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Regulatory Concerns about Medical Device Manufacturing using 3D Printing: Current State of the Issue

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Abstract

Custom-made implants, orthotics, orthoses, models for surgical planning and education, and much more are now created using 3D printers. In this article, the authors summarized information on laws and regulations in the domain of legal support for 3D printing of medical devices in Russia and abroad. 3D printing is one of the promising avenues in developing new methods of treatment, so immediate establishing of clear criteria for its legal regulation is necessary. As is, there are still many gaps in the legislative framework. The issues of the quality of 3D models, material standardization and manufacturing processes using 3D printing technologies remain unresolved. When using custom-made medical devices, respecting the rights of patients and preventing the use of prohibited or restricted materials are essential. Yet, legal barriers to this innovative direction of medicine must be avoided.

Keywords: legal regulation in medicine, 3D printing of medical devices, custom-made implants.

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Background

To date, medicine is likely the most rapidly growing branch of science, resulting in the emergence of new medical technologies. Up-to-date technical advances brought about the advent of 3D printers. This expanded significantly the possibilities for diagnosing and treating various pathologies through medical models created with their help.

3D printing provides the opportunity to create, layer-by-layer, a physical object from a mathematical model developed in the CAD system. Custom-made implants, orthotics, orthoses, models for surgical planning and education, and much more are manufactured now with the use of additive technologies [1–6]. Such a vast range of applications of medical devices manufactured using 3D printing necessitates their legal regulation. Since 3D printing is one of the promising avenues for developing new methods of treatment, both legal guidelines to its development and safety controls for medical devices manufactured using additive technologies [7, 8] are necessary.

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Legal regulation of the manufacture of medical devices using 3D printing in Russia

A medical device is legally defined in Para.1, Art. 38 of the Federal Law of November 21, 2011, No. 323-FZ "On Public Health Protection in the Russian Federation" as: "Any medical appliances, apparatuses, devices, equipment, materials, and other products used for medical purposes either separately or in combination with each other and with other accessories required for the use of these products as intended, including customized software, and designed manufacturer (producer) for the prevention, diagnosis, treatment and aftercare of diseases, monitoring of the human body for medical research, medical tests, rehabilitation, replacement, modification of anatomy or physiological functions of the body, pregnancy prevention or termination, the functional purpose of which is not implemented by pharmacological, immunological, genetic or metabolic impact on the human body. Medical devices can be recognized as interchangeable if they are comparable in functionality, quality and technical characteristics and are suitable to replace each other."

It should be noted that, according to Decree of the Government of the Russian Federation of December 27, 2012 No. 1416 "On Approval of the Rules for State Registration of Medical Products", mandatory requirements of effectiveness and safety are imposed on medical devices. When using medical devices in medical practice, a positive effect should be achieved. Harm to the patient is unacceptable.

In all cases of intervention in the sphere of human health by medical practitioners, healthcare professionals of scientific laboratories, and research institutes, a sound legal basis is needed to ensure the state's guaranteed protection of the human right to life, health and body integrity. Any intervention in the sphere of physical and/or mental health of a person should be prepared, organized and carried out in such a way that it does not violate the rights and legitimate interests of people, and it is these goals that legal science should serve [9].

The absence of legal instruments regulating the manufacture and use of custom-made medical devices does not allow for ensuring their safe use in patients. At present, the broad use of custom-made medical devices is governed by Para. 5, Art. 38 of the Federal Law No. 323-FZ of November 21, 2011 "On Public Health Protection in the Russian Federation", where it is determined that custom-made medical devices, manufactured to meet the specific requirements of medical specialists and intended solely for the personal use of a particular patient, are not subject to state registration. This is also confirmed by the Decree of the Government of the Russian Federation of December 27, 2012 No. 1416 "On Approval of the Rules for the State Registration of Medical Products" and a letter of the Federal Service for Healthcare Supervision of July 21, 2015 No. 04-21338/15.

Thus, custom-made medical devices manufactured using 3D printing, in conformity with the anthropometric indices of specific patients, are not subject to state registration. Based on the literal interpretation of the above statutory provision, it follows that the material from which the individual medical devices are made is subject to state registration.

However, this issue is not controlled by the executive authorities. Roszdravnadzor does not keep the state register of medical devices and organizations (individual entrepreneurs) that produce and manufacture custom-made medical devices. These medical devices are not subject to the provisions of Part 3, Art. 38 of the Federal Law No. 323-FZ of November 21, 2011 "On

Public Health Protection in the Russian Federation", providing for technical and/or operational documentation developed by a manufacturer (producer) of a medical device.

There are no clear regulatory laws regarding: quality of the 3D models themselves, standardization of materials and manufacturing processes using 3D printing technologies, assurance of the safety of objects printed using a 3D printer and reduction in the risk of printing prohibited or restricted objects [9–12] .

Another problem with manufacturing custom-made medical devices using 3D-technologies is copyright enforcement. The legal framework for copyright protection is determined in the Civil Code of the Russian Federation (Part 4). The systematic interpretation of Article 38 of the Federal Law No. 323-FZ of November 21, 2011 "On Public Health Protection in the Russian Federation", as well as Part 4 of the Civil Code of the Russian Federation, implies that the objects of copyright in the production of medical devices include regulatory, technical, operational documentation and other documents related to the broad use of medical devices (including technical tests, toxicological studies, preclinical and clinical trials), drawings and other documentation used in the manufacture of medical devices, as well as special software (Civil Code of the Russian Federation, Para.1, Art.1259).

However, custom-made medical devices do not undergo preclinical and clinical trials and are not subject to state registration. This raises the question: how will the original models created in the graphic editor be protected by copyright as intellectual property? Another concern that arises from the production of custom-made medical devices is how to not violate copyrights when printing a copy of a registered medical device using 3D printer?

Legal regulation of medical 3D printing in the USA

To date, the legal aspects of the regulation of additive technologies are most developed in the United States. 3D printing is widely used in all American lines of production: commercial, industry, medicine, construction, etc. However, there exist a number of unresolved legal issues. The legal norms for use of additive technologies in medicine for copying, quality, marketing and sales are not complete [13–15].

Technological development, as a rule, changes the established legal norms. In history, this happened more than once, starting with Johann Gutenberg and up to the IT revolution. Throughout history, in many countries, problems relating to the ban on the use of new technologies have been solved at the legislative level. It is believed that emerging technologies do not actually require changes in legislation. This strategy may work for some time, but sooner or later, lawmakers will have to face the need to adapt laws. Initially, legislation on product liability arose from contractual law, with many decisions made in the early 1960s in favor of manufacturers, since the general rule prohibited product users from suing manufacturers [16].

Medical practitioners and medical companies are increasingly using 3D printing to reduce the cost of vital personalized medical devices and implants. Specialists engaged in the study of the legal regulation of 3D printed objects argue that the legislation on 3D printing is slightly different from the legal regulation of conventional product manufacturing. Existing laws and subordinate regulations governing intellectual property rights were issued before the advent of 3D printing and therefore do not directly cover all of its capabilities. Medical devices are utilitarian, not artistic objects, and therefore have no basis for the protection of copyright [17, 18].

Activities related to 3D printing in the United States are controlled by three divisions of the U.S. Department of Health and Human Services: FDA's Center for Devices and Radiological Health, which regulates the use of medical devices; FDA's Center for Biologics Evaluation and Research; FDA's Center for Drug Evaluation and Research.

The Food and Drug Administration (FDA)* has developed a classification for 1.700 different devices and grouped them into 16 medical fields. This classification depends on the intended use, as well as on the indications for use, which can be found in the labeling of equipment. Each type is assigned one of three classes of regulation, depending on the level of control necessary to ensure safety and efficiency. The class to which the device belongs determines, among other things, the type of pre-marketing notification (price, trademark, etc.) required for FDA's approval for sale. Most class I equipment is exempt from notification, most class II and III devices require notification. In addition, the classification is based on risks for the patient. Class I includes devices with the lowest risk to health, class III - the highest risk. All three classes are controlled by the basic requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Regulatory control increases from class I to class III and is carried out throughout all 3D printing phases (Fig.) [19–21].

All registered institutions must be registered on the FDA website. By law, the FDA must issue a final decision within 30 days after the institution is accredited. All registration information is checked annually.

Control of quality and copying in the USA

Legal standards for the quality of 3D printed products include trademark law and product safety regulations. Manufacturers must guarantee their products.

Currently, the FDA is studying 3D printing technologies to gain the knowledge and experience necessary to evaluate the safety, effectiveness and quality of products developed as a part of the additive manufacturing process. As the 3D printed medical devices are commercialized, compliance with intellectual property laws will become increasingly important for medical device manufacturers [18, 19].

Anyone who uses or copies an existing CAD file to create a digital model for 3D printing is responsible to the owner of the file for copyright infringement. However, a person who uses a 3D scanner to create an image of an object for printing, and then creates a model from this image, can avoid liability for copyright infringement if he copies only the unprotected functional features of the object, and not an aesthetic or artistic element.

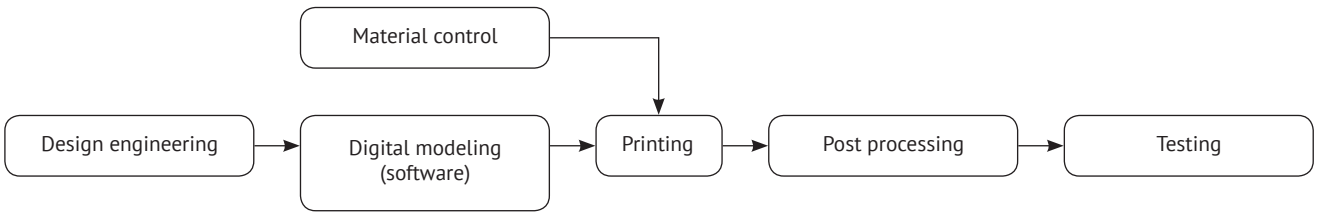

Fig. Regulatory control in the United States during 3D printing

On the one hand, trademarks help the device manufacturer to protect its products from counterfeiting. Printed on a 3D printer, an object that has a manufacturer's trademark will be governed by the Federal Law on Trademarks and Product Counterfeiting Law. On the other hand, 3D printed products that do not contain manufacturer's trademarks can easily be identified as unauthorized copies [20, 21].

Patent and trade secret in the USA

Patent law guarantees medical device manufacturers greater protection against unauthorized 3D printing and its products. It may be violated as follows:

– directly (the one who makes, uses, sells the claimed invention);

– indirectly (to those who consciously and actively advertise, promote, encourage others to violate the patent law).

Thus, the manufacturer of medical equipment, which patented his device or method of its creation, has the following rights:

– prohibit the production and sale of 3D-printed copies of his product;

– do not prohibit the use of 3D-printed copies of his product [19, 27];

– prohibit the use of 3D-printed copies of the product.

It is important to note that if a scanned product 3D-model is refined with new objects using computer_simulation that allows for avoiding copyright infringement. While a 3D-printed product or a method of its creation is protected by a patent, its further manufacture, use and sale are not considered a violation of the law.

A person not authorized to use the manufacturer's confidential and technical information when creating a 3D printed copy of a product is responsible for the misappropriation of the manufacturer's trade secret [22, 23].

Safety in production of 3D models in the USA

The FDA regulates medical 3D printing using the same mechanisms [*standards*] as conventional_medical devices. Therefore, they are also evaluated for safety and information effectiveness. It should be noted that when creating 3D-printed medical devices, it is necessary to observe labor protection rules for employees since plastic threads, combustible powders and high temperature are used [24–26].

The FDA determined the factors which may be grounds for bringing legal action against the manufacturer of a 3D-printed custom-made medical device:

1) use of a defective original product to create a digital model;

2) use of a defective original digital design;

3) use of a damaged digital file and its copies;

4) use of a faulty 3D printer;

5) use of damaged materials for 3D printing;

6) error in the computer simulation process by a specialist;

7) error in using a 3D printing technology by a specialist.

In the USA, hospitals are, in essence, "service providers". They are not associated with drug manufacturers, device manufacturers, or commercial marketers. Patients injured by the use of a 3D printed product face an additional obstacle: who is responsible — the 3D product manufacturer or the medical facility that provided services using the 3D printed product? [8, 30–33].

With intent to level the emerging concerns, on June 11, 2014 in New York, the Director of the FDA Biological Department, S.K. Pollack convened a workshop to amend legislation on the application of additive technologies, which, while only unilaterally, discussed a number of important issues.

How should the FDA certify "non-conventional manufacturers" (hospitals)? Will the FDA certify 3D printers? How will quality assessment systems be applied? Will the FDA deal only with 3D products and what are the requirements for manufacturers? [32]. As a result of the symposium, recommendations for regulating the use of additive manufacturing were drafted in 2017, which are intended to govern the design, manufacturing and production of devices, as well as software, the qualifications of bioengineers and the quality of the printer [33].

Legal regulation in Europe of the use of medical devices created by additive technologies

Monitoring the distribution and use of medical devices in European countries is regulated by various directives: Council Directive 90/385 EEC relating to active implantable medical devices, Council Directive 93/42/EEC relating to medical devices, Council Directive 98/79/EEC on *in vitro* diagnostic medical devices. All products are assigned the abbreviation CE. Medical devices, in particular custom-made implants created using additive technologies, belong to safety class III, but do not need direct CE certification [34, 35]. Currently, European regulators, in collaboration with the American Society for Testing and Materials, are also trying to improve the standardization process of 3D printing within the framework of the ISO and to rework European standards for supervision of the use of custom-made gadgets [36].

Conclusion

Interdepartmental commissions are currently working both in Russia and abroad to develop laws and regulations governing the manufacture and use of custom-made 3D printed medical devices. However, a legislative basis has not been finalized. Legislation in this sphere should ensure the following: safe use of custom-made 3D printed medical devices, respect for the rights of patients when applied, prevention of prohibited or restricted material use during their manufacture, and avoidance of legal barriers which could limit the development of additive technologies of 3D printing in medicine.

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