3D Printed Pharmaceuticals and Devices Article Series: Assessing, Managing, and Insuring Against Risk in the Next Era of Drugs and Medical Devices – Part 3

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The first two installments of this three-part series discussed the 3D printing industry and processes, its regulation, and the potential product liability risks facing those within the chain of distribution of 3D printed drugs and medical devices. There are still more questions than answers, both with respect to regulation and potential product liability. This third portion discusses some insurance considerations for mitigating risk in this uncertain regulatory and legal landscape.

Exposures

The potential liability exposures for 3D printing are similar to medical devices, but with interesting nuances due to the new technology and the stakeholders involved. These nuances and novelties preclude firm answers—not all the exposures can be foreseen and new risk can come to light at any time. However, below you will find the principal exposures that are currently observed for this technology.

Control

3D printing creates inherent risks for life sciences companies due to the different manufacturing capabilities and stakeholders involved with this process. The stakeholders in the supply and distribution chain of a typical 3D printing process are:

- Software designer
- Manufacturer of the 3D printer
- Raw material supplier for printed product
- Organization printing out product, whether hospital or pharmacy or clinic
- End user

This list may not look that different from the stakeholders in the supply chain of a typical life sciences company, however, there is one major distinction: the control the product manufacturer has over the process. In a typical manufacturing process, there is a manufacturing facility that does the quality check of the raw materials and the finished product before it is distributed to the final end user. A 3D printed product can be manufactured one at a time at a hospital or clinic using the raw materials that are bought for a particular printer. There can be minimal oversight of the final printed product and may be no quality checks done by the manufacturer. Accordingly, there are more opportunities for an issue to arise within the supply chain and manufacturing process that might not be caught before the product is used by the end user.

Materials

There are many types of materials that are used as the source material for 3D printed products, from biologics to plastics to metals. The product designer can recommend using a particular material and supplier for that material, but the end user of the printer does not have to follow that

recommendation. Possible exposures related to the source materials are contamination, new, potentially hazardous or faulty combinations of materials not previously tested, and inferior quality of materials used.

Software design

Software is a key part of the 3D printed product chain—without the software, there is no product. The software will be in the control of many of the stakeholders and could be modified in order to change the final result or product. Therefore, potential exposures arising from the software are both a faulty or amended software design as well as the vulnerability of the software design file to being hacked.

Printer

Each printer is its own unique device and needs to be adequately maintained by the stakeholder to be able to continue to produce the intended product each time. A printer that is itself a defective product, has parts that fail frequently, or cannot print a consistently quality product are some of the possible risks arising from the print hardware.

Risk Mitigation

Any stakeholder in the supply chain of a 3D printed product should approach the risks outlined above with the assumption that courts and claimants may take an expansive approach to allocating liability and they should plan accordingly. This may start with an assessment of the risks and benefits of the type of FDA approval. For some manufacturers, seeking exemption of FDA approval or pushing for clearance via the 510(k) process may be the most appropriate option. But others may do better to mitigate risk by seeking the more rigorous premarket approval (PMA), which brings with it the possibility of preempting certain types of claims. Document retention policies for any items concerning the design, testing, and regulatory submission and approval of 3D printed products should have parameters that span the lifetime of both the product and any possible claims.

Next, participants at various stages of the process might consider the establishment of quality control mechanisms and protocols specific to 3D printed products, taking into account the specific risks that may arise from the production process. Participants should consider their exposure while the product is in their control but should also consider the risks they may face after the product leaves their control and before it reaches the ultimate customer. These risks may include alteration of software or any aspect of the device. Input materials should be specified and, to the extent possible, the suppliers regularly qualified and verified. Obviously, all participants should take careful note of the FDA's Draft Guidance and stay informed of any relevant guidance promulgated by the FDA. Stakeholders should consider whether they may want to offer or require regular training on the use of their product to prevent misuse or alteration by entities unaccustomed to the manufacturing process.

Participants in this market who are involved with products that lack clear distinguishing characteristics, should consider adding identifying markers to the product that will allow their product to be differentiated from a competitor's. This might include an identifier at the CAD file level that prints a mark on each product, or a printer that will leave a microscopic marker on each product it prints. Participants should also ensure creation of digital rights management processes or other procedures to prevent unauthorized software sharing and create adequate statements

noting that the file or programs are protected intellectual property. The software design file should be unique for each customer and have a testing process to ensure that the final product accurately follows the original design of the product. Participants in the manufacture of a product that could conceivably face a possibility for recall (including a recall of the design files) should consider how they will track purchasers or users of software, printers, or 3D printed products so that recalls, if needed, can be quickly and efficiently implemented.

Participants at all stages of the manufacturing process should also consider contractual indemnification from both upstream and downstream participants, to safeguard themselves against liability for an error that occurred before they became involved with the product—such as a CAD file error—or an error that occurred after their involvement—such as misuse of a printer. Finally, each stakeholder should proactively engage with its insurers to fully account for the unique risks posed by 3D printed products.

Insurance

Products Completed Operations

In the area of 3D printing products liability claims may present the highest risk for manufacturers. An added issue for the insurance analysis will be the additional parties involved in the manufacturing and distribution of 3D printed products that could lead to a potential apportionment of liability among various parties. Some of these parties may be small companies or individuals with limited resources—which means the manufacturer could get stuck with other defendants' portion of a judgment under principles of joint and several liability.

Traditionally, products completed operations (PCO) coverage for life science industry manufacturers responds well to claims associated with these entities, in part due to the existing regulatory framework and oversight by the FDA. But 3D printing could present unique manufacturing defect claims as well as some unique defenses. In situations in which the product is 3D printed and sold by the recognized manufacturer, the typical product liability policy would likely respond to traditional product liability claims, such as manufacturing defect claims; design defect claims; and a failure to warn claims. Therefore, the question for insurance purposes then becomes whether 3D printing is truly different from other manufacturing processes? Most likely the answer would be, no. However, 3D printing is a new technology and because there is limited case law to date, it could give rise to other unique situations. For example, a manufacturer could purchase CAD software, sell the product's design, which could then be resold through a CAD file by one party, sold for downloading and printing by another, and then ultimately printed by an end user, possibly exposing all of these parties to product liability claims. This kind of situation would require identification of all the parties in the product's manufacturing process, analysis of each party's contribution to the end product, and apportionment of any liability among the parties.

In sum, if a product liability lawsuit is filed, who faces liability will depend on the respective role and contribution of each party to the end product. This will be a challenge for parties when seeking enforcement of contribution or contemplating subrogation. Companies using 3D printing in their manufacturing processes would be well served by requiring each company involved to address liability exposures contractually and to also secure their own product liability insurance protection.

Conclusion

3D printed drugs and medical devices present enormous promise for healthcare, and the recent explosion of the 3D printing industry may be a watershed moment for both medicine and manufacturing. But the highly democratic and unorthodox nature of the production processes for these products presents new challenges for regulatory agencies and courts, as well as uncertainties regarding risk and liability for many involved in the chain of distribution of a 3D printed product. And these uncertainties now may extend to entities that were not traditionally exposed to product liability risks, such as software designers and even health care providers who ultimately create the product for an end user. Facing such uncertainty and fluidity in both regulation and risk exposure, any entity moving into this industry should work to stay current on all regulation and proposed regulation, consider those risks that have been identified, and work with insurers and risk managers to limit their exposure through a combination of insurance and best practices.

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