Proposal toward "no-fault" civil liability regulation following Artificial Intelligence evolution in health-care*

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Abstract

Civil liability, in its traditional paradigm based on "deterrence", may be understood as indirect market regulation, since the risk to incur in liability for damages provide an incentive to invest in safety. Such an approach, however, appears inappropriate, beyond a certain limit, in medical liability since its continuous increases are nowadays incentivating more "defensive medicine" than further increases in safety. This disincentive doctors from relying on guidelines and standards which, at the aggregate level, are the safest path of action when compared with all alternatives.

Such a malfunction appears even more serious with respect to the use of artificial intelligence in health-care, which will greatly increase in the next future. In fact, robots and programs may "behave" far independently from instructions initially provided by programmers and constructors. Charging the latter with liability even if the damage derives from a perfectly "correct" functioning of algorithms and robots would maybe not provide any proper "deterrence", because damages would derive from a situation where there is no "fault" or "lack" in safety to blame or prevent. This could provide a disincentive to AI research, development and use, notwithstanding AI devices already show to be the safest choice when compared with all alternatives based only on human action.

Therefore, I propose that the law on redress in health-care, especially when practiced through artificial intelligence devices, should evolve from an issue of civil liability into one of financial management of losses, pursuant to no-fault redress schemes. Of course, such schemes should apply only in cases where there is no evidence that doctors and producers and programmers of AI devices acted in conditions of negligence, imprudence or unskillfulness and their activity appropriately complied with scientifically validated standards. In other cases, traditional civil liability rules would play a sound function of deterrence.

* L'articolo è stato sottoposto, in conformità al regolamento della Rivista, a referaggio a doppio cieco.

As a result, with reference to AI markets, "fault" and "no-fault" systems should co-exist as independent and alternative system of redress (a sort of "double track" legislation on redress for damages), in order to take advantage of the benefits brought by each of them, narrowing their flaws by their reciprocal interplay.

Summary

1. The "traditional" paradigm of civil liability based on deterrence and its different strategies of allocation of the obligation to compensate damages. – 2. Current centrality of the "traditional" paradigm of civil liability based on fault and deterrence. – 3. A contextual analysis within health-care: the "breach" of the "traditional" paradigm showed by defensive medicine. – 4. The further quest for a change of paradigm following the artificial intelligence revolution. – 5. The need for a new paradigm of (medical) civil liability law. Modern risk management and "no-blame" culture. – 6. A new paradigm of civil compensation for (medical) damages: toward evolution of the law of redress from an issue of civil liability into one of financial management of losses. – 7. Implementation of a new paradigm into legal systems. Room for harmonization in EU law. – 8. Beyond medical civil liability and toward a general "law of the horse" for artificial intelligence technologies.

Keywords

civil liability - no-fault - medical liability - health-care - artificial intelligence

1. The "traditional" paradigm of civil liability based on deterrence and its different strategies of allocation of the obligation to compensate damages

The current paradigm of civil liability laws is mainly based on the assumption that civil liability plays and should play an important role in deterrence. It is thought that any increase of liability on producers and suppliers of goods and services will increase investments in safety (because, in this view, higher investment in safety would be aimed at preventing incurring in liability), so that the tougher civil liability rules on producers and other professionals, the higher the overall level of safety within the system[1].

The idea that civil liability should have a function of deterrence presupposes that the obligation to compensate for damages should be allocated onto the person whom the legal systems identifies as the addressee of such deterrence.

Such a paradigm remained substantially constant over time (with very rare exceptions, some of which will be referred to below), even if, as it is examined below, legal sys-

[1] G. Calabresi, *The cost of Accidents: A Legal and Economic Analysis*, New Haven, 1970; R. Cooter - T. Ulen, *Law & economics*, Boston, 2008, 336-338; W.K. Viscusi - J. Hersh, *Assessing the Insurance Role of Tort Liability after Calabresi*, in *Vanderbilt Law and Economics Research Paper,* n. 12-35, 2013; C. Scognamiglio, *Danno morale e funzione deterrente della responsabilità civile*, in P. Sirena (ed.), *La funzione deterrente della responsabilità civile alla luce delle riforme straniere e dei Principles of European tort law*, Milano, 2011, 295 ss.

tems developed different strategies of allocation of the obligation to compensate for damages.

1.1. Back to ancient times: liability based on "fault"

The first, and most relevant, criterion of allocation of the obligation to compensate for damages is that of fault. The idea that redress for damages requires somebody's "fault" is deeply rooted in legal thinking from ancient times: it emerged in Justinian law and was further consolidated in the *jus commune* and canon law[2], beginning a thousand and five hundred years ago.
This idea, until recent times inspiring the whole system of civil liability, was eloquently called, in German literature, the "dogma of fault" (*Verschuldensdogma*)[3].

1.2. Evolution toward solidarity: liability based on "risk"

The above-mentioned paradigmatic centrality of "deterrence" evolved, but remained in place, when most relevant social, political and economic changes made legal thinking evolve toward an increasing quest for solidarity in all western legal systems, regardless of their civil-law or common-law basic structure[4] – even though with all odds inherent to these different traditions, where English law is traditionally less concerned with solidarity in private law than continental civil law systems.
The quest for solidarity, greatly prompted by the factual consequences and upheavals derived after the industrial revolution, brought legislators to consider unjust that damages following certain (intrinsically risky) activities should be borne by consumers and other end-users of goods and services unless a "fault" of producers or other professionals could be proven in court.
It was considered, therefore, that professional producers of goods and services should bear the risk of their activities *regardless* of their "fault" in causation of damages onto their clients and customers. This strategy of reallocation of liability, which evolved throughout the whole XX century, was believed to be efficient and ethically well-founded insofar as such professional producers were (and are) thought to be in a better position to assess the risk of their activities, to spread the cost of accidents and

[2] See, among others: H. Mazeaud - L. Tunc, *Traité théorique et pratique de la responsabilité civile délictuelle et contractuelle*, Paris, 1957, I, 422.

[3] This approach is represented by the well-known espression «*Nicht der shaden verplichtet zum schadensersatz, sondern die schuld*», formulated by R. von Jhering, *Das Shuldmoment im rőmischen Privatrecht*, Giessen, 1867, 40.

[4] See, e.g., in Italy A. De Cupis, *Il danno: teoria generale della responsabilità civile*, Milano, 1979, 66; in France L. Josserand, *Les transports,* in E. Thaller (ed.), *Traité général théorique et pratique de droit commercial*, vol. XVIII, Paris, 1910, 457; in Germany H. Sperl, *Über das Schadenersatzrecht nach dem deutschen bürgerlichen Gesetzbuche*, Wien, 1902, 154; in England see the comments made in M. Lunney - K. Oliphant, *Tort Law Text and Materials*, Oxford, 2000, 15. More in general and in comparative perspective see: S. Taylor, *Differing cultures of civil liability. In Medical Accident Liability and Redress in English and French Law*, Cambridge, 2015.

arrange for appropriate prevention policies[5].

Such evolution brought, among others, to a relevant variation in civil liability legislations (within the same paradigm based on deterrence, I believe), which lead to "asymmetric" discipline of civil liability and to the adoption of loss-spreading strategies for civil liability laws[6]. This new allocation strategy disregarded the concept of "fault" and considered as a criterion of imputation of the obligation to compensate damages the exercise of risky activities, instead.

Under a legal point of view, such an evolution widened liability imposed on professional producers as to include cases where the latter could not show that the damage was not attributable to them, cases where there was scientific uncertainty as to the cause of the harmful effects or even cases where such cause was unknown[7]. This development was pursued through similar techniques in all western legal systems, mainly: the inversion of the burden of proof[8] and the imposition of strict liability on producers and other professionals, the development of the precautionary principle in many fields of application *etc.*.

In medical civil liability the above mentioned move toward solidarity included sector-specific features, such as the imposition of an obligation of results with respect to many treatments and especially routine ones (in English law through the *res ipsa loquitur* doctrine[9], in Germany through the *Anscheinsbeweis* or *prima facie Beweis* doctrine[10] *etc.*). Some jurisdictions even turned extra-contractual medical liability into a contractual one (which favors patients, *inter alia*, as regards burden of proof) following the German doctrine of *Faktischesvertragsverhàltnisse*[11], as it happened in Italy with the theory of "*contatto sociale*"[12].

[5] G. Calabresi, *The cost of Accidents,* cit.

[6] M. Comporti, *Esposizione al pericolo e responsabilità civile*, Napoli, 1965. Under an economic point of view see R.D. Cooter, *Economic Theories of Legal Liability*, in *Journal of Economic Perspectives,* 5(3), 1991, 11 ss.

[7] R. Montinaro, *Dubbio scientifico e responsabilità civile*, Milano, 2012; in an economic analysis of law perspective see: M.G. Faure - L.T. Visscher - F. Weber, *Liability for Unknown Risk – A Law and Economics Perspective*, in *Journal of European Tort Law*, 7(2), 2016, 198 ss.

[8] On the burden of proof and its relevance in medical civil liability see, e.g. in Italy: G. Anzani, *Il riparto dell'onere probatorio nelle due specie di responsabilità civile*, in *Rivista trimestrale di diritto e procedura civile*, 2017, 238.

[9] Cfr. *Donoghue v Stevenson* [1932] AC 562.

[10] M. Stauch, *The Law of Medical Negligence in England and Germany: A Comparative Analysis*, Oxford and Portland (Oregon), 2008, 73 ss.

[11] G. Haupt, *Über faktische Vertragverhältnisse*, vol. 124, in *Leipziger Rechtswissenschaftliche Studien*, Leipzig, 1943.

[12] Italian Supreme Court, 22 January 1999, no. 589, in *Foro italiano*, 122(11), 1999, I, 3331 ss.; see, on this issue: C. Castronovo, *Obblighi di protezione*, in *Enciclopedia Giuridica*, Roma, 1990, *ad vocem*; R. Pardolesi - R. Simone, *Nuova responsabilità medica: il dito e la luna (contro i guasti da contatto sociale?)*, in *Foro it*aliano, 2017, V, 161 ss.

1.3. Further evolution: mandatory reallocation of liability

Legal systems moved even further in the direction of reallocating liability for damages through the adoption of different loss-spreading techniques and strategies, as it happened in all cases where different jurisdiction provided mandatory insurance for producers and professionals of specific goods and services.
In fact, also in this case the traditional paradigm based on (fault and) deterrence, focusing on the relationship between a damaged patient and a culpable doctor or organisation (hospital, clinic *etc.*), is held.
Mandatory insurance, in effect, is mainly thought to protect damaged consumers and other end-users of goods and services from the risk that producers or other professionals have an insufficient patrimony to pay redress *and not* to relieve the latter from deterrence. Therefore, it determines a mere reallocation of the obligation to pay compensation but does not modify the traditional paradigm of civil liability, insofar as producers or other professionals remain liable, may be called to pay redress in case insurance coverage is not applicable and are subject to deterrence indirectly – since insurers would shift onto producers and other professionals (by applying higher insurance premiums) the cost of any redress paid on their behalf.

2. Current centrality of the "traditional" paradigm of civil liability based on fault and deterrence

The evolution briefly recalled above, under § 1, even if relevant and innovative, represented a mere *incremental* advancement of the same traditional paradigm of civil liability based on "deterrence".
In fact, the developments just summarised were limited, basically, only to reallocate the "cost of accidents" from customers and users to producers and professionals (in health-care: from patients to doctors) within the same conceptual and legal framework already in place. What changed, in other terms, was balancing of interests, not rethinking techniques for satisfying them, insofar as the concept of "fault" was conceptually replaced, in some instances, by that of strict liability, simply in order to increase deterrence also to cases where fault could not be positively assessed in court, with the aim of inducing producers and other professionals to increase investments in safety correspondingly[13].
Legislation appears to consider invariably civil liability also for its potential of deterrence, so that new pieces of legislation frequently increase of civil liability as a regulatory technique, in order to foster investments in safety by producers and professionals.
Such an approach to the issue at stake is shown, e.g., in the Principles of European Tort Law (PETL) drafted by the European Group on Tort Law[14], especially as regards

[13] R. Savatier, *Traité de la responsabilité civile en droit française civil, administratif, professionnel, procédural*, Paris, 1945, vol. I, 3; M. Comporti, *Esposizione al pericolo,* cit., 27.

[14] Which may be read online at *civil.udg.edu*.

linking redress to liability to compensate damages [Art. 1:101(1)] and to liability based on fault and "strict liability" only [Title III]. The same approach seems to be upheld by scholars and even sophisticated studies, at supranational level have considered, and still consider, civil liability as performing the central function of *deterrence* along with that of compensation[15].

3. A contextual analysis within health-care: the "breach" of the "traditional" paradigm showed by defensive medicine

It ought to be noted that the paradigm of civil liability based on deterrence showed reliable and appropriate on several instances where empirical analysis indicates, in fact, that the increase of liability determined an incentive of producers and other professionals to invest in safer products and services. This happened, e.g., with reference to general consumer legislation enacted, among many others, through 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[16].

Such paradigm, however, showed inappropriate in other cases, as health-care. A rich and valuable literature shows, in fact, that the increase of asymmetric protection of patients through increases of medical civil liability does not produce, *beyond a certain limit*, any further increment in safety[17] but, instead, determines the adoption of "defensive" strategies (the so-called "defensive medicine"[18]) and imposes very relevant negative externalities.

In fact, the over-prescription of exams, treatments and medicines determines, even if in different forms depending on the relevant national health system, much relevant increases of costs[19]. This does not benefit patients, paradoxically, since the said over-prescription of exams, treatments and medicines determine an increase of iatrogenic risks and damages, along with "false positive" results.

National health-care systems as a whole do not benefit from massive increase of defensive strategies, which lead to inefficiencies and loss of quality (such as overcrowding of hospital beds and longer waiting lists for medical exams). The constant increase

15 OECD, *Medical Malpractice. Prevention, Insurance and Coverage Options*, Policy Issues in Insurance n. 11, 2006, 27.

16 On this issue it is possible to read, among others, the five reports on the application of Directive 85/374/EEC concerning liability for defective products (1995, 2000, 2006, 2011 and 2018), which may be found online at *ec.europa.eu*.

17 OECD, *Medical Malpractice,* cit., 16.

18 «Defensive medicine occurs when doctors order tests, procedures, or visits, or avoid certain high-risk patients or procedures, primarily (but not necessarily solely) because of concern about malpractice liability»: U.S. Congress, Office of Technology Assessment, *Defensive Medicine and Medical Malpractice*, OTA-H--6O2, Washington, DC, 1994, 1.

19 See e.g., for the USA, M.M. Mello - A. Chandra - A.A. Gawande - D.M. Studdert, *National Costs Of The Medical Liability System*, *Health Affairs*, 29(9), 2010, 1569.

in medical civil liability, moreover, induces corresponding increase of insurance premiums and, in jurisdictions where the amounts of judicial redress are not foreseeable reliably, abandonment of the sector by insurers.
Defensive medicine is also detrimental in its "negative" effects. In fact, fear of claims for redress may lead doctors and hospitals to refuse provision of treatments in particularly serious cases. Looking at the aggregate effects, it is also observed an abandonment of risky specialities by doctors, hospitals and universities.
What is most relevant to note is that, in health-care, beyond certain limits, the current paradigm of civil liability based on deterrence turns completely unreliable, since further increases of civil liability do not procure any gain in safety and, to the contrary and paradoxically, conduce to a reduction of market efficiency and satisfaction of patients, whose interest was pursued by the increase of liability in the first place.

3.1. Excessive liability on doctors and hospitals leads to ... less safe health care. The paradox of wrong incentives

The lesson taught by defensive medicine is that some pieces of legislation, which were thought to foster higher safety in health-care and better risk management, produced exactly the opposite results.
It is undisputed, e.g., that definition of evidence-based safety standards and, therefore, development of reliable guidelines require doctors and hospital to share information on risks, harmful events and latent errors and failures [20]. Several legal systems, however, do not provide doctors and hospitals with appropriate safe-harbours or confidentiality shields which would induce them to share the said information without fearing a claim for compensation. This determines a disincentive to share information, since this may amount, in law, to incur in civil liability.
As an example, a research carried out in 2006-2007 on around a thousand doctors in 18 Italian hospitals showed a shocking result: the great majority of doctors considered Reporting and Learning Systems much useful for their profession but less than half contributed to it providing relevant information fearing legal consequences[21].
Another example. It is undisputed that Evidence Based Medicine (EBM) allows, nowadays, development of most accurate and reliable guidelines whose application is capable of reducing the overall risk of deaths and damages[22]. The technical possibility to gather, process and manage big data, which shall evolve sharply also due to the pursue of open-access and open-data strategies by the EU[23], makes it possible nowadays to

[20] J. Reason, *Human Error*, New York, 1990; C. Bayley, *What medical errors can tell us about management mistakes*, in P.B. Hofmann - F. Perry (eds.), *Management mistakes in Healthcare: Identification, Correction and Prevention*, Cambridge, 2019, 74 ss.

[21] Quoted by S. Albolino - R. Tartaglia - T. Bellandi - A.M.V. Amicosante - E. Bianchini - A. Biggeri, *Patient safety and incident reporting: survey of Italian healthcare workers*, in *BMJ Quality & Safety*, 2010, 19:i8-i12.

[22] See, e.g.: S.A.R. Doi, *Understanding evidence in health care: Using clinical epidemiology*, South Yarra, VIC, Australia, 2012; JH. Howick, *The Philosophy of Evidence-based Medicine*, Wiley-Blackwell, 2011.

[23] In 2003, the European Commission set up a legal framework to allow the re-use of public sector

develop medical guidelines and databases incredibly more reliable[24]. However, current civil liability rules frequently provide doctors with an incentive *not* to apply them, since their respect may not be sufficient to relieve them from civil liability[25].

3.2. A proposal coming from empirical evidence: the need to relieve doctors and hospitals from civil liability when scientifically validated standardised rules are complied with

Having regard to the above arguments, I believe that the current situation requires a (r)evolution of the civil liability paradigm. As noted, after increases of civil liability on doctors and hospitals in the recent past, at this point medical civil liability does not enhance safety and, moreover, imposes severe negative externalities on the whole health care system. Moreover, as a very unexpected consequence, it worsens even the overall safety and satisfaction of patients, which were supposed to receive benefit by the increase of liability itself.

Relevance of this situation is shown by the many attempts, all around the world, to modify current medical civil liability legislations.

I claim that the above reported negative externalities could possibly be reduced if doctors and hospitals could be relieved from civil liability for damages in all cases where there is not evidence of negligence, imprudence or unskillfulness *and* scientifically validated standards of action (guidelines *etc.*) were correctly selected and complied with[26].

information through the so-called "PSI Directive" (Directive 2003/98/EC), last revised in 2013 by Directive 2013/37/EU. Open-data policies include the EU Open Data Portal, set up in 2012, following European Commission Decision 2011/833/EU on the reuse of Commission documents. On these issues see European Commission, *Open data*, at *ec.europa.eu*.

[24] G.H. Guyatt, *Evidence-based medicine*, in *ACP Journal Club*, 114(2), 1991, A-16; Evidence-Based Medicine Working Group, *Evidence-based medicine: a new approach to teaching the practice of medicine*, in JAMA, 268, 1992, 2420-25; D.L. Sackett - W.M.C. Rosenberg - J.A.M. Gray - R.B. Haynes - W.S. Richardson, *Evidence-Based Medicine: What it is and what it isn't*, in *BMJ*, 71(2), 1996, 312.

[25] The problem seems rather well-spread in different jurisdictions regardless of their belonging to either civil law or common law systems. See, e.g., as regards the USA: L.L. LeCraw, *Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, in *Journal of Oncological Practice* 3(5), 2007, 254. In the UK see S. Ash - S. Jo - M. Gunn, *Legal Considerations of Clinical Guidelines: Will NICE Make a Difference?*, in *Journal of R. Soc. Med.,* 96(3), 2003, 133 ss. In French law see E. Hondius (ed.), *The development of Medical Liability*, vol. III, Cambridge, 2010, 76. Under Italian law, Art. 7(3) of the law 8 March 2017, n. 24, expressly provides that respect of guidelines and best practices can be considered by the judge only with respect to the definition of redress and not on assessing civil liability in the first place.

[26] There is much research on the issue of medical guidelines and on the impact they have, or should have, on civil liability. On these issues see, e.g., in Italy: C.M. Masieri, *Linee guida e responsabilità civile del medico*, Milano, 2019; S. Calvigioni, *Linee guida e buone pratiche clinico-assistenziali*, in A.D. De Santis (ed.), *I profili processuali della nuova disciplina sulla responsabilità sanitaria*, Roma, 2017, 216 ss.; M. Franzoni, *Colpa e linee guida nella nuova legge*, in *Danno e responsabilità*, 2017, 278; C. Scognamiglio, *Regole di condotta, modelli di responsabilità e risarcimento del danno nella nuova legge sulla responsabilità sanitaria*, in *Corriere giuridico*, 2017, 740 ss. Comparative remarks are developed in S. Taylor, *Medical Accident Liability and Redress in English and French Law*, Cambridge, 2015. At a European level see: European Committee on Legal Co-operation (CDCJ), *Report on Medical Liability in Council of Europe Member States, A comparative study of the legal and factual situation in Member states of the Council of Europe*, 2005, in *rm.coe.int*; S.D. Ferrara - R. Boscolo-

It is not ignored that respect of standards could determine unwanted damages on patients in some cases. However, my claim is made on the basis of empirical evidence showing that standardisation, whenever possible and sensible, makes health-care systems safer, since following standard actions inspired by Evidence Based Medicine make overall accidents and damages lower than those experienced in a system where standards are not defined or complied with[27].

Said in other words, I suggest that legislations on redress for damages incurred in health care should provide incentives to strict adherence to scientifically validated standards, since this appears a safer strategy than any other.

It is unlikely that the solidarity approach to civil (liability) law, highlighted above under § 1.2, could admit that in such cases damaged patients should be deprived of redress *tout court*. This is why I believe that the proposed "paradigmatic" reform of the law of medical civil liability should be coupled with a "no-fault" redress system – as noted further below, under § 6.

It is reasonable to provide that any reform of civil liability legislation following the above-said principles should not prevent doctors from disapplying guidelines and standards when this appears appropriate in the single case. This should be an exception, however, and disapplication should be appropriately justified.

4. The further quest for a change of paradigm following the artificial intelligence revolution

The quest for (r)evolution of the civil liability paradigm based on deterrence, limiting in this phase our interest to medical liability, is made even more urgent by the so-called artificial intelligence revolution. In fact, such technological advance, along with the already mentioned big data revolution, make it foreseeable that in a relatively short time artificial intelligence shall play an increasingly more relevant role in health care, especially through machine learning and deep learning technologies, also with respect to the forthcoming massive robotisation of medical sector[28].

Devices based on artificial intelligence, however, evolve over time (and will do it much more in the next future) on the basis of the information and feed-back gathered and processed by thousands of different shared sources (so-called "machine learning" and

Berto - G. Viel (eds.), *Personal Injury and Damage Ascertainment under Civil Law*, Switzerland, 2016, esp. 537 ss.; S.D. Ferrara - E. Baccino - T. Bajanowski - R. Boscolo-Berto - M. Castellano - R. De Angel - A. Pauliukevičius - P. Ricci - P. Vanezis - D. Nuno Vieira - G. Viel - E. Villanueva, *Malpractice and medical liability. European Guidelines on Methods of Ascertainment and Criteria of Evaluation*, in *International Journal of Legal Medicine*, 127, 2013, 545 ss.

[27] See, e.g.: A.B. Haynes - T.G. Weiser - W.R. Berry et al., *A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population*, *New England Journal of Medicine*, 360, 2009, 491 ss.; P.G. Shekelle et al., *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*, Rockville (MD): *Agency for Healthcare Research and Quality*, 2013, which may be read at *ahrq.gov*.

[28] See, e.g.: *Artificial Intelligence and Machine Learning for Healthcare*, Sigmoidal, December 21, 2017, in *sigmoidal.io*; D. Hernandez, *Artificial Intelligence Is Now Telling Doctors How to Treat You*, in *WIRED*, June 2, 2014, which may be read at *wired.com*; PwC (June 2017), *What Doctor? Why AI and robotics will define New Health*, which may be read at pwc.com.

"deep learning"). This process clearly shows that the relationship of cause and effect, as regards causation of damages, may be not linear as we are used to believe. To the contrary, one may consider rather frequent (and even more frequent in the future, due to technological evolution) the possibility that robots and programs "behave" far independently from instructions initially provided by programmers and constructors.
I believe that application of the traditional paradigm of civil liability would determine, in this instance, further negative externalities. Under such paradigm, in fact, redress to damaged patients would require allocation of the obligation to compensate on producers and programmers of artificial intelligence devices (– the only "somebody" available to be imposed strict liability on[29]) either as culpable persons or, by way of strict liability, even without proof of any fault.
It is likely that the first alternative would not be followed, even if this solution is sometimes suggested in law literature[30], since the current solidarity approach[31] would not allow damaged patients not being paid redress unless a fault can be proven in court.
Therefore, it is much likely that strict liability will be the preferred strategy to deal with redress of damages caused by artificial intelligence devices[32]. I claim that this alternative, however, would not necessarily foster safety, since producers and programmers could not do much to foresee unforeseeable "behaviour" of robots and programs, which would be influenced by innumerable variables provided by databases, big data gathering and the end-users themselves.
In my view, therefore, civil liability could possibly induce no relevant virtuous investment in safety because no investment could prevent such kind of risks. On the other hand, the application of the traditional paradigm of civil liability, especially when designed as a strict liability regime, would expose producers and programmers to unforeseeable and potentially unlimited claims for civil liability without any possibility of reducing risks by increasing investment in safety (as far as damages following "unforeseeable" behaviour of AI algorithms are concerned). This would be likely, I believe[33], to disincentive them from entering into the market or developing it, thus hindering technological evolution; or to provide an incentive to move R&D and production into more favourable jurisdictions.
This would be a much relevant negative externality, since new technologies would determine a sensible increase in safety within health-care systems and reduce the overall number and relevance of damages and deaths (as available data already show with

[29] This consequence is highlighted by the significant title of K. Hao, *When algorithms mess up, the nearest human gets the blame*, 2019, in *technologyreview.com*.

[30] See, e.g.: B. Casey, *Robot ipsa loquitur*, in *ssrn.com*.

[31] See above, § 1.2.

[32] In favour of a strict liability regime see, e.g.: L. Buonanno, *Civil Liability in the Era of New Technology: The Influence of Blockchain*, in *European Law Institute,* at *europeanlawinstitute.eu*.

[33] Of course, several alternatives may be (and are) proposed in law literature. In favour of a strict liability regime see above, under footnote 41; in support of the application of the "traditional" paradigm of civil liability based on fault *tout court* see above, under footnote 39. A comparative analysis with reference to the different approaches upheld in the USA, Europe and China may be found in M. Infantino - W. Wang, *Algorithmic Torts: A Prospective Comparative Overview*, Transnational Law & Contemporary Problems, 28, 2018-2019, 309.

respect to the current situation[34]).

4.1. A proposal coming from empirical evidence: the need to relieve producers and programmers from civil liability when robots correctly comply with scientifically validated standardised rules

Current legislations on civil liability may represent a disincentive to the development and expansion of artificial intelligence and to the exploitation of the following benefits.

In fact, the possibility that robots and programs "behave" far independently from instructions initially provided by programmers and constructors led the European Parliament to propose «creating a specific legal status for robots, so that at least the most sophisticated autonomous robots could be established as having the status of electronic persons with specific rights and obligations»[35]. I believe that such a proposal is undesirable, since robots cannot and should not be considered as "persons" under current civil legislation[36]. However, it is clear that in such a proposed personality would be mainly used as a legal instrument aimed at circumscribing civil liability onto the robot and, thus, at shifting away all corresponding redress obligations from producers and programmers, in all cases when robots are capable of acting rather autonomously from their original design[37].

Such an issue represent one aspect (one of the most relevant, in fact) within the debate on whether modern technology requires *new specific* legislation or existing legislation and concepts may be adjusted to it; this being the so-called debate on the "law

[34] See, e.g.: K.W. Kizer - L.N. Blum, *Safe Practices for Better Health Care*, in K. Henriksen - J.B. Battles - E.S. Marks et al. (eds.), *Agency for Healthcare Research and Quality (US),* Rockville (MD), *Advances in Patient Safety: From Research to Implementation*, vol. IV, *Programs, Tools, and Products*, 2005, which may be read at *ncbi.nlm.nih.gov*.

[35] European Parliament, Committee on Legal Affairs, *Draft Report with recommendations to the Commission on Civil Law Rules on Robotics* (2015/2103(INL)), 31 May 2016, § 31, lett. f. See also, e.g.: A. Amidei, *Robotica intelligente e responsabilità: profili e prospettive evolutive del quadro normativo europeo*, in U. Ruffolo (ed.), *Intelligenza artificiale e responsabilità*, Milano, 2017, 63 ss.; G. Guerra, *La sicurezza degli artefatti robotici in prospettiva comparatistica*, Bologna, 2018.

[36] The issue is very wide and it is not possible to address it here appropriately. A discussion of the issue may be found in G. Wagner, *Robot, Inc: Personhood for Autonomous Systems*, in *Fordham Law Review*, 88, 2019, 591; G. Wagner, *Robot liability*, Münster Colloquium on EU Law and Digital Economy, Liability for Robotics and the Internet of Things 12.3.2018, in *ssrn.com*; H. Eidenmüller, *The Rise of Robots and the Law of Humans*, in *Zeitschrift für Europäisches Privatrecht*, 765, 2017, 771- 772; S. Chopra - L.F. White, *A Legal Theory for Autonomous Artificial Agents*, Michigan, 2011; B.-J. Koops - M. Hildebrandt - D.-O. Jaquet, *Bridging the Accountability Gap: Rights for New Entities in the Information Society?*, in *Minnesota Journal of Law Science & Technology*, 11, 2010, 497.

[37] This need is evidenced in law literature: see, e.g.: M.U. Scherer, *Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and Strategies*, in *Harvard Journal of Law & Tech*nology, 29, 2016, 399.
As noted below, we claim that such goal should be reached not upholding the current paradigm of civil liability, therefore finding a "culpable" person in the robot, but changing such paradigm, through the adoption of a no-fault system of redress, which would allow compensation to damaged patients independently from the identification of a "person", either producer or programmer (or the robot), to be held liable for that.

of the horse"[38].

Also in this case, as it happened with respect to medical civil liability, it appears that the problems and disincentives evidenced above are somehow connected to the issue of standardisation and standardised action. Therefore I claim that the negative externalities supposedly determined by the traditional paradigm of civil liability on artificial intelligence markets, could possibly be reduced if producers and programmers could be relieved from civil liability for damages in all cases where there is not evidence of negligence, imprudence or unskillfulness *and* the robot (both in its physical components and in its artificial intelligence aspects) complied with production and programming scientifically validated standards.

It is not ignored that mere respect of standards could determine unwanted damages on patients in some cases (which also in my proposed "no-fault" system would be allowed redress, as noted below). However, my claim is made on the basis of empirical evidence showing that in several cases (being destined to increase drastically in the next future) adoption of artificial intelligence and robots determines a relevant increase in safety within health-care systems and reduce the overall number and relevance of damages and deaths when compared to health-care based only on human action[39].

This means that provision of incentives to technological innovation, provided that it respects scientifically validated standards, appears a safer strategy than any other.

5. The need for a *new paradigm* of (medical) civil liability law. Modern risk management and "no-blame" culture

The law binds economic and social activities in order to contribute to the pursue of welfare; on the other hand, however, the law cannot define arbitrarily its goals and (especially) means. It need to take into the highest consideration the real functioning of economic and social contexts addressed, in order to develop well-grounded, affordable, reliable and effective rules[40].

The failure of the current paradigm of medical civil liability legislation based on deterrence, observed and empirically proved, requires a radical modification thereof. A similar evolution toward an alternative *paradigm* might be aimed at also with respect to artificial intelligence markets, which are likely to be prone to similar negative externalities when civil liability is applied as a regulatory strategy based on deterrence.

Such modification, as already observed, appears urgent in these days since it has be-

[38] Such debate may be dated back to F. Easterbrook, *Cyberspace and the Law of the Horse*, in *University of Chicago Legal Forum*, 1996, 207 and L. Lessig, *The Law of the Horse: What Cyberlaw Might Teach*, in *Harvard Law Review*, 113, 1999, 501. More recently see, among others: R. Calo, *Robotics and the Lessons of Cyberlaw*, in *California Law Review*, 103, 2015, 514; E. Stradella, *Approaches for Regulating Roboting Technologies: Lessons Learned and Concluding Remarks*, in E. Palmerini - E. Stradella, *Law and Technology. The Challenge of Regulating Technological Development*, Pisa, 2013, 345.

[39] See, e.g.: K.W. Kizer - L.N. Blum, *Safe Practices for Better Health Care*, cit.

[40] E. de Jong - M.G. Faure - I. Giesen - P. Mascini, *Judge-Made Risk Regulation and Tort Law: An Introduction*, in *Eur. Journ. Of Risk Research*, 9(1), 2018, 6 ss.

ing harshly influencing the functioning of markets *in the past years*, also by providing incentives to "defensive medicine" and imposing on health-care systems much higher costs for inefficiencies, extra-costs, redress of damages *etc.*. It is going to prevent development of markets toward intensive use of artificial intelligence and robotisation *in the future*, because of obsolete rules that would impose obligation to compensation to producers and/or programmers even in cases where machine learning or deep learning processes are in place and there is no "linear" causation of damage to a given patient. Moreover, it is going to impose on jurisdictions adopting such paradigm a competitive disadvantage in favour of jurisdiction more ready to follow-up with the needs and quests of the markets referred to.

What is surprising is that in branches of research other than law rather similar problems were deeply studied and scholars, on the basis of empirical research, reached the conclusion that risky activities incorporate a certain percentage of risk depending not on the person performing them but on the activities themselves[41]. It is rather a shared opinion, in these sectors, that errors happen and will happen – regardless of how civil liability is severe. This is the reason behind the proposal of discarding the "blame culture", which inspire and underpins current (medical) civil liability law, and replace it, at least in some instances (as briefly discussed below) by a "no-blame culture", rooted in risk management[42] and scientifically validated standardisation.

Notwithstanding literature on risk management is rather consistent on this point, lawyers and legislators seem likewise rather consistent in taking into consideration risk management only when applying existing legal concepts (so they design risk management adapting it to existing concepts), not in order to re-shape them (i.e.: they do not adapt concepts to the needs of appropriate risk management).

6. A *new paradigm* of civil compensation for (medical) damages: toward evolution of the law of redress from an issue of civil liability into one of financial management of losses

At this point a digression is required. It was noted, above, that negative externalities caused in health-care, and likely to be caused in artificial intelligence markets, by the traditional paradigm of civil liability could be reduced if doctors and hospitals, and producers and programmers of artificial intelligence medical devices, could be relieved from civil liability under certain conditions; in particular, when their activity is

[41] T. Aven, *Risk assessment and risk management: Review of recent advances on their foundation*, in *European Journal of Operational Research*, 253, 2016, 1 ss.; J. Aldred, *Justifying precautionary policies: Incommensurability and uncertainty*, in *Ecological Economics*, 96, 2013, 132 ss.; T. Aven, *The risk concept—Historical and recent development trends*, in *Reliability Engineering and System Safety*, 99, 2012, 33 ss.; D.V. Lindley, *Understanding uncertainty*, Hoboken, NJ, 2006; C.E. Althaus, *A disciplinary perspective on the epistemological status of risk*, in *Risk Analysis*, 25 (3), 2005, 567 ss.

[42] See, on this point, the "Swiss cheese model" developed in J. Reason, *The Contribution of Latent Human Failures to the Breakdown of Complex Systems*, in *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences*, 327, 1990, 475 ss.

not negligent, imprudent or unskilled and appropriately complied with scientifically validated standards[43].

Such a relief, however, could not lead to preventing damaged patients and end-users from redress. In fact, especially on the patients' side (which is the case of greatest interest, here), the right to redress for health damages is commonly recognised, in most jurisdictions, as deriving from acknowledged human and constitutional rights to health[44]. Therefore, any such prevention would certainly be inconsistent with the "solidarity" approach which now pervades juridical systems, recalled above under § 1.2.

With respect to this issue, my proposal is exactly that of developing a new paradigm aimed at maintaining redress for damages on the patients' side but shifting away from doctors and hospitals (when scientifically validated standard of action are complied with) and from robot producers and programmers (when scientifically validated standard of production and programming are complied with), the obligation to pay for such redress.

In other words, the law of redress needs to evolve from an issue of civil liability into one of financial management of losses, which would take into a much higher account the "systemic" need of appropriate functioning of complex institutions and markets (as modern health-care systems).

In fact, what could appear to favour single patients in the short run (e.g.: sentencing a doctor to compensate a certain damage suffered by the patient following a very complex surgical intervention, regardless for any negligence, imprudence or unskillfulness being ascertained in court) may eventually damage *all future patients* if it prevents the whole health-care system from functioning appropriately and developing into a more technological, evidence-based and safer system (because of the incentives and disincentives brought about by the sentencing itself; in the above example: doctors would refuse complex surgical interventions *tout court* not to incur in unforeseeable liability).

The possibility of balancing the two apparently conflicting goals noted above is not unknown, since "no fault" legislation on redress following medical damages may be found in some jurisdictions (esp. New Zealand but also Finland, Denmark and Sweden[45]). It is clear that the concept of "no-fault" is used, here, with reference to a system where redress is provided by a dedicated fund and not by a "culpable" or "strictly liable" agent (and not with reference to strict liability schemes, which also prescind from "fault" but operate in the opposite direction, by *imposing* liability on the agent *regardless of any culpability*).

[43] Such evolution was hoped also in OECD, *Medical Malpractice,* cit., 62 ss., however without deepening the issue.

[44] Limiting attention, here, to the international level, the right to health was firstly referred to in the Preamble to the Constitution of the World Health Organization (1946); then included, in Art. 25, in the Universal Declaration of Human Rights (UDHR, 1948) and in Art. 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966).

[45] A presentation of such systems may be found, for a first introduction, in OECD, *Medical Malpractice,* cit.

6.1. The need to improve the example coming from "no-fault" legislations

Even if the above-mentioned "no-fault" legislations provide a good example of financial management of losses in health-care markets and valuable ideas for future legislation on artificial intelligence devices, they appear only partially appropriate to reach the goals evidenced above.

First of all, in fact, such pieces of legislation are not targeted to the problem of standardisation but are mainly conditioned to the damaged patient waiving civil litigation, instead. Therefore, being mainly aimed at reducing litigation and "defensive medicine", they have a much narrower scope with respect to the issues dealt with here, in particular, as regards the needs brought about by the discussed technological evolution. I propose, instead, that redress of statistically "inevitable" damages coming notwithstanding compliance with scientifically validated standards, in health-care (especially when coupled with artificial intelligence), should *not* be imposed, in principle, on persons performing the relevant activities or supplying products onto the market. Said in other words, I believe that, in health-care, legal systems should bear the risk that application of scientifically validated standards could determine harmful consequences in individual cases insofar as, under a systemic point of view, such application allows a significant reduction of the overall risks and damages. This idea is not disruptive the way it seems at a first sight, if one thinks of some small and limited pieces of legislation (without any capability of extensive application by way of interpretation) which provide similar mechanisms of compensation in standardised medical activities bearing some statistical risks but much more beneficial effects: it is the case, e.g., of no-fault compensation following adverse effects attributed to vaccination, where adverse effects are very rare in comparison with the more than 2.5 million deaths prevented only in 2008 by vaccination[46].

Secondly, the pieces of legislation mentioned above are rather different from one another in different aspects and seem targeted to the different jurisdictions where they belong to, so that it appears difficult to transplant them, as they are, into different legal systems. Contextual differences between the exporting and the importing jurisdictions may also determine remarkable differences in the results one may expect from legal transplant. E.g., the simple adoption of a "no-fault" system may not reduce, in itself, excessive litigation (and, therefore, "defensive medicine").

It was noted, in fact, that the rather positive outcome experienced in New Zealand seems to depend on «the absence of a culture of suing in New Zealand» which pre-existed in the country[47]. Such a finding makes it unreliable that introduction of similar legislation could lead to similar results in jurisdiction where civil litigation is much

[46] World Health Organisation, *State of the world's vaccines and immunization*, Geneva, 2009, available on-line at *whqlibdoc.who.int*. On this issue see also: C. Looker - H. Kelly, *No-fault compensation following adverse events attributed to vaccination: a review of international programmes*, *Bulletin WHO*, 2011, on-line at *who.int* where see further references.

[47] K.A. Wallis, *No-fault, no difference: no-fault compensation for medical injury and healthcare ethics and practice*, in *British journal of general practice*, 67(654), 2017, 38–39.

higher and showed increase in the last decades[48]. It is necessary, therefore, to take into account cultural differences between countries and assess how much they may influence the outcome of the proposed reform, if the case developing corrective measures in order to reach the goals aimed at.

Thirdly, "no-fault" legislations are currently showing deficiencies as regards incentives to safety, in absence of the deterrence brought about by civil liability. Pure "no fault" models, in fact, raise concerns as to their appropriateness to limit the risk of moral hazard, exactly as it happens in New Zealand, since «the principal weakness of no-fault schemes is the difficulty of ensuring that the socially optimal amount of care is taken by potential loss-causers, as the links between their potential to cause loss and the costs of their actions are severed»[49].

Any reform toward evolution of the law of redress from an issue of civil liability into one of financial management of losses through "no-fault" systems, therefore, should not apply out of the scope defined above, i.e.: relief from liability in absence of negligence, imprudence or unskillfulness *and* in compliance with scientifically validated standards. Out of this scope, "no-fault" rules would unreasonably remove the deterrence effect that civil liability may still produce. This is why I believe that "no-fault" rules should be combined with "fault" rules in order to take advantage of the benefits brought by each of them, narrowing their flaws by their reciprocal interplay.

Moreover, in all cases where "no-fault" schemes apply, they should be matched with a discipline capable of providing incentives to safety. I believe that such an approach should be uncoupled from deterrence on individuals (e.g.: deterrence induced by civil liability should not be replaced with deterrence induced by disciplinary sanctions on employees) and should rather be inspired by organizational and procedural criteria, thus shifting paradigmatic centrality from individuals to systemic risk management, in adherence to the principles noted above under § 5.

6.2. Open issues and room for further research. Brief remark

The proposed evolution toward a new paradigm of civil liability in health-care, especially when coupled with the use of artificial intelligence devices, requires, of course, solution of many variables, which it is not possible to discuss here.

Among others, it would be necessary to define production of "scientifically validated" standards under the proposed "no-fault" systems. Definition of a third, independent, party in charge with redress to damaged patients in application of a "no fault" scheme, of its functioning and its funding, would also be needed. Similarly, definition of a standardized amount of compensation under a "no fault" scheme should also be provided.

Such issues cannot be discussed here, since this article is aimed at presenting general

[48] OECD, *Medical Malpractice,* cit., 16 ss.

[49] B. Howell - J. Kavanagh - L. Marriott, *No-fault public liability insurance: evidence from New Zealand*, in *Agenda*, 9(2), 2002, 147 and 137.

scopes and principles of my proposal, while the themes briefly listed here constitute rather detailed aspects thereof. However, as regards these aspects, it seems possible to take inspiration, at least in part, from jurisdictions where they were already developed in legislation, such as Sweden and New Zealand[50], even with the cautions highlighted above, under § 6.1.

7. Implementation of a *new paradigm* into legal systems. Room for harmonization in EU law

I believe that the proposal described above could have a strong potential of impact on legal systems. Therefore, I believe that the described development of a *new paradigm* of civil compensation for (medical) damages, from an issue of civil liability into one of financial management of losses, could, and should, have a sequel on public engagement.

Such an engagement would be mainly at national level but it appears that the European Union could develop it within its R&I policy agenda. In fact, EU harmonization of (medical) civil liability law is a rather controversial issue[51]; however, it is possible to highlight that grounding for such harmonization could be mainly based on several provisions of the TFEU, namely: the EU shared competence with member States on consumer protection under Art. 4(2)(f) TFEU; the EU shared competence with member States on safety in public health under Art. 4(2)(k) TFEU; the EU competence to carry out actions to support, coordinate or supplement the actions of the Member States in protection and improvement of human health under Art. 6(1)(a) TFEU; the EU taking into account, in the definition and implementation of its politics and actions, of the need to promote a high level of protection of human health under Art. 9 TFEU; the need that the EU, in defining and implementing any of its politics or activities, takes into account the need of consumer protection under Art. 12 TFEU; the particular relevance recognized to the need of an high level of health and consumer protection, in particular based on new developments based on scientific facts, when EU Commission issues its proposals for approximation of national legislations within the pursue of the goals of the internal market, which apply also to EU Parliament and Council under Art. 114(3) TFEU; the need to guarantee an high level of protection to human health in the definition and implementation of all politics and activities of the EU, in the pursue of the improvement of public health, under Art. 168(1) TFEU.

[50] A. Antoci - A. Fiori Maccioni - P. Russu, *The Ecology of Defensive Medicine and Malpractice Litigation*, *PloS one*, 11(3), 2016, e0150523; P.C. Weiler, *The Case for No-Fault Medical Liability*, in *MD Law Review*, 52(4), 1993, 908; A. Towse - P. Danzon, *Medical negligence and the NHS: an economic analysis*, in *Health Economics*, 8(2), 1999, 93. OECD, *Medical Malpractice,* cit., 13 ss., also mentions the cases of Denmark and Finland.

[51] See, e.g.: F. Toriello, *La responsabilità medica in prospettiva (incerta) di armonizzazione europea*, in *Responsabilità medica*, N2, 2017, 291.

8. Beyond medical civil liability and toward a general "law of the horse" for artificial intelligence technologies

For reasons of methodological stringency, this research was limited, as an exemplary field of investigation, on medical civil liability, where the proposed research address very important challenges. This sector is characterized by great complexity as regards both organisation and service supply, so that it represents a very interesting subject to research in with respect to civil liability. As a matter of fact, medical errors and mistakes are considered as mainly consequences of intrinsic complexity of relevant organisations and markets[52].

Moreover, it relates to the pursue of public health, which is recognised as a human right and a constitutional interest protected in most jurisdictions and legal systems[53] and has the opportunity to evolve, in the next few years, toward a much higher recourse to artificial intelligence and robotisation, which makes it important and urgent for civil liability regimes to adapt to foster such evolution instead of hindering or preventing it.

Finally, health-care is experiencing remarkable negative externalities because of the current regime of civil liability and has a great relevance over public expenditure, since public health appears to take a rather high percentage of the annual GDP in the jurisdictions examined[54] and current inefficiencies and negative externalities contribute to a large extent to such costs.

However, the conclusions eventually reached will aim at providing a new theoretical framework capable of application also to other sectors characterized by similar constraints and needs (as it happens, e.g., in meteorology, engineering, emergency service organisations *etc.*).

In this sense, I believe that no-fault redress schemes should rise, in relevant sectors and with reference to relevant cases, to the role of an independent and alternative system of redress on equal footing to "fault" civil liability – a sort of "double track" legislation on redress for damages. As I noted in dealing with medical civil liability, I believe that this is particularly true for sectors characterised by the so-called artificial intelligence revolution (especially when coupled with machine- and deep-learning), so that I claim that such technologies require a "law of the horse"[55] paradigmatically *different* from regulatory alternatives existing nowadays; a "law of the horse" that should be designed pursuant to a "no-fault" paradigm.

More generally, as a fist approximation, it is likely that my proposal could apply when (cumulative conditions) intrinsically risky activities are characterised by high depend-

[52] J. Reason, *Human Error,* cit.

[53] See above, footnote 44.

[54] With reference to the most recent years available (i.e.: 2016), the World Bank reports that current health expenditure amount to an average of 10.02% of the GDP in the world and 10,22% in the Euro area. More in particular, e.g.: 10,44% in Austria; 9,25% in Australia; 17,07% in the USA; 11,14% in Germany; 10,53% in Canada; 10,36% in the Netherlands; 11,54% in France; 8,97% in Spain; 8,94% in Italy; 9,8% in Portugal; 9,76% in the United Kingdom; 10,04% in Belgium.

[55] See above, footnote 38.

ence on science and/or technology; it is possible to develop reliable standard procedures, based on evidence and scientific method, to carry out these activities; adoption of standards produce, in the exercise of such activities, an overall reduction of negative outcomes when compared with discretionary case-by-case decisions.