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"Transplanting" Organ Donors with Printers: The Legal and Ethical Implications of Manufacturing Organs

Katherine A. Smith

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**“TRANSPLANTING” ORGAN DONORS WITH PRINTERS:
THE LEGAL AND ETHICAL IMPLICATIONS OF
MANUFACTURING ORGANS**

*Katherine A. Smith**

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I. INTRODUCTION

Right before our eyes, the rules of the game of life will become even more complicated. While the prolific English board game publisher John Wallis theorized there to be seven sequential stages of human life, this historical chronology will be significantly disrupted with the advent of three-dimensional (3D) bioprinting.¹ Three-dimensional bioprinting has provided a means to manufacture living tissues and organs, creating the fundamental pieces that sustain life.² This “game changer” invites the potential to defy the natural progression of life by enhancing humans’ overall health, vitality, and average life expectancy.

One of the greatest promises with the arrival of 3D bioprinting is an

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1. Cornell University, *The New Game of Human Life*. London: John Wallis, 1790, DIVISION OF RARE & MANUSCRIPT COLLECTIONS (2004), <http://rmc.library.cornell.edu/games/promoting/4.html> (stating that “[t]he New Game of Human Life created by John Wallis encouraged young players to develop proper moral character, learning the exigencies of the seven stages of life, from ‘Infancy’ to ‘Dotage,’ while navigating the paths of vice and virtue. Players advance or forfeit according to the moral nature of the character represented in the square they land on.”). Charles Hull, *Stereolithography (3D Printing)*, NATIONAL INVENTORS HALL OF FAME (2014), <http://invent.org/inductees/hull-charles/> (Charles W. Hull first invented commercial 3D printing in 1986. His method, which he titled “sterolithography,” involved sequentially printing thin layers of an ultraviolet cured-material to form a solid 3D structure. 3D bioprinting is the future of this long-standing technology.). Wai Hon Wah, *Introduction to STL Format*, POLYTECHNICAL UNIVERSITY OF HONG KONG (1999), http://download.novedge.com/Brands/FPS/Documents/Introduction_To_STL_File_Format.pdf (describing standard tessellation language (“STL”) as a facet-based embodiment that approximates surface and solid items only (points, lines, curves, and attributes such as layers and color in the CAD system will be ignored during the output process). Facets delineate the surface of a 3D object. Most 3D printers can only use a model if it has been exported to STL format.). Sean V. Murphy & Anthony Atala, *3D bioprinting of tissues and organs*, NATURE BIOTECHNOLOGY, 773 (2014), <http://www.nature.com/nbt/journal/v32/n8/full/nbt.2958.html> (also asserting that “[t]he development of solvent-free, aqueous-based systems enabled the direct printing of biological materials into 3D scaffolds that could be used for transplantation with or without seeded cells. The next step was 3D bioprinting as a form of tissue engineering, made possible by recent advances in 3D printing technology, cell biology and materials science. A related development was the application of 3D printing to produce medical devices such as stents and splints for use in the clinic.”).

2. Murphy & Atala, *supra* note 1 (addressing that “[the] complexities [of bioprinting] require the integration of technologies from the fields of engineering, biomaterials science, cell biology, physics and medicine. 3D bioprinting has already been used for the generation and transplantation of several tissues, including multilayered skin, bone, vascular grafts, tracheal splints, heart tissue and cartilaginous structures. Other applications include developing high-throughput 3D-bioprinted tissue models for research, drug discovery and toxicology.”).

answer to expediting the organ donor transplant process.³ This promise will help eradicate desperation, despair, and fear of premature death from patients awaiting organ donations. According to the Organ Procurement & Transplantation Network (OPTN), there are currently over 120,000 waiting list candidates in the United States.⁴ Also astonishing is that approximately 21 people die each day waiting for an organ transplant, a consequence of there being just under 12,000 donors and stringent regulations.⁵ 3D bioprinting would provide an ideal solution to the central issue—the availability of a donor—by eliminating the issue altogether. Never again would a family member have to sacrifice a vital organ or someone in the final stages of a fatal disease have to live with the notion that an organ may not come in time. The wait time would be little more than the amount of time it would take to print an organ; patients could be given a near-exact waiting time, putting their minds and their families' minds at ease.

Both federal and state legislatures have passed acts that attempt to provide safe and equitable systems for the allocation, distribution, and transplantation of donated organs.⁶ In 1984, Congress enacted the National Organ Transplant Act (NOTA), which created the OPTN and criminalized the exchange of human organs for valuable consideration.⁷

3. Tanya Lewis, *3D-Printed Human Embryonic Stem Cells Created for First Time*, LIVE SCIENCE, (Feb. 5, 2013, 8:27 AM ET), <http://www.livescience.com/26865-3d-printed-embryonic-stem-cells.html> (presenting a second consideration: those who do receive transplants run the risk of unforeseen medical complications and organ rejection. However, 3D bioprinting may solve that issue as well; it may be able to incorporate a patient's own stem cells to regenerate a living organ. Researchers at Heriot-Watt University in Edinburgh have created a cellular printer that uses living embryonic stem cells as its "ink." The researchers hope to use this new printing method "to make 3D human tissues for testing new drugs, grow organs, or ultimately print cells directly inside the body." Ultimately, rejection would become moot, reducing the number of complications and accelerating a patient's recovery time and reentry into their usual routine.).

4. *About Us*, UNITED NETWORK FOR ORGAN SHARING, <http://www.unos.org/about/index.php> (last visited Nov. 30, 2015) (stating that the United Network for Organ Sharing (UNOS) is a private, non-profit organization that manages the nation's organ transplant system and maintains the national registry for organ matching under contract with the federal government.). *Organ Procurement and Transplantation Network*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <http://optn.transplant.hrsa.gov> (last visited Nov. 30, 2015) (an official U.S. Government website managed by the Health and Resources Services Administration, U.S. Department of Health & Human Services).

5. *Organ Procurement and Transplantation Network*, *supra* note 4.

6. *Legislation and Policy*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <http://www.organdonor.gov/legislation/> (last visited Nov. 30, 2015).

7. *Selected Statutory and Regulatory History of Organ Transplantation*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <http://organdonor.gov/legislation/legislationhistory.html> (last visited Nov. 30, 2015) (asserting that NOTA also provided for the establishment of the Task Force on Organ Transplantation, created the Scientific Registry of Transplant Recipients, and formed an administrative unit within the Department of Health and Human Services to administer all

Accordingly, under Section 301 of NOTA, any individual convicted of buying or selling a human organ faces a five-year prison sentence and/or a sizeable fine.⁸ All 50 states have adopted the Uniform Anatomical Gift Act (UAGA), which explicitly prohibits the purchase and sale of organs if removal of the organ is intended after death.⁹ Notably, some states have included a provision prohibiting the purchase and sale of organs by living donors if removal is to occur before death.¹⁰

Consequently, with the introduction of such a capable technology comes concern for compliance with the law. This Note begins with a technical discussion of the technology of bioprinting and explains current engineering techniques and capabilities. Part II contains an in-depth survey of federal and state laws governing organ donation, analyzing the evolution of organ donor law. This part also presents arguments for and against live donor organ sales and compares and contrasts policy arguments dealing with the potentiality that a bioprinted organ will indeed be determined to be “an organ transplant for valuable consideration.” Part III turns to a discussion of the applicability of current law to 3D bioprinting, delving into the issue of whether federal NOTA restrictions will be applied to the sale of 3D bioprinted organs. This disturbing construction will mean that a manufactured organ will qualify as a “human organ” under Section 310 of NOTA such that selling the printed organs would violate the statute. Whether 3D printed organs would be considered “experimental treatment” is also discussed for purposes of whether this would present a roadblock to immediate patient access to manufactured organs. Part IV of this Note identifies the ethical implications associated with manufactured organs, specifically the potential for black market operations, and suggests that these implications may detract from the countless benefits bioprinted organs could provide. Finally, Part V speculates that 3D printed organs will, indeed, be construed to qualify as “human organs” under NOTA and that the NOTA limitations on the sale of human organs will apply to the sale of 3D bioprinted organs.

activities).

8. FindLaw, *Can I Sell an Organ?*, THOMSON REUTERS, <http://healthcare.findlaw.com/patient-rights/can-i-sell-an-organ.html> (last visited Nov. 30, 2015).

9. Robyn S. Shapiro, *Legal Issues in Payment of Living Donors for Solid Organs*, 7 CURRENT OPINION ON ORGAN TRANSPLANTATION, 375-79 (2002), available at http://www.americanbar.org/publications/human_rights_magazine_home/human_rights_vol30_2003/spring2003/hr_spring03_livingdonors.html.

10. *Id.*

II. 3D BIOPRINTING: ITS HISTORY AND ITS PROMISE

This Note begins by discussing the origin and history of 3D bioprinting. Part II.A explains 3D printing at its basic level and describes how a 3D printed model is produced. Part II.B provides an overview of the three main production methods of 3D printing. Part II.C gives examples of how 3D printing can be applied in various industries. Part II.D discusses researchers' goal of printing cells to form functional tissues and the challenges that come along with doing so. Part II.E contrasts traditional tissue engineering with 3D bioprinting tissue. Part II.F explains two methods of 3D bioprinting, extrusion printing and thermal ink-jet printing, as well as several details to consider when 3D bioprinting. Part II.G describes and provides examples of present-day success with manufacturing functional tissues and also discusses the limits researchers have faced in light of their success. Part II.H concludes by discussing the current financial state of funding 3D bioprinting research in light of other medical research and alludes to new monetary incentives for engaging in 3D bioprinting research.

A. *The Basics of 3D Printing*

Three-dimensional printing, also known as "rapid prototyping" or "additive manufacturing," provides a process for constructing 3D objects from a digital file known as a computer-aided design (CAD) model.¹¹ A CAD model is a digital, 3D representation of a physical object, typically created through the use of 3D modeling software. Generally, CAD models can be used for animation or visualization of an object, to make design changes to a product, to perform dimensional or comparative analysis of an object, or even for finite element analysis and computational fluid dynamics analysis.¹² Regarding 3D printing,

11. *What Is 3D Printing*, THE 3D PRINTING ASSOCIATION, <https://www.the3dprintingassociation.com/what-is-3d-printing> (last visited Nov. 30, 2015).

12. *Almost Everything You Always Wanted to Know About 3D Scanning*, DIRECT DIMENSIONS, http://www.dirDIM.com/lm_everything.htm (last visited Nov. 30, 2015). *Finite Element Analysis*, AUTODESK, <http://usa.autodesk.com/adsk/servlet/item?siteID=123112&id=17670721> (last visited Nov. 30, 2015) (explaining that "[f]inite element analysis (FEA) is a computerized method for predicting how a product reacts to real-world forces, vibration, heat, fluid flow, and other physical effects. Finite element analysis shows whether a product will break, wear out, or work the way it was designed. It is called analysis, but in the product development process, it is used to predict what is going to happen when the product is used."). *Computational Fluid Dynamics (CFD)*, SOLIDWORKS, <http://www.solidworks.com/sw/products/simulation/computational-fluid-dynamics.htm> (last visited Nov. 30, 2015) (detailing computational fluid dynamics, which "simulates fluid (either liquid or gas) passing through or around an object. The analysis can be very complex—for example, containing in one calculation

functional applications of 3D modeling include providing an outlet for inventorship, producing a repaired version of a damaged object, and manufacturing items desired on an impulse.¹³

CAD models can be produced in one of two ways: using 3D modeling software or using a 3D scanner. Three-dimensional modeling software varies from extremely complex, commercial programs, such as Autodesk's 3ds Max, to basic, free options like Google's SketchUp. While each software possesses a unique user-interface, on an elementary level, modeling is generally achieved through the use of principal, drawing, modification, construction, camera, and walkthrough tools for manipulation of a model in 3D space.¹⁴ Medical professionals regularly use 3D modeling software to teach medical students surgical procedures or to show a patient his or her potential "before and after" results prior to going under the knife.

Three-dimensional scanning characteristically operates by triangulation of a laser over a stationary object.¹⁵ A laser band scans across the physical subject transfiguring it into a 3D digital file.¹⁶ A relatively novel and robust exercise of 3D scanning capabilities is 3D facial scanning, which is a critically useful tool for identification and verification of individuals employed for homeland security.¹⁷

Three-dimensional printers work similarly to inkjet printers in that they utilize digital files to create a physical transformation of that file by depositing a selected medium layer-by-layer rather than drop-by-drop.¹⁸ The layers are also blended together in order to create a physical object that appears cohesive and whole.¹⁹ Each layer can be seen as a thinly

heat transfer, mixing, and unsteady and compressible flows. The ability to predict the impact of such flows on your product performance is time consuming and costly without some form of simulation tool.”).

13. *Almost Everything You Always Wanted to Know About 3D Scanning*, *supra* note 12.

14. SketchUp, *Drawing quickly*, TRIMBLE NAVIGATION LIMITED, <http://help.sketchup.com/en/article/115429> (last visited Nov. 15, 2015) (giving an overview of the tools drawing programs generally use: principal tools are tools that are used a lot to select and modify geometry; drawing tools are tools used to create geometry; modification tools are tools used to modify existing geometry; construction tools are tools used to create construction lines or points and document your model; camera tools are tools used to view geometry; and walkthrough tools are tools to explore your model).

15. Anselmo Lastra, et al., *3D Scanning for Biometric Identification and Verification*, INSTITUTE FOR HOMELAND SECURITY SOLUTIONS (2010), http://sites.duke.edu/ihss/files/2011/12/IHSS_Research-Brief_Lastra.pdf.

16. *Id.*

17. *Id.*

18. John Patrick Pullen, *You Asked: How Does 3-D Printing Work?*, TIME (Jan. 16, 2015), <https://time.com/3671722/3d-printing/>.

19. *Id.*

sliced horizontal cross-section of the eventual object with an approximate layer thickness of 100 microns.²⁰ To put that in perspective, a piece of printer paper is 100 microns thick.²¹ However, extremely high precision 3D printers exist, which can create layers as thin as 16 microns.²²

B. 3D Printing Technologies and Methods

There are various methods of 3D printing with each process adding layers generally by transferring multiple layers of a material onto a construction platform, starting with the bottom layer. Three main methods of 3D printing exist today, namely, selective laser sintering (SLS), fused deposition modeling (FDM), and stereolithography (SLA).²³

SLS employs a powerful laser to fuse tiny particles of metal, plastic, ceramic, or glass into a desired 3D shape.²⁴ The laser discriminately combines the powdered material by scanning the cross-sections generated by the 3D modeling program on the surface of the powder bed.²⁵ Once all cross-sections are scanned, the powder bed is lowered by one layer thickness.²⁶ Subsequently, a new layer of material is added on top of the prior layer, and the process is repeated until the object is completed.²⁷

FDM forms each layer of a 3D object by extruding metal or a

20. *Id.*

21. Lucas Mearian, *The first 3D printed organ—a liver—is expected in 2014*, COMPUTER WORLD (December 26, 2013 7:05 AM PT), <http://www.computerworld.com/article/2486952/emerging-technology/the-first-3d-printed-organ—a-liver—is-expected-in-2014.html>.

22. *PolyJet*, SOLID CONCEPTS, <https://www.solidconcepts.com/technologies/polyjet/> (last visited Nov. 30, 2015); see also MRSEC Education Group, *Size and Scale*, UNIVERSITY OF WISCONSIN-MADISON (2015), <http://education.mrsec.wisc.edu/36.htm> (stating that “[a] micrometer, also called a micron, is one thousand times smaller than millimeter. It is equal to 1/1,000,000th (or one millionth of meter). Things on this scale usually can’t be seen with your eyes. The diameter of a hair, which is 40-50 microns wide, is very hard to discern without the use of a magnifying glass. A magnifying glass will help you see a dust mite. Dust mites are usually around 400 microns long.”).

23. Mark Fleming, *What is 3D Printing? An Overview*, 3D PRINTER, <http://www.3dprinter.net/reference/what-is-3d-printing> (noting that “Fused Deposition Modeling” and its abbreviation, FDM, are trademarked by Stratasys. The company RepRap uses a similar process but has called it “Fused Filament Fabrication” (FFF) so as to not interfere with Stratasys’s trademark.).

24. 3D Printing.com, *What is 3D printing?*, GENESIS FRAMEWORK, <http://3dprinting.com/what-is-3d-printing/#whatitis> (last visited Nov. 30, 2015).

25. *Id.*

26. *Id.*

27. *Id.*

thermoplastic material through a heated nozzle onto a build platform.²⁸ The nozzle is capable of moving in both horizontal and vertical directions by a numerically controlled mechanism, directly controlled by a computer-aided manufacturing software package.²⁹ Each layer hardens immediately after it is deposited and bonds to the previous layer to form the eventual object.³⁰

SLA, the original method of 3D printing, operates using a liquid ultraviolet curable photopolymer resin and an ultraviolet laser to build an object's layers one by one.³¹ The ultraviolet laser beam is used to draw out the 3D model one layer at a time from the resin.³² To accomplish this, the laser beam traces a cross-section of the 3D model on the surface of the liquid resin.³³ Exposure to the laser light cures and solidifies the tracing on the resin and fixes it to the layer below.³⁴ Then, after the pattern descends by a distance equivalent to the thickness of one layer, a resin-filled blade glides across it, re-coating it with new liquid resin.³⁵ After the prior layer has been re-coated, the subsequent layer pattern is traced, joining the previous layer.³⁶

C. Applications of 3D Printing

The applications of 3D printing are limitless. The robustness of today's machines and surplus of material choices accommodate the imagination, inclusive of design visualization, prototyping, metal casting, architecture, healthcare, entertainment, and home use. Recent breakthroughs in 3D printing have been in the automotive, construction, biomedical, and biotechnology industries.

The automotive industry is taking full advantage of the seemingly endless capabilities of 3D printing. Local Motors, an American company, printed the first working, electric car at a trade show in

28. *Id.*

29. *Id.*; see also Clive Ferguson, *A History of Numerically Controlled Machine Tools*, ACADEMIA (1978), http://www.academia.edu/670021/A_history_of_numerically_controlled_machine_tools (defining numerical control as "the dimensional and sequential operation of a machine tool by means of coded numeric information . . . the information is used to cause, at the appropriate time, the movement of the part or parts being machined and for the tool or tools involved together with, in some cases, selection of correct speeds, feed rates, etc.").

30. *What is 3D Printing?*, *supra* note 24.

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

Chicago.³⁷ It was completed in just two days and is comprised of only 49 carbon fiber and plastic parts.³⁸ Additionally, Kevin Czinger, the Founder and CEO of Divergent Microfactories, Inc., built the first 3D printed supercar, called "Blade."³⁹ The supercar is composed completely of 3D printed aluminum nodes and carbon fiber connectors, and it weighs significantly less than one ton, can pump out as much as 700 horsepower, and can accelerate from zero to 60 in a little more than two seconds.⁴⁰ Blade demonstrates 3D printing's ability to produce products that can stand up to extreme forces and performance.⁴¹

Audi and Kia are also taking advantage of this progressive technology.⁴² While it has not been unusual for automotive companies to utilize 3D printed parts in prototypes, Audi and Kia are forerunners in taking it to the next step.⁴³ Both automotive companies are working toward including 3D printed parts within production vehicles. Audi is in the process of streamlining how its 3D printing techniques and automotive production methods work together so that it can use metal 3D printed parts in actual production, while Kia has introduced 3D printed parts into a concept car for presentation at the North American International Auto Show (NAIAS).⁴⁴

In construction, Amsterdam's Dus Architects is revolutionizing the industry by erecting the first 3D printed house.⁴⁵ While the process will take a total of three years, it will be compiled of 13 rooms made of interlocking plastic parts.⁴⁶ The 3D printing of homes will produce great benefits: zero waste, reduced costs, and completely recyclable parts.⁴⁷

37. Tracey Kirkland, *3D-printing: American company Local Motors releases world's first computer printed car*, ABC (October 13, 2014 10:17 AM), <http://www.abc.net.au/news/2014-10-13/american-company-makes-worlds-first-3d-printed-car/5810234>.

38. *Id.*

39. Eddie Krassenstein, *World's First 3D Printed Supercar is Unveiled*, 3D PRINT.COM (June 24, 2015), <http://3dprint.com/74810/3d-printed-supercar-blade/>.

40. *Id.*

41. *See generally id.*

42. Michael Molitch-Hou, *Kia Concept SUV Features 3D Printed Parts*, 3D PRINTING INDUSTRY (January 11, 2016), <http://3dprintingindustry.com/2016/01/11/64658/>; Tyler Koslow, *Audi Looks to Put 3D Printed Metal End Parts into Their Autos*, 3D PRINTING INDUSTRY (November 13, 2015), <http://3dprintingindustry.com/2015/11/13/audi-looks-to-put-3d-printed-metal-end-parts-into-their-autos/>.

43. *Id.*

44. *Id.*

45. Tom McKay, *Major Breakthrough in 3-D Printing Could End One of the World's Biggest Issues*, MIC NETWORK (Apr. 7, 2014), <http://mic.com/articles/87085/major-breakthrough-in-3-d-printing-could-end-one-of-the-world-s-biggest-issues>.

46. *Id.*

47. *Id.*

This use could also lead to the 3D printing of low-cost temporary housing for homeless and use of biodegradable materials for festivals.⁴⁸

Yale and Oxford Performance Materials (OPM) are collaborating to benefit biomedical applications that employ 3D printing.⁴⁹ Using OPM's high performance polyetherketoneketone (PEKK) polymer, the planned venture includes ten projects comprising a 3D printed PEKK prosthesis for rib replacement and 3D printed PEKK devices that deliver therapeutics for improved vertebral fusion.⁵⁰

One of the most innovative and progressive areas of 3D printing is in biotechnology for tissue engineering applications, which has been referred to as 3D bioprinting, organ printing, or computer-aided tissue engineering.⁵¹ The latest advances in 3D printing have allowed for the manufacture of intricate, functional, living tissue from biocompatible materials, cells, and supporting components.⁵² This application of 3D printing has been useful for regenerative medicine and addressing the lack of available tissues and organs for transplantation.⁵³

D. 3D Bioprinting Tissue Engineering

Although 3D printing has long been a tool to generate biotechnology devices, the present focus of many researchers has been on printing cells to form functional tissues.⁵⁴ The goal of 3D bioprinting, which has evolved from the amalgamation of early stereolithographic techniques and breakthroughs in biology, is to produce tissues and organs suitable for laboratory investigation, disease modeling, and therapeutics.⁵⁵ With large research universities and companies backing this technology, it is probable that 3D bioprinting will eventually become one of the principal areas of research and investment in the upcoming years.⁵⁶

48. *Id.*

49. Bridget Butler Millsaps, *Yale University and OPM Collaborate on Ten 3D Printing Projects to Further Biomedical Applications*, 3DPRINT.COM (Oct. 29, 2014), <http://3dprint.com/21912/yale-university-opm-3d-print/>.

50. *Id.* *Biomedical Raw Materials*, OXFORD PERFORMANCE MATERIALS, http://www.oxfordpm.com/biomedical_raw_materials.php (last visited Nov. 30, 2015) (defining PEKK as a biocompatible, thermoplastic polymer used for implantable medical devices).

51. Murphy & Atala, *supra* note 1.

52. *Id.*

53. *Id.*

54. Suraj Kannan, *The 3D Bioprinting Revolution*, HARVARD SCIENCE REVIEW (May 1, 2014), <http://harvardsciencereview.com/2014/05/01/the-3d-bioprinting-revolution/>.

55. *Id.*

56. *Id.* (identifying Harvard University and Organovo as large supporters of 3D bioprinting).

Three-dimensional bioprinting presents additional challenges not seen in non-biological 3D printing applications, including choice of biocompatible materials, cell types, cell growth and differentiation factors, and the fragilities associated with living cells and manufactured tissue.⁵⁷ With the help of technologies from the areas of engineering, biomaterials, cellular biology, physics, and medicine to address those intricacies, 3D bioprinting has already produced some promising results such as the generation and transplantation of multilayered skin, bone, vascular grafts, heart tissue, and cartilage.⁵⁸ Other relevant uses include developing high-throughput 3D bioprinted tissue models for research, drug discovery, and toxicology.⁵⁹

E. Traditional Tissue Engineering Versus Bioprinting

The National Institute of Biomedical Imaging and Bioengineering has defined tissue engineering as the "practice of combining scaffolds, cells, and biologically active molecules into functional tissues."⁶⁰ Tissue engineering aims to assemble functional constructs that repair, preserve, or improve damaged tissues or entire organs.⁶¹ Traditional tissue engineering generally follows a top-down approach where cells are seeded on a scaffold.⁶² Despite the fact that this method has resulted in some of the earliest clinical successes of tissue engineering, it does not permit sufficient temporal and spatial control of cells and growth factors seeded in the scaffold.⁶³ With this constraint, synthesized tissues in traditional tissue engineering have a limit to their complexity.⁶⁴

Three-dimensional bioprinting employs a customized bottom-up approach where discrete components of the tissue are arranged in such a fashion to permit formation of compound tissue construction.⁶⁵ This is made possible by CAD, which allows for careful placement of cells, materials, and morphogens to duplicate the varieties of organization

57. Murphy & Atala, *supra* note 1.

58. *Id.*

59. *Id.*

60. National Institute of Biomedical Imaging and Bioengineering, *Tissue Engineering and Regenerative Medicine*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <http://www.nibib.nih.gov/science-education/science-topics/tissue-engineering-and-regenerative-medicine> (last visited Nov. 30, 2015).

61. *Id.*

62. Kannan, *supra* note 54.

63. *Id.*

64. *Id.*

65. *Id.*

found in the body.⁶⁶ These strategies usually rely on cells' innate self-assembly and growth factor-driven mechanisms to create the functional biomimetic tissues.⁶⁷

F. Methods and Parameters of 3D Bioprinting

There are two different types of bioprinting methods. These include extrusion printing (contact) and thermal ink-jet printing (contactless).⁶⁸ In extrusion printing, which is the most common method of 3D bioprinting, filaments are pushed through a nozzle to generate a 3D structure.⁶⁹ Therefore, there is contact between the delivery apparatus and the "bio-ink."⁷⁰ In thermal ink-jet printing, small ink bubbles are produced by pulsing current through the heating component of the printhead.⁷¹ Subsequently, the change in pressure collapses the ink bubbles and expels the ink from the nozzle.⁷² Hence, there is no contact between the delivery apparatus and the bio-ink.⁷³

Compared to conventional 3D printing, 3D bioprinting involves greater complexities. It is vital to take into account several parameters with the development of 3D bioprinting, such as the resolution of the printing, material selection (bio-ink), and cell variability.⁷⁴ Deciding which 3D printer to utilize centers on what the desired resolution is.⁷⁵ Designing tissues involves macro and micro-scale control; thus, several methods must be employed to produce both the gross architecture and

66. *Id.*

67. *Id.*; see also Raphaël Devillard et al., *Cell patterning by laser-assisted bioprinting*, METHODS IN CELL BIOLOGY, 2014, at 119, 159-74, available at <http://www.ncbi.nlm.nih.gov/pubmed/24439284>.

68. Kannan, *supra* note 54.

69. *Id.*; see also Cameron J. Ferris et al., *Biofabrication: an overview of the approaches used for printing of living cells*, APPLIED MICROBIOLOGY AND BIOTECHNOLOGY, 2013, at 4243—58, available at <https://www.ro.uow.edu.au/cgi/viewcontent.cgi?article=1580&context=smhpapers>.

70. Kannan, *supra* note 54; Dan Ferber, *An Essential Step Toward Printing Living Tissues*, Harvard John A. Paulson School of Engineering and Applied Sciences (February 19, 2014), <https://www.seas.harvard.edu/news/2014/02/essential-step-toward-printing-living-tissues> (defining "bio-ink" as "functional inks with useful biological properties" or "tissue-friendly inks containing key ingredients of living tissues").

71. Kannan, *supra* note 54; see also Xiaofeng Cui et al., *Thermal Inkjet Printing in Tissue Engineering and Regenerative Medicine*, RECENT PATENTS ON DRUG DELIVERY AND FORMULATION, 2012, at 149-55, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3565591>.

72. Kannan, *supra* note 54.

73. *Id.*

74. *Id.*

75. *Id.*

detailed patterning of cells.⁷⁶ Similarly, the selection of bio-ink is critical.⁷⁷ Research and development of new bio-inks has been a high priority, including hydrogel mixtures and water-based inks.⁷⁸

G. Early Successes in Bioprinting

Several research groups have already achieved success with manufacturing functional tissues, including skin, blood vessels, cartilage, the bladder, and the uterus.⁷⁹ For instance, researchers at the Scripps Research Institute were able to produce artificial cartilage comprised of human chondrocytes in a hydrogel.⁸⁰ Additionally, scientists at Cornell University have constructed aortic valve conduits composed of various cell types and patterned cell distribution.⁸¹

However, these early achievements did not prevail without challenges. Although these advances have demonstrated how much potential 3D bioprinting holds, this technology is limited by the same obstacle as alternative tissue engineering methods: vascularization.⁸² Blood vessels are vital for transferring nutrients, oxygen, and wastes throughout thick tissues; without them cell death is inevitable.⁸³ Without vascularization, tissues produced by 3D printing are required to be very thin, a limitation that has until now barred the creation of larger tissues and organs.⁸⁴

H. Current Ventures in Bioprinting

In February of 2014, the Lewis Lab at the Harvard School of Engineering and Applied Sciences made an astounding discovery.⁸⁵ The

76. *Id.*

77. *Id.*

78. *Id.*

79. Kate Lyons, *Humans could be fitted with kidneys made on 3D PRINTERS thanks to Australian researchers who have already grown miniature organs in labs*, ASSOCIATED NEWSPAPERS, (May 23, 2014 2:08 PM EST), <http://www.dailymail.co.uk/sciencetech/article-2637158/Humans-fitted-kidneys-3D-printers.html>.

80. Kannan, *supra* note 54; *see also* *About The Scripps Research Institute*, THE SCRIPPS RESEARCH INSTITUTE, (2015), <http://www.scripps.edu/about/index.html> (stating that the Scripps Research Institute is a private, nonprofit medical research facility located in California, dedicated to research and education in biomedical sciences).

81. Kannan, *supra* note 54; *see also* Bin Duan et al., *3D Bioprinting of Heterogeneous Aortic Valve Conduits with Alginate/Gelatin Hydrogels*, J. BIOMED MATER RES A, 2013, at 1255-64, available at <https://ncbi.nlm.nih.gov/pmc/articles/PMC3694360>.

82. Kannan, *supra* note 54.

83. *Id.*

84. *Id.*

85. *Id.*

group used a customized inkhead bioprinter and inventive bio-inks, such as a gelatin-based ink for the scaffold and two cell-containing inks.⁸⁶ Notably, the seemingly most novel portion of the investigation was the use of a Pluronic-based bio-ink that switches from a solid to a liquid when cooled below 4° C.⁸⁷ Accordingly, the lab was able to produce 3D constructs with an intricate grid of Pluronic ink, which upon cooling resulted in liquidification of the Pluronic and creation of channels within the structure.⁸⁸ To convert these channels into vasculature, they were subsequently endothelialized.⁸⁹ The Lewis group used this Pluronic ink technique to print a construct of human umbilical vein cells, neonatal dermal fibroblasts, and vasculature.⁹⁰ Down the line, a bioreactor could be utilized for perfusion to allow for nutrient and oxygen flow within the structure.⁹¹

Organovo, a San Diego-based company, has also begun conquering the vasculature hurdle.⁹² The company stated that it had overcome vascularization to a degree in its endeavor to print the first functional liver.⁹³ They were able to produce liver tissue with a thickness of greater than 500 microns that could remain in a fully functional state for at least 40 days.⁹⁴ In order to create a working liver, various cell types with different functions must be combined.⁹⁵ Among the cell types Organovo utilized were fibroblasts and endothelial cells.⁹⁶ These are important players for developing a vasculature network, which allowed the company to print thick tissue with good cell variability.⁹⁷

In the future, the production of a fully-operative liver will be a landmark in 3D bioprinting history because it will prove that 3D printed tissue is capable of living long enough to test drug efficacy or to be

86. *Id.*; see also David B. Kolesky et al., *3D Bioprinting of Vascularized, Heterogeneous Cell-Laden Tissue Constructs*, *Advanced Materials*, May 21, 2014, at 3124-30, available at <https://www.onlinelibrary.wiley.com/doi/10.1002/adma.201305506/abstract>.

87. Kannan, *supra* note 54.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. Mearian, *supra* note 21.

93. *Id.*

94. *Id.*

95. *Id.* (describing the cell types making up a human liver. These include Kupffer cells for removing debris from the blood, stellate cells for regenerating tissue that has died or been injured, and sinusoidal endothelial cells, which make up the interior surface of blood vessels and lymphatic vessels.).

96. *Id.*

97. *Id.*

implanted into the body where it can mature.⁹⁸

I. The Incentivization of 3D Bioprinting

There is no doubt that the general field of 3D printing is booming. With the influx of new developments and uses of the technology, analysts at International Data Corporation, an American market research firm that specializes in information and consumer technology, forecasted that worldwide spending on 3D printing would total a mere \$2.7 billion in 2014.⁹⁹ However, they expect long-term growth of 29% a year, which is much greater than the normal trends in manufacturing.¹⁰⁰ Hopeful analysts at Morgan Stanley predict even faster annual growth of 34%, which amounts to more than \$20 billion in sales by 2020.¹⁰¹

Funding for whole organ regeneration research is currently less than \$500 million a year in the U.S., while cancer research and HIV/AIDS research receive \$5 billion and \$2.8 billion, respectively.¹⁰² While regenerative medicine is seen as the future of healthcare, the field is presently falling through the cracks.¹⁰³ In order to fuel the development of bioprinted organs, the Methuselah Foundation, a Virginia-based nonprofit that backs regenerative medicine research, announced a \$1 million prize for the first organization to print a fully functioning liver.¹⁰⁴ Additionally, the foundation has begun a campaign to finance research at major research institutions using Organovo's patented NovoGen Bioprinting technology.¹⁰⁵

III. THE EVOLUTION OF ORGAN DONOR LAW

Since as early as the 1800s, organ donation has been in existence.¹⁰⁶

98. *Id.*

99. George Anders, *HP's 3D Print Breakthrough Could Push Rivals 'Out of Business'*, FORBES (Oct.29, 2014 9:30 AM), <http://www.forbes.com/sites/georgeanders/2014/10/29/hps-3d-print-breakthrough-could-push-rivals-out-of-business/>.

100. *Id.*

101. *Id.*

102. Mearian, *supra* note 21.

103. *Id.*

104. *Id.*

105. PRNewswire, *Organovo and Methuselah Foundation Announce Funding of Bioprinting Research at Research Institutions*, ORGANOVO (Jul. 24, 2013), <http://ir.organovo.com/news/press-releases/press-releases-details/2013/Organovo-and-Methuselah-Foundation-Announce-Funding-of-Bioprinting-Research-at-Research-Institutions/>.

106. *Timeline of Historical Events Significant Milestones in Organ Donation and Transplantation*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <http://www.organdonor.gov/legislation/timeline.html> (last visited Dec. 2, 2015).

In 1869, the first skin transplant was performed. With such a sensitive exchange, it was foreseeable that in due time laws would be put into place to regulate this activity. However, it took over a century for the government to enact federal law to control organ donation and transplantation. In 1968, the first organ procurement organization, the New England Organ Bank, was formed.¹⁰⁷ In that same year, the National Conference of Commissioners on Uniform State Laws drafted the Uniform Anatomical Gift Act, which established the Uniform Donor Card as a legal document of gift in all 50 states, identified the types and priority of individuals who could donate a deceased person's organs, and enabled anyone over 18 years old to legally donate his or her organs upon death.¹⁰⁸ The biggest breakthrough in organ donor law came in 1984, when Congress passed NOTA.

This Note now explores how organ donation has evolved throughout the decades by way of Congress and in the eyes of the general public. Part III.A discusses the National Organ Transplant Act, which is still in effect today and outlawed the selling of human organs and established the OPTN and Scientific Registry of Transplanted Recipients.¹⁰⁹ It also provided for grants for the establishment, initial operation, and expansion of organ procurement organizations. This Part next discusses the Organ Donation and Recovery Improvement Act, which expanded the authority of NOTA. Part III.B presents the different arguments for and against live donor organ sales that the American Bar Association has presented. This Part explains that these arguments are applicable to 3D printed organ sales because the technology is intended to serve the same purpose—to expedite the distribution of organs for transplantation.

A. Federal Law: National Organ Transplant Act: Section 301 (C.F.R. 42 U.S. Code § 274e)

The field of organ donation and transplantation is one of the most

107. *Organ Procurement Organizations*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <http://organdonor.gov/materialsresources/materialsopolist.html> (last visited Dec. 2, 2015) (stating that Organ Procurement Organizations are nonprofit organizations that are “responsible for two main functions within their designated service area: 1) increasing the number of registered donors, and 2) coordinating the donation process when actual donors become available”).

108. *Id.*

109. *Id.* (explaining that the Organ Procurement and Transplantation Network was created to ensure fair and equitable allocation of donated organs and the Scientific Registry of Transplanted Recipients was implemented to conduct an ongoing evaluation of the scientific and clinical status of an organ transplantation.).

regulated areas of healthcare today.¹¹⁰ Both state and federal statutes have been enacted to attempt to provide the safest and most evenhanded system for distribution and transplantation of donated organs.¹¹¹

As stated above, in 1984 Congress enacted NOTA. This act created the OPTN, which is run by the United Network for Organ Sharing (UNOS), a private, non-profit organization under federal contract.¹¹² Federal regulations promulgated pursuant to NOTA provide a regulatory framework for the structure and operation of the OPTN where it is responsible for increasing and ensuring the effectiveness, efficiency, and equity of organ sharing in the national system of organ allocation and for increasing the supply of donated organs for transplantation.¹¹³ Section 301 of NOTA prohibits the purchase of organs under subsection (a), stating that "it shall be unlawful for any person to knowingly acquire, receive or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."¹¹⁴ Further, under subsection (b) "[a] violator of this law shall be fined not more than \$50,000 or imprisoned not more than five years, or both."¹¹⁵

NOTA explicitly defines the terms "human organ," "valuable consideration," and "interstate commerce."¹¹⁶ According to the original Section 301 of the 1984 version of NOTA, "human organ" in Subsection (c)(1) was defined as the "human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ specified by the Secretary of Health and Human Services (HHS) by regulation."¹¹⁷ However, Section 301 has been amended several times since its enactment.¹¹⁸ In 1988, Congress broadened the definition by inserting "any subpart thereof" after the listed organs and expanding the definition of "human" to include fetuses.¹¹⁹ Another amendment in 2007, crafted a new definition of "human organ," which states, "the term

110. *Legislation and Policy*, *supra* note 6.

111. *Id.*

112. *Id.*

113. *Id.*

114. National Organ Transplant Act, 42 U.S.C § 274 (1984).

115. *Id.*

116. *Id.*

117. *Id.*

118. Lingyun Kao, Flynn v. Holder, *a Narrow Interpretation of National Organ Transplant Act (NOTA) Reached Positive Policy Effects*, THE UNIVERSITY OF HOUSTON LAW CENTER, 3 (2013), [http://www.law.uh.edu/healthlaw/perspectives/2013/Kao_Flynn%20v.%20Holder,%20a%20Narrow%20Interpretation%20of%20National%20Organ%20Transplant%20Act%20\(NOTA\)%20Reached.pdf](http://www.law.uh.edu/healthlaw/perspectives/2013/Kao_Flynn%20v.%20Holder,%20a%20Narrow%20Interpretation%20of%20National%20Organ%20Transplant%20Act%20(NOTA)%20Reached.pdf).

119. *Id.*

‘human organ’ means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye bone, skin and intestine, including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract.”¹²⁰

However, the Secretary of HHS has since expanded the definition of human organs by adding vascularized composite allografts to the covered list of human organs under the OPTN final rule.¹²¹

Subsection (c)(2) of Section 301 does not define “valuable consideration” in terms of what it is, but rather what it is not. The term “valuable consideration” under the statute “does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing and lost wages incurred by the donor of a human organ in connection with the donation of the organ.”¹²² However, it has been recognized that “the title of a statute or

120. Public Health Service, Department of Health and Human Services Organ Procurement and Transplantation Network, 42 C.F.R. § 121.13 (2015).

121. *Id.*; see also *Final Rule*, OFFICE OF THE FEDERAL REGISTER (2013), https://www.federalregister.gov/articles/text/raw_text/2013/15/731.txt (discussing that a final rule issued by HHS was responsible for the addition of vascularized composite allografts; the rule went into effect on July 3, 2014. “The transplant community has referred to the transplants of intact vascularized body parts such as hands and faces as composite tissue allograft transplants. As tissues, these components have been under the regulatory jurisdiction of the Food and Drug Administration (FDA). For the reasons outlined in the NPRM, the Secretary believes that these components, based on their clinical characteristics, are more characteristic of organs as defined specifically in NOTA and subsequently by regulation in the case of intestines and blood vessels used in conjunction with organ transplantation. For the purpose of this regulation, these components are described as vascularized composite allografts (VCAs) . . . Pursuant to this rule, for a body part to be defined as a VCA, it must have all the following characteristics: A body part that is (1) Vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation; (2) containing multiple tissue types; (3) recovered from a human donor as an anatomical/structural unit; (4) transplanted into a human recipient as an anatomical/structural unit; (5) minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ’s utility for reconstruction, repair, or replacement—examples of minimal manipulation include cutting, grinding, and shaping of a VCA); (6) for homologous use (i.e., the replacement or supplementation of a recipient’s organ with an organ that performs the same basic function or functions in the recipient as in the donor, e.g., a hand from the donor is to be used as a hand in the recipient); (7) not combined with another article such as a device; (8) susceptible to ischemia and, therefore, only stored temporarily (e.g., cold storage in preservation medium and intended for implantation into a recipient within hours of the recovery) and not cryopreserved; and (9) susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.”).

122. National Organ Transplant Act, 42 U.S.C § 274 (1984); see also *Change to the Definition of “Human Organ” Under Section 301 of the National Organ Transplant Act of 1984*, OFFICE OF THE FEDERAL REGISTER (2013), <https://www.federalregister.gov/articles/2013/10/02/2013-24094/change-to-the-definition-of-human-organ-under-section-301-of-the-national-organ-transplant-act-of> (asserting that Congress’s amendment to Section 301 in 2007 also affected

section can aid in resolving ambiguity in the legislation's text."¹²³ Section 301 is titled "Prohibition of Organ Purchases," which does not explicitly mention "valuable consideration."¹²⁴ Thus, Professor Kevin Marshall suggests that reading Section 301's text in light of its title implies that the indistinct phrase "valuable consideration" addresses organ transfers "that could be considered to involve a 'purchase,' rather than all donations that may involve some exchange."¹²⁵

Subsection (c)(3) of Section 301 defines the term "interstate commerce." However, it is defined as prescribed by section 201(b) of the Federal Food, Drug, and Cosmetic Act.¹²⁶ The Food, Drug, and Cosmetic Act defines "interstate commerce" as "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body."¹²⁷ This subsection of NOTA has never been amended.

State law also prohibits the sale of organs in compliance with the Uniform Anatomical Gift Act (UAGA).¹²⁸ The initial version of the UAGA failed to expressly mention commerce in organs.¹²⁹ UAGA was amended in 1987 to bar unambiguously the purchase and sale of organs removed after death.¹³⁰ Although this prohibition does not cover living donor organ purchases and sales, some states have tailored the 1987 UAGA to include such a provision.¹³¹

B. Arguments for and Against Living Donor Organ Sales

What may be a precursor to 3D bioprinted organ sales is live donor organ sales. The American Bar Association has presented different arguments for and against live donor organ sales. These arguments are applicable to 3D printed organ sales because the technology is intended

Subsection (C)(2) by excluding paired donation from the definition of "valuable consideration").

123. *INS v. Nat'l Ctr. for Immigrants' Rights*, 502 U.S. 183, 189 (1991); *see also* C. Kevin Marshall, *Legality of Alternative Organ Donation Practices Under § 274e*, MEMORANDUM OPINION FOR THE GENERAL COUNSEL DEPARTMENT OF HEALTH AND HUMAN SERVICES, 41-2 (2007), <http://www.justice.gov/sites/default/files/olc/opinions/attachments/2015/05/29/op-olc-v031-p0040.pdf> (concluding that in statutory text, "employment" referred to "unauthorized employment," in accordance with the heading of § 274e).

124. Marshall, *supra* note 123.

125. *Id.*

126. 42 U.S.C. § 274.

127. Federal Food, Drug, and Cosmetic Act § 201, 21 U.S.C. § 321 (2015).

128. Shapiro, *supra* note 9.

129. *Id.*

130. *Id.*

131. *Id.*

to serve the same purpose—to expedite the distribution of organs for transplantation. However, because 3D bioprinted organs eliminate the live donor aspect, it strengthens or weakens any arguments involving the living donor.

1. Arguments Supporting Live Donor Organ Sales

The weightiest argument in support of live donor organ sales is that authorizing human organ sales would produce a greater supply of rare and life-saving resources.¹³² Economists' assertion that barring compensation for organs lessens supply is strengthened by years of reports of people's offers to sell their organs.¹³³ Thirty years ago during the NOTA hearings, one man submitted a letter to the U.S. House of Representatives Subcommittee on Health and the Environment in hopes of being compensated for his kidney to fund an education.¹³⁴ In another letter, a mother wanted to sell an organ to pay for her daughter's medical treatment¹³⁵

Another argument is that people should be able to do with their own body parts whatever they wish.¹³⁶ Just as police officers, fishermen such as in "Deadliest Catch," and steel workers are paid for their dangerous work, those who selflessly decide to assume the risk to give their organs to others should also be compensated.¹³⁷ Indeed, some contend that because hospitals, doctors, laboratories, and pharmaceutical companies charge patients for transplantation-related products and services, it is unfair for donors not to be compensated.¹³⁸

Bolstering each of these arguments is that despite the fact that transplantation using paid living donors is unlawful, it occurs. Because of this, it might be better to legalize the practice so that it could be regulated properly.¹³⁹

2. Arguments Against Live Donor Organ Sales

There are five main objections to permitting live donor organ sales. First is that the organ buyer-seller relationship would be exploitative and

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*

139. *Id.*

either cause or amount to an improper commodification of the body.¹⁴⁰ However, in rebuttal to this argument, society allows other exploitative practices, such as poorly paid labor practices, so why should organ sales be considered any more morally problematic?¹⁴¹

Second is that paid organ donation could exclude disadvantaged people who cannot afford to pay for an organ.¹⁴² A counter to this argument is that the government or a privately run organization under governmental control could purchase the organs and then allocate them in a fair and equitable way.¹⁴³ This would allow for compensation to the donor as well as a carefully regulated system to ensure impartial distribution.

Third is that live organ donor sales would undercut voluntary organ donation.¹⁴⁴ There is evidence showing that marketing in human organs would ultimately destroy people's present willingness to donate their organs out of altruism, thereby decreasing the supply of organs.¹⁴⁵ For example, when blood was first permitted for sale, the overall blood supply dropped sharply because the decrease in voluntary donations was larger than the increase in paid donations.¹⁴⁶ However, it is possible for analogous compensated and charitable situations to coexist, such as professional social work and charitable social work.¹⁴⁷

Fourth, incentivizing organ donation through compensation would undermine the autonomy of true donation because of money's manipulative and coercive impact.¹⁴⁸ As mentioned above, organ market supporters have indicated that it is not unusual for society to allow people to undertake risks for money when they engage in hazardous occupations such as mining and jockeying.¹⁴⁹ Additionally, people who donate an organ to a family member may be subject to a higher degree of coercion than those who sell their organs because of internal pressure from family members to save a loved one.¹⁵⁰

Finally, payment for organs would place an additional burden on the organ-recipient by greatly increasing the overall cost of

140. *Id.*
 141. *Id.*
 142. *Id.*
 143. *Id.*
 144. *Id.*
 145. *Id.*
 146. *Id.*
 147. *Id.*
 148. *Id.*
 149. *Id.*
 150. *Id.*

transplantation.¹⁵¹ However, compensation-supporters have argued that the scarcity of transplantable organs boosts the economic returns currently produced by transplant programs, and consequently, the financial incentives for donation would dwindle the overall costs of transplant procedures.¹⁵²

IV. APPLICABILITY OF EXISTING DONOR LAW TO 3D BIOPRINTING

Three-dimensional bioprinting will eventually supply a technology capable of expediting the organ donor process for waiting list candidates in dire need of organ transplantation. However, this technology may present an opportunity for capitalistic minds to exploit that desperation. Once organs are produced with great certainty of viability and little expectation of biological rejection, startups could assemble and begin manufacturing their own organs. While the OPTN is responsible for effectively distributing and handling donated transplanted organs, this new technology would override the OPTN-middleman. Taking that into account, there would be little to stop privately owned companies from producing their own organs and selling them directly to patients awaiting transplants.

This Note now turns to the critical questions regarding applicability of NOTA for 3D bioprinting. Part IV.A analyzes whether organs produced through 3D bioprinting will be considered “human organs” and subject to regulation under NOTA and concludes that NOTA will be applicable to bioprinted organs. Part IV.B examines what types of consideration received in exchange for a bioprinted organ would be considered “valuable consideration” under NOTA and concludes that compensation of any kind will violate NOTA’s prescription against receipt of “valuable consideration” in exchange for human organs. Part IV.C discusses the term “interstate commerce” under NOTA, concluding that an attempt to sell human organs within the United States, even human organs harvested outside of the United States, affects interstate commerce. Part IV.D explains whether 3D bioprinted organs would constitute “experimental treatment” and thus, whether waiting list candidates could promptly receive manufactured organs or be required to wait until after the FDA approval process. It concludes that similar to in-vitro organogenesis, 3D bioprinted organs will have to undergo FDA testing and approval, delaying any immediate promise of organ transplantation to waiting list candidates. Finally, Part IV.E explores

151. *Id.*

152. *Id.*

current organ trafficking and the great potential for black market operations of bioprinted organs, concluding that by Congress amending NOTA, it could either assert more control over or avoid such operations.

Because this is a technology that should come to fruition in the near future, applicable case law is nonexistent. However, there is common law exploring generally what may fall under the definitions within Section 301. This precedent can be used to help forecast what problems may arise with respect to 3D bioprinting. Also explored is whether 3D bioprinted organs would be perceived as a readily useable human organ or as an "experimental drug." The promise of solving the donor problem would be halted if, like in vitro grown organs, printed organs must undergo clinical testing.

A. Interpreting Section 301 of NOTA: What Qualifies as a "Human Organ?"

While Section 301 lists an expanse of "human organs," there is little case law interpreting this lexicon. In *Flynn v. Holder*, the Ninth Circuit held that the definition of "bone marrow," which is included under NOTA's definition of "human organ," did not encompass peripheral blood stem cells obtained through apheresis but only actual bone marrow extracted by aspiration.¹⁵³ In *Flynn*, the plaintiffs challenged the constitutionality of NOTA's ban on compensation for bone marrow transplants.¹⁵⁴ The Ninth Circuit based its decision wholly on "statutory interpretation of NOTA, not the plaintiffs' allegation that NOTA's prohibition on selling bone marrow violated the Equal Protection Clause of the U.S. Constitution, which prohibits the federal and state governments from denying any person the equal protection of the law."¹⁵⁵ The court reasoned that because NOTA does not ban blood

153. *Flynn v. Holder*, 684 F.3d 852, 855 (9th Cir. 2012). *Donating peripheral blood stem cells*, NATIONAL MARROW DONOR PROGRAM, <http://bethematch.org/support-the-cause/donate-bone-marrow/donation-process/donating-pbsc/> (last visited Dec. 2, 2015) ("Peripheral blood stem cell (PBSC) donation is one of two methods of collecting blood-forming cells for bone marrow transplants. The same blood-forming cells that are found in bone marrow are also found in the circulating (peripheral) blood. PBSC donation is a nonsurgical procedure, called apheresis. The donation takes place at an experienced blood center or outpatient hospital facility."). *Bone Marrow Aspiration and Biopsy*, CANCER.NET, <http://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/bone-marrow-aspiration-and-biopsy> (last visited Dec 2, 2015) ("Bone marrow aspiration and bone marrow biopsy are short medical procedures that collect a sample of bone marrow, the spongy tissue inside of bones, so it can be examined. The procedures, which are often done together, are used to diagnose some cancers, provide specific information about a blood cancer, or monitor the side effects and effectiveness of chemotherapy.").

154. *Flynn*, 684 F.3d at 852.

155. *Id.* at 865. Glenn Cohen, *Selling Bone Marrow—Flynn v. Holder*, THE NEW ENGLAND

donations and peripheral blood stem cell apheresis donation is essentially the same as a blood donation, it was permissive.¹⁵⁶

The *Flynn* court concluded that Congress could not have had the intent to address the apheresis method when it passed NOTA because the method did not exist at the time. Statutory interpretation was necessary in order to clarify the meaning of “bone marrow.” *Flynn v. Holder* narrowed the meaning of “bone marrow” in NOTA to include bone marrow obtained only directly, meaning through the aspiration method. Therefore, if bone marrow is printed directly from a 3D bioprinter (analogous to the aspiration method), it will likely fall under the definition of “human organ” of Section 301. However, if a 3D bioprinter were to use peripheral blood stem cells and subsequently transform the cells into bone marrow that would seem to circumvent the meaning of “bone marrow” in the statute in the same way peripheral blood stem cell apheresis does.

There are institutions currently producing lab-grown organs. Anthony Atala of Wake Forest has drawn international commendation for being the first scientist to implant lab-grown bladders in people, improving their urinary incontinence.¹⁵⁷ He grew the bladders from the patients’ own urothelial cells to diminish the chance of the organs being rejected by the patients’ bodies.¹⁵⁸ Atala is now helping a Pennsylvania-based company called Tengion to conduct more studies of the bladder with the idea of eventually seeking federal approval to sell the organs commercially.¹⁵⁹ While this is currently a mere thought, it can be inferred that the government would consider lab-grown organs to be “human organs”—hence, revealing why federal approval is needed.

B. Interpreting Section 301 of NOTA: What Qualifies as “Valuable Consideration?”

Intertwined with the interpretation of “bone marrow” under Section 301 in *Flynn v. Holder* was what constitutes “valuable consideration.” The court upheld NOTA’s ban on the sale of body parts for transplant

JOURNAL OF MEDICINE (2012), <http://www.nejm.org/doi/full/10.1056/NEJMp1114288?viewType=Print>.

156. Kao, *supra* note 118, at 1-2 (“[M]ost bone marrow stem cells are found in the bone marrow only, but a small number of them, called peripheral blood stem cells, also exist in the bloodstream.”).

157. Steve Johnson, *Lab-grown human organs: Companies lack funding to meet expectations*, SAN JOSE MERCURY NEWS (Dec. 9, 2007 1:50 AM PST), http://www.mercurynews.com/business/ci_7675722?nclick_check=1.

158. *Id.*

159. *Id.*

against plaintiffs who sought to incentivize bone marrow transplants by providing valuable consideration (a \$3,000 housing subsidy, scholarship, or charitable donation) to donors.¹⁶⁰ The Ninth Circuit upheld the law, "without applying heightened scrutiny to the statute, which would be required if the ban implicated a fundamental right, and found the statute constitutional after rational basis review."¹⁶¹ Compensation for reasonable personal expenses associated with travel and lost wages is acceptable (as are paired living donor chains, since the 2007 amendment of NOTA) but any other "valuable consideration" that might incentivize sources of organs is not.¹⁶²

In *Richards v. Holder*, the Ninth Circuit held that plaintiff did not have a constitutional right to buy a kidney.¹⁶³ In this case, plaintiff suffered from an end-stage renal disease and offered to pay \$50,000 to a kidney donor to minimize the waiting time for a kidney.¹⁶⁴ Plaintiff contended that NOTA violated his due process rights and exacted a taking without just compensation.¹⁶⁵ The court rejected plaintiff's contentions with *Flynn v. Holder* being the persuasive authority.¹⁶⁶ In *Flynn*, the court upheld NOTA's ban on compensation for human organs, noting that only a rational basis review was appropriate since NOTA did not involve a fundamental right.¹⁶⁷ The *Richards* court again held the right to offer money for the donation of an organ for transplant not to be fundamental, and therefore, concluded that plaintiff could not nullify the statute.¹⁶⁸

While *Flynn* and *Richards* address the issues of whether the purchasing of an organ is a fundamental right, they also help clarify what is meant by "valuable consideration." *Flynn* shows that the statute prohibits compensation of any kind, i.e. charitable, subsidy, or scholarship. *Richards* demonstrates that the statute prohibits direct payment of monies. Accordingly, intent is inconsequential; compensation is compensation. Therefore, if a 3D bioprinted organ is considered a "human organ" any form of compensation in exchange for

160. *Flynn*, 684 F.3d at 856.

161. *Richards v. Holder*, 2014 U.S. Dist. LEXIS 83431, 8 (D. Mass. June 19, 2014).

162. Michelle Meyer, *HHS Proposes Rule to Amend NOTA, Nullify Flynn v. Holder*, HARVARD LAW (Oct. 4, 2013), <http://blogs.law.harvard.edu/billofhealth/2013/10/04/hhs-proposes-rule-to-amend-nota-nullify-flynn-v-holder/>.

163. *Richards*, 2014 U.S. Dist. LEXIS 83431 at 12.

164. *Id.* at 3.

165. *Id.* at 1.

166. *Id.* at 10.

167. *Id.*

168. *Id.* at 12.

one will violate the statute.

C. Interpreting Section 301 of NOTA: What Qualifies as “Interstate Commerce?”

There are countless cases discussing the meaning of “interstate commerce.” However, there has been only one reported case related to organ trafficking in the United States.¹⁶⁹ The district court in *United States v. Wang* charged defendants in a one count indictment with conspiracy to sell human organs for use in human transplants, in violation of 42 U.S.C. § 274(e).¹⁷⁰ In this case, defendants attempted to sell human organs from executed Chinese prisoners in the United States.¹⁷¹ The indictment was not dropped because the charges set forth a jurisdictional basis between the alleged conspiracy and interstate commerce in the United States.¹⁷² The indictment stated that “the overt acts in furtherance of the alleged conspiracy occurred in the Southern District of New York and involved plans to sell organs in the United States.”¹⁷³ Further, the court found that it was a part and object of the conspiracy that the defendants, “unlawfully, willfully and knowingly would acquire, receive and otherwise transfer organs from executed Chinese prisoners, for valuable consideration for use in human transplantation, which transfer would affect interstate commerce.”¹⁷⁴

D. Would 3D Bioprinted Organs Qualify as an Experimental Treatment?

In *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, the United States Court of Appeals for the District of Columbia held that terminally ill, mentally competent patients who have exhausted all government-approved treatments do not have a fundamental right to experimental drugs that have only passed limited FDA safety trials.¹⁷⁵ Any government regulation offending this right,

169. Elizabeth Pugliese, *Organ Trafficking and the TVPA: Why One Word Makes a Difference in International Enforcement Efforts*, JOURNAL OF CONTEMPORARY HEALTH LAW & POLICY (2007), <http://scholarship.law.edu/cgi/viewcontent.cgi?article=1111&context=jchlp>.

170. *United States v. Cheng Yong Wang*, 1998 U.S. Dist. LEXIS 13481 (S.D.N.Y. Aug. 26, 1998).

171. *Id.*

172. *Id.*

173. *Id.* at 8.

174. *Id.* at 5.

175. Byron R. Chin, Note, *One Last Chance: Abigail Alliance v. von Eschenbach and the Right to Access Experimental Drugs*, 41 U.C. DAVIS L. REV. 1969, 1972 (2008), available at http://lawreview.law.ucdavis.edu/issues/41/5/notes/41-5_Chin.pdf.

including the FDA approval process, is subject to a rational basis analysis, under which "only regulations with no demonstrable rational relationship to a legitimate state interest would be invalid."¹⁷⁶

It is reasonable for terminally ill patients to want to undertake the risks associated with participating in a premarket drug study with the prospect that it could potentially save their lives.¹⁷⁷ However, due to the stringent qualifications for engaging in such a study, many do not meet the criteria.¹⁷⁸ These difficulties caused plaintiffs' challenge to the FDA approval process.¹⁷⁹

To determine whether a fundamental right existed, the court first applied the *Glucksberg* test and looked to history and tradition to note the difference between drug safety and effectiveness.¹⁸⁰ It found that the absence of government regulation alone failed to establish that the right was deeply rooted.¹⁸¹ Because a fundamental right was not implicated, the *Abigail* court applied a rational basis standard of review and determined that "the FDA's interest in protecting patients from unsafe drugs bore a rational relationship to the challenged regulations."¹⁸² Thus, the court granted the FDA's motion to dismiss.¹⁸³ With this holding, the court underscored "both the high hurdle that must be cleared to establish a right as fundamental and the deference due to legislatures in crafting a balance between the risks and benefits of medical technology where no fundamental right is implicated."¹⁸⁴

The persuasive reasoning the court supplies in *Abigail* applies with

176. *Id.*

177. *Id.* at 1981.

178. *Id.*

179. *Id.* at 1982.

180. *Id.* at 1986.

181. *Id.* at 1987

182. *Id.* *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 699 (D.C. Cir. 2007) (remarking that "terminally ill patients need not, however, always await the results of the clinical testing process." "The FDA and Congress have created several programs designed to provide early access to promising experimental drugs when warranted. For example, under the 'treatment IND' program, the FDA may approve use of an investigational drug by patients not part of the clinical trials for the treatment of 'serious or immediately life-threatening disease[s]' if there exists 'no comparable or satisfactory alternative drug or other therapy'; if '[t]he drug is under investigation in a controlled clinical trial'; and if the drug's sponsor 'is actively pursuing marketing approval of the investigational drug with due diligence.' The FDA reserves the right, however, to deny any treatment IND request if (1) the agency believes there is no 'reasonable basis' to conclude that the drug is effective; or (2) granting the request 'would . . . expose the patient . . . to an unreasonable and significant additional risk of illness or injury.' Sponsors may not profit from any approved treatment IND program and may only 'recover costs of manufacture, research, development, and handling of the investigational drug.'"). *Id.*

183. *Id.*

184. *Richards v. Holder*, 2014 U.S. Dist. LEXIS 83431, 11 (D. Mass. June 19, 2014).

greater force to the plaintiff's challenge in *Richards*. In *Abigail* the law forbade the use of particular experimental drugs to plaintiffs who were terminally ill and without any other treatment options.¹⁸⁵ By contrast, in *Richards* the law afforded plaintiff access to kidney transplants (although not without limitation), and he was availing himself of alternative treatment for his disease, specifically dialysis.¹⁸⁶ Following the "high hurdle" required to implicate a fundamental right established by the *Abigail* court, the Ninth Circuit in *Richards* found the right to offer cash for a kidney donation for transplant not to be fundamental.¹⁸⁷

Abigail and *Richards* set forth an interesting distinction. The court in *Abigail* found that the terminally ill "do not have a fundamental right to experimental drugs that have passed [initial phase] clinical testing" and thus, denied the plaintiffs' constitutional claim.¹⁸⁸ The *Richards* court found that terminally ill individuals have a fundamental right to a kidney transplant; access was only denied because a transplant cannot be given in exchange for valuable consideration. This is an important difference because whether a printed organ qualifies initially as a "human organ" or an experimental treatment dictates how soon a patient can receive a transplant. In the future, if the first printed organs are considered "human organs," they are immediately ready for implantation and saving lives. However, if the first printed organs must undergo clinical testing, and are therefore at that point in time considered experimental, a patient would not have a fundamental right to the bioprinted organs until they have progressed past the initial phase of testing.

Since an organ is created artificially through the use of a 3D printer, it could be argued either that it is experimental medical treatment or is a true organ because it functions necessarily the same as a naturally occurring organ. One way to analyze this new technology is in comparison to *in vitro* organogenesis, which was a precursor to 3D organ printing.¹⁸⁹ This area of development has already progressed into

185. *Id.* at 10.

186. *Id.*

187. *Id.* at 12.

188. *Id.* at 11.

189. *Definition of In vitro*, MEDICINENET.COM (Mar. 19, 2012), <http://www.medicinenet.com/script/main/art.asp?articlekey=4033> (explaining that *in vitro* organogenesis is a method for regenerating organs from stem cells in a test tube or other laboratory vessel outside of a living organism.); *see also* Drew Halley, *Growing Organs in the Lab*, SINGULARITY UNIVERSITY (June 8, 2009), <http://singularityhub.com/2009/06/08/growing-organs-in-the-lab/> (stating that this technology requires precise blueprints for each cell-differentiation step and that this method has already seen some promising results such as the generation of a bladder, which is in Phase II testing, meaning that it has already been implanted into individuals and studied

clinical testing, which is a strong indicator that 3D printing will also have to endure clinical testing, and thus, fits with the court's holding in *Abigail*. It is likely that even if an individual is terminally ill with no alternative treatment options, a 3D printed organ will not be a treatment option until it has completed initial clinical testing and proven safe and effective.¹⁹⁰ This dampens the almost-immediate gratification outlook for 3D printed organs, since clinical testing can take several years.¹⁹¹

E. Ethical Considerations of 3D Bioprinting

It is quite possible that with the arrival of 3D bioprinting, there will come black market operations for the purchase of bioprinted organs. Indeed, Facebook has already been an instrument used for selling black market organs.¹⁹² While this contemplation hinges on whether a printed organ is indeed a "human organ," it is likely that it will be, and therefore, is a topic that should not be ignored.

A 2012 report from the World Health Organization showed that more than one human organ is illegally purchased every hour worldwide, with the majority being kidneys.¹⁹³ Donors can include impoverished villagers, funeral home directors, and even victims of sex-

how the body adapts to it).

190. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 698 (D.C. Cir. 2007) ("Clinical testing for safety and effectiveness requires three or sometimes four phases.). See Food and Drug Administration, Department of Health and Human Services Investigational New Drug Application, 21 C.F.R. § 312.21(a)(1) (discussing that Phase I involves the initial introduction of a new drug into human subjects. A Phase I study usually consists of twenty to eighty subjects and is "designed to determine the metabolism and pharmacologic actions of the [new] drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness."). § 312.21(b) (stating that Phase II studies are "well controlled" and "closely monitored" clinical trials of no more than several hundred subjects, used to evaluate both the "effectiveness of the drug for a particular indication" and its "common short-term side effects and risks."). § 312.21(c) (explaining that Phase III studies are expanded clinical trials to "gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling."). 21 U.S.C.A. § 355(n)(1) (West, Westlaw through P.L. 114-114 (excluding 114-92, 114-94, 114-95 and 114-113) approved 12-28-2015) (noting that to guide the clinical testing process, Congress has directed the FDA to establish "[s]cientific advisory panels" to "provid[e] expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug.").

191. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 6, 2014), <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm>.

192. Emily Thomas, *Black Market For Organs Reportedly Alive And Well On Facebook*, THE HUFFINGTON POST (Mar. 10, 2014), http://www.huffingtonpost.com/2014/03/10/kidneys-sold-online-facebook-organ-donors_n_4936216.html.

193. *Id.*

trafficking or kidnapping.¹⁹⁴ Each of these groups includes people who have direct access to organs. However, with 3D bioprinting the pool can expand enormously. There would no longer be such a limitation. Anyone who could afford to purchase a printer, was appropriately trained, and had access to appropriate cells could in theory start their own black market brigade. Bottom-line, anyone with the motivation and time could establish an unlawful business.

Would this necessarily be a bad thing? If Congress were to amend NOTA to explicitly allow the selling of manufactured organs under controlled circumstances, it would eliminate these ethical issues. Because 3D bioprinting could create a surplus of manufactured organs, printed organs could be treated like any other living commodity, such as bananas, trees, and dogs. Notably, there is no law prohibiting the exchange of a dog for valuable consideration. No lives would have to be compromised, no family members would have to make sacrifices, and there would be no concern of atrophy of organ tissue. If a printed organ were to die, a new one could be printed out.

In theory, once 3D bioprinted organs are widely available, there would no longer be a use for donated organs for transplant. As a result, NOTA could be repealed. This would eliminate any confusion over regulating donated versus manufactured organs, eradicating any concern for black-market businesses. The process of organ transplantation could become as basic and routine as a tonsillectomy.

V. CONCLUSION

Section 301 of NOTA prohibits the purchase of human organs stating that “it shall be unlawful for any person to knowingly acquire, receive or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.” This Note concludes that it is likely that selling 3D printed organs would be a federal offense. The court’s treatment of the aspiration method in *Flynn v. Holder* and the analysis of federal approval for lab-grown organs bolsters the interpretation that a manufactured organ would be considered a “human organ.” The Ninth Circuit decisions in *Flynn v. Holder* and *Richards v. Holder* provide helpful insight into construction of “valuable consideration” under NOTA, suggesting that no compensation of any kind could be given in exchange for a bioprinted organ, including money, subsidies,

194. *Id.*

scholarships, or other charitable donations. Further, the court in *Flynn v. Holder* concluded that it is not a deprivation of life and liberty without due process of law to forbid the purchase of an organ, even under an end-stage disease situation. Similarly, the definition of "interstate commerce" under NOTA can be interpreted as commerce between any state or territory or any place outside thereof ("but only insofar as such commerce takes place within the United States").¹⁹⁵ While this does not cover intrastate commerce, all 50 states have adopted the UAGA that makes it unlawful to purchase or sell organs within that state. Based on the definitions provided in Section 301 and common law, it is likely that selling or purchasing a completed 3D printed organ anywhere in the United States would violate NOTA.

Unfortunately, the ethical ramifications of 3D bioprinting might detract from the benefits it promises to offer. While the use of 3D bioprinting could eventually save lives, until the federal government approves it, private creation and selling of 3D bioprinted organs would exacerbate organ selling on the black market. If Congress were to amend NOTA, however, to allow for the selling and purchasing of 3D printed organs, this could eliminate such black market activity.

Optimistically, after successful clinical testing and federal approval, 3D bioprinting could ultimately create a surplus of transplantable organs, and more importantly, make organs a widely available commodity by eliminating the donor. If John Wallis were to publish the "New, New Game of Life" today, it would likely include a few, bonus intermittent stages of life: Maybe an organ transplantation for a body tune-up to revert back to the prime of your life or a transplantation to escape death. With 3D bioprinting, the possibilities are endless and ultimately will allow the game of life to play on.

195. Commerce and Trade Definitions, 15 U.S.C. § 717a (2015) (Although not a part of the Federal Food, Drug, and Cosmetic Act, this section of the U.S. Code gives further insight into what Congress likely meant by "any place outside thereof.").