Life Sciences, Pharmaceuticals and Health Care

The Future of 3D Printing in Pharma, Medical Devices

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The concept seems like magic—a few strokes of a printer and a prescription medication or a customized medical device is available at your fingertips. Yet thanks to additive manufacturing, more commonly known as "3D printing," what seems almost unimaginable is indeed reality. The popularity and utility of additive manufacturing is rapidly increasing across countless industries. According to one report, the 3D printing industry grew to $5.165 billion in 2015, representing a 25.9 percent growth from 2014, (TJ McCue, Wohlers Report 2016: 3D Printing Industry Surpassed $5.1 Billion, FORBES, Apr. 25, 2016). The pharmaceutical and medical device industries are no exception, and are harnessing the power of 3D printing to make innovative medical advances and bring significant patient benefits. Nevertheless, the proliferation of 3D printing comes with a host of legal implications and uncertainties. As the use of 3D printing continues to expand and evolve in the pharmaceutical and medical device space, the existing FDA regulatory regime and traditional product liability principles will be challenged to adapt.

Although it may sound like something from a science fiction movie, 3D printing has been in existence for over 30 years. Developed by engineer and physicist Charles "Chuck" Hull in the 1980s, the first 3D printing patent was issued in 1986. The 3D printing process and technology varies, but it generally begins with an electronic blueprint, typically a computer-aided design (CAD) file created by modeling software or a 3D scan of an existing object. The 3D printer is prepared by setting raw materials, such as plastics or metals. The printer then builds the object according to the design specification by adding successive layers until the object is completed. In their early inception, 3D printers were large and expensive, which limited the technology to a small segment of the population. However, as new companies have entered the marketplace and the use of the technology has increased, 3D printers are becoming cheaper and far more accessible to both small businesses and individuals, leading some to speculate that the 3D printer may soon be a common fixture around the home.

There are currently 85 medical devices manufactured by 3D printing that have received FDA approval. These include craniofacial implants, titanium hips, and prostheses. Importantly, 3D printing in the medical device space can be used not only as an alternative manufacturing method for existing device components or medical devices, but to create devices that were not possible under conventional manufacturing methods, including but not limited to patient-specific or patient-matched devices. For example, Oxford Performance Materials's OsteoFab® Patient-Specific Facial Device (OPSFD), approved by the FDA in 2014, is a 3D-printed, patient-specific maxilliofacial implant used in complex facial reconstruction surgeries, (OPM Receives FDA Clearance for 3D Printed OsteoFab Patient-Specific Facial Device, Aug. 19, 2014, available at

http://www.oxfordpm.com/opm-receives-fda-clearance-3d-printed-osteofab-patient-specific-facial-device (last visited Sept. 15, 2016)). A 3D-printed, customized, and biodegradable tracheobronchial splint (TBS) is currently undergoing the FDA approval process. TBS is designed to treat a pediatric condition known as Tracheobronchomalacia (TBM), in which the tracheal walls collapse and severely restrict respiration. The efficacy of TBS has already proved both novel and life-saving; in 2012 and 2014, TBS's were successfully implanted into the airways of children suffering from TBS with FDA emergency clearance.

In March 2016, the FDA issued its first approval for a 3D-printed prescription medication, Spritam, a disintegrating oral tablet for the treatment of seizures manufactured by Aprecia Pharmaceuticals. Spritam is manufactured using ZipDose®, Aprecia's proprietary 3D printing platform. ZipDose® formulates pharmaceuticals up to 1,000 mg by "binding multiple layers of a powder blend using an aqueous fluid to produce a porous, water-soluble matrix that rapidly disintegrates with a sip of liquid." The rapid disintegration of Spritam and other pharmaceuticals manufactured using the ZipDose® platform is an important development, particularly in pediatric patients who struggle to swallow tablets and may complain about the taste, and in elderly patients who suffer from dysphagia and for whom conventional medication formulations can become difficult to swallow. Aprecia currently has three other medications in the pipeline that are manufactured using the ZipDose® technology. The names and indications for these medications have not been released.

The FDA's position toward 3D printing has been on the whole, quite positive, perhaps best indicated by the number of approvals of 3D-printed medical devices to date. Indeed, the FDA has treated 3D-printed devices no differently than devices manufactured by more conventional means. These tides may be changing. At present, the majority of medical devices manufactured by 3D printing are Class II medical devices—devices of medium risk, subject to appropriate regulatory controls to assure safety and effectiveness. These devices are typically approved by the FDA under the 510(k) approval process, by which FDA approval is granted after the manufacturer demonstrates the device in question is "substantially equivalent" to a legally marketed device. No clinical trials are required, and the focus of the approval is on safety and efficacy, not the manufacturing methods, (see Ariel M. Nissan, Regulating the Three-Dimensional Future: How the FDA Should Structure a Regulatory Mechanism for Additive Manufacturing, 22 B. U. J. SCI. & TECH. L. 267, 281 (2015)). As 3D printing continues to evolve in the medical device space, 3D-printed Class III devices—devices of the highest risk—will foreseeably be developed. Such devices will be subject to significantly higher regulatory review, which may include enhanced scrutiny of the manufacturing process. Further, in May 2016, the FDA released draft guidance containing technical considerations for additive manufactured devices. This guidance calls out specific considerations for FDA submissions for 3D-printed devices, including quality systems and device testing considerations unique to additively manufactured products. The guidance may impact the FDA approval process for both Class II and Class III 3D- printed devices going forward. Further, with only one FDA approval of an additively manufactured prescription drug, it is unclear if 3D-manufactured pharmaceuticals and medical devices can also be expected to alter current product liability principles. Numerous scholars and practitioners have debated whether a CAD file can be considered a "product," generally defined under products liability law as "tangible personal property distributed commercially for use or consumption," (see Restatement (Third) of Torts: Prod. Liab. Section 19(a). It is unclear whether both the "blueprint" for the 3D-manufactured drug or medical device as well as the product itself may give rise to an actionable products liability claim, but its implications are far-reaching and significant. If the pharmaceutical or medical device company creates only the CAD, and the CAD is not a product, is the company immune from liability? Would liability shift to those responsible for printing the drug or medical device? Some envision a world where eventually people will simply print their own prescription medications from home. In such a world, would individuals have no remedy for a defective medication at all?

Additively manufactured pharmaceuticals and medical devices have already had a tremendous impact on patient care and treatment, and the opportunities for growth and advancement in this area seem limitless. We can only speculate about the precise impact that 3D printing will have on regulatory oversight of drugs and medical devices and products liability principles, but change is certain. •

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