NOTE

A HARD PILL TO SWALLOW: VIABLE REGULATION OF 3-D PRINTED PHARMACEUTICALS

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I. INTRODUCTION

In less than twenty-five years, 3-D printed products have evolved from resin figures[1] to liver tissues.[2] Within the next five to ten years, Professor Lee Cronin plans to debut his pharmaceutical-printing 3-D "chemputer" on the consumer market.[3] What does this mean? 3-D printed drugs have the potential to provide the international community with the following benefits: containment of infectious disease epidemics by producing medications immediately at the source of the outbreak;[4] smaller carbon footprints from the shipment and storage of physical pharmaceuticals to consumers;[5] decreased costs associated with transporting drugs;[6] increased availability of medications in developing nations;[7] and one pill to replace

[1] In 1986, Charles Hull developed the first commercially available 3-D printer using the stereolithography (SLA) method, which produced 3-D resin models. Mark Fleming, *What Is 3D Printing? An Overview*, 3D PRINTER, http://www.3dprinter.net/reference/what-is-3d-printing (last visited May 20, 2015).

[2] In 2014, Organovo finished production of approximately four hundred 3-D printed liver tissues, and delivered them for testing for future use in human transplant procedures. *Organovo Delivers First 3D Printed Liver Tissue Ahead of Schedule*, 3DERS.ORG (Jan. 29, 2014), http://www.3ders.org/articles/20140129-organovo-delivers-first-3d-printed-liver-tissue-ahead-of-schedule.html?utm_source=twitterfeed&utm_medium=twitter.

[3] Bryan Le, *3D Printing Could Revolutionize Drugs*, THEFIX.COM (July 26, 2013), http://www.thefix.com/content/we-could-soon-3d-print-drugs-home91839.

[4] Lee Cronin, *Print Your Own Medicine*, TED.COM (June 2012), http://www.ted.com/talks/lee_cronin_print_your_own_medicine.html (envisioning that blueprints could be immediately sent to outbreak epicenters and mass printed quickly through "on the fly molecular assembly").

[5] Lisa Harouni, *A Primer on 3D Printing*, TED.COM (Nov. 2011), http://www.ted.com/talks/lisa_harouni_a_primer_on_3d_printing.html.

[6] 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/.

[7] Mark D. Symes et al., *Integrated 3D-Printed Reactionware for Chemical Synthesis and Analysis*, 4 NATURE CHEMISTRY 349, 349 (2012).

drug cocktails currently used to treat certain medical conditions.[8] However, despite the many potential benefits of 3-D printed pharmaceuticals,[9] this technology carries serious risks as well.[10] 3-D chemputers could provide criminals the means to print counterfeit pharmaceuticals and/or narcotics quickly and discreetly.[11] Additionally, unprecedented access to pharmaceutical components would make it easier for people to replicate a brand name drug manufacturer's product and produce patent-infringing counterfeit drugs.[12]

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.[13] As a result, there is a growing debate over how best to regulate this new technology in order to maximize the benefits to public health while mitigating the risk to public safety.[14] In the United States, this debate is fueled by the fact that the government may not be able to regulate the manufacture and distribution of 3-D printed drugs under current federal laws.[15] Moreover, lawmakers should

[8] *See* Goodman, *supra* note 6 (referring to synthetic organs, implants, and prosthetics); Cronin, *supra* note 4 (foreseeing pharmaceuticals that address individual needs down to the "cellular level").

[9] *See supra* notes 4–8 and accompanying text.

[10] *See, e.g.*, J.D. Tuccille, *Turn Your Desk into a Pharmaceuticals Factory*, REASON.COM (Aug. 29, 2013), http://reason.com/archives/2013/08/29/turn-your-office-into-a-pharmaceuticals ("3D printers have already raised interesting policy implications about the ability to control the production and possession of physical objects.").

[11] *See* Goodman, *supra* note 6 ("[T]here are valid concerns about the potential for 3D-printing to facilitate counterfeit pharmaceuticals and pill-form narcotics, which are already global problems.").

[12] *Id.*; Tim Adams, *The 'Chemputer' that Could Print Out Any Drug*, OBSERVER (July 21, 2012, 5:00 PM), http://www.theguardian.com/science/2012/jul/21/chemputer-that-prints-out-drugs (indicating that in the drug blueprint software, consumers would be provided the drug manufacturer's drug "recipe").

[13] *See* Thompson Wall, *How to Reign over the New 'Digital Economy,'* INC. (Jan. 22, 2015), http://www.inc.com/thompson-wall/how-to-reign-in-the-new-digital-economy.html ("[T]here's no stopping progress, and increasingly, the new economy revolves around technology, and what it means to be digital.").

[14] *See* Rick Kelly, *The Next Battle for Internet Freedom Could Be over 3D Printing*, TECHCRUNCH (Aug. 26, 2012), http://techcrunch.com/2012/08/26/the-next-battle-for-internet-freedom-could-be-over-3d-printing/ (arguing against regulatory interference by the government, specifically "any law that attempts to undermine freedom on the [I]nternet, no matter the consequences").

[15] *See* Daniel Harris Brean, *Asserting Patents to Combat Infringement via 3D Printing: It's No "Use,"* 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 771, 771 (2013) ("Under existing [patent] law, the distributors of digital representations of products are not 'making,' 'selling,' or 'using' the patented products or any 'component' thereof.").

acknowledge that this technology is on the horizon, and be proactive in addressing regulatory gaps and modifying statutes before 3-D printed drugs are introduced into the American consumer market. Proactively addressing regulatory deficiencies will allow consumers to share in the benefits of this revolutionary technology, while promoting the health and safety of the public.

This Note will explain how 3-D products are produced, detail how 3-D printers will be able to manufacture pharmaceuticals, outline the current U.S. pharmaceutical distribution chain, discuss ways 3-D printed drugs could alter the U.S. pharmaceutical distribution chain, examine the effectiveness of governmental attempts to regulate 3-D printed guns, analyze which parts of the current regulatory framework for pharmaceuticals would be helpful in regulating 3-D printed drugs, and articulate the measures that should be taken with regard to 3-D printed drugs in order to prevent and/or penalize misuse and to ensure public safety.

II. GENERAL BACKGROUND

3-D printing, also known as additive manufacturing, was invented by Chuck Hull over thirty years ago.[16] However, 3-D printers only became popular on the consumer market in the past few years; in 2013, Staples became the first major American retailer to offer 3-D printers—the "Cube" printer from 3-D Systems, priced at $1300.[17] Now that the technology is improving and the price of printers is going down, consumer demand for these printers is rapidly increasing.[18] Consumers can currently purchase a 3-D printer for as little as one hundred dollars.[19] Although the quality of 3-D printed products varies greatly

[16] Matthew Ponsford & Nick Glass, *'The Night I Invented 3D Printing,'* CNN (Feb. 14, 2014, 9:03 AM), http://www.cnn.com/2014/02/13/tech/innovation/the-night-i-invented-3d-printing-chuck-hall/; Harouni, *supra* note 5.

[17] Patrick Seitz, *Consumer Market for 3D Printers Put to Test at Staples*, INVESTOR'S BUS. DAILY (May 3, 2013, 12:50 PM), http://news.investors.com/technology-click/050313-654608-ddd-staples-team-to-sell-3d-printers-to-consumers.htm.

[18] Heather Kelly, *3-D Printing Tries to Find a Home*, CNN (Jan. 14, 2014, 9:11 AM), http://www.cnn.com/2014/01/14/tech/innovation/3d-printer-tech-ces/ (projecting the number of orders to grow by seventy-five percent in 2014, totaling over $133 million).

[19] This is a printer "tool kit" that requires assembly. Rinnovated Design, *The Peachy Printer—The First $100 3D Printer & Scanner!*, KICKSTARTER, https://www.kickstarter.com/projects/117421627/the-peachy-printer-the-first-100-3d-printer-and-sc (last visited May 20, 2015).

between different models, higher-end printers are able to quickly manufacture products so complex that they are incapable of being produced through any other method.[20] There are different types of additive manufacturing based on the materials used, but 3-D printers typically build plastic products using one of the following methods: vat photopolymerization;[21] powder bed fusion;[22] material jetting;[23] or material extrusion, such as fused deposit modeling (FDM) printers.[24] Although the mode of production differs between each of these manufacturing methods, FDM uses a four-step process to build a product layer by layer.[25] First, a 3-D "geometric representation" of the product is created using product design software.[26] Second, a machine slices this 3-D product representation into 2-D "blueprints."[27] Third, these blueprints are fed into a specialized printer, which contains the

[20] *See* Harouni, *supra* note 5 ("[3-D printers can] create structures which are more intricate than any other manufacturing technology, or in fact are impossible to build in any other way."). The more complex the product, however, the more advanced (read—expensive) the printer usually is. *See* Nick Allen, *Why 3D Printing Is Overhyped (I Should Know, I Do It for a Living)*, GIZMODO, (May 17, 2013, 9:11 AM) http://gizmodo.com/why-3d-printing-is-overhyped-i-should-know-i-do-it-fo-508176750 ("[People have] seen a 3D printed violin; a crazy shoe, and a wrench (yawn) which actually *works*, straight out of a printer. A very, very expensive, high-end printer which uses lasers or resins. These people think that they can create objects as well without much input or training, on a machine which costs $800 or less. . . . [B]ut as we know, that's not the full story."); Lyndsey Gilpin, *3D Printing: 10 Factors Still Holding It Back*, TECHREPUBLIC (Feb. 19, 2014, 11:33 AM), http://www.techrepublic.com/article/3d-printing-10-factors-still-holding-it-back/ ("Currently, printers less than $1,000 use a DIY-style kit that requires assembly of the machine itself and they often don't replicate the [computer-aided-designs, or CADs,] accurately. . . . For the most part, anything bigger or better than these costs well into the thousands (or even tens of thousands) of dollars.").

[21] For example, SLA printers. SLA printers create products by selectively curing a vat of photopolymer. *Types of Additive Manufacturing*, RAPIDMADE, INC., http://www.rapidmade.com/glossary/ (last visited May 20, 2015).

[22] For example, selective laser sintering (SLS) printers. SLS printers create products by melting powdered material into solid objects using lasers. *Id.*

[23] For example, multi-jet or poly-jet printers. Multi-jet and poly-jet printers create products by depositing layers of photopolymer that set when exposed to light. *Id.*

[24] *Id.*

[25] Jack Clark, *HP Unveils Cheaper, 3-D Printing System to Spur Sales*, BLOOMBERGBUSINESS (Oct. 29, 2014, 9:44 AM), http://www.bloomberg.com/news/articles/2014-10-29/hp-unveils-sprout-a-cheaper-faster-3-d-printing-system.

[26] Harouni, *supra* note 5.

[27] *See id.* ("[T]his data gets sent to a machine that slices the data into two-dimensional representations of that product all the way through—almost like slicing it like salami."); *see also* Cronin, *supra* note 4 (coining the term "blueprints").

3-D "ink"[28] necessary to create the intended product.[29] Finally, the printer builds the final 3-D product within a matter of hours by depositing and bonding together many layers of 3-D ink.[30]

III. PRINTING PHARMACEUTICALS: HOW IT WORKS & CONSUMER ACCESSIBILITY

The 3-D printers currently available in the consumer market are unable to produce pharmaceuticals.[31] However, in 2012, Professor Lee Cronin and his research team successfully modified a 3-D printer priced on the consumer market at $2000 in order to create "Reactionware"[32] at the University of Glasglow.[33] Using Reactionware, people who have access to the three required components of hardware,[34] software,[35] and "chemical inks"[36] would be able to print drugs at home—or anywhere.[37] The printing process for 3-D pharmaceuticals would be similar to the current FDM printing method. During the first step of the process, a geometric representation of the drug's chemical components would be created using specialized design software.[38]

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[28] *See* Harouni, *supra* note 5 (explaining that the "ink" is actually printing "material . . . [that] either starts as a liquid form or a material powder form").

[29] *Id.*

[30] *Id.*

[31] *See* Elizabeth Armstrong Moore, *Pharma Firms Could Soon Use 3D Printers to Create Drugs*, CNET (Apr. 18, 2012, 3:35 PM), http://news.cnet.com/8301-11386_3-57415909-76/pharma-firms-could-soon-use-3d-printers-to-create-drugs/ (forecasting that this technology will be unavailable for purchase for another five years, and even then, available only to pharmaceutical companies for up to twenty years).

[32] *Id.*

[33] Nikki Olsen, *3D Printing Laboratories: The Age of DIY Designer Drugs Begins*, INST. FOR ETHICS & EMERGING TECHS. (Apr. 26, 2012), http://ieet.org/index.php/IEET/print/5698. "Reactionware" is the term for 3-D printed vessels, which contain specific chemical molecules. *Id.* As opposed to the vessels normally used in laboratories, which only supply a place for chemical reactions to occur, the biological makeup of Reactionware causes it to actually become a part of the chemical reaction when other elements are added. *Id.*

[34] Here, the term "hardware" refers to a 3-D printer. *Id.*

[35] Similarly, the term "software" refers to blueprint software. *Id.*

[36] Moreover, the term "chemical inks" refers to ink containing specific chemical ingredients. *Id.*; *see also* Harouni, *supra* note 5 (indicating that customers can purchase ink, which is actually a polymer solution mixed with other chemicals).

[37] *See* Cronin, *supra* note 4.

[38] Symes et al., *supra* note 7, at 349; *see also 3D Printers Could Create Customised Drugs on Demand*, BBC NEWS (Apr. 18, 2012), http://www.bbc.co.uk/news/technology-17760085 [hereinafter *Customised Drugs*] (explaining how prescription drugs can be

Next, a program would deconstruct the drug's overall chemical components into a numbered series of individual chemical reactions.[39] This information would then be fed into a 3-D printer that has been preloaded with the chemical inks.[40] Finally, the printer would use a robotic syringe in order to "robocast"[41] the drug by depositing sequential layers of chemical ink, triggering a series of chemical reactions to produce the finished drug.[42]

Despite being on the cutting edge of technology, the components needed to print drugs will likely be made accessible by consumers because Cronin has prioritized public distribution of chemical inks and chemistry blueprint software.[43] He plans to market the software through user-friendly chemistry "apps," which will organize pharmaceutical blueprints into searchable databases, allowing consumers to print drugs that address their particular illnesses.[44] Currently, the majority of consumer 3-D printing components are sold online;[45] therefore, 3-D pharmaceutical hardware and chemical inks would likely follow this online distribution model.

IV. THE CURRENT PHARMACEUTICAL MANUFACTURING & DISTRIBUTION MODEL IN THE UNITED STATES

Drug manufacturers and distributors are major players in the United States economy. Spending on prescription pharmaceuticals reached almost $326 million in 2013[46] and

created by passing chemical constituents through a 3-D printer).

[39] Symes et al., *supra* note 7, at 349.

[40] *Id.*

[41] *Id.* Interestingly, robotic syringes are currently used to print 3-D printed liver tissue. Steven Leckart, *How It Works: A 3-D Printer for Liver Tissue*, POPULAR SCI. (Aug. 19, 2013, 9:00 AM), http://www.popsci.com/technology/article/2013-07/how-it-works-3-d-printer-liver-tissue.

[42] *See* Symes et al., *supra* note 7, at 349 (describing the process as "'printing-in' catalysts into the structure of the reactionware"); *see also Customised Drugs*, *supra* note 38 (likening the process to a "layer cake").

[43] Cronin, *supra* note 4.

[44] *Id.* ("[These apps would contain] embed[ded] biological and chemical networks like a search engine.").

[45] *See, e.g.*, Clark, *supra* note 25 (reporting that Hewlett-Packard's 3-D printer, "Sprout," would be available online, but only in a few retail stores). This also reflects the growing popularity of online retail sales over recent years. *See E-Commerce Sales*, NAT'L RETAIL FED'N, http://research.nrffoundation.com/Default.aspx?pg=46#.VVosSEtbxg0 (last visited May 20, 2015) (indicating a $35 million increase in e-commerce sales over the last five years).

[46] Prescription drug expenditures totaled $325.9 million measured from October 1, 2012, to September 30, 2013. Glen T. Schumock et al., *National Trends in Prescription Drug Expenditures and Projections for 2014*, 71 AM. J.

accounted for eleven percent of total healthcare expenditures in the United States.[47] American pharmaceutical companies were collectively worth approximately $359 billion in 2012.[48] These companies have become extremely profitable due to the growing role of pharmaceuticals in American healthcare.[49]

Under the current U.S. pharmaceutical distribution model, manufacturers produce drugs and then sell them to distributors and/or dispensers.[50] These distributors and dispensers fall into four categories: wholesalers (distributors), manufacturer direct sale (dispensers), self-warehousing (dispensers), and mail order (dispensers).[51] Wholesale distributors purchase more drugs from manufacturers than any of the other categories, and sell the drugs to the dispensers who do not purchase drugs directly from a manufacturer.[52] Dispensers then sell drugs to consumers.[53] At each step in the distribution chain there are storage costs, transportation costs, and profit margins for the seller.[54]

Within this distribution chain, pharmaceutical manufacturers are divided into two subgroups: brand name (pioneer) manufacturers and generic manufacturers.[55] Pioneer manufacturers invest large amounts of capital in order to research and develop new pharmaceuticals.[56] In order to protect

HEALTH-SYS. PHARMACY e6, e7 (2014).

[47] *Id.*

[48] Bruce Japsen, *Obamacare Will Bring Drug Industry $35 Billion in Profits*, FORBES (May 25, 2013, 10:29 AM), http://www.forbes.com/sites/brucejapsen/2013/05/25/obamacare-will-bring-drug-industry-35-billion-in-profits/.

[49] *See* Fed. Trade Comm'n v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 39 (D.D.C. 1998) ("[T]he pharmaceutical industry is one of the most dynamic and important segments of the national economy. Due to advances in medical science, there are a staggering number of prescription drugs for nearly every kind of health condition. Prescription drugs have become an essential elemental [sic] of modern health care.").

[50] *See id.* ("The distribution and delivery of prescription drugs from the manufacturer to the dispenser is not an easy task.").

[51] *Id.* at 39–40; *see also* KAISER FAMILY FOUND., FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 1 (2005) [hereinafter FOLLOW THE PILL], *available at* http://www.avalerehealth.net/research/docs/Follow_the_Pill.pdf (discussing the pharmaceutical supply chain).

[52] FOLLOW THE PILL, *supra* note 51, at 4.

[53] *Id.* at 9.

[54] Marshall Fisher, *What Is the Right Supply Chain for Your Product?*, HARV. BUS. REV. (Mar. 1997), https://hbr.org/1997/03/what-is-the-right-supply-chain-for-your-product.

[55] *See infra* notes 56, 58 and accompanying text.

[56] Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J.

their investments and recover research and development costs, pioneer manufacturers apply for patents, which prohibit competitors from duplicating a brand name drug for a period of twenty years.[57] In contrast, generic manufacturers wait until these patents expire, reproduce the drugs created by pioneer manufacturers, and sell them at discount.[58] Demand for generic drugs remains high as a result of this lower price tag—eighty percent of the prescriptions filled in 2012 were generic drugs.[59] All drug manufacturers, both pioneer and generic, must operate in accordance with strict federal laws in order to ensure that drugs are suitable for human use.[60] Although the specific manufacturing process differs based on the type of drug,[61] producing pharmaceuticals is a complicated and difficult process that requires specialized ingredients and equipment. For example, powder-filled capsules are produced in clean facilities, requiring a series of steps: measuring raw materials, granulating material components, blending granulated powders, compressing powder blends, filling capsules with compressed powder, coating capsules, and packaging the finished product.[62]

While manufacturers are driven by the competition between pioneers and generics, the wholesale distribution market is controlled by three companies: McKesson Corp.,

245, 252 (2012).

[57] 35 U.S.C. § 154(a)(2) (2012).

[58] Katherine Eban, *Are Generics Really the Same as Branded Drugs?*, FORTUNE (Jan. 10, 2013, 10:00 AM), http://fortune.com/2013/01/10/are-generics-really-the-same-as-branded-drugs/. Notably, the expiration of a patent has been referred to as "patent cliff." *See* Alexander J. Kalter, Note, *Generic Drugs Post Novo Nordisk*, 7 OHIO ST. ENTREPRENEURIAL BUS. L.J. 193, 219 (2012) (referring to the loss of patent protection for "ten of the [then] current best-selling medicines" in 2011 and 2012).

[59] Eban, *supra* note 58.

[60] *See* 21 U.S.C. § 360 (2012) (providing registration requirements for pharmaceutical manufacturers).

[61] *See* Stephen Brown et. al, *Liquid-Fill Based Formulation: Advances and Challenges*, 35 INNOVATIONS IN PHARMACEUTICAL TECH. 58, 58 (2010), *available at* http://edition.pagesuite-professional.co.uk//launch.aspx?eid=65e2e142-51ea-4faa-b0c4-2b76e3fab501. This production process changes based on the desired pharmaceutical product. Types of orally administered pharmaceutical products include solids (tablets, capsules, and powders); liquids (solutions, suspensions, and emulsions); and semisolids (gels). James E. De Muth, *Round Table: Pharmaceutical Dosage Forms—USP Approach*, U.S. PHARMACOPEIA 9, http://www.farmacopea.org.mx/cursos/memorias/8DM-USP.pdf (last visited May 20, 2015).

[62] *See, e.g.*, *Our Process*, CONTRACT PHARMACEUTICAL CORP., http://www.cpc.com/our-process/# (last visited May 20, 2015) (indicating the process for powder-filled capsule production).

AmerisourceBergen Corp., and Cardinal Health, Inc.[63] Together these three companies dominate approximately eighty-five percent of the market, generating approximately $288.9 billion in revenue in 2013.[64] In general, manufacturers and wholesale distributors have a symbiotic relationship.[65] Wholesale distributors make money by taking advantage of the disconnect between manufacturers and dispensers; wholesalers buy bulk quantities of drugs from manufacturers at a discount, store the drugs in warehouses, and meet the demand of dispensers in order to replenish their stock of drugs.[66] Manufacturers also benefit by selling their drugs to wholesalers.[67] By purchasing in bulk, wholesalers help manufacturers to cut manufacturing costs associated with filling small volume orders.[68]

The last step in the current distribution model is the dispensaries, which are more commonly referred to as pharmacies.[69] Under the current model, consumers obtain drugs from either retail or mail order pharmacies.[70] Pharmacists are vital actors in this distribution model because they are often the only members of the distribution chain that interact directly with

[63] Russ Britt, *'Big Three' Pharma Distributors Post Sharp Gains*, MARKETWATCH (Sept. 15, 2010, 5:17 PM), http://www.marketwatch.com/story/big-3-pharma-distributors-post-sharp-gains-2010-09-15.

[64] Adam J. Fein, *2014 Market Leaders: Top Pharmaceuticals Distributors*, MOD. DISTRIBUTION MGMT., http://www.mdm.com/2014_pharmaceuticals_mdm-market-leaders (last visited May 20, 2015).

[65] *See* ERNST & YOUNG, SEA OF CHANGE ON THE HORIZON 1 (2014), *available at* http://www.ey.com/Publication/vwLUAssets/ey-the-state-of-us-fund-distribution-in-2014/$File/ey-us-fund-distribution-report.pdf (discussing in a more general context the "complex symbiotic relationship between product manufacturers and distribution").

[66] FOLLOW THE PILL, *supra* note 51, at 9. However, larger dispensers such as retail chains often purchase drugs directly from manufacturers and maintain their own drug warehouses in order to avoid paying profit margins to drug wholesalers. *Major Categories of Wholesalers*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/ucm256477.htm (last updated May 25, 2011).

[67] *See Roles and Functions of Wholesalers*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/ucm256474.htm (last updated May 25, 2011) ("Drug wholesalers . . . improve purchasing economies and lower manufacturer costs by reducing the number of small volume sales by drug manufacturers.").

[68] *Id.*

[69] FOLLOW THE PILL, *supra* note 51, at 9.

[70] *Id.* at 10.

consumers.[71] As a result, pharmacists are expected, and sometimes obligated, to counsel customers and provide them with information about the safe and effective use of prescribed medications.[72] Pharmacies also enforce governmental rules that limit access to drugs used to make methamphetamines;[73] store data on prescription drug claims that allows various groups to track consumer trends;[74] and coordinate payment of medications through prescription drug benefit plans.[75]

V. HOW 3-D PRINTING COULD ALTER THE CURRENT U.S. PHARMACEUTICAL DISTRIBUTION CHAIN & THE POTENTIAL CHANGES IN HOW CONSUMERS OBTAIN DRUGS

The introduction of 3-D printed pharmaceuticals could radically alter the current U.S. distribution model. Under Cronin's proposed implementation scheme, 3-D chemputers will initially only be used by pharmaceutical companies.[76] As long as these chemputers remain under the exclusive control of pharmaceutical manufacturers, the drug distribution chain would likely continue to operate under its current model. Despite a shift in the method of manufacturing from granulators and compressors to 3-D printers, pharmaceutical manufacturers would still control production. Further, wholesale distributors and dispensers would still be instrumental in coordinating the storage, transportation, and delivery of the drugs from manufacturers to consumers. However, the current distribution model could be radically changed if consumers begin using 3-D printers to produce their own pharmaceuticals—a shift that Cronin projects will occur within the next seventeen years but

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71 *Id.*

72 *See, e.g.*, N.Y. COMP. CODES R. & REG. tit. 8, § 63.6(a)(8) (2015); *see also* WASH. ADMIN. CODE § 246-869-220(1) (2015). *But see* Luke v. Family Care & Urgent Med. Clinics, 246 F. App'x 421, 425 (9th Cir. 2007) ("The plain language of the [Washington] regulation restricts a pharmacist's role to counseling concerning the safe and effective administration of the medication, and does not impose any requirement to explain medical risks.").

73 *See* Combat Methamphetamine Epidemic Act of 2005, Pub. L. No. 109-177, § 711(b)(1), 120 Stat. 256, 257–61 (2006) (codified as amended at 21 U.S.C. § 830 (2012)).

74 FOLLOW THE PILL, *supra* note 51, at 9.

75 *Id.*

76 *See* Moore, *supra* note 31 ("The team . . . predicts that its reactionware tech will be used by pharmaceutical companies in five years and by the general public in 20.").

could be much sooner.[77] A consumer production model could obviate "the need for complex and expensive distribution chains."[78] Cronin envisions a distribution model in which consumers purchase 3-D printers and chemical inks on the consumer market, and drug blueprints directly from pharmaceutical manufacturers.[79] Using searchable chemistry apps, consumers would be able to search for and purchase drug blueprints as easily as they could search for and purchase a song on iTunes. In an interview Cronin indicated that "what Apple did for music, I'd like to do for the discovery and distribution of prescription drugs."[80]

A consumer-based production model could minimize or eliminate the need for pharmaceutical distributors and dispensers if manufacturers sold drug blueprints and chemical inks directly to customers. However, due to consumers' need for the physical components required to print drugs, a consumer production model would likely not eliminate roles in the current distribution chain,[81] but instead alter the roles that different groups play. The first role change that could occur is for brand name manufacturers to produce pharmaceutical blueprints and/or chemical inks instead of pharmaceuticals. Under a consumer production model, pioneer drug manufacturers would still be needed in order to research and develop new drugs

[77] *See id.* (relaying Cronin's 2012 projection that consumers will be printing pharmaceuticals within twenty years). If the introduction of 3-D printed guns has taught us anything, it is that once this technology gets into certain hands it can spread very quickly. *See* Nick Bilton, *The Rise of 3-D Printed Guns*, N.Y. TIMES, Aug. 13, 2014, http://www.nytimes.com/2014/08/14/fashion/the-rise-of-3-d-printed-guns.html?_r=1 ("In late 2012, when I first wrote that 3-D printers could be used to make functional pistols, gun enthusiasts and government officials said the concept was science fiction and would take years to become a reality, if ever. Yet it took only a few months before videos popped up online of working guns made from 3-D printers, some capable of firing dozens of bullets.").

[78] Phil Taylor, *3D Printing Starts to Take Hold in Pharma*, PMLiVE (Nov. 1, 2012), http://www.pmlive.com/pharma_news/3d_printing_starts_to_take_hold_in_pharma_444836. Others project that "transaction costs associated with manufacturing drugs on a large scale, and the transportation costs often associated with drug delivery, could be all but eliminated with this model." Goodman, *supra* note 6.

[79] Adams, *supra* note 12 ("[Y]ou follow a recipe that a drug company gives you. They will have validated that recipe in their lab. And when you have downloaded it and enabled the printer to read the software it will work. The value is in the recipe, not in the manufacture.").

[80] *Id.*

[81] *See* discussion *supra* Part IV.

because generic manufacturers, distributors, dispensers, and consumers as they exist today are not in the business of creating new drugs.[82] Allowing brand name pharmaceutical manufacturers to go out of business would eliminate the source of new drugs, thereby halting drug-based advances in the medical field and leaving the public in a dangerous position in the event of a new disease outbreak. Generic manufacturers, however, will probably fulfill a role in the distribution chain that is similar to their current role,[83] but instead of producing cheaper versions of drugs, generic companies could produce cheaper versions of chemical inks and blueprints subject to the same applicable regulatory restrictions for patented processes. Although unlikely, medical device manufacturers could join the pharmaceutical distribution chain if pharmaceutical capable 3-D printers are interpreted as "medical devices" under the Federal Food, Drug, and Cosmetic Act.[84] The magnitude of the role change for wholesale distributors and dispensers will depend on whether consumers will be able to purchase chemical inks and drug blueprints directly from drug manufacturers. There are few details regarding Cronin's distribution plans for chemical inks, but in contrast to drug blueprints that could be sold using a direct-purchase "app" model, chemical inks are still physical products that may still require warehousing and distribution through wholesale distributors and dispensers. Similar to the current distribution model, manufacturers could cut costs by selling chemical inks in bulk to wholesale distributors and large dispensers.[85] Under this model, wholesale distributors and dispensers could still be a part of the pharmaceutical distribution chain and consumers could continue to interact with dispensers in order to obtain chemical inks.

VI. REGULATORY ISSUES FOLLOWING THE ADVENT OF 3-D PRINTED FIREARMS

One way to forecast the regulatory difficulties that are likely to arise with the introduction of 3-D printed pharmaceuticals is to examine the effectiveness of the attempts to regulate 3-D printed

[82] *See* discussion *supra* Part IV.

[83] *See* discussion *supra* Part IV.

[84] *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 540–42 (codified as amended at 21 U.S.C. § 360c(a) (2012)) (proscribing specific classes of medical devices).

[85] *See* discussion *supra* Part IV.

firearms. When production of 3-D printed firearms began, many of these firearms fell under the control of the Undetectable Firearms Act (UFA).[86] However, the leading supplier of 3-D printed gun blueprints, Defense Distributed (DD),[87] has developed a model of gun that does not fall under the scope of this Act.[88] Further, DD has expressed its intention to continue evading and undermining governmental oversight of 3-D printed guns.[89] Instead of addressing these regulatory loopholes when the UFA came up for a vote in December 2013, Congress decided to extend the UFA in its current form.[90]

The U.S. Department of State, however, asserted jurisdiction over the posting of gun blueprints on the web under the International Traffic in Arms Regulations (ITAR), arguing that the disclosure of data to a "foreign person, whether in the United States or abroad, is considered an export under § 120.17 of ITAR."[91] Under ITAR, an exporter must either have a license to release qualifying data, or be exempt from the licensing requirement.[92] Therefore, the Department of State argued that

[86] *See, e.g.*, Nora Freeman Engstrom, *3D Printing and Product Liability: Identifying the Obstacles*, 162 U. PA. L. REV. ONLINE 35, 36 n.7 (2013) (citing 18 U.S.C. § 922(p)(1) (2006)).

[87] *See DD History*, DEF. DISTRIBUTED, http://defdist.org/dd-history/ (last visited May 20, 2015) (discussing the originators of the Wiki Weapon Project, which resulted in the mass distribution of internet blueprints for "the world's first printable handgun").

[88] *See* Derek Mead, *Congress's Plastic Gun Ban Left a 3D-Printed Loophole*, MOTHERBOARD (Dec. 13, 2013, 12:45 PM), http://motherboard.vice.com/blog/congresss-plastic-gun-ban-left-a-3d-printed-loophole ("Defense Distributed, which has taken the lead on 3D-printed guns, developed a version of its fully 3D-printed Liberator pistol that has a small chunk of metal inside—just enough to trip metal detectors that, under the UFA, must be calibrated to detect 3.7 ounces of steel.").

[89] *See DD History*, *supra* note 87 ("DD works to subvert the physical and digital architecture of oppression on behalf of the general public. DD fights for freedom primarily outside of court and government, writing and releasing software to aid in the disintermediation of state governments and large, collusive corporations.").

[90] *See* Burgess Everett, *Senate Passes Legislation on Undetectable Guns*, POLITICO (Dec. 9, 2013, 6:17 PM), http://www.politico.com/story/2013/12/senate-gun-safety-legislation-100906.html ("Republicans and the NRA accepted an extension of UFA, 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.").

[91] Letter from Glenn E. Smith, Chief, Enforcement Div., U.S. Dep't of State, to Cody Wilson, Def. Distributed 2 (May 8, 2013), *available at* http://www.exportlawblog.com/docs/Defense_Distributed.pdf.

[92] *See* 22 C.F.R. § 125.4 (2015) (setting forth the licensing exemptions for the exportation of data).

DD's posting of gun blueprints on the Internet without a license or exemption constituted a violation of ITAR,[93] and ordered DD to remove the gun blueprints from its website.[94] DD complied with the takedown order; however, the blueprints had already been downloaded over 100,000 times in the two days that they were posted on the website.[95] Additionally, while the order prohibited the company from keeping the blueprints on its website, the blueprints were uploaded to a peer-to-peer (P2P) anonymous file-sharing site called Pirate Bay,[96] where the blueprints are still available for download.[97] As if the continued availability of these blueprints on this site was not enough evidence of how difficult it is for federal regulators to cut off access to files on P2P networks, the Department of Homeland Security issued a bulletin to state and federal law enforcement agencies in 2013 warning that "[l]imiting access may be impossible."[98]

VIII. THE VIABILITY OF REGULATION OF 3-D PRINTED PHARMACEUTICALS UNDER CURRENT FEDERAL LAWS & REGULATIONS

As exemplified countless times throughout history, there is no stopping the introduction of a technology if there is a consumer demand for it. Instead of utilizing an ex post facto approach once the technology has already been released out of Pandora's box, Congress should instead proactively construct a regulatory framework that will allow citizens to reap the benefits of this new technology while promoting public health and safety. In order for this to happen, lawmakers must appreciate the global implications of the digitization of pharmaceuticals,[99] acknowledge

[93] *See* Letter from Glenn E. Smith to Cody Wilson, *supra* note 91, at 1.

[94] *Id.* at 2.

[95] Andy Greenberg, *State Department Demands Takedown of 3D-Printable Gun Files for Possible Export Control Violations*, FORBES (May 9, 2013, 2:36 PM), http://www.forbes.com/sites/andygreenberg/2013/05/09/state-department-demands-takedown-of-3d-printable-gun-for-possible-export-control-violation/.

[96] *Id.*

[97] *Browse Defense Distributed*, PIRATE BAY, https://thepiratebay.se/tag/Defense+Distributed/0/7 (last visited May 20, 2015); *see also* Bilton, *supra* note 77 ("It took me about five minutes to find these gun schematics online. A teenager who grew up on the Internet could probably find them in half that time.").

[98] Jana Winter, *Homeland Security Bulletin Warns 3D-Printed Guns May Be 'Impossible' to Stop*, FOX NEWS (May 23, 2013), http://www.foxnews.com/us/2013/05/23/govt-memo-warns-3d-printed-guns-may-be-impossible-to-stop/.

[99] *See* Deven R. Desai & Gerard N. Magliocca, *Patents, Meet Napster: 3D*

that current laws will not effectively regulate this technology,[100] and seize the opportunity to close regulatory gaps.[101]

Simply put, the regulation of 3-D printed pharmaceuticals under the current interpretation of federal and state laws may not be feasible.[102] Gaps in current copyright, patent, export, food and drug, and criminal laws and regulations provide loopholes for individuals who misuse 3-D pharmaceutical printers. However, lawmakers may be able to stich together a regulatory framework by combining and reworking aspects of all of these laws and regulations.

A. Regulating Pharmaceutical Software Blueprints Under Copyright Laws

For the most part, current federal copyright laws do not apply to the manufacturing and distribution of pharmaceuticals.[103] Copyright cases involving pharmaceuticals usually center on issues regarding product information materials.[104] Further,

Printing and the Digitization of Things, 102 GEO. L.J. 1691, 1692 ("Digitization changes any sector it touches.").

[100] *See id.* ("Disruption is not only a business or private matter; the underlying legal system is disrupted as well.").

[101] *See id.* ("[T]he laws governing the way things are made will need to make peace with the reality of digitized objects made of simple raw materials and software."). This has been an issue in the 3-D printed gun regulation debate. *See* Everett, *supra* note 90 ("[A]dvocates of gun control pushed to update the [UFA] to prepare it for an era when 3-D printers are able to construct firearms entirely of plastic, save for a metal firing pin. Republicans and the NRA accepted an extension of UFA, 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."). This heated debate over regulation may be less contested regarding pharmaceuticals than it is regarding gun control—a field rife with political controversy. *See* Erwin Chemerinsky, *Putting the Gun Control Debate in Social Perspective*, 73 FORDHAM L. REV. 477, 477 (2004) ("Conservatives, who generally favor more narrow interpretations of individual rights, urge a broad view of the Second Amendment, and for progressives it is just the opposite.").

[102] *See, e.g.*, Brean, *supra* note 15, at 771 ("Under existing law, the distributors of digital representations of products are not 'making,' 'selling,' or 'using' the patented products or any 'component' thereof . . . .").

[103] *See* 17 U.S.C. § 102(b) (2012) ("In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.").

[104] *See, e.g.*, Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc., 388 F. Supp. 2d 967, 979 (E.D. Wis. 2005) (explaining that federal law "require[s] virtually identical copying of package insert materials" in order to constitute copyright infringement).

current copyright laws do not extend protection to 3-D printed products.[105] Software products, however, are protected under copyright law.[106] Under current copyright laws, the owners of drug blueprint software copyrights would be able to file lawsuits against infringers for making unauthorized distribution of copies of the software[107] or for creating products that were copied in substantial part from the original software, sold commercially, and could affect the market for or value of the original software.[108] The copyright owners could retain some degree of control over the use and dissemination of the software by selling users licenses instead of selling them all of the rights to the product.[109] Many software products are currently being sold according to this sales model.[110] Under this model, consumers buy a nonexclusive license to use the blueprint software,[111] which limits a consumer's use of the product under the scope of the license.[112] In the licensing agreement, the copyright owner could prohibit licensees from tinkering with the blueprint software in an attempt to create new and potentially dangerous drugs, and prohibit them from making unauthorized copies of the software.[113]

Although copyright laws could legally limit the scope of a consumer's license to use drug software under current federal statutes,[114] copyright alone is likely not the most viable method of regulating 3-D printed pharmaceuticals. Even when copyright owners place restrictions in licensing agreements, users are often

105 Brean, *supra* note 15, at 771.

106 17 U.S.C. § 102.

107 *Id.* § 106.

108 *Id.* § 107.

109 *Id.* § 101.

110 *See, e.g.*, MAI Sys. Corp. v. Peak Computer Inc., 991 F.2d 511, 517 (9th Cir. 1993).

111 *Id.*

112 *See* Jacobsen v. Katzer, 535 F.3d 1373, 1380 (Fed. Cir. 2008) ("Generally, a 'copyright owner who grants a nonexclusive license to use his copyrighted material waives his right to sue the licensee for copyright infringement' and can sue only for breach of contract. If, however, a license is limited in scope and the licensee acts outside the scope, the licensor can bring an action for copyright infringement." (citations omitted) (quoting Sun Microsys., Inc. v. Microsoft Corp., 188 F.3d 1115, 1121 (9th Cir. 1999); Graham v. James, 144 F.3d 229, 236 (2d Cir. 1998))).

113 *Id.*

114 *See* 17 U.S.C. § 106 (listing the exclusive rights granted to the owner of copyright).

able to easily violate these restrictions.[115] This has become evident in other fields, like the music industry, where the digitization of products has rendered copyright laws ineffectual in controlling the unauthorized production and use of copyrighted products.[116]

In the music industry, copyright owners have experienced difficulty in controlling the number of copyright infringements, especially those occurring through P2P anonymous file-sharing networks.[117] Despite the intent of the Digital Millennium Copyright Act of 1998 (DMCA) to "brin[g] U.S. copyright law squarely into the digital age,"[118] copyright owners have been unable to eradicate the sharing of infringing files over P2P networks.[119] The difficulty in removing copyright-infringing material from these sites is due to statutory limitations on the liability of Internet service providers (ISPs) in the DMCA,[120] as well as the technical limitations on the ability of an ISP to

[115] *See generally* Samir Chopra & Scott Dexter, *The Freedoms of Software and Its Ethical Uses*, 11 ETHICS & INFO. TECH. 287 (2009) (discussing the effectiveness of software licensing restrictions on end users).

[116] FED. TRADE COMM'N, PEER-TO-PEER FILE-SHARING TECHNOLOGY: CONSUMER PROTECTION AND COMPETITION ISSUES 22 (2005), *available at* 2005 WL 1541114.

[117] *Id.*; *see also* STEALTHNET, http://www.stealthnet.de/en_index.php (last visited May 20, 2015) (providing a greater level of protection compared to other P2P networks by making it "nearly impossible to locate users who provide content within the [peer-to-peer] network").

[118] S. REP. NO. 105-190, at 2 (1998).

[119] Recording Indus. Ass'n of Am., Inc. v. Verizon Internet Servs., Inc., 351 F.3d 1229, 1232 (D.C. Cir. 2003) ("To date, owners of copyrights have not been able to stop the use of these decentralized programs."); Annemarie Bridy, *Is Online Copyright Enforcement Scalable?*, 13 VAND. J. ENT. & TECH. L. 695, 717 (2011) ("Because the DMCA was designed to deal with providers serving a centralized file-storage function, it has proven a poor fit in cases involving P2P, where the service provider functions only as a pass-through or conduit for the transfer of infringing material."). However, the major ISPs have extended an olive branch to copyright holders in the form of the "Six Strikes" private ordering agreement. Nate Anderson, *Major ISPs Agree to "Six Strikes" Copyright Enforcement Plan*, ARS TECHNICA, (July 7 2011, 11:06 AM), http://arstechnica.com/tech-policy/2011/07/major-isps-agree-to-six-strikes-copyright-enforcement-plan/ ("The result is 'copyright alerts,' a series of messages warning users that their (alleged) activity has been detected and that penalties could result if it continues. . . . ISPs have [also] agreed to institute 'mitigation measures' . . . [that] begin with the fifth or six alert, [which] may include 'temporary reductions of Internet speeds, redirection to a landing page until the subscriber contacts the ISP to discuss the matter or reviews and responds to some educational information about copyright, or other measures that the ISP may deem necessary to help resolve the matter.'").

[120] *See* 17 U.S.C. § 512 (2012) (limiting copyright infringement liability with respect to online material).

eradicate P2P files on a user's computer.[121] Under the DMCA, ISPs are not liable for infringing data transmitted by someone using the provider's Internet service,[122] so there is little incentive on the part of ISPs to ensure users are in compliance with federal laws. Even if ISPs were incentivized to remove noncomplying files, an ISP is physically incapable of doing so, because the ISP does not have the ability to control the files on its users' computers.[123]

Due to the complexity of these issues, copyright owners in the music industry have accepted, to a certain extent, the rampant copyright infringements in order to avoid costly litigation.[124] However, while music copyright owners have been reluctant to waste money litigating small-scale individual infringements by P2P users,[125] these owners are not without any recourse. Although it may not be cost-effective, copyright owners are entitled to file suit against small-scale decentralized infringers who use P2P networks to share infringing files.[126] Courts have held that although P2P file sharing qualifies as "speech" under the First Amendment, the First Amendment does not protect the anonymity of P2P users if doing so would prevent a copyright owner from being able to seek a judicial remedy for a copyright

[121] *See Verizon*, 351 F.3d at 1235 ("No matter what information the copyright owner may provide, the ISP can neither 'remove' nor 'disable access to' the infringing material because that material is not stored on the ISP's servers.").

[122] 17 U.S.C. § 512(b)(1).

[123] *See Verizon*, 351 F.3d at 1235 ("[An ISP cannot] remove or disable one user's access to infringing material resident on another user's computer because [the ISP] does not control the content on its subscribers' computers.").

[124] Jennifer Norman, *Staying Alive: Can the Recording Industry Survive Peer-to-Peer?*, 26 COLUM. J.L. & ARTS 371, 371 (2003) ("The plaintiffs in the case, various record companies and music publishers, chose not to sue the direct infringers, Napster's users. Instead, they used theories of secondary liability to hold Napster responsible for its users' actions. The reasoning behind this decision is clear: It is far easier to shut down one central location than to initiate millions of separate lawsuits against individual users (or even enough suits to achieve general deterrence).").

[125] However, the recording industry began to shift the focus of litigation back to individual P2P users after P2P networks were held not liable for contributory infringement of their users. *Verizon*, 351 F.3d at 1232. This issue is further complicated by the negative press and possible decline in business if large copyright holders sue users who may also be their customers. Norman, *supra* note 124, at 371–72.

[126] *See, e.g.*, *Verizon*, 351 F.3d at 1232 ("The [Recording Industry Association of America] has sent letters to and filed lawsuits against several hundred such individuals, each of whom allegedly made available for download by other users hundreds or in some cases even thousands of .mp3 files of copyrighted recordings.").

infringement.[127] This means that copyright owners may subpoena ISPs to determine the identities of anonymous infringing file-sharers, in order to file suit against individual infringing P2P users.[128] Copyright laws also provide the basis to pursue more effective claims against larger-scale centralized copyright infringers,[129] as well as decentralized inducers, such as bit torrent sites.[130]

The copyright owners of drug blueprint software will likely experience a similar volume of infringements to music industry copyright owners. Although most consumers will not have the technical skills to create the type of data needed to direct a 3-D printer to print a drug on their own, they will likely be able to access software programs that will do it for them.[131] Similar to P2P music file sharing, consumers will likely be able to find the infringing data they need online through P2P networks. Using these networks, consumers could obtain information about how to tinker with software or share unauthorized copies of software.[132] The copyright owners of drug blueprint software would be wise to follow the selective litigation approach to copyright infringement that has developed in the music industry. Initiating copyright infringement cases against small-scale individual file-sharers on P2P networks would be a poor investment of legal resources due to the number of potential litigants, and the difficulty of collecting on favorable judgments. Moreover, copyright owners should focus their efforts by filing

127 *See, e.g.*, Sony Music Entm't, Inc. v. Does 1–40, 326 F. Supp. 2d 556, 567 (S.D.N.Y. 2004) ("[D]efendants' First Amendment right to remain anonymous must give way to plaintiffs' right to use the judicial process to pursue what appear to be meritorious copyright infringement claims.").

128 *Verizon*, 351 F.3d at 1232.

129 *Id.* at 1232–33.

130 *See* Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936–37 (2005) ("[O]ne who distributes a device with the object of promoting its use to infringe copyright, as shown by clear expression or other affirmative steps taken to foster infringement, is liable for the resulting acts of infringement by third parties.").

131 *See* Harouni, *supra* note 5 ("Most of us . . . don't know how to create the data that a 3D printer reads. . . . [The average consumer] wouldn't know how to direct it to make what [he or she] want[s] it to. But there are more and more technologies, software and processes today that are breaking down those barriers.").

132 *See* STEALTHNET, *supra* note 117 (advertising "strong anonymity/security" for users to share files). This network presumably encourages the sharing of illegal information, as StealthNet's logo is a police officer Lego figurine with a red slash across him. *Id.*

copyright infringement claims against the largest and most profitable infringers, especially those that channel file searches through a centralized website.[133] This approach would have broader implications for reducing the availability of the blueprints and would increase the probability of collecting larger judgments on favorable decisions.

B. Regulating Pharmaceutical Blueprints Under Patent Laws

Currently, federal patent laws are integral to the regulation of pharmaceuticals.[134] Patent laws have two underlying purposes: to provide the inventor exclusive rights to the manufacture and distribute the patented product for twenty years in order to encourage innovation,[135] while at the same time encouraging competition by requiring the inventor to disclose information about the patented product that competitors can later replicate after the expiration of the patent.[136] Under existing patent laws, direct patent infringement occurs when an unauthorized party "makes, uses, offers to sell, or sells any patented invention."[137]

Patent laws protect pioneer[138] pharmaceutical manufacturers by shielding the processes developed by these manufacturers, and providing them the exclusive right to profit off of their initial investments in research and drug development.[139] Patent terms last twenty years under statute;[140] however, the average time a pioneer manufacturer enjoys exclusive marketing of its patented drug is now approximately eleven years due to length of time devoted to drug development.[141] Facing shrinking effective patent

133 *See Verizon*, 351 F.3d at 1232 (indicating that it was less difficult to shutdown Napster's P2P network due to its use of a centralized website search component).

134 *See* Mandy Wilson, Note, *Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation*, 90 KY. L.J. 495, 501–02 (2002) ("[P]atent protection has significant importance in the pharmaceutical industry.")

135 35 U.S.C. § 154(a)(2) (2012).

136 WENDY H. SCHACHT & JOHN R. THOMAS, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("THE HATCH-WAXMAN ACT") 4 (2005), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl3075601102005.pdf.

137 35 U.S.C. § 271(a).

138 SCHACHT & THOMAS, *supra* note 136, at 33.

139 *See* discussion *supra* Part IV.

140 35 U.S.C. § 154(a)(2).

141 Josh Bloom, *Should Patents on Pharmaceuticals Be Extended to*

lives,[142] pioneer manufacturers are often compelled to file suit against patent infringers in order to protect their profit stream.[143] These lawsuits highlight the conflicting policy implications of maintaining long effective patent lives for pioneer manufacturers, versus allowing generic manufacturers a certain amount of leeway to begin developing competing drugs during the patent life of a brand name drug. On one hand, market exclusivity protection is important for the continued development of new life-saving drugs. By ensuring a manufacturer's exclusive right to sell patented drugs, regulators help pioneer manufacturers to recover their initial investments more quickly, which in turn incentivizes these manufacturers to continue researching and developing new drugs.[144] On the other hand, market exclusivity inherently means there is less competition on the pharmaceutical market; therefore, drug prices are less affordable for consumers.[145] The passage of the Hatch-Waxman Act in 1984 and the Medicare Modernization Act of 2003 (MMA) attempted to balance these competing interests; however, new controversies developed as a result of the passage of these Acts.[146]

Currently, this war over competing policies is still being waged between pioneer and generic drug manufacturers and their corresponding advocates. However, the current risk of patent infringement other than by another major drug manufacturer is

Encourage Innovation? Yes: Innovation Demands It, WALL ST. J., Jan. 23, 2012, http://online.wsj.com/news/articles/SB10001424052970204542404577156993191655000.

[142] *Id.* ("In 1968, when development time was much shorter than today, most drugs had an effective patent life of about 17 years. Now companies usually have only about 11 years of market exclusivity for their drugs. And this number is expected to continue dropping as development times grow even longer—approaching a point where the costs and risks of development outweigh the rewards and research will stop.").

[143] Michael Bobelian, *Supreme Court Permits Antitrust Scrutiny of Pharma Settlements*, FORBES (June 18, 2013, 10:13 AM), http://www.forbes.com/sites/michaelbobelian/2013/06/18/supreme-court-permits-antitrust-scrutiny-of-pharma-settlements/.

[144] Wilson, *supra* note 134, at 496.

[145] Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417–18 (2001).

[146] *Id.* at 431–32, 462 (discussing issues such as brand name manufacturers stalling FDA approval of generics by "evergreening" patents, brand name manufacturers paying generics not to market competing drugs during the patent life of the brand drug through "pay-for-delay" settlements, and anti-competitive practices between manufacturers in relation to the 180-day exclusivity period for the first generic patent filer).

relatively low. This is due to the reliance of current patent laws on the "physical limits" on patent infringement, which "recognize[] the slim chance that an individual or a small business will have the wherewithal to make an infringing item from scratch."[147] Manufacturing drugs, whether they are brand name or generic, requires a lengthy and expensive process.[148]

On their own, current patent laws will likely be ineffective in regulating 3-D printed pharmaceuticals because the average consumer with a 3-D pharmaceutical printer will have the capability to infringe patents very easily.[149] This means that a teenager could replicate the manufacturing work currently being done in high-tech drug manufacturing facilities. This shift in the manufacturing process would undermine the effectiveness of current patent laws, which rely on the physical difficulties of manufacturing an infringing drug.[150]

Drug blueprint distributors, however, may be liable under theories of "active inducement" of patent infringement and "contributory infringement."[151] Blueprint distributors could be found liable for patent infringement if they engage in "active inducement . . . [or] at least willful blindness on the part of the distributors that their actions cause patent infringement . . . ."[152] Under this law, a distributor who obtains and sells drug blueprints for a patented drug could be found liable for patent infringement due to its willful blindness that the purchaser will likely use the blueprints to make unauthorized and infringing copies of the patented drug.[153] 3-D pharmaceutical printer

147 Desai & Magliocca, *supra* note 99, at 1694.

148 *Generic Drugs: Questions and Answers*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last updated Jan. 7, 2015).

149 *See* Goodman, *supra* note 6 ("With the capability of a bio-chemical 3-D printer and an archive of available drug designs, meanwhile, a patented drug could potentially be infringed by anyone.").

150 On a more basic level, it is debated whether the sale of digitized drug blueprints would constitute a "sale" under 35 U.S.C. § 271. This would mean the sale of chemical blueprints to a consumer, which would provide the consumer with the plans to print a patented drug, is not a "sale" for the purposes of patent infringement. Therefore, the risk of liability for patent infringement could fall entirely on the uninformed consumer. *See* Brean, *supra* note 15, at 790–93 (explaining how "an offer to sell CAD files for a patented product" does not constitute infringement of the patented product).

151 35 U.S.C. § 271(b)–(c) (2012).

152 Brean, *supra* note 15, at 771–72.

153 *Id.* at 795–96 ("[A]ny distributor of CAD files having actual knowledge or willful blindness that the file digitally represents a patented product will be

distributors could also be held contributorily liable for patent infringements if they sell the printers "knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use."[154] This could happen if the 3-D pharmaceutical printer market is driven primarily by consumers producing patent-infringing drugs. Although patent laws would occupy a smaller role in the regulation of 3-D printed pharmaceuticals compared to their current regulatory dominance, patent infringement could supply the basis to curb an infringer's efforts depending on the facts of the case.

C. Regulation Under Federal Export Laws & Regulations

In light of the U.S. Department of State's invocation of ITAR following the posting of 3-D gun blueprints on the Internet,[155] the government could likely assert a similar position against the exporting of drug blueprints. Although pharmaceuticals are not regulated under ITAR,[156] the government could still argue that the posting of drug blueprint data on the internet is an "export" subject to governmental oversight.

Under the Export Administration Regulations (EAR), the U.S. Department of Commerce controls the exportation of certain information over the Internet.[157] For the purposes of EAR, the term "export" is defined as follows:

> The export of encryption source code and object code software controlled for "EI" reasons under ECCN 5D002 on the Commerce Control List . . . includes downloading, or causing the downloading of, such software to locations (including electronic bulletin boards,

found liable for active inducement of infringement. . . . Since the resulting CAD files are distributed with the intention that they be printed, which itself constitutes a direct infringement by making the patented product, the distributor may thus be liable as an active inducer of that infringement."). However, litigants will likely have difficulty meeting the standard required for proving "willful blindness." *See* Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2070 (2011) ("[A manufacturer] must subjectively believe that there is a high probability that a fact [i.e., infringement] exists and . . . must take deliberate actions to avoid learning of that fact.").

154 35 U.S.C. § 271(c).

155 *See supra* notes 91–95 and accompanying text.

156 *See generally* 22 C.F.R. § 121.1 (2015) (providing twenty categories of defense "articles, services, and related technical data" subject to federal regulation).

157 15 C.F.R. § 734.2(b)(9) (2015).

> Internet file transfer protocol, and World Wide Web sites) outside the U.S., or making such software available for transfer outside the United States, over wire, cable, radio, electro-magnetic, photo optical, photoelectric or other comparable communications facilities accessible to persons outside the United States, including transfers from electronic bulletin boards, Internet file transfer protocol and World Wide Web sites, unless the person making the software available takes precautions adequate to prevent unauthorized transfer of such code.[158]

This means that the federal government has jurisdiction to regulate "encryption items" (EI)[159] that are either shared directly with foreign nationals over the Internet, or posted publically on the Internet such that they are available for foreign nationals to download. Exporters may only post or share EI information if licensed to do so, unless they are exempt from the licensing requirement under the "License Exception ENC."[160] This is similar to the licensing requirements under ITAR.[161] Because the Department of State effectively used this licensing requirement as a mechanism to force DD to take down 3-D gun blueprints on a traditional website,[162] the government could use this as a method to control the unauthorized posting and sharing of 3-D printed blueprints under EAR. Additionally, while federal courts have not decided whether electronic data constitutes an "article" subject to export laws, this argument has gained traction following a recent ruling by the International Trade Commission.[163]

Despite their role in the shutdown of DD's gun blueprint webpage, federal export laws and regulations are likely to be less effective in controlling the dissemination of drug blueprints shared through P2P file-sharing networks. This challenge is apparent due to the continued availability of 3-D gun blueprints

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158 *Id.* § 734.2(b)(9)(ii).

159 *Id.* § 742.15(a)(1).

160 *Id.*

161 22 C.F.R. § 123.1.

162 *See supra* notes 91–95 and accompanying text.

163 Lisa Shuchman, *ITC Rules Transmitted Data Can Be an IP 'Article,'* CORP. COUNS. (Apr. 4, 2014), http://www.corpcounsel.com/id=1202649832699/ITC-Rules-Transmitted-Data-Can-Be-an-IP-Article. *But see In re* Certain Digital Models, Digital Data, & Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, & Methods of Making the Same, Inv. No. 337-TA-833, slip op. (U.S. Int'l Trade Comm'n Apr. 9, 2014), *appeal docketed*, No. 14-1527 (Fed. Cir. June 5, 2014) (appealing the ITC's ruling).

and copyright infringing music files on P2P networks. As long as unauthorized exporters and copyright infringers are able to hide behind ISPs, the government will be less effective in regulating these technologies.

D. Regulation of 3-D Printed Pharmaceuticals by the Food & Drug Administration

The current mission of the Food and Drug Administration (FDA) is to protect the health of the public by regulating the clinical trials, marketing, labeling, and overall safety and effectiveness of drugs.[164] In order to carry out this mission, the FDA regulates drug manufacturers and wholesalers.[165]

The FDA regulates drug manufacturers by monitoring the safety and effectiveness of new and approved prescription drugs.[166] Drug manufacturers must receive FDA approval before introducing a new manufactured drug into interstate commerce.[167] Under the Food and Drug Act, "new drugs" are those not readily recognizable by experts who are trained to evaluate drugs for safety and effectiveness.[168] In order to be considered for approval by the FDA to produce new drugs, drug manufacturers must provide the following: clinical reports showing that the drug is safe and effective to use; a complete list of the drug's chemical components; a complete record of the drug's chemical composition and the methods used in creating the composition; complete information about manufacturing, processing, and packing methods; drug and drug component samples; the proposed labeling; and the patent number and expiration date of existing patents whose owner could reasonably assert a claim of patent infringement against the applicant.[169]

After the approval of a new drug, the FDA continues to regulate drug manufacturers in an effort to ensure continued

164 21 U.S.C. § 393(b) (2012).

165 *See infra* notes 166–86 and accompanying text.

166 *See* AM. COLL. OF PHYSICIANS, IMPROVING FDA REGULATION OF PRESCRIPTION DRUGS 2 (2009), *available at* http://www.acponline.org/advocacy/current_policy_papers/assets/fda.pdf (discussing the FDA's "current system of drug safety monitoring" with respect to the preapproval of new drugs).

167 *See* 21 U.S.C. § 355 (West, Westlaw through P.L. 113-296 approved 12/19/14) (proscribing application and approval guidelines prior to the introduction of any "new drugs" into interstate commerce).

168 21 U.S.C. § 321(p) (2012).

169 *Id.* § 355(b)(1).

compliance with FDA manufacturing standards.[170] Manufacturers can be in violation of FDA standards if they produce a drug that is characterized as an "adulterated" manufactured good.[171] A drug is deemed to be an adulterated manufactured good if its strength, quality, or purity is below the official standard, or is below the standard advertised by the manufacturer if there is no official standard.[172] These quality standards also apply to drug "components"[173] and raw materials,[174] meaning that the FDA not only regulates drugs, but the raw materials used to produce drugs as well.[175] Penalties for manufacturing an adulterated drug, or introducing or receiving an adulterated drug in interstate commerce, include up to a year prison and a $1000 fine.[176] If the violation is committed with an "intent to deceive," then penalties are increased to up to three years imprisonment and up to a $10,000 fine.[177] Manufacturers could face even more severe penalties if they knowingly violate FDA standards, thereby causing a risk to a person's health.[178] These penalties could include up to twenty years of imprisonment and fines up to $1,000,000.[179]

In addition to drug manufacturers, wholesale distributors are also regulated by the FDA.[180] Any person who engages in the

170 *See id.* § 351 (Supp. 2013) (setting forth standards for drug purity, strength, quality, and sanitation).

171 *Id.*

172 *Id.* § 351(b)–(c).

173 *See* 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.").

174 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).

175 21 U.S.C. § 351 (Supp. 2013) ("[T]he term 'current good manufacturing practice' includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.").

176 21 U.S.C. § 331(a)–(c) (2012).

177 *Id.* § 333(a)(2).

178 21 U.S.C. § 333(b)(7) (Supp. 2013) ("[A]ny person that knowingly and intentionally adulterates a drug . . . and has a reasonable probability of causing serious adverse health consequences or death to humans or animals [is subject to more severe penalties.]").

179 *Id.*

180 *See id.* § 360eee-2(b) (West, Westlaw through P.L. 113-296 approved 12/19/14) (setting forth the standards for prescription drug wholesale distributors).

wholesale distribution of pharmaceuticals must be licensed.[181] In order for an applicant to obtain a wholesale drug distribution license, the applicant must provide personal and business information.[182] Once the applicant provides this information, the state licensing body is required to consider an extensive list of statutory factors when determining whether to grant the license.[183] Additionally, an applicant can be denied a license if the licensing authority determines that "the granting of such a license would not be in the public interest."[184] Applicants who engage in the distribution of drugs after being denied a license could face severe penalties. Individuals who knowingly engage in the wholesale distribution of drugs without a license could be imprisoned for up to ten years and fined up to $250,000. After licensure, wholesale distributors are still subject to FDA regulation under the Prescription Drug Marketing Act.[185] Violation of the requirements under this Act results in the same level penalties for violating distributor licensing requirements.[186]

Despite the extensive oversight by the FDA over the current production of pharmaceuticals, the focus of this regulatory body

[181] *See id.* § 353(e) (requiring wholesale distributors engaged in interstate commerce of drugs to be licensed in the state in which the drug is distributed, or, in the alternative, licensed by the federal government); 21 C.F.R. § 205.4 (2015); 21 C.F.R. § 203.3(dd) ("Wholesale distributor means any person engaged in wholesale distribution of prescription drugs . . . .").

[182] 21 C.F.R. § 205.5.

[183] *Id.* § 205.6(a). Factors include prior drug distribution related convictions, any felony convictions, past work experience in the field, prior false information provided on an application for a manufacturing or distribution license, compliance under previous license requirements, willingness to comply with records requirements in cooperation with the licensing authority or law enforcement, or *any other factor* found to be relevant to public health and safety. *Id.*

[184] *Id.* § 205.6(b).

[185] Under this Act, distributors that are not "authorized distributors of record" must provide purchasers with drug "pedigree" information. *See 1.1 Regulatory Framework for the Distribution of Prescription Drugs*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/ucm256466.htm (last updated May 25, 2011) ("[A drug's] identifying statement [is] also known as the drug product's pedigree."); *see also* 21 U.S.C. § 353(d)(2)(A) (2012); 21 C.F.R. § 203.50.

[186] *See* 21 U.S.C. § 331(d) ("The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title [is a prohibited act]."); *id.* § 333(a)(1) ("Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both."). If the violation is committed with the "intent to defraud or mislead" then the penalty includes up to three years in prison, and up to a $10,000 fine. *Id.* § 333(a)(2).

will need to change following the introduction of 3-D printed drugs. The current FDA regulatory structure ensures pharmaceuticals are safe for consumers by requiring drug manufacturers to adhere to strict testing, production, packaging, and marketing standards. However, it will be much more difficult to regulate the drugs produced in a consumer's home.[187] In addition to the logistical impossibility of regulating consumers' home manufacturing sites, Congress may only regulate products that substantially affect interstate commerce.[188] However, 3-D printing components could fall under congressional oversight if they pass through or otherwise substantially affect interstate commerce.

Additionally, 3-D printed pharmaceuticals could still be effectively regulated by the FDA through the regulation of chemical inks. The chemical inks proposed by Cronin would contain chemical compounds,[189] which, when combined during the printing process, would create a drug intended to treat human diseases.[190] Therefore, chemical inks should qualify as drug "components" subject to FDA regulations. This means that chemical ink manufacturers would be required to comply with FDA manufacturing quality standards and chemical ink wholesale distributors would be subject to licensing requirements.

E. Criminal Statutes

Criminal statutes could provide an additional deterrent for pharmaceutical printer operators by supplying a charging tool for prosecutors. Under federal law, it is a crime for "any person knowingly or intentionally . . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance."[191] Controlled substances under this law include drugs like "date rape" pills, heroin, cocaine, and marijuana.[192] Penalties increase according to schedules that are

187 Goodman, *supra* note 6.

188 United States v. Lopez, 514 U.S. 549, 559 (1995) (citing U.S. CONST. art. 1, § 8, cl. 3).

189 *See* discussion *supra* Part III.

190 Cronin, *supra* note 4.

191 21 U.S.C. § 841(a).

192 *Id.* § 841(b).

based on the type and quantity of the substance.[193] Additionally, an individual who illegally manufactures a controlled substance, even if contained within state lines, is subject to federal prosecution.[194]

Despite the prevalence of pharmaceutical drug abuse in the U.S.,[195] pharmaceuticals are not included within the provisions of this statute. This may be the result of the current physical limits on a drug user or drug dealer's ability to manufacture these drugs.[196] However, following the introduction of 3-D pharmaceutical printers, drug dealers and abusers would be able to easily produce these pills. The definition of "controlled substances" should be expanded under this statute to included pharmaceutical drugs. This way, federal prosecutors will be able to charge drug dealers and abusers who use 3-D printers to print counterfeit drugs.

VIII. CONCLUSION

3-D printed pharmaceuticals will revolutionize the distribution of drugs in the United States and throughout the world. This technology carries with it promises of reduced transaction costs, increased availability, and convenience. Fortunately, limited regulation may be possible under current laws. However, there are regulatory gaps that need to be addressed soon because technology moves quickly, and can often outpace ex post facto attempts by lawmakers to implement effective regulatory controls. As a result, Congress should acknowledge the imminence of 3-D printing technologies, and should begin proactively addressing this issue. At the very least, Congress should immediately set up a task force to study the potential effects of 3-D printed drugs being introduced into the United States. Additionally, Congress should take action to proactively

193 *Id.*

194 *See id.* § 801 ("Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.").

195 *See* David L. Robinson, *Bridging the Gaps: Improved Legislation to Prohibit the Abuse of Prescription Drugs in Virginia*, 9 APPALACHIAN J.L. 281, 281 (2010) ("The abuse of prescription pain medicine continues to plague our great nation.").

196 *See supra* notes 149–50.

amend federal criminal statutes to include pharmaceuticals as "controlled substances," and assess the effect of reduced ISP liability protections on the effectiveness of copyright laws in the digital age.