



# FDA's Regulatory Framework for 3D Printing Of Medical Devices at the Point of Care Needs More Clarity

Detailed guidance can help providers and industry deliver safe, effective health solutions for patients

## Overview

To plan for the surgical separation of conjoined twin girls in 2020, surgeons at the University of Michigan C.S. Mott Children's Hospital needed realistic, life-size models of their patients' shared organs. Personalized models for such rare procedures are not readily available from medical device manufacturers, so radiologists from the health system and bioengineers from the university worked together to make their own with 3D printing technology, a process known as 3D printing at the point of care (or 3DPOC). Their customized devices and planning paid off: The sisters' 11-hour surgery—the first of its kind at the hospital—was a success.<sup>1</sup>

The twins' case highlights only one of the many ways that 3DPOC can improve patient outcomes. The technology allows for the customization of medical products—such as anatomical models, surgical guides, and prosthetics—for individual patients' precise needs at the treatment site.

But 3DPOC medical products, like those made by traditional means, also carry risks for patients if the products are not appropriately designed, printed, and used. Although U.S. Food and Drug Administration regulatory requirements apply to all medical devices regardless of how they are manufactured, 3DPOC products—because they're created outside of traditional settings—don't fit neatly into the agency's standard risk-based oversight system, raising questions of how agency policy might need to adapt to capture this emerging technology's capabilities and risks.

FDA has drafted an initial framework that outlines a range of potential manufacturing scenarios that will determine how and when the agency will regulate 3DPOC devices and when it will exercise its enforcement discretion. To help inform that framework, The Pew Charitable Trusts commissioned a regulatory analysis and conducted interviews with 17 experts from the medical field and from product manufacturing, seeking their feedback and expertise. (See Appendix A for a list of interviewees and methodology.) Among the key concerns that emerged:

- FDA's draft framework does not yet provide enough details on how regulations will be applied to 3DPOC facilities and their activities.
  - Ambiguity exists on how FDA will define the risks of different 3DPOC products, including how risk classification might be affected by how or where a device is printed.
  - It remains unclear what regulations will apply to health care facilities, device companies, and other providers involved in 3DPOC or what their legal liability will be, especially for health care facilities that may choose to print high-risk products or perform a range of manufacturing activities that may be regulated differently from each other.
  - The line between FDA-regulated device manufacturing and state-regulated medical practice is blurry.
- FDA may not have sufficient resources to effectively oversee devices that may be manufactured at hundreds of sites by entities, such as hospitals and other health care settings, that the agency does not typically regulate.
- Innovation is moving faster than government. This could pose risks to patients as increasing numbers of health care providers adopt 3D printing without clear federal guidance or oversight.

Interviews for this brief took place from February to April 2021, when FDA's proposed framework had divided 3DPOC manufacturing into five regulatory scenarios. In December 2021, the agency released a discussion paper that refined the number of potential scenarios down to three. The findings and recommendations in this brief, however, are still broadly relevant and can inform FDA's evolving regulatory approach to 3DPOC.

Based on the findings, Pew recommends that FDA should provide:

- **Clear guidance.** In its December 2021 discussion paper, the agency stated its intention to issue draft and final guidance documents based on feedback it receives. These guidance documents should concretely describe a regulatory framework for 3DPOC devices that is readily understandable by all who may be involved with 3DPOC, including personnel at health care facilities who may not be accustomed to the regulatory requirements imposed on traditional manufacturers. Guidance should clarify how the agency will define device risk and regulate those products accordingly. It should also set clear expectations for all 3DPOC designers, manufacturers, and users, particularly for health care facilities that print high-risk devices or fall under more than one scenario in the agency's framework.
- **Enforceable rules.** Since guidance documents are not enforceable, FDA also should develop regulations for 3DPOC manufacturing where necessary, especially for high-risk products. At a minimum, these regulations

should require all 3DPOC entities to register their facilities and tell the agency what types of devices they are manufacturing.

- **Timely and broadened oversight.** FDA should move quickly to issue official guidance and regulations, and enforce those regulations where necessary through premarket review, postmarket surveillance, and facility inspections. To bridge additional oversight gaps, the agency could consider partnering with professional medical societies and hospital accrediting organizations such as The Joint Commission, which can develop their own recommendations and certification standards for 3DPOC manufacturing and broaden the scope of oversight.

## Background

### Current FDA oversight of 3D-printed medical products

FDA defines 3D printing as “a process that creates a three-dimensional object by building successive layers of raw material” such as metals or ceramics. It is a type of additive manufacturing, though the agency uses the two terms interchangeably.<sup>2</sup> The technology has been used in medicine since the early 2000s to produce implants, surgical instruments, pharmaceuticals, and cells and tissues, among other products.<sup>3</sup> 3D printing allows for the creation of devices with complex internal geometries, such as spinal implants with a porous structure that can facilitate tissue growth and integration.<sup>4</sup> 3D-printed devices can also be manufactured as whole products that do not require the assembly of many components created separately.

In the U.S., FDA is tasked with ensuring the safety and effectiveness of health products such as drugs, biologics (products derived from sources such as cells or tissue), and medical devices, including medical products that are 3D-printed. The agency’s Center for Devices and Radiological Health (CDRH) regulates medical devices, including those that are 3D-printed, based on risk. It categorizes such products into one of three regulatory classes and applies increasing levels of oversight to products that pose greater risks to patients.<sup>5</sup> (See Appendix B.)

FDA does not regulate 3D printers themselves, but rather the manufacturing process and output of those printers if that output is a medical device. CDRH has commented on the regulation of 3D-printed medical products through public forums, formal guidance, and presentations, and has stated that its guidance on this topic is tentative and subject to change, given the evolving nature of the technology. (See Appendix B.)

Manufacturers are also increasing their research into the development of 3D-printed pharmaceuticals, which would typically fall under the jurisdiction of FDA’s Center for Drug Evaluation and Research (CDER). The agency approved its first 3D-printed pharmaceutical in 2015: an anti-epileptic drug designed for individuals who have trouble swallowing pills.<sup>6</sup> Although CDER has not provided formal guidance on the 3D printing of pharmaceutical products, the agency is expanding its research in this area and working with interested manufacturers through its Emerging Technology Program.<sup>7</sup>

Similarly, FDA’s Center for Biologics Evaluation and Research (CBER), which regulates biological products, has not published specific guidance on the use of bioprinting—the layer-by-layer positioning of biological materials—nor has it approved any 3D-printed biological products. The agency has, however, stated its intent to review regulatory issues associated with these types of products. CBER has also worked with interested manufacturers in this field.<sup>8</sup>

## Bioprinting

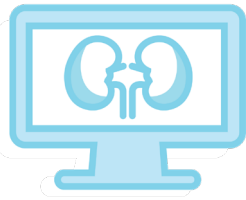


Bioprinting—which uses 3D-printing technology to create living tissue products such as bones or skin—is still in initial stages of research and development. That work may one day enable the creation of personalized organs and other body parts or help researchers test drugs and devices on products without the need for human or animal testing.<sup>9</sup> For example, researchers at Wake Forest Institute for Regenerative Medicine 3D-printed a microscopic model of the human body, including most of the vital organs. This model could then be used to research the effect of certain drugs before they are investigated in clinical trials.<sup>10</sup> Given the similar manufacturing process, future regulatory guidance for 3DPOC devices could have implications for bioprinting.

## FDA’s emerging approach to 3DPOC

3D printing is unique compared with other technologies as it allows for on-demand, decentralized manufacturing of medical products tailored to individual patients based on their imaging data.<sup>11</sup> (See Figure 1.) It also allows providers to develop prototypes of medical products.<sup>12</sup>

Figure 1

### Examples of 3D-Printed Products at the Point of Care

 <p><b>Anatomical models</b></p> <p>Clinicians and researchers at the Veterans Health Administration (VHA) use 3D printing in their medical centers across the U.S. to manufacture anatomical models to plan treatment and consult with patients.</p>	 <p><b>Prosthetics</b></p> <p>VHA clinicians and researchers also use 3D printing to manufacture orthotics and prosthetics customized to their individual patients’ needs.<sup>13</sup></p>	 <p><b>Implants</b></p> <p>The Hospital for Special Surgery (HSS) and LimaCorporate S.p.A. opened the ProMade Point of Care Center for Complex Orthopedic Solutions at HSS’ main campus in New York City. The center provides patient-specific 3D-printed products for joint replacement.<sup>14</sup></p>
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However, because the process occurs in somewhat novel settings (i.e., within health care facilities rather than large-scale manufacturing plants that generally produce high volumes of identical products), there are additional questions about how medical device regulations might be applied in these contexts. To clarify its approach to regulating 3DPOC devices, CDRH has begun developing a framework based on potential manufacturing

scenarios. The previous iteration of this framework—which was in place at the time of Pew’s interviews—included five scenarios (See Table 1), some of which were later combined in FDA’s December 2021 discussion paper. (See Table 2.)

Table 1<sup>15</sup>

## Earlier Version of FDA’s Framework Included 5 Manufacturing Scenarios for 3DPOC

Scenario	Description
A	Minimal-risk 3D printing by a health care professional
B	Device designed by manufacturer using validated process: turnkey system
C	Device designed by manufacturer using validated process: additional health care professional capability requirements
D	Manufacturer is co-located at the point of care
E	Health care facility becomes a manufacturer

Sources: U.S. Food and Drug Administration, Center for Devices and Radiological Health Additive Manufacturing Working Group; The American Society of Mechanical Engineers

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Table 2<sup>16</sup>

## Updated Version of FDA’s Framework Now Consists of 3 Scenarios for 3DPOC

Scenario	Description	Entity designing/ developing the device	Entity using the 3D printing system to produce devices	Entity responsible for complying with applicable regulatory requirements
1	Health care facility using a medical device production system (MDPS)	Traditional manufacturer	Health care facility	Traditional manufacturer
2	Traditional manufacturer co-located at or near the health care facility site	Traditional manufacturer	Traditional manufacturer, including any potential contract manufacturer	Traditional manufacturer, including any potential contract manufacturer
3	Health care facility assuming all traditional manufacturer responsibilities	Health care facility	Health care facility	Health care facility

Source: U.S. Food and Drug Administration

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There is not yet any draft or formal guidance, though the agency has had a series of webinars in collaboration with the American Society of Mechanical Engineers (ASME) to garner feedback on its previous five-scenario framework, in addition to the release of its discussion paper with an open docket for public comments.<sup>17</sup> As seen in Table 2, the paper presents three scenarios and poses key questions for stakeholder feedback on potential challenges and other factors that should be considered when developing future policy.

As the use of 3DPOC grows, medical organizations and other professional societies may choose to release their own recommendations, much as the Radiological Society of North America (RSNA) did in 2018 when it published guidelines for 3D-printed anatomical models.<sup>18</sup>

### Emerging Initiatives to Set Reimbursement Policies for 3DPOC Devices

Over the past decade, the use of 3D printing within hospitals has steadily expanded as the technology has continued to evolve alongside an emphasis on personalized medicine.<sup>19</sup> However, although some smaller-scale studies have shown real benefits of utilizing the technology—including decreased operating times, cost savings, and improved patient outcomes—its cost can be prohibitive for many health care facilities.<sup>20</sup> The use of the technology in patient care is not yet reimbursed by most insurance carriers, including the Centers for Medicare & Medicaid Services, meaning that a hospital or health care facility that wants to manufacture its own 3D-printed products is financially responsible for all aspects of a 3D-printing program, including purchasing and maintaining the printer, purchasing the software, and potentially hiring additional specialized employees.<sup>21</sup> During Pew’s interviews, experts described this up-front and ongoing financial commitment as a barrier to more widespread adoption.

To help address this concern, professional medical societies are undertaking several efforts to implement a reimbursement process for these products by collecting case data that demonstrates how the use of 3D-printed products in patient care can lead to improved outcomes. For example, through a proposal spearheaded by the American College of Radiology (ACR), the American Medical Association (AMA) implemented Category III Current Procedural Terminology (CPT) codes for 3D-printed anatomical models and guides in July 2019.<sup>22</sup> Health care professionals use CPT codes, which are developed and maintained by AMA, to specify medical procedures and obtain insurance reimbursements.<sup>23</sup> Although insurance companies are not required to provide reimbursements for services using Category III codes, gathering this data on the use of the technology and its effectiveness in patient care could eventually lead to the creation of permanent Category I codes, which are generally reimbursed by most insurance carriers.<sup>24</sup> In addition, ACR partnered with RSNA to form the RSNA-ACR 3D Printing Registry, a clinical data registry that collects case information from health care providers using point-of-care image-based anatomical models and surgical guides in order to provide evidence supporting the use of this technology in improving patient outcomes.<sup>25</sup>

## Analysis and Recommendations

### FDA’s scenario-based framework for 3DPOC devices needs more detail

FDA’s CDRH is developing a conceptual framework with different scenarios for regulating 3DPOC devices and their designers, manufacturers, and users. Through interviews and a commissioned regulatory analysis, however, Pew found many areas of ambiguity that FDA will need to address as this technology is implemented more broadly, including three overarching concerns:

- **Unclear alignment with existing risk-based framework.** The agency’s proposed framework outlines the potential manufacturing scenarios in which devices might be printed, but it does not provide insight into how these products will be evaluated in terms of risk, and thus what regulatory requirements might apply. Rather, it focuses more on identifying which parties will be responsible for ensuring compliance with regulatory requirements when point-of-care facilities may be using equipment and production systems developed by external entities.
- **Unclear requirements for different actors.** Despite the release of its discussion paper, the agency does not fully define what regulations will apply to health care facilities, device companies, and others involved in 3D printing a device at the point of care (POC), what their legal liability will be, or what regulatory obligations would apply to a health care facility that performs activities that fall under more than one scenario. For example, a health care facility could print minimal-risk (now known as “very low risk”) devices under Scenario 3 without much FDA oversight, use an FDA-reviewed system for some devices under Scenario 1 with potentially some oversight, and print higher-risk devices under Scenario 3 with a great deal of oversight. In this example, the health care facility is printing devices under multiple scenarios, and it is unclear which regulatory obligations it would have to meet, or how it should ensure appropriate compliance.
- **Unclear distinction between medical product and medical practice.** While FDA regulates medical products, state boards of medicine typically oversee the practice of medicine. However, some devices, such as anatomical guides used to plan surgery, fall into a gray area. Because 3DPOC often involves customization that reflects the medical provider’s relationship to an individual patient, some see its use more as a medical service than a device. As a result, experts had mixed opinions on whether FDA could regulate it and whether Congress should grant FDA additional authority to do so.

These concerns, and the ways they relate to each scenario, are outlined in greater detail below. As mentioned previously, interviews were conducted in the context of five scenarios.

Previously referred to as:	Now known as:
Scenario A: Minimal-risk 3D printing by a health care professional	Very low-risk devices under Scenario 3: Health care facility assuming all traditional manufacturer responsibilities

In the original framework, Scenario A was the only category that defined products based on their risk. Because it represented the lowest-risk devices, it would have likely required the least regulatory oversight from the agency, though FDA did expect health care facilities to utilize monitoring and risk mitigation strategies as well as any existing standards or certifications to ensure safety and effectiveness of their products.<sup>26</sup>

FDA’s discussion paper eliminates Scenario A as its own category. Instead, very low-risk devices are listed as an option under Scenario 3, in which the health care facility assumes all traditional manufacturer responsibilities. However, similar to the initial framework’s Scenario A, the agency states in its discussion paper that it is considering which level of regulatory flexibility might be appropriate for these types of devices when they are 3D-printed at the point of care.<sup>27</sup>

Experts outlined several concerns and questions regarding Scenario A:

**Defining “minimal risk” versus “very low risk” versus “lowest risk.”** FDA did not clearly define “minimal risk” or its connection to the current regulatory framework, which uses the term “lowest risk” when describing Class I products. Though the term was changed to “very low risk” in the discussion paper, it is still not clearly defined.



Although many experts agreed that FDA likely created this type of category for products that would require little to no oversight from the agency, there was no clear consensus on what those products should be, or on the type of oversight that should be established, if any.

**Potential loopholes.** Most of the experts Pew interviewed were concerned that, if “minimal risk” was not more clearly defined, it could serve as a loophole for some health care facilities to avoid oversight by claiming they are printing minimal-risk devices. In its discussion paper, FDA states it is considering a list of important characteristics that would help identify very low-risk devices, and feedback provided to the discussion paper could help the agency clarify this remaining ambiguity.<sup>28</sup>

**Qualifying products.** Although FDA has previously stated that this lower-risk scenario is explicitly not intended for implants or life-supporting or life-sustaining devices,<sup>29</sup> it is still unclear which products could fall under this scenario.

- *Nonpersonalized products.* Some experts mentioned that Scenario A could be used for nonpersonalized Class I devices such as tongue depressors.<sup>30</sup> However, this also poses some risk as these devices are typically printed multiple times, meaning that more than one faulty product could be used on multiple patients.
- *Assistive technology devices.* During interviews, it was noted that perhaps prosthetic, orthotic, and other assistive technology devices could be included under Scenario A, with the caveat that some standards or certification processes would be helpful to ensure that those products are safe and effective.
- *Anatomical models.* Experts had differing viewpoints on whether anatomical models—which they generally believed were the most common medical product printed at the point of care—could fit under this scenario. It depended, experts said, on the model’s use. For example, a general model of an organ used as a basic educational tool for health care providers and students, or as a visual aide for patients when obtaining informed consent, could easily fit under Scenario A with little to no oversight from the agency. However, when a health care provider prints and uses a patient-specific model to make decisions regarding diagnosis or treatment (e.g., planning surgery), some experts argued that FDA should not consider those products to be minimal risk and should exclude them from Scenario A. The agency would typically regulate similar, traditionally manufactured devices as well as diagnostic imaging software, as Class II, or moderate risk. Other experts maintained that printing these products is a medical practice that falls under state oversight of medicine rather than a medical product that falls under FDA’s oversight. Some experts also stated that the medical professionals involved in a patient’s care possess the most insight into how to develop an accurate and personalized model; therefore, regulations should not hinder their efforts to determine the most suitable care for their patient.

**Oversight.** In its discussion paper, FDA asks for feedback on best practices, oversight programs, and internal procedures that could be leveraged to ensure device quality, safety, and effectiveness.<sup>31</sup> During interviews, experts provided a few possibilities for which entities could be responsible for overseeing 3DPOC, in addition to best practices that could help with ensuring a product’s ongoing safety.

- *Providers.* In the absence of FDA oversight, many experts agreed that health care facilities would be responsible for mitigating potential risk of Scenario A products, and would need to develop and implement specific quality assurance processes for this purpose.
- *Nongovernmental organizations.* Experts also asserted that providers and patients could benefit from oversight by an independent entity, such as a hospital accreditor or a professional society, especially when hospitals are still learning how to use the new technology. These outside organizations would need to develop their own standards and processes for oversight, but, once finalized, these entities could potentially



assist health care facilities with implementing a quality assurance program for 3DPOC. The organization and level of oversight would depend on what products ultimately fall under this scenario.

- *Adverse event reporting.* Some experts had questions on how to monitor and report adverse events. FDA notes in its discussion paper that the health care facility would be responsible for complying with any “applicable regulatory requirements” for devices printed under Scenario 3, which would typically include adverse event reporting. It will be important for the agency to preserve this reporting obligation moving forward, as adverse event reports provide important insight into product safety and can help the agency target its oversight efforts.

Previously referred to as:	Now known as:
<p>Scenario B: Device designed by manufacturer using validated process: turnkey system</p> <p>Scenario C: Device designed by manufacturer using validated process: additional health care professional capability requirements</p>	<p>Scenario 1: Health care facility using a medical device production system (MDPS)</p>

In the previous framework, Scenarios B and C referred to situations in which devices would be printed by health care professionals at the POC but designed by an external manufacturer. These scenarios would have required FDA to approve or clear a validated process that the health care facility would implement. This validated process would have been sold as a turnkey, or ready-to-use, system most likely including software, hardware, and process parameters. In Scenario B, any post-processing steps would have been automatic or self-contained, whereas products printed under Scenario C would have required the users to complete additional steps in the manufacturing and post-production processes, such as sterilization or heat treatment.<sup>32</sup>

In FDA’s discussion paper, these scenarios are now combined and referred to as “Scenario 1: HCF [Health care facility] using a medical device production system (MDPS).” FDA defines MDPS as “a collection of the raw materials, software and digital files, main production equipment and post-processing (if applicable) equipment” for use by a health care provider or facility to manufacture a specific type of medical device at the POC.<sup>33</sup> The paper provides the example of a traditional manufacturer receiving FDA clearance for a 3D-printing MDPS that makes patient-specific anatomical skeletal models. The cleared system would include or specify “in the labeling a compatible scanner, design and manufacturing software, design limitations coded into the software, raw materials, compatible printer(s), and associated tooling.”<sup>34</sup> The health care facility would be expected to use the system within the scope of its labeling.<sup>35</sup>

The paper states that traditional manufacturers must obtain premarket approval or clearance for a device that would be made using an MDPS at the POC, when necessary according to device risk. Unlike the previous iteration of the framework, in which the allocation of regulatory responsibility between the manufacturer and health care facility was unclear, FDA states definitively in its discussion paper that the manufacturer of the marketed MDPS is responsible for complying with any regulatory requirements. It further states that a health care facility using an MDPS consistent with its labeling would, in general, not be considered a manufacturer.<sup>36</sup>

Ambiguity still remains, as the discussion paper notes that there may be certain exceptions that could raise additional compliance needs; however, it does not provide specific criteria or guidelines. For example, it states

that devices that require post-processing by the health care facility could have regulatory implications.<sup>37</sup> This is similar to the previous Scenario C, and it remains unclear what responsibilities would fall on a health care facility printing such devices.

Experts had many questions about Scenarios B and C, including which products could fall under each scenario, the difference in regulations that might be imposed on health care facilities versus manufacturers of systems, and potential risks that might arise from using such a system. Concerns specific to Scenarios B and C are explained in detail below.

**Qualifying products.** For Scenarios B and C, there was no consensus among experts on what types of devices could be printed safely using a turnkey system and what the regulatory scope would entail, with many respondents asking for more clarity on what exactly the differences between the two scenarios would look like in practice. Experts mentioned a wide array of devices, ranging from simple, typical low-risk Class I products to moderate-risk Class II anatomical models and surgical guides to high-risk Class III implants, with some experts theorizing that Scenario C is meant for high-risk products. Unlike the previous iteration of the framework, the discussion paper does provide examples of the types of devices that could theoretically be printed using an MDPS under this scenario. Though the inclusion of examples provides some clarity, questions remain about the types of post-processing activities that could trigger regulatory obligations for the health care facility, and for what types of devices. Indeed, in many interviews, experts brought up the increased risks associated with products that need to be sterilized, such as surgical cutting guides that are placed on a patient during surgery, or those that need to be biocompatible, such as implants, which stay within the body for the rest of a patient's life.

Many experts envisioned a system that goes beyond the ones that currently exist for anatomical models. These systems consist of an FDA-cleared software package that is validated for use on a limited number of 3D printers.<sup>38</sup> Experts mentioned many add-ons to a turnkey system that would be helpful for health care facilities when purchasing such a product, such as providing extensive training for anyone using the system, helping to establish a quality management system, and helping health care facilities meet other standards that are usually imposed on manufacturers of traditional devices. This could be incorporated as part of an extended service plan provided by vendors of turnkey systems to health care facilities. Similarly, for a 3DPOC MDPS, these add-ons could also prove helpful to health care facilities in ensuring that printed devices are safe and effective for their patients. As the field grows, market dynamics will likely determine the extent and limitations of these systems, given the unique needs of POC providers.

**False confidence in FDA-reviewed products.** Some experts mentioned that there might be fewer perceived risks with using an FDA-reviewed system, as the clearance or approval of the system itself theoretically provides some level of assurance about the manufacturing process. However, providers may then be less inclined to follow all necessary procedures as closely, which in turn could increase risks to patient safety.

**Off-label use.** Some experts expressed concern that overconfidence in FDA-reviewed systems would encourage providers to exercise their discretion and use the devices off-label—that is, for purposes other than the FDA-approved indications on the label. The risks associated with this were also highlighted in FDA's discussion paper, which states the importance for health care providers to consider the potential risks of using an MDPS system outside of its labeling and intended use.<sup>39</sup> Generally, off-label use, "when the intent is the 'practice of medicine,'" does not require FDA approval.<sup>40</sup> In addition, current regulations exempt licensed practitioners who manufacture or alter devices solely for use in their practice from product registration requirements.<sup>41</sup> However, as previously stated, using a 3DPOC system for unapproved purposes could unintentionally harm patients; for example, printing models of the brain using a system that is approved only to print cardiac models or using a different printer than the one that was cleared as part of the FDA-reviewed system could cause harm if it renders an inaccurate model, and would raise liability considerations for the provider and health care facility.

**Regulating providers.** Experts gave mixed responses on how FDA should oversee health care facilities that use FDA-reviewed systems. They raised many questions regarding the delineation of responsibility between manufacturers of 3DPOC systems and the systems' users (e.g., health care providers). Though the discussion paper does clarify that the system's manufacturer would be responsible for FDA compliance, it is ambiguous about devices that may require some post-processing and the type of regulatory oversight that might be imposed on facilities that print those devices. Furthermore, the discussion paper notes that there are additional regulatory requirements for entities not engaged in manufacturing activities, such as facilities that use the devices and need to report certain events to FDA and/or the manufacturer.<sup>42</sup> Some experts noted that the ACR, which accredits radiology programs, could play a similar role in accrediting 3D-printing programs. The risk of the device would correspond to the type of accreditation required, with higher-risk devices requiring more extensive requirements.

**Regulating manufacturers.** Experts raised many questions about the level of oversight that FDA would exert over manufacturers of 3DPOC systems and the entities that use the systems to manufacture devices. And though the discussion paper does provide more clarity, there are still several unanswered questions that FDA will need to address. For example, how much training would system manufacturers be required to provide health care facilities? To what extent would 3D-printing manufacturers be required to conduct postmarket surveillance versus the health care facilities using their products? And what kind of inspections would manufacturers be subject to?

**Liability.** Some experts questioned the extent to which designers, manufacturers, and users would be legally liable if 3DPOC devices harmed patients, especially if the products required significant post-processing and were considered higher risk.

Previously referred to as:	Now known as:
Scenario D: Manufacturer is co-located at the point of care	Scenario 2: Traditional manufacturer co-located at or near the health care facility site

In the earlier version of the framework, Scenario D was described as the co-location model, in which a traditional manufacturer, contract manufacturer, or other third party would have been responsible for setting up and managing its own operations on-site at the health care facility. FDA stated that it expected the co-located manufacturer to use its own equipment and personnel, or that the printed devices would not be considered minimal risk.<sup>43</sup>

In FDA's discussion paper, this scenario is now named Scenario 2 and similarly refers to when a traditional manufacturer co-locates at or near the health care facility. For example, a traditional manufacturer could lease space within a health care facility to print its FDA-reviewed spinal fusion cage at the POC. FDA expects a traditional manufacturer with a co-located manufacturing site to comply with the applicable regulatory requirements. However, the paper states that questions may remain about this scenario. For example, when patient-specific changes are made to a device that is already cleared or approved, the traditional manufacturer should look to existing guidance documents to see what its regulatory obligations may be.<sup>44</sup>

Experts understood Scenario D relatively well and expressed a mix of confidence and concern with how FDA defined the category. The concerns specific to Scenario D are explained in detail below.

**Qualifying products.** Most experts agreed that any type of device, including implants, could fit under this scenario, and that FDA should provide the same level of regulatory oversight to the co-located manufacturer as it would if the manufacturer was not co-located within the hospital. Like the current medical device paradigm, the level of regulatory scrutiny would correspond accordingly to the risk posed by the device being printed.

**Uniform risk.** Experts did not perceive a different level of risk for devices under this scenario, as the co-located manufacturer should be required to undergo all traditional regulatory requirements as it normally would outside of the POC setting and would likely have the necessary expertise to do so.

**Conflicts of interest.** Experts expressed concern that hospitals might want to use only those devices from the co-located manufacturer, despite potentially better options for patients.

**FDA inspection authority.** Experts questioned how far FDA would extend its inspection authority from the co-located manufacturing facility to the rest of the hospital.

Previously referred to as:	Now known as:
Scenario E: Health care facility becomes a manufacturer	Scenario 3: Health care facility assuming all traditional manufacturer responsibilities

Previously, Scenario E referred to a health care facility that sought to become an actual device manufacturer and therefore needed to comply with all traditional regulatory requirements. The hospital would control all 3D-printing operations, including device design, testing, and printing. An identical scenario is described in FDA’s discussion paper but is referred to as Scenario 3. The previous iteration of the framework stated that the products printed under Scenario E would be greater than minimal risk; however, no such caveat exists in the discussion paper.<sup>45</sup> As noted earlier in this brief, FDA also states that it is in the process of determining what level of oversight might be necessary for very low-risk devices printed under this scenario. The discussion paper says that existing capabilities and expertise, such as conformance with existing quality standards and already trained staff, could be leveraged to enable the health care facility to transition successfully to a traditional manufacturer of devices.<sup>46</sup>

Experts understood Scenario E relatively well and generally agreed that becoming a full-fledged device manufacturer would be realistic for only a handful of hospitals and health care facilities. Concerns specific to Scenario E are explained in detail below.

**Qualifying products.** Most experts agreed that Scenario E could include any type of device, as the hospital would have to meet the same requirements as traditional manufacturers. As previously stated, however, FDA will need to clearly define what types of devices are outside its scope of authority and those over which the agency may exercise enforcement discretion.

**Qualifying providers.** Many experts said that printing higher-risk devices is and should be an unlikely endeavor for most POC facilities, given the increased regulatory burden for printing such devices. For example, printing implants requires a higher level of design experience, a thorough understanding of biocompatibility requirements, and certain building and space specifications. Compliance with all necessary regulatory requirements, such as establishing and following the Quality System Regulation (which helps ensure that products meet applicable requirements and specifications),<sup>47</sup> would likely necessitate hiring additional staff such as regulatory experts, legal counsel, and engineers with expertise in device design and the technology.

**Oversight.** Experts agreed that FDA should exert full oversight over any facility that prints products as a traditional device manufacturer, though as in Scenario D, they questioned how far FDA would extend its inspection authority within the facilities. For hospitals that register as manufacturers, it was suggested that FDA should provide more leeway in approving a range of devices, so that POC facilities would not need to submit a new application for every device.

## **FDA does not have enough funding or resources to effectively regulate this growing field**

In addition to concerns and questions about FDA's framework, most experts Pew interviewed were concerned that FDA's inspection and enforcement resources are overstretched, and that the agency would likely not have enough capacity to appropriately oversee every POC facility, especially as the technology becomes more widely known and adopted. Several experts proposed outsourcing some oversight to other organizations—such as a hospital accreditor, professional medical association, or engineering society—though there were many questions about which authority should ultimately serve this role. No matter the organization, FDA would still need to work with it closely to ensure that efforts are complementary and not duplicative.

- **The Joint Commission.** Many experts suggested that The Joint Commission, the organization tasked with accrediting and certifying U.S. health care organizations and programs for patient safety and quality of care,<sup>48</sup> could inspect 3D-printing labs as part of its routine audits, with training from FDA. This could also include ensuring safety of the staff employed in 3D-printing labs, as long-term exposure to certain powders and material could prove harmful.
- **American College of Radiology (ACR).** Several experts mentioned the ACR as an appropriate oversight body. The organization is responsible for accrediting imaging facilities for requirements relating to equipment, medical personnel, and quality assurance; helping facilities meet governmental and payer criteria;<sup>49</sup> and maintaining several databases, including the previously mentioned joint RSNA-ACR 3D Printing Registry. Accreditation of 3D-printing labs could be incorporated into ACR's current practices, though some experts mentioned that 3D-printing is not restricted to radiologists, which would likely necessitate increased education to ensure that anyone under the organization's jurisdiction is able to comply with any necessary requirements.

For example, for mammography screening, ACR is one of four FDA-approved organizations serving as an accreditation body. The Mammography Quality Standards Act, which became law in October 1992, could serve as an example for how to coordinate oversight across multiple bodies when it comes to 3D printing. The legislation regulates mammography screening at the federal level, tasking the Department of Health and Human Services to develop enforceable standards through accreditation, certification, and inspection. FDA implements these regulations, partly by approving ACR as an accreditation body.<sup>50</sup> Similarly for 3D printing, FDA could appoint accreditation bodies to supplement its oversight responsibilities.

- **Engineering societies.** SME (formerly known as the Society of Manufacturing Engineers)<sup>51</sup> and ASME were suggested as possible sources of oversight, as both organizations are already involved with providing training and certifications, publishing standards and other best practices, and remain engaged with the FDA. As mentioned, ASME in particular has been working with the agency for the past few years to present its proposed framework and gather feedback.<sup>52</sup>
- **Accredited third-party inspection organizations.** Currently, medical device manufacturers in the U.S. are subject to routine compliance inspections, which can be conducted either by FDA personnel or accredited third-party organizations.<sup>53</sup> As these accredited organizations have experience with auditing traditional manufacturers of medical devices, they could play a similar role with 3DPOC facilities.

## Innovation is outpacing regulation

Experts were generally pleased with FDA's engagement process as the agency solicited and incorporated feedback from a variety of stakeholders involved with 3DPOC. However, many interviewees expressed concerns that the agency is moving too slowly, as this technology is already being implemented and used on patients. Furthermore, as noted earlier in the brief, there are several efforts underway to garner reimbursement for these activities. Though this may translate to greater access to these innovations, it could also mean greater patient risks, particularly if 3D-printing initiatives are deployed by health care providers who have limited experience with the technology or with the regulatory requirements associated with manufacturing a medical device. Many experts noted that gathering formalized feedback on a draft guidance can take several years and recommended that FDA release draft guidance as soon as possible and begin collecting feedback. The release of the discussion paper and collection of feedback is an encouraging first step in this direction.

## Recommendations for the agency as it continues to evolve its regulatory approach

Based on Pew's findings, the recommendations below may help guide FDA's thinking as it considers how to adapt current policy in order to ensure that the benefits of this emerging technology outweigh the risks.

- **Clear guidance.** The agency should move quickly to issue draft guidance that more concretely describes a risk-based regulatory framework for 3DPOC printing, clarifying how product risk will be defined and how that risk determination will correspond to the level of regulatory oversight. Until then, health care facilities will continue to use this technology to produce medical products that may not meet FDA's standards for safety and effectiveness.
  - The draft guidance should provide clear expectations on the requirements that each entity involved in manufacturing a medical device must meet. It should also provide clear guidelines for health care facilities that fall under more than one scenario.
  - Within the draft guidance, the agency should clarify which devices might be subject to enforcement discretion (because they present a low level of risk) or fall outside FDA's purview (because they do not qualify as a medical device).
- **Enforceable rules.** Since guidance documents are not enforceable, the agency should prioritize the development of regulations governing 3DPOC manufacturing where necessary, especially for high-risk products. At a minimum, to improve transparency, FDA should require that all POC manufacturers register their facilities and notify the agency of what types of devices they are manufacturing.
- **Timely and broadened oversight.** To address stakeholder questions, FDA should establish 3DPOC guidances and regulations quickly and enforce them through premarket review, postmarket surveillance, and facility inspections. Additionally, to bridge gaps in oversight, private organizations that already play quasi-oversight roles should develop their own recommendations and standards for 3DPOC manufacturing.

## **Conclusion**

3D printing at the point of care presents many promising opportunities to improve patient care with more customization. However, current regulations have not kept pace with the rapid change in this field, and regulatory oversight must evolve to ensure that medical products printed at the point of care are safe and effective. As the technology continues to advance and become more widely adopted, FDA and other stakeholders must work together to develop policies that ensure patient safety while creating the conditions to foster breakthrough innovations.



# Appendix A

## Methodology

To better understand the regulatory landscape around 3D printing and its use at the point of care, Pew reviewed relevant literature and commissioned a regulatory consulting firm, Greenleaf Health, to evaluate FDA's five-scenario 3DPOC framework through the lens of existing statutes related to medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA). As part of its analysis, Greenleaf Health also identified regulatory ambiguities that could pose challenges to FDA's authority in enforcing its jurisdiction over 3DPOC.

Pew also conducted a series of semistructured interviews with 17 experts (see below) to obtain a broad range of perspectives on the proposed five-scenario framework, including its potential impact, areas of confusion, and potential gaps in oversight where FDA guidance or additional oversight may be necessary to ensure patient safety. Interview experts were drawn from across medical centers, the medical device industry, and research institutions. The Pew research team then reviewed interview transcripts to identify broad themes and areas of agreement or disagreement. These findings were combined with the regulatory analysis provided by Greenleaf Health, as well as reviews of the literature.

## Experts interviewed

- **Andy Christensen**, president and owner, SOMADEN LLC; adjunct professor, department of radiology, University of Cincinnati
- **Benjamin Johnson**, vice president, portfolio and regulatory, 3D Systems Healthcare
- **Beth Ripley, M.D., Ph.D.**, deputy chief, Office of Healthcare Innovation and Learning, U.S. Department of Veterans Affairs; staff radiologist, VA Puget Sound Health Care System
- **Evan Hochstein**, senior health care solutions engineer, segment lead, Stratasys
- **Frank J. Rybicki, M.D., Ph.D.**, vice chair, operations and quality-radiology, and professor of radiology and biomedical engineering, University of Cincinnati
- **Jessica Coughlin**, head of health care market access, Stratasys
- **Jonathan Morris, M.D.**, neuroradiologist and medical director of the 3D Anatomic Modeling Laboratory, Mayo Clinic
- **Joseph Lipman**, director of device development, Hospital for Special Surgery
- **Justin Ryan, Ph.D.**, director and research scientist, Helen and Will Webster Foundation 3D Innovations Lab, Rady Children's Hospital-San Diego
- **Kenneth C. Wang, M.D., Ph.D.**, staff radiologist, Baltimore VA Medical Center; adjunct assistant professor, University of Maryland School of Medicine
- **Kim Torluemke**, regulatory affairs consultant, KT Regulatory Consulting, LLC
- **Laura Gilmour**, principal consultant, additive manufacturing and regulatory strategies, Veterans Health Administration
- **Meghan McCarthy, Ph.D.**, project lead, NIH 3D Print Exchange, and program lead, 3D Printing and Biovisualization, National Institute of Allergy and Infectious Diseases, National Institutes of Health; contractor, MSC, Inc.
- **Sam Murray**, director, regulatory affairs and quality assurance, Advanced Instruments, LLC
- **Scott Drikakis**, health care segment leader, Americas, Stratasys
- **Shafkat Anwar, M.D.**, associate professor of pediatrics and radiology; director, Pediatric Heart Center MRI and 3D+ Programs; and medical director, Center for Advanced 3D+ Technologies, University of California San Francisco
- **Victor Zambrano**, director, business model innovation, J&J 3D Printing Innovation and Customer Solutions

## Appendix B

### FDA review pathways for devices

Table B

### Federal Oversight of Medical Devices Is Tailored to Risk<sup>54</sup>

Regulatory classification	Level of risk	Review pathway	Example
<b>Class I</b>	Low risk	Typically exempt from premarket submission, though they still must comply with manufacturing and quality control standards.  Certain novel devices may also submit a De Novo request, meant for devices “that have never been marketed in the U.S., but whose safety profile and technology are now reasonably well understood,” instead of filing a full premarket application. <sup>55</sup>	Bandages, handheld instruments
<b>Class II</b>	Moderate risk	Some are exempt from premarket submission, though most undergo 510(k) review (named for the relevant section of the Federal Food, Drug, and Cosmetic Act), in which a manufacturer demonstrates that its device is “substantially equivalent” to an existing device on the market, reducing the need for extensive clinical research.  Certain novel devices may also submit a De Novo request—meant for devices “that have never been marketed in the U.S., but whose safety profile and technology are now reasonably well understood”—instead of filing a full premarket application. <sup>56</sup>	Infusion pumps, computed tomography (CT) scanners
<b>Class III</b>	High risk	Must submit a full application for premarket approval that includes data from clinical trials. FDA then determines whether sufficient scientific evidence exists to demonstrate that the new device is safe and effective for its intended use.	Pacemakers, deep-brain stimulators

Sources: U.S. Food and Drug Administration; J. Jin, “FDA Authorization of Medical Devices,” *JAMA* 311 no. 4 (2014): 435, <https://jamanetwork.com/journals/jama/fullarticle/1817798>

In addition to its traditional review pathways, FDA maintains an exemption for custom devices. A custom device may be exempt from premarket notification if it meets specific requirements under Section 520(b) of the Federal Food, Drug, and Cosmetic Act. These requirements are extensive and include, for example, that the manufacturer makes no more than five units of the device per year and that the device “is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat.”<sup>57</sup> As such, custom devices represent an extremely narrow category, and FDA has emphasized that despite potential confusion over the colloquial meaning of a “custom device,” a personalized 3D-printed device must also meet all the criteria of

Section 520(b) in order to qualify for an exemption.<sup>58</sup> FDA also maintains an exemption for humanitarian use devices, which refers to a medical device that is intended to benefit patients with a disease or condition that affects no more than 8,000 individuals in the U.S. per year. In 2021, FDA approved a first-of-its-kind 3D-printed implant to treat a rare bone disorder through the humanitarian device exemption pathway.<sup>59</sup>

## **Background of Center for Devices and Radiological Health regulations**

Medical devices are currently the most common type of 3D-printed medical product: More than 200 devices that utilize this technology have already received marketing authorization from FDA.<sup>60</sup> The Center for Devices and Radiological Health has provided some insight on the regulation of these products through its 2014 public workshop on additive manufacturing, as well as the subsequent 2017 guidance, which was crafted based on the feedback received during the workshop.

The agency's 2014 workshop, "Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing," sought to provide a forum for regulators, device manufacturers, additive manufacturing companies, and academia to discuss 3D printing.<sup>61</sup> Participants focused on five themes: materials used in 3D printing; design, printing, and post-printing validation; printing characteristics and parameters; physical and mechanical assessment of final devices; and biological considerations of final devices. In December 2017, FDA issued a guidance document based on the workshop discussion, titled "Technical Considerations for Additively Manufactured Medical Devices." Unlike most guidance documents, FDA characterized this one as tentative and evolving, acknowledging that 3D-printing technology is still developing and that any recommendations are likely to change with it. Furthermore, while it does address that POC may raise additional technical considerations, it does not discuss those aspects further.<sup>62</sup>

The 2017 guidance outlines technical considerations associated with an additively manufactured device "through the phases of design development, production process, process validation, semi-finished and final finished device testing."<sup>63</sup> Broadly, the guidance is divided into two topical areas: (i) design and manufacturing process considerations, and (ii) device testing considerations. The first section describes technical considerations that should be addressed to meet the quality system requirements for a device, in accordance with its risk class. The second section on device testing considerations describes the type of information that should be included in a regulatory application for an additively manufactured device. The type of premarket submission required is not determined by the fact that a medical device is additively manufactured; rather, it is determined by the regulatory classification of the device, which is based on its intended use and level of risk.<sup>64</sup>

Most recently, FDA released a discussion paper, "3D Printing Medical Devices at the Point of Care," which provides background information on 3D printing, the challenges presented by 3DPOC devices, and a potential approach for regulatory oversight. The paper also poses key questions to facilitate public comment, which will be used to develop draft guidance on the issue.<sup>65</sup>

# Appendix C

## Roles and responsibilities of medical device manufacturers

Table C.1

### Basic FDA-Regulated Roles in the Interstate Commerce of Medical Devices

Role	Activities	FDA regulations [21 C.F.R § ]
<b>Manufacturer</b>	<ul style="list-style-type: none"> <li>▪ A person who designs, fabricates, manufactures, remanufactures, prepares, propagates, compounds, assembles, or processes a device is a “manufacturer.”</li> <li>▪ A person who relabels, repacks, repackages, or reprocesses a device is considered a “manufacturer” for purposes of certain regulatory requirements.</li> <li>▪ A person who initiates specifications for a device that is manufactured by a second party is considered a “manufacturer” for purposes of certain regulatory requirements.</li> <li>▪ An initial importer of a foreign manufacturer is considered a “manufacturer” for purposes of certain regulatory requirements.</li> </ul>	803.3, 806.2(g), 807.3(d), 820.3(o), 821.3(c), 822.3(g)
<b>Specification developer</b>	<ul style="list-style-type: none"> <li>▪ A person who initiates specifications for devices that are manufactured by a second party (i.e., a contract manufacturer) for subsequent distribution by the person initiating the specifications is a “specification developer.”</li> <li>▪ A “specification developer” is considered a “manufacturer” for purposes of certain regulatory requirements.</li> </ul>	803.3, 806.2(g), 807.3(d), 820.3(o), 821.3(c), 822.3(g)
<b>Repacker, repackager, or relabeler</b>	<ul style="list-style-type: none"> <li>▪ A person who repackages or in any way changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the place of original manufacture is a “repacker, repackager, or relabeler.”</li> <li>▪ A person is not considered a “repacker, repackager, or relabeler” if that person merely packs previously packaged/labeled individual devices into packages for the convenience of the user.</li> <li>▪ A “repacker, repackager, or relabeler” is considered a “manufacturer” for purposes of certain regulatory requirements.</li> </ul>	803.3, 806.2(g), 807.3(d), 820.3(o), 821.3(c), 822.3(g)
<b>Initial importer</b>	<ul style="list-style-type: none"> <li>▪ An importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.</li> <li>▪ An initial importer is considered a “manufacturer” for purposes of the establishment and listing, quality systems, and postmarket surveillance requirements.</li> <li>▪ The medical device tracking regulation defines “importer” as “the initial distributor of an imported device who is subject to a tracking order. ‘Importer’ does not include anyone who only furthers the marketing, e.g., brokers, jobbers, or warehouseurs.”</li> </ul>	807.3(g), 807.3(d)(2), 820.3(o), 822.3(g), 821.3(b)
<b>Distributor</b>	<ul style="list-style-type: none"> <li>▪ A person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package is a “distributor.”</li> </ul>	803.3, 807.3(b), 807.3(s), 821.3(h)

Table C.2

## Overview of Statutory and Regulatory Requirements for Medical Device Manufacturers

Description of requirement	Applicability to device manufacturers
<p><b>Establishment registration and device listing</b></p> <p>The owner/operator of a device manufacturing establishment must register with FDA and file a list of devices being manufactured there for commercial distribution.</p> <p>FDCA § 510, 21 U.S.C. § 360; 21 C.F.R. part 807</p>	<p>The registration and listing requirements pertain to manufacturers. 21 C.F.R. § 807.20(a) (stating that manufacturers must “register and submit listing information for ... devices in commercial distribution”).</p>
<p><b>Inspections</b></p> <p>Every establishment required to register with FDA is subject to inspection by FDA pursuant to 21 U.S.C. § 374 (describing, among other things, the scope of inspections, the general process for conducting inspections, and recordkeeping requirements).</p> <p>FDCA § 510(h); 21 U.S.C. § 360(h); FDCA § 704; 21 U.S.C. § 374</p>	<p>All registered device manufacturers are subject to inspection by FDA according to a risk-based schedule. The statute lists the factors that must be considered in creating the risk-based schedule, such as “the compliance history of the establishment” and the “inherent risk of the device” (21 U.S.C. § 360(h)(4)). During an inspection, documents, product samples, manufacturing processes, and other items may be reviewed to determine compliance with the FDCA, including the requirements listed in this chart.</p>
<p><b>Premarket notification</b></p> <p>Every person who intends to market a new device must submit to FDA a notification of such intent, i.e., a 510(k), at least 90 days in advance. A person who has submitted a premarket approval application is deemed to have satisfied this requirement.</p> <p>FDCA § 510(k), 21 U.S.C. § 360(k); 21 C.F.R. part 807, subpart E</p>	<p>Manufacturers must submit premarket notification. 21 C.F.R. § 807.81(a) (stating that anyone required to register pursuant to 21 C.F.R. § 807.20 must submit a premarket notification).</p>
<p><b>Good Manufacturing Practices (GMPs)/Quality System Regulation (QSR)</b></p> <p>The methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use must comply with GMP requirements, which have been established by FDA in the QSR.</p> <p>FDCA § 520(f)(1), 21 U.S.C. § 360j(f)(1); 21 C.F.R. part 820.</p>	<p>Manufacturers must comply with all aspects of the GMP/QSR requirements applicable to the functions they perform. 21 C.F.R. § 820.1(a)(1) (stating that “[i]f a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged”).</p>
<p><b>Medical device reporting (MDR)</b></p> <p>Device user facilities, importers, and manufacturers must report deaths and serious injuries that a device has or may have caused or contributed to, must establish and maintain adverse event files, and must submit to FDA specified follow-up and summary reports. Distributors are required to maintain records of incidents (files). Manufacturers and importers are also required to report certain device malfunctions.</p> <p>FDCA § 519, 21 U.S.C. § 360(i); 21 C.F.R. part 803.</p>	<p>Manufacturers must comply with the MDR requirements in 21 C.F.R. part 803, subpart E. 21 C.F.R. § 803.10(c).</p>

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### **Notification and repair, replace, refund**

FDA can require public notification of an unreasonable risk of substantial harm from a marketed device, as well as the repair or replacement of a device, or the refund of the purchase price.

FDCA § 518, 21 U.S.C. § 360h

The notification requirement could apply to manufacturers, depending on the situation. FDCA § 518(a)(2), 21 U.S.C. § 360h(a)(2) (authorizing FDA to apply the notification remedy to the “persons and means best suited under the circumstances involved”).

The repair, replace, refund remedy applies to manufacturers. FDCA § 518(b)(1)(A), 21 U.S.C. § 360h(b)(1)(A) (authorizing FDA to apply the remedy to “the manufacturer, importer, or any distributor of [a] device, or any combination of such persons”).

### **Postmarket surveillance**

FDA may require postmarket surveillance for any device that is a permanent implant and whose failure may cause death or serious adverse health consequences, or is intended for use in supporting or sustaining human life, or potentially presents a serious risk to human health. FDA is also authorized to impose postmarket surveillance for any other device where necessary to protect the public health or to provide adequate safety or efficacy data.

FDCA § 522, 21 U.S.C. § 360l; 21 C.F.R. part 822

A manufacturer must comply with the postmarket surveillance requirements only upon specific order by FDA. 21 C.F.R. § 822.4.

### **Mandatory recalls**

FDA can order that the distribution of a device cease and that health professionals and device user facilities be notified if the agency finds that the device would cause serious adverse health consequences or death.

FDCA § 518(e), 21 U.S.C. § 360h(e); 21 C.F.R. part 810

The mandatory recall authority pertains to manufacturers. FDCA § 518(e)(1), 21 U.S.C. § 360h(e)(1) (stating that FDA’s mandatory recall authority applies to the “appropriate person,” including “manufacturers, importers, distributors, or retailers”).

### **Device tracking**

FDA can require device tracking for any Class II or Class III device that is permanently implantable, life sustaining, or life supporting, or whose failure would be likely to have serious adverse health consequences.

FDCA § 519(e), 21 U.S.C. § 360i(e); 21 C.F.R. part 821.

Manufacturers must comply with the device tracking requirement upon specific order by FDA. 21 C.F.R. § 821.1(a) (authorizing FDA to “require a manufacturer to adopt a method of tracking a class II or class III device” if certain conditions are met).

### **Reports of removals and corrections**

FDA can require the manufacturer or importer of a device to report any correction or removal of the device undertaken to reduce a risk to health or to remedy a violation of the FDCA that may present a health risk.

FDCA § 519(f), 21 U.S.C. § 360i(f); 21 C.F.R. part 806

Manufacturers must comply with the reports of removals and corrections requirement. 21 C.F.R. § 806.1(a) (requiring “device manufacturers and importers to report promptly to [FDA] certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA”).

## **Acknowledgments**

This brief was prepared by Zahra Younoszai with support from Michael Dobias, Emily McAndrew, and Liz Richardson of Pew's health care products project. Pew staff members Kimberly Burge, Lindsay Henry, Elham Khatami, Matt Mulkey, Cindy Murphy-Tofig, Bernard Ohanian, and Josh Wenderoff provided editorial assistance and helped prepare the brief for publication.

In addition, this brief benefited from the insights and expertise of Gregory Voss, research biomedical engineer at Minneapolis VA Health Care System, and Steven Pollack, science fellow at Carbon. Although they have reviewed the report, neither they nor their organizations necessarily endorse its findings and conclusions.



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