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3-D Printing and the Regulatory Future of Home Remedies: Pharma to Table

Article By:

Ross Campbell

Last August, the U.S. Food & Drug Administration ("FDA") approved its first drug produced by additive manufacturing or "3-D printing," the epilepsy medication *Spritam levetiracetam*.[i] While this technology has a certain futuristic sheen, the decision to green-light Spritam was fairly traditional. A company wanted to market a drug and the FDA required the usual proof of safety, efficacy, and good manufacturing practices per its "new drug application" procedure ("NDA").[ii] Making pills by layering rather than tableting did not overwhelm this analysis.

For now, this nod makes speculation over the regulation of the technology seem overwrought. While the agency recently conducted a workshop on 3-D printing, and suggested it will soon issue relevant guidance, it appears to be in no rush—the subject was dropped from its 2016 Guidance Agenda entirely. If this latest approval is any indication, the FDA will likely continue to address different aspects of this technology piecemeal as new applications come in.

Lingering questions still abound. Who is the "manufacturer" of a 3-D printed drug—the designer of its digital algorithm or the one who ultimately prints? This has implications where hospitals and pharmacies attempt to use this technology rather than rely on old distribution methods. Further, should these algorithms be strictly monitored or 3-D printers have built-in safeguards? Certain precautions may be necessary to prevent the hacking or unauthorized alteration of these files. If dose can be calibrated to the individual, it can become dangerously so.

In any event, it is not even clear how much the regulatory response to these questions matter. Where this technology holds the most promise to disrupt the pharmaceutical industry, agencies like the FDA may have the least to say. When users take 3-D printers and make drugs at home, the traditional approval process for new drugs may be inadequate—or even inapplicable. This essay touches on some of the core regulatory issues offered by this pairing (3-D Printing & Home Remedies), and offers suggestions from product liability cases and online piracy to help protect consumers.

3-D Printing is Close to Home

The day is not far off where 3-D printers become an ordinary household appliance. Already, improvements in price and performance have made them a hot gadget for the tech cognoscenti, who

are printing lamps, musical instruments, and even clothing in the comfort of their own homes. It is not hard to imagine the same with drugs. Indeed, some are actively working on making this a new normal.

Professor Lee Cronin, a leading medical researcher in this field, recently described how homebodies will soon be able to download online "recipes" for drugs—much like consulting a cookbook—and program their 3-D printers to make pills.[iii] To prove his point, Professor Cronin plans to construct and release a "chemputer" within the next five to ten years that is capable of printing pharmaceuticals from a universal chemical ink.[iv]

3-D printing thus creates new possibilities (rather than mere fancies) for self-medication. Using websites like *Thingiverse*,[v] anyone with a 3-D printer and the proper materials could conceivably fashion top-grade pharmaceuticals—a notion until now limited by the complexity of these drugs and the need for specialized knowledge and equipment. Perhaps more importantly, the legal space here currently resembles a vacuum, leaving only the market to dictate standards.

Regulators can try to keep pace. Even now lawmakers are struggling with the problem of 3-D printed guns. Efforts to ban them outright have been sluggish.[vi] The anonymity of the internet and cherished privacy of the home also pose significant hurdles of detection.[vii] With 3-D printed drugs, similar side-effects may occur.

Drug Distribution or Taste of Own Medicine?

There is real intrigue for the pairing of 3-D printing and home remedies. It is not clear who has regulatory authority here. The FDA and similar agencies are not often in the business of guarding what people can make in their own homes. So long as these pills are not of the illicit variety,[viii] it also seems difficult to articulate the public interest against people printing their own medicine, apart from those generalized concerns typical to DIY projects. People will probably always find ingenious ways to harm themselves with ordinary household ingredients. Further, the difference between following a recipe 'to the dot' and printing medicine using an algorithm is not quite obvious, at least as a matter of law.

Aside from the question of agency (who is the manufacturer?), more basic problems need sorting. Specifically, the usual cop on the beat—the FDA—may not be able to reach this technology at all.

A "drug" is first defined as an "article" for purposes of FDA jurisdiction.[ix] In the context of 3-D printing, it would feel strained to insist that a digital algorithm—or pure information—fits this description.[x] The word "article," if anything, seems to demand a material object. Therefore the regulatory issue could be stated: when a consumer goes online, downloads an algorithm, and prints pills—has there been a distribution of material *drugs* or simply an exchange of *information*?

Product liability cases may be instructive here. Courts have been reluctant to define information contained in books and videogames as a "product" for purposes of strict liability.[xi] However, a court has found that a navigational chart—something perhaps more closely resembling the technical detail found in an algorithm—can qualify.[xii]

If these cases could be harmonized, they might suggest that while information is ordinarily not a "product," it may nevertheless become so where consumers exercise little discretion in how it is used. (Or—is it more like a helpful *tip* or a strict *command*?) Therefore, at least in civil litigation, a

similar analysis may lead courts to find that digital algorithms used to print drugs are actually products because they resemble navigational charts more than books, especially where they automatically program printers with limited input from users.

This analogy may nevertheless not settle the question for FDA jurisdiction. "Articles," unlike products, could be said to exist in their own right—regardless of context. In other words, while information may turn into a product for purposes of strict liability depending on its use or level of consumer involvement, it does not necessarily become an article—something that is often understood in more objective terms. Again recalling the navigational chart, one could easily argue in good faith that its data—no way and no how—is a material object (or 'article'), while still admitting that legal alchemy may transmute it into a product when it harms users. Perhaps a more futurist Congress would have anticipated this problem and chosen a more accommodating word to define "drug."

This exercise in semantics hopefully at least demonstrates the regulatory gap offered by this technology. The key is that existing FDA jurisdiction is not a given for regulating 3-D printing in the home.

Perhaps other theories could find more purchase. As an alternative, the agency could plausibly target the raw materials used in 3-D printing as drug "components,"[xiii] though they must be "intended for [such] use."[xiv] When upgraded 3-D printers print a wide variety of objects from a basic stock of elementary materials—from pills to pacemakers—even this theory could eventually come short, as there may be no single intended use for such ingredients.

Finally, if regulators sought to restrict the sharing and use of drug algorithms, First Amendment concerns over the free spread of information should arise. For example, in rejecting liability for a failure to warn in cookbooks, courts have felt the need to explain how "ideas hold a privileged position in our society . . . . [and] are not equivalent to commercial products,"[xv] and have even felt "the gentle tug of the First Amendment and the values embodied therein" where a publisher was sued for their faulty description of wild mushrooms.[xvi] If such *ex post* attempts to expunge bad information seem awkward in the courtroom, *ex ante* efforts to restrict it may also be scrutinized.

Cloudy Market For Unapproved Drugs

It is also unclear how pharmaceutical companies who only offer digital algorithms should fare under current law. Whereas a new drug would ordinarily go through a series of regulatory hoops before it could be marketed for consumption, the steady proliferation of additive manufacturing offers a potential end run around this process.

The primary question would likely be whether these companies are ultimately marketing an algorithm or drugs, albeit indirectly. Alternative promotional techniques could create further wrinkles, such as a fremium software that allows users to print samples of unapproved drugs in their homes—drumming up demand—and introducing what these companies hope to get approved for ordinary markets.

With these vagaries in mind, new statutory or regulatory guidance appears necessary. Existing civil liability mechanisms may not be up to the task of managing this new relationship between designers and consumers—for instance, Professor Nora Engstrom has remarked that if "home 3-D printing really does take off, [product liability] litigation as we know it may, in large measure, dry up."[xvii]

Lessons From Online Piracy

This all brings to mind other attempts at control and prohibition in the information age. The digital market in illicit drugs is already a keen concern for police, with websites like the *Silk Road* providing a case study of drug deals fostered by the anonymity and hydra-headed quality of the internet.[xviii] The prospect of these transactions happening almost instantaneously—from click, to print, to dose—ups the ante, and offers challenges of prevention and detection familiar to the illegal downloading of copyrighted material.[xix]

Online piracy offers perhaps the best foreword to 3-D printed drugs. Just as a computer is a sophisticated device that can snatch data and produce a movie or Beatles album, a 3-D printer can do much the same with solid objects. This is no small irony considering the Motion Picture Association's infamous tin ear when it claimed that pirating films was the same as stealing cars.[xx]

Similar to the largely failed attempts to restrict file sharing, the prohibition model also seems unlikely to make headway against digital drug transactions (barring serious incursions into personal privacy). Overall it may be accurate to claim that fundamental changes are in the air, and that attempting to control how people access printable goods, like general access to data, is merely tilting at windmills.[xxi]

An Opportunity for FDA Leadership

Maybe the analogy to online piracy is not completely apt. Ordinary people may not print drugs with the same "devil may care" attitude they have for copying media. They should even welcome an online referee of sorts. Certainly, many would probably want assurance from a familiar authority figure that they are printing ibuprofen rather than cyanide.

Certification and regulation of online pharmaceutical companies therefore seems promising despite the usual difficulty of controlling file sharing, and companies may welcome oversight in this market.[xxii]

The time is ripe for such leadership. The great benefits of this technology, such as the convenience and customizability of 3-D printed drugs may be nurtured by guidance, while the dangers, such as file tampering and amateur online pharmacists, can be effectively headed off. The FDA seems ideal for the job. Given its relevant expertise and reputation, it should enter this market early and establish firm rules for distributing and marketing digital algorithms for drugs, even if their legal authority over this information is unclear.

Attempts to govern this technology should nonetheless come with humility. If the agency or other enforcers make requirements for online pharmaceuticals too onerous—or attempt to curtail and restrict this market altogether—it seems inevitable that some companies will offer their algorithms on digital black markets similar to the *Silk Road*. The FDA could instead maintain credibility by conceding that people will inevitably use 3-D printers to make pills at home, and then signal an intent to keep these consumers safe by any means—short of stifling this technology with a knee-jerk or draconian response.

For starters, the FDA should publish relevant guidance on what algorithms it considers subject to its jurisdiction as a "drug," which party it considers to be a manufacturer, and how it intends to monitor the use of these files for sake of quality assurance. The variability in 3-D printers and raw materials used to print pharmaceuticals will probably offer distinct challenges, and some creativity will be required. Coordinating with the early adopters in this community should therefore be prioritized in

order to better understand where existing models fall short.

Despite these challenges, the FDA should be able to readily command and bolster a legitimate online market in 3-D printed drugs. The reputational power of FDA approval goes beyond its mandate, and uniquely situates it to encourage responsible use of this technology.[xxiii] Its current reactive approach could otherwise leave it scrambling.

While 3-D printing stands to dramatically alter access to pharmaceuticals, the demand for traditional signs of safety should remain steadfast. Trust will likely always be a prized commodity—even more so when the digital cloud takes form and enters the home. If the usual actors do not address this need, it will be curious who will.

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[i] As of March 22, 2016, Spritam became immediately available to the public. *See* Benedict, *First FDA-Approved, 3D Printed Spritam Drug for Epilepsy Now Available*, 3Ders (Mar. 22, 2016), http://www.3ders.org/articles/20160322-3d-printed-fda-approved-epilepsy-drug-spritam-now-available.html [https://perma.cc/ND36-XU5V].

[ii] *See* Maya M. Eckstein & Kyle Sampson, *How Will the FDA Regulate 3D Printing*, Inside Counsel (Mar. 9, 2016), http://www.insidecounsel.com/2016/03/09/how-will-the-fda-regulate-3d-printing [https://perma.cc/HA9T-HWDS]. For an overview of the NDA approval process, see *New Drug Application (NDA)*, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/ [https://perma.cc/X8BM-MWBE].

[iii] *See* Oliver Wainright, *The First 3D-printed Pill Opens up a World of Downloadable Medicine*, Guardian (Aug. 5, 2015), http://www.theguardian.com/artanddesign/architecture-design-blog/2015/aug/05/the-first-3d-printed-pill-opens-up-a-world-of-downloadable-medicine [https://perma.cc/EDN4-4SZP].

[iv] *See* Bryan Le, *3D Printing Could Revolutionize Drugs*, The Fix (July 26, 2013), https://www.thefix.com/content/we-could-soon-3d-print-drugs-home91839 [https://perma.cc/G5Z7-4P8Q].

[v] An online bazaar for 3D printer blueprints licensed under a Creative Commons license.

[vi] *See* Burgess Everett, *Senate Passes Legislation on Undetectable Guns,* Politico (Dec. 9, 2013), http://www.politico.com/story/2013/12/senate-gun-safety-legislation-100906.html [https://perma.cc/SYC7-2TGG] ("Republicans and the NRA accepted an extension of UFA [Undetectable Firearms Act], but pushed back against legislation that would have required guns to have permanent metal pieces in them, intended to guard against the manufacture of arms on 3-D printers.").

[vii] *See* Andy Greenberg, *State Department Demands Takedown of 3D-Printable Gun Files for Possible Export Control Violations,* Forbes (May 9, 2013), http://www.forbes.com/sites/andygreenberg/2013/05/09/state-department-demands-takedown-of-3d-printable-gun-for-possible-export-control-violation/#78d738cb3fb7 [https://perma.cc/DW2C-2925] (discussing how gun blueprints have been uploaded to the file-sharing website Pirate Bay, effectively skirting restrictions).

[viii] Prohibitions against the manufacture or possession of controlled substances seem readily applicable to 3-D printing.

[ix] *See* 21 U.S.C.§ 321(g)(1) (2012).

[x] *Cf.* 3 Raymond T. Nimmer, The Law of Computer Technology § 12:31, at 12–78 (4th ed. 2013) (observing that "whether computer software qualifies as a tangible 'product'" has been mostly "unaddressed in modern case law").

[xi] *See* Winter v. G.P. Putnam's Sons, 938 F.2d 1033, 1034–36 (9th Cir. 1991) (declining "to expand products liability law to embrace the ideas and expression in a book"); *see also* Sanders v. Acclaim Entm't, Inc., 188 F. Supp. 2d 1264, 1277–79 (D. Colo. 2002) (noting how "intangible thoughts, ideas, and expressive content are not 'products' as contemplated by strict liability doctrine").

[xii] *See* Aetna Cas. & Sur. Co. v. Jeppesen & Co., 642 F.2d 339, 341–43 (9th Cir. 1981) (finding instrument approach chart to be a "defective product").

[xiii] 21 C.F.R.§ 210.3(b)(3) (2015) ("Component means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product."); 21 U.S.C.§321(g)(1) (2012) ("[Drugs are] articles intended for use as a *component* of any article . . . intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.") (emphasis added).

[xiv] *Id.*

[xv] Cardozo v. True, 342 So. 2d 1053, 1056–57 (Fla. Dist. Ct. App. 1977).

[xvi] Winter, 938 F.2d at 1037.

[xvii] Nora Freeman Engstrom, *3D Printing and Product Liability: Identifying the Obstacles*, 162 U. Pa. L. Rev. Online 35, 36 (2013). This article does an excellent job of laying out some of the difficulties in regulating 3-D printing under traditional frameworks—particularly the "tangible—intangible line" found in product liability cases. *Id.* at 39.

[xviii] For an excellent discussion on the *Silk Road*, see Joshuah Bearman, *Silk Road: The Untold Story*, Wired (May 23, 2015), http://www.wired.com/2015/05/silk-road-untold-story/ [https://perma.cc/7TYP-KMMA].

[xix] For a discussion of this problem*, see, e.g.*, Jamie Goodman, *3D Rx: The Future of Drug Manufacture and Delivery?*, Law in the Making (Feb. 19, 2013), http://lawitm.com/3d-rx-the-future-of-drug-manufacture-and-delivery/ [https://perma.cc/X342-QK4A] ("[T]here are valid concerns about the potential for 3D-printing to facilitate counterfeit pharmaceuticals and pill-form narcotics, which are already global problems.").

[xx] *See Piracy, It's a Crime*, Know Your Meme, http://knowyourmeme.com/memes/piracy-its-a-crime [https://perma.cc/V4S2-JFAJ].

[xxi] *Cf.* Victoria R. Graf, *A Hard Pill to Swallow: Viable Regulation of 3-D Printed Pharmaceuticals*, 25 Alb. L.J. Sci. & Tech. 593, 595 (2015) ("In the surging tsunami that is the digital revolution, attempts by the government and the pharmaceutical industry to stamp out the spread of 3-D printing will likely be futile.").

[xxii] For consumers, the certainty that online companies are *bona fide*, and for companies, a reliable source of customers and fair competition. Online piracy should also be less threatening to this business model—even with ready access to these algorithms on websites like Pirate Bay, many would likely still purchase them from a regulated, non-anonymous creator, out of fear of manipulation and for quality assurance.

[xxiii] *Cf.* Daniel Carpenter, *Reputation, Information and Confidence –The Political Economy of Pharmaceutical Regulation*, in Public Choice and Public Law (Daniel Farber & Anne Joseph O'Connell eds., 2010), *available at* http://www.healthpolicyfellows.org/pdfs/ReputationInformationandConfidencebyDanielCarpenter.pdf [https://perma.cc/4BWG-YLMZ] ("The regulatory power of the FDA stems from its reputation for scientific expertise and consumer protection.").

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