are freely available across the Internet.

²⁵ *Maker Club*, “10 Things to Know When You Know Nothing about 3D Printing,” August 16, 2015.

²⁶ Louis Columbus, “2015 Roundup of 3D Printing Market Forecasts and Estimates,” *Forbes*, March 31, 2015.

²⁷ See the website “Enabling the Future,” <http://enablingthefuture.org/about>.

²⁸ Robert Graboyes, “How to Print Yourself a New Hand,” *CNN*, October 24, 2014.

²⁹ Tarun Wadhwa, “The Digitalization of Prosthetics Is Transforming How Wounded Service Members and Veterans Recover,” *Singularity Hub*, February 4, 2016.

³⁰ Columbus, “2015 Roundup of 3D Printing Market.”

Regulators could try to ban the sale of specific 3-D printing applications, but enterprising minds would likely start using alternative payment methods (such as bitcoins) to conduct their deals. Moreover, payments are largely irrelevant in many cases because much of this activity is noncommercial and open-source in character. People are freely distributing blueprints for 3-D–printed prosthetics, for example, and they are even giving away those devices to people who need them.

Governments could use licenses and fines to threaten specific companies (especially those with deep pockets). But that is likely a losing strategy because 3-D printing is already so highly decentralized and is undertaken by average citizens (often in their homes and usually for no monetary gain). Attempting to make an example of a handful of corporate players to deter others from experimenting isn't likely to work in a world where “global innovation arbitrage” is possible.³¹ Innovators will just find more hospitable jurisdictions offshore to engage these activities.

What should be clear from the example of 3-D printing is that the practicality of control matters deeply and must be taken into account when formulating policy. It's not just that restrictions on medical choice undermine the right of citizens to determine their own treatments or decide what drugs they ingest and what medical devices they use. It is also the case that regulatory efforts aimed at limiting that freedom have so many corresponding enforcement costs that can spill over to society more generally.

³¹ Adam Thierer, “Global Innovation Arbitrage: Genetic Testing Edition,” *Technology Liberation Front*, December 12, 2014.

Importantly, the costs associated with such technological control regimes are only going to grow as the market for 3-D–printed drugs begins to develop, thereby letting companies, and then perhaps individuals, engage in decentralized pharmaceutical manufacturing.³²

The more profound takeaway here is that, at least for some medical devices and drugs, citizens may gain a right to try new drugs and devices before policy reforms are undertaken. Technological innovation may bring that right before law does in many cases.

The Bold Future of Highly Personalized Medicine

Indeed, a future of highly personalized medicine and body enhancement is already unfolding with the rise of genetic modification, wearable technology, and “biohacking.”

Genetic testing and genetic editing techniques, for example, are already raising challenging questions about future regulatory enforcement. Consider 23andMe, which has developed mail-order DNA-testing kits to allow people to learn more about their genetic history and their potential predisposition to various diseases. As Paul Howard has noted,

Rapid advances in inexpensive whole-genome sequencing tests, like 23andMe, are already allowing individuals to peer into their own medical futures and, even more powerfully, those of their children. We may not be far from a world where medical problems—from Alzheimer’s to cancer—will be identified while patients are still young and healthy enough to demand dramatic reforms to how medicines are researched and tested. The right to know our own medical futures may become even more important than the right to try.³³

In 2014, however, the FDA ordered 23andMe to stop marketing its at-home genetic analysis kit.³⁴ While the FDA’s move limits genetic innovation in the United States,³⁵ on the

³² Shelly Fan, “First 3D-Printed Drug Ushers in Era of Downloadable Medicine,” *Singularity Hub*, August 14, 2015; *Kurzweil AI*, “The ‘Chemputer’ That Could Print Out Any Drug,” July 26, 2012.

³³ Paul Howard, “Hail Mary Medicine,” *Wall Street Journal*, November 12, 2015.

³⁴ Larry Downes and Paul Nunes, “Regulating 23andMe to Death Won’t Stop the New Age of Genetic Testing,” *Wired*, January 1, 2014.

³⁵ Stephanie M. Lee, “23andMe’s Health DNA Kits Now for Sale in U.K., Still Blocked in U.S.,” *SF Gate*, December 2, 2014.

other side of the Atlantic, UK officials welcomed the firm. The United Kingdom’s Medicines and Healthcare products Regulatory Agency said 23andMe’s test can be used there, albeit with caution.³⁶ Again, this points to the potential for global innovation arbitrage to undermine some of the legitimacy of some traditional regulatory regimes. While the FDA might be able to slow some of these innovations, the global pressures may limit the practical effect of such control in the future. Indeed, the agency has recently taken steps to loosen regulation of 23andMe, although only for narrowly defined purposes.³⁷ Beyond mere genetic testing, sophisticated forms of “genetic editing” are set to emerge, which promise great hope for addressing diseases and other problems by repairing or altering DNA.³⁸ Again, much of this activity will be bottom-up and noncommercial in character. Nonprofit community labs (or “bio-hackerspaces”) are already popping up “that maintain laboratory facilities open to the general public, with a mission to make the practice of biotechnology available to all.”³⁹

It is likely, however, that many people (and many parents) will look to use those technologies to not only address their health and the health of their children, but also their potential attributes and capabilities.⁴⁰ Ethical issues associated with genetic alteration create controversy,⁴¹ especially as they pertain to technologically enhanced procreation.⁴² Nonetheless,

³⁶ Jessica Firger, “U.K. Approves Sales of 23andMe Genetic Test Banned in U.S.,” *CBS News*, December 3, 2014.

³⁷ Matthew Herper, “What 23andMe’s FDA Approval Means for The Future Of Genomics,” *Forbes*, February 20, 2015.

³⁸ Carl Zimmer, “Breakthrough DNA Editor Born of Bacteria,” *Quanta Magazine*, February 6, 2015.

³⁹ Ellen Jorgensen, “How DIY Bio-hackers Are Changing the Conversation around Genetic Engineering,” *Washington Post*, May 20, 2016.

⁴⁰ Alex Pearlman, “Geneticists Are Concerned Transhumanists Will Use CRISPR on Themselves,” *Motherboard*, December 3, 2015.

⁴¹ Joel Achenbach, “Who Is Smart Enough to Decide How to Improve the Human Species?,” *Washington Post*, January 5, 2016.

⁴² Witherspoon Council on Ethics and the Integrity of Science, “The Threat of Human Cloning: Ethics, Recent Developments, and the Case for Action,” *New Atlantis* 46 (Summer 2015).

a great many people likely will seek to take advantage of gene-editing technology even when their lives (or the lives of loved ones) are not at stake.

Similarly challenging questions are already being raised about the sort of technological enhancements people might make to their own capabilities using Internet-enabled or robotic technologies.⁴³ The increasing ubiquity of smartphones is helping to spur these developments as the “app-ification of medicine” (i.e., the development of medical smartphone applications) continues to expand.⁴⁴ The so-called Internet of Things (i.e., Internet-enabled physical technologies and devices) and the growing market for connected wearable devices (such as smart watches and fitness bracelets) are also thriving, and health and fitness applications are among the most popular technologies.⁴⁵ Meanwhile, sensor-based technologies (including temporary biotech tattoos⁴⁶) are already being manufactured that can be “mounted directly on the skin, where they can pick up a host of vital signs, including temperature, pulse, and breathing rate.”⁴⁷

Many of today’s wearable technologies could soon be embedded directly in the body and provide even more accurate, real-time diagnostics on the body’s condition. This development foreshadows a day, not far off, when biohacking could become more prevalent.⁴⁸ Biohacking

⁴³ “A juggernaut of change in the form of genetic engineering, mood- and character-altering drugs, nanotechnology, and advanced forms of artificial intelligence threaten to redesign our minds and bodies and redefine what it means to be human.” Wendell Wallach, *A Dangerous Master: How to Keep Technology from Slipping Beyond Our Control* (New York: Basic Books, 2015), 8.

⁴⁴ “Computers and the Internet are on the cusp of making healthcare more personal, consumer oriented, cost effective, innovative, agile, and entrepreneurial.” Bret Swanson, “The App-ification of Medicine 2.0,” U.S. Chamber of Commerce Foundation, September 22, 2015, 1.

⁴⁵ Thierer, “The Internet of Things.”

⁴⁶ Ben Coxworth, “Temporary Tattoo Could Let Diabetics Monitor Glucose Levels without Jabbing Themselves,” *Gizmag*, January 16, 2015; Emily Reynolds, “How Biotech Tattoos Will Turn You into a Quantifiable Canvas,” *Wired.CO.UK*, December 4, 2015.

⁴⁷ Elizabeth Gibney, “The Inside Story on Wearable Electronics,” *Scientific American*, December 1, 2015.

⁴⁸ Carolyn Y. Johnson, “As Synthetic Biology Becomes Affordable, Amateur Labs Thrive,” *Boston Globe*, September 16, 2008.

refers to efforts by average citizens (often working together informally) to enhance various human capabilities, typically by experimenting on their own bodies.⁴⁹ Collaborative forums, such as Biohack.Me, already exist where individuals can share information and collaborate on various projects of this sort.⁵⁰ Advocates of such amateur biohacking sometimes refer to themselves as “grinders,” which Ben Popper of *The Verge* defines as “homebrew biohackers [who are] obsessed with the idea of human enhancement [and] who are looking for new ways to put machines into their bodies.”⁵¹

No doubt, policymakers and regulators will continue to attempt to regulate these new technologies and practices. Practically speaking, however, access to many of these technologies or capabilities could become so highly decentralized that the public will increasingly gain a de facto right to try and will be making health and treatment decisions for themselves, regardless of what the law specifies.⁵²

The Need for a Shift toward Risk Education

What effect will developments such as these have on the future of medical regulation and the FDA’s powers? Again, there is no denying that dangers exist in a world where the right to try may be set to become the norm rather than the exception because of rapid technological change.

But the FDA needs to recognize that traditional command-and-control regulation is no longer a

⁴⁹ Glen Martin, “Biohackers’ Mining Their Own Bodies’ Data,” *SF Gate*, June 28, 2012; Jim McLauchlin, “The Future of Bionic Humans: What’s Next in Bio-Hacking?,” *LiveScience*, June 18, 2013.

⁵⁰ Keiron Monks, “Forget Wearable Tech: Embeddable Implants Are Already Here,” *CNN*, April 9, 2014.

⁵¹ Ben Popper, “Cyborg America: Inside the Strange New World of Basement Body Hackers,” *Verge*, August 8, 2012.

⁵² “The development of personalized medical devices is going to challenge the established way of doing things. . . . We need to adapt the drug development and approval process to the era of personalized medicine” because “the truth is the FDA can’t regulate personal medicine the way it has traditionally regulated treatments.” Olsen, *Right to Try*, 235–37, 242. Also see Peter W. Huber, *The Cure in the Code: How 20th Century Law Is Undermining 21st Century Medicine* (New York: Basic Books, 2013).

sensible strategy when technological innovation is radically decentralizing and democratizing drug and medical device experimentation. That approach is increasingly unworkable and imposes too many other costs on innovators and limits on personal liberty.

Thus, the agency needs to reorient its focus toward improved risk education and health literacy more generally.⁵³ The FDA's goal should be to help create a more fully informed citizenry that is empowered with more and better information about relative risk trade-offs. The FDA already engages in education through various product labeling as well as public education campaigns and strategies.⁵⁴ But this mission has always been secondary for the agency, which has instead tried to preemptively guarantee the safety and efficacy of drugs and devices. And much of the education the FDA does is explaining to companies and the public how to comply with its voluminous body of regulation.

A more comprehensive risk education campaign would build on the work that the FDA has done in its 2009 *Strategic Plan for Risk Communication*⁵⁵ as well as its 2011 report *Communicating Risks and Benefits: An Evidence-Based User's Guide*.⁵⁶ Risk education should focus on both the general public and the innovators who are providing new devices and treatments to the public.

⁵³ Lynn Nielsen-Bohlman, Allison M. Panzer, and David A. Kindig, eds., Institute of Medicine of the National Academies, *Health Literacy: A Prescription to End Confusion* (Washington, DC: National Academies Press, 2004), 5. Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." See Scott C. Ratzan and Ruth M. Parker, "Introduction," in *National Library of Medicine Current Bibliographies in Medicine: Health Literacy*, C.R. Selden, M. Zorn, Scott C. Ratzan, and Ruth M. Parker, eds., NLM Pub. No. CBM 2000-1 (Bethesda, MD: National Institutes of Health, US Department of Health and Human Services, 2000).

⁵⁴ See, for example, the FDA's web pages on "Tools and Educational Materials," <http://www.fda.gov/food/fooddefense/toolseducationalmaterials/default.htm>, and "Educational Materials for Students and Teachers," <http://www.fda.gov/food/foodscienceresearch/toolsmaterials/ucm2006975.htm>. Also see materials published by the FDA's Division of Industry and Consumer Education, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/ucm20041265.htm>.

⁵⁵ FDA, "FDA's Strategic Plan for Risk Communication," Fall 2009.

⁵⁶ Baruch Fischhoff, Noel T. Brewer, and Julie S. Downs, eds., *Communicating Risks and Benefits: An Evidence-Based User's Guide* (Washington, DC: FDA, 2011).

The FDA already uses guidance documents when markets and law are in a state of flux. For example, the FDA has recently issued guidance that exempts from regulation most mobile medical applications that run on smartphones and other mobile communication devices (such as health and wellness management apps).⁵⁷ In some cases, the FDA exempts the apps because the agency has decided the apps are not medical devices; in other cases, where the apps meet the definition of a medical device, the FDA has signaled its intent to exercise “enforcement discretion.” As with all of its guidance, the FDA reserves the right to change its mind, as it “will continue to evaluate the potential impact these technologies might have.”⁵⁸ But clearly, the agency is implicitly acknowledging that the world has changed and regulation cannot quite keep up with the rapid pace of technological change.

Going forward, the agency will likely have to reorient its focus in this way to cope with the rapidly evolving universe of not just mobile medical apps but also all the wearable technologies that are part of the larger Internet of Things.⁵⁹ The agency recently released a guidance document addressing cybersecurity in medical devices that encourages innovators and other stakeholders to address security vulnerability in a collaborative, flexible fashion.⁶⁰ This same model could be applied to 3-D printing and many other new technologies discussed in this paper. Guidance documents should be crafted that suggest various best practices for developers as well as risk education and public service messaging for the general public.

The downside of such guidance documents, on the one hand, is that they leave unanswered the question of exactly what regulatory authority the agency might bring to bear

⁵⁷ FDA, “Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff,” Guidance document, February 9, 2015.

⁵⁸ *Ibid.*, 7.

⁵⁹ Thierer, “The Internet of Things.”

⁶⁰ FDA, “Postmarket Management of Cybersecurity in Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff,” draft guidance document, January 2016.

against companies that are found to violate the voluntary principles or best practices in the documents. On the other hand, those guidance documents are usually superior to the alternative path of overly rigid, top-down, preemptive controls on innovation. Congress should monitor the FDA's use of such guidance documents closely to ensure that the agency does not abuse its broad regulatory discretion through arbitrary guidance actions.

Finally, keep in mind that the Federal Trade Commission (FTC) already possesses broad power to police health claims and insists that those claims must be truthful. But the FTC only evaluates those claims after products are on the market, and it only prosecutes companies that engage in "unfair or deceptive practices" that violate consumers' trust in some fashion.⁶¹ The FTC's ex post enforcement approach avoids many of the problems presented by the FDA's highly precautionary ex ante approach, which assumes that all innovation is essentially guilty until proven innocent. The FTC also frequently publishes consumer education materials that help the public understand the risks associated with various technologies.⁶² Thus, the FTC's existing enforcement powers and educational tools could help facilitate the FDA's transition to a new risk education-oriented agency.

Structural Reforms of FDA Are Still Needed

The FDA's drug and device approval authority will not go away entirely, of course, even though it will be strained significantly by the new technological and marketplace realities discussed here. The agency's review process will need to be comprehensively reformed and streamlined if it is to keep pace with these developments. Luckily, several reform models are available.

⁶¹ See 15 U.S.C. § 45(a) (2012).

⁶² See, for example, "About Us," *OnGuard Online*, <http://www.onguardonline.gov/about-us>.

A recent Mercatus Center working paper outlined one potential reform model that grants approval authority to multiple private certification bodies, allowing them to compete with the FDA and each other on the price, quality, and timeliness of approvals.⁶³ This model is similar to one that already exists in the European Union, which has reciprocity among private “notified bodies” that assess devices for safety standards. The EU model encourages speedier—but still safe—medical device approval.

A second solution involves global regulatory reciprocity among national drug and device approval agencies. This reform would end the FDA’s monopoly on drug and device approval and let drug and device manufacturers market their products in the United States once they had gained approval in another major market, such as the European Union or Japan. With international reciprocity agreements in place, “the FDA would have to compete for business,” argue George Mason University economists Daniel Klein and Alexander Tabarrok. “It would have to shape up or lose out on the fees that come with [drug and device approvals].”⁶⁴

A third reform model can be found in the “Free To Choose Medicine” proposal, which “would establish a dual track system for new drug testing that preserves the existing FDA-controlled process, while offering physicians and patients the choice to use not-yet-approved drugs after preliminary safety and efficacy testing.”⁶⁵ Reforms along these lines were recently introduced in Japan.⁶⁶ Importantly, this model also incorporates the “Tradeoff Evaluation Drug Database,” which would be “a publicly accessible database, giving patients, doctors,

⁶³ Williams, Graboyes, and Thierer, “US Medical Devices.”

⁶⁴ Alexander Tabarrok and Daniel Klein, “Reform Options,” *FDAReview.org*, accessed February 3, 2016, http://www.fdareview.org/09_reform.php.

⁶⁵ Gregory Conko and Bartley J. Madden, “Free to Choose Medicine,” *Engage* 14, no. 3 (October 2013): 4–13, <http://www.fed-soc.org/publications/detail/free-to-choose-medicine>.

⁶⁶ Bartley J. Madden and Vernon L. Smith, “Give the FDA Some Competition with Free to Choose Medicine,” *Forbes*, December 1, 2015.

pharmaceutical manufacturers, medical researchers, and regulators up-to-date information about the experience of patients using Free To Choose track drugs.”⁶⁷

Finally, another recent Mercatus Center paper, by Joseph V. Gulfo, Jason Briggeman, and Ethan C. Roberts, outlines a set of reforms to rein in the FDA’s overly broad discretion when making safety and effectiveness determinations. The authors show how the FDA has restated its own mission “from permitting new products that can advance health to demanding certainty that products will not cause any harm.”⁶⁸ By crafting an excessively precautionary standard, “the trend has been for the FDA to become more and more restrictive,” the authors note.⁶⁹ Beyond increasing the cost and time of drug development, more worrisome is the fact that “it has also moved the FDA from its proper role in making public health decisions to become an improper force driving private health decisions.”⁷⁰ The authors recommend that, at a minimum, Congress reasserts authority over food and drug regulation to make sure “safety” and “effectiveness” are properly defined and thus limits the FDA’s further intrusions into what should be private health decisions.⁷¹

Optimally, elements of all of those reforms would be adopted, although that would likely prove politically challenging. Regardless, more flexible approaches such as those described in this paper will be vital as the world of hyperpersonalized medicine unfolds.⁷² But even without such reforms, we should expect that the public would increasingly gain more control over more

⁶⁷ Conko and Madden, “Free to Choose Medicine,” 5, 7.

⁶⁸ Joseph V. Gulfo, Jason Briggeman, and Ethan C. Roberts, “The Proper Role of the FDA for the 21st Century,” *Mercatus Research*, Mercatus Center at George Mason University, February 2016, 3.

⁶⁹ *Ibid.*, 4.

⁷⁰ *Ibid.*, 6.

⁷¹ *Ibid.*, 29–30.

⁷² “Today’s world of accelerating medical advancements is ushering in an age of personalized medicine in which patients’ unique genetic makeup and biomarkers will increasingly lead to customized therapies in which samples are inherently small.” Madden and Smith, “Give the FDA Some Competition.”

of their medical treatment decisions because of the new technological realities described above. Because of these new realities, reform of the FDA's approval process should be accompanied by expanded risk education.

Overcoming Opposition and Getting Consent Mechanisms Right

The approach outlined here (i.e., reorienting the FDA's mission from being merely a risk regulator to becoming more of a risk educator) will encounter opposition from both strident defenders and opponents of the FDA.

Defenders of the FDA and its traditional approach will continue to insist that people cannot be trusted to make such important treatment decisions on their own, regardless of how much information they have at their disposal. The problem with that position is that it denies citizens the most basic of all human rights: the rights to live lives of their own choosing and to make the ultimate determinations about their own health and welfare. And, again, blindly defending the old system ignores the fact that traditional command-and-control regulatory methods are increasingly impractical, incredibly costly to enforce, or in some cases just easily ignored.

Opponents of the FDA, by contrast, will insist that the agency cannot even be trusted to provide the public with good information enabling consumers to make such decisions on their own. Critics will likely also argue that the agency might give the wrong information or try to nudge consumers in certain directions. Some of those concerns are valid, but if all that the agency is doing is providing the public with information about risk trade-offs, then at least citizens still remain free to seek alternative information from other experts and then choose their own courses of treatment.

The most important issue here will be getting consent mechanisms right. Even if all parties could agree that more fully informed citizens should be left free to make such decisions

on their own, those individuals would need to have provided clear and informed consent to the parties they might need to contract with when seeking new devices or treatments.

A clear consent process is particularly essential in a litigious society like the United States, where the threat of liability always looms large over doctors, nurses, hospital, insurers, and medical innovators. Those parties will only be willing to go along with an expanded right-to-try regime if they can be assured they won't be held to blame when citizens make controversial choices that the parties had advised against or had clearly laid out all the potential risks and other alternatives at citizens' disposal. This consent process will require not only an evolution of statutory law and regulatory standards, but also of the common law and insurance norms. Importantly, it must also be made clear to these parties that the fact that patients have gained a broader right to try alternative drugs and devices does not mean that insurers or the government must pick up the tab for them should things go wrong.

Finally, drug and medical device manufacturers may need to be immunized from onerous legal liability associated with experimental drugs and devices that Americans have consented to use.⁷³ Without such assurances, those companies will be far less likely to make their innovative products available to the public.

Conclusion

Every day that policymakers delay reforming the FDA is another day that Americans are being denied access to life-enriching drugs and medical devices. In his most recent book on the exciting (but largely yet unlocked) potential for personalized medicine, Eric Topol argues that,

⁷³ “The FDA needs to create ‘safe harbor’ for drug companies that provide their products to patients outside clinical trials, and make clear it will hold companies harmless in the regulatory process if they do the right thing and provide drugs for dying patients.” Olsen, *Right to Try*, 197.

“while paying lip service to innovation, [the FDA] has done little to alter its regulatory approval process to catalyze the ways that each individual can assume a greater role in in their medical care. That’s why your smartphone isn’t as smart as it could be in an ambiguous regulatory landscape.”⁷⁴ But it’s not just smartphones that are potentially being held back by the FDA; many other medical innovations are likely going unmade or unmarketed because of fear of this overbearing regulatory agency.⁷⁵

Unfortunately, not only has the FDA shown little interest in undertaking serious reform, but also Congress has engaged in only half-hearted window-dressing reforms; more serious structural reforms to the foundations of the United States’s archaic food and drug laws are rarely even considered.⁷⁶ The greatest hope for unlocking life-enriching medical innovations, therefore, may lie outside the political process. This essay has argued that, thanks to new technological capabilities, the public may increasingly enjoy a de facto right to try for many new medical devices and treatments. Technological innovation will decentralize and democratize medical decisions even when the legal status of such actions is unclear. Meanwhile, the ethical case for expanding right to try opportunities is only like to increase because of the powerful personal autonomy arguments in favor of allowing citizens a greater say in their medical decision. What this means is that—for both practical and ethical reasons—the idea of having a right to try might increasingly become the norm instead of the exception.

⁷⁴ Eric Topol, *The Patient Will See You Now: The Future of Medicine Is in Your Hands* (New York: Basic Books, 2015), 288–89.

⁷⁵ Scott Gottlieb, “Why Apple Dumbs Down Your Smartphone,” *Forbes*, December 4, 2015.

⁷⁶ Richard Williams, “The Importance of Garage-Style Thinking,” *U.S. News & World Report*, November 30, 2015.