Legal and Regulatory Considerations for 3D Bioprinting

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Introduction to the Reading List

Bioprinting is a type of 3D printing technology that uses living cells to fabricate biomimetic constructs. The precise layer-by-layer printing process creates bioengineered structures that more closely mimic the architecture of human tissues and organs than traditional tissue engineering. The hope is that this biotechnology is a promising alternative for tissue reconstruction, food production, and organ transplantation; however, there are biological and technical obstacles to overcome in order to manufacture functional bioconstructs. Moreover, the inclusion of living cells—the key component in bioprinting technologies—raises a host of ethical, legal, and social concerns highlighted in this collection. These challenges may be familiar to some readers and while the concerns are not novel, the novelty of bioprinted structures warrants careful examination.

This collection spotlights pressing legal and regulatory issues related to bioprinting materials, methods, and products. The lack and/or intricacies of national and international regulatory pathways are major challenges to clinical translation and commercialization. Despite ongoing achievements in bioprinting research, there are few [clinical trials in humans](https://pmc.ncbi.nlm.nih.gov/articles/PMC11834296/) to date that explicitly involve the printing of cell-laden products. Bioprinting is an attractive technology to advance personalized medicine and bioprinted medical devices can qualify for [regulatory exemptions](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/custom-device-exemption). Yet this adaptability presents unforeseeable risks and conflicts with large-scale randomized clinical trial design to assess product efficacy and safety.

There is also uncertainty around classifying and regulating unconventional bioprinted constructs as drugs, medical devices, biologics, or combination products. In the United States, this emerging technology is beyond the scope of the [FDA's "leapfrog guidance" for 3D printed medical devices,](https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fda-ushering-new-era-3d-printing-medical-products) effectively leaving bioprinting in a state of regulatory limbo. This further complicates the dynamic relationship between regulatory affairs and intellectual property interests. Like other innovations in science and technology, there is a strong interest to incentivize, legally protect, and profit from bioprinting research efforts. In general, existing legal and regulatory frameworks are reported to be insufficient to address current and potential challenges with bioprinting. This reading list introduces the above considerations and will expand as the science evolves.

General Ethical, Legal, and Social Issues (ELSI)

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Regulations and standards

Gilbert F, O'Connell CD, Mladenovska T, Dodds S. Print Me an Organ? Ethical and Regulatory Issues Emerging from 3D Bioprinting in Medicine. Sci Eng Ethics. 2018 Feb;24(1):73-91. doi: 10.1007/s11948-017-9874-6. Epub 2017 Feb 9. PMID: [28185142](https://pubmed.ncbi.nlm.nih.gov/28185142/).

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Sekar MP, Budharaju H, Zennifer A, Sethuraman S, Vermeulen N, Sundaramurthi D, Kalaskar DM. Current standards and ethical landscape of engineered tissues-3D bioprinting perspective. J Tissue Eng. 2021 Jul 29;12:20417314211027677. doi: 10.1177/20417314211027677. PMID: [34377431](https://pubmed.ncbi.nlm.nih.gov/34377431/); PMCID: PMC8330463.

Taylor S, Mueller E, Jones LR, Makela AV, Ashammakhi N. Translational Aspects of 3D and 4D Printing and Bioprinting. Adv Healthc Mater. 2024 Oct;13(27):e2400463. doi: 10.1002/adhm.202400463. Epub 2024 Jul 9. PMID: [38979857](https://pubmed.ncbi.nlm.nih.gov/38979857/).

Ownership and Property Rights

Adewale M. Your Organ Is Mine: Rethinking Ownership Issue in 3D Bioprinting. J Law Med. 2023 May;30(1):85-98. PMID: [37271953](https://pubmed.ncbi.nlm.nih.gov/37271953/).

Fatimi A. Exploring the Patent Landscape and Innovation of Hydrogel-based Bioinks Used for 3D Bioprinting. Recent Adv Drug Deliv Formul. 2022;16(2):145-163. doi: 10.2174/2667387816666220429095834. PMID: [35507801](https://pubmed.ncbi.nlm.nih.gov/35507801/).

Harbaugh JT. Do You Own Your 3D Bioprinted Body? Analyzing Property Issues at the Intersection of Digital Information and Biology. Am J Law Med. 2015;41(1):167-89. doi: 10.1177/0098858815591512. PMID: [26237986](https://pubmed.ncbi.nlm.nih.gov/26237986/).

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