US Medical Devices: Choices and Consequences

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ABSTRACT

The FDA's system for regulating medical devices has been criticized for retarding innovation because it adds uncertainty and costs to the invention process and delays the approval of devices. Because this system was created 40 years ago, it does not reflect societal changes in information technology, our understanding of safety, and international trade. Recent attempts to improve it by taking patient preferences into account are misguided because patient preferences are individualized: what is needed is a system that caters to individual risk-benefit preferences. We conclude that a new system of medical device approvals is needed—one that grants approval authority to multiple private bodies, allowing them to compete with the FDA and each other on the price, quality, and timeliness of approvals. Such a system would cater to healthcare entities' and patients' individual risk-benefit preferences. It would also spur innovation at a much greater rate than does the current institutional arrangement.

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What if you had cancer and someone had developed a nanobot (a tiny robot less than one-hundredth the width of a human hair) that could go to the site in your body where the cancer was beginning to spread? It would deliver a tiny, lethal dose to the cancerous cells.[1] You would not need radiation or chemotherapy, and your probability of survival would dramatically increase. Using nanobots like this may have risks, including risks as yet undiscovered, but chances are you would be willing to go forward anyway—and to consider waiving all liability claims.

But suppose this nanobot were stuck somewhere in the regulatory process when you (or your child, spouse, or parent) needed it. What if you had cancer, but you didn't know about this nanobot and neither did your physician? What if someone had come up with the idea for the nanobot but never developed it? Maybe because it took too long to get the idea approved, or the innovator didn't have millions of dollars to devote to the approval process, or the whole project was so uncertain that it didn't seem worthwhile.

These are all possible scenarios today because of the antiquated system of government oversight in the United States. Patients' and doctors' preferences don't matter. The Food and Drug Administration (FDA) is the only entity with a say about when and whether you'll be allowed to start using a new medical device.[2]

Today's regulatory system discourages choice and innovation. The FDA is stuck in the 20th century and only advances a little now and then when the pressure to approve devices (and medicines) is strong. Part of the problem is misaligned incentives. Regulators in the FDA know they get little credit for approving safe devices but will be harshly criticized for approving devices

1. See, for example, Janet Fang, "DNA Nanobots Set to Seek and Destroy Cancer Cells in Human Trial," *IFLScience*, March 18, 2015.

2. This is true unless you are insured by Medicare or Medicaid, in which you will have to wait on approval from the Centers for Medicare & Medicaid Services after your device receives FDA approval.

that later are found to have unanticipated risks. The safest position is a regulatory restraint mode that smothers innovation and denies patient and physician choice.

Throughout the 20th century and up to this day, regulation has typically been the domain of agencies such as the FDA. These agencies have staffs of experts in the field of the regulated good or service—a cognitive elite—presumably because said elite is better able to gather, process, and disseminate relevant information.

Modern medicine is moving toward patient centricity, meaning patients are taking greater control over medical decisions. But in the case of FDA decision-making, patient preferences are only a small part of the agency's decisions.[3] The FDA and other public and private organizations are now seeking to "objectify," that is, survey and collate, patient attitudes about risks and benefits so that experts can use this information to help make decisions.[4] That is certainly one way to take patient preferences into account, but there is an alternative: decentralize decision-making so that patients or physicians (or both together) can make their own informed decisions. This paper makes the case that most decisions about medical devices should be decentralized, with patients and physicians being the primary decision makers about who should approve most medical devices.

Over the decades, there have been many criticisms of the FDA's regulatory activity, particularly its handling of drugs and medical devices. This paper analyzes those criticisms about medical devices, but it also goes on to show that recent changes in society make those criticisms even more salient today. The primary changes that affect patient centricity are the advances in web information that allow individuals (patients and physicians) to make more informed decisions based on their individual risk preferences. This paper discusses how individuals will express their preferences through private organizations created to approve most medical devices, replacing the current approval process as conducted by one centralized government body (the FDA).

Although the FDA is precautionary in its approvals, the overall result of the medical device approval process is not precautionary about risk—not when people are unnecessarily suffering or dying because help is either too slow to arrive or doesn't exist owing to the huge mountain of costs and bureaucracy

3. As discussed below, the FDA is starting to gather patient preference information.
4. FDA, "Public Workshop—The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes, September 18–19, 2013," last modified January 16, 2015, http://www.fda.gov/medicaldevices/newsevents/workshopsconferences/ucm361864.htm.

that blocks the path of any innovator. Recent examples of system malfunction offer clues about how to establish a healthier future. For patients (a category that includes all consumers engaged in health monitoring or disease prevention activities), the most obvious recent example of a problem with the FDA is the case of 23andMe, a company that attempted to market a $99 home genetics test that has the purchaser spit into a cup, mail the cup to the company, and receive genetic information. The FDA ordered the company to cease production because it was offering medical advice (although the agency recently allowed it to resume operating in a limited form).[5] Meanwhile, the same product has been approved for sale in the United Kingdom.[6] This technology, like so many others, has the potential to save lives through early diagnosis of diseases such as type 2 diabetes and Alzheimer's.[7] By preventing such monitoring, the FDA may be risking people's lives by preventing early diagnosis.[8]

Another recent example of a problem with the FDA involved MelaFind, a technology that would have saved many thousands of lives had the product not suffered from regulatory delays.[9] MelaFind is a machine that helps dermatologists determine which moles are actually skin cancers. Early detection can prevent death from skin cancers, because they are 100 percent treatable. The FDA dragged the approval process on for years and let thousands of people die, an outcome that might not have occurred without the delay.[10]

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5. FDA Public Health Service, warning letter to Ann Wojcicki (CEO, 23andMe), November 22, 2013, http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm.
6. Stephanie M. Lee, "23andMe's Health DNA Kits Now for Sale in U.K., Still Blocked in U.S.," *SFGate*, December 2, 2014, http://blog.sfgate.com/techchron/2014/12/02/23andmes-health-dna-kits-now-for-sale-in-u-k-still-blocked-in-u-s/; Elizabeth Lopatto, "23andMe Expands to the UK Despite US Restrictions," *Verge*, December 1, 2014, http://www.theverge.com/science/2014/12/1/7316089/23andme-expands-to-the-uk-despite-us-restrictions.
7. Robert C. Green and Nita A. Farahany, "Regulation: The FDA Is Overcautious on Consumer Genomics," *Nature* 505, no. 7483, January 15, 2014.
8. "The information flood is coming. If not this Christmas season, then one in the near future. Before long, $100 will get you sequencing of not just the million genes 23andMe currently examines, but all of them. Regulators and medical practitioners must focus their attention not on raising temporary obstacles, but on figuring out how they can make the best use of this inevitable tidal wave of information." Larry Downes and Paul Nunes, "Regulating 23andMe Won't Stop the New Age of Genetic Testing," *Wired*, January 1, 2015, http://www.wired.com/2014/01/the-fda-may-win-the-battle-this-holiday-season-but-23andme-will-win-the-war.
9. Joseph V. Gulfo, *Innovation Breakdown: How the FDA and Wall Street Cripple Medical Advances* (Franklin, TN: Post Hill, 2014). The MelaFind premarket approval application was submitted to the FDA in July 2009 but not approved until November 2011. A process that is supposed to take six months took twenty-eight months. The FDA had signed an agreement about how clinical study was supposed to be performed, but later reneged on it. The company sued over the FDA's failure to stick to the agreement, and that became the source of a congressional hearing. The same product was approved in four months in Europe.
10. Ibid.

"The FDA does not have the staff to understand the thousands of different types of medical devices."

These two FDA examples demonstrate the problems with a centralized review system, many of which might be reduced by a system that shares responsibility for approvals between public and private bodies, empowering the decisions of patients and physicians.[11] Part of the problem is that the FDA does not have the staff to understand the thousands of different types of medical devices. To the agency's credit, it has instituted Advisory Committee Panels of clinical experts to supplement its staff's limited information and their attempts to monitor the wide variety of medical devices. But even these panels can never have access to individual patient preferences or keep up with information generated in real time by the web. That requires patient and physician choice and distributed approval centers.

Such a system will rely more on spontaneous information generated by users about the safety and efficacy of certain medical devices. This information will produce more rapid innovation, which in turn will mitigate the type of health problems that have persisted for decades under the FDA's precautionary regime. The FDA's slow, uncertain, and expensive system is neither necessary nor desirable when patients and physicians have access to information for individualized decisions and are able to make their own risk-benefit calculations. Under this system, we will still observe cautious physicians who want to be sure about products before using them. And consumers will have a wide variety of risk choices, so that the least risk-averse consumers will generate information for the more risk-averse ones. If certain organizations (hospitals, insurance agencies) want FDA approval of products (as opposed to approval by private bodies) before authorizing their use, they will certainly be able to request and wait for it, but others will be allowed to act based on the market approvals discussed below.

11. There are other examples, such as those recently cited in Bradley M. Thompson, "How the FDA Process Is Biased against New Technology," *Mobile Health News*, September 10, 2015.

Getting the FDA out of most of the premarket decisions would allow the agency to focus on a relatively narrow sphere of very high-risk devices that merit elevated concern. But for those products that do need premarket inspection, we recommend a system involving competing bodies of private experts, similar to the system the world uses to certify ship safety and the system for medical device approval now embraced by Europe. Such a system would move more quickly, more certainly, and more cheaply; it would likely issue in a new era of device innovation that the FDA's current system would never allow.

We are a nation of individuals; we don't all need or want FDA-approved medical devices. While some people clearly would not feel safe without FDA approval, others are more interested in taking more control of their own condition and treatment and would be willing to accept a private certification body where premarket approval is necessary. Because of their condition or inclination, they might feel they cannot wait and are willing to take on a little more risk to get the benefits. They now have access to much more information than ever before in history, and they would rely on a market that competes to get high-quality products to patients more quickly, and often at a lower cost. As these patients try new devices, the market would rapidly gain information about them. In this system even those who are risk averse would benefit from reforms that emphasize choice by informed patients and physicians. In a sense, the FDA would become both a competitor against private bodies and, for some, a safe harbor to choose if they do not trust nongovernmental institutions.

THE CURRENT SYSTEM OF FDA REGULATION

In the last hundred years, the FDA has grown to the point that it now regulates 25 cents of every dollar spent by Americans.[12] Twenty-seven years after the 1906 law that established the FDA, the agency recommended and got a complete revision of the original Food and Drug Act. This revision included "therapeutic devices" under the act for the first time.[13] In addition to medical devices, the FDA now regulates foods, drugs, biologics (e.g., vaccines), cosmetics, animal foods, and drugs, tobacco, and electronic products that give off radiation (e.g., microwave ovens). There are now hundreds of thousands of medical devices, including elastic bandages, wheelchairs, anesthetic equipment, MRI machines, home pregnancy kits, surgical masks, canes, hearing aids, needles,

12. FDA, "Executive Summary: Strategic Plan for Regulatory Science," last modified January 16, 2013, http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm268095.htm.
13. 1938 Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938).

surgical gloves, hip implants, insulin pens, medical robots, and extremely risky devices such as pacemakers and heart implants. Even electric toothbrushes require FDA approval before they can be marketed.

The Medical Device Amendments of 1976 is the primary law governing how the FDA regulates medical devices—and that law is now almost 40 years old.[14] President Kennedy wanted to make medical devices subject to the same types of approval as drugs, that is, premarket approval (Kennedy's Drug Amendments of 1962). Although Kennedy's bills did not pass, similar bills continued to be introduced until 1969, when the Supreme Court declared that at least one device—an antibiotic sensitivity disc used to help determine the proper antibiotic to give to a patient—should be considered a drug.[15] The court's decision opened the door to regulating devices as drugs are regulated.[16] Following that decision, President Nixon arranged for a committee in the Health, Education, and Welfare Department (now the Department of Health and Human Services) to determine when devices should be treated as drugs.[17] But it wasn't until the FDA established a "technically unauthorized" classification panel for the devices it was regulating that three individuals—a house staffer, a member of the pharmaceutical industry, and an FDA attorney—wrote the statute that became the Medical Device Amendments of 1976.[18] This law gave the FDA new authority to ensure the safety and effectiveness of medical devices, including both therapeutic and diagnostic ones.[19] The authors of the bill intentionally gave the FDA maximum discretion by using general language with no deadlines for FDA approvals.[20] As had happened frequently in the case of drugs, the FDA was a primary driver for expanding its own authority.[21]

Other laws supplement the FDA's control over medical devices, including the Public Health Service Act of 1944 (regulation of biological products) and the Safe Medical Devices Act passed in 1990 that (1) required manufacturers to report injuries and illnesses, (2) authorized the FDA to engage in postmarket

14. Medical Device Amendments of 1976 to the 1938 Food, Drug, and Cosmetic Act, Pub. L. 94-295 (May 28, 1976).
15. United States v. Bacto-Unidisk, 394 U.S. 784 (1969). Even though the device never touched the human body, the court was concerned that medical device legislation was inadequate and that the FDA could use drug laws for certain medical device products.
16. Institute of Medicine, "Public Health Effectiveness of the FDA 510(k) Clearance Process," 2010, chapter 2, p. 4.
17. Ibid., 5.
18. Ibid., 6.
19. Medical Device Amendments of 1976, Pub. L. 94-295.
20. Institute of Medicine, "Public Health Effectiveness," 6.
21. The manner in which the FDA expanded its drug authority is cataloged in Daniel Carpenter, *Reputation and Power* (Princeton, NJ: Princeton University Press, 2010).

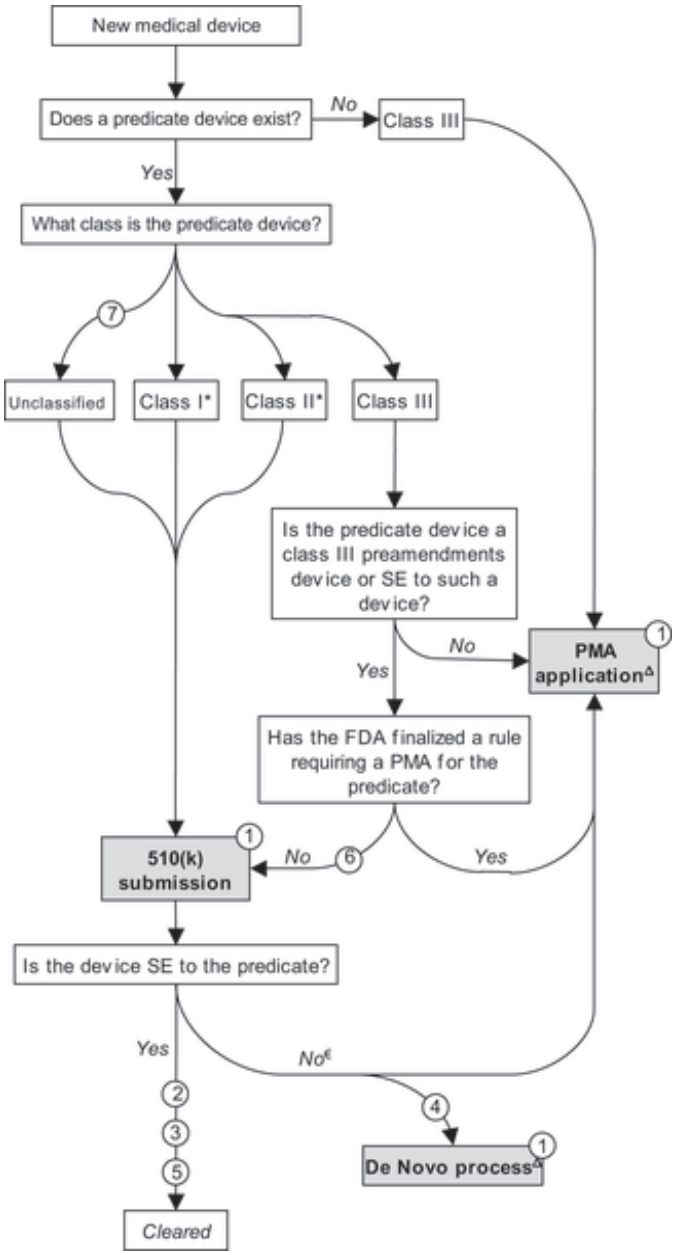
monitoring, and (3) gave the FDA the authority to order recalls.[22] The FDA has also gotten authorization to collect fees on medical devices, first from the 1992 Prescription Drug User Fee Act and Mammography Quality Standards Act, the 1997 Food and Drug Administration Modernization Act, and the 2002 Medical Device User Fee and Modernization Act. In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act, which includes the Medical Device User Fee Amendments (MDUFA III), which expire on September 30, 2017.[23] This last act required more manufacturers to pay a registration fee, set goals to speed up the approval process, and provided for an independent review of the FDA's premarket review process.[24] It is not clear whether this review will help to improve the FDA's process or make it worse.

The MDUFA III also set up a little-used de novo pathway for new devices that have no similar device already on the market, where approval decisions are based on risks and benefits.[25] The FDA now sorts devices into one of five categories: exempt, premarket notification, de novo, humanitarian, and premarket approval. With the exception of exempt devices, all categories require FDA approval before the products can go to market. The vast majority of devices fall into the premarket notification system (known as 510(k)) that is applied to low- and medium-risk devices. These are products for which there is a device already on the market that is similar to the one being proposed. All the above-mentioned laws and a multitude of regulations put the FDA at the center of all phases of medical device life, approving what may be produced, how it may be distributed, and what claims may be made about it by the manufacturer.[26] As mentioned earlier, this system may have been necessary in an environment where information was low and technological change slow, but it appears to be less important today.

Figure 1 shows how the FDA determines the approval procedures for each device (numbers refer to the different routes a device may take). SE stands for "substantially equivalent" and PMA for "premarket approval." The three classes of devices, I, II, and III, are arranged in order of risk, with class III

22. Public Health Service Act of 1944, 42 U.S.C. §§ 201–300 (1944); Safe Medical Devices Act of 1990, Pub. L. No. 101-629 (1990).
23. FDA, "Medical Device User Fee Amendments 2012 (MDUFA III)," last modified September 30, 2014, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/.
24. FDA, "Fact Sheet: Medical Device User Fee Amendments of 2012," last modified August 3, 2012, http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm313695.htm.
25. Emergo Group, "US FDA De Novo Submissions Support for Medical Devices and IVD Devices," accessed May 13, 2015, http://www.emergogroup.com/services/united-states/de-novo-submission.
26. Carpenter, *Reputation and Power*, 636.

FIGURE 1. FDA REVIEW OF MEDICAL DEVICES



Source: Jonas Z. Hines et al., "Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review," PLOS Medicine, July 13, 2010, http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000280.

* The FDA Modernization Act of 1997 exempted most class I devices and a small number of class II devices from 510(k) requirements.
[€] If the device is determined to be not substantially equivalent, the sponsor may submit a PMA application. Alternatively, a sponsor may request evaluation under the *de novo* pathway.
[Δ] The post-decision scheme is not illustrated.

Note: SE = substantially equivalent; PMA = premarket approval. Circled numbers refer to different approval routes a device can take.

devices being the riskiest. Products in the 510(k) classification must be substantially similar to an existing (already approved) device, known as a "predicate device." All de novo devices are initially considered high-risk or class III and need premarket approval unless the FDA has determined that they can go through the 510(k) process (step 6).

The "service" that the FDA performs is requiring manufacturers to produce information that the agency can use to make a decision about whether a product should be marketed. While much of that information would be considered necessary for virtually anyone making the decision, it is not clear that all the information the FDA requires would be necessary if physicians and patients were to make their own decisions through private market entities. These decisions are essentially about risk, because the use of medical devices—like every product—entails some risk. In the 1930s, when the FDA first acquired the authority to regulate devices, until as late as the 1970s, it may have been safe to presume that without the FDA the market would not provide sufficient information on these products. It is much harder in 2015, however, to imagine that any manufacturer could sell a medical device without generating sufficient information to satisfy either wary physicians (or hospitals) or the risk-benefit preferences of patients or consumers. We certainly trust our home appliances, the electrical work in our homes, and many other products and services to experts in various standard-setting organizations, such as UL (Underwriters Laboratories) and the National Fire Protection Association, that are subject to market pressures.

PROBLEMS WITH THE FDA'S CURRENT APPROACH

As the FDA's regulatory approval systems have developed over the decades, concerns have been growing. Historically, criticisms have centered on four major issues: uncertainty,[27] delays, costs, and disincentives.

27. This uncertainty is similar to the problem with the FDA's premarket approval for food ingredients (e.g., food and color additives). Manufacturers have complained that there is never any certainty that if a test finds a certain result, there will be a certain outcome (e.g., approval, rejection, or more testing). Part of the problem has been that if reviewers change, the criteria change. The FDA has attempted to address this problem with the "Redbook." The Redbook is the guidance for industry on the toxicological principles that govern premarket approval of food additives. US Food and Drug Administration, "Redbook: Guidance for Industry and Other Stakeholders; Toxicologial Principels for the Safety Assessment of Food Ingrediuents," July 2000 (revised July 2007), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm2006826.htm. However, as of 1999, the average time for approval of a direct food additive was over six years. Perhaps because of this, most food companies use the generally recognized as safe (GRAS) provision, which does not require FDA approval.

Uncertainty

There is no certainty at the start of the approval process that a device will be approved for market. Nor is there any certainty about how much testing will be necessary or how much time it will take before there is a "go" or "no go" decision from the FDA.[28] As a result, there is also no certainty about how much it will cost to supply the FDA with the required information.[29] One inventor who has had recent experience with the FDA described the problem with uncertainty this way: "Due to 'regulatory uncertainty,' a euphemism for 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."[30]

The uncertainty for medical devices is made worse by the fact that Medicaid and Medicare cover health care for approximately 117 million Americans, or about 37 percent of the population,[31] and these health agencies are not in sync with the FDA. One study found that "Medicare often added conditions [for reimbursement] beyond FDA approval, particularly for devices and most often restricting coverage to patients with the most severe disease." The study further found that "this discrepancy creates hurdles and uncertainty for drug and device manufacturers."[32] Although it may make sense to make independent judgments about the use of these devices and the payment for them, these problems will largely disappear if the FDA is restricted to dealing only with the highest-risk medical devices.

Another uncertainty inventors face is the problem of navigating between predicate devices[33] and patent infringement. This interface has been described

28. For a good example of FDA overreach, read Michael Mandel's account of MelaFind, a noninvasive melanoma screening device. "How the FDA Impedes Innovation: A Case Study in Overregulation" (Policy Brief, Progressive Policy Institute, June 2011). MelaFind's CEO, Joseph Gulfo, documented his battle for FDA approval in a book, *Innovation Breakdown*. Alex Tabarrok, review of *Innovation Breakdown*, by Joseph V. Gulfo, *Wall Street Journal*, August 11, 2014, http://www.wsj.com/articles/book-review-innovation-breakdown-by-joseph-v-gulfo-1407799461.

29. This issue dominated much of the MDUFA III amendment, which was supposed to make interactions between the FDA and applicants more predictable, compel the FDA to provide more detailed and objective criteria for an incomplete premarket submission, and streamline FDA review goals.

30. Gulfo, *Innovation Breakdown*, 46.

31. "Pulling It Together: Medicare, Medicaid, and the Multiplier Effect," Henry J. Kaiser Family Foundation, June 9, 2011, http://kff.org/health-reform/perspective/pulling-it-together-medicare-medicaid-and-the/.

32. James Chambers, Katherine May, and Peter Neumann, "Medicare Covers the Majority of FDA-Approved Devices and Part B Drugs, but Restrictions and Discrepancies Remain," *Health Affairs* 32, no. 6 (June 2013): 1109.

33. Predicate devices are devices that are already on the market and are similar to ones that are going through the FDA's approval process. Because they are similar, they are assumed to have similar risks

as "jagged and complicated."[34] If a 510(k) manufacturer lists a product as similar to a predicate device, it may be grounds for patent infringement.[35] A patent can only be issued for a product that is novel and "nonobvious," in that the product is differentiated from others preceding it, and no one with only a basic understanding of "the art" could have invented it.[36] Manufacturers may want to take advantage of being similar to a predicate device (to use the easier 510(k) process), but if they do, they may not be able to obtain a patent. In fact, this problem can discourage some manufacturers from pursuing the less expensive and less time-consuming 510(k) process and cause them to end up using the much more expensive premarket approval system.[37] One study found that only about 15 percent of products being approved through the 510(k) system actually have new technological characteristics.[38] Joseph Gulfo, the executive director of the Rothman Institute of Innovation and Entrepreneurship, found that about 95 percent of products being introduced are only "subtly different" from existing products on the market.[39] Although it is important to continually improve on products that are now on the market, ultimately this system is penalizing those with breakthrough technologies by setting up an incentive to show a little improvement, but not too much.

The point of the previous two examples is that inventors and innovators of medical devices face considerable hurdles that FDA regulations only add to, ultimately dis-

"One study found that only about 15 percent of products being approved through the 510(k) system actually have new technological characteristics."

and benefits. Most 510(k) approvals are for products that are similar to products already on the market (predicates).

34. Adam Lewin, "Medical Device Innovation in America: Tensions between Food and Drug Law and Patent Law," *Harvard Journal of Law and Technology* 26, no. 1 (Fall 2012) citing from Eric P. Raciti and James D. Clements, "A Trap for the Wary: How Compliance with FDA Medical Device Regulations Can Jeopardize Patient Rights," *IDEA* 46 (2006).
35. Lewin, "Medical Device Innovation in America."
36. Richard A. Epstein, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation* (N.p.: Institute for Policy Innovation Book, 2006). See, for example, p. 58.
37. Ibid.
38. Lewin, "Medical Device Innovation in America," 411.
39. Gulfo, *Innovation Breakdown*, 43.

couraging innovation. In an interview with entrepreneur Vinod Khosla, Sergey Brin, one of Google's founders, noted, "I think the regulatory burden in the U.S. is so high that . . . it would dissuade a lot of entrepreneurs."[40] In a similar vein, referring only to medical apps, former FDA senior advisor for medical technology Scott Gottlieb and former member of the FDA's Office of the Chief Counsel Coleen Klasmeier recently wrote,

> The FDA's regulatory dysfunction is driven by its 30-year failure to establish a coherent approach to regulating medically related software. Last fall the FDA issued guidance purporting to regulate only a limited subset of apps that qualify as "devices" under the law, and only if there is a meaningful risk to patients. The guidance says the FDA will regulate apps—using the same kinds of rules that apply to joint replacements and heart valves and the like—that display, transfer, store or convert patient-specific medical device data from a monitor (for example, a heart monitor) to a mobile platform. But under the guise of enabling innovation, the agency is making an already complex regulatory climate even harder to navigate.[41]

It is impossible to know the number of ideas that have never gotten off the ground owing to the uncertainty caused by such FDA regulations. Many potentially health-improving or lifesaving devices are simply left on a scratch pad or lying along the FDA approval path, having failed at one of the innumerable roadblocks.[42] As one study summarized it, "The lack of certainty and predictability in the review and approval process heightens risks of failure, raises the costs of development, makes the struggle to raise capital more difficult, and ultimately denies patients timely access to innovative treatments."[43]

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40. Vinod Khosla, "Fireside Chat with Google Cofounders, Larry Page and Sergey Brin," Khosla Ventures, July 3, 2014, http://www.khoslaventures.com/fireside-chat-with-google-co-founders-larry-page-and-sergey-brin.

41. Scott Gottlieb and Coleen Klasmeier, "Why Your Phone Isn't as Smart as It Could Be," *Wall Street Journal*, August 7, 2014.

42. Many studies support this claim. For example, one study shows that at MIT, only about one-third of the faculty transferred their ideas into commercial manufacturer's hands. National Academy of Engineering, Institute of Medicine, *New Medical Devices: Invention, Development and Use* (Washington, DC: National Academy Press, 1988), 40.

43. Battelle Technology Partnership Practice, "Gone Tomorrow? A Call to Promote Medical Innovation, Create Jobs, and Find Cures in America," June 10, 2010, 9, http://advamed.org/res.download/28.

Uncertainty is particularly problematic for start-ups. Medical device inventions most often are the product of individuals (physicians) or small firms, but, as just one study showed 10 years after passage, "the introduction of the Medical Devices Amendment in 1976 dramatically decreased the rate of new product introduction by young biomedical firms in Massachusetts."[44] As one owner of a small medical device firm more recently put it, "The entire ability of our business to grow has been blocked by FDA over the last 30 years."[45]

Delays

Both premarket approval and premarket notification (510(k)) can mean long waiting times that can be costly in terms of repaying loans and losing first-mover advantage. One study found that it takes an average of five months for the FDA to review and clear a 510(k) medical device.[46] That's an average, meaning many take longer—and, of course, that's only if the FDA doesn't reject a submission for being incomplete or improperly formatted.[47] Other studies show that decisions about 510(k)s took an average of 143 days as of September 30, 2012.[48] For PMA the average review time in 2010 was 419 days, which dropped to 266 days in 2012.[49] These times do not, of course, include the four to five years needed to conduct clinical trials in situations for which the FDA requires them.[50] Although the FDA does have target times for approval, it can stop the clock at any time by asking another question. Given that the FDA is held to standards that force it to be precautionary, the question is whether the information that comes from these questions is worth the delay they cause.

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44. Oscar Hauptman and Edward Roberts, "FDA Regulation of Product Risk and Its Impact upon Young Biomedical Firms," *Journal of Product Innovation Management* 4, no. 2 (June 1987): 138–48.
45. Brian Buntz, "FDA Is Suffocating the Small Businesses It Should Be Helping," Medical Device and Diagnostic Industry, October 27, 2011, http://www.mddionline.com/article/fda-suffocating-small-businesses-it-should-be-helping.
46. Emergo Group, "How Long It Takes the FDA to 'Approve' a 510(k) Submission," accessed May 13, 2015, http://www.emergogroup.com/resources/research/fda-510k-review-times-research.
47. Ibid. The uncertainty surrounding whether a submission is inadequate was raised in the 2012 MDUFA III legislation.
48. FDA, *Improvements in Device Review: Results of CDRH's Plan of Action for Premarket Review of Devices* (November 2012), 13.
49. Ibid., 18.
50. Lewin, "Medical Device Innovation in America," 409.

"If the FDA, as it appears, has been requesting more and more information, policymakers need to ask whether all the information the FDA requires is necessary to ensure the safety and efficacy of devices."

Costs

Ninety-nine percent of all medical devices fall under the 510(k) classification (about 1 out of 140 are classified PMA).[51] A 2010 study found that "the average total cost for participants to bring a low- to moderate-risk 510(k) product from concept to clearance was approximately $31 million, with $24 million spent on FDA-dependent and/or related activities."[52] In other words, more than 75 percent of the cost of getting a low- to medium-risk product to market is interacting with the FDA. One reason is that the paperwork is substantial. The FDA claims that the average submission is about 35 pages but some may run to 100 pages or more.[53] Even that number appears to be dated information, however; a more recent study found that many recent 510(k)s needed to "present significant laboratory, animal and/or clinical data running to thousands of pages."[54] For the riskier products that go through premarket approval, the costs are about $94 million, with $75 million spent on FDA approval.[55] If the FDA, as it appears, has been requesting more and more information, policymakers need to ask whether all the information the FDA requires is necessary to ensure the safety and efficacy of devices. Is it information that users—physicians and patients—would also find necessary before making their own decisions? Although beyond the scope of this report, it would be useful to get an independent third party to

51. Jeffrey N. Gibbs, Allyson Mullen, and Melissa Walker, "510(k) Statistical Patterns," Medical Device and Diagnostic Industry, December 2, 2014, http://www.mddionline.com/article/510k-statistical-patterns-12-02-2014.
52. Josh Makower, Aabed Meer, and Lyn Denend, "FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies," November 2010, 7, http://advamed.org/res.download/30.
53. FDA Premarket Notification 510K, last modified July 1 2015, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm.
54. Jeffrey K. Shapiro, "Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices," *Food and Drug Law Journal* 69, no. 3 (2014): 382.
55. Makower et al., "FDA Impact on U.S. Medical Technology Innovation," 7.

review the required information to ensure that, for those devices that the FDA should review, no more information is requested than is absolutely necessary.

Application fees are another cost on the way to FDA approval. Table 1 shows the mandatory application fees that must be paid to the FDA by medical device innovators during FY 2015. For some very small innovators that manage to invent devices cheaply, even the small business fee is excessive.

TABLE 1. FISCAL YEAR 2015 APPLICATION FEES FOR AN FDA-APPROVED MEDICAL DEVICE

Application type	Standard fee	Small business fee[a]
510(k)[b]	$5,018	$2,509
Premarket approval	$250,895	$62,724

Source: FDA, "MDUFA III Fees," last modified September 30, 2014, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm313673.htm.

(a) For small businesses with an approved small business determination.
(b) All types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the user fee. However, there is no user fee for 510(k)s submitted to the FDA by an FDA-accredited third-party reviewer.

In addition to the fees that firms must pay for individual device approvals, there is also an annual establishment registration fee of $3,646. For these fees, there are no waivers or reductions for anyone. While these costs may seem small to some, they are not so for many small device companies. After all, "more than 80 percent of medical device companies have fewer than 50 employees, and many (notably innovative start-up companies) have little or no sales revenue."[56]

Of course, it is also true that medical devices are subsidized by the government, through federal funding of research at the National Institutes of Health on the supply side and then federal funding of health care on the demand side. It's not clear how these interventions, coupled with payments to the FDA and the new medical device tax, cause the overall supply of medical devices to be either under- or overproduced, but it is clear that they do distort the market for these devices.

Disincentives

The FDA will always be more interested in preventing visible errors (where it has declared something is safe but it is not) than in preventing situations

56. "The Medical Device Industry in the United States," SelectUSA, accessed May 13, 2015, http://selectusa.commerce.gov/industry-snapshots/medical-device-industry-united-states.

where something is erroneously kept off the market for safety reasons. When people become ill or injured as a result of an approved device, that failure is highlighted as a government failure. But failure to approve safe devices is not visible, so there is no incentive to minimize such failures. The most recent time in the FDA's history when there has been concentrated incentive to approve a product is when HIV/AIDS patients made the failure to approve lifesaving drugs visible to the world.[57] The FDA has recently tried to move more quickly when drugs and medical devices are developed to treat severe or life-threatening conditions, but that only highlights the basic question: If the agency can move quickly in these situations, why can't it move quickly on more or even all approvals? No doubt such a question would bring the usual answer of insufficient resources, despite the fact that the FDA's overall budget has increased 865 percent over the last 15 years.[58]

Dealing with the FDA's processes has been described as "confusing, time-consuming, expensive and frustrating"[59] and "unpredictable and inefficient."[60] All these issues—uncertainty, delay, costs, and related disincentives associated with the FDA's premarket activities—increase the risk of either discouraging innovation entirely or slowing it down so that potential benefits are delayed (or created in other countries). Of course, the risk of beneficial products never reaching the market must be balanced against the risk of allowing harmful products on the market. But government incentives do not lend themselves to such careful balancing. That is why the process for clearing medical devices established in 1976 needs to be reevaluated and a new balance crafted based on current realities.

A more serious problem with the current system is that centralized, precautionary decision-making does not square with a patient-centric approach, where patients—sometimes together with their physicians—make key decisions about risks and benefits. Some, although not necessarily all, patients have an incentive to treat a condition relating to their own health and well-being more

57. On October 11, 1988, more than a thousand ACT UP demonstrators protested at FDA headquarters in Rockville, Maryland. "History of HIV & AIDS in the U.S.A.," AVERT, accessed May 20, 2015, http://www.avert.org/history-hiv-aids-us.htm#sthash.MAPKPmM9.dpuf.
58. Susan Dudley and Melinda Warren, "Regulators' Budget Increases Consistent with Growth in Fiscal Budget," Regulatory Studies Center, George Washington University, May 2015, 15.
59. Heather Thompson, "Top 10 Pitfalls of a 510(k) Submission and How to Avoid Them," *DeviceTalk* (Medical Device and Diagnostic Industry), August 15, 2013, http://www.mddionline.com/blog/devicetalk/top-10-pitfalls-510k-submission-and-how-avoid-them.
60. Heather Thompson, "How Much Does a 510(k) Device Cost? About $24 Million," *DeviceTalk* (Medical Device and Diagnostic Industry), November 22, 2010, http://www.mddionline.com/blog/devicetalk/how-much-does-510k-device-cost-about-24-million.

quickly than an external body would treat it, and their decisions will vary according to their individual circumstances and preferences. Even if all patients are not interested in making such decisions themselves, a patient-centric approach will benefit all consumers, because more devices will come on the market (and do so more quickly). In fact, one of the criteria in choosing a physician may be whether the physician either reflects the patient's general propensity for risk or, more likely, is willing to defer to the patient's propensities over the physician's own. However, with the FDA making decisions for everyone—and always doing so with an eye toward avoiding risk at all costs—patients and physicians (and their preferences) are cut out of the process.

Beyond the cost that FDA processes contribute to the overall cost of health care, the primary cost is the morbidity and mortality that is a natural result of excess precaution—including the additional pain, suffering, and death that comes about because of delays in getting devices to market. These problems arise because of devices that are stopped by the FDA in a process that should have been allowed, as well as devices that were conceived but never invented and never entered the approval process because of the headaches and resources required. As one inventor put it, the FDA almost always begins with a "reflexive 'no.'"[61] In some cases, it is because companies have not "established rapport" with the FDA, basically meaning they haven't sufficiently made friends, as though that has anything to do with whether a device is worthwhile.[62]

The case of MelaFind, mentioned earlier, demonstrates the magnitude of the problem. Every year 8,000 Americans die from melanoma, a cancer that is readily diagnosable but routinely missed on unaided physical evaluation. Earlier approval by the FDA of this diagnostic device (having a sensitivity of 98 percent) could potentially have resulted in many thousands of saved lives.[63] There have been countless studies of drug approval delays, and deaths resulting from such delays.[64] Other scholars have found that just speeding up reviews could benefit patients by a ratio of more than three to one.[65] One report suggests that delays in providing new drugs following the Drug Amendments of 1962 are

61. Gulfo, *Innovation Breakdown*, 22.
62. For a discussion, see Carpenter, *Reputation and Power*.
63. Gulfo, *Innovation Breakdown*, 137. While the average for PMA devices is 6 months, Melafind, which is not an intrusive technology (it never touches the body), took 27 months.
64. The delays are well known but just one example can be found in Dale H. Gieringer, "The Safety and Efficacy of New Drug Approval," *Cato Journal* 5, no. 1 (Spring/Summer 1985): 177–201. See also Paul Citron, "Perspectives: Medical Devices; Lost in Regulation," *Issues in Science and Technology* 28, no. 3 (Spring 2011).
65. T. J. Philipson et al., "Cost-Benefit Analysis of the FDA: The Case of the Prescription Drug User Fee Acts," *Journal of Public Economics* 92 (2008): 1306–25.

likely to be in the "hundreds of thousands (not to mention millions of patients who endured unnecessary morbidity)."[66]

THE DEVELOPMENT OF REMOTE DIAGNOSIS AND SELF-TREATMENT

Increasingly, we are seeing more devices, despite their function, being used by patients who wish to treat themselves. There are a number of ways to categorize medical devices. One way is how they function relative to the progression of an illness or injury. For example, are they preventive, corrective, or rehabilitative?[67] More comprehensively, the devices can be categorized according to use. For example, are they used for monitoring, screening, diagnosis, therapy, or rehabilitation?[68] Yet another way to categorize medical devices is by whether they are sold and used by consumers directly or by health professionals. The FDA refers to the former simply as consumer products.[69] No matter how products are characterized, more people appear to be interested in all aspects of health care, including access to their health information and making the decision about when to employ medical devices that provide monitoring, screening, diagnosis, therapy, and rehabilitation.

In moving toward making their own decisions, consumers are moving away from the medical paternalism practiced by doctors, hospitals, insurance agencies, and especially the federal government.[70] But there is likely to be resistance both from physicians who are concerned that "patients cannot understand the information or will get terribly confused and anxious without . . . spoon feeding by doctors"[71] and by the FDA, which still insists, for example, that the 23andMe genetic information must first be approved by the FDA and then pass through a doctor or genetic counselor before a patient can see it. No doubt there is a legitimate concern that some patients, as they always have, will make uninformed decisions, but that concern is unlikely to carry the day.

As patients begin to use their own diagnostic equipment, they will also have access to their own data. Again, not everyone will use this access; some

66. Dale H. Gieringer, "Consumer Choice and FDA Drug Regulation" (PhD dissertation, Department of Engineering-Economic Systems, Stanford University, 1984).
67. National Academy of Engineering, *New Medical Devices*, 3.
68. Ibid., 5.
69. FDA, "Consumer Products," last modified June 4, 2014, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/.
70. Eric Topol, *The Patient Will See You Now: The Future of Medicine Is in Your Hands* (New York: Basic Books, 2015).
71. Ibid.

will still rely on physicians because of a lack of interest or capabilities. And as patients (and people looking to stay healthy or to improve their capabilities) gain more access to devices and their own data, they will increasingly rely on sources other than doctors to make medical decisions.[72] This is already starting to take place: online patient sites such as WebMD and PatientsLikeMe, as well as IBM's Watson,[73] are being used to diagnose not just clinical illnesses but also precursors (biomarkers) to disease. Most of these developments have been written up in great detail in *The Patient Will See You Now* by Eric Topol, but the key message here is that more and more medical devices will be both developed for and used by people who are not healthcare providers.

Patients have also begun to avoid doctors' offices and hospitals (where infections are often transmitted). Instead, they seek remote treatment through telemedicine, where physicians can analyze data sent to them from patients who use their own devices. To meet this market demand, new virtual firms have sprung up: for example, Doctor on Demand, MD Live, American Well, and First Opinion. Providers also include the Mayo Clinic and Verizon.[74] Whether these patients are seeking to remotely engage doctors or to diagnose and treat their own conditions, the key is that patients, not healthcare providers, are using these medical devices, including software.

For example, the market for wearable health products has exploded with monitoring products such as Fitbit, Nike FuelBand, and Withings, but these have barely scratched the surface of the kinds of medical devices that consumers are ultimately looking to use.[75] Implantables, embeddables, and even ingestibles are already emerging as the next wave of "wearable" health and fitness technology.[76] Currently, these technologies are worn somewhere *on* the body,

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72. Steve Lohr, "The Healing Power of Your Own Medical Records," *New York Times*, March 31, 2015, http://www.nytimes.com/2015/04/01/technology/the-healing-power-of-your-own-medical-data.html?_r=0.

73. IBM's Watson is an artificial intelligence computer system that can answer questions posed in natural language.

74. Topol, *The Patient Will See You Now*.

75. 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), http://mercatus.org/publication/internet-things-and-wearable-technology-addressing-privacy-and-security-concerns-witho-0.

76. Cadie Thompson, "Wearable Tech Is Getting a Lot More Intimate," *Entrepreneur*, December 26, 2013, http://www.entrepreneur.com/article/230555; George Skidmore, "Ingestible, Implantable, or Intimate Contact: How Will You Take Your Micro-scale Body Sensors," *Forbes*, April 17, 2013, http://www.forbes.com/sites/singularity/2013/04/17/ingestible-implantable-or-intimate-contact-how-will-you-take-your-micro-scale-body-sensors; Martyn Landi, "Wearable Tech to Evolve Inside the Human Body," *Irish Examiner*, March 20, 2014, http://www.irishexaminer.com/world/wearable-tech-to-evolve-inside-the-human-body-262624.html; Tom Abate, "Stanford Engineer Invents Safe

but they might in the future be swallowed or implanted within the body, potentially even in the head.[77] Wristwatch sensors are another device that could do enormous good. By having the equivalent of an intensive care unit monitoring you from your wrist, your bedroom can substitute for a hospital room—that $4,500-a-night zone that puts you at risk of serious infections and other complications. Such devices could move patient monitoring away from hospitals to remote data surveillance centers. We might see, for example, many hospitals that would only include ICUs, operating theaters, and emergency rooms.[78] If this happens, demand for hospital-type services could be driven more by consumers than, for example, by hospital administrators and physicians.

Currently, there are personal devices in use or in development that capture "blood pressure, heart rhythm, respiratory rate, oxygen concentration in the blood, heart rate variability, cardiac output and stroke volume, galvanic skin response, body temperature, eye pressure, blood glucose, brain waves, intracranial pressure, muscle movements and many other metrics."[79] More incredible advances might be on the way, such as the regeneration of nerves with computer-assisted limbs.[80] In fact, we are not far off from a day when consumers will use 3-D printers to make their own medical devices from plans on the web. Such devices are already being designed by the University of Wisconsin's Open Source Medical Device program.[81] Of course, not all these devices will be used directly by patients, but some patients will want more and more input about when they should be allowed to use them.

Until now, these kinds of medical devices have been a relatively small proportion of the devices that are sent to the FDA for notification or approval each year. Yet, as many have noted, "The doctor-knows-best mindset is quickly fading, as people are no longer content to be back-seat patients and are instead demanding insight into their healthcare and the medical devices they use."[82] The FDA, in an attempt to keep up with these new types of consumer devices, issued draft guidance in January 2015 that indicated that it would not regulate

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Way to Transfer Energy to Medical Chips in the Body," Stanford University, May 19, 2014, http://news.stanford.edu/news/2014/may/electronic-wireless-transfer-051914.html.

77. Gary Marcus and Christof Koch, "The Future of Brain Implants," *Wall Street Journal*, March 14, 2014, http://online.wsj.com/news/articles/SB10001424052702304914904579435592981780528.

78. Eric Topol, "The Future of Medicine Is in Your Smartphone," *Wall Street Journal*, January 9, 2015, http://www.wsj.com/articles/the-future-of-medicine-is-in-your-smartphone-1420828632.

79. Topol, *The Patient Will See You Now*, 83.

80. National Academy of Engineering, "New Medical Devices," 11.

81. Topol, *The Patient Will See You Now*, 217.

82. Jamie Hartford, "Medical Device Makers Should Consider Patients as Consumers," Medical Device and Diagnostic Industry, September 16, 2013, http://www.mddionline.com/article/medical-device-makers-should-consider-patients-consumers.

consumer products intended to maintain or encourage a healthy lifestyle and having a very low risk to the safety of the user.[83] Of course, there is still considerable uncertainty about what products fall under these definitions.[84] In the pharmaceutical arena, patients are already expressing their frustration with the FDA's precautionary mindset by getting 11 states to pass right-to-try laws.[85] One could ask the question, if it is *your* health and *your* risk-benefit calculation, why is the right to try not a fundamental right that applies to any product or treatment that may help you?

It is likely that, as consumers begin to understand more and more about what is possible, they will reject the overemphasis on risk over benefit—that is, on precaution. These preferences relate not just to what is currently in development, but also to what could be in development if the FDA's approval process did not discourage so much innovation.

We can expect to see more of this kind of "citizen medicine," where people have "universal, free, immediate access to discoveries and innovation"[86] and drive those discoveries and innovation to monitor, diagnose, treat, rehabilitate, and even improve themselves over the original model.[87] These consumer devices will be developed and sold both in the United States and around the world. Information about their safety and efficacy will be accessible to anyone on the web, and the data also will come from around the world. This development will likely have

"It is likely that, as consumers begin to understand more and more about what is possible, they will reject the overemphasis on risk over benefit."

83. FDA, General Wellness, Policy for Low Risk Devices, Draft Guidance, January 20, 2015.
84. Jacqueline Chan and Suzan Onel, " FDA's Evolving Policy toward Health IT, Medical Apps, and Low Risk Devices," JDSUPRA Business Advisor, March 12, 2015, 2.
85. Ed Silverman, "More States Pass 'Right to Try' Laws, but Will These Make a Difference?," *Wall Street Journal* blog, March 27, 2015, http://blogs.wsj.com/pharmalot/2015/03/27/more-states-pass-right-to-try-laws-but-will-these-make-a-difference/. Right-to-try laws have been passed to allow terminal patients to try drugs not approved by the FDA.
86. Topol, *The Patient Will See You Now*, 211.
87. This is already happening as in the case described by A. J. Dellinger in "Night Vision Biohackers Defend Their Experiment," *Daily Dot*, April 3, 2015, http://www.dailydot.com/technology/biohacking-night-vision-safety/.

profound consequences for the precautionary model currently embodied in the FDA device review process.

THE FDA IN A WORLD OF RAPID TECHNOLOGICAL AND SOCIAL CHANGE

The FDA's mandate for premarket clearance of medical devices is to review for safety, effectiveness, and quality (covered by good manufacturing practices) before allowing the devices on the market. The presumption that gave rise to this mandate is that market forces, particularly postmarket forces that affect brand names, do not provide sufficient incentives for firms to exercise due diligence before going to market. These incentives may very well have been insufficient 40 years ago, but we are living in a different world than we were in 1976, and it is time to question whether the FDA's regulatory model—involving the precautionary premarket notification and clearance—remains the right model for today. Specifically, there have been technological, knowledge-based, and international developments that point to the need for a new model for FDA review.

Technological Developments: The Information Revolution

As the number of medical devices grows, so does their complexity—but at the same time, the growth in information technology has made information about these devices widespread and democratic. This information puts buyers much more in control of what they purchase and much less in need of protection.

Today, the variety of technological inventions is taxing the FDA's capacity to keep up. Eric Topol, author of *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care*, describes a taxonomy of technologies that he argues are converging to form a new medical paradigm to replace the old.[88] Topol's categories include information systems, imaging, genomics, wireless sensors, mobile connectivity and bandwidth, the Internet, social networking, and computing power and data universe. To that list, we can add other major technologies: robotics, nanotechnology, and 3-D printing, with the original plastic material giving way to metal, wood, and even living cells.[89]

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88. Eric Topol, *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care* (New York: Basic Books, 2012), Location 202 in Kindle edition.
89. Nancy Pardo, "3D Printed Organs Become More Complex," *Product Lifecycle Report* (PTC), April 25, 2014, http://blogs.ptc.com/2014/04/25/3d-printed-organs-become-more-complex/; "An Essential Step Toward Printing Living Tissues," Wyss Institute, February 19, 2014, http://wyss.harvard.edu/viewpressrelease/141.

In addition to the proliferation of devices, there are many areas of medical device development where the scale of production is minuscule. Where once the agency would have dealt with a single large manufacturer, now there may be a constellation of microdevelopers (small start-up firms with few people and a small budget). The initial capital outlay may be far smaller than in the past—in some cases, negligible.[90] "Biohackers" or average citizens—empowered with an abundance of information and access to inexpensive technologies—are building personally tailored medical devices or even modifying their own bodies. They are essentially practicing artisanal device manufacturing.[91] For example, a father used cellular communications technology to devise a remote-sensing device to measure his daughter's blood sugar levels.[92]

The FDA cannot keep up with these rapid-fire technological developments and is now confronted with what technology lawyer and consultant Larry Downes refers to as the "law of disruption," or the fact that "technology changes exponentially, but social, economic, and legal systems change incrementally."[93] This law is "a simple but unavoidable principle of modern life," Downes notes, and it has profound implications for the way businesses, government, and culture evolve going forward. "As the gap between the old world and the new gets wider," he argues, "conflicts between social, economic, political, and legal systems" will intensify and "nothing can stop the chaos that will follow."[94]

But while ubiquitous information networks and technologies create new challenges for the traditional FDA regulation of medical devices, they simultaneously open up new opportunities to overcome traditional rationales for regulatory intervention or market failures. In fact, we can expect to see websites that have the same kind of reputation effects that we normally associate with brick-and-mortar firms (discussed below).

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90. A MakerBot 3-D Printer, for example, costs in the neighborhood of $2,000.

91. Ben Popper, "Cyborg America: Inside the Strange New World of Basement Body Hackers," *Verge*, August 8, 2012, http://www.theverge.com/2012/8/8/3177438/cyborg-america-biohackers-grinders-body-hackers.

92. Kate Linebaugh, "Citizen Hackers Tinker with Medical Devices," *Wall Street Journal*, September 26, 2014, http://www.wsj.com/news/article_email/citizen-hackers-concoct-upgrades-for-medical-devices-1411762843-lMyQjAxMTA0NzI3OTIyNDkwWj?tesla=y.

93. Larry Downes, *The Laws of Disruption: Harnessing the New Forces That Govern Life and Business in the Digital Age* (New York: Basic Books, 2009), 2.

94. Ibid., 2–3. In a similar sense, Andy Grove, former CEO of Intel, once reportedly said that "high tech runs three-times faster than normal businesses. And the government runs three-times slower than normal businesses. So we have a nine-times gap." Lillian Cunningham, "Google's Eric Schmidt Expounds on His Senate Testimony," *Washington Post*, October 1, 2011, http://www.washingtonpost.com/national/on-leadership/googles-eric-schmidt-expounds-on-his-senate-testimony/2011/09/30/gIQAPyVgCL_story.html.

There are two types of market failure that drive much of government intervention: poor information in the marketplace and negative externalities—that is, effects from market transactions that are "external" to the transaction, such as noxious smoke from a factory.[95] The first problem is typically one where manufacturers know more about their products, particularly the defects in their products, than consumers do. This one-sided arrangement leads consumers to buy more (potentially lower-quality) products than they should. But such information asymmetries, particularly as imagined 55 years ago,[96] have been greatly attenuated thanks to the information revolution (although there is still poor information competing with good information on the web).[97]

Economists have long been concerned with the existence of information asymmetries between producers and consumers and have argued that "the difficulty of distinguishing good quality from bad is inherent in the business world."[98] The best that could be hoped for in the pre-Internet era was that consumer watchdogs, competition between firms, and brand goodwill would be enough to safeguard consumer welfare.[99]

But the Internet at least partially ameliorates this problem by providing consumers with robust search and monitoring tools to find more and better choices.[100] This lowers both search costs and transaction costs associated with commercial interactions.[101] Online e-commerce and the so-called sharing economy have blossomed thanks to these new technological realities. Medical devices are no different from other commodities that may entail some risk: we

95. Francis Bator, "The Anatomy of Market Failure," *Quarterly Journal of Economics* 72, no. 3 (August 1958), 351–79.
96. Ibid.
97. See, for example, Alex Tabarrok and Tyler Cowen, "The End of Asymmetric Information?," *Cato Unbound*, April 6, 2015, http://www.cato-unbound.org/2015/04/06/alex-tabarrok-tyler-cowen/end-asymmetric-information; Clay Shirky, *Here Comes Everybody: The Power of Organizing without Organizations* (New York: Penguin Press, 2008).
98. George A. Akerlof, "The Market for 'Lemons': Quality Uncertainty and the Market Mechanism," *Quarterly Journal of Economics* 84, no. 3 (August 1970): 488–500.
99. See Milton Friedman and Rose Friedman, *Free to Choose* (New York: Harcourt Brace Jovanovich, 1979), 223–24.
100. Adam Thierer, Christopher Koopman, Anne Hobson, and Chris Kuiper, "How the Internet, the Sharing Economy, and Reputational Feedback Mechanisms Solve the 'Lemons Problem'" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, May 2015).
101. Clay Shirky speaks of a "ladder of activities . . . that are enabled by social tools," creating greater opportunities for sharing, cooperation, collaboration, and collective action. This enables what he refers to as "ridiculously easy group-forming," which "matters because the desire to be part of a group that shares, cooperates, or acts in concert is a basic human instinct that has always been constrained by transaction costs." *Here Comes Everybody*, 47–54.

want them to work as advertised and cost is a consideration. The information age is facilitating both demands.

Moreover, information technology has facilitated the creation of countless reputational feedback mechanisms across the online ecosystem—such as product rating and review systems—that give consumers a more powerful voice in economic transactions.[102] The result is more fully informed and empowered consumers. "There has been a fundamental shift in the balance of power between consumers and salesmen over the last generation and it points in the direction of consumers," observes George Mason University economist Tyler Cowen.[103]

These reputational feedback mechanisms also help establish trust between suppliers and consumers.[104] "Reputational enforcement works by spreading true information about bad behavior," notes David Friedman. "People who receive that information modify their actions accordingly, which imposes costs on those who have behaved badly."[105] Vendors must always be on their toes and look to satisfy rapidly evolving demands from consumers and to gain (and keep) their trust.[106]

Because of these developments, modern information technology often does a better job of serving consumers than regulation does.[107] Beyond the obvious fact that the Internet and information technology give the public access to a broader range of goods and services, these new platforms and systems also offer consumers (including both patients and physicians) more information about those goods and services and empower them to come together and act on that information.[108]

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102. F. Randall Farmer and Bryce Glass, *Building Web Reputation Systems* (Sebastopol, CA: O'Reilly Media/Yahoo Press, March 2010), http://shop.oreilly.com/product/9780596159801.do.

103. Tyler Cowen, *Create Your Own Economy: The Path to Prosperity in a Disordered World* (New York: Dutton, 2009), 117.

104. "Online applications offer a new, additional means of enabling trust, thereby facilitating trading and sharing in a way that creates new consumer choices and positively impacts the economy." Randolph J. May and Michael J. Horney, "The Sharing Economy: A Positive Shared Vision for the Future," *Perspectives from FSF Scholars* 9, no. 26 (July 30, 2014), Free State Foundation, http://www.freestatefoundation.org/images/The_Sharing_Economy_-_A_Positive_Shared_Vision_for_the_Future_072914.pdf.

105. David D. Friedman, *Future Imperfect: Technology and Freedom in an Uncertain World* (New York: Cambridge University Press, 2008), 100.

106. R. Guha, Ravi Kumar, Prabhakar Raghavan, and Andrew Tomkins, "Propagation of Trust and Distrust," *Proceedings of the 13th International Conference on World Wide Web* (2004), 403–12, http://www.ra.ethz.ch/CDstore/www2004/docs/1p403.pdf.

107. Christopher Koopman, Matthew Mitchell, and Adam Thierer, "The Sharing Economy and Consumer Protection Regulation: The Case for Policy Change" (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, December 2014).

108. "By making it easier for groups to self-assemble and for individuals to contribute to group effort without requiring formal management [and its attendant overhead], these tools have radically altered

"In the near future, we expect that information on medical devices, including competing information, will be privately crowdsourced."

Consumers need information on the safety and effectiveness of medical devices before using them and certainly need to know if something is going wrong as the devices come into general use. The FDA view of information that arises as products begin to be used was encapsulated in a 2004 paper by an FDA medical device officer who claimed, "Safety and efficacy issues with medical devices and related procedures will come to light only if federal agencies are allowed to monitor them."[109] This statement was probably outdated in 2004 and certainly, as noted by John Moorhouse, "The case for government intervention is weakened by the Internet's powerful and unprecedented ability to provide timely and pointed consumer information."[110] Correspondingly, because the Internet and information technology alleviate the need for centralized information, and in light of the deficiencies associated with traditional regulatory mechanisms discussed above, consumer welfare may ultimately be better protected by loosening traditional regulations.[111]

Forty years ago, if a device was problematic, it most likely took some time for that information to reach the public consciousness. Individuals would experience problems with their devices and might contact either their doctor or the manufacturer. Doctors may or may not have told the relevant public health authorities, and if they did tell them, it would probably have been by letter (for which they were not compensated). Alternatively, if doctors had

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the old limits on the size, sophistication, and scope of unsupervised effort." Shirky, *Here Comes Everybody*, 21.

109. Larry Kessler et al., "Clinical Use of Clinical Devices in the 'Bermuda Triangle,'" *Health Affairs* 23, no. 1 (January 2004), 204, http://content.healthaffairs.org/content/23/1/200.full?ck=nck&related-urls=yes&legid=healthaff;23/1/200.

110. John C. Moorhouse, "Consumer Protection Regulation and Information on the Internet," in *The Half-Life of Policy Rationales: How New Technology Affects Old Policy Issues*, Fred E. Foldvary and Daniel B. Klein, eds. (New York: New York University Press, 2003), 139–40.

111. Arun Sundararajan, "Why the Government Doesn't Need to Regulate the Sharing Economy," *Wired*, October 22, 2012, http://www.wired.com/2012/10/from-airbnb-to-coursera-why-the-government-shouldnt-regulate-the-sharing-economy.

seen a few similar cases they may have written an article for a journal. Patients may have shared the information with their doctor but not necessarily the relevant authorities. In this scenario, the FDA's premarket clearance was probably necessary, as it took too long to find out that devices were unsafe or not working and to remove them from the market.[112]

In the medical device arena, both public and private postmarket surveillance has improved dramatically in the last 40 years, and the FDA itself reports some of this information through MedWatch.[113] Another effort comes from the nonprofit Brookings Engelberg Center for Health Care Reform, which is developing a National Medical Device Postmarket Surveillance System Planning Board in order to "create a robust tracking system, ensure the safety and effectiveness of medical devices and enhance the quality of patient outcomes."[114] If flaws are uncovered, electronic tags (called radio frequency identifications or RFIDs) are now coming on the market that will allow the devices to be quickly recalled.

This kind of information, essentially "big data," is becoming more available, thus reducing the cost of searching for and receiving information on individual products for both healthcare professionals and patients.[115] In the near future, we expect that information on medical devices, including competing information, will be privately crowdsourced.[116] Although manufacturers have incentives not to release information about problems with their own products, the incentives for patients are the exact reverse: to provide information about negative effects, not positive ones. In the case of a particularly dangerous (or particularly effective) device, news will likely spread peer-to-peer long before it can be collected, processed, and disseminated by the FDA. And organizations and websites collecting and issuing these data will emerge and vanish in

112. The FDA was created in 1906 when much medical care was still being provided by medicine shows traveling from town to town, and there was very little information about the products they were selling. So-called patent medicines, sold more widely than medicine from the traveling medicine shows, far too often contained ingredients that today are considered poisonous.
113. FDA, "MedWatch: The FDA Safety Information and Adverse Event Reporting Program," last modified May 7, 2015, http://www.fda.gov/Safety/MedWatch/.
114. "National Medical Device Postmarket Surveillance System Planning Board," Brookings Institution, Center for Health Policy, accessed May 13, 2015, http://www.brookings.edu/about/centers/health/focus-areas/biomedical-innovation/medical-devices-board#recent_rr/.
115. Viktor Mayer-Schönberger and Kenneth Cukier, *Big Data: A Revolution That Will Transform How We Live, Work, and Think* (New York: Houghton Mifflin Harcourt, 2013).
116. Richard Cramer, "Crowdsourcing Medical Decisions: Putting Big Data to Work in Healthcare," *Electronic Health Reporter*, August 5, 2013, http://electronichealthreporter.com/crowdsourcing-medical-decisions-putting-big-data-to-work-in-healthcare/.

an environment of fierce competition as quality improves rapidly.[117] Of course, there may be a role for the FDA to evaluate the decentralized evaluators.

Postmarket crowdsourcing also brings in a tremendous amount of data that will help eliminate problems with devices quickly. After all, every medical error is also an opportunity for medical innovation. While there will always be problems with any system, resilient systems learn about and correct mistakes through new innovation.[118] But a system (the FDA's) that says "No!" early on with too much emphasis on precaution and with obstacles to trial and error is doomed to stay technologically more or less in the same place.[119]

Rather than relying exclusively on (relatively) small clinical trials, crowdsourcing can gather information on devices used by heterogeneous populations with all their variations.[120] As one observer puts it, "Today, best clinical practices are most often derived through randomized clinical trials or expert opinion—yet neither approach addresses even a small fraction of the scope and complexity of patient and clinical variation that occurs in the real world."[121] It may be that some devices will turn out to be somewhat personalized, the way medicine will soon address patients on a genetic basis.[122]

Because the costs of information have been lowered dramatically, it is also more likely that firms that create and market bad devices will be rapidly exposed. This changes the incentives for firms to ensure that they do not suffer reputational losses to their brand, have to recall their product, or face liability suits. Not only does the incentive change for manufacturers, but drug stores, medical device wholesalers, hospitals, and even physicians will also want to

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117. We are already seeing this in groups such as PatientsLikeMe.com, where people compare treatments, symptoms, and experiences with others.

118. "Resilience is the capacity to use change to better cope with the unknown; it is learning to bounce back." Mary Douglas and Aaron Wildavsky, *Risk and Culture: An Essay on the Selection of Technological and Environmental Dangers* (Berkeley, CA: University of California Press, 1983), 196. "Regular, modest failures are actually *essential* to many forms of resilience—they allow a system to release and then reorganize some of its resources." Andrew Zolli and Ann Marie Healy, *Resilience: Why Things Bounce Back* (New York: Free Press, 2012), 13.

119. "Relative safety is not a static but rather a dynamic product of learning from error over time. . . . The fewer the trials and the fewer the mistakes to learn from, the more error remains uncorrected." Douglas and Wildavsky, *Risk and Culture*, 195. See also Adam Thierer, "Technopanics, Threat Inflation, and the Danger of an Information Technology Precautionary Principle," *Minnesota Journal of Law, Science & Technology* 14, no. 1 (2013): 309–86.

120. Pieter W. Huber, *The Cure in the Code: How 20th Century Law Is Undermining 21st Century Medicine* (Basic Books, 2013). Huber discusses the problems with so-called gold standard clinical trials when medicine is becoming individualized at the molecular level such that crowd-based trials are not generating useful information.

121. Ibid.

122. See, for example, Peter Cullis, *The Personalized Medicine Revolution* (Vancouver: Graystone Books, 2015).

protect their reputations by not selling (or prescribing) poor products.[123] It may also be possible for poor reputations to follow individuals from one firm to another, so being a start-up that can afford to go bankrupt is not necessarily any protection in the new information era. Most agree that personal information, particularly negative personal information, can follow a person once it has made its way onto the web.[124]

Knowledge Based: Changes in Understanding Social and Individual Risk

The FDA regulates risk associated with medical devices, both safety risk and risk of failure to perform properly. The general theory of risk that created the rules that determine how the FDA governs is one that views risks as static (unchanging) and that assumes the need for a centralized body to make a one-time decision based on that static risk. Our knowledge about risk has changed a great deal during the last decades, however.

Social risk. Our knowledge of the dynamic aspect of risk and safety has improved tremendously since 1976. In 1988, Aaron Wildavsky hypothesized that, rather than thinking about safety as a static concept, the way we achieve safety is by trial and error—that is, by multiple trials by decision makers with dispersed knowledge. This is thinking about "safety as a process, not a condition." He wrote, "Because safety must be discovered, and cannot be merely chosen . . . trial-and-error risk taking, rather than risk aversion, is the preferable strategy for securing safety." Wildavsky argued that wisdom is born of experience and that we can learn how to be wealthier and healthier as individuals and as a society only by first being willing to embrace uncertainty and even occasional failure:

> The direct implication of trial without error is obvious: If you can do nothing without knowing first how it will turn out, you cannot do anything at all. An indirect implication of trial without error is that if trying new things is made more costly, there will be fewer departures from past practice; this very lack of change may itself be dangerous in forgoing chances to reduce

123. Gordon Tullock, "Adam Smith and the Prisoners' Dilemma," *Quarterly Journal of Economics* 100 (1985): 1078, 1081. ("A reputation for being 'sound' is a valuable asset, and we should expect people to make every effort to get it.")
124. See, for example, Cheryl Conner, "Sharing Too Much, It'll Cost You," *Forbes*, October 19, 2012.

> existing hazards. . . . Existing hazards will continue to cause harm if we fail to reduce them by taking advantage of the opportunity to benefit from repeated trials.[125]

Trial without error is precisely what FDA preapproval of medical devices is aiming for: zero defects. As mentioned earlier, this is why most medical products are only slight variations on existing devices.

The anthropologist Joe Henrich notes that we often innovate by making mistakes that are occasionally improvements.[126] In addition, the more people that learn about the mistake, that is, the "connected population," the more likely the mistake will be a productive one as someone is likely to find a fix.[127] Again, this is a process of discovery, of finding small problems as we go along and either solving them or developing coping skills and strategies that make us more resilient over time.[128]

Science author Matt Ridley defined innovation as "spillovers," where innovations meet other innovations and mix, mate, and mutate. The web is one of the primary places where this happens.[129] Wildavsky argued that solving problems as they arise (mutating) is a better strategy than trying to anticipate and manage risks ex ante.[130] In fact, taking risks through the process of discovery ultimately makes us safer.[131] As ideas mix, mate, and mutate at a faster rate, the rate of new technological improvements could grow much more rapidly

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125. Aaron Wildavsky, *Searching for Safety* (New Brunswick, CT: Transaction Books, 1988), 38.
126. Joe Henrich, "Cultural Transmission and the Diffusion of Innovations: Adoption Dynamics Indicate That Biased Cultural Transmission Is the Predominate Force in Behavioral Change," *American Anthropologist* 103, no. 4 (December 2001): 992–1013.
127. Matt Ridley, *The Rational Optimist* (New York: HarperCollins Books, 2011), 77. The connected population are those on the web that improve on each other's improvements when there is a problem. This concept is illustrated by users improving on their 3-D generated prosthetic hands. See Robert Graboyes, "Fortress and Frontier in American Health Care" (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, October 2014).
128. Zolli and Healy, *Resilience*, 7–8. The authors define resilience as "the capacity of a system, enterprise, or a person to maintain its core purpose and integrity in the face of dramatically changed circumstances. . . . To improve your resilience is to enhance your ability to resist being pushed from your preferred valley, while expanding the range of alternatives that you can embrace if you need to. This is what researchers call preserving adaptive capacity—the ability to adapt to changed circumstances while fulfilling one's core purpose—and it's an essential skill in an age of unforeseeable disruption and volatility."
129. Ridley, *Rational Optimist*.
130. Wildavsky, *Searching for Safety*, 77–109.
131. Nassim Taleb has highlighted the benefits that flow from "using error as a source of information. If every trial provides you with information about what *does not* work," he notes, "you start zooming in on a solution—so every attempt becomes more valuable, more like an expense than an error. And of course you make discoveries along the way." *Antifragile: Things That Gain from Disorder* (New York: Random House, 2012), 71.

than in 1976, particularly as we are now able to take advantage of a worldwide "collective brain."

But the FDA's mandates can frustrate even a worldwide collective brain. FDA guidance on when to submit a 510(k) notification for changes to an existing device is now 17 years old.[132] The key phrase in this guidance is that any modification that "could significantly affect the safety or effectiveness of the device" needs to have a new submission.[133] The FDA also has good manufacturing practices (GMPs) that require manufacturers to document, verify, and validate any changes.[134] To help manufacturers decide whether they need to file a new 510(k), the agency includes rather complicated flowcharts where all the end points terminate in new documentation, testing, or a new 510(k) submission. For example, the FDA guidance states, "All changes to device design will require some level of design validation or evaluation to assure that the device continues to perform as intended."[135] In other words, the balance is tilted toward continual submissions and oversight by the federal government at every stage of development and marketing of medical devices (at least for product classes II and III).[136] This system presumes market forces will not react when there is a problem. If inventors must stop at every single stage to notify the FDA that an improvement has been made, the system is bound to discourage innovation.

In fact, the FDA's system for improvement simply ignores the typical life cycle of most devices. As one physician put it, "The way we use most medical devices in practice depends on post-introduction modifications of the devices. We work together—the physicians and the manufacturers and the engineers—on such modifications, and suggestions gradually get built into the device. Assessment of what we have accomplished becomes very important."[137] One study suggests that the lag between invention and use "to ensure the safety and efficacy of new interventions or advances" is 17 years.[138]

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132. FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)," January 10, 1997, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm.
133. Ibid.
134. Ibid.
135. Ibid. The FDA notes that "this guidance is not intended to address the need for submitting 510(k)s by remanufacturers of devices, who do not hold the 510(k) for the device."
136. These are medium-risk (II) and high-risk (III) devices. Medium-risk devices generally require 510(k) approvals, while high-risk devices virtually always require the more extensive premarket approval process (PMA).
137. National Academy of Engineering, "New Medical Devices," 11.
138. Zoe Slote Morris, Steven Wooding, and Jonathan Grant, "The Answer Is 17 Years, What Is the Question: Understanding Time Lags in Translational Research," *Journal of the Royal Society of Medicine* 104, no. 12 (December 2011), 510.

Individual risk. We are also coming to understand more and more that product satisfaction, both physical and mental, is individualized. As Peter Huber, author of *The Cure in the Code*, points out, we are much more genetically heterogeneous than previously understood.[139] Our differences are not just genetic; we also have different risk and benefit preferences.

The FDA more or less acknowledges the different preferences people have with respect to risks and benefits:

> FDA would consider evidence relating to patients' perspective of what constitutes a meaningful benefit when determining if the device is effective, as some set of patients may value a benefit more than others. It should also be noted that if, for a certain device, the probable risks outweigh the probable benefits for all reasonable patients, FDA would consider use of such a device to be inherently unreasonable.[140]

Why would the FDA need evidence about the distribution of risk-benefit tradeoffs that consumers would make with respect to a device? The very fact that there is a distribution, perhaps a broad distribution of risk-benefit tradeoffs that different consumers would make in different situations suggests that consumers individually are in the best position to make those tradeoffs themselves. But the FDA necessarily has to collapse the information into a single "go" or "no go" decision. Not only that, but the FDA denies consumers the choices that would be available to them if many more devices became available in a world not based solely on precaution.

If there is information that the FDA can bring to consumers to help them assess their options, that would seem to be clearly preferential to gathering and collating the preferences of 312 million current US consumers, not to mention future consumers.

In fact, the FDA admits as much here for implantable devices:

> The decision as to whether or not to implant the device is a matter of patient preference (perhaps with the involvement of a legally authorized representative) and medical opinion.

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139. Huber, *Cure in the Code*.

140. FDA, *Guidance for Industry and Food and Drug Administration Staff: Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications*, last modified October 1, 2012, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM296379.pdf.

> After full consideration of the likelihood of, and timeframe for, progression of disease and the predictability of future impairment without intervention, FDA is likely to approve the device as long as the labeling prominently addresses the 8% mortality rate and would provide through conditions of approval that only a very small group of highly trained physicians will be able to implant the device.[141]

The FDA recently held a workshop on how to elicit and validate patient preferences.[142] The stated purpose was to "discuss ways to incorporate patient preferences on the risk-benefit tradeoffs of medical devices into the full spectrum of the Center for Devices and Radiological Health (CDRH) regulatory decision making."[143] Much of the information that was presented to the FDA appears to have come from social science survey methodologies to elicit preference data from consumers on topics such as risk taking.[144] These surveys elicit data from individuals and then average their risk preferences. The averages are then used to make decisions about government programs to reduce population risks. Those kinds of average risk estimates are necessary for government programs that make *public* health decisions. But average risk preferences are not only unnecessary for *private* health decisions, they are undesirable. In this case, they are undesirable because they cannot represent the individual wishes of millions of different individuals.

Consumers have many different reasons for making the decisions they do. Their decisions vary by time and by individual circumstance, knowledge that the government simply cannot access.[145] In fact, research has shown that patients' preferences for treatment may vary widely from even their doctors' preferences.[146] Given the relatively close relationship between doctors and their patients, imagine how much larger the gap must be between patients and bureaucrats who have no relationship whatsoever. In some cases, the FDA fails to acknowledge even the most simplistic of differences between

141. Ibid.
142. FDA, Public Workshop—The Patient Preference Initiative.
143. Ibid.
144. An example of these types of surveys is called contingent valuation, which is widely used in the risk analysis field to estimate consumers' willingness to pay to reduce risk.
145. Friedrich Hayek, "The Use of Knowledge in Society," *American Economic Review* 35, no. 4 (1945).
146. A. Montgomery and T. Fahey, "How Do Patients' Treatment Preferences Compare with Those of Clinicians?," *Quality in Health Care* 1, no. 10 (2001): 39. The authors show that patients are less likely to want antihypertensive therapy than physicians do when the baseline risk is low.

different preferences, as demonstrated in a study that found the FDA had failed to account for gender differences for cardiovascular devices.[147] In fact, one thing consumers might be concerned with is cost, yet the FDA explicitly does not include lower costs as a benefit to consumers.[148]

These tensions will only intensify as innovative companies and physicians continue to devise ingenious ways to address ailments or to augment human capabilities. Inexpensive telecommunications, the Internet, nearly costless data processing, inexpensive travel, and inexpensive parcel delivery now effectively allow consumers and producers of medical devices to shop for alternative venues in other countries.

International Competition

More and more, the world is becoming an integrated market. The World Trade Organization reports that merchandise trade in 2000 was 22 times the level in 1950.[149] In 1997, "40 governments successfully concluded negotiations for tariff-free trade in information technology products."[150] It has therefore become even more important for countries to get first-mover advantages. Investopedia defines these advantages as

> a form of competitive advantage that a company earns by being the first to enter a specific market or industry. Being the first allows a company to acquire superior brand recognition and customer loyalty. The company also has more time to perfect its product or service.[151]

In order for a country to be able to compete in first-mover space, it must compete not just in the development of products but also in its regulations (which in turn affect product development). Not every product is susceptible to

147. S. S. Dhruva, L. A. Bero, and R. F. Redberg, "Gender Bias in Studies for Food and Drug Administration Premarket Approval of Cardiovascular Devices," *Circulation: Cardiovascular Quality and Outcomes* 4, no. 2 (2011).
148. "Should FDA Consider Costs When Reviewing Products?," Medical Device and Diagnostic Industry, February 15, 2015.
149. "The WTO in Brief: Part 1, The Multilateral Trading System—Past, Present and Future," World Trade Organization, accessed May 13, 2015, http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr01_e.htm.
150. Ibid.
151. "First Mover," *Investopedia*, accessed May 13, 2015, http://www.investopedia.com/terms/f/firstmover.asp.

first-mover advantages, as Fernando Suarez of Boston University and Gianvito Lanzolla of the London Business School point out; it depends on the pace of technological evolution and the pace of market evolution.[152] Peter Thiel points out that you may not want to be first, but you certainly don't want to be last mover, "to make the last great development in a specific market that has already set up established customer/vendor relationships."[153] Either way, delays and costs will force inventors and manufacturers to move to other countries.

We also now live in a world where global innovation arbitrage is possible.[154] Just as capital now moves like quicksilver around the globe as investors and entrepreneurs look for more hospitable tax and regulatory environments, the same is increasingly true of innovation more generally. Innovators can, and increasingly will, move to those countries and continents that provide a legal and regulatory environment more hospitable to entrepreneurial activity.

The United States is currently leading the world in the creation of new medical devices (about 38 percent of new medical devices in 2012), but that position is now threatened.[155] "The FDA review process is almost twice as long as that of its European counterpart (the European Medicines Agency) for devices not requiring clinical data, and almost three times as long for devices that do."[156] When presidents of medical device companies were asked what their biggest challenge was in 2014 (in the United States), more than 43 percent said the "changing regulatory environment."[157] In fact, the United States was the second most difficult market in which to introduce a new medical device, behind only China.[158] The 2011 PricewaterhouseCoopers Medical Technology Innovation Scorecard found that "the gap between innovation leaders and emerging economies is rapidly narrowing," and that "although the United States will hold its lead, the country will continue to lose ground during the

152. Fernando Suarez and Gianvito Lanzolla, "The Half-Truth of First-Mover Advantage," *Harvard Business Review* (April 2005).
153. Peter Thiel and Blake Masters, *Zero to One: Notes on Startups, or How to Build the Future* (London: Virgin Books, 2014), 58.
154. Adam Thierer, "Global Innovation Arbitrage: Genetic Testing Edition," *Technology Liberation Front*, December 12, 2014, http://techliberation.com/2014/12/12/global-innovation-arbitrage-genetic-testing-edition.
155. "The Medical Device Industry in the United States," SelectUSA, http://selectusa.commerce.gov/industry-snapshots/medical-device-industry-united-states.
156. Yair Holtzman, "The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad," Medical Device and Diagnostic Industry, July 17, 2012, http://www.mddionline.com/article/medtech-2012-SWOT.
157. "Outlook for the Medical Device Industry in 2015," Emergo Group, accessed May 13, 2015, http://www.emergogroup.com/research/annual-medical-device-industry-survey.
158. Ibid.

next decade." It goes on to say that "China, India, and Brazil will experience the strongest gains during the next 10 years."[159]

It's not just that medical devices may be created and manufactured in other countries. Patients are beginning to use medical tourism to explore other venues for treatment, and they are undoubtedly beginning to purchase medical devices from other countries as well, whether or not the devices are approved in the United States and even though by using them they may be breaking the law.[160]

THE FDA'S THIRD-PARTY REVIEW AND EXEMPTIONS

The FDA has already started down the path that we will suggest below with a third-party review system and a number of full or partial exemptions for some products. It currently has an ongoing—in fact, expanded—pilot program to allow accredited third-party reviewers to do an initial review of some medical devices.[161] The program was begun in 1997 and expanded in 2012 under the FDA Safety and Innovation Act of 2012.[162] In this program, medical device companies can submit their devices for a 510(k) review to approved third-party reviewers if their products are eligible for third-party review. The reviewers can make an initial determination about the products, but then the package is turned over to the FDA for final approval. The FDA must respond within 90 days unless agency regulators decide they need more information. The FDA still charges the same review fees, even though the product has gone through a third-party review for which customers must also pay.[163]

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159. 2011 PricewaterhouseCoopers Medical Technology Innovation Scorecard, cited in Scott W. Atlas, "Obamacare's Anti-Innovation Effect," *Wall Street Journal*, October 1, 2014, http://www.wsj.com/articles/scott-w-atlas-obamacares-anti-innovation-effect-1412204490.

160. Mark Huffman, "Feds Enlist International Help against Sales of Unapproved Drugs," Consumer Affairs, June 18, 2015. Medical tourism made news when NBA basketball star Kobe Bryant went to Germany in 2013 for knee surgery with a procedure still awaiting FDA approval here. See Kurt Helin, "Kobe Bryant Back in Germany for Annual Knee Treatment," *NBC Sports ProBasketballTalk*, September 11, 2014, http://probasketballtalk.nbcsports.com/2014/09/11/kobe-bryant-back-in-germany-for-annual-knee-treatment/.

161. FDA, Third Party Review, last modified June 25, 2014, http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/thirdparyreview/default.htm.

162. Alexander Gaffney, "Draft Guidance Establishes Accreditation Process for Third-Party Medical Device Reviews," Regulatory Affairs Professionals Society, February 15, 2013, http://www.raps.org/focus-online/news/news-article-view/article/2871/#sthash.pynD1ZXm.dpuf.

163. "US FDA Premarket Approval 510(k) for Medical Devices," TÜV SÜD, accessed October 5, 2015, http://www.tuv-sud.com/industry/healthcare-medical-device/market-approval-certification-for-medical-devices/u.s.-fda-premarket-approval-510k-for-medical-devices.

This is clearly a step in the right direction: as one group notes, "Third Party Reviewers clear devices in 68 days on average, more than 110 days faster than internal FDA reviewers."[164] These organizations will charge several thousand dollars for their service, but, for the money, applicants get a faster review and the expertise of engineers who understand specific types of medical devices, as well as the opportunity to get a product to market faster. Ultimately, it may be that the FDA is moving toward greater international harmonization.[165] It's not clear, however, whether these third party reviewers are only ensuring that applications are "complete" or whether they are relieving the FDA of review responsibilities by "recommending" approvals.[166] However, as one writer notes, perhaps in anticipation of debates today, "If FDA is seeking a solution to budgetary shortfalls in the future, it may consider relying more heavily on third parties. . . ."[167]

In fact, what we will argue below is not just that the pilot should be expanded, but that the FDA could be taken entirely out of the process for most devices. Instead, devices could be approved by private bodies that would get them on the market much more quickly, with at least the same level of safety and effectiveness as today's process and for much less money.

In addition to its recent upgrade of third-party review, and recognizing that it would be virtually impossible to clear all medical devices, the FDA (as well as Congress) has recently had to create exemptions for premarket clearance of some medical devices. For example,

"The FDA (as well as Congress) has recently had to create exemptions for premarket clearance of some medical devices."

164. "How Long It Takes the FDA to 'Approve' a 501(k) Submission," Emergo, accessed October 5, 2015, http://www.emergogroup.com/resources/research/fda-510k-review-times-research.
165. FDA, "Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I—Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Reviewers," February 15, 2013.
166. FDA, "Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff," August 4, 2015.
167. Chantel Carson, "510(k) Accredited Person Program: The Case for Third Parties," *Regulatory Focus*, April 2010, 28–30.

there is a "custom device" exemption that is based on either rare patients' needs or physicians' special needs.[168] In a somewhat arbitrary fashion, the FDA exempts these products if no more than five are produced each year.

The FDA also has guidance on its intention not to enforce certain unclassified, class II or class I devices from the 510(k) (premarket notification) requirements, a deal struck by the FDA in order to get user fees under the Medical Device User Fee Amendments of 2012.[169] These devices are exempt from premarket notification but not from registration and listing, labeling GMPs, and medical device reporting requirements.[170] Some of the devices that are exempt include over-the-counter denture cushions, speech aids, training devices for the hearing impaired (if they are battery operated), hemorrhoid cushions, medical support stockings, alcohol pads, surgical lamps, patient lubricants, and measuring devices for exercise.

The Center for Devices and Radiological Health has also issued draft guidance for comment on the low-risk devices that it does not intend to regulate—that is, they would not be covered by registration and notification requirements, good manufacturing practices, and medical device reporting requirements.[171] These products include exercise equipment, audio recordings, video games, software programs, and other products that are sold at retail.[172] The purpose of these products is to help maintain a healthy lifestyle that will reduce risks for numerous diseases or other conditions. These might include weight management, physical fitness, sleep management, or sexual functions. The devices are general wellness products if they do not reference, in any labeling, any specific disease or health condition—that is, they may refer to weight management but not obesity or eating disorders. This exemption applies only if the manufacturer claims that the product "*may help* to reduce the risk of" certain diseases or conditions. They are not invasive, have no inherent risk such as from lasers, and do not raise novel questions about usability or biocompatibility.

Finally, and perhaps most importantly, the FDA has recently issued guidance that exempts mobile medical applications.[173] "Mobile apps are

168. FDA, Custom Device Exemption Guidance for Industry and Food and Drug Administration Staff, January 14, 2014.
169. FDA, Intent to Exempt Certain Unclassified, Class II, and Class 1 Reserved Medical Devices from Premarket Requirement, August 14, 2015.
170. Ibid., 5.
171. FDA Center for Devices and Radiological Health, "General Wellness: Policy for Low Risk Devices; Draft Guidance for Industry and Food and Drug Administration Staff, January 20, 2015.
172. Ibid., 2.
173. FDA, "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff," February 9, 2015.

software programs that run on smartphones and other mobile communication devices. They can also be accessories that attach to a smartphone or other mobile communication devices, or a combination of accessories and software."[174] In some cases, the FDA exempts them because the agency has decided they are not medical devices, and in other cases, where they meet the definition of a medical device, the agency has signaled its intent to exercise "enforcement discretion." The FDA notes that these devices are "targeted to assisting individuals in their own health and wellness management."[175] As in all its guidance, the FDA ensures that it reserves the right to change its mind as it "will continue to evaluate the potential impact these technologies might have. . . ."[176]

The delineation of what is and is not a mobile medical app appears somewhat arbitrary: a light on your cell phone that is used as a flashlight is not, but if a doctor used it to examine a patient, then it is. These fine demarcations will continue to present a challenge for the FDA, as will all "wearable technologies" that are part of the larger picture of the "Internet of Things."[177]

Note that for any of these technologies that are not completely exempt, they are regulated under the following:

> Class I devices: General Controls, including:
>
> Establishment registration, and Medical Device listing (21 CFR Part 807);
> Quality System (QS) regulation (21 CFR Part 820);
> Labeling requirements (21 CFR Part 801);
> Medical Device Reporting (21 CFR Part 803);
> Premarket notification (21 CFR Part 807);
> Reporting Corrections and Removals (21 CFR Part 806); and
> Investigational Device Exemption (IDE) requirements for clinical studies of investigational devices (21 CFR Part 812).
>
> Class II devices: General Controls (as described for Class I), Special Controls, and (for most Class II devices) Premarket Notification.

174. Food and Drug Administration, "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, February 9, 2015.
175. Ibid., 6.
176. Ibid., 7.
177. Thierer, "Internet of Things."

> Class III devices: General Controls (as described for Class I), and Premarket Approval (21 CFR Part 814).[178]

No doubt, as pressure continues to stay on the FDA, it will continue to try to expand its third-party review system and to carve out exemptions in draft guidance. But the necessity for these ad hoc arrangements is precisely what creates a strong demand that we re-think the existing paradigm. The problems mentioned above still remain for most devices.

REDESIGNING THE MEDICAL DEVICE SYSTEM

It is time to unleash innovation in the medical device space in a way that has not been experienced since the 19th century, when Americans had a general "right to try." As we have seen, where the current system may have been totally appropriate 40 years ago, we live in a completely different world today. Today, with the information on risks and benefits available through the internet, it is much easier for patients to make informed decisions about their own risks and benefits than it was in 1976. We can therefore move toward a more patient-centric approach, particularly when risks are low or moderate. The risk takers who perceive the benefits to be worthwhile can take the lead; their experiences will provide information for others.

Unlike the case with pharmaceuticals, the effectiveness of medical devices does not depend on a dose—so safety and effectiveness can be considered separately. In some cases, trying an inefficacious device may cause a serious condition to worsen or even end up being irreversible. In these cases, safety and effectiveness deserve the same kind of consideration before a device is put on the market. For potentially high-risk devices such as pacemakers or devices for which effectiveness is important on the first use, the FDA should continue to fully investigate these devices before they go on the market.

But in the case of high-risk devices or any other devices, the incentives should be to lower the cost, time, and uncertainty now associated with getting medical devices to market. Throughout human history, there is only one institution that has ever been adept at satisfying those goals: the market. Our solution lies in creating market forces that include a new role for the FDA in which it performs only those functions for which it is best suited. These are largely

178. Food and Drug Administration, "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, February 9, 2015, 19.

information-gathering, enforcement, and high-risk device approvals. But for most premarket approvals, the FDA should be a competitor.

A NEW MODEL

Our new model will draw from two sources: current European institutions for medical device approval and an older model that continues to ensure maritime safety. Both models envision some degree of competition, not just between private bodies but between government and private bodies. Essentially, to be competitive, a key characteristic will be the degree to which an organization can create trust.

The transaction between buyers and sellers is one that involves a great deal of trust. Many people cannot imagine buying something from the Internet or from a person they do not know, likely will never know, and know nothing about without PayPal. But many people do look at the "Trust" indicators on eBay and decide to hand over credit card information. A merchant gains trust—essentially a reputation—through repetitive sales. "Competition is in a large measure competition for reputation or good will," noted Nobel Prize–winning economist F. A. Hayek.[179] In brick-and-mortar stores, trust comes about through brand names. Trust can also be built by third-party purveyors and third-party rating agencies such as UL and Moody's. Trust can also be developed through peer-to-peer reputational feedback mechanisms, where producers and customers rate each other using online mechanisms or digital apps.[180] Finally, trust is built because there are legal remedies when one party fails to live up to its side of the bargain.[181] As Dan Klein says, "Trust depends on the thickness and the pattern of the links.[182]

The FDA should compete in the market for trust. If manufacturers wish to have the FDA's blessing on a particular product, the FDA should offer that service the same as any other third-party reviewer and for a competitive price. The FDA would have to compete with private market approvers to earn trust over time and also compete on price, quality of review, and timeliness. A market competition based on time and quality of approvals would be vastly superior to oversight by Congress and the executive branch, which has brought us the

179. F. A. Hayek, *Individualism and Economic Order* (Chicago: University of Chicago Press, 1948), 97.
180. See Thierer, Koopman, Hobson, and Kuiper, "How the Internet, the Sharing Economy, and Reputational Feedback Mechanisms Solve the 'Lemons Problem.'"
181. Ibid.
182. Daniel B. Klein, "How Trust Is Achieved in Free Markets," *Issues in Ethics* 8, no. 3 (1997), http://www.scu.edu/ethics/publications/iie/v8n3/freemarkets.html.

system we have today. If competition improves the FDA's costs of approval and times to get approval, then the FDA may emerge as the best alternative.

As noted earlier, the European model of device approval is two or three times faster than the FDA. In fact, companies usually obtain approval for devices in the European Union (EU) years before they can get them approved in the United States.[183] In the EU, member governments certify private "notified bodies" that assess devices for safety standards set by the European Commission.[184] A notified body is a private competitive entity facing purposefully conflicting incentives. Each body has a motive to be slow and deliberate, as releasing harmful devices would bring adverse publicity and financial losses. At the same time, each notified body faces incentives to be fast and efficient. If manufacturers see a notified body as excessively slow and cautious, they will go to other notified bodies for approval. (The EU's system includes reciprocity agreements, so approval by one notified body is effectively approval by all.) The key here is that there is competition for speed and quality, precisely what we require here in the United States.

"The European model of device approval is two or three times faster than the FDA."

The approval process starts with the manufacturer obtaining a CE (Conformité Européenne) marking on a medical device. The marking is not a statement of quality but a verification that the manufacturer has met European Economic Community guidelines, similar to the FDA's premarket manufacturing guidelines in GMPs. In other words, it is a mark that is gained by being inspected by a private body to ensure that the product meets government standards. Obviously, the standards for medical devices could exceed GMPs. There are companies that help guide medical device manufacturers through this system. As one writer has noted, there is no

183. Allison Connolly, "Medical-Device Makers See EU Rules Slowing U.S. Approvals," *Bloomberg Business*, September 25, 2013, http://www.bloomberg.com/news/articles/2013-09-24/medical-device-makers-see-eu-rules-slowing-u-s-approvals.
184. Tabarrok, review of *Innovation Breakdown*.

evidence that the European model of device approval puts European patients at any more risk than US patients.[185]

But the United States doesn't necessarily need to follow the European model of device approval. Another, older model of ensuring safety—the maritime classification society model—was devised in the late 18th century by shipping firms. It is used to this day to maintain high technical standards in shipping.

Shipping is a complex undertaking, and it poses dangers as profound as those in medicine, if not more so. A shipping disaster, after all, can affect bystanders as well as those directly involved in the industry. Since the late 1700s, quality control in shipping has been managed via maritime classification societies. Beginning in the coffee houses of Georgian London, the industry, under the auspices of the United Nations Maritime Conference, established a system of self-regulation in 1948.[186] Governments laid down basic rules of the game. The International Maritime Organization (IMO) and the International Association of Classification Societies Ltd. (IACS) are two of the organizations that establish standards of seaworthiness and assess the compliance of individual firms and ships.[187] There are roughly 50 such societies at present. The IMO, a global authority for international shipping for 170 countries, is considering goal-based standards that move away from compliance to risk-based standards that allow flexibility.

Like the European Union model of medical device approval, classification societies compete with one another; they must because they are nongovernmental. As with the European Union device approval process, shipbuilders can shop around for the classification society of their choice. Originally, the societies bore no legal responsibilities for ships that failed to adhere to their directives although they were liable for improper assessments. A US system for medical devices could include at least some measure of liability.

One of the most important aspects about the societies is that they are experts at what they do. Inspectors are selected based on competence, impartiality, and fidelity.[188] A classification society typically relies on empirical experience gained from classifying a wide variety of ship types over many

185. Gulfo, *Innovation Breakdown*, 194.
186. International Maritime Association, "IMO in the United Nations," October 10, 2014, http://www.imo.org/en/KnowledgeCentre/IMOAndTheUnitedNations/Pages/default.aspx.
187. "Classification Society and IACS," Maritime Connector, accessed May 13, 2015, http://maritime-connector.com/wiki/classification-society/.
188. International Association of Classification Societies (IACS), "Classification Societies, What, Why, and How," 12, http://www.iacs.org.uk/document/public/explained/class_whatwhy&how.pdf.

years, coupled with appropriate research that contributes to the ongoing development of relevant, advanced technical requirements.[189] Their classifications do not guarantee safety because they do not control how a ship is manned, operated, and maintained between the periodic surveys that the societies undertake.[190] Similarly, the FDA cannot guarantee safety based on how a device is used once it has been approved. The certification is that the ship is in compliance and presumed safe at the point at which it is inspected. Each society continues to monitor the ships that it has classified as acceptable to ensure that they remain so.

Rand Simberg, an aerospace engineer, wrote about classification societies as a possible model for self-regulation of commercial space travel,[191] citing work by Michael J. Listner, Tommaso Sgobba, and Christopher Kunstadter.[192] The virtues of such an arrangement are multiple: classification societies are competitive; they face balanced incentives just as the European Union's device-approval system does; and they can experiment with different structures, staffing, and methodologies.

As in the case of shipping, the 21st century medical device industry exhibits characteristics that make national regulation difficult. As in the case of shipping, national borders are becoming less important to patterns of production, marketing, and consumption of medical devices. Somewhat differently, medical device production is becoming more nimble and mobile; the devices are getting smaller and are often much less expensive than their antecedents, and patients and consumers can shop internationally for devices, either by traveling, by parcel, or by the Internet. Increasingly, as well, the sharing economy is distributing medical devices in ways that defy oversight by the FDA. For example, 3-D printing, open-source software, and distribution without explicit payment (say, barter) eliminate the paper trail that made old-style regulation possible. As with shipping, "flags of convenience" are likely to be a critical element of device manufacturing going forward. And perhaps most importantly, shipowners and others in the industry will always know more about a vessel than any remote regulator can, so the classification societies use insiders' expertise rather than knowledge by outsider regulators. Certainly, because there are so many different types of medical devices, there would be

189. Ibid., 5.
190. Ibid., 4.
191. Rand E. Simberg, *Safe Is Not an Option* (Interglobal Media, 2013), Location 2789 in Kindle edition.
192. Michael J. Listner, Tommaso Sgobba, and Christopher Kunstadter, "Taking a Page from Maritime Practice to Self-Regulate the Commercial Space Industry," *Space Review*, March 4, 2013, http://www.thespacereview.com/article/2252/1.

an incentive to develop expertise in particular types of devices by reviewers who would work with manufacturers and physicians.

Under our model, the FDA could serve several useful roles. First, it could continue to set broad regulations about good manufacturing practices and aspects of safety and efficacy that could be monitored by nongovernmental bodies for the production of medical devices. However, the FDA would not be solely responsible for making the compliance determination. It could also compete with nongovernmental bodies for compliance decisions. In this system patients, physicians, and consumers who are the most risk averse could continue to rely on the FDA if they wish.

The agency must also continue to play an enforcement role. The FDA must have the authority to recommend prosecution of those deliberately cutting corners. The agency can investigate problems and publicize where and why they occur. If criminal negligence is involved, the FDA can refer cases to the US Department of Justice.

Congress could authorize the FDA, where necessary, to gather and publish information on postmarket issues, although much of this is likely to be done much more efficiently by private competing companies. Even as its role is forced to change to accommodate 21st century technological realities, the agency can still help educate the public about the relative risks patients face when choosing different treatments and devices. Again, the focus should be on empowering consumers, not limiting their choices.

Finally, the FDA can continue to be responsible for the most high-risk products where failure can lead to irreversible adverse effects. All these revisions will require a fairly complete rethinking of the FDA's role in medical devices, something that has not occurred since 1938.

CONCLUSION

This paper started with questions: What if treatments were available, or could be available, but the current system of FDA approvals for medical devices either prevented them from ever being invented or delayed them such that they couldn't be used to treat someone today? Do we have to continue with that system or can we take advantage of the developments of the last 40 years to speed up innovation that helps people and saves lives?

Modern regulation appeared at a time in which goods and services were rapidly growing more complex, differentiated, and unfamiliar. In this explosively industrializing economy, individual knowledge became more specialized. Hence, consumers were becoming less and less familiar with

the goods and services they were using. This was a world of black boxes, and regulation was seen as the means to illuminate the interiors of those boxes and control them before they reached consumers. To do this, regulation would centralize experts under a single institutional roof. These experts would conduct the difficult work of choosing topics for research, collecting data, turning it into useful scientific findings, and distributing the findings to policymakers.

The 21st century is different. This is an era in which consumers have access to data that are instantly available in comprehensible formats. Though we remain highly specialized in both our consumption and production, it is probably true that a consumer today has vastly greater access to information than even a regulator would have had during the previous century.

The FDA is like an old market town with roads arranged in a hub-and-spoke pattern, forcing all traffic through the center of town. But 21st century data are equivalent to today's traffic. Hub-and-spoke roads are perpetually jammed and notoriously inefficient. In response, we've added beltways and webs of alternative routes to accommodate today's traffic. Device approvals need an equivalent change, through a redesigned FDA or through replacement firms. Although there have been numerous new laws that have increased the size and scope of the FDA's authority over medical devices, there has been no systemic review of FDA basic operating laws for 108 years and it is now long past time. New medical devices are increasingly consumer products, and the same theories that gave us the information revolution can drive the next wave of medical device innovation.

What powered the information revolution was America's rejection of overly preemptive regulation based on a belief in the precautionary principle—that new innovations should be curtailed or disallowed until their developers can prove that they will not harm and will positively help individuals, groups, specific entities, cultural norms, or various existing laws, norms, or traditions.[193] In IT, by contrast, ongoing innovation and competition were judged to be superior to cowering before hypothetical worst-case fears and imposing precautionary controls. Pressing or persistent problems, if they developed at all, were addressed after all other options were exhausted. We need more of that sort of thinking to infuse the field of medical device regulation.

193. See Adam Thierer, *Permissionless Innovation: The Continuing Case for Comprehensive Technological Freedom* (Arlington, VA: Mercatus Center at George Mason University, 2014); Thierer, "Technopanics, Threat Inflation, and the Danger of an Information Technology Precautionary Principle."

Points that lead to the conclusion that we need this new thinking include the following:

- In the current system, the FDA has become overwhelmed with numerous and complex devices.
- Despite recent programs to speed up approval of medical devices, the FDA is fundamentally and necessarily a precautionary institution. It will always be more concerned about potential harm caused by approving an unsafe device than about potential (or certain) harm caused by inappropriately slowing down or inhibiting new, effective devices.
- Because of costs, delays, complexity, and uncertainty, too many health-improving inventions and innovations never make it to market or they are delayed so that people suffer or die needlessly.
- Although the United States has been the leader in medical device innovation, we will soon be seeing other countries take the lead in this area.
- More and more devices will be going straight to consumers, who will use them in every phase of health care, to monitor, diagnose, treat, rehabilitate, or even improve themselves.
- Consumers are willing to shop internationally for health care—in person, through the mail, or via the Internet.
- Increasingly, innovators are successfully seeking out more hospitable legal and regulatory climates in other countries.
- More and more health care will be delivered remotely with healthcare facilities primarily serving emergencies.
- We understand much more about risk and consumers now:
    - Neither risk reduction nor innovation takes place statically. As risk issues arise, entrepreneurs who are allowed to proceed on their own will make continuous improvements. Barriers to those improvements slow the progress of medical devices.
    - Depending on a number of factors such as health status and age, patients and physicians all have different risk-benefit preferences. No individual or organization can possibly know all those preferences, either currently or as they change over time. A one-size-fits-all device does not serve those different preferences.

    - With heterogeneous risk-benefit preferences, some less risk-averse patients and consumers will try new products first, providing information for those who are more risk averse.
- And finally, we live in an age in which we are able to rapidly access information about anything, including the safety and efficacy of medical devices. This access to information creates incentives for manufacturers (and everyone else in the supply chain) to provide safe and effective devices, because failure to do so risks lawsuits, recalls, and loss of business.

Given all the progress and all the problems, the real question before us is, What would the FDA's role in medical devices be if we were to create it anew? The answer lies in removing the FDA monopoly on approvals and creating private markets that will be responsive to patient and consumer choice.

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