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Ran in Pharmaceutical Manufacturing in October 2016

Three Big Risks in 3D Printing Pharmaceuticals

Are the risks of leveraging this new technology outweighing the benefits for drug makers?

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Since 3D printing emerged, the technology has been used to create everything from construction materials and automobile parts to cheeseburgers and sneakers.

3D printing has enormous potential across industries, and one of the most transformative applications has been in the medical field. The technology has been used to create prosthetic limbs, body tissue, dental restorations and more. In fact, as of December 2015 the FDA had cleared more than 85 3D-printed medical devices.

But one of the latest medical applications – 3D printed pharmaceuticals – has called into question whether the risks of leveraging this new technology outweigh the benefits for drug makers.

Manufacturing pharmaceuticals has been part of the 3D printing discussion for years, but it wasn't until Aprecia Pharmaceuticals won the first 3D printed drug approval in 2015 that it became evident the FDA was willing to play in this space. Aprecia's product, a tablet used to treat epilepsy, used a new process to make the medicine easier to consume – a significant advancement for patients suffering from seizures.

With this first drug now on the market, the future of pharmaceutical manufacturing could be poised to change dramatically. In the case of Aprecia, the 3D printing process is still controlled at the manufacturer level for now. But at some point pharmaceutical companies could transfer the creation process to pharmacies, hospitals and physicians with 3D printers, even leading to individualized treatment plans for patients.

While this technology holds great promise, it brings with it a number of risks. The use and abuse of 3D-printed drugs has been the subject of discussion and debate among pharma execs, insurers and the legal community – but the fact of the matter is, we've only scratched the surface of the complex risk landscape.

While there are many unknowns, three major risk areas should be part of the conversation.

1. Product Liability Risk

Common sense tells us that if a pharmaceutical company licenses its blueprint to pharmacies or healthcare providers to print drugs locally, it cannot possibly oversee the efficacy of every 3D printing operation. But it still needs to consider the potential product liability implications. Based on its role in providing the product blueprint alone, the firm may be partially responsible if an adverse incident or product defect claim arises.

In fact, parties across the manufacturing spectrum could be liable for the fallout. This might also include the printer manufacturer, the software designer, the material suppliers and the product manufacturer.

There is no litigation in this area yet, and therefore no precedent – so it's unclear which parties will be most susceptible to product liability claims. Pharmaceutical companies venturing into 3D printing should develop a strategy for licensing their blueprints to ensure they're financially and legally protected. The first conversations should include their lawyers and insurance brokers.

2. Cyber Risk

The proliferation of counterfeit medicines is perhaps the industry's greatest concern with 3D printing. Printers are much more vulnerable to hackers than traditional manufacturing processes, and the incredibly short production time magnifies the risk of counterfeits.

For example, a hacker gaining access to a drug maker's proprietary blueprint could bring the instructions to a manufacturing plant overseas to mass produce the drug. This exploitation of intellectual property could have a significant impact on a company's bottom line. Plus, improperly made drugs may go to market and cause harm to patients – hitting the company's financials and reputation.

Another concern is hackers making alterations to a drug's recipe or doses within a hospital or pharmacy where it's printed, leading to severe health consequences for patients.

While pharmaceutical companies can begin to protect themselves by adding tracer elements and watermarks to their formulations, they should also revisit their insurance policy to understand if – and to what extent – they're covered for a cyber breach.

3. The Safety and Efficacy of 3D Printers

Traditional mass-manufacturing facilities are subject to intense oversight from regulatory bodies, which keeps products safer and provides solace to the insurers who cover them. However, the FDA cannot regulate every instance of 3D printing, so determining the safety of products developed and responsibility for adverse events is a murky area.

The idea of individualized medicine – whereby a patient's age, weight, race or organ function could inform doses and production – has captivated medical community since 3D printing became a reality. But the possibility of a printer defect or manufacturing malfunction remains a concern, as does placing responsibility for such an incident.

Importantly, 3D printing manufacturers must be diligent about vetting their suppliers, as contaminated or defective materials may yield a faulty product and pose an even larger threat than the printers themselves.

Recommendations

3D printing technology has the potential to open doors in product development, manufacturing and distribution for pharmaceutical companies. It could help fulfill the promise of personalized medicine, a concept that is growing in popularity within the industry.

For a firm considering a future in 3D printing, understanding risk exposures should be one of the first steps in determining whether it's a worthwhile investment. Pharmaceutical companies should work closely with their IT and manufacturing colleagues to understand the risks, and then tap into insurance experts, their broker and underwriters to ensure that insurance coverage is properly crafted to address these three – and likely many other – risk exposures.

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