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GOVERNANCE OF 3D-PRINTING APPLICATIONS IN HEALTH: BETWEEN REGULATED AND UNREGULATED INNOVATION

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The article aims to examine how governance frameworks under regulatory and liability rules in the United States and Canada respond to the challenges and opportunities presented by three-dimensional printing (3DP) applications in health. The discussion demonstrates that 3DP applications in health currently fall between regulated and unregulated innovation, given that existing governance frameworks do not sufficiently capture 3DP's unique attributes and potential. In identifying approaches to regulatory intervention in the governance of 3DP innovation, the discussion outlines characteristics of 3DP that lend themselves to a model of innovation governance that would allow pre-emptive regulatory actions for optimal outcomes. Thus, the article advances the position that the state of the technology's development in health applications has matured to such a level that a dedicated regulatory framework is necessary for addressing the uncertainty of risks and for promoting an understanding of the applicability of existing regulatory requirements to guide the flourishing innovation.

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I. INTRODUCTION

Three-dimensional printing (3DP), often referred to by its near-analogue, 'additive manufacturing,' has been described as a disruptive technology that shifts control and authority away from manufacturers and towards user-innovators and other actors in product supply chains.[1] The technology creates disruptions in such diverse areas that it has become necessary to assess existing legal regimes and reconsider incumbent laws, regulations, and

1. Michael Weinberg, IT WILL BE AWESOME IF THEY DON'T SCREW IT UP: 3D PRINTING, INTELLECTUAL PROPERTY, AND THE FIGHT OVER THE NEXT GREAT DISRUPTIVE TECHNOLOGY (2010), www.publicknowledge.org/files/docs/3DPrintingPaperPublicKnowledge.pdf; (arguing 3D printing is "[t]he next great technological disruption"); Daniel Harris Brean, *Asserting Patents to Combat Infringement via 3D Printing: It's No "Use"*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 771, 774 (2013) ("3D printing has the capability to completely bypass traditional manufacturing and distribution practices"); Charles W. Finocchiaro, *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 & 480 (2013) (predicting that 3D printing "may have the potential to blur the bright line between consumers and producers," and that "3-D printing, in the long term, has the potential to have a similarly disruptive effect on IP by decentralizing the means of production and challenging many of the assumptions on which modern IP law are based"); Deven Desai, *How Democratized Production Challenges Society's Ability to Regulate*, *in* 3D PRINTING AND BEYOND 234, 247 (Dinusha Mendis et al. eds., 2019).

procedures.[2] As the technology becomes commonplace, its impact will be felt in many legal fields, including regulatory, intellectual property, insurance, environmental, transportation, contracts, and import/export domains.[3]

In the early stage of its emergence, the legal literature on 3DP encompassed diverse questions, touching upon safety, regulation, intellectual property, and liability: what should the appropriate government response be when individuals or organisations have the ability to print dangerous and illegal objects such as firearms and other weapons?[4] How will product liability laws apply to defective consumer products printed locally or at home?[5] How will intellectual property laws be impacted by the inherently infringing features of 3DP?[6] Debates on the legal and policy implications of 3DP, which these questions address, are often blighted with exaggerated expectations of the technology itself.[7] Nevertheless, there has been a

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2. Klaus Heine & Shu Li, *What Shall We Do with the Drunken Sailor? Product Safety in the Aftermath of 3D Printing*, 10 EU. J. RISK REG. 23, 24 (Mar. 2019).

3. *See generally* Jim Beck et al., 3D PRINTING OF MANUFACTURED GOODS: AN UPDATED ANALYSIS at 15-19 (Lisa Baird et al. eds., 2016), www.reedsmith.com/files/Publication/4f5bee57-afd8-48cd-b2dl-8f94fd6a0bd2/Preview/PublicationAttachment/b78l9f5-37ae-4ee3-bl5c-90a7a58b02d9/3D-Printing-White-Paper-Final-2nd-Edition-December-2016.pdf.

4. *See* Julian J. Johnson*, Print, Lock, and Load: 3-D Printers, Creation of Guns, and the Potential Threat to Fourth Amendment Rights,* 13 U. ILL. J.L. TECH. & POL'Y. 337 (2013); Symposium, *Guns Don't Kill People, 3D Printing Does? Why the Technology Is a Distraction from Effective Gun Controls,* 65 HASTINGS L.J. 1505 (2014).

5. *See* Nicole D. Berkowitz, *Strict Liability for Individuals? The Impact of 3-D Printing on Products Liability Law,* 92 WASH. U. L. REV. 1019 (2015); Shen Wang, *When Classical Doctrines of Products Liability Encounter 3D Printing: New Challenges in the New Landscape,* 16 HOUS. BUS. & TAX L. J. 104 (2016); Lucas S. Osborn, *Regulating Three-Dimensional Printing: The Converging Worlds of Bits and Atoms,* 51 SAN DIEGO L. REV. 553 (2014); James M. Beck & Matthew D. Jacobson, *3D Printing: What Could Happen to Products Liability When Users (and Everyone Else in Between) Become Manufacturers*, 18 MINN. J.L. SCI. & TECH. 143 (2017).

6. *See* Tesh W. Dagne, *Overview of Implications of Three-Dimensional Printing On Canadian Intellectual Property Law,* 31 CAN. INTELL. PROP. REV. 29 (2015); Symposium, *3D Printing and Beyond: Emerging Intellectual Property Issues with 3D Printing and Additive Manufacturing,* 34 CARDOZO ARTS & ENT L.J. 1, 32 (2016); Dukki Hong & Simon Bradshaw, *Digital Trade Mark Infringement and 3D Printing Implications*, *in* 3D PRINTING AND BEYOND: INTELLECTUAL PROPERTY AND REGULATION 99, 99-115, (Dinusha Mendis et al. eds., 2019).

7. *See* Leslie Mertz, *Dream It, Design It, Print It in 3-D: What Can 3-D Printing Do for You?* 4 IEEE PULSE 15 (2013); Weinberg, *supra* note 1, at 1; *The Third Industrial Revolution,* THE ECONOMIST (Apr. 21, 2012), http://www.economist.com/node/21553017; Deven R. Desai & Gerard N. Magliocca,

great deal of excitement and investment in the technology, as leading companies and innovators alike find applications for 3DP which extend beyond the initial purpose of prototyping.[8] As the technology has matured and become more sophisticated, new materials and possibilities have begun to substantially disrupt a range of sectors, including health and medicine,[9] food and nutrition,[10] education and research,[11] construction,[12] manufacturing,[13] and retail.[14]

While much of the predicted potential of 3DP technology remains unfulfilled due to its limited uptake,[15] its application in health has become one of the most fertile fields of innovation.[16] These health applications range from the manufacturing of medical devices and surgical models, to the fabrication of human tissues and organs, and to applications in pharmaceutical research and

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Patents, Meet Napster: 3D Printing and the Digitization of Things, 102 GEO. L.J. 1691 (2014).

8. *See e.g.*, Christopher Barnatt, *3D Printing,* EXPLAINING THE FUTURE BLOG (Jan. 30, 2016), www.explainingthefuture.com/3dprinting.html (predicting that "3D printing may therefore soon do for manufacturing what computers and the Internet have already done for the creation, processing and storage of information"); Davis Doherty, *Downloading Infringement: Patent Law as a Roadblock to the 3D Printing Revolution*, 26 HARV. J.L. & TECH. 353, 354 (2012) ("the ability to create prototypes almost immediately and manufacture custom designs in a cost-effective manner may well revolutionize modern industry").

9. Evan R. Youngstrom, *3D Printing and Healthcare: Will Laws, Lawyers, and Companies Stand in the Way of Patient Care*, 6 PACE INTELL. PROP. SPORTS & ENT. L. FORUM 91 (2016).

10. Deborah Lupton & Bethaney Turner, *Would You Eat a 3D Printed Pizza?*, THE CONVERSATION (Dec. 22, 2016), www.theconversation.com/would-you-eat-a-3d-printed-pizza-70335.

11. Simon Ford & Tim Minshall, *Invited Review Article: Where and How 3D Printing Is Used in Teaching and Education,* 25 ADDITIVE MANUFACTURING 131 (2019).

12. Josh M. Leavitt, *Practical and Legal Considerations of 3-D Printing Technology*, CONSTRUCTION EXECUTIVE (June 28, 2015), www.constructionexec.com/article/practical-and-legal-considerations-of-3-d-printing-technology.

13. Alexander E. Ackel, *Extending Liability to Micro-Manufacturers of the Future: Applying the Casual Seller Exception in the Context of 3-D Printing*, 8 IRVINE L. REV. 121, 122-23 (2018).

14. Jennifer B. Furey & Alana Van der Mude, *3D Printing: Potential Pitfalls for Retailers*, 35 LICENSING J. 15 (2015).

15. *See* Angela Daly, *Don't Believe the Hype? Recent 3D Printing Developments for Law and Society, in* 3D PRINTING AND BEYOND: THE INTELLECTUAL PROPERTY AND REGULATION 349 (Dinusha Mendis et al. eds., 2019).

16. Jim Banks, *Adding Value in Additive Manufacturing: Researchers in the United Kingdom and Europe Look to 3D Printing for Customization*, 4 IEEE PULSE 22, 22-26 (Winter 2013) ("While it is certain that the biomedical sector will be one of the most fertile fields for 3D printing innovations, it is important to appreciate what has already been achieved without expecting that rapid advances toward the most sophisticated applications will occur overnight.").

development.[17] With the growing development of the technology in these areas, it is necessary to make advances in filling the legal and regulatory gaps that underlie the governance of innovation in this field. As in any emerging technology, such efforts require an assessment of whether the legal and regulatory gaps would be addressed by new rules specifically targeting the unique capabilities of 3D printers and the CAD files on which they are based, or through the capture of applications that are enabled by the technology under existing rules.

This article aims to examine how existing regulatory and liability rules respond to the challenges presented by 3DP from the perspective of innovation governance. It also inquires whether they should be re-designed to foster innovation. The discussion demonstrates that 3DP applications currently fall between regulated and unregulated innovation, given that existing regulatory frameworks do not sufficiently capture 3DP's unique attributes and potential. In the U.S. and Canada, recent efforts have highlighted the challenge of assessing the efficacy and safety of 3DP applications in the health sector without a tailored framework.[18] The discussion illustrates the imperatives for a dedicated regulatory framework to guide the progress being made in various applications of the technology to the health sector. The proactive consideration of such regulatory actions regarding 3DP applications in health is consistent with a model of innovation governance, which lends itself to the unique attributes of the distributed innovation that defines the technology. Such a model takes the industry, rather than the individual firm, as the point of reference in determining the impact of regulation on the structure of the industry, and then relates the industry's structure to innovation. The scope of discussion is limited to analyzing the regulatory dynamics in the use of the technology across diverse areas of application from the perspective of innovation policy. It will resort to tangentially analyzing the role of tort law under the theories of strict liability and negligence as alternative venues to managing risk in the absence of a regulatory framework. This article advances the position that the state of the technology's development in health applications has matured to such a level that a dedicated regulatory framework is necessary for addressing the uncertainty of risks and promoting an understanding of the applicability of existing requirements.

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17. *See* discussion *infra* Section II.

18. *See* discussion *infra* Section IV on efforts to assess 3DP applications in the regulatory frameworks; *see also* Jeff Mason et al., *An Overview of Clinical Applications of 3-D Printing and Bioprinting,* CADTH ISSUES IN EMERGING HEALTH TECH. (Apr. 2019), www.ncbi.nlm.nih.gov/books/NBK542711/; Frederic Gilbert et al., *Print Me an Organ? Ethical and Regulatory Issues Emerging from 3D Bioprinting in Medicine*, 24 SCI. ENGINEERING ETHICS 73 (2018).

To accomplish this objective, Section II begins with a review of the range of 3DP applications in health with respect to medical devices and instruments, bioprinting applications, and pharmaceutical applications. Section III identifies approaches to regulatory intervention in the governance of 3DP innovation, namely, permissionless innovation and a precautionary approach. This section also discusses characteristics of 3DP that lend themselves to a model of innovation governance, which would allow preemptive regulatory actions, regarding the use of the technology for optimal outcomes in innovation. For instance, it is the distributed nature of innovation in 3DP that brings an element of uncertainty of risk among the diverse actors, who adopt a role that is traditionally fulfilled by manufacturers. In these circumstances, regulation serves a governance function for processes of technological change, coordinating the activities of the various actors and guiding the search for innovation systems.[19] Section IV assesses how existing regulatory regimes under the United States Food and Drug Administration (FDA) perform such a guidance function for the diverse applications of 3DP in health. It identifies gaps in approval pathways for medical devices, which increasingly necessitate approval for 3DP applications along an exemption pathway. While the mandate for regulating bioprinting applications is currently not clear, the existing regulatory norms do not adequately assess the safety or effectiveness of applications for pharmaceuticals where the FDA has a clear mandate. Section V examines Canada's approach to regulating 3DP applications. Although it is limited in scope to high-risk medical devices, the Canadian approach is instructive in considering the unique aspects of 3DP technology with respect to specific realms of application. Section VI briefly considers how liability law addresses the allocation of risk in the use of the technology in the absence of a tailored regulatory framework that can speak specifically to 3DP. The discussion reveals that it is challenging to account for risks in 3DP under established theories of strict liability and negligence in tort law. Finally, Section VII presents the conclusion.

II. 3D-PRINTING APPLICATIONS IN HEALTH

In the 3DP process, devices called 3D printers create objects by placing minute quantities of materials at predetermined locations.[20] These predetermined locations are indicated in digital files, known

19. *See* discussion *infra* Section III.C.

20. Brian Rideout, *Printing the Impossible Triangle: The Copyright Implications of Three-Dimensional Printing*, 5 J. BUS. ENTREPRENEURSHIP & L. 161, 163 (Nov. 2011).

as computer-aided design (CAD) files.[21] The process of creating these CAD files results in "virtual 3D models of an object,"[22] commonly used by professionals such as designers, engineers and architects to conceptualise physical objects before they are manufactured in the real world.[23] CAD files can be created either by using 3D-modelling software or by scanning existing objects with a 3D-printing scanner.[24] Moreover, scanned digital copies of physical objects can be modified and remodelled using software. CAD files that are designed in this way are used to 'print' a three-dimensional object by layering and fusing particles of a filament (often a polymer), powder, metal alloy, ceramic, biological material (for example human cells), or another mixture.[25] Printing technologies are becoming increasingly advanced, with variable speeds, bonding techniques, resolutions, and materials.[26]

The capabilities of 3DP, in contrast to the conventional 'subtractive' or 'transformative' manufacturing processes that dominate production today,[27] mean that during the two decades

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21. IAN GIBSON ET AL., ADDITIVE MANUFACTURING TECHNOLOGIES: 3D PRINTING, RAPID PROTOTYPING, AND DIRECT DIGITAL MANUFACTURING 1-41 (2d ed. 2014).

22. *Id.*

23. Todd May, *A Factory on Your Desk*, THE ECONOMIST (Sept. 3, 2009), www.economist.com/node/14299512.

24. GIBSON ET AL., *supra* note 21.

25. Michael H. Park, Note, *For A New Heart, Just Click Print: The Effect on Medical and Products Liability From 3-D Printed Organs,* 187 U. ILL. J.L. TECH. & POL'Y. 187, 192 (2015).

26. Currently, there are twenty-four 3D printing processes. C. Lee Ventola, *Medical Applications for 3D Printing: Current and Projected Uses*, 39 PHARMACY AND THERAPEUTICS 704, 705 (Oct. 2004). Seven major types of printing techniques are used in different health applications: (1) Material Extrusion in which material is selectively dispensed through a nozzle or orifice; (2) Material Jetting, where droplets of build material are selectively deposited; (3) Binder Jetting, which uses a liquid bonding agent that is selectively deposited to join powder materials; (4) Sheet Lamination in which sheets of material are bonded together to form an object; (5) Vat Photopolymerization that uses liquid photopolymer in a vat that is selectively cured by light-activated polymerization; (6) Powder Bed Fusion, which uses thermal energy to selectively fuse regions of a powder bed; and (7) Directed Energy Deposition in which focused thermal energy is used to fuse materials by melting them as the material is being deposited. COLLEEN T. DAVIES ET AL., 3D PRINTING OF MEDICAL DEVICES: WHEN A NOVEL TECHNOLOGY MEETS TRADITIONAL LEGAL PRINCIPLES (1st ed. 2015), www.reedsmith.com/en/perspectives/2015/09/3d-printing-of-medical-devices--when-a-novel-techn.

27. Subtractive manufacturing processes are those where materials are removed by cutting or drilling. *See* Helena Dodziuk, *Applications of 3D Printing in Healthcare*, 13 KARDIOCHIRURGIA I TORAKOCHIRURGIA POLKSA 283, 284 (2016).

following its invention in the 1980s,[28] the technology remained largely within the domain of architecture and engineering,[29] where it was often used as a means of experimenting with designs and for the purpose of rapid prototyping. As discussed above, however, the expiry of the first 3DP patents brought rapid development and the adoption of the technology across many more sectors.

In terms of health, advancements in technology introduced the possibility of creating complex geometric architectures, allowing for porous structures, tortuous internal channels, and internal support structures, which could not be easily created through traditional subtractive manufacturing. This shifted the focus of its early uses into more ambitious health applications.[30] As a field of technology, 3DP has an ecosystem of participants, which is widening and diversifying as more actors enter the field. Broadly speaking, this ecosystem consists of primary actors, such as 3DP machine manufacturers, CAD designers, 3D model distributors (usually different from designers), and 'printers' (large-scale operators and micro-sellers).[31] Secondary actors include: manufacturers and retailers of ink, filaments, and materials; educators; researchers; and others.[32] Advances in technology are widespread across the diverse participants in the 3DP ecosystem. However, the discussion in this Section is limited to applications of the technology that have significance as a result of developments in the technology as a whole—including both primary and secondary actors.

Most 3DP health applications are still some way off from being introduced into the consumer market. Hence, they do not pose immediate regulatory challenges. However, the discussion demonstrates how the healthcare industry is taking full advantage of the technology's new deployment in health applications, which is projected to reach USD $1.88 billion by 2022 for only medical devices.[33] There are three broad areas of application for 3DP in health, which are at varying levels of development: medical devices and instruments, the bioprinting of organs and implants, and the development of pharmaceutical drugs.

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28. *The Third Industrial Revolution*, *supra* note 7.

29. Ford & Minshall, *supra* note 11.

30. Paul Banwatt & Laura Robinson, *Dispatches from the Front Lines of 3D Copyright*, 28 INTELL. PROP. J. 237 (2016).

31. Adam Thierer & Adam Marcus, *Guns, Limbs and Toys: What Future for 3D Printing?*, 17 MINN. J.L. SCI. & TECH. 807, 807-08 (2016).

32. *Id.*

33. 3D Printing Medical Devices Market by Technology (3DP, EBM, LBM, Photopolymerization and DD), Component (3D Printers, 3D Bioprinters, Material (Plastic, Metal, Ceramic), Software & Services), Product Type (Prosthetics, Implant) - Global Forecast to 2022, MARKETS & MARKETS (2017), www.marketsandmarkets.com/Market-Reports/3d-printing-medical-devices-market-90799911.html.

A. Medical Devices and Instruments

In the field of medical devices, the application of 3DP ranges from its use in the mass-production of standard medical devices as a means of overcoming device complexity to its use in custom-made and customizable devices, which are either unique to an individual or capable of being individualized to specific patients.[34] In this respect, one of the areas in which 3DP holds some of its greatest promise is prosthetics, as these "can be customized according to individual taste [and the unique characteristics of the user] and cost much less than traditional alternatives."[35] Examples of the types of prosthetics that are currently being produced are artificial hands, legs, eyes, supportive exoskeletons, and even portions of an individual's face that have been surgically removed due to cancer.[36] One highly publicized example is the 3DP prosthetic hand, controlled by an EEG-equipped headband and produced by the (then) 17-year-old, Easton LaChapelle, who made his design available online "for anyone to refine, repurpose, and use."[37] There are also volunteer networks such as e-NABLE[38] and NotImpossible,[39] which design and provide affordable 3D-printed prostheses for landmine amputees in war zones in Africa and Asia.

Another area of increasing 3DP application is orthopaedic implants. As average lifespans have increased globally and physical activity among the elderly has increased, the demand for implants to last for decades, rather than for years, has increased accordingly.[40] This being the case, orthopaedic implants must be robust "in terms of their mechanical properties and responses to host biology."[41] Titanium and its alloys are widely used in orthopaedic applications "due to low cytotoxicity, high mechanical strength, and relative biological inertness."[42] The 3D printing of implants (e.g.,

34. *See* Mason et al., *supra* note 18, at 8.
35. Dodziuk, *supra* note 27, at 286.
36. *Id*.
37. *Id*.
38. *See* ENABLING THE FUTURE, www.enablingthefuture.org (last visited Apr. 21, 2020).
39. *See* NOT IMPOSSIBLE LABS, http://www.notimpossible.com (last visited Apr. 21, 2020).
40. Trina Majumdar et al., *Additive Manufacturing of Titanium Alloys for Orthopedic Applications: A Materials Science Viewpoint*, 20 ADVANCED ENGINEERING MATERIALS 1, 1 (2018).
41. *Id*.
42. *Id*.

replacement bones) allows for the programming of porosity into implants, which can provide for greater flexibility (similar to that of living bones), as well as significantly improved "molecular transport, waste removal, and cell-cell signalling," while at the same time promoting cell migration and capillary formation.[43] Adjusting the nano-scale surface roughness of implants also improves the attachment and integration of implants into patients' biological systems.[44] Thus, 3DP technology promises to vastly improve the function and form of titanium and its alloy-based implants.

Thus far, 3D-printed bones have been used to replace damaged bones in both the upper and lower extremities.[45] For example, the U.S. military[46] and Canadian Armed Forces[47] are developing this technology to reconstruct lost limbs and tissues.[48]

3DP has also attracted increased interest in dentistry because of the greater accuracy of 3D-printed dental models and casting patterns in restorative dentistry,[49] potential for better implant customization,[50] and more accurate surgical guides in implant

43. *Id.* at 2.

44. *Id.* at 2.

45. *See, e.g.*, Pamela Fayerman, *B.C. Motorcyclist Who Collided with Deer Walks Again Thanks to 3D-Printed Bone Replacement*, THE GUARDIAN (Aug. 7, 2019), www.theguardian.pe.ca/news/canada/bc-motorcyclist-who-collided-with-deer-walks-again-thanks-to-3d-printed-bone-replacement-339693/; *see also* Hitesh Lal & Mohit Kumar Patralekh, *3D Printing and Its Applications in Orthopedic Trauma: A Technological Marvel,* 9 J. CLINICAL ORTHOPEDIC TRAUMA, 260, 260-68 (2018).

46. Sarah Knapton, *Soldiers Could Have Their Bones Copied and 3D Printed in Case of Injury*, THE TELEGRAPH (Feb. 14, 2015), www.telegraph.co.uk/news/science/11413503/Soldiers-could-have-their-bones-copied-and-3D-printed-in-case-of-injury.html.

47. Christopher Bayley & Michael Kopac, *The Implications of Additive Manufacturing on Canadian Armed Forces Operational Functions,* 18 CAN. MILITARY J. 49 (2018).

48. Here, a 3DP scanner can help to visualize and plan for fracture repairs, while ensuring less material waste in the investigation of different options for part design, near-perfect customization of implants to patient needs, and greatly reduced costs. Linzhen Xie et al., *Three-Dimensional Printing Assisted ORIF Versus Conventional ORIF for Tibial Plateau Fractures: A Systematic Review and Meta-Analysis*, 57 INT'L J. SURGERY 35, 35-44 (2018).

49. Hawa Fathi et al., *The Accuracy of Fit of Crowns Made from Wax Patterns Produced Conventionally (Hand Formed) and via CAD/CAM Technology*, 24 EUR. J. PROSTHODONTIC RESTORATIVE DENTISTRY 10, 10-17 (2016).

50. Do Gia Khang Hong & Ji-hyeon Oh, *Recent Advances in Dental Implants*, 39 MAXILLOFACIAL PLASTIC & RECONSTRUCTIVE SURGERY 33 (2017).

dentistry.[51] By combining oral scanning, CAD design, and 3DP, "dental labs can accurately and rapidly produce crowns, bridges, plaster/stone models, and a range of orthodontic appliances such as surgical guides and aligners."[52] With the FDA's approval of denture material for 3DP,[53] there is a significant increase in cutting-edge solutions coming to dental laboratories through the use of 3DP for dentures,[54] dental crowns,[55] orthodontics,[56] and dental implants,[57] among others.

Furthermore, given its capacity to facilitate the observation of small and intricate structures in the nervous system, 3DP has significant applications in surgical-planning procedures in general,[58] with particular relevance for neurosurgery.[59] It has been noted that visualizing the relationship between complex structures in spinal surgery improves patient outcomes, while reducing the time spent on the operating table and peri-operative blood loss.[60] The adoption of 3DP is slowly growing in hospitals around the world, with the Ottawa Hospital being the first in Canada to launch an integrated 3DP programme for education and medical research.[61] Meanwhile,

51. George R. Deeb et al., *How Accurate Are Implant Surgical Guides Produced with Desktop Stereolithographic 3-Dimensional Printers?*, 75 J. ORAL MAXILLOFACIAL SURGERY 2559 (2017); Evanthia Anadioti et al., *Current and Emerging Applications of 3D Printing in Restorative Dentistry*, 5 CURRENT ORAL HEALTH REP. 133, 133-39 (2018).

52. Dodziuk, *supra* note 27, at 285.

53. EnvisionTEC, *EnvisionTEC Receives FDA Approval for E-Denture Material to 3D Print Removables*, ENVISIONTEC (Jun. 30, 2017), www.envisiontec.com/envisiontec-edenture-material-receives-fda-approval/.

54. Mehmet Selim Bilgin et al., *A Review of Computer-Aided Design/Computer-Aided Manufacture Techniques for Removable Denture Fabrication*, 10 EUR. J. DENTISTRY 286 (2016).

55. A. Dawood et al., *3D Printing in Dentistry*, 219 BRITISH DENTAL J. 521, 521-29 (2015).

56. Marta Revilla-Leon & Mutlu Özcan, *Additive Manufacturing Technologies Used for Processing Polymers: Current Status and Potential Application in Prosthetic Dentistry* 28 J. PROSTHODONTICS 146, 146-56 (2018).

57. Sanjna Nayar et al., *Rapid Prototyping and Stereolithography in Dentistry*, 2015 J. PHARMACY & BIOALLIED SCI. S216, S216-19 (2015).

58. *See* Mason et al., *supra* note 18, at 9.

59. *See* Michael Randazzo et al., *3D Printing in Neurosurgery: A Systematic Review*, 7 SURGICAL NEUROLOGY INT'L S801, S801-09 (2016).

60. Ben Wilcox et al., *Systematic Review of 3D Printing in Spinal Surgery: The Current State of Play*, 3 J. SPINE SURGERY 433, 433-43 (2017).

61. Kamarul A. Abdullah & Warren Reed, *3D Printing in Medical Imaging and Healthcare Services*, 65 J. MED. RADIATION SCI. 237, 238 (2018).

the technology is increasingly being deployed as an instrument of pre-surgical planning.[62]

The possibility of using a variety of printing materials, the capacity for customization, and the tools for designing and printing complex schemes and structures, as well as imaging and visualizing small and internal structures, has increased 3DP's implementation in diverse health applications and innovations. Although the technology was initially used in applications that operated in unsuitable conditions for the use of bio-materials, such as heat and pressure during the printing process, the discovery that living cells could be used as 'bio-ink' has opened the door to the revolutionary implementation of 3DP for diverse new health applications through a process referred to as 'bioprinting.'

B. Bioprinting

In the early 2000s, scientists discovered that "living cells could be sprayed through the nozzles of inkjet printers without damaging them."[63] Although "producing three-dimensional, vascularized cellular constructs of clinically relevant size, shape and structural integrity certainly remains a major challenge for tissue engineering,"[64] later advances in the research and development of bioprinting successfully resulted in tissue cell survival, opening up the possibility of producing "tissues for human applications and to [build] more complex tissues and solid organs."[65] Advances in the digital modeling of complex cell and tissue structures from a CAD file have taken place in medical imaging.[66] However, the key

62. For example, the printing of a specific human's organ with synthetic materials for practice before performance of operations. *See*, *3-D Printed Organs Help Houston Doctors Train for Complicated Surgeries*, ABC13.COM (Dec. 14, 2016), www.abc13.com/health/3-d-printed-organs-give-surgeons-practice-runs/1657014/.

63. *Printed Human Body Parts Could Soon Be Available for Transplant*, THE ECONOMIST (Jan. 28, 2017), www.economist.com/science-and-technology/2017/01/28/printed-human-body-parts-could-soon-be-available-for-transplant.

64. Timo Minssen & Marc Mimler, *Chapter 7: Patenting Bioprinting-Technologies in the US and*

Europe – The 5th Element in the 3rd Dimension, in 3D PRINTING, INTELLECTUAL PROPERTY & INNOVATION: INSIGHTS FROM LAW AND TECHNOLOGY (Wolters Kluwer, 2017).

65. Hyun-Wook Kang et al., *A 3D Bioprinting System to Produce Human-Scale Tissue Constructs with Structural Integrity*, 34 NATURE BIOTECHNOLOGY 312, 312–19 (2016).

66. *See* Sean V. Murphy & Anthony Atala*, 3D Bioprinting of Tissues and Organs*, 32 NATURE BIOTECHNOLOGY 773 (2014).

element in the advancement of bioprinting possibilities is the 'bio-ink' used in the bioprinting process.[67] Once the bio-ink is printed in the right shape, guided by the CAD file and using a special type of bioprinter,[68] cells are left to grow into tissues and the hydrogel solution used in the bio-ink serves as scaffolding, being either biodegradable or biocompatible.[69]

There is currently significant clinical and research success with regard to the diverse potential of bioprinting applications, although their development is still at a relatively nascent stage. With recent breakthroughs in a bioprinting technique for 'multivesicular and intravascular structures,' which enable the supply of nutrients and oxygen, the possibilities arising from the successful bioprinting of human tissues are being explored across a broad spectrum.[70] One of the most promising applications of successful bioprinting is in the use of printed human tissues for drug and cosmetic testing.[71] This application has significance for the discovery of novel drugs,[72] as well as for personalized medication through drug screening, disease modeling, and precision medicine applications.[73] There is also

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67. A bio-ink is primarily composed of cells that can usually be removed from a patient through biopsy. Cells can also be sourced from different individuals of the same species (allogenic cells) and may even comprise cells from different species (xenogenic cells). These cells are allowed to grow and multiply to form aggregates in a cell culture system. *See* Gabriela I. Coman, *3-D Bioprinting: 5 Things Medical Device Cos. Should Know*, LAW360 (Feb. 18, 2016, 10:53 AM), www.law360.com/articles/760558/3-d-bioprinting-5-things-medicaldevice-cos-should-know. A bio-ink will also contain additives in the form of hydrogels which possess certain properties that are essential for the success of bioprinting. (Commonly used as hydrogels are materials such as collagen, gelatin, fibrin, and other natural polymers.) Shuai Wang et al., *Smart hydrogels for 3D Bioprinting*, 1 INT'L J. BIOPRINTING 3, 4-5 (2015). While enabling the accurate deposit of the bio-ink and enhancing cell viability by providing a favourable environment for the cells in the printing process, the hydrogels contribute structural and mechanical support after the printing process. Dhakshinamoorthy Sundaramurthi et al., *3D Bioprinting Technology for Regenerative Medicine Applications*, 2 INT'L J. BIOPRINTING 9, 16, 21 (2016).

68. Christian Mandrycky et al., *3D Bioprinting for Engineering Complex Tissues*, 34 BIOTECHNOLOGY ADVANCES 422, 423, 426 (2016).

69. M. M. Stanton et al., *Bioprinting of 3D Hydrogels*, 15 LAB CHIP 3111 (2015).

70. *Organ Bioprinting Gets a Breath of Fresh Air*, SCIENCEDAILY (May 2, 2019), www.sciencedaily.com/releases/2019/05/190502143518.htm.

71. Shreya Mehrotra et al., *3D Printing/Bioprinting Based Tailoring of* In Vitro *Tissue Models: Recent Advances and Challenges*, 2 ACS APPLIED BIOLOGICAL MATERIALS 1385 (2019). For example, Organovo is a company established with a mission to provide printed tissues that may replicate human tissue for the purposes of drug testing. *See About,* ORGANOVO, https://organovo.com/about/.

72. Aishwarya Satpathy et al., *Developments with 3D Bioprinting for Novel Drug Discovery*, 13 EXPERT OPINION ON DRUG DISCOVERY 1115 (2018).

73. Andrea Mazzocchi et al., *3D Bioprinting for High-Throughput Screening: Drug Screening, Disease Modeling, and Precision Medicine Applications*, 6 APPLIED PHYSICS REV. 011302 (2019); Xuanyi Ma et al., *3D*

scientific progress being made with regard to the potential for bioprinting in personalized implants (for the replacement of damaged or injured bone, tissue, and cartilage)[74] and in the reconstruction of burned skin,[75] although these applications are largely at an experimental stage at this time.[76] The capabilities of bioprinting include a transformative effect on organ transplantation by facilitating the fabrication of complex solid organs, such as the kidney, heart, and liver.[77]

Nevertheless, developments in bioprinting, although remote from market accessibility, still raise a variety of issues concerning the regulation of technology, the ethical implications of commercialization, and broader societal effects.[78] This Article will further elaborate on the implications of diverse 3DP applications for the governance of innovation in the health sector, viewed through regulatory and non-regulatory paradigms. The following subsection first discusses the application of 3DP in pharmaceuticals.

C. Pharmaceuticals

Years of research and development in 3DP technology have led to its unique capabilities in pharmaceutical research and drug development. 3DP has the potential to "drastically disrupt the pharmaceutical industry [by reducing] costs and facilitat[ing] customization [by] increasing efficiency, maximizing resources, and eliminating outdated development procedures."[79] As indicated in the previous subsection, the printing of human tissues and organs

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Bioprinting of Functional Tissue Models for Personalized Drug Screening and In Vitro *Disease Modeling*, 132 ADVANCED DRUG DELIVERY REV. 235 (2018).

74. Julien Barthes et al., Chapter 14 - *Using 3-D Printing and Bioprinting Technologies for Personalized Implants*, in ADVANCES IN BIOMECHANICS AND TISSUE REGENERATION 269, 269-86 (2019); Peter Apelgren et al., In Vivo Human Cartilage Formation in Three-Dimensional Bioprinted Constructs with a Novel Bacterial Nanocellulose Bioink, 5 ACS BIOMATERIALS SCI. ENGINEERING 2482, 2482-90 (2019).

75. Mathew Varkey et al., *Skin Bioprinting: The Future of Burn Wound Reconstruction?*, 7 BURNS & TRAUMA 4 (2019).

76. *See* 3D PRINTING AND BIOFABRICATION 26 (Aleksandr Ovsianikov et al. eds., Springer Int'l Pub. 2016).

77. Ibrahim T. Ozbolat & Yin Yu, *Bioprinting Toward Organ Fabrication: Challenges and Future Trends*, 60 IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING. 691, 691 (2013); Phillip Ross, *3D-Printed Hearts From Human Fat Cells? Scientist Says 'Bioprinting' Organs Possible 'In 10 Years'*, INT'L BUS. TIMES (Nov. 23, 2013, 6:28 PM), www.ibtimes.com/3d-printed-hearts-human-fat-cells-scientist-says-bioprinting-organs-possible-10-years-1483568.

78. *See* Mathew Varkey & Anthony Atala, *Organ Bioprinting: A Closer Look at Ethics and Policies*, 5 WAKE FOREST J.L. & POL'Y 275, 277 (2015); Jasper L Tran, *To Bioprint or Not to Bioprint*, 17 N.C. J.L. & TECH. 123, 128 (2015); Frederick Gilbert et al.*, supra* note 18; Park, *supra* note 25.

79. Youngstrom, *supra* note 9, at 98-99.

enables doctors to test the efficacy of specialized drug treatments, without needing to subject patients to harsh clinical trials.[80] Such a possibility helps reduce the drug development costs that are related to preclinical and clinical trials, while at the same time maximizing data collection and analysis and rapidly advancing medical knowledge and access. Three major distinguishing attributes make 3DP an attractive platform for pharmaceutical applications: product complexity, personalization, and on-demand manufacturing.[81]

With respect to complexity, traditional compressed dosage forms are often made from a homogeneous mixture of active and inactive ingredients and are therefore frequently limited to a simple drug-release profile.[82] By digitally controlling the arrangement of the ingredients, 3DP enables a barrier to be created between the active ingredients, allowing them to be printed onto a matrix powder bed in layers that are typically 200 micrometers thick.[83] This introduces a new element into the evolution of dosage forms, which could bring about striking changes for rapid release,[84] modified release,[85] and combination drug products.[86] In addition, given that the structure of a drug product can affect drug release, 3DP enables the printing of complex geometries, which are porous and loaded with multiple drugs throughout but surrounded by barrier layers to modulate the release of products.[87] A practical application in this respect is an FDA-approved drug that disintegrates within seconds because of its

80. *Id*.

81. *See* James Norman et al., *A New Chapter in Pharmaceutical Manufacturing: 3D-Printed Drug Products*, 108 ADVANCED DRUG DELIVERY REV. 39, 42 (2017).

82. C. Lee Ventola, *Medical Applications for 3D Printing: Current and Projected Uses*, 39 PHARMACY & THERAPEUTICS 704, 710 (2014).

83. Iulia Ursan et al., *Three-Dimensional Drug Printing: A Structured Review*, 53 J. AM. PHARMACISTS ASS'N 136, 142 (2013).

84. Nayan G. Solanki et al., *Formulation of 3D Printed Tablet for Rapid Drug Release by Fused Deposition Modeling: Screening Polymers for Drug Release, Drug-Polymer Miscibility and Printability*, 107 J. PHARMACEUTICAL SCI. 390 (2018).

85. Alvaro Goyanes et al., *Development of Modified Release 3D Printed Tablets (Printlets) with Pharmaceutical Excipients Using Additive Manufacturing*, 527 INT'L J. PHARMACEUTICS 21 (2017).

86. Norman et al., *supra* note 81, at 42. Combination drugs are the most complex drug products that combine drugs, devices and/or biological products, leading to safer and more effective treatments either through careful and precise drug targeting, local administration or individualized therapy. *See also* Torsten Kneub, *Drug-Device Combination Products: An Overview*, 81 PHARMAZEUTISCHE INDUSTRIE 533, 533-34 (2019).

87. Natalja Genina et al., *Anti-Tuberculosis Drug Combination for Controlled Oral Delivery Using 3D Printed Compartmental Dosage Forms: From Drug Product Design to* In Vivo *Testing*. 268 J. CONTROLLED RELEASE 40, 40-48 (2017).

porous structure; the drug is printed using a 3DP process, which binds powders without compression.[88]

The design of personalized dosage forms is an aspect of personalized (also referred to as precision) medicine, which involves the tailoring of medical treatment to the individual characteristics of each patient.[89] In the conventional process, tablets are mass-manufactured in a limited number of discrete strengths, usually based on the dose required for a suitable effect in the majority of the population.[90] Given the ease of modifying digital designs in 3DP, the technology renders personalized doses possible through the printing of multiple small and individualized doses, which are tailored to the amount of drug to be delivered at the point of care, according to the patient's mass and metabolism.[91] This capability has benefits in ensuring the accurate dosage of growing children[92] and in personalizing the dosage of highly potent drugs.[93] Personalised dosage can also be enhanced by 3DP's capability to print bespoke and spatially separated material conformations, which assist in fabricating multi-layer constructs (polypills) with variable drug content and/or shape.[94] This is relevant for patients who have multiple chronic diseases. In addition, 3DP enables the printing of pediatric dosage forms that mimic candy or animal shapes, potentially improving children's acceptance of oral forms.[95]

Finally, 3DP's on-demand printing capability, similar to that of a home inkjet printer, is considered "useful in time—or resource—constrained settings such as disaster areas, emergency rooms, operating rooms, ambulances, intensive care units, and military

88. In 2015, the FDA approved SPRITAM, a drug with such property. FDA, HIGHLIGHTS OF PRESCRIBING INFORMATION — SPRITAM (2015), www.accessdata.fda.gov/drugsatfda_docs/label/2015/207958s000lbl.pdf.

89. FDA, PAVING THE WAY FOR PERSONALIZED MEDICINE: FDA'S ROLE IN A NEW ERA OF MEDICAL PRODUCT DEVELOPMENT (2013), www.fdanews.com/ext/resources/files/10/10-28-13-Personalized-Medicine.pdf.

90. Sarah J. Trenfield et al., *3D Printing Pharmaceuticals: Drug Development to Frontline Care*, 39 TRENDS IN PHARMACOLOGICAL SCI. 440, 445 (2018).

91. Norman et al., *supra* note 81, at 46.

92. Katherine Sanderson, *3D Printing and Its Pharmaceutical Application*, INT'L FED'N PHARMACEUTICAL WHOLESALERS, June 2015, at 1.

93. Nicklas Sandler et al., *Inkjet Printing of Drug Substances and Use of Porous Substrates-Towards Individualized Dosing,* 100 J. PHARMACEUTICAL SCI. 3386, 3386-95 (2011).

94. Pamela Robles-Martinez et al., *3D Printing of a Multi-Layered Polypill Containing Six Drugs Using a Novel Stereolithographic Method,* 11 PHARMACEUTICS 1, 2 (2019).

95. Nicolaos Scoutaris et al., *3D Printed "Starmix" Drug Loaded Dosage Forms for Paediatric Applications*, 35 PHARMACEUTICAL RES. 34, Jan. 2018; Univ. Coll. London, *3D Printed Animal-Shaped Tablets for Children*, U. C. LONDON SCHOOL OF PHARMACY (June 23, 2015), www.ucl.ac.uk/pharmacy/pharmacy-news/animal-shaped-tablets.

operations."[96] During the early stages of drug development, on-demand 3DP can help produce multiple drug iterations to test suitability within both animal and human models.[97] In frontline care, on-demand printing can also be useful for low-stability drugs with a tendency to degrade during storage. Such a tendency is insignificant, if printing is carried out for immediate use.[98] Thus, the on-demand printing of drugs has the potential to move centralized drug production towards decentralised facilities (for example, within the clinic, local pharmacies, or even in the patient's home.)[99]

Therefore, in the realm of pharmaceuticals, 3DP brings unique capabilities to the industry, which is already being transformed from the conventional model, where a central plant is designed exclusively for the manufacture of pharmaceutical products, into a manufacturing form that can be encapsulated in a single cartridge, whereupon all the chemical components are digitized into a very low-cost manufacturing format.[100] Nevertheless, as with bioprinting, developments in the application of 3DP to pharmaceuticals are still at a relatively early stage. However, with the FDA's approval of the first 3D-printed drug in 2015, progress is already being made and cutting-edge research is being published daily detailing the new possibilities that 3DP can bring.[101]

The application of 3DP in various areas of health, such as medical devices and instruments, bioprinting, and pharmaceuticals, raises several regulatory, legal, and ethical considerations that touch upon innovation policy and the governance of technology. The scope of this article is limited to analyzing the regulatory dynamics in the use of this technology across diverse areas of application, from the perspective of innovation policy. Recent scholarship on the regulatory aspects of 3DP are largely drawn on the debate as to whether the same regulation should apply to the various arenas of 3DP application or whether there are unique circumstances that necessitate different public policy considerations for the

96. Norman et al., *supra* note 81, at 46.

97. Genina et al., *supra* note 87.

98. Shaban A. Khaled et al., *Desktop 3D Printing of Controlled Release Pharmaceutical Bilayer Tablets*, 461 INT'L J. PHARMACEUTICS 105, 105-11 (2014).

99. Robbert Janssen et al., *TNO: The Impact of 3-D Printing on Supply Chain Management* (Apr. 2014), http://3din.nl/wp-content/uploads/2014/02/TNO-Whitepaper-3-D-Printing-and-Supply-Chain-Management-April-2014-web.pdf.

100. Philip J. Kitson et al., *Digitization of Multistep Organic Synthesis in Reactionware for On-Demand Pharmaceuticals*, 359 SCI. 314, 314 (2018).

101. *See* Sarah J. Trenfield et al., *The Shape of Things to Come: Emerging Applications of 3D Printing in Healthcare*, *in* 3D PRINTING OF PHARMACEUTICALS 14 (Abdul W. Basit et al. eds., 2018).

technology.[102] Underlying the discussion on regulatory and non-regulatory approaches to 3DP is the impact that either will have on advancing innovation while managing risk. The following Section briefly outlines the arguments on each side, which necessitate a closer examination of 3DP from the perspective of innovation governance.

III. MANAGING RISK AND THE GOVERNANCE OF INNOVATION

Innovation refers to the creation and introduction of something new. In this respect, technological innovation has been understood as a conscious attempt to bring about a change in the way man lives through technology. Thus, technological innovation is the process through which technological knowledge is developed and transformed into specific products, processes and services to meet human needs. Technological innovation is known to bring risks that liability laws are conventionally designed to compensate. In general, liability laws protect customers from defective or dangerous products entering the market. However, uncertainty in the legal regime governing liability is commonly acknowledged to have a negative impact on fostering innovation and on the development of new technologies.[103] In recent years, advances in fields such as artificial intelligence and sophisticated robotics (i.e. driverless cars, robot-assisted surgeries, and robot caregivers for the elderly and disabled) have generated lively policy debates over the adequacy of existing liability systems for regulating risks and whether these advances present an opportunity to redesign liability regimes with an impact on technological progress.[104]

Despite difficulties in assessing the implications of liability rules on any emerging technology *ex ante*, the unique circumstances of 3DP have brought to the forefront certain challenges that the technology presents to existing frameworks as it progresses. For

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102. For arguments against a new form of regulation, *see* Adam Thierer, *The Right to Try and the Future of the FDA in the Age of Personalized Medicine*, (Mercatus, Working Paper, 2016). For arguments favoring regulatory intervention, *see* Tran*, supra* note 78; Joseph J. Pantella, *Ready, Print, Fire! Regulating the 3D-Printing Revolution*, 8 J.L. TECH. & INTERNET 1 (2017).

103. *See* Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 285-315 (2008); George L. Priest, *The Effects of Modern Tort Law on Innovation and Economic Growth*, *in* RULES FOR GROWTH: PROMOTING INNOVATION AND GROWTH THROUGH LEGAL REFORM 273 (Ewing Marion Kauffman Foundation, 2011).

104. For example, in 2017, the European Parliament adopted a resolution containing recommendations for EU-wide legislation to regulate "sophisticated robots, bots, androids and other manifestations of artificial intelligence" and to establish legislative instruments related to the liability for their actions. *See* EUR. PARL. DOC. (COM A8-005/2017), www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html (last visited March 19, 2020).

example, the technology brings unique challenges to regulation and liability by disrupting the traditional chain of product manufacture, raising questions over the actual manufacturer of a product and over the product that should be the subject of regulation and liability.[105] These questions involve determining whether the designer of a CAD file is also the manufacturer. If so, and given the ease with which CAD files may be modified, the other question that arises concerns who the designer of the CAD file actually is. Is the manufacturer the person who prints the physical product? Moreover, should the manufacturers of the 3D printer and printing ingredients also be categorised as the manufacturers for regulatory and liability purposes? Thus, which product should be regulated: the 3D printer, the CAD file, or the physical product? The challenges introduced by 3DP are especially pronounced in the area of health, a highly regulated sector. However, before examining the regulatory framework for the application of technology in the health sector, it is necessary to explore the conceptual frameworks that have varying implications for the governance of innovation in 3DP.

A. Permissionless Innovation and Uncertainty of Risk

In examining new technologies that yield innovations with the potential for harm, policy-makers are usually placed in a dilemma of public policy choices. Which yields greater benefits of innovation: allowing the technology to develop and evolve on its own, until harm can be proven to result from the technology, or restricting innovation if any risks are foreseen?[106] Underlying innovation policy choices in this regard are two competing principles: permissionless innovation, derived from the U.S. Internet policy era of the 1990s, and the precautionary principle, having its roots in regulating harm and risks to human health and the environment.

Adam Thierer, widely credited with expounding the principle in relation to 3DP, defines permissionless innovation as:

> the notion that experimentation with new technologies and business models should generally be permitted by default. Unless a compelling case can be made that a new invention will bring serious harm to society, innovation should be

105. *See* Section VI, *infra*, for challenges in determining these for the purpose of tort liability in 3DP applications.

106. *See* Andrea O'Sullivan & Adam Thierer, *Regulators Should Allow the Greatest Space for AI Innovation*, 61 COMM. ACM 33, 33 (Dec. 2018); *see also* Nina Natalia Baranowska, *Public Authority Liability and the Regulation of Nanotechnology: A European Perspective*, 16 CAN. J.L & TECH. 107 (2018).

> allowed to continue unabated and problems, if they develop at all, can be addressed later.[107]

As Thierer and Marcus explain, the concept refers to the idea that unless harm can be proven to result from a technology, innovation should not be stifled through regulation, but rather allowed to occur without permission.[108] This, the above authors argue, is the approach adopted by the U.S. government throughout the 1990s and which they cite as a good lesson to note regarding 3DP.[109] By invoking the freedom to innovate as a significant feature, Chesbrough explains to innovators the efficiency and openness of a permissionless innovation approach, which has led to the creation of "[h]undreds and thousands of iOS and Android apps."[110]

Permissionless innovation's regulatory responses to managing risk in new technologies such as 3DP consist of 'resiliency' and 'adaptation.' These are 'bottom-up' approaches to regulation, which can evolve in response to the challenges that develop.[111] Resiliency aims to address potential technological risk through education, awareness-building, transparency and labelling, empowerment efforts, and industry self-regulation and best practices.[112] Meanwhile, adaptation involves learning to live with risk through trial and error experimentation, experience, coping mechanisms, and social norms.[113] In a permissionless innovation approach to emerging technologies, Thierer argues that the best way of managing risk and ensuring safety in 3DP technology is one that is based on "patience and regulatory humility," stating that "while 3DP could create some new and unique policy challenges, regulation should not be premised on hypothetical worst-case outcomes. Instead, policy-makers need to exercise patience and see if the common law or other existing legal remedies can solve the problems that develop."[114]

Notwithstanding the above, a cautious approach to unrestricted innovation has commonly been advocated, given the substantial risk and illegality that the technology may bring, especially in the health

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107. Adam Thierer, PERMISSIONLESS INNOVATION: THE CONTINUING CASE FOR COMPREHENSIVE TECHNOLOGICAL FREEDOM 1 (rev. and expanded ed. 2016).

108. Thierer & Marcus, *supra* note 31.

109. *Id*. at 821-24.

110. Henry Chesbrough & Marshall Van Alystyne, *Permissionless Innovation*, 58 COMM. ACM 24, 24 (2015). *See also* discussion of the impact of patent regulation for the development of 3DP in the health industry in Youngstrom, *supra* note 9.

111. *See* Thierer, *supra* note 102.

112. *See* Gary E. Marchant & Yvonne A. Stevens, *Resilience: A New Tool in the Risk Governance Toolbox for Emerging Technologies*, 51 U.C. DAVIS L. REV. 233 (2017); *see also* Thierer, *supra* note 102, at 105.

113. Thierer, *supra* note 102, at 106.

114. *Id*. at 119.

field.[115] As Gobble puts it, "where the possibility of harm is real, regulatory structures provide the trust consumers need," adding that "regulatory regimes need to be re-examined in light of emerging technologies."[116] In the context of 3D printing, Yanisky-Ravid and Kwan explain that "3D printing presents a double-edged sword: while it can offer so many benefits to society, it can also cause some potentially disastrous outcomes that should not be ignored."[117]

Consequently, there is an approach to policy-making that pivots on uncertainty, namely, the precautionary approach. There are two versions of this precautionary approach to regulating emerging technologies that seek access to markets: one is rooted in 'strong' precautionary principles and the other in 'weak' precautionary principles.[118] A strong precautionary approach requires regulation as a 'default response,' where risks are known to exist but their nature is unknown or uncertain.[119] Whereas the burden is typically on the government to specify unacceptable risks before regulating, a strong precautionary approach places a burden on the innovator to prove that although the innovation in question could pose a serious threat to human health, the environment, or national security, the associated risks fall within acceptable parameters.[120] In reviewing new drugs, for example, the developer must undertake the process of requesting permission from a regulator by demonstrating that a drug meets certain criteria related to its risks, side effects, and efficacy, before it can be sold.[121]

In a 'weak' precautionary approach, however, regulators act when serious risks arise or when it is unclear that the risks are sufficiently mitigated, thereby allowing regulators to actively monitor and manage harm or risk after allowing the innovation.[122] It is the prescription of criteria, the requirement of proof of having met them, and the continuous monitoring and management in both 'weak' and 'strong' precautionary approaches that the advocates of permissionless innovation criticize on the grounds that such an approach (1) requires that innovators prove the non-existence of

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115. *See* Pantella, *supra* note 102; *see also* 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 (2015).

116. MaryAnne M. Gobble, *Regulating Innovation in the New Economy*, 2015 RES. TECH. MGMT. 62, 62.

117. Shlomit Yanisky-Ravid & Kenneth S. Kwan, *3D Printing the Road Ahead: The Digitization of Products When Public Safety Meets Intellectual Property Rights – A New Model*, 38 CARDOZO L. REV. 101, 107 (2017).

118. *See* Noah M. Sachs, *Rescuing the Strong Precautionary Principle from Its Critics*, 2011 U. ILL. L. REV. 1285, 1295.

119. *Id.* at 1295.

120. *Id.* at 1292.

121. *Id.* at 1308.

122. *See* Pantella, *supra* note 102, at 7.

risks based on imaginary, worst-case scenarios before a product can be made available to the public, and (2) results in regulatory overreach, which impedes free experimentation and innovation, thereby negatively impacting human living standards and general economic welfare.[123] As a result, the precautionary approach in emerging technologies has been criticized for 'restricting innovation,' leading to higher prices for companies and higher-priced products for consumers.[124]

B. The Challenge of Distributed Innovation in 3D Printing

Divergent approaches to the governance of innovation are complicated by the unique set of circumstances in which 3DP innovation takes place, driven by users in a departure from the traditional manufacturer-led innovation path. In this respect, 3DP is a prime example of a distributed technology, which allows a "wide range of users [to] participate in the innovation process."[125] One such process is embodied in the 'maker movement', comprising "a broad range of inventors, designers, and tinkerers who are engaged in making things themselves, whether for fun or profit."[126] In 3DP, users alter and improve mass-produced goods to suit their needs. User innovation plays a significant role in today's economy because it draws control and authority away from manufacturers and places it in the hands of consumers. For example, users of sports equipment frequently customize equipment to fit their physique or enhance their performance.[127] Users may also modify videos, music, games, books, etc. to improve products, create parodies, or recreate items entirely.[128] Von Hippel explains that user contributions are steadily on the rise as computer and communications technology advances.[129] These developments make it easier for users to connect, share, and improve ideas, and ultimately come up with their own

123. *See* Thierer, *supra* note 102, at 106.

124. *See* Steve Clarke, *New Technologies, Common Sense and the Paradoxical Precautionary Principle*, *in* 3 EVALUATING NEW TECHNOLOGIES: METHODOLOGICAL PROBLEMS FOR THE ETHICAL ASSESSMENT OF TECHNOLOGY DEVELOPMENTS 159, 163 (Paul Sollie et al. eds., 2009); *see also* Steve Clarke, *Future Technologies, Dystopic Futures and the Precautionary Principle*, 7 ETHICS & INFO. TECH. 121, 123 (2006).

125. Albert C. Lin, *Herding Cats: Governing Distributed Innovation*, 96 N.C. L. REV. 945, 947 (2018).

126. *Id*. at 954.

127. William W. Fisher III, *The Implications for Law of User Innovation*, 94 MINN. L. REV. 1417, 1423 (2010).

128. *Id.* at 1418-22.

129. ERIC VON HIPPEL, DEMOCRATIZING INNOVATION § 2 (Cambridge, MA: The MIT Press, 2005).

creations.[130] Greater access to technology has also decreased the cost of innovation, so it is less expensive for users to create customized products.

From a regulatory perspective, the problem of distributed innovation in relation to 3DP has been identified by Yanisky-Ravid and Kwan: "[o]nce personal and industrial 3D printers become capable of massive production, it will be difficult to control and prevent widespread personal manufacturing."[131] Desai adds to this, stating that 3D printers "may be difficult to lock down let alone regulate, because they do not require centralization to have a large effect on society."[132] The overall reason for the regulation issue, as Marchant and Wallach explain, is that "no single entity is capable of fully governing any of these multifaceted and rapidly developing fields and the innovative tools and techniques they produce."[133] The above authors also add that with all these different groups, "inconsistent recommendations, duplication of efforts, and general confusion" may result.[134]

In light of the distributed nature of innovation in 3DP, what distinguishes the permissionless from the precautionary approach to innovation is a fundamental difference in innovation governance, whereby the question concerns the point at which a regulatory intervention should occur. One view is in support of the government proactively considering preemptive regulatory actions regarding the use of a technology, while the other advocates restraint until the use of a technology has progressed to a level where existing laws are circumvented. Determining the moment of regulatory intervention is especially crucial in a highly regulated area such as health. Therefore, it is necessary to consider the existing governance frameworks for the various uses of 3DP in health, and to understand the way in which these frameworks respond to the technology's implementation in the different applications. The interaction between existing governance frameworks and the technology highlights the imperatives for and against regulatory intervention based on additional criteria that go beyond those that already exist. Governance frameworks for 3DP applications in health exist under regulatory regimes and, in the absence of regulation, under liability law. The following section discusses the regulatory dimension of existing governance framework for 3DP applications in health.

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130. Eric von Hippel, *Horizontal Innovation Networks – By and for Users*, 16 INDUS. & CORP. CHANGE 293, 294-95 (2007).

131. Yanisky-Ravid & Kwan, *supra* note 117, at 107.

132. Desai, *supra* note 1, at 247.

133. Gary E. Marchant & Wendell Wallach, *Coordinating Technology Governance,* 31 ISSUES IN SCI. & TECH. 43, 43 (2015).

134. *Id*. at 44.

C. The Role of Regulatory Intervention for 3D-Printing Applications in Health

The various applications of 3DP reviewed above largely constitute the development of a new set of diverse products, using a sequence of steps that are defined by the new technology. Across most of the healthcare sector, a regulator will determine if or when a new product should enter a given market. Thus, in terms of the effect of regulation on innovation in emerging technologies, particularly in the area of health, regulation is often considered as a factor that increases the time and cost of innovation and its commercialization, thereby reducing the incentive to innovate.[135]

While some of the literature on the relationship between regulation and innovation has stressed the negative impact of regulation on innovation,[136] regulation is increasingly viewed as "a form of governance instrument, shaping the ways in which actors involved in the innovation process develop, implement and use innovations."[137] Thus, one model assesses the impact of regulation on innovation by taking into account the interaction between a firm's innovation decisions and regulatory measures at the level of the individual firm, while another takes the industry in general, rather than the individual firm, as the reference point for determining the impact of regulation on the structure of the industry, and then relates industry structure to innovation.

In the emerging technologies field, which carries an element of uncertainty among its diverse actors, regulation serves as a system of governance for processes of technological change. Regulation therefore coordinates the activities of the actors and "guide[s] the search" in innovation systems.[138] In the present context, there has been a shift in the regulation of new health technologies from the traditional state-sponsored 'command and control' approach to a

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135. *See, e.g.*, Ariel Dora Stern, *Innovation Under Regulatory Uncertainty: Evidence from Medical Technology*, 145 J. PUB. ECON. 181, 181–200 (2017).

136. *See, e.g.*, Joseph Golec et al., *Pharmaceutical R&D Spending and Threats of Price Regulation*, 45 J. FIN. & QUANTITATIVE ANALYSIS 239 (2010); David Gerard & Lester B. Lave, *Implementing Technology-Forcing Policies: The 1970 Clean Air Act Amendments and the Introduction of Advanced Automotive Emissions Controls in the United States*, 72 TECH. FORECASTING & SOC. CHANGE 761 (2005).

137. David Barberá-Tomás & Jordi Molas-Gallart, *Governance and Technological Change: The Effects of Regulation in Medical Devices*, *in* THE GOVERNANCE OF SOCIO-TECHNICAL SYSTEMS: EXPLAINING CHANGE 96 (Edward Elgar Pub., 2014).

138. Susana Borrás & Jakob Edler, *Three Pillars for a Conceptual Framework*, *in* THE GOVERNANCE OF SOCIO-TECHNICAL SYSTEMS: EXPLAINING CHANGE 23 (Edward Elgar Pub., 2014).

situation where the state 'steers' rather than 'rows.'[139] This shift has been led by the need for regulatory certainty and stability as highly sought-after regulatory 'desirables' over the past 30 years.[140]

Such a preference for a regulatory approach to innovation can be seen in the health sector, with respect to the shift from a tort liability regime towards a federal regulatory approval regime in the U.S. regarding the development of new drugs and devices. The Supreme Court in *Riegel v. Medtronic* held that the Medical Device Amendment of 1976 (MDA) preempted state common law claims that challenged the safety and effectiveness of FDA-approved medical devices.[141] This ruling meant that almost[142] all common law claims would be summarily dismissed once a product was granted FDA approval. In short, federal preemption is considered as the 'carrot,' encouraging manufacturers to seek voluntary FDA approval for safety and effectiveness, while tort law is the 'stick.'[143]

Although analogous preemption against common law claims does not exist in Canada, compliance with regulatory requirements generally serves as a defence, especially in circumstances where a statute or regulation has required a product to be manufactured or designed in a specific way that is allegedly faulty.[144] Given these

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139. *See* Anne-Maree Farrell et al., *Regulatory 'Desirables' for New Health Technologies*, 21 MED. L. REV. 1, 4-5 (2013); *see also* Michael Moran, THE BRITISH REGULATORY STATE: HIGH MODERNISM AND HYPER-INNOVATION 6 (Oxford: Oxford Univ. Press, 2003).

140. *Id*. at 2.

141. Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008).

142. The federal preemption clause doesn't prevent claims based on a state's medical device regulations that "parallel[s]" a federal regulation. *Id*. Also, claims can still be lodged against doctors who are negligent or strictly liable in the use of a medical device. McMurtrie v. Iolab Corp., 914 F. Supp. 1372, 1373 (E.D. La. 1995) (holding that plaintiff's state law claims of negligence and strict liability were not preempted by federal law). Also, preemption is available to FDA approvals that underwent an oversight of "rigorous regime." *See* David Brennan, *Federal Preemption of All State Law Tort Claims in* Riegel v. Medtronic*: A Need to Undo a Serious Wrong*, 36 W. ST. U.L. REV. 137 (2008).

143. Marilyn Uzdavines, *Dying for a Solution: The Regulation of Medical Devices Falls Short in the 21st Century Cures Act*, 18 NEV. L.J. 629, 648-53 (2018). This characterization is considering that the relative costs of undergoing FDA review for approval or complying with FDA regulations are small when compared to the potential costs of mass tort lawsuits and punitive damages. *See* Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 953–54 (1996); Neil M. Issa, *Preemption of State Law Claims Involving Medical Devices: Why Increasing Liability for Manufacturers Is a Perilous but Pivotal Proposition*, 17 VAND. J. ENT. & TECH. 1085 (2015).

144. While non-compliance to regulatory requirements may generally be evidence of a failure to exercise a reasonable standard of care, compliance is usually not a defense, but it will always be some evidence as to the reasonableness of a defendant's behavior. *See generally* Waleska Vernon, *The Canadian*

variations in approach, it is necessary to examine how various applications of 3DP are considered under the regulatory rules in the U.S. and Canada. In light of the fact that most 3DP applications to date have received approval under the FDA, the following discussion will consider how the FDA approaches 3DP in its regulatory oversight.

IV. 3D PRINTING UNDER THE REGULATORY PATHWAYS OF THE FOOD AND DRUG ADMINISTRATION

As a government entity that is responsible for protecting public health, the FDA regulates medical products by ensuring the safety, efficacy, and security of drugs, biological products, and medical devices.[145] The FDA identifies one of its mandates as "helping to speed innovations that make medical products more effective, safer, and more affordable."[146] In the context of 3DP, the FDA recognizes its wide-ranging applications, categorizing them as either medical devices, biologics, or drugs.[147]

In the early stages of the technology's development, it was argued that a 3D printer itself could qualify as a medical device under the FDA's definition: "an instrument, apparatus, implement, machine [or] contrivance . . . which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[148] Given the potential for the advanced use of 3D printers in medical applications and their impact on the final output, it could be argued that a 3D printer should also be classed as a medical device in its own right.[149] However, the FDA seems to have adopted a different interpretation and has gone beyond this classification, considering that the 'intended purpose' of a 3D printer is not to serve as a medical device but rather as a non-medical manufacturing tool.[150] Thus, 3D

Perspective: Trends in Drug and Medical Device Class Actions in Canada, 61 FOOD & DRUG L.J. 569 (2006).

145. *See What We Do*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2018), www.fda.gov/about-fda/what-we-do.

146. *Id*.

147. *See 3D Printing of Medical Devices*, U.S. FOOD & DRUG ADMIN. (Mar. 26, 2020), www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices.

148. *Is The Product A Medical Device?*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2019) www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm; *see also* Ariel M. Nissan, *Regulating the Three-Dimensional Future: How the FDA Should Structure a Regulatory Mechanism for Additive Manufacturing (3D Printing),* 22 B.U.J. SCI. & TECH. L. 267, 279 (2016).

149. *See* Davies et al., *supra* note 26, at 2.

150. Technical Considerations for Additive Manufactured Devices, Draft Guidance for Industry and Food and Drug Administration Staff; Availability 81 Fed. Reg. 28877 (May 10, 2016).

applications in health fall under the regulatory purview of the FDA as either medical devices, biologics, or drugs, but the 3D printer does not yet seem to be recognized as a manufacturing tool. This is significant, because if a 3D printer were to be recognized as a manufacturing tool, constituting a component of the manufacturing process for devices, it would be covered and regulated by the Quality System (QS) and Good Manufacturing Practice (GMP) regulations.[151] However, while the categorization of 3DP outputs in the 'devices' category seems to exclude the 3D printer from being regulated as a manufacturing tool, its applications in the categories of 'biologics' and 'drugs' may still necessitate its regulation as such. Therefore, in order to understand the regulatory reach of the FDA over 3DP, it is necessary to examine the FDA's consideration of the technology under each of these categories.

A. Medical Devices

In terms of 3DP regulation, the FDA states that it regulates 3DP medical devices "through the same pathways as traditional medical devices; therefore, [the devices] are evaluated according to the safety and effectiveness information submitted to [the FDA] by the manufacturer."[152] The FDA regulates all medical devices according to Class characterizations: Class I, Class II, or Class III. There are different standards and regulations for devices falling into each of these classes, based on the level of risk that they pose and the level of control needed to ensure safety and efficacy. Class I devices are usually simple, like bandages or tongue depressors,[153] which imply a low level of risk and therefore require low regulatory control. Class II devices carry higher risk and require greater regulatory control.[154] Finally, Class III devices bear the greatest risk and require an approval process. According to the FDA, "a Class III device [is] one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential,

151. *See Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2018), www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ [hereinafter *Quality System Regulation*].

152. *Medical Applications of 3D Printing*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2017), www.fda.gov/medical-devices/3d-printing-medical-devices/medical-applications-3d-printing.

153. *See Product Classification*, U.S. FOOD & DRUG ADMIN. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm.

154. Examples of Class II devices include powered wheelchairs and some pregnancy test kits. See *Consumers (Medical Devices)*, U.S. FOOD & DRUG ADMIN. (Apr. 14, 2020), https://www.fda.gov/medical-devices/resources-you-medical-devices/consumers-medical-devices.

unreasonable risk of illness or injury."[155] Medical devices classified as such must follow the regulatory pathways of either 'Premarket Approval' (PMA), 'Premarket Notification,' or 'Exemptions.' Medical devices manufactured using 3DP can be assessed under any of these regulatory pathways, irrespective of their classification. In applications so far, the vast majority of 3DP-based medical devices are assessed either through the Premarket Notification or Exemption category; however, the potential for assessment under the PMA pathway exists as 3DP continues to be used in advanced applications. The following discussion will briefly examine each of these regulatory pathways, before looking at the FDA's consideration of 3DP applications under these pathways.

1. Premarket Approval

According to the FDA, "[p]remarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices," which adds to the fact that the process "is, in effect, a private license granted to the applicant for marketing a particular medical device."[156] Applied to all Class III devices, unless they fall into the category of 'Exemptions,' PMA involves the manufacturer submitting all clinical data and support for the claims that they make about the device itself to the FDA.[157] This pathway is reserved for devices that do not resemble anything else that is currently available on the market. As such, it is an extensive process, wherein the manufacturer itself must substantiate that a device's biocompatibility, physical characteristics, efficacy, and risk to patients is appropriate.[158] The PMA process also includes control of the actual manufacture of devices, including methods of designing, purchasing, and packaging through QS regulation or GMPs.[159]

2. Premarket Notification

Premarket Notification (also referred to as the '510(k) process') is a less rigorous approval process than the PMA, which all Class I, II, and III devices must undergo, unless exempted.[160] It consists of

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155. *PMA Approvals*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2018), www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals.

156. *Id.*

157. 21 C.F.R. § 814.20 (2019).

158. *Id*. *See* Rachel Dykema, *Printing for the Perfect Fit: Balancing FDA Regulation of 3D Printed Medical Devices*, 2019 WIS. L. REV. 593, 604 (2019).

159. *Quality System Regulation*, *supra* note 151.

160. There are certain exemptions for Class I/II products from the 510(k) process. *See Medical Device Exemptions 510(k) and GMP Requirements,* U.S. FOOD & DRUG ADMIN. (Apr. 13, 2020),

"[receiving] an order, in the form of a letter, from the FDA which finds the device to be substantially equivalent (SE) [to another device which is already on the market] and states that the device can be marketed in the U.S.," thereby "[clearing] the device for commercial distribution."[161] In this category, the threshold of approval is the determination that the 'reliability and safety' of the device for which approval is sought is 'substantially equivalent' to that of a device that has already been legally marketed. Thus, no independent clinical trials, site monitoring or other essential FDA oversight is required to demonstrate reasonable assurance of the safety and effectiveness of a device for its intended use under the PMA process.[162]

3. Exemptions

While the PMA and 510(k) processes are the primary approval pathways for ensuring the safety, reliability and effectiveness of most devices before their release onto the market, there are exemptions from these processes in certain cases, where the pathways may limit access to patient care. These exemptions include the humanitarian device exemption,[163] which is an incentive for the development of devices for the treatment or diagnosis of rare diseases or conditions; the emergency use exemption,[164] when a need arises to use a device in a life-threatening situation, which requires that the patient be treated immediately; the compassionate use exemption,[165] when the treating physician believes that the device will be of benefit in diagnosing, monitoring, or treating a disease or condition; and most pertinently, the custom device exemption (CDE). Relevant to 3DP, given the 'custom' nature of many 3D-printed devices, the CDE provides approval for individualized Class III devices under certain conditions.[166]

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www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm; *see also Premarket Notification*, U.S. FOOD & DRUG ADMIN., www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

161. *See* Premarket Notification*, supra* note 160.

162. *See* Brennan, *supra* note 142, at 146.

163. 21 C.F.R. § 814.100 (2019).

164. *Expanded Access for Medical Devices*, U.S. FOOD & DRUG ADMIN., www.fda.gov/medical-devices/device-advice-investigational-device-exemption-ide/expanded-access-medical-devices#compassionate.

165. *Id*.

166. In order to qualify for the CDE, the device must meet several requirements, including:

1. The device is created or modified in compliance with an order of a physician or dentist.

2. It deviates from performance standards of other similar devices.

3. It is not generally available in its finished form.

4. It is specific to an individualized pathology that no other device is domestically available to treat.

4. 3D Printing Applications in Medical Devices

Given the FDA's position in treating 3D-printed devices as their non-3D printed equivalents, its approval database does not include information on claiming the use of 3DP as a manufacturing process. However, an examination of press releases and journal articles revealed that by 2015, the FDA had approved 85 3D-printed medical devices,[167] and as of December 2017, more than 100 3D-printed devices currently on the market had been reviewed by the FDA.[168] Applications such as hearing aids, cranial plates, facial implants, orthopedic implants, spinal cages, knee trays, dental devices, and custom surgical guides have already been approved.[169] The FDA has evaluated the safety and efficacy of these devices without considering their manufacturing process. This evaluation has mainly been based on whether such 3D-printed devices are at least substantially equivalent to conventionally manufactured counterparts under the 510(k) process.[170] When the FDA requires additional information, like the type of printer used or the material inputs into the 3D-printed product, this information is used to qualify and evaluate the product in the same way that the manufacturing device and input materials are qualified and evaluated in any other manufacturing process.[171] In 2012, the FDA

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5. It is intended to meet the needs of an individual patient.

6. It is assembled from components or manufactured and finished on a case-by-case basis.

7. It may have common or standardized design characteristics.

8. It is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigation would be impractical.

9. The device may be manufactured at a rate of no more than 5 units per year.

See 21 U.S.C. § 360j(b) (2006); U.S. FOOD & DRUG ADMIN., CUSTOM DEVICE EXEMPTION: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, FOOD DRUG COSM. L. REP. P 350784 (Jan. 14, 2014) (updated Sep. 24, 2014).

167. *See* Davies et al., *supra* note 26, at 8.

168. *Statement by FDA Commissioner Scott Gottlieb, M.D., on FDA Ushering in New Era of 3D Printing of Medical Products; Provides Guidance to Manufacturers of Medical Devices*, U.S. FOOD & DRUG ADMIN. (2017), www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fda-ushering-new-era-3d-printing-medical-products.

169. *See* Steve Pollack, Presentation, *U.S. Food & Drug Admin., 3D Printing: What We Know And What We Don't*, https://perma.cc/63Z6-SVC2 (listing custom implants (skull plates, orthopedic implants, and customized emergency devices); orthopedic devices (acetabular cups for hip replacements, spinal cages, and knee trays); and dental devices (temporary bridges and reconstructive implants)).

170. *See* Nissan, *supra* note 148, at 281-82.

171. *See* Natalija Bacic et al., *Responsible Use of High-Risk Medical Devices: The Example of 3D Printed Medical Devices*, 297 BELG. HEALTH CARE KNOWLEDGE CENTRE (KCE) 1, 16-17 (2018) (noting that in the FDA's

approved a 3D-printed trachea for a six-week old infant, applying the emergency use exemption.[172] However, this approval did not elicit any new biocompatibility concerns, since the device was made of the same material as is used in sutures.[173] The success of printing with a bioresorbable material, which allowed the device to dissolve as the infant's own cells produced a cartilage matrix, led to further research into the development of a similar device, which is currently being considered by the FDA for humanitarian use.[174]

So far, most of the FDA's 3DP approvals have been issued via the 510(k) process, within the boundaries of substantial equivalence for Class I and II devices. However, the technology's unique capability to replicate the complex contours of a human structure, such as the skull, and to enable surface detail that promotes cell growth and attachment to be captured has motivated the research and development of customizable and implantable 3D-printed medical devices.[175] Such applications, if fully developed, result in new devices, which mainly fall within the Class III device category. In addition, while printing devices at a central facility and shipping them out to specific locations allows the quality, biocompatibility, and sterility of the materials to be regulated, decentralized printing in 3DP technology poses a unique challenge because the structure of some devices includes a porous coating, with the potential to trap excess printing materials that need to be sterilized correctly.[176]

Thus, most of the research and development on medical devices in the Class III category push the boundaries of substantial equivalence and look for opportunities for approval through the emergency use, humanitarian use, or CDE pathways. This is a demonstration of the novel content of 3DP technology, whereby it presents challenges to evaluating the safety and effectiveness of devices that are manufactured using the technology under existing

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assessment of medical devices manufactured using 3DP, "[I]nput material is qualified and evaluated in

the same way as the input material of any other manufacturing process using appropriate quality control systems").

172. David A. Zopf et al., *Bioresorbable Airway Splint Created with a Three-Dimensional Printer*, 368 NEW ENG. J. MED. 2043, 2043 (2013).

173. *Id*.

174. *See* Robert J. Morrison et al., *Regulatory Considerations in the Design and Manufacturing of Implantable 3D-Printed Medical Devices*, CLINICAL & TRANSLATIONAL SCI. 594, 595 (2015).

175. In 2013, Oxford Performance Materials conducted an implantation for a man in which 3D printed plates replaced 75% of his skull. *Oxford Performance Materials Named One of Fast Company's Most Innovative Companies of 2016*, OXFORD PERFORMANCE MATERIALS (Mar. 8, 2016), www.oxfordpm.com/oxford-performance-materials-named-one-fast-companys-mostinnovative-companies-2016.

176. Davies et al., *supra* note 26.

approval processes.[177] In recognition of this, the FDA is engaged in efforts that are necessitated by the unique aspects of 3DP, as opposed to traditional methods of manufacturing medical devices.

In 2017, the FDA released its initial guidance on 'technical considerations' for 3D-printed medical devices.[178] While restricted to medical devices, thereby excluding biologics and pharmaceuticals from coverage, the guidance covers quality considerations, manufacturing considerations, and the information required for the submission of regulatory notifications based on device classifications.[179] The guidance is meant to supplement, not replace, existing applicable guidance, and as stated, does "not establish legally enforceable responsibilities."[180] The FDA noted that this guidance "describe[s] the Agency's current thinking" about the technology and that it would evolve as understanding developed with regard to factors such as non-traditional manufacturing sites and supply chains, the use of biological printing material, and point-of-care device considerations.[181] In addition to issuing guidance, the FDA conducts primary research at several sites to help understand the impact of 3DP on the safety and quality of medical technologies in order to inform policy development and guidance updates.[182] In its Emerging Technology Program, the FDA also provides support for innovation and access through early engagement with manufacturers hoping to bring their 3D-printed products to the market.[183]

As discussed above, 3DP challenges the scope of existing regulatory approval paths for medical devices. Despite the FDA's position, namely that it does not regulate 3D printers as medical devices or treat 3D-printed devices any differently from those produced using traditional manufacturing methods, approval for 3D-printed devices has been increasingly granted under the exemption pathways. In addition, the FDA engages in the development of guidance and other activities, which consider the unique features of 3DP as a manufacturing device. These efforts point to the future development of a regulatory pathway that is

177. *See* Joan E. Adamo et al., *Regulatory Interfaces Surrounding the Growing Field of Additive Manufacturing of Medical Devices and Biological Products*, 2 J. CLINICAL & TRANSLATIONAL SCI. 301, 301 (2018).

178. U.S. FOOD & DRUG ADMIN., TECHNICAL CONSIDERATIONS FOR ADDITIVE MANUFACTURED MEDICAL DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2017), www.fda.gov/media/97633/download.

179. *Id*.

180. *Id*.

181. *Id*. *See also* Mason et al., *supra* note 18.

182. *See* U.S. FOOD & DRUG ADMIN., *supra* note 178.

183. *See Emerging Technology Program*, U.S. FOOD & DRUG ADMIN., www.fda.gov/about-fda/center-drug-evaluation-and-research/emerging-technology-program (last visited Mar. 14, 2020).

uniquely suited to 3DP applications. However, the quandary introduced by 3DP into existing regulatory frameworks is more pronounced in the realm of applications other than medical devices, namely biologics and pharmaceuticals.

B. Biologics

The 'biologics' regulatory category includes the use or incorporation of biological, cellular, or tissue-based products in 3DP.[184] Thus, the creation, use, and distribution of 3D-printed organs or implants, which incorporate biological, cellular, or tissue elements through bioprinting, present a regulatory quandary that differs from the problems arising with regard to medical devices. Although the technology has not matured enough to bring these challenges to the fore, two aspects of bioprinting can be identified as posing regulatory challenges: the printing of organs and the printing of implants that incorporate biological, cellular, or tissue materials.

The latter category ordinarily follows the regulatory pathways for medical devices, as discussed above and mainly in the Class III category. However, the unique capability of 3DP in enabling such implants to be printed based on biological, cellular, and tissue inputs places them outside such regulatory purview. The bioprinting of organs, if achieved through future developments in 3D printing, raises the question of who has regulatory competence: the FDA or the federal body that handles organ donations—the Organ Procurement and Transplantation Network (OPTN)—along with state-level organ-procurement organizations (OPOs).[185] It may be argued that the latter's clear mandate for the examination and distribution of donated organs from *living* or *deceased* donors and an absence of reference to artificial organs plays in favor of the FDA's assumption of regulatory competence.[186] The definition of 'human organs' under the National Organ Transplant Act of 1984 (NOTA) is ordinarily understood to refer to organs "from a human donor as an anatomical/structural unit" in a form that is "minimally

184. U.S. FOOD & DRUG ADMIN., *supra* note 178.

185. The OPTN was created to facilitate the process of matching donor organs to patients while state-level OPOs establish criteria for acceptable donor organs. *See About the OPTN*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, http://optn.transplant.hrsa.gov/govemance/about-the-optn/ (last visited Mar. 14, 2020); ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, OPTN Policies (2020), https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.

186. *See* About the OPTN, *supra* note 185 (stating the National Organ Transplant Act of 1984 (NOTA) defines "human organ" as "the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.").

manipulated (i.e. processing that does not alter the original relevant characteristics of the organ)."[187] In addition, the FDA's competence in regulating bioprinted organs can be established through analogy with its existing mandate for medical implants (such as the artificial heart), which have a variety of functions, such as replacing body parts or supporting organs and tissues.[188]

Within the regulatory ambit of the FDA, bioprinted organs and implants face an uncertain regulatory fit, due to their borderline nature as "part medical device, part biological," in addition to their individualized, custom-made feature, which suggests their potential for exemption.[189] The FDA has excluded bioprinted products from its guidance on medical devices, on the ground that they "may necessitate additional regulatory and manufacturing process considerations and/or different regulatory pathways."[190]

While it does not currently provide any guidance on the subject, the FDA seems to address the use or incorporation of biological, cellular, or tissue-based products in 3DP within its considerations under the regenerative medicine umbrella. Its guidelines refer to the Center for Biologics Evaluation and Research (CBER) when attempting to assess 3DP issues pertaining to products containing biologics, cells, or tissue.[191] Despite holding an informative conference on 'Innovations in 3D Bioprinting,' the CBER has not engaged in developing any guidance for the approval of bioprinted organs or implants.[192] Thus, innovations in bioprinted organs and implants that are currently at the level of clinical research lack a regulatory framework to assess the uncertainty of harm through approval. In this context, if research and development progress to the level of new bioprinted products, the absence of a regulatory framework for approval could prove to be an obstacle to patients' access. Such a lack of regulatory fit can also be observed with 3DP applications in pharmaceutical drugs.

C. Pharmaceuticals

187. *See* detailed discussion of the qualification of human organs as different from 3D printed organs in Elizabeth Kelly, *FDA Regulation of 3D-Printed Organs and Associated Ethical Challenges*, 166 U. PA. L. REV. 523, 523-25 (2018).

188. *See* Park, *supra* note 25, at 198.

189. *See* Gilbert et al., *supra* note 18, at 79, 84-85.

190. *See* U.S. FOOD & DRUG ADMIN., *supra* note 178, at 2.

191. *See 3D Printing of Medical Devices,* U.S. FOOD & DRUG ADMIN., www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices (last visited Mar. 14, 2020).

192. On March 2016, CBER convened a conference which focused on "3D Modeling and Printing of Tissues and Organs." *See* 2016 FDA FISCAL YEAR DIRECTOR REP., https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/fy-2016-report-director.

In pharmaceuticals, 3D-printing applications follow a separate regulatory pathway from those taken by medical devices and biologics. There are three pathways for pharmaceuticals used by the FDA's Center for Drug Evaluation and Research (CDER) when issuing approvals under the Federal Food, Drug, and Cosmetic Act: the 505(b)(1) and 505(b)(2) pathways for new drugs and the 505(j) pathway for generic drugs.[193]

In 2015, Spritam (levetiracetam), an anti-seizure medication used to treat epilepsy, became the first 3D-printed drug to be approved in the US.[194] Levetiracetam itself is not a new formula; the process of producing it in 3D-printed form (called 'ZipDose') merely improved upon a disintegrating process.[195] Thus, the CDER approved the drug according to the existing 505(b)(2) regulatory pathway as "a new drug application (NDA)" for large-scale industrial production.[196] While this is the only FDA-approved pharmaceutical to date, Trenfield et al. provide a list of at least 20 other pharmaceuticals that have been produced using 3DP technology, which, despite not being approved, demonstrate how the technology can be used to produce many different pharmaceuticals.[197] Even though the existing regulatory pathways are flexible enough to allow the integration of 3DP as a manufacturing tool for complex drugs at an industrial level of production,[198] as discussed above, the main attraction of 3DP applications in pharmaceuticals is their potential to manufacture highly personalized and on-demand drugs that "…optimize beneficial effects while reducing side effects, made in real-time using digital recipes."[199]

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193. *See* Akm Khairuzzaman, *Regulatory Perspectives on 3D Printing in Pharmaceuticals*, *in* 3D PRINTING OF PHARMACEUTICALS 215, 217 (Abdul W. Basit & Simon Gaisford eds., 2018).

194. Robert J. Szczerba, *FDA Approves First 3-D Printed Drug*, FORBES (Aug. 4, 2015, 8:24 AM), www.forbes.com/sites/robertszczerba/2015/08/04/fda-approves-first-3-d-printed-drug/#3118fad55675.

195. Jennifer Kite-Powell, *FDA Approved 3D Printed Drug Available In The US*, FORBES (Mar. 22, 2016, 4:38 PM), www.forbes.com/sites/jenniferhicks/2016/03/22/fda-approved-3d-printed-drug-available-in-the-us/#23ea7abb666b.

196. *Applications Covered by Section 505(b)(2)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2 (last visited Mar. 14, 2020); Maisa R. P. Araújo et al., *The Digital Pharmacies Era: How 3D Printing Technology Using Fused Deposition Can Become a Reality*, PHARMACEUTICS, Mar. 19, 2019, at 1, 9.

197. Trenfield et al., *supra* note 90, at 441-43.

198. Khairuzzaman, *supra* note 193, at 219 (noting that "[existing] pathways are flexible enough to address new technologies").

199. Ivar Mendez, *3D Printers: A Revolutionary Frontier for Medicine*, THE CONVERSATION (Sep. 19, 2017, 6:34 PM), https://theconversation.com/3d-printers-a-revolutionary-frontier-for-medicine-83031.

From a regulatory perspective, the challenge stems from unique questions raised by 3DP as a distributed manufacturing process for the personalized and on-demand printing of drugs: namely, how to ensure quality control for 3D-printed dosage forms; how to define methods of necessary process control in the 3D-printing of dosages when undertaking personalized drug-printing; and how the on-demand 3DP of pharmaceuticals may be realised in practice.[200] While existing regulatory pathways address these questions via established pharmaceutical processes, which have integrated the quality and safety assessment of dosages,[201] 3DP requires evaluation to prevent the unique risks that can be remedied through controls of raw materials, processes, and defects in the final product.[202] Therefore, unlike medical devices, 3DP in the field of pharmaceuticals inherently involves unique considerations and variables through which the final product is determined by inputs and processes, as well as by unique features of modes of operation, material inclusion, and post-processing techniques in relation to 3DP.[203]

Taking into account the above considerations, the CDER's Office of Pharmaceutical Quality has, through its Office of Testing and Research, engaged in research on the technical aspects of applying 3DP to drug products, in addition to developing a 'risk map' of variation in the ingredients used in traditional manufacturing from those that apply to 3DP processes.[204] The CDER is also working with the Centre for Devices and Radiological Health to identify the regulatory issues surrounding the extent of control over 3D printers, printing materials, intermediates, and products, in order to ensure quality in drug products.[205]

As can be seen from the discussion in this Section, the FDA is increasingly leaning towards regulatory intervention for 3DP innovations in health, but in several different ways. For example, in terms of medical devices, its position is that the various applications can be assessed under existing approval pathways, without any need

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200. *See* Trenfield et al., *supra* note 90, at 447.

201. *See* Norman et al., *supra* note 81, at 40-42.

202. *See id.* at 47-48.

203. *See* Tim Feuerbach et al., *Characterization of Fused Deposition Modeling 3D Printers for Pharmaceutical and Medical Applications*, 23 PHARMACEUTICAL DEV. & TECH. 1136, 1136–45 (2018); Pravin Shende & Sudhir Agrawal, *Integration of 3D Printing with Dosage Forms: A New Perspective for Modern Healthcare*, 107 BIOMEDICINE PHARMACOTHERAPY 146, 146–54 (2018).

204. Ahmed Zidan, *CDER Researchers Explore the Promise and Potential of 3D Printed Pharmaceuticals*, U.S. FOOD & DRUG ADMIN. (2011), www.fda.gov/drugs/news-events-human-drugs/cder-researchers-explore-promise-and-potential-3d-printed-pharmaceuticals.

205. *Id.*; *see also* Pinak Khatri et al., *Formulation Strategies for Solid Oral Dosage Form Using 3D Printing Technology: A Mini-Review*, 46 J. DRUG DELIVERY SCI. & TECH. 148, 154 (2018).

for special consideration of 3DP as a manufacturing technology. However, existing pathways are increasingly pushed to the limit, and some crucial innovations have acquired approval through exemption pathways. Class III devices manufactured using 3DP require additional scrutiny as part of the 'rigorous' PMA regime, which warrants preemption from common law claims that challenge the safety and effectiveness of medical devices.[206] In the context of bioprinting, the FDA's regulatory reach is necessitated as a matter of competence, having regard to the unique capability of 3DP technology to replicate organs and enable bio-implants. The distinctively risk-based assessment of 3DP as a manufacturing technology for pharmaceuticals necessitates the FDA's regulatory intervention.

Hence, from the perspective of innovation governance, the set of circumstances in which innovative 3DP applications are undertaken suggests a precautionary intervention to guide the unique capabilities of 3DP technology *ex ante*. The permissionless innovation perspective capitalizes on the distributed features of the technology to advocate for *ex post* thinking, which favours existing liability and self-regulatory regimes to guide the technology's development. Before addressing the relevance of such regimes, the next Section will examine the regulatory environment for 3DP applications in Canada, which provides an important lesson in targeting a class of devices for additional scrutiny.

V. REGULATION OF 3D PRINTING IN CANADA

As with the US, Canada has also begun taking the necessary steps to regulate the use of 3D printing, with more consideration given to the 3DP of medical devices. With respect to the regulation of medical devices and drugs in general, the Canadian Government explains that

> [t]he Therapeutic Products Directorate (TPD) applies the Food and Drug Regulations and the Medical Devices Regulations under the authority of the Food and Drugs Act to ensure that pharmaceutical drugs and medical devices

206. The U.S. Supreme Court preempted medical devices from common law claims challenging the safety and effectiveness of medical devices through reliance on the "rigorous regime" of PMA as adequate oversight on Class III medical devices. *See* Sadaf Bathaee, *The Supreme Court's Bright Line Ruling in* Riegel v. Medtronic, Inc. *Gives Manufacturers of Defective Medical Devices Broad Immunity*, 29 J. NAT'L ASS'N ADMIN. L. JUDICIARY 645, 662 (2009).

> offered for sale in Canada are safe, effective and of high quality.[207]

Thus, the Food and Drugs Act and the Medical Devices Regulations provide the regulatory framework for medical devices, with the latter offering a more in-depth explanation of what constitute medical devices, their classifications, and their licensing requirements.

Medical devices are classified according to the Canadian Risk-Based Classification System (RBCS) under the aegis of the TPD of Health Canada.[208] As in the US, devices are classified from I to IV by means of specific classification rules, with Class I representing the lowest risk and Class IV representing the highest.[209] All Class III and IV medical devices require a review of evidence of their safety and effectiveness before they are authorized for use.[210] The Medical Devices Regulation sets out requirements for manufacturers' obligations, safety, effectiveness, labelling, and advertising for their licensing in each class.[211] The Regulations also set standards for the prescription and therapeutic use of 'custom-made' devices.[212] According to the TPD, the Medical Device Bureau (MDB) is entrusted with the review of applications for new and amended licenses for medical devices in addition to providing expedited access to medical devices in cases of emergency while also contributing to the development of policy and regulation regarding new medical devices.[213]

With regard to 3DP, Health Canada recognises the new challenges that customized medical devices can present for

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207. *Legislation and Guidelines - Medical Devices*, GOV'T OF CANADA (Apr. 12, 2011), www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/legislation-guidelines.html; *see also* Yi-Jung Chen et al., *A Comparative Study of Medical Device Regulations: US, Europe, Canada and Taiwan,* 52 THERAPEUTIC INNOVATION & REG. SCI. 62, 65 (2018).

208. Sandeep K. Gupta, *Medical Device Regulations: A Current Perspective*, 8 J. YOUNG PHARMACISTS 6, 8 (2016).

209. Medical Devices Regulations, SOR/98-282, s.6. (Can.).

210. *Id*., s.1.

211. *Id.*, s.9-24.

212. A custom-made device is defined in s.1 of the Regulations as:

> …a medical device, other than a mass-produced medical device, that … is manufactured in accordance with a medical professional's written direction giving its design characteristics [and] differs from medical devices generally available for sale [and] is [either] for the sole use of a particular patient of that professional [or] for use by that professional to meet special needs arising in the course of his or her practice." *Id.*, s.1.

213. *Therapeutic Products Directorate*, GOV'T OF CANADA, www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/therapeutic-products-directorate.html#a4.

regulators.[214] In order to address these challenges, it published new guidance which describes "the information and evidence that companies should provide when applying for medical device license for a 3D printed implantable medical device."[215] The document, *Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing*, was released on April 30, 2019, and represents the Canadian equivalent of the U.S. *Technical Considerations for Additive Manufactured Medical Devices* from 2017.[216] It is explained as "aligning closely with established international advisory on the subject," and "has been deemed the 'first phase' of a developing 3DP policy for the nation."[217]

From a regulatory framework perspective, the Health Canada guidance document differs from the FDA's approach to 3DP in several ways but relates to it in others. In terms of scope, it is limited to providing guidance for manufacturers (including hospitals that produce 3D-printed devices for distribution outside their organizations) regarding "evidence to support pre-market Class III and IV license applications for implantable medical devices manufactured by 3DP processes" and is supplementary to existing evidence requirements.[218] This excludes many non-implantable medical devices and instruments that could be 3D-printed, in addition to custom-made devices that are explicitly excluded.[219] Similar to the FDA's guidance, the document does not cover bioprinted organs, implants, or pharmaceuticals.

In line with the FDA's approach of not regulating the 3D printer as a manufacturing tool, the guidance states: "[t]he same evidence requirements apply to 3D printed devices as those for non-3D printed devices in terms of their characterization and evidence of safety and effectiveness, including physical and mechanical bench testing, biocompatibility testing, software validation and clinical evidence.[220]

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214. *Increasing Access To 3D Printed Implantable Medical Devices for Patients,* HEALTH CANADA (Apr. 30, 2019), www.canada.ca/en/health-canada/news/2019/04/increasing-access-to-3d-printed-implantable-medical-devices-for-patients.html.

215. *Id.*

216. *Guidance Document - Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing* HEALTH CANADA (Apr. 30, 2019), www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/3d-licensing-requirements/document.html.

217. Beau Jackson, *Health Canada Aligns with FDA Guidance for 3D Printed Medical Devices*, 3D PRINTING INDUSTRY (May 14, 2019, 11:31 AM), https://3dprintingindustry.com/news/health-canada-aligns-with-fda-guidance-for-3d-printed-medical-devices-155378/.

218. HEALTH CANADA, *supra* note 216.

219. *Id.* at art. 1.2.

220. *Id.*

Unlike the FDA's 510(k) process of solely proving substantial equivalence of a finished device to one that is already available on the market, irrespective of the manufacturing process, the Health Canada guidance includes a policy under which manufacturers must state whether 3DP was used to produce the entire device or just a component of it.[221] As additional information must be submitted for devices that incorporate 3DP in either form, as part of the evidence demonstrating the safety and effectiveness of the 3D-printed device, the Canadian guidance is more prescriptive than the FDA's, and takes into account the unique features of 3DP technology in its approval of devices. Thus, although it is applicable to a narrower category of devices, the Canadian document provides regulatory guidance, which requires a full account of the safety of the machinery, materials and processes involved in building therapeutic devices in Class III or IV, over and above the baseline reporting requirements for safety and efficacy.

From the perspective of innovation governance, Health Canada's approach provides the desired regulatory certainty for positively coordinating the activities of the actors to 'guide the search' in innovation systems.[222] Such guidance from the FDA offers the necessary certainty for approval under its PMA pathway, thereby paving the way for 3D-printed devices to be released as new products onto the market, where they do not demonstrate substantial equality with existing devices. However, the significance of the Canadian approach to innovation governance for new products is diminished by the difference between the two jurisdictions, concerning the implications of compliance for such approval requirements. While requirements for approval along the PMA pathway serve as a 'ceiling' and preempt future common law challenges in the US,[223] the requirements in Canada are seen as imposing regulatory 'floors,' "such that compliance with such regulatory schemes has not generally been regarded as dispositive of product liability claims."[224]

The above discussion indicates that in neither the U.S. nor Canada are there any dedicated regulatory schemes to accommodate the vast majority of 3DP applications in health. Instead, existing regulatory frameworks are being stretched to

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221. *Id*. (stating "[t]he device description should state whether the entire device or only a component of the device is 3D printed").

222. *See* discussion, *supra* Section III.C.

223. *See* discussion, *supra*, accompanying note 143.

224. *See* Craig Lockwood et al., *Product Liability Defence North and South of the Border: Is There Such Thing As Canadian Pre-Emption?*, (2015) www.osler.com/osler/media/Osler/reports/product-liability/Product-Liability-Defense-Preemption-in-Canada.pdf (citing Buchan v. Ortho Pharmaceutical (Canada) Ltd (1986), 54 OR (2d) 92, 34 ACWS (2d) 328 (Ont CA); Wuttunee v. Merck Frosst Canada Ltd., 2007 SKQB 29, 291 Sask R 161).

accommodate the unique features of 3DP as a manufacturing technology in various applications. However, regulatory considerations are at a more advanced level for medical devices, both in the U.S. and Canada, albeit at varying levels and within diverse scope. With respect to the deployment of the technology in bioprinting, medical instruments, pharmaceuticals, and a broad category of medical devices, current research and development largely falls outside the regulatory purview. While the permissionless innovation perspective of innovation governance favours such absence of regulatory reach as a necessary feature of distributed innovation in 3DP, in order to support progress and innovation in emerging technologies, it is still important that any risks arising from these applications are appropriately regulated. Thus, it is essential to examine how, in the absence of regulatory intervention, liability regimes regulate the risks associated with such emerging technology, thereby providing the desired certainty and stability for guiding the technology's development. Consequently, the following Section discusses the questions raised by 3DP with respect to the existing liability regimes.

VI. LIABILITY REGIMES FOR 3D-PRINTING APPLICATIONS

Despite the difference between the U.S. and Canada regarding the role of regulatory compliance in common law liability,[225] the allocation of risk, where it does not fall under any regulatory regime, is left to be resolved under liability laws in both jurisdictions. Without pretending to provide extensive discussion of 3DP's implications for liability laws under the two jurisdictions,[226] this Section briefly highlights a number of specific aspects of 3DP applications in health, with regard to risk allocation in tort law. In the US, the liability regime for 3DP applications in most States will either be that of strict product liability or negligence.[227] In Canada, however, there is no strict liability in tort, [228] as the plaintiff must always prove that her damage was caused by the manufacturer's negligence. This discussion will therefore briefly examine the prospects of liability claims under strict liability in the U.S. and under negligence in Canada.

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225. *See* discussion, *supra*, accompanying note 143.

226. *See* detailed discussion in Beck & Jacobson, *supra* note 5; Evan M Malloy, *Three-Dimensional Printing and a Laissez-Faire Attitude toward the Evolution of the Products Liability Doctrine*, 68 FLA. L. REV. 1199 (2016); Patrick J. Comerford & Erik P. Belt, *3DP, AM, 3DS and Product Liability*, 55 SANTA CLARA L. REV. 821, 825-30, 832, 835-36 (2015); Wang, *supra* note 5; Berkowitz, *supra* note 5.

227. Beck et al., *supra* note 3, at 153.

228. *See* Bruce Feldthusen et al., *Product Liability in North America* § 347 (2008).

The US's strict product liability relies on a manufacturer-based 'chain-of-sale or control' concept, which, first and foremost, involves a determination of what a 'product' actually is, and who should be called the 'manufacturer.'[229] 3DP has multiplied the number of possible 'products' to include the digital blueprint in the form of the CAD file and the printed physical item. Under the *Restatement of Torts* (Third), a 'product' is defined as "tangible personal property distributed commercially for use or consumption" and as such, the CAD file does not qualify as 'tangible' personal property.[230] Conversely, the courts have held that non-tangible items, such as electricity, qualify as products for purposes of imposing strict liability.[231] While no case law exists on the question of whether a CAD file may be considered as a 'product' for the purpose of tort liability, such non-tangible assets as maps and navigational charts have likewise been held to be products, particularly in the aeronautical context.[232] Meanwhile, in the non-tort liability context, CAD files used in 3D printing were not 'articles' under the Tariff Act of 1930.[233] Thus, by analogy, the digital files used in 3DP may not be 'products' in themselves.[234]

The challenge in qualifying the CAD file as a 'product' makes it difficult to find a remedy for a defective CAD file under product liability theory. There are several ways in which CAD files can create defective products: by having a defective software or scanner when creating an original design; through a defective digital design, due to acquiring a defective file or downloading the file incorrectly; through human error in the digital design; or by using the wrong format for the printer.[235] Furthermore, due to the open-source nature of some 3D designs, it is difficult to trace a faulty design back to its original creator. It is also equally challenging to prove that the

229. Beck et al., *supra* note 3.

230. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 19 (AM. LAW INST. 1999).

231. *See*, *e.g.*, Smith v. Home Light and Power Co., 695 P.2d 788, 789 (Colo. 1984) (holding "electricity itself is a product"); Schriner v. Penn. Power & Light Co., 501 A.2d 1128, 1133 (1985) (holding that "electricity can be a 'product,' within the meaning of § 402A"); Stein v. S. Cal. Edison Co., 7 Cal. App. 4th 565, 571 (1992).

232. Brockelsby v. United States, 767 F.2d 1288, 1295 (9th Cir. 1985) (holding that an aeronautical chart "was a defective product for purposes of analysis under section 402A"); Saloomey v. Jeppesen & Co., 707 F.2d 671, 676-77 (2d Cir. 1983) (holding that navigational charts were products under section 402A, and that mass production and marketing of charts required that the defendant bear the costs of accidents proximately caused by the charts).

233. *See* ClearCorrect Operating v. ITC, 810 F.3d 1283 (Fed. Cir. 2015).

234. Beck et al., *supra* note 3, at 16.

235. Some of these scenarios are outlined in Davies et al., *supra* note 26, at 18; *see* Eric Lindenfeld, *3D Printing of Medical Devices: CAD Designers as the Most Realistic Target for Strict, Product Liability Lawsuits*, 85 U. MO.-KAN. CITY L. REV. 79 (2016).

design was not substantially altered after it left the control of the original designer, before making its way to the consumer plaintiff.[236]

By qualifying the 3D-printed item as a product, conventional tort liability applies to traditional manufacturers using 3D printers to create tangible objects.[237] However, who is the manufacturer in 3DP? In addition to the blurred distinction between consumers and manufacturers, when it comes to individuals using 3D printers to produce items for their own use in their own homes, the possible defects or errors in the 3DP process may be located at different stages of the 'manufacturing' process and are not limited to the location of the 3D printer. Hence, unique to 3DP, questions arise as to who could potentially be liable for 3D-printed products that cause harm: the manufacturer of the 3D printer, the designer of the CAD file, the supplier of the ink/filament/material, or the person who 3D-prints the product. Each of these participants in the 3DP process play a significant role in the functioning of the 3D printer to print a product. This results in some difficulty in ascertaining which of the three categories of product defect the defect actually falls into: manufacturing, design, or warning of defects.[238]

Regarding 3DP applications in health, 3D printers may be located onsite in hospitals, physicians' offices, local pharmacies, or patients' homes. Thus, any of these may be considered to be a 'commercial seller or distributor.'[239] However, hospitals are currently considered to be 'service providers' rather than commercial sellers, as they are not affiliated with device or drug manufacturers in the 'commercial sphere.'[240] The Pennsylvania Supreme Court clarified that hospitals are suppliers of 'services,' not 'products' for the purposes of strict liability, stating that "the thrust of the inquiry is… not on whether a separate consideration is charged for the physical material used in the exercise of medical skill, but what service is being performed to restore or maintain the patient's health."[241] As service providers, hospitals and other point-

236. *Id*.

237. Beck et al., *supra* note 3, at 17.

238. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (AM. LAW INST. 1998).

239. *Id.* at 1.

240. *Id.*; James M. Beck & Anthony Vale, *Drug and Medical Device Product Liability Deskbook* § 8.05[1] (2015).

241. Cafazzo v. Central Medical Health Services, Inc., 668 A.2d 521, 532 (1995); *see also* Hollander v. Sandoz Pharm. Corp., 289 F.3d 1193, 1217, n.22 (10th Cir. 2002) (applying Oklahoma law and following "majority of jurisdictions" in declining to hold hospital liable for strict product liability); Vergott v. Deseret Pharm. Co., 463 F.2d 12, 16, n.5 (5th Cir. 1972) (applying Texas law and holding that a "hospital is not a seller engaged in the business of selling the product" under section 402A); Wages v. Johnson Reg'l Med. Cent., 916 F. Supp. 2d 900, 904 (W.D. Ark. 2013) (holding that hospitals cannot be considered product suppliers under the Arkansas Products Liability Act merely

of-service printers cannot be held strictly liable for personal injuries arising from defective products.[242]

Given the unique capability of 3DP technology in point-of-care manufacturing, hospitals, physicians' offices and local pharmacies may cross the line from being service providers to becoming sellers of a product, or to becoming sufficiently 'engaged in the business' of selling such a product by incorporating onsite 3D printers,[243] thereby opening themselves up to product liability claims. However, this is a significant leap in jurisprudence and is not supported with desired policy objectives in health.[244]

The difficulty involved in bringing a liability claim against a commercial seller or manufacturer of a defective 3D-printed product may mean that plaintiffs can seek to recover damages by pursuing negligence claims. As the only available option in Canada,[245] the first step in proving negligence is to establish that the product poses "an unreasonable risk of harm to persons or property when used as foreseeably intended due to the negligent design, manufacture, or warning." [246] Thus, the product must be defective; products that are merely shoddily made, but not dangerous, do not typically attract tort liability.[247] Moreover, generally speaking, plaintiffs must experience some manner of personal injury or property damage caused by the defective product, in order to have

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because the hospital uses the product during a medical procedure); Samuels v. Health & Hosp. Corp. of City of New York, 432 F. Supp. 1283,1284-85 (D.C.N.Y. 1977) (applying New York law and holding that "the doctrine of strict liability in tort is inapplicable to the service by the hospital of providing blood transfusions).

242. Davies et al., *supra* note 26.

243. The current framework of product liability law only applies to commercial sellers, those "engaged in the business of selling or otherwise distributing products*"* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 1-2 (AM. LAW INST. 1998).

244. *See* Lindenfeld, *supra* note 235, at 101.

245. For discussion of claims for damages caused by 3D printed product based on negligence theory, *see* Davies et al., *supra* note 26, at 19.

246. To prove negligence, the following elements must be pled and established by the plaintiff:

(a) product was defective in that it posed an unreasonable danger or risk of harm to person or property when foreseeably used;

(b) the defendant owed a duty of care to the plaintiff with respect to the product;

(c) the defendant was negligent in failing to meet the applicable standard of care;

(d) the defendant's breach of the standard of care caused or contributed to the defect;

(e) the defect caused or contributed to the plaintiff's damages; and

(f) the plaintiff's damages were reasonably foreseeable.

More v. Bauer Nike Hockey Inc, 2011 BCCA 419; More v. Bauer Nike Hockey Inc, 2010 BCSC 1395.

247. *Id*.

a claim in negligence, as the defective condition alone is insufficient for bringing a claim. Consequently, negligence for the purpose of tort liability for damages or injuries caused by defective products falls under three main subheadings: (1) negligent manufacture, (2) negligent design, and (3) negligent failure to warn.[248]

For negligent manufacture and negligent design to subsist, it is crucial to determine who owes a duty of care to the plaintiff.[249] The plaintiff must prove that the cause of the injury was a specific actor in the chain of manufacture and supply: the 3DP equipment manufacturer, the ink/filament/material manufacturers, the CAD designer, or the person who printed the item. While the concept of negligence is well-established in Canadian jurisprudence, 3DP machine manufacturers, material providers, CAD designers, and those who 'click print' are rarely the same parties; meaning that it can prove to be more difficult to establish negligence on the part of any specific party, compared to conventional, centralized supply-chain processes. Given that 3DP applications are based on highly complex and novel digital models, which have not previously been practical in conventional manufacturing, it may be difficult to demonstrate that any alternatives to the designs used could have been more reasonable to adopt in the manufacturing process. It is possible that CAD designers are most vulnerable to negligent design claims, but even the FDA has questioned 3DP stakeholders who control or own the design process: the software vendor, the end-user, or the company who made the printer.[250]

Manufacturers have a duty to warn consumers of any "inherent and reasonably known risk[s] of harm" in the use of their products, and where "danger is not manifestly obvious to foreseeable users during foreseeable use, manufacturers have a duty to warn users of the known risk and how to avoid it."[251] Liability is centred on the adequacy of this warning in the face of the manufacturer's knowledge of risk. Manufacturers may also satisfy their duty to warn by warning intermediaries.[252] Where an intermediary has been warned (or is aware of the risk), that intermediary "may be liable for failing to pass the warning on to the ultimate user."[253]

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248. *Id*.

249. Davies, *supra* note 26, at 17; Gartin v. S&M NuTec LLC, 245 F.R.D. 429, 439 (C.D. Cal. Apr. 5, 2007).

250. CADTH, *Focus On: 3-D Printing*, HEALH TECH. UPDATE 12 (June 2016), https://cadth.ca/sites/default/files/pdf/HTU_Newsletter_Issue_17_e.pdf.

251. Hollis v. Dow Corning Corp., [1995] 4 SCR 634. A similar tort liability based on negligence theory in the US states that when the manufacturer or seller knows or should know that there is a risk that is not obvious to the user, there is a duty to warn of the danger. *See* 63 AM JUR. 2D PROD. LIAB. § 212 (2015).

252. *See Hollis*, *supra* note 251.

253. *Id*.

The duty to warn is likely to depend on the product being printed, and the passing on of the duty to warn may be the most salient point with respect to 3DP applications in health. Well-developed in the U.S. within the context of a physician-patient relationship,[254] the 'learned intermediary' doctrine applies in Canada "either where a product is highly technical in nature and is intended to be used only under the supervision of experts, or where the nature of the product is such that the consumer will not realistically receive a direct warning from the manufacturer before using the product."[255] This covers many 3DP applications, especially in Class III and IV products, where these products are fabricated through bioprinting, represent a new breakthrough, and are still at an experimental level. Given the difficulty of establishing a traditional product 'manufacturer,' a duty to warn may be imposed on either the physicians or some other entity involved in the creation of such products, who may be expected to avail themselves of the available information on the risks of using the final 3D-printed product.

As the discussion in this Section illustrates, it can be challenging to account for risks in 3DP applications through traditional tort liability regimes, whether under liability or negligence theory. In the absence of regulatory certainty to decrease the potential for risks caused by the incorrect use or fabrication of 3DP products, the unique attributes of the technology introduce uncertainty as to who is liable for damages in traditional tort liability regimes. In recognition of these challenges, parties in Europe are urged to limit their risk of liability through clear contracts.[256] Participants in the 3DP manufacturing process can limit risk among themselves by imposing contractual conditions, which include the type and quality of material to be used, requirements for use, presentation, and the instructions to be followed when printing.[257] Nevertheless, with respect to the allocation of risk to the ultimate patient, such options may not be ideal alternatives.

VII. CONCLUSION

The widespread accessibility of 3DP across different sectors has triggered a number of legal issues surrounding consumer safety, counterfeiting, and product liability. As the technology moves from the realm of artistic and hobby use to mainstream applications in health, questions arise over the framework governing innovation in

254. *Kirk v. Michael Reese Hosp. & Med. Cent.*, 513 N.E.2d 387, 392 (Ill. 1987).

255. *Hollis, supra* note 251.

256. DE CLERCQ. *Legal Aspects of 3D Printing from a European Perspective*. White Paper. (2015), https://issuu.com/eddycastro3/docs/white_paper_legal_aspect_of_3d_prin.

257. *Id*.

these areas of application. The traditional structures of vertical innovation and product manufacturing are challenged, as 3DP shifts innovation to decentralized networks of actors, with a focus on customization and patient-specific product development. Thus, the need for clearer, more reliable standards arises in order to prevent arbitrary litigation, provide patients with certainty, and achieve policy and judicial consistency while balancing the interests of innovators, consumers, and other stakeholders in 3DP.

The discussion reveals that given the unique set of circumstances of 3DP applications in health, a proactive approach to regulating the risks associated with the technology is necessary for filling gaps along the existing pathways for medical devices. Both 'weak' and 'strong' precautionary approaches to innovation governance favour the prescription of criteria, the requirement of proof of having met those criteria, and the continuous monitoring and management of risk. Such regulatory measures take the whole 3DP industry as a point of reference in determining the impact of regulation on the structure of the industry, considering the diverse actors in the structure of the technology's innovation. In doing so, regulatory certainty and stability among the diverse participants in 3DP can be achieved as a socially and industrially desirable objective, which considers the distinctively risk-based assessment of 3DP as a manufacturing process.

The FDA's current guidelines provide prescriptive specifications for technical consideration, regarding higher risk devices, based on proof of substantial equivalence to existing devices. This, however, falls short of a prescriptive guideline for the approval of devices as new self-standing products. The lack of guidance on 3DP as a manufacturing technique for new products limits the viability of research and development for products that do not currently exist on the market. With respect to bioprinting applications, there is a need for a clear assumption of regulatory competence, especially when it comes to organs for transplant. The unique aspects of printing with bio-inks for tissues and implantable devices can only be addressed through prescriptive conditions of certainty for approval. In pharmaceuticals, 3DP applications introduce unique risk factors into variations in processes, raw materials, and equipment, impacting on the utility of the final dosage. As such, it is necessary to re-examine existing regulatory guidelines so that 3DP may be considered a unique manufacturing process.

Given that traditional tort liability is not easily applied in the context of 3DP, it will be a long time before general concepts in tort law adapt to these new technologies, including 3DP. Regulatory guidance for 3DP across diverse areas would provide the certainty that existing liability rules fail to offer. Proactive guidance on the allocation of risk would also help realize the potential of 3DP in the democratization and personalization of medical devices, drug-

manufacturing, and other health applications, thereby ultimately benefiting the whole of society.