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Aline Albuquerque[1]
Arthur Regis[1]

# LEGAL MECHANISMS OF PATIENT SAFETY: RETHINKING THE LEGAL FRAMEWORK OF THE THEME IN BRAZIL

*Mecanismos jurídicos de segurança do paciente: repensando o tratamento legal do tema no Brasil*

[1]Universidade de Brasília. Brasília/DF, Brasil.

Correspondence: Aline Albuquerque. E-mail: alineaoliveira@hotmail.com

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## ABSTRACT

The judicialization of medicine is a growing phenomenon in Brazil. There is a gradual increase in suits against physicians as a result of adverse events. This article aimed to identify and synthesize the legal mechanisms adopted by different countries to deal with topics related to patient safety and harm to patients resulting from health care. Considering the premises previously established in this article and its scope, the following mechanisms were categorized: (i) mechanisms of extrajudicial resolution of conflicts in health care; (ii) mechanisms of patient complaint system; (iii) mechanisms of compensation for faultless or administrative harm; and (iv) mechanisms of disclosure and apology. It is a theoretical and documentary study, based on the specialized literature on each of the subjects covered by the mechanisms and the Report of Patient's Right in the European Union (2016). It is concluded that the Brazilian model, centered on the judicialization of medicine, leads to the weakening of the bonds of trust established between health professionals and patients and to the expenditure of excessive material and human resources by the State and by the parties involved in the lawsuits, without the result of the legal action guarantees the expected satisfaction of the demands; and, still, there is no systemic improvement in the quality of health services as a result of lawsuits.

**Keywords**
Harms; Patient Rights; Adverse Events; Civil Liability; Patient Safety.

## RESUMO

A judicialização da medicina é um fenômeno crescente no Brasil, ou seja, há um incremento paulatino de demandas judiciais em face de profissionais de medicina em decorrência de eventos adversos. Este artigo objetivou identificar e sintetizar os mecanismos jurídicos adotados por distintos países para lidar com temas relacionados à segurança do paciente e aos danos aos pacientes decorrentes dos cuidados em saúde. Considerando as premissas previamente estabelecidas neste artigo e seu escopo, foram categorizados os seguintes mecanismos: (i) solução extrajudicial de conflitos em cuidados em saúde; (ii) sistema de queixas de pacientes; (iii) compensação de danos sem culpa ou administrativos; e (iv) *disclosure* e pedido de desculpas. Tratou-se de estudo teórico e documental, que se alicerçou na literatura especializada sobre cada um dos temas que são objeto dos mecanismos assinalados e no Relatório da União Europeia acerca dos Direitos dos Pacientes, de 2016. Conclui-se que o modelo brasileiro centrado na judicialização da medicina conduz ao enfraquecimento dos laços de confiança estabelecidos entre profissional de saúde e paciente e ao dispêndio de recursos materiais e humanos excessivos pelo Estado e pelas partes envolvidas nas ações judiciais, sem que o resultado da ação judicial garanta satisfação das demandas; e, ainda, não se tem como resultante das ações judiciais a melhoria sistêmica da qualidade dos serviços de saúde.

**Palavras-Chave**
Danos; Direitos dos Pacientes; Eventos Adversos; Responsabilidade Civil; Segurança do Paciente.

## Introduction

The judicialization of medicine is a growing phenomenon in Brazil, that is to say, there is a gradual increase in legal demands in the face of medical professionals as a result of adverse events. According to data released in 2017[1], there is an annual increase of 250% in the number of lawsuits involving physicians and, in 2016, 7% of medical professionals in activity had already been defendants in lawsuits. As far as specialties are concerned, those involving the greatest number of lawsuits are gynecology and obstetrics (42.6%), traumato-orthopedics (15.91%), plastic surgery (7%) and general surgery (7%). According to data from the National Council of Justice (CNJ), 5,739 cases related to medical error were processed in 2016 in Brazilian courts[2].

Although there is in Brazil there is a growing picture of the judicialization of patient's dissatisfaction with adverse events - considering here that adverse event is synonymous with error, defined as "a failure to execute an action plan as intended or application of an incorrect plan"[3] - or the result of health care, there is no noticeable incorporation of legal mechanisms with the objective of reducing it and, at the same time, contributing to the improvement of the quality of health care and the well-being of the patient. In contrast, the costs of medical criminal liability stand out, despite the difficulty of specifying them; in the United States, for example, it is estimated to have been $ 55.6 billion in 2008[4].

The Brazilian situation can be attributed to several factors; considering only the legal aspect, the following can be listed: (i) the gap between the traditionalist civilist perspective of responsibility in the health sphere and the new approach brought by patient safety; (ii) the incorporation, to a certain extent, of the North American model of defensive medicine, which is based on medical practice from the perspective of the protection of the litigation professional (consequently, physicians perform procedures and adopt treatments to avoid their exposure to lawsuits[5]; research by Panella et al. demonstrates that defensive medicine is costly for health

[1]BIANCHI, Fernando. Crescimento das ações judiciais e reclamações éticas contra médicos. *O Estado de S. Paulo*, São Paulo, 21 out. 2017. Available at: https://politica.estadao.com.br/blogs/fausto-macedo/crescimento-das-acoes-judiciais-e-reclamacoes-eticas-contra-medicos/. Accessed on: 31 Oct. 2018.

[2]JUDICIALIZAÇÃO da saúde no Brasil em números. *Ipog Blog*, 20 nov. 2017. Available at: https://blog.ipog.edu.br/saude/judicializacao-da-sade-em-numeros/. Accessed on: 29 Oct. 2018.

[3]PROQUALIS - Centro Colaborador para a Qualidade do Cuidado e a Segurança do Paciente. *Taxonomia*. Classificação Internacional para Segurança do Paciente (ICPS). Organização Mundial de Saúde. Available at: https://proqualis.net/aula/taxonomia-classifica%C3%A7%C3%A3o-internacional-para-seguran%C3%A7a-do-paciente-icps. Accessed on: 20 Jul. 2019.

[4]MELLO, Michelle M.; CHANDRA, Amitabh; GAWANDE, Atul A.; STUDDERT, David M. National costs of the medical liability system. *Health Aff (Millwood),* v. 29, n. 9, p. 1569–1577, sep. 2010. http://dx.doi.org/10.1377/hlthaff.2009.0807.

[5]SEKHAR, M Sonal; VYAS, N. Defensive Medicine: A Bane to Healthcare. *Ann Med Health Sci Res*., v. 3, n. 2, p. 295-296, abr./jun. 2013. http://dx.doi.org/10.4103/2141-9248.113688

systems and does not bring any benefit to the patient)[6]; (iii) the culture of litigation, which, according to Lucena Filho, points to the concentration of resolution of conflicts; in the Judiciary, "founded on the winner-loser logic"[7]; (iv) predominance of the paternalistic model of health care, which leads to a reduction in the role of the patient in the therapeutic process and in the ways of coping with the adverse event. Thus, it appears that Brazil is behind when compared to advanced countries in terms of safeguarding patient rights and promoting the quality of health care and patient safety.

Patient safety has the nodal task of "reducing, to the minimum acceptable, the risk of unnecessary harm associated with health care"[8]. In the process of theoretical-practical construction of patient safety, the liability of professionals was rethought to build a new paradigm on the subject through the proposition of two systems: the system of systemic error, which is a simple human error, without intentionality; and the system of negligence, which consists in the failure to achieve a certain standard of health care due to an incorrect decision. Thus, the first emphasizes the adverse event and promotes a non-punitive culture, while the second emphasizes the professional's decision-making-process and treats error as negligence[9]. It is stressed that, in Brazil, there is no distinction between the two systems, as the legal system and the theories of Civil Law or Consumer Law do not differentiate between the system systemic error and the system of negligence.

In effect, this article aims to identify and synthesize the legal mechanisms adopted by different countries to deal with topics related to patient safety and harm to patients resulting from health care. In this article, legal mechanisms are understood as "bodies, legally established administrative procedures and laws" that have the aim of create legal effects; in this line, Lobato, Moreira and Pinto use the expression "legal mechanisms" as a means of "implementation of patient right to safety in health organizations"[10]. This study is based on the following premises, which will not be discussed: (i) the legal mechanisms of

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[6]PANELLA, Massimiliano *et al*. Prevalence and costs of defensive medicine: a national survey of Italian physicians. *J Health Serv Res Policy*, v. 22, n. 4, p. 211-217, Oct. 2017. http://dx.doi.org/10.1177/1355819617707224.

[7]LUCENA FILHO, Humberto Lima de. *A cultura da litigância e o Poder Judiciário*: noções sobre as práticas demandistas a partir da justiça brasileira. p. 2 Available at: http://www.publicadireito.com.br/artigos/?cod=84117275be999ff5. Accessed on: 29 Oct. 2018.

[8]ORGANIZAÇÃO MUNDIAL DA SAÚDE *apud* MENDES, Walter. Taxonomia em segurança do paciente. *In*: SOUSA, Paulo; MENDES, Walter (Orgs.). *Segurança do paciente:* conhecendo os riscos nas organizações da saúde. Rio de Janeiro: EAD/ENSP, 2014. p. 57-72.

[9]SOHN, David H. Negligence, genuine error, and litigation. *International Journal of General Medicine*, n. 6, p. 49-56, 2013. http://dx.doi.org/10.2147/IJGM.S24256.

[10]FARIA, Paula Lobato; MOREIRA, Pedro Sá; PINTO, Laura Souza. Direito e segurança do paciente. In: SOUSA, Paulo; MENDES, Walter (Orgs.). *Segurança do paciente:* conhecendo os riscos nas organizações da saúde. Rio de Janeiro: EAD/ENSP, 2014. p. 122.

patient safety must have as objective the promotion of the patient rights and the increase the quality of health care; (ii) the extrajudicial resolution of conflicts in the health environment must be a priority; (iii) the distinction between the system of systemic error and the system of negligence must permeate the responsibility of the health professional. Therefore, this study has the purpose of stimulating the discussion on the subject in Brazil, as well as the revision of the national legal mechanisms.

Thus, it is essential to rethink the legal treatment of harm in the sphere of health care. For example, the Council of Europe Recommendation [11] on patient safety and prevention of adverse events in health care highlighted the fact that legislation is one of the most important regulatory mechanisms in health care, that is, there is recognition that the law helps to change the professional culture in health[12].

Thus, there is the understanding that self-regulation is not enough to account for patient rights and the socially constructed consensus that patient safety is a shared value that requires laws consistent with that objective. In contrast, it is recognized that the adoption of laws and legal mechanisms is not enough to change a professional culture, but the symbolic and coercive value of a law and legal mechanisms on patient safety is fundamental to start the introducing process of a new culture in the country. Similarly, there are other legal mechanisms that contribute to a new approach to patient safety from a perspective of the experience of the ombudsman of the patient, in Norway[13], of the ombudsman/health care mediator, in the United States[14], and of other mechanisms for extrajudicial resolution of conflicts that prove to be of great value to support patients in the event of harm. In addition, there are patient complaint systems[15] and, in order to encourage the culture of disclosure of adverse events, several countries have adopted laws on disclosure that deal with the disclosure of adverse events in specific contexts – for example, the United Kingdom, Canada, Australia, New Zealand and the United States. In the same sense, some countries have passed "apology laws",

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[11] EUROPEAN COUNCIL. *Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01)*. Available at: https://ec.europa.eu/jrc/sites/jrcsh/files/2_June_2009%20patient%20safety.pdf. Accessed on: 20 Jul. 2019.

[12] GUILLOD, Olivier. Medical error disclosure and patient safety: legal aspects. *J Public Health Res*., v. 2, n. 3, Dec. 2013. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4147746/pdf/jphr-2013-3-e31.pdf. http://dx.doi.org/10.4081/jphr.2013.e31.

[13] MOLVEN, Olav. The patient's rights to complain, handling complaints, and sanctions against healthcare providers. *In*: MOLVEN, Olav; FERKIS, Julia (Eds.). *Healthcare, welfare and law.* Oslo: Gyldendal, 2010. p. 165-175

[14] MONTIJO, Mark *et al*. Bridging physician-patient perspectives following an adverse medical outcome. *The Permanent Journal*, v. 15, n. 4, p. 85-88, 2011.

[15] MIRZOEV, Tolib; KANE, Sumit. Key strategies to improve systems for managing patient complaints within health facilities – what can we learn from the existing literature? *Global Health Action*, v. 11, n. 1, 2018. http://dx.doi.org/10.1080/16549716.2018.1458938.

for example the United States[16] and Canada, which provide for an apology after the occurrence of adverse events without being used to substantiate any subsequent indemnity action[17]. Laws on disclosure and the apology must be part of a broader public policy, that is, it is necessary to have professional guidance in this regard and professional incentives to expand disclosure.

As for the negative demarcation of this study, it is emphasized that this article does not have conflicts of interests involving Consumer Law or user rights[18] as its work theme, nor does it deal with the participation of the patient in monitoring the safety conditions or their engagement in patient safety actions[19].

Considering the premises previously established in this article and its scope – to identify and systematize the legal mechanisms of patient safety – the following mechanisms were categorized, based on articles and books, as well as the Report of Patient's Rights in the European Union [20]: (i) mechanisms of extrajudicial resolution of conflicts in health care; (ii) mechanisms of patients complaints system; (iii) mechanisms of compensation for faultless or administrative harm; and (iv) mechanisms of disclosure and an apology. Each of the mechanisms will be exemplified by exposing experiences of their implementation in different countries. It should be recorded that this study does not aim to analyze each of the mechanisms from the perspective of effectiveness, nor to deepen them.

This is a theoretical and documentary study, based on specialized literature on each of the themes that are the subject of the mechanisms mentioned and in the Report of Patient's Rights in the European Union from 2016. This article is structured in five parts, the first four being intended for each of the mechanisms and the last, to present the state of the art on the subject in Brazil.

## I. Mechanisms of extrajudicial resolution of conflicts in health care

Several countries in Europe use the ombudsman for the resolution of conflicts concerning the violation of patient rights, including the occurrence of[21]harm. The ombudsman supports the patient, because it assumes the meaning that he is the most vulnerable part in the care relationship, and assists him in the realization

[16] APOLOGY laws: talking to patients about adverse events. *Medical Economics*, June, 10 2014. Available at: https://www.medicaleconomics.com/articles/apology-laws-talking-patients-about-adverse-events. Accessed on: 20 Jul. 2019.

[17] GUILLOD, Olivier. *op. cit*., e 311.

[18] See distinction in ALBUQUERQUE, Aline. *Direitos humanos dos pacientes*. Curitiba: Juruá, 2016.

[19] On the subject see SANTOS, Margarida Custódio; CRICKET, Ana Monteiro. Envolvimento do paciente: desafios, estratégias e limites. *In*: SOUSA, Paulo; MENDES, Walter (Orgs.). *Segurança do paciente:* conhecendo os riscos nas organizações da saúde. Rio de Janeiro: EAD/ENSP, 2014. p. 159-186.

[20] EUROPEAN COMMISSION. *Patients' Rights in the European Union Mapping eXercise*. Luxembourg: Publications Office of the European Union, 2016

[21] EUROPEAN COMMISSION. *Patients' Rights in the European Union Mapping eXercise*, *cit.*

of his rights, in the resolution of conflicts or in the formalization of complaints. The ombudsman operates in the administrative scope, and his interaction with the patient is informal. Mediation is not necessarily provided by ombudsman, according to the European model, it is a mechanism adopted only in some countries and is not widely used[22]. In the United States, there is the mechanism of the ombudsman/health care mediator, which listens to patient complaints, performs informal investigations in the hospital environment and facilitates frank and transparent dialogues between patients and health professionals. The role of ombudsman/mediator consists of seeking to understand the dissonant perspectives of the parties involved in the conflict and their convergences with a view to overcoming their suspicions and fears, in order to ensure a better understanding of the intentions of each of them[23]. Some examples of ombudsman mechanisms in Europe and the United States will then be given.

Austria has a *Health Care Quality Act*[24] and several agencies dealing with the subjective of patient safety, among which the Health Quality Service, the Austrian Chamber of Medical Initiative in Quality and the Patient Safety Platform stands out. In 2002, an ombudsman system was established, through which the search for compensation and issues related to patient harm are resolved through administrative structures. In 2009, 9,561 complaints were processed by the ombudsman service; of these, 917 were resolved using the Patient's Compensation Fund tool and 800 were resolved by independent physicians. Thus, in the Austrian system it is the services of ombudsman that generally deal with patient complaints, including those involving negligence and bad practice. In the same sense, there are arbitration bodies composed of physicians, dentists and other health professionals with the aim of dealing with issues outside the courts, in order to prevent patients and professionals from being subjected to time-consuming and expensive processes. These bodies work together with the services of ombudsman[25].

The ombudsman of health and social services – the patient's ombudsman, in Norway, was created by initiatives implemented in health services in 19 counties. In 1999, when the *Patient's Rights Act*[26] was passed, the patient's ombudsman became a legal mechanism linked to the Ministry of Health and to the Health Care Services. Since then, the ombudsman has been financed by public resources and provides services at no cost to patients; moreover, as each county must have one. The ombudsman has the competence to carry out investigations in health

[22] EUROPEAN COMMISSION. *Patients' Rights in the European Union Mapping eXercise, cit.*
[23] MONTIJO, Mark *et al. op. cit.*
[24] HOFMARCHER, Maria M. *Austria*: Health system review. *Health Systems in Transition*, v. 15, n. 7, p. 1-291, 2015. Available at: http://www.euro.who.int/__data/assets/pdf_file/0017/233414/HiT-Austria.pdf. Accessed on: 29 Oct. 2018.
[25] HOFMARCHER, Maria M. *op. cit.*
[26] *The Act of 2 July 1999 No. 63 relating to Patients' Rights* (the Patients' Rights Act). Available at: https://app.uio.no/ub/ujur/oversatte-lover/data/lov-19990702-063-eng.pdf. Accessed on: 10 Jul. 2019.

services and receive complaints from patients, from which he can contact professionals and providers of health services to report the patient's dissatisfactions. The ombudsman also helps the patient to dialogue with the health team. As for complaints and conflict resolution, ombudsman can act informally, through dialogue with the health team and service providers, or formally, requesting that a decision be reversed or as an intermediary between the patient and the agencies responsible for processing complaints or as those responsible for compensating harm to patients[27].

In the northeastern and the southeastern of California, in the United States, the Ombudsman/Health Care Mediator Program was established in 2003, with 28 ombudsmen. The main objective of the *ombudsman* service is to resolve disputes involving patients, considering the quality of health care. Since it was implemented, the program has achieved 90% satisfaction among physicians and clinical staff. This success of the Californian ombudsman is due to his essential role in the education of health professionals, teaching them to: (i) report unexpected adverse outcomes; (ii) listen better to patients and take into account their perspective on adverse events; (iii) make a sincere apology; and (iv) to restore trust in the relationship with the patient through transparent communication[28].

## II. Mechanisms of patient complaints system

A robust patient complaints system is a crucial element of the good *performance* of health systems[29]. In addition, the patient's perspective inferred from the complaints system contributes to a less restrictive approach to patient safety, as it incorporates his experience and that of family members. Thus, the quality of health care, and its improvement, must also be motivated by patient complaints and dissatisfactions. As for harm prevention, patients commonly pay prior attention to errors and may contribute to avoiding them. In some European countries and in the United States, studies indicate that patient complaints provide valuable material for investigating the origin of adverse events, which is crucial for improving patient safety[30]. In the same direction, Mirzoev and Kane support the importance of health systems making use of patient complaints in order to improve their *performance*[31] .

The complaint system mechanisms allow the patient to give a return to health services about his experience, the care he received, the quality of the health

[27] MOLVEN, Olav. *op. cit.,* p. 165-175.
[28] MONTIJO, Mark *et al*. *op. cit*.
[29] MIRZOEV, Tolib; KANE, Sumit. *op. cit*.
[30] RÅBERUS, Anna; HOLMSTRÖM, K. Inger; GALVIN, Kathleen; SUNDLER, Annelie J. The nature of patient complaints: a resource for healthcare improvements. *International Journal of Quality in Health Care,* v. 31, n. 7, p. 556-562, Aug. 2019.
[31] MIRZOEV, Tolib; KANE, Sumit. *op. cit*.

team and the availability of supplies, as well as complain when his experience does not align with his expectations. The complaints system is a relevant source of identification of problems related to patient safety for health institutions, as patients present a more accurate perception of the problematic issues that emerge from their care[32].

Likewise, patient complaints consist of essential material for increasing health services. For example, in the United Kingdom, the Francis[33] Report reported 1,200 preventable deaths over three years at the Mid-Staffordshire NHS Foundation Trust hospital. The Report found that, during this period, patient complaints exposed the low quality of health care and problems of neglect[34]. In this sense, experiences in Sweden and Finland highlight the importance of improving the complaints system, through the creation of opportunities and spaces within health services for patient to easily express their demands and communicate their complaints, as well as show that the patient's awareness about the channels of complaint and their rights is effective in improving their ability to express their dissatisfactions[35].

It should be noted that a study in the United Kingdom cited by Mirzoev and Kane demonstrated that the complaints refer to issues of patient safety and quality of health care (33.7%); to issues related to management, such as the admission and discharge process, financial and other issues of this nature (35.1%); and problems concerning the relationship between health professional and patient, such as conduct and communication (29.1%). The research carried out by Råberus, Holmström, Galvin and Sundler on the complaints system in Sweden categorized patient complaints into: (i) access to health services; (ii) continuity of care and patient follow-up; (iii) incidents and harm to the patient; (iv) communication; (v) attitudes and approach; and (vi) patient's will and health care options. Particularly regarding communication, the study showed that the failures are related to problems in patient safety and their unsatisfactory experiences[36].

In Europe, examples of complaint-receiving services are the Office of Patient's Rights of Greece; the Negligence Commission of Romania; and the Health Care Surveillance Authority of Slovakia. In more detail, the National Agency for Patient's Rights and Complaints of Denmark, whose task is to provide service to receive complaints from patients and to process them, including complaints about professional conduct and decisions on compensation harm. In addition, the Danish

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[32] READER, Tom W.; GILLESPIE, Alex; ROBERTS, Jane. Patient complaints in healthcare systems: a systematic review and coding taxonomy. *BMJ Quality & Safe,* v. 23, n. 8, p. 678-689, Aug. 2014. http://dx.doi.org/10.1136/bmjqs-2013-002437.

[33] FRANCIS, R. *Report of the mid-Staffordshire NHS Foundation trust public inquiry*. London: The Stationary Office, 2013.

[34] READER, Tom W.; GILLESPIE, Alex; ROBERTS, Jane. *op. cit*. p. 678-689.

[35] MIRZOEV, Tolib; KANE, Sumit. *op. cit*.

[36] RÅBERUS, Anna; HOLMSTRÖM, Inger K.; GALVIN, Kathleen; SUNDLER, Annelie J. *op. cit.*

agency focuses on ensuring that information derived from adverse events and litigation cases is used to prevent harm[37].

In the Netherlands, patients can count on comprehensive legislation on the complaints system, the *Healthcare Quality, Complaints and Disputes Act* from 2016[38]. The independent ombudsmen, in Finland, and the Patient Advisory Committee, in Sweden, have demonstrated how to make the complaint process more independent and improve its monitoring. In the United Kingdom, the local medical committees and the Patient Advice and Liaison Service are successful experiences[39].

In Norway, health oversight bodies located in the counties are tasked with receiving complaints from patients, and the health oversight body has the power to impose sanctions against health professionals or institutions. In addition to this formal system of complaints, there are two others: the patient can try to obtain a solution to his problem or express his dissatisfaction through the patient's ombudsman; and if the patient had suffered harm due to health care that caused him economic losses, he may require compensation in the Norwegian patient compensation system[40].

## III. Mechanisms of compensation for faultless or administrative harm

There is a movement in Europe towards the system of compensation for faultless harm, in which the liability of the healthcare professional or the health provider is not required, so only the proof of harm to the patient[41]is required.

In the United Kingdom, there is a tension between English civil liability law and the patient safety agenda. In the Bristol Inquiry[42], it was pointed out that the culture of fault is one of the biggest barriers to the notification of sentinel events, learning and improving security. In its institutional structure, the United Kingdom has the National Patient Safety Agency, the Care Quality Commission and the *National Health Service Litigation Authority* – NHS (NHSLA). The attributions of these three bodies involve compensation for clinical and non-clinical

[37] DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY; THIRD HEALTH PROGRAMME (2014-2020). *Patient 'rights in the European Union, cit.*

[38] GOVERNMENT OF THE NETHERLANDS. *Healthcare Quality, Complaints and Disputes Act (WKKGZ)*. Available at: https://www.government.nl/topics/quality-of-healthcare/healthcare-quality-complaints-and-disputes-act-wkkgz. Accessed on: 20 Jul. 2019.

[39] MIRZOEV, Tolib; KANE, Sumit. *op. cit*.

[40] MOLVEN, Olav. *op. cit.,* p. 150-164.

[41] DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY; THIRD HEALTH PROGRAMME (2014-2020). *Patient 'rights in the European Union, cit.*

[42] SECRETARY OF STATE FOR HEALTH. *The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995*. Learning from Bristol. Available at: http://webarchive.nationalarchives.gov.uk/20090811143822/http://www.bristolinquiry.org.uk/final_report/the_report.pdf. Accessed on: 20 Oct. 2018.

liability in the face of the NHS (NHSLA) and learning from complaints. When the Litigation Authority is sufficiently aware of a case, it makes a decision on the merits and, if it concludes that the liability exists, quantifies and resolves the complaint, usually through negotiation[43]. The NHS has a specific reparation law, as well as the Compensation Act 2006[44]. These laws contributed to creating a culture of administrative compensation, but the design of a system without fault or systemic error has not yet been incorporated into the NSH (NHSLA).

New Zealand, Sweden and Denmark have adopted the system of compensation for faultless harm. Therefore, the patient's compensation is resolved administratively, that is, the patient can request compensation for the harm suffered without resorting to the law firm. A group of experts decides on the case and the compensation. According to such a system, compensation is paid without the need to prove fault, and information about what happened is used to improve patient safety[45].

After studies that demonstrated that lawsuits aiming at the compensation for harms took years and were costly for the patients, because the burden of proof fell on them, Austria adopted a new model in 2001[46]. The new model was based on the patient compensation fund, whose resources come from a daily fee paid by hospitalized patients and which is administered by the regional advocacy of the patient. The amount to be reimbursed is decided by an independent regional committee. Thus, if the patient suffers any harm, he may be reimbursed based on the fund despite an action for harms and without the need to comply with all the legal requirements required for the filing of such an action[47].

For the past 30 years, there has been an attempt to reduce the legalization of medicine in the United States. The first generation of reforms began in the 1970s, by limiting the amount of indemnification resulting from non-economic harms - considering that economic harms are those that can be calculated, such as medical expenses and loss of salary. Such action was taken with the aim of reducing the financial gains of law firms and their exorbitant profits; soon, there was opposition from groups of lawyers, mitigating the impact of the reform. Currently, there is a proposal for administrative courts for the health area, which would assess the decisions through a panel of medical specialists to decide on cases of malpractice.

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[43] UNITED KINGDOM - *UK. National Health Service* – NHS. *Litigation Authority*. Available at: http://www.nhsla.com/Pages/Home.aspx. Accessed on: 02 Dec. 2017.

[44] UNITED KINGDOM - *UK. National Health Service* – NHS. *Redress Act 2006*. https://www.legislation.gov.uk/ukpga/2006/44/pdfs/ukpga_20060044_en.pdf; UNITED KINGDOM - *UK. The National Health Service* - NHS. *Compensation Act 2006*. Available at: https://www.legislation.gov.uk/ukpga/2006/29/pdfs/ukpga_20060029_en.pdf. Accessed on: 2 Dec. 2017.

[45] SOHN, David H. *op. cit.,* p. 49-56.

[46] DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY; THIRD HEALTH PROGRAMME (2014-2020). *Patient 'rights in the European Union, cit.*

[47] HOFMARCHER, Maria M. *op. cit*.

This proposal derives from an administrative approach to deal with the neglect that has been under debate for more than 40 years. The authors studied administrative compensation models, such as those adopted in Scandinavian countries and New Zealand, which have been shown to reduce costs and speed up the resolution of complaints, in addition to attracting greater support from physicians and society. Considered that the United States is a federation, the state of Virginia has a program designed to compensate for severe neurological harm to neonatal patients similar to that adopted in Denmark[48].

## IV. Legal mechanisms of disclosure and apology

The disclosure, which consists of "reporting incidents to patients and families"[49], and apology implies acknowledging the event and the professional's role in its occurrence and genuine regret for the patient harm[50]. The disclosure and apology mechanisms in cases of adverse events, although highly recommended for the promotion of patient rights and safety, are not easily incorporated into the practice of health care, as highlighted in the European Union's Report[51]. In contrast, studies reveal that the complete disclosure is associated with greater patient satisfaction and contributes to increasing their confidence in the health team. As a more positive response for the patient, disclosure reduces the likelihood that the patient will seek punishment from physicians[52]. According to Lucian Leape's understanding of the Bristol Inquiry, an important instrument in the United Kingdom, when something goes wrong, patients generally want three approaches: (i) someone to tell them what happened; (ii) a doctor who is sorry; and (iii) an attitude that ensures that the occurrence will not be repeated. According to Leape, patients do not want the professional to be punished, but rather to assume responsibility[53]. Indeed, Linda Mulcahy, in her research reported in the Report of UK National Audit Office, found that patients want compensation when something serious happens, but not only that: they also want to take responsibility, prevent future adverse events, an explanation and an apology[54].

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[48] MELLO, Michelle M.; KACHALIA, Allen Kachalia; STUDDERT, David M. *Medical liability*: prospects for Federal Reform. Available at: https://www-cdn.law.stanford.edu/wpcontent/uploads/2017/04/nejmp1701174.pdf. Accessed on: 02 Dec. 2017.

[49] SANTOS, Margarida Custódio; GRILO, Ana Monteiro. *op. cit.,* p. 178.

[50] MAcDONALD, Noni; ATTARAN, Amir. Medical errors, apologies and apology laws. *CMAJ,* v. 180, n. 1, p. 11, Jan. 2009. http://dx.doi.org/10.1503/cmaj.081997.

[51] DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY; THIRD HEALTH PROGRAMME (2014-2020). *Patient 'rights in the European Union, cit.*

[52] LEE, Michael J. On patient safety: do you say "I'm sorry" to patients? *Clin Orthop Relat Res*., v. 474, n. 11, p. 2359-2361, Nov. 2016. http://dx.doi.org/10.1007/s11999-016-5025-7.

[53] SECRETARY OF STATE FOR HEALTH. *The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995, cit.*

[54] SECRETARY OF STATE FOR HEALTH. *The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995, cit.*

The disclosure polices require health professionals to inform the patient or his representative that an incident has occurred and to express their regret, as well as to give a factual explanation of the event, detailing the potential consequences for the patient. These policies contribute to the reduction of litigation, especially that related to obtaining information from the patient. Although these policies are recommended, less than 30% of harmful events are revealed to patients[55].

In the European context, patient rights laws do not provide an explanation and apology to the patient as to what happened in their health care, although the European Union considers both mechanisms as key elements to avoid patient complaints and, therefore, the judicialization of medicine[56].

In the United States, as pointed out about the reforms undertaken in order to contain the excess of lawsuits in the face of physicians, the second generation of reforms involves the resolution of conflicts through alternative mechanisms, such as the "anticipated excuses" programs, developed by some hospitals and that encourage dialogue between the parties involved[57]. As for excuse laws, there is pressure for states in the United States to adopt them. Based on such laws, the doctor's apology to the patient or his family cannot be used for future litigation. Thus, currently, several states in the country have such laws, however, in terms of protecting future litigation, there is a variation. Some laws, such as those of the states of Colorado and Washington, provide the excuse related to the failure of the professional, while those of other states, provide only as empathy for the professional, but not as recognition of his lack. These laws aim to promote frank and transparent communication in health care. It is extracted from the literature on the subject that being transparent with the patient decreases the likelihood of litigation[58]. Furthermore, the apology has a profound curative effect on the patient, as well as contributing to reducing the health professional's feeling of fault or shame[59].

In Australia, apology and expressions of regret are considered central elements of disclosure. As such, all Australian jurisdictions have laws designed to protect statements of apology and regret after health care incidents. It is important to note that the apology does not translate into a confession

[55] HARRISON, Reema; BIRKS, Yvonne; BOSANQUET, Kate; IEDEMA, Rick. Enacting open disclosure in the UK National Health Service: a qualitative exploration. *J Eval Clin Pract*. V. 23, n. 4, p. 713-718, Feb. 2017. http://dx.doi.org/10.1111/jep.12702.

[56] DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY; THIRD HEALTH PROGRAMME (2014-2020). *Patient 'rights in the European Union, cit.*

[57] MELLO, Michelle M.; KACHALIA, Allen Kachalia; STUDDERT, David M. *op. cit.*

[58] LEE, Michael J. *op. cit.,* p. 2359–2361.

[59] MAcDONALD, Noni; ATTARAN, Amir. *op. cit.,* p. 11.

by the health professional that he committed a failure for the purposes of his legal accountability[60].

In the United Kingdom, since 2015, new guidelines, produced by the General Medical Council, the Nursing and Midwifery Council[61] and the Care Quality Commission[62], provide for the imperative to support physicians, nurses and midwives in fulfillment of their professional obligation to deal with errors and adverse events with honesty and transparency[63].

The mechanisms of disclosure and apology still challenge the countries' legal systems, since it is necessary to ensure a frank and transparent explanation to the patient about what happened, as well as a sincere apology, without such conducts trigger the accountability of the health professional[64].

## V. State of the art of legal mechanisms for patient safety in Brazil

Despite the consensus in Brazil on the importance of patient safety and the prevention of harm in health care, in the legal sphere, there is no adoption of the mechanisms identified and consolidated in several countries in the world. In fact, in Brazil, the Civil Code and the Consumer Protection Code, applicable to the relationship between healthcare professionals and patients, express the traditional model of civil liability. It is argued that the country does not have a national law of patient rights and safety. In the same way, there is no legal framework about the mechanisms of the complaints system, extrajudicial resolution of conflicts, disclosure and apology. Compensation for harm to patients still follows the logic of Civil Law or the Consumer Protection Code.

In Brazil, the main state initiative in favor of patient safety is the National Program of Patient Safety (PNSP), instituted by Ordinance no. 529/2013[65] of the Ministry of Health (MS) and which is configured as the landmark in patient safety in Brazil. The PNSP considers the relevance and magnitude that adverse events have in Brazil, the priority given by the World Health Organization (WHO) to the theme and that risk management focused on quality and patient safety encompasses a range of principles and guidelines, including the

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[60] COMMOWEALTH OF AUSTRALIA. *Australian Open* Disclosure *Framework Better communication:* a better way to care. Available at: https://www.safetyandquality.gov.au/wp-content/uploads/2013/03/Australian-Open-Disclosure-Framework-Feb-2014.pdf. Accessed on: 20 Oct. 2018.

[61] GENERAL MEDICAL COUNCIL. *Openness and honesty when things go wrong*: The professional duty of candour 2015. Available at: https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/openness-and-honesty-professional-duty-of-candour.pdf. Accessed on: 29 Oct. 2018.

[62] CARE QUALITY COMMISSION. *Regulation 20*: Duty of candour. Available at: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour. Accessed on: 29 Oct. 2018.

[63] HARRISON, Reema; BIRKS, Yvonne; BOSANQUET, Kate; IEDEMA, Rick. *op. cit.,* p. 713-718.

[64] FARIA, Paula Lobato; MOREIRA, Pedro Sá; PINTO, Laura Souza. *op. cit.,* p. 115-134.

[65] MINISTÉRIO DA SAÚDE. *Portaria n. 529, de 01 de abril de 2013.* Available at: http://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt0529_01_04_2013.html. Accessed on: 14 Oct. 2020.

establishment of a culture of patient safety. Thus, the PNSP recognizes that it is essential to build and consolidate the culture of patient safety, but it is imperative to establish that the consolidation of such culture is conditioned to the innovation of the legal mechanisms of patient safety, as demonstrated in this study through the experience of different countries.

In 2013, the Brazilian Health Regulatory Agency (ANVISA) produced the series of publications "Patient Safety and Quality in Health Services"[66]. In 2015, in continuity with the content previously produced and aiming at improving the theme, Anvisa published the "Integrated Plan for the Sanitary Management of Patient Safety in Health Services: Monitoring and investigation of adverse events and evaluation of patient safety practices"[67]. Despite the extreme value of the materials produced by Anvisa, considering that its legal competence is limited to health surveillance - according to article 1 of Law no. 9,782/1999[68] -, it is not up to it to formulate legal mechanisms for patient safety. Therefore, such initiatives do not meet the need for legal formalization of the legal mechanisms discussed in this article.

Register the regulatory gap in the country regarding the object of this article. Thus, in order to explore the possibility of having, at a future time, a legislation that could encompass some of the legal mechanisms exposed in this study, we sought, on the official page of the Chamber of Deputies and the Federal Senate, bills on security of the patient. The draft bills founded were: Federal Senate Bill no. 605/2011[69] (Bill no. 3598/2012 in the Chamber of Deputies), which aims at the "mandatory maintenance of a hospital infection control program by hospitals in the country, to include the prevention of medication errors", using the patient safety as a justification; the Bill no. 6520/2016[70] (which is attached to Bill no. 3598/2012), which establishes the "mandatory creation and maintenance of

[66] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA - ANVISA. Série: Segurança do Paciente e Qualidade em Serviços de Saúde. Available at: http://proqualis.net/noticias/s%C3%A9rie-seguran%C3%A7a-do-paciente-equalidade-em-servi%C3%A7os-de-sa%C3%BAde. Accessed on: 21 May. 2018.

[67] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA - ANVISA. *Plano Integrado para a Gestão Sanitária da Segurança do Paciente em Serviços de Saúde*. Monitoramento e Investigação de Eventos Adversos e Avaliação de Práticas de Segurança do Paciente. Brasília-DF, 2015. Available at: file:///C:/Users/Samsung/Downloads/PLANO_INTEGRADO.pdf. Accessed on: 21 May. 2018.

[68] BRASIL. *Lei n. 9.782, de 26 de janeiro de 1999*. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. Available at: http://www.planalto.gov.br/ccivil_03/leis/l9782.htm. Accessed on: 14 Oct. 2020.

[69] SENADO FEDERAL. *Projeto de Lei n. 605/2011*. Altera a Lei n. 9.431, de 6 de janeiro de 1997, que dispõe sobre a obrigatoriedade da manutenção de programa de controle de infecções hospitalares pelos hospitais do País, para incluir a prevenção de erros de medicação. Available at: https://www25.senado.leg.br/web/atividade/materias/-/materia/102562. Accessed on: 14 Oct. 2020.

[70] CÂMARA DOS DEPUTADOS. *Projeto de Lei n. 6520/2016*. Dispõe sobre a obrigatoriedade da criação e manutenção de comissões de segurança do paciente nos hospitais do País. Available at: http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=2117747. Accessed on: 14 Oct. 2020.

patient safety commissions in hospitals in the country"; the Bill no. 9602/2018[71], which is limited to dealing with the issue of notification when adverse events occur in aesthetic procedures; the Bill no. 4156/2015[72], which deals with civil, administrative and criminal liability in medical residency; and two projects currently filed, which are Bill no. 6659/2002[73], setting the compensation for medical error at 100 minimum wages or five times the amount paid by the patient, and Bill no. 6738/2006[74], determining the rite of the summary procedure in cases of bodily injury due to medical error.

Based on the four mechanisms that are the object of this article - (i) mechanisms of extrajudicial resolution of conflicts in health care; (ii) mechanisms of patient complaints system; (iii) mechanisms of compensation for faultless or administrative harm; (iv) mechanisms of disclosure and apology -, it appears that the Brazilian legal system does not comply with any of them. In effect, there is no legal provision by the ombudsman for health care or for the patient or any other type of service designed to resolution of conflicts related to the patient rights or to the occurrence of adverse events. Notwithstanding the recognition of advances undertaken by professionals specialized in mediation in health care, there is no institutionalization of services with such a desideratum in hospitals and within the scope of the country's health secretariats. It should be noted that conciliation and mediation mechanisms within the scope of the Judiciary Branch do not fit in with the mechanism for extrajudicial resolution of conflicts in health care, as the mechanism must be part of health services, and not the Judiciary Branch.

Regarding the mechanisms of patient complaints systems, there is no legal provision in Brazil. Some hospitals and clinics have ombudsman services and there is the Ombudsman of the Unified Health System (SUS), but such services do not operate uniformly and there is no legal discipline that gives them minimum standards required according to international criteria - for example, to be focused on the patient or open and submitted to *accountability*[75] .

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[71] CÂMARA DOS DEPUTADOS. *Projeto de Lei n. 9602/2018*. Estabelece a notificação compulsória, no território nacional, de eventos adversos associados a procedimentos estéticos. Available at: http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=2168250. Accessed on: 14 Oct. 2020.

[72] CÂMARA DOS DEPUTADOS. *Projeto de Lei n. 4156/2015*. Altera a Lei n. 6.932, de 7 de julho de 1981, para incluir os §§ 6º a 9º do art. 1º, para discriminar a responsabilidade civil, administrativa e penal do médico preceptor ou staff. Available at: http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=2075803. Accessed on: 14 Oct. 2020.

[73] CÂMARA DOS DEPUTADOS. *Projeto de Lei n. 6659/2002*. Fixa a indenização decorrente de erro médico em 100 (cem) salários mínimos ou 5 (cinco) vezes o valor pago pelo paciente. Available at: http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=50265. Accessed on: 14 Oct. 2020.

[74] CÂMARA DOS DEPUTADOS. *Projeto de Lei n. 6738/2006*. *Projeto de Lei n. 6738/2006*. Estabelece a aplicação de procedimento sumário nos processos de lesão corporal por erro médico. Available at: https://www.camara.leg.br/proposicoesWeb/fichadetramitacao?idProposicao=317417. Accessed on: 14 Oct. 2020.

[75] MIRZOEV, Tolib; KANE, Sumit. *op. cit*.

As for the compensation for faultless or administrative harm, as pointed out in this article, Brazil still follows the traditional model of civil liability based on the fault of the health professional.

Finally, in relation to disclosure and apology, there is no law that provides for them, which does not provide legal certainty to the health professional or hospital that intends to install them as an important patient safety measure.

## VI. State of the art analysis of legal mechanisms of patient safety in Brazil

From the studies developed in the field of patient safety, the existence of two systems that address the legal repercussions of the adverse event in the sphere of health care is identified: the systemic error, which deals with the adverse event and promotes culture non-punitive, and the system of negligence, which deals with negligent error[76]. In Brazil, the traditional legal field makes no distinction between systems of systemic error and system of negligence. Neglect consists of failure to achieve a certain standard of health care, that is, it is an incorrect decision, while systemic error is a simple human error, without intentionality. The system of systemic error recognizes that human error is a component of health care, so the answer to this event is systemic, as punishment does not reduce future errors and hinders the creation of a safer environment - on the contrary, it encourages them to hide the mistakes. According to research in the area, malpractice or negligence is not the predominant one[77] and, therefore, it is necessary to start giving different legal treatment to systemic error and to negligence in Brazil, a necessary condition for the implementation of the legal mechanisms advocated in this study.

Thus, there is currently a gap in the country between the traditionalist perspective of civil liability in the health sphere and the new approach guided by patient safety. This distinction leads to reflection on the legal treatment of harm in the sphere of health care, the responsibility of the agents involved and the establishment of legal patient safety mechanisms in a given legal order. In this sense, it appears that, in Brazil, this theme is still treated, from the legal, doctrinal and jurisprudential point of view, from obsolete institutes of Civil Law or Consumer Law, notably, to the extent that it was not incorporated into the legal framework the responsibility in the light of "no blame"[78] nor is there specific legislation contemplating the legal mechanisms of patient safety. In contrast, it is recognized that the adoption of legal mechanisms by legislation is not enough to change a professional culture, but the legislation that embodies the mechanisms mentioned in this article has the role of legitimizing

[76] SOHN, David H. *op. cit.,* p. 49-56.
[77] *Id.Ibid.*
[78] FARIA, Paula Lobato; MOREIRA, Pedro Sá; PINTO, Laura Souza. *op. cit.,* p. 115-134.

certain claims[79], such as the movement for security of the patient. In effect, it is the "expressive function of the law"[80], according to the studies by Goodman and Jinks, which consists of the effect of the laws of: (i) signaling values and moral consensus; (ii) placing certain conducts in the sphere of the objectionable; (iii) giving visibility to themes that are not treated and that are invisible to a large part of society; (iv) causing behavioral changes[81].

Thus, as can be seen in the state of the art exhibition in Brazil with regard to the legal mechanisms of patient safety, there is no legislation in the legal system that contemplates them. There is a legal gap regarding the extrajudicial resolution of conflicts in health care; the existence of a patient complaints system; compensation for faultless or administrative harm; and disclosure and apology. This legal gap in Brazil and the related delay can be attributed to several factors, such as the fact that patient safety is a recent issue even in the health sphere (the PNSP, for example, was launched in 2013). However, this article highlights the traditional perspective of civil liability in the sphere of health care, which is still linked to the search for the punishment of the professional who caused the harm, moving away from the patient safety approach centered on the vision of the adverse event, in the learning that the adverse event provides, in its prevention and in its communication. Thus, it appears that the traditional legal view on the health professional's civil liability based solely on the concepts of malpractice, recklessness and negligence is not consistent with the perspective brought by patient safety based on the "no blame culture"[82], compromising the reporting of adverse events with a focus on prevention and systemic change in the health care process. In effect, a perspective based on individual guilt encourages the culture of secret and removes the culture of disclosure, which hinders future harm prevention[83]

Therefore, it appears that the Brazilian legal system is still in an incipient stage when it comes to legislation on patient safety and the related legal mechanisms. Although some hospitals report disclosure, such as Hospital Sírio-Libanês[84], it is essential to provide legal certainty to health professionals when communicating the adverse event to patients and family members. Therefore, it is essential to have "excuse laws", which provide for an apology after the occurrence of adverse events without the possibility of being employed in any subsequent indemnity

[79] GOODMAN, Ryan; JINKS, Derek. *Socializing states*. Oxford: Oxford, 2013.
[80] *Id. Ibid.,* p. 146.
[81] *Id. Ibid.*.
[82] FARIA, Paula Lobato; MOREIRA, Pedro Sá; PINTO, Laura Souza. *op. cit.,* p. 124.
[83] GUILLOD, Olivier. *op. cit*., e 311.
[84] HOSPITAL SÍRIO-LIBANÊS. *Relatório de Sustentabilidade*. 2018. Available at: https://www.hospitalsiriolibanes.org.br/institucional/relatorio-sustentabilidade/Documents/relatorio-de-ustentabilidade-2018.pdf. Accessed on: 20 Jul. 2019.

action[85]. In the same sense, the financial reparation of the harms caused to the patient without the need to prove guilt and in an administrative environment[86] presupposes a new legal model of civil liability coupled with the system of systemic error. The examples above illustrate the path yet to be followed in the legal field with the aim of introducing, in the national order and in the daily practice of legal professionals, new ways of dealing with adverse events in health care, which include organs, instances, and forms of reparation and other mechanisms of a legal nature. Likewise, it is maintained that this innovative vision is associated with a more profound change, which was not the subject of this study, regarding the concept of civil liability in the health sphere. Consequently, it is hoped that this article will contribute to original research on the new legal framework of civil liability in the field of health care.

## Final Considerations

The occurrence of adverse events and, eventually, harm to patients as a result of health care is inevitable; what can and should be done is to reduce it to a minimum, the central role of patient safety. For this purpose, legal mechanisms must be adopted by States with a view to contributing to the cultural changes advocated by patient safety. In the same sense, ensuring patient rights and making them effective obviously contributes to the reduction of harms and the increase in the quality of health care. Therefore, it is essential that there is a thorough review of the Brazilian legal framework in order to adjust it to the new legal mechanisms implemented in different countries and to a conception of responsibility in the healthcare environment that takes into account the fair culture and the systemic error. It is concluded that the Brazilian model, centered on the judicialization of medicine, leads to the weakening of the bonds of trust established between health professionals and patients and to the expenditure of excessive material and human resources by the State and by the parties involved in the lawsuits, without the result of the legal action guarantees the expected satisfaction of the demands; and, still, there is no systemic improvement in the quality of health services as a result of lawsuits.

[85] GUILLOD, Olivier. *op. cit*., e 311.
[86] SOHN, David H. *op. cit.,* p. 49-56.

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Aline Albuquerque – Post-doctorate in Human Rights at the Human Rights Centre at University of Essex (England); post-doctorate in Health and Human Rights at the Institute of Human Rights at Emory University (United States). Accredited Professor of the Post-Graduation in Bioethics from the *Universidade de Brasília* (UnB). Brasília/DF, Brasil. E-mail: alineaoliveira@hotmail.com

Arthur Regis – Doctorate and Masters in Bioethics from the *Universidade de Brasília* (UnB). Advogado. Brasília/DF, Brasil.