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# STUDENT NOTES



### 3-D BIOPRINTING: NOT ALLOWED OR NOT ALLOWED?

ROBERT JACOBSON

James Richards suffered from end stage renal disease.<sup>1</sup> The only effective treatment for his disease was to receive a kidney transplant.<sup>2</sup> Instead of enduring painful dialysis treatments while waiting for an estimated four to five years on the organ donor list, Richards was willing to spend \$50,000 to purchase a kidney from a donor.<sup>3</sup> However, the purchase of organs is explicitly banned by the National Organ Transplantation Act (NOTA).<sup>4</sup> In an effort to ease his suffering, Richards brought an action against the government to declare the ban on organ sales a violation of due process under the Fifth Amendment.<sup>5</sup> However, Richards' action failed since "the right to offer cash for the donation of an organ for transplant" is not a "fundamental" right.<sup>6</sup>

But what if there was another way that Richards could spend his \$50,000 on a kidney without violating the law? 3-D bioprinting may be the solution. This technology uses bioprinters to place cells or "bio-ink" in a precise layout, layer-by-layer, until the desired tissue is formed.<sup>7</sup> Scientists have already used 3-D bioprinting to successfully transplant

1. The facts pertaining to James Richards are taken from *Richards v. Holder*, CIV.A. No. 13-13195-LTS, 2014 WL 2805280, at \*2 (D. Mass. June 19, 2014).

2. *Id.*

3. *Id.*

4. 42 U.S.C. § 274e (2007) ("[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation").

5. U.S. CONST. amend. V ("No person shall be . . . deprived of life, liberty, or property, without due process of law").

6. *Richards*, 2014 WL 2805280, at \*5.

7. See Gunjan Sinha, *Cell Presses*, 32 NATURE BIOTECHNOLOGY 716 (Aug. 5, 2014), <http://www.nature.com/nbt/journal/v32/n8/full/nbt.2983.html>; *Bioprinting Process*, ORGANOVO, <http://www.organovo.com/science-technology/bioprinting-process> (last visited Feb. 28, 2016);

ears,<sup>8</sup> windpipes,<sup>9</sup> vaginas,<sup>10</sup> and noses.<sup>11</sup> However, scientists have not yet perfected the art of bioprinting fully-functioning complex organs such as kidneys.<sup>12</sup> As new developments in simpler forms of 3-D bioprinting continue to proliferate, and as scientists inch ever closer to printing functional hearts and kidneys, a critical mass of the American public will begin to debate the moral and ethical concerns of printing organs.<sup>13</sup>

Due to the seemingly plain language of NOTA, it is likely that a group with moral or ethical concerns about printing organs will challenge the legality of 3-D bioprinting as a whole, or any particular method of 3-D bioprinting. It has been said that “most every party up and down through the [3-D bioprinting] supply chain will be named in a lawsuit.”<sup>14</sup> This Note will explore the considerations that will be analyzed by a court during a challenge to the legality of 3-D bioprinting techniques under NOTA. Part I analyzes the technology of 3D-bioprinting; Part II analyzes the background of NOTA, the motivations for its enactment, and how 3-D bioprinting implicates these motivations; Part III analyzes how the language of NOTA applies to 3-D bioprinting; and Part IV proposes amendments to NOTA to reduce ambiguity about the legality of 3-D bioprinting.

8. Sinha, *supra* note 7.

9. Bob Aronson, *Artificial and Bioengineered Organs Can End the Shortage*, BOB'S NEWHEART (Feb. 10, 2013), <https://bobsnewheart.wordpress.com/category/ending-the-organ-shortage-solutions/>.

10. Alice G. Walton, *The Science of Lab-Grown Organs: Vaginas, Noses Now Possible*, FORBES (Apr. 12, 2014), <http://www.forbes.com/sites/alicegwalton/2014/04/12/the-science-of-lab-grown-organs-vaginas-noses-now-possible/>.

11. *Id.*

12. See Suraj Kannan, *The 3D Bioprinting Revolution*, 27 HARV. SCI. REV. 3 (Spring 2014), <http://harvardsciencereview.com/2014/05/01/the-3d-bioprinting-revolution/>; Malcolm Ritter, *As More Patients Get Lab-grown Body Parts, Scientists Face Challenge of Making Complex Organs*, GLOBAL NEWS (June 17, 2013), <http://globalnews.ca/news/647828/as-more-patients-get-lab-grown-body-parts-scientists-face-challenge-of-making-complex-organs/>.

13. Brandon Griggs, *The Next Frontier in 3-D Printing: Human Organs*, CNN (Apr. 5, 2014), <http://www.cnn.com/2014/04/03/tech/innovation/3-d-printing-human-organs/index.html> (“A research director at Gartner Inc., the information-technology research and advisory firm, believes 3-D bioprinting is advancing so quickly that it will spark a major ethical debate by 2016.”); Kannan, *supra* note 12, at 4 (“[T]he question of who can produce 3D organs must be addressed before further clinical developments can proceed.”).

14. Russ Banham, *3D Bioprinting of Human Tissues Introduces Array of Liabilities*, HARTFORD, <https://www.thehartford.com/resources/life-science/3d-printing-liabilities> (last visited Jan. 15, 2016).

## I. EXAMINATION OF 3-D BIOPRINTING TECHNOLOGY

3-D bioprinting is an umbrella term generally covering the utilization of computer-aided design (CAD) tools to “control the placement of cells, materials, and morphogens to replicate the types of organization found in the human body.”<sup>15</sup> How the cells are placed and what materials are used varies greatly between implementations and the specific organ or cellular mass being printed. In order to understand how the law will apply, it is necessary to understand the intricacies of how the technology works. For example, how a court in the future interprets NOTA may depend on a plurality of factors: Are human cells used in the process? Do the human cells derive from the transplantee? Are there artificial cells contained in the printed product (*e.g.*, scaffolding)? Do the artificial cells degenerate?

Tissue engineering technology has existed long before the onset of 3-D bioprinters.<sup>16</sup> These technologies largely focused on developing skin replacements using artificial materials for burn victims.<sup>17</sup> For example, in 1998, Organogenesis, Inc. (“Organogenesis”) received the first recommendation for approval by the Food and Drug Administration (FDA) for its product Apligraf (commercially known as Graftskin) Human Skin Equivalent, used for the treatment of venous leg ulcers.<sup>18</sup> Apligraf is manufactured by culturing human foreskin cells in a bovine collagen.<sup>19</sup> Apligraf functions by encouraging the patient’s own skin cells to regrow, rather than forming the cellular basis for the recovered skin.<sup>20</sup> To this end, the cells that constitute the Apligraf product degrade over time, disappearing completely from most patients.<sup>21</sup>

15. Kannan, *supra* note 12, at 2.

16. Stephen F. Badylaka & Robert M. Nerem, *Progress in Tissue Engineering and Regenerative Medicine*, 107 PNAS 8 (2010), <http://www.pnas.org/content/107/8/3285.full> (“The 1980s and 1990s were the ‘go-go years’ of tissue engineering.”).

17. See Badylaka & Nerem, *supra* note 16; Sinha, *supra* note 7, at 5.

18. *Apligraf*, ORGANOGENESIS, <http://www.organogenesis.com/products/apligraf.html> (last visited Feb. 28, 2016).

19. Larissa Zaulyanov & Robert S Kirsner, *A Review of a Bi-layered Living Cell Treatment (Apligraf®) in the Treatment of Venous Leg Ulcers and Diabetic Foot Ulcers*, 2 CLINICAL INTERVENTIONS IN AGING 93, 93 (2007) (More particularly “culturing human foreskin-derived neonatal fibroblasts in a bovine type I collagen matrix over which human foreskin-derived neonatal epidermal keratinocytes are then cultured and allowed to stratify.”).

20. *Id.*

21. *Id.*

As another example of an earlier tissue engineering product, Osteopore International Pte Ltd (“Osteopore”)<sup>22</sup> developed a similar solution for regenerating a fractured skull.<sup>23</sup> Osteopore’s process starts with digitally scanning the patient’s skull to generate a computer rendering of the skull. Osteopore then converts the computer rendering into a CAD file detailing the exact shape of the void in the patient’s skull.<sup>24</sup> A 3-D printer (not a bioprinter) creates the void-filling product using a bio-compatible polymer that is then attached to the patient’s skull such that the void is covered.<sup>25</sup> Like Apligraf, this polymer fosters the regeneration of the patient’s own bone to fill in the void.<sup>26</sup> As the patient’s bone regrows naturally, the polymer degrades leaving just the patient’s natural cells once the skull is fully healed.<sup>27</sup>

Unlike the skin and bone grafts of Apligraf and Osteopore that encourage natural cell regeneration, 3-D bioprinting technology further enables scientists to print tissue that can (eventually) replicate the vasculature of even the most complex organs, like the kidney.<sup>28</sup> Also unlike skin and bone grafts, these bioprinted organs are intended to remain in the body permanently as a replacement for the patient’s original organ. In some cases, the implanted organ is only partially developed, relying on the patient’s body to fully generate the functionality of the transplanted organ.<sup>29</sup>

Currently, companies are developing 3-D bioprinters that are able to print tissues that mimic the target organ’s functionality on a smaller scale.<sup>30</sup> For example, Organovo Holdings Inc. (“Organovo”)<sup>31</sup> utilizes 3-D bioprinters to print small cultures of liver tissues to more accurately

22. OSTEOPORE, <http://www.osteopore.com.sg/> (last visited Mar. 29, 2016).

23. *Our Technology*, OSTEOPORE,

<https://web.archive.org/web/20130813132216/http://osteopore.com.sg/tech.htm> (last visited Apr. 16, 2016).

24. *Id.*

25. *Id.*

26. *Id.*

27. U.S. Patent No. 6,730,252, at 1 (filed Sept. 20, 2001),

<http://www.google.com/patents/US6730252>.

28. Anthony Atala, *Printing a Human Kidney*, TED (Mar. 2011),

[http://www.ted.com/talks/anthony\\_atala\\_printing\\_a\\_human\\_kidney](http://www.ted.com/talks/anthony_atala_printing_a_human_kidney).

29. TENGION, <http://www.tengion.com/technology/platform.cfm> (last visited Mar. 29, 2016) (The implanted organ that regenerates inside the patient is referred to as a “neo-organ.”).

30. Laura Hockaday, *3D Bioprinting: A Deliberate Business*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Jan. 1, 2015), <http://www.genengnews.com/gen-articles/3d-bioprinting-a-deliberate-business/5379/> (See Table 1 for a list of companies).

31. ORGANOVO, <http://www.organovo.com/> (last visited Mar. 29, 2016).

test the toxicity of potential medications.<sup>32</sup> Organovo is capable of printing human cells (as extracted via a biopsy or tissue sampling) and adhesive cells into an arrangement that mimics a natural human organ.<sup>33</sup> These printed cells may also be referred to as “bio-ink” and encourage cellular cohesion and prevent cellular decay.<sup>34</sup> The voids left between the spaces occupied by the bio-ink form tubes in which bodily fluids may pass through the bioprinted tissue.<sup>35</sup>

In addition to printing cells layer-by-layer, Organovo also prints bio-ink onto a pre-formed scaffold.<sup>36</sup> The scaffold is formed in a manner that encourages the printed cells to grow in such a way so that cells will naturally develop into the desired tissue.<sup>37</sup> After the printing process is completed, the printed cells are incubated for about two days to foster cellular cohesion and development.<sup>38</sup> Over time, the scaffold decomposes leaving only trace amounts of the scaffold in the finished tissue.<sup>39</sup> Although Organovo is not currently bioprinting organs for transplantation, Organovo does intend to eventually develop a transplantable product.<sup>40</sup> Further, researchers at the Wake Forest Institute for Regenerative Medicine (“WFIRM”) have developed the ability to engineer miniature livers from human liver cells that are able to function in similar ways to natural livers while in a lab environment.<sup>41</sup> As described more fully below, it is these bioprinted organs being developed by research teams at

32. Organovo Holdings Inc., *The Bioprinting Process*, YouTube (Oct. 26, 2014), [https://www.youtube.com/watch?v=s3Cij26YS\\_U](https://www.youtube.com/watch?v=s3Cij26YS_U).

33. U.S. Patent Application. No. 13/612,768, at 25 (filed Sept. 12, 2012), <https://www.google.com/patents/US20130190210>.

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.* (“[T]he cellular components of the tissues contain a detectable, but trace or trivial amount of scaffold, e.g., less than 2.0%, less than 1.0%, or less than 0.5% of the total composition. [The] trace or trivial amounts of scaffold are insufficient to affect long-term behavior of the tissue, or array thereof, or interfere with its primary biological function.”).

40. *3D Human Tissues for Medical Research & Therapeutics*, ORGANOVO, <http://www.organovo.com/tissues-services/3d-human-tissues-medical-research-therapeutics/> (last visited Mar. 29, 2016).

41. *See Replacement Organs and Tissues*, WAKE FOREST INST. FOR REGENERATIVE MED., <http://www.wakehealth.edu/Research/WFIRM/Projects/Human-Liver.htm> (last updated Dec. 22, 2015) (The methods from 2010 described in the article do not implement 3-D bioprinters; however, WFIRM is currently using 3-D bioprinters to produce organ prototypes); *see also Using Ink-Jet Technology to Print Organs and Tissue*, WAKE FOREST INST. FOR REGENERATIVE MED., <http://www.wakehealth.edu/Research/WFIRM/Our-Story/Inside-the-Lab/Bioprinting.htm> (last updated Jan. 4, 2016). In any event, lab-grown organs implicate many of the same ethical and legal concerns of creating transplantable organs using a 3-D bioprinter.



Organovo and WFIRM which contain a majority of natural human cells that are most likely to implicate the statutory restrictions imposed by NOTA.

## II. BACKGROUND ON THE NATIONAL ORGAN TRANSPLANTATION ACT (NOTA)

### *A. Motivations Behind NOTA*

NOTA was originally enacted in 1984, establishing the "Organ Transplantation and the Organ Procurement and Transplantation Network."<sup>42</sup> The purpose of NOTA was "to promote equitable access to and effective use of multiple organs and tissues, and to address technical, ethical and financial issues involved in organ transplantation."<sup>43</sup> To that end, NOTA was tailored to "improve the supply of vital human organs" by helping tissue banks with the "retrieval, processing, preservation, storage, and distribution of tissues."<sup>44</sup> These tissues included the human kidney, liver, heart, lung, and pancreas as well as any other organ deemed appropriate, including bone and skin.<sup>45</sup>

In addition to establishing organ transplant networks, NOTA also enacted a prohibition on the sale of organs.<sup>46</sup> Prior to the enactment, advertisements for the sale of organs were visible throughout America, and "one Virginia entrepreneur went so far as to obtain a license for the import and export of human organs."<sup>47</sup> Distinctly aware of the existence of these organ procurement networks, the Senate enacted this prohibition believing that "individuals or organizations should not profit by the sale of human organs for transplantation."<sup>48</sup> It was the view of the Senate that "human body parts should not be viewed as commodities."<sup>49</sup>

This commodification raised several concerns with Congress and the American public at large. Congress prohibited the sale of organs for three reasons: the religious belief that one's soul is inextricably tied to their body, the lack of an altruistic system raises concerns about the quality of the organ supply, and because the free-market sale of organs

42. Act of Oct. 19, 1984, Pub. L. No. 98-507, 98 Stat. 424.

43. S. REP. 98-382, at 15 (1984), as reprinted in 1984 U.S.C.C.A.N. 3975, 3981.

44. H.R. CONF. REP. 98-1127, at 15 (1984), as reprinted in 1984 U.S.C.C.A.N. 3989, 3991.

45. *Id.*

46. 98 Stat. at 424, 431.

47. Thomas H. Murray, *On the Human Body as Property: The Meaning of Embodiment, Markets, and the Meaning of Strangers*, 20 U. MICH. J.L. REFORM 1055, 1057 (1986).

48. S. REP. 98-382, at 16 (1984), as reprinted in 1984 U.S.C.C.A.N. 3975, 3982.

49. *Id.*

will entrench social inequality by benefiting the wealthy at the expense of the poor.

From a religious perspective, “Judaism and Christianity embrace a tradition that refuses to separate radically the body from the ‘person.’”<sup>50</sup> Thus, when one sells their organ to another person, the part of his or her spiritual essence contained within the organ is also being sold. Said another way, the sale of one’s organs is both a sale of one’s body and spirit. Thus, the sacredness of the human condition is disturbed by the sale of an organ from one person to another.<sup>51</sup> To this end, ethicists feared that people will “suffer subtle, psychological harm if society begins to regard body parts as commodities for trade.”<sup>52</sup>

Commodification of organ transplantation also offends the principles of altruism that form the basis of the present organ donation system.<sup>53</sup> Representative Henry Waxman feared that, “[i]f [people are allowed to sell their kidneys] . . . our efforts to promote voluntary organ donations would collapse.”<sup>54</sup> These fears persisted despite the lack of evidence any sales of organs actually occurred.<sup>55</sup> In particular, many feared that the lack of altruism would lead to a proliferation of organ sales for organs that are unfit for transplantation.<sup>56</sup> Even beyond these safety concerns, altruists more simply believe that organ donations “belong to the world of gift, as distinct from the market realm.”<sup>57</sup>

Finally, there is the concern that the sale of human organs creates a market in which the wealthy can purchase health and longevity at the

50. Murray, *supra* note 47, at 1069.

51. *Id.* at 1070.

52. Beverly Ray Burlingame, *Commercialization in Fetal-Tissue Transplantation: Steering Medical Progress to Ethical Cures*, 68 TEX. L. REV. 213, 215 (1989).

53. Gil Siegal & Richard J. Bonnie, *Closing the Organ Gap: A Reciprocity-Based Social Contract Approach*, 34 J.L. MED. & ETHICS 415, 416 (2006) (“incentive-based approaches have been strongly resisted by many transplantation specialists and bioethicists because they would displace altruism with self-interest as the driving force in the system, and would offend the spirit, if not the letter, of the National Organ Transplantation Act (NOTA) prohibition against ‘valuable consideration’ for organ donation.”).

54. *Flynn v. Holder*, 684 F.3d 852, 860 n. 30 (9th Cir. 2012) (quoting *National Organ Transplant Act: Hearing on H.R. 4080 Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 98th Cong. 26 (1984) (statement of Rep. Waxman)).

55. “[T]he mere existence of such proposals threatens the voluntary donation system.” Julia D. Mahoney, *Altruism, Markets, and Organ Procurement*, 72 LAW & CONTEMP. PROBS. 17, 22 (Summer 2009) (quoting H.R. REP. NO. 98-575, at 22-23 (1983)).

56. *Flynn*, 684 F.3d at 860 (“Compensation to donors might also degrade the quality of the organ supply, by inducing potential donors to lie about their medical histories in order to make their organs marketable”); Mahoney, *supra* note 55, at 22 (“Congress was also influenced by expert testimony that bodily materials purchased from sources posed greater health hazards than ones acquired through gift.”).

57. Mahoney, *supra* note 55, at 17.

expense of the poor.<sup>58</sup> These market inequalities are “especially repugnant to our ideal of justice.”<sup>59</sup> According to this theory, laws should protect the impoverished from the temptation of permanently foregoing an organ for temporary financial gain.<sup>60</sup>

*B. How Does 3-D Bioprinting Implicate the Motivations Behind the Prohibition on the Sale of Organs?*

Many of the motivations that led to the enactment of NOTA and the prohibition of purchasing organs for transplantation still apply to 3-D bioprinting technology. However, many of these concerns can be minimized or eliminated by restricting 3-D bioprinting implementations to only those where the human inputs are gathered from the intended recipient. The ability to minimize many of these concerns may influence a court in ultimately determining the legality of the sale of 3-D bioprinted organs.

3-D bioprinting involves the printing of human cells, and thus, these human cells raise the concern that the sanctity of the body will be diluted.<sup>61</sup> Even at the cellular level, concerns about the interconnectivity between body and spirit persist.<sup>62</sup> The ethicists may not draw the distinction that merely individual cells, and not the whole organ, is implicated by bioprinting. Instead, allowing the purchase of bioprinted organs represents a dangerous slide into the purchasing of human beings. If an organ can be owned simply because it was printed, how does one draw a line between transplanting a single organ and a collection of organs that were printed?<sup>63</sup> Similar ethical concerns are raised by the possibility that healthy individuals will seek transplants of organs that may confer benefits beyond their natural organs. For example, it might eventually be possible to extract cells from a person who has developed

58. Murray, *supra* note 47, at 1088.

59. *Id.*

60. “To protect the vulnerable, many argue, the law should prevent people from selling their organs.” Mahoney, *supra* note 55, at 28.

61. Scott B. Rae, *The Ethics of Fetal Tissue Transplantation*, CHRISTIAN RESEARCH INST. (Apr. 17, 2009), <http://www.equip.org/article/the-ethics-of-fetal-tissue-transplantation/#christian-books-2>.

62. *Id.*

63. Leon Kass has raised similar arguments in criticizing ownership rights in genetically engineered organisms. See LEON KASS, TOWARD A MORE NATURAL SCIENCE 151 (1985) (“If a genetically engineered organism may be owned because it was genetically engineered, what would we conclude about a genetically altered or engineered human being?”).

an immunity to a type of liver disease and sell a line of transplantable livers containing the same immunity.<sup>64</sup>

However, 3-D bioprinting may alleviate the offense to the body's sanctity by restricting the human inputs for bioprinted organs to the cells gathered from the patient himself. If an organ is printed from one's own genetic material, then there is no potential source of genetic tampering. The patient is able to maintain the same genetic makeup that existed prior to the implantation of the bioprinted organ. Although there still are other artificial cells that are introduced in the process of bioprinting, these constitute no more offense to the body's sanctity than the application of an ointment to a wound or implanting a screw into a damaged joint.

In addition to the ethical concerns, there is a scientific reason to confine the transplantation of bioprinted organs to organs based on genetic material gathered from the patient: it reduces the risk of organ rejection.<sup>65</sup> The closer the genetic similarities between organ and recipient, the more likely the body is to accept the organ.<sup>66</sup> Bioprinting an organ from one's own genetic material ensures the highest likelihood that the organ will not be rejected by the patient's immune system. Accordingly, the restriction that a transplantable bioprinted organ must be derived from a patient's own cells represents an alignment of both the moral principles guiding NOTA and the scientific principles fundamental to reducing the risk of rejection in organ transplantation.

Additionally, 3-D bioprinting tends to escape the concerns of a degradation in the quality of transplantable organs due to the lack of an altruistic guiding principle. The FDA requires rigorous testing before approving a biological product to be commercialized.<sup>67</sup> The 3-D printed products that are currently available on the market, such as Apligraf and Osteopore Bone Void Filler, have been subjected to rigorous review by

64. "[W]e are heading toward a future in which we have more direct control over cell proliferation and differentiation." Sean V. Murphy & Anthony Atala, *3D Bioprinting of Tissues and Organs*, 32 NATURE BIOTECHNOLOGY 773, 782 (2014), <http://www.nature.com/nbt/journal/v32/n8/pdf/nbt.2958.pdf>.

65. "[R]ejection of bioprinted constructs by the host immune system is a potential problem that can be overcome by using an autologous source of cells." *Id.* at 781.

66. See generally *id.*

67. See *FDA Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) Product List, Regulation of Tissues*, FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/RegulationofTissues/ucm150485.htm> (last updated May 12, 2009) (information pertaining to FDA approval of tissue products).

the FDA.<sup>68</sup> For example, the FDA requires that manufacturers “establish that its product is biocompatible and can be effectively sterilized, and demonstrate that its facility has sufficient cleanliness and design controls.”<sup>69</sup> Further, Organogenesis performed two different clinical trials in order to convince the FDA to approve Apligraf: one study “found that treatment with bioengineered skin was more effective than compression therapy,” and the other assessed Apligraf’s success rate at treating a wound as compared to saline-moistened gauze.<sup>70</sup> Moreover, for transplantable tissues, the FDA may require even more stringent testing than the already significant testing required for the approved grafts.<sup>71</sup> This high standard of regulatory approval ensures that only safe and effective biological products are available for purchase.

Further, 3-D bioprinting nearly eliminates the risks of infecting the patient with a disease derived from the transplanted organ. NOTA was amended in 1988 at a time the American public was becoming aware of the AIDS epidemic.<sup>72</sup> The amendments to NOTA enacted language specifically targeted to the prevention of AIDS in the national supply of organs.<sup>73</sup> These amendments “had the purpose of preventing the spread of HIV and AIDS and, to that end, specifically stat[e] that no organs can be donated by those with HIV.”<sup>74</sup> There is no reason to believe that similar safeguards couldn’t be established for 3-D bioprinted organs. However, restricting 3-D bioprinting to the use of human cells from the intended recipient nearly eliminates the fear of communicating AIDS (or

68. Letter from Celia M. Witten, Ph.D., M.D., to Michael Sabolinski, M.D. (June 26, 2000) (on file at [http://www.apligraf.com/professional/support\\_and\\_resources/regulatoryDocumentation.html](http://www.apligraf.com/professional/support_and_resources/regulatoryDocumentation.html)); Letter from Mark N. Melkerson, Acting Dir., Ctr. for Devices and Radiological Health to Alexander Yeo (Mar. 17, 2006) (on file with Osteopore).

69. Hockaday, *supra* note 30, at 4.

70. Zaulyanov, *supra* note 19.

71. Hockaday, *supra* note 30, at 4. Tegnion has since been purchased by RegenMedTx. See REGENMEDTX, <http://www.regenmedtx.com/clinicaltrials/> (last visited Mar. 29, 2016) (information pertaining to Tegnion’s clinical trials for their implantable neo-kidneys and neo urinary conduit products as part of the FDA approval process as conducted now by RegenMedTx). Cf. Lyndsey Gilpin, *New 3D Bioprinter to Reproduce Human Organs, Change the Face of Healthcare: The Inside Story*, TECHREPUBLIC (Aug. 1, 2014), <http://www.techrepublic.com/article/new-3d-bioprinter-to-reproduce-human-organs/> (“[Bioprinting] is all new territory for the FDA, and the bioprinting landscape is advancing faster than anyone can keep up with.”).

72. “[NOTA] was amended at the height of the AIDS scare to ban transplants from HIV-infected donors.” *HIV Positive Organ Donation and Transplantation 2012*, HIV2HIV.ORG, <http://hiv2hiv.org/about/history.php> (last visited Mar. 29, 2016).

73. “[S]trike ‘organs,’ and insert the following: ‘organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.’” S. 2889, 100th Cong. (1988) (also contains a title directed to AIDS research).

74. Amy Vandenbroucke, *HIV and Organ Donation: Illinois’ Solution to Organ Donation Shortages*, 9 DEPAUL J. HEALTH CARE L., 1285, 1313 (2006).

other similarly transmitted diseases) as the patient will already have or be free of the communicable disease. Consequently, 3-D bioprinting also furthers the 1988 amendments' goal of minimizing the risk of contamination in the nation's organ supply.

The final factor weighing on the drafters of NOTA is social injustice and equality of access to organ transplants. 3-D bioprinting fails to promote equality of access. Even if a company received approval to market a functional bioprinted organ, it will still be extremely expensive.<sup>75</sup> Acceptance of bioprinted organs by medical insurers is uncertain,<sup>76</sup> leaving the patients potentially on the hook for the entire bill. Crucially, these expenses will probably be unaffordable to the poorer segments of society, in effect, establishing a two-tier organ replacement system: those with money can purchase a bioprinted replacement organ, while those without must wait on the lengthy organ donation list. The only silver lining for the poor is that there will likely be fewer people on the organ donation list as those who can afford it will simply purchase bioprinted organs.<sup>77</sup>

Despite the inequality of access, the fears of the wealthy harvesting organs from the poor are still ameliorated. If one were to sell their organic material, far less is needed to create a bioprinted organ than to transplant the same organ. To this end, only a biopsy, and not a complete organ, may be required from the third party cellular donor.<sup>78</sup> As a result, the donor may still retain his or her own organ with minimal long-term damage.<sup>79</sup> Further, as previously mentioned, if 3-D bioprinting is restricted to cells gathered from the intended recipient, gathering cells

75. "[T]he total bioificial heart could cost about \$100,000 in today's dollars, not counting \$150,000 or so in hospital and surgery costs." Laura Unger, *Researchers Closing in on Printing 3-D Hearts*, COURIER-J. (May 29, 2013, 5:45 PM) (video available at <http://www.usatoday.com/story/tech/2013/05/29/health-3d-printing-organ-transplant/2370079/>).

76. "[I]nsurance agents need to do a tremendous amount of research to stay ahead of the curve . . . [o]therwise they can be hit with a professional liability lawsuit for failing to do proper due diligence." Banham, *supra* note 14.

77. See generally Stephanie Innes, *Instead of Waiting for Donor Organs, Patients Could Have New Ones Grown in the Lab*, ARIZ. DAILY STAR (Oct. 27, 2013), [http://tucson.com/news/local/education/college/instead-of-waiting-for-donor-organs-patients-could-have-new/article\\_4036181d-150c-5bfb-a7a2-781c9fc0ef8b.html](http://tucson.com/news/local/education/college/instead-of-waiting-for-donor-organs-patients-could-have-new/article_4036181d-150c-5bfb-a7a2-781c9fc0ef8b.html).

78. See generally Associated Press, *Lab-grown Organs Might be Solution to Transplant Woes*, N. Y. DAILY NEWS (June 17, 2013), <http://www.nydailynews.com/life-style/health/scientists-work-grow-organs-transplants-article-1.1374818>.

79. As "needle biopsy" technology improves, the risks and discomfort inherent to traditional biopsy procedures may also be reduced. See generally *Ultrasound Guided Fine Needle Aspiration Biopsy of the Thyroid*, RADIOLOGICAL SOC'Y OF N. AM., INC., <http://www.radiologyinfo.org/en/info.cfm?pg=thyroidbiopsy> (last reviewed Aug. 22, 2014).

from the desperate and impoverished would remain outlawed. This restriction again causes the 3-D bioprinting technology to align with the goals of NOTA.

In summary, 3-D bioprinting may generally support the motivations that caused Congress to pass NOTA. For the previously described reasons, these motivations may be further promoted by restricting 3-D bioprinting to applications where the donor and donee are the same individual. However, policy is not the sole focus of courts. Thus, when a future court analyzes the issue of whether the sale of 3-D bioprinted organs violates the explicit language provided in NOTA, the court will necessarily examine the specific language of the act.

### III. THE LANGUAGE OF NOTA

The language prohibiting the sale of organs is as follows:

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. The preceding sentence does not apply with respect to human organ paired donation.<sup>80</sup>

In order to fully understand this provision, the future court will explore how previous courts and other interpretative bodies have defined each word of the Act. Of particular importance, the legal definition of “human organ,” and “valuable consideration,” as well as whether 3-D bioprinting implicates “interstate commerce” will likely be the crux of the dispute.

#### *A. What Is a “Human Organ?”*

NOTA only prohibits the transfer of a “human organ” or any subpart thereof.<sup>81</sup> But what exactly is a “human organ?” Not surprisingly, this is not an issue that has been the subject of many legal rulings. Fortunately, NOTA itself provides a definition for what constitutes a human organ: “the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.”<sup>82</sup> Remembering the struggle of James Richards, it is clear that

80. 42 U.S.C. § 274e (2007).

81. *Id.*

82. *Id.*

transplanting a functioning kidney or other listed organ falls within the prohibition.<sup>83</sup>

However, 3-D bioprinting involves many scenarios that are not as clear as a kidney transplant. Is a polymeric material (like Apligraf and Osteopore) that encourages the regeneration of a recipient's cells a "human organ?" The majority of people, and more importantly a court, would most likely have no problem answering in the negative. But what about when the transplanted "organ" comprises human biological materials that have been printed onto an artificial scaffolding? Does it matter if the scaffolding disintegrates over time, leaving just the human-derived biological materials behind? The timing of the transplantation may matter as well. Do the human biological materials become a "human organ" upon maturing in a lab to a point where it develops the function of a human organ? Conversely, if the transplanted human biological material is a neo-organ<sup>84</sup> that will develop full functionality inside the recipient's body, was a "human organ" transplanted? The ultimate determination may rest on an understanding of what the "human" in "human organ" means.

### 1. What is "Human?"

Because NOTA only bans transplanting "human" organs, if a 3-D printed organ is not "human," then it is not covered by the prohibition.<sup>85</sup> Looking to the legislative history, one may gather some insight into what "human" means under NOTA.<sup>86</sup> In addition to the aforementioned AIDS countermeasures, the 1988 amendments to NOTA added the phrase "derived from a fetus" in reference to a subpart of the organ.<sup>87</sup> This phrase was adopted in response to the widely-reported news that fetal organ transplants had positive effects in treating Parkinson's disease<sup>88</sup> (similar fetal transplant techniques had also been used for the previous 20 years to treat DiGeorge syndrome<sup>89</sup>) sparking a backlash from Judeo-

83. *Richards v. Holder*, CIV.A. No. 13-13195-LTS, 2014 WL 2805280, at \*1 (D. Mass. June 19, 2014).

84. TENGION, *supra* note 29 (defining a neo-organ as "[a] new organ or new tissue replacing or augmenting a patient's original native organ or tissue").

85. § 274e.

86. *Cf.* "Legislative history is not just unlikely to reflect the genuine purpose of Congress; it is increasingly likely to portray a phony purpose." Anthony Scalia & John F. Manning, *Dialogue on Statutory and Constitutional Interpretation*, 80 GEO. WASH. L. REV. 1610 (2011-2012).

87. S. 2889, 100th Cong. (1988).

88. Lee M. Sanders et al., *Ethics of Fetal Tissue Transplantation*, 159 WEST. J. MED. 400, 401 (1993).

89. *Id.*



Christian groups still upset over the Supreme Court's decision in *Roe v. Wade*.<sup>90</sup> These groups were concerned that fetal organ transplants provide an incentive for mothers to induce abortions solely for the purpose of organ donation.<sup>91</sup>

In this context, it is plausible that those attempting to ban the sale of 3-D bioprinted organs will draw parallels between a lab-grown organ and the transplanted fetal tissues. If fetal tissue that has not fully grown into a functioning organ is considered a "human" organ, then so might lab-grown organs that have not fully grown into functioning organs. A closer look at fetal organ transplantation technology reveals other similarities. Fetal organ transplantation starts with fetal tissue cells that have not fully developed specific organ functionality.<sup>92</sup> These fetal cells "proliferate more rapidly and more often than mature, fully differentiated cells. [Fetal cells] may produce high levels of angiogenic and neurotrophic factors, which enhance their ability to grow once they are grafted and may also facilitate regeneration of surrounding host tissues."<sup>93</sup>

In some aspects, this use of fetal tissue transplants is similar to the implementation of 3-D bioprinting technology pioneered by Tengion, Inc. ("Tengion"), wherein a neo-organ is implanted into a patient for subsequent regeneration into a full organ.<sup>94</sup> In both cases, the implanted human biological material is derived from an organ within the protections of NOTA.<sup>95</sup> In both cases, the implanted human biological materials do not exhibit full organ functionality prior to implantation. Finally, in both cases, the implanted human biological materials later grow into a properly functioning human organ *in vivo*.

One avenue of distinguishing 3-D bioprinting from fetal organ transplants may be the "relative humanity" between their respective biological materials. For pre-functional organs, it may be argued that if

90. "One wonders if government sponsorship of fetal tissue transplants would have the same legitimizing influence on abortion that *Roe v. Wade* did." See generally Rae, *supra* note 61, at 4; see also John A. Robertson, *Fetal Tissue Transplants*, 66 WASH. U. L. Q. 443, 443 (1988), [http://openscholarship.wustl.edu/law\\_lawreview/vol66/iss3/2](http://openscholarship.wustl.edu/law_lawreview/vol66/iss3/2).

91. Robertson, *supra* note 90, at 461.

92. See generally 15 ROYAL COMMISSION ON NEW REPRODUCTIVE TECHNOLOGIES, BACKGROUND AND CURRENT PRACTICE OF FETAL TISSUE AND EMBRYO RESEARCH IN CANADA (1994).

93. Alan Fine, *Transplantation of Fetal Cells and Tissue: An Overview*, 151 CAN. MED. ASSOC. J. 1261 (1994).

94. TENGION, *supra* note 29.

95. 42 U.S.C. § 274e (2007) ("human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin").

one cellular source is further along the development path, it may be considered more “human.” As previously discussed, some implementations of 3-D bioprinting may begin with a biopsy of the desired organ.<sup>96</sup> From the biopsy, the progenitor cells (“specific healthy cells within a patient’s own body. . . that are capable of maturing into specific tissues and regenerating”)<sup>97</sup> are extracted.<sup>98</sup> These extracted progenitor cells are “genetically committed” to becoming the desired cell type, but not differentiated.<sup>99</sup> For example, a biopsy of a patient’s bladder will lead to the extracted progenitor cells to regenerate into a bladder after it is printed onto a scaffolding, but the specific cell type that any one cell may become is still unknown.<sup>100</sup>

For fetal organ transplants, the source cells are extracted during a similar stage of development. The methods of Dr. Langston’s 1987 fetal organ transplant research that led to the 1988 amendments to NOTA relied on grafting fetal neural cells into the brain of a patient suffering from Parkinson’s disease.<sup>101</sup> The research revealed that Parkinson’s disease patients have improper dopamine regulation.<sup>102</sup> Dr. Langston extracted fetal neural tissue from the dopaminergic region of the fetus for implantation.<sup>103</sup> These grafted cells helped regrow neural cells that demonstrated better dopamine regulation.<sup>104</sup>

However, the grafted neural tissue was further along the developmental path. The grafted neural cells had already differentiated into dopaminergic cells. The 3-D printed cells could still differentiate into any of the variety of different types of cells required to develop the desired organ.<sup>105</sup> Because the 3-D bioprinted cells have not been differentiated

96. TENGION, *supra* note 29.

97. *Id.*

98. *Id.*

99. Differentiation is “the processes by which immature cells become mature cells with specific functions.” *NCI Dictionary of Cancer Terms*, NAT’L CANCER INST., <http://www.cancer.gov/dictionary?Cdrid=46445> (last visited Mar. 29, 2016).

100. TENGION, *supra* note 29

101. Sanders, *supra* note 88, at 401.

102. Tetsuya Ishii & Koji Eto, *Fetal Stem Cell Transplantation: Past, Present, and Future*, 6 *WORLD J. STEM CELLS* 404, 407 (2014).

103. See Paul E. Greene & Stanley Fahn, *Status of Fetal Tissue Transplantation for the Treatment of Advanced Parkinson Disease*, 13 *NEUROSURG FOCUS* (2005); Ishii & Eto, *supra* note 102, at 407.

104. Ishii & Eto, *supra* note 102, at 407.

105. The use of pluripotent cells which may grow into many different types of cells may increase the likelihood of succeeding on this argument; however, the 3-D bioprinting implementations discussed herein use cells that have already been “genetically determined.” See TENGION, *supra* note 29.

yet, it may be argued that the printed cells are less “human” than the fetal organ tissues targeted by the 1988 amendments.

To counter, challengers to 3-D bioprinting may argue that even if the source cells are less “human” than the fetal tissue, they still meet the statutory definition of human. Moreover, it will likely be difficult for a judge to buy into a relative humanity argument as both cells are still derived from a “human.” Furthermore, this line of reasoning avoids the vigorous debate about when life begins, as even a “non-living” human is still “human.”

The proponents of 3-D bioprinting may also argue that the extracted cells do not develop into a full human. Unlike fetal tissue which may be extracted from a fetus that will grow into a fully functioning human (if it is not already considered a “human” in the fetal state), the organ cells extracted via a biopsy can only develop into the desired organ. Accordingly, due to these cells only being able to grow into a subpart of a human, rather than a full human, these cells may be considered something less “human.”

Moreover, proponents of 3-D bioprinting may further argue their implanted organs also contain a scaffolding that is not derived from human biological materials.<sup>106</sup> To this end, there are many other contexts in which a human organ may be implanted with non-human materials. A heart does not cease to be a human heart simply because a metal stent was inserted into an artery. Further, the non-human scaffolding is biodegradable, leaving behind only trace amounts of the inorganic material. Conceptually, it is difficult to imagine a “non-human” material degrading into something that becomes a “human” organ.

However, the best arguments on behalf of 3-D bioprinting relate to the public policy behind the 1988 amendments. The main reasons behind the ban on fetal organ transplants were: (1) the fear of incentivizing abortions;<sup>107</sup> (2) a lack of consent (it is immoral to allow a mother to consent to abortion on behalf of the fetus and the fetus obviously is unable to give consent to be aborted);<sup>108</sup> (3) the conflation of the fetus as both the donor and the donation;<sup>109</sup> and (4) the commercialization of fetal tissue.<sup>110</sup> On the whole, most of the concerns with prohibiting fetal organ transplants are not applicable to 3-D bioprinting, as it avoids the

106. See *id.*; Organovo Holdings Inc., *supra* note 32.

107. Robertson, *supra* note 90, at 467.

108. Rae, *supra* note 61, at 6.

109. *Id.*

110. Robertson, *supra* note 90, at 472.

need to extract tissues from a fetus. Because the 3-D printed material is extracted from the eventual non-fetal recipient, there is no risk of incentivizing abortions and the legal awkwardness of the fetus as both the donor and the donation. Moreover, consent is a non-issue since the donor and donee are the same individual. However, as discussed above, there are still concerns related to the commercialization of human tissues. That said, despite the biological similarities between a fetal organ donation and implanting a 3-D bioprinted neo-organ, public policy may result in a willingness to interpret “human” in favor of a scientific breakthrough.<sup>111</sup>

## 2. What Is a “Subpart Thereof?”

As stated above, NOTA prohibits the transplanting of human organs or any subpart thereof. Unlike the meaning of “human,” the meaning of the phrase “subpart thereof,” as it is used in NOTA, has been interpreted by courts.<sup>112</sup> In *Flynn v. Holder*, the Ninth Circuit faced the issue of whether bone marrow stem cells extracted from a donor’s blood stream is considered a subpart of the donor’s bone marrow or the donor’s blood stream.<sup>113</sup> If the bone marrow stem cells were considered a subpart of the donor’s bone marrow, the procedure at issue would violate NOTA, as the list of prohibited organs for transplantation specifically lists bone marrow (and, therefore, a subpart thereof).<sup>114</sup> Conversely, if the bone marrow stem cells were considered a subpart of the donor’s blood stream, then the procedure did not violate NOTA as blood donations are not prohibited under NOTA.<sup>115</sup>

The *Flynn* court held that “subpart” “refer[s] to the organ from which the material is taken, not the organ in which it was created.”<sup>116</sup> This meant that because the bone marrow stem cells were extracted from the donor’s blood stream, the stem cells were not actually a “subpart” of the bone marrow, but rather, a subpart of the donor’s blood vessels.<sup>117</sup>

Thus, 3-D bioprinting technologies involving bio-ink derived from biological material gathered from a donor’s blood stream, or other non-

111. William Eskridge, *Dynamic Statutory Interpretation*, 135 U. PA. L. REV. 1479 (1987).

112. *Flynn v. Holder*, 684 F.3d 852, 863 (9th Cir. 2012).

113. *Id.*

114. 42 U.S.C. § 274e (2007).

115. *Id.*

116. *Id.*

117. *Flynn*, 684 F.3d at 864.

prohibited organ, are not covered by NOTA's prohibition. While not all 3-D bioprinting applications can utilize cells derived from these sources, this is at least good news for Organovo's bone tissue bioprinting projects that rely on bone marrow stem cells.<sup>118</sup> However, 3-D printing that relies on cells gathered directly from the donor's prohibited organ may still be prohibited. For instance, when Tengion collects a bladder biopsy,<sup>119</sup> the bioprinted and regenerated organ may still legally be a "subpart" of the original bladder.

Moreover, despite the definition of "subpart" drawn in *Flynn*, 3-D bioprinting using stem cells gathered from a blood stream, or other non-prohibited sources, may not be legal by the time the future court challenge occurs. In response to the ruling, Congress has attempted (and failed) to pass amendments to NOTA that would redefine subpart to include the peripheral cells found in the blood stream.<sup>120</sup> Similarly, the Health Resources and Services Administration (HRSA) tasked with enforcing NOTA proposed a regulation to interpret "human organ" to include bone marrow "without regard to the method of . . . collection."<sup>121</sup> While the regulation has not been approved either, it is clear there is still a strong resistance to legalizing any form of stem cell-derived transplants. Beyond the present legal ambiguities involved in the meaning of "human organ," these efforts introduce an extra uncertainty about the legal future of 3-D bioprinting.

To distinguish from *Flynn* and the proposed amended interpretations, 3-D bioprinting companies may argue that blood marrow is typically implanted in the same developmental condition as it was extracted.<sup>122</sup> In contrast, for many 3-D bioprinting techniques, the extracted cells have undergone *in vitro* regeneration to form a neo-organ.<sup>123</sup> It could be argued that this regeneration transforms the extracted stem cells from being a subpart of the donor organ into a new

118. *Three Dimensional (3D) Bone Derived from Stem Cells as a Novel Model for Mineralization*, ORGANOVO, <http://organovo.com/three-dimensional-3d-bone-tissues-derived-from-stem-cells-as-a-novel-model-for-mineralization/> (last visited Mar. 29, 2016).

119. Bladders are not specifically listed in NOTA's prohibition since bladder transplants are not currently practiced; however, bladders still are covered under the "other organ regulated by HHS" category.

120. H.R. 589, 113th Cong. (2013).

121. Change to the Definition of "Human Organ" Under Section 301 of the National Organ Transplant Act of 1984, 78 Fed. Reg. 191,60812 (Oct. 2 2013) (to be codified at 42 C.F.R. pt. 121). The proposed amendment also expanded the list of organs specifically mentioned.

122. See generally *Bone Marrow Transplant*, U.S. NAT'L LIBRARY OF MED., <http://www.nlm.nih.gov/medlineplus/ency/article/003009.htm> (last updated Mar. 2, 2016).

123. TENGION, *supra* note 29.

organ, separate from the donor organ.<sup>124</sup> The line at which a cell would transform from a “subpart” to a neo-organ having an individual identity is a difficult one to draw and has not been addressed by the courts. Moreover, a court may instead analyze the neo-organ through a temporal shift in which the neo-organ is considered a “subpart” of the future-developed organ rather than a “subpart” of the organ it was extracted from. Similarly, if the neo-organ has grown to a point where it is a “human organ” on its own merit, then there is no need to debate whether it is a “subpart” of a human organ.

This tightrope is a difficult one to traverse, and provides for a range of possible outcomes. Due to the wide latitude for interpretation in this area, it is likely that a large focus of the battle for the legality to sell 3-D bioprinted organs will revolve around the definition of a “human organ” and a “subpart” of a human organ. This is the area of the statute that has had the least amount of jurisprudence and, thus, where clever argument may wield the most influence. Those that view 3-D bioprinting as immoral have strong literal support that the bioprinted organs are subparts of human organs. Conversely, proponents of 3-D bioprinting can point to facts that these technologies reduce demand for fetal tissues and avoid, and perhaps further, many of the purposes of the 1988 amendments.<sup>125</sup>

### *B. What Is a “Valuable Consideration” Under NOTA?*

Rather than defining what “valuable consideration” means, NOTA provides a list of what “valuable consideration” does not include. In particular, NOTA states that “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.”<sup>126</sup> This is an exhaustive list that includes the medical procedures involving the donation and subsequent implantation of a human organ. Without this language, doctors would be unable to perform medical operations for legally obtained human organs, such as those received through an organ transplant network.

124. *Moore v. Regents of Univ. of Cal.*, 51 Cal. 3d 120, 140 (Cal. 1990) is irrelevant to this scenario as *Moore* dealt with ownership rights in cells, not whether NOTA’s prohibitions applied.

125. Robertson, *supra* note 90, at 461.

126. 42 U.S.C. § 274e (2007).

Further, the U.S. Department of Justice (the “DOJ”) has issued a memorandum to the Health and Human Services Department to clarify whether “human organ paired donations” are included in “valuable consideration.”<sup>127</sup> A “human organ paired donation” occurs when two patients in need of an organ each have found donors willing to donate their organ to their respective patient.<sup>128</sup> However, in many cases, the willing donor and the patient have non-compatible blood types.<sup>129</sup> If both patients are compatible with the other patient’s donor’s blood type, then these two patients can swap donors in a “human organ paired donation.”<sup>130</sup>

In finding that “human organ paired donation procedures” for kidneys do not implicate “valuable consideration,” the DOJ stated that the process does not “involve[] the buying or selling of a kidney [nor] otherwise commercialize[] the transfer of kidneys.”<sup>131</sup> The DOJ reasoned that because NOTA is limited to applications of “interstate commerce” (discussed below in Section D), “valuable consideration” must also include a pecuniary or commercial benefit.<sup>132</sup> The DOJ ultimately decided that the definition of “valuable consideration” in this context means “the buying and selling of organs for monetary gain or to organ exchanges that are otherwise commercial.”<sup>133</sup> This result was codified in a 2007 revision to NOTA in which it explicitly states that an agreement to donate and receive human organs is not “valuable consideration.”<sup>134</sup>

For companies like Organovo, Tengion, and Organogenesis, this presents a problem. These companies may rely on hospitals and other medical facilities to perform the biopsy and the subsequent implantation. Thus, their profits are, in part, derived from the growth of the organ in their private labs. A sale of the bioprinted organ is most likely a “commercial transfer” implicated in the DOJ’s definition of “valuable consideration.”<sup>135</sup> Thus, a sale of a bioprinted organ is likely covered by NOTA,

127. Memorandum from C. Kevin Marshall, Deputy Assistant Att’y Gen. on the Legality of Alternative Organ Donation Practices Under 42 U.S.C. § 274e to Daniel Meron, Gen. Counsel, Dep’t of Health & Human Servs. (Mar. 28, 2007), <https://www.justice.gov/sites/default/files/olc/opinions/2007/03/31/organtransplant.pdf>.

128. UNITED NETWORK FOR ORGAN SHARING, I HAVE A LIVING DONOR WHO DOESN’T MATCH, WHAT CAN I DO?: OPTN KIDNEY PAIRED DONATION PILOT PROGRAM 2 (2015), [https://www.unos.org/wp-content/uploads/unos/Living\\_Donation\\_KidneyPaired.pdf](https://www.unos.org/wp-content/uploads/unos/Living_Donation_KidneyPaired.pdf).

129. *Id.*

130. *Id.*

131. *Id.* at 1.

132. *Id.* at 2.

133. *Id.* at 6.

134. 42 U.S.C. § 274e (2007).

135. UNITED NETWORK FOR ORGAN SHARING, *supra* note 128, at 4.

assuming the bioprinted organ is considered a “human organ” as discussed above.

However, the 3-D bioprinting companies may be able to utilize clever business workarounds to avoid this problem. Under the DOJ’s definition of “valuable consideration,” it is unclear if sale of an organ bioprinting *service* is covered. The 3-D bioprinting companies may structure their business such that they charge only for the service of actually bioprinting. To prevent a change in ownership, these companies may claim that the owner of the biopsy sample merely lends the biological material for processing and that no sale of the organ itself ever occurs. In this scenario, it can be argued that since there was no “commercial transfer” of any ownership interest in a human organ, the sale of the bioprinting service is not incorporated in the definition of “valuable consideration.” While this specific type of transaction has never been the subject of a legal opinion, through clever business engineering, these 3-D bioprinting companies may reduce the risk that their operations are barred by the prohibitions defined by NOTA. Furthermore, because the costs of removal, transportation, and implantation are exempted from “valuable consideration” under NOTA,<sup>136</sup> a hospital is able to charge to extract a biopsy, ship it to a 3-D bioprinting company, and implant it back into the patient without receiving “valuable consideration.”

Moreover, the 3-D bioprinting companies may compare their procedures to a human organ paired donation in arguing that their process does not implicate receiving “valuable consideration.” For these 3-D bioprinting procedures, it can be said that a patient has found a donor (the same patient) that is willing to donate an organ but is incompatible for donation. Instead of the incompatibility originating from, for example, blood type differences between the patient and the donated organ, in this case the incompatibility is due to a lack of biological maturity between the organ the patient requires and the donated biological material. In both cases, the patient has found an alternative organ to implant that is compatible: for human organ paired donation, it is the second donor; for 3-D bioprinting it is the resultant bioprinted organ. In a sense, by purchasing a 3-D bioprinted organ, the patient has exchanged the incompatible organ (the biopsy material) for one that is compatible (the bioprinted organ).

Through this logic, the only difference between human organ paired donations (which is exempted from NOTA’s protections) and 3-

136. § 274e.



D bioprinting an organ is the origin for the organ incompatibility. However, this still may require a judicial opinion to clarify. Thus, in order to be more certain about this interpretation, it may be helpful for the 3-D bioprinting industry to request that the Department of Health and Human Services seeks another clarifying memorandum from the DOJ related to their particular processes. As such, it is more likely that an administrative ruling may control whether 3-D bioprinting implicates reception of “valuable consideration” than a court when deciding the fate of 3-D bioprinting. Under the principle of deference to administrative agency interpretations laid forth in *Chevron, U.S.A., Inc. v. Natural Resource Defense Council, Inc.*, future courts would likely be bound by such an administrative agency’s interpretation, as long as the interpretation is considered reasonable.<sup>137</sup>

*C. Does 3-D Bioprinting Implicate “Interstate Commerce?”*

NOTA is a federal regulation enacted by Congress under the Commerce Clause, thus it is only enforceable to the extent that interstate commerce is implicated.<sup>138</sup> The current framework for modern Commerce Clause jurisprudence was defined by Chief Justice Rehnquist in *U.S. v. Lopez*.<sup>139</sup> In order for Congress to have the power to regulate an activity under the Commerce Clause, the regulated activity must fall within one of three categories: (1) the “use of the channels of interstate commerce”;<sup>140</sup> (2) “the instrumentalities of interstate commerce, or persons or things in interstate commerce”;<sup>141</sup> and (3) “activities having a substantial relation to interstate commerce.”<sup>142</sup> As part of category (2), enforcement of prescription medication labeling requirements for medications shipped across state lines have been found to be a valid assertion of the Commerce Clause power.<sup>143</sup> Since medicines shipped across state lines can be constitutionally regulated under Congress’s Commerce Clause power, it is likely that if the lab in which a 3-D bioprinting

137. “Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.” *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984).

138. U.S. CONST. art. I, § 8, cl. 3.

139. See generally *United States v. Lopez*, 514 U.S. 549, 549 (1995).

140. *Id.* at 558.

141. *Id.*

142. *Id.* at 558–59.

143. *United States v. Sullivan*, 332 U.S. 689, 696 (1948).

company prints an organ is in a different state than the patient, then the shipment of the organ across state lines may also be regulated.

Congress may still be able to regulate the 3-D bioprinting industry if it has a “substantial relation” to interstate commerce in cases in which the 3-D bioprinting lab is within the same state as the patient. In 1995, a dentist alleged that the Americans with Disabilities Act did not apply to dentists because dentistry is purely a local practice.<sup>144</sup> The dentist argued that the activity being regulated should be narrowly defined (filling a cavity) as opposed to the broad practice of dentistry.<sup>145</sup> The court rejected this argument, finding that filling cavities is an economic activity and that “regulation of an economic enterprise that trades in interstate commerce, even one centered on filling cavities, lacks the commercial element or nexus to commercial activity.”<sup>146</sup>

In a more recent Commerce Clause case relating to the medical profession, the Supreme Court faced a challenge to the individual mandate for individuals to purchase health insurance under the Affordable Care Act.<sup>147</sup> Instead of taking a broad definition of the activity being regulated under the Commerce Clause (the insurance industry as a whole), the Supreme Court narrowly defined the activity to be the failure to purchase health insurance.<sup>148</sup> Since not purchasing health insurance is economic *inactivity* rather than economic activity, Congress had no authority to enact the legislation under the third prong of the *Lopez* framework for Commerce Clause jurisprudence.<sup>149</sup> This implies that the converse, a person actively purchasing health insurance (including insurance that covers 3-D bioprinting) is an economic activity within the meaning of the Commerce Clause.

Even under this narrow view of the activity being regulated, it is likely that Congress will have authority to regulate 3-D bioprinting under the Commerce Clause. When a patient has a biopsy removed and the bioprinted organ implanted, economic activity similar to a dentist filling a cavity occurs. In fact, it can be said that implanting an organ is simply filling a bodily cavity with an organ, just like a dentist fills a tooth cavity

144. *Abbott v. Bragdon*, 912 F. Supp. 580, 593 (D. Me. 1995) *aff'd*, 107 F.3d 934 (1st Cir. 1997) *vacated*, 524 U.S. 624 (1998) (The applicability of the Commerce Clause was not challenged on appeal).

145. *Id.*

146. *Id.* at 594.

147. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012).

148. *Id.* at 2587.

149. *Id.* at 2593 (The Supreme Court held that the individual mandate could still be enacted under the Congress's power to raise taxes).

with a filling. It is unlikely that a court will find that 3-D bioprinting is economic inactivity that has no substantial impact on interstate commerce. As a result, Congress was likely within its constitutional authority under the Commerce Clause when it enacted NOTA.

#### IV. PROPOSED AMENDMENTS TO NOTA

As described above, there is much uncertainty about whether the language of NOTA prohibits the implantation and/or sale of bioprinted organs. Because Congress likely has authority under the Commerce Clause to regulate 3-D bioprinting, the language of the prohibition is applicable to 3-D bioprinting practices. While the 3-D bioprinting companies may be able to raise arguments that the specific language of NOTA does not apply to their practices, due to a lack of jurisprudence in this area, there is still uncertainty about how courts will interpret NOTA. Given the potential benefits to the many people languishing away on waiting lists yet to receive a donated organ, the rapid development and implementation of 3-D bioprinting practices should be encouraged through the legal system.

One proposal to amend NOTA to remove such legal uncertainty is as follows:

Old version:

(a) Prohibition

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. The preceding sentence does not apply with respect to human organ paired donation.<sup>150</sup>

Proposed version:

(a) Prohibition

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer another's human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. The preceding sentence does not apply with respect to human organ paired donation.

Under this proposal, acquiring, receiving, or otherwise transferring one's own human organ is not prohibited. However, this proposal raises a tricky question: when the 3-D bioprinting company bioprints an organ,

150. § 274e.

whose is it? While this proposal has the benefit of simplicity, it is unclear if “another” is reference to an organ another person owns and/or controls (like an organ at an organ bank), or an organ extracted from another person. To this end, it can be argued that either the 3-D bioprinting company or the patient owns the organ, or some combination thereof. Under Locke’s labor theory of property, the 3-D bioprinting company took biological materials and applied labor and ingenuity to create something new.<sup>151</sup> Moreover, courts have previously recognized that doctors may gain ownership rights for producing a commercially valuable cell line based on a patient’s lymphokines.<sup>152</sup> Accordingly, if the 3-D bioprinting company retains at least some ownership rights of the bioprinted organ, then it may be argued that that the implanted organ is still an organ of another. To remove this possible ambiguity, this proposal would require defining “another’s human organ” to mean an organ containing biological material from another human.

Even with removing this ambiguity, this proposal may still face resistance because it might not prohibit one from *selling* their own organ for valuable consideration. Purchasers of another’s human organ would still violate the prohibition, but since the biological material of the organ is the same as the person selling the organ, the prohibition would not apply to the seller. In effect, this would create a single-sided prohibition for a disfavored activity, much like how several European countries handle anti-prostitution laws.<sup>153</sup> This style of regulation has not been popular in America.<sup>154</sup> Any proposal that creates a similar type of market for human organs is unlikely to be enacted.

That said, it may be argued that this buyer-side prohibition is no different than the current regulation regime. The title of the act is “Prohibition of organ *purchases*” (emphasis added). Under some theories of

151. “Briefly stated, the fundamental concept of the labor theory of property acquisition is that people are entitled to hold, as property, whatever they produce by their own initiative, intelligence, and industry.” (internal citations omitted) Francis A. Citera, *Vested Seniority Rights: A Conceptual Approach*, 36 U. MIAMI L. REV. 751, 756 (1982).

152. *Moore v. Regents of Univ. of Cal.*, 51 Cal. 3d 120, 145 (Cal. 1990)

153. Max Waltman, *Criminalize Only the Buying of Sex*, N. Y. TIMES (Apr. 20, 2012), <http://www.nytimes.com/roomfordebate/2012/04/19/is-legalized-prostitution-safer/criminalize-buying-not-selling-sex>

154. “In the United States prostitution is completely criminalized/prohibited, except for in rural areas of Nevada.” Malinda Bridges, *What’s Best for Women: Examining the Impact of Legal Approaches to Prostitution in Cross-National Perspective and Rhode Island* (R.I. Coll., Honors Project Overview, Paper No. 54 (2012)).

interpretation, the title lends import in how to interpret provisions contained therein.<sup>155</sup> Accordingly, because the title only implies a prohibition on purchases, it may be argued that sales are not covered. Moreover, the text makes it unlawful for one to “acquire, receive, or otherwise transfer” a human organ.<sup>156</sup> Under the canon of *ejusdem generis*, “[w]here general words follow specific words in a statutory enumeration, the general words are usually construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words.”<sup>157</sup> Thus, while the words acquire and receive only refer to the purchasing party, it may be interpreted that they similarly impute “otherwise transfer” with restriction falling on the purchasing act. Regardless, the proposed amendment calls attention to this ambiguity and may spur Congress to act to clarify the legality of 3-D bioprinting.

Another potential proposal is to modify the definition of human organ as follows:

Old version:

(1) The term “human organ” means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.<sup>158</sup>

Proposed version:

(1) The term “human organ” means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation. The term “human organ” shall not be construed to mean a biopsy extracted for regenerative purposes nor the resulting output.

Under this proposal, the inputs and outputs of the 3-D bioprinting process are explicitly excluded from the definition of “human organ.” The phrase “regenerative purposes” is broader than “3-D bioprinting” and covers similar technologies that may develop at some point in the future. By avoiding the issue of ownership in the bioprinted organ, this proposal is less likely to introduce further legal uncertainty than the

155. *Yates v. United States*, No. 13-7451, slip op. at 10 (11th Cir. Feb. 25, 2014).

156. 42 U.S.C. § 274e (2007).

157. *Yates*, slip op. at 15-16.

158. § 274e.

prior amendment. However, “regenerative purposes” may be broad enough to include the highly-controversial field of human cloning. In order to avoid any extra controversy, it may be wiser for proponents of 3-D bioprinting to avoid such a broad scope. Accordingly, it may be required to define “regenerative purposes” to specifically exclude human cloning.

One last proposal attempts to ensure the legality of 3-D bioprinting through amending the definition of “valuable consideration” as follows:

Old version:

(2) The term “valuable consideration” 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.<sup>159</sup>

Proposed version:

(2) The term “valuable consideration” does not include the reasonable payments associated with the removal, transportation, implantation, processing, regeneration, printing, 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.

Under this final proposal, the actual actions that occur in the 3-D bioprinting process are excluded from the definition of valuable consideration. By excluding regeneration and printing from “valuable consideration,” a patient or an insurer is free to compensate the 3-D bioprinting company for producing an implantable organ. However, this proposal entails the same issues with the broad scope of “regeneration.” Moreover, this is an oblique location to modify NOTA to ensure the legality of 3-D bioprinting. Accordingly, it is more likely that this proposed amendment would be enacted along with either of the previous amendments.

## V. CONCLUSION

While it may be difficult to predict the exact outcome of a legal challenge to bioprinting, this Note has identified the key issues and the arguments that will be raised in such a challenge. We must not forget that

159. *Id.*

as these legal issues are settled through litigation, those like James Richards<sup>160</sup> continue to suffer. Congress should proactively act to pass the proposed (or otherwise similar) amendments to NOTA. Only through definitive congressional action will we ensure that only technological, and not legal, barriers prevent those suffering from kidney failure and other debilitating diseases from finally getting the peace they deserve.

160. Richards v. Holder, CIV.A. No. 13-13195-LTS, 2014 WL 2805280, at \*2 (D. Mass. June 19, 2014).