

PHD IN

"SOCIAL THEORY, DIGITAL INNOVATION AND PUBLIC POLICIES" XXXV CYCLE

DOCTORAL THESIS IN:

"Ethical and Legal Challenges of AI-Based Healthcare: The Responsibility of the Physician and Health Administration"

Medical liability is an important branch of law in which, in the first place, the expectations of patients' recovery are compared with the doctor's duty to provide them with adequate and possibly decisive care.

Unfortunately, medicine is not an exact science, so it happens that the patient may not always be fully satisfied with the care he has received: it is precisely in this case that the law comes into play, with the first objective of preventing dangerous situations and the second objective of guaranteeing compensation for the damage caused by that doctor who has not acted diligently, prudence, competence, and by the health company that has disregarded the contractual obligations concluded with the patient.

One of the main issues that animate the debate around medical liability, object of the thesis study, is that relating to the use of Artificial Intelligence tools in medicine, these are engineering, biomedical, mechanical or IT third party elements, which support the daily work of the doctor.

In our legal system, the identification of the person responsible becomes even more complex if we think of the legislative changes that have occurred in health matters, in fact there has been a transition from contractual liability for the doctor to liability, brought back by doctrine and jurisprudence, in the channel of non-contractual liability.

In the health system, the use of artificial intelligence is based on virtuous results.

This type of technology is able to give a percentage of risk to develop, based on certain results, certain diseases, using some characteristics of patients already hospitalized.

It should be remembered that medical activity is based on the interpretation of the man's narrative, physical examination and clinical, therapeutic and diagnostic evaluations of his body.

The anamnesis is the true fulcrum of the health service as it is aimed at collecting personal information to investigate the patient's malaise.

The problem arises from the fact that medical science is not only based on scientific evidence but also on the specificity of the case and on the patient's narrative.

Human-machine interaction in actions/omissions poses liability problems in case of damage to third parties. Responsibility, in fact, in these cases is not easy to solve. The problem is given by the fact that this new technological approach brings with it new realities that can hardly find a normative reference, even analogically, in the civil code.

The starting point of this thesis study is given by the dichotomy that has been created between artificial intelligence and human intelligence. At the end of the research carried out, it will be understood that this is a false contrast.

Anyone who thinks that an algorithm can override the advice of a doctor is mistaken. Technology is also fallible, and its supervision will necessarily be entrusted to man.

In order to help in the health sector, an AI algorithm must guarantee performance equal to or superior to that of a human being in the specific tasks assigned to it.

But many of the decisions that doctors make on a daily basis are incredibly complex and require a much more complex approach than that offered by the use of artificial intelligence in data processing.

We could refer to "the autonomy of artificial intelligence" trying to identify the quantum of "contribution" of the human being: to understand when it is minimal and therefore artificial intelligence is completely autonomous even in its updates or when human intervention is essential.

In the context of hospitals, however, artificial intelligence almost always needs the human contribution because it is through that contribution that the final result is reached. Here then the need will arise, in order

not to charge non-existent responsibilities, to analyze the responsibility, if necessary separating the various profiles.

To realize the enormous potential of AI to transform healthcare for the better, AI stakeholders, including AI leaders, physicians, patients, ethicists, and legislators, need to engage in the ethical and legal debate about how AI is successfully implemented in practice.

The reconstruction of the responsibility that this thesis study is committed to achieving will proceed through jurisprudential and doctrinal orientations and the reconstruction of the strategies concerning the ethics and law of AI in health in the European Community.

Although we talk about artificial intelligence systems in an all-encompassing way, they are also systems or products that have significant differences. Just think of the fact that the surgical robot is used by a subject who has a specific competence and professional training, while the driverless car could in the abstract also be driven by a person with reduced sensory abilities, to realize the differences existing in the field of artificial intelligence.

In this sense, we must ask ourselves to what extent a regulatory solution that embraces all types of artificial intelligence, without making specific differentiations due to their specific characteristics and the sector where they impact, represent the preferable solution.

There is currently no fully harmonised EU regulatory framework for liability in AI and robotics such as care and medical robots. However, Europe has taken several steps to address the issue of ethics and responsibility. It is difficult to establish whether the proposals made within the European Union are able to adequately respond to the multiplicity of problems caused by advanced robotics. They certainly have the merit of providing for the adoption of new legal rules for artificial intelligence.

This is an essential path in order to provide certainty both to operators in the sector and to users of smart products and advanced artificial intelligence systems, with the introduction of an objective liability regime for those subjects who seem better able to contain risks and avoid or decrease their negative consequences.