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MEDICAL CIVIL LIABILITY WITHOUT DETERRENCE: PRELIMINARY REMARKS FOR FUTURE RESEARCH

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I. Introductory Remarks	88
II. The “Traditional” Paradigm of Civil Liability based on Deterrence	91
A. Evolution Toward a “Solidarity Approach”	92
B. The Remaining Centrality of the “Traditional” Paradigm ...	95
III. The “Breach” of the “Traditional” Paradigm in Healthcare and Defensive Medicine	97
A. Defensive Medicine as an Obstacle Toward Safer Healthcare Risk Management	99
B. A Claim in Favour of Relieving Doctors and Hospitals from Liability	102
IV. The Need for a <i>New Paradigm</i> of (Medical) Civil Liability in the Wake of Artificial Intelligence.....	103
V. Shifting Liability Away from Doctors, Hospitals, and Producers and Programmers of AI devices.....	109
VI. From Civil Liability to Financial Management of Losses....	110

ABSTRACT

The traditional deterrence-based paradigm of civil liability may be understood as indirect market regulation, as the risk of incurring liability for damages provides an incentive to invest in safety. Such an approach, however, has proven to be inappropriate in medical civil liability. Extensive literature shows that the increase in the asymmetric protection of patients by extending medical civil liability beyond a certain limit does not improve safety; instead, that strategy determines the adoption of “defensive” techniques (the so-

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called “defensive medicine”). Paradoxically, this approach leads to a reduction in market efficiency and overall patient safety.

The traditional paradigm of medical civil liability, moreover, is very likely to prevent the intensive use of artificial intelligence and robotization to further develop the healthcare landscape. In fact, under the current paradigm of civil liability, redress is allowed only insofar “somebody” is identified as liable to pay damages (either because of fault or based on strict liability). However, robots and software may “behave” far independently from instructions initially provided by designers and programmers. This possibility may represent a disincentive to new AI technologies, as in this model designers and programmers could be held liable even if the damage derives from the “correct” operation of algorithms and robots.

This article proposes that the law of redress in healthcare should evolve from an issue of civil liability to one of financial management of losses. No-fault redress schemes could be an interesting and valuable regulatory strategy in order to allow such an evolution. Also, some pieces of “no fault” legislation are discussed, and a few proposals and comments are provided.

Keywords: healthcare, medical malpractice, civil liability, “no-fault,” strict liability, guidelines, artificial intelligence, robots

I. INTRODUCTORY REMARKS

Civil liability may be considered, under a *functional* point of view, as a technique of indirect market regulation, since the risk to incur liability for damages provides an incentive to invest in safety.¹ The idea is that any raise of the stick of civil liability for a given activity would determine a corresponding increase of efforts, by firms and professionals operating in the relevant market, aimed at reducing the risk or compensation until the point where, roughly

1. On the different “functions” of civil liability, among others, see H. Koziol, *Comparative conclusions*, in BASIC QUESTIONS OF TORT LAW FROM A COMPARATIVE PERSPECTIVE 746 (H. Koziol ed., Jan Sramek Verlag 2015).

speaking, any further investment in safety would cost more than the risk to pay redress to damaged clients and users.

The above technique of indirect market regulation may work only insofar as the risk to compensate damages is allocated onto the same subject called to invest further resources in safety. Therefore, such a *paradigm*² of civil liability invariably requires identification of a person liable for redress, which is likely to be the *producer* of a given product of the *provider* of a given service.³

This deterrence-based approach works in several scenarios (e.g., damages for defective products), but is inappropriate in others, such as healthcare, where increased liability may lead, and has actually lead, to “defensive medicine” strategies (i.e., practices that are not in the interest of patients, aimed at protecting doctors against potential plaintiffs),⁴ which have proven to be harmful for the whole system and also for patients themselves.⁵

It seems, therefore, necessary to unwind the increase of civil liability against doctors and hospitals in order to guarantee that healthcare systems may develop a more efficient and safer approach.

2. A *paradigm* is the conceptual tool defining methods and problems and solving problems accepted by a given community: see T. KUHN, *THE STRUCTURE OF SCIENTIFIC REVOLUTIONS* (U. Chicago Press 1962). Paradigms influence interpretation in two ways. First, they allow one to detect objects and relationships that *each paradigm* allows to detect, but they prevent detection of objects and relationships incompatible or “hidden” to it (*id.* at 151). Paradigms, in other words, provide schemes with which is it possible to “order” the world (*id.* at 44), so that without such schemes there would be only a “great blooming, buzzing confusion” (*id.* at 141, quoting William James). Second, and consequently, the paradigm accepted in each moment represents the conceptual tool with which one defines problems that are considered solvable and the relevant solution methods. See *id.* at 58 and 138, where reference is made to “normative” functions of paradigms.

3. See *infra* §§ II and III.

4. “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 I* (Government Printing Office 1994).

For the sake of completeness, one should note that some authors contest the relevance of defensive medicine in this field; see, e.g., M. J. Saks & S. Landsman, *The Paradoxes of Defensive Medicine*, 30 *HEALTH MATRIX* 25.

5. See *infra* § IV.

This is especially so because the negative consequences brought by defensive medicine are particularly harsh, both in terms of costs for national communities and of the increase in other negative externalities.

This complex situation does not allow for simple solutions but requires a well-designed action to allow public healthcare to remain in place the way we know it. The claim in this paper is that the problem of defensive medicine could be much reduced by introducing an alternative compensation system for damage caused by medical treatments.

This claim, calling for an evolution towards an alternative *paradigm*, may also be extended to artificial intelligence markets, as they are likely to be prone to similar negative externalities when civil liability is applied as a regulatory strategy based on deterrence.

In this article, I propose that “no-fault” systems, existing in many countries, may provide direction for a future reform. The concept of “no fault” is used here with reference to a system where redress is provided by a dedicated fund regardless of any fault by the agent being established; it does not make reference, instead, to strict-liability schemes that likewise ignore “fault” as a condition to impose liability but operate in the opposite direction, by *imposing* the obligation to redress on agents *regardless of their culpability*.

I also recall peculiarities and weaknesses of such schemes, in order to demarcate the scope of their usability as models for reform. As evidenced in the title, this article is aimed at representing as a call toward the setting of a research agenda on the issue, rather than having the ambition of providing fully worked-out answers. These may be a long way ahead, but I believe that a clear statement of the pitfalls of current legislation and the scope of its future reformation represent a sound step in that direction.

II. THE “TRADITIONAL” PARADIGM OF CIVIL LIABILITY BASED ON DETERRENCE

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, aimed at preventing liability. The belief is that the tougher civil liability rules on producers and other professionals, the higher the overall level of safety within the system.⁶

As noted above, such technique of indirect market regulation may work only insofar as the risk to compensate damages is allocated to the same subject called to invest further resources in safety. This may be done via fault-based liability or strict liability. The first one is rooted in fault and requires an “offender,” i.e., a person found responsible for a given damage and therefore liable to redress it.

In fact, the idea that civil liability requires somebody’s “fault” is deeply rooted in legal thinking: it emerged in Justinian law and was further consolidated in the *jus commune* and canon law,⁷ beginning approximately one thousand and five hundred years ago. This idea, inspiring the whole system of civil liability as a paradigmatic principle, was called, in German literature, the “dogma of fault” (*Verschuldensdogma*). This approach is represented by the well-known expression “*Nicht der Schaden verpflichtet zum Schadensersatz, sondern die Schuld*” (the obligation to pay compensation derives from fault, not from damage), formulated by von Jhering.⁸

6. G. CALABRESI, *THE COST OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS* (Yale U. Press 1970); R. COOTER & T. ULEN, *LAW & ECONOMICS* 336-338 (6th ed., Pearson/Addison Wesley 2008); J. Hersch & W. Kip Viscusi, *Assessing the Insurance Role of Tort Liability After Calabresi*, 77 L. & CONTEMP. PROBS. 135 (2014). More recently, see Andrew F. Popper, *In Defense of Deterrence*, 75 ALB. L. REV. 181 (2011).

7. Among others, see H. MAZEAUD & A. TUNC, 1 *TRAITÉ THÉORIQUE ET PRATIQUE DE LA RESPONSABILITÉ CIVILE DÉLICTUELLE ET CONTRACTUELLE* 422 (5th ed., Éditions Montchrestien 1957).

8. R. VON JHERING, *DAS SHULDMOMENT IM RÖMISCHEN PRIVATRECHT* 40 (Brühl 1867).

A. Evolution Toward a “Solidarity Approach”

The paradigmatic centrality of “deterrence” evolved over time but remained in place when most relevant social, political and economic changes made legal thinking advance toward an increasing quest for solidarity in all western legal systems, regardless of their civil-law or common-law basic structure⁹—though the common law is traditionally less concerned with solidarity in private relationships than the civil law is.

The quest for solidarity, greatly prompted by the factual consequences and upheavals derived from the industrial revolution, made legislators to consider it unjust that damages following certain (intrinsically risky) activities should be borne by consumers and other end users of goods and services unless “fault” by producers or other professionals could be proven in court.

Such evolution brought a relevant variation in civil liability legislations (within the same paradigm, I believe), which lead to an “asymmetric” discipline of civil liability and to the adoption of loss-spreading strategies for civil liability laws.¹⁰ Under such development, which evolved throughout the whole 20th century, legislators reallocated the cost of accidents from customers and end users to producers and other professionals, since the latter were thought to be in a better position to spread the cost of accidents and arrange for appropriate prevention policies.

9. In Italy *see, e.g.*, A. DE CUPIS, *IL DANNO: TEORIA GENERALE DELLA RESPONSABILITÀ CIVILE* 66 (Giuffrè 1979); in France, *see* L. JOSSERAND, *Les transports*, in *XVIII TRAITÉ GÉNÉRAL THÉORIQUE ET PRATIQUE DE DROIT COMMERCIAL* 457 (Edmond-Eugène Thaller ed. 1910); in Germany, *see* H. SPERL, *ÜBER DAS SCHADENERSATZRECHT NACH DEM DEUTSCHEN BÜRGERLICHEN GESETZBUCH* 154 (Manz Verlag 1902); in England, *see* M. LUNNEY & K. OLIPHANT, *TORT LAW TEXT AND MATERIALS* 15 (Oxford U. Press 2000). For a more general and comparative perspective, *see* S. TAYLOR, *DIFFERING CULTURES OF CIVIL LIABILITY IN MEDICAL ACCIDENT LIABILITY AND REDRESS IN ENGLISH AND FRENCH LAW* (Cambridge U. Press 2015).

10. M. COMPORI, *ESPOSIZIONE AL PERICOLO E RESPONSABILITÀ CIVILE* (Morano 1965). For an economic point of view, *see* R. D. COOTER, *Economic Theories of Legal Liability*, 5 *J. ECON. PERSP.* 11-30 (1991).

In other words, liability became less dependent on the *fault* that caused the damage and was more and more dependent upon the *risky nature* of some activities (among which one should especially note industrial production).

This need to reallocate the cost of accidents to producers and other professionals widened the potential of deterrence raised by civil liability law. The borders of civil liability were extended beyond the cases where plaintiffs could establish “fault” by the producer or professional, i.e., to all those cases where producers and professionals could not show that the damage was not attributable to them, cases in which there was scientific uncertainty as to the cause of the harmful effects or even where such cause was unknown.¹¹

This evolution was pursued through similar techniques in different western legal systems, mainly the reversal of the burden of proof 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, this path included sector-specific evolutions, such as the imposition of an obligation of result with respect to many therapies and especially routine ones (in English law through the *res ipsa loquitur* doctrine,¹² in Germany through the *Anscheinsbeweis* or *prima facie Beweis* doctrine,¹³ etc.). Some jurisdictions even turned extra-contractual medical liability into contractual liability (which favors patients, *inter alia*, as regards the burden of proof) following the German doctrine of *faktische*

11. R. MONTINARO, DUBBIO SCIENTIFICO E RESPONSABILITÀ CIVILE (Giuffrè 2012); for an economic analysis of law perspective, see M. G. Faure, L. T. Visscher, F. Weber, *Liability for Unknown Risk – A Law and Economics Perspective*, 7 J. EUR. TORT LAW 198-228 (2016).

12. See *Donoghue v Stevenson* [1932] AC 562.

13. M. STAUCH, THE LAW OF MEDICAL NEGLIGENCE IN ENGLAND AND GERMANY: A COMPARATIVE ANALYSIS 73 (Hart Publ'g 2008).

Vertragsverhältnisse,¹⁴ as it happened in Italy with the theory of *contatto sociale*.¹⁵

As briefly noted above, this evolution, even if relevant and somehow innovative, represented mere *incremental* advancement of the same traditional paradigm based on deterrence. In fact, the development just summarized was limited, basically, only to reallocate the “cost of accidents” from customers and users to producers and professionals (in healthcare, from patients to doctors and hospitals) within the same conceptual and legal framework already in place (including the deterrence function).

What changed, in other terms, was the balancing of interests, not rethinking techniques to satisfy them, insofar as the concept of deterrence was widened. In some cases that widening was toward strict liability, simply in order to widen its potential 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 accordingly.¹⁶

The same (mere) *incremental* evolution may be observed in the adoption of loss-spreading techniques, such as the provision of mandatory insurance for producers and professionals. In fact, mandatory insurance is mainly thought to protect damaged consumers and other end users of goods and services from the risk that producers or other professionals have insufficient patrimony to pay redress.

It is certainly true that the development of insurance is based on a solidarity model, aimed at spreading losses among all insured producers and professionals, and it is likewise true that in markets where mandatory insurance is provided the deterrence element is diluted by insurance itself, insofar as the extra cost of negligence is

14. G. Haupt, *Über faktische Vertragsverhältnisse*, 124 LEIPZIGER RECHTSWISSENSCHAFTLICHE STUDIEN (1943).

15. Cass. Jan. 22, 1999, No. 589; on this issue, see C. Castronovo, *Obblighi di protezione*, in ENCICLOPEDIA GIURIDICA (Treccani 1990).

16. R. SAVATIER, 1 TRAITÉ DE LA RESPONSABILITÉ CIVILE EN DROIT FRANÇAIS CIVIL, ADMINISTRATIF, PROFESSIONNEL, PROCÉDURAL 3 (2d ed., Librairie générale de droit et de jurisprudence 1945); M. COMPORTI, ESPOSIZIONE AL PERICOLO E RESPONSABILITÀ CIVILE (Morano 1965).

marginally distributed amongst all the insured. However, the mere existence of insurance coverage may not necessarily modify the traditional paradigm of civil liability based on deterrence. In fact, insurance determines a reallocation of the obligation to pay compensation, but producers and other professionals may remain liable for damages in case insurance coverage is not applicable (e.g., when the event is not covered by the contract or in case of willful misconduct or, often, even gross negligence). In any case, they remain subject to deterrence at least indirectly, since after paying compensation insurers would shift to the relevant producers and professionals the cost of any redress paid on their behalf by applying higher insurance premiums.¹⁷

B. The Remaining Centrality of the “Traditional” Paradigm

The above-mentioned paradigm may be considered indisputable in legislation, where civil liability is invariably considered also for its potential of deterrence and, therefore, the increase of civil liability is considered as a regulatory technique to foster investments in safety by producers and professionals. Also in law-and-economics literature, the paradigm is very rarely contested: it is sometimes disputed *if* civil liability rules should be imposed in some sectors to enhance safety instead of *ex ante* regulation and *when* such rules could be capable of producing appropriate incentives. However, it is assumed that civil liability plays an indirect-regulation role, insofar as the cost of compensating harmed customers and end users (whether or not it is spread out to the entire sector by insurance) represents an incentive of producers and other professionals to invest in safer products and services.

17. The relationship between insurance coverage and deterrence is discussed by G. Wagner, *Tort Law and Liability Insurance*, 31 GENEVA PAPERS ON RISK AND INS.—ISSUES AND PRACTICE 277 (2006); H. Luntz, *Torts and Insurance: The Effect on Deterrence* (conference paper) (Dec. 2010), available at <https://perma.cc/GH6A-2JG9>; S. Shavell, *On the Social Function and the Regulation of Liability Insurance*, 25 GENEVA PAPERS ON RISK AND INS.—ISSUES AND PRACTICE 166 (2000).

This consensus on the traditional paradigm prevails even when civil liability rules are approached critically, for instance, by authors reconsidering the efficiency of civil liability rules in preventing safety risks. In pursuing such strategies, however, they seem to suggest a preference for *ex ante* regulation with reference to some markets.¹⁸ Occasionally, the literature points out that the incentives produced on safety by civil liability rules may be inappropriate in some markets. However, critics tend to focus on the context in which such rules are applied rather than on the rules and their design.¹⁹

It is not common, in fact, that steps are taken to rethink and redesign the concept of civil liability; most of the times, the latter keeps being considered, as such, invariably designed as a deterrence instrument (even if sometimes not appropriate) having a direct positive impact on safety.

Even sophisticated studies at the supranational level have considered, and still consider, civil liability as performing the central function of *deterrence* along with that of compensation.²⁰ A similar approach is to be found in the Principles of European Tort Law (PETL) drafted by the European Group on Tort Law,²¹ especially as regards linking redress to someone's liability to compensate damage (art. 1:101(1)) and to liability based either on fault or "strict liability" (Title III). This comes as no surprise, since the Principles represent a summary of existing European laws, in which the deterrence-based paradigm is certainly in place.

18. See, e.g., M. G. Faure, *The Complementary Roles of Liability, Regulation and Insurance in Safety Management: Theory and Practice*, J. RISK RES. (2014); M. G. Faure, *Private Liability and Critical Infrastructure*, 6 EUR. J. RISK REG. 229-243 (2015).

19. See, e.g., Rebecca K. Viscusi, *Does Product Liability Make Us Safer?*, 35 REGULATION 24-31 (2012).

20. OECD, *Medical Malpractice. Prevention, Insurance and Coverage Options*, 11 POLICY ISSUES IN INSURANCE 27 (2006).

21. EUROPEAN GROUP ON TORT LAW, *PRINCIPLES OF EUROPEAN TORT LAW: TEXT AND COMMENTARY* (Springer 2005).

III. THE “BREACH” OF THE “TRADITIONAL” PARADIGM IN HEALTHCARE AND DEFENSIVE MEDICINE

The deterrence paradigm proves to be reliable and appropriate in several instances, e.g., with reference to general consumer legislation such as Council Directive 85/374/EEC of July 25, 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, imposing strict liability on producers for damage caused by defective products.²²

The paradigm, however, proves inappropriate in other cases, such as healthcare. A rich and valuable literature shows that the increase in the asymmetric protection of patients by extending medical civil liability *beyond a certain limit* does not improve safety²³ but, instead, determines the adoption of “defensive” strategies (the so-called “defensive medicine”) and brings about a number of negative externalities that are listed below.

A significant externality is that costs related to defensive medicine account for a relevant percentage of the overall cost incurred with respect to national health systems. Preliminarily, one should note that health expenditure binds a relevant part of the GDP

22. The liability for defective products clearly shows how the function of deterrence is implemented, in civil law systems, pursuant the idea of “solidarity,” as evidenced above. One may think, in this respect, of the very inspiration of Directive 85/374/EEC, insofar as liability without fault on the part of the producer (established under art. 1) was thought to be “the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production.” The deterrence function is evidenced in different passages of that directive, e.g., art. 6, which provides that “a product is defective when it does not provide the safety which a person is entitled to expect,” taking into account all relevant circumstances.

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), available at <https://perma.cc/P8EP-AQZS>.

23. OECD, *supra* note 20, at 16; M. Catino, *Blame Culture and Defensive Medicine*, 11 COGNITION, TECH. & WORK 245-253; M. Catino & S. Celotti, *The Problem of Defensive Medicine: Two Italian Surveys*, in DETECTION AND PREVENTION OF ADVERSE DRUG EVENTS 206 (R. Beuscart, W. Hackl & C. Nøhr eds., IOS Press 2009); M. Catino, *Why do Doctors Practice Defensive Medicine? The Side-Effects of Medical Litigation*, 15 SAFETY SCIENCE MONITOR 1 (2011).

throughout the world and is currently moving upward. Limiting attention to the last years, the world average expenditure in healthcare grew, from 2000 to 2017, from 8.622% to 9.896% of the GDP. In the euro area the increase moved from 8.640% to 10.135%; in the U.S., from 12.503% to 17.061%.²⁴

It is not possible to provide any accurate estimate of how much such an expense is due to defensive medicine; however, available data show that the latter amounts to a rather high percentage thereof. As an example, one may consider that a study, conducted by authors from Harvard University and the University of Melbourne and published in 2010, concluded that more than 80% of the overall annual USA medical liability system costs (estimated to be \$55.6 billion in 2008 dollars, or 2.4% of total healthcare spending), i.e., \$45.6 billion, were due to defensive medicine.²⁵ As regards Italy, in 2014-2015 defensive medicine was estimated to cost roundly 10 billion euros a year (i.e., 10.5% of the GDP) and to represent the first category of healthcare waste (26% of the total).²⁶ One may also add the following:

- over-prescription of exams, therapies, and medicines that causes an increase of iatrogenic risks and damage;
- some inefficiencies and loss of quality of the healthcare system;
- abandonment of the sector by insurers and an overall increase of insurance premiums;

24. World Bank, *Current Health Expenditure (% of GDP)*, WORLD BANK OPEN DATA, available at <https://perma.cc/467C-Z5CM>.

25. M. M. Mello, A. Chandra, A. A. Gawande & D. M. Studdert, *National Costs of the Medical Liability System*, 29 HEALTH AFFAIRS 1569 (2010). It ought to be noted that such a number did not “attempt to estimate social costs or benefits of the malpractice system, such as damage to physicians’ reputations or any deterrent effect it may provide.”

26. V. Di Gregorio, A. M. Ferriero, M. L. Specchia, S. Capizzi, G. Damiani & W. Ricciardi, *Defensive Medicine in Europe: Which Solutions?*, 25 EUR. J. PUBLIC HEALTH 145. This study also highlighted that in Europe litigation for medical malpractice increased significantly over the last decade, ranging from more than 50% in Britain, Scandinavia, the Baltic countries, and Eastern Europe to more than 200–500% in Germany, Italy, the Iberian and Mediterranean Area countries.

- abandonment of risky specialities by doctors, hospitals and universities;
- the refusal to provide treatment in particularly serious cases.

What is most relevant is that, in some sectors such as healthcare, beyond certain limits the current paradigm of civil liability based on deterrence is completely unreliable, since further increases of civil liability do not procure any gain in safety and, to the contrary and paradoxically, lead to a reduction of market efficiency and overall patient safety.

A. Defensive Medicine as an Obstacle Toward Safer Healthcare Risk Management

Moreover, the deterrence paradigm, as it is currently understood and applied in most western jurisdictions, produces perverse effects capable of preventing, or at least hindering, the development of well-grounded risk-management systems.

In fact, several civil liability systems, inspired by the traditional paradigm, provide doctors with a disincentive to share information on risks, harmful events, and latent errors and failures. They are required to define evidence-based safety standards and, therefore, develop reliable guidelines,²⁷ since this may increase their risk of being held liable. As an example, a research carried out in 2006-2007 on approximately one thousand doctors in eighteen Italian hospitals showed a shocking result: the great majority of doctors considered reporting and learning systems very useful for their profession, but less than half of them made any contributions of relevant information fearing legal consequences.²⁸ Italian legislation on this issue changed in 2017 in light of this problem, even if it is not clear

27. J. REASON, *HUMAN ERROR* (Cambridge U. Press 1990); C. Bayley, *What Medical Errors can Tell us About Management Mistakes*, in *MANAGEMENT MISTAKES IN HEALTHCARE: IDENTIFICATION, CORRECTION AND PREVENTION* 74-83 (P. B. Hofmann & F. Perry eds., Cambridge U. Press 2019).

28. See S. Albolino, R. Tartaglia, T. Bellandi, A. M. V. Amicosante, E. Bianchini & A. Biggeri, *Patient Safety and Incident Reporting: Survey of Italian Healthcare Workers*, 19 *BMJ QUALITY & SAFETY* (2010).

whether the solution proposed is capable of resolving it completely.²⁹

In addition, it is undisputable that evidence-based medicine (EBM³⁰) nowadays allows the development of more accurate and reliable guidelines whose application is capable of reducing the overall risk of death and damage.³¹ However, the current civil liability rules provide doctors with a disincentive to apply them consistently, since their observance may not be sufficient to relieve them from civil liability³²: the problem seems rather well spread in

29. It ought to be noted that civil liability law was reformed, in Italy, through Law No. 24 of March 8, 2017. As regards the issue at stake, art. 16 provides that reports and documents resulting from clinical risk management cannot be acquired or used in the context of legal proceedings. Even if this rule appears to take into consideration the problem discussed above, in the text, it still leaves two problems open. First of all, it is possible that such information could be published in the semi-annual report provided by art. 1, co. 539, let. d *bis*, Law No. 208 of December 28, 2015 on adverse events occurred within the facility, the causes that produced the adverse event, and the resulting initiatives put in place. Secondly, it is not clear whether such information could be obtained by the Ombudsman under art. 2 of Law 24/2017. On this issue, see E. Marchisio, *Evoluzione della responsabilità civile medica e medicina "difensiva,"* 1 RIVISTA DI DIRITTO CIVILE 212 (2020); L. M. Franciosi, *The New Italian Regime for Healthcare Liability and the Role of Clinical Practice Guidelines: A Dialogue Among Legal Formants,* 11 J. CIV. L. STUD. 371 (2018).

30. G. H. Guyatt, *Evidence-Based Medicine*, 114 ACP J CLUB A-16 (1991); Evidence-Based Medicine Working Group, *Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*, 268 JAMA 2420-25; D. L. Sackett, W. M. C. Rosenberg, J. A. M. Gray et al., *Evidence-Based Medicine: What it is and What it Isn't*, 312 BMJ 71-72.

31. See, e.g., S. A. R. DOI, UNDERSTANDING EVIDENCE IN HEALTH CARE: USING CLINICAL EPIDEMIOLOGY (Palgrave Macmillan 2012); J. H. HOWICK, THE PHILOSOPHY OF EVIDENCE-BASED MEDICINE (Wiley-Blackwell 2011).

32. 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 in Italy, see, e.g., C. M. MASIERI, LINEE GUIDA E RESPONSABILITÀ CIVILE DEL MEDICO (Giuffrè Francis Lefebvre 2019); Simone Calvigioni, *Linee guida e buone pratiche clinico-assistenziali, in I PROFILI PROCESSUALI DELLA NUOVA DISCIPLINA SULLA RESPONSABILITÀ SANITARIA* 216 (A. D. De SANTIS ed., RomaTrE-Press 2017); M. FRANZONI, *Colpa e linee guida nella nuova legge*, 22 DANNO E RESPONSABILITÀ 278 (2017); C. Scognamiglio, *Regole di condotta, modelli di responsabilità e risarcimento del danno nella nuova legge sulla responsabilità sanitaria*, 34 CORRIERE GIURIDICO 740 (2017). Comparative remarks are developed in SIMON TAYLOR, MEDICAL ACCIDENT LIABILITY AND REDRESS IN ENGLISH AND FRENCH LAW (Cambridge U. Press 2015). At the European level, see HERMAN NYS, 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), available at <https://perma.cc/6ZWP-UUJG>; PERSONAL

different jurisdictions, regardless of their belonging to either civil law or common law traditions.³³

Interestingly, in other areas of scholarship, such problems are studied in depth and scholars reached the conclusion that risky activities incorporate a certain percentage of risk depending not on the person performing them but on the activities themselves.³⁴ Errors happen and will happen regardless of how severe civil liability is. There is, therefore, no point in increasing it beyond the limit where all actors in the relevant market are disadvantaged.

This situation is not going toward market self-correction. Instead, the market is reacting by adjusting to the perverse incentives provided by the law, so that “medicine of jurisprudential obedience”³⁵ is nowadays induced from doctors’ very university

INJURY AND DAMAGE ASCERTAINMENT UNDER CIVIL LAW 537 (S. D. Ferrara, R. Boscolo-Berto & G. Viel eds., Springer 2016); S. D. Ferrara, E. Baccino, T. Bajonowski, 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*, 127 INTL. J. LEG. MED. 545-557.

33. In regard to the United States, see, e.g., L. L. LeCraw, *Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, 3 J. OF ONCOLOGY PRACTICE 254 (2007). In the U.K., see S. Ash, S. Jo & M. Gunn, *Legal Considerations of Clinical Guidelines: Will NICE Make a Difference?*, 96 J. ROYAL SOC’Y MED. 133-138 (2003). In connection with French law, see III THE DEVELOPMENT OF MEDICAL LIABILITY 76 (Ewoud Hondius ed., Cambridge U. Press 2010). Under Italian law, see art. 7(3) of Law No. 24 of March 8, 2017, which expressly provides that respect for guidelines and best practices can be considered by the judge only with respect to the definition of redress and not when assessing civil liability in the first place.

34. On this point, see the “Swiss cheese model” developed in J. Reason, *The Contribution of Latent Human Failures to the Breakdown of Complex Systems*, 327 PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY OF LONDON B, BIOLOGICAL SCIENCES 475-484 (1990). Also see T. Aven, *Risk Assessment and Risk Management: Review of Recent Advances on their Foundation*, 253 EUR. J. OPERATIONAL RESEARCH 1-13 (2016); J. Aldred, *Justifying Precautionary Policies: Incommensurability and Uncertainty*, 96 ECOLOGICAL ECONOMICS 132-140 (2013); T. Aven, *The Risk Concept—Historical and Recent Development Trends*, 99 RELIABILITY ENGINEERING AND SYSTEM SAFETY 33-44 (2012); DENNIS V. LINDLEY, UNDERSTANDING UNCERTAINTY (Wiley 2006); C. E. Althaus, *A Disciplinary Perspective on the Epistemological Status of Risk*, 25 RISK ANALYSIS 567-588 (2005).

35. A. Fiori, *La medicina delle evidenze e delle scelte sta declinando verso la Medicina dell’obbedienza giurisprudenziale?*, 4 RIVISTA ITALIANA DI MEDICINA LEGALE 925-931 (2007). On this issue, see also E. J. Cassell, *Consent or*

education.³⁶ The current situation, therefore, requires a prompt revolution of the civil liability paradigm, since past increases of liability on doctors and hospitals in the recent past did not enhance safety and, instead, imposed severe negative externalities on the whole healthcare system.³⁷

B. A Claim in Favour of Relieving Doctors and Hospitals from Liability

The above-reported negative externalities could be reduced, without losing the safety and efficiency of the healthcare system if doctors and hospitals could be relieved from civil liability for damages in cases in which there is no evidence of negligence, imprudence, or unskillfulness *and* scientifically-validated standardized actions (guidelines, among others) are observed.

This claim is made based on the assumption (and its relevance is limited insofar as this assumption is confirmed, which is to be verified when drafting guidelines) that following standard actions inspired by evidence-based medicine makes overall accidents and damage lower than those experienced in a system in which standards are not defined or observed.³⁸ In other words: even if the observance of standards could determine unwanted damages on patients in some cases, adherence to scientifically-validated standards should be

Obedience? Power and Authority in Medicine, 352 NEW ENGL. J. MED. 328-330 (2005).

36. W. F. Johnston, R. M. Rodriguez, D. Suarez & J. Fortman, *Study of Medical Students' Malpractice Fear and Defensive Medicine: a "Hidden Curriculum?"*, 15 WEST. J. EMERGENCY MED. 293-298 (2014); K. J. O'Leary, J. Choi, K. J. D. Watson & M. V. Williams, *Medical Students' and Residents' Clinical and Educational Experiences With Defensive Medicine*, 87 ACADEMIC MEDICINE 142 (2012).

37. See OECD, *supra* note 20.

38. 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*, 360 NEW ENGL. J. MED. 491 (2019); P. G. Shekelle et al., *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (2013), available at <https://perma.cc/7GC7-CT4Z>.

promoted in all cases in which such adherence appears, at a systemic level, as a safer strategy than any other.

Of course, this should not prevent doctors from leaving aside guidelines and standards when this appears appropriate in a particular case, in order to apply their professional knowledge. This approach should be an option in those specific instances in which, in their judgment, guidelines are not suitable: professional knowledge should not be depreciated by defensive medicine. In fact, practitioners understand and experience defensive medicine “as unnecessary and meaningless medical actions, carried out mainly because of external demands that run counter to the GP’s professionalism.”³⁹ This possibility to depart from the standard, however, would not contradict the “safe harbor” nature of adherence to the standard.

IV. THE NEED FOR A *NEW PARADIGM* OF (MEDICAL) CIVIL LIABILITY IN THE WAKE OF ARTIFICIAL INTELLIGENCE

As far as its scope is concerned, the law regulates economic and social activities in order to contribute to the pursuit of welfare. But the law cannot define its goals and means arbitrarily. It needs to take into the highest consideration the functioning of economic and social contexts addressed, in order to develop well-grounded, affordable, reliable, and effective rules.⁴⁰

As noted above, the failure of the deterrence paradigm may be observed and empirically proved. This conclusion is indisputable when one notes that the recent increases in civil liability worsened the position of both doctors *and* patients, also plaguing healthcare systems with significant negative externalities. A radical modification is therefore required.

39. E. A. Hvidt, J. Lykkegaard, L. B. Pedersen, K. M. Pedersen, A. Munck & M. K. Andersen, *How is Defensive Medicine Understood and Experienced in a Primary Care Setting? A Qualitative Focus Group Study Among Danish General Practitioners*, 7 *BMJ OPEN* (2017).

40. E. R. de Jong, M. G. Faure, I. Giesen & P. Mascini, *Judge-Made Risk Regulation and Tort Law: An Introduction*, 9 *EUR. J. RISK RES.* 6-13 (2018).

Such a modification appears particularly important these days because of the incentives to practice “defensive medicine.” What may even be more relevant, however, is that the traditional paradigm of medical civil liability is very likely to prevent the development of markets toward intensive use of artificial intelligence and robotization, which are likely to play an increasingly more relevant role in healthcare, especially through machine learning and deep learning technologies.

In fact, artificial intelligence can contribute to healthcare in two main areas. The first one relates to developing medical *knowledge and standards*. This is happening through the use of sophisticated algorithms that combine big data in order to relate a much higher number of variables and allow drafting medical guidelines and databases that are incredibly more reliable.⁴¹ Such a change, it ought to be noted, will evolve sharply also due to the pursuit of open-access and open-data strategies by most legal systems, including the EU.⁴²

The second one relates to the use of artificial intelligence in *performing* medical activities—artificial intelligence provides robots with the ability to execute even complex interventions with an increasingly higher autonomy.⁴³

41. G. H. Guyatt, *Evidence-Based Medicine*, 114 ACP JOURNAL CLUB A-16 (1991); Evidence-Based Medicine Working Group, *Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*, 268 JAMA 2420-25 (1992); 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*, 71 BMJ 312 (1996).

42. In 2003, the European Commission set up a legal framework to allow the reuse of public sector 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, *Shaping Europe's Digital Future, Policy: Open Data*, <https://perma.cc/SA5Z-HKS4>.

43. See, e.g., *Artificial Intelligence and Machine Learning for Healthcare*, SIGMOIDAL, Dec. 21, 2017, <https://perma.cc/9AAV-K7EJ>; D. Hernandez, *Artificial Intelligence Is Now Telling Doctors How to Treat You*, WIRED, June 2, 2014, available at <https://perma.cc/3UFH-7LPA>; PWC, *What Doctor? Why AI and robotics will define New Health, June 2017*, available at <https://perma.cc/TT7M-TFPT>.

Even if artificial intelligence can contribute to develop much safer healthcare, its development could be hindered by the “traditional” paradigm of civil liability law. In fact, the current paradigm allows redress to damaged patients under the rules that need to identify a “somebody” liable to pay such compensation either because of his or her fault or by virtue of a strict liability rule. This means that, in case of damage produced by a robot, judges and lawyers would seek to impose civil liability either on its producer or on the author of the computer program that makes it work—the only “somebody” available to be held liable; the “nearest human,” as it was noted.⁴⁴

This does not consider that artificial intelligence systems evolve over time (and will do so even more in the near future) on the basis of the information and feedback gathered and processed by thousands of different shared sources (the so-called “machine learning” and “deep learning”). In fact, it may be said that robots do not only perform activities, they also *learn* how to perform them over time.⁴⁵

In fact, the possibility that robots and programs “behave” far independently from instructions initially provided by programmers and constructors is extremely probable. This possibility has 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.”⁴⁶ I understand that the main reason for this proposal is that of using legal personality as a technique to

44. K. Hao, *When Algorithms Mess Up, the Nearest Human the Blame*, MIT TECH. REV. (May 28, 2019) available at <https://perma.cc/WSW9-RP9Q>.

45. H. SURDEN, *Machine Learning and Law*, 89 WASH. L. REV. 1 (2014); S. RUSSEL & P. NORVIG, *ARTIFICIAL INTELLIGENCE. A MODERN APPROACH* 693 (Pearson College Div. 2010).

46. EUROPEAN PARLIAMENT, Committee on Legal Affairs, *Draft Report with Recommendations to the Commission on Civil Law Rules on Robotics* (2015/2103(INL)), § 31(f) (May 31, 2016). See also A. Amidei, *Robotica intelligente e responsabilità: profili e prospettive evolutive del quadro normativo europeo*, in INTELLIGENZA ARTIFICIALE E RESPONSABILITÀ 63 (U. Ruffolo ed., Giuffrè 2017); G. GUERRA, *LA SICUREZZA DEGLI ARTEFATTI ROBOTICI IN PROSPETTIVA COMPARATISTICA* (Il Mulino 2018).

hold the robot liable and, therefore, insulate its obligations (including redress for damage) from those of its producer and programmer. I believe that such proposal is undesirable, since robots cannot and should not be considered “persons” under current civil law.⁴⁷ That approach, however, clearly shows the need to shift “obligations” away from producers and programmers when robots are capable of acting rather autonomously from their original design.⁴⁸

All what was noted above with reference to artificial intelligence clearly shows that the cause-and-effect relationship as regards damage causation in this field might not be linear as we are used to believing⁴⁹ (though not everybody agrees⁵⁰) and that adoption of a “no-fault” approach (within the meaning defined above, under §1⁵¹)

47. The issue is very wide, and it is not possible to address it here appropriately. A discussion of the issue can be found in G. Wagner, *Robot, Inc.: Personhood for Autonomous Systems*, 88 *FORDHAM L. REV.* 591 (2019); G. Wagner, *Robot Liability* (Münster Colloquium on EU Law and Digital Economy, Liability for Robotics and the Internet of Things) (Mar. 12, 2018), available at <https://perma.cc/435N-MGC7>; H. Eidenmüller (2017), *The Rise of Robots and the Law of Humans*, *ZEITSCHRIFT FÜR EUROPÄISCHES PRIVATRECHT*, 765, 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?*, 11 *MINN. J. L. SCI. & TECH.* 497 (2010); A. Bertolini, *Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules*, 5 *L., INNOVATION AND TECH.* 214-247; C. Boscarato, *Who is Responsible for a Robot's Action? An Initial Examination of Italian Law Within a European Perspective*, in *TECHNOLOGIES ON THE STAND: LEGAL AND ETHICAL QUESTIONS IN NEUROSCIENCES AND ROBOTICS* 393 (B. van der Bergh & L. Klaming eds., Wolf Legal Publishers 2011).

48. This need appears in legal literature: for example, see M. U. Scherer, *Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and Strategies*, 29 *HARV. J.L. & TECH.* 399 (2016).

49. With specific reference to artificial intelligence, see E. A. Karnov, *The Application of Traditional Tort Theory to Embodied Machine Intelligence*, in *ROBOT LAW* 51 (R. Calo, A.M. Froomkin & I. Kerr eds., Edward Elgar 2016); M. U. Scherer, *Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies and Strategies*, 29 *HARV. J.L. & TECH.* 353-400 (2016).

50. D. C. Vladeck, *Machines Without Principals: Liability Rules and Artificial Intelligence*, 89 *WASH. L. REV.* 117 (2014); F. P. Hubbard, *Sophisticated Robots: Balancing Liability, Regulation, and Innovation*, 66 *FLA. L. REV.*, 1803 (2014).

51. This is with reference to a system in which redress is provided by a dedicated fund and not by a “culpable” 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.

to medical liability could prove more efficient than the current system.

There is undoubtedly no convergence on this issue and many proposals have been made⁵² in order to address artificial intelligence devices, either fault-based rules⁵³ or strict-liability regimes,⁵⁴ including an extension of the rules on defective products⁵⁵ or on animals under the custody of humans.⁵⁶ However, I claim that the application of the traditional paradigm of civil liability would not foster safety even with respect to these technological issues; instead, it would expose producers and programmers to unforeseeable and potentially unlimited claims for civil liability without any “fault” or any disregard for a foreseeable risk being in place. This would likely deter them from entering the market or developing it, thus hindering technological evolution—what is sometimes called the risk of “technology chilling.”⁵⁷

52. A comparative analysis with reference to the different approaches in the U. S., Europe, and China can be found in M. Infantino & W. Wang, *Algorithmic Torts: A Prospective Comparative Overview*, 28 *TRANSNATL. L. & CONTEMP. PROBS.* 309 (2018). An attempt at reconstructing the different strategies available under Italian law was made by U. Ruffolo, *Per I fondamenti di un diritto della robotica self-learning: dalla machinery produttiva all’auto driverless: verso una “responsabilità da algoritmo”?*, in *INTELLIGENZA ARTIFICIALE E RESPONSABILITÀ* 1-30 (U. Ruffolo ed., Giuffrè 2017).

53. See, e.g., R. Abbott, *The Reasonable Computer: Disrupting the Paradigm of Tort Liability*, 86 *WASH. L. REV.* 1 (2018); B. Casey, *Robot Ipsa Loquitur*, 108 *GEO. L.J.* 225 (2019).

54. In favor of a strict-liability regime, see, e.g., L. BUONANNO, *CIVIL LIABILITY IN THE ERA OF NEW TECHNOLOGY: THE INFLUENCE OF BLOCKCHAIN, BLOCKCHAIN AS THE BACKBONE OF A NEW TECHNOLOGY-BASED CIVIL LIABILITY REGIME* (European Law Institute 2019), available at <https://perma.cc/G8K3-6SK8>.

55. J. S. Borghetti, *LA RESPONSABILITÉ DU FAIT DES PRODUITS : ÉTUDE DE DROIT COMPARÉ* 495 (LGDJ 2004).

56. E. Schaerer, R. Kelley & M. Nicolescu, *Robots as Animals: A Framework for Liability and Responsibility in Human-Robot Interactions* 72 (paper presented at the XVIII IEE International Symposium on Robot and Human Interactive Communication, Toyoma, Japan) (Sept. 27, 2009), <https://perma.cc/N9PY-XUYN>.

57. Among others, see W. K. Viscusi & M. J. Moore, *Rationalizing the Relationship Between Product Liability and Innovation*, in *TORT LAW AND THE PUBLIC INTEREST. COMPETITION, INNOVATION, AND CONSUMER WELFARE* 125 (P. H. Schuck ed., W. W. Norton & Company 1991); *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* (P. W. Huber & R. E. Litan eds., Brookings Institution Press 1991); G. Parchomovsky & A. Stein, *Torts*

Also, in this case it appears that the problems and disincentives evidenced above are somehow connected to the issue of standardization and standardized action. In my opinion, the above-noted problems and disincentives, capable of affecting the market of artificial intelligence devices, could be reduced if producers and programmers could be relieved from civil liability for damage at least in certain cases: when there is no evidence of negligence, imprudence, or unskillfulness *and* the robot (both in its physical components and in its artificial intelligence aspects) complied with scientifically validated production and programming standards.⁵⁸

Of course, in this case respect for standards could lead to unwanted damage to patients. However, my claim is made on the same assumption (to be further verified in all relevant cases) that in several cases, the adoption of artificial intelligence and robots determines a relevant increase in safety within healthcare systems and reduces the risk of injury and death when compared to healthcare based only on human action.⁵⁹

It is undisputable that investments in research on new technologies should be fostered and supported or, at least, not discouraged: new technologies produce a sensible increase in safety within healthcare systems and reduce the risk of injury and death, as available data already show with respect to the current situation.⁶⁰

and Innovation, 107 MICH. L. REV. 285 (2008). The problem is also discussed in J. Morgan, *Torts and Technology*, in *THE OXFORD HANDBOOK OF LAW, REGULATION AND TECHNOLOGY* 522 (R. Brownsword, E. Scotford & K. Yeung eds., Oxford U. Press 2017).

58. For the issue of technical safety standards with specific reference to robots is dealt with, among others, see G. GUERRA, *LA SICUREZZA DEGLI ARTEFATTI ROBOTICI IN PROSPETTIVA COMPARATISTICA* 104 (Il Mulino 2018) and G. S. Virk, *The Role of Standardisation in the Regulation of Robotic Technologies*, in *LAW AND TECHNOLOGY. THE CHALLENGE OF REGULATING TECHNOLOGICAL DEVELOPMENT* 311 (E. Palmerini & E. Stradella eds., Pisa U. Press 2013).

59. See, e.g., K. W. Kizer & L. N. Blum, *Safe Practices for Better Health Care*, in *IV ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION* (K. Henriksen, J.B. Battles, E.S. Marks et al. eds., Agency for Healthcare Research and Quality 2005), available at <https://perma.cc/V9P5-9RHQ>. So the provision of incentives to technological innovation, provided that it respect scientifically validated standards, appears as a safer strategy than any other.

60. See *id.*

This is one of the reasons why I believe that modern technology, sometimes, requires *new specific* legislation instead of mere *adjusting* of existing laws; a “law of the horse,” as it was said⁶¹: without appropriate *ad hoc* legislation, in fact, rules developed centuries ago in very different contexts could provide perverse incentives and produce undesirable negative externalities.

V. SHIFTING LIABILITY AWAY FROM DOCTORS, HOSPITALS, AND PRODUCERS AND PROGRAMMERS OF AI DEVICES

As shown above, the healthcare system is affected by a set of perverse incentives induced by the traditional paradigm of civil liability law. The problem could be reduced by shifting the liability away from doctors, hospitals, and producers and programmers of AI devices.

What is most important to note, however, is that such shifting away should not reduce civil liability and the corresponding patients’ right to redress in case of damage. In fact, on the patients’ side, claims for redress based on health injury are commonly recognized, in most jurisdictions, as deriving from acknowledged constitutional rights to health. The right to health was also internationally recognized in the Preamble to the Constitution of the World Health Organization (1946); it was then included in art. 25 of the Universal Declaration of Human Rights (1948) and art. 12 of the International Covenant on Economic, Social and Cultural Rights (1966).

Moreover, the “solidarity” approach that now pervades legal systems, briefly mentioned above,⁶² would not allow that damaged

61. The debate on whether modern technology requires *new specific* legislation or existing legislation and concepts may be adjusted to it may be dated back to F. Easterbrook, *Cyberspace and the Law of the Horse*, U. CHI. LEG. FORUM 207 (1996) and L. Lessig, *The Law of the Horse: What Cyberlaw Might Teach*, 113 HARV. L. REV. 501. More recently, among others, see R. Calo, *Robotics and the Lessons of Cyberlaw*, 103 CAL. L. REV. 514 (2015); E. Stradella, *Approaches for Regulating Roboting Technologies: Lessons Learned and Concluding Remarks*, in *LAW AND TECHNOLOGY: THE CHALLENGE OF REGULATING TECHNOLOGICAL DEVELOPMENT* 345 (E. Palmerini & E. Stradella eds., Pisa U. Press 2013).

62. See *supra* § II. A.

patients not be compensated for any damage incurred because of medical therapies. Redress in favor of damaged patients may be considered, as such, a non-controversial right, which would be rather difficult to repeal.

However, at closer sight, the redress of wrongs suffered by medical patients does not necessarily imply that the obligation to pay be imposed on doctors and hospitals, or producers and programmers of AI devices. What the solidarity approach requires, in fact, is that the loss does not remain with the damaged patients; its imposition on doctors and hospitals, or producers and programmers of AI devices, should depend on whether it enhances or, instead, weakens safety.

VI. FROM CIVIL LIABILITY TO FINANCIAL MANAGEMENT OF LOSSES

The thesis in this article is that a new legal approach should be developed in medical civil liability law, aimed at maintaining redress for damage on the patients' side (micro-systemic level) but shifting the obligation to pay for such redress away from doctors and hospitals (when there is not evidence of negligence, imprudence, or unskillfulness *and* scientifically validated standards of action are complied with). A further claim is that a similar development should shift away that obligation also from producers and programmers of artificial intelligence devices, when there is no evidence of negligence, imprudence, or unskillfulness *and* scientifically validated standards of production and programming are complied with. This evolution would reduce incentives to practice defensive medicine, reduce disincentives to invest in medical technology, and decrease inefficiencies and negative externalities deriving from defensive medicine (macro-systemic level).⁶³

In other words, the law of redress for medical damage should evolve from an issue of civil liability to one of financial management of losses, which would take into a much higher account the

63. Such evolution toward a "no-fault" system was also supported in OECD, *supra* note 20, at 62 *et seq.*, however without deepening the issue as to how it could be pursued.

“systemic” need of appropriate functioning of complex institutions and markets such as modern healthcare systems. One may note that this evolution could appropriately be carried out at the European level, even if the matter is rather controversial and excessively cumbersome to be discussed in this article.⁶⁴

In fact, what appears to favor a single patient in the short run (e.g., sentencing a doctor to compensate the damage suffered by the patient after a very complex surgical intervention, whether or not evidence of fault is adduced) may eventually damage *all future patients* if it prevents the whole healthcare 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 example: doctors would refuse future complex surgical interventions).

The possibility of balancing these two apparently conflicting goals is not unknown to some legal systems. “No-fault” legislation on redress following medical damage (within the meaning of “no-fault” adopted here, which makes reference to a system where redress is provided by a dedicated fund regardless of any fault by the agent being established *and not* based on strict-liability schemes⁶⁵) may be found in some jurisdictions like New Zealand, Finland, Denmark, and Sweden.⁶⁶

A detailed exam of such models would fall beyond the scope of this article. However, it may be noteworthy to highlight that “no-fault” schemes appear to differ, at a very broad view, with respect to five main variables: the extent of eligibility criteria for compensation (which may be limited to specified damage, as it happens in Virginia and Florida with respect to birth-related neurological

64. See, e.g., F. Toriello, *La responsabilità medica in prospettiva (incerta) di armonizzazione europea*, 2 *RESPONSABILITÀ MEDICA* 291 (2017); G. Wagner, *The Project of Harmonizing European Tort Law*, in *EUROPEAN TORT LAW 2005* 670 (H. Koziol & B.C. Steininger eds., Springer 2006); H. Koziol, *Comparative Conclusions*, in *BASIC QUESTIONS OF TORT LAW FROM A COMPARATIVE PERSPECTIVE* 686 (H. Koziol ed., Jan Sramek Verlag 2015).

65. See *supra* § I.

66. See OECD, *supra* note 20, for a presentation on these systems.

injury,⁶⁷ or apply to all “treatment injuries,” as in New Zealand after reform in 2005⁶⁸); whether the scheme prevents continued access to courts or not; how these schemes are funded (mainly: privately, publicly, or through a mixed scheme⁶⁹); whether redress is imposed a financial cap or not; definition of the financial entitlement (only economic or also non-economic damages).⁷⁰ It is not clear whether such pieces of legislation are simply capable of being “transplanted” into different legal systems and of reducing (if not resolving) the problem of defensive medicine. Several issues need be taken into account in this respect.

First, such foreign “no-fault systems” are not targeted at the problem of standardization and are mainly conditioned upon the damaged patient waiving civil litigation, instead. Therefore, they have a narrower scope with respect to the issue of enhancing standardization in view of a safer system. I propose, instead, that, as far as healthcare is concerned, legal systems should tolerate that the application of scientifically validated standards could determine harmful consequences in individual cases insofar as, under a systemic

67. In regard to Virginia, see VA. CODE ANN. §§ 38.2-5000 *et seq.*, known as the Virginia Birth-Related Neurological Injury Compensation Act. Further information may be found on the program website: <https://perma.cc/9AE9-SNME>. With respect to Florida, see FLA. STAT. §§ 766-301 *et seq.* Further information may be found on the program website: <https://perma.cc/5S2F-KYZ5>.

68. In fact, reforms in 2005 removed the final “fault” element still present in the system and designed it as a true “no-fault” scheme, see M. Bismark & R. Paterson, *No-Fault Compensation In New Zealand: Harmonizing Injury Compensation, Provider Accountability, And Patient Safety*, 25 HEALTH AFFAIRS 1.

69. In regard to financing, there are several models available, ranging from systems financed through contributions made by healthcare providers to systems funded via tax revenues. See OECD, *supra* note 20, for a comparative analysis on this issue; M.M. Mello, A. Kachalia & D.M. Studdert, *Administrative Compensation for Medical Injuries: Lessons from Three Foreign Systems* (2011), available at <https://perma.cc/F9LQ-AMUS>; K. DICKSON, K. HINDS, H. BURCHETT, G. BRUNTON, C. STANSFIELD & J. THOMAS, NO-FAULT COMPENSATION SCHEMES: A RAPID REALIST REVIEW (UCL Institute of Education 2016); T. Vandersteegen, W. Marneffe, I. Cleemput & L. Vereeck, *The Impact of No-Fault Compensation on Health Care Expenditures: An Empirical Study of OECD Countries*, 119 HEALTH POLICY 367 (2015).

70. These variables are compared among different “no-fault” compensation schemes in DICKSON ET AL., *supra* note 69.

point of view, such application allows a significant reduction of the overall risks and damages.⁷¹

Even if this idea is somehow disruptive and would influence the way this issue is understood, also under an ethical point of view, its feasibility may be found in some small and limited pieces of legislation (without any possibility of extensive application by way of interpretation) that provide similar mechanisms of compensation in standardized medical activities bearing some statistical risks but much more beneficial effects: it is the case, for example, of compensation following adverse effects attributed to vaccination, whose adverse effects are very rare in comparison with the more than 2.5 million deaths prevented only in 2008 by vaccination.⁷² The issue resembles, under this point of view, that of mandatory seat belt in

71. In other and more detailed words, under the proposal made in this article, redress of (statistically) “inevitable” damages resulting from compliance with scientifically-validated standards, within sectors characterized by high risk and high scientific or technological content, should *not* be imposed on persons performing the relevant activities or supplying products to the market as long as there is no evidence of negligence, imprudence, or unskillfulness *and* given criteria, to be developed within an agreed framework, are complied with (*e.g.*, treatment is appropriate, guidelines complied with scientific validation principles and were applied appropriately, etc.).

72. A review of World Health Organization Member States based on 2018 data showed that no-fault compensation systems for vaccine injuries have been developed in a few high-income countries for more than 50 years, mostly at the central or federal government level, and are government-funded. Claimants are compensated with either: lump-sums; amounts calculated based on medical care costs and expenses, loss of earnings or earning capacity; or monetary compensation calculated based on pain and suffering, emotional distress, permanent impairment or loss of function; or combination of those. It is noteworthy that, in most jurisdictions, vaccine injury claimants have the right to seek damages either through civil litigation or from a compensation scheme, but not both simultaneously; see R. G. Mungwira, Ch. Guillard, A. Saldaña, N. Okabe, H. Petousis-Harris, E. Agbenu, L. Rodewald & P.L.F. Zuber, *Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, 15 PLoS ONE (2020). On this issue, see also WHO, STATE OF THE WORLD’S VACCINES AND IMMUNIZATION (3d ed., 2009), available at <https://perma.cc/DAK5-34BX>; C. Looker & H. Kelly, *No-fault compensation following adverse events attributed to vaccination: a review of international programmes*, BULLETIN OF THE WHO (2011), available at <https://perma.cc/4KVD-79XB>; C. Looker & H. Kelly, *No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes*, 89 BULLETIN OF THE WHO 371; S. F. HALABI & S. B. OMER, *A Global Vaccine Injury Compensation System*, 317 JAMA 471 (2017).

motor vehicles: as it was noted, “seat belts can cause injuries but it is vastly more likely that they will protect you. It is all about probabilities and the chances are on the side of wearing seat belts.”⁷³

Second, foreign “no-fault” systems recalled above are rather different and their features depend upon the different jurisdictions they belong to. As noted above, within the existing “no-fault” schemes there is no uniformity as to the extent of eligibility criteria for compensation; whether the scheme should prevent continued access to courts or not; how these schemes are to be funded (the option being via tax revenues, privately, or via a mixed solution); whether a financial cap should be imposed on redress;⁷⁴ whether the financial entitlement should limit to economic damage or include also non-economic damage. Moreover, in some cases they apply rather automatically upon the occurrence of the event (as it happens in Florida and Virginia if proof is given that the neurological birth injury occurred as a result of the birth process) while in others an avoidability standard is adopted (as in European Nordic countries such as Sweden, Norway, Finland, and Iceland, where it is verified whether injuries could have been avoided if the care provided had been of optimal quality).⁷⁵ Finally, the effect for the community depends on the legal and institutional context the scheme operates in, in particular with reference to the way the social security net is designed in each different country.⁷⁶

Therefore, it appears difficult to transplant any given scheme into a different jurisdiction without adaptation. I believe that there is much room for future research in order to classify the most relevant variables, within legal systems, capable of influencing the way “no-fault” schemes (with the usual warning on the meaning of this concept adopted here⁷⁷) may operate and define how such schemes

73. A. Giubilini & J. Savulescu, *Vaccination, Risks, and Freedom: The Seat Belt Analogy*, 12 PUB. HEALTH ETHICS 237 (2019).

74. See, *supra* note 69, and the text this footnote refers to.

75. On this issue, see DICKSON ET AL., *supra* note 69, at 9.

76. *Id.* at 4.

77. See *supra* § I.

need be adjusted in order to adapt to the different legal systems they are implemented into.

Third, the legal transplant of any of such foreign “no-fault systems” may not reduce, in itself, excessive litigation (and, therefore, “defensive medicine”). As it was noted, the rather positive outcome experienced in New Zealand seems to depend on “the absence of a culture of suing in New Zealand” that pre-existed in the country,⁷⁸ which makes it unreliable that introduction of similar legislation could lead to similar results in jurisdiction where civil litigation is much higher and showed increase in the last decades.⁷⁹ 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.

Fourth, foreign “no-fault systems” are currently showing deficiencies as regards incentives to safety, in the absence of the deterrence brought about by civil liability⁸⁰: in fact, pure “no-fault” models (within the meaning referred to here) 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.”⁸¹ In this sense, I claim that “no-fault” schemes, within the meaning proposed here, should not apply out of the scope briefly mentioned here (i.e., compliance with scientifically validated

78. K. A. Wallis, *No-Fault, no Difference: No-Fault Compensation for Medical Injury and Healthcare Ethics and Practice*, 67 BRITISH J. GEN. PRACTICE 38-39 (2017).

79. OECD, *supra* note 20, at 16 *et seq.*

80. In general, on this point, *see also* DICKSON ET AL, *supra* note 69, at 5; K. Wallis, *New Zealand's 2005 'No-Fault' Compensation Reforms and Medical Professional Accountability for Harm*, 126 NEW ZEALAND MED. J. 33 (2013). Of course, such a point is raised with particular emphasis by those who believe that deterrence should be considered as an *indispensable* effect of legislation on redress; *see, e.g.*, A. Popper, *In Defense of Deterrence*, 75 ALB. L. REV. 181.

81. B. Howell, J. Kavanagh & L. Marriott, *No-Fault Public Liability Insurance: Evidence from New Zealand*, 9 AGENDA 137 (2002).

standards where there is no evidence of negligence, imprudence, or unskillfulness); otherwise the system would lose the deterrence factor that civil liability may still offer (e.g., providing application of “fault” rules in case of negligence).

Moreover, such “no-fault” schemes 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. In any case, where these schemes apply, they should be matched with a set of rules capable of providing incentives for safety. I believe that, in those cases where no one can be blamed for ignoring the standards established, such set of rules should be uncoupled from deterrence on individuals (e.g., deterrence induced by civil liability should not be replaced with deterrence induced by disciplinary sanctions, as it happened in New Zealand) and should rather be inspired by organizational and procedural criteria, thus shifting paradigmatic centrality from individuals to systemic risk management.⁸²

Of course, such an evolution would need to be accompanied by a cultural shift aimed at abandoning the desire for revenge often felt by damaged patients and their families and at rediscovering the importance of a constructive relationship between doctors and patients. This issue falls outside the scope of this article and, regretfully,

82. Such a shift would be particularly relevant if one considers that many (if not *most* of the) medical injuries relate to unavoidable human error in a context of system failure: see *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (L. T., Kohn, J.M. Corrigan & M.S. Donaldson eds., National Academies Press 2000); K. Watson & R. Kottenhagen, *Patients’ Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe*, 25 *EUR. J. HEALTH L.* 1 (2018). New Zealand is a relevant example in this respect. Before 2005, in New Zealand compensation was granted upon evidence of medical error. Since all findings of error were reported to the Medical Council, “compensation could bring disciplinary repercussions for doctors,” which discouraged doctors and sometimes even patients from participating in the compensation claims process. This knot was untied in 2005, when eligibility was extended to all injuries caused by treatment and the prior reporting duties were replaced by a new duty to report “*risk of harm to the public*” to the “*authorities responsible for patient safety*,” which reduced doctors’ fear and improved information flows within the system: see K. A. Wallis, *No-Fault, No Difference: No-Fault Compensation for Medical Injury and Healthcare Ethics and Practice*, 67 *BRITISH J. GEN. PRACTICE* 38 (2017).

cannot be dealt with here. It is relevant to note, even only incidentally, that such a shift would require a more appropriate and effective attitude to dialogue in healthcare,⁸³ in particular as regards acquisition of the informed consent.⁸⁴

Finally, foreign “no-fault systems” are designed, interpreted, and applied as “exceptions” to “common” civil liability systems, which are considered applicable by default. On the other hand, I believe that no-fault redress schemes (following the lexical convention proposed in this research) should rise, in relevant sectors and with reference to relevant cases, to the role of an independent and alternative system of redress on an equal footing to “fault” civil liability—a sort of “double track” legislation on redress for damage.

Of course, the adoption of such a redress system for medical injuries, targeted at the need to foster standardization of medical treatments, would require the definition of many different variables—which may only be briefly referred to here. First, it is based on the objective definition of certain standards as “scientifically validated,” also requiring an appropriate validation system. A third, independent party, must be in charge of assessing redress to damaged patients in application of the scheme, and care must be taken of its functioning and funding. It will also be needed to define standardized amounts of compensation. This is a critical issue under a systemic point of view, and the acceptance of such standardized compensation may strongly depend upon the way the social security net is designed in each different country.⁸⁵ On all these issues, it seems

83. As it was noted, “the doctor-patient relationship is shaped by the quality and manner of information exchange”: see K. Watson & R. Kottenhagen, *Patients’ Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe*, 25 EUR. J. HEALTH L. 1.

84. On this issue, see, e.g., R. R. FADEN & T. L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* (Oxford U. Press 1986); L. Asveld, *Informed Consent in Fields of Medical and Technological Practice: An Explorative Comparison*, 10 TECHNE: RESEARCH IN PHILOSOPHY AND TECHNOLOGY 18 (2006).

85. It is acknowledged that “no-fault” schemes are likely to lead to lower compensation in favor of damaged patients. There appears to be evidence to suggest that “no-fault” schemes providing standardized compensation are more easily

possible to draw inspiration, at least in part, from jurisdictions such as Sweden and New Zealand.⁸⁶

accepted in countries such as New Zealand and Scandinavia, where healthcare is understood as an important provision by central government and other forms of social insurance exist. On the other hand, countries with less of a social security safety net to support individuals with ongoing health and disability issues, such as the U.S., are understandably more reluctant to deny claimants the possibility of attaining damages through the court process: *see* DICKSON ET AL., *supra* note 69, at 4, 54.

86. A. Antoci, A. Fiori Maccioni & P. Russu, *The Ecology of Defensive Medicine and Malpractice Litigation*, 11 PLOS ONE (2016); P. C. Weiler, *The Case for No-Fault Medical Liability*, 52 MD. L. REV. 908 (1993); A. Towse & P. Danzon, *Medical Negligence and the NHS: An Economic Analysis*, 8 HEALTH ECON. 93. *See* OECD, *supra* note 20, at 13 *et seq.*, which also mentions the cases of Denmark and Finland.