FOR SALE, PRINTED ORGAN, NEVER WORN: ENABLING SALE OF BIOLOGICAL PROSTHETIC ORGANS TO ACCELERATE DEVELOPMENT OF BIOPRINTING TECHNOLOGY

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Thousands of people die each year waiting for an organ transplant. To combat this shortage, bioprinted organs have been created through developments in 3-D printing technology. The National Organ Transplant Act ("NOTA") established the Organ Procurement and Transplantation Network ("OPTN") in 1984 to address the organ shortage and improve organ matching. NOTA outlaws the purchase and sale of organs, which on its face seems to solve the issue of inequitable distribution of organs, but also has the effect of hampering development and research into organ bioprinting with the long-term impact of keeping bioprinted organs out of reach for the majority of the population.

This Note argues that until bioprinting technology has advanced enough to where the bioprinted organs have a predictable success rate and an established production assembly, the sale of such bioprinted organs should be allowed to garner funding for further development. After such organs become more reliable, defining a separate class for bioprinted organs will allow the guidelines of the OPTN to be used to derive a system of determining priority for organ recipients, and procurement of a custom bioprinted organ should be incorporated into plans for improving the OPTN's operations.

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I. INTRODUCTION

"For sale, baby shoes, never worn." While the authorship of this short story is up for debate,[1] the emotions it evokes are universally understood: grief, pain, and loss over a life taken far too soon. Seventeen people die each day waiting for an organ transplant, and over 100,000 people are on the national organ transplant waiting list.[2] In an effort to reduce wait times and rejection rates of organ transplantation, 3-D printing of organs, or "bioprinting," has evolved as a subset of 3-D printing. But this technology is still in its very early stages, and growing fully functional complex organs is still years, if not decades, away.[3] The startup costs to print such organs are also extremely high.[4] Whereas donated organs will go to the most compatible recipient,[5] bioprinted organs are only limited by the technology and costs required. Therefore, wealthy individuals who have the means to pay for a custom organ will benefit from the technology far sooner and at a far greater rate than those patients who cannot afford a bioprinted organ and must continue to wait for a compatible donated organ.[6]

This Note recommends that bioprinted organs be offered for sale so that those who can afford to purchase them will benefit from the technology as it currently exists, and also financially contribute towards the ongoing research in the bioprinting field. These financial contributions will help accelerate the development timeline of making bioprinted organs available to the general population. Part II of this Note will explain the background of organ donation, bioprinting, and the challenges present in both fields. Part III of this Note will discuss the inefficiencies of current systems in place for organ donation, analyze the applicability of current law and policy to the novel field of bioprinting, and compare the goals and policy of organ donation and bioprinting. Part IV will expand upon the recommendation to offer bioprinted organs for sale while the technology is not yet commercially viable on a grand scale, and address concerns about the ethics and impact of such a policy. Part V will conclude the Note by summarizing the key points and emphasizing the benefits of the Recommendation.

1. Nikola Budanovic, *"For Sale, Baby Shoes, Never Worn": Tracing the History of the Shortest Story Ever Told*, VINTAGE NEWS (Sept. 24, 2017), https://www.thevintagenews.com/2017/09/24/for-sale-baby-shoes-never-worn-tracing-the-history-of-the-shortest-story-ever-told/?chrome=1 [https://perma.cc/TL5D-KV5F].

2. *Organ, Eye and Tissue Donation Statistics*, DONATE LIFE AM., https://www.donatelife.net/statistics/ (last visited Nov. 5, 2023) [https://perma.cc/5MMF-GRXH].

3. Melissa Little & Gordon Wallace, *Printing the Future: 3D Bioprinters and Their Uses*, AUSTL. ACAD. OF SCI., https://www.science.org.au/curious/people-medicine/bioprinting (last visited Nov. 5, 2023) [https://perma.cc/54GY-2XGF].

4. Dr. J, *How Much Does 3D Printing Organs Cost? The Actual Numbers*, 3DBIOLOGY.COM, https://www.3dbiology.com/3d-printing-organs-cost/ (last visited Nov. 5, 2023) [https://perma.cc/6G4Q-HRWG].

5. *How Are Patients Selected to Receive a Transplant?*, DONOR ALL., https://www.donoralliance.org/newsroom/donation-essentials/patients-selected-receive-transplant/ (Apr. 24, 2023) [https://perma.cc/5ZU3-2A22].

6. *See* James Jeffery, *3D Printing Human Organs—But Where's the Money for It?*, GUARDIAN (July 17, 2013, 8:30 AM), https://www.theguardian.com/technology/2013/jul/17/3d-printing-organs-money [https://perma.cc/2DH3-2RNR] (hypothesizing that the billion-dollar investments into bioprinting research to create viable solutions may be initially covered by those seeking vanity procedures such as breast augmentations).

II. BACKGROUND

A. Organ Donation

Organ donation is a highly effective, and, in some cases, necessary treatment for a variety of medical conditions.[7] Since the latter half of the 20th century, legislation has been dedicated to the regulation and oversight of organ donation and transplant matching across the country.[8] But the matching and transportation systems set up to fulfill this legislation's purpose have become highly inefficient and wasteful in comparison to analogous systems used in shipping and delivery industries, adding additional costs and risk to an already expensive and risky procedure.[9]

1. Why Organ Donation Is Necessary

There are many illnesses that are best treated by transplantation of the affected tissues or organ. For example, there are at least 36,000 new cases of various forms of leukemia and at least 69,000 new cases of lymphoma each year, two illnesses that are best treated through bone marrow transplantation.[10] There are also inherited immune system and metabolic disorders that are rarer, but have a higher mortality rate (especially for children) and can best be treated through transplantation.[11] End-stage renal disease is best treated by transplantation of both the liver and the kidney as a matched-pair, compared to the donation of only the liver or the kidney, and matched-pair donation is a more effective treatment than dialysis.[12] Many other organs in end-stage failure, such as hearts[13] and lungs,[14] can only be effectively treated through transplantation, and for some people with type-1 diabetes, a pancreas transplant is a potential cure.[15]

While the improvement of quality of life for patients receiving transplants is hard to quantify, it is known that the cost of dialysis is almost four times as

7. *Diseases Treatable by Transplants*, BE THE MATCH, https://bethematch.org/transplant-basics/how-transplants-work/diseases-treatable-by-transplants/ (last visited Nov. 2, 2023) [https://perma.cc/Y429-WEZZ].

8. *Uniform Anatomical Gift Act*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/uniform_anatomical_gift_act (last visited Nov. 5, 2023) [https://perma.cc/BNR5-9XT2].

9. Blake Farmer, *Transplant Agency Is Criticized for Donor Organs Arriving Late, Damaged or Diseased*, NPR (Aug. 17, 2022, 4:54 PM), https://www.npr.org/sections/health-shots/2022/08/17/1118009567/damaged-and-diseased-organs-the-agency-overseeing-transplants-faces-intense-scru [https://perma.cc/8UMP-G3GQ].

10. *See Diseases Treatable by Transplants*, *supra* note 7.

11. *Id.*

12. Michael J. Eerhart et al., *Kidney After Liver Transplantation Matched-Pair Analysis: Are Kidneys Allocated to Appropriate Patients to Maximize Their Survival?*, 104 TRANSPLANTATION 804, 804–05 (2020).

13. M. Chadi Alraies & Peter Eckman, *Adult Heart Transplant: Indications and Outcomes*, 6 J. THORACIC DISEASE 1120, 1120 (2014).

14. Marc Hartet et al., *Lung Transplantation: A Treatment Option in End-Stage Lung Disease*, 111 DEUTSCHES ÄRZTEBLATT INT'L 107, 107 (2014).

15. *Pancreas Transplant*, MAYO CLINIC (May 24, 2022), https://www.mayoclinic.org/tests-procedures/pancreas-transplant/about/pac-20384783 [https://perma.cc/6RC7-TA57].

expensive as the cost of kidney transplants for those in end-stage renal failure.[16] Transplantation treats symptoms of organ and tissue diseases at the source, which is especially important in cases of terminal and irreversible organ failure that can no longer be mitigated through medication or other therapies.[17] It is clear that organ donation provides hope to thousands of individuals with end-stage organ diseases, and, therefore, the importance of organ donation cannot be overstated.

2. Traditional Organ Donation

In 1968, the original Uniform Anatomic Gift Act ("UAGA") was enacted to provide a federal framework for anatomical gifts.[18] The UAGA allows the donation of organs or parts of organs by a decedent or their surviving relatives to medical research, those in need of replacement organs, and other specified purposes.[19] Every organ is matched based on a variety of characteristics such as blood type, height, weight, and other medical factors.[20] Different organs have different factors that must be considered in order to be matched to a recipient.[21] For a donated heart or liver, the three main factors considered are (1) medical urgency—how urgently a potential recipient needs a transplant based on how long the recipient may live without a transplant;[22] (2) distance from donor hospital;[23] and (3) pediatric status.[24] For donated lungs, in addition to those factors, other factors considered are (4) survival benefit and (5) waiting times.[25] Kidneys require assessment of many factors, including (6) donor/recipient immune system compatibility and (7) whether they were a prior living donor, in addition to the previously listed factors.[26]

Living donation (*i.e.*, donation of an organ by a living person instead of a deceased donor) is most commonly done with kidneys, although uterus donation and organ segment donation, such as liver segment donation, are also possible.[27] Living donors must be older than eighteen years of age and be in generally good physical and mental health.[28] For postmortem donation, people of all ages and

16. P.J. Held, F. McCormick, A. Ojo & J.P. Roberts, *A Cost-Benefit Analysis of Government Compensation of Kidney Donors*, 16 AM. J. TRANSPLANTATION 877, 879 (2016).

17. Josep M. Grinyó, *Why Is Organ Transplantation Clinically Important?*, 3 COLD SPRING HARBOR PERSPS. MED. 1, 1 (2013).

18. *See Uniform Anatomical Gift Act*, *supra* note 8.

19. *Anatomical Gift Act*, UNIFORM L. COMM'N, https://www.uniformlaws.org/committees/community-home?CommunityKey=015e18ad-4806-4dff-b011-8e1ebc0d1d0f (last visited Nov. 5, 2023) [https://perma.cc/A98L-X6DX] (click on "Summary" hyperlink, in between "Bill List" and "Enactment History").

20. *How We Match Organs*, UNOS (Sept. 14, 2023), https://unos.org/transplant/how-we-match-organs/ [https://perma.cc/2FW3-GT4M].

21. *Id.*

22. *Liver Policy: Medical Urgency*, UNOS, https://unos.org/policy/liver/medical-urgency/ (last visited Nov. 5, 2023) [https://perma.cc/J8HA-9NPM].

23. *See How We Match Organs*, *supra* note 20.

24. *Id.*

25. *See id.*

26. *Id.*

27. *Living Donation*, UNOS, https://unos.org/transplant/living-donation/ (last visited Nov. 5, 2023) [https://perma.cc/66PM-GNF5].

28. *Id.*

medical histories can be considered potential donors, since it is the medical condition at the time of death that determines which organs and tissues remain eligible for donation.[29] Many organs are transplanted through organ donation, the most common being the kidney, liver, heart, lungs, pancreas, and intestines.[30] An average of 100,000 people are on the waiting list for donated organs, but only half the needed organs are donated every year.[31] Each deceased donor can provide an average of 3.5 organs, and there are roughly 14,000 deceased donors per year.[32] Even including the 6,000 organs provided by living donation, there are still only 55,000 organs donated a year, roughly 55% of the yearly demand.[33] In addition to organs, tissues are also transplanted, the most common being bones, tendons, ligaments, skin, heart valves, blood vessels, and corneas.[34] But of the approximately 3.3 million tissue grafts donated yearly, only about three-fourths of those grafts are actually transplanted.[35]

3. Difficulties with Traditional Organ Donation

Organ donation, while extremely important to the treatment of many patients, is not without its shortcomings. Not every donated organ is transplanted—each year over 60% of donated hearts and lungs must be discarded since these tissues must be transplanted within four hours of being kept on ice.[36] One-quarter of potential donor kidneys go to waste, partially due to antiquated computer systems, tracking technology, and transportation schemes in use by the United Network for Organ Sharing ("UNOS"), the nonprofit agency that oversees organ donations and transplants.[37] UNOS manages the Organ Procurement and Transportation Network ("OPTN"), the system established by the National Organ Transplant Act ("NOTA") to link all professionals involved in organ donation in the United States.[38]

a. UNOS as the OPTN Under NOTA

UNOS is a private nonprofit organization that works under contract and oversight of the federal government to "provide fair and equitable access to

29. *Facts About Organ Donation*, UNOS, https://unos.org/transplant/facts/ (last visited Nov. 5, 2023) [https://perma.cc/273N-8UY8].

30. *Transplant Safety Overview: Key Facts*, CDC (Oct. 13, 2022), https://www.cdc.gov/transplantsafety/overview/key-facts.html [https://perma.cc/PX9A-PEXZ].

31. *See id.*

32. *Id.*

33. *See id.*

34. *Id.*

35. *Id.*

36. *Groundbreaking Technology Successfully Rewarms Large-Scale Tissues Preserved at Low Temperatures*, EUREKALERT! (Mar. 1, 2017), https://www.eurekalert.org/news-releases/720188 [https://perma.cc/JDU2-PDW4].

37. *See* Farmer, *supra* note 9.

38. *About*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/about/ (last visited Nov. 5, 2023) [https://perma.cc/3TTZ-N8W8].

transplant for everyone in need."[39] In 2022, UNOS oversaw 1 million transplants, the highest number of organ transplants of any country in the world.[40] Through their contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services, UNOS's four strategic goals are to (1) increase the number of transplants; (2) provide equity in access to transplants; (3) improve waitlisted patient, living donor, and transplant recipient outcomes; and (4) promote living donor and transplant recipient safety.[41]

The National Organ Transplant Act was passed in 1984 and established a "task force" that analyzed and prepared a report on the state of "the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation."[42] Along with establishing the task force, which would dissolve three months after the submission of the report, NOTA also established the OPTN, tasked with creating "(i) a national list of individuals who need organs, and (ii) a national system . . . to match organs and individuals included in the list."[43] The OPTN was also tasked with assisting organ procurement organizations (such as UNOS) with distribution of the organs and other tasks related to optimizing the operations and efficacy of the new organ donation system.[44] The OPTN is required to publish an annual report on "the scientific and clinical status of organ transplantation."[45]

The Secretary of Health and Human Services ("Secretary") is allowed to make grants for the "establishment, initial operation, and expansion of qualified organ procurement organizations"[46] but may not "make a grant for more than one organ procurement organization which serve the same service area."[47] The Secretary also maintains a registry of all recipients of organ transplants as well as analysis of the information contained in the registry.[48] UNOS operates as the main organ procurement organization cooperating with the OPTN as defined in NOTA.[49] UNOS must abide by section 371 of NOTA, which requires it to be a nonprofit entity, allows it to be reimbursed by the Social Security Act for the procurement of kidneys, grants authority to obtain payments for nonrenal organs provided to transplant centers, and has a defined service area that serves at least fifty potential organ donors each year, along with other rules.[50]

In combination with the establishment of the OPTN, Title III of NOTA outlaws the purchase of human organs.[51] The term "human organ" includes (but

39. *See Strategic Goals*, UNOS, https://unos.org/about/strategic-goals/ (last visited Nov. 5, 2023) [https://perma.cc/98ZW-P5C6].
40. *Id.*
41. *Id.*
42. National Organ Transplant Act, Pub. L. No. 98-507, tit. I, § 101(b)(1)(A), 98 Stat. 2339, 2339 (1984).
43. *Id.* at tit. II, § 372(b)(2)(A).
44. *Id.* § 372(b)(2).
45. *Id.* § 376.
46. *Id.* § 371.
47. *Id.* § 374(b)(1).
48. *Id.* § 373.
49. *See Strategic Goals*, *supra* note 39.
50. *See* National Organ Transplant Act § 371(b)(1).
51. *Id.* at tit. III, § 301.

is not limited to) "human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin."[52] The purchase of the organs themselves is prohibited, but paying for related costs such as surgery, transportation, preservation, etc. are not prohibited and form the basis for the high costs of organ transplantation.[53] Title IV of NOTA outlines the bone marrow registry demonstration and study, requiring the registration of bone marrow donors in addition to the registration of organ transplant recipients.[54] Because bone marrow and stem cells completely regenerate, bone marrow can technically be donated several times in a donor's lifetime.[55] While it is rare to be matched more than one or two times, the establishment of this registry enables easier matching of donors to patients for faster and more efficient treatment outcomes.[56]

b. Current Risks

The current transport system relies on both commercial and private flights, which each have their own drawbacks.[57] Commercial flights are dependent on airport operating hours and flight availability, meaning that moving the majority of organs (organ donation tends to occur in the evening or early morning) is potentially delayed.[58] Private flights, which are needed more often for successful organ transport over long distances, are limited by the availability of charter planes and pilots.[59] This scarcity of suitable transportation leads to extreme pressure on organ procurement travel teams, which in turn leads to lower safety standards as these teams are forced to accept riskier transportation options.[60] The fatality rate for procurement air travel is 1,000 times higher than scheduled commercial aircraft, meaning that the surgeons using air travel for procurement have one of the riskiest jobs in medicine.[61] This increased risk translates to increased insurance costs—up to $20,000 more to transport a liver over air travel as compared to ground transport.[62]

Living organ donation (donation of an organ by a living donor), which provides a significant portion of the organs donated each year, constitutes a big risk for the organ donor.[63] According to Dr. Anthony Atala, director of the Wake Forest Institute for Regenerative Medicine, performing surgery on someone

52. *Id.*
53. *Id.*
54. *Id.* at tit. IV.
55. *Frequently Asked Questions*, ASIAN AM. DONOR PROGRAM, https://www.aadp.org/learn/faq/ (last visited Nov. 5, 2023) [https://perma.cc/94XK-3UYR].
56. *See id.*
57. Lara C. Pullen, *Tackling the Growing Problem of Transporting Organs*, 19 AM. J. TRANSPLANTATION 1603, 1603 (2019).
58. *Id.*
59. *Id.* at 1603–04.
60. *Id.* at 1604.
61. *Id.*
62. *Id.*
63. Kristen Rogers, *When We'll Be Able to 3D-Print Organs and Who Will Be Able to Afford Them*, CNN (Mar. 10, 2023, 10:40 AM), https://www.cnn.com/2022/06/10/health/3d-printed-organs-bioprinting-life-itself-wellness-scn/index.html [https://perma.cc/ADK5-4KXC].

"who doesn't need it . . . [is] usually not the preferred way to go because then you're taking an organ away from somebody else who may need it, especially now as we age longer."[64] The immediate risks related to surgery include pain, bleeding, blood clots, infections, wound complications, hernias, and potentially even death, which are undesirable even when surgery is necessary, as in the case of the recipient.[65] Therefore, to risk such complications without a personal need for surgery is not ideal. There are also risks of developing mental health issues, such as depression and anxiety, or feelings of regret or resentment if the donated organ does not work properly after transplant into the recipient.[66]

Despite intense screening requirements for donated organs, graft loss and death can still occur from infectious pathogens transmitted through transplanted donor organs and tissue.[67] Organ donation can also be extremely costly for both the living donor and the recipient.[68] While the recipient's insurance will cover the donation surgery, "acquisition fee," and transplant surgery, anything that falls outside of the transplant evaluation is not covered by insurance.[69] Such external costs could include physicals, travel, lodging, and lost wages incurred over the course of the donation.[70] The costs of treatments covered by insurance, often subsidized by the government, are in the millions of dollars annually.[71] Just 500 additional donors saved the government over $30 million in one year.[72] Compared to other therapies used to treat diseases caused by malfunctioning or failing organs, organ replacement remains the most effective treatment both in terms of the recipient's health and the costs required to achieve such results.[73] In order to better serve the population in need of organ replacement, bioprinted organs can fill the need left by insufficient and inefficient organ donation.

B. Bioprinting Organs

Bioprinted organs are made using bioprinters that use 3-D printing principles combined with organic materials.[74] The nature of organic materials is sometimes at odds with the requirements of 3-D printing, which results in many

64. *Id.*

65. *Living-Donor Transplant: Overview*, MAYO CLINIC (Mar. 8, 2023), https://www.mayoclinic.org/tests-procedures/living-donor-transplant/about/pac-20384787 [https://perma.cc/TXG8-W6UM].

66. *Id.*

67. *See Transplant Safety Overview: Key Facts*, *supra* note 30.

68. *Living Donation Costs*, UNOS, https://transplantliving.org/financing-a-transplant/living-donation-costs/ (last visited Nov. 5, 2023) [https://perma.cc/2YBJ-5A3S].

69. *Id.*

70. *Id.*

71. Mark A. Schnitzler, Krista L. Lentine & Thomas E. Burroughs, *The Cost Effectiveness of Deceased Organ Donation*, 80 TRANSPLANTATION 1636, 1637 (2005).

72. *Id.*

73. *See* Jennifer Whitlock, *Ways to Pay for an Organ Transplant Surgery*, VERYWELL HEALTH (Apr. 9, 2020), https://www.verywellhealth.com/how-to-pay-for-an-organ-transplant-surgery-3157022 [https://perma.cc/Q82R-MSDQ]; *Transplantation*, WORLD HEALTH ORG., https://www.who.int/health-topics/transplantation (last visited Nov. 5, 2023) [https://perma.cc/KKB5-2AY8].

74. *See* Little & Wallace, *supra* note 3.

limitations and compromises in the final product that must be adjusted for.[75] The manufacturing process itself is fraught with various points of failure that current technology is insufficient to overcome.[76] It is, therefore, of utmost importance for both academic and commercial laboratories to research all aspects of the bioprinting process in order to discover and develop more efficient and consistent results.[77]

1. Process of Bioprinting Organs

Bioprinted organs are created using 3-D printers.[78] 3-D printers work through a process called additive manufacturing.[79] Instead of printing solely on the horizontal plane, 3-D printers also move and print vertically.[80] The printer is loaded with a material such as plastic or ceramic, which is deposited by a nozzle moving horizontally and vertically to build up a three-dimensional shape layer by layer.[81] The layers are deposited in a liquid form, but solidify to create a stable, whole piece.[82] 3-D printers are being used in a wide variety of fields to create parts and products for cameras, prototypes, toys, jewelry, and many other applications.[83]

Bioprinters work in exactly the same manner as 3-D printers.[84] They are essentially 3-D printers specialized to deposit biomaterials instead of plastic or ceramics.[85] The biomaterials are deposited in the form of "bioinks," liquids that contain specific cells such as kidney cells, skin cells, and so forth, in order to build a specific tissue type.[86] The bioinks also contain organic or synthetic materials that "glue" the cells in the bioink together, providing structure and stability as the printed tissue is created.[87] After printing the initial structure, the cells proliferate while the extrinsic structure degrades until the final organ is comprised mainly of cells.[88] There are many techniques adapted from general 3-D printing for use in bioprinting, such as extrusion, laser, microvalves, inkjet, and tissue fragment printing.[89] Extrusion-based bioprinting is the most popular

75. *See* Hongli Mao et al., *Recent Advances and Challenges in Materials for 3D Bioprinting*, 30 PROGRESS NAT. SCI.: MATERIALS INT'L 618, 618–20 (2020).

76. *See* Nadia Tsao, *Challenges on the Road to 3D Bioprinted Organs*, IDTECHEX (July 24, 2017), https://www.idtechex.com/en/research-article/challenges-on-the-road-to-3d-bioprinted-organs/11400 [https://perma.cc/PR3H-B6KS].

77. Silvia Santoni, Simone G. Gugliandolo, Mattia Sponchioni, Davide Moscatelli & Bianca M. Colosimo, *3D Bioprinting: Current Status and Trends–A Guide to the Literature and Industrial Practice*, 5 BIO-DESIGN & MFG. 14, 24 (2022).

78. *See* Little & Wallace, *supra* note 3.

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

bioprinting technique due to its capability of printing hydrogels with varying viscosities and high cell densities.[90] Bioink is extruded through the printer nozzle and built up in thin layers to achieve the desired structure.[91] Other methods, such as microvalves and inkjet printing, use droplets of bioink to build up tissue structures.[92] Each method has its own pros and cons, and there is ongoing research into developing combinations of these techniques as well as new approaches to further advance the capabilities of bioprinting.[93]

2. Challenges in Bioprinting

Bioprinting is more challenging than standard 3-D printing for several reasons. One is that organic tissues have much smaller and more complex structures than other products created by 3-D printing, and each structure must serve several functions.[94] Another is that the materials currently best suited for 3-D printing are usually inhospitable for organic growth and biological processes in one or more ways.[95] Finally, the manufacturing process is not inherently supportive of the delicate nature of cells and other biological products.[96] It will require a thorough understanding of both biological and mechanical properties to strike the balance necessary for consistent production of bioprinted organs.

a. Organ Complexity

Tissues and organs have extremely complex anatomies, requiring nerves, capillaries, and other minute internal structures throughout that are difficult to implement through artificial construction.[97] When printing bone, the resulting tissue must have the appropriate mechanical integrity while also allowing for the creation of new tissue in order to fuse with a patient's natural bones.[98] Another difficulty with bone grafts is creation of the bone-cartilage interface that is essential for the comfort and functionality of the bone implant.[99] Skin has multiple layers with different characteristics defining each layer, not to mention the need for nerves, blood vessels, and other elements to be present in the printed tissue.[100] Blood vessels themselves are extremely complex, as they range in size from a few millimeters in diameter to capillaries only a few cells across, but must allow for transfer of nutrients from the blood to the surrounding tissue.[101]

90. Srikanthan Ramesh et al., *Extrusion Bioprinting: Recent Progress, Challenges, and Future Opportunities*, BIOPRINTING, Nov. 17, 2020, at 2.
91. *Id.* at 7.
92. *See* Little & Wallace, *supra* note 3.
93. *Id.*
94. *Id.*
95. *See* Mao et al., *supra* note 75, at 620.
96. *See* Tsao, *supra* note 76.
97. *See* Little & Wallace, *supra* note 3.
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*

Researchers have developed solutions to some of the problems presented by bioprinting. With bone tissue, a scaffold is printed in the exact shape of the replacement bone and then coated with stem cells combined with bioink, which is then implanted into the body and replaced by new bone once the scaffold disappears.[102] Blood vessels are created using self-assembly techniques, allowing the cells' innate ability for self-directed growth to merge with bioprinted tubes and deliver nutrients to cells.[103] Functional bladders have been printed using 3-D molds soaked with cells that were incubated before being transplanted into the recipient's body.[104] There are many innovative approaches being developed every day, but it will still be many years before bioprinted organs become a generically viable option for transplantation.[105]

b. Biomaterial Requirements

The materials used for bioprinting must have different characteristics based on their specific use in the organ's construction while still being compatible with the human body.[106] The printability, biocompatibility, mechanical properties, and degradation properties are all considered when choosing natural or synthetic biomaterials for bioprinting.[107] Natural materials such as collagen or gelatin are desirable due to their inherent similarities to the extracellular matrix ("ECM") and general biocompatibility.[108] But the downside of natural materials is the weakness of their structural integrity.[109] On the other hand, synthetic materials have more control over mechanical properties and have greater structural integrity but tend to be less biocompatible.[110] The ideal 3-D biomaterial balances printability, biocompatibility, mechanical properties, biodegradability, and sterilization stability.[111]

Studying the ECM has long been a focus in regenerative medicine—the ECM is where cells are located, providing structural support as well as biochemical signals to manage cellular processes.[112] Each tissue and organ has its own specific ECM with differing chemical and biological properties that are designed to support cell migration, proliferation, differentiation, and other cellular functions.[113] Without replicating the ECM in bioprinted organs, the resulting printed cellular structure cannot support the proliferation of cells to grow a properly functioning organ.[114] ECM-derived biomaterials, such as collagen, gelatin,

102. *Id.*
103. *Id.*
104. *Id.*
105. *Id.*
106. *See* Mao et al., *supra* note 75, at 618.
107. *Id.*
108. *Id.* at 618–20.
109. *Id.* at 620.
110. *Id.*
111. *Id.* at 618.
112. *Id.* at 621.
113. *Id.*
114. *Id.*

alginate, etc., are very biocompatible and printable, but they do not have the mechanical properties necessary for many applications.[115] Decellularized ECM has been tested as another option, but it faces the same mechanical weaknesses as other natural biomaterials.[116] Composite materials introduce nano-objects into the printable material to add specific properties, such as toughness, mechanical strength, printability, etc., to improve the suitability of the printed material for bioprinting purposes.[117]

c. Manufacturing Complications

The manufacturing requirements for the production of bioprinted organs pose their own difficulties. The cells loaded into bioink are very sensitive to mechanical stress, a necessary force for extruding bioink through the tiny opening of a printer nozzle.[118] To protect the cells in the bioink, the noncellular components of bioinks are combined to create a shear-force thinning bioink.[119] But this resulting low-viscosity bioink is unable to maintain its shape after printing and tends to flow and spread after extrusion from the nozzle, ruining the shape of the printed structure.[120] This viscosity paradox is a key focus in additive manufacturing—while viability at the cellular level is of great concern during printing, viability of the overall printed structure depends on the mechanical strength of the bioink used to create the structure.[121] Also, cells require very specific environmental conditions to maintain viability such as temperature and humidity.[122] Because bioink droplets can be as small as twenty μm in diameter, it can take hours or days to print a full-sized structure.[123] Maintaining the precise environmental conditions for that long to preserve cell viability is very difficult, and there is ongoing research into improving the speed of bioprinters to address this problem.[124]

One innovation to address this problem is the integration of microfluidic devices into bioprinters.[125] This allows for switching between different bioinks quickly and can increase printing speeds, resulting in speeds up to fifteen times faster than traditional bioprinters.[126] Another printer innovation is the addition of electrospinning techniques to develop a class of printers called electrohydrodynamic 3-D printers, which have the ability to print much higher-resolution

115. *Id.*
116. *Id.*
117. *Id.* at 626.
118. *See* Tsao, *supra* note 76.
119. *Id.*
120. *Id.*
121. *Id.*
122. *Id.*
123. *Id.*
124. *Id.*
125. Maryam Tavafoghi, Ali Khademhosseini & Samad Ahadian, *Advances and Challenges in Bioprinting of Biological Tissues and Organs*, 45 ARTIFICIAL ORGANS 1441, 1441 (2021).
126. *Id.*

constructs that also have strong mechanical properties.[127] But the high voltage required in the electrospinning process limits the addition of cells to the electrospun fibers.[128] Some scientists have been experimenting with in situ 3-D printing using microextrusion techniques to print tissue-specific constructs directly in the body.[129] There are many exciting directions that research into bioprinting is taking to improve the viability and functionality of bioprinted organs.

3. Current Players in the Industry

Many scientists performing research into bioprinting and regenerative medicine come from universities, independent laboratories, or specialized companies. In the United States, the key universities publishing advancements in bioprinting are the University of California at San Diego ("UCSD"), Harvard University ("Harvard"), Wake Forest University ("Wake Forest"), and the Massachusetts Institute of Technology ("MIT").[130] At UCSD, the focus of the research is on the process of bioprinting itself and optimizing the printing process.[131] Harvard and MIT tend to focus their research on vascularization and the heart, while Wake Forest leans towards the process, cartilage, and articulations.[132] Due to the academic nature of research at universities, the advancements developed in university settings are generally more focused on the biological elements of bioprinting rather than the mechanical components of the printing process.[133]

In comparison, companies in the bioprinting industry focus on technological improvements of biomaterials and bioprinters.[134] These companies have commercialized their research and sell materials, bioprinters, and consulting services to other fields.[135] As of 2019, the global bioprinting industry was valued at $586 million, with predictions setting the global value reaching almost $2 billion by 2025.[136] Analysis of seventy bioprinting companies in 2020 revealed that almost two-thirds of the market is built up of bioprinter and bioink sales, while the remaining one-third is composed of a variety of bioprinting services offered to clients, such as specific tissue constructs or custom tissue partnerships.[137] One-fifth of the market is composed of university spin-off startups, with the rest composed of established bioprinting companies.[138]

This difference in commercial focus versus academic focus has far-reaching implications for the field of bioprinting. Due to the competitive nature of the

127. *Id.*
128. *Id.*
129. *Id.* at 1443.
130. *See* Santoni et al., *supra* note 77.
131. *Id.* at 24.
132. *Id.*
133. *See id.* at 15.
134. *Id.* at 28.
135. *Id.*
136. *Id.*
137. *Id.* at 28–29.
138. *Id.* at 29.

industry, bioprinting companies are now trying to develop all-in-one bioprinting platforms that include multitools, support for multimaterial printing, and custom software.[139] By focusing on services and commercial product development, companies can secure funding for their research from investors looking to get in on the bioprinting market as it rapidly grows.[140] But it is equally important to focus on the biological and cellular properties of bioprinting performed by universities.[141] Technological advancements are all well and good, but cells have an innate ability to self-organize and specialize—during gestation, every organ and tissue is created to ideal functionality using this ability.[142] By focusing on unraveling the mysteries of cellular behavior, it may be possible to direct cellular growth in a manner much more effective than growth strictly governed by the technological capabilities present in the field. Because academic research is not as attractive or lucrative to investors as commercial research, it may be necessary to rely on commercial pursuits to secure funding for academic research.[143] For example, a solution for lumpectomies developed by TeVido may be used for breast augmentation, and so the cosmetic surgery market may be the source of funding for academic research focused on this subset of transplant development—enabling further progress on the road to developing effective solutions for medical transplant purposes.[144]

4. Goals of Bioprinting

Bioprinted organs are necessary for the future of medicine. Keeping a patient on dialysis costs around $270,000, and the cost of a kidney transplant is around $440,000.[145] In comparison, the cost of a 3-D printer is around $100,000 (a one-time purchase), and even including the costs of surgery and maintenance, a bioprinted kidney will be much cheaper than the current options.[146] Waiting for an organ match from a donated kidney could take months, if not years, while it could take only hours to print a kidney that is a perfect match for the recipient.[147] The success rate for kidney transplants from deceased donors (the source of the majority of donated organs) is 96% at one year and 79% at five years.[148] Bioprinted organs that are an exact match for the recipient would likely be more

139. *Id.*

140. *See id.* at 31.

141. *See id.* at 22.

142. *See* Raul Artal-Mittelmark, *Stages of Development of the Fetus*, MERCK MANUAL CONS. VERSION, https://www.merckmanuals.com/home/women-s-health-issues/normal-pregnancy/stages-of-development-of-the-fetus (Sept. 2022) [https://perma.cc/UQQ9-ETTH].

143. *See* Jeffery, *supra* note 6.

144. *Id.*

145. *See* GlobalData, *3D-Printed Organs and Their Affordability*, MED. DEVICE NETWORK (June 15, 2022), https://www.medicaldevice-network.com/comment/3d-printed-organs-affordability/ [https://perma.cc/5FTB-DN7A].

146. *Id.*

147. *See* Carlota V., *The Most Promising 3D Bioprinting Projects*, 3DNATIVES (Feb. 2, 2023), https://www.3dnatives.com/en/bioprinting-projects-3d-printed-organs-070420205/#! [https://perma.cc/D96Q-DD7Z].

148. *What Is a Kidney Transplant?*, FRESNIUS KIDNEY CARE, https://www.freseniuskidneycare.com/treatment/transplant (last visited Nov. 5, 2023) [https://perma.cc/2TVU-YPRP].

effective several years after the surgery;[149] however, this efficacy will not be known for sure until printed kidneys become available as a viable option.

Aside from providing bioprinted organs for transplant, bioprinting can also solve another problem in pharmaceutical and cosmetic research: clinical testing.[150] Bioprinted tissues can change medicinal development by providing more accurate tissue models that duplicate human tissues.[151] Rather than testing using animal tissues or human volunteers—which is accompanied by a myriad of ethical complications—or relying on synthetic and dissimilar assay models, bioprinted tissues will be useful in developing many different treatment methods.[152] Tissue maturation can be more rapidly monitored, and consistency of tissue used for testing will be better maintained by using identically printed tissues.[153] Bioprinted tissues and organs open doors to a wide variety of medical treatments and therapies, and it is important to properly regulate and fund the research in this field for the benefit of the public.

III. ANALYSIS

Legal organ donation systems are a lifesaving network of private, public, and volunteer efforts across the country.[154] Unfortunately, the systems currently in place are outdated and inefficient, resulting in organ wastage and lost lives.[155] This Part of the Note will analyze the operations of the current systems to identify key weaknesses and areas with potential for improvement. Part III will also discuss the law and policy currently in place regarding organ donation and its impact on the classification and status of bioprinted organs. Finally, the overlap between the goals of organ donation and bioprinting will be assessed to determine how established policy can be applied to the novel area of bioprinting to further and accelerate bioprinting research and development.

A. Legal Organ Donation

Organ transplants provide the best outcomes for patients with terminal and irreversible organ failure.[156] Kidney transplants are touted as the quintessential example of organ transplantation greatly improving a patient's health and quality of life while also being the cheaper option in the long run than the alternative

149. *See Current and Future Benefits of 3D Bioprinting*, BRINTER, https://www.brinter.com/benefits-of-bioprinting/ (last visited Nov. 5, 2023) [https://perma.cc/F3S2-JUXC].

150. *See 3-D Tissue Bioprinting Program Goals*, NAT'L CTR. FOR ADVANC. TRANSLATIONAL SCIS. (Sept. 13, 2018), https://ncats.nih.gov/bioprinting/about/goals [https://perma.cc/2XJL-R7AS].

151. *See id.*

152. *Id.*

153. *Id.*

154. *Organ Procurement Organizations*, UNOS, https://unos.org/transplant/opos-increasing-organ-donation/ (last visited Nov. 5, 2023) [https://perma.cc/ZR6K-M63Z].

155. *See* Blair L. Sadler & Alfred M. Sadler, Jr., *Organ Transplantation Is at a Crossroads. Major Reform Is Needed*, STAT (Aug. 18, 2022), https://www.statnews.com/2022/08/18/organ-transplantation-is-at-a-crossroads-major-reform-is-needed/ [https://perma.cc/NJN3-6WTC].

156. Grinyó, *supra* note 17, at 1.

(dialysis).[157] For children with end-stage organ diseases, organ transplants not only give them a second chance at experiencing a full life, but also improve the quality of life for their parents or caregivers.[158] Children with transplants have higher school scores and higher connection levels with other children their age compared to children being treated through medication and radiointervention.[159] Therefore, organ donation not only improves the life of the patient, but also the lives of the people in the patient's life.[160]

1. Reduction in Efficacy and Wastage of Donated Organs

More people over the age of sixty-five are both receiving and donating organs, but the rate of allograft failure is still very high for organs with a higher donor age and older organ recipients.[161] Therefore, the older organs that are being donated are less effective, and organs from younger donors that are transplanted into older patients have reduced efficacy and viability as compared to if they were transplanted into younger patients.[162] While donated organs are scarce enough compared to their demand, a significant number of them are not being used to their full potential due to being implanted in older patients who need a transplant.[163]

The wastage of viable organs is itself undesirable, and it is especially heinous considering the costs of the organ transplantation process. To be added to the national transplant waiting list, extensive and expensive testing must be undertaken by the patient[164]—including blood work, imaging studies, psychological evaluation, cancer and surgery tolerance evaluations, and even financial counseling—all before a transplant center adds the potential patient to the list of patients waiting for a transplant.[165] After the initial testing (which can cost tens of thousands of dollars), the cost of the surgery itself, the following hospitalization, and the medications taken in the year after surgery can exceed $500,000.[166] Patients usually need both a primary and secondary form of insurance in order to cover the bills resulting from an organ transplant.[167] When viable organs are wasted, patients spend longer on waiting lists awaiting a transplant, only getting

157. *Id.*

158. Pauline Duvant et al., *Quality of Life of Transplanted Children and Their Parents: A Cross-Sectional Study*, 16 ORPHANET J. RARE DISEASES 364, 364 (2021).

159. *Id.* at 367.

160. *Id.* at 375.

161. M. Abecassis et al., *Solid Organ Transplantation in Older Adults: Current Status and Future Research*, 12 AM. J. TRANSPLANTATION 2608, 2609 (2012).

162. *See id.* at 2614.

163. *Id.* at 2615.

164. *See* Whitlock, *supra* note 73.

165. *See* Jennifer Whitlock, *How to Get on the Waiting List for an Organ Transplant*, VERYWELL HEALTH, https://www.verywellhealth.com/organ-transplant-waiting-list-requirements-3156951 (Nov. 4, 2022) [https://perma.cc/GXM3-ATVW].

166. *See* Whitlock, *supra* note 73.

167. *Id.*

sicker and potentially less tolerant of surgery as they wait their turn.[168] Due to the financial toll that the initial testing, surgery, and postsurgical care take on the already sick patient,[169] anything that reduces the likelihood of the expensive surgery's success is an unacceptable obstacle.

2. Effects of Outdated OPTN Practices

NOTA provided extremely necessary framework for organ donation through the establishment of the OPTN back in the 1980s, when organ donation had just become a viable option for treating patients with renal failure.[170] But the OPTN's infrastructure is extremely outdated and inefficient in 2022, and it results in wastage of viable organs and disparate treatment based on geography, race and ethnicity, and other factors.[171] UNOS, as the government contractor for the OPTN, tracks organ transportation using phone calls and paper manifests, rather than more modern tracking systems in use by companies such as Amazon, DoorDash, or FedEx.[172] These modern systems are capable of tracking thousands of orders a day across the country and providing location information precise enough to alert customers of delivery times down to the minute.[173] Meanwhile, UNOS relies on organ procurement organizations ("OPOs"), nonprofit organizations responsible for organ procurement, to report to the OPTN and follow the legal and regulatory requirements regarding organ offerings.[174] Instead of a unified transportation system, organs are transported through a "cobbled-together system of OPOs and courier and private aircraft and commercial aircraft."[175] These inefficiencies result in many organs going to waste due to inequities between geographic regions in waiting list length and organ availability.[176]

Minority populations are also much less likely to receive live donor transplants due to the unavailability of adequate pre- and post-surgical care in regions where minority populations are higher.[177] These disparities have only worsened in the last two decades, as organs are typically matched to a recipient of the same

168. Kimberly Kindy, Lenny Bernstein & Dan Keating, *Lives Lost, Organs Wasted*, WASH. POST (Dec. 20, 2018), https://www.washingtonpost.com/graphics/2018/national/organ-transplant-shortages/ [https://perma.cc/3N94-DDUW].

169. *See* Whitlock, *supra* note 73.

170. *See* Sadler & Sadler, Jr., *supra* note 155.

171. *Id.*

172. JoNel Aleccia, *How Lifesaving Organs for Transplant Go Missing in Transit*, KFF HEALTH NEWS (Feb. 10, 2020), https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/ [https://perma.cc/B9JW-ENHK].

173. *Id.*

174. *See Organ Procurement Organizations*, *supra* note 154.

175. Aleccia, *supra* note 172.

176. *As Thousands Wait for Transplants, Medical Centers Fight to Keep Livers Close to Home*, NPR (May 17, 2019, 6:00 PM), https://www.npr.org/sections/health-shots/2019/05/14/723371270/new-liver-donation-system-takes-effect-despite-ongoing-lawsuit [https://perma.cc/BL8A-WNGL].

177. Xun Luo, et al., *Disparity Persists: Racial and Ethnic Minority Patients Still Less Likely Than White Patients to Get Live Donor Kidney Transplants*, JOHNS HOPKINS MED. (Jan. 23, 2018), https://www.hopkinsmedicine.org/news/newsroom/news-releases/disparity-persists-racial-and-ethnic-minority-patients-still-less-likely-than-white-patients-to-get-live-donor-kidney-transplants [https://perma.cc/WJG8-EPZ9].

race or ethnicity as the donor and the diseases that would preclude live donation present a higher burden in Black and Hispanic populations than they did twenty years ago.[178]

UNOS has faced legal issues with its allocation practices and was forced to roll back its new nationwide liver allocation system in 2019 after U.S. District Judge Amy Totenberg ordered the halt to the new rules.[179] The new system was the subject of a lawsuit that claimed the rule changes would "waste viable livers, result in fewer transplants and likely cause deaths."[180] The distribution of the donated livers was the key issue in the suit, a problem based greatly in the geographical complications of organ transportations.[181] It is faster to receive a donated organ in less densely populated areas such as the South and Midwest, whereas patients have to wait until they are closer to death before receiving a transplant in more densely populated areas like New York or California.[182] The new system proposed sending donated organs to the sickest patients first regardless of their location in order to combat the geographic disparity, but around a dozen hospitals in Kansas, Georgia, and other states filed the lawsuit claiming that rural patients will be harmed when donated organs are lost to big cities.[183] Therefore, both UNOS's current and new organ transportation systems directly result in inferior medical outcomes.

B. Bioprinting Organs Under the Current Organ Donation Regime

Currently, sale of bioprinted organs is illegal due to the prohibition of sale of "human organs" under NOTA.[184] Because bioprinting technology is not yet consistent and effective enough to produce bioprinted organs on a commercial scale,[185] it may seem that defining the statutory classification of organs that barely exist yet would be putting the cart before the horse. But it is important to identify and acknowledge the role that bioprinted organs will play in fulfilling the missions of NOTA, UNOS, and the OPTN early on so that by the time bioprinted organs are a viable option for patients needing a transplant, the systems for obtaining bioprinted organs will have been long-established and be effectively managed.[186]

178. *Id.*

179. *Nationwide Liver Transplant Policy Caught Up in Court Case*, AP NEWS (May 20, 2019, 4:31 PM), https://apnews.com/article/8009ebf3808845fda70ca7ce3a91fa58 [https://perma.cc/CZC6-HUZG].

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.*

184. National Organ Transplant Act, Pub. L. No. 98-507, § 301, 98 Stat. 2339, 2346 (1984).

185. Lindner Nils & Blaeser Andreas, *A Perspective on the Current State and Future Potentials of Process Automation in 3D-Bioprinting Applications*, 10 FRONTIERS BIOENGINEERING & BIOTECHNOLOGY (May 20, 2022), https://www.frontiersin.org/articles/10.3389/fbioe.2022.855042/full [https://perma.cc/9ZHG-47DN].

186. *See Strategic Goals*, *supra* note 39.

1. Law and Policy

As discussed previously, NOTA was passed in the early 1980s, decades before the technology to bioprint organs existed.[187] NOTA explicitly prohibits the sale of human organs in Title III of the Act under penalty of imprisonment, a maximum fine of $50,000, or both.[188] Human organ sales were made illegal to ensure that wealthy individuals did not have "an unfair advantage for obtaining donated organs and tissues."[189] Bioprinted organs are made of human material and perform the same functions as the organs described in NOTA's definition.[190] Therefore, although current bioprinting technology is not yet advanced enough to consistently produce organs for transplant, the organs produced through bioprinting, even today, are technically illegal to sell under NOTA.[191]

a. National Organ Transplant Act Definition

"Human organ" is defined in NOTA 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 by regulation."[192] At first blush, bioprinted organs appear to fall under the NOTA definition of "human organ." But the spirit of NOTA's definition is to prohibit the sale of "primarily *naturally* existing compositions of matter" (*i.e.*, organs grown in and taken from human bodies).[193] Bioprinted organs are laboratory-developed tissues grown in artificial environments, and therefore are not covered by the spirit of NOTA's prohibition.[194]

b. Food, Drug, and Cosmetic Act Definitions

An alternative classification would be designating bioprinted organs as products, such as a "drug," "device," or "biological product."[195] The Food, Drug, and Cosmetic Act ("FDCA") defines a "drug" as:

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National

187. *See* National Organ Transplant Act, § 301.

188. *Id.*

189. *Can You Sell Organs in the United States?*, DONOR ALL. (May 21, 2021), https://www.donoralliance.org/newsroom/donation-essentials/can-you-sell-organs [https://perma.cc/8XTA-86ZL] (quoting PAYMENT SUBCOMM. OF THE ETHICS COMM., FINANCIAL INCENTIVE'S FOR ORGAN DONATION (June 1993), https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/financial-incentives-for-organ-donation/ [https://perma.cc/2AY5-EXL6]).

190. *See supra* Subsection II.B.1.

191. *See* Shelly Simana, *Reflections on Bioprinting Law: How Should 3D-Bioprinted Organs Be Classified, and What Does It Mean to Treat Them as "Property"?*, STAN. L. SCH. BLOGS: L. & BIOSCIENCES BLOG (Sept. 12, 2022), https://law.stanford.edu/2022/09/12/reflections-on-bioprinting-law-how-should-3d-bioprinted-organs-be-classified-and-what-does-it-mean-to-treat-them-as-property/ [https://perma.cc/UTR4-SXG4].

192. National Organ Transplant Act, § 301.

193. Simana, *supra* note 191.

194. *Id.*

195. *Id.*

> Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).[196]

Bioprinted organs are transplanted to mitigate and treat diseases and to improve the bodily functions of the organ recipient.[197] Therefore, bioprinted organs do fall under the FDCA's definition of "drug." The FDCA defines a "device" as:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[198]

Again, bioprinted organs are intended to mitigate and treat diseases in humans and affect (improve) the function of the human body, and their function does not rely on chemical or metabolic actions.[199] Therefore, bioprinted organs could also be considered a "device" under the FDCA.[200] But "drug" and "device" have connotations of synthetic therapies,[201] which does not apply to the biologic nature of bioprinted organs.

c. Public Health Service Act Definition

A more appropriate classification may be "biological product," defined by the Public Health Service Act ("PHSA") as "[a] virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."[202] But the closest element to bioprinted organs in the set listed by the PHSA is "analogous product,"[203] which seems too vague to comfortably classify bioprinted organs.

196. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1).

197. *Cf.* Eerhart et al., *supra* note 12, at 804.

198. 21 U.S.C. § 321(h)(1).

199. *Cf. Pancreas Transplant*, *supra* note 15.

200. *Cf. id.*; 21 U.S.C. § 321(h)(1).

201. Alan Russell, *Institutional Profile: McGowan Institute for Regenerative Medicine*, 5 REGENERATIVE MED. 23, 24 (2010) ("Once constructed only of synthetic components, these devices may now be either fully artificial or bioartificial. . . .").

202. Public Health Service Act, 42 U.S.C. § 262(i).

203. *Id.*

d. Shortcomings of Established Definitions

Returning to the FDCA and applying the definition of "combination product" seems most applicable to bioprinted organs: "[a] product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity."[204] Because bioprinted organs fall under the definition of both "drug" and "device,"[205] they would satisfy the definition of "combination product." This definition would mean that bioprinted organs would not be subject to the sales prohibition established by NOTA, and their creation and development could be directly funded by sales to patients rather than stalled due to waiting on securing grant funding.[206] This line of reasoning requires many generalizations, however, and does not inspire confidence in the ability to step out from the umbrella of NOTA's prohibition. Without language that clearly separates bioprinted organs from the law and policy currently governing donated organs, it is likely that bioprinted organs will be fruitlessly grouped with donated organs under current interpretations.[207] Therefore, this Note's Recommendation proposes a new, specific definition for classifying bioprinted organs. This definition recognizes the unique nature of bioprinted organs as both organic matter and artificial creation,[208] and it cleanly removes bioprinted organs from the organs prohibited from sale under NOTA. The new definition and the necessity of allowing the sale of bioprinted organs are further elaborated in the Recommendation.

2. Overlap in Policy and Effect of Organ Donation and Bioprinting Research

Organ donation and bioprinting of organs share the same end goal: saving lives.[209] Replacing failing organs with functional organs not only improves the health outcomes of the patient, but also the quality of life for their caregivers and families.[210] While UNOS in its current operation as the OPTN focuses on locating, securing, and transporting donated organs across the country, the language of the OPTN Strategic Roadmap makes it clear that the end result of these goals is to maximize the number of lifesaving transplants possible.[211] There are many factors that make one patient's transplant more successful than another's. For example, older patients often have comorbidities that can reduce the general quality of life after the transplant occurs.[212] Older transplant recipients are also more likely to have early readmissions after transplantation, and the mortality

204. 21 C.F.R. § 3.2(e) (2023).

205. *See supra* notes 191–98 and accompanying text.

206. *See generally* Wei Yang Tham, *Science, Interrupted: Funding Delays Reduce Research Activity but Having More Grants Helps*, PLOS ONE, Apr. 26, 2023.

207. *See* Simana, *supra* note 191.

208. *See* Russell, *supra* note 201.

209. *See* GlobalData, *supra* note 145; *Strategic Goals*, *supra* note 39.

210. *See* Duvant et al., *supra* note 158, at 364.

211. *See Strategic Goals*, *supra* note 39.

212. *See* Grinyó, *supra* note 17, at 5.

rate in patients older than sixty years in the first year after transplantation is over double the rate found in younger patients.[213] Because of the lower life expectancies of older patients, it may seem that allocation of limited donor organs to older patients is inefficient or wasteful from a purely resource-oriented perspective.[214] But patients of all ages have an equal right to a healthier and better quality of life—instead of considering the comorbidities and lower life expectancies as reasons to restructure the allocation of donated organs, they should be taken as motivation to encourage the funding and development of bioprinted organs.

By making bioprinted organs a viable option for transplant, the burden on UNOS as the OPTN will greatly lessen. Bioprinted organs specifically tailored to address the comorbidities and other conditions present in older patients will have a higher success rate after transplantation and lower readmission rates, allowing donated organs to be transplanted to a greater number of patients closer to the donors and resulting in a higher success rate of donor transplantations.[215] In addition, effective bioprinting of organs will allow for more accurate assay testing of new drugs and other therapies for various illnesses.[216] This will, in turn, help speed up the process of developing new drugs that will help treat the comorbidities of older patients and increase the success rate of organ transplantation.[217]

To make bioprinted organs a viable option for transplantation and assay testing as fast as possible, funding from all possible sources must be secured to ensure thorough and efficient research in the field. Currently, NOTA forbids the sale of human organs.[218] This means that funding cannot be secured by providing bioprinted organs in exchange for funding from wealthy individuals.[219] This restriction within NOTA impedes the strategic goals of the OPTN established by NOTA to increase the number, equity, efficiency, safety, and outcomes of transplants.[220] While organ sales may not be an effective long-term or permanent solution for equitable outcomes of organ transplantation, they are an essential and necessary step for the rapid development of the bioprinting field.

IV. RECOMMENDATION

Bioprinted organ sales should be legalized in order to accelerate the research timeline for mass accessibility to this technology. This Part of the Note will outline the proposed solution for the problem of insufficient transplant organ supply discussed in Parts II and III of this Note. The process for making both bioprinted and donated organs more accessible is discussed—improvements to the current system and a new definition for classifying bioprinted organs are

213. *Id.*
214. *See id.*
215. *See Current and Future Benefits of 3D Bioprinting*, *supra* note 149.
216. *See 3-D Tissue Bioprinting Program Goals*, *supra* note 150.
217. *See id.*
218. National Organ Transplant Act, Pub. L. No. 98-507, § 301, 98 Stat. 2346 (2018).
219. *See id.*
220. *See Strategic Goals*, *supra* note 39.

determined. Concerns regarding the ethics and potential inequalities of this approach are also addressed.

A. Making Organs More Legally Accessible

There are many avenues to increase the number of organs available for transplantation. Enabling the sale of bioprinted organs will provide a huge increase in available organs and transplantation success rates, and the sooner this sale is allowed, the faster the technology can develop and receive FDA approval to make bioprinted organs a common option for transplantation patients.[221] While bioprinted organs are still being developed and tested, additional organ donations can be more efficiently collected and used by updating the priority criteria for organ matching and more equally discussing organ donation with minority populations.[222]

1. Enabling Sale of Bioprinted Organs

Until bioprinting technology has advanced enough to where the bioprinted organs have a predictable success rate and an established production assembly for mass production, the sale and pre-sale of individual bioprinted organs should be allowed to garner funding for further development. After production of such organs becomes more reliable, the guidelines of the OPTN should be used and updated to derive an improved system of determining priority for organ recipients, and procurement of a custom bioprinted organ should be covered by insurance in a similar manner to specialized treatments or therapies.

To determine when organs have become reliable enough to move from sale to insurance, the FDA Step 3 and 4 rules for drug approval may be referenced.[223] Step 3 concerns clinical research and is based on studies of the way a drug will interact with the human body.[224] By viewing a 3D-printed organ as a drug as defined by the FDCA,[225] Step 3 will require organ printers to submit an application including animal study and toxicity data, manufacturing information, clinical protocols, prior human research data, and information about the investigator.[226] Step 3 includes four phases of testing, each phase requiring progressively higher numbers of study participants and longer periods of testing.[227] Phase 1 is to determine the safety and dosage of the tested drug; for printed organs, the

221. *See The Drug Development Process*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process [https://perma.cc/A78Q-AXYD].

222. Alexandra K. Glazier, *The Lung Lawsuit: A Case Study in Organ Allocation Policy and Administrative Law*, 14 J. HEALTH & BIOMEDICAL L. 139, 145 (2018). *See* Ben Jealous, Jayme Locke & Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, HEALTH AFFS. (Dec. 17, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20201211.229975/full/ [https://perma.cc/HDJ2-ART7].

223. *See The Drug Development Process*, *supra* note 221.

224. *See Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/8RKY-D3RE].

225. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1).

226. *Step 3: Clinical Research*, *supra* note 224.

227. *Id.*

dosage is not applicable, but the safety of the printed organ is.[228] The length of the study is several months, but due to the length of the course of medications required after transplantation surgery, this Note proposes a one-year period of study for Phase 1.[229] This overlaps with Phase 2, which requires a study between several months and two years long with up to several hundred participants to determine efficacy and side effects.[230]

The number of participants in testing printed organs will be much lower than in testing drugs because the costs associated with organ transplantation are prohibitive to widespread testing.[231] In order to ensure the thorough testing and approval of printed organs, priority will be given to wealthier patients who can afford to pay for printed organs and are willing to participate in the clinical studies on organ printing. By offering printed organs to wealthier patients first, the testing of the printed organs will occur sooner, and approval for general production may also occur sooner.[232] This will allow less-affluent patients to receive an organ printed and implanted by thoroughly tested methods and make printed organs more accessible to a wider range of people. Phase 3, when the efficacy and monitoring of adverse reactions is studied, requires 300 to 3,000 participants.[233] Depending on demand and availability, less-affluent patients may be included in this stage of the trial, and the investors who have been gathering market shares of the bioprinting industry will work the same way drug investors do in funding clinical research.[234] Phase 4 requires several thousand patients,[235] which may not be feasible for bioprinted organ testing and instead may be replaced by a full approval and release of the bioprinted organ technology.

2. Improvements to Current System

The present OPTN is handicapped by several decades worth of outdated legislation, administrative hang-ups, and biased policies.[236] By redefining bioprinted organs as a class, the OPTN can benefit from additional organs available to patients in need.[237] Also, updating existing procurement and matching practices can ensure organs are being sourced from and matched to the largest number of recipients.[238]

228. *Id.*
229. *See id.*
230. *Id.*
231. *See* Whitlock, *supra* note 73.
232. *See id.*
233. *See Step 3: Clinical Research*, *supra* note 224.
234. Rachana Pradhan, *The Business of Clinical Trials Is Booming. Private Equity Has Taken Notice.*, KFF HEALTH NEWS (Dec. 2, 2022), https://khn.org/news/article/business-clinical-trials-private-equity/ [https://perma.cc/93BZ-44UP].
235. *See Step 3: Clinical Research*, *supra* note 224.
236. *See infra* Subsection IV.A.2.
237. *See* Simana, *supra* note 191.
238. *See generally* sources cited *supra* note 222.

a. New Statutory Definition for Bioprinted Organs

This Note previously analyzed several statutory definitions currently present in active policy in order to attempt to categorize bioprinted organs.[239] None of the current available definitions appropriately categorize bioprinted organs due to the novel and unprecedented nature of bioprinted organs compared to other drugs or devices.[240] Instead, this Note proposes a new category: "biological prosthesis." While similar to the PHSA's "biological product" definition, "biological prosthesis" more accurately defines the role bioprinted organs (and future bioprinted products) play in treatment of illnesses and properly separates them from "human organs" as defined by NOTA. A "biological prosthesis" would be defined as "an artificial body part created from biological products that substitutes for a missing or defective part of the body as a treatment or cure of a disease or medical condition." Here, "biological products" refer to the PHSA definition,[241] and the overall definition adds the prosthetic purpose of bioprinted organs and tissues while emphasizing their artificial nature.[242] Since this definition does not fall under the spirit of NOTA's definition ("primarily naturally existing compositions of matter"),[243] bioprinted organs categorized as biological prostheses would be eligible for sale.

b. Geography-Based Priority of Transplant Recipients

By allowing the sale of bioprinted organs, the burden on UNOS will be lessened, and more individuals will have access to lifesaving organs. Until the technology in the bioprinting field reaches the point where the average person would be able to secure a custom bioprinted organ, other reform efforts in the current OPTN can improve access to donated organs. A recent reformation that improved the allocation of donated organs was the shift from match sequencing based on donation service area ("DSA") to matching based on geographical distance.[244] This change came as a result of a lawsuit arguing that since DSAs were constructed for administrative purposes and were arbitrary boundaries that were not consistent in size, using them to determine organ allocation was in conflict with the implementing regulations ("Final Rule") of NOTA.[245] Now, instead of prioritizing recipients within the same DSA, even if there are recipients that are closer but happen to fall on the wrong side of the DSA boundary, organs are now

239. *See supra* Subsection III.B.1.

240. *See supra* Subsection III.B.1.

241. *See* Public Health Service Act, 42 U.S.C. § 262(i).

242. *Prosthesis*, DICTIONARY.COM, https://www.dictionary.com/browse/prosthesis (last visited Nov. 5, 2023) [https://perma.cc/K55G-ANQ8] ("[A] device, either external or implanted, that substitutes for or supplements a missing or defective part of the body.").

243. *See* Simana, *supra* note 191.

244. *Kidney Allocation System*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/professionals/by-organ/kidney-pancreas/kidney-allocation-system (last visited Nov. 5, 2023) [https://perma.cc/UGB3-8TGZ].

245. *See* Glazier, *supra* note 222, at 148.

matched to the geographically closest eligible recipient.[246] This has improved the equity in access to donated organs by minimizing the impact of a patient's geographic location.[247]

c. Equal Representation of Minority Organ Donors

Another urgent reform that must be undertaken to decrease the inequality of access to donated organs is prioritizing organ recovery from minority patients. Fewer minority organ donors mean fewer minority recipients, and therefore more deaths in minority communities, especially in the Black community.[248] Families of Black patients are half as likely to be approached for donation by OPOs than families of white patients, and the level of service provided for the Black families that are approached is less sensitive and compassionate.[249] This directly leads to fewer Black donors, and therefore fewer Black transplant recipients.[250] New regulations on OPOs would ensure that the objective standards in place will prevent OPOs from choosing which families they will and will not approach about organ donation, especially since families who have more contact with OPOs are three times more likely to donate.[251] By equally approaching patient families and appropriately providing resources, time, and compassion to families in the bereavement process, the number of organs from minority donors will increase, saving more minority lives and therefore more lives overall.[252] This reform would take additional stress and burden off of UNOS and further the strategic goals of the OPTN system.[253]

3. Funding of Bioprinted Organ Development

Bioprinted organs would not be the first medical product that was available only to the wealthy before the technology became affordable for the general population. DNA analysis and genetic testing were only available to the "extremely rich" just a decade ago—now, likely over 100 million people have had their DNA analyzed using kits like 23andMe and Ancestry.[254] In the 1990s, the cost of a mitral valve repair decreased by 50% in five years, making it more accessible to a wider scope of the population in less than a decade.[255] Biopharmaceuticals, diagnostics, and medical devices have all found success in securing funding, but

246. *See Kidney Allocation System*, *supra* note 244.
247. *See* Glazier, *supra* note 222, at 148.
248. *See* Jealous et al., *supra* note 222.
249. *Id.*
250. *Id.*
251. *Id.*
252. *Id.*
253. *See Strategic Goals*, *supra* note 39.
254. *See* Lin Taylor, *Identity Crisis: Data Misuse an Unseen Twist in DNA Testing*, REUTERS (Dec. 12, 2018, 7:24 PM), https://www.reuters.com/article/us-health-dna-privacy-feature/identity-crisis-data-misuse-an-unseen-twist-in-dna-testing-idUSKBN1OC03T [https://perma.cc/6TF7-JZT9].
255. Adam Pick, *Costs of Heart Valve Surgery*, HEARTVALVESURGERY.COM (Sept. 17, 2020), https://www.heart-valve-surgery.com/costs-fees-estimates-money-insurance.php [https://perma.cc/UUZ2-ZS6P].

their timeline for the return on investment is more agreeable to investors than the ten or more years necessary for the first results of bioprinting technologies to become commercially viable.[256]

Bioprinted organs have a much longer development timeline than the other medical technologies venture capitalists typically invest in.[257] This poses a chicken-and-egg problem: increased funding would enable faster development of start-up successes of bioprinting operations, but investors are hesitant to fund such research because the timeline as it currently manifests is too long for their business interests.[258] Therefore, allowing sales of individual bioprinted organs to wealthy individuals who can afford a higher price tag on medical technologies will help to bridge the gap between the funding currently available and the costs to make bioprinted organs available on a widespread commercial basis.[259] This would be analogous to how clinical trials find participants for drug testing.[260]

Currently, the clinical trial sponsor covers research-related costs and any special testing required as part of the clinical trial.[261] Other costs, such as routine tests or treatment that would be part of the standard treatment plan, are usually covered by either the participant or their insurance.[262] Randomized controlled trials ("RCTs") and clinical trials in general function by a small group of people taking on the risk of experimental drugs and treatments in exchange for (1) getting early access to and benefit from a drug or treatment that could potentially improve their illness and quality of life, and (2) providing valuable clinical research that benefits society by helping scientists and medical professionals improve future drugs and treatments.[263] By allowing bioprinted organs to be tested in a similar manner, with resource-rich individuals being able to both sponsor such trials and also receive a custom-printed organ if they are so in need, bioprinting technology research can be better funded and further developed in a shorter amount of time—just like RCTs.[264]

B. Potential Problems of This Approach: Perception Versus Reality

The idea of paying for an organ brings with it many unsettling questions of ethics and equality. Organ sales are specifically discouraged in order to prevent exploitation of resource-poor individuals,[265] as well as to remove at least one economic barrier to transplantation for more equal distribution of donated

256. *See* Jeffery, *supra* note 6.

257. *Id.*

258. *Id.*

259. *Id.*

260. Amanda McDowell, *Do Patients Have to Pay for Clinical Trials?*, ANTIDOTE (May 10, 2023), https://www.antidote.me/blog/do-patients-have-to-pay-for-clinical-trials [https://perma.cc/QLH8-TU2T].

261. *Id.*

262. *Id.*

263. Cecilia Nardini, *The Ethics of Clinical Trials*, ECANCER, Jan. 2014, at 1–2.

264. *Id.* at 2.

265. *See* Elizabeth Kelly, *FDA Regulation of 3D-Printed Organs and Associated Ethical Challenges*, 166 U. PA. L. REV. 516, 543 (2018).

organs.[266] Bioprinted organs, however, do not come with the ethical risks inherent to standard organ procurement and can actually ameliorate the current conditions of organ procurement.[267]

1. Unauthorized Organ Procurement

There are many concerns regarding the ethics of allowing the sale of bioprinted organs. The UAGA passed in 1968 was revised in 2006 to encourage donations and address shortages.[268] The UAGA includes specific provisions requiring that the documentation necessary to become an organ donor must be signed without coercion.[269] This includes financial coercion, as "black-market" unauthorized organs are sourced through highly unethical means, including payments to individuals from lower-income regions around the world.[270] Aside from paying individuals to part with their organs, more extreme instances occur, such as kidnapping and killing individuals to harvest their organs for sale on the black market.[271] It is for these reasons that organ sales have been prohibited in many countries including the United States, in order to prevent such dangerous systems and practices from expanding beyond their current borders.[272] But bioprinted organs have none of the ethical uncertainties and risks associated with the sale of donated organs. There is no harm to humans, and no risk of physical or financial coercion in the process to obtain the organ for transplant.[273] Additionally, widespread sale and implementation of bioprinted organs into the current organ transplantation scheme will greatly reduce the demand that the black market currently fills, in turn reducing the unethical practices that provided the organs to supply that demand.[274]

2. Socioeconomic Discrimination

NOTA currently prohibits socioeconomic discrimination in access to donated organs through its ban on organ sales.[275] By allowing bioprinted organs to be sold to provide further funding for the development of the field, concerns arise about the inequality in access that would be provided based on class and financial resources. Realistically, the number of people who can afford to pay for individual bioprinted organs ahead of commercial viability is far outweighed by the

266. Mary Simmerling, *Beyond Scarcity: Poverty as a Contraindication for Organ Transplantation*, AMA J. ETHICS (June 2007), https://journalofethics.ama-assn.org/article/beyond-scarcity-poverty-contraindication-organ-transplantation/2007-06 [https://perma.cc/R5VX-M97C].

267. Anya Adair & Stephen J. Wigmore, *Paid Organ Donation: The Case Against*, 93 ANNALS ROYAL COLL. SURGEONS ENG. 191, 191–92 (2011).

268. *See Uniform Anatomical Gift Act*, *supra* note 8.

269. Britta Martinez, *Uniform Anatomical Gift Act (1968)*, THE EMBRYO PROJECT ENCYCLOPEDIA (Aug. 5, 2013), https://embryo.asu.edu/pages/uniform-anatomical-gift-act-1968 [https://perma.cc/VH3J-5NR6].

270. *See* Kelly, *supra* note 265, at 543.

271. *Id.*

272. *See* Adair & Wigmore, *supra* note 267.

273. *Id.*

274. *Id.*

275. *See* Simmerling, *supra* note 266.

number of people who need transplanted organs. Because there are less than 10,000 deceased donors each year and almost 100,000 people on UNOS's waiting list, the number of bioprinted organs being created and implanted will have a negligible effect on the balance of patients remaining on the list every year.[276]

The immediate concern for the resource-poor is that even if they are matched with a donor organ, the cost of medications such as immunosuppressants can be "a real and significant barrier to successful organ transplantation based on the socioeconomic circumstances of the recipient."[277] To truly equalize successful organ transplantations between the resource-rich and the resource-poor, guaranteed access to post-transplant medications is a minimum requirement.[278] To make more affordable medications, faster testing and more accurate assay models are necessary, and as discussed above,[279] bioprinting tissues will help make this possible.[280]

V. CONCLUSION

Bioprinted organs are poised to be the next big innovation in healthcare. Providing effective, personalized treatment for thousands of patients in varying stages of organ failure, bioprinted organs offer a renewed chance at a healthier life without the endless waiting on donor lists and a reduced risk of transplant rejection.[281] Many more patients will be able to receive organ transplants in a timely manner without being subject to the variables and risks present in the current organ matching and procurement system.[282] But these benefits will only come to fruition when bioprinted organs become a feasible option for patients on a larger scale. As the field currently stands, bioprinted organs are a reality, but not a practicality.

To bring the field to that state necessary for widespread implementation of bioprinted organs, much funding is needed. This funding is currently operating under the academic framework of securing grant money and investors through outreach and applications to those who have a business interest in the field.[283] But this is a very time-consuming process and requires scientists and developers to spend time drafting grant proposals and investment pitches that could be spent further developing current bioprinting tech.[284] Currently, bioprinted organs are not offered for sale because they are technically illegal to sell under NOTA's

276. *Id.*
277. *Id.*
278. *Id.*
279. *See supra* Subsection II.B.4.
280. *See 3-D Tissue Bioprinting Program Goals*, *supra* note 150.
281. *See supra* Subsection II.A.3.
282. *See* Pullen, *supra* note 57.
283. *3D Bioprinting Market Grows at Rate of 21% Supported by Rising Funding for Research as Per The Business Research Company's 3D Bioprinting Global Market Report 2021*, BUS. RSCH. CO. (Oct. 14, 2021, 11:30 AM), https://www.globenewswire.com/news-release/2021/10/14/2314512/0/en/3D-Bioprinting-Market-Grows-At-Rate-Of-21-Supported-By-Rising-Funding-For-Research-As-Per-The-Business-Research-Company-s-3D-Bioprinting-Global-Market-Report-2021.html [https://perma.cc/MA22-WSW9].
284. *See generally* Tham, *supra* note 206.

definition of "human organ."[285] Therefore, bioprinted organs should be considered "biological prostheses" and be offered for sale, so that wealthy patients who can afford to pay for cutting-edge technology can put their money towards the advancement of the field in exchange for a personalized organ that matches their exact needs. This will speed up the timeline of bioprinted organs becoming an option for the general population, thereby reducing wait times, organ waste, morbidity rates for transplanted patients, and unauthorized procurement. Bioprinted organs do not come with the ethical risks and physical risks to donors that are inherent to donated organs,[286] and therefore should not be prohibited from sale under NOTA.

Bioprinted organs provide a release valve for the increasingly pressurized OPTN,[287] by allowing the OPTN to keep donated organs as close as possible to their donor city and avoid transportation delays and mishaps while simultaneously providing patients in rural areas with optimized organs for their own therapeutic needs. Matching organs based on age, race or ethnicity, and existing comorbidities will no longer present a logistical conundrum for UNOS and the OPOs in the transportation network across the United States.[288] The sale of bioprinted organs benefits the field of healthcare and will bring the field forward to where thousands of people will be able to live happier, healthier lives.

285. *See* Simana, *supra* note 191.
286. *See supra* Section IV.B.
287. *See* Sadler & Sadler, Jr., *supra* note 155.
288. *Id.*