READY, PRINT, FIRE! REGULATING THE 3D-PRINTING REVOLUTION

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INTRODUCTION

On May 3, 2013, the first completely plastic 3D-printed gun was fired.[1] It was printed with a melted polymer material on an $8,000 printer.[2] The gun fired one shot and then exploded into shards.[3] Less than three weeks later another individual using a cheaper, stronger polymer and a printer that was a quarter of the cost, printed a different plastic gun.[4] This gun fired nine consecutive rounds.[5] In March of 2015, Mr. Joseph DeSimone gave a TED Talk entitled *What if 3D Printing was 100x Faster?*[6]. During the 15-minute talk he printed a complex, golf ball-sized object that consisted of "concentric geodesic structures[7] with linkages between each structure."[8] The object is impossible to manufacture using traditional manufacturing methods, including molding and milling.[9] Where a typical 3D printer would have taken three hours or more to print the object, Mr. DeSimone demonstrated that newer 3D printing technology could print the object in less than seven minutes.[10] These just a few examples that demonstrate how quickly 3D-printing technology is advancing.

Today a 3D printer costs less than $500 and can print nearly any object modeled with three-dimensional modeling software.[11] The widespread availability of 3D printers combined with the ability to print objects subject

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[1] Gerald Walther, *Printing Insecurity? The Security Implications of 3D-Printing of Weapons*, 21 SCI. AND ENGINEERING ETHICS 1435, 1435 (2015).

[2] 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/#12e43340511e.

[3] *Id.*

[4] Andy Greenberg, *$25 Gun Created with Cheap 3D Printer Fires Nine Shots*, FORBES (May 20, 2013, 11:51 AM), http://www.forbes.com/sites/andygreenberg/2013/05/20/25-gun-created-with-cheap-3d-printer-fires-nine-shots-video/#6cf5736d457e.

[5] *Id.*

[6] Joseph DeSimone: *What if 3D Printing Was 100x Faster?*, TED.COM (Mar. 2015), https://www.ted.com/talks/joe_desimone_what_if_3d_printing_was_25x_faster?language=en.

[7] *See, e.g.*, U.S. Patent No. 4,796,394 A (filed Nov. 13, 1987). Geometrically, this can be conceptualized by imagining how one might approximate a sphere using a set of line segments.

[8] DeSimone, *supra* note 6.

[9] *Id.*

[10] DeSimone, *supra* note 6.

[11] *See* Bulent Yusuf, *20 Best 3D Printers Under $500 / $1000*, ALL3DP (updated November 2, 2016), https://all3dp.com/best-cheap-budget-3d-printer-affordable-under-1000-budget/.

to legal restrictions, for example guns and drugs, demanded the attention of governments around the world,[12] and some have already taken action. In 2015, New South Whales, Australia enacted a bill that made it a crime to possess "digital blueprints for the manufacture of firearms on 3D-printers."[13] Additionally, in 2013 Philadelphia became the first U.S. city to enact an ordinance prohibiting the 3D printing of firearms or firearm parts by anyone not licensed by the Attorney General to manufacture firearms under 18 U.S.C. § 923(a).[14] Although these actions appear to be primarily concerned with the unregistered manufacture of firearms, 3D printing presents other significant issues that governments should consider. These include dangers associated with the 3D printing of weapons other than firearms[15] and its implication to commercial air travel, the health risks associated with the ability to 3D print food[16] and drugs,[17] and the industrial safety and health hazards that may arise with 3D printing's enablement of home-based manufacturing, which some claim is the basis of the next industrial revolution.[18] Though some lawmakers took steps to address one of the many issues that 3D printing presents, the revolutionary nature of the technology suggests a broader question: what approach, if any, *should* be taken to manage the broader set of risks associated with 3D printing?

To address this question, this Article argues that governments ought to proactively consider preemptive legislative or regulatory actions regarding 3D printing. The primary considerations should be to ensure that as 3D printing technology evolves, existing laws are not circumvented; that the technology does not put the health and safety of the public at risk; and that it does not sacrifice national security. This is not to suggest a knee-jerk reaction to uncertain or imaginary dangers, but rather an approach that permits lawmakers to react meaningfully and efficiently to real dangers as

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[12] *See* Bridget B. Millsaps, *New South Wales, Australia: Parliament Passes Law Banning Possession of 3D Files for Guns*, 3DPRINT.COM (Nov. 20, 2015), https://3dprint.com/106940/australia-ban-3d-files-guns/.

[13] Firearms and Weapons Prohibition Legislation Amendment Bill 2015 (NSW) sch 1 item 7 (Austl.).

[14] PHILA., PA., CODE §§ 10-2000 to -2003 (2016) (effective Dec. 4, 2013); *see also* Gilman Louie, *I 3D-Printed an AR-15 Assault Rifle – And it Shoots Great,* BUS. INSIDER (Dec. 4, 2013, 9:58 AM), http://www.businessinsider.com/i-3d-printed-an-ar-15-assault-rifle--and-it-shoots-great-2013-12 (discussing the Philadelphia law in light of the ability to print components of a semi-automatic rifle).

[15] *See* Michael A. Parker, *Designer Creates Incredible 3D Printed Crossbow*, 3DPRINT.COM (Mar. 8, 2016), https://3dprint.com/122934/3d-printed-crossbow/; *See also* Mary-Ann Russon, *3D Printed Plastic Knives Can Bypass Courtroom Security Detectors, Dutch Students Discover*, INT'L BUS. TIMES (Apr. 29, 2015, 3:37 PM BST), http://www.ibtimes.co.uk/3d-printed-plastic-knives-can-bypass-courtroom-security-detectors-dutch-students-discover-1498936.

[16] Jasper L. Tran, *3D-Printed Food*, 17 MINN. J.L. SCI. & TECH. 855, 861-64 (2016).

[17] Lee Cronin, *Print Your Own Medicine*, TED.COM (June 2012), https://www.ted.com/talks/lee_cronin_print_your_own_medicine?language=en.

[18] Elizabeth J. Kennedy & Andrea Giampetro-Meyer, *Gearing Up for the Next Industrial Revolution: 3D Printing, Home-Based Factories, and Modes of Social Control*, 46 LOY. U. CHI. L.J. 955, 955 (2014-2015).

they manifest themselves, while not impeding innovation in 3D printing and supporting technologies.

To accomplish this objective this Article looks at the concepts of "permissionless innovation" and the "precautionary principle."[19] These concepts represent opposing ends of the regulatory spectrum; the former promoting a "wait-and-see" approach while the latter promotes a preemptive or preventative approach to government regulation.[20] After defining these terms the Article will describe the characteristics of technologies that lend themselves either to permissionless innovation or to the precautionary principle. It will provide a few specific areas where policies of each type have been employed, and why it may or may not have been appropriate. The Article then describes 3D printing and its characteristics in order to explain why it would be irresponsible for governments not to take some preemptive steps regarding 3D printing. These steps should be designed to manage the significant health, safety, and national security risks that 3D printing presents, while promoting innovation that enhances and improves our standard of living and the general economic welfare. In this sense, the article responds in opposition to Messrs. Adam Thierer's and Adam Marcus' position in their 2016 article *Guns, Limbs, and Toys: What Future for 3D Printing?*,[21] in which they argue that permissionless innovation should be the default position for 3D printing technology.[22]

I. BACKGROUND

A. PERMISSIONLESS INNOVATION

In his revised and expanded 2016 book, *Permissionless Innovation: The Continuing Case for Comprehensive Technological Freedom*, Mr. Therier defines permissionless innovation as "refer[ring] to the notion that experimentation with new technologies and business models should generally be permitted by default."[23] The crux of the argument is that lawmakers should "permit" uninhibited experimentation and risk-taking with new technologies until and unless there is a compelling reason to do otherwise.[24] That is, only upon the occurrence of a real harm or problem, or the demonstration that serious harm will come to society as a result of

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[19] Adam Thierer, PERMISSIONLESS INNOVATION: THE CONTINUING CASE FOR COMPREHENSIVE TECHNOLOGICAL FREEDOM, 8-10, 26-29 (2016).
[20] *See* Adam Thierer, *Who Really Believes in "Permissionless Innovation"?*, TECHLIBERATION.COM (Mar. 4. 2013), https://techliberation.com/2013/03/04/who-really-believes-in-permissionless-innovation/ (explaining "The Risk Response Continuum" and its applicability to technological risk).
[21] Adam Thierer & Adam Marcus, *Guns, Limbs, and Toys: What Future for 3D Printing?*, 17 MINN. J.L. SCI. & TECH. 805, 805 (2016).
[22] *Id.* at 806.
[23] Thierer, *supra* note 19, at 1.
[24] *Id.* at 128-29.

unchecked innovation, should lawmakers act.[25] The primary rationale for the position is rooted in economics.[26] Defaulting to permissionless innovation, the argument goes, "helps advance long-term economic growth."[27]

Perhaps the most compelling example of the extraordinary difference that permissionless innovation made, relates to its impact on Internet-based technologies. Mr. Therier cited the Telecommunications Act of 1996[28] as a key enabler of permissionless innovation that in turn resulted in the explosive growth of Internet capabilities.[29] In particular, § 230 of the Act protected actions taken by Internet service providers to block or screen offensive material and eliminated liability for those actions.[30] It also eliminated liability associated with enabling other content providers to similarly block or screen offensive material.[31] More importantly, the Act shielded Internet service providers from being treated as the publisher or speaker of content provided by another content provider.[32] Section 230 also eliminated liability pursuant to any state law inconsistent with it.[33] This "immunization" from liability for content traveling on service-provider networks was intended to allow the facilitation of free speech via the Internet and the development of beneficial interactive computer services ("ICSs").[34] Along with "The Framework for Global Electronic Commerce" released by the Clinton administration, § 230 formed the basis for the Internet's explosive growth because it precluded precautionary governmental regulations.[35] Rather, it promoted private-sector self-regulation.[36] For example, it encouraged ICS providers to police defamatory or illegal content through self-regulation by providing immunity where they acted as a "Good Samaritan" in blocking that content.[37] Personal data protection or privacy, is another important area where ICS providers self-regulate.[38]

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[25] Thierer, *supra* note 20.
[26] Thierer, *supra* note 19, at 7-8.
[27] *Id.* at 10.
[28] 47 U.S.C. § 230 (1996).
[29] Thierer, *supra* note 19, at 14.
[30] 47 U.S.C. § 230.
[31] *Id.*
[32] *Id.*
[33] *Id.* § 230(d)(3).
[34] *Id.* § 230(a)(3), (5).
[35] Thierer, *supra* note 19, at 15.
[36] 47 U.S.C. § 230(c); *see also id.*
[37] 47 U.S.C. § 230(c); *see also* Andrew M. Sevanian, *Section 230 of the Communications Decency Act: A "Good Samaritan" Law Without the Requirement of Acting as a "Good Samaritan,"* 21 UCLA ENT. L. REV. 121, 121 (2014) (outlining a circuit court split in the application of § 230 immunity to ICSs'). Facebook's removal and reinstatement of the "Napalm Girl" photo of a naked 9-year-old girl fleeing a 1972 napalm attack in Vietnam is a recent example of this type of self-regulation in action. *See The Story Behind the 'Napalm Girl' Photo Censored by Facebook*, TIME.COM: LIGHTBOX (Sept. 9, 2016, 2:25 PM), http://time.com/4485344/napalm-girl-war-photo-facebook/.
[38] *See, e.g.*, *The Need for Privacy Protections: Is Industry Self-Regulation Adequate?: Hearing Before the S. Comm. on Commerce, Science, and Transportation*, 112th Cong. 1 (2012) (Statement of Sen. Amy Klobuchar).

There is no question that the permissionless innovation approach resulted in profound beneficial changes to the general economic welfare.[39] The question is, does the fact that permissionless innovation worked well for the Internet, make it an appropriate default position for other technologies? In his book, Mr. Therier asserts that permissionless innovation should be the default for Big Data, Internet of Things, Private Drones, Wearable Technologies, Immersive Technologies, Smart Cars, the Sharing Economy, and 3D Printing.[40] With the exception of private drones, smart cars, and 3D printing, all of these are primarily information collection or information sharing technologies. "Big Data" refers to the collection and analysis of large amounts of shared data to detect patterns applicable to some purpose.[41] "Internet of Things" refers to a vast collection of sensors that collect data on physical phenomena and share that data on the Internet other processes use.[42] For example, an application of the "Internet of Things" concept is a collection of thermometers that measure and share historical temperature data that is then used by a "smart" thermostat to adjust the heating or cooling of a building. "Wearable Technology" is a particular category of sensors that are worn and collect data on the wearer's physical activities and conditions.[43] "Immersive Technologies" are interactive information-based simulations that make digital information seem real.[44] Finally, the "Sharing Economy" is information sharing via the Internet about un- or under-utilized resources (e.g., cars, apartments, or houses).[45] Drones and smart cars also use information collection to accomplish their tasks, however, unlike the other technologies described above, they can, and do, have significant physical real-world, and potentially disastrous, effects.[46] It is not surprising that lawmakers have sought to take action related to these two technologies. Legislation, for instance, has been introduced to address concerns smart car remote hacking,[47] and Congress ordered the FAA to "come up with a plan to integrate drones into domestic airspace" because of safety issues related to the sharing of that airspace with commercial airplanes.[48] It would seem that

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[39] *See* Thierer, *supra* note 19, at 14.
[40] *Id.* at 11-12, 18-19, 60-61, 72-73, 78-79, 98-99, 103-04, 118-19.
[41] Jonathan Shaw, *Why "Big Data" is a Big Deal*, HARV. MAG. (Mar.-Apr. 2014), http://harvardmagazine.com/2014/03/why-big-data-is-a-big-deal.
[42] Daniel Burrus, *The Internet of Things Is Far Bigger than Anyone Realizes*, WIRED (Nov. 2014), https://www.wired.com/insights/2014/11/the-internet-of-things-bigger/.
[43] Thierer, *supra* note 19, at 72.
[44] Zaid Mahomedy, *What is Immersive Technology?*, IMMERSIVE AUTHORITY (Aug. 23, 2015), http://www.immersiveauthority.com/explain-immersive-technology/.
[45] *The Rise of the Sharing Economy; Peer-to-peer Rental*, THE ECONOMIST (Mar. 9, 2013), http://www.economist.com/news/leaders/21573104-internet-everything-hire-rise-sharing-economy.
[46] Conner Forrest, *12 Drone Disasters that Show Why the FAA Hates Drones*, TECHREPUBLIC. (Mar. 20, 2015), http://www.techrepublic.com/article/12-drone-disasters-that-show-why-the-faa-hates-drones.
[47] Thierer, *supra* note 19, at 98.
[48] *Id.* at 60 (citing Keith Laing, *Feds Miss Deadline to Legalize Drones*, THEHILL: POLICY (Oct. 1, 2015, 1:43 PM), http://thehill.com/policy/transportation/255638-feds-miss-deadline-to-legalize-drones).

where physical safety resulting from the real-world effects of a technology is a concern, lawmakers feel compelled to respond to its potential dangers. Like smart cars and drones, 3D printing breaches, are referred to here as the digital-physical divide. The digital-physical divide is the area that distinguishes between the purely digital information space and the physical world. Three-dimensional printing breaches divide in a way that can cause physical harm like smart cars and private drones. For this reason it is argued here that 3D printing is not a reasonable candidate for lawmakers to apply permissionless innovation, but rather some degree of a precautionary approach.

B. Precautionary Approach

There are two primary versions of what is commonly referred to as the precautionary approach.[49] One is rooted in "strong" precautionary principles and the other in "weak" precautionary principles.[50] Both types pivot on uncertainty.[51] A strong precautionary approach requires regulation as a "default response" when risks are known to exist but their nature is unknown or uncertain.[52] Whereas typically the burden is on the government to specify unacceptable risks before regulating, a strong precautionary approach instead places a burden on the innovator to prove that although its innovation *could* create a serious threat to human health, the environment, safety, or national security, that it will not.[53] Professor Noah M. Sachs, in his article entitled "*Rescuing the Strong Precautionary Principle from its Critics*" explained why a strong precautionary principle is sometimes an appropriate risk management approach that incentivizes the internalization of risks inherent in potentially dangerous products seeking access to markets.[54] In particular, he argues that when an activity involves "pervasive uncertainty about the harm that might result." application of the strong precautionary principle is appropriate.[55] A strong precautionary approach would require an innovator to prove that the associated risks are acceptable, for example, requiring a chemical manufacturer to demonstrate to a regulatory agency that a chemical can be safely used before it is made available to the public.[56] Professor Sachs points to the Food and Drug Administration's ("FDA") process for reviewing new drugs as an example of the strong precautionary principle at work.[57] The FDA's process requires a drug company to demonstrate that a drug meets certain criteria related to

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[49] Noah M. Sachs, *Rescuing the Strong Precautionary Principle from its Critics*, 2011 U. Ill. L. Rev. 1285, 1295 (2011).
[50] *Id.* at 1292-99.
[51] *Id.* at 1291-92.
[52] *Id.* at 1295.
[53] *Id.* at 1288.
[54] *Id.* at 1287.
[55] *Id.* at 1291.
[56] *Id.* at 1292.
[57] *Id.* at 1290.

its risks, side effects, and efficacy before it can be sold.[58] In essence, a drug company must request and receive permission from the FDA before it can sell a new drug to the public.

Although Professor Sachs argues that the FDA's process has not prevented the U.S. from "developing the most innovative and profitable pharmaceutical industry in the world,"[59] it is the permission-requesting nature of the strong precautionary approach that permissionless innovation rails against.[60] This is because when applied to technology generally, a strong precautionary approach (1) requires that innovators prove the non-existence of risks based on imaginary worst-case scenarios before a product can be made available to the public, and (2) results in regulatory overreach that impedes free experimentation and innovation, which negatively impacts human standards of living and the general economic welfare.[61]

A weak precautionary approach permits regulation when facing scientific uncertainty, which provides more flexibility to lawmakers.[62] In other words, it is "concerned with the timing of governmental decision making" and enables lawmakers to apply precautionary regulations only when serious risks arise or when it is unclear that the risks are sufficiently mitigated.[63] Professor Sachs identifies the Clean Air Act and the Resource Conservation Act as examples where a weak precautionary principle is at work because they provide flexibility to regulators to act when harm is detected.[64] In the areas of commercial chemicals (including drugs), clean air, and resource conservation, there are potential real-world harms or risks to individuals or large numbers of people that seem appropriate to be monitored and managed more actively than the permissionless innovation approach would permit.

This Article argues that 3D printing is less akin to a digital or information technology that can safely be left to freewheeling innovation, but rather, is a technology with inherent risks that could cause real-world harm. To better understand why a weak precautionary approach is more appropriate in the 3D printing context an overview of the technology is helpful.

C. WHAT IS 3D PRINTING?

Three-dimensional printing is often referred to as "additive" manufacturing.[65] Additive manufacturing involves the creation of an object

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[58] *Id.* at 1308.
[59] *Id.*
[60] Thierer, *supra* note 19, at 28.
[61] *Id.*
[62] Sachs, *supra* note 49, at 1295.
[63] *Id.*
[64] *Id.*
[65] Stephanie Crawford, *How 3-D Printing Works*, HOWSTUFFWORKS.COM (Mar. 1, 2011), http://computer.howstuffworks.com/3-d-printing.htm.

layer by layer.[66] It is comparable to a paper printer, but instead of printing a single layer of ink, the 3D printer prints numerous consecutive layers of liquefied or powdered plastics, metals, or other chemicals one on top of the other.[67] As the liquefied or powdered materials cool, they bind and harden, allowing the printing of additional layers, resulting in a three-dimensional object.[68]

The primary benefit of additive manufacturing is that it allows for the manufacturing of objects that are impossible to achieve with traditional manufacturing processes.[69] A simple example is the manufacturing of a hollow sphere.[70] The creation of a hollow sphere on its own is impossible to achieve with traditional methods, absent some type of breach of the outer wall.[71] A hollow sphere is typically manufactured by molding two hemispheres together, which results in a seam between the two halves.[72] In contrast, additive manufacturing methods enable a seamless spherical exterior wall with no breach or seam.[73] Thus, additive manufacturing enables mass production of objects previously impossible to achieve.[74]

A 3D printer requires a blueprint to print an object.[75] Blueprints most commonly take the form of .stl[76] or .amf[77] files, which are generated from computer-aided design ("CAD") programs.[78] CAD software, such as AutoCad,[79] allows users to model in three dimensions and is ubiquitous in

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66 *Id.*
67 *Id.*
68 Parham Azimi, et al., *Emissions of Ultrafine Particles and Volatile Organic Compounds from Commercially Available Desktop Three-Dimensional Printers with Multiple Filaments*, 50 ENVTL. SCI. & TECH. 1260, 1260 (2016).
69 DeSimone, *supra* note 6.
70 *See* Eleanor Hutterer, *Explosiv3Design*, 1663, Mar. 2016 at 2.
71 *Id.*
72 *Id.*
73 *Id.*
74 DeSimone, *supra* note 6.
75 *See* Anna M. Luczkow, *Haute Off the Press: Refashioning Copyright Law to Protect American Fashion Designs from the Economic Threat of 3D Printing*, 100 MINN. L. REV. 1131, 1145 (2015-2016).
76 A .stl (stereolithography) file is one that complies with the standard tessellation language which allows for the description of the layout of three-dimensional objects. *See* *.STL File Format In 3D Printing: Explained in Simple Terms*, ALL3DP.COM (Apr. 21, 2016), https://all3dp.com/what-is-stl-file-format-extension-3d-printing/.
77 A .amf file follows the additive manufacturing file format. Although similar to a .stl file it enables richer object detail, and addresses several shortcomings of the .stl format such as being able to more easily define surface area and internal object structures which are very difficult to accomplish with the .stl format. *See* Hod Lipson, *Additive Manufacturing File Format (AMF) Allows for Volumetric Specifications*, ENGINEERING.COM (Aug. 14, 2012), http://www.engineering.com/3DPrinting/3DPrintingArticles/ArticleID/4703/Additive-Manufacturing-File-Format-AMF-Allows-for-Volumetric-Specifications.aspx.
78 Crawford, *supra* note 65; Kyle Dolinsky, *CAD's Cradle: Untangling Copyrightability, Derivative Works, and Fair Use in 3D Printing*, 71 WASH. & LEE L. REV. 591, 600 (2014).
79 *Autocad Overview*, AUTODESK, http://www.autodesk.com/products/autocad/overview (last visited Jan. 6, 2017).

nearly every industry that designs and creates tangible products.[80] There are also numerous, free CAD software programs that can be used to create 3D-object blueprints; perhaps most familiar is Google's SketchUp.[81] As a result, there are hundreds of thousands of objects already available to be 3D printed.[82] For example, Thingiverse, "a design community for discovering, making, and sharing 3D printable things," boasts over 630,000 3D models available for download and print.[83] The only limitation to the size of an object is the size of the available printer.[84] Online businesses such as Royal Philips Electronics allow users to make, buy, and sell custom-designed products, while other industries use 3D printers to print objects as large as aircraft wings and walls of buildings.[85]

The 3D-printing technology is advancing at a staggering pace, driven both by users of the technology and its creators.[86] Notably, the versatility of printing materials continues to expand beyond the various polymer plastics and metals.[87] Today they also include bio-matter and chemicals.[88] Doctors printed a variety of body parts including kidneys and polymer bones with 3D-printers.[89] To accomplish this, 3D printers are modified to print using biomaterials. The printer then prints three-dimensional structures based on blueprints modeling human organs or bones.[90] These bio-matter structures are later infused with living cells that grow across them to create medically viable tissues, organs, and bones.[91]

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[80] Katie Nielsen, *CAD Software: The Many Uses for Computer-Aided Design*, TOPTENREVIEWS.COM (July 5, 2011), http://www.toptenreviews.com/software/articles/cad-software-the-many-uses-for-computer-aided-design/.

[81] James Coppinger, *Five Top Free CAD Packages*, ABOUT.COM (Sept. 30, 2016), http://cad.about.com/od/Personal_CAD/tp/Five-Top-Free-Cad-Packages.htm.

[82] *MakerBot Thingiverse*, THINGIVERSE, http://www.thingiverse.com/about/ (last visited Jan. 8, 2017).

[83] *Id.*

[84] *See* Peter Jensen-Haxel, *3D Printers, Obsolete Firearm Supply Controls, and the Right to Build Self-Defense Weapons Under Heller*, 42 GOLDEN GATE U. L. REV. 447, 454 (2011-2012) (describing the correlation in printer size and what parts it can create).

[85] *Id.* at 453

[86] *Id.* at 454

[87] *Id.* at 451; (detailing all the fields where 3D printers have been adopted); *see also* Nancy S. Giges, *Top 10 Materials for 3D Printing*, ASME.ORG (Aug. 2014), https://www.asme.org/engineering-topics/articles/manufacturing-processing/top-10-materials-3d-printing (describing several materials "beyond common and improved plastics" used in 3D printing); *The Highest Quality 3D Printing Materials in the Industry*, SHAPEWAYS, http://www.shapeways.com/materials (last visited Jan. 8, 2017).

[88] *See* Heidi Ledford, *The Printed Organs Coming to a Body Near You*, NATURE NEWS (Apr. 15, 2015), http://www.nature.com/news/the-printed-organs-coming-to-a-body-near-you-1.17320;; *see also* Cronin, *supra* note 17.

[89] Ledford, *supra* note 88, at 13.

[90] *Id.*

[91] Anthony Atala, *Printing a Human Kidney*, TED.COM (Mar. 2011), https://www.ted.com/talks/anthony_atala_printing_a_human_kidney?language=en#t-995179.

Chemists printed pharmaceuticals with "chemical inks,"[92] and NASA experimented with 3D-printed food in support of long-term space travel by loading printers with powdered "'building blocks' of food."[93] Additionally, the printers themselves are getting cheaper, faster, and smaller.[94] Indiegogo, for example, crowd-sourced a project and developed a portable 3D printer that fits into a small carry-on bag.[95]

Lawmakers should consider the possible dangers presented by advancements in 3D-printing. The next section discusses a few of these concerns and the danger that they present in support of the thesis that, "permissionless," innovation is inappropriate in the 3D-printing context. The section following gives a set of recommendations that adopt a weak precautionary approach to preemptive regulation.

II. CONCERNS OF 3D PRINTING

A. PRINTED WEAPONS

As discussed above, the printing of weapons, particularly firearms, demanded the attention of lawmakers.[96] Unlike in other countries, the U.S. has no prohibitions on building your own handgun.[97] Although federal law requires that a 3D-printed gun is detectible by a walk-through metal detector,[98] state law governs gun registration, and only a few states require it.[99] There is, however, significant concern in the U.S. about the proliferation

[92] Dominic Basulto, *Why it Matters that the FDA Just Approved the First 3D-printed Drug*, WASH. POST, Aug. 11, 2015, https://www.washingtonpost.com/news/innovations/wp/2015/08/11/why-it-matters-that-the-fda-just-approved-the-first-3d-printed-drug/; *see also* Cronin, *supra* note 17, at 3.

[93] Aaron Souppouris, *NASA Is Funding a 3D Food Printer, and It'll Start with Pizza*, THE VERGE (May 21, 2013 7:24 AM), http://www.theverge.com/2013/5/21/4350948/nasa-funding-3d-food-printer-pizza.

[94] Thierer, *supra* note 21, at 808 (citing 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/#65419efd1dc6).

[95] *Freaks3d: the World's First Portable 3d Printer*, INDIEGOGO, https://www.indiegogo.com/projects/freaks3d-the-world-s-first-portable-3d-printer#/ (last visited Jan. 8, 2017) (showing the description of the crowdsource request for the printer) [hereinafter *Freaks3d*].

[96] *See* Millsaps, *supra* note 12, at 2.

[97] Jensen-Haxel, *supra* note 84, at 459.

[98] 18 U.S.C. § 922 (2015) ("It shall be unlawful for any person to manufacture…any firearm that...is not detectable as the Security Exemplar, by walk-through metal detectors calibrated and operated to detect the Security Exemplar").

[99] *See generally Registration of Firearms*, LAW CENTER TO PREVENT GUN VIOLENCE, http://smartgunlaws.org/gun-laws/policy-areas/gun-owner-responsibilities/registration-of-firearms/ (last visited Jan. 8, 2017) [hereinafter *Registration of Firearms*]. In July of 2016 California passed Assembly Bill No. 857, which, effective July 1, 2018, requires that any manufactured firearm not bearing a unique serial number receive one from the California Department of Justice within 10 days of manufacture. Assemb. B. 857, 2015-2016 Reg. Sess. (Ca. 2016).

of military style semi- or fully-automatic firearms.[100] In fact, when the maker of the first 3D-printed handgun made the blueprints available online, the State Department asked the organization to take the files down and argued this violated the Export Control Act.[101] Nevertheless, users downloaded the files more than 100,000 times worldwide and remain attainable on the Internet today.[102] Nor did this isolated act by the State Department slow the progress of those intent on pushing the envelope of 3D-printable firearms; blueprints for machine guns are on the way if not already available.[103]

While firearms generate concern, 3D Printers produce other deadly weapons, including knives, daggers, and even crossbows.[104] Some of these items passed through metal detectors undetected.[105] Although 3D-printed weapons are not always structurally up to the task of their design, researchers are addressing the issue. At Purdue, researchers created a system that can detect and improve structural weaknesses in 3D-printable models.[106] From the perspective of printable weapons, this should cause concern for lawmakers because where weapons would require traditionally stronger materials, stronger materials might have been required (e.g., steel), manufacturers can use cheaper and lighter materials to print structurally enhanced objects, presumably giving them the characteristics of being made from much stronger materials. Thus, the viability of printed weapons will increase as the technologies supporting 3D printing advance to address their limitations.

Considering these advancements in light of the national security precautions taken to secure air travel since 9/11, the concerns are daunting. Currently, Transportation Security Administration ("TSA") focuses security scans on searching for "any weapon, explosive, or incendiary on or about each individual's person or accessible property."[107] This regulation has enabled

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[100] *See* Walther, *supra* note 1, at 1436 (citing Andy Greenberg, *State Department Demands Takedown of 3D-Printable Gun Files for Possible Export Control Violations*, FORBES (May 9, 2013), http://www.forbes.com/sites/andygreenberg/2013/05/09/state-department-demands-takedown-of-3d-printable-gun-for-possible-export-control-violation/#26021a8c3fb7).

[101] *Id.*

[102] *Id.* (citing Andy Greenberg, *3D-Printed Gun's Blueprints Downloaded 100,000 Times in Two Days (With Some Help from Kim Dotcom)*, FORBES (May 8, 2013), 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/#6ee5abf188c6).

[103] Louie, *supra* note 14; *See* Bridget Butler Millsaps, *Cody Wilson Announces Impending Release of 3D Files for $150 Machine Gun; Some Fear He Is 'Making Things Easier' for Terrorists*, 3DPRINT.COM (Jan 25, 2016), https://3dprint.com/116658/wilson-3d-files-machine-gun/.

[104] Parker, *supra* note 15; Russon, *supra* note 15.

[105] Russon, *supra* note 15.

[106] Ondrej Stava, et al., *Stress Relief: Improving Structural Strength of 3D Printable Objects*, 31 ACM TRANSACTIONS ON GRAPHICS, July 2012, at Article No. 48, http://hpcg.purdue.edu/bbenes/papers/Stava2012sigg.pdf; *see also* Andy Greenberg, *The Bullet that Could Make 3-D Printed Guns Practical Deadly Weapons*, WIRED (Nov. 5, 2014, 6:30 AM), https://www.wired.com/2014/11/atlas-314-3-d-printed-guns-bullets/.

[107] 49 C.F.R. § 1544.201 (2016).

TSA agents to detect attempts to carry 3D-printed weapons, including 3D-printed guns, onto domestic flights.[108] However, the regulation does not preclude an individual from carrying a 3D printer or printing material onto a commercial airplane because neither is a weapon, explosive, or incendiary.[109] Once an individual is beyond a security checkpoint for a domestic flight and admitted to a "sterile area," (i.e., the secure area where airplanes are boarded), TSA does not require any further security checks, including during an interim domestic layover.[110] It is hardly difficult for a committed bad actor to carry on a portable 3D printer and either while waiting to board or over a domestic layover, print weapons to carry onto the onboarding airplane. It is important to note that these weapons need not be guns to be deadly; they could include knives, daggers, crossbows, and even explosives.[111]

Although the printing of weapons is perhaps the most concerning, it is not the only issue lawmakers should be considering when thinking about if and how to regulate the burgeoning 3D printing industry. Scholars and scientists have identified numerous other issues regarding 3D printing that raise legal, ethical, and public health concerns.[112] The following sections discuss a few of these additional challenges.

B. PRINTED FOOD

NASA has already committed funds to research 3D-printed food in the hopes of addressing the needs of astronauts on long-distance space travel.[113] The idea is that a 3D printer would use cartridges containing basic "building blocks" of food (e.g., powdered proteins, sugars, carbohydrates, and oils)[114] to produce foods such as pizza.[115] Although this Star Trek-like idea may seem to be a stretch of the imagination, within a year of NASA's funding, an unaffiliated company created the "Foodini," which produces 3D-printed food ready to cook.[116] The concept is also applicable to more earthly

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108 Julia Zorthian, *Airport Security Finds 3d Printed Gun in Carry-On at Reno Airport*, TIME (Aug. 11, 2016), http://time.com/4448069/tsa-3d-printed-gun-reno/.

109 49 C.F.R. § 1544.201.

110 *See* 49 C.F.R. § 1540.5 (2016) (defining "sterile area" as a portion of the airport allowing passengers access to boarding aircraft); C.F.R § 1544.201 (requiring individual screening for access to a sterile area). (Because enplaning occurs in the same location as deplaning, deplaning occurs in a sterile area).

111 Hutterer, *supra* note 70, at 2, 4.

112 *See e.g.*, Dolinsky, *supra* note 78 (copyright); Kennedy & Giampetro-Meyer, *supra* note 18 (environmental health, labor, safety); Tran, *supra* note 16 (food safety and agriculture).

113 Souppouris, *supra* note 93.

114 Christopher Mims, *The Audacious Plan to End Hunger with 3-D Printed Food*, QUARTZ (May 20, 2013), http://qz.com/86685/the-audacious-plan-to-end-hunger-with-3-d-printed-food/.

115 Souppouris, *supra* note 93.

116 Jacopo Prisco, *'Foodini' Machine Lets You Print Edible Burgers, Pizza, Chocolate*, CNN (Dec. 31, 2014, 1:06 AM), http://www.cnn.com/2014/11/06/tech/innovation/foodini-machine-print-food/.

problems such as food scarcity and malnutrition.[117] At least one scholar, Mr. Jasper L. Tran, in a 2016 article entitled *3D-Printed Food*, has explained a few of the issues related to food safety and labeling that might arise from 3D-printed food, as well as some of the potential legal implications.[118] The nearer-term risks, and those that might be of concern to companies producing printers like the Foodini, are related to food poisoning, contamination, and food allergies.[119] Mr. Tran argues that existing regulations promulgated by the U.S. Department of Agriculture ("USDA") and the FDA likely cover these issues.[120]

The primary policy concerns arise from possible dramatic changes in food production and the short- and long-term impact that these changes could have on humans.[121] Presuming that food production could be simplified to a core set of agricultural products, there is concern about how the human body might react, over the long-term to food that is printed rather than harvested.[122] The concern stems from the same fear that drives opposition to food derived from genetically modified organisms ("GMOs"): is it ultimately safe for consumption?[123] Only after years of debate did the U.S. pass a law requiring foods containing GMOs to be labeled so that consumers can find relevant information on a product's GMO content.[124] Like the uncertainty about the long-term health effects of GMOs, there is significant legal uncertainty about the liability with regards to the long-term health effects of NASA-type food printing.[125] The question for U.S. lawmakers is whether they should take a parallel approach to 3D-printed food as it has with GMOs, by focusing on the product itself rather than the process (i.e., the fact that the product was 3D printed).[126]

Lawmakers should be deliberate in making decisions about whether, how, and when to address these concerns. Although there is no current legislation directly addressing 3D-printed food, the new GMO labeling law may provide some precautionary effect to the 3D-printed-food industry. Since GMO-based foods must be labeled if "building block" food cartridges used in food printing contain GMOs, producers must provide a way for consumers to attain that information.[127] This enables consumers of 3D-printed food to make informed consumption decisions, albeit with some effort.

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[117] Tran, *supra* note 16, at 861-64.
[118] *Id.*
[119] *Id.* at 870.
[120] *Id.*
[121] *Id.* at 869-79.
[122] *Id.* at 874.
[123] *Id.* at 875.
[124] Michal Addady, *President Obama Signed This GMO Labeling Bill*, FORTUNE (July 31, 2016, 4:49 PM), http://fortune.com/2016/07/31/gmo-labeling-bill/.
[125] Tran, *supra* note 16, at 874.
[126] *Restriction on Genetically Modified Organisms: United States*, LIBRARY OF CONGRESS (June 9, 2015), https://www.loc.gov/law/help/restrictions-on-gmos/usa.php.
[127] *See* 7 U.S.C. § 1639(b)(2) (2016).

As 3D-printed food technologies continue to advance, lawmakers should also remain alert to any particular changes taking place in the agricultural sector. Because 3D-printed food can simulate variety from "building blocks" of food, a reduction in the variety of grown food required from the agricultural sector could result.[128] Such a reduction will contribute to an already significant decline in "agrobiodiversity."[129] Further increasing the similarity of diets worldwide creates incentives for farmers to reduce crop diversity and favor high-yield crops, which creates greater risks of food shortages should a crop fail due to an epidemic disease or some other catastrophe.[130] Although high-yield crops can feed more people, they also tend to be lower in nutrient content.[131] The result is that a reduction in the variety of agricultural products driven by 3D food printing may well increase, rather than decrease, worldwide malnutrition.[132]

C. PRINTED DRUGS

The printing of drugs parallels the approach to 3D printing food. In 2012, Professor Lee Cronin, Chair of Chemistry at the University of Glasgow gave a TED talk describing an approach and a vision for the future of pharmaceuticals made possible by 3D printing.[133] Similar to how NASA-type food printing requires food "building block" cartridges, Professor Cronin proposes a universal set of "chemical inks" that would be used to print drugs from a downloadable blueprint of a drug molecule.[134] He also envisions the possibility of being able to print personalized drugs at home and on demand.[135] He and his team proved the feasibility of the idea by developing and printing a drug on a modified, commercially available 3D printer.[136] Pharmaceutical companies have continued to innovate around the idea.[137] Aprecia Pharmaceuticals developed a technology called ZipDose©,

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128 *See* Tran, *supra* note 16, at 862; *see also* B. Thompson, *Community-Centered Food-Based Strategies for Alleviating and Preventing Malnutrition*, in IMPACTS OF AGRICULTURE ON HUMAN HEALTH AND NUTRITION, VOLUME 1, 185, 188 (Ismail Cakmak, Ross M. Welch, eds., 2009).
129 Laura Rojas, *Why Most of Our World's Food Crops Are Becoming Extinct*, THE PLAID ZEBRA (Mar. 25, 2015), http://www.theplaidzebra.com/why-most-of-our-worlds-food-crops-are-becoming-extinct/.
130 *Id.*
131 *Id.*
132 Thompson, *supra* note 128, at 188.
133 Cronin, *supra* note 17.
134 *Id.*
135 *Id.*
136 Nikki Olson, *3D Printing Laboratories: The Age of DIY Designer Drugs Begins*, INST. FOR ETHICS AND EMERGING TECH. (Apr. 26, 2012), http://ieet.org/index.php/IEET/more/olson20120426 (Discussion of new technical and ethical challenges for 3-D printing drugs).
137 *FDA Approves the First 3D Printed Drug Product*, APRIA PHARMACEUTICALS (Aug. 3, 2015), https://www.aprecia.com/pdf/2015_08_03_Spritam_FDA_Approval_Press_Release.pdf (Press release about 3-D printed drug).

which uses 3D-printing technology to produce a drug formulation that "rapidly disintegrates with a sip of liquid."[138] Using the technology, it developed a 3D-printed drug that in 2015 was the first to be approved by the FDA.[139] As Professor Cronin implies in his talk, the benefits that 3D-printing technology brings to the pharmaceutical industry are too great to be ignored,[140] but neither can the risks. Ms. Nikki Olson, in an article describing Professor Cronin's work, asserted, the "negative potentials" of the technology are great and will be a "nightmare for medical and law enforcement communities."[141]

There are numerous reasons that using 3D printers to print drugs will be a "nightmare" for the medical and law enforcement communities. One reason parallels trying to take 3D blueprints of firearms off the Internet, namely that once drug blueprints are posted and made available online, they will be virtually impossible to completely take down.[142] In the pharmaceutical space this suggests that the organic chemistries for drug molecules could be downloaded and printed by anyone with access to Professor Cronin's "chemical inks." We know these inks exist in some form given both his experiments and the ZipDose© technology. It is important to note that drugs can be printed with commercially available, albeit modified, 3D printers.[143] This suggests that it is possible to modify a commercially available 3D printer to print drugs at home. The resulting complication for law enforcement arises when amateur chemists attain and modify commercial 3D printers, download chemical blueprints, and customize them to print designer or otherwise illicit drugs. Because the bases for many dangerous and recreational drugs are already available, there exists the possibility of creating new designer drugs without the laboratory footprint typically required to do so, making it more difficult for law enforcement to detect.[144]

Although the criminal aspect of automating illegal drug creation is concerning,[145] there are other concerns still that warrant consideration. For example, state lawmakers or courts will need to consider where liability falls when there is an adverse reaction to a 3D-printed drug.[146] Typically product liability lies with the manufacturer or a member of the product distribution

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138 *Id.*
139 *Id.*
140 Cronin, *supra* note 17.
141 *Id.*
142 Walther, *supra* note 1, at 1436.
143 Olson, *supra* note 136.
144 *Id.*
145 Brian Krassenstean, *3 Dangers Society Faces from 3D Printing*, 3DPRINT.COM (July 16, 2015), https://3dprint.com/81526/3d-print-dangers/.
146 Ann Robinson, *Welcome to the Complex World of 3D-printed Drugs*, THE GUARDIAN (Aug. 21, 2015, 9:52 AM), https://www.theguardian.com/sustainable-business/2015/aug/21/welcome-to-complex-world-of-3d-printed-drugs-spritam-fda.

chain.[147] When a drug manufactured by a process in which a pharmaceutical company delivered 3D-drug blueprints to be printed by a pharmacist or physician, or even forwarded to the patient to print and the drug caused a patient injury, who in the manufacturing chain is liable? Does strict product liability apply to such a scenario? Should it?

Federal lawmakers should also consider whether patent infringement is an issue that they should address in light of this new technology.[148] Currently § 287(c) of the Patent Act—the Medical Liability Exception—shields physicians who use "a patented method 'while performing a medical activity with the goal of treating a human being'" from patent infringement liability.[149] Although the exception does not apply to patented drugs, it is far from clear how patent law applies in light of 3D-printing technology.[150] Hypothetically, suppose a physician customizes or modifies a patented drug blueprint and prints it to address a particular patient's needs. Is this an infringement that the Medical Liability Exception fails to cover?[151] The ability for physicians to 3D print customized drugs for individual patients has strong public benefit implications, which raises the novel question of whether a fair-use component ought to be added to the Medical Liability Exception for physicians such as the one in the hypothetical.[152]

This article raises these issues not to suggest answers, but to suggest that they deserve consideration. Freewheeling innovation with 3D printing in the pharmaceutical and medical industries is fraught with potential issues, and lawmakers should provide these industries with guidance regarding their liabilities as the democratization and personalization of drug production progresses.

D. PRINTED PRODUCTS (MANUFACTURING)

Perhaps the greatest impact that 3D printing will have on society is the ability to self-manufacture products in the privacy of one's own home.[153] Some argue that 3D printing puts the world on the brink of the "next industrial revolution."[154] The current revolutionary state makes it possible for individuals to design and manufacture products and then sell them on any

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[147] Richard A. Epstein & Catherine M. Sharkey, CASES AND MATERIALS ON TORTS 711 (10th ed. 2012).
[148] Carrie E. Rosato, *The Medical Liability Exemption: A Path to Affordable Pharmaceuticals?*, 42 FL. ST. L. REV. 1067, 1070 (2015).
[149] *Id.* at 1071 (quoting Fariba Sirjani & Dariush Keyhani, *35 U.S.C. § 287 (C): Language Slightly Beyond Intent*, 3 BUFF. INTELL. PROP. L.J. 13, 13-14 (2005)).
[150] *Id.* at 1087.
[151] *See generally id.*
[152] *See id.* at 1091 (arguing that courts could consider interpreting the Medical Liability Exception as having a fair use component and thus consider the 3D printing of a drug as a process that would fall under the exception).
[153] Kennedy & Giampetro-Meyer, *supra* note 18, at 958.
[154] *Id.*

number of e-commerce sites.[155] While there are significant economic benefits to this home-based movement there are also concerns.[156] One concern is that private homes may become largely unregulated factories.[157] Although 3D printing allows for the creation of objects not previously able to be created in the home, it does not dispense with more tedious tasks of assembly, finishing, and packaging; tasks strikingly similar to those that drove the passage of the Fair Labor Standards Act of 1938 ("FLSA").[158] Because the combination of 3D printing and global e-commerce creates greater opportunities for self-employment, there is also greater opportunity to engage family members as employees.[159] Family members, and children in particular, who may be home anyway become obvious candidates for tedious tasks.[160] Although the oppressive child labor provision of the FLSA generally does not apply to parents employing their children, it does apply where the child is engaged in manufacturing.[161] Subsequently, violations of minimum wage and child labor laws may result.[162] Historically, these violations have been notoriously difficult or impossible to detect in home-based settings leaving them *de facto* unregulated.[163]

Other concerns relate to health hazards posed by 3D printing itself, for instance "some of these [3D] printers emit ultrafine particles ("UFPs") at concentrations" that may cause serious illnesses or death.[164] Studies of desktop 3D printers demonstrate that UFP emissions can vary with the type of printer, the printing material, the temperature the printing material is heated to, and the shape of the object printed.[165] The concern is that unlike larger factories, home-based factories will put 3D printers to use in enclosed spaces that are not sufficiently ventilated, exposing family-member employees to significant health risks.[166] The FLSA is difficult to enforce in

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155 *Id.*
156 *Id.*
157 *Id.* at 958-59.
158 Notes and Comment, *Child Labor in Industrial Home Work*, 17 SOC. SERV. REV. 88, 88-89 (Mar. 1943) [hereinafter *Child Labor*].
159 Wendy Cunningham & Carlos Ramos Gomez, *The Home as Factory Floor: Employment and Remuneration of Home-based Workers* 4, n.4, (World Bank, Policy Research Working Paper, May 2004), http://elibrary.worldbank.org.mutex.gmu.edu/doi/pdf/10.1596/1813-9450-3295.
160 *Id.*
161 29 U.S.C. § 203(l).
162 Kennedy & Giampetro-Meyer, *supra* note 18, at 958-59.
163 *Child Labor*, *supra* note 160, at 88; *see also id.*
164 Kennedy & Giampetro-Meyer, *supra* note 18, at 962-63 (citing *3D Printers May Pose Indoor Air Pollution Risk*, GALLONDAILY (July 29, 2014), https://gallondaily.com/2013/07/29/3d-printers-may-pose-indoor-air-pollution-risk/).
165 *See* Azimi, et al., *supra* note 68, at 1264; Stephens, et al., *Ultrafine Particle Emissions from Desktop 3D Printers*, 79 ATMOSPHERIC ENV'T 334, 336 (2013).
166 Kennedy & Giampetro-Meyer, *supra* note 18, at 962 (citing Dominique Mosbergen, *3D Printers May be as Hazardous to Your Health as Cigarettes, According to New Study*, HUFFINGTON POST (July 24, 2013, 6:15 PM), http://www.huffingtonpost.com/2013/07/24/3d-printers-health_n_3646133.html).

home-based worksites.[167] The Occupational Safety and Health Administration will only conduct an inspection of a home-based worksite engaged in manufacturing when it "receives a complaint or referral that indicates that a violation of a safety or health standard exists that threatens physical harm, or that an imminent danger exists…."[168] Because home-based factory employers may not be aware of their responsibilities under the Occupational Safety and Health Act ("OSHA") or of the dangers inherent in the process of 3D printing,[169] health and safety standard violations may not be discovered until it is too late.

Some argue that the FLSA and the OSHA should be modified to more effectively address risks inherent in home-based 3D-printing factories in the oncoming industrial revolution.[170] It is not clear in either case, however, that changes to those particular statutes are needed. Rather changes to the regulatory scheme to educate owners of 3D printers planning to sell products that are 3D printed at home may go a long way to address these concerns. The following section discusses this and several recommendations addressing some of the concerns discussed above.

III. RECOMMENDATIONS

Although 3D printers will enable dramatic societal improvements, they also present significant risks to health, safety, and national security that will become more serious as 3D printers rise to ubiquity. Outlined here are a few recommendations that lawmakers might consider when thinking about how to manage the inherent risks of 3D printing while not hindering the dramatic progress and ongoing innovation of the technology.

A. PREVENT WEAPONS ON AIRCRAFT

The first and most pressing consideration relates to the ability to print weapons. Now that 3D printers are portable (i.e., small, capable, and able to be powered by battery)[171] and available for purchase by the general public,[172] every scheduled flight is at risk of bad actors manufacturing deadly weapons within sterile areas for use on later flights. Although it is not clear that firearm ammunition has yet been manufactured on a 3D printer, other deadly weapons such as knives, daggers, [173] crossbows,[174] and explosives

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167 *Child Labor*, *supra* note 160, at 88-89.
168 Kennedy & Giampetro-Meyer, *supra* note 18, at 981-86 (citing U.S. DEP'T OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DIRECTIVE NO. CPL 2-0.125 HOME-BASED WORKSITES (Feb. 25, 2000)).
169 *Id.* at 985-86.
170 *Id.* at 981-86.
171 *Freaks3d*, *supra* note 95; *see also Portabee GO*, Portabee 3D Printer, http://portabee3dprinter.com/shop/portabee-go/ (last visited Jan. 8, 2017).
172 *See* FREAKS3D PRINTER, http://www.elecfreaks.com/freaks3D/ (last visited Jan. 4, 2017) (selling fully assembled Indiegogo Freaks3D portable printers for $550.00).
173 Russon, *supra* note 15.
174 Parker, *supra* note 15.

have been.[175] TSA should consider modifying existing regulations to address the risks that 3D printers could pose when accessible as a carry-on item by requiring them, as well as printing materials, to be checked. This will foreclose the ability of potential bad actors to manufacture deadly weapons after having successfully passed through a security checkpoint into a sterile area.

The regulation describing the general requirements of TSA's Airport Security Program states in relevant part that:

> (a) No person may operate an airport subject to § 1542.103 unless it adopts and carries out a security program that—
> (1) Provides for the safety and security of persons and property on an aircraft operating in air transportation or intrastate air transportation against an act of criminal violence, aircraft policy, and the introduction of an unauthorized weapon, explosive, or incendiary onto an aircraft;…[176]

Section 1542.103 of the regulation describes what an airport operator's security program must include, like a description of the sterile areas,[177] that is "the portion of an airport defined in the airport security program that provides passengers access to boarding aircraft…."[178] The description must also provide the "measures used to control access" to sterile areas.[179] Once someone enters a sterile area, however, there are no further access control measures prior to boarding the airplane. This creates an opportunity for bad actors carrying 3D printers to arrive early for a flight and print an otherwise prohibited object *within* the sterile area, or alternatively to do the same after deplaning on a layover at an interim airport. In other words, the regulation does not consider the possibility that one might manufacture "an unauthorized weapon, explosive, or incendiary"[180] *after* passing through security.

There are numerous ways to mitigate the possibility that a person could manufacture a weapon, explosive, or incendiary once in the sterile area; one obvious approach is to increase security monitoring within the sterile areas, however, this likely requires a significant increase in manpower. The mitigation recommended here is to modify § 1542.101 to read, in relevant part, as follows:

> (a) No person may operate an airport subject to § 1542.103 unless it adopts and carries out a security program that—
> (1) Provides for the safety and security of persons and property on an aircraft operating in air transportation

[175] Hutterer, *supra* note 70, at 2, 4.
[176] 49 C.F.R. § 1542.101.
[177] *Id.* § 1542.103(6) (2016).
[178] *Id.* § 1540.5.
[179] *Id.* § 1542.103(6)(iii).
[180] *Id.* § 1542.101.

> or intrastate air transportation against an act of criminal violence, aircraft policy, and the introduction of an unauthorized weapon, explosive, ~~or~~ incendiary, *or additive manufacturing component* onto an aircraft;….

This change would force a modification to existing "measures used to control access" to sterile areas. The benefit of this over increased manpower to monitor sterile areas is that it places the monitoring for 3D printers at the point of access control, where the search for weapons, explosives, and incendiaries occurs, thus leveraging the efficiency of existing measures already employed. Because portable 3D printers are not yet widely owned and may not be readily recognizable by TSA agents today, additional training will be required. Under 49 C.F.R. § 1542.213 "individuals performing security-related functions…[must be] briefed" to the extent necessary "to perform their duties." To enable the modification proposed here, these briefings must provide enough information so that TSA agents can recognize portable 3D printers, their critical components, and printing materials.

One would hope that the reality of 9/11 dispels any critique that the risks described here are imaginary. While permissionless innovation is certainly desirable to further technological advancements, where innovations empower the ingenuity of bad actors, some degree of precaution seems prudent. The recommended approach here strikes a balance that meaningfully ensures public safety without impinging upon the ability to innovate around 3D printing. Because the potential dangers in other policy areas are less imminent, the following recommendations are still precautionary but less urgent.

B. Labeling 3D-Printed Food

Lawmakers should consider the high likelihood that 3D-printed food and drugs will become mainstream. To respond to this, Congress should ensure that the FDA is empowered to deal with the implications, particularly from a food and drug safety perspective.

Regarding 3D-printed food, lawmakers might consider legislation analogous to the recent GMO labeling law, which requires that there be a way for consumers to attain information about the bioengineered content in a given food.[181] Similarly, Congress could provide the FDA with the authority to require labeling of food that is 3D printed if it becomes apparent that such labeling is desired or necessary. Neither the Fair Package and Labeling Act[182] or the Federal Food, Drug, and Cosmetic Act[183] ("FFCA") appear to provide a mechanism for labeling 3D-printed food. However,

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[181] 7 U.S.C.A. § 1639b(b)(2).
[182] 15 U.S.C. §§ 1451-1461
[183] 21 U.S.C. §§ 341-350

under § 343 of the FFCA ("Misbranded food"), the Secretary of Health and Human Services ("HHS") can require a label if there is a finding "that the food presents a threat of serious adverse health consequences or death to humans or animals."[184] Currently, however, this applies only to imported food, as the notification requirement only applies where the label is required under § 381 ("imports and exports"), which includes misbranding.[185] Thus, the only existing authority available to the FDA to enforce a labeling requirement for 3D-printed food fails to cover food that is 3D printed domestically for domestic consumption.

There are two ways to remedy this shortfall. Congress could pass legislation similar to the GMO labeling law; or Congress could modify § 343 of the FFCA to empower the Secretary of HHS to require labeling *any* time there is a finding that food presents a threat of serious adverse health consequences. Passing an act similar to the GMO labeling statute could amend either the Fair Package and Labeling Act or the FFCA to create a direct requirement that all 3D-printed foods be labeled. Noting that the GMO labeling law took years to pass, this approach is likely the less efficient of the two.[186] The alternative of amending the existing FFCA, would broaden the definition of "misbranded food" to include *any* food that is found to present a "threat of serious adverse health consequences or death to humans or animals" and permit labeling as necessary. The amended statute might read thus:

> (v) Failure to label; health threat
> If--
>
> > (1)it fails to bear a label required by the Secretary under *this title, including* section 381(n)(1) ~~of this title~~ (relating to food refused admission into the United States);
> > (2)the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and
> > (3)upon or after notifying the owner or consignee involved that the label is required*, including* under section 381 of this title, the Secretary informs the owner or consignee that the food presents such a threat.

These changes would allow the FDA to enforce a labeling requirement on 3D-printed food if it is found to be a health hazard, regardless of its status as an import or an export. There are multiple benefits to this approach. First, as a precautionary act, empowering the FDA to require labeling may incentivize manufacturers of Foodini-type products, as well as food producers, to take precautions to prevent a labeling requirement. Second, an act is a weak precautionary approach, because unlike a statute requiring 3D-

[184] *21 U.S.C.* § 343(v)(2)-(3).
[185] 21 U.S.C. § 381(a)
[186] Addady, *supra* note 124.

printed food to be labeled, it allows the FDA to "wait and see" if labeling is required. At the same time, an act allows labeling to be required more quickly than waiting for Congress to respond if a need arises. In this sense, the approach is a meaningful compromise between the objectives of precautionary and permission-less policies.

C. IN-HOME MANUFACTURING

Finally, although state product liability laws may appropriately address issues with the drive toward distributed and localized (i.e., in-home) manufacturing of products,[187] lawmakers should consider how the 3D printer-driven "industrial revolution" might impact the effectiveness of occupational health and safety, and labor laws. Specifically, it may be necessary to address how those laws are enforced in small, home-based manufacturer environments. We have known for years that this type of enforcement is notoriously difficult[188] and the Occupational Safety and Health Administration ("OSHA") will not typically investigate a home-based manufacturer unless it is notified of a violation.[189]

One recommendation is to require registration of 3D printers used for commercial purposes. Under the OSHA, States may "assume responsibility for development therein of occupational safety and health standards relating to any occupational safety or health issue with respect to which a Federal standard has been promulgated…."[190] In order to accomplish registration, the Secretary of Labor would need to promulgate a rule requiring that 3D printers used for home-based commercial manufacturing be registered.[191] Since it may be difficult or impossible for the federal government to create a national registry, this may be better left to the States to implement via their concurrent OSHA authority, similar to how current firearm registration is left to them.[192]

The goal of the registration would be to encourage registrants to undergo education designed to ensure that home-based commercial manufacturers are equipped with the relevant knowledge of applicable OSHA and State standards and hazards laws.[193] This knowledge is especially important in light of two potential issues. First there is the likelihood that small home-based manufacturers will employ the assistance of children living in the home where the business also resides.[194] These child employees may be at risk of occupational harm from the nature of 3D printing itself, for example, the high temperatures required and the spraying of hot polymers

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[187] *Cf.* Epstein & Sharkey, *supra* note 147, at 713.
[188] *Child Labor*, *supra* note160, at 88-89.
[189] U.S. DEP'T OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DIRECTIVE NO. CPL 2-0.125 HOME-BASED WORKSITES (Feb. 25, 2000).
[190] 29 U.S.C. § 667 (2015).
[191] *Id.,* § 655.
[192] *Registration of Firearms*, *supra* note 99
[193] Kennedy & Giampetro-Meyer, *supra* note 18, at 985-86.
[194] *Id.,* at 958-59.

and resins from printer nozzles.[195] Education about these issues would ensure that home-based manufacturers take appropriate precautions to prevent violations of OSHA and State-law based standards. Second, the potential release of UFPs may put everyone living in the household at risk of localized environmental harms.[196] Education, prompted by printer registration may help home-based manufacturers to understand the risks and take appropriate precautions to ensure proper ventilation of their homes and better secure the health and safety of their spouses and children.

An educational program would also put home-based manufacturers on notice that they are not covered under FLSA's "oppressive child labor" exception for parents employing children because the exception specifically does not apply where children are engaged in manufacturing.[197] The implication of this is that if an investigation or inspection determines that a manufacturing activity results in oppressive child labor, the Secretary of Labor can bring an action to enjoin that act or practice as unlawful.[198] An injunction of a critical activity could shut down a business completely, so it is important that would-be parent employers are educated to avoid creating substandard working conditions that may harm both their business and their children.[199]

Neither the registration nor the education need be onerous. Registration could happen at point of sale, or it could happen voluntarily since not every purchaser of a 3D printer is intent on starting a small manufacturing business. For this reason, voluntary registration is preferable and should be encouraged. For instance, companies selling 3D printers might provide rebates, or better warranties if a 3D printer is registered. Alternatively, States interested in ensuring FLSA compliance could offer tax breaks on revenues generated by home 3D-printer-based manufacturers that register their printers. Finally, Internet e-commerce sites that enable individuals to become sellers, such as eBay, Amazon, Etsy, etc., might require sellers of 3D-printed items to verify that they have undertaken some level of education prior to enabling their accounts. These incentives gently augment the more significant incentive for small 3D-printing businesses to attain the information in order to avoid finding themselves subject to an unexpected investigation.

The education itself could take a variety of forms, from simple documentation to online training. Whatever the form, it should describe the applicable laws, employer responsibilities, and the known risks of 3D printing in home-based scenarios. Certainly small business owners would prefer a small amount of education to an injunction that could destroy their business for the violation of a law that they failed to know applied to them

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195 *Id.,* at 984.
196 *Id.* at 962-63, *citing* "*3D Printers May Pose Indoor Air Pollution Risk*," *from* GALLONDAILY (July 29, 2014), https://gallondaily.com/2013/07/29/3d-printers-may-pose-indoor-air-pollution-risk/). Last Accessed 3/20/17.
197 29 U.S.C. § 203(l).
198 *29 U.S.C.*. § 212(b)-(c).
199 Kennedy & Giampetro-Meyer, *supra* note 18, at 967-68.

or find themselves subject to extensive liability for injuries caused by illegal working conditions.

Although precautionary in nature, this "register and educate" approach would likely promote innovation and the advancement of 3D printing technology. An educated user is more likely to properly use the technology and innovate around its limitations. As a result, a precautionary registration and education program in this case might more effectively promote innovation than a permissionless approach to innovation would.

CONCLUSION

3D printers are revolutionizing the way we think about manufacturing everything from weapons to medicines. One of the fundamental differences between 3D printing and information technologies is that 3D printers breach the digital-physical divide. They convert digital data (information) into real world objects in a way only before known to science fiction.[200] This breach of the digital-physical divide comes with both significant opportunities and significant dangers. The dangers are not confined to virtual space; they threaten health, safety, and national security and cause real damage to humans, including death.[201] This Article argues that where a technology is capable of real-world harms, it is not an appropriate candidate for permission-less innovation because it fails to balance the potential human harms with the potential benefits of freewheeling experimentation. In light of the risks posed by 3D printing, a more prudent approach is a precautionary one that provides a framework to manage these risks while promoting innovation and allowing the technology to flourish and improve our standard of living and the general economic welfare.

To accommodate ongoing innovations in 3D printing, this Article recommends a governance approach that leverages weak precautionary principles. These recommendations include three relatively light-handed actions that federal or, in some cases, state lawmakers could take to address the risks to health, safety, and national security associated with 3D printing. The first is to modify existing TSA regulations to prohibit 3D printers from being carried onto aircraft; the second is to empower the FDA to require labeling of 3D-printed consumables if it deems that such labeling is necessary; and the third is to establish a registration and education system for owners of 3D printers who intend to use them for home-based commercial manufacturing purposes.

None of these recommendations dilute, in any significant way, the elixirs of innovation that will continue to drive 3D printing forward. Indeed, some incentivize innovation around the responsible use and safety of the

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[200] Drew Nelson, "*Making it Real with 3D Printing*," from *INFOWORLD.COM* (Dec. 11, 2012), http://www.infoworld.com/article/2616159/open-source-software/making-it-real-with-3d-printing.html.

[201] Kennedy & Giampetro-Meyer, *supra* note 18, at 962-63; Greenberg, *supra* note 2; *See Generally* Julia Zorthian, *Airport Security Finds 3d Printed Gun in Carry-On at Reno Airport*, TIME (Aug. 11, 2016), http://time.com/4448069/tsa-3d-printed-gun-reno/.

technology with greater efficiency and less delay than permission-less innovation would.