Insights & Analyses

Medical Negligence During the Pandemic: The Italian Choice for Criminal 'Shields' and the Need for Further Reform

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Abstract

Despite the many reforms carried out by the Italian lawmaker over the years, the subject of healthcare professionals' criminal liability has remained strongly controversial among scholars and has raised some criticism regarding the current state of the domestic framework. Ever since the outbreak of the pandemic, then, concerns have been growing due to the inadequacy of the system to properly face the crisis.

After an introduction aimed at providing an overview of the domestic legislation and case law, the paper specifically focuses on the issues posed by the sanitary emergency. By analysing the Italian choice to introduce specific shield-provisions (*norme scudo*), it will be argued whether a better regulation of the subject-matter, together with a careful evaluation of the subjective features of negligence, would represent a preferable approach to deal with the long-standing issue of criminal responsibility arising from medical malpractice.

I. Introduction

In the last few years, the dramatic outbreak of Covid-19 pandemic has severely tested the responsiveness of both the national health system and the legal framework. Besides the difficulties deriving from the spread of a dangerous disease and the need for a concrete strategy to deal with its health-related damages, one of the most challenging problems that has been faced on a legal level was related to the issue of responsibility of healthcare professionals involved in the management of the crisis.

Worries have been expressed, in particular, regarding the legal consequences that were likely to affect the professionals who fought the pandemic since its very beginning, often without adequate means or specific knowledge, and necessarily relying on off-label medications. Not only those individuals had to deal with an unprecedented sanitary crisis, but also with the risk of facing legal proceedings aimed at assessing their civil and criminal responsibility for the deaths and damage occurred.

In this scenario, the calls for a better protection of healthcare professionals

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have arisen from many parts. In Italy, such claims have been granted, leading to the approval of provisions that were intended to narrow criminal responsibility in relation both to vaccine inoculation and to medical activity in a broader sense.

The decision to resort to shield laws to protect healthcare professionals from criminal charges started a lively debate, inspiring a deeper analysis on the adequacy of the Italian legal framework. In a field that has always been controversial,[1] indeed, the new challenges posed by the pandemic have contributed to enrich a years-long debate on the subject, underpinning the discussion around a new reform in this area.

This article aims to recall the main issues of such a significant debate: through an analysis of the evolution of the relevant legal framework, as shaped in the past and during the pandemic, it will point out the major flaws of the existing regulation in order to draw some conclusions and suggest possible improvements.

II. The Evolution of Healthcare Professionals' Liability Model

The subject of criminal liability of healthcare professionals has always been a matter of deep consideration in Italy, where both law and case law have known relevant changes through the years.

Before 2012 and 2017, when specific provisions were adopted to introduce a special regime for medical responsibility, cases of deaths or injuries caused by medical malpractice were adjudicated under Arts 589 (manslaughter) and 590 (negligent injuries) and 43 (negligence) of the Italian Criminal Code. Besides specific negligence, which implies the breach of written precautionary rules, Art 43 Criminal Code defines three forms of so-called generic negligence: unskillfulness (*imperizia*), negligence (*negligenza*) and imprudence (*imprudenza*). Generally speaking, negligence can be defined as lack of care resulting in the omission of the required measures; imprudence is involved when some action is carried out without taking all the precautions needed; unskillfulness is a form of qualified negligence that implies non-compliance with technical rules (so-called *leges artis*).

When dealing with healthcare activity, generic negligence is usually at stake: the perspective of immutable written rules appears inconsistent in a field where every clinical situation presents its own peculiarities and demands individual solutions that the professional has the duty to provide with due diligence, according to the parameters of Art 43 Criminal Code.

For a significant time period, however, when applying the law, judges

[1] See, among the others, P. Piccialli, *La responsabilità penale in ambito medico sanitario* (Milano: Giuffrè Francis Lefebvre, 2021); D. Chindemi, *Responsabilità del medico e della struttura sanitaria pubblica e privata* (Milano: AltalexCedam, 5th ed, 2021); M. Caputo, *Colpa penale del medico e sicurezza delle cure* (Torino: Giappichelli, 2017); S. Aleo et al, *La responsabilità penale del medico* (Milano: Giuffrè, 2007).

tended to exclude criminal liability, rarely convicting the individuals involved in cases of malpractice.[2] The grounds for this mild approach towards defendants were usually found under Art 2336 of the Italian Civil Code:[3] the provision, which applies to work performance contracts, limits the responsibility of the professional to gross negligence, if the service required is characterised by a significant level of technical complexity.

The Constitutional Court, when requested to assess the legitimacy of such an approach under the principle of equality set forth in Art 3 Constitution,[4] highlighted the importance, on the one hand,

> 'not to mortify the initiative of the professional with the fear of unfair retaliation in the event of failure and, on the other, not to indulge on the behalf of the inconsiderate decision or reprehensible omissions of the professional'.[5]

Therefore, the Court found that Art 2236 Civil Code could be used to limit healthcare professionals' liability without representing an unequal treatment in their favour.

As interpreted by the Constitutional Court, however, Art 2236 Civil Code could only by applied in cases of high complexity, where some technical mistake had been committed. Such a limitation, though, raised significant doubts on the borders between unskillfulness, imprudence and negligence, due to the uncertainty of the distinction.[6]

Later, the same idea of a direct application of Art 2236 Civil Code in criminal proceedings was strongly objected by scholarship and jurisprudence; firstly rejected 'for the purposes of criminal law, on the assumption that civil law and criminal law are different domains',[7] the regime of Art 2236 Civil Code was lately intended as a mere rule of experience, that the judge could deploy in the assessment of individual fault.[8]

[2] This period lasted until the 1980s: see L.M. Franciosi, 'Italy - The New Italian Regime for Healthcare Liability and the Role of Clinical Practice Guidelines: A Dialogue Among Legal Formants' 11 *Journal of Civil Law Studies*, 371, 381 (2018).

[3] Art 2236 Civil Code (Liability of the performer of a work): 'If the performance implies the solution of technical issues of particular difficulty, the performer is not liable for damages unless in the event of her malice or gross negligence'.

[4] Art 3 Constitution: 'All citizens have equal social dignity and are equal before the law, without distinction of sex, race, language, religion, political opinion, personal and social conditions. It is the duty of the Republic to remove those obstacles of an economic or social nature which constrain the freedom and equality of citizens, thereby impeding the full development of the human person and the effective participation of all workers in the political, economic and social organisation of the country'.

[5] L.M. Franciosi, n 2 above,381-382.

[6] F. Basile and P.F. Poli, 'La responsabilità per 'colpa medica' a cinque anni dalla legge Gelli-Bianco' *Sistema penale*,17 May 2022, 1, 16.

[7] L.M. Franciosi, n 2 above, 382.

[8] Corte di Cassazione 5 April 2011 no 16328, *Rivista italiana medicina legale*, 859 (2011);

The overcoming of the old judicial deference towards healthcare professionals led to a strong reaction of healthcare professionals, who started hiding behind the so-called defensive medicine,[9] a phenomenon that can relate both to the refuse to treat the most critical patients – negative defensive medicine – and to the habit of prescribing several analyses, mostly useless, in order to avoid future disputes and complaints – positive defensive medicine. This occurrence caused a huge increase in the health costs coupled with a general decline in the quality of health care and in the transparency of the therapeutic alliance between doctors and patients.

It was in order to fight this ineffective and expensive trend that some specific provisions were introduced, in 2012 and, shortly after, in 2017.

III. Legislative Intervention

1. Decreto Balduzzi

The first attempt to reduce the area of criminal liability of healthcare professionals was made in 2012, with the so-called 'decreto Balduzzi'; Art 3 of decreto legislativo 13 September 2012 no 158 stated that

> 'the healthcare professional who, in carrying out his/her professional activities, adheres to the guidelines and best practices accredited by the scientific community, cannot be held criminally liable for minor negligence, whilst the obligation for compensation, as defined in Art 2043 Civil Code, persists'.[10]

The rationale behind the reform was found in the will to exempt from criminal consequences those cases of negligence where the doctor – or another healthcare professional – was accused of a slight deviation from the precautionary rule, regardless the fact that is was qualified in terms of imprudence, negligence or unskillfulness. As the previous experience had proven, the distinction

see also Corte di Cassazione 1 February 2012 no 4391, *Diritto penale e processo*, 1104 (2012).

[9] D.M. Toraldo et al, 'Medical malpractice, defensive medicine and role of the "media" ' in Italy' 10 *MultidisciplinaryRespiratoryMedicine*, 1-7 (2015). See also G. Forti et al eds, *Il problema della medicina difensiva. Una proposta di riforma in materia di responsabilità penale nell'ambito dell'attività sanitaria e gestione del contenzioso legato al rischio clinico* (Pisa: Edizioni ETS, 2010); A. Roiati, *Medicina difensiva e colpa professionale medica in diritto penale. Tra teoria e prassi giurisprudenziale* (Milano: Giuffrè, 2012); A. Manna, *Medicina difensiva e diritto penale. Tra legalità e tutela della salute* (Pisa: Pisa University Press, 2014); R. Bartoli, 'I costi «economico-penalistici» della medicina difensiva' *Rivista italiana di medicina legale*, 1107 (2011).

[10] A. Feola et al, 'Medical Liability: The Current State of Italian Legislation'22 *European Journal of health law*, 357 (2015); A. Vallini, 'L'art. 3 del 'Decreto Balduzzi' tra retaggi dottrinali, esigenze concrete, approssimazioni testuali, dubbi di costituzionalità' *Rivista italiana di medicina legale*, 735 (2013).

between such notions was often problematic; with decreto Balduzzi, instead, the qualification of the mistake in terms of imprudence, negligence or unskillfulness became irrelevant, as the law introduced a form of exemption for every error that was expression of slight negligence.

The main issue, in this case, arose from the interpretation of that provision: it was deemed somehow contradictory to refer such a limitation to conducts described as perfectly consistent with the guidelines and best practices, resulting in a sort of '*culpa sine culpa*'.[11] As the behaviour of the professionals were described by law as matching the ideal rule to be followed, the true meaning of the provision was questioned by the jurisprudence that sought to understand the scope of application of the waiver of responsibility.

Nonetheless, as the case law later suggested,[12] the provision had to be interpreted as an exemption clause intended to avoid criminal consequences for those professionals who adapted their conduct to guidelines and best practice, but failed in applying them, or followed them in situations where the peculiarities of the case should have suggested to disregard them.

Besides those guidelines and practices, indeed, a whole set of ordinary precautionary rules was still existing: violating those rules may constitute negligence, despite adhering to the clinical recommendations. Nevertheless, the law intended to partially exclude criminal liability, as long as the deviation from the diligence expected was slight: in other terms, the professionals were shielded in cases of wrong or inappropriate application of the guidelines, as far as the mistake wasn't expression of gross negligence.[13]

As regards the distinction between gross and slight negligence, though, the law did not provide any clue: the definition of the degree of negligence that could entail the punishability of the agent was in fact left to the judicial interpretation,[14]that enhanced factors such as the discrepancy of the conduct from the required behaviour, the degree of predictability of the harmful event and the specific context where the action or omission took place.[15]

[11] P. Piras, '*In culpa sine culpa*. Commento all'art. 3 I co. l. 8 novembre 2012 n. 189 (linee guida, buone pratiche e colpa nell'attività medica' *Diritto penale contemporaneo,* 26 November 2012, 1-5; Id, '*Imperitia sine culpa non datur*. A proposito del nuovo art. 590 *sexies*' *Diritto penale contemporaneo*, 269 (2017); L. Risicato, 'La metamorfosi della colpa medica nell'era della pandemia' *Discrimen,* 25 May 2020, 1-9.

[12] Corte di Cassazione 9 April 2013 no 16237, *Cassazione penale,* 2984 (2013), with note of C. Cupelli, 'I limiti di una codificazione terapeutica. Linee guida, buone pratiche e colpa grave al vaglio della Cassazione'.

[13] G.M. Caletti, 'Tra 'Gelli-Biancoe'Balduzzi': un itinerario tra le riforme in tema di responsabilità penale colposa del sanitario' *Responsabilità medica Diritto e pratica clinica,* 97, 109 (2017).

[14] P.F. Poli, *La colpa grave. I gradi della colpa tra esigenze di* extrema ratio *ed effettività della tutela penale* (Milano: Giuffrè, 2021), 388.

[15] F. Basile and P.F. Poli, n 6 above, 23. See Corte di Cassazione 9 April 2013 no 16237, n 12 above; Corte di Cassazione 11 May 2016 no 23283, *Diritto penale contemporaneo*,27 June 2016, with note of C. Cupelli, 'La colpa lieve del medico tra imperizia, imprudenza e negligenza:

Further issues, then, involved the quality of guidelines and best practices. The sources that were likely to be taken as parameters for the professionals' behaviour were not defined by the law, hence not only Medical Associations but also private firms could elaborate their own guidelines, thus resulting in a problem of legitimacy. Especially when drafted by stakeholders carrying economic interests, such as pharmaceuticals companies, the lawfulness of the guidance provided was highly controversial: profit-driven interests and considerations of resource-saving could ultimately affect the quality of the drafting.[16]

In order to solve the problems pointed out during the short period of time where decreto Balduzzi was in force, a new reform was developed and approved, less than five years later: so-called legge Gelli-Bianco.

2. Legge Gelli-Bianco

With legge 8 March 2017 no 24, a further step was made towards a better definition of the concept of accountability for medical malpractice: according to Art 590-*sexies* of the Italian Criminal Code, as introduced by legge Gelli-Bianco,

> 'if death or injuries have been caused by lack of skill, conviction is to be ruled out, provided that the guidelines published by the National Health Service had been complied with, or, in the absence of these, best healthcare practices, under the condition that such recommendations were well-suited to the specific case'.[17]

Compared to the past, the 2017 reform has been praised for some relevant improvements, such as the attempt to entrust the approval of Guidelines to a formal and public procedure: according to the system of accreditation designed by the law, the guidelines 'need to be crafted by public and private bodies and institutions, as well as scientific and technical orders and associations listed in a specific registry'.[18] Therefore, healthcare professionals need to conform their conduct to directives crafted on the basis of evaluations aimed to ensure the best care possible, and not guided by profit motives or potential cost-savings.

Meanwhile, the role of best practices becomes ancillary: unlike decreto Balduzzi, which equalised them with guidelines, legge Gelli-Bianco allows the

il passo avanti della Cassazione (e i rischi della riforma alle porte)'; Corte di Cassazione 8 May 2015 no 22405, available at www.dejure.it.

[16] G.M. Caletti, 'Tra 'Gelli-Biancoe'Balduzzi': un itinerario'n 13 above, 103.

[17] C. Cupelli, 'Lo statuto penale della colpa medica e le incerte novità della legge Gelli-Bianco' *Diritto penale contemporaneo,* 200 (2017); A. Massaro, 'L'art. 590-sexies c.p., la colpa per imperizia del medico e la camicia di Nesso dell'art. 2236 c.c.' *Archivio penale,* 1-52 (2017); G.M. Caletti and M.L. Mattheudakis, 'Una prima lettura della legge "Gelli-Bianco" nella prospettiva del diritto penale' *Diritto penale contemporaneo*, 84 (2017).

[18] G.M. Caletti, 'Tra 'Gelli-Biancoe 'Balduzzi': un itinerario'n 13 above,121, where the Author underlines that the model of accreditation, monitoring and updating of the guidelines seems inspired by the National Institute for Health and Care Excellence (NICE) in England.

use of best practices only in case where no guideline is available, as it happened right after the approval of the law, during the extended period of accreditation of official recommendations. As a result of the complexity of the accreditation process, the implementation of the system took in fact a long time: suffice to say that, before February 2020, only three official guidelines had been approved.[19]

Nonetheless, Art 590-*sexies* Criminal Code has also raised some concerns: the absence of any reference to the degree of the negligence, in contrast to the previous provision from decreto Balduzzi, has been strongly criticised and shortly led to the intervention of the United Sections of the Court of Cassation.

Right after the approval of the bill, indeed, a conflict emerged within the Italian Supreme Court: the first decision that applied the new provision[20] stated its logical contradictoriness,[21] due to the inconsistency between the two conditions required – the lack of skill and the accordance to appropriate guidelines. It was deemed impossible, indeed, to imagine a situation where the conduct, perfectly fitting the one described by guidelines and adequate to the clinical situation, was nevertheless characterised by lack of professional skill.

Considering the supreme value of health set forth in Art 32 Constitution, moreover, the Court suspected the unconstitutionality of a waiver of criminal responsibility for medical mistakes that, relying on the literal drafting of the provision, could also be macroscopic. According to the judges, ultimately, Art 590-*sexies* Criminal Code could only entail that the conducts of healthcare professionals had to be judged pursuant to the standards set by official guidelines.

Shortly after, instead, a second judgment[22] referred the new provision to those cases of 'un-skilled execution of proper and adequate clinical guidelines',[23] intending the new exemption as meant to operate where the error consisted in *imperitia in executivis,* with exclusion of any waiver for gross or slight negligence in the choice of the guideline (*imperitia in eligendo*).

According to this decision, moreover, the real purpose of the law was 'to avoid any differences in the degree of fault in the event of harm due to unskillfulness of the healthcare provider':[24] the lack of skill that could trigger the non-punishability clause of Art 590-*sexies* Criminal Code was therefore to be intended as including both slight and gross negligence.

The conflict was solved, after few months, by a decision held by the United Sections of the Court of Cassation:[25] although finding it possible to apply Art

[19] Nowadays, seventy guidelines are published in the national system for the guidelines (so-called S.N.L.G.), some of which have already been updated since their approval.

[20] Corte di Cassazione 7 June 2017 no 28187, *Diritto penale contemporaneo*, 280 (2017).

[21] See L.M. Franciosi, n 2 above, 397.

[22] Corte di Cassazione 31 October 2017 no 50078, *Diritto penale contemporaneo*, 7 November 2017.

[23] L.M. Franciosi, n 2 above,399.

[24] ibid 400.

[25] Corte di Cassazione-Sezioni unite 22 February 2018 no 8770, *Diritto penale contemporaneo,* 1 March 2018. See G.M. Caletti, 'Il percorso di depenalizzazione dell'errore

590-*sexies* Criminal Code in the event of a mistake occurred during the execution of an appropriate guideline, as stated in the latter decision, the judge rejected the idea of an exemption unbound from the degree of the violation, sharing the issues of constitutional legitimacy that justified the *interpretatio abrogans* followed by the Court in its first decision.

Therefore, the Court stated that

> 'the release of the healthcare professional from liability occurs when the harmful event is caused by the slight unskillfulness of the professional during the execution of the adequate accredited guidelines'.[26]

In this way, it reintroduced the requirement – previously foreseen under decreto Balduzzi – of the slight deviation from the standard of conduct. Although justified by the necessity to grant a satisfactory level of safeguard for health and to avoid inequalities, the solution went against the literal wording of the law, setting a clear example of judicial 'creationism', carried out in breach of the principles of separation of powers and legality.[27]

IV. New Challenges Arising from the Pandemic

With the epidemic outbreak, the achievement of a reasonable balance between health protection and the creation of a sheltered environment for healthcare activities was made even more complicated;[28] when dealing with a new disease in the exceptional context of a world-wide crisis, facing unexpected risks and an unconceivable pressure on the National Health Service, errors were made, and the problem of their legal consequences arose dramatically.

medico. Tra riforme 'incompiute', aperture giurisprudenziali e nuovi orizzonti per la colpa grave' *Diritto penale contemporaneo,* 1 (2019).

[26] L.M. Franciosi, n 2 above,403.

[27] R. Blaiotta, 'Niente resurrezioni, per favore. A proposito di S.U. Mariotti in tema di responsabilità medica' *Diritto penale contemporaneo,* 28 May 2018, 1-10; C. Cupelli, 'L'art. 590-*sexies* c.p. nelle motivazioni delle Sezioni Unite: un'interpretazione 'costituzionalmente conforme' dell'imperizia medica (ancora) punibile' *Diritto Penale Contemporaneo*, 246 (2018). In fact, even if the clarification was meant to overcome the doubts of constitutionality of the new regulation, it determined a significant reduction of the area of exemption granted by the law.

[28] F. Palazzo, 'Pandemia e responsabilità colposa' *Sistema penale,* 26 April 2020; R. Bartoli, 'Il diritto penale dell'emergenza 'a contrasto del coronavirus': problematiche e prospettive' *Sistema penale,* 24 April 2020, 1-15; Id 'La responsabilità colposa medica e organizzativa al tempo del coronavirus. Fra la "trincea" del personale sanitario e il "da remoto" dei vertici politico-amministrativi' *Sistema Penale*, 85 (2020); A. Gargani, 'La gestione dell'emergenza Covid-19: il 'rischio penale' in ambito sanitario' *Diritto penale e processo,* 887 (2020); M. Caputo, 'La responsabilità penale degli operatori sanitari ai tempi del Covid-19. La gestione normativa dell'errore commesso in situazioni caratterizzate dall'emergenza e dalla scarsità di risorse', in G. Forti ed, *Le regole e la vita. Del buon uso di una crisi, tra letteratura e diritto* (Milano: Vita e Pensiero, 2020), 109-113; P. Veneziani, 'La colpa penale nel contesto dell'emergenza Covid-19' *Sistema penale,* 28 April 2022, 1-17.

The need for a special protection against the criminal risk, in particular, stemmed from the impossibility to apply Art 590-*sexies* Criminal Code to the harmful events occurred during the pandemic; as a consequence of the unprecedented situation and the unknown disease, no guideline or good practice could be found and used to reduce the area of fault to gross negligence, especially in the early stages of the epidemic. Moreover, given the rapidly evolving scientific landscape, a system relying on accredited guidelines seemed unsuited to face the emergency: the situation required, instead, great adaptation to new circumstances and a significant speed in updating.[29] Furthermore, many of the doctors, nurses and professionals employed to tackle the pandemic were either retired or un-qualified to carry out the required tasks. It was thus important to grant an exemption from the ordinary functioning of so-called fault 'for taking up the task', which occurs when someone accepts and carries out assignments that transcend his/her skills and knowledge: once again, as this kind of fault falls out of the area of unskillfulness, Art 590-*sexies* Criminal Code proved incapable of protecting them.

Apart from giving rise to reservations about the real usefulness of the provision introduced in 2017, the pandemic highlighted the inadequacy of the legal system and required special provisions to be urgently adopted.

V. The Italian Response to the Crisis: The Drafting of Shield-Provisions

1. The Shield from Vaccine-Inoculation Liability

The first attempt to narrow doctors and other healthcare professionals' accountability during the pandemic was realised in the peculiar field of the vaccine-inoculation activity: in order to safeguard professionals from the danger of trials and complaints in relation to the use of vaccines that could provoke harmful events, the Parliament adopted legge 28 May 2021 no 76, converting prior decreto legge 1 April 2021 no 44.[30] The decree provided a specific rule of non-accountability for deaths or injuries related to the inoculation of vaccine, which occurred despite the full compliance with the protocols and instructions issued for the administration of the treatment.

[29] F. Furia, 'Lo 'scudo penale' alla prova della responsabilità da inoculazione del vaccino anti SARS-CoV-2' *Archivio penale,* 1, 8 (2021).

[30] See P. Piras, 'La non punibilità per gli eventi dannosi da vaccino anti Covid-19' *Sistema penale*, 23 April 2021; E. Penco, '"Norma-scudo" o "norma-placebo"? Brevi osservazioni in tema di (ir)responsabilità penale da somministrazione del vaccino anti Sars-Cov 2' *Sistema penale*, 13 April 2021; G. Amato, 'Scudo penale per i vaccinatori che somministrano le dosi. La responsabilità penale' *Guida al diritto* 47 (2021); L. Fimiani, 'Nuovo 'scudo penale' (decreto-legge 1° aprile 2021, n. 44): è una norma tautologic*a?'Giurisprudenza penale,* 1-6 (2021); D. Micheletti, 'Lo scudo penale a favore dei vaccinatori nel quadro delle norme dichiarative di atipicità' *Discrimen,* 7 March 2022, 1-9.

With Art 3 of decreto-legge no 44/2021, the lawmaker pursued the goal of a 'responsibility lockdown',[31] meaning the creation of an area of total impunity for those employed in the vaccination campaign. On the nature of the provision, the legal doctrine seemed divided: some referred to it as a 'memento-provision'[32] or a 'placebo-provision',[33] meant to stress the concept of negligence as already known, while others preferred qualifying it as a non-punishability clause, deriving from political consideration,[34] or an excuse,[35] referring to conducts lacking culpability. At a closer look, though, a strong argument in favour of the first stance is that the Report accompanying the decree clearly specifies that Art 3 must be considered 'expression of the general principle of subjective imputation'.[36] As the limitation of criminal accountability is intended to operate when the vaccine is inoculated in accordance with the instructions from the competent authorities and the Government, such a requirement should exclude criminal liability on the common grounds of negligence: it follows that Art 3 doesn't seem to add anything to the normal functioning of fault.

Nonetheless, this opinion carries the idea that the instructions given by sanitary and governmental authorities must be regarded as authentic precautionary rules, apt to constitute and exhaust the objective element of the negligent violation. Under Art 590-*sexies* Criminal Code, on the contrary, the potential ability of other rules of conduct, different and additional to the technical rules, to justify some reprimand, has always been acknowledged.[37] In addition, unlike Art 590-*sexies* Criminal Code, the provision of Art 3 of the decree doesn't require the professional to determine whether the given instructions fit the singular case.

In this way, Art 3 appears broader than Art 590-*sexies* and different from the ordinary assessment of fault: it can be argued that, according to the provision, the respect of the instructions is enough to exclude any other form of guilt, at least for what concerns the procedure of triage and inoculation.[38] Other

[31] G. Losappio, 'Responsabilità penale del medico, epidemia da 'Covid19' e 'scelte tragiche' (nel prisma degli emendamenti alla legge di conversione del d.l. c.d. 'Cura Italia" *Giurisprudenza Penale*, 1, 7 (2020).

[32] Relazione n. 35/2021 dell'Ufficio del Massimario della Corte di Cassazione, in *Sistema penale,* 24 June 2021, 10.

[33] E. Penco, n 30 above.

[34] F. Furia, n 29 above,9, but also A. Amato, n 30 above, 47.

[35] J. Della Valentina, 'La responsabilità penale medica negli scenari post covid-19: appunti sulla natura dogmatica delle aree di esclusione della punibilità' *Sistema penale,* 3 December 2021, 1, 22-23.

[36] Relazione illustrativa al decreto *Sistema penale,* 2 April 2021, 1, 5.

[37] S. Dovere, 'Linee guida, regole cautelari e responsabilità colposa del sanitario', in P. Piccialli ed, n 1 above, 167-198, and Corte di Cassazione 5 April 2018 no 15718, available at www.dejure.it, where it is excluded the binding nature of guidelines. See also G.M. Caletti, 'Tra 'Gelli-Bianco' e 'Balduzzi': un itinerario'n 13 above, 106-107.

[38] The vaccination process, however, needs to be respectful of the instructions given by EU and national authorities, in regard to personal exemptions (eg hypersensitivity to the active

authors, by contrast, deem it possible to preserve the area of negligent accountability for all those behaviours held by the vaccinator in breach of common precautions, such as the wrong use of face-mask or the failure to sterilise the seat.[39]

In any case, although it achieved the highly symbolic task to soothe and reassure those involved in the vaccination activities – thus preventing a defensive attitude that would have risked hindering the campaign itself – the choice to introduce such a limitation was strongly objected by those who found it useless, if not counterproductive.

The choice to introduce a specific cause of non-punishability for vaccinators, indeed, could increase – and had actually increased – the population's feeling of insecurity, giving the impression of an unknown and unsafe medication. On a general level, moreover, the approval of a vaccination shield proved some lack of trust in the work of the judicial authorities,[40] who had often showed a strict attitude towards medical malpractice.

This last critical issue, though, appeared even more clear right after the approval of the second shield, introduced during the parliamentary debate on the decree.

2. The General Limitation of Healthcare Professionals' Liability

Besides the vaccination-shield, Art 3-*bis* of decreto-legge no 44/2021 provided a peculiar form of impunity for deaths and injuries caused by the healthcare professionals during the pandemic: according to that provision, indeed, the offences set forth in Arts 589 and 590 of the Italian Criminal Code could be punished only if committed with gross negligence.

The effect of the new provision, qualified as a clause of exclusion of responsibility,[41] was a reduction of the area of liability for healthcare professionals who caused deaths or injuries during the state of emergency, due to the exceptional circumstances. Those individuals, indeed, could be held responsible for such events only if found guilty of gross negligence. Art 3-*bis,* comma 2, clarified that the assessment of negligence had to be carried out taking into consideration the context of intense pressure deriving from the pandemic, and, more specifically, the poor understanding of the disease, the circumstances of staff and equipment shortages, as well as the lower level of

substance), storage, dosage, inoculation, and so on.

[39] F. Furia, n 29 above, 10. In such cases, nonetheless, it seems that major issues would be posed by the difficulties in proving causation. In the assessment of criminal liability for Covid-related deaths, in general, the issue of causation raised serious issues: P. Piras, 'Il nesso causale SARS-CoV-2 e le morti nelle R.S.A.: si può provare?'*Sistema penale,* 14 April 2022, 1-11 and S. Zirulia, 'Nesso di causalità e contagio da covid-19' *Sistemapenale,* 20 April 2022, 1-19.

[40] F. Furia, n 29 above, 2.

[41] J. Della Valentina, n 35 above, 29. As a consequence, it must be deemed as an exception to the rule, subject to strict interpretation.

knowledge and skill of the non-specialised personnel employed.

Unlike the system foreseen under legge Gelli-Bianco, the exemption was not limited to unskillfulness: even though the novelty of the disease and the lack of knowledge might emphasise the issue of unskillfulness, it was clear that the emergency situation and the pressure it determined on both sanitary structures and professionals was likely to determine errors of inactiveness and imprudence too; as far as the mistake was strictly linked to the emergency, though, every kind of slight negligence had to be regarded as non-punishable. In this respect, the clause provided by Art 3-*bis* of decreto-legge no 44/2021 seemed to reject some of the main features that distinguished legge Gelli-Bianco from the previous system: for the purposes of the exception clause, indeed, the difference between unskillfulness, negligence and imprudence returned to be irrelevant, while the evaluation of the degree of fault was made – once again – essential.

In any case, the exemption was temporally limited to the duration of the state of emergency, which was firstly declared on 31 January 2020 and ended on 31 March 2022.[42]In addition to the temporal limitation, the clause was also functionally restricted to those events that occurred because of the state of crisis determined by the first outbreak of the pandemic and the following peaks. In addition, it has been noted that the rule expressly covered the case of manslaughter (Art 589 Criminal Code) and negligent injuries (Art 590 Criminal Code) caused in the exercise of the profession, other than causally linked to the emergency situation:[43] as they are not recalled by the provision, doubts persist whether different criminal offences, such as epidemics (Arts 438 and 452 Criminal Code) or misconduct in public office (Art 328 Criminal Code)[44] should be somehow exempted too. The introduction of the shield, moreover, could not serve the purpose of regulating the so-called 'tragic choices'[45] in the event of an imbalance between needs and available resources.

The choice to introduce in the legal system such an exemption – albeit temporally and functionally limited – confirmed the importance of the distinction between slight and gross negligence, and represented a clear sign in support of the professionals employed in the fight against the virus.

At the same time, the need for such a provision exposed some of the flaws

[42] P. Piras, 'La non punibilità' n 30 above. Nonetheless, the shield will also cover deaths and injuries occurring after the deadline of the state of emergency, as a consequence of conducts carried out during its duration.

[43] ibid

[44] ibid

[45] C. Newdick et al, 'Tragic choices in intensive care during the COVID-19 pandemic: on fairness, consistency and community' 46 *Journal of Medical Ethics*, 646 (2020); P. Sommaggioand S. Marchiori, 'Tragic choices in the time of pandemics' 1 *BioLawJournal. Rivista di BioDiritto, Special Issue* (2020); G.M. Caletti, 'Emergenza pandemica e responsabilità penali in ambito sanitario. Riflessioni a cavaliere tra 'scelte tragiche'e colpa del medico' *Sistema penale*, 5 (2020); G. Losappio, n 31 above, 1-16; L. Risicato, n 11 above, 6-7. On the subject, see also C. Newdick, *Who Should We Treat?* (Oxford: Oxford University Press, 1995).

of the pre-existing system. The main problem appears to be that all the parameters listed by the decree to evaluate the intensity of the violation should be normally considered in every instance of malpractice – and, more generally, in every case of negligence. It has been affirmed for years, especially by scholars, that the reproach for a negligent conduct should not give up a thorough assessment of the subjective element of fault, in accordance with Art 27 of the Constitution.

After verifying that a precautionary rule has been violated, and that the violation has ended in the occurrence of the foreseeable and avoidable event it was meant to prevent, the judge should always wonder whether the required behaviour – the one that would have prevented the harm from happening – could also be demanded from the individual who found himself in that situation. It is in relation to such factors as a stressful environment, the urgency of the situation, the tiredness of the agent due to shifts' organisation or heavy workloads, that the context becomes significant in order to measure the diligence that could reasonably be required from any individual in that same position. It is clear, then, that the choice to equip the law with some expressly listed criteria with the aim to determine the degree of negligence may also be seen as an attempt to mitigate the unpredictability of the decisions issued by Courts, often reluctant to assess the subjective features of fault.

In the light of the above, it is possible to make a criticism of the general state of the criminal system, as it results from both the law and the case law. Apart from the risk of being intended as an unjustified privilege for certain categories of individuals,[46] the need for a specific exemption gives the impression of a system which does not normally enhance the factors listed in Art 3-*bis* comma 2 but rather sentences the accused on the basis of the mere assumption of an objective violation of a precautionary rule, with disregard for any other consideration related to the author of the conduct or the specific environment.[47] The exemption of criminal responsibility for those individuals who couldn't do any better because of the abnormal context of action where they found themselves, on the contrary, should derive from the application of general principles: it should be seen as the direct result of the principle of culpability and not as a form of unjustified immunity.

Overall, therefore, the recent experience shows the inadequacy of the present legal system, as resulting from the previous reforms, and underpins the need for more systematic responses.

[46] A. Gargani, n 28 above, 889, where it is also noted that the creation of a shield can give the impression of an impunity space made necessary due to serial violations of the precautionary rule.

[47] See C. Cupelli, 'Gestione dell'emergenza pandemica e rischio penale: una ragionevole soluzione di compromesso (d.l. 44/2021)' *Sistema penale,* 1 June 2021.

VI. Conclusions

The spread of the pandemic has shown all its devastating power, not only on the sanitary level, but also on the legal one. Besides imposing new challenges, the emergency revealed all the flaws of the legal framework, which appeared helpless in front of its magnitude. The criminal risk, that immediately followed the sanitary one, has endangered the very tightness of the system, showing a lack of natural antibodies – or at least a total underestimation of the existing ones – and revealing the urge for better rules.

As the shields are falling due to the end of the state of emergency, the issue of healthcare professionals' liability suggests that it could be the right moment for a general rethinking of the matter.[48]

With a view of improving the overall regulation of negligence, indeed, the recent experience seems to suggest the need to take into serious consideration the subjective profiles of the conduct, giving credit to the theories of negligence based on what can be reasonably demanded from the agent under the circumstances.

Furthermore, the legislative choice to provide sanitary personnel with a shield restricting their criminal liability clearly demonstrates the possibility – or even the necessity - to go beyond the provision of Art 590-*sexies* Criminal Code and provide a remedy against its unsatisfactory formulation by adding, in the first place, a clear reference to slight negligence.

In addition, the possibility to extend the favourable treatment to all the forms of negligence should be evaluated too, in order to solve the problems deriving from the distinction between carelessness, negligence and unskillfulness: the borders of those types of fault, indeed, often appear too subtle to allow an objective and foreseeable classification of the conduct.[49]

As concerns the subjective scope of application of the exemption of slight negligence, lastly, it should also be considered whether to extend the waiver of responsibility to other classes of professionals that can be involved in the solution of highly technical and complex problems: in order to remedy the potential disparity of treatment between different professional orders, however, the attenuation of the criminal liability should be always carried out having regard to the specific interests that are involved in each field and their fair balancing.[50]

It is not under question that, to realise any of these changes, a careful

[48] M.L. Mattheudakis, La punibilità del sanitario per colpa grave. Argomentazioni intorno a una tesi (Genzano di Roma: Aracne, 2021).

[49] C. Cupelli, 'La legge Gelli-Bianco e il primo vaglio della Cassazione: linee guida sì, ma con giudizio' *Diritto penale contemporaneo,* 280, 284 (2017).

[50] P.F. Poli, n 14 above, 433. The Author also considers the perspective of a general limitation, in order to exclude the criminal relevance of slight negligence in every situation (416-432). See also G.M. Caletti, 'Tra 'Gelli-Bianco' e 'Balduzzi"n 13 above, 99, where the Author draws a comparison with other countries, where the model of negligence is already limited to gross negligence (Common Law systems), or *faute qualifiée* (France, at least for what concerns medical malpractice).

evaluation and a strong political commitment are needed; nonetheless, in the wake of the sanitary emergency which clearly showed the urge for a better regulation, the perspective of a future reform appears closer, and even more desirable.