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3D Printing Medical Devices and the Disruption of Product Liability Law and Regulation

I. 3D printing and its development in the medical device sector

What is 3D printing?

3D printing is a relatively new form of manufacturing called "additive manufacturing" that has been around since the 1980s. It is a more efficient way to manufacture products because there is little waste. And because the process does not involve molds or assembly, this manufacturing process is ideal for customization.

To 3D "print" a product one needs a 3D printer, the raw materials (usually plastic or metal – but it can be many other types of material), and a computer aided design ("CAD") file which tells the printer how the materials are to be organized into whatever shape is desired. If customization is required, an image file can be used to further customize the printing of a product to a specification.

While efficiency and customization advantages are certainly useful aspects of this process, the most interesting aspect of 3D printing for our purposes is the effective democratization of the manufacturing process. 3D printers and 3D printing break down the traditional barriers to the manufacturing process, which previously required large sums of capital and equipment. Now armed with a 3D printer (and the prices are coming down), the raw materials and the CAD file, just about anyone can manufacture a product, including for our purposes, a medical device.

Medical Devices we are already manufacturing using this process.

There are a host of different types of medical devices currently being printed. These include surgical instruments, anatomical modeling devices, prosthetics, implants, wearables, and even human tissue and organs, using a process called "bio printing."

The cost of 3D printing surgical instruments is a fraction of the cost of traditional manufacture. Moreover, 3D printing allows for the creation of shapes that were previously unavailable in the normal manufacturing process. This has allowed doctors to create new types of surgical

instruments as well as anatomical models of human anatomy for use in planning for and even engaging in test runs on complex surgeries.

3D printing has led to the cost efficient and customizable manufacture of prosthetics and implants the neatly fit into the anatomy of a patient. The manufacturing process is quite adept and allows for the building of a medical device around a sensor without the cost of assembly in the manufacturing of wearable devices.

Perhaps the most promising medical devices already being printed, with more types on the horizon, is the "printing" of human tissue, skin, bone and even organs. This process holds the promise of using a person's own cells to print a new kidney, liver, or heart, which would avoid rejection and eliminate the heart breaking need to wait for a human donor for a much-needed organ. Earlier this year, scientists successfully 3D printed a human heart. Within a generation, we will hopefully see regular printing and implantation of human organs into human patients.

The key players involved in 3D printing medical devices.

There are several different groups involved in 3D printing right now. These include traditional medical device manufacturers who see the advantages of efficiency and customization, and therefore, are using this process to augment, supplement or even replace traditional manufacturing processes.

Hospitals and doctors are also printing these medical devices themselves and then using them on patients. Most major hospital systems now have 3D printing capabilities, and they are saving money by printing medical devices instead of buying them. Moreover, their own need for customization and efficiency is driving the use of the 3D printing process for these point of service users. Third parties are also presenting hospitals and doctors with the opportunity to use their facilities (for a fee) to manufacture medical devices used in patient care. It is the manufacture and use of 3D printed medical devices at the point service by hospitals and doctors that is the focus of this presentation.

II. The disruption of the traditional FDA regulation of medical devices caused by 3D printing

The traditional pathway to design, manufacture, and sale of medical devices

Under normal circumstances, a medical device is designed and manufactured by a company that then distributes the device through a distribution network to the ultimate users (doctors, hospitals, or patients). To sell these medical devices, the traditional manufacturer must secure "clearance" or "approval" from the FDA to do so. This is done either through a rigorous premarket approval ("PMA") process or a slightly less rigorous 510K process.

The FDA regulatory pathway is dependent upon the type of medical device to be sold and is based on risk. Class 1 devices, such as bandages, handheld surgical instruments, or gloves are considered lowest risk and have the fewest controls. Class 2 devices (such as many implants, some infusion pumps, needles, and powered wheelchairs) require greater scrutiny, but generally use the 510K clearance process. Class 3 devices, the highest risk category, are generally needed

to support human life (heart valves, pacemakers, or defibrillators) and therefore require the most scrutiny. These products undergo the PMA process and are FDA approved for sale.

Many devices are cleared through the 510K process which requires that the device be substantially equivalent to an already cleared and marketed device to be sold in the United States. To date, the FDA has cleared dozens of 3D printed medical devices through the 510K process. However, it has only done so with respect to applications made by traditional manufacturers who have adopted 3D printing into their normal manufacturing process. It is important to note that FDA does not clear/approve materials or manufacturing processes – but rather the medical device constructed via these methods for its intended use and user population.

For all cleared medical devices, manufacturers must follow good manufacturing practices and other statutory and regulatory requirements (pre- and post-market), which the FDA oversees. In the case of approved devices, a company's quality system and manufacturing data are reviewed and inspected prior to approval.

The FDA's regulatory response to far

The FDA issued a "leapfrog" guidance regarding 3D printing of medical devices in December 2017. This is the last official statement by the FDA regarding 3D printing of medical devices. The guidance provides that 3D printing by traditional manufacturers must follow the traditional regulatory requirements. They must follow all statutory and regulatory requirements for good manufacturing and processing of medical devices. The guidance says nothing specific to point of service 3D printing and use of medical devices. FDA guidance also states that the ideas set forth represent "current thinking" of the FDA and are non-binding recommendations which may be subject to change.

Point of Service 3D printing and use of medical devices will disrupt this process.

Since the regulatory process outlined by the FDA is focused on the sale of medical devices by traditional manufacturers, what are the regulatory requirements for medical devices that are not sold, but instead are manufactured and used at the point of service? There is no clear answer to this question. Will they be governed by the practice of medicine? Will a unique, new, and innovative pathway for these products be developed?

One of the key values of 3D printing is the fact that almost anyone can manufacture a product themselves. Most advanced printers permit the creation of more advanced products, even medical devices by persons who can then use them without going through any type of sales process.

Since doctors and hospitals are currently manufacturing and using medical devices, effectively outside of the regulatory and statutory requirements that focus on the sale of medical devices, and the FDA is almost certainly aware this is happening, one must assume that the FDA has determined that the point of service manufacture and use of medical devices falls outside the scope of its purview. Most likely (although this has never been clearly articulated by the FDA),

the FDA views the manufacture and use of a medical device by a hospital or doctor to be the "practice of medicine," which is to be regulated by the local medical boards, and not the FDA.

III. The disruption of product liability law caused by 3D printing and what this means for the future of product liability of point of service manufacturers and users of 3D printed

The traditional product liability strict liability standard

Most product liability lawsuits lead with a strict liability claim against the product designer/ manufacturer. Strict liability is typically the easiest cause of action to prove against a product seller because the elements to be proven are simply that the product is defective in some way and that this defect caused an injury.

Negligence is often pleaded as well. However, negligence carries a higher burden for a plaintiff. A plaintiff must often prove a duty and breach of a duty, which usually includes attention to a standard of care that defendant must exercise in their operations. Proving negligence requires an exploration of the inner processes of a defendant to find out "what happened." It also requires that the defendant breach a duty to the plaintiff.

Strict liability only requires proof that the product was defective and so the focus is on the product. A defendant need not have done anything "wrong" to be liable in strict liability for a defective product.

The law of most states allows a product manufacturer to be sued in strict liability for a defective product. Three different types of defects are typically at issue: (1) a design defect; (2) a manufacturing defect; and/or (3) a defective warning to the user. Like the FDA regulations, the focus is on the sale the product. Anyone within the stream of commerce, including the manufacturer, distributor or retailer is subject to potential strict liability for a defective product (again, regardless of any "wrongdoing" on the part of the defendant).

In general, the reason for strict liability as an available cause of action stems from the fact that an injured person should not have to figure out why the product failed or who is at fault. If the product failed or the warning was deficient, this is enough. It is also clear that if the product fails – liability will generally lie with the manufacturer or designer of the product, who will usually protect downstream sellers.

How the traditional strict liability standard falls apart in the face of point of service manufacture and use of medical devices.

In the 3D printing process – the use of the strict liability standard for a defective medical device falls apart. This is because the responsibilities for a product which was once centralized into a single designer/manufacturer and downstream sellers, has now been decentralized into a many different and diverse actors, any one of which could be the cause of a defective 3D printed medical device.

The list of potential causes of a defective 3D printed medical device – manufactured and used at a point of service – might include (1) the predicate device designer if the predicate device was

defectively designed; (2) the CAD file designer mistake; (3) a corruption of the CAD file with many possible sources – or no source; (4) a mistake in the copying, sharing or uploading of a CAD file – particularly for an open sourced CAD file; (5) a defect in the 3D printer; (6) a defect in the raw materials; (7) human error in the printing process; (8) human error in the post-production process; (9) human error in the implementation of the digital design or in the image scanning – for a custom device; or (10) some error in the warnings associated with the device. This is not a complete list of those who might be responsible for a defective 3D printed device, but it underscores the diverse nature of those who might be "at fault" if a 3D printed device fails.

Given the diversity of this list and those who might be responsible for a defective medical device, the reasons for holding any one person identified above (or all of them) strictly liable for the defect in the medical device no longer exist. It is not clear or obvious who is at fault or who should be held responsible for the fact that the device has failed. For example, it would be unjust to hold the printer manufacturer strictly liable for a defectively printed medical device. If that were the case, no one would be able to manufacture 3D printers. Similarly, if the cause of the defect was the corruption of a CAD file, and it is not clear how it came to be corrupted, holding the entire group strictly liable does not make any sense.

What liability standard is likely to emerge in the face of 3D printing of medical devices by hospitals and doctors?

In the face of this disruption, we will likely see a strong push to abandon the strict liability standard as a basis for liability for those involved in the point of service manufacturing and use of medical devices. This would mean a return to a negligence standard in these circumstances. Given the fact that the FDA is likely to find the manufacture and use by hospitals and doctors of 3D printed medical devices to be the practice of medicine – a return to a negligence standard seems to make a lot of sense.

There is presently no legal precedent on what standard will be used. This will be a significant source of contention between plaintiffs (who will want to keep the strict liability standard) and defendants (who will advocate for its abandonment in these circumstances).

IV. Open questions presented by 3D printing of medical devices

There are several open questions that will have to be resolved by the courts in the coming years. These include, "who is a manufacturer?" when a medical device is manufactured by a hospital or doctor. Is it the hospital which owns the printer or someone else?

Who is the designer of the product? Is it the predicate device designer, the CAD file designer, the printing doctor who incorporates a patient specific image, or someone else?

What is the "product" for a product liability claim – especially for a strict liability cause of action? Is it the printed medical device, the 3D printer, the CAD file, or something else?

Should a 3D printed device come with a warning? If so, who is responsible for that warning – the CAD designer, the person who printed the device, someone else?

The law is very thin in answering these questions.

V. Risk management solutions

Given the uncertainties surrounding the 3D printing of medical devices, but the fact that this is already a billion-dollar business, what can policyholders and insurers do to protect themselves from this risk? We will discuss several options:

- Identify the risks associated with a particular operation.
- Look to emerging industry standards for 3D printing, particularly in the absence of FDA regulation.
- Employment of "use restrictions" particularly on CAD files and 3D printers.
- Non-traditional manufacturers may need to diversify their insurance.
- More attention may be given to indemnity/hold harmless agreements between the various players.
- Close following of regulatory and legal developments; and
- Knowledge of the heightened risks associated with point of service manufacturing, use and sale of medical devices to third parties (this is happening).