FDA Technical Guidelines on 3D-Printed Machines Provides Clarity to Pharmaceutical Manufacturers

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Last year, we shared a white paper which outlined three major risks associated with 3D printing in the Life Sciences space. In our paper, we noted the enormous potential for 3D printing to revolutionize the industry. However, we also knew it was important to point out the many uncertainties and exposures that companies looking to pursue 3D-printed drugs and medical devices might face with this pioneering technology. At least two of the risks we outlined previously are included in the FDA's first ever guidance for pharmaceutical manufacturers using 3D-printed technology.

That full guidance can be found here.

As we shared in our previous paper, "the FDA cannot regulate every instance of 3D printing, so determining the safety of products developed and responsibility for adverse events is murky." While that remains true, the technical guidelines begin to provide some detail around the expectations of the FDA with respect to safety. It clarifies recommendations related to 3D manufacturers' submission requirements as well as the agency's thought process on "various approaches to 3D printing, including device design, testing of products for function and durability, and quality system requirements."

The guidelines also address cybersecurity. While the issue is only briefly covered, it makes clear that manufacturers will be responsible for ensuring the protection of PII, PHI, and other patient related information.

There is still much for the FDA and the industry to learn and understand with the rapidly advancing 3D Printing and Additive Manufacturing. As noted in its statement yesterday, the new guidelines are "only intended to provide the FDA's initial thoughts on an emerging technology with the understanding that our recommendations are likely to evolve as the technology develops in unexpected ways."

What is clear, however, is that the risks we have been discussing must continue to remain central in any risk management or insurance plan.

From an insurance perspective, the guidance provides a framework for mitigating certain insurable risks. Underwriters of product liability and other available insurances for Additive Manufacturing Processes will no doubt evaluate an insured's risk management practices and knowledge of

advanced technology when differentiating companies and pricing their products. We suggest you work closely with your broker to “tell your story” to the underwriters to ensure you have best in class terms and conditions.

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