

MANUFACTURING CONSUMER PROTECTION FOR 3-D PRINTED PRODUCTS

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Additive manufacturing, also known as “3-D printing,” is an exciting technology with the potential to revolutionize a host of industries and transform the ways in which products reach consumers. Products printed using this 3-D technology raise a number of legal and policy issues, particularly in the realm of products liability law. Despite that, this Note argues that slow-moving legislation will likely be the least effective means to address this rapidly changing industry. The reasons for rejecting a legislative approach to the 3-D printing industry are three-fold: (1) government regulation goes against the open-source spirit of the 3-D printing industry; (2) the industry is equipped to develop innovative solutions for many of its own legal and regulatory problems; and (3) when legal issues do arise that require litigation, courts are better equipped to resolve those issues on a case-by-case basis. When regulation is necessary, administrative rulemaking should be preferred over comprehensive legislation because the rulemaking process requires extensive industry involvement through the notice and comment process, and agencies are more quickly able to amend and issue new rules to address changing technology.

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INTRODUCTION

Imagine that one day your coffee maker breaks and you decide to buy a new one. Instead of heading to the nearest store, you go online, download a digital file, and then “print” a new coffee maker, all from the comfort of your home. While the technology is not quite there yet, it is rapidly developing, and this scenario could soon become a reality.¹ Additive manufacturing, commonly known as “3-D printing,”² is a manufacturing process “based on the principle of joining thin layers of materials, both solid and liquid, in horizontal cross-section, to build up a real, three-dimensional object from a digital model.”³ Although 3-D printing has been used mainly by manufacturers or hobbyists who can afford the high initial cost,⁴ the price of 3-D printers has dropped in recent years,⁵ making consumer use of 3-D printers more widespread. In fact, experts predict that consumer access to 3-D printing will grow exponentially in the next year or two as

1. A consumer can already download an “electric coffee maker” digital file from the 3-D printing website Thingiverse and print it at home, but this model would require additional skill and knowledge to assemble. Siemen, *Electric Coffee Maker*, MAKERBOT THINGIVERSE (May 30, 2014), <http://www.thingiverse.com/thing:348199>; see also Siemenc, *Electric Coffee Maker*, INSTRUCTABLES, <http://www.instructables.com/id/Electric-Coffee-Maker/> (last visited Feb. 1, 2015).

2. Although additive manufacturing is a more technically precise term, I will refer to the technology as “3-D printing” throughout this Note due to its more widespread colloquial use.

3. MAYER BROWN, HOW TO EXPLORE THE POTENTIAL AND AVOID THE RISKS OF ADDITIVE MANUFACTURING 3 (2014). This video is a great example of the 3-D printing process: Practical Projects, *3-D Printing Timelapse—General Electric Jet Engine Model*, YOUTUBE (Dec. 3, 2014), <https://www.youtube.com/watch?v=FaVVVsJlvug>.

4. See Jeremy Hsu, *3D Printing: What a 3D Printer Is and How it Works*, LIVESCIENCE (May 21, 2013, 12:57 PM), <http://www.livescience.com/34551-3d-printing.html>.

5. See, e.g., Search Results for “3-D Printer,” AMAZON, http://www.amazon.com/s/ref=sr_pg_3?fst=as%3Aoff&rh=n%3A16310091%2Cn%3A6066126011%2Cn%3A6066127011%2Ck%3A3-D+printer&page=3&sort=price-asc-rank&keywords=3-+printer&ie=UTF8&qid=1420837225 (last visited Feb. 1, 2015) (showing 3-D printers for sale starting at \$349). Prices have rapidly gone down in the last two years, and are likely to continue to plummet. See Charles W. Finocchiaro, *Personal Factory or Catalyst for Piracy? The Hype, Hysteria, and Hard Realities Consumer of 3-D Printing*, 31 CARDOZO ARTS & ENT. L.J. 473, 489 (2013) (quoting the typical price of a 3-D printer at \$1,749 just two years ago).

a result of improving printer technology and because of new players like computer and software company Hewlett-Packard entering the marketplace.⁶

This new technology has incredible potential to revolutionize countless industries, such as medicine,⁷ pharmaceuticals,⁸ and architecture.⁹ From 3-D-printed organs¹⁰ that could save lives to customized prosthetics that allow users to do things that would never have been possible before now,¹¹ to expanding access to medical devices in developing nations¹²—the potential of 3-D printing is truly staggering. The Obama Administration has wholeheartedly embraced this technology, launching America Makes in 2012¹³ to “provide the innovation infrastructure needed to support new additive manufacturing technology and products in order to become a global center of excellence for additive manufacturing.”¹⁴ A number of federal agencies¹⁵ have acquired 3-D printers, including NASA, which recently sent a 3-D printer to the International Space

6. Brian Krassenstein, *Why Experts Are Likely Underestimating the 2015 3D Printing Market*, 3DPRINT (Jan. 12, 2015), <http://3dprint.com/34560/2015-3d-printing-gartner/>.

7. See, e.g., Te Edwards, *Researchers Use 3D Printed Models to Save Lives with Delicate Ventricular Surgery*, 3DPRINT (Jan. 30, 2015), <http://3dprint.com/40946/3d-printed-models-save-lives/>; James O’Toole, *3-D Printed Organs Are on the Way*, CNN MONEY (Nov. 4, 2014, 12:41 PM), <http://money.cnn.com/2014/11/04/technology/innovation/3-D-printed-organs/>.

8. See, e.g., David McNamee, *3D Printing May Make Individualized Medicine More Affordable*, MEDICAL NEWS TODAY (Oct. 25, 2014, 12:00 AM), <http://www.medicalnewstoday.com/articles/284381.php>.

9. See, e.g., Eddie Krassenstein, *Andrey Rudenko Reveals Plan to 3-D Print Bases on the Moon and Buildings in Earth’s Deserts*, 3DPRINT (Jan. 29, 2015), <http://3dprint.com/40739/3d-printer-moon-deserts/>; Eddie Krassenstein, *Andrey Rudenko Plans to 3-D Print a 2-Story ‘Zero Energy’ House in 5 Days with Advanced 3-D Printer*, 3DPRINT (Jan. 27, 2015), <http://3dprint.com/40154/3d-printed-house-rudenko/>.

10. Edwards, *supra* note 7.

11. John Biggs, *Teen Can Play Guitar Thanks to a 3D-Printed Prosthetic Hand*, TECH CRUNCH (Feb. 2, 2015, 4:24 PM), <http://techcrunch.com/2015/02/02/teen-can-play-guitar-thanks-to-a-3d-printed-prosthetic-hand/>.

12. Bridget Butler Millsaps, *e-NABLE Volunteers Set Sights on Full-Scale Project for 3D Printing Prostheses in Haiti*, 3DPRINT (Jan. 22, 2015), <http://3dprint.com/38968/e-nable-prosthetics-haiti/>.

13. America Makes was previously called the National Manufacturing Innovation Institute. *When America Makes, America Works*, AMERICA MAKES, <https://americamakes.us/> (last visited Mar. 1, 2015).

14. Press Release, White House, *We Can’t Wait: Obama Administration Announces New Public-Private Partnership to Support* (Aug. 16, 2012), available at <http://www.whitehouse.gov/the-press-office/2012/08/16/we-can-t-wait-obama-administration-announces-new-public-private-partners>.

15. See Jelmer Luimstra, *Will a 3D Printer Help the FBI to Fight Terrorists?*, 3DPRINTING (June 22, 2014), <http://3dprinting.com/news/will-3d-printer-help-fbi-fight-terrorists/> (describing the Department of Justice’s acquisition of a 3-D printer); see also Marcus Weisgerber, *The Defense Industry is Expanding the Use of 3D Printing*, DEFENSE ONE (Sept. 29, 2014), <http://www.defenseone.com/technology/2014/09/defense-industry-expanding-use-3-D-printing/95396/> (describing the Department of Defense’s use of multiple 3-D printers).

Station, allowing astronauts to remotely print tools that otherwise would have taken months to arrive.¹⁶

Much of the legal scholarship on 3-D printing focuses on the disruptive and potentially negative impacts of the technology, including dire warnings of its potential to destroy intellectual property protections¹⁷ and, even more sinister, its potential to create an untraceable, undetectable arsenal of 3-D printed weapons.¹⁸ This Note takes a more positive position—it examines the legal, technological, and policy implications of 3-D printed products and concludes that innovation in this area should not be stifled by oppressive government regulation.

This Note focuses on 3-D printed products, which range from medical devices¹⁹ to pizza²⁰ to light-up Harry Potter wands,²¹ and liability for consumer injuries caused by product defects. Thus far, there has been limited discussion of products liability as it relates to 3-D printing in legal scholarship.²² This Note fills

16. James Temperton, *NASA Just E-mailed a Wrench to Space*, ARSTECHNICA (Dec. 19, 2014, 9:40 AM), <http://arstechnica.com/science/2014/12/nasa-just-e-mailed-a-wrench-to-space/>.

17. See, e.g., Deven R. Desai & Gerard N. Magliocca, *Patents, Meet Napster: 3D Printing and the Digitization of Things*, 102 GEO. L.J. 1691 (2014) (analyzing patent law issues that 3-D printing raises); Davis Doherty, *Downloading Infringement: Patent Law as a Roadblock to the 3D Printing Revolution*, 26 HARV. J.L. & TECH. 353 (2012) (analyzing patent law issues that 3-D printing could create); Finocchiaro, *supra* note 5, at 475 (describing the idea of “Napster Fabling,” that “as 3-D printing becomes available to the general public, peer-to-peer services will be flooded with schematics for physical products, which would pose a similar threat to designers and manufacturers as Napster and its progeny did to the entertainment industry[.]” and describing the limits to this idea); Anne Lewis, Comment, *The Legality of 3D Printing: How Technology is Moving Faster Than The Law*, 17 TUL. J. TECH. & INTELL. PROP. 303, 311–17 (2014) (discussing potential patent infringement issues from 3-D printing).

18. See, e.g., Kyle Dolinsky, Note, *CAD’s Cradle: Untangling Copyrightability, Derivative Works, and Fair Use in 3D Printing*, 71 WASH. & LEE L. REV. 591 (2014) (analyzing copyright issues and 3-D printing); Lewis, *supra* note 17, at 304–11 (discussing potential legal issues surrounding 3-D printed guns and state and federal legislation to regulate these weapons); Katie Fleschner McMullen, *Worlds Collide When 3D Printers Reach the Public: Modeling a Digital Gun Control Law After the Digital Millennium Copyright Act*, 2014 MICH. ST. L. REV. 187 (describing various issues surrounding government regulation of 3-D printed guns).

19. *New Trends in 3D Printing—Customized Medical Devices*, ENVISION TEC., <http://envisiontec.com/trends-in-3d-printing-of-customized-medical-devices/> (last visited Apr. 5, 2015).

20. Marty Sliva, *CES 2015: We Ate 3D-Printed Pizza*, IGN (Jan. 8, 2015), <http://www.ign.com/articles/2015/01/08/ces-2015-we-ate-3d-printed-pizza>.

21. TuxedoDiplomat, *LED Wand Inspired by Harry Potter*, MAKERBOT THINGIVERSE (Nov. 16, 2012), <http://www.thingiverse.com/thing:34675>.

22. Only two works of legal scholarship that discuss 3-D printing and products liability have been published. Nora Freeman Engstrom was the first to write on products liability and 3-D printing and her article provides an excellent discussion of potential issues, particularly involving hobbyist sellers. Nora Freeman Engstrom, *3-D Printing and Product Liability: Identifying the Obstacles*, 162 U. PA. L. REV. ONLINE 35, 36 (2013). Lucas Osborn has also provided an excellent discussion of product liability involving computer-aided design file designers, but his treatment is necessarily brief as his article covers a wide range

a hole in the literature by expanding the products liability discussion and providing a map for creating effective and efficient 3-D printing policy. Part I provides an overview of 3-D printing technology, including a discussion of current uses, and the limits to this technology in printing tangible products. Part II outlines how 3-D printing disrupts the manufacturing supply chain and, in some instances, nearly eliminates it entirely. Section A discusses four different manufacturing frameworks through which a 3-D printed product might reach a consumer. Section B outlines how strict products liability law would apply in each framework to provide redress for consumers injured by defective products, and explores potential problems and solutions. Finally, Part III argues that the 3-D printing industry and the courts are better equipped than Congress to address the majority of legal issues stemming from 3-D printing. With its huge promise to revolutionize a wide array of industries that directly impact consumers, Congress should not stifle 3-D printing's potential with crippling over-regulation; instead, private industry and the courts are better positioned to regulate this new, and ever-changing, technology.

I. WHAT IS 3-D PRINTING, AND WHY IS EVERYONE SO AFRAID OF IT?

A 3-D printer uses instructions from a digital file—often a computer-aided design (“CAD”) file—and follows the file’s digital blueprint to print a product.²³ An individual can design a CAD file using 3-D modeling software, or by scanning a physical object.²⁴ The 3-D printer then reads the CAD file and “prints” the object using a variety of filaments, including plastic, ceramics, metal, or even food.²⁵ To print an object, the 3-D printer builds an object by adding layer upon layer of filament until the object is complete.²⁶

Although the technology continues to evolve, the average consumer would find it difficult to use a 3-D printer without training,²⁷ so hobbyists currently dominate the industry. A recent episode in the popular television show *The Big Bang Theory* featured two characters using a 3-D printer, and illustrates some of the limitations of 3-D printing technology as it currently stands.²⁸ In the episode, the characters buy an expensive 3-D printer with the intention of printing miniature replicas of themselves, but the only item they printed before returning the printer

of legal issues involving 3-D printing in addition to products liability, including intellectual property, environmental law, and domestic firearm manufacturing. Lucas S. Osborn, *Regulating Three-Dimensional Printing: The Converging Worlds of Bits and Atoms*, 51 SAN DIEGO L. REV. 553, 571 (2014).

23. Hsu, *supra* note 4.

24. *Id.*; *Sense 3D Scanner*, CUBIFY, <http://cubify.com/Products/Sense> (last visited Apr. 5, 2015).

25. Hsu, *supra* note 4.

26. *Id.*

27. See, e.g., Chris Elsworthy, *The Disconnect Between 3D Printing Software & Hardware*, 3DPRINT (Mar. 1, 2015), <http://3dprint.com/47718/3d-printer-hardware-software/>.

28. *Big Bang Theory: The Cooper/Kripke Inversion* (CBS television broadcast Jan. 31, 2013).

was a whistle that took them three hours to print, and which they acknowledged would have only cost \$0.25 if it had been traditionally manufactured. Similarly, the average consumer would struggle to print anything much beyond decorative items, because objects take a long time to print, require a large amount of filament, and demand complicated assembly that usually involves non-3-D printed parts.²⁹ Those who are able to harness the technology, however, are able to print functional and innovative products. Many 3-D printer owners use the printers to replicate broken appliance parts,³⁰ some of which would likely be hard to find or expensive to purchase. With advancing technology and increased ease of use, consumers should soon be able to print many household products, some of which may be complicated and potentially dangerous, and may thus expose various parties to potential liability for resulting injuries.

II. 3-D PRINTED PRODUCTS, LIABILITY FOR DEFECTS, AND CONSUMER PROTECTION

A. *How 3-D Printing Disrupts Traditional Manufacturing Supply Chains: Four Ways 3-D printed Products Reach Consumers*

Before examining potential liability for defects, it is necessary to discuss how 3-D printed products reach consumers. With consumers and new industries increasingly embracing 3-D printing, the technology will continue to revolutionize not only manufacturing, but also supply chain and logistics processes—decreasing the environmental impact of shipping, inventory, and waste by allowing consumers to print at home efficiently.³¹ 3-D printed products can reach a consumer in at least four distinct ways.

First, companies like Amazon or Shapeways may sell 3-D-printed items, many of them custom or unique, and send them directly to the consumer. Amazon recently launched an online shop for 3-D printed products, allowing consumers to purchase everything from artistic jewelry to miniature figurines of themselves.³² In such an arrangement, the consumer receives the product as she normally would, but the manufacturing process differs. Second, a hobbyist may directly sell 3-D printed products that the hobbyist has designed and manufactured to the consumer.

29. See, e.g., EricthePoolBoy, *Toyota 4 Cylinder Engine*, MAKERBOT THINGIVERSE (Jan. 22, 2015), <http://www.thingiverse.com/thing:644933>.

30. David Galloway, *Replicate Broken Appliance Parts with a 3D Printer*, LIFEHACKER (Mar. 18, 2012, 1:00 PM), <http://lifelhacker.com/5894289/replicate-broken-appliance-parts-with-a-3-d-printer>.

31. Hans-Georg Kaltenbrunner, *How 3D Printing is Set to Shake Up Manufacturing Supply Chains*, GUARDIAN (Nov. 25, 2014, 9:18 AM), <http://www.theguardian.com/sustainable-business/2014/nov/25/how-3d-printing-is-set-to-shake-up-manufacturing-supply-chains>.

32. *Amazon's 3D Printing Store*, AMAZON, http://www.amazon.com/b/ref=to_pnav_storetab_3-Dp?ie=UTF8&node=8323871011 (last visited Feb. 1, 2015). Shapeways is another example of this, but on an even larger scale. SHAPEWAYS, <http://www.shapeways.com/> (last visited Feb. 1, 2015). On Shapeways, many of the CAD files are designed by third-party artists, but Shapeways prints the products and sends them directly to the consumer. *Run Your Business on Shapeways with 3D Printing*, SHAPEWAYS, <http://www.shapeways.com/sell> (last visited Feb. 1, 2015).

For example, many sellers on the online artisan marketplace Etsy design their own CAD files and sell products that they 3-D print and ship to consumers, ranging from Batman cookie cutters to 3-D printed T-Rex shower heads.³³ Third, a consumer can purchase a CAD file (or download it from an open-source website like Thingiverse³⁴) and print the item at home on her own 3-D printer. Martha Stewart recently entered the 3-D printing arena by opening a digital store on MakerBot.³⁵ There, a consumer can download CAD files for \$0.99 to print unlimited coasters, napkin rings, and votive holders.³⁶ This type of manufacturing has the most potential to expand as the price of desktop 3-D printers continues to plummet and as technology improves, making 3-D printers more accessible to non-hobbyists. Fourth, a consumer can scan a product, use special software to render it as a CAD file, and print the product (often a replacement part) on her 3-D printer.³⁷ These four manufacturing processes disrupt the way products traditionally reach consumers, potentially leaving consumers more vulnerable to defective products.

B. Liability for Defective 3-D Printed Products

As consumers begin to print increasingly dangerous and complex products at home, they may seek redress in the courts for injuries sustained through a product's use. Because 3-D printing disrupts the traditional manufacturing supply chain, the strict products liability framework may be forced to change to accommodate this new technology.³⁸ To understand the issues raised by 3-D printing, it is useful to examine how products liability principles apply to each of the four manufacturing frameworks discussed above.³⁹

1. Traditional Manufacturers and Sellers Sell 3-D Printed Products

If a consumer buys a defective 3-D printed product from Amazon or Shapeways, traditional strict products liability principles would likely apply.

33. Search Results for "3-D Printed," ETSY, <https://www.etsy.com/search?q=3-D%20printed> (last visited Apr. 5, 2015).

34. *About*, MAKERBOT THINGIVERSE, <http://www.thingiverse.com/about> (last visited Feb. 1, 2015) ("As the world's largest 3D printing community, we believe that everyone should be encouraged to create and remix 3D things, no matter their technical expertise or previous experience. In the spirit of maintaining an open platform, all designs are encouraged to be licensed under a Creative Commons license, meaning that anyone can use or alter any design."). The Smithsonian also recently opened a 3-D printing website, where users can download CAD files and print a variety of historical and artistic products, including 3-D-printed ornaments from the White House's ornament challenge, for free. *Smithsonian X 3-D*, SMITHSONIAN, <http://3d.si.edu/> (last visited Feb. 1, 2015).

35. Rain Noe, *Martha May Make MakerBot Mainstream*, CORE77 (Nov. 17, 2014), http://www.core77.com/blog/business/martha_may_make_makerbot_mainstream_27909.asp.

36. *Martha Stewart Living*, MAKERBOT DIGITAL STORE, <https://digitalstore.makerbot.com/martha-stewart> (last visited Feb. 1, 2015). Consumers can purchase filaments in those shades from the same digital store.

37. *E.g.*, Galloway, *supra* note 30.

38. Engstrom, *supra* note 22.

39. *See supra* Part II.A.

Under the doctrine of strict liability, “one engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.”⁴⁰ A product is “defective” under the Restatement (Third) of Torts if it has a manufacturing or design defect, or if it is accompanied by an inadequate instruction or warning.⁴¹ The theory underlying the imposition of strict products liability is threefold: (1) those who manufacture and sell products tend to be enterprises; (2) imposing liability on enterprises is fair because those who profit from the risk should bear the costs of accidents; and (3) enterprises are better than injury victims at absorbing and distributing losses.⁴²

Because both Amazon and Shapeways would likely be considered commercial sellers, traditional strict products liability would apply to them, regardless of the process by which the products are manufactured. One complicating factor, however, is that both Amazon and Shapeways print and sell products that are designed by third parties.⁴³ They hold themselves out as service providers rather than manufacturers, and may attempt to contract out of liability for defects and instead hold CAD-file designers responsible.⁴⁴ Although this question is not settled in case law, independent designers of products are generally not held strictly liable for defects in their designs, but may be liable for negligence in their designs.⁴⁵ If the manufacturing process caused defects, Shapeways could be strictly liable, but it could argue that it was not a “manufacturer” and rather a service provider with little knowledge of the product it prints or opportunity to consider product safety.⁴⁶ Indeed, this seems to be what Shapeways is attempting to do in its Terms and Conditions for independent sellers.⁴⁷ Even though these companies may attempt to evade liability in future cases by arguing that they are merely “service providers,” companies like Amazon and Shapeways should be held strictly liable under traditional products liability law because doing so not only satisfies consumers’ expectations but is also consistent with the principles of fairness and cost-efficiency⁴⁸ underlying the imposition of strict liability for product defects.

40. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (1998).

41. *Id.* § 2.

42. See Engstrom, *supra* note 22. But see Alan Schwartz, *The Case Against Strict Liability*, 60 FORDHAM L. REV. 819 (1992).

43. Osborn, *supra* note 22.

44. *Terms and Conditions*, SHAPEWAYS, http://www.shapeways.com/terms_and_conditions (last visited Feb. 1, 2015) (In its agreement with designers and sellers, under “Limitation of Liability,” Shapeways states that it will “not be liable for any . . . indirect, incidental, exemplary, special, punitive or consequential loss or damage of any kind howsoever arising and whether caused by tort (including negligence)” It further limits its liability in tort including negligence to not “exceed the fee received from you by Shapeways for the relevant order”).

45. Melissa Evans Buss, *Products Liability and Intellectual Property Licensors*, 27 WM. MITCHELL L. REV. 229, 313–14 (2000).

46. Osborn, *supra* note 22.

47. See *Terms and Conditions*, *supra* note 44.

48. See *supra* note 41 and accompanying text.

2. *Hobbyist Sellers Design, Print, and Sell 3-D Printed Products*

The law becomes more complicated when hobbyist sellers get involved. For example, if a consumer bought a product from an Etsy seller who designed, manufactured, and shipped the product directly to the consumer, strict liability may or may not apply. Strict products liability applies only to commercial sellers,⁴⁹ while occasional or casual vendors, such as a “housewife who makes and sells contaminated jam,” fall outside the scope of strict liability.⁵⁰ Whether the Etsy seller would be a “commercial seller” depends on the frequency and volume of sales, and the existence and nature of any marketing.⁵¹ If sellers are no longer enterprises, and instead are sole proprietor hobbyists, is imposing strict liability still justified?⁵² Under this framework, a simple negligence standard may be more equitable depending on the circumstances because the majority of these sellers are small, sole proprietorships. Strict liability, however, could be applied on a case-by-case basis, using a flexible analysis that considers the policy considerations underlying the imposition of strict liability⁵³ to determine when an entity is a “commercial seller” rather than an “occasional or casual seller,”⁵⁴ making this area best suited for the courts.

3. *Consumer 3-D Prints Products Designed by a Third Party*

When an additional player is involved—an independent CAD-file designer—the law becomes even more complicated. A CAD-file designer could be a recognized business entity, an individual, or even a group of identifiable or anonymous individuals. For example, a consumer could purchase a CAD file from MakerBot’s digital store in order to print an item from Martha Stewart’s line on her 3-D printer (also purchased from MakerBot). If the consumer were injured because of a defect in the product, the consumer could try to bring a strict liability claim against two companies: the 3-D printer manufacturer—MakerBot—and the CAD-file designer—Martha Stewart’s company—but both claims would have difficulties.

49. A commercial seller is one “engaged in the business of selling or otherwise distributing products.” RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (1998).

50. Engstrom, *supra* note 22, at 37.

51. *Id.*; *see also* Abco Metals Corp. v. Equico Lessors, Inc., 721 F.2d 583, 584 (1983) (quoting Dunham v. Vaughan & Bushnell Mfg. Co., 42 Ill.2d 339, 344 (1969)) (“Imposition of strict liability upon sellers . . . as well as upon manufacturers arises from their ‘integral role in the overall producing and marketing’ of a defective product.”).

52. Engstrom, *supra* note 22, at 40.

53. *Id.* at 37.

54. *See, e.g.*, Jaramillo v. Weyerhaeuser Co., 906 N.E.2d 387, 391–93 (App. N.Y. 2009) (“The casual or occasional seller of a product does not undertake the special responsibility for public safety assumed by those in the business of regularly supplying those products, nor is there the corollary element of forced reliance on that undertaking by purchasers of such goods. As a practical matter, the occasional seller has neither the opportunity, nor the incentive, nor the protection of the manufacturer or seller who puts that product into the stream of commerce as a normal part of its business, and the public consumer does not have the same expectation when it buys from such a seller.”).

Suits against both companies would be challenging because the plaintiff would have to prove that the 3-D printer itself was defective at the time it left the manufacturer, and the plaintiff would face both practical and legal challenges to bringing a suit against the CAD-file designer. A products liability suit against MakerBot, or even a negligence suit, would be difficult because the plaintiff would have to show the printer itself was defective at the time that it left the manufacturer's possession, not just that the printer manufactured a defective product.⁵⁵ The plaintiff could also attempt to bring a claim against the CAD-file designer, but would face difficulties here because strict liability applies only to "products," defined as "tangible personal property."⁵⁶ Courts have sometimes found computer software to be "products" when mass-marketed rather than customer-specific.⁵⁷ In this hypothetical case, the plaintiff may be able to pursue a suit against the CAD-file designer, Martha Stewart, because the file would have been mass-marketed and sold for a fee, even though nominal.

Nevertheless, a plaintiff may not be able to recover against a CAD-file designer who is not an identifiable entity. CAD files are rarely downloaded from a known business entity, like Martha Stewart, and are, in fact, rarely purchased at all. What more commonly happens, complicating the products liability analysis, is that a consumer downloads a free, open-source CAD file from a website like Thingiverse⁵⁸ (or, for files such as gun parts that Thingiverse will not host, Pirate Bay⁵⁹) and prints the file on her 3-D printer. Because these files are free, not mass-marketed,⁶⁰ and the author is hard to locate because the files are often edited and re-edited by multiple authors, it is likely that the plaintiff could not pinpoint a particular CAD-file designer to sue in this context. Further, even if the file were created by an identifiable author and mass-marketed, it would still be difficult for the plaintiff to argue that the designer was a commercial seller if the file was free.⁶¹ As a result, it is unlikely that a plaintiff could successfully bring a products liability claim against a CAD-file designer when, as is most common, the file is downloaded from a free, open-source website like Thingiverse. A plaintiff could potentially bring a claim under another theory like negligence (if the CAD-file designer were identifiable).⁶² Because of the practical challenges to these suits,

55. Engstrom, *supra* note 22, at 38; *see, e.g.*, Miller v. Ford Motor Co., 287 Ga. App. 642, 644 (2007).

56. Engstrom, *supra* note 22, at 38; Osborn, *supra* note 22, at 568.

57. Osborn, *supra* note 22, at 569.

58. *See supra* note 34 and accompanying text.

59. *See* Alyssa Newcomb, *The Pirate Bay Rises Again, Back Online Two Months After Swedish Police Raid*, ABC NEWS (Feb. 2, 2015, 10:43 AM), <http://abcnews.go.com/Technology/pirate-bay-rises-back-online-months-swedish-police/story?id=28662407>.

60. Osborn, *supra* note 22, at 569.

61. *Id.*

62. *See* William C. Powers, Jr., *Distinguishing Between Products and Services in Strict Liability*, 62 N.C. L. REV. 415, 425 (1984) (criticizing negligence in the products liability context as being "defendant friendly"); *see also* Osborn, *supra* note 22, at 567. For an analysis of CAD files under the Uniform Commercial Code, *see* Osborn, *supra* note 22, at 572–77.

policymakers should seek cooperation from the industry⁶³ to keep CAD-file designers identifiable and accountable.

4. Consumer 3-D Prints a Product from a CAD File Automatically Created by a Scanner

When the consumer scans, designs, and prints a part entirely on her own, the consumer may have the most difficult time seeking recovery if she is injured by a defective product. What commonly happens in this context is that a consumer decides to print a replacement part for an appliance. To do this, the consumer may decide to scan a product using a scanner like the MakerBot Digitizer.⁶⁴ The scanner then automatically creates a CAD file that the consumer can choose to modify before printing it on a 3-D printer. If the 3-D printed replacement part is then defective, whom can the consumer sue? In this context, she is effectively the manufacturer and potentially even the designer.⁶⁵ A consumer could attempt to bring a products liability or negligence suit against the scanner manufacturer, MakerBot, if the CAD file created by the scanner were defective. This would be difficult, however, because the plaintiff would have to show that the scanner, software, or filament was itself defective at the time it left the manufacturer's possession and control.⁶⁶ The law here is particularly unsettled and has the potential to leave consumers vulnerable to defective products without the ability to seek redress. In Part III, I offer a means for best dealing with this ambiguity by seeking solutions from the industry, the courts, and, as a last resort, from the regulatory process.

III. THE 3-D PRINTING INDUSTRY AND THE COURTS ARE MOST EQUIPPED TO ADDRESS LEGAL ISSUES ARISING FROM THE TECHNOLOGY

Products printed using 3-D technology raise a host of legal and policy issues. Slow-moving legislation will often be the least effective means to address the rapidly changing industry. Instead, policymakers should encourage industry involvement in order to reach creative solutions and turn to the courts to address legal issues on a case-by-case basis as they arise. When regulation is necessary, administrative rulemaking should be preferred over comprehensive legislation

63. For example, policymakers could seek cooperation from Thingiverse to ensure that CAD-file designers are identifiable or to require testing the reliability of CAD files before allowing files to be posted on the site. The industry has already proven to be engaged and willing to cooperate with various government agencies, including the Patent and Trademark Office and the Food and Drug Administration. *See* Press Release, U.S. Patent & Trademark Office, USPTO to Host Additive Manufacturing Partnership Meeting (Mar. 5, 2014), *available at* <http://www.uspto.gov/about-us/news-updates/uspto-host-additive-manufacturing-partnership-meeting-0>; *see also infra* Part III.

64. *Makerbot Digitizer*, MAKERBOT, <http://store.makerbot.com/digitizer> (last visited Apr. 5, 2015).

65. There is an argument that, even though the consumer creates the CAD file with the scanner, either the original designer of the physical part or the software engineer of the scanner would be the designer. The law is certainly unsettled in this area.

66. *See supra* note 55 and accompanying text.

because the rulemaking process requires extensive industry involvement through the notice and comment process and agencies are able more quickly to amend and issue new rules to address the changing technology. The reasons that this approach is preferred are threefold: (1) government regulation goes against the open-source spirit of the 3-D printing industry; (2) the industry is equipped to develop innovative solutions to many of its own legal and regulatory problems; and (3) when legal issues do arise that require litigation, courts are equipped to resolve those issues on a case-by-case basis.

First, extensive government regulation goes against the open-source, innovative spirit of the 3-D printing industry, which is equipped to solve many of its own problems. Rather than helping, oppressive legislation could prompt industry players to try to skirt around the legislation instead of cooperating to find an amicable solution. For example, in response to concerns about 3-D printed guns, Congress reauthorized the Undetectable Firearms Act, which bans guns that cannot be picked up by metal detectors or x-ray scanners.⁶⁷ Although this action symbolically limits 3-D printed weapons that are entirely made out of plastic, it is difficult to enforce.⁶⁸ Nevertheless, industry hosts like Thingiverse have begun to self-regulate by deciding not to allow users to post designs for weapons,⁶⁹ and by taking down CAD files if they are posted.⁷⁰ Now digital files for weapons are largely only available on Pirate Bay and similar free, illegal-download sites. Although these alternative sites exist, files hosted there are less reliable.⁷¹ Additionally, the location and address of the site frequently changes or the site may periodically vanish from the web if it is taken down by a government entity, making access to the site difficult.⁷²

Second, the 3-D printing industry is well equipped to develop solutions to regulatory and legal issues that may be more effective than legislation. For example, a Danish company that sells 3-D printer parts and related software recently announced that it has come up with a “firearm component detection algorithm.”⁷³ This software would work like antivirus software to detect CAD files

67. Derek Mead, *Congress’s Plastic Gun Ban Left a 3D-Printed Loophole*, MOTHERBOARD (Dec. 10, 2013, 12:45 PM), <http://motherboard.vice.com/blog/congresss-plastic-gun-ban-left-a-3D-printed-loophole>.

68. McMullen, *supra* note 18, at 210–13.

69. *MakerBot Terms of Use*, MAKERBOT THINGIVERSE, <http://www.thingiverse.com/legal> (last visited Feb. 1, 2015) (“You agree not to use the Site or Services to collect, upload, transmit, display, or distribute any User Content . . . that . . . promotes illegal activities or contributes to the creation of weapons, illegal materials or is otherwise objectionable.”).

70. McMullen, *supra* note 18, at 212–13.

71. *E.g.*, Christina Cawley, *Why Safe Torrenting Died with the Pirate Bay*, MAKEUSEOF (Dec. 20, 2014), <http://www.makeuseof.com/tag/pirate-bay-closure-security-nightmare-waiting-happen-priority/>.

72. *See, e.g.*, Hannah Francis, *File-sharing Site The Pirate Bay Back Online with Reports of ‘Staff’ Rifts*, SYDNEY MORNING HERALD (Feb. 2, 2015, 2:27 PM), <http://www.smh.com.au/digital-life/digital-life-news/filesharing-site-the-pirate-bay-back-online-with-reports-of-staff-rifts-20150202-133q6x.html>.

73. Cyrus Farviar, *Worried About Accidentally 3D Printing a Gun? New Software Will Prevent It*, ARS TECHNICA (June 23, 2013, 10:45 AM),

with the components to print firearms and, if enabled, would not allow the user to print a gun.⁷⁴ This type of technology could be utilized in a variety of ways, for example, to allow a user to print a gun only after buying the file from a licensed source. This is just one example of an effective solution for regulating 3-D printed products that comes from the industry, and could be embraced by the industry, but does not stifle innovation. Policymakers should encourage similar cooperation and continue to involve the 3-D printing industry before seeking to regulate.

Third, when problems arise that result in products liability litigation, the courts will be the most equipped to resolve these disputes on a case-by-case basis to accommodate this rapidly changing technology.⁷⁵ Additionally, many issues involving 3-D printing will need to be evaluated on a case-by-case basis, such as whether and when to impose strict liability on hobbyist manufacturers.⁷⁶ A strict legislative framework would likely create problems because hobbyist manufacturers vary greatly in size, marketing, and number of sales, making a categorical framework inappropriate. A bright-line rule in this area could leave consumers without adequate redress, or could inequitably burden small sole proprietorships. Instead, a flexible approach, which is most practicable through the courts, that evaluates each hobbyist seller on a case-by-case basis and takes into consideration the underlying principles for imposing strict liability would be more equitable to both the seller and the consumer. As a result, courts will often be best equipped to address legal issues raised by 3-D printing.

Finally, when regulation is necessary,⁷⁷ administrative rulemaking, rather than comprehensive legislation, will be most effective. The Food and Drug Administration (“FDA”) is a good model for seeking and encouraging industry involvement when regulation is necessary. In October 2014, the FDA held a two-day public workshop on additive manufacturing of medical devices.⁷⁸ The purpose

<http://arstechnica.com/business/2013/06/worried-about-accidentally-3D-printing-a-gun-new-software-will-prevent-it/>.

74. *Id.*

75. For example, in *Sony Corp. v. Universal City Studios*, the Supreme Court responded to new and rapidly changing technology when it decided that Universal could not prevail in a copyright infringement suit against Sony for selling the “Betamax” home video tape recorder. 464 U.S. 417, 421 (1984). In subsequent years, this technology flourished, spawning the VCR, DVD players, and eventually leading to MP3 players and other devices. Congress eventually passed legislation to this effect, but not until over 10 years later. *See* 17 U.S.C. § 1201(k) (2012).

76. *See supra* Part II.B.2.

77. For example, policymakers could decide that regulation of 3-D-printed weapons is necessary and could direct a regulatory agency like the Bureau of Alcohol, Tobacco, Firearms, and Explosives to promulgate a body of rules through the notice and comment process to regulate these weapons effectively. This process would involve both the public and industry stakeholders, making it a more effective regulatory process than sweeping legislation.

78. Notice No. 96, 79 Fed. Reg. 28,732–33 (May 19, 2014); U.S. FOOD & DRUG ADMIN., *Public Workshop—Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing, October 8–9, 2014*, <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm397324.htm> (last visited Apr. 5, 2015).

of the workshop was “to provide a forum for FDA, medical device manufacturers, additive manufacturing companies, and academia to discuss technical challenges and solutions of 3-D printing”⁷⁹ with the goal of eventually promulgating regulations for assessing 3-D printed medical devices in the future. Rather than publishing a proposed rule in the Federal Register and seeking industry involvement only through the notice and comment process, the FDA first hosted the forum and reportedly had excellent communication with industry stakeholders.⁸⁰ The FDA will now likely go through the notice and comment process before promulgating final rules, which will further involve the industry. This type of meaningful industry involvement is highly desirable in the realm of 3-D printing, and will result in the most effective regulation when regulation is required. While legislation could be useful in some areas of the law, promoting industry self-regulation accomplishes many of the same goals and still allows for the open-source, creative, and innovative environment that has typified the 3-D printing movement up until this point.

CONCLUSION

3-D printing is an exciting technology with the potential to revolutionize a host of industries, including the ways in which products traditionally reach consumers. Although 3-D printing poses many legal and regulatory issues, Congress should regulate as little as possible in this area and should instead encourage the industry to self-regulate and develop innovative solutions to the legal issues raised by 3-D printing. When regulation is necessary, administrative rulemaking should be preferred over comprehensive legislation because the rulemaking process requires extensive industry involvement through the notice and comment process and agencies are able more quickly to amend and issue new rules to address changing technology. The innumerable benefits of this technology are exciting. While there are some risks to the technology, policymakers should limit regulation of the industry and, instead, seek industry cooperation to keep consumers and the public safe while supporting the innovative and open-source 3-D printing industry.

79. Notice No. 96, 79 Fed. Reg. 28,732–33.

80. See, e.g., Jen Owen—E-NABLE, *The FDA: e-NABLING the Future of 3D Printing*, ENABLING THE FUTURE (Oct. 10, 2014), <http://enablingthefuture.org/2014/10/10/the-fda-e-nabling-the-future-of-3d-printing/> (quoting an attendee who stated that his impressions of the FDA were “incredibly positive” and further stated that the National Institute of Health had “gone the extra mile to maintain lines of communication and accommodate our needs on the exchange”).