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TO BIOPRINT OR NOT TO BIOPRINT

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Recent scholarship on regulating 3D printing implicitly presumes the same regulation should apply to printing from both non-biological materials and biological materials. However, this presumption is mistakenly grounded. Technically, bioprinting is a subcategory of 3D printing. However, printing from biological materials presents different public policy considerations than printing from non-biological materials. When experimenting with mammalian genetic materials, emerging technological and scientific advances attract strong political, regulatory, and ethical debates. The societal scrutiny is further heightened when the genetic materials are from humans.

One analyst group speculates a global debate in 2016 as to whether to regulate bioprinting or ban it altogether. Banning bioprinting altogether is an easy solution, but it will stop technology and science from progressing. The more difficult question is how the law should regulate bioprinting. Current regulations on synthetic biology are not sufficiently comprehensive to regulate bioprinting because bioprinting moves synthetic biology's production out of the laboratory and into everyone's home. After analyzing different ways to regulate bioprinting, this Article offers a novel framework to regulate bioprinting: except for research and life-threatening emergency, the legislature and the medical profession should jointly regulate access to bioprinting's blueprints, sources, and bioprinters.

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I. INTRODUCTION

"Everything you can imagine is real."

—Pablo Picasso

For example, Australian researchers recently were able to 3D-print brain tissue.[1] Five decades ago, Star Trek introduced the Replicator concept—a machine that can create anything out of thin air.[2] Who would have thought such a sci-fi myth could be real?[3] Well, it is—the 3D printer is a modern day Replicator.[4] 3D printers are technically not "new"—engineers have been using them since the 1980s.[5] Nonetheless, 3D printers are finally available for

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[1] Rodrigo Lorezno et al., *3D Printing of Layered Brain-Like Structures Using Peptide Modified Gellan Gum Substrates*, 67 BIOMATERIALS 264, 264–73 (2015) (demonstrating "a novel process to create a 3D brain-like structure consisting of layered primary cortical cells encapsulated in hydrogels representing cortical tissue").

[2] In Star Trek, the Replicators originally synthesized meals on demand, but took on other uses in the later series. *See Star Trek: The Original Series* (NBC television broadcast Sept. 8, 1966–June 3, 1969) (referring to "food synthesizer"); *Star Trek: The Next Generation* (NBC television broadcast Sept. 28, 1987–May 23, 1994); *Star Trek: Enterprise* (NBC television broadcast September 26, 2001–May 13, 2005) (referring to "protein resequencer" and "bio-matter resequencer").

[3] *See* CHRIS ANDERSON, MAKERS: THE NEW INDUSTRIAL REVOLUTION 8–9, 58–59 (2012); (stating that the first wave of "geeks" are "rushing to explore this strange new world" of 3D printing which is "quickly becoming a mainstream phenomenon."); James Bruce, *3D Printing – Sci-Fi Myth Or Reality?*, MAKEUSEOF (Aug. 31, 2011), http://www.makeuseof.com/tag/3d-printing-scifi-myth-reality/; Clive Thompson, *We Need a Fixer (Not Just a Maker) Movement*, WIRED (June 18, 2013, 6:30 AM), http://www.wired.com/2013/06/qq_thompson; *see also Grey's Anatomy: Two Against One* (ABC television broadcast Nov. 8, 2013) (showing medical staff fighting over their 3D printer to build new lifesaving organs).

[4] Deven R. Desai, *The New Steam: On Digitization, Decentralization, and Disruption*, 65 HASTING L.J. 1469, 1471 (2014) [hereinafter Desai, *New Steam*]. For background information on 3D printing, see generally discussion *infra* Part II.A.

[5] Melissa A. Barnett, *The Next Big Fight: 3D Printing and Intellectual Property*, LEXOLOGY (Jan. 31, 2014), http://www.lexology.com/library/detail.aspx?g=2fdd3f59-3a6a-4066-9ded-56501a8aaa45.

purchase.[6] With time, 3D printers will get "cheaper, faster, and more mainstream."[7] Soon, 3D printers will be just another home appliance,[8] and unsurprisingly, people will forget about how the 3D printer was once science fiction.[9]

By the same token, people mistakenly have the same skepticism about bioprinting.[10] Yet, Dr. Anthony Atala[11] recently gave two TED talks,[12] *Growing New Organs*[13] and *Printing a*

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[6] *See, e.g.*, *3D Printers,* STAPLES, http://www.staples.com/3D-Printers/cat_CL211598 (last visited Oct. 23, 2014); *see also Price Compare – 3D Printers*, 3DERS, http://www.3ders.org/pricecompare/3dprinters/ (last visited Oct. 23, 2014) (comparing prices of 3D printers).

[7] Alex Hern, *3D Printers Get Cheaper, Faster - and More Mainstream*, THE GUARDIAN (Sept. 24, 2013 12:59 PM), http://www.theguardian.com/technology/2013/sep/24/3d-printers-get-cheaper-faster-and-more-mainstream.

[8] Steven Kurutz, *A Factory on Your Kitchen Counter*, N.Y. TIMES (Feb. 20, 2013), http://www.nytimes.com/2013/02/21/garden/the-3-d-printer-may-be-the-home-appliance-of-the-future.html?pagewanted=all; *see also* Mark A. Lemley, *IP in a World Without Scarcity*, 90 N.Y.U. L. REV. 460, 474–75 [hereinafter Lemley, *IP Without Scarcity*] (anticipating a time where the general public will have ready access to 3D printers).

[9] Some examples of common-place technological advancements that people once considered science fiction are robots, robotic body parts (arms, legs), spray-on skin and most recently, self-driving vehicles.

[10] Bioprinting is also referred to as 3D Bioprinting. For a discussion on bioprinting, see generally discussion *infra* Part II.C. Note that bioprinting does not refer to "DNA bioprints," which is "a simplified DNA nonisotopic fingerprinting system using biotin-labeled probes." *See, e.g.*, Sérgio D.J. Pena et al., *DNA Bioprints: Simple Ponisotopic DNA Fingerprints with Biotinylated Probes*, 12 ELECTROPHORESIS 146, 146–52 (1991).

[11] Dr. Anthony Atala is a practicing surgeon and the director of the Wake Forest Institute for Regenerative Medicine. *Anthony Atala*, TED, http://www.ted.com/speakers/anthony_atala (last visited Oct. 23, 2014) ("[Our lab uses] a desktop inkjet printer, but instead of using ink, we're using cells.").

[12] *See Our Organization*, TED, http://www.ted.com/about/our-organization (last visited Oct. 23, 2014) ("TED is a nonprofit devoted to spreading ideas, usually in the form of short, powerful talks (18 minutes or less).")

[13] *Anthony Atala: Growing New Organs*, TED (Oct. 2009) http://www.ted.com/talks/anthony_atala_growing_organs_engineering_tissue (presenting that instead of harvesting or transplanting human organs, Anthony Atala's lab grows human organs—from muscles to blood vessels to bladders, and more) [hereinafter TED talk: *Growing New Organs*].

Human Kidney, [14] presenting that the emerging field of bioprinting—printing mammalian or human body parts[15]—is also real and bioprinters will soon be widely available.[16] Scientists made bioprinting possible[17] by marrying the concepts of 3D printing and synthetic biology.[18]

We live in a digitization age.[19] Computers and the Internet digitize information.[20] While 3D printing digitizes tangible goods,[21] bioprinting digitizes human body parts[22] and, potentially, human

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[14] *Anthony Atala: Printing a Human Kidney*, TED (Mar. 2011), http://www.ted.com/talks/anthony_atala_printing_a_human_kidney [hereinafter TED talk: *Printing Human Kidney*] (demonstrating a 3D printer using living cells to output a transplantable kidney).

[15] *See* discussion *infra* Part II.C.

[16] Bioprinters are already available for research purposes. *See, e.g.*, Daniel J. Thomas, *Technology to Bioprint Tissues on Demand in 3D is Here*, 3DERS (Sept. 21, 2014), http://www.3ders.org/articles/20140921-technology-to-bioprint-tissues-on-demand-in-3d-is-here.html [hereinafter 3DERS: *Bioprint Tissues on Demand*]; Alec, *'3D Bioprinting Solutions' to Reveal First Russian 3D Bioprinter in Late October*, 3DERS (Sept. 25, 2014), http://www.3ders.org/articles/20140925-russian-company-3d-bioprinting-solutions-to-reveal-their-bioprinter.html, [hereinafter 3DERS: *Russian 3D Printer*].

[17] *See* discussion *infra* Part II.C.

[18] Synthetic biology aims to design an organism from scratch or modify an existing organism for useful purposes. *See generally* discussion *infra* Part II.B and notes 172–174 and accompanying text.

[19] Devan R. Desai & Gerald N. Magliocca, *Patents, Meet Napster: 3D Printing and the Digitization of Things*, 102 GEO. L.J. 1691, 1692 (2014) [hereinafter Desai & Magliocca, *Napster*]; Desai, *New Steam*, *supra* note 4, at 1469. "Digitization" (or "digitalization") means the process of converting information into a digital format. *See* MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (10th ed. 1998).

[20] *See* Lemley, *IP Without Scarcity*, *supra* note 8, at 469–71.

[21] Desai & Magliocca, *Napster*, *supra* note 19, at 1692; *see also* Lucas S. Osborn, *Of PhDs, Pirates and the Public: Three-Dimensional Printing Technology and the Arts*, 1 TEX. A&M L. REV. 811, 819–23 (2014) [hereinafter Osborn, *3D Printing & Arts*] (discussing 3D printing's digitization of everyday things and ancient arts).

[22] *Cf.* TED talk: *Growing New Organs*, *supra* note 13 (presenting that instead of harvesting human organs, Anthony Atala's lab grows human organs such as muscles, blood vessels, bladders, and more).

beings.[23] Although digitization offers many benefits, it also brings challenges,[24] which disrupt both business[25] and law.[26]

Recent scholarship on regulating 3D printing implicitly presumes the same regulations should apply to printing from both non-biological materials and biological materials.[27] However, this presumption is mistaken. For example, an individual recently diagnosed with lung cancer could simply print another compatible lung from her home bioprinter and have a doctor replace her current lung with this new lung.[28] It would be ridiculous to regulate a 3D-printed lung the same way as a common household item, for example, a 3D-printed fork. Although bioprinting is a subcategory of 3D printing,[29] printing from biological materials presents different public policy considerations than printing from non-biological materials.[30] When experimenting with mammalian genetic materials, as scientists did in the past with the cloning of

[23] Osborn, *3D Printing & Arts*, *supra* note 21, at 815–19.

[24] Desai & Magliocca, *Napster*, *supra* note 19, at 1692.

[25] *See, e.g.*, Lemley, *IP Without Scarcity*, *supra* note 8, at 474 ("A world in which sophisticated 3D printers are widely available would change the economics of things in a fundamental way . . .").

[26] *E.g.*, Lucas S. Osborn, *Regulating Three-Dimensional Printing: The Converging Worlds of Bits and Atoms*, 51 SAN DIEGO L. REV. 553, 562–92 (2014) [hereinafter Osborn, *Regulating 3D Printing*] (discussing that 3D printing raises legal issues in intellectual property law, environmental law, contract law, products liability, criminal law, and firearms control). *See generally* discussion, *infra* Part III.A and notes 161–166 and accompanying text.

[27] *See, e.g.*, Jasper L. Tran, *3D Printing and the Law*, 31 J. INFO. TECH. & PRIVACY L. 505 (2015); Desai & Magliocca, *Napster*, *supra* note 19, at 1703–20; Osborn, *Regulating 3D Printing*, *supra* note 26, at 562–92. *But see* Lemley, *IP Without Scarcity*, *supra* note 8, at 472–79 (distinguishing 3D printing and bioprinting).

[28] This assumes that such bioprinter can easily load this individual's biological information to print a compatible lung.

[29] *See* discussion, *infra* Parts II.A. and II.C.

[30] For a discussion on the ethical, legal and policy issues behind commercializing genetic research, *see generally* THE COMMERCIALIZATION OF GENETIC RESEARCH: ETHICAL, LEGAL, AND POLICY ISSUES (Timothy A. Caulfield & Bryn Williams-Jones eds., 1999).

Dolly,[31] emerging technological and scientific advances attract strong political, regulatory, and ethical debates.[32] When the genetic materials are from humans, such as during human stem cell research,[33] the societal scrutiny is further heightened.[34]

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[31] Dolly (July 5, 1996–Feb. 14, 2002) was the first mammal (sheep) cloned from an adult somatic cell using nuclear transfer. For a discussion on cloning and Dolly, *see generally* Anne McLaren, *Cloning: Pathways to a Pluripotent Future*, 288 SCIENCE 1775–80 (2000); Ian Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810–13 (1997).

[32] *See, e.g.*, Lori B. Andrews, *Is There A Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643 (1998) [hereinafter Andrews, *Right to Clone?*]; Katheryn D. Katz, *The Clonal Child: Procreative Liberty and Asexual Reproduction*, 8 ALB. L.J. SCI. & TECH. 1 (1997) [hereinafter Katz, *Clonal Child*]; John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371 (1998) [hereinafter Robertson, *Human Cloning*]; Janet A. Warrington, *The Ethics of Reproductive Cloning*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 471 (2003) [hereinafter Warrington, *Reproductive Cloning*].

[33] Stem cell research dates back to the 1960s. *See* Andy J. Becker et al., *Cytological Demonstration of the Clonal Nature of Spleen Colonies Derived from Transplanted Mouse Marrow Cells*, 197 NATURE 452–54 (1963). Stem cells are undifferentiated cells that can divide and differentiate into specialized cells. For a discussion on stem cells, see generally Bernard E. Tuch, *Stem Cells—A Clinical Update*, 35 AUSTRALIAN FAM. PHYSICIAN 719–21 (2006) [hereinafter Tuch, *Stem Cells*].

[34] *See, e.g.*, Leili Fatehi & Ralph F. Hall, Symposium, *Enforcing the Rights of Human Sources to Informed Consent and Disclosures of Incidental Findings from Biobanks and Researchers: State Mechanisms in Light of Broad Regulatory Failure,* 13 MINN. J.L. SCI. & TECH. 575 (2012) [hereinafter Fatehi & Hall]; Heather Johnson Kukla, Note, *Embryonic Stem Cell Research: An Ethical Justification*, 90 GEO. L.J. 503 (2002) [hereinafter Kukla, *Ethical Justification*]; William McGeveran et al., *Deidentification and Reidentification in Returning Individual Findings from Biobank and Secondary Research: Regulatory Challenges and Models for Management*, 13 MINN. J.L. SCI. & TECH. 485 (2012) [hereinafter McGeveran, *Biobank*]; Radhika Rao, *Coercion, Commercialization, and Commodification: The Ethics of Compensation for Egg Donors in Stem Cell Research*, 21 BERKELEY TECH. L.J. 1055 (2006) [hereinafter Rao, *Ethics of Compensation*]; David E. Winickoff et. al., *Opening Stem Cell Research and Development: A Policy Proposal for the Management of Data, Intellectual Property, and Ethics*, 9 YALE J. HEALTH POL'Y, L. & ETHICS 52 (2009) [hereinafter Winickoff, *Policy Proposal*]. *See generally* Henry T. Greely, Symposium, *The Control of Genetic Research: Involving the*

Research involving the use of bioprinted products inside and outside the human body triggers different ethical concerns.[35] To illustrate, using bioprinted products inside a human body may trigger biosafety concerns and violate human dignity. Other ethical concerns include the questionable sources of the biomaterials as well as how to eliminate their "waste." Although most of these ethical concerns are not unique to bioprinting, regulating bioprinting will likely differ from regulating 3D printing.

One analyst group speculates a global debate in 2016 regarding whether to regulate bioprinting or ban it altogether.[36] Banning bioprinting altogether[37] is an easy solution, but it will stop technology and science from progressing.[38] The more challenging solution would allow bioprinting, which would raise the difficult question how the law should regulate the technology. Current regulations on synthetic biology[39] are not sufficiently comprehensive to regulate bioprinting because bioprinting moves synthetic biology's production out of the laboratory and into the home.[40] Currently, what regulation the bioprinting technology must abide by still leaves a big question mark—a "grey" area—because

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"Groups Between," 33 HOUS. L. REV. 1397 (1997) (discussing the control of human genetic research).

[35] *See* discussion, *infra* Part III.A.

[36] Press Release, The Gartner Group, Gartner Says Uses of 3D Printing Will Ignite Major Debate on Ethics and Regulation (Jan. 29, 2014), *available at* http://www.gartner.com/newsroom/id/2658315 ("Rapid development of 3D bioprinters will spark calls to ban the technology for human and nonhuman use by 2016"). For a discussion on the bioprinting market, see generally ROOT ANALYSIS PRIV. LTD., 3D BIOPRINTING MARKET, 2014 - 2030 (2014).

[37] *See* The Gartner Group, *supra* note 36. This statement presumes no research exception. For a discussion of the research exception, see discussion, *infra* Part IV.A.2.

[38] This question presumes that 3D printing will not be banned altogether. For a discussion of an outright ban on bioprinting, see discussion, *infra* Part IV.A.1.

[39] *See e.g.*, Andrew W. Torrance, Symposium, *Synthesizing Law for Synthetic Biology*, 11 MINN. J.L. SCI. & TECH. 629 (2010) (analyzing the legal regime behind synthetic biology); *see also* discussion, *infra* Part III.B.2.

[40] *Cf.* Kurutz, *supra* note 8 (discussing that 3D printer will soon be just another home appliance). *See generally* discussion, *infra* Part II.B (comparing bioprinting to synthetic biology).

bioprinting regulation could fall under human stem cell research regulation for bioprinting ink, organ transplantation regulation for bioprinted organs, or both.[41] After analyzing different ways to regulate bioprinting, this Article offers a novel framework to regulate bioprinting: except for research and life-threatening emergencies, the legislature and the medical profession should jointly regulate access to bioprinting's blueprints, sources, and bioprinters.[42]

This Article proceeds in five parts. Part II provides the scientific facts and current regulation on 3D printing, synthetic biology and bioprinting. Part III analyzes and synthesizes the rationales for regulating bioprinting by comparing it to 3D printing, synthetic biology, stem cell research, organ transplantation, and cloning. Part IV explores different ways to regulate bioprinting. Part V proposes regulating bioprinting through joint efforts of the legislature and the medical profession to maximize bioprinting's advantages while also considering the rationale behind bioprinting. Part V further addresses the proposal's advantages and implications, and then rebuts some of the common counterarguments against this proposal. Part VI concludes.

II. BIOPRINTING: THE STEPCHILD OF 3D PRINTING AND SYNTHETIC BIOLOGY

To understand bioprinting, it is only natural to first introduce its parents: 3D printing and synthetic biology. This Part provides scientific facts on 3D printing in Section A, synthetic biology in Section B, and bioprinting in Section C. Three-dimensional printing stacks multiple layers of two-dimensional printing on top of one another. Synthetic biology synthesizes DNA artificially to replicate organisms. Bioprinting, in short, is the three-dimensional printing of synthetic biological organs.

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[41] *See* discussion, *infra* Part III.D.
[42] *See* discussion, *infra* Part V.A.

A. *The Mother of Bioprinting: 3D Printing*

Michelangelo carved statues by "hew[ing] away the rough walls that imprison the lovely apparition to reveal it to the other eyes as [his] see it."[43] 3D printing accomplishes the opposite—it transforms manufacturing.[44] 3D printers[45] add another dimension to our current (2D) printers.[46] Rather than printing ink, 3D printers print three-dimensional objects.[47] 3D printers print by setting raw materials into two-dimensional patterns on a platform and gradually raising to stack each layer on top of the next until completion.[48] Current 3D printers can print in materials like plastic,

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[43] Saad Shaikh & James Leonard-Amodeo, *The Deviating Eyes of Michelangelo's David*, 98 J. ROYAL SOC. MED. 75, 75 (2005) (quoting Michelangelo) ("In every block of marble I see a statue as plain as though it stood before me, shaped and perfect in attitude and action. I have only to hew away the rough walls that imprison the lovely apparition to reveal it to the other eyes as mine see it.").

[44] Desai & Magliocca, *Napster*, *supra* note 19, at 1719.

[45] 3D printing modalities include extrusion, photolithography, and stereolithography. For the latest news on 3D printing, see 3DERS, http://www.3ders.org (last visited Oct. 23, 2014) (providing latest news and developments of 3D printing technology and 3D printers).

[46] For a discussion on the history of printing, see generally WARREN CHAPPELL & ROBERT BRINGHURST, A SHORT HISTORY OF THE PRINTED WORD (2000) (covering history of printing from the earliest alphabets, through the evolution of the printing press, the contributions of great printers and typographers, and twentieth century graphic technology).

[47] *E.g.*, HOD LIPSON & MELBA KURMAN, FABRICATED: THE NEW WORLD OF 3D PRINTING 68–84 (2013); Osborn, *3D Printing & Arts*, *supra* note 21, at 813. ("3D 'printers' are only superficially related to current 2D printers. Rather than printing 'ink,' they 'print' (expel) solid or molten material. Further, they print not just in two dimensions, but also move in a third direction: the printer head moves up (or the base moves down) to stack layer upon layer of expelled material until a three-dimensional object is formed.").

[48] Desai & Magliocca, *Napster*, *supra* note 19, at 1695–96. Although 3D printing theoretically includes printing by subtraction (rather than just addition), this Article only focuses on 3D additive printing. Desai & Magliocca note that 3D printing by subtraction raises many of the same legal issues as additive 3D printing. *Id.* at 1692 n.1. For a discussion on 3D printer by subtraction (such as milling machine), see generally Tom Owad, *When Less Is More: The Takeaway on Milling vs. 3D Fabrication*, MAKE, Winter 2013, at 10, 11.

metal, ceramic, cement, wood, food, and human cells.[49] Like the "Star Trek Replicator",[50] 3D printers can print anything, from a lithium-ion microbattery[51] to a bionic ear.[52]

To print an object, 3D printers need an electronic blueprint to follow—a Computer-Aided Design file ("CAD file").[53] Users can create CAD files by designing from scratch or scanning an object.[54] Like Microsoft Word documents, photographs and music, users can edit and share CAD files with others through the Internet.[55]

3D printing is still in its infancy, but its potential is significant.[56] The introduction of 3D printing completely revolutionizes the world of tangible goods,[57] from manufacturing[58]

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[49] LIPSON & KURMAN, *supra* note 47, at 68–75; Osborn, *3D Printing & Arts*, *supra* note 21, at 813–14. 3D printing that prints in human cells is called "bioprinting." For a discussion on bioprinting, see discussion, *infra* Part II.C.

[50] *See* discussion, *supra* Part I and note 2.

[51] Ke Sun et al., *3D Printing of Interdigitated Li-Ion Microbattery Architectures*, 25 ADVANCED MATERIALS 4539, 4539–43 (2013). A microbattery is sized at a grain of sand. *Id.*

[52] Manu Mannoor et al., *3D Printed Bionic Ears*, NANO LETTERS (2013), http://www.princeton.edu/~nverma/VermaLabSite/Publications/2013/MannoorJiangJamesKongMalatestaSoboyejoVermaGraciasMcAlpine_NanoLetters2013.pdf [hereinafter Mannoor, *Bionic Ears*].

[53] Osborn, *3D Printing & Arts*, *supra* note 21, at 814. This is unsurprising given that 2D printers also need an electronic blueprint to print—a Microsoft Word document or the like.

[54] *Id.* ("Various Computer-Aided Design ('CAD') programs (Google Sketchup, AutoCAD, etc.) allow users to design and modify three-dimensional objects on a computer.").

[55] *Id.* at 814–15.

[56] Lemley, *IP Without Scarcity*, *supra* note 8, at 471 ("3D printing is in its infancy as a technology, but already the potential for transformation is clear").

[57] *See* Richard A. D'Aveni, *3-D Printing Will Change the World*, HARV. BUS. REV. (Mar. 2013), http://hbr.org/2013/03/3-d-printing-will-change-the-world/.

[58] *See* Barack Obama, Remarks by the President in the State of the Union Address (Feb. 12, 2013), http://www.whitehouse.gov/the-press-office/2013/02/12/remarks-president-state-union-address ("3D printing . . . has the potential to revolutionize the way we make almost everything"); Desai & Magliocca, *Napster*, *supra* note 19, at 1695 ("3D printing reorders access to the means of production").

to art[59] or even healthcare.[60] 3D printing eliminates cost of distribution and substantially reduces cost of manufacturing.[61]

B. *The Father of Bioprinting: Synthetic Biology*

Synthetic biology is relatively young compared to 3D printing.[62] The interdisciplinary field[63] of synthetic biology[64] builds on genetic engineering[65] to design an organism from scratch[66] or modify an existing organism for useful purposes.[67] Recent synthetic biology advances include synthesizing DNA artificially (*i.e.*, creating DNA parts),[68] creating novel replicating

[59] Osborn, *3D Printing & Arts, supra* note 21, at 815–17.

[60] Kathryn Doyle, *3 Ways 3-D Printing Could Revolutionize Healthcare*, FORBES (Aug. 22, 2013), http://www.forbes.com/sites/xerox/2013/08/22/3-ways-3-d-printing-could-revolutionize-healthcare/ [hereinafter Doyle, *Revolutionize*] (discussing that 3D printing could revolutionize healthcare through scaffolding, medical devices and human tissues). *See generally* discussion on Bioprinting, *infra* Part II.C.

[61] Lemley, *IP Without Scarcity*, *supra* note 8, at 474–75.

[62] *Id.* at 479 ("[s]ynthetic biology is at an earlier stage than 3D printing").

[63] The interdisciplinary field of synthetic biology combines disciplines such as biotechnology, evolutionary biology, molecular biology, systems biology, and biophysics. Synthetic biology builds on genetic engineering.

[64] Synthetic biology's definition has been heavily debated among people in natural sciences, human sciences, arts, and politics. This Article adopts the definition based on synthetic biology's functional aspect, stemming from molecular biology and biotechnology.

[65] Drew Andy, *Foundations for Engineering Biology*, 438 NATURE 449, 449–53 (2005) (describing the considerable promise and limitations of synthetic biology).

[66] In May 2010, Craig Venter's group created the first synthetic genome of a bacterium *Mycoplasma mycoides* at a cost of over $40 million. *See* Press Release, J. CRAIG VENTER INST., First Self-Replicating Synthetic Bacterial Cell (May 20, 2010), http://www.jcvi.org/cms/press/press-releases/full-text/article/first-self-replicating-synthetic-bacterial-cell-constructed-by-j-craig-venter-institute-researcher/home/.

[67] Mark A. J. Roberts et al., *Synthetic Biology: Biology by Design*, 159 MICROBIOLOGY 1219, 1219–1220 (2013) (holding synthetic biology is defined as "design and construct[ion] [of] novel biologically based parts, devices and systems, [and] redesign[ing] existing natural biological systems, for useful purposes").

[68] *Id.*

microorganisms,[69] and using microbes as biofactories[70] or as biological computers.[71] Even the U.S. Supreme Court has taken interest in synthetic biology, allowing the patenting of disease-resistance crops,[72] "new" organisms,[73] and shorter DNA sequences[74] as long as they are not naturally occurring.[75]

Synthetic biology builds on gene assemblers[76] by linking together four natural nucleotides (A, C, G, T)[77] into a new, synthetic strand of genetic material.[78] Recently, synthetic biologists even created two new, synthetic nucleotides (X, Y).[79] Currently,

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[69] *See, e.g.*, Daniel G. Gibson et al., *Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome*, 329 SCIENCE 52, 52–56 (2010).

[70] *See* Jerome Bonnet et al., *Rewritable Digital Data Storage in Live Cells via Engineered Control of Recombination Directionality*, 109 PROC. NAT'L ACAD. SCI. U.S. 8884, 8884–89 (2012).

[71] *See* Paul Oldham et al., *Synthetic Biology: Mapping the Scientific Landscape*, 7 PLOS ONE e34368, e34368 (2012).

[72] *See, e.g.*, Bowman v. Monsanto, 133 S. Ct. 1761, 1761–69 (2013) (adjudicating dispute over patent on genetically-modified soybean seeds).

[73] *See* Diamond v. Chakrabarty, 447 U.S. 303, 303–18 (1980) (adjudicating dispute over patent on oil-eating bacteria).

[74] *See* Ass'n for Molecular Pathology v. Myriad, 133 S. Ct. 2107, 2107–20 (2013) (adjudicating dispute over patents on two breast cancer susceptibility genes).

[75] Lemley, *IP Without Scarcity*, *supra* note 8, at 475–79; *see also* 35 U.S.C. § 101 (2012) (excluding product[s] of nature from patentable subject matters).

[76] *See, e.g.*, Monya Baker, *De Novo Gene Assembly: What Every Biologist Should Know*, 9 NATURE METHODS 333, 333–37 (2012).

[77] Nucleotides are base pairs for DNA and RNA that make up all genetic materials: As pair with Ts, and Cs pair with Gs. For background information on nucleotides, see generally BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 120–21 (4th ed. 2002).

[78] Lemley, *IP Without Scarcity*, *supra* note 8, at 477.

[79] Andrew Pollack, *Scientists Add Letters to DNA's Alphabet, Raising Hope and Fear*, N.Y. TIMES, May 7, 2014. (needs a page cite or weblink) *See generally* Denis A. Malyshev et al., *A Semi-Synthetic Organism with an Expanded Genetic Alphabet*, 509 NATURE 385, 385–88 (2014) (discussing the successful insertion of X-Y base pair into the common bacterium *E. coli*, which subsequently reproduced normally, replicating the X and Y along with the natural nucleotides).

synthetic biologists are developing "BioBricks"[80]—biological parts consisting of individual DNA modules assembled together to construct organisms.[81]

In this model, genes become both computers and builders.[82] The possibilities are limitless—"the ability to manipulate organisms to do anything imaginable may lead to new products that are currently unimaginable."[83] For example, synthetic biology may allow for obtaining "cheap, organic, self-constructing housing" from genetically modified plants that grow into a building,[84] or ordering custom genes at the doctor's office.[85]

C. *The Birth of Bioprinting*

Combining 3D printing's mechanics[86] and synthetic biology's raw materials[87] results in bioprinting.[88] Using BioBricks as the basic building blocks, 3D printers can print a mammalian or human body part (altogether as bioprinting's "products").[89] Like

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[80] For a discussion on Biobrick, see generally Reshma P Shetty et al., *Engineering BioBrick Vectors from BioBrick Parts*, 2 J. BIOLOGICAL ENGINEERING 1, 1–12 (2008). As of 2008, there were already over 2,000 BioBricks available from the Registry of Standard Biological Parts. *Id.* Note that Biobrick is different from Biosimilar, a type of pharmaceutical drug. For a discussion of biosimilar, see generally Vinita Banthia, Note, *Biosimilar Regulation: Bringing the United States Up to Speed with Other Markets*, 16 MINN. J.L. SCI. & TECH. 879, 879–916 (2015).

[81] Lemley, *IP Without Scarcity*, *supra* note 8, at 476.

[82] *Id.* at 476–77.

[83] *Id.* at 479.

[84] *Id.* at 477; *see* Tom McKeag, *Will Synthetic Biology Lead to Truly Living Buildings?*, GREENBIZ (June 16, 2010), http://www.greenbiz.com/blog/2010/06/16/will-synthetic-biology-lead-truly-living-buildings.

[85] Lemley, *IP Without Scarcity*, *supra* note 8, at 479.

[86] *See* discussion, *supra* Part II.A.

[87] *See* discussion, *supra* Part II.B.

[88] *See* Ken Doyle, *Bioprinting: From Patches to Parts*, 34 GENETIC ENGINEERING & BIOTECHNOLOGY NEWS 1, 1 [hereinafter Doyle, *From Patches to Parts*]. Bioprinting modalities include photolithography, magnetic bioprinting, stereolithography, and direct cell extrusion. *See* Piyush Bajaj et al., *3D Biofabrication Strategies for Tissue Engineering and Regenerative Medicine*, 16 ANN. REV. BIOMEDICAL ENGINEERING 247, 247–76 (2014).

[89] *See* Doyle, *From Patches to Parts*, *supra* note 88 at 1.

synthetic biology, bioprinting has a wide range of uses: anything from repairing[90] and replacing[91] broken body parts to adding newly engineered tissues.[92]

Readers might ask—how is this possible? 3D printing's precision and synthetic biology's sterilization technique convert the sci-fi myth of creating mammalian or human body parts into reality.[93] Bioprinting only requires a 3D printer, a blueprint to follow (so the bioprinter knows exactly what it needs to print), and human cells as raw materials (similar to ink in the 2D printer).[94] As Dr. Anthony Atala[95] puts it: we can grow organs instead of transplanting them.[96] Beyond bioprinting body parts, some speculate future possibilities of printing mammalian or human clones ("cloneprinting"),[97] and bringing back extinct animals.[98]

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[90] *See* Xiaofeng Cui et al., *Direct Human Cartilage Repair Using Three-Dimensional Bioprinting Technology*, 18 TISSUE ENGINEERING PART A 1304, 1304–12 (2012).

[91] *See* Sean V. Murphy & Anthony Atala, *3D Bioprinting of Tissues and Organs*, 32 NATURE BIOTECHNOLOGY 773, 773–85 (2014) [hereinafter Murphy & Atala] (discussing how surgeons can transplant bioprinted organs).

[92] *See, e.g.*, Stefanie Michael et al., *Tissue Engineered Skin Substitutes Created by Laser-Assisted Bioprinting Form Skin-Like Structures in the Dorsal Skin Fold Chamber in Mice*, 8 PLOS ONE e57741, e57741 (2013).

[93] *See* discussion, *supra* Parts II.A and II.B.

[94] *See generally* Jasper L. Tran, *Patenting Bioprinting*, HARV. J.L. & TECH. DIGEST (2015), http://jolt.law.harvard.edu/digest/patent/patenting-bioprinting [hereinafter Tran, *Patenting Bioprinting*].

[95] *See* Atala, *supra* note 11.

[96] TED talk: *Growing New Organs*, *supra* note 13. Technically, bioprinting prints organs, but does not "grow" organs.

[97] Thomas Frey, *How Long Before I Can 3D Print a Replacement Body for Myself?*, FUTURISTSPEAKER (May 22, 2014), http://www.futuristspeaker.com/2014/05/how-long-before-i-can-3d-print-a-replacement-body-for-myself/;
Patrick J. Lynch, *Is Bioprinting the Pathway to Human Cloning?*, SCIENCE QUICK PICKS (Feb. 29, 2012), http://pontotriplo.org/quickpicks/is-bioprinting-pathway-human-cloning.html [hereinafter Lynch, *Bioprinting the Pathway to Cloning*]; *see, e.g.*, Dann Albright, *How 3D Printing Humans Might Be Possible Some Day*, MAKEUSEOF (Oct. 23, 2014), http://www.makeuseof.com/tag/3d-printing-humans-might-possible-day/. For a discussion on cloneprinting, see generally discussion, *infra* Part III.A.5.

Bioprinting is at an even earlier stage of development than 3D printing or synthetic biology.[99] Early commercial applications of bioprinting will likely be drug testing[100] and skin grafting.[101] Although bioprinters are currently available,[102] bioprinting is still a future technology.[103] Compared to 3D printing, "there is still a long way to go before [bioprinting] becomes affordable, available, and commercially interesting."[104]

There are currently no regulations on bioprinting.[105] Similarly, there has also been no litigation on bioprinting, and none is expected anytime soon.[106] In 2014, the United States Patent and Trademark Office ("USPTO")[107] published the first two patent applications[108] on bioprinting,[109] assigned to an "early-stage

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[98] *See, e.g.*, JURASSIC PARK (Universal Pictures, Amblin Entertainment 1993) (bringing back dinosaurs); *cf.* THE FIFTH ELEMENT (Gaumont 1997) (recreating a perfect being from a DNA block). *But see, e.g.*, Andy Roast, *De-Extinction: Mammoth Prospect, or just Woolly?*, BBC NEWS (Aug. 20, 2013), http://www.bbc.com/news/science-environment-23602142 ("[N]o-one is seriously considering bringing back dinosaurs . . . .").

[99] *See* discussion *supra* Parts II.A and II.B.

[100] ROOT ANALYSIS, *supra* note 36, at 10.

[101] *See* Lin Edwards, *Printed Cells to Treat Burn Victims*, PHYS.ORG (Apr. 12, 2010), http://phys.org/news190269898.html.

[102] *See, e.g.*, 3DERS: *Bioprint Tissues on Demand*, *supra* note 16; 3DERS: *Russian 3D Printer*, *supra* note 16.

[103] *Cf.* Lemley, *IP Without Scarcity*, *supra* note 8, at 479 ("I don't expect to be printing my own organisms any time soon.").

[104] 3DERS: *Russian 3D Printer*, *supra* note 16.

[105] *See* Mathew Varkey & Anthony Atala, *Organ Bioprinting: A Closer Look at Ethics and Policies*, 5 WAKE FOREST J.L. & POL'Y 275, 284–86 (2015); Michael H. Park, Note, *For A New Heart, Just Click Print: The Effect on Medical and Products Liability from 3-D Printed Organs*, 2015 U. ILL. J.L. TECH. & POL'Y 187, 191–97 (2015).

[106] *Cf.* Lemley, *IP Without Scarcity*, *supra* note 8.

[107] *See generally About Us*, USPTO, http://www.uspto.gov/about-us (last visited Oct. 27, 2014) ("USPTO is the federal agency for granting U.S. patents and registering trademarks.").

[108] *See* 35 U.S.C. § 122 (2012) ("[E]ach application for a patent shall be published . . . promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under this title."). *See generally* 35 U.S.C. § 282(b)(2) (2012) (presuming granted patents are valid until challenged).

regenerative medicine" company named Organovo.[110] In fact, Organovo was the first company/entity to commercialize bioprinting,[111] with plans to test toxicity on its 3D liver model in December of 2014.[112] The Organovo bioprinter can print skin tissue, heart tissue, blood vessels, and other basic tissues for surgical therapy and transplantation.[113]

III. RATIONALES BEHIND REGULATING BIOPRINTING

To come up with the rationale for regulating the newly emerging field of bioprinting, it is helpful to look at and synthesize from the rationales of similar existing technologies. This Part analyzes and synthesizes the rationales for regulating bioprinting by comparing it to 3D printing, synthetic biology, stem cell research, organ transplantation, and cloning. Section A examines some possible bioprinting ethical arguments. Section B compares bioprinting to these technologies. Section B concludes that from the least to highest required regulatory scrutiny, the order for these technologies is: (1) 3D printing, (2) synthetic biology, (3) bioprinting, (4) stem cell research, and (5) organ transplantation.[114] Section C further synthesizes public policy to begin thinking about bioprinting regulation. Section D discusses the current regulatory framework that bioprinting would abide by.

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[109] *See, e.g.*, U.S. Patent Publication No. 20140093932 A1 (filed Mar. 11, 2013) (Murphy et al., applicants); U.S. Patent Publication No. US20140012407 A1 (filed Mar. 11, 2013). *See generally Bioprint Patent*s, FRESHPATENTS, http://tgs.freshpatents.com/Bioprint-bx1.php (last visited Oct. 27, 2014) (updating published bioprinting patents and patent applications).

[110] *See generally About Organovo*, ORGANOVO, http://www.organovo.com/company/about-organovo (last visited Nov. 1, 2014) ("[Organovo] design[s] and create[s] functional human tissues using our proprietary three-dimensional bioprinting technology."). For a thorough discussion on patenting bioprinting, see Tran, *Patenting Bioprinting*, *supra* note 94.

[111] *See* Doyle, *From Patches to Parts*, *supra* note 88.

[112] ROOT ANALYSIS, *supra* note 36, at 10.

[113] Murphy & Atala, *supra* note 91, at 773–85.

[114] *See* discussion, *infra* Part III.B.

A. *Bioprinting Ethics*

Although there are many ways to analyze bioprinting ethics, this Article applies four ethical frameworks to examine some bioprinting ethical arguments.[115] Note that this is not the only way to analyze bioprinting ethics. Although this section does not cover all the possible ethical arguments regarding bioprinting, it serves as a starting point to a discussion of bioprinting ethics.[116]

1. *Intrinsic*

Research involving bioprinted products used inside and outside a human body trigger different ethical concerns. For example, using bioprinted products inside a human body may implicate biosafety concerns and raise issues over whether human dignity has been violated.[117] Other ethical concerns include the questionable sources of the biomaterials as well as how to eliminate their waste.[118]

Some of the concerns with bioprinting come from a religious perspective in which technologies that alter a biological state are viewed as a violation of religious principles.[119]

Others may be concerned about the sources of stem cells used in bioprinting ink, because some stem cells are derived from the

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[115] *Cf.* J. Burkhardt, What can Nano Learn from Bio? Presentation at the Institute of Food and Agricultural Sciences Conference on Nanotechnology (2005) (applying four ethical frameworks to nanotechnology).

[116] This kind of ethical framework was initially adopted from biological science to nanotechnology. Given that bioprinting combines (synthetic) biology and computer science (3D printing), this framework makes the most sense.

[117] *See* Varkey & Atala, *supra* note 105, at 284.

[118] *Cf.* Sibel Tunali Akar et al., *Biosorption Potential of the Waste Biomaterial Obtained from Cucumis melo for the Removal of Pb2+ Ions from Aqueous Media: Equilibrium, Kinetic, Thermodynamic and Mechanism Analysis*, 185–86 CHEMICAL ENGINEERING J. 82, 82 – 90 (2012).

[119] *See* Christian Brugger, *Printers Aren't Just For Homework Anymore: The Science and Ethics of Bioprinting*, CULTURE OF LIFE FOUND (Sept. 9, 2013), http://www.culture-of-life.org/2013/09/10/pr-intersarent-just-homework-anymore-science-and-ethics-bioprinting/; s*ee also* John Zingarelli, *Is "Creation" A Religious Concept?*, 8 REGENT U. L. REV. 35, 39 (1997) (discussing God and "natural" matters).

destruction of human embryos.[120] For those who view human embryos as human beings, killing embryos would be wrong, even if doing so can save human life.[121]

Environmentalists may be concerned about the possibility of bioprinters emitting unhealthy air and contributing to environmental pollution.[122] The public generally might worry about the safety of bioprinted products, especially when used in a human body, *e.g.*, issues like malfunction incidents, and who should bear liability for such incidents? A government branch most familiar with health and human services, as suggested later in this Article, would be fully capable to handle these safety issues.[123]

2. *Consequential*

For the cosmetic industry, there might be a similar problem to that of "designer babies"[124]: "athletes and people seeking body modification for personal satisfaction or to gain an edge for themselves."[125] It does not seem unreasonable to presume that "individuals will try to find ways to enhance themselves with 3D printing if they can get an advantage,"[126] given that "[s]ome athletes already assume significant risks to increase their performance on the field using illegal substances with serious side

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[120] *See* Brugger, *supra* note 119.

[121] *See* Bonnie Steinbock, *The Morality of Killing Human Embryos*, 34 J.L. MED & ETHICS 26, 32–34 (2006).

[122] *See* Lyndsey Gilpin, *The dark side of 3D printing: 10 things to watch*, TECHREPUBLIC (Mar. 5, 2014 4:51 AM), http://www.techrepublic.com/article/the-dark-side-of-3d-printing-10-things-to-watch/. For a study on 3D printing's emission, *see generally* Brent Stephens, et al., *Ultrafine particle emissions from desktop 3D printers*, 79 ATMOSPHERIC ENVIRONMENT 334, 334–39 (2013) (discussing that bioprinters using PLA filament emitted 20 billion ultrafine particles/minute, and the ABS emitted up to 200 billion particles/minute for heating plastic and printing small figures).

[123] *See* discussion *infra* Part V.A.

[124] *See* Sonia M. Suter, *A Brave New World of Designer Babies?*, 22 BERKELEY TECH. L.J. 897, 929–34 (2007).

[125] Richard Adhikari, *Bioprinting, Part 2 - The Ethical Conundrum*, TECHNEWSWORLD (Mar. 27, 2014 6:30 AM PT), http://www.technewsworld.com/story/80205.html.

[126] *Id.*

effects, . . . [and o]thers might seek enhancements to help achieve their ideal of beauty."[127]

Subsequently, if enhanced bioprinted body parts are desirable, a black market may emerge.[128] An extreme example might be that having a hand with six functional fingers could be viewed as "better" than having one with five functional fingers. Furthermore, if one is "desperate and [has expired health insurance] and need[s] a new [body part], [s/he would] go to the black market stalls."[129] But more problems arise when an individual buys a defective body part or receives a transplant from a black-market surgeon—for example, whom to sue when there arise surgical complications or infection.[130]

3. *Right/Consent Base*

Traditional human rights activists may argue that bioprinting violates human dignity and integrity.[131] However, human dignity is increasingly used as a "form of general condemnation and as blanket justification for regulatory restraint," and "on its own, [is a] dubious justification for policies that are aimed at constraining controversial biotechnologies."[132]

Assuming brain transplantation is possible, some express concern that brain transplantation using bioprinted brains would risk losing that individual's identity and personality by memory loss, character, psychological development, and brain-body history.[133] The counterargument would be that bioprinting solves

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[127] *Id.*

[128] *See* MICHELE GOODWIN, BLACK MARKETS: THE SUPPLY AND DEMAND OF BODY PARTS 170–71 (2013) [hereinafter GOODWIN, BODY PARTS BLACK MARKETS] (discussing the black market for organs).

[129] Hop Lipson & Melba Kurman, *Navigating the Ethical Minefield of Bio-Printing*, BIGTHINK, http://bigthink.com/in-their-own-words/navigating-the-ethical-minefield-of-bio-printing (last visited Dec. 15, 2014).

[130] *Id.*

[131] *See* Timothy Caulfield & Roger Brownsword, *Human Dignity: A Guide to Policy Making in the Biotechnology Era?*, 7 NATURE REV. GENETICS 72, 72–76 (2006).

[132] *Id.* at 72.

[133] *See id.*

the current organ shortage in organ transplantation,[134] for which the benefits might outweigh the potential risks/harms.[135]

Moreover, another argument is that patients for new or experimental treatments often serve as guinea pigs."[136] Although most people would have a choice whether they would use a bioprinted product, some people, especially those on the organ transplantation waitlist, are desperate.[137] This form of experimentation can be viewed as coercion—desperate terminal patients have no choice but to accept an experimental bioprinted organ.[138]

4. *Structural/Procedural*

Some economists might argue, "[j]ust because something works in the lab doesn't mean it will work in the marketplace, especially with the cost of healthcare."[139] Accordingly, the United States might be better off economically by investing in healthcare resources elsewhere.[140] However, the counterargument is that bioprinting might actually preserve more healthcare resources in the long run.[141] For example, instead of continuously fixing an organ over and over again, it might make more sense to replace that organ.

Bioprinting could create an inequality between different countries because bioprinting could advance unabated in countries with less-restrictive government oversight, whereas clinical trials and testing of organs for transplantation in the United States could

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[134] *See* discussion *infra* Part V.B.2.
[135] *See* discussion *infra* Part III.C.3.
[136] Adhikari, *supra* note 125.
[137] *See id.*
[138] *Cf.* Leonard W. Schroeter, *Human Experimentation, the Hanford Nuclear Site, and Judgment at Nuremberg*, 31 GONZ. L. REV. 147, 153 (1995–96) (discussing human experimentation as coercion).
[139] Adhikari, *supra* note 125 (quoting Charlie Whelan, Healthcare and Life Science Director of Consulting at Frost & Sullivan).
[140] *See* Dan W. Brock & Daniel Wikler, *Ethical Issues in Resource Allocation, Research, and New Product Development*, *in* DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES 259 (Dean T. Jamison et al. eds., 2d ed. 2006).
[141] *See* discussion *infra* Part V.B.2.

take up to a decade given the Food and Drug Administration's ("FDA")[142] stringent reviews.[143] The United States already has guidelines to handle patients being exposed to new medical technologies. For example, "[t]he FDA has strict safety and efficacy standards for implants made from a patient's own cells,"[144] and "[h]ospital oversight boards would regulate donor issues, cells and tissue for informed consent."[145] The United States, which has been known as a world leader in technology,[146] might fall behind at its own game when it comes to bioprinting.[147] Furthermore, bioprinting's "ability to build customized human anatomical parts has pervasive appeal in medical device markets especially in economically weak and war-torn regions where it addresses high demand for prosthetic and other medical devices."[148] Another concern is that large population regions with inadequate access to

[142] For background on the FDA, see generally *About FDA: What We Do*, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited Nov. 4, 2014).

[143] *See* Lucas Mearian, *Bio-Printing Human Parts will Spark Ethical, Regulatory Debate: 3D Printing also Threatens Intellectual Property Rights*, COMPUTER WORLD (Jan. 29, 2014 6:33 AM PT), http://www.computerworld.com/article/2486998/emerging-technology/bio-printing-human-parts-will-spark-ethical--regulatory-debate.html?page=2.

[144] Adhikari, *supra* note 125 (quoting Jordan Miller, Assistant Professor of Bioengineering at Rice University).

[145] *Id.* (citing Kevin E. Healy, Chair of the Bioengineering Department at University of California, Berkeley).

[146] *See, e.g.*, *U.S. Remains the Dominant Leader in Science and Technology Worldwide*, HOMELAND SECURITY NEWS WIRE (June 15, 2008), http://www.homelandsecuritynewswire.com/us-remains-dominant-leader-science-and-technology-worldwide.

[147] *See also* Kevin G. Coleman, *US Moving From Technology Leader To Laggard*, INFORMATIONWEEK (Dec. 2, 2013 2:15 PM), http://www.informationweek.com/government/cybersecurity/us-moving-from-technology-leader-to-laggard-/d/d-id/1112861 (discussing how the U.S. is lagging in research and development (R&D), science, and technology investments).

[148] Mearian, *supra* note 143.

emerging healthcare technology, such as China or India,[149] could face inequality issues.

Additionally, some bioprinted products could become cheaper and more accessible but other products like functioning hearts, which could be extremely complex to bioprint, would "likely be only accessible to those willing to pay for personalized treatments."[150] If some new bioprinted products are more expensive than existing treatments, healthcare would likely not cover such cost, and thus, only the rich would be able to afford them.[151] Consequently, the division between the rich and the poor would grow larger.[152]

B. *Comparing to Existing Regulations*

After analyzing bioprinting ethics, it seems as though the ethics of bioprinting are not unique to bioprinting itself, but have surfaced before in existing technologies, such as 3D printing, synthetic biology, stem cell research, organ transplantation and cloning.[153] Therefore, it makes sense to compare bioprinting with the listed technologies to determine where bioprinting falls on the ethical spectrum. In doing so, this Article explains the rationales behind each technology's regulation, whether such regulatory approach's results are "good" or "bad," and what and how bioprinting regulation can learn from the listed technologies. This Article also provides the current regulations on those existing technologies as a starting point to think about regulating bioprinting.

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[149] *See, e.g.*, Yarlini Balarajan et al., *Health Care and Equity in India*, 377 LANCET 505, 505–15 (2011) (India).

[150] Adhikari, *supra* note 125 (quoting Kirstin Matthews, Fellow in Science and Technology Policy at Rice University's Baker Institute).

[151] *See id.*

[152] *See id.* ("This will continue to expand the access divide between the haves and the have nots.").

[153] Some of these ethical issues are discussed in detail later. *See* discussion *infra* Part V.C.

1. *Much Higher Scrutiny than 3D Printing*

As previously mentioned,[154] recent scholarship on regulating 3D printing[155] implicitly presumes the same regulation should apply both to bioprinting and 3D printing. Technically, bioprinting is a subcategory of 3D printing.[156] 3D printing can print both non-biological and biological matters.[157] However, non-biological items *e.g.*, a pencil, are ready to use, whereas bioprinting's products, such as an ear[158] or a lung, require surgeons and doctors' assistance.

Further, printing from biological materials presents different public policy considerations than printing from non-biological materials. Compared to non-biological materials, experimenting with mammalian genetic matter generates strong political, regulatory and ethical debates.[159] The societal scrutiny heightens when the genetic materials are from humans.[160] Because bioprinting involves the use of mammalian and human genetic materials, bioprinting will be subject to much higher scrutiny than 3D printing.

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[154] *See* discussion *supra* Part I.

[155] *See, e.g.*, Desai & Magliocca, *Napster*, *supra* note 19, at 1703–20; Osborn, *Regulating 3D Printing*, *supra* note 26, at 562–92.

[156] *See* discussion *supra* Parts II.A and II.C (discussing that bioprinting is a type of 3D printing that prints from BioBricks).

[157] *See* discussion *supra* Part II.A.

[158] *See* Adam Shaw, *Growing an Ear: How 3D Bio Printing Could Change the World*, BRIT. AIRWAYS: BUS. LIFE (June 5, 2013), http://businesslife.ba.com/Ideas/Features/Growing-an-ear-how-3D-bio-printing-could-change-the-world.html (Cornell scientists "are not just printing life—like copies of ears—they are actually producing real ears, made of human tissue, that function as normal ears and could be transplanted on to humans."); *cf.* Mannoor, *Bionic Ears*, *supra* note 52 (discussing 3D printing bionic ears).

[159] *See, e.g.*, Andrews, *Right to Clone?*, *supra* note 32; Katz, *The Clonal Child*, *supra* note 32; Robertson, *Human Cloning*, *supra* note 32; Warrington, *Reproductive Cloning*, *supra* note 32.

[160] *See, e.g.*, Fatehi & Hall, *supra* note 34; Kukla, *Ethical Justification*, *supra* note 34; McGeveran, *Biobank*, *supra* note 34; Rao, *Ethics of Compensation*, *supra* note 34; Winickoff, *Policy Proposal*, *supra* note 34.

Unfortunately, 3D printing has already faced many legal challenges[161] in intellectual property (IP) law,[162] environmental law,[163] contract law,[164] products liability,[165] criminal law, and firearms control.[166] 3D-printing-related litigation is emerging and robust, especially in the patent infringement context.[167] One analyst

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[161] Osborn, *Regulating 3D Printing*, *supra* note 26, at 562–92; Desai & Magliocca, *Napster*, *supra* note 19, at 1692.

[162] Osborn, *Regulating 3D Printing*, *supra* note 26, at 582–92; Daniel Harris Brean, *Asserting Patents to Combat Infringement via 3D Printing: It's No "Use"*, 23 FORDHAM INTELL. PROP., MEDIA & ENT. L.J. 771 (2012); Davis Doherty, Note, *Downloading Infringement: Patent Law as a Roadblock to the 3d Printing Revolution*, 26 HARV. J.L. & TECH. 353 (2012) (outlining possible patent infringement scenarios and culpable infringers arising from consumer use of 3D printers). *But see* Joseph C. Storch, *3-D Printing Your Way Down the Garden Path: 3-D Printers, the Copyrightization of Patents, and a Method for Manufacturers to Avoid the Entertainment Industry's Fate*, 3 N.Y.U. J. INTELL. PROP. & ENTM'T L 249, 309 (2014) (proposing that "manufacturers should not engage in a litigation strategy of suing individual consumers or a legislative strategy of seeking to increase fines or criminal penalties for such violations[, but instead,] acknowledge their loss of a technical monopoly, and the concomitant loss of legal monopoly protection that practically accompanies such a paradigm shift").

[163] Osborn, *Regulating 3D Printing*, *supra* note 26, at 564–66 (3D printing reduces waste but could emit toxic fumes).

[164] *Id.* at 571–72 (raising questions like whether CAD files are "goods," whether CAD file sellers are "merchants," and sale vs. license).

[165] *Id.* at 566–71 (raising questions like whether CAD files are "products," who to sue for "selling" or "otherwise distributing" such products, and whether strict liability should apply to "manufacturing" defect).

[166] *Id.* at 576–82. Recently, Sen. Charles Schumer (D-NY) and Sen. Bill Nelson (D-FL) have introduced legislation to expand the undetectable firearms law to ban 3D-printed guns. *See* Press Release, Sen. Charles E. Schumer, U.S. Sen. for N.Y., *Schumer*, *Nelson Call for Revamping, Extending Reagan-Era Firearms Act that Bans New Practice of Creating Undetectable Guns, at Home, with 3-D Printer*, BILLNELSON.SENATE.GOV (June 13, 2013), http://www.billnelson.senate.gov/newsroom/press-releases/schumer-nelson-call-for-revamping-extending-reagan-era-firearms-act-that (last visited Sept. 4, 2015).

[167] *See, e.g.*, 3D Sys., Inc. v. Formlabs, Inc., No. 13-cv-7973, 2014 WL 1904365 (S.D.N.Y. May 12, 2014) (patent infringement); Barranco v. 3D Sys. Corp., No. 13-cv-00412, 2014 WL 1091740 (D. Haw. Mar. 17, 2014) (contractual claims); Stratasys, Inc. v. Microboards Tech., LLC, No. CIV. 13-

group even predicts an annual global IP loss of at least $100 billion from 3D printing by 2018.[168]

2. *Slightly Higher Scrutiny Than Synthetic Biology*

Bioprinting stems from synthetic biology.[169] However, bioprinting differs in that bioprinting moves synthetic biology's production out of the laboratory to everyone's home.[170] Although both bioprinting and synthetic biology still require doctors' assistance,[171] bioprinting is more accessible than synthetic biology. Therefore, bioprinting deserves slightly higher scrutiny than synthetic biology.

Legally, synthetic biology is subject to the same bioethics and biosecurity issues as recombinant DNA and genetically modified organisms because these processes all utilize the same source—biological materials.[172] Except for the regulation of DNA synthesis companies,[173] synthetic biology presumably follows existing

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3228 DWF/TNL, 2015 WL 1608344 (D. Minn. Apr. 10, 2015); 3D Sys., Inc. v. Formlabs & Kickstarter, No. 12-cv-03323 (D. S.C.) (patent infringement—pending settlement);, 3D Sys., Inc. v. EnvisionTec, Inc., No. 05-74891, 2011 WL 4691937 (E.D. Mich. Oct. 6, 2011) (patent infringement—ended in a settlement shortly after the district court's infringement ruling); *see also, e.g.*, Doherty, *supra* note 162 (outlining possible patent infringement scenarios and culpable infringers arising from consumer use of 3D printers). For a discussion on patent litigation, *see generally* Jasper L. Tran, *Timing Matters: Prior Art's Age Infers Patent Nonobviousness*, 50 GONZ. L. REV. 189 (2015); Jasper L. Tran, *Software Patents: A One-Year Review of* Alice v. CLS Banks, 97 J. PAT. & TRADEMARK OFF. SOC'Y 532 (2015).

[168] *Gartner: 3D Printing to Result in $100 Billion IP Losses per Year*, 3DERS.ORG (Oct. 14, 2013) [hereinafter *$100 Billion IP Losses*], http://www.3ders.org/articles/20131014-gartner-3d-printing-to-result-in-100-billion-ip-losses-per-year.html. (last visited Sept. 4, 2015).

[169] *See* discussion, *supra* Parts II.B. and II.C.

[170] *Cf.* Kurutz, *supra* note 8 (discussing that 3D printer will soon be just another home appliance).

[171] *See* discussion, *supra* Parts II.B. and II.C.

[172] *See* Hans Bügl et al., *DNA Synthesis and Biological Security*, 25 NATURE BIOTECHNOLOGY 627, 627–29 (2007).

[173] *See id.*

regulations of genetic engineering and pathogen research.[174] Following this line of logic, some might argue that bioprinting would likely fall under the same regulation regime.[175]

3. *Slightly Less Scrutiny Than Stem Cell Research*

What bioprinting and stem cell research have in common is that they both involve using genetic materials from mammals, including humans.[176] However, the source of the genetic materials differs. Stem cell researchers harvest stem cells from mammalian newborns,[177] whereas bioprinting takes advantage of synthetic biology's technology[178] and uses synthetic BioBricks,[179] which are created in a laboratory.[180] Because synthesizing new genetic materials is likely more humane and acceptable than harvesting genetic material from existing living mammals and humans, bioprinting will be subject to slightly less scrutiny than stem cell research.

Until recently, the U.S. banned stem cell research and thus, made no scientific progression in the field of stem cell research. In 2009, U.S. President Barack Obama issued an Executive Order

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[174] PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES 36, 56–72 (2010), *available at* http://permanent.access.gpo.gov/gpo9019/PCSBI-Synthetic-Biology-Report-12.16.10.pdf (recommending no changes to policy or oversight and calling for continued funding of the research and new funding for monitoring, study of emerging ethical issues, and public education). But, over 100 environmental and civil society groups advocate for a worldwide ban on the release and commercial use of synthetic organisms and the use of synthetic biology in human genome or human microbiome until more robust regulations and rigorous biosafety measures are established. *See* FRIENDS OF THE EARTH ET AL., THE PRINCIPLES FOR THE OVERSIGHT OF SYNTHETIC BIOLOGY (2012),) *available at* http://www.synbioproject.org/site/assets/files/1270/principles_for_the_oversight_of_synthetic_biology.pdf.

[175] *But see* discussion, *infra* Parts IV and V (discussing how regulating bioprinting would likely be more complicated).

[176] *See* discussion, *supra* Part II.C and note 33.

[177] *See* Tuch, *Stem Cells*, *supra* note 33.

[178] *See* discussion, *supra* Parts II.B. and II.C.

[179] *See* discussion, *supra* Part II.B and notes 80–81.

[180] *See* discussion, *supra* Part II.C.

titled "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells" to remove the ban and allow further research using stem cells.[181] Current human stem cell research still must adhere to the National Institute of Health's ("NIH"[182]) guidelines.[183] Furthermore, other federal regulations govern various aspects of Human Embryonic Stem Cell Research, including:

> Human subjects protection for donors of somatic cells and oocytes and for some donors of embryos. Medical privacy protections. Laboratory standards for investigators whose work will result in products that require Food and Drug Administration (FDA) approval. Safety reviews of laboratory work that involves genetic alteration of [human stem] cell lines. Animal care committee reviews of [human stem] cell research that uses nonhuman animals. Various rules governing the importation of biological materials or the transfer of medical data from other countries. [184]

In short, stem cell research is regulated one way or another.

4. *Much Less Scrutiny Than Organ Transplantation*

Although both bioprinting and organ transplantation[185] involve human genetic materials, they do not draw from the same source. With the exception of kidneys, each individual has only one of

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[181] Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009); *see also* Bill Mears, *Supreme Court Allows Federal Stem Cell Research to Continue*, CNN (Jan. 8, 2013, 12:28 PM EST), http://www.cnn.com/2013/01/07/justice/stem-cell-appeal/ ("Supreme Court . . . dismissed a long-standing appeal from scientists who tried to block funding of stem cell research on human embryos.").

[182] *See generally About NIH*, NAT'L INST. OF HEALTH, http://www.nih.gov/about/ (last visited Dec. 16, 2014).

[183] *See National Institutes of Health Guidelines on Human Stem Cell Research*, NAT'L INST. OF HEALTH (July 7, 2009), http://stemcells.nih.gov/policy/pages/2009guidelines.aspx (last visited Dec. 16, 2014); *see also* Draft National Institutes of Health Guidelines for Human Stem Cell Research Notice, 74 Fed. Reg. 18,578-01 (Apr. 23, 2009) (discussing drafted guidelines for human stem cell research).

[184] GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH 63 (Nation Resource Council and Institute of Medicine) (2005), *available at* http://www.nap.edu/catalog/11278/guidelines-for-human-embryonic-stem-cell-research.

[185] The term "organ transplantation" used throughout this Article includes both organ harvesting and transplantation.

each organ needed to live,[186] creating a worldwide shortage of available organs[187] for organ transplantation, which "mandates the need to guard the ethical standard of medical priorities for those patients that depend on the transplantation to save their lives."[188] Thus, organ transplantation regulations are universally extensive, complex, and extremely strict.[189] Conversely, bioprinting creates organs from scratch.[190]

While organ failure might occur in both bioprinting and organ transplantation[191] bioprinting body parts from an individual's own genetic materials avoids the problem of transplant rejection, [192] even though such body parts from bioprinting might still malfunction. In a way, bioprinting revolutionizes organ transplantation[193] and should not be subject to the extremely high level of scrutiny currently used for organ transplantation; instead, bioprinting should be subject to a lower level of scrutiny.

Current regulation of organ transplantation in the U.S. falls under the National Organ Transplantation Act (NOTA) of 1984,

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[186] Each individual has 2 kidneys, but only needs one to live.

[187] Rafael Beyar, *Challenges in Organ Transplantation*, 2 RAMBAM MAIMONIDES MED. J. e0049(1), e0049(2) (2011); *See also* Rachel Johnson et al., *Kidney Donation and Transplantation in the UK from 1998 to 2007*, CLINICAL TRANSPLANTATION 75, 75–88 (2008).

[188] Rafael Beyar, *Challenges in Organ Transplantation*, 2 RAMBAM MAIMONIDES MED. J. e0049(1), e0049(2) (2011).

[189] *See, e.g.*, UNITED NETWORK FOR ORGAN SHARING, TALKING ABOUT TRANSPLANTATION: WHAT EVERY PATIENT NEEDS TO KNOW 3–27 (2013) *available at* http://www.unos.org/docs/WEPNTK.pdf.

[190] *See, e.g.*, TED talk: *Growing New Organs*, *supra* note 13. *See generally* discussion, *supra* Part II.C.

[191] *See* Christopher J. E. Watson & John H. Dark, *Organ Transplantation: Historical Perspective and Current Practice*, 108 BRITISH J. ANESTHESIA i29, i29–42 (2012) (discussing organ failure by transplantation).

[192] Transplant rejection occurs when the transplanted recipient's immune system rejects and destroys the transplanted tissue. For a discussion on transplant rejection, *see generally* Christoph Frohn et al., *The Effect of HLA-C Matching on Acute Renal Transplant Rejection*, 16 NEPHROLOGY DIALYSIS TRANSPLANTATION 355, 355–60 (2001).

[193] *Cf.* Doyle, *Revolutionize*, *supra* note 60 (discussing that 3D printing could revolutionize healthcare through human tissues).

which establishes the framework for whole organ recovery and allocation.[194] Prior to 1984, whether the FDA had authority to regulate the marketing of human organs was controversial.[195] Of course, some people still go abroad for organ transplantation, which avoids United States regulations entirely.[196]

> [NOTA] (1) provided federal funding for regional federal procurement agencies; (2) established a national organ procurement and transplantation network (OPTN) to manage the procurement and distribution of solid donor organs; (3) mandated funding of transplant-related medication and surgical transplant procedures by Medicaid/Medicare; (4) established a task force to formally study organ transplant allocation problems; and (5) specifically prohibited the sale of donor organs for transplantation though the ban does not apply to blood, sperm or ova. The solid organ donor program is purely voluntary, both for living and cadaveric organ transplantation.[197]

An interesting question for further research is whether a bioprinted organ would be subject to NOTA under the organ transplantation rule.

5. *Special Case: Cloneprinting Subject to Higher Scrutiny than Cloning*

Since cloning is possible[198], cloneprinting would technically be possible as well. Because bioprinting body parts is already happening, a next step would be bioprinting "fully functional

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[194] *See* National Organ Transplant Act, 98 Stat. 2339 (1984).

[195] *See, e.g.*, Bruce Patsner, *Human Organ Transplantation in the U.S. – Crossing New Lines?*, UNIV. OF HOUSTON HEALTH LAW PERSPECTIVES (Aug. 19, 2008), http://www.law.uh.edu/healthlaw/perspectives/2008/(BP)%20organ.pdf; DAVID K.C. COOPER & ROBERT P. LANZA, XENO: THE PROMISE OF TRANSPLANTING ANIMAL ORGANS INTO HUMANS 226 (2000).

[196] *See* GOODWIN, BODY PARTS' BLACK MARKETS, *supra* note 128.

[197] Patsner, *supra* note 195.

[198] *See generally* Susanna Hornig Priest, *Cloning: A Study in News Production*, 10 PUB. UNDERSTANDING OF SCI. 59, 59–69 (2001) (discussing thee cloning ethical debate and public perception of cloning and the ethnical debate surrounding cloning). For example, scientists have successfully cloned a sheep (the Dolly sheep) in 2004. *See supra* note 31 and accompanying texts.

human[s]". [199] Given the fundamental differences between bioprinting and cloneprinting, the regulations governing each will likewise need to be different.[200]

Imagine a future where an individual can simply bioprint another clone of herself at home; this is a scary yet exciting vision. Theoretically, cloneprinting would simply serve as a quick, easy modality of production.[201] This comparison assumes that the future of bioprinting makes it possible to cloneprint a mammalian or human clone.[202]

Unlike bioprinting body parts, cloneprinting does not require doctors' assistance before the "products," *i.e*., clones, are ready for use. Similar to how bioprinting differs from synthetic biology, cloneprinting differs from cloning in that cloneprinting moves clone production out of the laboratory and into everyone's home, making cloneprinting more accessible than cloning.[203] Likewise, cloneprinting calls for slightly higher scrutiny than cloning.[204]

The U.S. House of Representatives voted whether to ban all human cloning, both reproductive and therapeutic, in 1998, 2001, 2004, and 2007, and prevented all bills from passing.[205] Currently, there is a 2010 bill in the House of Representatives Energy and Commerce Committee with a section banning federal funding for human cloning.[206] The U.S. has no federal law that bans cloning

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[199] Lynch, *Bioprinting the Pathway to Cloning*, *supra* note 97 ("[T]here has been a way found to create functional organs; therefore a scientists 'logical' second step is creating a fully functioning human!").

[200] This Article will only discuss regulating bioprinting but not cloneprinting. When cloneprinting becomes real, cloneprinting will be a topic for another Article.

[201] *Cf.* Desai & Magliocca, *Napster*, *supra* note 19, at 1719 (discussing 3D printing transforms effect on manufacturing).

[202] *See* discussion *supra* Part II.C. and note 98.

[203] *Cf.* Kurutz, *supra* note 8 (discussing that the 3D printer will soon be a common home appliance).

[204] *See* discussion *supra* Part III.B.2 (concluding that bioprinting deserves slightly higher scrutiny than synthetic biology).

[205] *Human Cloning*, ATLANTIS ONLINE, http://atlantisonline.smfforfree2.com/index.php?topic=26838.0;wap2 (last visited Dec. 17, 2014).

[206] *See* H.R. 4808, 111th Cong. (2010).

completely,[207] as any such laws might raise difficult constitutional issues similar to the issues seen in the abortion debate.[208] Nonetheless, thirteen states have banned reproductive cloning and three states prohibit use of public funds for cloning.[209]

C. *Public Policy Behind Regulating Bioprinting*

As analyzed above,[210] from the lowest to the highest scrutiny, the scrutiny order should be: (1) 3D printing, (2) synthetic biology, (3) bioprinting, (4) stem cell research, (5) organ transplantation, and in the special case of cloneprinting, (6) cloning would be less scrutinized than (7) cloneprinting.[211] Given that U.S. biotechnology policy "adopts a precautionary approach when it comes to stem cells and cloning,"[212] a precautionary regulation serves as a good starting point.

1. *A "Relaxed" Federal Standard*

Regulating bioprinting needs a standard rather than a rule.[213] Assuming a 3D printer and bioprinter use the same hardware,

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[207] *Cloning: Frequently Asked Questions*, NPR, http://www.npr.org/news/specials/cloning/faq_blanknav.html (last visited Aug. 14, 2015) ("Is human cloning banned in the United States? In the United States, there are no federal laws specifically regarding human cloning.").

[208] *See, e.g.*, Janet L. Dolgin, *Embryonic Discourse: Abortion, Stem Cells, and Cloning*, 31 FLA. ST. U. L. REV. 101, 114–35 (2003).

[209] *See Human Cloning Laws*, NAT'L CONF. OF STATE LEGISLATURES, http://www.ncsl.org/research/health/human-cloning-laws.aspx (last visited Dec. 17, 2014).

[210] *See* discussion *supra* Part III.B.

[211] *See also* Murphy & Atala, *supra* note 91, at 773–85.

[212] Adam D. Sheingate, *Promotion Versus Precaution: The Evolution of Biotechnology Policy in the United States*, 36 BRIT. J. POL. SCI. 243, 243 (2006).

[213] *See generally* Russell B. Korobkin, *Behavioral Analysis and Legal Reform: Rules vs. Standards Revisited*, 79 OR. L. REV. 23, 33 (2000) [hereinafter Korobkin, *Rules vs. Standards*]; Louis Kaplow, *Rule vs. Standard: An Economic Analysis*, 42 DUKE L.J. 557, 611–16 (1992) (comparing the differences between using a rule and a standard in term of cost). A standard depends on the facts and applies on a case-by-case basis whereas a rule clearly lays out what qualifies and what does not without leaving much ambiguity left.

almost every household would have access to such hardware.[214] The upside of having a rule for regulating bioprinting is that given the sheer volume of access to bioprinters, regulating bioprinting needs consistency, favoring a strict rule rather than evaluating on a case-by-case basis via a broad standard.[215] However, the downside for having a rule for regulating bioprinting is that bioprinting's wide range of uses[216] makes it hard to come up with "one rule [that] fits all."[217]

Congress needs to regulate bioprinting at a federal level for consistency. If Congress leaves bioprinting regulation up to the states, bioprinting regulations would likely vary across the country. Furthermore, an individual can "work around" the regulations in any state by simply crossing the restricted state's border to get bioprinted "products" in a non-restricted state.[218] Congress may find a constitutional basis to regulate bioprinting through its inherent power to regulate interstate commerce through the Commerce Clause—after all, bioprinted products would likely either travel through interstate commerce, utilize the instrumentality of commerce, or have a cumulative effect on interstate commerce.[219]

Bioprinting regulations need to be "relaxed" to avoid creation of a grey or black market for synthetic human body parts.[220] Strict

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[214] *Cf.* Kurutz, *supra* note 8 (discussing that 3D printer will soon be a common home appliance).

[215] *See* Korobkin, *Rules vs. Standards*, *supra* note 213.

[216] *See* discussion *supra* Part II.C.

[217] *Cf.* Mark Hellowell, *One Rule Fits All?*, THE LAWYER (June 2, 2002), http://www.thelawyer.com/one-rule-fits-all/97205.article.

[218] *Cf.* Barry Friedman & Genevieve Lakier, *"To Regulate," Not "To Prohibit": Limiting the Commerce Power*, 2012 SUP. CT. REV. 255, 258–59 (2012) (questioning whether the Commerce Clause, properly understood, "includes the power not only to . . . 'protect' interstate markets but also to 'eradicate' them").

[219] *See* U.S. CONST. art. I, § 8, cl. 3 (stating that Congress shall have power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes").

[220] For a discussion of grey market, see generally John J. McNamara, *Attention Gray Market Shoppers:* K Mart Corp. v. Cartier, Inc. *Fails to Clarify*

bioprinting regulations would most likely create a grey/black market for synthetic human body parts (and possibly clones).[221] Conversely, there would be no point in the existence of a grey or black market if bioprinting regulations were "relaxed."

2. *Positive Public Perception*

The public perception of bioprinting is generally positive: the public is excited about bioprinting and its possibilities.[222] Unfortunately, because the public is less tolerant of risks,[223] there have been some concerns about the ethics of cloneprinting, which presumably carries the same ethical concerns as cloning.[224] Further, religious groups that fundamentally oppose some aspects of science and technology will have even greater opposition to bioprinting, given what bioprinting can do.[225]

Ideally, society would most likely want to avoid the scenario where only a few individuals gain economic benefits from bioprinting while the rest of society pays for bioprinting's extremely high cost. Still, society may want to incentivize individuals who invent and improve bioprinting by allowing them

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the Clouded Area of Gray Market Goods, 38 CATH. U. L. REV. 933, 938–39 (1989) ("The gray market appears to benefit consumers by offering brand name goods at reduced prices. Gray market goods, however, are often of lower quality than goods sold by authorized distributors. In many cases, gray market goods are subject to different production standards than goods marketed by authorized distributors, thus giving rise to inferior and even unsafe products.")

[221] *Cf.* GOODWIN, BODY PARTS' BLACK MARKETS, *supra* note 128, at 7 (discussing the black market which stemmed from the strict regulations of organ transplantation).

[222] *See, e.g.*, TED talk: *Growing New Organs*, *supra* note 13; TED talk: *Printing Human Kidney*, *supra* note 14.

[223] *See, e.g.*, Dirk Scheer & Ortwin Renn. *Public Perception of Geoengineering and Its Consequences for Public Debate*, 125 CLIMATIC CHANGE 305, 305 (2014) ("people seem to cautiously support research but oppose deployment while attitude formation depends on personal values and belief systems").

[224] *See, e.g.*, Andrews, *Right to Clone?*, *supra* note 32; Katz, *The Clonal Child*, *supra* note 32; Robertson, *Human Cloning*, *supra* note 32; Warrington, *Reproductive Cloning*, *supra* note 32.

[225] *See* discussion *supra* Part II.C.

to recoup their research and development ("R&D") investment.[226] This rationale parallels with the creation of Intellectual Property rights.[227] Conversely, the government can subsidize R&D cost with taxpayers' money, but research dependent on government funding would likely lead to a slower growth rate than privately funded research.[228]

3. *Potentially Significant Benefits vs. Very Low Risks*

Bioprinting carries potentially significant benefits and very low risks. Overall, bioprinting is a big step for scientific and technological progression. Bioprinting benefits society at large by providing spare body parts, thereby extending or even saving lives. [229] Furthermore, bioprinting could be a step towards immortality, where an aged human would replace old tissues with new bioprinted tissues.[230] Although using bioprinted body parts comes with a few inherent risks, such as malfunction or complete

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[226] *Cf.* Lila Feisee, *Are Biotechnology Patents Important? Yes!*, 1 PTO TODAY 9, 9 (2000) ("[b]iotechnology is one of the most research intensive and innovative industries in the global economy today").

[227] *See generally* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 275–80 (1977).

[228] Simply because the private industry has more money to fund research compared to the government. *See* Daniel J. Howard & Frank N. Laird, *The New Normal in Funding University Science*, 30 ISSUES IN SCIENCE & TECHNOLOGY no. 1 (2013), http://issues.org/30-1/the-new-normal-in-funding-university-science/ [hereinafter Howard & Laird, *Funding*].

[229] Although currently a purely scientific fictional concept, providing clones could also theoretically save lives by a transfer of one's memory onto his/her replacement clone. The concept of saving lives via bioprinting could open many possibilities, for example, bioprinting could theoretically make criminals more difficult to apprehend, because they could "escape" into a replacement clone (perpetually). Most recently, the movie Self/less portrays this concept of criminals "shedding their old bodies" by moving their conscious minds into new body hosts. *See* SELF/LESS (Endgame Entertainment & Entertainment 2015).

[230] *See, e.g.*, Varkey & Atala, *supra* note 105, at 291 (2015) (discussing using bioprinting "to replace diseased and injured tissue," "to fight the negative consequences of aging," and "to extend human lifespan").

failure,[231] insurance companies or manufacturer warranties can alleviate some of these concerns.[232]

Cloneprinting more mammals, especially extinct mammals, could drastically affect ecology[233] because cloneprinting would likely disrupt Darwin's "survival of the fittest" theory. Some view this disruption as a risk while others view it as a benefit, depending on whether one is animal-friendly or environment-friendly.[234]

Another benefit of bioprinting organs from stem cell sources is that the process can be repeated indefinitely, whereas, there is a limit to how many organs are available for harvest from living humans. This is relevant due to the current shortage of organs for transplant. Allowing the bioprinting of functional organs would likely solve the organ shortage. This is a clear improvement for organ transplantation, assuming no complications arise. Furthermore, bioprinting could add backup organs for transplantation when mishaps occur in the operation room.

On a macro level, the most visible advantage of bioprinting is that it will replenish the low supply of organ transplantation, thus, saving more lives. Bioprinting would also help people achieve better health and lengthen human lives by replacing aging organs with new ones.[235] The improved health that bioprinting would achieve could result in a lower workload for physicians, who would have fewer sick patients to see. This in turn would likely free up physicians' time from treatment so they could devote their

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[231] *See supra* Part III.A.4 (discussing that bioprinted body parts can malfunction or completely fail).

[232] *See, e.g.*, William K. Jones, *Product Defects Causing Commercial Loss: The Ascendancy of Contract over Tort*, 44 U. MIAMI L. REV. 731 (1990).

[233] *See, e.g.*, Roast, *supra* note 98 ("Bringing back animals that have gone extinct (albeit locally) might just influence ecosystems of the future.").

[234] Animal-friendly people would want more animals whereas environment-friendly people would not want more (or too many) animals affecting the balance of the current ecology. *Cf.* Allen Pursell et al., *Too Many Deer: A Bigger Threat to Eastern Forests than Climate Change?*, COOL GREEN SCI (Aug. 22, 2013), http://blog.nature.org/science/2013/08/22/too-many-deer/.

[235] *See, e.g.*, Lawrence O. Gostin & Anna Garsia, *Governing for Health As the World Grows Older: Healthy Lifespans in Aging Societies*, 22 ELDER L.J. 111–12 (2014).

time to other research areas, thus, preserving healthcare resources overall.[236] On the micro level, there might be financial issues associated with bioprinted organ affordability.

Further, bioprinting would likely have positive effects on society. As a result of the health benefits that bioprinting offers, and the lives it saves, there would likely be more individuals to add to the work force, helping the economy overall. This would likely encourage more innovation and technological advancement—resulting in an overall positive feedback loop for society.

Bioprinting could also fix genetic defects. For example, with bioprinting, an individual born with four fingers could print another hand with all five fingers as replacement. For another example, an individual with mismatched teeth could get a perfect teeth replacement instead of getting orthodontic braces.

The risks of bioprinting are mostly still unknown. For example, as discussed above,[237] there is some possibility of bioprinters emitting unhealthy air and contributing to environmental pollution.[238] Furthermore, people might worry about the safety of bioprinted products, especially when used in the human body. These worries include malfunction incidents and who should bear liability for such incidents.

D. *Current Regulatory Framework that Bioprinting Would Likely Have to Abide by*

Regulating bioprinting belongs in the grey area between an outright ban and no regulation because it could fall under human stem cell research regulation, or organ transplantation regulation, or both. The human stem cell used for bioprinting ink could fall under human stem cell research regulation if it were used for research purposes. However, what about commercial applications of bioprinting ink using human stem cells—would commericial applications also fall under current human stem cell research regulations even though it is not for research? Once an organ is

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[236] *See id.*
[237] *Supra* Part III.A.1.
[238] *See* Gilpin, *supra* note 122.

bioprinted and ready for transplantation into a human body, the organ transplantation regulations might be triggered. For example, medical use of bioprinted tissues or organs in humans for therapeutic purposes automatically triggers FDA oversight, or, even before that, to perform skin grafting via bioprinting on humans, one must apply for the FDA's permission to carry out human trials.[239] These unclear situations call for a clear regulation specifically for bioprinting.

IV. WAYS TO REGULATE BIOPRINTING

This Part explores different ways to regulate bioprinting and evaluates them under several criteria: flexibility, speed, political feasibility, safety, and promotion of innovation. Section A contemplates an outright ban or a ban with research and emergency exceptions, whereas Section B discusses self-regulation. Section C explores some other regulatory ideas: (1) subjecting to approval by different authorities, such as the legislative branch, the judicial branch and/or the medical profession or (2) regulating individual's access to blueprints, to raw sources, or to the bioprinter.

It is important to establish criteria to determine when a regulatory framework constitutes a "good" outcome. This will make it possible to compare different approaches and how they achieve these outcomes. This Article compares the different approaches in flexibility, speed, political feasibility, safety, and promotion of innovation.[240]

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[239] Edwards, *supra* note 101.

[240] Flexibility describes how broadly a regulation could apply to different situations. Speed describes how quickly a regulation could resolve various cases and controversies arising from the technology in question. Political feasibility describes how likely a regulation would be able to pass through Congress and the President—in other words, achieving agreement among people with different political views.

A. *Baning Bioprinting*

1. *Outright Ban*

As alluded to earlier,[241] an outright ban on bioprinting is an easy answer to the question of how to regulate bioprinting. However, such a ban would halt all research, resulting in no progress in this area of science and technology, and prevent the use of bioprinting from saving many lives. Although banning bioprinting would be the safest option, this approach would be inflexible—there would be no wiggle room for bioprinting whatsoever. Banning bioprinting represents one extreme end of various solutions and would be unlikely to gather political feasibility to pass in the federal legislature. Rather than promoting innovation, this approach would instead stunt innovation. Thus, an outright ban on bioprinting is the most unattractive and unlikely solution.

2. *Ban With Research and Emergency Exceptions*

A quick fix to the flaws of an outright ban is to carve out some exceptions, such as those for research and emergencies. To overcome a halt in the progression of science,[242] it makes sense to allow a narrow exception for research and experimentation. The scope of research could be up for debate: who qualifies to conduct the research, what funding sources are available for the research, whether private companies could invest in or conduct research, who would have oversight and regulatory power over the researchers, and other aspects would be debated.[243] One approach could mirror the research and experimentation exception in patent law. Under common law, one incurs no patent infringement liability for use that is "for amusement, to satisfy idle curiosity, or

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[241] *See* discussion, *supra* Part I.

[242] *See* discussion, *supra* Part IV.A.1.

[243] *See* MEGHAN B. COULEHAN & JONATHAN F. WELLS, *Guidelines for Responsible Data Management in Scientific Research* (2005), *available at* http://ori.hhs.gov/images/ddblock/data.pdf; NICHOLAS H. STENECK, *Introduction to the Responsible Conduct of Research* (2000), *available at* https://www.mtu.edu/research/administration/integrity-compliance/pdf/rcrintro.pdf.

for strictly philosophical inquiry,"[244] and a use is not experimental if it has "the slightest commercial implication."[245]

To save lives, it makes sense to allow an emergency exception.[246] Many doctors believe in a "general duty not to let people die."[247] However, there is no *legal* duty to not let people die, absent some special relationship between the parties.[248] Otherwise, many would be outraged from the immorality of not saving patients-in-need[249] and watching them die when we have the technology to save them.[250] Further, UCLA Law Professor Eugene Volokh would argue that these patients-in-need have the constitutional right to medical self-defense.[251]

Like the research exception, the scope of this exception could also be up for debate: whether bioprinting should be limited to only life-threatening conditions, and how immediate the life-threatening conditions must be (for example, immediate transplantation for lung failure[252] vs. slow death from lung

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[244] Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

[245] Embrex v. Service Engineering, 216 F.3d 1343, 1353 (Fed. Cir. 2000) (Rader, H., concurring).

[246] *See supra* Part IV.A.1.

[247] *See* JAMES RACHELS, *Killing and Letting Die*, *in* ENCYCLOPEDIA OF ETHICS 947–50 (Lawrence Becker & Charlotte Becker eds., 2d ed. 2001) [hereinafter RACHELS, *Letting Die*] (discussing the "general duty not to let people die").

[248] For a discussion on the law regarding good Samaritans, see generally Robert Justin Lipkin, *Beyond Good Samaritans and Moral Monsters: An Individualistic Justification of the General Legal Duty to Rescue*, 31 UCLA L. REV. 252 (1983).

[249] The "patients-in-need" refer to those patients in life-threatening situations.

[250] *Cf.* RACHELS, *Letting Die*, *supra* note 247, at 947 ("[Like killing someone,] it is also bad to let someone die.").

[251] *See also* Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1845–46 (2007) (arguing for the constitutional right of medical self-defense to use "experimental drug therapies for the terminally ill or market-based solutions to the organ shortage.").

[252] *See, e.g.*, Jonathan E. Spahr et al., *Lung Transplantation for Cystic Fibrosis: Current Concepts and One Center's Experience*, 6 J. CYSTIC FIBROSIS 334, 334–50 (2007).

cancer).[253] At the very least, people with imminent life-threatening conditions should be allowed to use bioprinted products.

The exceptions make this approach seem more morally reasonable than an outright ban, and it is still a relatively safe option. However, this approach is not flexible either. Unlike the outright ban discussed above, it would be more politically feasible to pass a law that banned bioprinting while allowing for exceptions. This approach would allow some innovation in the research realm, but not much in the commercial application.

B. *Self-Regulation*

On the opposite side of the regulation spectrum to an outright ban would be no regulation whatsoever, *i.e.*, allowing citizens to self-regulate.[254] Law and economics theory as well as anti-paternalism[255] support the self-regulation proposal: no regulations would mean that the government depends on the market to sort itself out and puts all trust to each individual, assuming that the individual would do the "right" thing.[256] The government can still offer a supportive role through education and relaying safety information to the public.[257] Because bioprinting bears very low risks,[258] this proposal might be suitable.

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[253] *See* Darrell Spurlock, Jr., *Signs of Death for End Stage Lung Cancer*, LIVE STRONG (Mar. 7, 2011), http://www.livestrong.com/article/50668-signs-death-end-stage-lung/.

[254] *See* OECD REPORT, ALTERNATIVES TO TRADITIONAL REGULATION 6 (2005).

[255] For a discussion on law and economic theory and anti-paternalism, see generally Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1541 (1998) ("In its normative orientation, conventional law and economics is often strongly antipaternalistic. . . .[B]ounded rationality pushes toward a sort of anti-antipaternalism—a skepticism about antipaternalism, but not an affirmative defense of paternalism."). *But see* Jonathan Klick & Gregory Mitchell, *Government Regulation of Irrationality: Moral and Cognitive Hazards*, 90 MINN. L. REV. 1620, 1626 (2006) ("paternalistic interventions may exacerbate irrational tendencies by creating moral and cognitive hazards").

[256] *Id.*

[257] *See* OECD REPORT, *supra* note 254, at 7.

[258] *See supra* Part III.B.3.

However, this view implies completely open access to bioprinting technology, resulting in no recoupment in R&D cost investments for inventors.[259] Alternatively, the government can subsidize R&D costs with taxpayers' money, but research dependent only on government funding would most likely lead to a slower growth rate than privately funded research.[260] In the end, self-regulation may be slightly better than an outright ban,[261] but it is still an unattractive solution.

This approach is the most flexible, but the least safe of all options. This extreme opposite to an outright bad would be unlikely to gather political feasibility as well, because some would support it while others would not. In fact, no passage of law is needed because there is no regulation. However, this approach would promote innovation at full speed, in both the research and commercial realms.

C. *Other Possible Regulations*

The happy medium between a ban and self-regulation is to enact a moderate amount of regulations. Such regulations should derive from the synthesized rationales behind regulating bioprinting.[262] This paternalistic approach[263] could explore different parties available for oversight, or restrict access to different bioprinting ingredients.

1. *Granting Intellectual Property Rights on Bioprinting Technology*

One way to incentivize innovation and investment in R&D is to allow inventors to recoup those investments by granting IP rights to those inventors.[264] Lila Feisee[265] argues that patenting biotechnology is important:

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[259] *See id.*
[260] *See* Howard & Laird, *supra* note 228.
[261] *See supra* Part IV.B.
[262] *See supra* Part III.B.
[263] *See generally* SARAH CONLY, AGAINST AUTONOMY: JUSTIFYING COERCIVE PATERNALISM (2012) (discussing and defending paternalism).
[264] *See* Kitch, *supra* note 227, at 275–80.

> Biotechnology patents allow for the dissemination of potentially valuable scientific information. The availability of the information disclosed in biotechnology patents enables others in the field of science to build on earlier discoveries. Not only can other researchers use the information in a patent, but by disclosing cutting edge scientific information, the patent system avoids expensive duplication of research efforts. It is only with the patenting of biotechnology that some companies, particularly small companies, can raise capital to bring beneficial products to the market place or fund further research. In addition, this capital provides jobs that represent an immediate public benefit independent of the technological benefits. Continuing employment opportunities represent a national resource for the future because they encourage the youth of today to become the scientists and inventors of tomorrow. Thus, the patent system not only fosters benefits to our society today, but ensures our future ability to innovate and grow.[266]

Unfortunately, granting IP rights for bioprinting will drive up the cost to bioprint (with a portion going towards paying for inventors' IP rights), resulting in a longer time before bioprinting can become more affordable and available to everyone.[267] Further, granting bioprinting patents can be complicated,[268] *e.g.*, the USPTO may grant a patent for a method of printing a lung but not for a lung itself because lungs are "products of nature"[269] found in every

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[265] Lila Feisee is the Vice President of International Affairs for Biotechnology Industry Organization and was a Supervisory Patent Examiner for the Biotechnology group at the USPTO. *Lila Feisee*, LINKEDIN, https://www.linkedin.com/in/lilafeisee (last visited Nov. 4, 2014).

[266] Feisee, *supra* note 226, at 9–12.

[267] *See also* MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY (2010) (arguing that license fees, regulations and patents are now so misused that they drive up the creation cost and slow down the diffusion rate of new ideas).

[268] This is a common issue faced by inventors: the composition of matter is not patentable but the process for making that composition of matter is novel and patentable. Also, there are so-called "product-by-process" claims that allow an inventor to claim a product created by a specific process, provided that product is different from the prior art in some way.

[269] *See also* Ass'n for Molecular Pathology v. Myriad, 133 S. Ct. 2107, 2116–17 (2013) (holding that naturally occurring DNA segments precludes patent eligibility). *See generally* 35 U.S.C. § 101 (2012) (discussing patentable subject matters).

human. Nonetheless, this is the patent examiners' job, and the USPTO can take care of this intricacy.[270]

As stated above,[271] the government can alternatively subsidize R&D costs with taxpayers' money, but research dependent only on government funding would most likely slow science progression.[272] Put simply, privately funded research often has deeper pockets than government-funded research. Thus, steady science progression demands granting IP rights for bioprinting technology.

2. *Prohibiting Sales*

It is important to prohibit sales of bioprinted body parts.[273] Fairness and equality favor accessibility for everyone and ideally we do not want a few business-minded people to take advantage of this new technology for their own self-serving commercial interests.[274] Otherwise, such commodification of bioprinted body parts would undermine bodily integrity and science's credibility.[275] This is especially relevant now given that public trust in science has been declining[276] (partially due to technophobia[277] and many religious influences[278]).

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[270] *See* Brian Fung, *Inside the Stressed-out, Time-Crunched Patent Examiner Workforce*, WASH. POST, July 31, 2014, http://www.washingtonpost.com/blogs/the-switch/wp/2014/07/31/inside-the-stressed-out-time-crunched-patent-examiner-workforce/. At the USPTO, a patent examiner's job is to decide which invention is patentable and to grant patents. For a more thorough discussion on patenting bioprinting, see generally Tran, *Patenting Bioprinting*, *supra* note 94.

[271] *See supra* Part IV.C.1.

[272] *See* Howard & Laird, *supra* note 228.

[273] *See generally* GOODWIN, BODY PARTS BLACK MARKETS, *supra* note 128 (discussing the black market for organs).

[274] *Cf.* YVONNE DENIER, EFFICIENCY, JUSTICE AND CARE: PHILOSOPHICAL REFLECTIONS ON SCARCITY IN HEALTH CARE 76–79 (2007) (discussing the right to universal healthcare).

[275] *See* Stephen Wilkinson & Eve Garrard, *Bodily Integrity and the Sale of Human Organs*, 22 J. MED. ETHICS 334, 334–39 (1996). *But see* Stephen Wilkinson, *Commodification Arguments for the Legal Prohibition of Organ Sale*, 8 HEALTH CARE ANALYSIS 189, 189–201 (2000).

[276] *See* Carolyn Abbot, *Bridging the Gap – Non-state Actors and the Challenges of Regulating New Technology*, 39 J.L. SOC'Y 329, 351–58 (2012) (discussing the challenges facing the public trust in "non-state actors" and emerging technologies).

Unfortunately, these businessmen can simply "work around" such prohibition of *bona fide* sales[279] by donating bioprinted "products" and receiving the money as a gift.[280] But if the government decided to prohibit both sales and donation, consumers would have no way to access bioprinted products.[281] Therefore, it makes sense to prohibit sales of bioprinted products.

3. *Subject to Approval*

One perspective from which to think about regulating bioprinting is to subject bioprinting uses to approval,[282] but it begs the question: who should regulate bioprinting? Some available parties for oversight are administrative agencies, courts, and medical professionals.[283]

The legislature can either establish and delegate to a new agency[284] dedicated solely to regulating bioprinting or depend on

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[277] Technophobia is a fear of emerging technology. *See generally* Adam Thierer, *The Internet of Things and Wearable Technology: Addressing Privacy and Security Concerns without Derailing Innovation*, 21 RICH. J.L. & TECH. 6, 32 (2015).

[278] *See, e.g.*, Answers Staff, *Religious Beliefs on Selling Organs*, ANSWERS, http://religion.answers.com/controversy/religious-beliefs-on-selling-organs (last visited Oct. 3, 2015).

[279] *See, e.g.*, U.S. CUSTOMS AND BORDER PROTECTION, WHAT EVERY MEMBER OF THE TRADE COMMUNITY SHOULD KNOW ABOUT: BONA FIDE SALES & SALES FOR EXPORTATION TO THE UNITED STATES (2005), *available at* http://www.cbp.gov/sites/default/files/documents/icp010r2_3.pdf (discussing *bona fide* sales and the factors determinative of *bona fide* sales).

[280] *Cf.* Donald B. Tobin, *Political Advocacy and Taxable Entities: Are They the Next "Loophole"?*, 6 FIRST AMEND. L. REV. 41, 90–93 (2007) (discussing the "loophole" behind gift tax).

[281] *Cf.* GOODWIN, BODY PARTS BLACK MARKETS, *supra* note 128 (discussing the case of organ transplantation, where organ sales were prohibited and only donations were allowed).

[282] Another underlying question is whether such approval is on a case-by-case basis or differs based on different types of bioprinted products.

[283] *See generally* Marcia L. McCormick, *Federal Regulation and the Problem of Adjudication*, 56 ST. LOUIS U. L.J. 39 (2011).

[284] The U.S. Supreme Court has allowed some delegation of legislative power but such delegation must comply with the "intelligible principle" test. *See* Mistretta v. United States, 488 U.S. 361, 372–73 (1989) (citing Am. Power & Light Co. v. SEC, 329 U.S. 90, 92 (1946)) (deeming a delegation of legislative

existing agencies[285] such as the Department of Health & Human Services (HHS)[286] or the Food and Drug Administration (FDA). In order to delegate, the legislature must take care of administrative law issues, such as whether the new agency or existing agencies have authority to regulate bioprinting.[287]

Inherent in the judicial power from the Constitution's "Case or Controversy" Clause,[288] courts may be available to approve the uses of bioprinting's "products."[289] However, it might not make much sense to exhaust judicial resources for oversight when courts would most likely be busy with adjudicating disputes as well.[290] Alternatives for subsequent disputes may be subject to Alternative

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power "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority"); Wayman v. Southard, 23 U.S. 1, 1–2 (1825).

[285] *See also* Leili Fatehi et al., *Recommendations for Nanomedicine Human Subjects Research Oversight: An Evolutionary Approach for an Emerging Field*, 40 J. LAW MED. ETHICS 716, 716 (2012) [hereinafter Fatehi, *HSR Oversight*] (explaining that human subjects research on nanomedicine interventions is subject to many oversight rules and regulations.); Susan M. Wolf & Cortney M. Jones, *Designing Oversight for Nanomedicine Research in Human Subjects: Systematic Analysis of Exceptional Oversight for Emerging Technologies*, 13 J. NANOPARTICLE RES. 1449, 1449 (2011) ("Certain types of human subjects research, however, have provoked creation of additional mechanisms and rules beyond the [DHHS] Common Rule and [FDA] equivalent.").

[286] For background on the HHS, see generally *About HHS*, HHS, http://www.hhs.gov/about/ (last visited Nov. 5, 2014) ("[The HHS] protect[s] the health of all Americans. The HHS[,] provid[es] for effective health and human services and fostering advances in medicine, public health, and social services.").

[287] *Cf.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 485–86 (2001) (deciding issue of the Environmental Protection Agency's (EPA) administrative authority); Am. Lung Ass'n v. EPA, 134 F.3d 388, 392 (D.C. Cir. 1998); Marc Landy, *EPA and Nanotechnology: The Need for a Grand Bargain?*, *in* GOVERNING UNCERTAINTY: ENVIRONMENTAL REGULATION IN THE AGE OF NANOTECHNOLOGY 80–101 (Christopher J. Bosso ed., 2010) (discussing the EPA's institutional capacity to regulate nanotechnology).

[288] *See* U.S. CONST. art. III, § 2, cl. 1.

[289] For example, there may be a controversy between an individual and another administrative agency on the issue of whether an individual can use bioprinting's "product."

[290] *See* McCormick, *supra* note 283, at 62.

Dispute Resolution (ADR), such as mediation or arbitration.[291] Because courts are cloaked with the shroud of impartiality and judicial independence,[292] they may not want to be involved in, and face being blamed for, erroneous bioprinting approval. Although an option to appeal[293] may mitigate this, this proposal still seems unattractive.

The legislature can also defer to medical professionals' judgment.[294] Some may say that regulating bioprinting is the legislators' job, not medical professionals' job.[295] Regardless, this makes the most sense for three reasons: (1) unlike medical professionals, the public and the legislators lack the requisite scientific and health knowledge;[296] (2) the general public trusts

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[291] *See generally* Rachel Jacobs, *Should Mediation Trigger Arbitration in Multi-Step Alternative Dispute Resolution Clauses?*, 15 AM. REV. INT'L ARB. 161 (2004) (discussing alternative dispute resolution, mediation, and arbitration).

[292] *See also* Maria Dakolias & Kim Thachuk, *The Problem with Eradicating Corruption in the Judiciary*, *in* THE CHALLENGE OF CHANGE FOR JUDICIAL SYSTEMS 140 (Marco Fabri & Philip M. Langebroek eds., 2000) ("Judicial independence [is] an important guarantee of impartiality and non-partisanship.").

[293] *See, e.g.*, FED. R. APP. P. 4 (discussing the right to appeal).

[294] *See* Nadia N. Sawicki, *Doctors, Discipline, and the Death Penalty: Professional Implications of Safe Harbor Policies*, 27 YALE L. & POL'Y REV. 107, 166 (2008) ("[L]egal delegation of regulatory power to the medical profession itself engenders trust in the profession.").

[295] *But cf. id.*

[296] *See, e.g.*, Joseph Chien, *Between Scientific Discourse and Lay Knowledge: Understanding the Non-Medical Use of Stimulants*, 22 S. CAL. REV. L. & SOC. JUST. 185, 193–97 (2013) (discussing the public's lack of medical knowledge in non-medical uses of stimulants); Clifford F. Hawkins, *Writing and Speaking in Medicine. Writing the MD Thesis*, 2 BRIT. MED. J. 1121, 1121–24 (1976) (discussing the medical professionals possessing scientific and health knowledge); David Ropeik, *The Perception Gap: Recognizing and Managing the Risks that Arise when We Get Risk Wrong*, 50 FOOD & CHEM. TOXICOLOGY 1222, 1222–25 (2012) (discussing the public's simplistic "perception gap" of risks based on the media); Scheer & Renn, *supra* note 223, at 305 ("Existing studies on geoengineering perceptions show low levels of awareness and a lack of knowledge.").

medical professionals for health-related issues;[297] and (3) medical professionals are in the best position to assess an individual's health needs[298] without allowing room for abuses of bioprinting technology. For example, doctors can approve bioprinting uses similar to how they approve medical marijuana uses—on a need-based basis.[299] If not subject to medical professionals' judgment for a need-based basis, then why would an individual want extra spare parts if she does not need them? Perhaps to hoard these spare parts,[300] just in case, but such a hoarder's mindset does not make much economic sense.[301] Thus, deferring to medical professionals' judgment might work, but it should only be based on need.

One may ask how deferring to medical professionals' judgment differs from the research exception, as discussed above.[302] Both are similar in some ways, but deferring to medical professionals' judgment is more expansive and also covers the emergency exception discussed above.[303] Further, the emergency exception assumes doctors would always do the right thing, and not let individuals die, whereas this may not always hold true.[304] Congress

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[297] *But see* Abbot, *supra* note 276, at 351–58 (discussing the challenges facing the public trust in "non-state actors" and emerging technologies).

[298] *See generally* INSTITUTE OF MEDICINE, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE (Bernard Lo & Marilyn J. Field eds, 2009) (discussing the expertise medical professionals have when it comes to health).

[299] *See generally* Michael Berkey, *Mary Jane's New Dance: The Medical Marijuana Legal Tango*, 9 CARDOZO PUB. L. POL'Y & ETHICS J. 417 (2011) (discussing the legality of medical marijuana).

[300] This assumes an individual cannot donate or sell bioprinted "products," given the prohibition against sales and donation of bioprinted "products." *See supra* notes 273–81 and accompanying text.

[301] *See* Keith Sharfman, *The Law and Economics of Hoarding*, 19 LOY. CONSUMER L. REV. 179, 183–90 (2007).

[302] *See supra* notes 235–38 and accompanying text.

[303] *See* Ariel R. Schwartz, *Doubtful Duty: Physicians' Legal Obligation to Treat During an Epidemic*, 60 STAN. L. REV. 657, 668–81 (2007) (discussing physicians' duty in absence of an "emergency").

[304] *But see* Rachels, *Letting Die*, *supra* note 247, at 947–50 (discussing the "general duty not to let people die"). For instance, Congress would be deferring to a doctor, wherein it could be the very doctor that would not "do the right thing" and would in fact "let the individuals die." *See id.*

can avoid the wrong side of this assumption by both deferring to medical professionals' judgment and including the emergency exception.[305]

4. *Regulating Individuals' Access*

Another perspective to think about regulating bioprinting is to regulate individuals' access to the bioprinting ingredients—bioprinters, raw sources, or blueprints.

If 3D printing and bioprinting use the same printer, then regulating an individual's access to the printer becomes moot unless the 3D printer is also regulated—a very unlikely solution because 3D printers are already widely available for sale. If 3D printing and bioprinting use different printers, bioprinters can be regulated by only granting access to the bioprinter to those trustworthy ones who regulate the bioprinter's access by approval as discussed above.[306]

The private sector would likely provide the raw materials,[307] which can be regulated by subjecting them to approval by an administrative agency, as discussed above.[308] Regulating bioprinting's raw materials can be analogous to requiring approval for access to dangerous chemicals by the Environmental Protection Agency (EPA).[309] However, although bioprinting's basic building blocks are relatively small in size,[310] one bioprinted "product" still

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[305] *See supra* notes 235–38 and accompanying text.

[306] *See supra* notes 273–94 and accompanying text.

[307] *See* VIRGINIA HAUFLER, A PUBLIC ROLE FOR THE PRIVATE SECTOR: INDUSTRY SELF-REGULATION IN A GLOBAL ECONOMY 105–22 (Carnegie Endowment for Int'l Peace 2001) (discussing the role of businesses in the modern world).

[308] *See supra* notes 273–77 and accompanying text.

[309] *See* Toxic Substances Control Act, 15 U.S.C. §§ 2601–29 (2012) (requiring the EPA to compile, keep current, and publish a list of each chemical substance manufactured or processed in the U.S.). *See generally About EPA*, EPA, http://www2.epa.gov/aboutepa/our-mission-and-what-we-do (last visited Nov. 9, 2014) (stating that its mission is "to protect human health and the environment").

[310] *See* Varkey & Atala, *supra* note 105, at 275–78 (discussing how each building block for bioprinting is composed of cells or tissue).

needs a substantial amount of "raw materials" [311] to print, potentially making keeping track of the sources difficult.

Regulating blueprints can be tricky because it depends on whether the blueprints are genetic-dependent.[312] If they are not genetic-dependent, blueprint files should have restricted access to avoid easy sharing and copying. One possible solution is to regulate blueprint files from the cloud. Because individuals will most likely access blueprints from the cloud,[313] such blueprints could be regulated through licensing, such as through a one-time end user license agreement.[314]

Conversely, if the blueprints are genetic-dependent,[315] the next question is how does genetic-dependent bioprinting work—most likely a lung blueprint only needs last-step input of an individual's genetic material rather than the beginning. If so, regulating such blueprints can be analyzed similar to a non-genetic-dependent blueprint. If a blueprint needs an individual's genetic information in the beginning, regulating access to the blueprint becomes more complicated. For example, can blueprints be subject to

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[311] For a discussion of bioprinting's "raw materials," *see generally supra* notes 86–113 and accompanying text.

[312] This means a blueprint depends on each individual's genetic information.

[313] *See* David A. Couillard, *Defogging the Cloud: Applying Fourth Amendment Principles to Evolving Privacy Expectations in Cloud Computing*, 93 MINN. L. REV. 2205, 2216 (2009) (stating that "[c]loud platforms give users 'anywhere access' to applications and data stored on the Internet"); *see also* William Jeremy Robison, *Free at What Cost?: Cloud Computing Privacy Under the Stored Communications Act*, 98 GEO. L.J. 1195, 1199–204 (2010) (discussing the era of cloud computing).

[314] *See generally* Justin M. Ackerman, *An Online Gamer's Manifesto: Recognizing Virtual Property Rights by Replacing End User Licensing Agreements in Virtual Worlds*, 6 PHOENIX L. REV. 137 (2012) (discussing end user licensing agreements).

[315] *See* Rob Stein, *Combining The DNA Of Three People Raises Ethical Questions*, NPR (Nov. 10, 2014 3:03 AM), http://www.npr.org/blogs/health/2014/11/10/360342623/combining-the-dna-of-three-people-raises-ethical-questions?utm_source=facebook.com&utm_medium=social&utm_campaign=npr&utm_term=nprnews&utm_content=2035 (discussing the ethical issues of DNA transplantation and combining DNA of three people).

censorship—without violating the First Amendment[316]—before scanning or feeding the bioprinter an individual's genetic information? Answers to this question and other similar mechanistic questions would necessarily affect bioprinting blueprints' regulation.

V. HOW SHOULD WE REGULATE BIOPRINTING?

The billion-dollar question[317] is how to regulate bioprinting, given the "grey" status of where bioprinting would fall on the current regulatory framework of stem cell research and/or organ transplantation.[318] After exploring some options for regulating bioprinting,[319] the extreme ends of no regulation or self-regulation seem fairly unattractive and unlikely.[320] This Article proposes a solution somewhere in the middle, taking into account the rationales behind regulating bioprinting.

A. *Joint Efforts of the Legislature and the Medical Professionals*

A worthwhile solution to the problem will likely be a combination of different ways to regulate bioprinting.[321] This Article proposes that except for research and emergency, bioprinting regulation should be a joint effort of a federal administrative agency and the medical profession. Specifically, the medical professionals should have access to bioprinters whereas the administrative agency should regulate access to bioprinting's basic building blocks and blueprints upstream. Further, IP rights on

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[316] U.S. CONST. amend. I.

[317] *Cf. $100 Billion IP Losses*, *supra* note 168 (discussing the prediction of an annual global IP loss of at least $100 billion from 3D printing by 2018). By the same token, because bioprinting is a subcategory of 3D printing, bioprinting will be another billion-dollar industry that needs regulation. *See supra* notes 86–113 and accompanying text.

[318] *See supra* notes 1–42, and accompanying text

[319] *See generally supra* notes 240–316 and accompanying text.

[320] *See supra* notes 240–61 and accompanying text.

[321] *See supra* notes 240–53, 273–305 and accompanying text.

bioprinting should be allowable but there should be a prohibition against sales.[322]

The administrative agency should be an existing one rather than a new one for a smooth transition—an already-existent agency's infrastructure would save time, money, and "easing" in of the new regulations. The HHS would be the most appropriate agency to regulate access to bioprinting's basic building blocks and blueprints upstream because the HHS is most familiar with handling research and likely emerging technology related to health and human services. Furthermore, when issues arise, such controversies may be ironed out in the judicial system.

B. *Advantages and Implications*

This proposal takes the "relaxed" stand to allow possibly the broadest uses of bioprinting while still regulating access to it and avoiding abuses. The advantage of this proposal will also align with advantages of using bioprinting itself because this proposal facilitates the development and progression of bioprinting.

1. *Allowing Science and Technology to Progress*

This "relaxed" proposal allows for the broadest use of bioprinting while still keeping it in check.[323] This allows science and technology to progress at a steady growth rate without hindering it, thus promoting innovation. More science and technology advances lead to a positive feedback loop, resulting in better bioprinting technology.

Some people might criticize this proposal as too "relaxed," but this is a compromise between no regulation and a complete ban, as explained above. The trade-off is advancement of science and technology—some benefits might be worth the risks.

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[322] For an extensive discussion of this proposal's application, *see generally supra* notes 240–316 and accompanying text.

[323] *Cf.* Thierer, *supra* note 277 (discussing how keeping emerging technology in check stems from people's fear of emerging technology).

2. *Bringing Along Many Health-Related Benefits*

This proposal takes the "relaxed" approach to allow the broadest uses of bioprinting while still regulating it. It puts trust in the medical professionals to exercise their medical judgment.[324] Here, the advantage of this proposal aligns with the advantages of using bioprinting, as discussed above: providing individuals with better health, lengthening human lives, saving more lives, solving the organ shortage, preserving healthcare resources, and benefiting the society overall.[325]

3D printers provide a method to print objects in a quick and easy way. Bioprinters provide an easy method to print organs, which has not been accomplished before. This advantage stems from 3D printing's inherent benefits. Allowing relaxed regulation on bioprinting will ease the manufacturing and production of organs, allowing more organs to be produced.

C. *Defenses Against Conventional Criticisms*

1. *"Playing God"*

A common religious criticism to modern biotechnology is the "playing God" objection.[326] To "play[] God" is to disregard of God's creation, and to alter things that are "natural.""[327]

"Playing God" is a widely used criticism that has surfaced in "anesthesia against pain, the birth control pill, transplantation medicine and diagnosing brain death, stem cell research[,] genetic engineering," and synthetic biology.[328] If scientists and doctors

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[324] *Cf.* DAVID DESTENO, THE TRUTH ABOUT TRUST: HOW IT DETERMINES SUCCESS IN LIFE, LOVE, LEARNING, AND MORE (2014) (discussing the general mechanics and benefits of trust).

[325] *See supra* notes 229–38 and accompanying text.

[326] *See* Peter Dabrock, *Playing God? Synthetic Biology as a Theological and Ethical Challenge*, 3 SYS. & SYNTH. BIOL. 47, 47 (2009) ("Almost every step forward in research has provoked vehement protest against the disregarding of creation").

[327] *Id.* at 47–54. *Cf.* Cecil A.J. Coady, *Playing God*, *in* HUMAN ENHANCEMENT 155–80 (Julian Savulescu & Nick Bostrom eds., 2009) (arguing using neuroenhancement is like "playing God").

[328] *See* Dabrock, *supra* note 326, at 47–48.

"play[] God," they risk offending some religious groups. But if they do not "play[] God," they would not progress and move forward with scientific innovations and discoveries, and we would not be saving as many lives.[329] In this situation, it may be better to "play[] God" while keeping ethical considerations in mind.[330]

2. *Supporting Designer Babies and Undercutting the Cosmetic Surgery Industry*

Imagine an individual was born with brown eyes but wanted blue eyes, he can print a pair of blue eyes to swap with the brown ones he currently has. This raises a problem similar to the "designer babies" situation.[331] However, the counterargument is that bioprinting a body part replacement is not much different than getting cosmetic surgery, allowing individuals to receive, for example, fake breasts or a rhinoplasty. In fact, the world condones cosmetic surgery and people in the United States are the biggest consumers of cosmetic surgery.[332] But the cosmetic surgery industry itself would oppose a "relaxed" bioprinting regulation because bioprinting would likely undercut the cosmetic industry's business. Nonetheless, the cosmetic surgery industry's loss-of-business concern should not outweigh bioprinting's most obvious advantage of saving human lives.

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[329] Some would argue that scientific progression and not playing God are not mutually exclusive by carving out what scientific advancement is okay and what is not under God's eyes. But in reality, it is either you "play God" or you do not. No one gets to decide what is allowed under God's eyes—otherwise those few who interpret God's view would control the world of science.

[330] Tran, *Patenting Bioprinting*, *supra* note 94.

[331] *See* Suter, *supra* note 124.

[332] *See, e.g.*, Lizzie Dearden, *Top 10 Countries for Cosmetic Surgery Revealed as Figures Show Rising Demand for Penis Enlargements and Other Procedures*, THE INDEPENDENT (July 30, 2014), http://www.independent.co.uk/life-style/health-and-families/health-news/top-10-countries-for-cosmetic-surgery-revealed-as-figures-show-industry-is-booming-worldwide-9636861.html ("The United States topped the international chart, with almost 4 million people going under the knife or needle.").

VI. CONCLUSION

Bioprinting carries little risks compared to the enormous potential benefits of the technology. The billion-dollar question is how to regulate bioprinting, given the murky status of where bioprinting would fall on the current regulatory framework of stem cell research and organ transplantation. The human stem cells used for bioprinting ink could fall under human stem cell research regulation if used for research purposes, and/or even commercial application. Once an organ is bioprinted and ready for transplantation into a human body, the organ transplantation regulations might be triggered. For example, medical use of bioprinted tissues or organs in humans for therapeutic purposes automatically triggers FDA oversight, or even before that, to perform skin grafting via bioprinting on humans, one must apply for FDA's permission to carry out human trials.

This proposed bioprinting regulation suggests that, except for research and emergency, bioprinting regulation should be a joint effort of a federal administrative agency and the medical profession. Specifically, medical professionals should have access to bioprinters whereas the administrative agency should regulate access to bioprinting's basic building blocks and blueprints upstream. Furthermore, IP rights on bioprinting technology should be allowable but there should be a prohibition against sales. The overseeing administrative agency should be an existing one rather than a new one for a smooth transition. The HHS would be most appropriate to regulate access to bioprinting's basic building blocks and blueprints upstream. Furthermore, when issues arise, such controversies may be ironed out in the judicial system.

Using this "relaxed" standard allows science and technology to progress, and promotes innovation. Furthermore, this proposal would likely provide individuals with better health, lengthen human lives, save more lives, solve the organ shortage, preserve healthcare resources, and benefit society overall.