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Disrupting the Market for Ineffective Medical Devices

Wendy Netter Epstein

The current debate over medical device regulation pits safety against innovation. Those in favor of greater regulation point to the need to protect patients from the harms of insufficiently tested devices. Those in favor of less regulation cite the need to promote innovation and move potentially lifesaving devices to market faster.[1] At present, the less regulation, more innovation camp is winning the debate – in part on the argument that postmarket surveillance systems can adequately address safety concerns. But framing the debate this way leaves out key inputs: efficacy and relative effectiveness.

Not all innovation is created equal nor is it equally desirable. The best innovation creates medical devices that are superior to current alternatives, either because they lead to better patient outcomes or because outcomes are just as good, but the care is cheaper. The ideal innovation creates devices that are both clinically better and cheaper. While the potential for devices to significantly improve health outcomes is great – and many devices have had such a positive impact – the prevalence of ineffective devices is nonetheless troubling.[2]

In 2016, the 21st Century Cures Act was signed into law.[3] The Act was designed in large part to accelerate device development and approval. But even under the

[1] See Daniel B. Kramer et al., Ensuring Medical Device Effectiveness and Safety: A Cross-National Comparison of Approaches to Regulation, 69 Food & Drug L. J. 1, 6 (2014); Rita F. Redberg, Improving the Safety of High-Risk Medical Devices, 68 DePaul L. Rev. 327 (2019); US Food & Drug Admin., FDA In Brief: FDA continues Steps to Promote Innovation in Medical Devices that Help Advance Patient Safety Through the Safer Technologies Program (Sept. 18, 2019), www.fda.gov/news-events/fda-brief/fda-brief-fda-continues-steps-promote-innovation-medical-devices-help-advance-patient-safety-through. Compare, e.g., Report Criticized F.D.A. on Device Testing, N.Y. Times (Jan. 15, 2009) (arguing for stricter regulation of devices) with FDA Seeks to Toughen Defibrillator Regulations, N.Y. Times (Mar. 22, 2013) (arguing for looser device regulation).

[2] Debra Jackson et al., Medical Device-Related Pressure Ulcers: A Systematic Review and Meta-Analysis, 92 Int'l J. Nursing Studies (2019); Rushi K.Talati et al., Major FDA Medical Device Recalls in Ophthalmology from 2003 to 2015, 53 Can. J. Ophthalmology 98 (2017), https://doi.org/10.1016/j.jcjo.2017.08.001.

[3] Aaron S. Kesselheim & Jerry Avorn, New "21st Century Cures" Legislation: Speed and Ease vs Science, 317 JAMA 581 (2017).

somewhat stricter regulatory regime that had been in place prior to the Act, there was evidence that ineffective and expensive medical devices were used pervasively. One study identified nearly forty such ineffective medical devices.[4] As shown in Chapter 1, the use of these devices can harm the health of patients and adds significant costs to an already immensely costly system.

Perhaps none of this is surprising given that market mechanisms can be ineffective at promoting ideal device innovation, the regulatory regime is underpowered (even when the Food and Drug Administration (FDA) requires evidence of effectiveness, the bar is low),[5] and the products liability and tort systems do little to force providers to assess relative efficacy.[6] This chapter describes the serious negative consequences that flow from the use of ineffective medical devices and explores some solutions, focusing on the underexplored role that providers and payors might play in beginning to address this problem.

13.1 THE KIND OF INNOVATION WE WANT VERSUS THE MEDICAL DEVICES WE GET

Sometimes medical devices are brand new innovations in that they do not replace anything that came before them. For instance, the stethoscope was first invented in 1816 to improve upon the only method that existed at the time to listen to a patient's heart – placing one's ear on the patient's chest.[7] More often, however, medical devices purport to be improvements to treatments that already exist – an improvement over an existing device (say a next-generation pacemaker) or an alternative to another practice (for example, substituting device technology to control hypertension for pharmaceutical therapy).[8] But how do we evaluate what type of medical device innovation is most desirable?

There are two primary dimensions to consider: the extent to which the device improves patient outcomes[9] and the effect on cost. The best new medical devices simultaneously improve patient outcomes and reduce cost. But we may also be

[4] Diana Herrera-Perez et al., Meta-Research: A Comprehensive Review of Randomized Clinical Trials in Three Medical Journals Reveals 396 Medical Reversals, 8 eLife 45183 (2019).

[5] Sanket S. Dhruva et al., Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices, 302 JAMA 2679 (2009); Sarah Y. Zheng et al., Characteristics of Clinical Studies Used for US FDA Approval of High-Risk Medical Supplements, 318 JAMA 619 (2017).

[6] Id.; 21 U.S.C. § 360(c) (describing the 510k process). Although note that the US premarket authorization process does contain an effectiveness requirement, whereas the European Union's performance standard is more lenient. See the Official Journal of the European Union for Harmonised European standards for medical devices, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2020:090I:TOC.

[7] Sherwin B. Nuland, Doctors: The Biography of Medicine 24, 220 (1988).

[8] Gregory J. Millman, Medical Devices as Drug Replacements, Wall St. J. (May 28, 2012), https://blogs.wsj.com/source/2012/05/28/medical-devices-as-drug-replacements/?mod=google_news_blog.

[9] How to measure improved patient outcomes is a matter of significant controversy. See generally Christopher Buccafusco & Jonathan S. Masur, Drugs, Patents, and Well-Being, 98 Wash U. L. Rev. 1403 (2021).

happy when new devices either improve outcomes or are cheaper. One thing is clear: we do not want devices that score poorly on both patient outcome and cost metrics. To the extent our current system is prompting new devices that simultaneously add cost and do not improve patient outcomes,[10] that is problematic. Yet there is a growing body of evidence showing that such devices are getting approved (or cleared) by the FDA and are being used in practice, without patient knowledge.

When medical devices are determined to be unsafe, it is front page news. Consider the plight of surgical mesh used to repair hernias that had severe side effects,[11] the cement application device used in spinal fusions that grew bone where it was not supposed to,[12] or metal-on-metal replacement hips that caused flesh-rotting metallosis.[13] These devices were recalled, class action lawsuits were filed, and policymakers rightly focused on how these harms could have been avoided.[14] But the same is not true of ineffective medical devices – those that might not be killing people or causing horrendous side effects, but that can nonetheless cause considerable harm when they do not do what they are supposed to do.

Consider the example of the bispectral index monitor (BIS) intended to address anesthesia awareness, which occurs when surgical patients under general anesthesia are aware of events that happened during the surgery after they awaken, sometimes feeling pain.[15] These experiences are associated with posttraumatic stress disorder and anxiety. The BIS monitor was designed to fix the problem by measuring consciousness, allowing the anesthesiologist to titrate anesthesia to avoid awareness.[16] The device was approved by the FDA in 1996. Its use spread so much that BIS monitors were in more than half of all operating rooms.[17] Then, ten years after FDA approval, a large, randomized trial that compared use of the BIS monitor with standardized monitoring procedures found no benefit of the BIS monitor to

[10] Device effect on patient outcomes may be highly heterogeneous. Devices may only be effective for a small sliver of the population but used broadly.

[11] Sheila Kaplan & Matthew Goldstein, F.D.A. Halts U.S. Sales of Pelvic Mesh, Citing Safety Concerns for Women, N.Y. Times (Apr. 16, 2019), www.nytimes.com/2019/04/16/health/vaginal-pelvic-mesh-fda.html.

[12] Joe Carlson & Jim Spencer, Medtronic Agrees to Settlement with Five States in Infuse Case, Star Trib. (Dec. 13, 2017), www.startribune.com/medtronic-agrees-to-settlement-with-five-states-in-infuse-case/463955203/.

[13] Jeanne Lenzer, Can Your Hip Replacement Kill You?, N.Y. Times (Jan. 13, 2018), www.nytimes.com/2018/01/13/opinion/sunday/can-your-hip-replacement-kill-you.html.

[14] Ralph F. Hall, To Recall or Not to Recall, That Is the Question: The Current Controversy over Medical Device Recalls, 7 Minn. J. L. Sci. & Tech. 161 (2005).

[15] Se Woo Park et al., Bispectral Index Versus Standard Monitoring in Sedation for Endoscopic Procedures: A Systematic Review and Meta-Analysis, 61 Digestive Diseases and Sciences 814 (2016); Medical Advisory Secretariat, Bispectral Index Monitor: An Evidence-Based Analysis, 4 Ont. Health Tech. Assessment Series 1 (2004).

[16] Id.

[17] Vinay Prasad et al., A Decade of Reversal: An Analysis of 146 Contradicted Medical Practices, 88 Mayo Clinic Proceedings 790 (2013).

anesthesia awareness.[18] The monitors were not necessarily unsafe, but they were ineffective and costly.

The story of hip protectors is similar. Hip protectors are devices designed to protect older patients, typically who suffer from osteoporosis, from fracturing their hips in a fall.[19] The FDA has approved a number of different hip protector devices.[20] But now, several postmarket studies have been conducted. None have found evidence that hip protectors are effective in preventing hip fractures.[21] In some studies, patients were more likely to fracture hips when using hip protectors than when not.

Mechanical cardiopulmonary resuscitation (CPR) devices provide a final example. When a patient goes into cardiac arrest, delivering high-quality CPR improves patient outcomes.[22] CPR, however, can be difficult to perform correctly – both to perform chest compressions at the right rate and to compress the chest to the right depth. Mechanical CPR devices ostensibly reduce human error by performing automated CPR at a specified rate and to a specified depth.[23] These devices were originally introduced in the 1960s and have been approved or cleared by the FDA.[24] They are expensive, at an average price of $15,000 each, and are increasingly being used, particularly by EMS agencies.[25]

Counterintuitively, many studies have now shown that mechanical CPR leads to worse patient outcomes than manual CPR, particularly when used outside the hospital.[26] Mechanical CPR is both more costly than manual CPR and also leads to poorer health outcomes. Yet its use persists.

These examples are likely the tip of the iceberg. While these devices were studied after adoption, most do not get the postmarket randomized trial treatment.[27] Nonetheless, the systematic study of medical device effectiveness that has been done provides further reason for concern.

In 2019, authors conducted a comprehensive review of the randomized clinical trials published in three leading medical journals – The Journal of the American Medical Association and the Lancet between 2003 and 2017, and the New England

[18] Michael S. Avidan, Anesthesia Awareness and the Bispectral Index, 358 N. Engl. J. Med. 1097 (2008).

[19] Douglas P. Kiel et al., Efficacy of a Hip Protector to Prevent Hip Fracture in Nursing Home Residents, 298 JAMA Int'l Med. 413 (2007).

[20] Id.

[21] Id.

[22] Monica E. Kleinman et al., 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, 132 Circulation (2015).

[23] Kurtis Poole et al., Mechanical CPR: Who? When? How?, 22 Critical Care 140 (2018).

[24] Id.

[25] Oren Wacht et al., Mechanical CPR Devices: Where is the Science?, J. Emergency Med. Serv. (2019), www.jems.com/2019/11/12/mechanical-cpr-devices-where-is-the-science/.

[26] Poole, supra note 23; Joachim Marti et al., The Cost-Effectiveness of a Mechanical Compression Device in Out-Of-Hospital Cardiac Arrest, 117 Resuscitation 1 (2017).

[27] It is not always the case that devices do not work for anyone, but often devices are being deployed in populations for which they are ineffective. See, e.g., Anahad O'Connor, Heart Stents Still Overused, Experts Say, N.Y. Times (Aug. 15. 2013), http://well.blogs.nytimes.com/2013/08/15/heart-stents-continue-to-be-overused/?_r=1.

Journal of Medicine between 2011 and 2017.[28] The study aimed to identify medical reversals, which the authors define as "practices that have been found, through randomized controlled trials, to be no better than a prior or lesser standard of care."[29] BIS monitors, hip protectors, and mechanical CPR devices, are all medical reversals.

The authors' review found close to forty medical reversals involving medical devices.[30] The authors only studied randomized controlled studies that had been published in leading medical journals, but of those studies, a surprisingly high 13 percent of all randomized trials were medical reversals.[31] These findings are consistent with other analyses that have been conducted.[32]

The next section explores why it is likely that many ineffective devices have prevailed in the market despite the fact that they do not work (or work less well) than other less-expensive options.

13.2 WHY INEFFECTIVE MEDICAL DEVICES ARE IN USE

How exactly do we end up with ineffective medical devices? In theory, three protections should prevent or at least minimize the occurrence: markets, the regulatory regime, and tort law.[33] In practice, however, all are flawed.

13.2.1 *Market Insufficiencies*

Well-functioning markets should check false claims of effectiveness. If a vacuum is advertised to pick up pet hair and it turns out that it does a lousy job, word will get out and people will not buy the vacuum. If the vacuum is merely adequate at picking up pet hair, but the model is more costly than similarly effective alternatives, consumers will not buy the vacuum. In the medical device context, if a glucose monitoring system does not accurately read glucose levels, and this fact is discoverable, patients should not buy it. And if the glucose monitoring system is adequate but more expensive than alternatives, people should not buy it.

But several characteristics make the medical device market unique. First, while a consumer can see whether the vacuum does a good job removing pet hair, a patient

[28] Diana Herrera-Perez et al., Meta-Research: A Comprehensive Review of Randomized Clinical Trials in Three Medical Journals Reveals 396 Medical Reversals, 8 eLife 45183 (2019), https://elifesciences.org/articles/45183.

[29] Id.

[30] See also Daniel J. Niven et al., Towards Understanding the De-Adoption of Low-Value Clinical Practices: A Scoping Review, 13 BMC Med. 255 (2015); Desir´ee Sutton et al., Evidence Reversal-When New Evidence Contradicts Current Claims: A Systematic Overview Review of Definitions and Terms, 94 J. Clinical Epidemiology 76 (2018).

[31] Herrera-Perez, supra note 28.

[32] Id.

[33] Patent law is also unhelpful. The USPTO reviews devices for usefulness, but there is no mechanism to assess effectiveness. See 35 U.S.C. § 101.

often cannot tell if the medical device does what it is supposed to do. Most patients are unable to tell if they need the medical device in the first place and are ill-equipped to select the best one even if they have access to necessary information, which they often do not. Second, patients are not making decisions alone. They must rely on doctors and other providers to act as their agents to choose the most effective device. But providers can be swayed by reimbursement rates, conflicts of interest such as side deals with device manufacturers, a desire to experiment with the latest technology, and pressure from patients and advocacy groups. When a device is not effective, it is not necessarily in the best interests of the provider to disclose that information. And even after evidence is shared that a device does not work, providers who have used a device for a long time may be hesitant to change their practices. Finally, another complication is that a third-party payor typically reimburses for device cost, lessening the impact of cost considerations on decision making. So low-value and high-value devices can be profitable just the same.

13.2.2 *Regulatory Failures*

When markets alone are not sufficient, we turn to regulation. One might assume that the FDA only approves devices that are both safe and effective. But that may not be the case.

To start, the FDA classifies devices based on risk to the patient, with Class I devices being low risk (e.g., bandages), Class II being intermediate risk (e.g., wheelchairs), and Class III being highest risk (e.g., implantable pacemakers). As others in this volume have noted, more than 80 percent of devices are exempted from the FDA's premarket approval process based on their classification and either do not require review or are instead permitted to be marketed following clearance through the 510(k)-approval pathway.[34]

Let us start with the 510(k) pathway. Devices subject to its requirements need not provide independent evidence of effectiveness. Manufacturers only need establish that the device is "substantially equivalent" to a predicate device already on the market. Devices have been cleared even if the predicate had been removed from the market or if the predicate had been initially approved without judging effectiveness.[35] While the 510(k) pathway must exist for minor adjustments to approved devices, concerns about the process are well documented.[36]

But even for Class III devices that must submit to the more rigorous premarket review process, where evidence of effectiveness is theoretically required, there is still

[34] Institute of Medicine, Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years (2011), www.nap.edu/catalog/13150/medical-devices-and-the-publics-health-the-fda-510k-clearance.

[35] Gail A. Van Norman, An Overview of Approval Processes: FDA Approval of Medical Devices, 1 JACC 277 (2016).

[36] Id.

little guarantee that the device will be effective and even less so that it will be better for patient outcomes and less costly.[37] The Federal Food, Drug & Cosmetic Act is vague about what a showing of effectiveness requires[38] and the federal regulations do not provide much additional guidance, stating:

> There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, *will provide clinically significant results*.[39]

But the term "clinically significant results" is not defined in the medical device statute or in the regulations. It is nonetheless generally understood that even a study without statistical significance can be enough to gain approval for a device.[40] Often applications are approved based on a single clinical study that might not even be a randomized trial.[41] There has been almost no focus in case law on what it means for a medical device to be "effective," which is consistent with the secondary importance that effectiveness plays relative to safety of medical devices.[42]

To put a sharper point on it, consider the difference in effectiveness approval standards for devices and drugs. For a drug to be approved by the FDA, a manufacturer must submit at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness.[43]

There might be good reason for not requiring the same level of evidence for medical devices – in that it is more difficult and costly to run trials of sufficient size given heterogeneity of test subjects for at least some medical devices as compared to drugs.[44] And yet, studies that are not blinded and nonrandomized often provide poor evidence.[45] Thus, the regulatory framework does little to prevent ineffective devices from hitting the market.

[37] See Neel U. Sukhatme & M. Gregg Bloche, Health Care Costs and the Arc of Innovation, 104 Minn. L. Rev. 955, 982 (2019).

[38] 21 U.S.C. § 360(c)(a)(2)(A–C).

[39] 21 C.F.R. § 860.7(e)(1) (emphasis added).

[40] Jonathan J. Darrow, Pharmaceutical Efficacy: The Illusory Legal Standard, 70 Wash. & Lee L. Rev. 2073, 2073–4 (2013).

[41] Sanket S. Dhruva et al., Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices, 302 JAMA 2679 (2009); Sarah Y. Zheng et al., Characteristics of Clinical Studies Used for US Food and Drug Administration Approval of High-Risk Medical Device Supplements, 318 JAMA 619 (Aug. 15, 2017).

[42] Stephanie P. Fekete, Litigating Medical Device Premarket Classification Decisions for Small Businesses: Have the Courts Given the FDA Too Much Deference? The Case for Taking the Focus Off of Efficacy, 65 Cath. U. L. Rev. 605, 630 (2016).

[43] 21 C.F.R. § 314.126.

[44] Marianne Razavi et al., U.S. Food and Drug Administration Approvals of Drugs and Devices Based on Nonrandomized Clinical Trials: A Systematic Review and Meta-analysis, 2 JAMA Network Open 11 (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2749563.

[45] See Deepak L. Bhatt et al., A Controlled Trial of Renal Denervation for Resistant Hypertension, 370 N. Engl. J. Med. 1393 (2014).

13.2.3 *Limited Role for Products Liability and Tort Law*

Another check that should deter companies from selling – and doctors from using – ineffective medical devices is products liability and tort law. A patient who was harmed by an ineffective device should be able to sue the manufacturer who sold it or the doctor who used it.

But the US Supreme Court in *Riegel v. Medtronic, Inc.*,[46] held that federal law preempts state law products liability claims for devices that were approved through the FDA's premarket approval process. For such devices, the FDA has in theory adjudged effectiveness. Despite the very limited nature of the review in practice, individuals harmed by such ineffective devices cannot sue manufacturers under products liability doctrine.

Claims are preserved for devices cleared through the 510(k) pathway for which there is no effectiveness screen.[47] However, this can be of little help if the patient does not learn of device ineffectiveness and its contribution to poor health outcomes, as is often the case. For this reason, cases that do get brought tend to be based on safety issues rather than effectiveness concerns.

Another potential check on ineffective devices is the right to sue the medical provider who used an ineffective medical device to the detriment of the patient. These types of cases could, in theory, motivate doctors not to use ineffective devices – or to rely on evidence of effectiveness more consistently in making treatment choices. In practice though, there are a number of hurdles. The first is that just mentioned – that patients often will not discover that the device was ineffective. Second, a doctor using a device approved (or cleared) by the FDA for the purpose approved by the FDA will generally not be liable under the custom and practice-based malpractice standards.[48] If a doctor can prove that he or she followed the same course as a reasonable provider would under the same circumstances, the doctor will generally prevail. A doctor could be liable for failure to warn a patient about potential dangers of a device, but if this information is not easily discoverable by the doctor (for instance if randomized controlled trials have not been done that have shown the device to be ineffective), there will be no liability.

As a practical matter then, products liability and tort law are underpowered to deter the use of ineffective medical devices.

13.3 THE HARM CAUSED BY INEFFECTIVE MEDICAL DEVICES

The harm that flows from unsafe devices is clear. But ineffective medical devices also cause harm – in worse health outcomes and the waste of valuable financial

[46] Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).
[47] See Medtronic, Inc. v. Mirowski Family Ventures, LLC, 571 U.S. 191 (2014).
[48] Mark Herrmann & Pearson Bownas, Keeping the Label Out of the Case, 103 Nw. U. L. Rev. Colloquy 477, 480 (2009).

resources. Also, more subtly but still importantly, ineffective devices provide a false sense that problems have been solved, quelling innovation in necessary areas, and engendering mistrust in the health care system.

13.3.1 *Worse Health Outcomes: The Hazy Line Between Safety and Effectiveness*

Perhaps the most famous example of an ineffective medical device concerns stents. For over a decade, in stroke patients, many physicians looked for the narrowing of the smaller vessels in the brain. If they were found, physicians placed stents – small metal mesh tubes – to prop open the vessel for the purpose of reducing future risk of stroke.[49] In 2011, a robust randomized controlled trial was conducted – the first of its kind to test the effectiveness of the stenting procedure, although it had already been approved by the FDA and had been in use for a decade. The study found that stents were not effective in preventing a stroke, and in fact, actually led to worse health outcomes.[50]

This example shows how the line between safety and effectiveness can be a blurry one. Often times, when a choice is made to use a device that is ultimately ineffective, it is to the exclusion of a different device (or medication) that works better. Not all medical reversals will result in worsened health outcomes. But there is a heightened risk.

Relatedly, ineffective medical devices can lead to patient harm by giving a false sense of security. The use of hip protectors may (subconsciously) have led nursing home personnel to do less to prevent falls. And because it does not work to lessen fractures, the result might be an increase in hip fractures. An anesthesiologist who relied on the BIP monitor to prevent anesthesia awareness may have been lulled into not as diligently checking other signals of awareness, resulting in increased patient trauma.

While often times the harm from ineffective medical devices is not as obvious as from devices that are deemed unsafe, ineffective medical devices still make patients worse off.

13.3.2 *Economic Harms*

The other obvious harm that flows from the use of ineffective devices is economic. The US health care system is more expensive than that of all other industrialized nations.[51]

[49] See Marc Chimowitz et al., Stenting Versus Aggressive Medical Therapy for Intracranial Arterial Stenosis, 365 N. Engl. J Med. 993 (2011). A similar approach was used in coronary patients.

[50] Id.; Vinayak K. Prasad & Adam S. Cifu, Ending Medical Reversal: Improving Outcomes, Savings Lives (2015).

[51] See, e.g., Karen Davis et al., Mirror, Mirror on the Wall, 2014 Update: How the Performance of the U.S. Health Care System Compares Internationally, The Commonwealth Fund (June 16, 2014),www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2014_jun_1755_davis_mirror_mirror_2014.pdf.

By some estimates, a third of all US health care spending is unnecessary.[52] That includes spending on ineffective medical devices.

While medical devices currently only account for about 6 percent of health care spending in the United States, the market is growing rapidly.[53] In 2018, the US market was valued at $169 billion,[54] and it is on a strong growth trajectory with revenues expected to double in the next decade.[55]

Additionally, the cost of an ineffective medical device often goes beyond just the cost of the actual device. We pay doctors to place the devices. Sometimes additional scans and diagnostics are ordered because of the medical device.[56] Surgeries may be required to remove ineffective implanted devices.

13.3.3 *Other Harms*

There are other less obvious harms that flow from the use of ineffective medical devices. For one, the appearance that a device exists to solve a problem – when in reality it does not – stifles innovation in that domain. The use of ineffective medical devices also harms public trust in the medical system and specifically in medical providers.

13.4 INCENTIVIZING EFFECTIVENESS

In the current system, ineffective medical devices (and comparatively ineffective ones) are too frequently approved by the FDA and used on patients. Practices concerning these devices are often difficult to stop once they become a part of the standard of care and they can cause both significant patient harm and unnecessary expense. But in order to fix the problem, ineffective medical devices have to be identified, and if they are adopted before identification, there must be a mechanism for discontinuing them. These are not easy problems to solve.

Many scholars promote stricter regulatory standards for ex ante proof of effectiveness.[57] While this would be a logical solution – requiring manufacturers to prove effectiveness before any patients are harmed and any funds are unnecessarily spent – making this change in practice is difficult. There is a strong movement to

[52] See Sarah Kliff, We Spend $750 Billion on Unnecessary Health Care. Two Charts Explain Why, Wash. Post (Sept. 7, 2012), www.washingtonpost.com/news/wonk/wp/2012/09/07/we-spend-750-billion-on-unnecessary-health-care-two-charts-explain-why.

[53] Martin Wenzl & Elias Mossialos, Prices for Cardiac Implant Devices May Be Up to Six Times Higher in the Us Than in Some European Countries, 37 Health Affairs 1570 (2018).

[54] Medical Devices Market Size, Share, and Industry Analysis By Type, Fortune Business Insights (Apr. 2019), www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085.

[55] Id.

[56] This was the case with intracranial stents where MRIs were frequently ordered just to search for narrowed arteries in need of stents. Prasad, supra note 17 at 90.

[57] See, e.g., Dhruva, supra note 41.

reform the 510(k) process, which might address those devices that are cleared without any effectiveness review at all. But as to the Class III premarket authorization process, the FDA is under pressure to get devices to market quicker and at a lower cost, which is at odds with tightening effectiveness standards.

One way to address the cost concerns would be for the government to fund this research. But that does not do anything to lessen the overall cost of the endeavor, nor does it address the time-to-market concerns.

The other commonly proposed solution is to improve the postmarket surveillance process – which is already underway with the 21st Century Cures Act.[58] There are initiatives like the National Evaluation System for health Technology (NEST) – a public-private partnership intended to conduct active surveillance on postmarket medical devices.[59] And the Patient-Centered Outcomes Research Institute (PCORI) already conducts postmarket comparative effectiveness research on drugs and devices.[60]

The concept is laudable. But as currently conceived, the postmarket surveillance process largely depends on voluntary reporting. The FDA does not have the resources to police and ensure compliance.[61] The postmarket surveillance process is also more likely to identify safety concerns than effectiveness concerns. While the FDA can also order postmarket clinical studies, that is generally only in response to adverse events reports. The process could be improved with a registry that requires reporting of all device-related patient outcomes. The registry would have to be actively monitored and analysed to produce useful information.[62]

PCORI's medical device research intended to aid doctor and patient decision making is also a step in the right direction. But it lacks a mechanism to incentivize using the results of the work. For instance, the law currently forbids government payors from adjusting reimbursement on the basis of PCORI data.[63]

It may be possible to build on these ideas, but the role that both providers and payors play in constraining the use of ineffective devices also deserves more focus.

[58] See 21st Century Cures Act, Pub. L. No. 114–255, § 3058(b)(5)(C), 130 Stat. 1033, 1129 (2016).

[59] US Food & Drug Administration, Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health, www.fda.gov/media/112497/download.

[60] Dave A. Chokshi, A Course in Reversal, 387 The Lancet 1266 (2016), www.healthaffairs.org/do/10.1377/hblog20150403.046100/full/; Lise Rochaix, Incorporating Cost-Effectiveness Analysis Into Comparative-Effectiveness Research: The French Experience, Health Aff. Blog (Apr. 3, 2015), www.healthaffairs.org/do/10.1377/hblog20150403.046100/full/. There may also be an expanded role for independent technology assessment. See Mitchell D. Feldman et al., Who Is Responsible for Evaluating the Safety and Effectiveness of Medical Devices? The Role of Independent Technology Assessment, 23 J. Gen. Internal Med. 57 (2008).

[61] Megan C. Andersen, 21st Century Cures Act: The Problem with Preemption in Light of Deregulation, 52 U. Mich. J. L. Reform 801, 817–18 (2019); Corinna Sorenson & Michael Drummond, Improving Medical Device Regulation: The United States and Europe in Perspective, 92 The Milbank Quarterly 114 (2014).

[62] Opinion: 80,000 Deaths. 2 Million Injuries. It's Time for a Reckoning on Medical Devices, N.Y. Times (May 4, 2019), www.nytimes.com/2019/05/04/opinion/sunday/medical-devices.html.

[63] See Affordable Care Act, Pub. L. No. 111–148, § 6301(c), 124 Stat. 119 (2010).

While providers may not often be held liable when devices are ineffective, they would still benefit from better technology that makes their jobs easier and results in better outcomes for patients. In recognition of this, there are initiatives to involve professional societies in the identification of ineffective devices.[64] For instance, the Choosing Wisely campaign tasked medical societies with preparing lists of ineffective interventions, including medical devices.[65] But Choosing Wisely has to have data on which to base its recommendations. It can be helpful in uprooting ineffective devices when new studies suggest lack of efficacy (or when PCORI data does). But providers are unlikely to run or fund studies of devices themselves. Nonetheless, working to change professional norms can be impactful. More broadly, medical education has started to focus decision making more squarely on evidence and data.[66] If providers can learn to rely less on the imprimatur of FDA approval or clearance and more on reliable studies of devices, it can make a big impact.

Perhaps the most promise, however, lies in an expanded role for private payors – and possibly even for government payors. Payors have the motivation to quell the use of ineffective devices.[67] Profit-motivated insurers, but even government payors, benefit from higher-quality, less-expensive care. Payors could make a huge impact by tying reimbursement decisions to data of effectiveness, as is the practice in most European countries.[68]

Admittedly, there are many reasons we might be leery of US payors playing this role. Insurers may take an overly aggressive stance in denying coverage, motivated more by profit maximization than by the betterment of patient health and the banishment of truly ineffective devices. Also, medical device efficacy may be heterogeneous. Even if a device is not effective for certain patients, it may nonetheless be for others. This can be hard to discern from studies, particularly if the test population is not diverse. Payors might also not have as much leverage as they do in other reimbursement decisions in a world of limited alternatives.

But the biggest impediment to tying reimbursement to effectiveness data is the lack of the data on which these decisions might rely. Payors are already engaging

[64] Medical record data is also an under-utilized source of information on medical devices. Alison Callahan et al., Medical Device Surveillance with Electronic Health Records, 2 Npj Digital Med. 1 (2019).

[65] Choosing Wisely Campaign, http://www.choosingwisely.org/; Wendy Netter Epstein, Nudging Patient Decision-Making, 92 Wash. L. Rev. 1255 (2017).

[66] See Jane P. Gagliardi et al., Innovation in Evidence-Based Medicine Education and Assessment: An Interactive Class for Third- and Fourth-Year Medical Students, 100 J. Med. Library Ass'n 306 (2012).

[67] Rebecca S. Eisenberg & W. Nicholson Price II, Promoting Healthcare Innovation on the Demand Side, 4 J. L. & Bioscience 3, 14–23 (2017).

[68] Cornelia Henschke & Rita F. Redberg, Medical Device Price Differentials in the U.S. and Europe – Rethinking Price Regulation?, Health Aff. Blog (Dec. 7, 2018), www.healthaffairs.org/do/10.1377/hblog20181206.716970/full/ (discussing how both efficacy and cost-effectiveness data informs reimbursement decisions in many European countries). In the United States, Government payors are constrained by law in how they may make reimbursement decisions. See Rachel E. Sachs, Delinking Reimbursement, 102 Minn. L. Rev. 2307, 2315 (2018).

private technology assessment organizations to do effectiveness analyses, but those assessments are limited by the lack of published data on which to conduct the analyses. So perhaps the better question is what can payors do to incentivize the creation of the necessary data?

Payors may be able to better mine and use their own data to assess effectiveness. Or they could use their bargaining power to incentivize the study of device effectiveness. Payors negotiate with manufacturers over the price the payor is willing to pay for a device. While refusing reimbursement entirely may be impossible, payors can condition reimbursement on manufacturer agreement to fund or participate in a study of device effectiveness. The Government already does this to a limited degree. The Centers for Medicare and Medicare Services (CMS) may conditionally approve reimbursement for a device while requiring that additional evidence be collected about device effectiveness through a clinical trial or device registry.[69]

Payors can also play a more active role in steering providers away from devices that may be ineffective based on the results of those studies.[70] In general, payors have bargaining power that could be better employed to promote the study, not just of device safety, but also of device effectiveness.

[69] See James D. Chambers et al., Private Payers Disagree with Medicare Over Medical Device Coverage About Half the Time, 34 Health Affairs (Aug. 2015).

[70] See Wendy Netter Epstein, The Health Insurer Nudge, 91 S. Cal. L. Rev. 593 (2018).