

# Lawyer Insights

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## How will the FDA regulate 3D printing?

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Pharmaceutical and medical device manufacturers increasingly are using 3D printing (aka “additive manufacturing”) to manufacture their drugs and devices. Indeed, the Food and Drug Administration already has approved or cleared numerous 3D-printed products, including a prescription drug product and a variety of medical devices, from orthopedic implants to surgical guides for a range of procedures.

After initially indicating that it would provide guidance on the use of 3D printing in manufacturing FDA-regulated products, FDA has fallen silent. What does the future hold for FDA regulation of 3D printing?

### FDA’s approach to 3D-printed drugs and devices

The FDA has approved or cleared 3D-printed products via traditional drug and device approval pathways. Under the approval pathway for drugs, FDA will approve a new drug application (NDA) if it determines, based on adequate and well-controlled clinical investigations, that the new drug is safe and effective under the conditions of use in its proposed labeling. Likewise, under the approval pathway for moderate risk medical devices (the so-called 510(k) pathway), FDA will “clear” a medical device for marketing if it is substantially equivalent (i.e. at least as safe and effective) as a legally marketed, or predicate, device. To be substantially equivalent, the new device must (1) have the same intended uses as the predicate device and (2) either have (a) the same technological characteristics as the predicate device or (b) different technological characteristics that do not raise new issues of safety or effectiveness.

3D-printed drugs and devices that have been approved or cleared by FDA via traditional approval pathways include:

- Aprexia Pharmaceuticals Co.’s epilepsy drug, Spritam® (levetiracetam) tablets, a prescription drug for the treatment of epileptic seizures that could be used by more than 3 million people. The 3D printing process makes Spritam tablets more porous than typical pills, so that they melt in your mouth with only a sip of water.
- Oxford Performance Materials, Inc.’s OsteoFab® Patient-Specific Facial Device, an orthopedic implant used in facial reconstruction surgery. 3D printing allows for the manufacture of patient-specific maxillofacial implants that can be created from an individual’s magnetic resonance imaging (MRI) or computerized tomography (CT) scan.

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- Zimmer Biomet Holdings' Unite3D™ Bridge Fixation System, which eliminates the need for the plates, screws, and staples used in traditional arthrodesis (joint fusion surgery) and instead relies on a 3D-printed "osteoconductive matrix designed to provide for biological incorporation."
- At least 85 other 3D-printed medical devices cleared via FDA's 510(k) approval pathway.

Given FDA's approach to 3D-printed drugs and devices, it seems unlikely that the increased use of 3D printing will be stymied by onerous or ill-fitting regulatory requirements. FDA's approval of Spritam, the epilepsy medication, suggests a future of bespoke medications that are customized for specific patients. Similarly, FDA's clearance of 3D-printed prosthetics suggests an era when individually-measured and customized prosthetics will be 3D-printed at hospitals for specific patients. To be sure, 3D printing is at the forefront of personalized medicine, with tailor-made drugs and devices manufactured on demand and customized to meet the unique needs of specific patients.

### **Is the existing FDA regulatory framework sufficient?**

To date, virtually all of the 3D-printed medical devices being legally marketed were cleared by the FDA via the traditional 510(k) pathway. A handful of 3D-printed devices also were authorized via the emergency use pathway, which allows a physician to treat a patient with unapproved medical devices under certain emergency circumstances. Other potential pathways to approval for 3D-printed medical devices include the compassionate use pathway, which allows an investigational device to be used in cases where alternative therapies are unsatisfactory, and the custom device exemption pathway, which allows a custom device to be created to comply with a physician's order. For 3D-printed drugs, only the standard NDA approval process is available.

FDA's existing regulatory framework is based on mass production of one-size-fits-all products. 3D printing technology, however, holds the promise of production of customized drugs and devices for specific patients. Are new regulatory approval pathways needed for FDA review of 3D-printed drugs and devices? Should FDA issue guidance explaining how this new can fit into the existing framework?

At a minimum, FDA guidance regarding the application of existing FDA regulation to 3D-printed drugs and devices would be useful. Despite the increased usage of 3D printing in drug and device manufacturing, many manufacturers are holding back due to regulatory uncertainty. Unanswered questions include:

- How will FDA treat non-traditional device "manufacturers," such as hospitals?
- Will FDA regulate 3D printers as medical devices? Or, will FDA only concern itself with 3D-printed products?
- Will a manufacturer's sharing of its design files for a 3D-printed product constitute promotion of the product? If so, will manufacturers be obliged to share risk information whenever they share design files?
- When will FDA consider a 3D-printed device to be a "custom device"? Will such 3D-printed custom devices be exempt from premarket approval requirements and mandatory performance standards?
- How will FDA execute its inspection program? How will quality systems and good manufacturing practice requirements be applied to the 3D printing of drugs and devices?

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**Questions like these abound.**

Unfortunately, guidance from FDA on 3D printing-related issues seems unlikely. In October 2014, the FDA held a public workshop and requested comments on the “challenges of additively manufacturing medical devices,” suggesting it was preparing guidances for industry on the subject. The FDA further stated in its 2015 Guidance Agenda that it intended to publish a draft guidance on 3D printing as “resources permit.” Yet, no such guidance appeared in 2015. FDA’s recently published 2016 Guidance Agenda drops 3D printing completely, suggesting that the agency now has no plans to address the subject publicly. Instead, FDA likely will continue to develop its regulatory approach in the context of particular NDA and 510(k) submissions.

**Conclusion**

The FDA’s approvals and clearances of 3D-printed drugs and devices are strong evidence that the agency can review 3D-printed products under its existing regulatory paradigm. Unique questions raised by the new technology, however, suggest that there will be much back-and-forth between manufacturers and the agency. Although specific guidance from FDA would be useful, it appears that this back-and-forth will occur in the context of particular submissions. Given FDA’s approach, manufacturers of 3D-printed drugs and devices are well-advised to plan ahead and engage the agency early in the development of their products.

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