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ORIGINAL ARTICLE

Uncertain But Not Unregulated: Medical Product Regulation in the Light of Three-Dimensional Printed Medical Products

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Abstract

As applications of three-dimensional (3D) printed medical products are being translated into clinical practice, stakeholders are increasingly concerned about whether current regulatory frameworks are able to regulate such products. With more additive manufacturing (AM) and 3D printed medical products being brought into clinical use and the assumption that usage will be more widespread in the future, a (perceived) lack of or inadequacy of regulation by some stakeholders is often depicted as a hindrance to the comprehensive translation of AM and 3D printed medical products into clinical use. This article addresses this uncertainty by analyzing existing medical product regulations and their applicability to AM and 3D printed medical products to assess the degree of regulatory oversight they administer. It concludes that there are specific legal questions that need to be clarified, but the products are not expected to ''disrupt'' existing legal frameworks.

Keywords: 3D printing, medical product regulation, medical device regulation, bioprinting, custom made, additive manufacturing

Introduction

With medical applications of three-dimensional (3D) printing* becoming more commonplace in clinical practice,[1] and predictions for further growth in this sector,[2,3] concerns about the degree of regulatory oversight over 3D printed medical products have been raised by industry and regulators.[4–9] These include concerns that existing regulatory frameworks may be ''disrupted'' by the advent of 3D printed medical products and may no longer be fit for purpose for this mode of manufacturing. Although regulatory and legal concerns in respect of 3D printing are discussed beyond purely medical applications,[10,11] concerns about the effective regulation of 3D printed medical applications have been identified as particularly critical[12] because of the direct potential impacts on peoples' lives and wellbeing. Different areas of law, such as intellectual property, negligence, and other consumer protection laws, will be applicable to medical products resulting from 3D printing processes.[13–15] In this article we limit our focus to analyzing medical product regulations and their applicability to 3D printed medical products as this is the primary prospective mode of regulation for medical products.

In this article, we address the perceptions of regulatory uncertainty by critically reviewing existing medical product regulations and their application to 3D printing. The current literature generally focuses on 3D printing for consumer products more generally.[16–20] There is a need for a more nuanced and detailed consideration of the issues that arise for 3D printed medical products. The analysis illustrates that regulatory frameworks for medical products are in principle applicable to 3D printed medical products and may be more adaptive to new manufacturing methods than they are

*In this manuscript, we are using the term ''3D Printing'' interchangeably with ''Additive Manufacturing.'' While there is a technical difference between those two terms, the Wohlers Report 2018[3] identified ''3D printing'' as ''de facto standard'' term (p.17).

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perceived to be by some commentators. The potential for regulatory disruption does not stem from the product being made using 3D printing methods, but rather because of specific characteristics of that process, such as personalization and decentralization. These characteristics may lead to uncertainties as to how the frameworks will be applied to 3D printed medical products showing these specific characteristics. Regulators seem aware of these uncertainties and equipped to respond to them. Thus, the fears of some that the regulatory system may not be able to adequately address 3D printing in the health sector may be overstated.

After briefly describing the uses of 3D printing in medical applications in the Three-Dimensional Printing and Its Medical Applications section, in Medical Product Regulation and 3D Printed Medical Products section we analyze selected regulatory frameworks, how products are categorized within those frameworks, and how this applies to 3D printed medical products. As will be discussed below, most 3D printed medical products that are expected to come to market in the coming years will most likely fit within the established category of medical devices in the existing regulatory frameworks. Therefore, in Three-Dimensional Printed Medical Devices and Existing Regulatory Frameworks section we examine some key aspects of the medical device frameworks in Australia, the United States, and the European Union (EU), and how they regulate 3D printed medical products as examples of whether the current frameworks are sufficiently flexible to adjust to any challenges posed by new manufacturing processes. We focus on these jurisdictions, because 3D printed medical products are manufactured in all these markets. In addition, all three jurisdictions have established regulatory frameworks and bodies for medical products that have already reacted in some form to 3D printing in the health sector. However, detailed analysis and comparison of these frameworks is outside the scope of this article. In the Other Legal Approaches Beyond Medical Product Regulations section, we describe the role negligence plays in regulating 3D printed medical products. In the Conclusion section, we state that the fears of some that the regulatory system may not be able to adequately address 3D printing of medical products may be overstated.

Three-Dimensional Printing and Its Medical Applications

Three-dimensional printing was first used more than 50 years ago and commercial systems were in the market in the late 1980s.[3] Thus, the technology is not as new as is sometimes portrayed. Nevertheless, advancements in the hardware and software aspects of the technology allowed the transition from using 3D printing as a rapid prototyping and tooling instrument to using the technology to manufacture end products.[5] The technologies are still in different stages of development with research being undertaken to deepen the understanding of the processes, and expanding the variability and enhancing the mechanical properties of built materials.[21]

Suggested benefits of using 3D printing to manufacture medical products over other manufacturing technologies are the spatial accuracy in the printout, the option to personalize a product efficiently and cost effectively (personalization),[22,23] and the possibility to manufacture outside traditional industrial manufacturing settings, possibly closer to the patient (decentralization).[24,25] In the health sector the technology is currently being used to manufacture medical devices, such as anatomical models, personal protective equipment, surgical equipment, or surgical implants.[5] To manufacture these products, polymers and metals are predominantly used.[7] There is ongoing research and discussion about the possibility of so-called ''bioprinting,'' the process of incorporating living cells into the printing process.[26] Bioprinting, however, shows many more layers of complexity compared with printing with inanimate materials, and remains in an early research phase.[27] How recent advances in 3D printing in the health sector will manifest in standard patient care remains contentious: although some suggest that 3D printing will revolutionize health care,[28,29] others argue that caution is warranted because of the paucity of rigorous testing and long-term data about the products.[6]

Despite uncertainties as to how 3D printing will manifest in the health sector, a growing body of contributions identifies uncertainty about whether and how regulatory frameworks are and will be applicable to 3D printed medical products.[2] It is argued that this uncertainty has the potential to pose a barrier to the translation of 3D printed medical products into health contexts.[30–33] Some stakeholders argue that a stringent regulatory approach may be prohibitive to the full realization of the health care applications of 3D printing,[4–7] whereas others are concerned that regulatory loopholes or subpar regulatory oversight might impact safety and quality assurance, and therefore may have an impact on patient safety.[34]

Although these concerns are a common note in discussions on the applications of 3D printing in the health sector,[6,32,35] only a few contributions go beyond stating general concerns and identifying specific issues.[36–38] Of those, the majority address concerns regarding the regulation of bioprinted medical products.[39–44] Concerns about the regulation of 3D printed medical products that do not use biological material are less frequently analyzed and thus far only from a U.S. regulatory perspective.[31,45,46] Other contributions do not make a distinction between the different regulatory categories. Although some authors identify which types of 3D printed medical products are in their scope when claiming that there is regulatory uncertainty, the majority make these claims without categorizing the products into the different product categories. For example, one author analyzes medical device regulations in the United States but includes in this bioprinted products.[31] This, however, may lead to further confusion as the term ''medical device'' is a regulatory category, that, for example, may not encompass bioprinted products. As some 3D printed medical products are being already used in a clinical context, and others are maturing rapidly; uncertainties about the regulation of 3D printed medical products and any lack of clarity in existing regulatory frameworks need to be addressed.

Medical Product Regulation and 3D Printed Medical Products

Medical products regulation

Medical product regulations are a subset of consumer safety law in most jurisdictions with the general aim to foster public health by assessing the safety and efficacy of medical products that enter a jurisdiction's market.[47] For a product

to be allowed to be made, sold, imported, and used within a jurisdiction, it has to comply with the set of rules and regulations applicable to the product in question.[48] So far, there is no 3D printing-specific regulatory framework in any jurisdiction. This, however, does not result in 3D printed medical products being unregulated, as medical product regulations are technology agnostic in that they do not differentiate according to the mode of manufacturing used to produce a product. Therefore, the comprehensive existing regulatory regimes for medical products are in principle applicable to 3D printed medical products.[49] Table 1 provides an overview of the main legal instruments regulating medical products in the respective jurisdictions. At this point in time, there are no medical products regulations at an international level. Nonetheless, harmonization of the regulations has been identified as an important goal by medical product regulators. An example is the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world, whose aims are to accelerate international medical device regulatory harmonization.[50] In the absence of binding international regulations, national regulatory frameworks are the main point of reference for the regulation of medical products.

Which regulatory frameworks are applicable to a specific product is dependent on different factors, such as the market the product is being produced for, the specific product and its risk category, and whether certain exemptions may apply. First, it needs to be determined which medical product regulations a particular product is subject to. Regulatory bodies have the power to regulate medical products within the confines of that jurisdiction. Therefore, products that are sold in the Australian market will be regulated under a different regulatory framework to products being intended to be sold in the United States. With 3D printing an international enterprise, a number of regulatory frameworks may apply to a single product. Although the regulatory frameworks in different countries show substantial overlap, there are still differences that can become relevant in determining how a particular product is regulated. For example, a relevant difference may be how specific jurisdictions define product categories. In most nations, medical products are regulated through categories. Different regulatory rules apply if a product is considered a pharmaceutical, biological, or medical device. This differentiation allows the regulatory framework to address specific risks and benefits associated with each product category.[51] The scope of the different categories is determined through statutory definitions that are applied to specific products.[52] The American Food and Drug Administration (FDA), for example, sorts products into these categories by identifying the product's main function, referred to

Table 1. Overview of Main Legal Instruments Regulating Medical Products in the Respective Jurisdictions

Jurisdiction	*Main legal instruments regulating medical products*	
United States	*FD&C Act*	Federal Food Drug & Cosmetics Act (*FD&C Act*) (Title 21 United States Code)
EU	*MDR*	Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L, 5.5.2017, p.1–175 (*MDR)*
	IVD Regulation	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p.176–332 (*IVD Regulation*)
	Cell and Tissue Directive	Directive 2004/23/EC of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells, OJ L 102, 7.4.2004, p.48–58 (*Cell and Tissue Directive*)
	ATMP Regulation	Regulation (EC) No 1394/2007 of the European Parliament and of the Council of November 13, 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ l 324, 10.12.2007, p.121–137
	Medicinal Products for Human Use Directive	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p.67–128
	EMA Regulation	Regulation (EC) No 726/2004 of the European Parliament and of the Council of March 31, 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p.1–70
Australia	*The Act 1989*	The Therapeutic Goods Act 1989 (Cth)
	Therapeutic Goods Regulation 1990	Therapeutic Goods Regulations 1990 (Cth)
	Medical Device Regulations 2002	Therapeutic Goods (Medical Devices) 2002 (Cth)

ATMP, Advanced Therapeutic Medicinal Product; EU, European Union.

as ''primary mode of action.'' Different 3D printed medical products will fall into different categories depending on their characteristics, leading to a 3D printed pharmaceutical product being considered under the rules and regulations for pharmaceuticals. For example, a 3D printed medical implant may be considered under the rules applicable to medical devices.

Although every jurisdiction has its own regulations, they are harmonized in that they are designed to ensure a product's safety, quality, and efficacy before the product is allowed to be marketed legally.[51] These principles form the basis for the regulations and underlie the documentation and reporting responsibilities for manufacturers and sponsors.[53] All medical product regulations are fundamentally rooted in product safety considerations.[51] Under ideal circumstances, any harm should be foreseen and minimized as much as possible while maintaining the product's benefit. The greater the foreseen benefit, the more risks generally will be tolerated.[53] To achieve this clearance for a specific product, a manufacturer or sponsor of a medical product will approach the relevant regulatory body with evidence that the product fulfills the intended purpose while balancing risks and benefits and maintaining sufficient quality through the implementation of quality control mechanisms. If the evidence is deemed sufficient by the regulatory body, the manufacturer will receive clearance and the product can be marketed legally as a medical product in the respective jurisdiction.[47]

The three categories: devices, drugs, and biologics

Medical product regulation is a broad term that refers to the wider field of government regulations that determine which medical products can be marketed legally and under which circumstances. Medical product is an umbrella term encompassing a number of regulatory categories. As discussed previously, the categorization does not differentiate between products made with different manufacturing technologies. Rather, it focuses on differentiating between product types that fulfill their intended purpose in different ways, for example, mechanically or metabolically. The dominant differentiation is between medical devices, drugs (pharmaceuticals/medicines), and biologics, as seen in the United States,[54] Australia[55] and the EU.[56] Although the definitions for each category differ slightly in detail between jurisdictions, they have in common that medical devices will be understood to be some sort of apparatus that is used in the diagnosis, prevention, or treatment of a disease, mainly functioning mechanically, whereas a pharmaceutical or drug will predominantly function pharmacologically. Biologic products are understood to be any biologically based substance that could include viruses, vaccines, blood, and blood components or derivatives.

As for any other medical product, the distinction between categories raises questions under which category 3D printed medical products will be regulated. As already established, different 3D printed medical products will fall under different categories, as it is not the mode of manufacture that establishes an affiliation with a category. Rather—as for any non-3D printed medical product—the category is determined by applying the definitions of the respective product categories (devices, pharmaceuticals, and biologics) in the specific jurisdiction to the product in question.

Three-dimensional printed medical products that do not contain any drugs or biologics will, in most jurisdictions, be classified as medical devices. In the United States, in 2017, the FDA released a technical considerations document for 3D printed medical devices, detailing how the FDA understands 3D printed medical devices to fit the existing regulatory pathways.[57] According to the FDA, numerous 3D printed medical devices have been cleared for the American market through the existing regulatory pathways.[58] In Europe and Australia there are also a number of examples of 3D printed products being marketed and regulated as medical devices. Among those are, for example, metal spinal implants,[59] and metal hip implants (ARTG entry 320142).

Three-dimensional printed medical products that contain pharmaceuticals will most likely be considered under the drugs category. An example is ''Sprintam,'' a 3D printed drug to treat epilepsy, which was approved by the FDA in 2015. The drug was approved through the New Drug Application process under section 505(b)(2) of the Federal Food, Drug, and Cosmetics Act, without reference to its mode of manufacture.[60]

For products that may be produced in the future containing biological materials (bioprinted products) there is continuing uncertainty in the literature as to how they could and should be regulated and whether there is need for regulatory reform. Some question whether bioprinted products can be regulated using existing categories, or whether there may be need for a *sui generis* category for such products.[61] Others point to social and ethical concerns, and discuss a prohibition of parts of the technology, or the technology as a whole.[38,62] A prohibition is easier to enforce, but may not be in the long-term interest of science, research, or society.[63] Despite bioprinting research being in its infancy, a lack of evidence of its timely translation into clinical practice, and the subsequent uncertainties regarding specific products and their risk profiles, bioprinting regulation is discussed more frequently in the literature than 3D printing of medical devices. The incorporation of biological material into medical products undoubtedly increases the complexity of regulating them compared with other 3D printed medical products, thus heightening the need for regulatory debate should the products come closer to clinical translation. Nonetheless, without a clear risk profile of such products, statements of how they will and should be regulated remain speculative.[64]

Combination products

It has been suggested that 3D printing may require its own specific category within medical product regulation.[38] For products that clearly fit within one of the established categories, such an approach seems contraindicative, as none of the classifications take the manufacturing method into account and, as discussed previously, the products manufactured so far fit the existing regulatory framework. For products that do not fit the established categories, because they integrate aspects of two or more categories, formulating a new category to encompass them could be a way to respond to uncertainty. Such an approach, however, would again only provide regulatory certainty in terms of products that clearly fit the new category. As technologies emerge and products develop further, every new technology could warrant a new

category that ultimately may prove unworkable as category types would proliferate while uncertainties would remain.

Concerns about the regulation of products that span more than one product category, for example, by fulfilling the statutory definition for ''device'' and ''drug'' are neither novel regulatory challenges nor specific to 3D printed medical products. For example, in 1990 the U.S. legislation (the Safe Medical Device Act) addressed this issue.[65] This action was in response to concerns that regulators were not equipped to effectively and safely oversee novel products at the intersection of the different product categories.[65–68] These concerns are rooted in a product's complexity, rather than its attribute of being manufactured by means of 3D printing. The discussion therefore goes beyond 3D printing and bioprinted products and encompasses different advances in the fields of tissue engineering, cell biology, gene therapy, and materials science to name only a few.[65] Whereas the complexity of any product, or novel aspects of a medical product may present ongoing challenges to regulators, it does not mean the products are left unregulated. Regulators have established tools to sort products into different categories that may address or partially address any emerging challenges.[52] The existing legal instruments relevant to complex products have been described as ''piecemeal,'' as there are a number of different regulatory instruments addressing different stages of the manufacturing and distribution cycle.[37] In the following section we provide an overview over the existing regulatory frameworks in the United States, the EU, and Australia that most likely will be applied to bioprinted products.

In Europe, 3D printed products containing biologics may be considered Advanced Therapeutic Medicinal Products (ATMPs) in the form of tissue engineered products.[37,40] Tissue engineered products, according to Article 2(1)(b) of Regulation (EC) No 1394/2007 (ATMP Regulation), refers to a product that contains or consists of engineered cells or tissues and is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing, or replacing human tissue. Relevant legal instruments that are applicable to those products include the ATMP Regulation, the EC Tissues and Cells Directive (Directive 2004/23/EC), potentially pharmaceutical regulations and the new Medical Device Regulation (Regulation [EU] 2017/745 [MDR]).

In the United States, bioprinted products may be considered combination products.[44] They may therefore be regulated according to the relevant aspects from dual or multiple existing categories that the regulator deems relevant to the assessment.[41] Whether and how this categorization will change in the future is uncertain. At this point in time, there is no FDA approved or cleared biologic product made by 3D Printing in the United States that has been approved through conventional regulatory pathways.[69] Nevertheless, the Center for Biologics Evaluation and Research (CBER) at the FDA claims to have received numerous inquiries related to bioprinting and bioprinted cellular products.[69] Ricles *et al.* state that the FDA has had, up until now, relatively fewer opportunities to evaluate bioprinted products—compared with 3D printed medical devices—because 3D printed biologics is an emerging area of development.[69]

For Australia, 3D printed products containing biologics will at the moment be regulated as Biologicals, as the Therapeutic Goods Act 1989 states that anything that comprises, contains, or is derived from human cells or human tissues is considered a biologic and regulated as such (Part 3 2A Section 32A Therapeutic Goods Act 1989 [*Cth*]). However, the Therapeutic Goods Administration (TGA) in Australia indicated their intention to adapt this framework in a consultation document on ''personalized and custom made devices.'' They intend to regulate ''products that contain as a component, but that are not wholly comprised of human origin material'' not as a biologic, as it is the case now, but as a medical device. Products intended to be captured are ''3D bioprinting or printing of patient specific implants that incorporate human origin material.'' As in other jurisdictions, the biologic component would still need to comply with relevant regulatory requirements applicable to biologics. The reasoning given for this change is international alignment of the regulations with other jurisdictions.[9] This aspect of the consultation was not adopted in the recent legislative amendment to the *Therapeutic Goods (Medical Device) Regulations 2002.*

Following questions about the applicability of the frameworks, is the question of what kind of regulatory oversight the different systems establish when applied to 3D printed medical products and if that level of oversight is sufficient in light of the risks the products pose. As most products that are already in use or are expected to be cleared for use in the near future most likely will be considered as medical devices, we discuss this regulatory category in more detail below.

Three-Dimensional Printed Medical Devices and Existing Regulatory Frameworks

As established, 3D printed medical devices that fulfill the definition of a ''medical device'' in a particular jurisdiction are subject to the risk-based device testing and reporting frameworks for medical devices. The frameworks seem adequate to regulate 3D printed medical devices, as they are not inherently different to other medical devices in principle. Nonetheless, characteristics of 3D printed products, namely their potentially personalized nature and decentralized manufacturing capabilities, may have an impact on regulation and oversight.[9]

Personalized devices

Medical device regulation establishes further device classes that correspond with progressively more robust information and testing requirements to effectively regulate the different risk levels in different medical devices.[70] For example, a plaster is associated with relatively few risks for the patient, whereas a neurological implant is associated with a higher level of risk. Thus, regulators established systems in which low-risk medical devices may be marketed with little to no oversight, whereas for high-risk devices more stringent evidence and testing frameworks apply to ensure their safety and efficacy.

The risk-based regulatory system underlies all medical device regulations with a few exceptions where some devices may be exempt from the otherwise applicable regulations for their risk category. Such exemptions differ in detail in different jurisdictions, but mostly have in common that they are designed to give faster access to devices that are needed urgently and therefore cannot take the time to go through a regulatory procedure, or where the commercialization of a product is unlikely, because of the rarity of the disease (so-called orphan devices).[71,72] One example, which is especially important in the context of 3D printed medical devices, is exemption for

personalized medical devices, also known as ''custom devices'' or ''custom made devices.'' When a medical device is manufactured specifically for one particular patient an exemption can be granted by the regulator for the device to bypass most, if not all, regulatory approval requirements.[73] However, a custom device exemption does not mean a product is ''unregulated.'' Rather, these exemptions lighten formal approval requirements, but still put the onus of ensuring compliance with the applicable regulations on the manufacturer.[74,75]

These custom-made exemptions were established in times where the manufacture of a device specifically for one patient was associated with relatively low risks, because of the relative lack of complexity associated with personalization.[76] Examples include glass eyes, prosthetic limbs, and prescription lenses. Today, 3D printing technologies allow for easy, fast, and potentially economically sensible options for personalization. This begs the question of whether these exemptions are still appropriate to govern highly sophisticated products, which have a greater risk profile, such as implantable devices.[76] Although this discussion is not limited to 3D printed products, the 3D printing is considered a key driver toward personalization on a much larger scale, thus making the concerns about the exemption more pressing.[76] At present, some personalized medical devices are exempted from more robust levels of risk assessment.

Different jurisdictions chose to frame the exemption differently in terms of what constitutes a custom-made device and what the regulatory consequences of this categorization are. The U.S. FDA addressed challenges posed by high-risk custom-made devices by amending the legislation (section 520(b) of the Food, Drugs and Cosmetics Act (FD&C Act), effective July 9, 2012), to narrow the scope of the exemption, now limiting the exemption to five devices per device type per year for one manufacturer.[74] This limitation has been critiqued as arbitrary and circumstantial, as the definition of ''device type'' remains open to interpretation.[77]

The EU incorporated a new wording for the custom-made device exemption into their new MDR. The regulation was planned to take effect from May 2020 (Art. 123 Sec. 2 MDR), but the European Commission adopted a proposal to postpone the date by one year to prioritize measures to address the coronavirus pandemic.[78] The new Article 2 (1) (3) of the MDR states that ''…devices which are mass produced by the means of industrial manufacturing processes (…) shall not be considered to be custom made devices.'' What ''industrial manufacturing processes'' means and whether it relates to the process or whether the manufacturer is a company, institution, or individual is not defined, or is it accompanied by regulatory guidance documents. This leaves questions about the intended scope of the provision open.[79] The MDR also introduces the requirement for third-party oversight of the manufacture process for Class III implantable custom-made devices (Article 52 (8) MDR), thus effectively limiting the scope of the exemption to Class I, II and IIa devices. An exemption exists for health institutions if various conditions are met, such as that the device is not transferred to another legal entity, that the manufacture and use of the devices occurs under appropriate quality management systems, and that the health institution(s) justifies in its documentation that the target patient group's specific needs cannot be met by an equivalent device available on the market (Article 5 Sec. 5 MDR). This is discussed in more detail below.

Another medical device regulator to recently address this issue is Australia's TGA. It recently passed the *Therapeutic Goods Amendment Legislation Amendment (2019 Measures No.1) Regulations 2019* (Cth) amending the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth). Among other amendments, this legislation refines the scope and of the custom-made exemption. The legislation redefined the custom-made exemption and refined the requirements for manufacturers under the exemption. The new definition effectively narrows the scope and distinguishes between truly custom-made devices that shall stay within the scope of the exemption and other devices that are being personalized to some extent, but still shall be considered under the conventional regulatory pathways.[80] The requirements for the exemption have been adjusted to also impose documentation and reporting responsibilities on the manufacturer (*Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* (Cth.) Part 2 Item 4; Part 4 Item 24), largely aligning with the EU framework.

The IMDRF has attempted to clarify how personalized devices fit within existing regulatory frameworks. In a nonbinding working paper, they differentiated between genuine one off products that should remain exempt from risk-based regulatory pathways and products that, despite the possibility of being personalized to an extent, are at base the same product and should remain subject to traditional regulatory pathways.[81] However, a weakness of the document is indicated by inconsistencies in the use of the proposed terms that also creates uncertainty.[64]

Narrowing the custom-made exemptions in all jurisdictions will result in more 3D printed medical products being assessed through the ''standard'' approval pathways. Whether those are appropriate and even manageable has caused controversy, because stakeholders have identified them as potentially cost prohibitive and simply unworkable.[82] On the contrary, it has been argued that simply the fact that a medical device is produced with 3D printing technologies and is personalized to a greater or lesser extent, should not allow it to bypass regulatory systems and negate the risk-based regulatory approach[82] given the primary concern is patient safety.

Decentralization

Another aspect of the 3D printing manufacturing process that may be cause for regulatory concern is the decentralized way in which 3D printed medical products, especially devices, can be manufactured. The technology enables the movement from manufacturing processes based in an industrial setting to production within institutions or by individuals in a home setting. The risk in this is that decentralized manufacturing could result in some actors being seen to avoid the regulatory frameworks imposed on the industrial sector and produce products that do not meet accepted safety and quality standards, which may, depending on the nature of product, place the public at risk in the short, medium, or long term. Individuals using 3D printing to manufacture medical products, who are not traditional medical device manufacturers, may not be aware of the applicable regulations or may not consider themselves to fall within the scope of the regulations.[83] A current example of uses of 3D printing to manufacture medical products outside conventional medical product manufacturing settings are the ways in which the

technology is used to respond to supply shortages because of the COVID 19 pandemic. Manufacturers of personal protective equipment, ventilator parts, and so on, have included automotive companies, universities, and home-based individuals.[84–86] There are varying degrees of risk levels associated with the products that are being produced. In the context of a global crisis, there may be legitimate reasons to embrace decentralized manufacture and reduced regulatory oversight, but whether this is in the public interest for all types of medical products in a noncrisis situation given the possible implications for safety remains an open question.

As for ''custom-made'' devices, the EU regulatory frameworks for ATMPs (Art. 28 (2) ATMP Directive) and the MDR (Art. 5 (5) MDR) include provisions for health institutions or hospitals, respectively, to be exempt from most regulatory requirements, except for provisions on general safety and performance requirements, when preparing or manufacturing certain products. In parallel with the custom-made exemption, these provisions reduce regulatory oversight and put the onus of ensuring compliance with the necessary safety and performance requirements on the manufacturer, in this instance the hospital or health institution. Both provisions are critiqued for a lack of definitional clarity (e.g., what constitutes a ''health institution'' and what constitutes ''routine/non routine'' and ''industrial'' production is not defined).[36,40,49] The provisions, if used widely, would allow manufacturers to largely bypass risk-based regulatory oversight. The European Commission stated in their 2014 report on the ATMP exemption that ''if the hospital exemption became the normal route to market advanced therapies, there would be detrimental consequences for public health.''[87] However, despite this, the European Commission introduced a similarly worded exemption in the new MDR.

The recent Amendment to the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) also introduced the concept of ''medical device production system.'' This is a novel regulatory term under which an (apparently closed) system comprising raw materials and manufacturing equipment can be used to manufacture specific low-risk medical devices. The system is certified as a medical device, and enables ''health professionals, or a suitably qualified person within a healthcare facility'' to manufacture the medical devices the system has been designed to manufacture without becoming the legal manufacturer of those devices. The responsibility of the legal manufacturer would lie with the manufacturer of the medical device production system.[80] This regulatory approach is novel internationally.[76] The proposal has been controversial with some voicing doubts as to its manageability and regulatory value.[82] The TGA sees this feedback as stemming ''from a misunderstanding of how the regulations would apply.''[88] The proposed changes have now been implemented with the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* (Cth.).

Whether point-of-care manufacturing, or even at-home printing, will cause regulatory challenges largely depends on the uptake of such nontraditional manufacturing outside industry settings. Should such manufacturing become more commonplace, it could result in challenges for the enforcement of existing regulatory frameworks, as efficient oversight over manufacturing outside industry contexts is likely to require an increase in resources.

Other Legal Approaches Beyond Medical Product Regulations

Medical product regulations are not the only laws and regulations applicable to 3D printed medical products. Other areas of law, such as negligence, product liability, or even criminal law, are applicable to new technologies, such as 3D printing.[89] Medical product regulations adopt a prospective approach as they in essence seek to ensure the safety and efficacy of medical products before an adverse event.[51] Tort and criminal law, however, have retrospective effect, after an adverse event has occurred and seek to compensate or punish. The changes 3D printing introduces into the supply chain and manufacturing workflow have opened up intensive debates regarding how these changes may impact on liability, especially in the product liability area.[18,90–92] In particular it is argued that with the potential for multiple actors to be involved in the design and manufacturing process, it may be unclear which of those actors is responsible for the harm. The same reasoning can be applied to 3D printed medical products.[36,63,93]

Conclusion

Three-dimensional printed medical products are not unregulated *per se*. Although there remains some uncertainty regarding personalized medical products and the potential of decentralized manufacturing processes, the existing regulatory frameworks seem mostly equipped to oversee the products that are currently being manufactured. The call for additional (3D printing) manufacturing specific regulations may be rooted in an informational disconnect between industry and regulators. As we have argued elsewhere, precise language and definite terms are an essential part of furthering the conversation,[64] nevertheless equally so is an understanding and an appreciation of the existing regulatory structures and processes. Given that many devices manufactured by 3D printing have been cleared through the existing pathways, and judging from the regulators' first reactions, the frameworks may be more adaptive than has been presumed, if they are able to be enforced effectively.

In addition, although 3D printing in theory may evoke complex legal questions both around the design of law and about its enforcement, whether these theoretical questions will become of practical importance will be determined by the uptake of the technology in medical settings.[83] Given how the technology is currently used, and is likely to be used in the foreseeable future, its regulatory ''disruptiveness'' may be overstated. There is no evidence that 3D printed medical products would not fit within established regulatory frameworks, or that these systems would not maintain a sufficient level of safety and efficacy of the products *per se*. Thus, it is not so much 3D printing processes that are at issue, but rather specific aspects, such as personalization or the potential for decentralized manufacture. Although the regulators that have been examined in this article have already identified and are responding to the regulatory questions in respect of the impact of personalization on existing regulatory frameworks,[9,81] the second concern, decentralization, so far remains largely unaddressed. However, these issues may raise questions about education and enforcement, rather than pointing to a need for regulatory reform.

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