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INTRODUCTION

We stand on the cusp of the next great industrial revolution thanks to technological innovations and developments that could significantly enhance the welfare of people across the world. "Inventions previously seen only in science fiction, such as artificial intelligence, connected devices and 3D printing, will enable us to connect and invent in ways we never have before," notes a recent World Economic Forum report on the amazing technological revolutions that could be coming.[1]

This Article will focus on how one of those modern inventions—3D printing—could offer the public significant benefits, but not without some serious economic, social, and legal disruptions along the way.[2] We begin in Part I by explaining what 3D printing is and how it works. We also discuss specific applications of this technology and its potential benefits. In Part II, we turn to the policy frameworks that could govern 3D printing technologies and itemize a few of the major public policy issues that are either already being discussed, or which could become pertinent in the future. Then, in Part III, we offer some general guidance for policymakers who might be pondering the governance of 3D printing technologies going forward. Finally, we suggest making the default policy position for 3D printing "permissionless innovation." This is the notion that innovation should generally be allowed without prior restraint, and that problems, if they develop at all, are better dealt with in an *ex post* fashion. Contrary to the many other articles and position papers previously penned about 3D printing policy,[3] which only selectively defend permissionless

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1. WORLD ECON. FORUM, DEEP SHIFT: TECHNOLOGY TIPPING POINTS AND SOCIETAL IMPACT 3 (2015), http://www3.weforum.org/docs/WEF_GAC15_Technological_Tipping_Points_report_2015.pdf.

2. THOMAS CAMPBELL ET AL., ATL. COUNCIL, STRATEGIC FORESIGHT REPORT: COULD 3D PRINTING CHANGE THE WORLD? 1 (2011), http://www.atlanticcouncil.org/publications/reports/could-3d-printing-change-the-world ("Now another new technology is gaining traction that may change the world. 3D Printing/Additive Manufacturing (AM) is a revolutionary emerging technology that could up-end the last two centuries of approaches to design and manufacturing with profound geopolitical, economic, social, demographic, environmental, and security implications.").

3. *E.g.*, Jasper Tran, *The Law and 3D Printing*, 31 J. MARSHALL J. INFO. TECH. & PRIVACY L. 505, 505 (2015), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2581775 (providing a concise overview of the literature on the legal status of 3D printing and noting that "[r]ecent years

innovation in narrow circumstances, we endorse it as the default rule across all categories of 3D printing applications.

I. BACKGROUND

A. HOW 3D PRINTING WORKS

3D printing, or what is more accurately labeled "additive manufacturing," refers to technology that "moves us away from the Henry Ford era mass production line, and will bring us to a new reality of customizable, one-off production."[4] Working from digital blueprints, 3D printers let users fabricate or replicate almost any product imaginable using various materials.[5] But unlike a milling machine which starts with a solid block of metal or wood and cuts away material until only the final form remains, 3D printers print objects layer-by-layer.[6]

Think of a normal "2D" inkjet printer like you may have on your desk right now. It works by spraying ink at a piece of paper.[7] On most inkjet printers, the print heads move left to right and rollers move the paper forward and backwards below the print head.[8] In other words, the printer prints in two dimensions: the head moves in the x-axis and the paper moves in the y-axis.[9]

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have seen extraordinary growth in the amount of legal scholarship and practice at the intersection of law and 3D printing.").

4. Mark Fleming, *What Is 3D Printing? An Overview*, 3D PRINTER, http://www.3dprinter.net/reference/what-is-3d-printing (last visited Jan. 15, 2016).

5. *See* Imran Ali, *The Future of Work: From Bits to Atoms*, GIGAOM (Feb. 10, 2010, 9:00 AM), http://gigaom.com/2010/02/10/the-future-of-work-from-bits-to-atoms (3D printing companies can provide "services that enable product designers to submit designs, have prototypes manufactured for review and then listed in online stores where customers can customize them, place orders and have items shipped"); *3D Printing Basics*, 3DERS.ORG, http://www.3ders.org/3d-printing-basics.html (last visited Jan. 15, 2016) (noting products ranging from aerospace parts to toys and jewelry are being fabricated out of materials ranging from plastics to metals to wax).

6. Deven R. Desai & Gerard N. Magliocca, *Patents, Meet Napster: 3D Printing and the Digitization of Things*, 102 GEO. L.J. 1691, 1692 n.1 (2014); Fleming, *supra* note 4 (describing 3D printers).

7. Chris Woodford, *Inkjet Printers*, EXPLAIN THAT STUFF, http://www.explainthatstuff.com/inkjetprinters.html (last updated Nov. 12, 2015).

8. *Id.*

9. *See id.*; *see also* Fleming, *supra* note 4 ("3D printers . . . create a three dimensional object by building it layer by successive layer, until the entire object is complete. It's much like printing in two dimensions on a sheet of paper, but with an added third dimension: UP. The Z-axis.").

Many 3D printers work in a very similar fashion. To add the third dimension, instead of rolling a sheet of paper underneath the print head, the print head moves in two dimensions over a plate that can move up and down to add the third dimension.[10]

Instead of ink, basic 3D printers use spools of plastic filament, not that much different from the filament used in a grass trimmer.[11] 3D printers can also use wood, metal, ceramics, concrete,[12] molecules for medicine,[13] and even human cells.[14] And some printers can use multiple materials at once, making it possible to print working circuits.[15] Another major benefit of additive printing is that it is possible to print working mechanisms like gears in a single step.[16]

B. MARKET POTENTIAL OF 3D PRINTING

3D printers are gaining more widespread adoption and promise to significantly alter the way many goods are

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10. Fleming, *supra* note 4.

11. For an amusing account of what happens when an experimenter actually substitutes trimmer nylon filament for proper 3D printer plastic filament, see Jeremie Francois, *3D Printing with Cheap Nylon Trimmer Line/String*, 3D PRINTER IMPROVEMENTS (Apr. 27, 2013, 1:48 AM), http://www.tridimake.com/2013/04/3D-printing-with-cheap-trimmer-line.html.

12. Tran, *supra* note 3, at 508.

13. Ben Lillie, *A 3D Printer for Molecules: Lee Cronin at TEDGlobal 2012*, TED BLOG (June 26, 2012, 10:38 AM), http://blog.ted.com/lee-cronin-at-tedglobal2012/ ("For me the cool bit, going into the future, is the idea of taking your own stem cells with your own genes and environment and printing your own medicine.").

14. *See* Kevin Bullis, *EmTech: 3-D Printing Complex Kidney Components*, MIT TECH. REV. (Sept. 24, 2014), http://www.technologyreview.com/news/531106/emtech-3-d-printing-complex-kidney-components.

15. Lucas Mearian, *3D Circuit-Board Printer a Smash Hit on Kickstarter*, COMPUTERWORLD (Feb. 17, 2015, 12:55 PM), http://www.computerworld.com/article/2885188/3d-circuit-board-printer-a-smash-hit-on-kickstarter.html (describing a printer capable of printing using thermoplastics and silver inks simultaneously); *see also* Joseph Young, *The World's First Multi-Layer 3D Circuit Board Printer*, 3DPRINTING.COM (June 3, 2015), http://3dprinting.com/3dprinters/the-worlds-first-3d-multi-layer-circuit-board-printer (covering a company entering 3D circuit board printer manufacturing).

16. Hod Lipson et al., *3-D Printing the History of Mechanisms*, 127 J. MECHANICAL DESIGN 1029, 1029, 1032 (2005), http://creativemachines.cornell.edu/papers/JMD05_Lipson.pdf (describing process of replicating historical machines with gears). *See generally Kinematic Models for Design Digital Library*, CORNELL U. LIBR., http://kmoddl.library.cornell.edu (last visited Jan. 15, 2016) (digital repository useful for 3D printed replications, which includes "19th-century machine elements").

manufactured in the near future.[17] In mid-2013, technology researchers at Gartner estimated a forty-nine percent jump in sub-$10,000 3D printer sales over the previous year.[18] They estimate that "[w]orldwide shipments of 3D printers will reach 496,475 units in 2016."[19] Wohlers Associates, Inc. reported that the additive manufacturing market "grew at a compound annual growth rate . . . of 35.2 percent to $4.1 billion in 2014."[20]

And the Consumer Technology Association (CTA) reports that 3D printer sales are expected to generate $152 million in total revenue (wholesale) in 2016 in the U.S. (up thirty-eight percent over 2015).[21] Gartner is forecasting that shipments of 3D printers will increase by one hundred percent every year until 2018.[22]

According to Siemens, over the next five years "3D printing will become 50% cheaper and up to 400% faster."[23] As the costs to produce 3D-printed items continue to fall, marketplaces are emerging to facilitate transactions. For example, Shapeways is an online marketplace that prints and ships over 120,000 3D

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17. *See, e.g.*, Louis Columbus, *2015 Roundup of 3D Printing Market Forecasts and Estimates*, FORBES (Mar. 31, 2015, 8:30 PM), http://www.forbes.com/sites/louiscolumbus/2015/03/31/2015-roundup-of-3d-printing-market-forecasts-and-estimates ("Prototyping continues to dominate the reasons why enterprises pursue 3D printing, with the opportunity of improving new product development and time-to-market being long-term goals.").

18. John Biggs, *Gartner Estimates Home 3D Printer Shipments Will Grow 49% This Year*, TECHCRUNCH (Oct. 3, 2013), http://techcrunch.com/2013/10/03/gartner-estimates-home-3d-printer-shipments-will-grow-49-this-year ("Gartner expects 56,507 sub-$10,000 3D printers to ship in 2013 . . . [and] 98,065 units sold in 2014 and double that in 2015. . . . [These estimates lead to the conclusion that] 3D printing is now on Gartner's radar and . . . they expect the market to grow considerably.").

19. Press Release, Gartner, Gartner Says Worldwide Shipments of 3D Printers to Reach More Than 490,000 in 2016 (Sept. 29, 2015), http://www.gartner.com/newsroom/id/3139118.

20. TJ McCue, *$4.1 Billion Industry Forecast in Crazy 3D Printing Stock Market*, FORBES (July 30, 2015, 8:13 AM), http://www.forbes.com/sites/tjmccue/2015/07/30/4-1-billion-industry-forecast-in-crazy-3d-printing-stock-market.

21. Press Release, Consumer Tech. Ass'n, IoT Will Drive Consumer Tech Industry to $287 Billion in Revenues, an All-Time High, According to Consumer Technology Association (Jan. 4, 2016) (describing U.S. sales projections).

22. *Id. Cf.* Liam Tung, *3D Printers Shipments to Double Each Year Until 2018's $13.4bn Market*, ZDNET (Oct. 27, 2014), http://www.zdnet.com/article/3d-printers-shipments-to-double-each-year-until-2018s-13-4bn-market/ (citing 2014 Gartner report predicting 100% worldwide annual growth until 2018).

23. Columbus, *supra* note 17.

printed products[24] using more than fifty-five materials[25] every month to customers across 140 countries.[26]

C. 3D PRINTING'S POTENTIAL BENEFITS

The ramifications of 3D printing for average citizens could be enormous because the technology "may have the potential to blur the bright line between consumers and producers."[27] As digital visionary Esther Dyson notes,

> The Internet changed the balance of power between individuals and institutions. . . .
>
> [And] I think we will see a similar story with 3D printing, as it grows from a novelty into something useful and disruptive—and sufficiently cheap and widespread to be used for (relatively) frivolous endeavors as well. We will print not just children's playthings, but also human prostheses—bones and even lungs and livers—and ultimately much machinery, including new 3D printers.[28]

Brian Proffitt of *ReadWrite* says "Once we link together innovations like 3D printing, the Internet of Things, and Big Data, the sky's the limit on what we can dream up. We won't just be able to build any object we need—it will instantly become part of our networked world."[29]

The McKinsey Global Institute discussed the revolutionary potential of 3D printing in a major 2013 report on disruptive technologies:

> Until now, 3D printing has largely been used by product designers and hobbyists and for a few select manufacturing

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24. Andrea Smith, *Q&A with Shapeways: How to Get Hired at a Forward-Thinking 3D Printing Company*, CYBERCODERS (Feb. 3, 2015), http://www.cybercoders.com/insights/qa-with-shapeways-how-to-get-hired-at-a-forward-thinking-3d-printing-company.

25. *See* Rachel Siford & Jordan Bowman, *Student Starts Own 3D Printing Business*, THE OSPREY (Nov. 11, 2015), http://www.theosprey.info/business/3d-printing. These materials include platinum, gold, rose gold, white gold, wax, porcelain, and full color plastic. Mansee Muzumdar, *Shapeways in 2014: A Year in 3D Printing and What's Next for 2015*, SHAPEWAYS BLOG (Dec. 29, 2014), http://www.shapeways.com/blog/archives/19390-shapeways-in-2014-a-year-in-3d-printing-and-whats-next-for-2015.html.

26. *See* Smith, *supra* note 24.

27. Charles W. Finocchiaro, Note, *Personal Factory or Catalyst for Piracy? The Hype, Hysteria, and Hard Realities of Consumer 3-D Printing*, 31 CARDOZO ARTS & ENT. L. J. 473, 473 (2013).

28. Esther Dyson, *3D Fantasies*, PROJECT SYNDICATE (July 24, 2013), http://www.project-syndicate.org/commentary/how-3d-printing-will-change-the-world-by-esther-dyson.

29. Brian Proffitt, *How We'll 3D-Print the Internet of Things*, READWRITE (Oct. 2, 2013), http://readwrite.com/2013/10/02/3d-printing-internet-of-things#awesm=~oj7KcYZXH93jxD.

> applications. However, the performance of additive manufacturing machinery is improving, the range of materials is expanding, and prices (for both printers and materials) are declining rapidly—bringing 3D printing to a point where it could see rapid adoption by consumers and even for more manufacturing uses. With 3D printing, an idea can go directly from a 3D design file to a finished part or product, potentially skipping many traditional manufacturing steps. Importantly, 3D printing enables on-demand production, which has interesting implications for supply chains and for stocking spare parts—a major cost for manufacturers. 3D printing can also reduce the amount of material wasted in manufacturing and create objects that are difficult or impossible to produce with traditional techniques.[30]

Thus, McKinsey concludes in a separate report, 3D printing "appears ready to emerge from its niche status and become a viable alternative to conventional manufacturing processes in an increasing number of applications."[31]

Indeed, 3D scanning and printing is already in use commercially today. It has been estimated that "67% of manufacturers are already using 3D printing" in some fashion.[32] There are already more than ten million 3D-printed hearing aids in use worldwide.[33] Boeing is manufacturing some airplane parts using 3D printing.[34] Comedian and car collector Jay Leno has used 3D printing to replicate worn-out parts to restore classic cars.[35] And there is at least one vehicle that will have all of its exterior components made by 3D printers.[36]

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30. JAMES MANYIKA ET AL., MCKINSEY GLOB. INST., DISRUPTIVE TECHNOLOGIES: ADVANCES THAT WILL TRANSFORM LIFE, BUSINESS, AND THE GLOBAL ECONOMY 8 (2013), http://www.mckinsey.com/insights/business_technology/disruptive_technologies.

31. Daniel Cohen et al., *3-D Printing Takes Shape*, MCKINSEY Q., no. 1, 2014, at 40, http://www.mckinsey.com/insights/manufacturing/3-d_printing_takes_shape.

32. Columbus, *supra note* 17 ("Of these, 28.9% are experimenting to determine how 3D printing can be optimally integrated into their production processes. 24.6% are using 3D printing for prototyping.").

33. Joris Peels, *3D Printing in Medicine: What's Happening Right Now*, I.MATERIALIZE (Feb. 25, 2011), https://i.materialise.com/blog/3d-printing-in-medicine-what-is-happening-right-now-in-patients.

34. MANYIKA ET AL, *supra* note 30, at 108 ("Boeing currently prints 200 different parts for ten aircraft platforms.").

35. Jay Leno, *Jay Leno's 3D Printer Replaces Rusty Old Parts*, POPULAR MECHANICS (June 7, 2009), http://www.popularmechanics.com/cars/a4354/4320759.

36. Alexander George, *3-D Printed Car Is as Strong as Steel, Half the Weight, and Nearing Production*, WIRED (Feb. 27, 2013, 6:23 AM), http://www.wired.com/2013/02/3d-printed-car.

But average citizens are also using 3D printers for a wide variety of applications. "People can print custom jewelry, household goods, toys, and tools to whatever size, shape, or color they want," notes Lyndsey Gilpin of *TechRepublic*.[37] She further suggests "[t]hey will also be able to make replacement parts right at home, rather than ordering them and waiting for them to be shipped."[38]

As will be noted below in Part IV, 3D printing and additive manufacturing technologies will produce many benefits such as these because "3D printing's possibilities really are practically limitless."[39] In the process, however, these technologies will disrupt many existing business models, social norms, and even some laws and regulations.[40]

Before discussing those issues, we discuss two general "visions" about how these and other modern technologies might be governed.

II. COMPETING GOVERNANCE VISIONS FOR 3D PRINTING

A. THE RANGE OF RESPONSES TO TECHNOLOGICAL RISK

In a 2013 article in the *Minnesota Journal of Law, Science & Technology*, one of the authors sketched out a framework for thinking about different approaches to confronting technological risk as well as differing policy perspectives about the governance of emerging technologies more generally.[41]

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37. Lyndsey Gilpin, *10 Industries 3D Printing Will Disrupt or Decimate*, TECHREPUBLIC: HARDWARE (Feb. 12, 2014, 1:09 PM), http://www.techrepublic.com/article/10-industries-3d-printing-will-disrupt-or-decimate.

38. *Id.*

39. SHAWN DUBRAVAC, DIGITAL DESTINY: HOW THE NEW AGE OF DATA WILL TRANSFORM THE WAY WE WORK, LIVE, AND COMMUNICATE 176 (2015).

40. *See* Freddie Dawson, *How Disruptive Is 3D Printing Really?*, FORBES (Sept. 30, 2014, 6:19 PM), http://www.forbes.com/sites/freddiedawson/2014/09/30/how-disruptive-is-3d-printing-really ("[3D printing] could also lead to confusion in the marketplace . . . . More worryingly, it may also result in a wide variation in standards and quality as regulators and government agencies struggle to keep up or act as enforcers in an increasingly growing, changing global market."). Dawson's analysis admits that the potential for this level of disruption is premised on 3D printing achieving mainstream use. *Id.*

41. Adam Thierer, *Technopanics, Threat Inflation, and the Danger of an Information Technology Precautionary Principle*, 14 MINN. J.L. SCI. & TECH. 309, 379–85 (2013) [hereinafter Thierer, *Technopanics*].

That article outlined how, generally speaking, cultural attitudes about most past technologies have typically followed a common cycle that witnesses initial resistance, gradual adaptation, and then eventual assimilation of new technologies into society and the economy.[42] "More often than not, citizens have found ways to adapt to technological change by employing a variety of coping mechanisms, new norms, or [other] creative fixes."[43]

However, in the early stages of any technology's life cycle when concerns still run high about its potentially disruptive effects, it is not uncommon for some policymakers, academics, policy activists, incumbent businesses, or other organizations to suggest that preemptive policy constraints should be put in place to deal with their respective concerns about the new technology in question.[44] These negative initial reactions toward a new technology can occasionally reach a fever-pitch and result in a "full-blown 'moral panic' or 'technopanic,'" defined as "intense public, political, and academic responses to the emergence or use of media or technologies, especially by the young."[45]

Policy actions that proscribe certain uses of new technologies, or which at least require the creators of new technologies to seek the prior blessing of public officials before they deploy those innovations, are motivated by *precautionary principle* reasoning.[46] Generally speaking, the precautionary principle "refers to the belief that new innovations should be curtailed or disallowed until their developers can prove that they will not cause any harms to individuals, groups, specific

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42. *Id*. at 352–61.

43. ADAM THIERER, PERMISSIONLESS INNOVATION: THE CONTINUING CASE FOR COMPREHENSIVE TECHNOLOGICAL FREEDOM viii (2014) [hereinafter PERMISSIONLESS INNOVATION]; *see also* Adam Thierer, *Muddling Through: How We Learn to Cope with Technological Change*, TECH. LIBERATION FRONT (June 30, 2014) [hereinafter Thierer, *Muddling Through*], https://techliberation.com/2014/06/17/muddling-through-how-we-learn-to-cope-with-technological-change/.

44. For a brief illustration on both sides of one such debate, see Nicola Twilley, *Join the Debate: 3D Printed Guns or Government Regulation?*, GIZMODO (Apr. 1, 2014, 2:00 PM), http://gizmodo.com/join-the-debate-3d-printed-guns-or-government-regulati-1555676392 (discussing the merits of regulating 3D print designs for guns).

45. Thierer, *Technopanics*, *supra* note 41, at 311.

46. PERMISSIONLESS INNOVATION, *supra* note 43, at vii.

entities, cultural norms, or various existing laws, norms, or traditions."[47]

Those who apply variations of the precautionary principle believe that lawmakers should regulate new technology "early and often" to "get ahead of it" and address any number of hypothetical worst-case scenarios.[48] Thus, those endorsing precautionary principle-based regulation generally recommend *ex ante* policy solutions be devised to head-off those problems they fear on the grounds that it is "better to be safe than sorry."[49] They advocate against letting new technologies into the wild before some governmental body has reviewed and approved them.[50]

B. PERMISSIONLESS INNOVATION

A very different vision for innovation policy exists which, for lack of a better phrase, can be referred to as *permissionless innovation*.[51] The term is of recent but uncertain origin, although it has been a popular term in Silicon Valley and has frequently been heard in discussions about technology policy since the rise of the commercial Internet in the mid-1990s.[52] Permissionless innovation is often credited with spurring the explosion of commercial and cultural activity that accompanied the rise of the Internet.[53]

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47. *Id.*

48. John Frank Weaver, *We Need to Pass Legislation on Artificial Intelligence Early and Often*, SLATE: FUTURE TENSE (Sept. 12, 2014, 3:53 PM), http://www.slate.com/blogs/future_tense/2014/09/12/we_need_to_pass_artificial_intelligence_laws_early_and_often.html.

49. *See* Steve Clarke, *Future Technologies, Dystopic Futures and the Precautionary Principle*, 7 ETHICS & INFO. TECH. 121, 121 (2005).

50. *See id.* at 122 (noting the precautionary principle argument that "we should always err on the side of caution").

51. *See* PERMISSIONLESS INNOVATION, *supra* note 43, at vii.

52. *E.g.*, Vinton G. Cerf, *Keep the Internet Open*, N.Y. TIMES (May 24, 2012), http://www.nytimes.com/2012/05/25/opinion/keep-the-internet-open.html (deploying the term in support of call for continued international Internet freedom). The term is also related to another popular Silicon Valley saying, "It's easier to ask forgiveness than it is to get permission." That saying is also of uncertain origin, although it is often attributed to Grace M. Hopper, a computer scientist who was a rear admiral in the United States Navy. *See* Diane Hamblen, *Only the Limits of Our Imagination: An Exclusive Interview with RADM Grace M. Hopper,* CHIPS AHOY (July 1986), http://web.archive.org/web/20090114165606/http://www.chips.navy.mil/archives/86_jul/interview.html.

53. *E.g.* Mike Masnick, *Silicon Valley Was Built on Permissionless Innovation; We Shouldn't Give That Up Just Because 'Bitcoin' Is Involved*,

Permissionless innovation "refers to the notion that experimentation with new technologies and business models should generally be permitted by default."[54] One argument for adhering to this policy vision is that, "[u]nless a compelling case can be made that a new invention will bring serious harm to society, innovation should be allowed to continue unabated, and problems, if they develop at all, can be addressed later."[55] In other words, to the extent policy remedies are needed at all, those subscribing to the permissionless innovation vision would recommend those solutions be *ex post* in character, and focused on addressing concrete, not hypothetical, harms.[56]

The clash between the competing policy paradigms of "precautionary principle" and "permissionless innovation" is already evident in many other technology policy discussions today, ranging from debates over the Internet of Things and wearable technologies,[57] driverless cars,[58] private drones,[59] "big data,"[60] the "sharing economy,"[61] and more. It would not be

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TECHDIRT (July 10, 2015, 10:42 AM), https://www.techdirt.com/blog/innovation/articles/20150710/00070631607/silicon-valley-was-built-permissionless-innovation-we-shouldnt-give-that-up-just-because-bitcoin-is-involved.shtml.

54. PERMISSIONLESS INNOVATION, *supra* note 43, at vii.

55. *Id.*

56. *Id.* at 75 ("To the extent that any corrective action is needed to address harms, ex post measures, especially via the common law, are typically superior.").

57. *E.g.*, Adam D. Thierer, *The Internet of Things and Wearable Technology: Addressing Privacy and Security Concerns Without Derailing Innovation*, 21 RICH. J.L. & TECH., no. 2, 2015, at 1–4 [hereinafter Thierer, *Internet of Things*], http://jolt.richmond.edu/v21i2/article6.pdf.

58. *E.g.*, Adam Thierer & Ryan Hagemann, *Removing Roadblocks to Intelligent Vehicles and Driverless Cars*, 5 WAKE FOREST J.L. & POL'Y 339, 339 (2015).

59. *E.g.*, Adam Thierer, *Permissionless Innovation & Commercial Drones*, TECH. LIBERATION FRONT (Feb. 4, 2015), http://techliberation.com/2015/02/04/permissionless-innovation-commercial-drones ("We need to open up the skies to the amazing innovative potential of commercial drone technology, especially before the rest of the world seizes the opportunity to jump into the lead on this front.").

60. *E.g.*, Adam Thierer, *Privacy Law's Precautionary Principle Problem*, 66 ME. L. REV. 467, 470–76 (2014) ("Ours is a world of unprecedented individual information sharing through user-generation of content and self-revelation of data.").

61. *See* Christopher Koopman, Matthew Mitchell & Adam Thierer, *The Sharing Economy and Consumer Protection Regulation: The Case for Policy Change*, 8 J. BUS. ENTREPRENEURSHIP & L. 529, 530–34 (2015), http://mercatus.org/publication/sharing-economy-and-consumer-protection-regulation-case-policy-change.

surprising, therefore, to witness this same clash of visions and corresponding policy proposals play out for 3D printing and additive manufacturing as these technologies generate more attention.[62]

C. PROBLEMS WITH PRECAUTIONARY POLICYMAKING & THE CASE FOR PERMISSIONLESS INNOVATION

The downside of the precautionary principle-based approach to policymaking is that attempting to anticipate and preemptively legislate to avoid any potential hazards associated with a new technology can potentially undermine the many benefits associated with that technology.

There is an important difference between adopting precautionary approaches in one's household or business versus the arena of public policy.[63] Simply put, scale matters.

> When individuals and institutions apply anticipatory, precautionary thinking and policies in their own lives or business decisions, they bear the cost of those efforts. By contrast, when precautionary thinking is converted into preemptive policy prescriptions, the cost of those actions will be borne by a far greater universe of actors.[64]

Thus, precautionary policies that might make sense for individuals, families, or organizations might not be sensible when applied to society at large.

Policies and regulatory systems based on precautionary thinking focus on preemptive remedies that aim to predict the future and its hypothetical problems. But if public policy is rooted in fear of hypothetical worst-case scenarios "it means that best-case scenarios will never come about."[65] "Wisdom [. . . and progress are] born from experience, including experiences that involve risk and the possibility of occasional mistakes and failures."[66] As the old adage goes, "nothing ventured, nothing gained."[67]

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62. *E.g.*, Twilley, *supra* note 44 (debating whether governments should regulate 3D printed guns).

63. *See* Thierer, *Internet of Things*, *supra* note 57, at 47 ("Regardless of whether the technical regulatory specifications for 'permissioned' products and services are published in advance or whether firms must seek special permission before they offer a new product or service, both varieties of preemptive regulation have the same effect: they raise the cost of starting or running a business or nonbusiness venture and therefore discourage activities that benefit society.").

64. *Id.* at 46.

65. *Id.*

66. PERMISSIONLESS INNOVATION, *supra* note 43, at viii.

67. Thierer, *Internet of Things*, *supra* note 57, at 47.

In practice, "permissioning" innovation can raise the cost of doing business by creating barriers to new entry and competition.[68] This can limit what Angela Benton, founder and CEO of NewME Accelerator, refers to as "democratized entrepreneurship," or the sort of modern start-up culture that means "[j]ust about anyone can afford to launch a business."[69] Permissioning innovation can greatly retard this process because traditional regulatory policies and systems tend to be quite rigid, overly bureaucratic, costly, and slow to adapt to new realities.[70]

As a result, precautionary regulatory prescriptions or bans can limit innovations that yield new and better ways of doing things.[71] For consumers, overly prescriptive and precautionary policies can raise the cost of goods and services, diminish the quality of those goods and services, or limit the range of choices that the public has at its disposal.[72]

D. THE IMPACT OF POLICY DEFAULTS ON GLOBAL COMPETITIVENESS

Precautionary principle-based regulation can also have profound macroeconomic consequences by discouraging the sort of entrepreneurialism that fuels economic growth and

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68. *See* ORG. FOR ECON. CO-OPERATION & DEV., POLICY BRIEF: COMPETITION AND BARRIERS TO ENTRY 4 (Jan. 2007), http://www.oecd.org/competition/37921908.pdf (noting that some regulatory agencies recognize that "licensing procedures, territorial restrictions, safety standards, and other legal requirements may unnecessarily deter or delay entry").

69. Angela Benton, *Angela Benton on the Future of Entrepreneurship*, WALL STREET J. (July 7, 2014, 3:53 PM), http://online.wsj.com/articles/angela-benton-on-the-future-of-entrepreneurship-1404762819.

70. *See* HAL ABELSON, KEN LEDEEN & HARRY LEWIS, BLOWN TO BITS: YOUR LIFE, LIBERTY, AND HAPPINESS AFTER THE DIGITAL EXPLOSION 291 (Mark Taub et al. eds., 2008) ("Laws, regulations, and bureaucracies change much more slowly than the technologies they govern.").

71. *See* AARON WILDAVSKY, SEARCHING FOR SAFETY 183 (Ellen Paul ed., 1988) ("Regulation, because it deals with the general rather than with the particular, necessarily results in forbidding some actions that might be beneficial. Regulators cannot devise specifications sufficiently broad to serve as guidelines for every contingency without also limiting some actions that might increase safety. Because regulation is anticipatory, regulators frequently guess wrong about which things are dangerous; therefore, they compensate by blanket prohibitions.").

72. PERMISSIONLESS INNOVATION, *supra* note 43, at viii.

competitive advantage.[73] Economists, political scientists, and historians have found that a country's "innovation culture"—or its "attitudes towards innovation, technology, exchange of knowledge, entrepreneurial activities, business, uncertainty and related behavior"—has a profound impact on that nation's economic growth and overall standard of living.[74] Europe's dismal experience with digital innovation over the past two decades is particularly instructive in this regard.

Beginning in the mid-1990s, the United States and the European Union adopted very different policy approaches toward the Internet and digital commerce, specifically as it pertains to online advertising and the data collection practices that have powered online commerce over the past two decades.[75] Starting in 1995 with the adoption of its "Data Protection Directive,"[76] the EU has consistently instituted highly restrictive policies governing online data collection and

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73. "Economic growth results from innovation—the introduction of new, products, processes, and services." NATHAN ROSENBERG & L. E. BIRDZELL, JR., HOW THE WEST GREW RICH: THE ECONOMIC TRANSFORMATION OF THE INDUSTRIAL WORLD 264 (1986). "[T]he underlying source of the West's ability to attract the lightning of economic revolutions was a unique use of experiment in technology and organization to harness resources to the satisfaction of human wants." *Id.* at 33; *see also* DARON ACEMOGLU & JAMES A. ROBINSON, WHY NATIONS FAIL: THE ORIGINS OF POWER, PROSPERITY, AND POVERTY 430 (Crown Bus. ed. 2012) ("[S]ustained economic growth requires innovation, and innovation cannot be decoupled from creative destruction, which replaces the old with the new in the economic realm and also destabilizes established power relations in politics.").

74. Stephen Ezell & Philipp Marxgut, *Comparing American and European Innovation Cultures*, *in* SHAPING THE FUTURE: ECONOMIC, SOCIAL, AND POLITICAL DIMENSIONS OF INNOVATION 157, 158 (Austrian Council for Res. & Tech. Dev. ed. 2015) (citing GEERT HOFSTEDE, CULTURE'S CONSEQUENCES: COMPARING VALUES, BEHAVIORS, INSTITUTIONS AND ORGANIZATIONS ACROSS NATIONS (Jim Brace-Thompson et al. eds., 2d ed. 2001)); *see also* Manoj K. Singh, *Building an Innovation-Conducive Culture*, 3 GIL EBULLETIN, no. 11, 2010, http://www.growthconsulting.frost.com/web/images.nsf/0/7A09A2436872FBD8802577DE00610EB0/$File/GIL10%20ebull%20V1Q11_fromthetrenches.html.

75. *See generally* Christopher Mims, *Hats Off to Web Advertising. No, Really.*, WALL STREET J. (July 6, 2015, 10:56 AM), http://www.wsj.com/articles/where-would-we-be-without-internet-ads-1436120809?mod=ST1 (preferring the U.S. model, and further noting that "without ads, there would be no Gmail, no Facebook, no countless other services on which we all rely every day . . .").

76. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281) 31.

use.[77] The EU's approach has been shaped by precautionary principle thinking at every turn, based largely on concerns about privacy and data security.[78] Combined with "a deeply ingrained fear of failure that is a bigger impediment to entrepreneurship on the Continent than in other regions,"[79] the EU's general aversion to risk and change has greatly discouraged innovation in Europe.[80]

The United States adopted a very different policy disposition that generally favored risk-taking, tolerated failures, and allowed for certain disruptions or well-established business and social norms.[81] Disruptive technologies were generally accepted in the U.S. and it resulted in the "explosive growth of the Internet and America's information technology sectors (computing, software, Internet services, etc.) over the past two decades."[82] In Europe, digital innovators generally

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77. *See* JOSH LERNER, THE IMPACT OF PRIVACY POLICY CHANGES ON VENTURE CAPITAL INVESTMENT IN ONLINE ADVERTISING COMPANIES 1–2 (2012), http://www.analysisgroup.com/news-and-events/news/affiliate-joshua-lerner-studies-the-effect-of-privacy-policies-on-venture-capital-and-innovation ("[T]he EU e-Privacy Directive, which regulates the electronic collection and use of personal data in the EU more tightly than in other countries, has reduced VC investment in EU-based businesses that lend themselves to the use of such data . . . . We find that VC investment in online advertising companies decreased significantly in the EU relative to the U.S. after passage of the EU e-Privacy Directive. Our results suggest that the EU e-Privacy Directive has led to an incremental decrease in investment in EU-based online advertising companies of approximately $249 million over the approximately eight-and-a-half years from passage through the end of 2010. When paired with the findings of the enhanced effects of VC investment relative to corporate investment, this may be the equivalent of approximately $750 million to $1 billion in traditional R&D investment.").

78. *See id.* at 6 ("The e-Privacy Directive guarantees confidentiality of communications and regulates treatment of traffic and location data.").

79. Matt Moffett, *New Entrepreneurs Find Pain in Spain*, WALL STREET J. (Nov. 27, 2014, 7:28 PM), http://www.wsj.com/articles/new-entrepreneurs-find-pain-in-spain-1417133197.

80. *See, e.g.*, Anna Prior, *How Fear Can Derail an Entrepreneur*, WALL STREET J. (Aug. 24, 2015), http://www.wsj.com/articles/how-fear-can-derail-an-entrepreneur-1440381701 (interviewing Philipp K. Berger: "There's a huge difference between the U.S. culture and the German culture. In the U.S., it seems to be a lot more acceptable to fail. It's the 'fail and stand up' culture. It's accepted to some degree as part of the normal part of the entrepreneurial process. That's different in Germany. There's more of a stigmatization of a failed entrepreneur, so that drives more fear.").

81. *See id.*

82. Adam Thierer, *Embracing a Culture of Permissionless Innovation*, CATO INST. (Nov. 2014), http://www.cato.org/publications/cato-online-forum/embracing-culture-permissionless-innovation [hereinafter Thierer, *Embracing a Culture*]; *see also* JAMES MANYIKA & CHARLES ROXBURGH,

floundered and still today it remains difficult to name a major information technology company based in the EU.[83]

A 2015 ranking of the world's most innovative companies revealed that eight of the top ten most innovative companies are based in the U.S. and that most of them are involved in computing.[84] Another recent survey revealed that, based on market capitalizations, the world's "fifteen most valuable Internet companies today have a combined market value of nearly $2.5 trillion[, but] none of them are European."[85] However, eleven are based in the U.S.[86]

Rather than attempt to isolate the relative influence on Europe's Internet and digital commerce sectors of its data collection regulations versus its cultural fear of failure, we see these as two sides of the same coin. Entrepreneurs exhibit a fear of failure by not investing in new industries and technologies. Policymakers exhibit a fear of failure by implementing *ex ante* regulations of new industries and technologies. In this Article, we argue that U.S. policymakers should continue to emulate the same permissionless approach to innovation that has served the online sector so well in the past.

MCKINSEY GLOBAL INSTITUTE, THE GREAT TRANSFORMER: THE IMPACT OF THE INTERNET ON ECONOMIC GROWTH AND PROSPERITY 1, 3 (2011), http://www.mckinsey.com/industries/high-tech/our-insights/the-great-transformer (discussing the development of the Internet and its impact on economic growth, and also noting "the United States has thus far led in terms of its Internet Infrastructure"); *see, e.g.*, Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175, 185 (2014) ("When . . . [the Internet] began to emerge in the 1980s and 1990s, the FCC 'self-consciously adopted a policy of non-regulation."). Not all risks when left unchecked have resulted in success stories. *See id.* at 185–86 (discussing the fallout resulting from nonregulation of the U.S. derivatives market).

83. *See* James Pethokoukis, *Why Does the US Generate More Fast-Growing Tech Startups than Europe*?, AM. ENTER. INST. (July 10, 2015, 11:41 AM), https://www.aei.org/publication/why-does-the-us-generate-more-fast-growing-tech-startups-than-europe.

84. *See* Barry Jaruzelski et al., *The Top Innovators and Spenders: 2013*, STRATEGY&, http://www.strategyand.pwc.com/global/home/what-we-think/global-innovation-1000/top-innovators-spenders (last visited Feb. 4, 2016).

85. Larry Downes, *Europe's Innovation Deficit Isn't Disappearing Any Time Soon*, WASH. POST (June 8, 2015), http://www.washingtonpost.com/blogs/innovations/wp/2015/06/08/europes-innovation-deficit-isnt-disappearing-any-time-soon (citing an annual Internet trends report released by Kleiner Perkins partner Mary Meeker).

86. *Id.*

Because they discourage beneficial forms of entrepreneurial creativity that fuel economic growth and global competitiveness, preemptive policy constraints premised on precautionary principle reasoning should generally be reserved for those rare circumstances when a thorough benefit-cost test predicts immediate, irreversible, and catastrophic consequences.[87] In other words, the burden of proof is on those who favor preemptive, precautionary controls to explain why ongoing trial-and-error experimentation with new technologies or business models should be disallowed.[88]

E. HOW TO ENSHRINE PERMISSIONLESS INNOVATION AS THE POLICY DEFAULT FOR 3D PRINTING

U.S. policymakers should consider endorsing the ethic of permissionless innovation as the foundation of their 3D printing policy, just as they did for the Internet more generally two decades ago.[89]

Permissionless innovation became the cornerstone of American Internet policy beginning the early 1990s through a series of crucial decisions.[90] First, in the early 1990s, the Clinton Administration opened the Net to commercial

87. *See* Adam Thierer, *A Framework for Benefit-Cost Analysis in Digital Privacy Debates*, 20 GEO. MASON L. REV. 1055, 1105 (2013) ("It is not enough to simply invoke the importance of values like 'privacy' and 'safety' without thinking through the consequences of regulations aimed at preserving or enhancing them, especially when 'there are less expensive or burdensome ways of accomplishing the same end.'").

88. *Id.* at 1104–05.

89. *See* White House, *The Framework for Global Electronic Commerce: Read the Framework* (July 1997), http://clinton4.nara.gov/WH/New/Commerce/read.html ("Governments can have a profound effect on the growth of commerce on the Internet. By their actions, they can facilitate electronic trade or inhibit it. Knowing when to act and—at least as important—when not to act, will be crucial to the development of electronic commerce."); SHANE GREENSTEIN, HOW THE INTERNET BECAME COMMERCIAL: INNOVATION, PRIVATIZATION, AND THE BIRTH OF A NEW NETWORK 13 (Princeton Univ. Press 2015) ("At first a military research organization had sole responsibility for managing the precursors to the Internet. A new era began in 1985, when the National Science Foundation accepted responsibility for managing the aspect of the Internet that supported research throughout universities. Privatization began during this second era, around 1989, and eventually brought about the end of government stewardship.").

90. *See* GREENSTEIN, *supra* note 89, at 95, 399 (describing the Clinton administration's preference for privatization on domain names and the WiFi spectrum). *See generally* White House, *supra* note 89.

activity.[91] It had previously been mostly reserved for the use of government agencies and university researchers.[92] Of course, 3D printing does not require a similar privatization effort because the means of production are already fully decentralized.[93] But the commercial opening of the Net clearly spawned a remarkable amount of creative activity[94] and makes it clear why the ability to innovate in a permissionless fashion is essential to both online activity and subsequent types of innovative activity, including 3D printing.

The legal framework that developed for the Internet throughout the mid- to late-1990s is even more instructive for the formation of public policy for 3D printing. In 1996, a bipartisan group of congressional lawmakers passed, and President Bill Clinton signed, the Telecommunications Act of 1996 (Telecom Act).[95] What was particularly notable about the Act is that congressional lawmakers avoided regulating the Internet like earlier communications and media technologies.[96]

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91. Management of Internet Names and Addresses, 63 Fed. Reg. 31,741, 31,742 (June 10, 1998) ("In 1992, the U.S. Congress gave NSF statutory authority to allow commercial activity on the NSFNET").

92. *Id.*; *see* GREENSTEIN, *supra* note 89, at 13.

93. *See generally* Ann Thorpe, *Design-for-3D Printing as Community Organizing*, DESIGNACTIVISM.NET (Nov. 18, 2013), http://designactivism.net/archives/867 ("Organizing disrupts typical, centralized systems of power, shifting decision making and fabrication from the hands of experts to the hands of regular people.").

94. David Post, *A Bit of Internet History, or How Two Members of Congress Helped Create a Trillion or So Dollars of Value*, WASH. POST (Aug. 27, 2015), https://www.washingtonpost.com/news/volokh-conspiracy/wp/2015/08/27/a-bit-of-internet-history-or-how-two-members-of-congress-helped-create-a-trillion-or-so-dollars-of-value (discussing how the open and liability limited nature of the U.S. Internet helped nurture the creative process necessary to spawn the various Internet giants we have today, such as Google and Amazon).

95. Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996); COMMON CAUSE EDU. FUND, THE FALLOUT FROM THE TELECOMMUNICATIONS ACT OF 1996: UNINTENDED CONSEQUENCES AND LESSONS LEARNED 7 (2005), http://www.commoncause.org/research-reports/National_050905_Fallout_From_The_Telecommunications_Act_2.pdf (providing background of the passage of the act).

96. Telecommunications Act of 1996, title IV–Regulatory Reform, Sec. 401 ("Notwithstanding section 332(c)(1)(A) of this Act, the Commission shall forbear from applying any regulation or any provision of this Act to a telecommunications carrier or telecommunications service, or class of telecommunications carriers or telecommunications services, in any or some of its or their geographic markets, if the Commission determines that - (l) enforcement of such regulation or provision is not necessary to ensure that the charges, practices, classifications, or regulations by, for, or in connection with

Instead of trying to preemptively pigeonhole the Internet into traditional regulatory classifications, American lawmakers gave the medium a chance to be "born free" as opposed to in regulatory captivity. In this sense, therefore, the Internet benefited from "a policy of benign neglect."[97]

The Telecom Act did include one affirmative Internet-oriented provision, however, that would be essential to both the commerce and social growth of the medium. Section 230 of the Communications Decency Act, a portion of the Telecom Act, immunized online intermediaries from onerous liability for the content and communications that travelled over their networks.[98] The immunities granted by Section 230 let online speech and commerce flow freely, without the constant threat of legal action or onerous liability looming overhead for digital platforms.[99] Today's vibrant Internet ecosystem likely would not exist without Section 230.[100]

Another important Internet policy development took place in 1997 with the release of the Clinton Administration's *Framework for Global Electronic Commerce*, which outlined the U.S. government's approach toward the then-emerging digital economy.[101] The *Framework* recommended reliance upon "civil

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that telecommunications carrier or telecommunications service are just and reasonable and are not unjustly or unreasonably discriminatory; (2) enforcement of such regulation or provision is not necessary for the protection of consumers; and (3) forbearance from applying such provision or regulation is consistent with the public interest.").

97. 151 CONG. REC. H10332 (Nov. 16, 2005) (statement of Rep. Zoe Lofgren), http://www.gpo.gov/fdsys/pkg/CREC-2005-11-16/html/CREC-2005-11-16-pt1-PgH10332.htm ("Far from governing the Internet, the United States has followed what can best be described as a policy of benign neglect.").

98. Communications Decency Act of 1996, 47 U.S.C. § 230(c)(2) (2012) (removing liability for intermediaries for information provided by another content provider).

99. Adam Thierer, *The Greatest of All Internet Laws Turns 15*, FORBES (May 8, 2011, 2:36 PM), http://www.forbes.com/sites/adamthierer/2011/05/08/the-greatest-of-all-internet-laws-turns-15 ("There are many technological and economic reasons for this unprecedented explosion of speech and human interaction, but the primary legal reason lies with Sec. 230. If not for the immunities granted by Sec. 230, online speech and commerce would have been severely stifled because of the threat of legal action.").

100. Post, *supra* note 94 ("Yet it is impossible to imagine what the Internet ecosystem would look like today without it [(Section 230)]. Virtually every successful online venture that emerged after 1996 — including all the usual suspects, viz. Google, Facebook, Tumblr, Twitter, Reddit, Craigslist, YouTube, Instagram, eBay, Amazon — relies in large part (or entirely) on content provided by their users, who number in the hundreds of millions, or billions.").

101. White House, *supra* note 89.

society, contractual negotiations, voluntary agreements, and ongoing marketplace experiments to solve information age problems."[102] Specifically, it said:

> The private sector should lead. The Internet should develop as a market driven arena not a regulated industry. . . . [G]overnments should encourage industry self-regulation and private sector leadership where possible.
>
> Governments avoid undue restrictions on electronic commerce. . . . [P]arties should be able to enter into legitimate agreements to buy and sell products and services across the Internet with minimal government involvement or intervention. . . .
>
> Where governmental involvement is needed, its aim should be to support and enforce a predictable, minimalist, consistent and simple legal environment for commerce.[103]

A similarly relevant policy development occurred in 1998, when Congress enacted the Internet Tax Freedom Act, which blocked all levels of government in the U.S. from imposing discriminatory taxes on the Internet.[104]

This early history of Internet policymaking proffers several lessons for 3D printing policy. The high-level lesson here is that policy attitudes and incentives matter.[105] Through both statements and policy actions, U.S. policymakers signaled that permissionless innovation would be the norm for the Internet and digital technology in America and gave innovators an "unambiguous green light" to let their minds run wild and experiment with an endless array of exciting new devices and

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102. Adam Thierer, *15 Years On, President Clinton's 5 Principles for Internet Policy Remain the Perfect Paradigm,* FORBES (Feb. 12, 2012, 1:16 PM), http://www.forbes.com/sites/adamthierer/2012/02/12/15-years-on-president-clintons-5-principles-for-internet-policy-remain-the-perfect-paradigm; *see also* White House, *supra* note 89.

103. White House, *Framework for Global Electronic Commerce Executive Summary* (July 1997), http://clinton4.nara.gov/WH/New/Commerce/summary.html.

104. Internet Tax Freedom Act, Pub. L. No. 105-277, 112 Stat. 2681–719, 2726 (1998) ("No State or political subdivision thereof shall impose any of the following taxes . . . multiple or discriminatory taxes on electronic commerce." "It is the sense of Congress that no new Federal taxes similar to the . . . [prohibited state taxes] . . . should be enacted with respect to the Internet and Internet access.").

105. Adam Thierer, *How Attitudes about Risk & Failure Affect Innovation on Either Side of the Atlantic*, TECH. LIBERATION FRONT (June 19, 2015), http://techliberation.com/2015/06/19/how-attitudes-about-risk-failure-affect-innovation-on-either-side-of-the-atlantic (arguing that the U.S. regulatory scheme's incentivization of risk taking and allowance for failure cause U.S. Internet startups to thrive where their EU counterparts fail).

services.[106] "The Net prospered precisely because governments—for the most part—allowed the Internet to grow organically, with civil society, academia, private sector and voluntary standards bodies collaborating on development, operation and governance," observes Vint Cerf, one of the fathers of the Internet.[107]

That same vision and policy approach can govern 3D printing. Lawmakers can articulate and defend a vision of permissionless innovation for 3D printing and send a clear signal to citizens that entrepreneurial activity of both commercial and non-commercial varieties will be acceptable, even optimal. The next section offers more detail about how policymakers can do so.

III. POLICY FAULT LINES FOR 3D PRINTING

The growth of 3D printing and additive manufacturing will raise a variety of public policy concerns as these technologies disrupt not only existing markets and incumbent firms, but also the laws and rules that currently govern them.[108] In fact, the tension between permissionless innovation and precautionary principle thinking is already on display in many different ways, and more efforts to preemptively regulate 3D printers are likely to surface as additive manufacturing technologies grow more popular.[109] This Section highlights some of the more notable current or future policy fault lines that will be opened up by the rise of 3D printing.

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106. Thierer, *Embracing a Culture*, *supra* note 82 ("This policy disposition resulted in an unambiguous green light for a rising generation of creative minds who were eager to explore this new frontier for commerce and communications. . . . The result of this 'freedom to experiment' was an outpouring of innovation.").

107. Cerf, *supra* note 52.

108. *E.g.*, Giulio Coraggio, *Top 3 Legal Issues of 3D Printing!*, TECH.'S LEGAL EDGE (Sept. 7, 2015), http://www.technologyslegaledge.com/2015/09/07/top-3-legal-issues-of-3d-printing (considering whether 3D printing is akin to piracy, who is liable for 3D printer manufactured products, and whether replicas are privacy threats).

109. *See, e.g.*, Cory Doctorow, *Congressman Calls for Ban on 3D Printed Guns*, BOING BOING (Dec. 9, 2012, 11:37 AM), http://boingboing.net/2012/12/09/congressman-calls-for-ban-on-3.html (describing Representative Steve Israel's call for a ban on 3D printed "Wiki Weapons").

A. PROPOSED GENERAL POLICY FRAMEWORK FOR 3D PRINTING

In exploring the particular policy challenges associated with 3D printing, we generally argue that permissionless innovation remains the sensible public policy default. The general framework we propose entails a ten-part checklist that policymakers should follow when approaching the evolution of dynamic technologies like 3D printing.

1) Permissionless innovation as the default: Begin with permissionless innovation as the asserted policy default. For 3D printing, this means that policymakers would make it clear in their policy pronouncements that innovators in this space will generally be given wide leeway in their creative endeavors and that policy will not be based on hypothetical concerns or addressed through *ex ante* regulatory controls. Citizens will generally be left at liberty to experiment with 3D printing technology and problems that develop will be addressed in an *ex post* fashion.[110]

2) Protect free speech: Policymakers should reiterate the importance of the First Amendment for emerging information technologies.[111] Just as courts have found source code to be speech,[112] policymakers should make it clear that the First Amendment protects both the blueprints that explain how to

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110. *See* ITHIEL DE SOLA POOL, TECHNOLOGIES OF FREEDOM 246 (Harvard Univ. Press 1984) (discussing regulation of information markets, Pool stressed that "enforcement of the law must be after the fact, not by prior restraint; . . . regulation is a last recourse. In a free society, the burden of proof is for the least possible regulation of communication").

111. JONATHAN W. EMORD, FREEDOM, TECHNOLOGY, AND THE FIRST AMENDMENT 310 (Pac. Res. Inst. of Pub. Pol'y 1991) ("If we are to avoid the losses in freedom that would be associated with content and structural controls on the new media forms, it will be imperative for the courts to embrace the First Amendment print model standard and apply it to the new forms. Unless the Supreme Court rededicates itself to preserving the core values of the First Amendment and rejects the notion that each new technology should be subjected to a different standard of protection, speech and press in the next century will unnecessarily suffer regulatory restraints that will abridge freedom.").

112. *E.g.*, Bernstein v. U.S. Dept. of State, 922 F. Supp. 1426, 1436 (N.D. Cal. 1996) (ruling that "[f]or the purposes of First Amendment analysis, this court finds that source code is speech"); *see also* Universal City Studios v. Corley, 273 F.3d 429, 449–50 (2d Cir. 2001) ("Having concluded that computer code conveying information is 'speech' . . . we next consider, to a limited extent, the scope of the protection that code enjoys.").

fabricate 3D-printed objects and even 3D printers themselves.[113]

3) Immunize intermediaries: To advance permissionless innovation as a policy guideline, it may be necessary to immunize some intermediaries from punishing forms of liability, or at least limit liability in some fashion to avoid a chilling effect on innovation.[114] In the case of 3D printing, the manufacturers of 3D printing devices and the website operators hosting blueprints for 3D-printed objects may need to be protected from liability to avoid chilling innovation. In this sense, a "Section 230 for 3D printing" might be needed.

4) Rely on existing legal solutions/common law: Existing laws and legal standards might already exist that can be used to address policy concerns about emerging technologies such as 3D printing. As Judge Frank H. Easterbrook noted in his 1996 essay, *Cyberspace and the Law of the Horse*, "the best way to learn the law applicable to specialized endeavors is to study general rules."[115] He argued that there was nothing particularly unique or special about the cyber-realm that necessitated either a rethinking of traditional legal standards or an entirely new class of rules for the Internet.[116] The same insight is applicable to 3D printing. Beyond existing statutes that might be applicable to new technologies, many common law solutions exist to deal with the problems that occur when things go wrong with new technologies, including 3D printers.[117] The common law has dealt with products liability and accident compensation in an evolutionary way through a variety of mechanisms, including strict liability, negligence, design defects law, failure to warn, and breach of warranty.[118]

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113. Jasper L. Tran, *Press Clause and 3D Printing*, 14 NW. J. TECH. & INTELL. PROP. 75 (2015), http://papers.ssrn.com/sol3/Papers.cfm?abstract_id=2614606 (arguing that 3D printers are protected under the First Amendment's "Press Clause" just like 2D printers and printed material).

114. *See supra* notes 98–100 and accompanying text for an example of limiting intermediary liability in the context of hosting websites.

115. Frank H. Easterbrook, *Cyberspace and the Law of the Horse*, 1996 U. CHI. LEGAL F. 207, 207.

116. *Id.* at 207–08.

117. *Id.* (arguing that just because a technology is new does not necessarily mean that a novel branch of law is needed to deal with it).

118. *See* JOHN VILLASENOR, BROOKINGS INST.: CTR. FOR TECH. INNOVATION, PRODUCTS LIABILITY AND DRIVERLESS CARS: ISSUES AND GUIDING PRINCIPLES FOR LEGISLATION 7–14 (Apr. 2014),

5) Insurance & competitive options: New sectors and technologies often create economic tensions and raise questions about how new risks might be addressed.[119] Insurance markets or new forms of competition might solve some of those problems, whether perceived or real.[120] For 3D printing, insurance contracts might emerge to cover manufacturers worried about defective devices—either the underlying 3D printer itself or the goods manufactured with the 3D printer.[121] Insurance products might also help guard against intellectual property-related claims.[122] As that process unfolds, new competitors will undoubtedly emerge to offer different 3D printing products and applications that satisfy other public needs and demands. Importantly, solutions and developments such as these are not always immediately evident and they take time to evolve, which counsels patience and humility among policymakers.

6) Educational approaches: Policymakers should also consider how educating both the public and producers about the proper use of new technologies can satisfy policy goals in a less costly and more effective fashion. The goal of such media

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http://www.brookings.edu/~/media/research/files/papers/2014/04/products-liability-driverless-cars-villasenor/products_liability_and_driverless_cars.pdf.

119. *See* Easterbrook, *supra* note 115, at 210–16 (discussing new technologies, their risks, and what regulatory schemes can and ought to be used for them).

120. Susannah Levine, *3D Printing Offers New Risk Challenges*, RISK & INS. (March 17, 2014), http://www.riskandinsurance.com/3d-printing-offers-new-risk-challenges (discussing various insurance issues that may arise with 3D printers); *see also* Adam Thierer et al., *How the Internet, the Sharing Economy, and Reputational Feedback Mechanisms Solve the "Lemons Problem,"* 11–24 (Geo. Mason U. Mercatus Ctr., Working Paper, May 2015), http://mercatus.org/sites/default/files/Thierer-Lemons-Problem.pdf; Adam Thierer et al., *How the Internet, the Sharing Economy, and Reputational Feedback Mechanisms Solve the "Lemons Problem,"* 1 (Geo. Mason U. Mercatus Ctr., Working Paper Research Summary, May 26, 2015), http://mercatus.org/sites/default/files/Thierer_Lemons-Problem-sum.pdf (citing a study that shows that "reputational feedback mechanisms . . . help correct these information deficiencies better than traditional regulatory approaches").

121. Hannah Rose Mendoza, *Insuring 3D Printing, An Industry About to Expand?*, 3DPRINT.COM (Sept. 23, 2014), http://3dprint.com/15362/insuring-3d-printing (arguing that Zurich Insurance's recent report listing 3D printing as one of the biggest potential growth areas in the realm of insurance implies that the company has already begun to consider how to go about providing insurance to 3D printing manufacturers, meaning that insurance coverage for 3D printing manufacturers may be likely in the near future).

122. Levine, *supra* note 120 (implying that the insurance industry will need to adapt to be able to service the changing intellectual property landscape as 3D printing promises to alter it drastically).

literacy and "digital citizenship" efforts is to devise common sense guidelines to facilitate the assimilation of new technologies into society and encourage ethical behavior, promote civility and respect, and encourage the proper use of new technologies.[123] For 3D printing technologies, that could include lessons that explain the dangers associated with building applications that might have deleterious societal impacts, including weapons, dangerous medical devices, or counterfeit products.

7) Consider industry self-regulation and best practices: The Clinton Administration's *Framework* for Internet policy stressed that "governments should encourage industry self-regulation and private sector leadership where possible."[124] Generally speaking, such self-regulation can include, but is not limited to: private codes of conduct or "best practice" guidance for developers, third-party certification and accreditation of devices or their standards, and corporate labeling and transparency efforts. Organizations and corporations engaged in 3D printing practices may wish to work together to formulate such voluntary guidelines and encourage others in their community to adopt sensible best practices.

8) Social norms and pressures: Even in the absence of existing laws or regulations, policymakers should wait to see whether social norms and societal attitudes evolve. More than the law can regulate new technologies.[125] Social pressure and private norms of acceptable use often act as a "regulator" of the uses (and misuses) of new technologies because, quite often, "norms dissuade many practices that are feasible but undesirable."[126] In other words, some of today's concerns about the misuse of 3D printers may fail to materialize in a serious way, or the public may come to view those activities more favorably in the future.

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123. *See* COMMON SENSE MEDIA, DIGITAL LITERACY AND CITIZENSHIP IN THE 21ST CENTURY 1 (June 2009), http://www.katyisd.org/parents/Documents/Digital%20Library.pdf (defining "digital literacy" and "digital citizenship" in the context of how to educate children on technology use).

124. White House, *supra* note 103.

125. Thierer, *Muddling Through*, *supra* note 43 ("[M]ore than law can regulate behavior—whether it is organizational behavior or individual behavior.").

126. DANIEL CASTRO & ALAN MCQUINN, INFO. TECH. & INNOVATION FOUND., THE PRIVACY PANIC CYCLE: A GUIDE TO PUBLIC FEARS ABOUT NEW TECHNOLOGIES 28 (2015), http://www.itif.org/publications/2015/09/10/privacy-panic-cycle-guide-public-fears-about-new-technologies.

9) Targeted legal measures: If all else fails, policymakers can adopt targeted legislation as needed to address the most challenging concerns where the potential for clear, catastrophic, immediate, and irreversible harm exists.

10) Evaluate: Even when new legislation or regulation is being considered for emerging technologies such as 3D printing, a strict benefit-cost analysis should be conducted to determine whether the specific rule being considered will achieve the desired goal without imposing excessive burdens on society.[127]

Below, we apply this framework to three different areas of particular concern for 3D printing: firearms, medical applications, and intellectual property.

B. FIREARMS

Although it is not currently a widespread practice, the manufacturing of 3D-printed firearms has already attracted considerable media,[128] academic,[129] and public policy

127. *See generally* SUSAN E. DUDLEY & JERRY BRITO, REGULATION: A PRIMER (Geo. Wash. U. Reg. Stud. Ctr. ed., 2nd ed. 2012) ("Understanding the impetus for regulation, the incentives faced by regulators and regulated parties, and the underlying market conditions that lead to regulation is essential for evaluating the consequences of regulatory actions and the legislation that enables them. This knowledge is important not only for understanding the effects of proposed new regulations, but for examining whether existing regulations are achieving their intended goals.").

128. *E.g.*, Mark Gibbs, *The End of Gun Control? [Updated]*, FORBES (July 28, 2012, 4:24 PM), http://www.forbes.com/sites/markgibbs/2012/07/28/the-end-of-gun-control/#2715e4857a0b4f179f8112bc; Andy Greenberg, *I Made an Untraceable AR-15 'Ghost Gun' In My Office—And It Was Easy*, WIRED (June 3, 2015, 7:00 AM) [hereinafter Greenberg, *Untraceable AR-15*], http://www.wired.com/2015/06/i-made-an-untraceable-ar-15-ghost-gun.

129. *E.g.*, Julian J. Johnson, *Print, Lock, and Load: 3-D Printers, Creation of Guns, and the Potential Threat to Fourth Amendment Rights*, 2013 U. ILL. J.L. TECH. & POL'Y 337, 338 (2013); Rory K. Little, *Guns Don't Kill People, 3D Printing Does? Why the Technology is a Distraction from Effective Gun Controls*, 65 HASTINGS L.J. 1505, 1505 (2014); Peter Jensen-Haxel, Comment, *3D Printers, Obsolete Firearm Supply Controls, and the Right to Build Self-Defense Weapons Under* Heller, 42 GOLDEN GATE U. L. REV. 447, 447 (2012).

attention.[130] The legal status of 3D-printed guns and the designs for those guns remains unclear, however.[131]

In the United States, firearm production, distribution, and use are already governed by an extensive array of federal, state, and local laws and regulations.[132] At the federal level, the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) is responsible for firearm regulation, including the enforcement of, among other laws, the National Firearms Act of 1934 and the Gun Control Act of 1968,[133] which lay out the requirements to obtain a Federal Firearms License.[134]

Scholars who have examined the intersection of federal firearms regulation and 3D printing generally conclude "the current regulatory landscape of firearms suggests that the creation of 3-D printed guns for personal use would not be illegal."[135] This is because the regulatory system is focused on

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130. *E.g.*, *3D-Printed Guns Under Spotlight in US Law Renewal*, GUARDIAN (Dec. 3, 2013, 3:40 PM), http://www.theguardian.com/world/2013/dec/03/us-3d-printed-gun-ban; Dara Kerr, *Congress: Undetectable 3D-Printed Guns are Still Illegal*, CNET (Dec. 9, 2013, 5:56 PM), http://www.cnet.com/news/congress-undetectable-3d-printed-guns-are-still-illegal.

131. Johnson, *supra* note 129, at 353 ("An assessment of the current regulatory landscape of firearms suggests that the creation of 3-D printed guns for personal use would not be illegal. However, many considerations remain.").

132. *See, e.g.*, Gun Control Act of 1968, 18 U.S.C. §§ 921–31 (2012) (amending the National Firearms Act to, *inter alia*, address constitutional concerns); National Firearms Act, 26 U.S.C. §§ 5801–72 (2012) (creating an excise tax and registration requirements for certain firearms). *See generally* BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES, ATF NATIONAL FIREARMS ACT HANDBOOK i (2009), https://www.atf.gov/firearms/docs/atf-national-firearms-act-handbook-atf-p-53208/download ("[A] 'user friendly' reference book enabling the user to quickly find answers to questions concerning the NFA.").

133. *See* BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES, *supra* note 132, at 3.

134. Gun Control Act of 1968, § 921 (addressing definitions of who must be licensed); Commerce in Firearms and Ammunition, 27 C.F.R. § 478.41(a) (2012) ("Each person intending to engage in business as an importer or manufacturer of firearms or ammunition, or a dealer in firearms shall, before commencing such business, obtain the license required by this subpart for the business to be operated. Each person who desires to obtain a license as a collector of curios or relics may obtain such a license under the provisions of this subpart.").

135. Johnson, *supra* note 129, at 353.

the sale and distribution of firearms and not as concerned with creation of firearms for personal use.[136]

The ATF allows unlicensed manufacturing of firearms for personal use (i.e. not for resale or distribution).[137] Manufacturers who want to sell or distribute arms must register for a license with the ATF,[138] engrave and record identification numbers for each gun,[139] and perform the necessary background checks.[140]

Importantly, the Undetectable Firearms Act of 1988 (UFA) requires that all guns, whether made for personal or commercial use, contain trace amounts of metal that can be detected through screening.[141] Senator Chuck Schumer and Representative Steve Israel have proposed revisions to the UFA that would expand the number of weapons controlled under the Act and more explicitly criminalize fully plastic weapons, including 3D-printed guns made of nothing but plastic.[142] Proposals to regulate 3D-printed firearms have also been introduced in the state of New York.[143]

Defense Distributed, a Texas-based non-profit advocacy organization, is focused on defending the rights of those engaged in the 3D printing of firearms.[144] The organization,

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136. *Id.* at 343–44 (discussing the general areas of focus of the Gun Control Act of 1968 and the National Firearms Act).

137. BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES, Q&A: 3-D PRINTING TECHNOLOGY OF FIREARMS (2013), https://www.atf.gov/file/4566/download ("An individual may generally make a firearm for personal use. However, individuals engaged in the business of manufacturing firearms for sale or distribution must be licensed by ATF.").

138. *Id.* ("Any person 'engaged in the business' as a manufacturer must obtain a license from ATF.").

139. National Firearms Act, 26 U.S.C. § 5842 (2012).

140. Gun Control Act of 1968, 18 U.S.C. § 922(t) (2012).

141. Undetectable Firearms Act of 1988, Pub. L. No. 100-649, 102 Stat. 3816, § 2(a) (1988).

142. Andy Greenberg, *Bill to Ban Undetectable 3D Printed Guns Is Coming Back*, WIRED (Apr. 6, 2015, 7:00 AM), http://www.wired.com/2015/04/bill-ban-undetectable-3-d-printed-guns-coming-back; *Schumer Announces Support For Measure To Make 3D Printed Guns Illegal*, CBS N.Y. (May 5, 2013, 12:17 PM), http://newyork.cbslocal.com/2013/05/05/schumer-announces-support-for-measure-to-make-3d-printed-guns-illegal.

143. Dara Kerr, *3D-Printed Guns May Face Regulations, Bans in New York*, CNET (June 13, 2013, 8:38 PM), http://news.cnet.com/8301-11386_3-57589294-76/3d-printed-guns-may-face-regulations-bans-in-new-york.

144. *See About Defense Distributed*, DEF. DISTRIBUTED, https://defdist.org/about/# (last visited Jan. 26, 2016) (explaining the mission of the organization).

which was founded in 2012 by Cody Wilson, a former law student at the University of Texas, has attracted a great deal of media and policy attention.[145] In 2012, Wilson was named by *Wired* magazine as one of "The 15 Most Dangerous People in the World."[146] The Defense Distributed website lists as its mission to "defend the human and civil right to keep and bear arms as guaranteed by the United States Constitution" and "collaboratively produce, publish, and distribute to the public without charge information and knowledge related to the digital manufacture of arms."[147] In 2012, Defense Distributed launched its first effort to promote this vision, the Wiki Weapon Project, which aimed to collect the necessary schematics to build a 3D-printed gun and publish them online.[148] The group faced numerous setbacks from private service providers such as the crowdfunding platform Indiegogo and 3D printer manufacturer Stratasys, which did not want to be associated with these activities.[149] However, those efforts did not derail the project.[150] On May 5, 2013, Defense Distributed

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145. Kelsey D. Atherton, *Defense Distributed's Cody Wilson on Being Told to Remove 3-D Printed Gun Plans: "We Win,"* POPULAR SCI. (May 9, 2013), http://www.popsci.com/technology/article/2013-05/defense-distributeds-cody-wilson-takedown-notice-we-win; Alan Feuer, *Cody Wilson, Who Posted Gun Instructions Online, Sues State Department*, N.Y. TIMES (May 6, 2015), http://www.nytimes.com/2015/05/07/us/cody-wilson-who-posted-gun-instructions-online-sues-state-department.html; Andy Greenberg, *3-D Printed Gun Lawsuit Starts the War Between Arms Control and Free Speech*, WIRED (May 6, 2015), http://www.wired.com/2015/05/3-d-printed-gun-lawsuit-starts-war-arms-control-free-speech/; Brian Krassenstein, *3D Printed Gun Lawsuit Filed: Cody Wilson Challenges the US State Department*, 3DPRINT.COM (May 7, 2015), http://3dprint.com/63487/cody-wilson-3d-printed-gun/.

146. Noah Sachtman et al., *The 15 Most Dangerous People in the World*, WIRED (Dec. 19, 2012, 6:30 AM), http://www.wired.com/2012/12/most-dangerous-people (listing Mr. Wilson as number fourteen on their list).

147. *About Defense Distributed*, *supra* note 144.

148. Andy Greenberg, *'Wiki Weapon Project' Aims to Create a Gun Anyone Can 3D-Print at Home*, FORBES (Aug. 23, 2012, 9:00 AM), http://www.forbes.com/sites/andygreenberg/2012/08/23/wiki-weapon-project-aims-to-create-a-gun-anyone-can-3d-print-at-home/#1a847e85ca6f.

149. Robert Beckhusen, *3-D Printer Company Seizes Machine from Desktop Gunsmith*, WIRED (Oct. 1, 2012, 2:06 PM), http://www.wired.com/2012/10/3d-gun-blocked/ (explaining Stratasys's response); Fidel Martinez, *Indiegogo Shuts Down Campaign to Develop World's First Printable Gun*, DAILY DOT (Aug. 27, 2012, 3:36 PM), http://www.dailydot.com/news/indiegogo-3d-printed-gun-campaign/ (explaining Indiegogo's response).

150. Andy Greenberg, *Meet the 'Liberator': Test-Firing the World's First Fully 3D-Printed Gun*, FORBES (May 5, 2013, 5:30 PM), http://www.forbes.com/sites/andygreenberg/2013/05/05/meet-the-liberator-test-firing-the-worlds-first-fully-3d-printed-gun/.

released the schematics for the "Liberator," a single-shot pistol, online for anyone to download and use.[151]

The response to the Liberator was intense. The plans were downloaded over 100,000 times in only two days.[152] The Department of Homeland Security issued a bulletin worrying that 3D-printed guns could be "impossible" to stop.[153] And days after Defense Distributed published the Liberator schematics online, the Directorate of Defense Trade Controls (DDTC) of the U.S. State Department issued a cease and desist letter to Cody Wilson, citing the agency's International Traffic in Arms Regulations (ITAR).[154] The DDTC asserts regulatory authority over the transmission of certain arms through the Arms Export Control Act (AECA) and "the AECA's implementing regulations," ITAR Parts 120–130.[155]

By the State Department's logic, publishing 3D printing schematics qualifies as exporting arms secrets, in the same manner that exporting strong cryptography was targeted in the 1990s in the so-called "Crypto Wars."[156] At that time, the State Department attempted to use those regulations to crack down

151. *Id.*

152. *See* Andy Greenberg, *3D-Printed Gun's Blueprints Downloaded 100,000 Times in Two Days (With Some Help From Kim Dotcom)*, FORBES (May 8, 2013, 5:12 PM), http://www.forbes.com/sites/andygreenberg/2013/05/08/3d-printed-guns-blueprints-downloaded-100000-times-in-two-days-with-some-help-from-kim-dotcom/ [hereinafter Greenberg, *Downloaded 100,000 Times*].

153. 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.

154. Letter from Glenn E. Smith, Chief, Enforcement Div., Office of Def. Trade Controls Compliance, to Cody Wilson, Director, Defense Distributed (May 8, 2013) (writing Mr. Wilson with orders to cease and desist). For full reprinted text of the letter see 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/#29168763fb77.

155. *Id.*

156. Andy Greenberg, *3-D Printed Gun Lawsuit Starts the War Between Arms Control and Free Speech*, WIRED (May, 6, 2015, 5:08 PM), http://www.wired.com/2015/05/3-d-printed-gun-lawsuit-starts-war-arms-control-free-speech/ ("Wilson's lawsuit, two decades later, is taking another shot at ITAR with the same first amendment argument. Only this time the fight isn't over code erroneously labeled as a weapon. The code in question actually *is* a weapon.").

on cryptography research and reporting.[157] The move was challenged in court in *Bernstein v. U.S. State Department*.[158] The court determined that source code is speech by definition, but the particular ITAR enforcement at issue was moved to the Commerce Department during the proceedings, thereby rending the ruling mostly moot.[159]

Following the State Department's letter, Wilson removed the schematics from his personally hosted website, but the designs remained online for months, garnering hundreds of thousands of downloads in the meantime.[160]

In 2015, Defense Distributed launched a lawsuit against the DDTC, arguing a violation of Wilson's First Amendment speech rights.[161] In another parallel to the Crypto Wars, Wilson's lawyers argued that source code for 3D-printed guns represents a form of speech (as *Bernstein v. U.S. State Department* successfully argued in the 1990s).[162] In subsequent proceedings, Wilson has added Second and Fifth Amendment violations to his list of complaints.[163] A few months after Wilson launched these lawsuits, the State Department

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157. *Id.* ("In the 1990s, the same regulations were used to threaten cryptographers with prosecution for posting online the first freely available strong encryption tools. Under ITAR regulations, a piece of uncrackable crypto software like PGP was considered a military munition.").

158. Bernstein v. U.S. Dep't of State, 922 F. Supp. 1426, 1436 (N.D. Cal. 1997).

159. *Id.* ("For the purposes of First Amendment analysis, this court finds that source code is speech."); Bernstein v. U.S. Dep't of State, 974 F. Supp. 1288, 1293 (N.D. Cal. 1997) ("On November 15, 1996 President Clinton . . . ordered that jurisdiction over export controls on nonmilitary encryption products and related technology be transferred from the Department of State to the Department of Commerce.").

160. *See* Greenberg, *Downloaded 100,000 Times*, *supra* note 152; John P. Mello, *Banned 3D Printed Gun Files Will Never Truly Vanish From the Web*, PCWORLD (May 10, 2013, 11:44 AM), http://www.pcworld.com/article/2038487/banned-3d-printed-gun-files-will-never-truly-vanish-from-the-web.html ("Schematics for 3D printing a working handgun have been yanked from their original website by order of the State Department—but the files remain online at the Pirate Bay website and elsewhere.").

161. Feuer, *supra* note 145.

162. *See id.* ("Defense Distributed[] has filed suit against the State Department, claiming that its efforts to stop him from publishing his plans, which are no more than computer code, amount to a prior restraint on free speech."); *see also Bernstein*, 922 F. Supp. at 1436.

163. Complaint at 10–13, Defense Distributed v. U.S. Dep't of State, 2015 WL 2149795 (W.D.Tex.) (No. 1:15-cv-372).

proposed new regulations that would amend ITAR language to explicitly outlaw the publishing of such schematics.[164]

Meanwhile, Defense Distributed has subsequently created Ghost Gunner, a for-profit subsidiary, which creates computer-numerical-controlled (CNC) mills used to manufacture firearms.[165] These CNC mills can be used to help create metallic lower receivers for guns that have no serial number, making them harder for law enforcement officials to trace later.[166] A *Wired* journalist who used the Ghost Gunner to create his own AR-15 called the device "a tiny, easy-to-use, anarchic rifle factory" that "may signal a new era in the gun control debate, one where the barrier to legally building an untraceable, durable, and deadly semiautomatic rifle has reached an unprecedented low point in cost and skill."[167]

Beyond the legality of 3D-printed guns and devices such as the Ghost Gunner, the practicality of even enforcing traditional regulatory efforts in this new technological environment remains equally unclear.[168] For the reasons already identified earlier, it is extremely difficult—and in some cases largely impossible—to limit the free flow of information once it has been released on the Internet through peer-to-peer distribution mechanisms and platforms.[169] 3D printing blueprints for gun

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164. *See* International Traffic in Arms: Revisions to Definitions of Defense Services, Technical Data, and Public Domain; Definition of Product of Fundamental Research; Electronic Transmission and Storage of Technical Data; and Related Definitions, 80 Fed. Reg. 31,525, 31,528 (proposed June 3, 2015) (to be codified at 22 C.F.R. pts. 120, 123, 125, 127) (proposing an ITAR requirement that "one must seek and receive a license or other authorization from the Department or other cognizant U.S. government authority to release ITAR controlled 'technical data.'").

165. *FAQ*, GHOST RUNNER, https://ghostgunner.net/faq.html (last visited Jan. 26, 2016).

166. Elizabeth Van Brocklin, *'Ghost Gun' Murders and Trafficking Cases Are a Law Enforcement Nightmare Come True*, TRACE (Oct. 16, 2015), http://www.thetrace.org/2015/10/ghost-gun-lower-receiver-california (describing how 3D printers are allowing for the rapid creation of untraceable guns and how this is creating difficulties for California police).

167. Greenberg, *Untraceable AR-15*, *supra* note 128.

168. *See* Doctorow, *supra* note 109 (arguing that banning 3D printed guns would likely be unworkable and would interfere with 3D printers' lawful uses).

169. *See, e.g.*, Mello, *supra* note 160 (discussing how Wilson's prohibited 3D printed gun files will always remain available somewhere on the Internet). *See generally* Dov Wisebrod, *The Free Flow of Information: Can it be Regulated?*, WISEBROD.COM (Mar. 1995), http://www.wisebrod.com/docs/dw-spch.htm ("I won't go into detail about [the Internet's] operation, but suffice it to say that it was built with such tremendous capacity for connectivity and communication, that it was hard to stop people from barging in and linking up. The ease of

designs are going to be just as hard to "bottle up" as the unlicensed online distribution of copyrighted music and movies.[170]

Likewise, digital rights management (DRM) schemes, which could theoretically aim to impose technical restrictions on the use of 3D printers for the manufacturing of guns, would also likely be easily defeated.[171] As will be noted below in Section III.D.1., DRM schemes have not been workable in other contexts related to intellectual property enforcement, and they are perhaps even less likely to be effective if imposed on 3D printers.[172]

Likewise, imposing liability on third parties—sites hosting schematics, search engines, and manufacturers of devices—seems neither workable nor wise. There exists a broad spectrum of general purpose technologies that can be used to facilitate criminal activity. Cars are an essential element in any "getaway plan," for example, but auto manufacturers are not regulated to account for such activities.[173] Computers can

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linking up meant open access, and if anyone could join you quickly got anarchy. Open access and anarchy. These two elements are integral to the Internet, and it is crucial for potential regulators to recognize their effects.").

170. Nick Bilton, *Internet Pirates Will Always Win*, N.Y. TIMES (Aug. 4, 2012), http://www.nytimes.com/2012/08/05/sunday-review/internet-pirates-will-always-win.html ("The way people download unauthorized content is changing. . . . [I]t will be much harder to trace and to stop . . . [and i]t is only going to get worse. Piracy has started to move beyond the Internet and media and into the physical world. . . . [and a]lthough 3-D printing is still in its infancy, it is soon expected to become as pervasive as illegal music downloading was in the late 1990s. Content owners will find themselves stuck behind ancient legal walls when trying to stop people from downloading objects online.").

171. *See* Doctorow, *supra* note 109 ("However, what Rep Israel doesn't say is how he hopes to accomplish his goal. Firmware locks for 3D printers? A DMCA-like takedown regime for 3D shapefiles that can be used to generate plastic firearms (or parts of plastic firearms?). A mandate on 3D printer manufacturers to somehow magically make it impossible for their products to print out gun-parts? Every one of those measures is a nonsense and worse: unworkable combinations of authoritarianism, censorship, and wishful thinking. Importantly, none of these would prevent people from manufacturing plastic guns. And all of these measures would grossly interfere with the lawful operation of 3D printers.").

172. *See* Janko Roettgers, *DRM FAIL: Five Broken Copy Protection Schemes*, GIGAOM (Sep. 17, 2010, 1:49 PM), https://gigaom.com/2010/09/17/drm-fail-five-broken-copy-protection-schemes-2/ (compiling a list of DRM failures).

173. Modern vehicle technology, however, may be used to assist law enforcement. *E.g.*, A.J. Bayatpour, *"OnStar Was Extremely Helpful:" Technology Helps Police Arrest Attempted Bank Robbery Suspects*, FOX6 (Sept.

be used to facilitate a wide variety of crimes as well.[174] And, going back further, "[p]aper printers can be used to create instruments of fraud, but we do not ban paper printing at home."[175]

Following the general logic of permissionless innovation and understanding the importance of keeping intermediaries free of punishing liability for what others might do with their general purpose technologies and platforms, the proper focus of regulation should remain on the user and uses of firearms, regardless of how they are manufactured.[176]

As with cars, computers, or paper printers, "criminal law properly focuses on the products of technology and their criminal uses," and policymakers "should celebrate technological innovation and attempt to regulate its misuse without inhibiting creative development."[177] Moreover, although "lawsuits alleging negligent distribution plagued the firearm industry until 2005,"[178] the Protection of Lawful Commerce in Arms Act[179] "effectively ended the 'gun tort' era" by granting gun manufacturers immunities for such legal actions.[180] By extension, it seems likely that those who use 3D printers to create firearms will also be immunized from civil actions.[181]

14, 2015, 9:39 PM), http://fox6now.com/2015/09/14/technology-helps-milwaukee-police-arrest-attempted-bank-robbery-suspects/ ("This incident was the second in less than a week in which OnStar led Milwaukee police to a stolen car.").

174. *See generally Cybercrime*, INTERPOL, http://www.interpol.int/Crime-areas/Cybercrime/Cybercrime (last visited Feb. 11, 2016) ("More and more criminals are exploiting the speed, convenience and anonymity of the Internet to commit a diverse range of criminal activities that know no borders, either physical or virtual, cause serious harm and pose very real threats to victims worldwide.").

175. Little, *supra* note 129, at 1505.

176. *Id.* at 1510 ("[T]he challenge is to control dangerous guns and the people who use, or now make, them for criminal purposes—not to fear or inhibit the innovation itself.").

177. Little, *supra* note 129, at 1505.

178. Jensen-Haxel, *supra* note 129, at 463.

179. Protection of Lawful Commerce in Arms Act, Pub. L. No. 109–92, 119 Stat. 2095 (2005).

180. Jensen-Haxel, *supra* note 129, at 463.

181. *See id.* at 465 ("Being immunized against civil liability, [firearm] manufacturers presumably would also be shielded from civil actions arising from haphazard piecemeal distribution arrangements.").

For these reasons, some scholars have referred to regulatory concerns about 3D-printed firearms as a "red herring"[182] while others have similarly noted that:

> [T]he technology of 3D printing is a distraction, albeit a relevant and fascinating one, from the question of whether and how best to regulate guns generally. . . .
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> . . . .
>
> . . . [I]f the danger and misuse of guns is the problem, then gun control must focus on those issues. The means by which guns are manufactured and distributed are relevant, but are not the central concern.[183]

Because "a gun made with a 3D printer that fires semi-automatically and is not overly concealable is no more deadly than any weapon available on the shelf,"[184] only "policy levers other than legal restrictions on the technology itself can handle the challenges posed by the fact that 3D printers make it easier to produce guns."[185]

In its agency guidance on 3D-printed firearms, the ATF says that, "When ATF receives credible information regarding the illegal possession of firearms, it will investigate and take appropriate action. If individuals neglect to follow Federal laws and regulations surrounding firearms, ATF will investigate their activities."[186] Beyond traditional restrictions on the sales, distribution, and use of firearms, increased education may be an important part of the solution.[187] That may be the only path left open to policymakers and regulators in the wake of the Supreme Court's 2008 ruling in *District of Columbia v. Heller*.[188] In *Heller*, the Court concluded that the Second Amendment served to "guarantee the individual right to

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182. Desai & Magliocca, *supra* note 6, at 1700 (2014).

183. Little, *supra* note 129, at 1509–10. (They argue that "reasonable gun control . . . seems to be entirely separate from the *means* of manufacturing guns," and, therefore, "[o]ne must 'control' guns, not 3D printing—or at least, not control 3D printing more so than any other aspect of gun production, possession, and use; or more than any other technology that facilitates crime."). *Id.* at 1509.

184. Jensen-Haxel, *supra* note 129, at 492.

185. Desai & Magliocca, *supra* note 6, at 1702.

186. BUREAU OF ALCOHOL, TOBACCO, FIREARMS & EXPLOSIVES, *supra* note 137.

187. *See* Jensen-Haxel, *supra* note 129, at 494. ("It will also hopefully refocus energy on bipartisan educational campaigns regarding the proper use, storage and manufacture of self-defense weapons, with a special aim of reducing household accidents.").

188. District of Columbia v. Heller, 554 U.S. 570 (2008).

possess and carry weapons in case of confrontation."[189] The Court also stressed "the inherent right of self-defense,"[190] as well as "the right of law-abiding, responsible citizens to use arms in defense of hearth and home."[191]

By extension, therefore, "*Heller* may create a right for individuals to make their own weapons to be used in self-defense and may protect certain processes and materials involved in making firearms."[192] This would almost certainly include the use of 3D printers to manufacture firearms for personal use.

In sum, if permissionless innovation is to guide the evolution of 3D printing, "blanket illegalization of home production [of firearms] is an inappropriate approach"[193] for both legal and practical reasons.

C. HEALTH TECHNOLOGY & MEDICAL DEVICES

Health technology is another area likely to be impacted by 3D printers. As Brian Proffitt suggests, "[v]ery soon . . . the day will come when a patient in need of a custom medical device, such as a prosthesis or stent, can have such an object manufactured within minutes right at the healthcare facility, instead of waiting for days to get the device delivered from a factory."[194]

In fact, 3D-printed medical devices are already being used to improve and even save lives.[195] Researchers at the University of Michigan have 3D-printed splints to help children with a rare breathing disorder called tracheobronchomalacia.[196] Splints are not the only such instance of 3D-printed medical devices being implanted into the human body. 3D printing is providing new solutions to a variety of medical problems: 3D-

189. *Id.* at 592.
190. *Id.* at 628.
191. *Id.* at 635.
192. Jensen-Haxel, *supra* note 129, at 449.
193. *Id.* at 494.
194. Proffitt, *supra* note 29.
195. Jerome Groopman, *Print Thyself*, NEW YORKER (Nov. 24, 2014), http://www.newyorker.com/magazine/2014/11/24/print-thyself; Alexander Howard, *6 Amazing 3D-Printed Body Parts That Changed Patients' Lives*, HUFFINGTON POST (Oct. 9, 2015, 10:53 AM), http://www.huffingtonpost.com/entry/3d-printed-body-parts_560ed88ce4b076812701f9b7.
196. Jim Teddder, *3-D Printed Device Helps Children with Rare Breathing Disorder*, VOICE OF AM. (May 3, 2015), http://learningenglish.voanews.com/content/three-d-printed-device-rare-breathing-disorder/2744108.html.

printed titanium meshes are used for cranial reconstruction,[197] the layer-by-layer method of 3D printing to uniquely place active and inactive ingredients in ways that result in epilepsy pills with specialized disintegration times,[198] 3D-printed titanium sternum and ribs substitute for a cancer patient's own,[199] and 3D-printed neonatal catheters help premature newborns.[200]

Meanwhile, average citizens are using 3D printing to help others with various medical needs. Michael Balzer, a software engineer, used 3D imaging software and a 3D printer to create life-size replicas of his wife's skull in an attempt to seek less invasive approaches to her impending cranial surgery.[201] And prosthetic hands and arms are being 3D-printed by volunteers to help victims of war[202] or children born with limb deficiencies.[203]

Decentralized production of medical devices such as 3D-printed prosthetics could raise policy concerns at the U.S. Food and Drug Administration (FDA). How the FDA's convoluted regulatory regime for prosthetics[204] might apply to 3D-printed

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197. Lizette Borreli, *Chinese Girl Becomes World's First To Receive Full Skull Reconstruction Via 3D Printing*, MED. DAILY (July 16, 2015, 2:17 PM), http://www.medicaldaily.com/chinese-girl-becomes-worlds-first-receive-full-skull-reconstruction-3d-printing-343390.

198. Mike Murphy, *The FDA Has Approved the First Drug Made by a 3D Printer*, QUARTZ (Aug. 3, 2015), http://qz.com/471030/the-fda-has-approved-the-first-drug-made-by-a-3d-printer.

199. Mike Murphy, *Doctors Have Implanted a 3D-Printed Ribcage in an Actual Human Being*, QUARTZ (Sept. 11, 2015), http://qz.com/500409/doctors-have-implanted-a-3d-printed-ribcage-in-an-actual-human-being.

200. Bridget Butler Millsaps, *Northeastern University: Researchers Invent 3D Magnetic Printing, Make Neonatal Catheters*, 3DPRINT.COM (Nov. 4, 2015), http://3dprint.com/103885/nu-3d-neonatal-catheters.

201. Sara Breselor, *Man Saves Wife's Sight By 3D Printing Her Tumor*, MAKE (Jan. 14, 2015, 5:00 AM), http://makezine.com/2015/01/14/hands-on-health-care.

202. Andrea Chang, *With Ingenuity and a 3-D Printer, Group Changes Lives*, L.A. TIMES (Apr. 25, 2014, 3:00 AM), http://www.latimes.com/business/la-fi-c1-3d-printing-prosthetics-20140425-m-story.html.

203. *See About Us*, ENABLING THE FUTURE, http://enablingthefuture.org/about (last visited Jan. 23, 2016) ("[C]hildren and adults who are born missing fingers . . . can come [here] to find stories of other people who have upper limb differences and who are using 3D printed devices that can help them with daily tasks that are easier to perform with 2 fully functional hands.").

204. *Cf.* Robert Graboyes, *How to Print Yourself a New Hand*, CNN (Oct. 24, 2014, 8:11 PM), http://www.cnn.com/2014/10/24/opinion/graboyes-3-d-

prosthetics remains unclear, as it will likely be difficult for regulators to stop bottom-up innovation of this sort given its highly decentralized and even non-commercial nature.[205] Nonetheless, it is worth briefly considering the FDA's current regime for the regulation of prosthetics in more detail because it potentially foreshadows the many challenges to come for the FDA and other agencies as 3D printing becomes more widespread in society.

Prosthetics are medical devices in a traditional regulatory sense, but it does not appear that those parties who are currently creating new 3D-printed limbs are going to the FDA and asking for permission to do so.[206] Instead, they are simply engaging in this sort of innovation without prior approval.[207]

What are the difficulties for one who wishes to 3D print prosthetic legs, arms, or hands? Under federal regulations, owners and operators of establishments engaged in the manufacture or processing of medical devices are required to register their products with the FDA.[208] Does this apply to an ordinary citizen that is 3D printing prosthetic body parts at their home? The FDA also requires keeping records of all medical devices manufactured[209] and reporting complaints associated with the use of these devices.[210] How much would compliance with these requirements cost for someone who charitably 3D prints arms for amputees?

There are numerous complications to a regulatory strategy based on imposing licenses and fines on specific companies, organizations, or individuals using 3D printers to create prosthetic limbs. To the extent they exist, larger corporate players in the 3D printing space might make a more feasible

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printer-prosthetics ("New drugs, devices and procedures typically wait for years as regulators sort through stacks of proposals and tons of data.").

205. Adam Thierer, *The Right to Try, 3D Printing, the Costs of Technological Control & the Future of the FDA*, TECH. LIBERATION FRONT (Aug. 10, 2015), http://techliberation.com/2015/08/10/the-right-to-try-3d-printing-the-costs-of-technological-control-the-future-of-the-fda.

206. *See* Graboyes, *supra* note 204 ("The proliferation of printed hands began when Jon Schull at the Rochester Institute of Technology formed e-NABLE . . . to connect people who need hands with people who are interested in building them.").

207. *Id.*

208. 21 C.F.R. § 207.7(c) (2015) ("Owners and operators of establishments engaged in manufacture or processing of medical devices shall register and list their products with the Center for Devices and Radiological Health, FDA.").

209. 21 C.F.R. § 820.180 (2015).

210. 21 C.F.R. § 820.198 (2015).

regulatory target. But 3D printing is already highly decentralized and often undertaken by average citizens in their own homes.[211] Thus, it will be challenging for the FDA to impose its traditional licenses and penalties on the many individuals creating novel medical applications using 3D printing technology. Moreover, even if some larger corporate entities become the target of regulation, many of those firms will simply engage in a form of "global innovation arbitrage" and find more hospitable jurisdictions offshore where they can experiment more freely with technologies and applications.[212] What should be clear is that the practicality of control matters deeply and must be taken into account when formulating policy. And the complexity associated with such efforts to control technology is only going to increase.[213]

Instead of resisting permissionless innovation of this sort, the FDA should acknowledge that traditional regulatory approaches may no longer work in light of the remarkably decentralized world of medical device experimentation that is currently unfolding.[214] Nonetheless, legitimate dangers exist in a world where such freewheeling experimentation takes place.[215]

211. *Cf.* John Aziz, *How 3D Printing Could Take Over the Manufacturing Industry*, THE WEEK (May 27, 2013), https://theweek.com/articles/464169/how-3d-printing-could-take-over-manufacturing-industry ("Home-based 3D printing has the potential to lower costs, and decentralize and democratize manufacturing, especially as technologies improve and as more complex multi-material printers become available."); Gilpin, *supra* note 37 (explaining "home 3D printers are becoming smaller and more affordable" and as a result "[p]eople can print custom jewelry, household goods, toys, and tools").

212. *See, e.g.*, Adam Thierer, *Global Innovation Arbitrage: Genetic Testing Edition*, TECH. LIBERATION FRONT (Dec. 12, 2014), http://techliberation.com/2014/12/12/global-innovation-arbitrage-genetic-testing-edition (describing "global innovation arbitrage" in the context of a genetic testing company, 23andMe, which faced more regulatory obstacles in the U.S. than it did in the United Kingdom).

213. Compare with Samuel Arbesman, *It's Complicated: Human Ingenuity Has Created a World that the Mind Cannot Master. Have We Finally Reached Our Limits?*, AEON (Jan. 6, 2014), https://aeon.co/essays/is-technology making-the-world-indecipherable, which is an essay suggesting that as technology becomes more sophisticated, its effects are harder to predict.

214. *See supra* notes 201–203 and accompanying text (describing individuals using 3D printers to solve their medical problems who did not wait for formal government approval).

215. *See supra* notes 128–130 (describing concerns with the regulation of 3D-printed guns).

The FDA should consider reorienting its focus toward improved *risk education* and *health literacy* more generally.[216] Their goal should be to help create a more fully-informed citizenry that is empowered with more and better information about relative risk trade-offs. The FDA already engages in various product labeling efforts as well as public education campaigns and strategies.[217] However, this has always been a secondary mission for the agency, which has instead focused on trying to preemptively guarantee the safety and efficacy of drugs and devices.[218] Furthermore, much of the "education" the FDA does is basically explaining to companies and the public how to comply with its voluminous body of regulation.[219]

A more comprehensive risk education campaign would build upon the work that the FDA has done in its 2009 *Strategic Plan for Risk Communication*[220] as well as its 2011 report on *Communicating Risks and Benefits: An Evidence-*

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216. *See* INST. OF MED. OF THE NAT'L ACADAMIES, HEALTH LITERACY: A PRESCRIPTION TO END CONFUSION xi (Lynn Nielsen-Bohlman et al. eds., Nat't Academies Press 2004), http://www.nap.edu/openbook.php?record_id=10883 ("[H]ealth literacy . . . remains a neglected, final pathway to high-quality health care." (emphasis omitted)). Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." CATHERINE R. SELDEN ET AL., CURRENT BIBLIOGRAPHIES IN MEDICINE: HEALTH LITERACY vi (Karen Patrias ed., 2000).

217. *See* U.S. FOOD & DRUG ADMIN., A FOOD LABELING GUIDE: GUIDANCE FOR INDUSTRY (2013), http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf; *Tools & Educational Materials*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/food/fooddefense/toolseducationalmaterials/default.htm (last visited Jan. 23, 2016); *Contact Us—Division of Industry and Consumer Education (DICE)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs—DivisionofIndustryandConsumerEducation/ucm20041265.htm (last visited Jan. 23, 2016).

218. *Cf. Statement of FDA Mission*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm298331.pdf (last visited Feb. 12, 2016) ("FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.").

219. *See, e.g.*, A FOOD LABELING GUIDE: GUIDANCE FOR INDUSTRY, *supra* note 217 (describing the many regulations for labeling food).

220. U.S. FOOD & DRUG ADMIN., FDA'S STRATEGIC PLAN FOR RISK COMMUNICATION 1 (2009), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM183683.pdf ("The purpose of this document is to describe the U.S. Food and Drug Administration's strategy for improving how the agency communicates about regulated products.").

Based User's Guide.[221] Risk education should focus on both the general public and the innovators who are providing new devices and treatments to the public.

The FDA already uses guidance documents when markets and law are in a state of flux. For example, the FDA has recently issued guidance that exempts from regulation most mobile medical applications that run on smartphones and other mobile communication devices (such as health and wellness management apps).[222] In some cases, FDA exempts them because they have decided they are not medical devices and, in other cases, where they meet the definition of a medical device, they have signaled their intent to exercise "enforcement discretion."[223] As with all of its guidance, the FDA reserves the right to change its mind and "will continue to evaluate the potential impact [of] these technologies."[224] But clearly the agency is implicitly acknowledging that the world has changed and regulators cannot keep up with the rapid pace of technological change.

Going forward, the agency will likely have to reorient its focus in this way to cope with the rapidly evolving universe of not just mobile medical apps, but also all the "wearable technologies" that are part of the larger "Internet of Things," which refers to the growing universe of interconnected and sensor-driven personal devices and household or workplace appliances.[225] Guidance documents should be crafted that suggest various best practices for developers as well as risk education and communication messaging for the general public. This same model could be applied to 3D printing and many other new technologies.

Finally, it is important to keep in mind that the Federal Trade Commission (FTC) already possesses broad power to

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221. U.S. FOOD & DRUG ADMIN. RISK COMMC'N ADVISORY COMM., COMMUNICATING RISKS AND BENEFITS: AN EVIDENCE-BASED USER'S GUIDE (Baruch Fischhoff et al. eds., 2011), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM268069.pdf.

222. *See generally* U.S. Food & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 13 (2015), http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf ("[B]ut it is important to note that the FDA intends to apply its regulatory oversight *to only the subset* of mobile apps identified below . . . ." (emphasis added)).

223. *Id*. at 15–18.

224. *Id*. at 7.

225. Thierer, *Internet of Things*, *supra* note 57, at 1.

ensure that health claims are truthful.[226] But the agency only evaluates these claims after products are on the market and it only prosecutes companies that engage in "unfair or deceptive practices" that violate consumers' trust in some fashion.[227] The FTC's *ex post* enforcement approach[228] avoids the problems presented by the FDA's highly precautionary *ex ante* approach,[229] which assumes that all innovation is essentially guilty until proven innocent. The FTC also frequently publishes consumer education materials that help the public understand the risks associated with various technologies.[230] Thus, the FTC's existing enforcement powers and educational tools could help facilitate the FDA's transition to a new risk education-oriented agency.

D. INTELLECTUAL PROPERTY

Unlike firearms and medical devices, intellectual property cases are usually civil matters: when rights are infringed, it's the rightsholders that must identify and file suit against the infringers.[231] Many of the intellectual property issues likely to arise with 3D printing have been a fact of life since high-speed Internet access became ubiquitous. Rightsholders have developed strategies for dealing with infringement that should easily map to 3D printing.

3D printing is the trifecta of intellectual property infringement. Imagine a father uses his 3D scanner and 3D printer to make an identical copy of one of his son's action figures. The action figure is probably of a copyrighted

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226. *See Health Claims*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/business-center/advertising-and-marketing/health-claims (listing various guidelines for companies that make health-related claims).

227. 15 U.S.C. § 45(a)(2) (2012) (enabling the FTC to enforce the prohibition on "unfair or deceptive acts or practices in or affecting commerce"); *see* Maureen K. Ohlhausen, *The Procrustean Problem with Prescriptive Regulation*, 23 COMMLAW CONSPECTUS 1, 2 (2014) ("[R]eformers should look for guidance to the FTC's successful, evolving approach to Internet-related issues, including its ex post enforcement of basic competition and consumer protection rules.").

228. *See* Ohlhausen, *supra* note 227, at 2.

229. *See generally supra* notes 202–207 (describing FDA regulation of medical devices).

230. See *About Us*, ONGUARDONLINE.GOV, http://www.onguardonline.gov/about-us (last visited Jan. 23, 2016), for a website managed by the FTC that helps people "be safe, secure and responsible online."

231. *See* Verne Kopytoff, *Before You File Suit*, BLOOMBERG BUS. (Oct. 2, 2012), http://www.bloomberg.com/bw/articles/2012-10-02/before-you-file-suit.

character, marked with a trademarked company logo,[232] and may contain a patented mechanism (e.g. a rocket-firing arm).[233] That single 3D-printed object thus will infringe trademarks, patents, and copyrights.

Trademarks "[prevent] others from copying a source-identifying mark . . . which seeks to promote competition by protecting a firm's reputation."[234] The trademark "quickly and easily assures a potential customer that *this* item—the item with this mark—is made by the same producer as other similarly marked items that he or she liked (or disliked) in the past."[235] Although it's quite easy today to distinguish an action figure made with a consumer-grade 3D printer from one purchased at a store, the difference is quickly eroding.[236] For some types of objects (e.g. abstract jewelry) it may already be difficult to tell a difference.[237]

The Patent and Copyright Clause of the Constitution empowers Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[238] The goal of both patents and copyrights is to give creators a limited monopoly over the fruits of their intellectual labors.[239] Just as computers and Internet distribution have enabled rampant copyright infringement for music, movies, and books,[240] 3D printers may soon do the same

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232. *See generally* David W. Ehrlich, *"Do I Need a License to Make This Toy?"*, FROSS ZELNICK LEHRMAN & ZISSU, P.C. (2006), http://www.frosszelnick.com/sites/default/files/20090506100400_90_PUBLISHED_PDF.pdf (explaining whether a license from a copyright or trademark is needed for "[a]ction figures and dolls").

233. *Cf.* U.S. Patent No. 264,109 (filed Aug. 13, 1979) (showing the original action figure design patent for Boba Fett, of Star Wars fame).

234. Qualitex Co. v. Jacobson Prod. Co., 514 U.S. 159, 163–64 (1995).

235. *Id.* at 164.

236. *See* Mashable Video, *A Scary-Accurate 3D-Printed Action Figure is Your New Favorite Selfie*, MASHABLE (Aug. 13, 2015), http://mashable.com/2015/08/13/3d-printed-action-figure/#uGCV2QiqXPqK (describing a photo booth that can produces tiny figures of the whoever is in the booth).

237. *See generally Jewelry*, SHAPEWAYS, http://www.shapeways.com/marketplace/jewelry/ (last visited Feb. 13, 2016) (displaying many pieces of jewelry that can be created from a 3D printer and are available for purchase).

238. U.S. CONST. art. I, § 8, cl. 8.

239. *See id.*

240. *See* ADVISEN, INTELLECTUAL PROPERTY AND THE INTERNET: COPYRIGHT INFRINGEMENT LIABILITY IN THE DIGITAL ERA 1 (2010), https://www.advisen.com/downloads/Intellectual_Property.pdf.

for sculptures, architectural models, toys, jewelry, and any other industries based on the sale of small plastic goods.

While the action figure example described above is the most straightforward example of using a 3D printer to infringe intellectual property rights, it is not the only way these rights can be violated. A more complicated situation is when someone creates a digital model of an existing object and uploads the model to Thingiverse, a website that lets users share models that other users can download and print on their own 3D printers.[241] In this situation, rightsholders may have a valid infringement claim against the creator of the 3D model, the online sharing site, and the end user that actually prints the model.[242] They could also choose to go after the creator of the 3D printer used to print the model on a theory of contributory liability, similar to the arguments used against Napster: that the 3D printer manufacturer had actual knowledge of infringement and supplied material support for that infringement.[243]

Another situation is when the designer of the 3D model posts their design to an online marketplace like Shapeways, which allows users to create a digital storefront, upload their designs, choose the materials to use when printing, and set prices.[244] Shapeways then handles taking orders, printing the items, and shipping them to consumers—for a small fee.[245] What is the future of intellectual property when average citizens can produce objects more easily than they are produced by assembly lines?[246] For guidance, we look to cases involving other technologies.

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241. *See About Thingiverse*, THINGIVERSE, https://www.thingiverse.com (last visited Feb. 19, 2016).

242. *But see* Timothy Holbrook, *How 3-D Printing Threatens Our Patent System*, SCIENTIFIC AM. (Jan. 6, 2016), http://www.scientificamerican.com /article/how-3-d-printing-threatens-our-patent-system1/ (suggesting that a 3D design file does not infringe a patent unless the creator of the file has actual knowledge of the relevant patent).

243. *See* A&M Records, Inc. v. Napster, Inc., 239 F.3d 1004, 1022 (9th Cir. 2001) ("Napster has *actual* knowledge that *specific* infringing material is available using its system, . . . it could block access to the system by suppliers of the infringing material, and . . . it failed to remove the material." (emphasis added)).

244. SHAPEWAYS, ABOUT SHAPEWAYS (2015), http://static1.sw-cdn.net/files/cms/press/Shapeways-Fact-Sheet-2015-Q3.pdf.

245. *Id.*

246. *See generally* Desai & Magliocca, *supra* note 6, at 1698 (contemplating a society in which 3D printing use is ubiquitous); Matt Schruers, *3D Printing:*

1. Copyright

Digitization, ubiquitous broadband, anonymous file sharing, and cheap playback devices have resulted in rampant copyright infringement.[247] But long before the Internet revolution, the Supreme Court narrowly upheld the idea that "the sale of copying equipment, like the sale of other articles of commerce, does not constitute contributory infringement if the product is widely used for legitimate, unobjectionable purposes."[248] That case dealt with VCRs,[249] but the argument also applies to 3D printers.

Section 512 of the Digital Millennium Copyright Act (DMCA), passed in 1998, exempts Internet intermediaries from copyright infringement liability provided they follow certain rules: they must promptly block access to alleged infringing material (or remove such material from their systems) when they receive notification of an infringement claim from a copyright holder or the copyright holder's agent.[250] These notices are commonly referred to as DMCA takedown notices and the limitation of liability is referred to as a "safe harbor."[251]

The 2005 case against the Grokster file sharing service established that "one 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."[252] In response, file sharers designed distributed networks that were much harder to shut down.[253] Record labels

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Sorry, This Seat Is Reserved, DISRUPTIVE COMPETITION PROJECT (Feb. 14, 2013), http://www.project-disco.org/intellectual-property/021413-3d-printing-sorry-this-seat-is-reserved (explaining the revolutionary nature of 3D printing).

247. *See* STAN J. LIEBOWITZ, FILE-SHARING: CREATIVE DESTRUCTION OR JUST PLAIN DESTRUCTION? 1, 4, 8 n.27 (2005), https://www.utdallas.edu/~liebowit/intprop/destruction4.pdf.

248. Sony Corp. of Am.. v. Universal City Studios, Inc., 464 U.S. 417, 442 (1984).

249. *Id*. at 417.

250. 17 U.S.C. § 512 (2012) ("Limitations on liability relating to material online").

251. *See Digital Millennium Copyright Act*, ELEC. FRONTIER FOUND., https://www.eff.org/issues/dmca (last visited Feb. 13, 2016).

252. Metro-Goldwyn-Mayer Studios, Inc., v. Grokster, Ltd., 545 U.S. 913, 919 (2005).

253. *Cf.* Pamela Samuelson, *Three Reactions to MGM v. Grokster*, 13 MICH. TELECOMM. & TECH. L. REV. 177, 195 (2006) ("Yet, the entertainment industry has neither sued nor shut down all of p2p file sharing services. It appears,

tried suing infringers directly, but the public backlash caused them to abandon this strategy.[254]

Copyright owners then used governmental pressure to implement a system called the Copyright Alert Program (CAP).[255] CAP is a "graduated response" system in which rightsholders work with Internet service providers to identify and send warning notices (the "Alert" part of the name) to infringers.[256] After multiple warnings, Internet Service Providers (ISPs) must enact "mitigation measures" that may include temporarily throttling the speed of the user's Internet connection and could include permanently disconnecting the user from the Internet.[257]

The result of the case law is that manufacturers of 3D printers are not likely to be sued for copyright infringement unless they advertise their devices as being wonderful devices for copyright infringement.[258] The online services used to share designs will be treated no differently from services used to share movies and music.[259] If they host infringing content, they will receive DMCA takedown notices and will likely remove the infringing content as refusing to do so could result in them

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moreover, that the *Grokster* decision has not stopped or even slowed down p2p file-sharing." (internal footnotes omitted)).

254. *See generally* BILL D. HERMAN, THE FIGHT OVER DIGITAL RIGHTS: THE POLITICS OF COPYRIGHT AND TECHNOLOGY 10–11 (Cambridge Univ. Press 2013); David Kravets, *Copyright Lawsuits Plummet in Aftermath of RIAA Campaign,* WIRED (May 18, 2010, 1:24 PM), http://www.wired.com/2010/05/riaa-bump/ (discussing the negative economic period that led to the decrease in litigation).

255. *See* CTR. FOR COPYRIGHT INFO., MEMORANDUM OF UNDERSTANDING 7 (2011), http://www.copyrightinformation.org/wp-content/uploads/2013/02/Memorandum-of-Understanding.pdf.

256. *Id.* at 8.

257. *Id.* at 8, 11.

258. *See* Metro-Goldwyn-Mayer Studios, Inc., v. Grokster, Ltd., 545 U.S. 913, 936–37 (2005) ("We adopt it here, holding that one 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.").

259. *E.g.*, Bryan J. Vogel, *The Maker Community and IP: Lessons From the Digital Millennium Copyright Act*, INSIDE3DP (Nov. 17, 2014, 12:06 PM), http://www.inside3dp.com/maker-community-ip-lessons-digital-millenium-copyright-act/ ("HBO sent a takedown notice to a site offering to sell a 3D-printed, smartphone charging dock shaped like the Iron Throne from HBO's 'Game of Thrones' TV series . . . .").

losing their safe harbor protection and being held liable themselves.[260]

Although Digital Rights Management (DRM) systems have been used in the past in an attempt to protect copyrighted works, they have all been quickly defeated.[261] What *has* been somewhat effective (and requires no additional regulations) is "fingerprinting," which refers to technology that automatically searches the Internet for infringing copies of those works, and sends DMCA takedown notices and/or settlement agreements.[262] There likely will soon be similar technologies for searching for 3D models that infringe copyrights. While this may seem incredibly difficult, researchers are already developing 3D facial recognition systems.[263]

2. Patents

Under U.S. law, there are two main types of patents: utility patents and design patents.[264] Both may apply to 3D printing. Utility patents cover inventions that are a "new and useful process, machine, manufacture, or composition of matter."[265] For example, many of the processes used in 3D printing are patented.[266] Design patents cover "any new, original and ornamental design for an article of

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260. *See id.*; *see also Digital Millennium Copyright Act supra*, note 251 (describing DMCA takedown notices).

261. *See, e.g.*, Robert Levine, *Unlocking the iPod*, FORTUNE (Oct. 23, 2006, 2:54 PM), http://archive.fortune.com/magazines/fortune/fortune_archive/2006/10/30/8391726/index.htm; Roettgers, *supra* note 172 (listing "the most glorious DRM failures").

262. *See Technology: Our Service & How it Works*, RIGHTSCORP, http://www.rightscorp.com/solution/technology (last visited Jan. 26, 2016); *cf.* YouTube Help, *How Content ID Works*, YOUTUBE, https://support.google.com/youtube/answer/2797370 (explaining YouTube copyright procedures).

263. ANIMETRICS, http://animetrics.com/ (last visited Feb. 13, 2016) (offering ForensicaGPS, a 3D facial recognition software for law enforcement).

264. *Types of Patents*, U.S. PAT. & TRADEMARK OFF. (Oct. 3, 2013), http://www.uspto.gov/web/offices/ac/ido/oeip/taf/patdesc.htm.

265. 35 U.S.C. § 101 (2012).

266. *See* DOMENICO IPPOLITO ET AL., 3D PRINTING AND UTILITY PATENTS 2–3 (2014), http://www.slwip.com/documents/2014-09-093DPrintingandUtilityPatents.pdf (presenting a chart that lists the "Patent Counts for 3D Printing Companies").

manufacture."[267] For example, one of the most famous design patents is for the Statue of Liberty.[268]

3D objects can probably be protected by *both* copyright and design patents, but because one needs to file an application to obtain a patent, design patent infringement is not very common.[269] On the other hand, if the U.S. Patent and Trademark Office required all new design patent applications to include a 3D model file, those files would make an excellent database that printing services could use to verify that submitted jobs are not infringing any existing design patents. This would be very similar to the Content ID system used by YouTube to deal with infringing videos.[270]

3. Trademarks

As stated above, trademarks are meant to prevent sellers from confusing customers and require that the trademark be registered with the U.S. Patent and Trademark Office.[271] Trademarks can be names, phrases, words, symbols, designs, and even sounds and colors.[272] Trademarks can be placed on the product itself, but they are also used on packaging and in advertisements.[273] The fashion industry has been dealing with fake purses, shoes, and clothing for years, and the counterfeiters are always getting better.[274] But just as anti-counterfeiting laws have done little to stop counterfeiting,[275]

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267. 35 U.S.C. § 171 (2012) ("Patents for designs").

268. Dennis Crouch, *Patenting the Statue of Liberty*, PATENTLY-O (Oct. 20, 2008), http://patentlyo.com/patent/2008/10/patenting-the-s.html.

269. *See* MPEP 1512-74 to 76 (9th ed. Rev. 7, Oct. 2015) (explaining the "Design Patent/Copyright Overlap").

270. *See* YouTube Help, *supra* note 262.

271. See *supra* notes 234–235 for background on trademarks.

272. U.S. PAT. & TRADEMARK OFF., PROTECTING YOUR TRADEMARK: ENHANCING YOUR RIGHTS THROUGH FEDERAL REGISTRATION 2 (2015); *see, e.g.*, Qualitex Co. v. Jacobson Prods. Co., Inc., 514 U.S. 159, 159 (1995) (discussing trademarks as applied to color); *Trademark "Sound Mark" Examples,* U.S. PAT. & TRADEMARK OFF., http://www.uspto.gov/trademark/soundmarks/trademark-sound-mark-examples (last modified Aug. 30, 2012, 10:57 AM).

273. *See* Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763 (1992) (discussing the concept of "trade dress").

274. *See generally* Elizabeth Holmes, *The Finer Art of Faking It*, WALL STREET J. (June 30, 2011), http://www.wsj.com/articles/SB10001424052702304791204576401534146929212 (illustrating the counterfeit fashion industry).

275. *See, e.g.*, Miriam Bitton, *Rethinking the Anti-Counterfeiting Trade Agreement's Criminal Copyright Enforcement Measures*, 102 J. CRIM. L. &

new laws aimed specifically at 3D manufacturing are not likely to have much effect on trademark infringement. Manufacturers of 3D-printed objects may likely be more successful at distinguishing their products from counterfeits by using distinctive packaging rather than attempt to bring trademark infringement suits.

IV. CONCLUSION

3D printing presents enormous opportunities while also raising thorny economic, social, and even some ethical issues. This reality will, no doubt, lead to some calls for preemptive, precautionary solutions to those perceived problems.

However, it is highly unlikely that regulators will seek an outright ban on 3D printers because it is a general purpose technology that has many other socially-beneficial uses. The FDA and ATF lack jurisdiction to regulate in such a sweeping fashion. And even if an agency possessed such authority, 3D printing technology is already too diffuse, growing too rapidly, and being utilized for so many alternative uses that the public is not likely to support such a ban.

It is equally unlikely that these agencies will seek to regulate the inputs used by 3D printers—namely plastics and glue—which are widely available. And any efforts aimed at regulation of 3D blueprints (e.g. the underlying design schematics used by 3D printers) would almost certainly violate the First Amendment of the U.S. Constitution. It would also be extraordinarily difficult to suppress such blueprints because they are freely available across the Internet.

Another possibility would be for the government to try to ban the sale of specific 3D printing applications such as unapproved prosthetics and firearms. But enterprising minds would likely start using alternative payment methods (e.g. Bitcoin)[276] to conduct their deals. Regulation of sales would be further complicated by the fact that so much 3D-printed activity is currently non-commercial and open-source in character.

CRIMINOLOGY 67, 67 (2012) (arguing the Anti-Counterfeiting Trade Agreement "mimics the U.S. approach" and thus is "flawed in light of the U.S. experience to date with criminal enforcement of copyright law").

276. BITCOIN, https://bitcoin.org/en/ (last visited Feb. 13, 2016) ("Bitcoin uses peer-to-peer technology to operate with no central authority or banks; managing transactions and the issuing of bitcoins is carried out collectively by the network.").

We believe the difficulty in regulating 3D printing is not a bug, but a feature.[277] There are compelling reasons to keep the public policy default position for 3D printing as permissionless innovation. The best public policy approach toward 3D printing is one rooted in patience and regulatory humility.[278] While 3D printing could create some new and unique policy challenges, regulation should not be premised on hypothetical worst-case outcomes.

Instead, policymakers should be patient and see how society responds to these challenges, how social norms evolve, and how alternative resolution techniques—legal or otherwise—develop to address problems that arise. Permissionless innovation should remain the policy default for 3D printing.

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277. Michael Weinberg, *3D Printing: Lack of Permissions is a Feature, Not a Bug*, PUBLIC KNOWLEDGE (Apr. 6, 2011), https://www.publicknowledge.org/news-blog/blogs/3d-printing-lack-permissions-feature-not-bug.

278. Maureen K. Ohlhausen, Comm'r, Fed. Trade Comm'n,, Remarks before the U.S. Chamber of Commerce: The Internet of Things and The FTC: Does Innovation Require Intervention? 3–4 (Oct. 18, 2013), https://www.ftc.gov/sites/default/files/documents/public_statements/internet-things-ftc-does-innovation-require-intervention/131018chamber.pdf (stressing how it is "vital that government officials, like myself, approach new technologies with a dose of regulatory humility, by working hard to educate ourselves and others about the innovation, understand its effects on consumers and the marketplace, identify benefits and likely harms, and, if harms do arise, consider whether existing laws and regulations are sufficient to address them, before assuming that new rules are required").