Nutter insights

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3D Printing: Health Care Miracle, Product Liability Nightmare, or Both?

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Q How is 3D printing revolutionizing health care?

A: 3D printing has the potential to dramatically change the way health care is delivered. The U.S. Food and Drug Administration (FDA) has already approved the use of 3D printing in the pharmaceutical space. The technology is being used to bind together layers of powder with aqueous fluid to create pills that dissolve with just a drop of water, delivering medications quickly and effortlessly.

3D printing is also changing the way medical professionals deliver prosthetic care, like hip and knee replacements. In the very near future, physicians will be able to design and produce customized medical devices to satisfy the immediate needs of their patients using on-site printers. Not only will hospitals and other providers be equipped to print using metal or plastic, they will be able to "bioprint." Bioprinting involves layering cells, sometimes using a dissolvable scaffold, to form human tissue or organs. Patients around the globe already have successfully received 3D printed jawbones, dental implants, and ears. Although the challenges posed by printing complex human organs are great, bladder, skin, and liver prototypes have already been developed.

Q How will the FDA regulate 3D manufactured medical devices?

A: The FDA recently released "leap-frog" guidance for medical device manufacturers aimed at giving the industry a sense of their initial thinking. The FDA suggested that, at least preliminarily, 3D printed devices and products will be required to follow the same regulatory requirements as their non-3D printed counterparts. However, it also stressed that because of the unprecedented levels of product customization available through 3D printing, manufacturers and firms should engage with the FDA's pre-submission process before going to market.

Q Health care delivery is always fraught with challenges. Which entities will face liability if a 3D printed solution fails?

A: Liability remains a somewhat open question, because 3D printing is both relatively novel and extremely intricate. It's likely that at first courts will try to apply the same theories of liability used to evaluate tangible things produced using traditional manufacturing processes—by examining the design, manufacture, and distribution of the defective product.

However, 3D printing turns the traditional manufacturing process on its head. Is the "manufacturer" the person or entity that designs and emails a CAD file? Or is it the person who downloads and prints it? Is the "product" the pharmaceutical or medical device, or is it the CAD file itself? The rationale supporting the traditional products liability regime relies on the economic power of the commercial sellers and manufacturers as a justification for fixing them with liability. As courts begin to address these types of questions, they will have to grapple with the interesting issues raised by shoehorning new technology into an old legal framework.

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