Is EU legal regulation stifling the growth of medical 3D printing?

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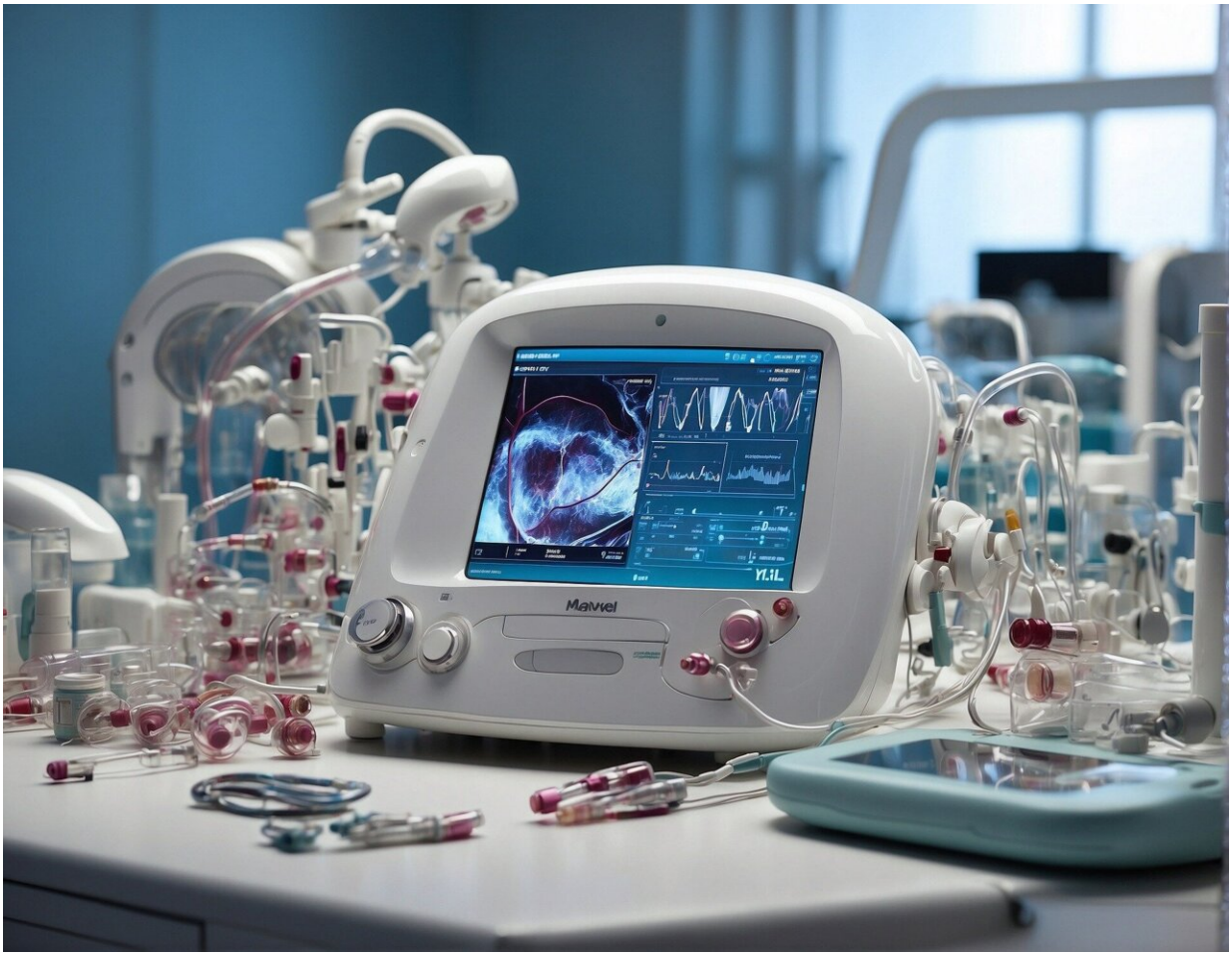

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Medical 3D printing, also known as additive manufacturing, is the use of

3D printing technology to create medical devices, implants and prosthetics.

Published in *Healthcare*, an article titled "Core Legal Challenges for Medical 3D Printing in the EU" examines the potential issues posed by EU regulation on the broader adoption of 3D printing in medical applications.

Co-authored by Dr. Marc Mimler, Senior Lecturer in Law, The City Law School, it specifically analyzes EU legislation and case law on the key issues of pre-market approval and post-market liability of these devices, in addition to intellectual property (IP) considerations and data protection.

The analysis finds several gaps and uncertainties in the current laws. The study suggests that while the law aims to protect patients, regulation that is more flexible may be needed to encourage innovation and improve patient care sooner, preventing avoidable harms to them.

Over the past few years, 3D printing has developed to a point where it is widely used across several industries. In 2022, the European medical 3D printing market was estimated to be worth £432 million. Medical 3D printing has the potential to revolutionize the health care sector by enabling innovative care. However, the regulatory framework governing these devices is crucial to ensuring their safety and efficacy.

In the European Union (EU), the Medical Device Regulation (MDR) governs these products, but there is an ongoing debate about whether these regulations unnecessarily hinder the benefits of innovation in 3D medical printing.

The EU's approach to regulating medical devices involves both pre-market and post-market regulations. The pre-market regulation

categorizes medical devices into risk classes, from Class I (low risk—e.g., band-aids) to Class III (high risk—e.g., life-supporting devices). Importantly, the method of production does not influence the risk classification, meaning 3D printed products can be found across all classes.

The MDR, which replaced the Medical Device Directive in 2021, has faced criticism for not specifically addressing 3D printed or personalized medical devices. A separate guidance document on personalized devices was released to clarify some of these issues.

Pre-market regulation

The article outlines how one part of the MDR's pre-market regulation, called "Custom Device Exemption," allows certain devices made per a written description by an authorized person to bypass some requirements, like CE marking, but must still comply with quality management and other regulatory obligations.

However, the MDR also states that "'patient-matched'" devices (for a specific patient) produced through a reproducible process do not qualify for Custom Device Exemption and must follow a stricter regulatory pathway.

The authors suggest that in the MDR, drawing the distinction between "patient matched" and "mass-customized" devices (which are prescribed generically, and then adapted to individuals) is still a gray area for 3D printed medical devices, hence regulatory compliance in this area remains uncertain also.

The MDR also provides a regulatory exemption for in-house, non-industrial manufacturing of 3D printed devices within health institutions (such as hospitals), known as the Health Institution Exemption. This

exemption aims to foster innovation within health care settings by reducing regulatory burdens, while still maintaining key quality management systems and other regulatory compliance aspects.

However, many questions remain about what processes and what entities this exemption covers, for example, how might it cover an industrial partner co-located at the health institution?

Post-market regulation

Post-market regulations involve surveillance and monitoring of medical devices after they enter the market. The EU has a more rigorous approach compared to other jurisdictions like the U.S., where, for example, compliance with pre-market regulations might provide a full defense against liability claims. In the EU, such compliance offers only partial protection.

The authors suggest that currently under the MDR, product liability for 3D printed devices is currently unclear due to the boundary between medical negligence and product liability being "blurred" and complicated by a potentially "decentralized production model" and the many different parties that could be involved in delivering these devices to patients.

As well as the surgeon who may have helped design, manufacture, and also implant a 3D printed device in a patient, other parties involved in the manufacture and checking of the device, such as third-party manufacturers, or in-house manufacturers (at a health institution, for example), could also be responsible for defects in the final product.

They outline how the newly proposed EU Product Liability Directive (PLD), which is an update to the current Product Liability Directive instituted in 1985, aims to better address the modern day's digital

challenges. The proposed changes expand the definition of "product" to include software, digital files and services, broadening the scope of liable parties.

This revision aims to clarify liability attribution in the 3D printing ecosystem, where determining the "manufacturer" can be complex due to the decentralized production model.

Data protection and intellectual property rights (IPR)

The article authors also highlighted the uncertainty around data protection and intellectual property (IP) laws relating to 3D printed medical devices, and how this may contribute to an unwelcoming environment for innovation.

They cited the understandable data protection issues which surround several phases of the 3D printed medical device process, such as imaging or 3D digitizing of patients' personal (e.g., biometric or health) data, which fall under the scrutiny of the EU General Data Protection Regulation (GDPR).

They also particularly noted the lack of current intellectual property (IP) legislation surrounding the computer aided design (CAD) files that are the blueprints used to manufacture 3D printed medical devices, and which will need to be addressed to ensure the smooth running of business models surrounding new, innovative products.

What does this mean?

The authors argue that the conservative, and in many places, ambiguous requirements of current legislation could unnecessarily hamper innovation in the field, delaying important new care to patients.

Including in the following ways:

- Small companies or institutions might find it challenging to navigate the complex regulatory scene, especially when producing tailored 3D printed devices.
- The need for extensive documentation, validation and quality management systems could slow down the time-to-market for innovative solutions.

More information: Ante B. V. Pettersson et al, Core Legal Challenges for Medical 3D Printing in the EU, *Healthcare* (2024). DOI: 10.3390/healthcare12111114

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