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## Medical Devices: Worrying Parallels to Our Nation's Prescription Drug Concerns?

You are seated on the padded examination table at your doctor's office as she uses the stethoscope to listen to your heart. She can hear the unmistakable tick of the pacemaker implanted in your heart to control abnormal heart rhythms. Prior to her examination, the nurse used an inflatable cuff and stethoscope to measure your blood pressure and a thermometer to take your temperature. These are all examples of medical devices we come in contact with during our interactions with the healthcare system.

For the last few years, pharmaceuticals have taken center stage in the debate around rising healthcare costs, but medical devices are an industry with many parallels to

pharmaceuticals. Like drugs, devices are regulated by the U.S. Food and Drug Administration (FDA); tremendous innovation has helped patients lead longer, healthier lives but inadequate oversight and hidden pricing of devices may be contributing to cost growth and safety concerns.

This issue brief examines the evidence around medical device spending and safety oversight.

### Should Consumers Be Concerned?

In many ways, medical devices have revolutionized the care we receive, but the way these products are regulated and marketed may be contributing to healthcare spending growth and exacerbating patient safety concerns.

### Spending on Medical Devices

Overall medical device spending is a relatively small portion of total health spending, but this industry segment features high rates of growth and high profit margins. Studies indicate that spending on medical devices accounts for about 4 to 6 percent of total healthcare spending in the U.S.<sup>1</sup> (Inconsistencies in definitions of the medical device market contributes to wide variation in estimates of the size of the device market and rates of growth.) One study found that the device market grew by approximately 4 to 5 percent from 2009 to 2016<sup>2</sup>—growing at roughly at the same rate as overall national health expenditures.<sup>3</sup> Of greater concern, large medical device companies also tend to have 20 to 30 percent profit margins.<sup>4</sup> Moreover, the Medicare Payment Advisory Commission (MedPAC) estimates that spending on devices may be growing at twice the annual rate of drug expenditures.<sup>5</sup>

### SUMMARY

*The medical device industry exhibits many concerning parallels to the pharmaceutical industry. Like drugs, devices are regulated by the U.S. Food and Drug Administration (FDA); tremendous innovation has helped patients lead longer, healthier lives but inadequate oversight and hidden pricing of devices may be contributing to cost growth and safety concerns. Overall medical device spending is a relatively small portion of total health spending, but this industry segment features high rates of growth and high profit margins. Moreover, scant device oversight may be resulting in medical harm. A majority of devices on the market today did not undergo clinical trials.*

## What are Medical Devices?

The FDA defines a medical device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes”<sup>6</sup>

The market dynamics for pricing medical devices can vary greatly depending on the device. Markets for conventional devices such as surgical gloves and other routine surgical supplies are fairly competitive. These products are viewed as interchangeable commodities. Companies compete heavily on price and often need high sales volumes to be profitable.

In contrast, markets for advanced products like implantable medical devices are shrouded in mystery, much like their pharmaceutical counterparts. Markets for advanced devices are harder to enter, and are less competitive, which allows device companies to charge higher prices and earn substantial profits.<sup>7</sup> An important sub-category here are Implantable Medical Devices (IMD) due to enhanced safety concerns. These are devices that are inserted into the human body to replace a missing body part, support a damaged body part, or modify an important body function.<sup>8</sup> Examples

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of implantable devices include orthopedic rods, pins, and screws used to repair fractured bones; artificial hip joints used to replace hip bones worn by arthritis; and cardiac pacemakers used to restore an irregular heart rhythm.

Anecdotally, the device industry has a reputation for generating high profits with high prices.<sup>9</sup> Similar to pharmaceuticals, the U.S. spends more on medical devices than Europe. One study found that cardiovascular devices like pacemakers and stents were five times more expensive in the U.S. compared to Germany.<sup>10,11</sup>

Hard data on prices for advanced medical devices is hard to come by. For one, a number of device companies require hospitals to agree to “gag clauses” that prevent them from comparing the prices of medical devices with other healthcare institutions, further contributing to a lack of pricing transparency.<sup>12</sup> As a result, very little data is available on the average price paid by hospitals for implantable devices.

One study revealed that the list price for a total hip implant increased 300 percent from 1998 to 2011, though it is unclear why.<sup>13</sup> Manufacturers cite technological improvements as the main reason for rising prices, though nearly all hip and knee implants are made by five companies. Critics have described these companies as a cartel, working together to fix sky-high prices that rise more than 5 percent a year.<sup>14</sup> Moreover, devices are often reimbursed through a packaged payment. Everything from bandages and IV bags to software and surgical equipment deployed during a hospital visit can be classified as a medical device and these are often bundled into the overall hospital payment for the stay. The exception: durable medical equipment, or equipment that is primarily used for medical purposes and can withstand repeated use, is typically billed directly.

As a result of this secrecy, there is believed to be tremendous price variation in what is paid for advance devices. A survey conducted in 2012 found that prices paid varied greatly between hospitals for the same device. For example, prices for implantable defibrillators varied by almost \$9,000.<sup>15</sup>

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Evidence has shown that, as with hospital-administered drugs, hospitals pass along large markups to insurers—contributing to the price variation paid by consumers and insurers. One study found that private insurers paid nearly double what hospitals paid to purchase knee and hip implants from manufacturers.<sup>16</sup> Researchers revealed that the cumulative differences between average selling price and insurer payments for total knee arthroplasty was approximately \$225.3 million.<sup>17</sup> Another study found that hospitals charged up to 20 times their own costs for procedures like CT scans.<sup>18</sup> Hospitals work with group purchasing organizations (GPOs) for discounts, but may not be passing these savings onto patients or their insurers. Markups can depend on how much market power a hospital system wields. Researchers found hospitals that dominate their regional markets were more likely to set high markups. System-affiliated hospitals also had higher charge-to-cost ratios (a measure of what a hospital charged vs their actual expense) than government-run and nonprofit hospitals.<sup>19</sup>

Other studies demonstrated that hospital markups may vary by type of payer. Patients paying out of pocket for cosmetic surgery often pay a lower price for breast implants than what hospitals charge insurers for reconstructive surgery. One study shows that Medicare is also able to negotiate lower prices for implants, compared to private payers.<sup>20</sup> An analysis found that the amount hospitals pay for a given device usually accounts for 30 to 80 percent of the payment they receive from Medicare.

In 2008, Medicare paid about \$33,000 for the surgical procedure to implant a cardiac defibrillator, even though hospitals paid about 75 percent of that for the device itself.<sup>21</sup>

Other factors that may be driving up prices include the fact that physicians are generally not financially responsible for the cost of the device and may have financial connections to the device industry. High-volume surgeons may receive multiple payments from manufacturers for a variety of activities (e.g., research, consulting, and promotional speaking engagements). Physician ownership of entities—such as physician-owned specialty hospitals, ambulatory surgery centers or MRI facility—can also lead to conflicts of interest. Some studies have shown that physicians tend to use more of a manufacturer's products and are associated with higher healthcare spending when they have a financial relationship with manufacturers.<sup>22</sup>

Surgeon preferences can drive demand for devices. Device sales reps are often present during surgeries that involve medical devices. Though some physicians welcome their expertise, this practice also helps device manufacturers build relationships with providers, sometimes at the expense of consumers. In certain situations, device reps have encouraged surgeons to use more elaborate devices that are more expensive for the hospital.<sup>23</sup> This upselling can raise expenditures on medical devices, not only for the hospital but also the patient.

Also at play: Institutions with expensive machinery seek to increase its use in order to recoup acquisition costs. If equipment is used less than expected, institutions can experience a negative rate of return. In order to avoid that, they may use these devices more than necessary.<sup>24</sup>

### **Concerns about Effectiveness and Safety**

Many have expressed alarm that expensive investments in technology are being made ahead of the evidence. For example, one study found that outcomes from intensity-modulated radiation therapy (IMRT) and robotic surgery for men with low-risk prostate cancer was no different from compared to those who simply choose to do nothing, sometimes known as watchful waiting.<sup>25</sup>

**Table 1**  
**FDA's Medical Device Classification**

Risk Class	Examples	Safety/Effectiveness Controls	Regulatory Pathway
I (Low)	forceps, enema kits, tongue depressors, elastic bandages and surgical clamps	General Controls	Self-registration or 510(k)
II (Medium)	intravenous tubing, urinary catheters and x-ray systems	General Controls or Special Controls	510(k) Premarket approval
III (High)	pacemakers and replaceable heart valves	General Controls, Special Controls and Pre-market Authorization	Premarket approval Clinical trials

Source: Ankit Geete, Regulation of Medical Devices in U.S. <https://www.slideshare.net/AnkitGeete/regulation-of-medical-devices-in-us> (accessed Feb. 13, 2019).

Moreover, scant device oversight may be resulting in medical harm. A majority of devices on the market today did not undergo clinical trials.

The FDA classifies medical devices based on the risk they pose to patients, with Class I being the least risky and Class III being the riskiest. Each class of devices is subject to different data submission requirements (see Table 1). A majority of devices are approved through FDA's 510(k) pathway, whereby their level of risk is assessed based on comparisons to devices already on the market. In 2017, 82 percent of the devices approved by the agency used this pathway.<sup>26</sup>

The FDA places the lowest evidentiary burden on Class I devices like forceps, enema kits, elastic bandages and surgical clamps. Manufacturers looking to market a Class I device need not submit a premarket notification application to the FDA and simply have to comply with General Controls, or basic provisions that allow the FDA to monitor and regulate certain classes of devices. However, they must list their product with the agency.<sup>27</sup> Under this protocol, these devices are often not tested on people until they hit the market.

In 2018, the FDA recalled a Class I cranial depth gauge after it displayed cranial depth improperly, which led to the biopsy of healthy tissue.<sup>28</sup>

Examples of Class II devices, which make up about 40 percent of devices on the market,<sup>29</sup> include: intravenous tubing, urinary catheters and x-ray systems. Class II devices are subject to Special Controls, which include: labeling requirements, post-market surveillance, performance standards and guidance documents. If a “substantially equivalent” device has already been marketed, Class II device manufacturers can gain approval through the 510(k) pathway.<sup>30</sup> However, a report from the National Academy of Medicine noted that demonstrating that a device is “substantially equivalent” does not guarantee its safety or effectiveness.<sup>31</sup>

Perhaps the most famous example of a Class II device that called safety standards into question is surgical mesh. Citing reports of malfunctions that lead to death, the FDA was forced to recall surgical mesh used for transvaginal organ prolapse repair. Many companies stopped marketing the surgical mesh after the agency ordered manufacturers to conduct post-market surveillance studies. As a result, the agency reclassified it as a Class III device.<sup>32</sup> Of the 3 to 4 million women, worldwide, who were implanted with mesh for urinary incontinence and prolapse, approximately 200,000 had complications. More than 100,000 lawsuits have been filed against surgical mesh manufacturers.<sup>33</sup>

Another Class II device that created waves was a specialty endoscope, sometimes called a duodenoscope, after it spread drug-resistant bacteria. These reusable duodenoscopes are inserted through a patient's throat to look at their gastrointestinal tract using a light. The FDA ordered device manufacturers to conduct post-market surveillance studies and found that 3 percent of samples collected tested positive for "high concern" bacteria. One manufacturer, Olympus, agreed to pay \$85 million for failing to report adverse events to regulators. At least 35 patients have died since 2013 due to infections they acquired from Olympus's duodenoscopes.<sup>34,35</sup>

Class III devices, which make up about 10 percent of devices on the market, are often long-term implantable devices or ones needed to sustain life, such as pacemakers and replaceable heart valves.<sup>36</sup> Class III is subject to the highest evidentiary burden.<sup>37</sup> Class III devices require premarket approval (PMA) from the FDA, meaning that manufacturers must carry out randomized control trials or other studies to demonstrate safety and effectiveness.

Though devices of a new type are generally automatically classified as Class III, as of 1997, the FDA can review *de novo* requests for new devices that pose low-to-moderate risk based on standards for Class I and Class II devices. Device manufacturers have to provide evidence that risks can be mitigated through General or Special Controls alone.<sup>38</sup> In late 2018, the FDA approved a CMV Assay Test System, which functions as a diagnostic test to detect cytomegalovirus (CMV) in newborns, through this pathway.<sup>39</sup> The agency also permitted marketing of another device, the Brainsway, which uses transcranial magnetic stimulation (TMS) for the treatment of obsessive compulsive disorder. TMS uses magnetic fields to stimulate nerve cells in the brain. Of course, because these devices are classified as Class I or II devices, which are not subject to the same stringent controls as Class III devices, and do not have a predicate product on the market, safety issues may arise.<sup>40</sup>

Device manufacturers may also use the FDA's supplement pathway when they make changes to existing devices. The supplement pathway is used when amendments or supplements are submitted to the FDA for changes to the original Premarket Approval (PMA) submission. Depending on the type of changes a manufacturer wants to make, the modified device faces differing evidentiary burdens (see Table 2). Clinical trials are not required to make minor updates, even for high-risk devices. As described by the FDA, some changes, like ones that alter performance, design and principles of operation, require a PMA supplement. However, changes that do not affect the device's safety or effectiveness have no PMA requirements.<sup>41</sup>

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Though supplemental approvals allow patients to benefit from incremental innovation, safety and effectiveness should not be sacrificed, especially for high-risk devices. A Harvard study revealed that 99 percent of cardiac devices were approved using the supplement pathway between 1979 and 2012.<sup>42</sup> Many of these devices are life-sustaining implantable devices like pacemakers, implantable cardioverter-defibrillators, and resynchronization therapy devices. Nearly half of approved cardiac supplements were approved through the 30-day notice pathway, which merely requires preclinical data. Between 2010 and 2012, only 23 percent of cardiac devices approved through the 180-day regulatory pathway— that often have significant design and labeling changes— included clinical data on safety and effectiveness.<sup>43</sup>

This approach to oversight may mean that devices are not effective or they may lead to patient harm. A recent investigation conducted by International Consortium of Investigative Journalists found that 1.7 million medical device related injuries and 83,000 deaths were reported to the FDA during a 10-year period.<sup>44</sup>

**Table 2**  
**FDA Regulation Categories for Premarket Approval Supplements**

Type of Supplement	Type of Device Changes	Data Required	Reviewer	Year Category Formally Introduced
Panel-Track	Significant design change; new indication	Clinical; limited preclinical data in some cases	Panel of subject matter experts and FDA staff	1990
180-Day	Significant design change; labeling change	Preclinical; confirmatory clinical data in some cases	FDA staff	1986
Real-Time	pacemakers and replaceable heart valves	Preclinical only	FDA staff	1997
Special	Minor design change	No specific data requirements	FDA staff	1986
30-Day Notice	Manufacturing change	No specific data requirements	FDA staff	1997

Source: Rome, Benjamin N., Daniel B. Kramer, and Aaron S. Kesselheim, "FDA Approval of Cardiac Implantable Electronic Devices via Original and Supplement Premarket Approval Pathways, 1979-2012," *JAMA*, Vol. 311, No. 4 (January 2014).

Due to the lack of clinical studies, medical devices may be overused or used in the wrong population altogether. Providers themselves often do not know about the risks associated with a given device due to a lack of transparency.

## Addressing Medical Device Spending

### Price Transparency

Lack of price transparency significantly limits the ability of hospitals to be "prudent purchasers" of devices. As noted above, device manufacturers typically insist on a confidentiality agreement ("gag clause") in the purchasing contract with hospitals.

One strategy advocated by policymakers is increased price transparency in the market by restricting gag clauses and disclosing prices. The theory is that by gathering and spreading pricing information available for multiple vendors or versions of the same medical device, hospitals can engage their physicians in discussions about the cost and quality profiles of each manufacturer's product.<sup>45</sup>

Banning gag clauses or adopting mandatory price disclosure would require legislation at the state or federal

level, which has proven controversial and difficult to enact.<sup>46</sup> Recent progress banning pharmacy gag clauses may pave the way for such efforts.

One study points out that even if mandatory price disclosure allows hospitals to negotiate lower device prices, consumers and insurers may not benefit unless hospitals pass along their savings.<sup>47</sup>

### Volume Purchasing

Antitrust laws prevent hospitals from cooperating directly with one another to negotiate the prices they charge. However, hospitals are permitted to join forces through group purchasing organizations that are allowed to negotiate discounts and pass them on to participating hospitals. Realizing savings from volume discounts depends, in part, on the availability of information on benchmark or fair prices for devices.<sup>48</sup>

### Value-Based Purchasing Approaches

As payers in our healthcare system move away from fee-for-service towards value-based payments for care, medical device companies are lagging behind. Aside from

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the fact that devices are often bundled together with other hospital services, true value-based purchasing remains relatively rare (as is also the case with pharmaceuticals).<sup>49</sup>

Limited pilots provide insight as to how these arrangements might work. Hospitals participating in Centers for Medicaid and Medicare Service's (CMS) Bundled Payments for Care Improvement (BPCI) or Comprehensive Care for Joint Replacement (CJR) initiatives have started bundling payments for knee and hip replacements. Under these programs, hospitals receive a flat fee from Medicare to cover the cost of surgeries. One study found that Baptist Health System in San Antonio saw costs for joint implant devices fall by 29 percent after enrolling in a voluntary Medicare bundled-payment program due to surgeons working with the hospital to negotiate lower prices with device manufacturers.<sup>50</sup> Researchers theorized that savings realized by Baptist Health System may have outpaced other health systems due to their gainsharing program that allowed surgeons to share in hospital savings. Hospitals in 67 markets are now required to participate in Medicare's CJR program. Participating hospitals will receive a bonus if they surpass CMS's cost and quality targets.<sup>51</sup>

A few device manufacturers, Medtronic, GE Healthcare and Philips, have made some headway with tying payments to outcomes. Medtronic currently has signed more than 1,000 contracts with hospitals and clinics for their absorbable antibacterial envelopes (Tyrx). As per the risk-sharing agreement, Medtronic will reimburse hospitals for costs associated with failures to prevent infections in cardiac implants. They have also contracted with Aetna to tie payments to performance for their insulin pumps. In addition, GE has entered into six risk-based partnerships tying outcomes to payments for their products. A Partnership between Philips, a device manufacturer, and the Georgia Regents Medical Center

realized \$7 million in market savings in the first 18 months compared to "business as usual" procurement.<sup>52</sup> These efforts have not yet been evaluated in terms of outcomes or patient savings.

Though a few medical device companies have already entered into value-based purchasing agreements, the medical device trade group, AdvaMed, asserts that "safe harbors" needed to be added to the Anti-Kickback Statue before medical device companies can really participate in alternative payment models.

The Anti-Kickback statute was created to stop device manufacturers from offering kickbacks, bribes and rebates to providers in an attempt to boost sales. However, the HHS Office of the Inspector General (OIG) allows for exceptions, called "safe harbors," when agreements meet certain criteria.<sup>53</sup> To date, OIG has issued 28 safe harbors. Medical device manufacturers assert that these safe harbors aren't sufficient to allow most companies to enter into contracts that tie payment to outcomes. As a result, AdvaMed is proposing new safe harbors that would allow for price adjustments based on outcomes targets and for device manufacturers to provide remedies if those outcomes are not achieved.<sup>54</sup>

## Price Regulation

One reason devices are more expensive in the U.S. than in Europe is that European countries have centralized health authorities that negotiate with device manufacturers. These centralized entities can make decisions about reimbursement levels after assessing clinical data on safety and efficacy. Germany, for example, links reimbursement to patient outcomes. A device manufacturer must demonstrate a proven benefit before they are allowed to enter into price negotiations. When there isn't enough evidence to demonstrate benefit, temporary coverage is granted while post-market data is gathered.

A widely read 2013 *New York Times* story tells the story of a man without coverage who needed a hip replacement. In the U.S., he was quoted a price for just the joint implant at the "list price" of \$13,000, (excluding hospital, surgeon or rehab fees.)<sup>55</sup> In Belgium, the government-approved list price for the same hip implant was about \$4,000 and could be marked up by only \$180.

## Addressing Safety—Proposed Medical Device Regulatory Changes

After stories of patient safety concerns went viral, the FDA expressed an interest in modernizing medical device regulation. To date, the agency has emphasized increased post-market surveillance.

In November 2018, the FDA announced plans to “modernize the 510(k)” pathway. The agency’s approach abbreviated the approval process for certain low-risk devices, claiming that this will free up resources to assess higher-risk devices. Updates to streamline the process include: using newer devices as the comparator product for ones being assessed by the FDA, allowing manufacturers that develop well-understood device types to rely on objective safety and effectiveness criteria to demonstrate equivalence instead of relying on predicate devices, and establishing a new “Safety and Performance Based Pathway.”<sup>56</sup>

Many proposed changes focus on creating a system for enhanced post-market oversight for medical devices. Every five years, the medical device industry renegotiates a user fee agreement with the FDA. The most recent agreement, contained in the FDA Reauthorization Act of 2017, called for the creation of a summary reporting system for adverse events instead of requiring that these events be reported on an individual basis. However, deaths and serious injuries would still have to be reported to the agency on an individual basis.<sup>57</sup> Though this change makes it easier for device manufacturers to report adverse events, it may do little to enhance safety before a device enters the market.

Another proposed program to improve post-market safety, FDA’s National Evaluation System for Health Technology (NEST), is still under development. NEST will focus on developing real-world evidence strategies to allow for enhanced decision-making about medical devices. Though the program has been under development for nearly a decade, the agency’s Coordinating Center selected eight real world evidence test cases in 2018.<sup>58</sup>

One could argue that new requirements for clinical testing before a high-risk device is on the market would do more to preserve patient safety than improving post-

market surveillance and making changes to which devices can be used as comparator products through the 510(k) pathway. Some critics have written off the proposed changes as “window dressing,” citing that 35 percent of the agency’s budget for regulating devices comes from device manufacturers.<sup>59</sup>

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What about our neighbors across the pond? Though Europe has many of the same device patient safety issues as the U.S., their process is less centralized. Recently, the European Union passed a law to improve data transparency, which would require device manufacturers to share certain safety and effectiveness information with providers.<sup>60</sup>

## Conclusion

The evidence demonstrates that there are clear safety and cost issues associated with medical devices. In order to improve patient safety and reduce spending on devices, policy solutions must focus on improving pre-market regulation and enhancing transparency around device pricing, safety and effectiveness.

The FDA is already making necessary improvements to post-market surveillance procedures and adverse event reporting to reduce patient harm once a device is on the market, but more must be done to rectify the pre-market approval process.

Many of the safety issues created by the current state of medical device regulation can be mitigated by requiring pre-market approval and clinical studies for all implanted device, including ones seeking approval for significant design changes through the supplement pathway. Data on safety and effectiveness, especially for high-risk devices, should be made publicly available so that providers and patients can be well informed. Legislation could be similar to new safety transparency laws enacted in Europe.

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Transparency in pricing procedures and negotiations will also improve value for patients. In addition to new regulations focusing on safety and efficacy, the presence of medical device sales reps in the provider setting should be regulated to prevent upselling.

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