

Orange County Bar Association

HEALTH CARE LAW SECTION

November Meeting

LIVE WEBINAR: Thursday, November 10, 2022 | 11:00 AM - 12:00 PM

Speakers:

John Fuson, Esq.

Partner, Crowell & Moring LLP

Hilary Johnson, Esq.Counsel, Crowell & Moring LLP

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3D Printing at the Point of Care: Compliance and Liability Concerns

3D printing of medical devices at the point of care ("POC") has the potential to revolutionize the medical devices industry, accelerating the production process, allowing personalized devices, promoting innovations in patient care, and lessening reliance on traditional supply chain models. However, this innovative practice poses serious unanswered questions in terms of health care entity regulatory responsibility, IP issues, and product liability. This session will provide (1) a primer on how the FDA regulates medical devices, (2) an outline of how FDA plans to regulate 3D printing of devices at the point of care and legal issues raised by this new model as compared to traditional manufacturing, (3) an examination of the state of product liability litigation when it comes to 3D printed devices and the potential product liability risks when healthcare facilities take on the role of traditional manufacturers, and (4) an analysis of different intellectual property scenarios healthcare facilities must be aware of when 3D printing POC devices.

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