Liability arising from the use of Artificial Intelligence for the purposes of medical diagnosis and choice of treatment: who should be held liable in the event of damage to health?

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1. Chapter I: Introduction

1.1. Background

Research developments within the scope of artificial intelligence (hereinafter also referred to as "AI") are responsible for the creation of ground-breaking technology. At this point, the scientific community knows and accepts that AI technology has the potential to surpass human intellectual capacity, reaching potentialities that humans may not be able to control neither understand. Considering that AI technology has been overcoming its initial potentialities[1], the risks comprised in it have also increased. In fact, AI technology relies on machine learning (hereinafter also referred to as "ML") which provides algorithms with the capability of making its own decisions and provides innovative and unforeseen solutions, circumstance that will expand the potential hazards of relying on AI technology.[2] [3] [4]

Although ML/AI technology might be applied in several different sectors (banking, financing, etc.), the limitation of this work shall be the analysis of the applicability of this technology on healthcare, given that as acknowledged by Jeff Bezos[5] "*healthcare is going to be one of those industries that is elevated and made better by machine learning and artificial intelligence*". [6] [7]

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[1] Holmes, Mark *Are We Underestimating the Impact of AI?*, available on http://www.lawtechnologytoday.org/2017/06/the-impact-of-artificial-intelligence/

[2] Machine learning "*rather than pushing the commands by programmer regarding how to solve; it explains how to proceed towards learning to solve the problem on its own. (…) it works by learning to identify patterns in data and then make predictions from those patterns*" – *Cf.* Jha, Vishakha *Machine Learning Algorithm - Backbone of emerging technologie*s, available on http://www.lawtechnologytoday.org/2017/06/the-impact-of-artificial-intelligence/

[3] Elman, Jeremy and Castilla, Abel *Artificial intelligence and the law*, available on https://techcrunch.com/2017/01/28/artificial-intelligence-and-the-law/

[4] Although machine learning can be divided in three categories: supervised, unsupervised and reinforcement, the current work will not focus on the differences between each type of machine learning. - *Cf.* Ray, Sunil *Essentials of Machine Learning Algorithms (with Python and R Codes)*, available on https://www.analyticsvidhya.com/blog/2017/09/common-machine-learning-algorithms/

[5] Founder of Amazon.

[6] Torres, Juan *Amazon Is Really Serious About Making Healthcare a Part of Its Future*, available on https://futurism.com/amazons-healthcare-plans/

[7] It is estimated that "*86 percent of health care provider organizations, life science companies and technology vendors currently use some form of AI with the current average spend being $38 million per company*" - *Cf.* Chung, Jason *What Should We Do About Artificial Intelligence in Health Care?*, available on https://ssrn.com/abstract=3113655

Examples of the use of eHealth technology[8] are: medical records, health assistance, medication management, organization of patient routes, or solutions to improve diagnosis and treatment plans hence enable more informed medical decisions on grounds of electronic data availability. In view of the fact that better health care strongly relies on the ability to achieve accurate diagnosis and provide personal treatments that meet the patient's profile, this thesis will focus on AI tools used for the purposes of medical diagnosis and choice of treatment.[9]

Examples of AI technology in the scope of clinical diagnosis are **DeepMind Health**, which is being developed on basis of ML algorithms, in order to proficiently detect differences between cancerous and healthy tissues[10], or **Medical Sieve**[11] which is deemed as the next generation of cognitive assistant designed to assess radiology images in order to detect medical conditions in a faster and reliable way.[12] **Microsoft** is also developing[13] the **Project Hanover** in order to (by

[8] Which, as defined by the World Health Organization consists on the *application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives*, available on http://www.who.int/health-technology-assessment/about/healthtechnology/en/

[9] ML technology is also being developed in view of empowering patients to control their health conditions on their own, *i.e.* without resorting to medical follow-up. This field of development is of extreme relevance since it envisages health care optimization by reducing unnecessary overall health costs. Micro biosensors and devices – such as mobile apps – are the main used technology to achieve this purpose. More than merely enabling patients to monitor their health condition, technology of this nature also has great potential in the scope of diagnosis. App solutions like the **Somatix** software – "*a data-analytics B2B2C software platform company whose ML-based app uses "recognition of hand-to-mouth gestures in order to help people better understand their behavior and make life-affirming changes", specifically in smoking cessation*" and **Skinvision –** a skin cancer detection app **-** are examples of what has been said. – *Cf.* Faggella, Daniel *Applications of Machine Learning in Pharma and Medicine* available on https://www.techemergence.com/machine-learning-in-pharma-medicine/

Babylon also created an app which offers "*medical AI consultation based on personal medical history and common medical knowledge. Users report the symptoms of their illness to the app, which checks them against a database of diseases using speech recognition. After taking into account the patient's history and circumstances, Babylon offers an appropriate course of action*." Moreover, this app provides medical follow-up by reminding its users to take their medication and by monitoring their health evolution. – *Cf.* The Medical Futurist, *Artificial Intelligence Will Redesign Healthcare* available on http://medicalfuturist.com/artificial-intelligence-will-redesign-healthcare/

Another exciting solution in the scope of diagnosis is **Bili Screen**, an app "*designed to help users identify pancreatic cancer early with an algorithm that analyzes selfies*" – *Cf.* Shailin, Thomas *Democratized Diagnostics: Why Medical Artificial Intelligence Needs Vetting* available on https://www.linkedin.com/pulse/democratized-diagnostics-why-medical-artificial-needs-shailin-thomas/?lipi=urn%3Ali%3Apage%3Ad_flagship3_profile_view_base%3BjQEvkTluSpaxaQRjqZ7iiQ%3D%3D and Shailin, Thomas *Artificial Intelligence, Medical Malpractice, and the End of Defensive Medicine* available on http://blogs.harvard.edu/billofhealth/2017/01/26/artificial-intelligence-medical-malpractice-and-the-end-of-defensive-medicine/

Despite the relevance of all these AI tools in the scope of medical diagnosis and choice of treatment, the same are out of the scope of this thesis considering that we'll focus on AI technology which is not used directly by the patient but by a clinician.

[10] Faggella, Daniel *op cit.*

[11] AI algorithm developed by IBM.

[12] The Medical Futurist, *op cit.*

[13] In collaboration with the Knight Cancer Institute.

resorting to ML) "*develop AI technology for cancer precision treatment, with a current focus on developing an approach to personalized drug combinations for Acute Myeloid Leukemia (AML).*"[14] The most relevant example in this realm is **IBM Watson** which enables physicians to provide better evidence-based treatment. The algorithm comprised in this technology analyses "*the meaning and context of structured and unstructured data in clinical notes and reports that may be critical to selecting a treatment pathway. Then by combining attributes from the patient's file with clinical expertise, external research, and data, the program identifies potential treatment plans for a patient*."[15] This piece of AI and its successor **Watson for Oncology** - which targets cancer patients - provide access to patient medical information and relevant medical knowledge in a simple and smooth way, therefore, optimizing the selection of personalized treatment options[16] [17].

Under MEDDEV 2.1/6 July 2016[18] (hereinafter also referred to as MEDDEV) technology of this nature is nominated Decision Support Software (hereinafter also referred to as "DSS" or clinical decision support software "CDSS") and defined as "*computer based tools which combine medical knowledge databases and algorithms with patient specific data (…) intended to provide healthcare professionals and/or users with recommendations for diagnosis, prognosis, monitoring and treatment of individual patients*"[19].

Given the sensitiveness of this particular field of activity, it is of use to fully assess if the legal framework is prepared to provide appropriate answers to the eventual negative effects of this technology[20] from a liability point of view, in order to ensure accountability in this realm. As it

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[14] *Ibidem.*
[15] *Ibidem.*
[16] Faggella, Daniel *op cit.*
[17] Resorting to the technology comprised in IBM Watson, IBM also launched Watson for oncology which focuses on the diagnosis and choice of treatment of cancer patients – *Cf.* Chung, Jason *Hey Watson, Can I Sue You for Malpractice? Examining the Liability of Artificial Intelligence in Medicine* available on https://ssrn.com/abstract=3076576
[18] Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices
[19] MEDDEV 2.1/6 July 2016 distinguishes between: **software** *"(…) a set of instructions that processes input data and creates output data*''; **standalone software** "*software which is not incorporated in a medical device at the time of its placing on the market or its making available*"; **expert function software** "*software which is able to analyse existing information to generate new specific information according to the intended use of the software*", and **software as a medical device** "*software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device*".
[20] Greenberg, Anastasia *Artificial Intelligence in Health Care: Are the Legal Algorithms Ready for the Future?* available on https://mjlh.mcgill.ca/2017/10/06/artificial-intelligence-in-healthcare-are-the-legal-algorithms-ready-for-the-future/

will be seen, IBM Watson has been the main target of debates concerning liability arising from the use of AI technology in the health sector. This technology has indeed triggered the debate over how misdiagnosis and wrong plan treatments (chosen in light of the output of the algorithm) must be addressed under the liability regimes currently in force.

The need to define liability rules in the scope of eHealth was indeed acknowledged already in 2004 by the European Commission (hereinafter also referred to as "EC") initiative *e-Health technology*[21] and afterwards by the *Digital Single Market Strategy* launched by the European Commission in May 2015.[22] In fact, in the scope of the e-Health technology initiative, the EC stated that "*certainty of e-Health product and service liability within the context of existing product liability legislation would be beneficial. Information and communication technology developments should contribute to a safer working environment for practitioners; and greater legal certainty with regard to e-Health services within the context of freedom of movement of people, goods and services is increasingly necessary*"[23]. More recently, the European Parliament adopted on February 16th of 2017 the Parliament Resolution no. 2015/2103(INL) under the heading "*Civil Law Rules on Robotics*" (hereinafter also referred to as "PR 2015/2103"), as a possible response to the many legal and complex challenges that lie ahead. In whereas AB. it is stated that new civil liability rules are necessary[24] and concerns regarding the use of robotics in health sector[25] are expressly addressed in points 33 to 36 in which the

[21] Commission of the European Communities Communication from the Commission to the Council, the European Parliament, the European Economic and Social committee and the Committee of the Regions *e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area* {SEC(2004)539} Brussels, 30.4.2004 COM (2004) 356 final, available on https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52004DC0356&from=EN

[22] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - *A Digital Single Market Strategy for Europe - COM(2015) 192* final available on https://ec.europa.eu/digital-single-market/en/news/digital-single-market-strategy-europe-com2015-192-final

[23] Commission of the European Communities *op cit.* p 19

[24] Whereas AB. of the PR 2015/2103 mentions that "*whereas the more autonomous robots are, the less they can be considered to be simple tools in the hands of other actors (such as the manufacturer, the operator, the owner, the user, etc.); whereas this, in turn, questions whether the ordinary rules on liability are sufficient or whether it calls for new principles and rules to provide clarity on the legal liability of various actors concerning responsibility for the acts and omissions of robots where the cause cannot be traced back to a specific human actor and whether the acts or omissions of robots which have caused harm could have been avoided".*

[25] It must be clarified that whenever the wording "*robotics*" is used in this thesis, the same encompasses the AI tools (for medical diagnosis and choice of course of treatment) here under analysis, considering that regardless of its specific features, a robot is an object in which a certain behavior was inscribed – *Cf.* Palmerini, E.; Bertolini, A., Battaglia F.; Koops, B..; Arnevale, A.; Salvini, P. *RoboLaw: Towards a European framework for robotics regulation* available on https://www.sciencedirect.com/science/article/pii/S0921889016305437

need to "*safeguard and protect patients' health*" is stressed.[26] One of the European countries which seems to be fully aware of the need to rethink classical liability rules in the scope of AI health solutions is the United Kingdom (hereinafter also referred to as "UK"), which conducted a deep analysis on the subject by bringing to the table all the stakeholders involved: academia, legal professionals, technology developers and manufacturers, health care institutions, etc. In the final report it is mentioned that action is needed in four key areas "*a) Legal liability – the basis upon which legal liability can be established in respect of an artificial intelligence technology; b) Issues of causation and accountability – the basis for determining which party is to be considered liable (or is prepared to accept liability) for artificial intelligence, which does not perform as expected; c) Use of AIs in seeking to perform or discharge existing legal obligations; and d) Legal status – the extent to which a legal status should be afforded to an AI*."[27]

Despite the individual countries and European Union (hereinafter also referred to as "EU") efforts described *supra*, there is not yet, a piece of EU legislation which addresses liability arising from the use of AI for healthcare purposes. Therefore, *a priori*, these situations will be governed by each Member States' rules on law of contracts or torts, in accordance with the specificities of the case.[28] In true, the legal and scientific communities are still discussing if liability arising from the use of AI should be regulated or just being subject to the laws that Member States currently have in place, such as privacy and data protection, consumer protection, medical devices, civil liability or criminal liability laws, etc.

In fact, as clarified by Andrea Bertolini "*If, then, a notion of robot is to be elaborated (…) it may be as follows: a machine which (i) may either have a tangible physical body, allowing it to interact with the external world, **or rather have an intangible nature—such as a software or program**, (ii) which in its functioning is alternatively directly controlled or simply supervised by a human being, or may even act autonomously in order to (iii) perform tasks, which present different degrees of complexity (repetitive or not) and may entail the adoption of non-predetermined choices among possible alternatives, yet aimed at attaining a result or provide information for further judgment, as so determined by its user, creator or programmer, (iv) including but not limited to the modification of the external environment, and which in so doing may (v) interact and cooperate with humans in various forms and degrees*.", *Cf.* Bertolini, Andrea *Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules* available on https://www.tandfonline.com/doi/abs/10.5235/17579961.5.2.214 emphasis added.

[26] PR 2015/2103

[27] UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume - House of Lords (UK)* - Statement of Cooley (UK) LLP (written evidence AIC0217) *available on* https://www.parliament.uk/documents/lords-committees/Artificial-Intelligence/AI-Written-Evidence-Volume.pdf

[28] Andoulsi, Isabelle and Wilson, Petra *Understanding Liability in eHealth: Towards Greater Clarity at European Union Leve*" in George, Carlisle; Whitehouse, Diane and Duquenoy, Penny *eHelath: Legal, Ethical and Governance Challenges*, Springer 2013

Another element to be borne in mind is that products and services delivered in the scope of health care are typically highly regulated considering the aim to ensure that they are safe and efficient, as well as to guarantee that the data generated through eHealth tools is accurate and reliable.[29] In that sense, actors involved in the health sector are normally bound by hard law regulation. However, legislators cannot ignore the fact that excessively rigid regulation and disproportional liability regimes over developers and manufactures might stifle innovation and development of AI for health care purposes[30], and that heavy liability regimes upon the physicians using the technology might compromise the acceptance of CDSS by the medical community. Therefore, the drafting of an efficient liability regime requires a "*right balance between consumer protection and industrial profitability*"[31] which means that the development of technology must be stimulated without jeopardizing patient's safety.

Ascertaining and clearly allocating liability in this realm is a subject that must be brought to the table considering that AI technology is becoming crucial in the medical field. Firstly, the financial costs connected with health care play a huge share in countries' economies all over the world. This is the reason why there is an obvious interest in adopting technologies that allow costs' reduction by resorting to tools which save physician's time when diagnosing patients or prescribing treatments. Furthermore, these DSS tools have the potential to reduce or fully eliminate costs arising from misdiagnosis; costs related to the performance of unnecessary additional medical tests; or costs related to the prescription of treatments that could have been prevented if an accurate diagnosis had been made at an earlier stage of the disease.[32] Moreover, it is of general interest to develop technology that enables health care institutions to provide the best care and medical solutions possible to patients, enhancing public health and safety.[33] Advanced technology might, indeed, allow patients to receive more efficient treatment plans in

[29] Tsang, Lincoln; Kracov, Daniel A.; Mulryne, Jacqueline; Strom, Louise; Perkins, Nancy; Dickinson, Richard; Wallace, Victoria M. and Jones, Bethan *The Impact of Artificial Intelligence on Medical Innovation in the European Union and United States*, available on https://www.arnoldporter.com/~/media/files/perspectives/publications/2017/08/the-impact-of-artificial-inteelligence-on-medical-innovation.pdf

[30] Petit, Nicolas *Law and regulation of artificial intelligence and robots: conceptual framework and normative implications*, available on https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2931339

[31] Lenardon, Joao Paulo de Almeida *The regulation of artificial intelligence* available on http://arno.uvt.nl/show.cgi?fid=142832

[32] Marr, Bernard *The Amazing Ways How Artificial Intelligence And Machine Learning Is Used In Healthcare*, available on https://www.forbes.com/sites/bernardmarr/2017/10/09/the-amazing-ways-how-artificial-intelligence-and-machine-learning-is-used-in-healthcare/#71eee5dc1c80

[33] *Ibidem*

a timely manner, which will lead to better survival and remission rates.[34] In fact, CDSS are an example of the fact that current societies are moving from a classical health paradigm to the adoption of e-health solutions by resorting to information and communication technologies (ICT) for medical purposes[35], circumstance that accentuates the need to discuss liability in this realm.

1.2. Research Question

In light of the background described *supra* this thesis will focus on ***Liability arising from the use of Artificial Intelligence for the purposes of medical diagnosis and choice of treatment: who should be held liable in the event of damage to health?*** It will be pondered if the current legal framework is suitable to address situations in which damage to health arises when a physician follows the output of an AI tool for diagnosis or choice of treatment purposes.

Liability arising from the circumstances described will be examined under three possible legal paths: current medical malpractice rules; under the general defective's products rules applicable to medical devices; or by the putative adoption of a new liability framework, under which the technology will be held liable itself.

1.3. Significance and Chapters Overview

As mentioned *supra* there is no legal framework which specifically addresses liability arising from the use of AI for the purposes of medical decision-making, being still under discussion if rules of these nature should be drafted or not. The relevance of conducting a research on liability arising from the use of AI for the purposes of diagnosis and choice of course of treatment in the context of e-health rests with the fact that if, on the one hand, proper liability rules (governing

[34] *Ibidem*

[35] In line with what has been said, the McKinsey Global Institute conducted a study on the U.S.A. health care system, in which was concluded that by applying big data strategies which typically rely on machine learning technology *"to better inform decision making could generate up to $100 billion in value annually across the US health-care system, by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.*"- *Cf.* Cattell, Jamie; Chilukuri, Sastry and Levy, Michael *How big data can revolutionize pharmaceutical R&D*, available on https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/how-big-data-can-revolutionize-pharmaceutical-r-and-d

liability and allocating liability among agents) must be implemented in order to avoid hazardous, irresponsible and harmful practices. On the other hand, there is an undeniable and permanent need of stimulating and nurturing scientific development in this respect as well as to stimulate the use of these technologies among the medical community. An aim that might be compromised by placing an excessive liability burden upon technology creators or upon the users. In summary, it must be warranted that technology makers will live up to the responsibility of designing safe technology for medical purposes, and that users will make use of this tools in a conscious and critical way, without jeopardizing or risking the development of the technology or the acceptance of the same within the medical community. Rules providing for clear liability allocation are needed, but a fair and appropriate balance must be struck between all the interests involved herein.

Within Chapter II it will be assessed if liability arising from the use of AI for medical diagnosis and choice of treatment shall be determined under medical malpractice rules, hence, if the medical actor using the AI technology should be held liable. The specificity of this reality rests with the fact that the use of DSS encompassing AI involves two entities - the physician and the machine - since medical decisions are taken by the physician in light of the outcome provided by the technology. Therefore, liability should not just rest with the Doctor, nor just with the machine. If Doctors are simply held liable, there's a risk of the medical community not embracing DSS AI technology which is proven to have higher accuracy rates than humans, compromising the achievement of more accurate diagnosis and more informed/knowledgeable treatment decisions. If, on the other, liability is merely allocated to the technology itself or its manufacturer, Doctors might merely rely on the outcome of the CDSS tool instead of making a critical and empirical assessment of it; phenomenon which has been called defensive medicine. In other words, the level of autonomy of the machine shall be and the margin of intervention of the physician resorting to the technology shall be discussed, in order to determine if the damage caused to the patient must be addressed under medical malpractice rules, which apply when physicians do not comply with the standard of care owed to patients. Emphasis will be provided to the physicians' duty of care when using DSS technology and to the possibility of medical institutions being held liable under vicarious liability.

In a second stage, focus will be given to the qualification of CDSS tools, considering that the complex features of the AI incorporated in CDSS bring uncertainty regarding its qualification.

Firstly, it is discussed if due to the dual nature of hardware and software, liability arising herein should be assessed under the defective products' rules. Secondly, it is discussed if these tools should be qualified as a mere product or as the provision of a medical service. Furthermore, it is debated if the same must be deemed a medical device, therefore, be subject to medical devices' legislation. This question is of importance considering that if the AI tools under assessment are deemed medical devices, the same will be subject to the Defective Products Directive, Council Directive 85/374/EEC of 25 July 1985 concerning liability for defective products (hereinafter also referred to as "DPD") which provides for a strict liability regime upon manufacturers. Therefore, if one concludes that given its medical purpose DSS should be qualified as a medical device, the manufacturer will be subject to more severe rules under the defective's product liability regime, hence, more vulnerable to liability claims. The suitability of medical devices laws to DSS solutions is, however, arguable. CDSS tools are quite more complex than classical medical devices due to the black box nature of the AI technology incorporated in them, and due to the fact that these solutions imply the intervention and connection between many actors: the physician who uses the technology, as well as all the industrial agents involved in its design, development, manufacture and data input. The rationale behind such discussion rests with the fact that it might not be fair to make the manufacturer of the technology strictly liable (under the DPD) for damages to health arising from the use of a CDSS tool, when the manufacturer nor the agent in charge of the coding component of the technology will be able to identify or explain the error occurred.

In Chapter IV it will be assessed the possibility of granting personhood to DSS systems in order to hold the technology liable itself. The relevance of such sub research question is explained by the fact that if liability is directly allocated to the AI, Courts will no longer face the difficult task to ascertain who the liable agent is. On the other hand, making AI liable itself means *a priori* deeming the manufacturer or the technology designer/ developer directly liable, regulatory option which might slow down the progress of technology of this nature, since manufacturers will likely fear being easily subject to liability claims, which naturally represent a heavy financial burden. Under this sub research an assessment will be made on the merits and limitations of providing personhood to AI used for the purposes of diagnosis and choice of treatment as a mean to allocate liability.

At last, conclusions will be drafted in response to the questions raised and some possible regulatory solutions in this realm will be suggested.

1.4. Methodology

The research questions mentioned above will be assessed under a public interest framework, in light of a descriptive/state of the art approach which entails the assessment of primary and secondary sources. Without prejudice to the choice of a doctrinal legal research, when relevant, empirical knowledge will be taken is consideration.

2. Chapter II: Liability arising from the use of AI for the purposes of medical diagnosis and choice of course of treatment under malpractice

2.1. Liability in the scope of Clinical Decision Support Software

AI for the purposes of medical diagnosis and choice of treatment is becoming a common tool in the hands of physicians all over the world. More than merely relying on their personal medical knowledge, Doctors are now assisted by machines (as IBM Watson, Watson for Oncology or Deep Mind) which assess the clinical data of the patient in light of the medical data to which the algorithm was fed, providing more accurate diagnosis and choices of treatment. Although the benefits behind the use of this technology are unquestionable, it is also unquestionable that this eHealth paradigm represents a disruption of the classical relationship between the parties involved in the delivery of health care services. If, before, a patient who suffered harm or damage in the course of a diagnosis or treatment prescribed by a physician would easily identify the agent against who to take action (the Doctor or the medical institution under which the Doctor provided the health care services), today with the use of AI tools, such line became blurry considering that other than the Doctor there is another entity which might have caused the harm, *i.e.*, the algorithm's output which the physician followed.[36] The reality described brings several questions regarding allocation of liability. Namely, it shall be discussed if the traditional concepts of medical negligence and standard of care suit this new reality. In that sense, it will be assessed herein if malpractice rules must be shaped and adapted[37] or if the intervention of CDSS disrupts the relationship between the practitioner and patient so severely[38] that malpractice rules should be disregarded and disputes arising in this scope must be framed exclusively under product's liability regimes.

[36] Andoulsi, Isabelle and Wilson, Petra *op cit.*, p. 165.
[37] Greenberg, Anastasia *op cit.*
[38] Such concern is addressed in point 33 of the PR 2015/2103 which mentions that "*the use of such technologies should not diminish or harm the doctor-patient relationship, but should provide doctors with assistance in diagnosing and/or treating patients with the aim of reducing the risk of human error and of increasing the quality of life and life expectancy*".

In sum, within this chapter a reflection will be made upon what happens when a practitioner (the technology user) misdiagnoses or prescribes a wrong course of treatment in light of the outcome of the algorithm used.

2.1.1. Brief considerations on liability

Before assessing liability in the context e-health under malpractice rules, it is of use to refer that liability applies to realities of a different nature. It can apply "*to a duty or obligation arising from an express or implied contract or other legal relationship*"[39] and assume different variations. Namely, it can be deemed vicarious if "*the duty of care is held by a party other than the one directly connected to the party harmed, as in the case of an employer who is liable for acts of his and her employee*"[40], which means that patients harmed might seek for compensation directly from the practitioner or, on grounds of vicarious liability, from the healthcare enterprise (*e.g.* hospitals, clinics, etc.) within which the patient was treated.

A main distinction is also made between fault-based liability under which "*the party harmed as a result of the failure to comply with a duty of obligation will need to show that a duty existed, that a harm resulted from the failed or poor execution of that duty, and that the party with the duty acted negligently in failing to execute the duty properly*"[41] and non-fault liability in which "*the party suffering harm may obtain a compensation without having to show any negligence on the part of the manufacturer or service provider, he or she will only have to show a causal link between the product or service and the harm*".[42] [43] The latter form of liability is also referred to as strict liability. Strict liability is intended to stimulate an increase of the investments in product's safety and to facilitate claims by the consumers against producers.[44]

[39] Andoulsi, Isabelle and Wilson, Petra *op cit.*
[40] *Ibidem*
[41] *Ibidem*
[42] *Ibidem*
[43] Non-faultbased liability is a common principle of EU consumer protection laws, being based on Directive 93/13/EEC on unfair contract terms; Directive 1999/44/EC on sales and guarantees and Directive 97/7/EEC on distance selling.
[44] Palmerini, E. *et al. Robotlaw… op. cit.*

Medical liability is deemed fault/negligence-based[45] and it serves two purposes: compensate harmed patients for injuries suffered and prevent or discourage unreasonable dangerous practices.[46] [47] Bearing in mind such functions, it must be ensured that any response to the liability regulatory challenges that lie ahead must comply with the same.

Although a possibility exists of getting redress under the strict liability regime in light of the DPD against the manufacturer or algorithm developer[48] – in the event of damage to health caused by an AI tool in the course of medical treatment as a result of bugs[49], glitches, or other software failures[50] – medical malpractice rules will *a priori* apply when a malpractice behaviour takes place as a consequence of the use of a DSS comprising AI.

As explained by HOLLY COX, medical malpractice occurs "*when the conduct of a doctor, hospital, or other medical professional falls below the applicable standard of care and injures the patient"*.[51] The Author further highlights two specific situations in which the use of software for clinical purposes falls under malpractice: using outdated software and failure to warn. According to the Author, in order to prevent security vulnerabilities - which might lead to errors in the output provided by the algorithm - medical institutions and practitioners using software tools are obliged to update the IT systems used, therefore, failure to comply with such practices will trigger liability under malpractice. Secondly, if a wrong medical decision occurs and the Doctor failed to previously inform the patient that the diagnosis or treatment chosen relied on

[45] As explained by W. Nicholson Price, *"patients can recover under a strict liability theory for injuries arising from products that are defective due to manufacturing defects, design defects, or failure to warn of risks. However, neither health-care providers nor health-care facilities are typically held strictly liable for defects in the products they provide, sell, or use. Such cases might be brought against black-box medicine developers*." – *Cf.* Price, W. Nicholson *Medical Malpractice and Black-Box Medicine* available on https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2910417

[46] *Ibidem*

[47] In other words, Nicolas Petit explains that "*liability laws serve two functions: a corrective function and an incentive function. The former aims to "to remove past harm by providing a solvent target to victims*", the later envisages to "*deter the future occurrence of damage, by confiscating the gains of harmful conduct*" – *Cf.* Petit, Nicolas *op cit.*

[48] *Ibidem*

[49] An example of what has been said is the ARKON anesthesia delivery system used in hospitals to deliver oxygen, anesthetic vapor, and nitrous oxide to patients during surgical procedures. In 2014, the FDA stated that such device was not deemed safe considering that due to software bug, the system could be easily shut through the connection with a mobile phone, which would might lead to hypoxemia (low blood oxygen) or even death of the patients using such device – *Cf.* Goodin, Dan *Bug can cause deadly failures when anesthesia device is connected to cell phones* available on https://arstechnica.com/information-technology/2014/04/bug-can-cause-deadly-failures-when-anesthesia-device-is-connected-to-cell-phones/

[50] Cox, Holly *Medical Device Software: Who Is Responsible When Something Goes Wrong?* available on https://ohiotiger.com/medical-device-software-defects/

[51] *Ibidem*

a certain software, the former might also be held liable under malpractice rules.[52] The medical duty to inform is only complied with if the physician provides the patient clear and understandable information regarding the medical decision taken, hence, allowing the patient to make an informed decision. Such duty to inform[53] gains particular relevance in the scope of choice of course of treatment when AI tools are used, given that not solely the patient shall be aware that the practitioner has followed an algorithm outcome, as the later shall be provided with an explanation on the basic functioning of the algorithm used. As it will be referred, such understanding brings several problems considering that it is arguable if Doctors using technology of this nature are obliged to have knowledge on how the software works, hence, if the same should be held liable in the event of damage caused by the lack of knowledge on how the software operates.

Despite the situations pointed out above, the conclusion that a certain medical decision made under the use of an AI tool (and which resulted in harm to patient) triggers liability upon the practitioner, naturally requires a case by case assessment. A key concept in such assessment is the notion of medical negligence which will be discussed in the following point.

Lastly - but before engaging any analysis on the challenges posed by liability in the scope of DSS - it should be mentioned that the focus of this work is civil liability, which means that criminal liability will be left out of the assessment.

2.1.2. Medical malpractice

As pinpointed *supra* the concept of medical malpractice is key within the subject of liability arising from the use of AI, considering that it is necessary to assess if medical errors (regarding diagnosis and choice of treatment) made by practitioners when following the output of a CDSS should be deemed malpractice.

In the words of JASON CHUNG "*medical malpractice applies where a physician is negligent in failing to meet the professional standards of medicine and, as a result, injures a patient who is*

[52] Cox, Holly *op. cit.*
[53] Brazier, Margaret and Cave, Emma *Medicine, Patients and the law*, sixth edition, Manchester University Press, 2016, p. 136 and 145

entitled to recover damages".[54] In that sense, in order to successfully ground a malpractice claim, the injured patient has to demonstrate: (*i*) that the practitioner had a duty of care towards the patient; (*ii*) that the defendant failed to comply with the standards of care to which was obliged to; (*iii*) that a damage arose from the behaviour of the defendant; and (*iv*) the existence of a causal link between the act or failure to act and the damage[55] [56].

Having briefly explained the concept of malpractice it shall be assessed if the concept is broad enough to encompass situations in which the damage did not arise directly from a failure of the Doctor in the diagnosis or choice of treatment (when following his own personal medical judgement) but is a result of the decision of the Doctor to follow the algorithms output. It seems safe to assume that a positive answer should be granted to such question, *i.e.*, if the patient is able to fulfil the evidence requirements described, the practitioner might be held liable under malpractice rules regardless of the intervention of the machine. Such statement comes, however, with full awareness of how difficult it will be to apply the traditional concept of malpractice when the use of AI is involved in the medical action under assessment. As a matter of fact, and as highlighted by SHAILIN THOMAS "*medical malpractice laws exist to protect patients, and as algorithms take on a larger role in the medical decision-making process, they will become a less viable means of policing diagnosis and treatment decisions*".[57]

In fact, it shall be anticipated that plaintiffs will face a difficult task to prove causality between the damage to health and the behaviour which caused the harm, circumstance which will severely unprotect the patient - party who should be awarded with the more protective regime - putting him under the legal requirement of achieving a *probation diabolica*. It shall be stressed that under medical malpractice rules, the burden of proof rests with the Claimant – who, further than proving the damage has to prove that the damage arose as a consequence of a careless medical practice[58] - therefore, it is up to the patient to prove that the use of the technology (which led to a certain medical decision) fell below the standard of care required.[59]

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[54] Chung, Jason *Hey Watson… op cit.*
[55] *Ibidem*
[56] Kennedy, Ian and Grubb, Andrew *Medical law*, third Edition, Oxford University Press, February 17 2005
[57] The Author points out, however, that the difficult applicability of medical malpractice rules in this realm, should not necessarily be seen as a bad thing considering that "*strict malpractice liability laws don't necessarily correlate with better outcomes for patients*" – *Cf.* Shailin, Thomas *Democratized… op cit.*
[58] Brazier, Margaret and Cave, Emma *op cit*., p. 214
[59] *Ibidem* p. 199

Still in this scope, the concept of medical error - which can be defined as the *failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)* [60] - gains relevance. Medical errors in this regard might be of varied natures such as: diagnosis errors caused by AI operating in the field of radiology, medication errors caused by the failure of a medical management software, treatment interruptions due to failures of software, etc. Herein, we are however focusing on faults concerning diagnosis and choice of course of treatment caused by the use of DSS. Once again it must be concluded that in the event of medical fault (with an impact on the patient's health condition) which arose from a medical course of action decided upon an AI outcome, the classical concept of medical error will still apply.

2.1.3. Medical Negligence and standard of care

If until now was discussed the suitability of medical practice rules to medical errors arising from the use of AI CDSS. At this point, it shall be addressed how to ascertain if the physician (technology's user) must be held liable. In order to answer such question, it is of use to determine if the Doctor's behaviour was negligent.

Negligence in this realm arises when the patient is able to prove that by resorting to the technology used, the practitioner was careless, *i.e.*, did not comply with the standard of "*reasonably skilled and experienced doctor*"[61] [62]. Assessing if a certain medical behaviour shall be deemed negligent[63] is, – especially when DSS are involved - however, a difficult task.[64]

In traditional medical practice claims the main element to ascertain if the defendant's behaviour was qualified as negligent is foreseeability.[65] In sum, despite not being a condition *sine qua*

[60] La Pietra, L.; Molendini, Calligaris; Quattrin, R.; Brusaferro, S. *Medical errors and clinical risk management: state of the art* available on https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2639900/pdf/0392-100X.25.339.pdf
[61] Brazier, Margaret and Cave, Emma *op cit*., p. 199
[62] Kennedy, Ian and Grubb, Andrew *op cit.*
[63] Giesen, Dieter I*nternational medical malpractice: a comparative law study of civil liability arising from medical care*, Springer Netherlands, 1988, p. 104 and 105
[64] As mentioned by Charles J. Lewis "*What the civil wrong, or tort, or negligence involves, insofar as it is susceptible to analysis, is a duty of care, a breach of that duty, and loss occasioned by that breach, but these ingredients do not exist separately or in vacuo. They will always be related to the particular facts of the case; they overlap and interact; moreover they need to be considerably further defined before the analysis is of any practical use*." - *Cf.* Lewis, Charles J. *Medical Negligence*: a practical guide, third Edition, Tolley 1995, p. 159
[65] *Ibidem*, p. 159

non, the foreseeability of the risks involved in the medical decision is used as an indicator of a substandard of care. Such requirement is now challenged by the use of AI given that when medical decisions are taken using black box algorithms, the way of functioning of the machine is opaque[66] and the practitioner is incapable to understand to what extent or how likely it is to obtain a wrongful output. In the health care context, the current use of black box technology brings additional concerns considering that medical decisions should not be grounded on automated means which the physicians cannot understand, nor can the software developers explain. It can be argued that compliance with the standard of care requires the Doctor to apply the machine's output critically. In fact, several Authors argue that considering that DSS has the purpose to extend and enhance the Doctor's existing knowledge and not to replace it[67], the last word should always rest with the Doctor, therefore, negligence claims in this realm shall follow the classical concept of standard of care. Despite the merits of such argument, it seems quite evident that with the use of sophisticated AI tools for the purposes of diagnosis and treatment, the line between what are foreseeable and unforeseeable risks, became blurry.

On the other hand, it shall be referred that the medical standard of care to which Doctors are obliged is limited by the state of medical science and knowledge at the time of treatment[68], which means that if Doctors are using technology comprising algorithms and means of functioning which not even the designers and developers of the technology are able to understand, the formers *a priori* – and unless under the standard of the reasonable Doctor it was foreseeable that the diagnosis or treatment prescribed does not suit the patient's profile - should not be deemed negligent and held liable under malpractice rules, for having followed the output provided by the algorithm. In accordance with such understanding W. NICHOLSON PRICE explains that "*Because neither providers nor developers know the relationships underlying the recommendations of black-box medicine, the physician cannot stand as merely the final step in*

[66] The Association for Computing Machinery US Public Policy Council (USACM) clarifies that algorithms are opaque when it is impossible to "*determine when their outputs may be biased or erroneous*". In addition, this Association explains that algorithms can be opaque due to several reasons such as "*technical (the algorithm may not lend itself to easy explanation), economic (the cost of providing transparency may be excessive, including the compromise of trade secrets), and social (revealing input may violate privacy expectations)*" – *Cf. Association for Computing Machinery US Public Policy Council (USACM), Statement on Algorithmic Transparency and Accountability*, January 12 2017, available on https://www.acm.org/binaries/content/assets/public-policy/2017_usacm_statement_algorithms.pdf

[67] When assessing liability arising from the use of IBM Watson, Jason Chung stresses that "*IBM is being accurate when it says that all Watson is currently meant to do is provide information and analyze data to advise the human in charge*." – *Cf.* Chung, Jason, *What Should… op cit.*

[68] Giesen, Dieter *op cit.*, p. 110 and 111

a sequence of care. Once she has decided to use a particular black-box algorithm - itself a complex choice - she cannot understand and thus verify the algorithm's recommendation against her body of substantive expertise; she can only accept what the algorithm recommends or not."[69]

What has been said represents a significant change in the scope of malpractice actions, since the opacity and unforeseeably of the AI algorithms of the DSS challenge the principle underlying liability, according to which Courts can only compensate damages arising from foreseeable injuries.[70]

In light of the specificities described above, NICHOLSON PRICE claims that when AI technology is used in the course of medical decisions, the assessment of compliance with the standard of care – in order to ascertain if the physician should be held liable – should be made under different levels, according to the severity or impact of the technology's use on the patient's medical condition. If the AI CDSS represents minimal risk "*the standard of care might require no particular inquiry of the recommendations of a black-box algorithm*"[71], therefore, the Doctor can rely on the outcome of the system without compromising the compliance with the standard of care owned to the patient. An example of a minimal risk situation might be found in the use of an AI tool in the course of choice of treatment to ascertain the medicine's dosage that must be prescribed to a certain patient with a stable clinical condition, when being scientifically known that such medicine is deemed harmless regardless of the dosage prescribed. If, on the other hand, the AI software is used for riskier decisions (*e.g.* diagnosis of a patient with a risky clinical picture and a complex medical record's history, which requires a deep medical assessment, therefore, the diagnosis and subsequent medical action to be followed has the potential to aggravate the patient's health) the Doctor using the technology is obliged to assess the suitability of the DSS for the patients' condition.[72] [73]

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[69] Price, W. Nicholson *op. cit.*

[70] Stanford University *Artificial intelligence and life in 2030 one hundred year study on artificial intelligence - Report of the 2015 study panel*, September 2016 available on https://ai100.stanford.edu/sites/default/files/ai100report10032016fnl_singles.pdf

[71] Price, W. Nicholson *op. cit.*

[72] *Ibidem*

[73] In line with Nicholson Price's view, Joao Lenardon suggests that companies should internally classify the algorithms comprised in the technology "*according to their use, complexity, or danger so apply different levels of exigency, and perform various types of control*". The Author further claims that such classification system should then be used to create different levels of liability – *Cf.* Lenardon, Joao Paulo de Almeida *op cit.*

2.2. Liability of the technology user: should the Doctor be held liable?

It is an ethical dilemma to question if a physician who made a medical error by following a DSS tool should or not be held liable. Somehow ironically the legal community has also been facing the dilemma on whether practitioners should be held liable in case of disregarding AI tools' outcomes and follow their own personal judgement.[74]

In somehow analogous cases, Courts have been stating that the use of outdated information or outdated devices is deemed substandard of care and practitioners might be held liable on such grounds[75]. In true, Doctors are obliged to keep up to date with technological developments in the field of medicine "*being judged under standard of awareness and sophistication to be expected of a doctor in his sort of practice*"[76]. Notwithstanding that, there is not yet a rendered judgement under which it was assessed the connection between reliance or disregard of DSS tools in the course of the provision of health care services, and medical negligence.[77] Some Authors anticipate, however, that it is a matter of time until a significant body of Doctors will believe that – due to its impressive accuracy rates in the scope of diagnosis and choice of course of treatment - reliance on AI tools will be deemed an acceptable practice (in line with the standard of care to which Doctors are obliged to) therefore, medical malpractice rules will exonerate Doctors from negligence claims when the error was caused by following an AI outcome.[78] In line with such view, it is generally accepted that Courts are not likely to punish Doctors who committed medical errors due to the use of advanced CDSS and will be "*reluctant to impose liability for failure to use newer, better technologies*"[79], otherwise the adoption of these technologies among the medical community would be compromised.

As easily foreseen, this understanding implies a second interpretation. *I.e.*, as soon as the use of AI tools within the medical community becomes generally accepted, Doctors will be easily held negligent if a medical error exists as a result of disregarding the AI tool's outcome. Such

[74] UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* - written evidence (AIC0055) – Statement of Professor Chris Reed *op. cit.*
[75] Price, W. Nicholson *op cit.*
[76] Brazier, Margaret and Cave, Emma *op cit*., p. 207
[77] Diamond, George A. MD; Pollock, Facc, Brad H. MPH; Work, Jeffrey W. MD *Clinician Decisions and Computers, Seminar on computer applications for the cardiologist-VI* - Geiser, Edward A. MD; Skorton, FACC, David J. MD; FACC, Guest Editors, JACC Vol. 9, No.6 June 1987
[78] UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* - written evidence (AIC0055) – Statement of Professor Chris Reed *op. cit.*
[79] Price, W. Nicholson *op cit.*

view is shared by Jason Chung who – when assessing liability arising from IBM Watson – claims that "*a physician may be held directly or vicariously liable for failing to properly consider Watson's recommendations, especially given Watson's accuracy in providing diagnostic and treatment options as evidenced by high concordance rates with licensed physicians*".[80] Other Authors refer to these circumstances stating peremptorily that by not consulting a computer decision aid, the practitioner will be held liable on grounds of failure to exercise reasonable care in the provision of health care services.[81]

Despite the above, there is still no consensus on if Doctors should be exonerated from liability claims in the event of being misled by the algorithm. As referred above, there are still several Authors who claim that all AI DSS currently used for the purposes of diagnosis and treatment still rely on human intervention, consequently, the use of the technology should by no means replace the expert human's clinical judgement.[82] Authors who share such view, state that the user can be held liable as long as "*he should have known the advice was substandard*".[83] In line with such argument, it can be pondered if technology's manufacturers might actually make use of the sophisticated user defense in the case of a harm caused by the use of the AI system in order to exonerate themselves from liability. According to such defense "*the manufacturer is not liable for supplying a product to a knowledgeable user who has reason to know of any dangerous condition in the product*".[84]

Within this scope, and in respect to IBM Watson, IBM has been claiming that given the necessary human intervention mentioned above, the entity to be held liable must be the user (under malpractice rules), further claiming that there are no grounds to extend liability to the designer, developer or manufacturer of AI CDSS.[85] Others argue that the extension of liability

[80] Chung, Jason *Hey Watson… op cit.*
[81] Diamond, George A. *et al. op cit.*
[82] "*However, at this juncture it must be noted that the efforts in AI that are currently most likely to lead to use in clinical practice – such as using deep learning to analyse and classify medical images like eye scans much more efficiently than current techniques allow – will not involve replacing an expert human's clinical judgement, but instead augmenting it, with final responsibility for diagnosis and treatment remaining with the clinician*." – *Cf.* UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* - written evidence (AIC0234), Statement of DeepMind, *op. cit.*
[83] Diamond, George A. *et al. op cit.*
[84] Wu, Stephen S. *Summary of selected robotics liability cases* available on http://ftp.documation.com/references/ABA10a/PDfs/2_5.pdf
[85] Chung, Jason, *What Should… op. cit.*

is legally grounded on the fact that in light of the tasks performed, IBM Watson shall be seen as an advisor, therefore, must be subject – to a certain extent – to a duty of care.

2.2.1. Implications of holding the Doctor liable

In the previous point was referred that although part of the legal community defends that Doctors should be not be held liable for medical errors caused by applying the diagnosis or treatment suggested by the AI software, there are still Authors who argue that the intervention of the AI software within the medical decision does not exclude liability of the user. The latter group defends that the Doctor can still be deemed negligent if demonstrated that by resorting to the outcome provided by the technology, the same fell into a substandard of care practice. It is not clear though what the standard of care should be for a Doctor using AI software in this scenario. Such fact carries a risk of liability uncertainty but also stimulates discussions around the design of such standard as well as around the implications of adopting the same.[86]

Above was seen that NICHOLSON PRICE suggests a qualification of the risk comprised in the use of the technology in order to provide different levels of standard of care required to the Author, according to the level of risk. Notwithstanding that, it is clear that even in the scope of the use of technology which comprise a high risk to the patient's health, excessively stringent standards bring acceptance obstacles within the medical community. One of the obstacles that will likely arise if an obligation of ascertaining the quality of the machine and the outcome provided is put upon the user is defensive medicine.

Defensive medicine occurs when Doctors or medical experts assume that inputs provided by advanced technological means lead "*to practice a stronger and more surreptitious defensive medicine, that is to choose for the most plausible option that defends them against potential controversies*".[87] The phenomena of defensive medicine is a key social element which cannot

[86] Price, W. Nicholson *op. cit.*
[87] Cabitza, Federico *The Unintended Consequences of Chasing Electric Zebras*, available on *http://www.dsi.unive.it/HUML2016/assets/Abstract/Cabitza.pdf*

be ignored when allocating liability arising from medical errors caused as a result of AI technology.[88] [89]

As highlighted by SHALIN THOMAS "*both medicine and the law will have to adapt as machine learning algorithms surpass physicians in their ability to diagnose and treat disease*".[90] [91] The Author establishes a link between the use of ML/AI technologies in the health sector, defensive medicine and liability, highlighting that if it is true that reliance on algorithms can have the effect of decreasing "*the pressure physicians feel to order unnecessary tests and procedures to avoid malpractice liability*"[92], it is also true that in the event physicians disagree with the diagnosis/course of action suggested by the algorithm and intend to deviate from it, the same will order "*more diagnostic tests and procedures than a patient's condition warrants*"[93] since no medical actor will want to stand, within the scope of a liability claim, "*in front of a jury trying to explain why (…) ignored the algorithm's warning*".[94]

Within this new paradigm of medical decision-making relying on AI technology, the assessment on if the physician complied with the applicable standards of care becomes deeper and more complex. In a nutshell, if liability is transferred from the technology developer to the medical expert resorting to it, the later will be in the tough position of justifying *(i)* why he/she uncritically followed the diagnosis or course of action suggested by the machine or *(ii)* why and on which grounds, he/she deviated from the machine's output.[95]

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[88] Moreover, Federico Cabitza stresses unintended consequences of other nature, such as *overreliance* on technology support systems which can lead to results of two different natures: overdependence which "*occurs when habitual users of these systems either forget, ignore or even stop conceiving any safety net, plan B, or contingency plan (…) technology abuse, that is the use of the system beyond actual needs"* and overconfidence which *"relates to three ways of thinking: thinking that the DSS will never fail; thinking that it will never harm; and thinking that it will never be wrong.*" - *Cf. Ibidem*

[89] The concept of overreliance was initially studied and developed by Raja Parasuraman - *Cf.* Parasuraman, Raja *Complacency and Bias in Human Use of Automation: An Attentional Integration* available on http://journals.sagepub.com/doi/pdf/10.1177/0018720810376055

[90] Shailin Thomas, *Democratized… op. cit.*

[91] Shailin Thomas, *Artificial… op. cit.*

[92] Shailin Thomas, *Democratized… op. cit.*

[93] *Ibidem*

[94] *Ibidem*

[95] Although Authors like Federico Cabitza argue that "*accountability and responsibility will be at the human side for a long time*" and believe that allocating liability to the AI system itself is a distant reality - *Cf.* Cabitza, Federico *op cit.* - such possibility, as will be discussed in the following chapters, is already under debate in the scope of several jurisdictions, namely in the context of the European Union by virtue of the PR 2015/2103.

Considering the implications mentioned above, some Authors argue that although accountability in the scope of the use of AI technology (with black box features) in healthcare must be achieved - by means of "*independent validation of algorithmic results and the qualifications of the developers*" - such task and liability arising from non-compliance with said obligations should not rest with the Doctor using the technology but with the hospital institution within which the diagnosis or treatment was provided. According to NICHOLSON PRICE, although the user might still play a role in assessing the level of risk comprised in the technology and in detecting wrongful outcomes "*facilities are best suited to evaluate algorithms at the point of implementation, and should ensure that algorithms - as a whole - are high quality according to measurable characteristics*".[96]

2.2.2. Extending liability to medical institutions

Until this moment, duty of care as an obligation that rests with the Doctor has been discussed, however, hospital institutions are also bound by such duty. In true, health care enterprises also owe a duty of care towards patients, therefore, can be subject to liability claims. In fact, hospital institutions have the duty to "*provide adequate facilities for patient care including well-functioning equipment necessary for adequate care*".[97] Under such duty, liability might arise from the negligent choice and implementation of poor-quality of AI software systems to be used for the purposes of diagnosis and treatment. In that sense, medical institutions can be held liable directly or indirectly, under vicarious liability.[98] In analogy with negligent claims against Doctors, there is also a standard to be borne in mind, the *standard of a reasonable hospital.*[99]

Following what has been said, one might ask if hospital institutions must be held liable for cases in which the medical error was caused by an AI CDSS, when the designer and manufacturer should be the entities holding liability. Addressing such question, it must be referred that hospitals are typically not liable for the use of defective devices, however, if demonstrated that hospitals were negligent in the evaluation of the AI software acquired and that there was a

[96] Price, W. Nicholson *op. cit.*
[97] *Ibidem*
[98] As mentioned *supra* vicarious liability "*provides that when a person who is an employee commits a tort in the course of his employment, his employer is also responsible to the victim"* - *Cf.* Brazier, Margaret and Cave, Emma *op cit*., p. 234
[99] Price, W. Nicholson *op. cit.*

failure to ensure that the algorithms comprised in it do not meet high-quality and safety standards, hospitals might indeed be held liable in the event of a damage to health caused by a failure of the system which led to a wrong diagnosis or choice of an inappropriate treatment. In fact, in the United States of America (hereinafter also referred to as "US") such view has been endorsed by several doctrines (doctrine of collectives, alternative liability doctrine, enterprise liability, or market-share liability) under which Courts have been increasingly holding hospitals liable for failure to meet safety standards in the scope of the adoption of health care equipment or devices of every nature. Underlying these doctrines entailing enterprise liability is the idea that "*between an innocent plaintiff and negligent defendants, the latter should bear the cost of the injury, especially where medication is involved*"[100], *i.e.*, liability should rest with the entity with the deeper pockets.[101]

Liability of the hospital under the circumstances described can also be grounded on the fact that although hospitals are not able to ensure that every clinical decision made by its medical body is correct, there is a duty to ensure that Doctors providing services within the institution are reasonably proficient.[102] From such duty two implications might be outlined. Firstly, a parallel can be drawn between the choice of the medical body and the choice of the DSS to conclude that hospitals are indeed liable in respect to the selection of the resources (human or non-human) used within its facilities. Secondly, from the duty to hire reasonable proficient Doctors it can be equated the existence of a duty to properly prepare the Doctors to use the technology[103], hence, make hospitals liable for medical errors caused by an inappropriate use of the diagnosis and treatment AI tool.

Shifting liability from the user to the hospital institution is deemed as an option which allows more certainty to liability claims, hence, more protection to the victims. Moreover, Courts will

[100] Giesen, Dieter *op cit.* p. 22 and 23
[101] Chung, Jason *Hey Watson… op. cit.*
[102] Price, W. Nicholson *op. cit.*
[103] Such concerns are expressed in point 33 of the PR 2015/2103: "*Underlines the importance of appropriate education, training and preparation for health professionals, such as doctors and care assistants, in order to secure the highest degree of professional competence possible, as well as to safeguard and protect patients' health; (…) emphasises the special importance of training for users to allow them to familiarise themselves with the technological requirements in this field; draws attention to the growing trend towards self-diagnosis using a mobile robot and, consequently, to the need for doctors to be trained in dealing with self-diagnosed cases*".

be dismissed from the complex assessment of whether liability should rest with the Doctor or the medical institution.

3. Chapter III: Qualification of the technology as a mean to ascertain the liability rules to be applied

3.1. Liability arising from the use of AI tools for the purposes of medical diagnosis and choice of course of treatment under the legislation currently in force

As it has been stated, so far no specific liability rules exist to address damages arising from the use of AI technology, not in the health sector nor in any other scope of application. In that sense, liability disputes arising in this domain are governed and decided – either under malpractice rules, as seen *supra* – or under the legislation currently in place applicable to defective products, as well as under the general domestic regimes of liability in light of tort law rules[104].

Given the lack of legislation in this field, focus will now be given to the legal instruments which might cover liability arising from the use of AI clinical support software systems in order to ascertain if and how the same can apply to this reality.

The framework of the AI DSS here under assessment is confined to two main instruments: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices[105] and the Council Directive 85/374/EEC of 25 July 1985 on the approximation

[104] Cole, George S., *Tort Liability for Artificial Intelligence and Expert Systems*, 10 Computer L.J. 127 (1990) in The John Marshall Journal of Information Technology & Privacy Law Volume 10, Issue 2 Computer/Law Journal - Spring 1990 Article 1, available on https://repository.jmls.edu/cgi/viewcontent.cgi?article=1416&context=jitpl

[105] Which despite still being under grace period of application aims to amend Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 as well as to repeal Council Directives 90/385/EEC and 93/42/EEC.

of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.[106] [107]

Although CDSS are *a priori* covered by Regulation (EU) 2017/745 provides for extensive safety rules connected to liability, it does not provide for a liability regime. In that sense, the Directive 85/374/EEC is the most relevant text in the scope of products liability. With regard to this SARA E. DYSON explains that "*Products liability is the area of law that provides redress and holds manufacturers responsible when their products—whether medical devices or other types of products — malfunction and cause harm to users. What underpins this theory of liability is the premise that a manufacturer that profits from the sale of a defective product must bear the costs of remuneration when it injures someone.*".[108] As already referred, the cornerstone of Directive 85/374/EE is the strict liability regime it imposes upon the manufacturer of the defective product.

Despite the fact that the common understanding is that this Directive – which covers medical devices - applies, therefore, a producer, importer or supplier of an eHealth technology "*is liable for any damage or harm caused by a defect in that product and must pay compensation to anyone harmed*"[109], several Authors have been questioning if the defective's product regime suits AI in general and AI for the purposes of health care in particular. In true, it is a complex

[106] The following EU legal instruments potentially applicable in this realm were excluded:
Directive 2006/42/EC of the European Parliament and of the council of 17 May 2006 on machinery – which aims at harmonising health and safety requirements applicable to machinery hence ensuring a high level of protection, whilst pursues free circulation of machinery within the EU market – is excluded considering that the same does not cover the use of machines for health care purposes as the AI CDSS here under assessment.
The conclusion above also applies to the *Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market*, considering that – even if the use of AI CDSS is qualified as the provision of a service and not a product – health services are excluded from the scope of this Directive.
Directive 1999/44/EC on Sales and Guarantees – with the purpose of providing consumers for redress when acquiring a product which does not "*conform to what was foreseen in the contract*", hence, providing a minimum level of consumer protection in the market - solely applies to products delivered directly to the consumer. Therefore, without prejudice of its applicability to AI eHealth solutions such as apps with medical purposes, those AI solutions are out of the scope of this thesis that targets AI CDSS solutions which requires the involvement of physicians and are not directly acquired and used by the consumer/patient.
[107] The *Directive 2001/95 EC of the European Parliament and of the Council of 3 December on General Product Safety* targets both products *de per si* and products which deliver services, by providing for general safety requirements which include an authorisation to place products in the market. Despite the complex nature of AI medical decision-making software, some Authors argue that these solutions are still products, hence, must fall under this Directive. Such Directive does not provide, however, for rules on allocation of liability.
[108] Dyson, Sara E. *Medical Device Software & Products Liability: An Overview (Part I)* available on https://www.medtechintelligence.com/feature_article/medical-device-software-products-liability-overview-part/
[109] Andoulsi, Isabelle and Wilson, Petra *op. cit.*, p. 165

task to determine which liability regime applies to damages arising from the use of AI for health purposes. Such task reveals to be difficult given the uncertainty that exists regarding the classification of AI technology used for diagnosis and treatment purposes.

Firstly, AI DSS – as IBM Watson, Watson for Oncology or DeepMind - have a dual nature of software and hardware. This reveals to be a problem considering that controversy exists regarding the application of the defective products regime to software[110], once software does not a have the nature of a material good, reason why it should not be subject to strict liability. The counter-argument used in this regard is that the moment the software is embedded in a tangible good, it shall be qualified as a product, hence, the defective product regime (and inherently, strict liability) applies. Such reasoning is also used to defend the qualification of diagnosis and treatment of AI tools as medical devices, *i.e.*, regardless of the non-tangible nature of the software comprised in the technology, once the same is embodied in any kind of physical medical device, it assumes such classification.

Another element to be considered in the subject of the qualification of CDSS is the fact that these solutions may not be deemed as mere products but as the provision of health care services[111.] For such reason, ISABELLE ANDOULSI and PETRA WILSON argue that both product liability and services liability regimes might apply to eHealth tools and solutions.[112] Said Authors further mention that "*the concept of an eHealth product is a difficult one, as in practice such a product may be made up of a number of software packages and hardware devices, as well as devices with embedded software (…) EHealth products may thus be made up of regulated products, such active implantable medical devices and in vitro diagnostic medical devices, as well as a range of other products which have no specific health related regulations*".[113]

[110] In the words of Sara E. Dyson "*Whether software can be the subject of a strict liability claim is contentious*" - *Cf.* Dyson, Sara E. *op. cit.*
[111] Andoulsi, Isabelle and Wilson, Petra *op cit.*
[112] *Ibidem* p. 165
[113] *Ibidem*, p. 171

Such understanding poses, however, the question of if and when DSS comprising AI technology should be deemed traditional medical devices [114] [115], considering that its software nature and its way of functioning (resembling more to a medical advisory service and not to a mere product) does not suit the concept of product, hence, should not be subject to strict liability.

In sum, there are several EU level legal instruments which – sometimes through an over-stretched process of analogy[116] – can be applied in the scope of claims on grounds of wrongful diagnosis or choice of treatment caused by the use of AI tools. However, even if no controversy would arise and the applicability of the DPD was unanimous, such laws do not provide for rules on allocation of liability. In fact, the Directive only provides for a principle of responsibility of the manufacturer under a strictly liability regime, which by no means addresses the complexity underlying the use of AI tools for diagnosis and treatment. As it will be discussed, AI tools of this nature involve several different agents, both in the process of the creation of the technology (which requires technology designers and developers of the software, as well as the manufacturer of the hardware) and in the moment of its use (requiring the intervention of the physician).

The current chapter will precisely focus on the complexity of this reality and, therefore, address the problem of the unsuitability of the legal framework in place to ensure allocation of liability and proper redress in the event of damage to health caused by the use of AI CDSS tools.[117]

3.2. Qualification of AI clinical decision support software

The question now formulated is of extreme relevance considering that in the event DSS comprising AI is deemed a medical device, hence Medical Devices legislation applies, this

[114] Mulryne, Jacqueline; Strom, Louise; Wallace, Victoria M.; Jones, Bethan; Tsang, Lincoln and Kracov, Daniel A. *What's the deal with Watson? Artificial Intelligence Systems and Medical Software Regulation in the U.S. and EU* available on https://www.digitalhealthdownload.com/2017/02/whats-deal-watson-artificial-intelligence-systems-medical-software-regulation-u-s-eu/

[115] In this regard Isabelle Andoulsi and Petra Wilson argue that "*where a medical device forms part of an eHelath application, the special liability rules for medical devices will have to be followed, or where a patient suffers damage as a result of a decision taken that is based on a decision support tool, the doctor sued by the patient may in turn have recourse against the product supplier*." – *Cf.* Andoulsi, Isabelle and Wilson, Petra *op. cit.*, p. 165.

[116] *Ibidem*

[117] *Ibidem*

technology will have to comply with the certification procedures[118] established under such legislation.[119] As a result, technology manufacturers and developers will be subject to stricter and more rigid liability rules given that Claimants will be in a more favourable position to prove and claim damages.

In a first hypothetical scenario, if the technology manufacturer distributes DSS which was not CE marked, liability will arise automatically. In a second scenario and assuming that the manufacturer complied with every technical standard applicable and obtained the CE marking, in the event of harm it will still be easier for Claimants to hold the manufacturer liable considering that the former might access the technical specificities that the technology should have complied with, fact that will make it easier to identify the technical fault which caused the damage and prove the causal link between the machine's fault and the damage.

Furthermore, if AI tools used for the purposes of clinical diagnosis and choice of treatment are deemed medical devices, and, hence, subject to the DPD, the manufacturer will be subject to strict liability. Such circumstance brings issues with regard to fair allocation of liability in this realm, considering that potential medical errors caused by pursuing the outcome of an AI tool might – and will likely – not be related to the manufacture of the hardware but related to different stages of the design and development of the algorithms underlying the machine, or even by the negligent use of the tool made by the physician. For such reason, it is hereby anticipated that the defective product's regime – which encompasses an assumption of liability upon the manufacturer triggered by a manufacturing defect, a design defect or a failure to warn[120] - should not be blindly applied in the course of wrongful diagnosis or choices of treatment which occur due to a failure of the AI clinical support software system. In true, an

[118] For an explanation on the certification procedure of medical devices – *Cf.* World Health Organization Geneva, *Medical Device Regulations Global overview and guiding principles*, 2003, available on http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf

[119] Still regarding the qualification of DSS tools, Isabelle Andoulsi and Petra Wilson claim that that "*Where an eHealth product is marketed and it contains medical devices such devices will need to be CE marked, as will eHealth software which aggregates and processes the data obtained from devices*" - *Cf.* Andoulsi, Isabelle and Wilson, Petra *op cit.*

[120] Jason Chung explains that under the umbrella of products liability, plaintiffs may sue for manufacturing defects, design defects, and failures to warn. Manufacturing defects are "*implied when a good is not produced according to its specification or under the malfunction doctrine when there is an unexplainable accident*." Design defects may be found to have occurred "*where the foreseeable risks of harm could have been reduced or avoided by use of a reasonable alternative design."* Finally, a failure to warn claim may arise based on a *"manufacturer's duty to provide instruction about how the product can be safely used and to warn consumers of hidden dangers."* - *Cf.* Chung, Jason *Hey Watson… op. cit.*

assessment must be conducted in order to ascertain if the failure shall be judged under the product's liability regime or on grounds of negligence, and herein the qualification of the AI tool plays an important role. In fact, the product's liability regime should only apply if the product is defective itself. If the failure lies with an act or omission of the manufacturer - or any other agent – which caused the defect, we are in the field of negligence.[121]

Before engaging into the discussion of the qualification of DSS, a brief comparative illustration on this matter will be provided by showing how this matter has been dealt with in the US and the EU.

3.2.3 The US example

Under the US jurisdiction, the entity responsible for supervising medical devices is the Food and Drugs Administration (hereinafter "FDA"). The classification criteria in regard to medical devices followed by FDA relies on an intent approach, which means that the first element to be born in mind is if the manufacturer intended to develop the device for medical purposes.[122]

A certain product (hardware or software) is qualified as a medical device if deemed so in light of the definition of medical device provided for in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.[123] If the requirements of such definition are met, the device will be categorized in accordance with the risks posed by it[124] and be subject to FDA's jurisdiction, hence, be subject to stricter liability rules.

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[121] Dyson, Sara E. *op cit.*

[122] Tsang, Lincoln *et al*. *The Impact… op. cit.*

[123] According to section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act, a medical device might be any "*instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes*."

[124] Similarly to as provided for in the EU medical devices' legislation, within the US the medical devices are subject to a regulatory continuum and classified into Class I, II or III. - *Cf.* Tsang, Lincoln *et al*. *The Impact… op. cit.*

The definition above does not include, however, software functions which are excluded pursuant to section 520(o).[125] In fact, in December 2016 the Cures Act was amended in order to exclude from the definition of medical device certain types of software[126], henceforth, leaving the same out of FDA's supervision powers and free from the medical device's pre-market authorisation procedure.[127]

Considering the explanation above it is understandable that US companies are making efforts to escape FDA's jurisdiction. In fact, it is acknowledged that IBM - one of the most relevant technology developers and providers in the sector of AI technology with clinical purposes - has been conducting lobbying efforts in order to exempt AI technologies such as IBM Watson and Watson for Oncology from the scope of application of the 21st Century Cures Act.

It must be said, however, that despite IBM's attempts to circumvent the law and escape its application, FDA has been issuing guidance in this regard and in December 8th of 2017 stated that although CDSS[128] [129] is excluded from its margin of supervisory powers, FDA still has regulatory jurisdiction over stand-alone software.[130] Moreover, if so far it has been argued that AI technology as IBM Watson should not be regulated as a medical device considering that the software in question – although extremely advanced – still relies on human intervention, it is expected that given the fast pace evolution in this realm, this argument will fall.[131] [132]

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[125] FDA U.S. Food & Drug Administration – U.S. Department of Health and Human Services *Is The Product a Medical Device?*, available on https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm

[126] "*On December 13, 2016, the Cures Act was enacted. Section 3060(a) of this legislation, titled 123 "Clarifying Medical Software Regulation", amended the FD&C Act to add section 520(o), which describes software functions that are excluded from the definition of device in 201(h) of the 125 FD&C Act. Section 3060(d) of the Cures Act amended section 201(h) of the FD&C Act to state 126 that the term device does not include the software functions excluded pursuant to section 520(o).*" - *Cf.* FDA U.S. Food & Drug Administration *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act Draft Guidance for Industry and Food and Drug Administration Staff*, available on https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf

[127] Chung, Jason *Hey Watson… op. cit.*

[128] Under the US laws and FDA guidance texts issued in this regard, there are four categories of software with medical purposes: a) MMA's (Mobile Medical Apps); b) MDDS (Medical Device Data Systems); c) SAMD (Software as a Medical Device); and d) CDSS (Clinical Decision Support Software). – *Cf.* Tsang, Lincoln *et al*. *The Impact… op. cit.*

[129] Green, Epstein Becker *FDA Guidance on Decision Support Software: Implications for Industry* available on https://www.lexology.com/library/detail.aspx?g=667bab5b-6457-4bb8-9421-fb7e0dfd8e3d

[130] Jacqueline Mulryne, Louise et. al. *What's the deal… op cit.*

[131] *Ibidem*

[132] In the words of Jason Chung "*as AI becomes more pervasive, the current legislative and regulatory vacuum will most certainly be addressed. Therefore, IBM, and other AI manufacturers would be wise to embrace a regime that*

Furthermore, FDA has already stated its intents to optimize regulation of AI eHealth technologies perhaps through a certification procedure under which technologies will have to be approved before being placed in the market[133] – a model closer to the European MD procedure. The supervisory authority also announced that a new Digital Health Unit which focuses on AI-driven medical software will be created.[134] Consequently, it is safe to assume that that the current regulatory state of affairs is likely to change.

3.2.4 The EU example

Within the EU, software used for medical purposes is not excluded by medical devices legislation, hence, it might be deemed as a medical device. That being said, to qualify DSS comprising AI as a medical device is by no means a straightforward task to be conducted. Instead, such judgement call requires a case-by-case assessment, in light of the features and purposes of the software. The complexity of the decision is explained by the fact that software does not ordinarily act or interact with the human body "*to restore, correct or modify bodily functions*".[135] Thus, it has to be assessed if the medical effect of the use of the software is as relevant as to make it fall under the scope of application of the medical devices regulation[136], or if the software is a mere tool to assist in the clinical diagnosis and choice of treatment for the patient.[137]

Discussion concerning the qualification of AI software with medical purposes gained significant relevance with IBM Watson. In fact, the community discussed if this AI software should simply be deemed a data management tool which enhances clinical diagnosis and choice of treatments, or if, due to its vast and advanced capabilities, the same should be qualified as medical device, thus be subject to the medical devices regulation. While the subject is still under discussion within the US, the EU provided a clear response in this regard. The EU legislator expressly broadened - in article 2 (1) of the Medical Devices Regulation - the definition of

addresses what AI actually does and limits the application of standards of strict liability." - *Cf.* Chung, Jason *Hey Watson… op. cit.*

[133] *Ibidem*

[134] Tsang, Lincoln *et al. The Impact… op. cit.*

[135] *Ibidem*

[136] Which is determined by the definition of medical device provided for in article 1 (2) of the Directive 93/42/EC, and article 2(1) of the Medical Devices Regulation.

[137] Jacqueline Mulryne, Louise et. al. *What's the deal… op. cit.*

medical device by encompassing in the same medical software for the purposes of prediction and prognosis of diseases[138] [139] especially targeting AI software as IBM Watson or Watson for Oncology.[140] In line with the broadening of the definition of medical device, the Regulation now expressly provides for a classification system for software.[141] The Regulation also addresses security concerns in the scope of software used for medical purposes. In Annex I – Chapter II 17.1. it is referred that both medical devices incorporating software or software itself "*shall be designed to ensure repeatability, reliability and performance in line with their intended use*" and in Annex II 6.1 a software verification and validation procedure is established.

Despite the legal framework above, several Authors mention that "*not all the software used in healthcare setting is considered to be a medical device*"[142] [143], and that - as mentioned *supra* - such decision relies on an assessment regarding the functionality and intended purpose of the software. Software which aims to make anatomical calculations on the human body or image enhancing software with diagnosis functions is typically qualified as medical device. On the other hand, some Authors claim that – despite the broadening of the definition of medical device in the new Regulation - AI software which strives for providing diagnosis or informed decisions regarding treatment is an assisting tool, therefore, should not be qualified as a medical device.[144]

The discussions surrounding the classification of health software have, however, seen some clarity in past year with the Judgement rendered by the Court of Justice of the European Union (hereinafter "CJEU") in the case SNITEM (Syndicat National de l'Industrie des Technologies

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[138] Hancher, Leigh and Földes, Maria Eva *Revision of the Regulatory Framework for Medical Devices in the European Union: The Legal Challenges* available on https://www.cambridge.org/core/services/aop-cambridge-core/content/view/84BEEDBC594702B73327246A7B60CDAB/S1867299X0000307Xa.pdf/revision_of_the_regulatory_framework_for_medical_devices_in_the_european_union_the_legal_challenges.pdf

[139] *Cf.* Tsang, Lincoln *et al. The Impact… op cit.*

[140] Moreover, in article 2 (2) the Regulation expanded its application to accessories of medical devices, *i.e.*, to devices which are intended to be used with medical devices.

[141] Under ANNEX VIII 6.3 – Rule 11 it is established that "*Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause: — death or an irreversible deterioration of a person's state of health, in which case it is in class III; or — a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.*".

[142] Tsang, Lincoln *et al. The Impact… op. cit.*

[143] Frank, Sharon *A new model for European Medical Device Regulation: a comparative analysis in the EU and the USA*, Europa Law Pub, 2003, p.38

[144] When assessing IBM Watson, Jason Chung argues that "*Machine or not, Watson most definitely is, and is marketed as, a member of the team. Likewise, the products liability regime is not a good fit, as Watson is definitely not a typical medical device."* - *Cf.* Chung, Jason *Hey Watson… op. cit.*

Medicales) v. Philips France, within which the qualification of software as medical device was discussed under articles 1(1) and (2) (a) of the MD Directive.[145] The CJEU draw attention to recital 6 of Directive 2007/47/EC[146], according to which "*software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device*.", highlighting that the qualification of software as medical device does not rely on its use in the medical context[147] but on the (medical) purpose intended by the manufacturer. Such understanding is aligned with point (19) of ANNEX VIII of the new Medical Devices Regulation.

In sum, the CJEU ruled that regardless of acting in the human body or not, the standalone software[148] in question[149] was a medical device by stating that "*software, of which at least one of the functions makes it possible to use patient-specific data for the purposes, inter alia, of detecting contraindications, drug interactions and excessive doses, is, in respect of that function, a medical device (…) even if such software does not act directly in or on the human body*". The judgement rendered constitutes an endorsement of MEDDEVS 21/6[150] which establishes that "*software, which is intended to create or modify medical information might be qualified as a medical device*". As stressed by KOROLYN ROUHANI-ARANI, this decision "*will have a direct impact on what is a fast-evolving med-tech scene that is innovating in novel ways*

[145] Council Directive 93/42/EEC of 14 June 1993

[146] Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

[147] The ECJ also clarified that "s*oftware that, while intended for use in a medical context, has the sole purpose of archiving, collecting and transmitting data, like patient medical data storage software*" is not deemed a medical device - *Cf.* Judgment of the European Court (Fourth Chamber) of 7 December 2017 - Case no. C 329/16: Syndicat national de l'industrie des technologies médicales (Snitem) and Philips France v Premier ministre and Ministre des Affaires sociales et de la Santé.

[148] Under MEDDEV "*stand alone software' means software which is not incorporated in a medical device at the time of its placing on the market or its making available*."

[149] The Philips' software under assessment had the purpose of "*cross-references patient-specific data with the drugs that the doctor is contemplating prescribing, and is thus able to provide the doctor, in an automated manner, with an analysis intended to detect, in particular, possible contraindications, drug interactions and excessive dosages, is used for the purpose of prevention, monitoring, treatment or alleviation of a disease*" – *Cf.* Judgement: Case C 329/16 *supra*

[150] Tsang, Lincoln *et al. The Impact… op. cit.*

to use machine learning, autonomous decision making and artificial intelligence to enhance efficiency and accuracy in disease intervention and medical diagnosis and management".[151]

In light of the Phillips judgement as well as of the content of both the new Medical Devices Regulation and MEDDEVS 21/6, there is little margin to still affirm that AI medical decision support software does not qualify as a medical device. However, the reservations upon the applicability of the defective product's liability regime to CDSS comprising AI (in light of its qualification as medical device) still remain.

3.3. Liability of the technology manufacturer in light of the complexity of AI tools for the purposes of medical diagnosis and choice of course of treatment

As mentioned above, the apparent EU understanding of qualifying DSS as medical devices does not exclude the problems raised regarding the unsuitability of the Defective Product's Directive. As stated, the AI algorithms used for the purposes of diagnosis and treatment are too complex to be subject – in virtue of its qualification of medical device - to the general principle of strict liability provided by the DPD.

In true, such regime reveals to be too modest to address liability arising from damages to health caused by the use of software which comprises AI algorithms with a black box nature.

Secondly, the suitability of medical devices laws to CDSS is arguable considering that AI technology is quite more complex than classical medical devices, due to the fact that these solutions imply the intervention and connection between many actors: the physician who uses the technology, as well as all the industrial agents involved in the design, development and manufacture of the product. As explained by ANASTASIA GREENBERG "*The issue with a strict liability regime for AI is that unlike a traditional defective "product", a human (the physician) and AI are going to work together in the decision making process, making it difficult to point the finger at the manufacturer, software developer or the physician alone*.".[152]

[151] Rouhani-Arani, Korolyn *Standalone Software caught by Medical Device Regulation*, available on http://www.kemplittle.com/site/articles/kl_bytes/standalone-software-caught-by-medical-device-regulation
[152] Greenberg, Anastasia *op. cit.*

As far as these agents are concerned, it must be stressed that the AI technology does not solely rely on hardware and software (code underlying the functioning of the machine), but there's also a data component. Considering that the outcome of the tool will be a result of a data input operation, liability might be extended to the entity in charge of the data input. The rationale behind such discussion rests with the fact that it might not be fair to hold the manufacturer of the technology strictly liable (under the defective's product Directive) for damages to health arising from the use of the AI when the manufacturer, the developer, nor the agent in charge of the coding component of the technology might not be able to identify or explain the error occurred.

3.3.1 Implications of erroneous or biased data input

As explained *supra*, machine learning technology relies on data. Data are indeed the element which feeds the system[153], allowing it to provide for responses and to keep it learning.[154] In fact "*machine learning algorithms are highly "data hungry" often requiring millions of observations to reach acceptable performance levels*". [155] [156] Therefore, the quantity[157] and quality of the input data are a major issue for the development of CDSS, considering that errors or bias in the algorithms input data can distort the computational model and lead to erroneous

[153] In this regard Bernard Marr explains that "Machine *learning algorithms improve the more data they are exposed to. If there is one thing the healthcare systems has in abundance, it's data. Due to different storage systems, ownership and privacy concerns, and no established process that allows people to easily share data with each other, there is a major amount of analysis that's not currently being done that could glean tremendous results for patients, doctors and healthcare organizations.*" – *Cf.* Marr, Bernard *op. cit.*

[154] In fact, as outlined by the Medical Futurist Institute "*With the evolution of digital capacity, more and more data is produced and stored in the digital space. The amount of available digital data is growing at a mind-blowing speed, doubling every two years. In 2013, it encompassed 4.4 zettabytes, however by 2020 the digital (…) will reach 44 zettabytes, or 44 trillion gigabytes (!)*". Within such article is also stressed the idea that the use of artificial intelligence, more than an option it's becoming the only mean capable of letting humans keeping track of all the big data currently generated – *Cf.* The Medical Futurist, *Artificial Intelligence Will Redesign Healthcare* available on http://medicalfuturist.com/artificial-intelligence-will-redesign-healthcare/

[155] Ziad, Obermeyer and EJ, Emanuel *Predicting the Future - Big Data, Machine Learning, and Clinical Medicine* available on https://www.ncbi.nlm.nih.gov/pubmed/27682033

[156] In this context, the World Economic Forum named this universe of data with potential AI use, open AI ecosystem. As also explained by the Medical Futurist Institute "*An open AI ecosystem refers to the idea that with an unprecedented amount of data available, combined with advances in natural language processing and social awareness algorithms, applications of AI will become increasingly more useful to consumers. It is especially true in the case of medicine and healthcare"* - *Cf.* The Medical Futurist *op. cit.*

[157] In the words of Anastasia Greenberg "*Machine learning is able to take in complex data made up of billions of data points; the more complex the input data that the machine is trained on, the more information it has available for making accurate predictions*" - *Cf.* Greenberg, Anastasia *op cit.*

results. Medical decision support software systems are nothing but an extremely fast and advanced processing system of medical knowledge data and patients' history data. Therefore, if the data introduced in the system are erroneous or inaccurate, the software will provide a mistaken diagnosis or treatment, which – if not detected by the physician applying the technology – will likely cause damage to the patient's health or even death.

As stressed by the Association for Computing Machinery US Public Policy Council (hereinafter "USACM") - other than data input errors - there are many challenges regarding the design and technical aspects of algorithms. Among those challenges, this association identified the concern of preventing bias from the onset data.[158] In true, one of the risks associated with the performance of machine learning within diagnosis and choice of treatment is the possible bias of the data collected and afterwards inserted in the machine. Such bias can "*substantially affect both performance and generalizability*" of the algorithm. [159] [160] By generalizability of the algorithm is meant that the same must be fed by a universe of data sufficiently wide to allow for accurate outcomes. If, by contrast, the algorithm works under a limited pool of data, the same is likely to become biased and provide inaccurate outcomes. The situation described has occurred with IBM Watson which – regardless of its successful diagnosis and treatment rates in the US - when used in hospitals in Europe and Asia[161] revealed to be unreliable. The wrong outcomes of the machine in geographical contexts different than the US, were explained by the fact that most of the medical articles included in the system were written by American Authors in light of the medicine practices of the US, circumstance that led the machine to provide for erroneous diagnosis and inappropriate courses of treatment, which did not suit the patients' profiles nor were in line with the medicine practices followed by the local physicians.

Data bias is certainly a factor to be considered when ascertaining liability arising from medical errors as a result of a defective machine learning outcomes, given that further than considering if liability should rest with the technology provider or user, the imputation of liability might be

[158] USACM *op. cit.*
[159] Ziad, Obermeyer and EJ, Emanuel *op. cit.*
[160] Anastasia Greenberg also draws attention to the phenomenon of "*overfitting*", which is another problem related to data. As explained by the Author "*the more complex the input data that the machine is trained on, the more information it has available for making accurate predictions, but the higher the risk of overfitting. Overfitting occurs when algorithms become very good at modelling the current dataset but cannot successfully generalize to a new dataset – the dataset used to make decisions pertaining to new patients*" - *Cf.* Greenberg, Anastasia *op. cit.*
[161] Gorski, David *IBM's Watson versus cancer: Hype meets reality*, available on https://sciencebasedmedicine.org/ibm-watson-versus-cancer-hype-meets-reality/

extended to a third party, *i.e.*, the one responsible for the collection and treatment of the data inserted in the algorithm. As stated by the international law firm Cooley (UK) LLP "*Implicit within the definition of artificial intelligence set out above is the combination of big data sets and algorithms. This leads to a proliferation of potential parties accountable for the loss, beyond the designer and manufacturer of the core product or software, to include the designer of the algorithm, the coder of the algorithm, the implementer/integrator of the algorithm, the owner of the data set that has been interpreted, the creator of the original data point, and so on*.".[162]

3.3.2 The use of Black-Box algorithms

It is a common understanding among both the legal and scientific community that by means of AI technology, technological tools are getting so complex and autonomous that humans no longer have understanding (nor control) over the way the machine is working. Such technological state of affairs has been designated *black box*, expression which illustrates the fact that machine learning systems have become obscure or opaque due to the fact that the way the same process and provide data or knowledge from the input data patterns is, in several cases, incomprehensible even for those who programmed/coded the machine.

In order to understand such phenomenon, some introductory explanations concerning the functioning of AI are necessary. Resorting to the explanation provided by LEE BELL "*AI is a branch of computer science attempting to build machines capable of intelligent behavior*"[163] while machine learning is "*the science of getting computers to act without being explicitly programmed*".[164] In sum, while AI concerns the building of intelligent machines, ML consists

[162] UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* written evidence (AIC0217) – Statement of Cooley (UK) LLP. *op. cit.*
[163] Bell, Lee *Machine learning versus AI: what's the difference?* available on http://www.wired.co.uk/article/machine-learning-ai-explained
[164] Stanford University, *Definition of machine learning* available on https://online.stanford.edu/course/machine-learning-1

on the implementation of compute methods or algorithms[165] that support the AI comprised in the machine, allowing it to become smarter. Machine learning is "*the enabler for AI*".[166]

The scientific community has been acknowledging ML's huge potentialities mainly due to the fact that rather than merely relying on the commands designed by a programmer, this technology identifies and learns to solve problems on its own without the need of programming machines to act in a certain way. As easily anticipated, machine learning is widely used in the scope of AI clinical support software tools. An example of what has been said concerns ML in the scope of tumour detection, in which algorithms are provided with large amounts of data (reports, images, etc.) regarding tumour and no tumour diagnosis, enabling the machine to recognize, classify and, therefore, provide a diagnosis on the basis of pattern extraction from all the data previously provided. Such technology is also used in clinical support software system tools as IBM Watson, Watson for Oncology and DeepMind Health.

Therefore, the use of black box technology has obvious severe implications in the health sector. In this realm, Authors refer to the concept of *black box medicine*, which in the words of W. NICHOLSON PRICE happens when "*algorithms troll through tremendous databases of health data to find patterns that can be used to guide care (…) These decisions differ in kind from previous data-based decisions because blackbox medicine is, by its nature, opaque; that is, the bases for black-box decisions are unknown and unknowable*.".[167] In addition, the Author explains that health data[168] are proliferating at an incredible rapid pace[169] through machine learning algorithms that "*can find that sort of complex underlying pattern in the data — but cannot explain or even state what those patterns are*".[170]

Considering that under the defective products' legislation, liability is triggered by the abnormal performance of the product, such regime does not fit AI which by nature is uncertain and

[165] As defined by the USACM, an algorithm is "*a self-contained step-by-step set of operations that computers and other 'smart' devices carry out to perform calculation, data processing, and automated reasoning tasks. Increasingly, algorithms implement institutional decision-making based on analytics, which involves the discovery, interpretation, and communication of meaningful patterns in data*." – *Cf.* USACM *op. cit.*
[166] Bell, Lee *op. cit.*
[167] Price, W. Nicholson *op. cit.*
[168] Examples of health care data are: clinical records, pharmacy records, medical test results, or even, genome sequencing - *Cf. Ibidem*
[169] Therefore, black box medicine "*seeks to exploit the tremendous amount of data being generated in health care to find and use these underlying relationships*" - *Cf.* Price, W. Nicholson *op. cit.*
[170] *Ibidem*

unpredictable. This creates a problem among the Claimants who will face difficulties firstly in detecting the failure and secondly in proving causation between the failure and the damage, given that "*it is technically hard to trace the cause of a system's output, because the A.I. is not linear and there is no line of code that can be traced as the cause. Therefore, it is difficult to find a 'defect', and even harder to find the causal link between such defect and the damage*".[171]

In sum, classical defective products liability' schemes are triggered based on a certain standard of performance expected from a product under a foreseeability criterion, but self-learning algorithms challenge such premise. For such reason the output generated by AI CDSS comprises a loss of control – among the programmer but especially among the hardware's manufacturer – which makes allocation of strict liability unjustified.

There are a few authors who refute the validity of such argument, claiming that damages caused by software must always be attributable to the technology producer since it is up to him to decide "*what kind of technique to use in order to achieve the best result possible, both in terms of sophistication and functionality of the robot as well as safety; only the producer could in fact devise and conceive possible methods aimed at preventing damage deriving from the proper—or even improper—use of its product*".[172] Such understanding seems, however, a quite simplistic approach to the reality here under assessment.

Additionally, as discussed, strict liability regimes require the mere proof of a defect to hold the agent liable, despite of the faultiness or negligence of the manufacturer, circumstance which does not suit a reality in which so many agents are involved both in the creation and use of the technology. The process of creation of AI decision making software tools is quite complex. The technology (hardware and software) might be created and assembled by different parties and there might be margin from the user to shape the technology in light of its adaptable features, reason why "*The coders, the compilers, the dataset builders, the trainers, the users. All of them contribute to the functioning of the system and ultimately influence the outcome*.".[173] [174] As a

[171] Lenardon, Joao Paulo de Almeida *op. cit.*
[172] Palmerini, E. *et al. Robotlaw… op. cit.*
[173] Lenardon, Joao Paulo de Almeida *op cit.*
[174] Accordingly, Cooley UK LLP stresses that "*In terms of causation, the use of artificial intelligence technologies in products which then go on to cause a loss, raises the question of how we will readily be able to determine who, as a matter of strict law, is to be held properly accountable – especially in circumstances where one or more parties might have contributed to the loss*." - *Cf.* UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* - written evidence (AIC0133) – Statement of Kemp Little LLP *op. cit.*

result, a principle of allocation of liability upon the manufacturer does not seem fair or balanced. Instead, harmonized regulation should "*serve to assign responsibilities and give precise rules about liability relating to artificial intelligence*"[175] under a shared responsibility principle.

3.3.3 Conclusions

The concerns posed *supra* were addressed by the Medicines and Healthcare products Regulatory Agency, who stated that proper regulation must exist "*where AI meets the definition of a medical device*".[176]

These apprehensions were also addressed in the PR 2015/2103, under two perspectives. From the victim's point of view, whereas AH refers that considering that in order to get compensation the Claimant has to prove the causal link between the damage and the defect, strict liability does not suffice, in light of the fact that in the scope of damages caused by the advanced technology, the victim has less resources to fulfil this evidence requirement.[177] From the manufacturers' or technology developers' perspective, whereas AI stresses that the applicability of Directive 85/374/EEC does not suit this reality, given that "*the current legal framework would not be sufficient to cover the damage caused by the new generation of robots, insofar as they can be equipped with adaptive and learning abilities entailing a certain degree of unpredictability in their behaviour, since those robots would autonomously learn from their own variable experience and interact with their environment in a unique and unforeseeable manner*".

Lastly, it must be mentioned that despite the deep assessment on DSS made by the CJEU within the Phillips Judgement, the same does not make any considerations regarding the algorithms comprised in the technology and at any moment addresses the specificities of the incorporation of AI black box algorithms in these tools.

What has been said also applies to both the Medical Devices Regulation and MEDDHEV's which at any moment refer to specific software comprising AI features, and that as far as liability is concerned, merely refer in ANNEX VIII (66) that "*the conditions for liability in such*

[175] Lenardon, Joao Paulo de Almeida *op. cit.*
[176] UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* - written evidence (AIC0134) – Statement of The Medicines and Healthcare products Regulatory Agency (MHRA) *op. cit.*
[177] This subject matter is addressed in 2.1.2.

cases, including issues of causality and the level of damages and sanctions, should remain governed by national law".

Reliance on liability domestic regimes does not suit this realm, which in order to ensure accountability and liability requires harmonized rules, as typically occurs with products used for services provided in the field of medicine. In fact, if some Member States – in light of the Defective's Product Directive – follow the understanding that the hardware's manufacturer must be liable; while other Member States follow the understanding that the manufacturer should be exonerated from liability and the AI software developer must be liable; and other Member States deem that these disputes must be judged under medical malpractice rules and follow the tendency of holding the user liable, then AI software decision tools will only be adopted in Member States providing favourable regimes to the technology's developers (who are responsible for the research and development of these tools), therefore, medicine advancements within the EU will be severely compromised.

4. Chapter IV: Liability of the AI technology itself in the scope of clinical decision support software

4.1. Reflections upon the need to create new liability rules

After assessing the liability arising from the use of AI clinical support software in light of medical malpractice rules and defective product's rules, it is time to reflect upon the need of implementing a new liability regime aiming at holding the technology liable itself, or, instead, merely resorting to the regulatory schemes already in place.

This subject matter was deeply discussed in the UK following the government's initiative *Artificial Intelligence Committee AI in the UK: ready, willing and able?* in which all relevant stakeholders in the field were heard.

Against the need of creating a new liability regime for AI, the Law Society of England and Wales stated that "*there is no obvious reason why the growth of AI and the use of data would require further legislation or regulation*"[178] considering that "*most AI is embedded in products and systems, which are already largely regulated and subject to liability legislation*".[179] Accordingly, the law firm Bristows LLP stated that given the current development state of AI and that there is not yet a significant interaction between machines without human intervention, AI is "*not really different from current technology especially when it comes to reviewing issues of liability for non-performance (…) if the software does not work, then the software developer is at fault because there is a functionality issue*".[180]

Taking the opposite view, the international law firm Baker McKenzie argued that regulatory work should be initiated[181] in order to avoid a later on reactive regulation.[182]

As a downside of creating specific liability rules applicable to AI, it is mentioned that rigid liability rules upon AI developers and manufacturers will require the allocation of a certain

[178] UK's Parliament *AI in the UK: ready, willing and able? - Chapter 9: Shaping artificial intelligence (UK)* available on https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/10013.htm#_idTextAnchor143
[179] *Ibidem*
[180] UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume… op. cit.*
[181] Namely by facilitating self-regulation schemes and resorting to standard settings - *Cf.* UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* - *Cf. Ibidem*
[182] UK's Parliament *AI in the UK: ready, willing and able? - Chapter 9… op. cit.*

amount of money to every AI DSS tool, circumstance that will raise the production costs and create barriers to the introduction of technology in society with the consequence of slowing down medical progress achieved through AI means.[183] Furthermore, some Authors outline that if specific liability rules are created, legal experts will face the difficulty of engaging in discussions regarding what constitutes the threshold between an AI health tool or another system or machine which has similar technology which might or might not be deemed a form of AI.[184] In line with what has been said Joao Lenardon stresses that new regulation might "*augment the existing bureaucracy, and possibly create legal contradictions and loopholes, ultimately hindering the development of A.I. and generating other damages, like the exploitation of such loopholes*".[185] [186] Another downside identified, within the scope of health care – a highly regulated field - is that a new liability regime might bring an overlap of regulators, especially considering the EU's CE marking system in place for medical devices.[187] Lastly, from a competition point of view, if European technology manufacturers are subject to stricter rules, these will be in a disadvantage with countries without specific liability regimes.[188]

On the other hand, it has been argued that specific rules foster professionalization and the qualification of personnel in the field, making the AI culture more responsible and transparent.[189] From the consumer's perspective, clear liability rules generate safer technology considering that technology manufactures will be more compelled to avoid to commercialize CDSS which contain or are suspected to contain technical failures.[190] As a matter of fact, liability rules posed *ex ante* lead to an increase in safety investments as well as ensure recovery for harm caused to individuals.[191] The main motivation behind the drafting of a liability regime

[183] Petit, Nicolas *op. cit.*
[184] Chung, Jason *Hey Watson… op. cit.*
[185] Lenardon, Joao Paulo de Almeida *op cit.*
[186] Notwithstanding such point of view, Joao Paulo de Almeida Lenardon refers that "*However, artificial intelligence is a disruptive technology that brings new economic and societal changes, which the current law is not perfectly suited to address, especially when coupled with hardware that allows A.I. to interact with the world. This unsuitability of the current laws creates legal gaps and can lead to problems*." - *Cf. Ibidem*
[187] UK's Parliament AI *in the UK: ready, willing and able? - Chapter 9… op cit.*
[188] *Ibidem*
[189] Lenardon, Joao Paulo de Almeida *op. cit.*
[190] *Ibidem*
[191] Palmerini, E. *et al. Robotlaw… op. cit.*

should not be punishment of the technology producer over a technical failure but distributing or socializing the costs triggered by the use of AI in the health sector.[192]

A point to be considered is that liability litigation is a worry among those who develop products to be used in health care, hence, several Authors argue that clear and specific liability rules must be established in order to avoid uncertainty, considering that legal uncertainty "*has an adverse effect on investments*".[193] Supported by Ryan Calo's view on this subject, NICOLAS PETIT refers that "*Uncertain liability rules could act as disincentives to investment into open robotics markets, and channel the flow of capital towards narrow robot functionality where producers can better manage risk, leaving open robotics underdeveloped*.".[194] The Authors mentioned do not solely raise the possibility of creating a specific regime for AI and robotics manufacturers, they mention that such regime could entail a form of immunity, in analogy with the immunities provided to, by instance, website operators.[195]

There are several Authors who explicitly claim for the adoption of a specific liability regime. ANASTASIA GREENBERG states that "*AI does not easily fit into any existing private law regimes for compensating patients who will inevitably suffer harm from the however small amount of errors.".*[196] As an alternative solution to traditional tort law systems[197] [198], would be to remove AI from the private law system and create compensation schemes. These compensation schemes would be funded by the technology manufacturers and developers and would be activated in the event of being necessary to cover compensation for health damages arising from the use of CDSS.

There are also some Authors who believe that new liability rules must be created but by relying on the concept of legal personhood and adapt it in order to make the AI technology itself liable.[199] In the following points focus will be given to this legal construction under which

[192] *Ibidem*
[193] Petit, Nicolas *op. cit.*
[194] *Ibidem*
[195] *Ibidem*
[196] Greenberg, Anastasia *op. cit.*
[197] Galasso, Alberto and Luo, Hong, *Punishing Robots: Issues in the Economics of Tort Liability and Innovation in Artificial Intelligence* available on http://www.nber.org/chapters/c14035.pdf
[198] J.K.C. Kingston, *Artificial Intelligence and Legal Liability*, available on https://www.researchgate.net/publication/309695295_Artificial_Intelligence_and_Legal_Liability
[199] Chung, Jason *Hey Watson… op. cit.*

personhood is provided to AI in view of making the technology directly liable for the damages caused in the course of the use of DSS.

4.2. Providing personhood to AI used for the purposes of medical diagnosis and choice of course of treatment as a mean to ensure liability

Establishing culpability in the scope of AI use for clinical purposes is a hot topic. Such circumstance is explained by the fact that it is a complex task to assign *mens rea* when the DSS here under discussion often rely on black box algorithms which operate in an opaque way. Classical liability schemes require – to hold someone liable – *mens rea, i.e.*, intent, understanding and control over the behavior which led to the damage. In that sense, it reveals to be troublesome to allocate liability when the wrongful diagnosis or treatment are not a consequence of a human behavior but a result of an opaque algorithm's output not understandable or controllable. In light of such difficulties, the legal community has been discussing several potential liability approaches that might suit these circumstances. Among such approaches are the possibility to assign personal liability to directors of companies responsible for the design and development of the AI technology; the possibility of - under the identification doctrine - identifying the natural person who is the "*direct mind and will*"[200] of the company; or identifying a specific individual personally responsible for the wrongdoing (*e.g.,* the programmer culpable for writing a wrongful line of code). These approaches, however, do not seem to be up to the challenges raised above. In fact, as clarified by The Royal College of Radiologists within the public hearing held by the UK on AI "(…) *if the 'directing mind and will' in a particular case is no longer that of a human being, even these attempts seem likely to fail. Indeed, not only will it prove even more difficult to find mens rea on the part of a human being in the company, it will not even be possible to prove causation, on the basis that the directors and even the programmers may be able to argue that there has been something akin to the 'free voluntary action' of a third party*"[201]. The referred College also draws attention to the fact that such state of affairs "*of course provides a great incentive for human agents to avoid finding out what precisely the ML system is doing, since the less the human agents know, the*

[200] UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* - written evidence (AIC0146) – Statement of The Royal College of Radiologists *op. cit.*
[201] *Ibidem*

more they will be able to deny liability for both these reasons.".[202] Such uncertainty is however a risky edge for the society to be seated on. The opacity of ML technology used for health care purposes must entail accountability considering that the AI technology here under analysis has "*the potential to affect the morbidity and mortality of millions via little understood algorithmic decision-making processes*".[203] The risk mentioned herein is intensified by the fact that – if the Defective Products Directive is applied – article 7 provides for a liability exemption. Under such disposition – which is in line with article 15 of the Medical Devices Directive and article 1, chapter 1, Annex I of the Medical Devices Regulation – the manufacturer of the technology is entitled to a state of the art defense, which means that, liability will not arise "*if the state of scientific and technical knowledge at the time when the respective producer put the product into circulation was not such as to enable the existence of the defect to be discovered".* The applicability of such defense might represent a responsibility gap in this realm.

Considering the reflections above, if, until now, this thesis addressed allocation of liability in light of two possible scenarios: holding the user of the AI technology liable (Doctor applying the technology or the hospital institution within which the health services under dispute were provided), or holding the developer or manufacturer of the technology liable under the defective product's rules; it is now time to open a third gate and reflect upon the possibility of holding the AI DSS technology liable itself.

In this scope – although some controversy exists - there seems to exist an understanding that the logical path to hold AI liable itself is assigning personhood to it, which means resorting to a legal fiction under which the machine/algorithm is equated to a human professional in the field, hence, deem it liable for any damages caused by it. In fact, several Authors have been defending this solution, claiming that it would bring more predictability in Court proceedings - since it would dismiss the Courts of the complex task to determine the liable agent – and contribute to the avoidance of liability claims end-up in high technical disputes which represent high costs - due to the necessary involvement of experts in the field and the need to educate qualified judges[204] - circumstance that would put defendants who claim medical damages arising from the use of AI in an unbalanced position.

[202] *Ibidem*
[203] Chung, Jason *Hey Watson… op. cit.*
[204] An analogy can be drawn with infringement actions concerning pharmaceutical patents.

Lastly it is referred that providing personhood to the DSS itself and holding it liable would bring technology developers more certainty on the legal implications of AI, therefore, helping defining how far to go when providing AI with autonomy and decision-making power within clinical decision-making.

4.2.1. Analogy with a medical student: the IBM Watson case

Despite the arguments posed above, several Authors have been contesting the extension of the concept of personhood to AI, arguing that personhood entails morality and human/emotional intelligence, which are "*central to the enjoyment of full rights and legal responsibilities of natural persons*".[205]

This reasoning has been used in order to contest the provision of personhood to AI software systems currently in use for the purposes of diagnosis and treatment. Under the spotlight of this controversy is the most advanced AI tool in this sector, IBM Watson. It has been claimed that this piece of AI is not provided with emotional intelligence or intuition which are required elements of overall intelligence, that provide the ability to make good decisions[206], hence, personhood should not be granted to it. Such argument is, however, easily deconstructed. As referred in the statement rendered by the law firm Kemp Little LLP "*Personhood is a fundamental cornerstone of our legal system – and we have shown over the centuries a willingness to flex the concept to suit new requirements of society*".[207] An example of the evaluation of the concept of personhood among civil societies is the provision of personhood to legal persons, when the concept was initially designed to be exclusively applied to natural persons.

In that sense, Authors who support the view that AI software as IBM Watson should be granted with personhood argue that if we look into the functionalities of these tools, mainly they "*collect information from patients, analyze patient records, survey existing texts, and test hypotheses in order to make diagnostic and treatment recommendations*".[208] Authors further stress that these

[205] Chung, Jason *Hey Watson… op cit.*
[206] *Ibidem*
[207] UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume…* - written evidence (AIC0133) – Statement of Kemp Little LLP *op. cit.*
[208] Chung, Jason *Hey Watson… op. cit.*

AI tools are not used without the intervention of a physician who supervises the applicability of the outcome of the algorithm. In that sense, it has been argued that bearing in mind the tasks developed by the tool as well as the fact that such tasks are supervised by a resident or attending physician, the IBM Watson – or any other equivalent AI clinical support software systems – must be granted with personhood under the legal fiction of analogizing it to a medical student. In light of what has been referred, JASON CHUNG claims that "*Much like students, Watson can, with periodic guidance, independently "learn" from texts and apply that knowledge to specific medical cases. It also communicates desirable treatment options in a manner intelligible to humans*."[209], thus, the AI technology itself can be deemed liable under malpractice rules.

The referred Author also assessed the analogy between IBM Watson and a consulting physician and nonetheless concluded that such alternative must be avoided, given that – differently to what happens with medical students - consulting physicians do not have a direct interaction with the patient, consequently, there is no Doctor-patient relationship, circumstance which would preclude malpractice claims against IBM Watson.

Still according to JASON CHUNG "*Watson should be classified as a legal person for the purposes of apportioning liability so that Watson's activities can be insured at a level that rises to that of a medical student*.".[210] The Author further explains that this analogy approach would ease allocation of liability in case of medical errors caused by the wrong outcome of the AI technology since both the technology and its user could be deemed negligent. The technology, on grounds of a wrong medical decision not in line with the standard of care to which was bound; and the user applying the technology, on grounds of negligent delegation of a task that the machine – in analogy with a medical student - was not ready to perform.[211] The author supports his view on the opinion that the fact that AI tools as IBM Watson do not comprise human morality, does not mean that the same are not up to the task of providing more informed, appropriate and accurate decisions, and concludes that for the time being these AI tools are not, and shall not be independent - they should "*play games, not God*"[212] - reason why the medical student analogy fully fits this reality.

[209] Chung, Jason *Hey Watson… op. cit.*
[210] *Ibidem*
[211] *Ibidem*
[212] *Ibidem*

Without jeopardizing the merits of such legal construction, it should be pointed out that the same might, however, present a loophole given that several courts have been stating that the standard of care to which Doctors are bound, does not vary in accordance with the degree of experience of the physician.[213] Henceforth, junior or medical Doctors are subject to the same standards of care of any other experienced physician. In sum, if courts will follow this understanding, the analogy between AI DSS loses sense, and all in all, tools as IBM Watson will be judged under medical malpractice rules as a reasonable professional in the field, not as a medical student. Despite such possible loophole, the merits of this analogy approach should not be disregarded, instead, the difficulties raised should be faced as mere obstacles to be surpassed.

4.2.2. The *status of electronic persons* under the EU Parliament Resolution no. 2015/2103(INL) on "*Civil Law Rules on Robotics*"

Although the provision of personhood to AI sounds like a distant reality, the EU has already shown some willingness in adopting such legal concept.

In fact, last year the EU Parliament launched a Resolution within which it is recognized that advancements in the field of robotics and AI used for healthcare purposes might require new civil liability rules.[214] The PR 2015/2103 further reflects upon the possibility of creating a new legal category under which autonomous robots[215] [216]can be held liable *per se*.[217] [218]

[213] Some judgments have in fact been stressing that "*no allowance is made for inexperience*" - *Cf.* Brazier, Margaret and Cave, Emma *op. cit.*, p. 200.
[214] Whereas AB. and points 33, 34, 35 and 36 of the PR 2015/2103.
[215] It seems to be of relevance to clarify that although no reference is made to AI within the PR 2015/2103 such technology is encompassed in the broad definition of robot, as explained *supra*.
[216] In the scope of AI comprised in the clinical support software systems, it is arguable if the system should be deemed independent. If, one the one hand, the tool requires the intervention of a physician who applies the outcome provided by the robot; on the other, the medical decisions rendered by the machine are taken autonomously. Therefore, in the event a new legal instrument is drafted some controversy is expected regarding its applicability to AI clinical support software systems like IBM Watson.
[217] Whereas AC. and AD. of the PR 2015/2103
[218] Being expressly pondered that "*where a robot can take autonomous decisions, the traditional rules will not suffice to give rise to legal liability for damage caused by a robot, since they would not make it possible to identify the party responsible for providing compensation and to require that party to make good the damage it has caused*" - Whereas AF. of the PR 2015/2103

Under the liability section, it is also referred that a new legislative instrument must be drafted and adopted and that the same must be combined with the use of non-legislative instruments, such as guidelines and codes of conduct.[219]

Although no specific rules are suggested on allocation of liability arising from the use of AI DSS, it is mentioned that the new legal instrument to be adopted must follow either a strict liability, or a risk management approach.[220] By risk management approach is meant a liability scheme which does not focus on the individual person who acted negligently "*but on the person who is able, under certain circumstances, to minimise risks and deal with negative impacts*".[221] Such approach is in line with the deep pockets doctrine already referred to.

The most innovative aspect of this Resolution is the fact that – although being referred that for the time being responsibility must lie with a human and not a robot - it asks for an impact assessment on the creation of "*a specific legal status for robots in the long run, so that (…) could be established as having the status of electronic persons"*.[222] It seems that under the notion of status of electronic person, the EU is willing to embrace the paradigm of providing personhood to DSS comprising AI.

4.2.3. Merits and limitations

After explaining the concept of personhood as a mean to hold the AI used for clinical purposes liable it is now time to look into the advantages and trade-offs of following such course of action.

From the perspective of the developer and/or manufacturer of the technology, there are a few advantages to be highlighted. Firstly, it is mentioned that allocation of liability to the technology itself allow technology developers and manufacturers to operate under a more predictable liability regime. The reasoning behind such statement is explained by the idea that if AI CDSS are held liable in analogy with a medical student, then compensations provided to victims under malpractice rules will be capped, circumstance that would ease obtaining insurance cover for

[219] Point 51 of the PR 2015/2103
[220] Point 53 of the PR 2015/2103
[221] Point 55 of the PR 2015/2103
[222] Points 59 f) of the PR 2015/2103

health damages caused.[223] Secondly, it is seen as an advantage that if such liability paradigm is adopted, claims against manufacturers or designers will be judged in light of malpractice rules, therefore, the strict liability regime of defective products will not apply.[224] As a result, entities responsible for the conception of the technology will be shielded from being strict liability - which arises without proving the fault, only the damage - in this domain, where potential unpredictable consequences (based on self-learning machine algorithms) are likely to take place.[225]

From the patient and a general interests' perspective there are also significant advantages in resorting to this liability approach. At first, this solution does not require the creation of a new field of substantive law, since medical malpractice rules will apply and a harmonized standard of care in this scope can be followed. Another plus of this approach is avoiding a case by case assessment of the technology and its use in order to identify who is the agent to be held liable. Still in the scope of judicial disputes, this approach exonerates Claimants from proving and Courts from assessing if the technology *sub judice* has an AI nature and which are the duties of the parties involved in the process of the generation and applicability of the diagnosis or treatment outcome provided by the algorithm. From a procedural law point of view, by providing personhood to DSS, the technology will be deemed a party (Defendant) and victims will obtain greater access to information involving the patient's care under the use of the technology. [226] [227] Therefore, Claimants will gain a deeper understanding of the AI tool and of the failure that led to the wrongful diagnosis or treatment, circumstance which will equalize power between the parties involved in the litigation (patient and corporation).

Moreover, although capping liability – under the medical student's analogy – seems like a beneficial solution for those involved in the technology making, such cap also brings

[223] Jason Chung Chung, Jason, *What Should… op. cit.*
[224] *Ibidem*
[225] Such argument is however disputable considering that the PR 2015/2103 (point 53) does not exclude the possibility of creating a strict liability principle in the scope of damages caused by AI.
[226] Chung, Jason, *What Should… op. cit.*
[227] In fact, as explained by Jason Chung - resorting to Eric Turkewitz view - when assessing IBM Watson "*those named in a lawsuit have a higher evidentiary burden than "non-party witnesses". This means that parties to a lawsuit must provide copies of statements and other evidence that may be otherwise privileged during the process of conducting internal committee reviews. As such, if Watson is named as a defendant in a civil suit, those suing may be able to gain greater access to Watson's logs to determine its exact involvement (perhaps over involvement) and history on the case*." - *Cf.* J Chung, Jason *Hey Watson… op. cit.*

advantages to the society, since hospital institutions will be more likely to adopt advanced AI DSS under the security net that a liability cap will apply in the event of a malpractice claim.[228] Lastly, a benefit which also serves all the parties involved in this realm is the fact that the analogy between AI DSS and medical students, allows for the creation of a more predictable framework for future advances in this realm, considering that the concept of personhood and the analogy underlying it can evolve and mature accordingly to the technology's capabilities. If, in the future, CDSS comprising AI (as IBM Watson) mature to a level in which no human intervention is required, then medical malpractice rules might still apply in light of an analogy between the AI tool and an experienced Doctor. Such possibility suits the Claimant (who does not need to ascertain who to bring proceedings against), the manufacturers and developers of the technology (who will more easily prepare their defense in Court by analogizing the facts under dispute to a typical health damage caused by a medical student or Doctor), and the Courts (which in light of said analogy will be more sure about the standard of care which was owed by the AI software towards the patient).

Such solution does not come, however, without certain limitations. Authors like JEREMY ELMAN and ABEL CASTILLA claim that "*An AI by design is artificial, and thus ideas such as liability or a jury of peers appears meaningless. A criminal courtroom would be incompatible with AI (unless the developer is intending to create harm, which would be its own crime).*"[229] Although this topic was already addressed in the scope of the difficulties of the applicability of the *mens rea* concept to AI, it has to be reiterated that this argument is easily overcome. Firstly, because liability is being herein assessed from a civil point of view, not a criminal point of view. Secondly - even in the scope of criminal law – there are several jurisdictions in which criminal action against legal persons is allowed without the need to prove an intent to cause damage. Other Authors refer that the provision of legal personhood to a software agent does not bring significant advantage since the technology itself is not in the position to earn a revenue and hence pay for any compensation.[230] Such argument, however, seems as a misconception of the real obstacles behind claiming damages for medical errors caused by AI tools. As demonstrated above, the merits of adopting such a liability approach rest are the assurance that the task to

[228] *Ibidem*
[229] Elman, Jeremy and Castilla, Abel *op. cit.*
[230] Palmerini, E. *et al. Robotlaw… op. cit.*

identify who will be held liable and to prove causation in such a complex realm are alleviated, allowing for more successful rates in claims filed in order to recover damages arising from the medical error caused by AI medical decision-making software. Moreover, this liability approach would allow for the adoption of an insurance coverage system under which each software would be registered and provided with an insurance policy number.[231] Therefore, in case of the technology being held liable, the Court conviction would lead to an immediate activation of the insurance amount reserved to said DSS.

[231] Such view is supported by point 59. of the PR 2015/2103, according to which "*Calls on the Commission, when carrying out an impact assessment of its future legislative instrument, to explore, analyse and consider the implications of all possible legal solutions, such as:*
a) establishing a compulsory insurance scheme where relevant and necessary for specific categories of robots whereby, similarly to what already happens with cars, producers, or owners of robots would be required to take out insurance cover for the damage potentially caused by their robots;
b) ensuring that a compensation fund would not only serve the purpose of guaranteeing compensation if the damage caused by a robot was not covered by insurance;
c) allowing the manufacturer, the programmer, the owner or the user to benefit from limited liability if they contribute to a compensation fund, as well as if they jointly take out insurance to guarantee compensation where damage is caused by a robot;"

5. Chapter V: Conclusions and findings

In light of the analysis conducted it is safe to state that the current civil liability framework does not suit this new paradigm in which medicine relies on DSS tools comprising AI for the purposes of achieving more accurate diagnosis and more informed choices of treatment.

As seen, liability arising from the use of AI in the health sector might be framed under malpractice rules, however, the use of CDSS tools drastically disrupts the typical relationship between Doctor and patient, circumstance which carries causation issues, making it difficult for the harmed patient to establish a causal link between the harm and the illicit conduct. Therefore, in the event legislators follow the understanding of assessing health damages under medical malpractice rules, the concept of medical negligence will have to be reshaped.

It was also concluded that the plain applicability of medical devices norms, hence, the assessment of liability in this realm under the Defective Products' Directive brings the danger of unfair liability allocation, considering the fact that AI reveals to be a reality much more complex than the technology comprised in classical medical devices. Despite that and in light of the fact that the new MD Regulation broadened the definition of medical device in order to encompass software used for the purposes of medical diagnosis and treatment (deeming it Class II risk software), if such legislation is deemed applicable, the approval procedure must be redesigned in order to create a semi-certification procedure under point 35 of the PR 2015/2103- more flexible but still based on standards and able to ensure a reasonable level of control - compatible with black box features of AI technology. Such certification procedure and inherent liability approach would however face the drawback of the fact that if there are no qualified bodies responsible for the assessment of these CDSS tools, as stressed by Jerry Fishenden, technology manufacturers will stop labelling its software as AI in order to escape regulation.[232]

Following the above, the possibility of assigning personhood to the technology itself (by resorting to the legal fiction of the medical student) as a mean to ensure accountability within the use of AI for health care purposes was identified as a course of regulatory action to be followed. Such option, however, will only produce relevant effects if harmonization at the EU

[232] UK's Parliament *AI in the UK: ready, willing and able? - Chapter 9… op cit.*

level is achieved. In that sense, attention was drawn to the fact that reliance on domestic civil regimes will have an adverse effect on the development and acceptance of AI CDSS.

Although allocation of liability must be clarified in this realm, it is understood that a one fits all norm (allocating liability to the user, developer, manufacturer or the AI itself) is a utopian idea. Nevertheless, legal principles should be developed in order to ensure accountability and liability among the stages of development of the technology and its afterwards use. A shared liability principle - sharing liability among all the stakeholders involved in the development, manufacture and use of the technology – must be considered, in order to avoid leaving the victim (harmed patient) with the heavy burden of demonstrating and proving the medical error and a causal link between the error and the damage.

In line with the need of creating a legal principle of shared liability, the role of self-compliance should not be disregarded, henceforth, stakeholders involved in this process must follow codes of conduct (created internally or externally). Although this approach – which is not politically legitimised – brings the risk of non-transparency[233] one might look into such regime as a mean to ease patients to obtain redress since such system would discharge victims from proving the software's specific failure which led to the damage and give them the right to claim for compensation on the basis of non-compliance with a rule or safety standard provided for in the code of conduct. In this regard, must be mentioned the US initiative held by the USACM, which developed an ACM Code of Conduct encompassing principles to be applied "*during every phase of system development and deployment to the extent necessary to minimize potential harms while realizing the benefits of algorithmic decision-making*".[234] [235] Under such Code of Conduct seven principles were established: (i) Awareness*: Owners, designers, builders, users, and other stakeholders of analytic systems should be aware of the possible biases involved in their design, implementation, and use and the potential harm that biases can cause to individuals and society; (ii)* Access and redress*: Regulators should encourage the adoption of mechanisms that enable questioning and redress for individuals and groups that are adversely affected by algorithmically informed decisions; (iii)* Accountability*: Institutions should be held*

[233] Lenardon, Joao Paulo de Almeida *op. cit.*
[234] USACM *op. cit*
[235] USACM *op. cit.*

responsible for decisions made by the algorithms that they use, even if it is not feasible to explain in detail how the algorithms produce their results; (iv) Explanation*: Systems and institutions that use algorithmic decision-making are encouraged to produce explanations regarding both the procedures followed by the algorithm and the specific decisions that are made. This is particularly important in public policy contexts; (v)* Data provenance*: A description of the way in which the training data was collected should be maintained by the builders of the algorithms, accompanied by an exploration of the potential biases induced by the human or algorithmic data-gathering process; (vi)* Auditability*: Models, algorithms, data, and decisions should be recorded so that they can be audited in cases where harm is suspected; and (vii)* Validation and test*: Institutions should use rigorous methods to validate their models and document those methods and results. In particular (…) to assess and determine whether the model generates discriminatory harm.*[236]

These principles address some of the main obstacles to compensation for damages in the scope of the use of CDSS tools. The principles of awareness and data provenance aim to provide guidance in the scope of the collection of the onset data under which the system will work and allow patients to gather evidence on the software failure that led to a wrong diagnosis or treatment option when such failure is a result of a data error or data bias.

On the other hand, the principles of accountability and explanation address the black box technology concerns, by promoting transparency practices to be adopted among those who develop or use technology of this nature. Under these principles, institutions using algorithms for clinical decision-making purposes must produce explanations on the way how algorithms work, even if - due to the algorithm's obscurity and opacity – it is not possible to provide a detailed and full explanation. Moreover, under the accountability principle it is clearly established that institutions using black box algorithms for decision making purposes shall be deemed liable for the decisions taken, regardless of not being feasible to have full knowledge on how the algorithm works. Such understanding is of major importance, since the lack of knowledge on how algorithms used for medical diagnosis and treatment work, cannot be deemed a liability's cause of exclusion. The principle of auditability is key, given that the same aims to oblige institutions to maintain records of the models, algorithms and data used, as well

[236] USACM *op. cit.*

as of the decisions taken in this realm, as a mean of promoting transparency and ease access to information in the event of audits. In our view, these auditing mechanisms are another step towards the achievement of a more clear and defined allocation of liability in the scope of machine learning's use and once again facilitate the victims' chances of getting compensation for damages caused following a wrong diagnosis and prescription of a mistaken treatment.

In sum, there is consensus between the technological, legal and medical community that transparency and accountability principles and rules shall be designed and applied in this scope in order to, more than defining liability allocation between the actors involved, provide more protection to all patients whose diagnosis, medical treatments, or medical decisions of any nature are substantially decided by machine learning algorithms.

If I could time travel into the future, my first port of call would be the point where medical technology is at its best because, like most people on this planet, I have this aversion to dying.

Neal Asher

6. Bibliography

6.1. Primary Sources

6.1.1.1. Table of legislation

1. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

2. Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)

3. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

4. Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts

5. Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts

6. Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts

7. Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)

8. Directive 2000/31 (of the European Parliament and of the Council of 8 June 2000) on certain aspects of information society services

9. 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

10. Directive 2001/95 EC of the European Parliament and of the Council of 3 December on General Product Safety

11. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)

12. Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market

13. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning

medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market

14. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

15. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

16. European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL))

17. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 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

18. 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

6.1.2. Table of cases

1. Judgment of the European Court (Fourth Chamber) of 7 December 2017 - Case no. C 329/16: Syndicat national de l'industrie des technologies médicales (Snitem) and Philips France v Premier ministre and Ministre des Affaires sociales et de la Santé.
2. Judgment of the European Court (Second Chamber) of 19 November 2009 - Case no. C-288/08: Kemikalieinspektionen v Nordiska Dental AB
3. Judgement of the Missouri Court of Appeals of January 30th, 2001 - Redfield v. Beverly Health and Rehab. Inc., 42 S.W.3d 703 (Mo. Ct. App. 2001)
4. Judgement of the United States Court of Appeals for the third circuit, no. 09-2042, Roland C. Mracek v. Bryn Mawr Hospital; Intuitive Surgical, Inc. (opinion)
5. Judgment of the Supreme Court, Appellate Division, Fourth Department, New York, *Jones v. W + M Automation, Inc*

6.2. Secondary Sources

6.2.1. Books

1. Andoulsi, Isabelle and Wilson, Petra *Understanding Liability in eHealth: Towards Greater Clarity at European Union Leve*l in George, Carlisle; Whitehouse, Diane and Duquenoy, Penny *eHelath: Legal, Ethical and Governance Challenges*, Springer 2013
2. Brazier, Margaret and Cave, Emma *Medicine, Patients and the law*, sixth edition, Manchester University Press, 2016
3. Cooper, Diana Marina *The application of a "sufficiently and selectively open license" to limit liability and ethical concerns associated with open robotics* in Calo, Ryan; Froomkin, A. Michael; Kerr, Ian *Robot Law*, Edward Elgar Publishing Limited, 2016
4. Croft, Elizabeth A. and Loos, H.F. Machiel Van der *The Open Roboethics initiative and the elevator- riding robot* in Calo, Ryan; Froomkin, A. Michael; Kerr, Ian *Robot Law*, Edward Elgar Publishing Limited, 2016
5. Frank, Sharon *A new model for European Medical Device Regulation: a comparative analysis in the EU and the USA*, Europa Law Pub, 2003.
6. Giesen, Dieter *International medical malpractice: a comparative law study of civil liability arising from medical care*, Springer Netherlands, 1988
7. Hubbard, F. Patrick *Allocating the risk of physical injury from "sophisticated robots": Efficiency, fairness, and innovation* in Calo, Ryan; Froomkin, A. Michael; Kerr, Ian *Robot Law*, Edward Elgar Publishing Limited, 2016
8. Karnow, Curtis E.A. *The application of traditional tort theory to embodied machine intelligence* in Calo, Ryan; Froomkin, A. Michael; Kerr, Ian *Robot Law*, Edward Elgar Publishing Limited, 2016
9. Kennedy, Ian and Grubb, Andrew *Medical law*, third Edition, Oxford University Press, February 17 2005
10. Lewis, Charles J. *Medical Negligence: a practical guide*, third Edition, Tolley 1995.

11. Millar, Jason and Kerr, Ian, *Delegation, relinquishment, and responsibility: The prospect of expert robots* in Calo, Ryan; Froomkin, A. Michael; Kerr, Ian *Robot Law*, Edward Elgar Publishing Limited, 2016

12. Mils, Peter *Ethical Reuse of Data from Health Care: Data, Persons and Interests* in *The Ethics of Biomedical Big Data - Law, Governance and Technology Series* 29, Brent Daniel Mittelstadt Luciano Floridi Editors, Springer 2016

13. Richards, Neil M. and Smart, William D. *How should the law think about robots?*, in Calo, Ryan; Froomkin, A. Michael; Kerr, Ian *Robot Law*, Edward Elgar Publishing Limited, 2016

14. Smith, Bryant Walker *Lawyers and engineers should speak the same robot language* in Calo, Ryan; Froomkin, A. Michael; Kerr, Ian *Robot Law*, Edward Elgar Publishing Limited, 2016

6.2.2. Articles

1. Abreu, Pedro Henriques and Santos, Miriam Seoane *Predicting Breast Cancer Recurrence Using Machine Learning Techniques: A Systematic Review* available on https://dl.acm.org/citation.cfm?id=2988544

2. Association for Computing Machinery US Public Policy Council (USACM), Statement on Algorithmic Transparency and Accountability, January 12 2017, available on https://www.acm.org/binaries/content/assets/public-policy/2017_usacm_statement_algorithms.pdf

3. Bell, Lee *Machine learning versus AI: what's the difference?* available on http://www.wired.co.uk/article/machine-learning-ai-explained

4. Bertolini, Andrea *Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules* available on https://www.tandfonline.com/doi/abs/10.5235/17579961.5.2.214

5. Bramer, Max and Petridis, Miltos *Artificial Intelligence XXXIV 37th SGAI International Conference on Artificial Intelligence, AI 2017, Cambridge, UK, December 12-14, 2017, Proceedings*, available on https://link.springer.com/book/10.1007%2F978-3-319-71078-5

6. Buning, Madeleine de Cock; Belder, Lucky and Bruin, Roeland de *Mapping the Legal Framework for the introduction into Society of Robots as Autonomous Intelligent Systems* available on http://www.caaai.eu/wp-content/uploads/2012/08/Mapping-L_N-fw-for-AIS.pdf

7. Burgess, Matt *Holding AI to account: will algorithms ever be free from bias if they're created by humans?*, availalable on https://www.wired.co.uk/article/creating-transparent-ai-algorithms-machine-learning

8. Cabitza, Federico *The Unintended Consequences of Chasing Electric Zebra*s, available on http://www.dsi.unive.it/HUML2016/assets/Abstract/Cabitza.pdf

9. Cattell, Jamie; Chilukuri, Sastry and Levy, Michael *How big data can revolutionize pharmaceutical R&D* available on https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/how-big-data-can-revolutionize-pharmaceutical-r-and-d

10. Chung, Jason *What Should We Do About Artificial Intelligence in Health Care?* available on https://ssrn.com/abstract=3113655

11. Chung, Jason *Hey Watson, Can I Sue You for Malpractice? Examining the Liability of Artificial Intelligence in Medicine* available on https://ssrn.com/abstract=3076576

12. Cole, George S., *Tort Liability for Artificial Intelligence and Expert Systems*, 10 Computer L.J. 127 (1990) in The John Marshall Journal of Information Technology & Privacy Law Volume 10, Issue 2 Computer/Law Journal - Spring 1990 Article 1, available on https://repository.jmls.edu/cgi/viewcontent.cgi?article=1416&context=jitpl

13. Cox, Holly *Medical Device Software: Who Is Responsible When Something Goes Wrong?* available on https://ohiotiger.com/medical-device-software-defects/

14. Diamond, George A. MD; Pollock, Facc, Brad H. MPH; Work, Jeffrey W. MD *Clinician Decisions and Computers*, Seminar on computer applications for the cardiologist-VI Geiser, Edward A. MD; Skorton, FACC, David J. MD; FACC, Guest Editors, JACC Vol. 9, No.6 June 1987

15. Dijkstra, Edsger W. *The threats to computing science*, available on http://www.cs.utexas.edu/users/EWD/transcriptions/EWD08xx/EWD898.html

16. Domingos, Pedro *A Few Useful Things to Know About Machine Learning* available on https://homes.cs.washington.edu/~pedrod/papers/cacm12.pdf

17. Dyson, Sara E. *Medical Device Software & Products Liability: An Overview (Part I)* available on https://www.medtechintelligence.com/feature_article/medical-device-software-products-liability-overview-part/

18. Easterbrook, Frank H. *Cyberspace and the Law of the Horse* available on https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=2147&context=journal_articles

19. Elman, Jeremy and Castilla, Abel *Artificial intelligence and the law*, available on https://techcrunch.com/2017/01/28/artificial-intelligence-and-the-law/

20. English Oxford Living Dictionaries, available on https://en.oxforddictionaries.com/definition/chatbot

21. Faggella, Daniel *Applications of Machine Learning in Pharma and Medicine* available on https://www.techemergence.com/machine-learning-in-pharma-medicine/

22. Futurism, *The Rise of Smart Machines Puts Spotlight on 'Robot Rights'* available on https://futurism.com/smart-machines-robot-rights/

23. Galasso, Alberto and Luo, Hong, Punishing Robots: Issues in the Economics of Tort Liability and Innovation in Artificial Intelligence available on http://www.nber.org/chapters/c14035.pdf

24. Garnier, Emmanuel *Why the EU Considers Prescription Support Software a Medical Device* available on https://www.medtechintelligence.com/feature_article/eu-considers-prescription-support-software-medical-device/

25. Gazit, Lior *Trading cancer for data* available on http://web.a.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=0&sid=544b7d2d-1125-4d00-9767-4933c39d8202%40sessionmgr4006

26. Gholipour, Bahar *We Need to Open the AI Black Box Before It's Too Late* available on https://futurism.com/ai-bias-black-box/

27. Goodin, Dan *Bug can cause deadly failures when anesthesia device is connected to cell phones* available on https://arstechnica.com/information-technology/2014/04/bug-can-cause-deadly-failures-when-anesthesia-device-is-connected-to-cell-phones/

28. Gorski, David *IBM's Watson versus cancer: Hype meets reality*, available on https://sciencebasedmedicine.org/ibm-watson-versus-cancer-hype-meets-reality/

29. Greenberg, Anastasia *Artificial Intelligence in Health Care: Are the Legal Algorithms Ready for the Future?* available on https://mjlh.mcgill.ca/2017/10/06/artificial-intelligence-in-healthcare-are-the-legal-algorithms-ready-for-the-future/

30. Green, Epstein Becker *FDA Guidance on Decision Support Software: Implications for Industry* available on https://www.lexology.com/library/detail.aspx?g=667bab5b-6457-4bb8-9421-fb7e0dfd8e3d

31. Hancher, Leigh and Földes, Maria Eva *Revision of the Regulatory Framework for Medical Devices in the European Union: The Legal Challenges* available on https://www.cambridge.org/core/services/aop-cambridge-core/content/view/84BEEDBC594702B73327246A7B60CDAB/S1867299X0000307Xa.pdf/revision_of_the_regulatory_framework_for_medical_devices_in_the_european_union_the_legal_challenges.pdf

32. Holmes, Mark *Are We Underestimating the Impact of AI?*, available on http://www.lawtechnologytoday.org/2017/06/the-impact-of-artificial-intelligence/

33. Jejelola, O. J. *Legal research: an overview of a research proposal* available on https://eujournal.org/index.php/esj/article/viewFile/4130/3966

34. Jha, Vishakha *Machine Learning Algorithm - Backbone of emerging technologies*, available on http://www.lawtechnologytoday.org/2017/06/the-impact-of-artificial-intelligence/

35. J.K.C. Kingston, Artificial Intelligence and Legal Liability, available on https://www.researchgate.net/publication/309695295_Artificial_Intelligence_and_Legal_Liability

36. Knight, Kill *The Dark Secret at the Heart of AI* available on https://www.technologyreview.com/s/604087/the-dark-secret-at-the-heart-of-ai/

37. La Pietra, L.; Molendini, Calligaris; Quattrin, R.; Brusaferro, S. *Medical errors and clinical risk management: state of the art* available on https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2639900/pdf/0392-100X.25.339.pdf

38. Lenardon, Joao Paulo de Almeida *The regulation of artificial intelligence* available on http://arno.uvt.nl/show.cgi?fid=142832

39. Mulryne, Jacqueline; Strom, Louise; Wallace, Victoria M.; Jones, Bethan; Tsang, Lincoln and Kracov, Daniel A. *What's the deal with Watson? Artificial Intelligence Systems and Medical Software Regulation in the U.S. and EU* available on

https://www.digitalhealthdownload.com/2017/02/whats-deal-watson-artificial-intelligence-systems-medical-software-regulation-u-s-eu/

40. Nail, Gauri and Bhide, Sanika S. *Will the future of knowledge work automation transform personalized medicine?*, 2014, available on https://www.sciencedirect.com/science/article/pii/S221206611400012X

41. Neil, Savage *Better Medicine Through Machine Learning* available on https://cacm.acm.org/magazines/2012/1/144803-better-medicine-through-machine-learning/fulltext

42. Palmerini, E.; Bertolini, A., Battaglia F.; Koops, B..; Arnevale, A.; Salvini, P. *RoboLaw: Towards a European framework for robotics regulation* available on https://www.sciencedirect.com/science/article/pii/S0921889016305437

43. Palmerini, Erica *The interplay between law and technology, or the RoboLaw project in context* available on http://www.robolaw.eu/RoboLaw_files/documents/Palmerini_Intro.pdf

44. Parasuraman, Raja *Complacency and Bias in Human Use of Automation: An Attentional Integration* available on http://journals.sagepub.com/doi/pdf/10.1177/0018720810376055

45. Paschalidis, Yannis *How Machine Learning Is Helping Us Predict Heart Disease and Diabetes* available on https://hbr.org/2017/05/how-machine-learning-is-helping-us-predict-heart-disease-and-diabetes

46. Petit, Nicolas *Law and regulation of artificial intelligence and robots: conceptual framework and normative implications*, available on https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2931339

47. Price, W. Nicholson *Medical Malpractice and Black-Box Medicine* available on https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2910417

48. Ray, Sunil *Essentials of Machine Learning Algorithms (with Python and R Codes)*, available on https://www.analyticsvidhya.com/blog/2017/09/common-machine-learning-algorithms/

49. Rehmann, Wolfgang and Heimhalt Diana *Product Liability for Medicines and Medical Devices in the European Union* available on https://united-kingdom.taylorwessing.com/synapse/ti-eu-medical-product-liability.html

50. Rouhani-Arani, Korolyn *Standalone Software caught by Medical Device Regulation* available on http://www.kemplittle.com/site/articles/kl_bytes/standalone-software-caught-by-medical-device-regulation

51. Siems, Mathias M. *Legal originality*, available on https://papers.ssrn.com/sol3/papers.cfm?abstract_id=976168~

52. Shailin, Thomas Artificial Intelligence, Medical Malpractice, and the End of Defensive Medicine available on http://blogs.harvard.edu/billofhealth/2017/01/26/artificial-intelligence-medical-malpractice-and-the-end-of-defensive-medicine/

53. Shailin, Thomas, Democratized Diagnostics: Why Medical Artificial Intelligence Needs Vetting available on https://www.linkedin.com/pulse/democratized-diagnostics-why-medical-artificial-needs-shailin-thomas/?lipi=urn%3Ali%3Apage%3Ad_flagship3_profile_view_base%3BjQEvkTluSpaxaQRjqZ7iiQ%3D%3D

54. Stanford University *Artificial intelligence and life in 2030 one hundred year study on artificial intelligence - Report of the 2015 study panel, September 2016* available on https://ai100.stanford.edu/sites/default/files/ai100report10032016fnl_singles.pdf

55. Stanford University, *Definition of machine learning* available on https://online.stanford.edu/course/machine-learning-1

56. The Medical Futurist, *Artificial Intelligence Will Redesign Healthcare* available on http://medicalfuturist.com/artificial-intelligence-will-redesign-healthcare/

57. Torres, Juan *Amazon Is Really Serious About Making Healthcare a Part of Its Future* available on https://futurism.com/amazons-healthcare-plans/

58. Tsang, Lincoln; Kracov, Daniel A.; Mulryne, Jacqueline; Strom, Louise; Perkins, Nancy; Dickinson, Richard; Wallace, Victoria M. and Jones, Bethan *The Impact of Artificial Intelligence on Medical Innovation in the European Union and United States* available on https://www.arnoldporter.com/~/media/files/perspectives/publications/2017/08/the-impact-of-artificial-inteelligence-on-medical-innovation.pdf

59. Wang, Qian; Shi, Yinghuan; Suk, Heung-Il; Suzuki, Kenji *Machine Learning in Medical Imaging 8th International Workshop, MLMI 2017, Held in Conjunction with MICCAI 2017, Quebec City, QC, Canada, September 10, 2017, Proceedings*, available on https://link.springer.com/book/10.1007%2F978-3-319-67389-9

60. William, Wong *What's the Difference Between Machine Learning Techniques? Machine learning is a hot topic, but what does this subset of artificial intelligence really mean?* available on http://web.a.ebscohost.com/ehost/detail/detail?vid=0&sid=0433f520-96d7-4ca5-8301-8675097c4c69%40sessionmgr4009&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ%3d%3d#AN=123710623&db=bsh

61. Wired, *It Begins: Bots Are Learning to Chat in Their Own Language*, available on https://www.wired.com/2017/03/openai-builds-bots-learn-speak-language/

62. World Health Organization Geneva, *Medical Device Regulations Global overview and guiding principles*, 2003, available on http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf

63. World Health Organization, *Health technology* available on http://www.who.int/health-technologyassessment/about/healthtechnology/en/

64. Wu, Stephen S. *Summary of selected robotics liability cases* available on http://ftp.documation.com/references/ABA10a/PDfs/2_5.pdf

65. Ziad, Obermeyer and EJ, Emanuel *Predicting the Future - Big Data, Machine Learning, and Clinical Medicine* available on https://www.ncbi.nlm.nih.gov/pubmed/27682033

66. Zittrain, Jonathan *Berkman Klein Center and MIT Media Lab to collaborate on the ethics and governance of artificial intelligence – Harvard Law Today* available on https://today.law.harvard.edu/berkman-klein-center-mit-media-lab-collaborate-ethics-governance-artificial-intelligence/

6.2.3. Documents issued by official bodies

1. European Commission, *Taskforce to take Health and Digital policies further* available on https://ec.europa.eu/digital-single-market/en/blog/taskforce-take-health-and-digital-policies-further

2. European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A Digital Single Market Strategy for Europe - COM(2015) 192 final available on https://ec.europa.eu/digital-single-market/en/news/digital-single-market-strategy-europe-com2015-192-final

3. European Commission, MEDDEV 2.1/6 July 2016 *guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices*, available on https://ec.europa.eu/docsroom/documents/17921

4. Commission of the European Communities *Communication from the Commission to the Council, the European Parliament, the European Economic and Social committee and the Committee of the Regions e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area {SEC(2004)539} Brussels, 30.4.2004 COM (2004) 356 final*, available on https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52004DC0356&from=EN

5. FDA U.S. Food & Drug Administration – U.S. Department of Health and Human Services *Is The Product a Medical Device?*, available on https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm

6. FDA U.S. Food & Drug Administration *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act Draft Guidance for Industry and Food and Drug Administration Staff*, available on https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf

7. House of Commons Science and Technology Committee, *Robotics and artificial intelligence Fifth Report of Session 2016–17* available on https://publications.parliament.uk/pa/cm201617/cmselect/cmsctech/145/145.pdf

8. UK's Parliament, *AI in the UK: ready, willing and able? Chapter 7: Healthcare and artificial intelligence (UK)*, available on https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/10011.htm#_idTextAnchor107

9. UK's Parliament *AI in the UK: ready, willing and able? - Chapter 9: Shaping artificial intelligence (UK)* available on https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/10013.htm#_idTextAnchor143

10. UK's Parliament, *Select Committee on artificial intelligence collated written evidence volume - House of Lords (UK)* available on https://www.parliament.uk/documents/lords-committees/Artificial-Intelligence/AI-Written-Evidence-Volume.pdf

11. UK's Parliament, *Ethical and legal issues (UK)* available on https://publications.parliament.uk/pa/cm201617/cmselect/cmsctech/145/14506.htm

12. UK's Parliament, *Summary of conclusions and recommendations* available o https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/10014.htm

6.2.4. Press

1. Beal, James and Jehring, Andy *ROBOSTOP Facebook shuts off AI experiment after two robots begin speaking in their OWN language only they can understand*, available on https://www.thesun.co.uk/tech/4141624/facebook-robots-speak-in-their-own-language/

2. Collins, Tim *The future of robot communication? Facebook's AI bots accidentally invent a new LANGUAGE while training to negotiate with one another*, available on http://www.dailymail.co.uk/sciencetech/article-4620654/Facebook-accidentally-invents-new-machine-language.html

3. Field, Matthew *Facebook shuts down robots after they invent their own language* available on https://www.telegraph.co.uk/technology/2017/08/01/facebook-shuts-robots-invent-language/

4. LaFrance, Adrienne *An Artificial Intelligence Developed Its Own Non-Human Language*, available on https://www.theatlantic.com/technology/archive/2017/06/artificial-intelligence-develops-its-own-non-human-language/530436/

5. Marr, Bernard *The Amazing Ways How Artificial Intelligence And Machine Learning Is Used In Healthcare* available on https://www.forbes.com/sites/bernardmarr/2017/10/09/the-amazing-ways-how-artificial-intelligence-and-machine-learning-is-used-in-healthcare/#71eee5dc1c80

6. Novartis *Novartis announces ground-breaking collaboration with IBM Watson Health on outcomes-based care in advanced breast cancer* available on

https://www.novartis.com/news/media-releases/novartis-announces-ground-breaking-collaboration-ibm-watson-health-outcomes

7. Ross, Casey and Swetlitz, Ike *IBM pitched its Watson supercomputer as a revolution in cancer care. It's nowhere close'*, available on https://www.statnews.com/2017/09/05/watson-ibm-cancer/