SHADOW LINES AND SCAPEGOATS: MEDICAL CRIMINAL LIABILITY IN ITALY IN THE FRAMEWORK OF NATIONAL AND INTERNATIONAL MEDICAL GUIDELINES

Giulia Funghi and Alessandro Rosanò*

1. Introduction

In the book of Leviticus, one can find a set of rules, both religious and social, given by God to the Jews through Moses during their crossing of the Sinai desert. Among those, one is particularly well-known, and reached the modern audience by means of metaphor: the one of the scapegoat. In case of a fault that could have breached the link with God, the Jewish people had to make a penitative sacrifice. This sacrifice is mentioned several times in the Holy Bible, but perhaps the most illustrative depiction is the one below:

> And if a soul sin, and commit any of these things which are forbidden to be done by the commandments of the Lord; though he wist it not, yet is he guilty, and shall bear his iniquity. And he shall bring a ram without blemish out of the flock, with thy estimation, for a trespass offering, unto the priest: and the priest shall make an atonement for him concerning his ignorance wherein he erred and wist it not, and it shall be forgiven him. It is a trespass offering: he hath certainly trespassed against the Lord.[1]

Despite its innocence, a ram was to be killed in order to ensure forgiveness from the Lord so as to reinstate a positive relationship with Him and avoid that the trespasser, and through him the whole people were hit by God's malevolence. As time passed, the expression began taking up a metaphorical meaning, and at present a scapegoat is a person who is blamed for a negative occurrence that may not be ascribed to such individual, but for which he[2] has to pay nevertheless.[3]

The following article attempts to investigate how medical guidelines originally developed by health professionals serve as a reference point in the practice of medicine and how they have been used by the Italian courts in an effort to blame doctors for a natural event such as a person's death, so as to turn the medical profession into a sort of scapegoat.[4]

---

* Giulia Funghi is a student at the Law School of the University of Padua, Italy and is President of ELSA Italy. Alessandro Rosanò is a Ph.D. student at the Law School of the University of Padua, Italy and a trainee lawyer. The original version of this article was submitted to the ELSA Malta Law Review as the winning essay of the first national essay competition on health law organised by ELSA Italy.

1 Lv 5, 17-19.

2 All references to the masculine in this article are taken to refer also to the feminine.

3 Nicola Zingarelli, *Vocabolario della Lingua Italiana* (12th edn, Zanichelli 2010) 381.

4 Concerning the relation between medical guidelines and medical criminal liability, please see: Giorgio

2. Definitions

Guidelines: the definition of guidelines which is often mentioned by international scholars is the one ratified in 1992 by the Institute of Medicine (hereinafter 'IOM')[5] which defines them as 'systematically developed statements to assist practitioners and patients decisions about appropriate health care for specific clinic circumstances'.[6] Sometimes guidelines have been recognised for having an incentivising and promotional effect, in cases when they are used to provide suggested behaviours in the approach to clinical issues, while in other cases, namely when they detail a list of discouraged behaviours,[7] they tend to have a negative effect. More specifically, they are statements of suggested options available to treat a particular condition. At the same time, they are a means to allow rationalisation in the use of health resources and to direct the physician's choices by reference to the so-called evidence-based medicine.[8] Not only, they are a means to draw up suggested treatment protocols with experts from the scientific community - health experts as well as juridical scholars -, given that in any case it is necessary to re-evaluate their findings from time to time, as well as including also the essential contributions of administrators, users and patients.[9]

The techniques by which guidelines are drawn up vary. However, it is worth noting at least the one implemented by the Consensus Conference. This is a method that implies carrying out several workshops composed of different specialised doctors, other professionals and patients, in order to reach the best possible interpretation of scientific

---

Marinucci, 'La responsabilità colposa: teoria e prassi' (2012) Rivista italiana di diritto e procedura penale 3; Teresa Campana, 'La correlazione tra inosservanza delle 'linee guida' e responsabilità del medico' (2012) Cassazione penale 556; Giuseppe Marra, 'L'osservanza delle c.d. 'linee guida' non esclude di per sé la colpa del medico' (2012) Cassazione penale 557 *et sequitur*; Francesca Consorte, 'Colpa e linee guida' (2011) Diritto penale e processo 1227 *et sequitur*; Franco Introna, 'Responsabilità professionale medica e gestione del rischio' (2007) Rivista italiana di Medicina Legale 663 *et sequitur*; Angelo A Bignamini, 'Evidence based medicine e linee guida di pratica clinica: soluzione o parte del problema?' (2001) Medicina e morale 225 *et sequitur*; Gianfranco Iadecola, 'Il valore dell'«opinione» dell'ordine professionale e delle società scientifiche nel contenzioso penale' (2001) Rivista italiana di Medicina Legale 13 *et sequitur*.

5 An independent NGO, part of the United States National Academies, established in 1970 with the aim of allowing the circulation of medical knowledge and carrying out research on that field <http://www.iom.edu> accessed 28 June 2012.

6 IOM, Committee on Quality Health Care in America, *Crossing the Quality Chasm: A new Health System for the 21st Century* (National Academy Press 2001) 151.

7 Elena Terrosi Vagnoli, 'Le linee guida per la pratica clinica: valenze e problemi medico-legali' (1999) Rivista italiana di Medicina Legale 194, 224.

8 Mauro Barni, *Consulenza medico-legale e responsabilità medica* (Giuffrè Editore 2002) 33. Please see Michele Portigliatti Barbos, 'Le linee-guida nell'esercizio della pratica clinica' (1996) Diritto penale e processo 891, where the author states that medical guidelines have a mixed nature, being, at the same time, ethical, professional and juridical rules.

9 Mauro Bilancetti, Francesco Bilancetti, *La responsabilità penale e civile del medico* (Cedam 2010) 686.

evidence and assessment of the risk/benefit ratio, which is not just limited to sheer medical practice, but rather is a combination of different skills, demands and interests.[10]

The reason why guidelines are being used all the more often is due to the excessive and at times uncontrolled growth of health expenditure in the industrialised countries, as well as in the doctors' inefficient use of technological devices in their practice[11] and the need to regulate often inappropriate clinical behaviours.[12] As such, guidelines should aim to overcome in an objective fashion the unsystematic and unreliable outlook of a single physician's intuitions and assessment of clinical evidence, by forcing practitioners to increase previous abilities, first and foremost reading medical papers.[13]

One should bear in mind the difference between guidelines and two other similar yet different concepts, i.e. protocol and standard. Protocol: a protocol is a rigid sequence of pre-established behaviours, for instance in the course of clinical trials, which it is absolutely impossible to derogate from.[14] Standards: standards are the minimum or maximum value of a certain index, which may be used, for example, in establishing the quality of assistance.[15] Unfortunately, at times the Italian Parliament has enacted legislation on the issue without considering the difference between the three definitions above, as can be seen, for example, from this:

> *Management della spesa sanitaria. Le parti si impegnano ad istituire presso il Ministero della Sanità un gruppo di lavoro per la raccolta delle informazioni necessarie per la definizione di protocolli diagnostici e terapeutici utili per l'orientamento professionale del medico, allo scopo di programmare la medicina del territorio e di valutare l'efficacia degli interventi.*[16]

---

10 For further information on alternative methods available please see: Terrosi Vagnoli (n 7) 204, 205.

11 Vittorio Fineschi, Paola Frati, 'Linee-guida: a double edged-sword. Riflessioni medico-legali sulle esperienze statunitensi' (1998) Rivista italiana di Medicina Legale 665.

12 Giovanni Federspil, Cesare Scandellari, *Linee-guida e pratica clinica. Atti del seminario: Linee guida nella pratica medica: riflessi etico deontologici, responsabilità professionale e consenso informato* (Edizioni Regione Toscana 1999) 20, 21.

13 Eventually reaching a situation in which their actions, or lack of them, are justified (in light of the burden of the proof). Mauro Barni, 'Evidence-based medicine e medicina legale' (1998) Rivista italiana di Medicina Legale 3, 4.

14 Alberto Donzelli, Donatella Sghedoni, *Le linee guida cliniche tra conoscenze, etica e interessi*, (FrancoAngeli 1998). For an in-depth analysis, please see Matteo Caputo, ''Filo d'Arianna' o 'Flauto magico"? Linee guida e checklist nel sistema della responsabilità per colpa medica', *Diritto Penale Contemporaneo,* <http://www.penalecontemporaneo.it/upload/1342387755MC.lineeguida.checklist.DPC_con%20link.pdf> accessed 14 March 2013.

15 Terrosi Vagnoli (n 7) 194.

16 Please see D.P.R. 13.08.1981, s 23 (G.U. 8 September 1981, n. 246). Translation: 'Health expenditure management. The parties agree to establish a workgroup within the Ministry of Health in order to collect the necessary information for defining diagnostic and treatment protocols useful for the practitioners' professional training, so as to plan territorial medicine and evaluate the effectiveness of

In this context, the best term would have been 'guideline' rather than 'protocol'. With time, the two concepts (guideline and protocol) have come to mean the same fact, although the leading medical and scientific scholars disagree. Indeed, it is clear that the role of guidelines is not to bind the practitioners under all circumstances, as if the doctor's hand were replaced by the guidelines, as much as it should be to lead them in order to prevent and avoid risks, while at the same time acknowledging the paramount importance of giving them freedom in carrying out their job.[17] Obviously it is important to recall that all human activities are subject to a certain, albeit minimal risk of mistakes: that is why medical mistakes are considered to constitute acts of *negligence* only when the faulty behaviour is unacceptable, considering the existence of a minimum standard of care to be expected by physicians and the problem of lack of respect for the rules of the medical profession (insofar as they should be reasonably applied).

3. The Court's understanding of Guidelines and related issues

It is well-known that pursuant to Section 43, paragraph 1, third sentence,[18] of the Italian Criminal Code, the basis for a negligent criminal act is the fact that the offender has unintentionally perpetrated a criminal behaviour by breaching certain rules of conduct

---

the interventions carried out'.

Regarding the confusion operated by Italian legislation about the concepts of guideline, standard, and protocol, please see : D.P.R. 27.03.1992 (G.U. 31 March 1992, n. 76); *D. Min. Salute* (Translation: Decree of the Health Minister) n. 280 (G.U. 17 May 1996); *Delibera della Giunta della Regione Lombardia* (Translation: Resolution of the Regional Committee of Lombardia) 6 August 1998 n VI/38133 (B.U. 4 September 1998), as reported in Antonio Farneti, Monica Cucci, Sonia Scarpati, *Problemi di responsabilità sanitaria* (Giuffrè Editore 2007) 128.

[17] Lucian L Leape and Coll., 'The nature of adverse events in hospitalized patients' (1991) 324 New England Journal of Medicine 377, and Francesco Introna, 'Metodologia medico legale nella valutazione della responsabilità medica per colpa' (1996) Rivista italiana di Medicina Legale 1321.

For what concerns this particular point, one could also be reminded about the discipline of the Code of Medical Deontology ratified by the National Council of Medical and Dentistry Boards on 16 December 2006. S 4 therein, entitled 'Freedom and independence in the practice of medicine' acknowledges that medical practitioners have the inalienable right to practice independently and freely but also imposes the duty to act according to scientific principles. Even more clearly, s 13 entitled 'Medical prescription and treatment', despite recognising that a physician is free to plan, establish and carry out any necessary therapy and diagnostic investigation (§ 2), reiterates that this should be done according to updated and experimented scientific data (§ 3); that the decision should be construed against reliable scientific data and proven methodology (§ 4) and the prohibition to adopt scientifically unsound therapies and diagnostic exams (§ 5). (The Italian text can be found in Bilancetti, Bilancetti (n 9) 1037).

[18] *'Il delitto è colposo, o contro l'intenzione, quando l'evento, anche se preveduto, non è voluto dall'agente e si verifica a causa di negligenza o imprudenza o imperizia, ovvero per inosservanza di leggi, regolamenti, ordini o discipline'.*

to which compliance was expected in the situation.[19] Therefore, negligence has a two-fold function: identifying the objective behaviour and the subjective fault of the agent in a given situation in order to ascribe the event to the offender despite their unwillingness to cause it based on his offence, colliding against the safeguard of the juridical interest behind it.[20] The legal definition above includes a situation when the crime was not originated by negligence, reckless behaviour or inexperience, but rather by the lack of compliance with legal provisions, rules, orders and established practices. The first three cases are commonly referred to as general negligence, while the last one is called specific negligence. It is possible to identify a common trait in these two classes, namely the lack of compliance with prior rules of conduct which, had they been observed, would have avoided the offence.[21] Insofar as specific negligence is concerned, the rules are written, and the laws refer to four kinds of sources, including guidelines.[22]

What is the advantage of using guidelines in the context of criminal proceedings? By using guidelines, the standard of care in cases of negligence, that is the rule of conduct expressed by the anticipated behaviour, is clearly established, contrarily to what occurs when a model agent is taken as reference (such as with the ancient Roman standard of '*homo eiusdem professionis et condicionis*').[23]

The Italian Court of Cassation has recognised the value of guidelines from the criminal point of view as follows:

> *In tema di risarcimento del danno, il medico chirurgo, nell'adempimento delle obbligazioni contrattuali inerenti alla propria attività professionale, è tenuto ad una diligenza che non è solo quella del buon padre di famiglia ex art. 1176, comma 1, c.c., ma è quella specifica del debitore qualificato, come prescritto dall'art. 1176, comma 2, c.c., la quale comporta il rispetto di tutte le regole e gli accorgimenti che nel loro insieme costituiscono la conoscenza della professione medica*.[24]

---

[19] Ferrando Mantovani, *Diritto penale. Parte generale* (6th edn, Cedam 2009) 327.

[20] Mauro Ronco (ed), 'Il reato', *Commentario sistematico al Codice Penale* (Zanichelli Editore 2007). Considering this vast subject matter, please see Donato Castronuovo, *La colpa penale* (Giuffrè Editore 2009).

[21] Roland Riz, *Lineamenti di diritto penale. Parte generale* (5th edn, Cedam 2006) 264.

[22] It may be underlined that negligence is the lack of care, attention and diligence concerning a conduct that should have been realised, while it wasn't; reckless behaviour is the lack of diligence concerning an active conduct that shouldn't have been realised, or shouldn't have been realised the way it was, and inexperience is the lack of specific knowledge or aptitudes concerning a profession (Ronco (n 20) 540, 541).

[23] That is the ideal prototype of a judicious and careful person, who practise the same profession, or performs the same duties or carries out the same activity of the agent, in accordance with the criteria of predictability and preventability of the event.

[24] Court of Cassation (Civil Division), 11 March 2002, in *Giustizia Civile Massimario* (2002) 435. Translation: 'For what concerns tort liability, in performing their contractual obligations arising from a

The following is an actual case adjudicated by the Criminal Division of the Court of Cassation.[25]

Due to a backache with pain in the right leg, Mr P was hospitalised and Prof G treated the patient with surgery, which resulted in complications leaving Mr P's leg debilitated. Mr P underwent new surgery with a partial recovery of the leg's functions, yet it was now impaired with a motor deficit. Eventually, he was dismissed from the hospital. Both at First Instance and on Appeal Prof G was found guilty of negligent bodily harm pursuant to Section 590 of the Italian Criminal Code. Specifically, in the First Instance, the expert witness for the prosecution noticed that the situation after the first surgery featured a higher risk of complications, which would have suggested using a different technique than the one actually used by the operating surgeon.

The Court of Cassation found that the physician's choice to undergo the more risky procedure, in contrast with the canons of medical science, was enough to determine an instance of reckless behaviour. Such a determination was also effected due to the fact that the charged surgeon was a specialist, and his knowledge of medicine could not be evaluated as lightly as that of a general practitioner.

On this point, the courts now maintain an almost unanimous opinion, which the authors shall investigate further so as to understand exactly how the judges operate in dealing with proceedings on the matter. When there is an alternative between numerous therapies, all of which hold equal technical merit, it is up to the practitioner's discretion to choose between them. As such, their negligence shall be assessed based on whether the physician complied with the rules of conduct of their profession aimed at reducing the risks associated with the treatment of choice.[26] Thus, according to the courts, doctors are bound by universally recognised professional rules,[27] either written or not,

professional activity, medical practitioners are subject to a standard of care which is not only the one of the good family father, as required by s 1176 (1) of the Civil Code. Indeed, it is the care of a qualified debtor, as mentioned in s 1176 (2) of the Civil Code, which entails respect for all the rules and wisdom constituting the body of knowledge of the medical profession'.

[25] Court of Cassation (Criminal Division), 6 November 2008, in *DeJure* <http://dejure.giuffre.it/> accessed 28 June 2012.

[26] Court of Cassation (Criminal Division), 1 July 2008, in *Rivista italiana di Medicina Legale* (2009) 481. Please see also Court of Cassation (Civil Division), 8 September 1998, in *Giustizia Civile Massimario* (1998) 1867.

[27] Court of Cassation (Criminal Division), 2 July 2002, in *Ragiusan* (2003) 526. For what concerns cases in which medical practitioners were held responsible for not complying with guidelines without a reason, please see: Court of Cassation (Criminal Division), 12 July 2011, Court of Cassation (Criminal Division), 9 June 2011, Court of Cassation (Criminal Division), 2 March 2011, Court of Cassation (Criminal Division), 12 January 2011. For what concerns cases in which criminal liability was not considered because of the compliance with guidelines, please see Court of Cassation (Criminal Division), 12 June 2012, Court of Cassation (Criminal Division), 2 March 2011, Court of Cassation (Criminal Division), 5

also when they perform an activity that is recognised as risky, as these rules are aimed at preventing unlawful risks from occurring in the course of medical practice. In the lack thereof, it is possible to argue a case for negligent criminal behaviour[28]. It has to be stated, by the way, that no negligence is to be found when the event is foreseeable but occurred notwithstanding compliance with all the technical rules. Negligence may be found only when damage is foreseeable and could be avoided by complying with the relevant rules of conduct.[29] Furthermore, the duty of diligence, which is ascribed upon all medical practitioners, include the duty to previously inform the patient in writing and the obligation to make use of other physicians' skills, given that once a surgery is decided all the technical data needed to proceed is presumed, taking into account the standards of diligence, skilfulness and required knowledge.[30] In addition, in order to establish causation between the negligent behaviour and harmful event, it is not enough to prove that the behaviour caused the event, but it is necessary to ascertain the breach of a rule of caution which had been set specifically to avoid the occurrence of the harmful event in question.[31]

In practice, the courts tend to find negligence whenever there is established an objective breach of a *'lex artis'*.[32] At the basis of this tendency there seems to be the concern for the patient's possibility to claim damages for the harm as well as the actual amount of damages to which such individual should be entitled. It is clear therefore that guidelines are designed to aid the work of lawyers, especially of the judge, who are called to make a decision on the topic of medical liability. Indeed, these classes of judgements imply the necessary documentation of all medical choices made and, thus, an assumption of liability from the practitioners. They support the behaviour of health professionals, sometimes leading to the practice of extreme forms of defensive medicine.[33] Moreover, in so doing, the subjective aspect of the crime is clearly neglected, which may lead to an unacceptable form of objective criminal liability.

February 2010. For all these sentences, please see Caputo (n 14) 22.

[28] Court of Cassation (Criminal Division), 21 November 1996, in *Cassazione penale* (1998) 819.

[29] See (n 23).

[30] Court of Cassation (Criminal Division), 6 December 1990, in *Cassazione penale* (1992) 2754. Concerning the issue of informed consent please see: Ennio Grassini, Rodolfo Pacifico, *Il consenso informato: le basi, la pratica e la difesa del medico* (Seed 2012) 107 *et sequitur*.

[31] Court of Cassation (Criminal Division), 18 March 2004, not published yet, see Bilancetti, Bilancetti (n 9) 673.

[32] This refers to the law of the skill; the rules that regulate a professional duty. Further elaboration of this concept is found further on in the text.

[33] Barni (n 13) 40, 41. Concerning this issue, please see: Alessandro Roiati, *Medicina difensiva e colpa professionale medica in diritto penale* (Giuffrè Editore 2012) 2 *et sequitur*; Roberto Bartoli, 'I costi «economico-penalistici» della medicina difensiva' (2011) Rivista italiana di Medicina Legale 1107 *et sequitur*; Luciano Eusebi, 'Medicina difensiva e diritto penale «criminogeno»' (2011) Rivista italiana di Medicina Legale 1085 *et sequitur*; Alessandro Roiati, 'Medicina difensiva e responsabilità per colpa medica' (2011) Rivista italiana di Medicina Legale 1125 *et sequitur*.

Another issue lies with the expression usually employed by the courts when referring to medical guidelines. Although the Romans called them '*leges artis*', suggesting that they are rules pertaining to a specific field, in actual fact they lack the basic characteristic of fixed rules, given the mixed nature of guidelines; their wide margins of uncertainty and room for subjective appreciation. Indeed, the on-going development of science and technology is so fast that one needs to master an increasingly complicated body of knowledge, which makes it difficult to identify a clear path to follow that is accepted by all and may in turn make it difficult to use guidelines in court cases like they have been used so far. There is, indeed, a lack of statutory acknowledgement of the role of guidelines, both in terms of their binding nature and probatory value. Furthermore it would be advisable to include a specific form of liability for those who are responsible for drawing up the guidelines in case of harm caused to a patient by following their guidelines.[34]

In addition, one should mention that the guidelines should not be granted an absolute value in court, since there is another level of criticality to be considered. As a matter of fact, one ought to and must question oneself as far as the institutions drawing up the guidelines are composed and the scholarly authority of each member of the panel.

At the beginning of this paper it was stated that the drawing up of guidelines is a multi-disciplinary enterprise which is, or should be, undertaken by physicians as well as by lawyers, public health officers and patients. Each of these groups brings along a specific interest related to their field of expertise, which will inevitably reflect on how to interpret the guidelines. For example, while physicians will tend to ensure that the guidelines provide effective advice to the treating doctor; lawyers may focus on having certain clear-cut reference to use in court in the context of a liability case, whereas public health officers will be interested in the financial aspects of the treatment in terms of costs and effectiveness, patients may care more about the quality of the service provided.[35] Patients, then, should represent the need for a user-friendly medicine, so that rules may be understandable to them, even if they do not have specific knowledge in the medical field.

Although in a way this may appear to be one of the strengths of guidelines, especially if they are interpreted as the careful blend of different positions, it is also a weakness in the pathological cases related to the positions of each group. Especially with regard to medical practitioners, there could be a case of conflict of interest; it means that a medical evaluation or treatment aimed at safeguarding a primary interest, such as health, may be unlawfully affected by secondary interests.[36] In other terms, this may

[34] Terrosi Vagnoli (n 7) 190, 191, 221.

[35] Donzelli, Sghedoni (n 14) 84, 85.

[36] IOM, *Conflict of interest in medical research, education, and practice* (The National Academies Press 2009) 46. Concerning this issue, please see Robert Steinbrook, 'Guidance for Guidelines' (2007) The

result in a situation where there is a clear dichotomy between a physician's private interest and their professional obligations, which may affect their scientific good faith and the ability to deal with the issue at stake. For instance, one may consider the situation in which a guideline prescribes the use of drugs produced by the very pharmaceutical company sponsoring the activity of the technical panel responsible for drawing it up. This example shows that in addition to excluding all the subjects who have conflicting interests, or having them take a secondary role in case of less serious conflict, it would be necessary to introduce a financial disclosure mechanism in order to understand the advantages for the doctors, both actual or potential, linked to a certain drafting of the guidelines, as well as the implementation of a disincentive system to avoid the stay of conflicts.[37] The risk, which is far from remote without any control mechanism, is that guidelines may become the result of a compromise, thus lowering the standards of care in a situation where the preferred option of treatment is not the most medically viable one but rather the one upon which all groups can agree: a system which partially dissatisfies all lobbyists so that none is completely unhappy.

In the end, another point worth mentioning is that concerning the evaluation of the extent of liability. Judges – and in turn physicians – need to deal with real cases. Guidelines should not, and cannot, be interpreted as fixed, inderogable rules in order to find the medical practitioner guilty. Once the principle of reality is neglected in favour of the provisions of the guidelines, the reply from medical practitioners could be the opposite: that is, a high degree of defensive medicine, so that doctors fail to act out of fear to be held accountable, especially in those fields which are traditionally more risky.[38] On this point, one may recall what has been happening in the American courts: there, the judges have underlined the need to proceed first with an evaluation of the scientific grounds of guidelines with the use of expert witnesses, in order to allow the courts to understand the binding force and widespread use at national and international level. In some cases, the evaluation was so critical of the guidelines and detected so much inconsistency that the courts ruled that physicians should have opposed the suggested practice rather than abiding by it.[39]

New England Journal of Medicine 331 *et sequitur*. It must be considered that the very Italian Court of Cassation cast several doubts on the way medical guidelines are elaborated. Please see Court of Cassation (Criminal Division), 1 February 2012, wherein it was stated that sometimes medical guidelines are obsolete and ineffective and, often, they are cynical, indolent and the results of totally economical choices. For this sentence, please see Caputo (n 14) 23.

[37] IOM, *Clinical Practice Guidelines We Can Trust* (The National Academies Press 2011) 62.

[38] In this sense, physicians' worries are treated in Fabio Buzzi, 'Il medico tra Scilla (la 'perdita di chances') e Cariddi (gli 'interventi compassionevoli'), con l'incombente naufragio dell'accertamento medico-legale del nesso di causalità e della valorizzazione delle linee guida', (2011) Rivista italiana di Medicina Legale 563, 564. [Translation: 'The physician between Scylla ('loss of chances') and Charybdis ('piteous interventions'), with the impending wreck of the medico-legal verification concerning causation and the value of guidelines'].

[39] To confirm see Terrosi Vagnoli (n 7) 226-227. Contrarily, see Fineschi, Frati (n 11) 667: at the beginning of the nineties Maine and Minnesota introduced new legislation governing the issue which

4. The true role of expert witnesses

Although it is unquestionable that the statements from expert witnesses provide an effective means of proof in order to expand the judge's knowledge on the matter and cover its lack of technical expertise when taking their ruling, in the specific case of medical litigation, and particularly with regards to compliance with the guidelines, a clarification is needed. Medicine is a combination of three elements: science, insofar as it is a body of knowledge acquired through human speculation, aimed at understanding the relationship between cause and effect by means of quantitative language, objective observation, calculation, the systematic control of hypothesis and empirical experimentation;[40] technology, as it is progressively more dependent on the devices and instruments available in light of the technical progress; and art, as the personal touch and experience of each physician is needed and absolutely essential.[41]

Given that, blessing the guidelines with the value of a mere scientific preposition would mean adapting one's outlook to a rather deterministic and unmotivated view of medicine, or in any case a stereotype. If it is true that the subject of science/medicine is not the illness but the ill patient, one should not fail to recognise that this situation is extraordinary and the phenomena observed are unique, as they stem from a sequence of unrepeatable events.[42]

Hence, it follows that the guidelines should be treated as if they were an educated maxim; that is as a rule of behaviour underlying a judgment of probability rather than certainty. Strictly speaking, an educated maxim is encompassed by the idea of '*id quod plerumque accidit*'[43] so that the repeated observation of a phenomenon leads the observer to conclude that, in most cases, starting from a given situation the final outcome will be the same. Consequently, it is up to the judge to identify the correct maxim to use from time to time considering the best expertise available on the matter and the issues regarding the case at stake.[44] Once made aware of this, the expert witness and the judge should be able to give the right weight to the guidelines.

---

provides that for the cases of malpractice, practitioners may use the guidelines only to demonstrate the lack of criminal liability; however, the patients may not base their accusation on the breach of guidelines.

[40] Angelo Fiori, Daniela Marchetti, 'I garanti del sapere scientifico medico in sede giudiziaria' (2011) Rivista italiana di Medicina Legale 479 *et sequitur*.

[41] Introna (n 17) 1323.

[42] 'Empiricism tailored on every single case', according to Angelo Fiori, Daniela Marchetti, *Medicina legale della responsabilità medica* (Giuffrè Editore 2009) 305.

[43] Translation: the case that seems to be most likely to happen.

[44] Paolo Tonini, *Diritto processuale penale. Manuale breve* (Giuffrè Editore 2010) 159. Regarding the English experience, one should consider the so called 'Bolam' test: a doctor is not negligent if what he did would be endorsed by a responsible body of medical opinion in the relevant speciality at the material time. Please see *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

In light of the above, one last issue has to be considered, which may affect the reasoning of both parties. It is a phenomenon known in the psychological sciences as *hindsight bias*. That is a kind of fallacy whereby the reasoning is distorted based on the tendency to overvalue what one knows or should have known which leads to the consideration that the occurrence of an event that has actually happened was more likely to occur. In other terms, the fact that a certain event happened leads the person making the decision to believe that its occurrence was highly likely, or even inevitable.[45]

On the topic, one could mention the result of an experiment carried out at the beginning of the nineties[46] with the participation of 110 anaesthesiologists who were required to assess the following situation. During a surgery - in this case a Caesarean section - anaesthetics were required. Half the sample pool was told that in the course of the surgery there was a temporary complication – the woman in labour underwent cardiac arrest and had to be resuscitated – with a completely successful outcome for both the mother and her newborn child. The other half was told that following the same complication the mother had died and her child suffered cerebral damage. All the anaesthesiologists were asked to evaluate whether the anaesthetic drug given was adequate. The results were as follows: the drug was considered mostly adequate by the doctors who were told of the positive outcome while those who were told the negative outcome considered the same treatment generally inadequate. This was due to the fact that their evaluation had considered only the outcome on the case, instead of being based on the treatment itself, intended as a sequence of acts which could not have led to either one of the outcomes.

Human beings tend to give more relevance to what catches their attention most – such as an unsuccessful outcome – and consider it significantly more likely to occur after it has in fact happened, just because of its occurrence. One may ask how to overcome such a standstill. The most obvious solution, that is avoiding to let the expert know the outcome of a given treatment or surgery, is not viable as whenever an expert is called to give its testimony in a criminal proceedings it is obviously because a negative outcome has happened. One may consider, then, the importance of considering the judge the ultimate expert, acknowledging the possibility for the court to discard the findings of the experts by motivating the reasons for doing so.[47] As such, if the court realised the mistake made by its appointed experts, it might discard their findings and either appoint a new one or base its ruling upon the expert witness appointed by one of the

---

[45] Rino Rumiati, *Decidere* (il Mulino 2009) 44.

[46] Robert A Caplan, Karen L Posner, Frederick W Cheney, 'Effect of Outcome on Physician Judgments of Appropriateness of Care' (1991) 265 Journal of the American Medical Association 1957. Please see also Ketti Mazzocco, Paolo Cherubini, Rino Rumiati, 'Effetto framing: implicazioni in ambito medico' (2005) Annali Italiani di Medicina Interna 1 *et sequitur*.

[47] Court of Cassation (Criminal Division), 8 May 2003, in *Diritto e giustizia* (2003) 29, 78.

other parties. It is also possible to envisage that the courts should act pre-emptively upon appointing the expert pursuant to Section 226 of the Criminal Code. In so doing, they may clarify that the experts should concentrate on the medical procedure followed rather than focusing exclusively on its outcome[48] and consider it as the final moment of a sequence, a situation that may occur regardless of the procedure chosen. Yet again, in the case that the issue is not raised by the defence during cross examination (Section 501 of the Criminal Procedure Code) the sitting judge may raise it him/herself by asking questions and clarifications pursuant to Section 506, paragraph 2.[49] Furthermore, at the time of making their decision, judges should carry out an *ex ante* judgment, placing themselves in the same time and situation as the accused medical practitioner was when he made his choice, thus considering the whole range of data available which prompted for a specific decision rather than another.[50]

However, most expert witnesses involved in criminal proceedings seem to be aware of the issue as it was outlined above.[51] One should ask whether judges are equally conscious of the issue, of its risks and possible influence on the expert witness' final considerations, or the extent that judges are trained and have a minimal knowledge of the basis of logical deduction and reasoning fallacies. This is unlikely to be the case, as most Law graduates, as well as the judges in general, are not required to study these issues during their academic career.[52] Hence, the issue remains that, given the lack of a specific training on the subject, expert witnesses and judges may possess the technical skills but probably not the specific competency needed to avoid the typical reasoning mistakes done by human beings when considering the implications of a particular

---

48 Paraphrasing what was said by Christine Jolls, Cass R Sunstein, 'Debiasing through Law' (2006) 35 The Journal of Legal Studies 236, regarding the instructions given by the judge to the members of the jury in the American criminal justice system.

49 One could remind the view of Angelo Fiori, 'I problemi delle perizie e delle consulenze medico-legali nel regime dell'attuale codice di procedura penale' (1998) Rivista italiana di Medicina Legale 205, 209 contrary to the oral examination of expert witnesses as this would be highly risky due to the excess of emotions involved. In contrast with the written expert statement pursuant to s 227 of the Code of Criminal Procedure, expert witnesses may tend to give subjective, apodictic, imprecise, unreliable answers. However, this may help understand whether an expert witness was influenced by hindsight bias.

50 Gianfranco Iadecola, Marco Bona, *La responsabilità dei medici e delle strutture sanitarie. Profili penali e civili* (Giuffrè Editore 2009) 80.

51 Buzzi (n 38) 565 underlines that in the case of medical liability following anticipated discharge, practitioners are only held accountable if an unfavorable outcome presents itself, with a typical ex post reasoning.

52 In this sense, Carlo Bona, *Sentenze imperfette* (il Mulino 2010) 69. For further details about the different approach in use in the United States please see Daniel Kahneman, 'Judgment and Decision Making: a Personal View' (1991) 2 Psychological Science 142, 145, and the bibliography therein. It should be underlined, however, that Italian judges are increasingly more aware of the issues surrounding this subject as stated in Gabrio Forti, Francesco Centonze, 'Diritto e sapere scientifico in campo sanitario: un progetto di integrazione multidisciplinare' (2011) Rivista italiana di Medicina Legale 915 *et sequitur*, which investigates also the risks associated with *hindsight bias*.

decision on the final outcome.[53]

5. Conclusion

Based on what has been outlined above, the following are a few general considerations. However, before looking in depth at the issue of medical liability as it is outlined by professional guidelines, it seems appropriate to make a few assumptions regarding Criminal Law in general, which will hopefully demonstrate some of the difficulties associated with putting too much weight on criminal penalties.[54]

As a matter of fact, the body of Criminal Law has developed over time as a tool to control society, in order to subject an offender to a negative consequence for them, being concurrently an appeasing measure for society: first and foremost, the limitation and deprivation of personal freedom; then, a reduction of the offender's property, the loss of the freedom to work and, finally, a breach of one's reputation. This has been and still is justified for the safeguard of certain juridical goods, which are deemed as legally relevant interests, pre-existing the legislator. However, the current issue is whether or not there has been an excessive instrumentation of Criminal Law, i.e. the idea that the law has a symbolic value and serves to calm down the public's desire for punishment following certain shocking events for the community. Increasingly over time, Criminal Law has acquired an 'inclusive nature' where the concepts of legal and natural criminality are drifting away from each other while they ought to be the least possible differentiated, in order to successfully identify the actual instances of antisocial behaviour in need of repression.

Given its symbolic-expressive nature, Criminal Law is the branch of the law which is mostly affected by the course of history and politics; in so, it has an inherent danger of becoming a form of 'ritualised violence' which is seldom reflected on the repression of behaviours against the people's feelings and emotions rather than for the safeguard the juridical interests at the bottom of our legal system.[55] Indeed, given that most criminal law scholars agree that Criminal Law should be used as a last resort, the parliament and the courts ought to remember that criminal proceedings should be confined to the most serious offences and introduce other forms of penalties for the less serious cases. According to the cases, this could be implemented by resorting to civil liability or disciplinary and administrative penalties while criminal judgments should be celebrated only when no other form of protection would be effective.

[53] W Kip Viscusi, 'Jurors, Judges and the Mistreatment of Risk by the Courts' (2001) 30 The Journal of Legal Studies 109.

[54] For the following considerations please see: Adelmo Manna, *Corso di diritto penale. Parte Generale* (Cedam 2012) 19, 30 and Mantovani (n 19) XXVII.

[55] Mantovani (n 19) 186, 188.

Thus, coming to the bottom of the issue, despite the strong call for criminal repression of medical liability, it may be suggested that the sheer breach of a professional rule should not be enough to constitute criminal liability, but rather should be an unlawful act to be sanctioned according to the rules of professional liability. Such rules should be enforced by the physician's professional bodies responsible for the safeguard of the medical profession. If, as discussed at length above, the commission of a crime implies a breach of the rules regulating civil co-existence in a society (based on danger to the community and social hazard), and, given its nature, criminal law should be the last rather than the first means, then one should conclude that a therapeutic mistake may be simply due to the wrong choice of therapy. In addition, it should not be forgotten that such mistake occurs in the context of an activity aimed at the patient's interest, namely treating his/her condition. Furthermore, such activity is carried out in a fundamentally uncertain condition, since each patient's physiological response is unique.

Thus, there is a clear underlying issue holding physicians instrumentally liable, as if they were scapegoats for human fallacies, based on an exacerbated exaltation of the objective breach of diligence and making do with the need for the offender's subjective fault. Indeed, in Criminal Law, weight is attributed not only to the material behaviour considered in itself, but whether this behaviour was 'ordered to an end or not',[56] i.e. the behaviour should be evaluated not only in terms of natural causality but also in light of an axiological appreciation of the act committed.

It seems therefore appropriate to rethink the core of physician's medical liability as follows: only malicious or seriously culpable behaviours such as the ones of severe negligence, reckless behaviour, inexperience or breach of the basic professional rules of conduct insofar as the offender has failed to notice what all others would notice (*'non intelligere quod omnes intellegunt'*)[57] should be criminally prosecuted. This seems to be the purpose pursued by the legislator, if one considers the statement made in a recent law approved by the Italian Parliament.[58] Section 3 of this law states:

> *l'esercente le professioni sanitarie che nello svolgimento della propria attività si attiene a linee guida e buone pratiche accreditate dalla comunità scientifica non risponde penalmente per colpa lieve. In tali casi resta comunque fermo l'obbligo di cui all'art. 2043 del codice civile. Il giudice, anche nella determinazione del risarcimento del danno, tiene debitamente conto della condotta di cui al primo periodo.*[59]

---

[56] Ronco (n 20) 538.

[57] Translation: not to understand what everyone is able to understand.

[58] Please see law 08.11.12, n. 189 (G.U. 10 November 2012, n 263).

[59] Translation:

> A medical practitioner who, attending his own profession, complies with guidelines and best practices validated by scientific community, will not be held liable, under criminal

Concerning this article, there has already been a sentence in which the Court of Cassation has recognised that this new legislation has partially decriminalized all the considered cases of simple negligence, because of the lack of criminal disvalue, so only the discipline of tort law can be applied under these circumstances.[60]

Obviously, for such a system to be effective there would need to be a stronger statutory framework clarifying the true worth of guidelines for the purpose of criminal judgment, with a long series of difficulties to be expected, both in terms of the technique used in drawing up the statute and, before that, the need to mediate between the juxtaposed interests of the parties involved, for one reason or another, in the matter.

For all other cases, only disciplinary liability should be implemented, administered by the self-regulated professional bodies of medical practitioners.[61] The following example shall illustrate the latter point: it must be differentiated between punishing a doctor who has deliberately and orderly pursued the patient's worst interests, or when the unfortunate outcome of a procedure is the result of their serious fault, from the very different instance of a doctor who has failed to inform a patient of certain technical dangers involved in the procedure, such as for example, a detailed list of its steps or the kind of machinery used in it. While in the first two cases turning to Criminal Law is indispensable, the last case would be addressed far more efficiently by internal health committees with the power to impose varying sanctions such as fines, admonitions and formal reprimand, suspension from work or dismissal, including the loss of one's medical licence.[62]

> law in the case of simple negligence. Nonetheless, in such a case, it shall not prejudice the provisions of s 2043 of the Civil Code [i.e. the article concerning tort law]. The judge, also in determining the amount of the compensation for damages, duly considers the behaviour foreseen in the first sentence.

Concerning this particular and new point and the issues regarding it, please see Paolo Piras, 'In culpa sine culpa. Commento all'art. 3 I co. l. 8 novembre 2012 n. 189', *Diritto Penale Contemporaneo*, <http://www.penalecontemporaneo.it/upload/1353763675PIRASculpa.pdf> accessed 14 March 2013.

60 Court of Cassation (Criminal Division), 29 January 2013 (not published yet).

61 The Code of Medical Deontology, in s 2 entitled 'Disciplinary power and sanctions', clarifies that Disciplinary Committees have the power to sanction with the penalties imposed by the law and based on the seriousness of the offence the breach of the obligations, prohibitions and duties imposed by the Code as well as any other action or omission that may be detrimental to the decorum of the medical profession or its fair practice.

62 Please see D.P.R. 5.4.1950, n. 221 (G.U. 16 May 1950, n 112) for the Italian statutory framework.