# 8 Social and Legal Considerations for Artificial Intelligence in Medicine

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## Contents



**Abstract**

Artificial intelligence is becoming seamlessly integrated into our everyday lives, augmenting our knowledge and capabilities in driving, avoiding traffic, finding friends, choosing the right movie, or finding the perfect song, and, perhaps most importantly, it is entering into healthcare and medical diagnostics with large brave strides. As this twenty-first century "man meets machine" reality is unfolding, several social and juristic challenges emerge for which we are in general poorly prepared. We here review social dilemmas where individual interests are at odds with the interests of others, and where artificial intelligence might have a particularly hard time making the right decision. Examples thereof are the well-known social dilemmas of autonomous vehicles and vaccination. We also review juristic challenges, with a focus on torts and product liability that are due to artificial intelligence, resulting in the claimant suffering a loss or harm. Here the challenge is to determine who is legally liable, and to what extent. We conclude with an outlook and with a short set of guidelines for constructively mitigating described challenges, with a focus on artificial intelligence in medicine.

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## Introduction

A broad body of literature anticipates that in the years to come, intelligent objects will overtake more and more jobs that people have traditionally performed, from driving, diagnosing diseases, providing translation services, and drilling for oil to even milking cows, to name just some examples [1]. In 1999, a British visionary Kevin Ashton coined the term "Internet of Things" (IoT) to describe a general network of things linked together and communicating with each other as computers do today on the Internet [2]. The connection of objects to the Internet makes it possible to access remote sensor data and to control the physical world from a distance [3]. Data communication tools are changing "tagged things" into "smart objects" with sensor data supporting a wireless communication link to the Internet [4, 5]. This means that the manufacturer can make fewer visits, reducing costs and producing less disruption and higher satisfaction for the customer [6]. Remote diagnostics, where complex manufactured products are monitored via sensors, may not, however, only be important for repairing industrial machines but also for human health, such as remote control of pacemakers [7]. The widespread use of Wi-Fi and 4G enables the communication with smart objects without the need of a physical connection, such as to control customers' home heating and boiler from their mobile or laptop. Mobile smart objects can move around and GPS makes it possible to identify their location [3]. This technology facilitates the development of so-called connected or automated cars that enable the driver automatic notification of crashes and speeding, as well as voice commands, parking applications, engine controls, and car diagnosis. It is foreseen that trucks will soon no longer need drivers, as computers will drive them, without the need for rest or sleep. Moreover, each Philips or Samsung TV comes nowadays with an application called "Smart TV," which consolidates video on demand function, the Internet access, as well as social media applications [8]. Objects are thus becoming increasingly smart and consequently autonomous. There are many implications of this in the field of medical law, in particular in relation to the mobile health apps, e.g., a smart phone that is acting as a thermometer or as a blood pressure monitor, applications that tract events, retrieve medical content, or allow patient-doctor communication.

However, autonomous objects will also cause accidents, invade private space, fail surgeries and fail to diagnose cancer, and even engage in war crimes [9]. As autonomous objects will become more and more commonplace on streets, on the skies, in households, and in medicine, their social and legal status will only grow in importance. Considering that autonomous objects are not a matter of "if" but rather of "when" such technology will be introduced, the regulatory dimension might be decisive in this respect, as is the prior identification of socially challenging situations where not only the user but also others may be adversely affected. If the activity of autonomous objects, and more generally of artificial intelligence, is not properly regulated, it will not be broadly accepted as a more efficient and safe alternative to human controlled objects or human decision-making. However, the autonomy we give to machines may render many established legal doctrines obsolete, and more importantly, affect what we judge to be "reasonable" human activity in the future.

Modern businesses and technological developments thus need to be followed by appropriate regulation that will control the associated hazards and thus enable the industry to flourish. At the same time, regulation has to leave enough flexibility so that law does not restrict technological development. This development is also extremely important in the field of medicine, where technological developments bring about a special revolution in terms of medical devices, but which must also be accompanied at the right time by appropriate regulation, in order to take advantage of the benefits that new technologies bring to patients and to avoid potential threats, either in the form of products which may harm human health or in the form of tampering with personal data and the right of individuals to confidentiality. Considering that the industry, the consumers, and patients are getting increasingly smart, smart regulatory solutions need to follow [10], establishing the right balance between safety, liability, and competition on one side and innovation and flexibility on the other. In this respect, regulatory requirements can either restrict technological development, in particular if liability for potential errors is strict or if taxation encourages human workforce, or boost it, if the standard of liability is set so that safety of computer performance is compared to the safety of certain human activity, such as driving.

In the European Union in particular, there are delicate discussions taking place on who should be competent to set the rules in this respect, Member States or EU institutions. Moreover, it is also important that this regulatory process does not bypass democratic governance principles and that industry is included in the regulatory process, as well as that self-regulation replaces legislation where possible, so that only general regulatory requirements are set by the public authorities and the market defines the technical solutions [11, 12].

In what follows, we will review social and juristic challenges of artificial intelligence in more detail, and then proceed with conclusions and guidelines as to how they might be successfully overcome.

## Social Challenges

Preceding regulation and any legal action that may follow is the identification of situations where artificial intelligence is likely to be particularly challenged when it comes to making the right decision. Some situations are of course very clear-cut. A movie recommendation system should obey parental restrictions and not serve up R rated or NC-17 rated content to a child. Likewise, an autonomous vehicle should not crash into a wall for no apparent reason. But oftentimes situations are far less clear-cut, in particular when not only the user but also others are involved.

Social dilemmas are situations where what is best for an individual is not the same, or is even at odds, with what is best for others. Already in the early 1980s, Robert Axelrod [13] set out to determine when individuals opt for the selfish option, and when they choose to cooperate and thus take into account how their actions would affect others. Of course, cooperation is a difficult proposition because it entails personal sacrifice for the benefit of others. According to Darwin's fundamental On the Origin of Species, natural selection favors the fittest and the most successful individuals, and it is therefore not at all clear why any living organism should perform an altruistic act that is costly to perform but benefits another. In Axelrod's famous tournament, the so-called tit-for-tat strategy proves to be the most successful in the iterated prisoner's dilemma game. The strategy is very simple. Cooperate first, then do whatever the opponent is doing. If the opponent was cooperative in the previous round, the strategy of tit-for-tat is to cooperative. If the opponent defected in the previous round, the strategy of tit-for-tat is to defect. This is similar to reciprocal altruism in biology.

But what about artificial intelligence, and one-off situations where the "machine" has to determine whether to act in favor of the owner (or user), or in favor of others? This was brought to an excellent point by Bonnefon et al. [14], who studied the social dilemma of autonomous vehicles. Inevitably, such vehicles will sometimes be forced to choose between two evils, such as running over pedestrians or sacrificing themselves and their passenger to save the pedestrians. The key question is how to code the algorithm to make the "right" decision in such a situation? And does the "right" decision even exist? Research found that participants in six Amazon Mechanical Turk studies approved of autonomous vehicles that sacrifice their passengers for the greater good and would like others to buy them, but they would themselves prefer to ride in autonomous vehicles that protect their passengers at all costs. Put differently, let others cooperate, i.e., sacrifice themselves for the benefit of others, but we would prefer not to.

An in essence, the same social dilemma emerges with vaccination. Old-school vaccination strategies, although admittedly easy to implement, demand that a certain fraction of the population needs to be vaccinated for herd immunity to set in. But with major progress in the structure and function of social networks [15], the same problem could be approached more systematically, by means of determining key individuals in such networks, and vaccinating them based on various metrics related to centrality, betweenness, and influence. Factors that could also be considered include temporal aspects such as traveling and commuting. A contemporary review of these developments is by Wang et al. [16]. Such advancements call for artificial intelligence, but they inevitably create a social dilemma. Will the individuals chosen for vaccination agree to this? Should they agree to being vaccinated for the good of others? Of course, the right thing to do is to agree, but the choice may nag on some of the vaccinated. Why us, why not others? The initially mentioned "old-school" strategies avoid this dilemma by essentially demanding all be vaccinated. Perhaps this is the easiest solution to the dilemma – to avoid it altogether. But easy as it may be, it neglects major progress done in many fields, including network science and digital epidemiology, and it precludes our capitalization on this progress. How many doses of vaccine could have been saved and used elsewhere for efficient immunization? How many people would not have needed to cope with some of the more adverse side effects? Would it be ethical to reward those that do get vaccinated, or even punish those that decline? We arrive at a much more complex playground of human decision-making, augmented by artificial intelligence, where a rich plethora of different strategies is at our disposal to promote cooperation [17]. But altogether, we arrive at, or rather we are faced with, the same conclusion as with the autonomous vehicles: let others cooperate and sacrifice themselves for the benefit of others, not "us."

This is nothing if not a brutally honest outcome of a social dilemma situation involving us, humans. We are social, and we are compassionate, and we care for one another, but in rather extreme situations, Darwin still has the best of us. It is important to understand that cooperation is the result of our evolutionary struggles for survival. As a species, we would unlikely survive if our ancestors around million years ago had not started practicing alloparental care and the provisioning for the young of others. This was likely the impetus for the evolution of remarkable other-regarding abilities of the genus Homo that we witness today [18]. Today, we are still cooperating, and on ever larger scales, to the point that we may deserve being called "SuperCooperators" [19]. Nevertheless, our societies are also still home to millions that live on the edge of existence, without shelter, without food, and without having met the most basic needs for a decent life [20].

So what can we expect from artificial intelligence in terms of managing social challenges, and in particular social dilemmas? We certainly have the ability to write algorithms that would always choose the prosocial, cooperative action. But who want to drive a car that may potentially kill you to save the lives of others? According to Bonnefon et al. [14], indeed not many of us. Hence, their conclusion, "regulating for utilitarian algorithms may paradoxically increase casualties by postponing the adoption of a safer technology." We thus have the knowledge and the ability to program supremely altruistic machines, but we are simply too self-aware, too protective of ourselves, to then be willing to use such machines.

This in turn puts developers and engineers into a difficult position. Which is either to develop machines that are save but very few would want to buy, or to develop machines that may kill many to save one and will probably sell like honey. Nevertheless, the situation may not be as black and white, as artificial intelligence itself may learn how best to respond. Indeed, a recent review by Peysakhovich and Lerer [21] points out that, because of their ubiquity in economic and social interactions, constructing agents that can solve social dilemmas is of the outmost importance. And deep reinforcement learning is put forward as a way to enable artificial intelligence to do well in both perfect and imperfect information bilateral social dilemmas.

Well over half a century ago, Isaac Asimov, an American writer and professor of biochemistry at

Boston University, put forward the Three Laws of Robotics. First, a robot may not injure a human being or, through inaction, allow a human being to come to harm. Second, a robot must obey the orders given it by human beings except where such orders would conflict with the first law. And third, a robot must protect its own existence as long as such protection does not conflict with the first or the second law. Later on, Asimov added the fourth law, which states that a robot may not harm humanity, or, by inaction, allow humanity to come to harm. But this does not cover social dilemmas, or situations, where the machine inevitably has to select between two evils. Recently, Nagler et al. [22] proposed an extension of these laws, precisely for a world where artificial intelligence will decide about increasingly many issues, including life and death, thus inevitably facing ethical dilemmas. In a nutshell, since all humans are to be judged equally, when an ethical dilemma is met, let the chance decide. Put in an example, when an autonomous car has to decide whether to drive the passenger into a wall or overrun a pedestrian, a coin toss should be made and acted upon accordingly. Heads it's the wall, tails it's the pedestrian. No study has yet been made as to what would potential buyers of such a car make of knowing such an algorithm is embedded in the car, but it is likely safe to say that, fair as it may be, some would find it unacceptable.

Ultimately, the problems that arise when a machine's designer directs it toward a goal without thinking about whether its values are all the way aligned with humanity's, or when the machine is designed to "SuperCooperator" standards, rather harming the user than others around, we need good regulation and a prepared juristic system to tackle the challenges. This, however, leads us to a new set of challenges, namely, those that are mainly juristic.

## Juristic Challenges

Considering its multifaceted character, artificial intelligence inherently touches upon a full spectrum of legal fields. Firstly, new technology raises issues concerning patentability, joint infringement, and patent quality [23]. New relies on communication between two or more smart objects and consumers, and it is challenging whether inventors of certain types of IoT applications will be able to overcome the test for patent eligibility. Moreover, even if they obtain patents on new methods and protocols, the patents may still be very difficult to enforce against multiple infringers [23].

Furthermore, as collecting and analyzing data is progressively spreading and an increasing number of companies and health institutions have started to exploit the possibilities arising from collection and exploitation of potential data, so that added value can be created [24], this information explosion (also called "data deluge") unlocks various legal concerns that could stimulate a regulatory backlash. While it is claimed that data has become the raw material of production, and a new source of immense economic and social value [25], Big Data has been identified as "the next frontier for innovation, competition, and productivity" [26]. This is extremely relevant for the medical sector, where research is crucially dependent upon gathering sufficient amount of relevant data. On the other hand, however, open questions range from who is entitled to use this data, can data be traded, and, if so, what rules apply to this. Health data are considered particularly delicate and therefore call for special legal protection. Yet, if the rules for collecting this data are too strict, development of new medicines and health appliances might be hindered. To prevent diminishing the data economy and innovation, "smart" regulation is needed to establish a balance between beneficial uses of data and the protection of privacy, nondiscrimination, and other legally protected values. The harvesting of large data sets and the use of modern data analytics presents a clear threat for the protection of fundamental rights of European citizen, including the right to privacy [27].

Thirdly, ICT is changing the role of the consumer "from isolated to connected, from unaware to informed, from passive to active" [28]. This process is sometimes also called "digitalization" of the consumer [29], considering that people are increasingly able to use digital services. The younger generations are grown up with digitalization and are eagerly in the forefront of adopting new technology. This could mean that the traditional presumption in consumer law that a consumer is uninformed and thus requires special legal protection no longer holds true. Nevertheless, the change is so rapid that the pre-Internet generations hardly follow the suit and new manufacturing methods bring new dangers for consumers. As the health sector greatly involves elderly generations, it is important they are included in the development and medical advances in this field while also adapting consumer law to the new challenges.

Finally, tax policy will play a very important role in the age of intelligent objects, particularly considering that human labor costs are increasing, so that it is broadly expected that automation will lead to significant job losses. As the vast majority of tax revenues are now derived from labor, firms avoid taxes by increasing automation. It is thus claimed that since robots are not good taxpayers, some forms of automation tax should be introduced to support preferences for human workers.

The focus of this section is on tort law aspects of intelligent objects, such as robots increasingly used in medicine. Tort law shifts the burden of loss from the injured party to the party who is at fault or better suited to bear the burden of the loss. Typically, a party seeking redress through tort law will ask for damages in the form of monetary compensation. Tort law aims to reduce accidents, promote fairness, provide peaceful means of dispute resolution, etc. [30].

According to the level of fault, torts fall in three general categories:

(a) Intentional torts are wrongs that the defendant deliberately caused (e.g., intentionally hitting someone).
(b) Negligent torts occur when the defendant's actions were unreasonably unsafe, meaning that she has failed to do what every (average) reasonable person would have done (e.g., causing an accident by speeding).
(c) Strict (objective) liability torts do not depend on the degree of care that the defendant used; there is no review of fault on the side of the defendant; rather, courts focus on whether harm is manifested. This form of liability is usually prescribed for making and selling defective products (products' liability).

Multifaceted character of artificial intelligence brings challenges in the field of regulating liability for damage caused by intelligent objects.

## Tort Law

In relation to automated systems, various safety issues may arise, despite the fact that manufacturers and designers of robots are focused on perfecting their systems for 100% reliability and thus making liability a nonissue [31]. It can happen that robotic technology fails, either unintentionally or by design, resulting in economic loss, property damage, injury, or loss of life [32]. For some robotic systems, traditional product liability law will apply, meaning that the manufacturer will bear responsibility for a malfunctioning part; however, more difficult cases will certainly come to the courts, such as a situation, where a self-driving car appears to be doing something unsafe and the driver overrides it – was it the manufacturer's fault, or is it the individual's fault for taking over [33].

Similar difficulties may arise in relation to remotely piloted aircrafts (so-called civil drones). In the USA, a case concerning civil drones already appeared before the courts, when US Federal Aviation Administration issued an order of a civil penalty against Raphael Pirker, who in 2011, at the request of the University of Virginia, flew a drone over the campus to obtain video footage and was compensated for the flight. First instance, the court decided that a drone was not an aircraft, while the court of appeal ruled to the opposite. The cases ended in 2015 with a settlement of $1.100.

The starting point for examining "computer-generated torts" [30] is – or at least should be – that machines are, or at least have the potential to be, substantially safer than people. Although media broadly reported on the fatality involving Tesla's autonomous driving software, it is generally accepted that self-driving cars will cause fewer accidents than human drivers. It is stated that 94% of crashes involve human error. Moreover, medical error is one of the leading causes of death [34]. Consequently, artificial intelligence systems, like IBM's Watson, that analyze patient medical records and provide health treatment do not need to be perfect to improve safety, just better than people.

If accident reduction is in fact one of the central, if not the primary, aims of tort law, legislators should adapt standards for tort liability in case of harm caused by intelligent objects in such a way that law encourages investment in artificial intelligence and thus increases safety of humans. Most injuries people cause are evaluated under a negligence standard, where a tortfeasor is liable in case of unreasonable conduct. If her act was not below the standard of a reasonable person, the harm is thought to be pure matter of chance for which no one can be held accountable. When computers cause the same injuries, however, a strict liability standard applies, meaning that it does not matter whether someone is at fault for the harm caused or not. This distinction has financial consequences and discourages automation, because computer controlled objects incur greater liability for the producer or owner than people. Moreover, if we want to improve safety through broader use of automation, current regulation has the opposite effect.

As currently product's liability is strict, that is independent of fault, while human activity is measured according to the standard of a reasonable person, legal scholars claim that in order to incentivize automation and further improve safety, it is necessary to treat a computer tortfeasor as a person rather than a product. It is thus defended that where automation and digitalization improve safety, intelligent objects should be evaluated under a negligence standard, rather than a strict liability standard and that liability for damage would be compared to a reasonable person [30]. Additionally, when it will be proven that computers are safer than people, they could set the basis for a new standard of care for humans, so that human acts would be assessed from the perspective what a computer would have done and how using the computer humans could avoid accidents and the consequent harm.

Nevertheless, jurists broadly defend strict liability for intelligent objects or in some respects even broader than currently foreseen, particularly in terms of the bodies involved that could be held liable – from the producer, distributer, seller, but also the telecommunication provider, when, for example, the accident was caused due to the lack of Internet connection. At the European Union level, considering that the Product Liability Directive (85/374/EEC) does not apply to intangible goods, inadequate services, careless advice, erroneous diagnostics, and flawed information are not in themselves included in this directive. It is nevertheless important that when damage is caused by a defective product, used in the provision of a service, it will be recoverable under the Product Liability Directive [35], regulating strict liability test (see also EU Court's decisions on Cases C-203/99, Veedfald, and C-495/10, Dutrueux). Many acts by robots used in medical procedures will thus come within the ambit of this Directive, including software that is stored on a tangible medium. This means that in case the consumer, whose car causes an accident due to malfunctioning software, or a patient, who suffers the wrong dosage of radiation due to a glitch in the consumer software, may bring a claim under the Product Liability Directive against the producer of software [36]. When software is supplied over the Internet (so-called non-embedded software), however, potential defects do not fall within the scope of this directive, and a specific directive on the liability of suppliers of digital content is needed.

As far as product safety regulation is concerned, Article 2(1) of Directive 2001/95 on general product safety defines the reach of the product safety regime to include any product intended for consumer use or likely to be used by consumers "including in the context of providing a service." Nevertheless, this does not cover safety of services [37]. It is hence for the EU Member States to adopt legislation setting safety standards for services, which is not the preferred solution in times of extensive technological development. Analysis of the suitability of existing safety regulations is, for example, needed in relation to software-based product functions that can more and more be modified after delivery.

It is also essential to understand, however, that the more autonomous the systems are, the less they can be considered simple tools in the hands of other actors and that overly stringent regulation, expecting perfection instead of acceptable robot behavior, may discourage manufacturers from investing money in innovations, such as self-driving cars, drones, and automated machines [38]. Smart regulation is thus again needed, taking into account all the involved stakes.

While intelligent objects are imitating the work of humans, as well as their legal liability, the question also arises, whether robots will be entitled to sue, be sued, and also be engaged as witnesses for evidence purposes. Currently, it is not possible to sue a robot as they are considered property, just like an umbrella. Intelligent objects do not have legal identity and are not amendable to sue or be sued. If a robot causes harm, the injured party have to sue its owner or its manager. However, comparing the robots to companies, for procedural purposes companies were also not treated as separate legal entities from the human owner for a long time in history [30]. Nevertheless, over time legislators and courts abandoned the model of treating corporations solely as property and awarded them an independent artificial personality that allowed them to sue and be sued. In respect of the robots, it will thus need to be established whether they are more like an employee, a child, an animal, a subcontractor, or something else [39].

Related to this, 3D printing turns traditional service providers into manufacturers, making the relevant legislation applicable also to them. Specific regulatory challenges in this respect arise in the medical field, where 3D printing brings the ability to print replacement body parts, organs, bones, and even skin. In this situation, medical doctors and dentists provide a bundle of services – besides the ordinary patient treatment, they make a digital design of the implant and printing the implant in their offices with a 3D printer. Each device is designed and manufactured based on a patient's medical image data, which ensures a perfect fit with his unique anatomy. Low price and high functionality 3D printed medical devices may save lives and have important consequences on the social security systems; however, the regulation needs to contemplate the risks involved and maintain patient safety standards. Under current EU Medical Devices Directive (93/42/EEC), 3D printed medical devices fall in the category of "custom-made medical devices," similar to orthopedic shoes that are not strictly regulated. In relation to 3D printed medical implants (such as prosthetic limbs, hips, or teeth), however, it is widely accepted that they require more stringent quality requirements to address the needs and potential risks [12]. Nevertheless, it seems that EU regulators are supporting the status quo, considering that the Explanatory Memorandum to the future Medical Devices Regulation states that "Manufacturers of medical devices for an individual patient, so called 'custom-made devices', must ensure that their devices are safe and perform as intended, but their regulatory burden remains low." What is thus needed to assure patients' safety is to subject the manufacturers of higher risk 3D custom printed devices to a conformity assessment and to require CE marking of the input material (in the same way as materials that are currently used for creating a dental filling). Keeping current uncertainties might lead to different national interpretations of risk related to 3D printed medical devices and a fragmentation of the internal market, thus harming both the consumers and the business.

## Conclusions and Guidelines

Artificial intelligence certainly has the potential to make our lives better, especially so in medicine. It is in fact already happening, but as the adoption of any new technology, the welcoming of artificial intelligence into our lives is not without challenges and obstacles along the way. We have here reviewed some of the more obvious social and juristic challenges, for which we are nevertheless not well prepared. In particular, we have reviewed social dilemmas as traditionally demanding situations, in which we find ourselves torn between what is best for us and what is best for others around us and for the society as a whole. It is difficult enough for us to do the right thing in such situations, and now we have to essentially build machines that will, with more or less self-training, be able to do the right thing as well. The essential question is whether we expect artificial intelligence to be prosocial, or whether we expect it to be bent on satisfying an individual, the owner, or the company of which property it is. The meme "is my driverless car allowed to kill me to save others?" brings the dilemma to the point. It is relatively easy and noble to answer yes without much thought, but who would really want a car that could potentially decide to kill you to save other strangers? Research done thus far indicates that not many, depending of course on some details as to who might the passengers be and how many others would potentially be saved. But regardless of these considerations, one of such cars is an unlikely entry on the top of any wishing list. There are of course many similar situations that have the same hallmark properties of a social dilemma, like whether or not we should be vaccinated. If a large enough fraction of a population says no, then we will lose herd immunity, and long forgotten diseases will surely return. To be vaccinated, on the other hand, is a difficult decision for some because of possible side effects of the vaccine.

Therefore, the answer to the question whether we want artificial intelligence to be prosocial or not certainly has no easy or universally valid answer. As is so often the case, it depends on the situation, and also on the juristic circumstances either decision would create.

As industry and technology are changing hastily, all the involved stakeholders have to utterly consider whether the society can adjust to this development equally fast and whether people develop the necessary technological skills. While some commentators claim that EU may adopt the legislation concerning digitizing industry too fast, since it is not yet known how exactly smart industry will develop, others call for immediate response to avoid distinct legislative activities by individual states. Robotization in many aspects makes sense and it is thus reasonable that it gets regulatory support. However, this does not mean that it is always necessary to rush into new regulation, when amending existing legislation would suffice.

In reviewing the social and juristic challenges of artificial intelligence in medicine, we propose the following set of guidelines:

(i) Improving the digital skills of the workforce for medical professions requires public measures with pertinent financial support.
(ii) Strict liability for the marketing of autonomous healthcare services and medical diagnostics discourages investment in this field, thereby decreasing the potential of robotization to make these services safer and more accessible and affordable. This can be considered as the main regulatory paradox with respect to the introduction of artificial intelligence into new areas of application, including medicine.
(iii) Patients' safety needs to be ensured by subjecting the manufacturers of higher risk 3D custom printed devices to a conformity assessment and to require CE marking of the input material (in the same way as materials that are currently used for creating a dental filling).
(iv) Before autonomous services enter into medicine, liability issues need to be clearly set by legislation, so that it is not left to the user to search and prosecute the liable entity in courts.
(v) Obligatory black box to record the functioning of the intelligent object and help ascertain liability in cases of potential faults.
(vi) No fine print. The user should be informed how the artificial intelligence will react in critical situations, as well as be made accurately aware of all drawbacks, possible errors, misdiagnosis, and things that can go wrong when relying on it.

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