The onus probandi inversion in characterizing medical error by the Brazilian Law

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Resumo O erro médico é um dos temas mais instigantes no debate em torno da judicialização da medicina. No Brasil, mais de dez anos após a elaboração do Código de Defesa do Consumidor, constata-se considerável aumento na abertura de processos por erro médico. O dispositivo normativo da inversão do ônus da prova, resultante das mudanças na legislação advindas da Constituição de 1988, constitui indubitável ganho jurídico, político e social. No entanto, do ponto de vista ético-profissional o dispositivo normativo interfere diretamente em uma instituição social que deve ser preservada: a relação médico-paciente. Essa relação definiu ao longo da história o papel social do médico não como mero prestador de serviço, mas como aquele que está legalmente habilitado, tecnicamente apto e socialmente legitimado para exercer a arte da medicina.

Palavras-chave: Erro médico. Prova pericial. Defesa do consumidor. Inversão do ônus da prova. Legislação. Carta magna. Papel do médico.

Just as everywhere in the world, superposition of legal events to medical activity has been growing, during the last decades, in Brazilian society. Medical error is one of the major and challenging topics in this superposition. Bringing to surface the intersection of legal (inversion of the burden of proof) and political (the 1988 Constitution and changes in Brazilian legislation) event within the scope of patient-physician relationship, the current text intends to incite debate on the judicial realm of medicine. With the target novelty, that highlights vital intersections to the bioethical context, the approach to the topic adds up to several publications about medical error.

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Many authors have painstakingly dissected the conceptual elements involved in the problematic of the medical error, which have greatly contributed to the recognition of unarguable importance of the burden of proof while legal instrument. Despite this ascertainment, it should be highlighted the shaking that such legal instrument can cause to patient-physician relationship– that is why if in one hand positive gains are emphasized and desirable of

this legal instrument, in the other hand, it contrasts the threat that misunderstanding such rule can cause to this relationship.

This threat perceived when a medical error was an issue in TV news about one year ago. At the time, in national broadcasting, it was disseminated that in the last six year suits involving malpractice had a 200% increase in Brazil – the majority relates to labor care and plastic surgery cases. At the end of the reporting, an opportune observation on the Consumer Protection Code regarding the patient-physician relationship stating that it *is not reduced to a service renderer and a consumer* [1].

One of the topics of the complex and relevant interaction between medicine and Law is sheltered under the designation of *medical error*. For the nonprofessional, the mentioning of the expression brings up the notion that the doctor has done something wrong, causing some kind of harm to patient. For a lawyer or a doctor, for the bioethicist or specialist in law philosophy, the expression evokes mainly concepts. While a lawyer or a doctor may attain to the exercise the art of training and the philosopher to dissect theories in his creative isolation, it will be for the bioethicist to search to comprehend the process from its definition to medical error evidences and consequences. Thus, it is crucial for the bioethicist to have, first, the conceptual delimitations that follow his task. Bearing in mind that the audience for this article is primarily composed by medical-doctors and other professionals of the health sector, often not to fond of legal expression, it is fit, in order to make reading easy, to state the concept of a few essential terms for better understanding, such as responsibility, medical act and subject-matter jurisdiction.

Responsability

Responsibility is a term that evolved in the legal context and it expresses the obligation that an individual has to comply with the established by convention or by law. *Civil responsibility*, based in the Roman maxim of *not injuring anyone*, implies that once anyone causing harm to another, he is obliged to repare or compensate for the harm unfairly done. In the evolution of legal regime, isolated rules regime was abandoned in order to adopt the Lex Aquilia or Aquilian Law, characterized by a systemized regime in such way that all losses caused to someone, derived from a certain type of action, are liable to punishment[2,3].

Thus, *subjective responsibility* rises from an understanding of the Aquiline Law, which searches to reach the damage beyond illicit attribute, that is, author's culpability gets special relevance. Therefore, either by willful misconduct or guiltily or even by mere negligence, the author is obliged to repair it. While subjective responsibility is based in guilt, presupposing a certain level of predictability of infringement to the right of other, *objective responsibility* is based in risk. Based on risk theory, the evidenced occurrence of harm is enough to make responsible the one whose activity causes

its existence. It applies to both to corporations under public and private law, renderers of public service. They have to prove that they did not make the error. The liability element is the damage nor guilt – just as in subjective responsibility in which whomsoever accuses has the burden to provide the evidence [2,3].

Generally, the term *hyposufficiency* was applied in relation to consumer and supplier to characterize a disadvantageous situation of the first related to the latter. Therefore, it requires that in case of damage for the first, he is not forced to provide evidences, since he is considered in a disadvantageous position or hyposufficient. The burden of proof that normally would be of the plaintiff becomes a liability of the accused: the supplier. Currently, in the context of patient-physician context, predominant understanding among Brazilian judges applies to cases where there is a lack of capacity for the patient to provide evidence. It is understood: such presumption is not aprioristic and general, considering that patient would be, in any case, in disadvantage in relation to physician, but only in instances in which, yes, he would be in considerable disadvantage in providing evidence. Example: conflicts involving radiotherapeutic, chimiotherapeutic or other extraordinary means of treatments, whose access to information and material necessary to provide evidence exposes the patient to an undeniable disadvantage situation in relation to physician. Given the hyposufficiency, the similarity of a consumer-supplier relatioinship applies to this case, the burden of proof inversion, falling into the medical-doctor and accuses such obligation[2,3]. It is should be noticed that some of the medical specializations, such as aesthetic plastic surgery, get differentiated approach, where the burden of results not of means is attributed to the specialist[4].

Medical act

The approach to *medical error* forces the accurate understanding of its meaning, differentiating it from its common understanding where the physician's action links to an expectation of cure – and in the worst hypothesis, to a non-improvement. The patient's imaginary, or that of the society at large, hardly has the possibility that after clinical intervention the final status achieved could be worse than the previous one; or less still, that a situation with unwanted or unforeseen result be achieved.

It should be noticed that we do not refer to expectations supported in rational process, but rather in those that rely in society's general imaginary, which can include the physician himself and, very often, other health professionals. These expectations reflect representations that social imaginary builds on physicians, in general, and on the knowledge and practices of medicine, in special. They are expressed in several behaviors adopted in the patient-physician relationship or in the references to such relationship, as well as behaviors associated to it, perceivable by the collectivity.

Definition, in force, of medical act set by the Federal Council of Medicine (CFM) through Resolution no. 1,627/01 as *every technical-professional procedure practiced by legally qualified doctor*[5]. This means that accountability for damage to patient as approached now applies exclusively to the relationship involving a professional. It should be highlighted that, despite painful and delaying processing, it is underway in the Senate the bill on Medical Act (PL 7,703/06) [6], which regulates the exercise of medicine and establishes the physician's exclusive act – which, after approval, will go for presidential sanction.

Subject-matter jurisdiction

According to definitions listed in the reference vocabulary[7], subject-matter jurisdiction is that which *is said of the thing, material (economic value) or immaterial (moral interest), that constitutes or may constitute object of jurisdiction*. In reality, this definition passes by a broad spectrum of authors and thinkers, mainly those who dedicated themselves to the relation between jurisdiction and moral: from Plato to Kant or from Hart to Habermas, valuable contributions encompass this relation and favor arguments that provide definition of *subject-matter jurisdiction*.

The notion of subject-matter, and the moral Law that is bonded to it, both describes and prescribes human behavior, a finding achievable by resorting to classics in philosophy and thought, and to analysis of the bonds of law and word, as Hart and Habermas[8,9] did it so well, for instance.

It is in his own image and of the world surrounding him that man bases knowledge; epistemology that lends him the concepts and meaning that, at every age, permitted him to define good and evil.

In this context, definition of subject-matter jurisdiction results from the interaction of self-attributed bonds; of progressive disconection between religion, moral and Law, as well as of growing institutional life in society, culminating, at pinacle of Illuminism, with the State as guarantor of conventions and goods under its guardianship. Without diminishing the importance of so many other thinkers of subject-matter jurisdiction, Plato, Kant and Habermas are presented here as respresentatives of three instances when the notion of *subject-matter* stops been something external to human being, and to become internal and recognized in reason; finally, to be established in relation to speech in communication process[9,10,11]. They are different understanding of *subject-matter* and the bond of individual to the notion of good and of law. It is in the contours of this understanding that draws State's role in the guardianship of this good.

The *subject-matter*, which medicine deals since its beginning[12], offers an excelent transition example from tradition to law made positive in official law when prescription of human behavior in social relations is approached. Medicine also is a fertile ground for questioning to enlargement of State intervention in these relations – which even when the limits of the approach proposed in this text are considered, it is present.

Major foundation of Western philosophical thought, relevant to current approach, is born with Plato (427-347 A.C.): his belief in ideas, mainly in the most elevated one – that of the good. Plato extracts [13,14] a key-concept for a whole path of concepts that dominated western philosophy, even if his theory looses, generally, importance among philosophers later on. The Idea of good, adopted by Augustine (354-430) and Thomas Aquinas (1224-1274), the idea of good will last not only in Christian thought and in modern conception of God but also in the philosophy of Law[15,16].

Kantian rationalism arises as a dividing line between the old and modern thought. Kant condemns traditional speculation in metaphysics, as for him we cannot have knowledge of the world beyond what it appears to us, thus, revolutionizing epistemology and metaphysics. He does not only oppose platonic thought as He inaugurates faith in reason. The supreme good is with the morally good will, of the individual when complying with his duty. Man is not Just a theoretical being, but one that acts. Kant establishes major division between old, medieval and modern by placing action and on human will the *duty* of action and, consequently, its subjection to ruling of reason [15,17,18,19].

Jointly with the criticism of Lights, which extends to kantian rationalism, seems to have begun a disconstruction of concept until then attribute to believes and values that led, as it is credited, to the saddest political events in human kind history– críticism that until now spills on legal positivism[18]. Instrumentalism attributed to Lights and relativism brought in post-modern speeches if faced by Habermas who, through his theory of communicative action [20], recovers the illuminist idea of social consensus, giving a new dimension to philosophy of Law. Within the scope of current approach, it should be Said that it is in language and in the action of communication that *good* stablishes, via consensus and linked to discursive competence, and its link to components of the linguistic community, conferring validity and legitimacy to the prescription of behaviors; at same time, it also configures the link level to norm, that is, the coercive force of good to be under tutelage.

It is worth highlighting that if within the scope of episteme occurs the displacement of lessons from the past to lessons to the present, and from lessons of the present to the intentions of the future, the notion of *good* and of *subject-matter* will also suffer the influence of this displacement. That is how the forevision of damage, or of its simple possibility, already starts claiming the State tutelage. This displacement better perceived in contemporary claims related to environment and genetic heritage, for example, sinthesized by Hans Jonas in his *principle of responsability*[21].

Despite the different theoretic-philosophical or pragmatic-legal standpoints pertinent to debate, it suffices for the purpose of current topic the understanding of “subject-matter” as been everything that is valuable for human being or for society and,

therefore, under State tutelage through legislation that protect them. The following are examples of subject-matter: life, health, freedom, property, marriage, family, honor; finally, values that are important to society. Subject-matter, therefore, is everything that is protected by legislation in force in a country, expressing something valuable for society and deserving State tutelage.

Injury is a tutored subject-matter that constitutes a crime itself. This is a relevant and central feature in preparing Medical Act bill, but it does not seem to receive due attention by involved actors, either favorable or against Bill 7,703/06. It should be noticed that, in this context, medical act is not restricted to a professional performance that requires technical competence, as often has been claimed by oppositors to a normatization stage, just as established in other societies. Its legalization implies the understanding that the State exercises its tutelage on subject-matter, such as life and health, through a professionally qualified and duly recognized physician – reason why current debate in Brazil for its approval did not occur in those places.

The setting of medical act under the form of Law is part of understanding not only professional competences, but as well in the form of the *state of law* to tutor subject-matter valuable to society: life and health. This understanding of medicine and of professional doctor, in its meaning and institutional role, seems to be not so well consolidate not only by the society as, in general, by health professionals themselves.

The implications derived from adopting exotic text in Medical Act bill may have repercussion both in shared accountability that will be subjected other actor– in addition to doctor, in the health care context – and, mostly, in the tutelage that the *state of law* is committed to in reference to subject-matter such as life and health. At least as text departs from the coherence required by the Brazilian legal system recently adopted, starting with the 1988 Constitution. In relation to medical professional exercise, the *state of law* punctuates, coherently, in addition to requirement of an academic degree (or diploma), as well as the requirement of professional recognition by the State that, in Brazil, takes place with registration in the council of medicine.

Physician's exclusive acts do not restrict to technical competence in a particular procedure. The fact that even for student attending his last year in a medical college, it is prohibited to act without the legal support of qualified doctor, not been enough for him to prove that, after years of training, he considers himself capable to undertake a given procedure, is exemplifies well this.

The burden of proof inversion

If the proposed topic is the *burden of proof inversion* in the specific case of medical error in the Brazilian legislation, the first point to be approached will be, necessarily, that one without which

there would not be any speeches about medical error: the presumption that someone suffered a damage derived from the action or omission of a medical professional. The damage or loss that, independently of its nature, moral or material, generates an unbalance[2].

This claim, originated from the unbalance in the professional relationship, will characterize *accountability*. In fact, accountability for damage or loss could arise from any social relationship, but as this article deals with the professional relation established between a doctor and a patient as the specific kind of social relationship, reflection restricts, particularly, to a relational mode. In legal context, accountability implies the duty to indemnify damage, as a way of reestablishing the balance in the social or professional relationship. The accountability concept is, thus, a dividing line between the notions that a nonprofessional has about what is a medical error and of what justifies this designation.

The checking of damage occurrence to a patient in the professional relationship leads to legal, administrative, or disciplinary penalties. In order for a medical professional be accountable for a medical error, that is, to have the obligation to indemnify for the damage to restore lost balance in professional relationship, attention must be paid to criteria that attribute guilt or willful misconduct to him. Characterization of guilt or willful misconduct requires that there is damage and the cause-effect relation between the professional and the claimed damage[2,3,22,23]. José de Aguiar Dias[24] sinthesizes very well the requiremnts for characterizing guilt or willful miscondut applicable to patient-physician professional relationship, which implies accountability for the professional: 1) a verified damage or loss is necessary, independently of its nature: material, moral or other; 2) there must be a causal nexus relation between the action practiced by physician and the attributed damage; 3) force majeure or victim's exclusive guilt overturns the claim for physician's civil suit accountability, as it suppresses the causal nexus; 4) legal or administrative authorization does not free physician from accountability.

Once the elements that characterize professional's accountability for medical error are understood, the question is: *and what about the burden of proof inversion*? In characterizing medical error, this inversion would constitute a simple legal occurrence minor relevance in the current topic if it was not for the concomitance of events that establish the bizarre relation between two article in the Consumer Protection Code (Art. 14, § 4º; Art. 6º, VIII) [25] and a topic of crucial interest for bioethics: the patient-physician relationship.

The Consumer Protection Code (Law no. 8,078/90) went in force, at the begining of the 1990s, with the mentioned Art. 14, § 4º, it conferred a special feature to doctors' accountability by establishing that it was investigated by means of guilt verification, as generally established for other liberals. Additionally, it adopted in its Art. 6, VIII, the *onus probandi incumbit actori* theory (the burden of proof is on the author) aiming at giving to the patient more balance in the defense of his rights, bearing in mind the

fragility of consumer-patient status. As mentioned, the inequality of the relationship between a doctor and a patient has, in legal language, the designation of *hyposufficency*. It represents in the patient the debility caused by illness and in the doctor the mastering of knowledge. The burden of proof inversion means, thus, a simple normative device of exception before which the defendant is the author, justified by the hyposufficency attributed to patient[2,3,25,26]. Despite the non unanimity among authors regarding legal nature of the medical professional's act, either extracontractual or contractual – what in certain way returns to whom has the burden of proof –, the fact is that the burden of proof inversion in terms medical civil responsibility began to have legal support in the Consumer Protection Code [2,27].

The intersection of legal and political events of major relevance for this topic is set, but it is not just that. It will be present in several topics discussed under the scope of bioethics in the Brazilian context. This simultaneousness of events, converging to bioethics field, becomes a decisive period, for us, in the beginning of the 1990s. The 1988 Constitution gets the certification status that the country would be committed in the construction of a *lawful denicratic state*[28], fertile ground for the new *medical ethics of modernity*. The massive dissemination of cases involving medical professional's exercise in gross errors scandals and in unhuman and morally reprehensible trials, which in large portion of Northern Hemisphere got space in mass communication media since the 1970s[29], also arrived in Brazil with a few years delay. However, just as in the rest of the world, as consequence of freedom of press, an outcome of the *democratic transition*[30,31]. The new Magna Carta and the redefinition of constitutionally guaranteed individual rights also pointed toward the configuration of an autonomist ethics, compatible both to liberal democracies and to bioethics, which in Europe and in the United States became a field of knowledge.

Therefore, it was in this climate of *neatly writing out Brazil* that Consumer Protection Code establishes the *burden of proof inversion* mechanism as innovative and challenging element for the patient-physician relationship. It is mostly challenging when the legal context is not anymore a reference, but the ethical-professional context of the relationship, markedly paternalist since its genesis. It cannot be forgotten that this relationship, a classic topic in medical ethics, expresses intrinsic social values that reflect in the understanding of social roles performed by doctors and patients.

The new contractual model suggests an implicit understanding that the patient expects from the doctor, above all, the rendering of a competent specialized service. It is unarguable the relevance of technical competence, indispensable even to characterized the doctor in the professional relationship. However, technical competence is not enough. The counter-paternalist *ethos* of modern medical ethics seems misunderstood, if virtue and trust, symbols of Hippocratic trust of medicine, are

relegated to a second level and the medical professional transmuted into an evidence provider.

Attention is to be paid that the problematic is not only in a doctor be, depending on the legal pertinence, requested by a judge to provide proof. The core of the issue rests in the interference of the new legal device in the quality of patient-physician relationship. In this sense, it seems problematic and dangerous if, particularly in the case of this relationship (that cannot be summarized into a common instance of consumer-supplier), the effort to turn parties materially equal (by means of distribution of the burden of proof) overlays the request that doctors should pay attention to values as trust and humanitarian treatment to their patients.

It is pertinent in such context to question: do the ill person vulnerability and the hyposufficiency in question have the same nature of that one which recognizes consumer as the weaker party in relation to supplier? What consequences, in the medium and long terms, may arise from this legal device for the patient-physician relationship? There are reports, still not systemizes in literature, that in Brazil some specialist would only accept appointments patient that would allow full recording of the consultation and adopted procedures as prevention for eventual legal processes. That is, despite predominant understanding among Brazilian judges, who attribute the term hyposufficient to patients who have disadvantage in constituting proof, in which case the burden of proof inversion would apply, has had among doctors and patients, as well as among their lawyers, a not so clear view of this interpretation. Perhaps, this lack of understand may have motivated doctors to look for protection mechanism; and, in the side of unsatisfied patients, a run for indemnification – sometimes justifiable, and others not. Thus, and perhaps, be the explanation for the extraordinary growth in number of lawsuits with medical error allegations.

In one hand, the growing legalization of medical behavior certainly imposed due to the institutional and democratic consolidation process differently from what happened in recent past when, in large measure, they were legitimated satisfactorily through implicit social contract. In the other hand, the practice of a defensive medicine that, such as in the United States of America (USA), also gets contour in Brazil expresses undesirable weakening of crucial social contracts – the case of implicitly established contract in the patient-physician relationship that presupposes a relationship based in trust and humanitarian treatment. If the growing legalization of medicine constitutes cause or effect of the deterioration attributed to that relationship, it is sufficient its mention, as it extrapolates the purpose of the current approach.

The burden of proof inversion was, consequently, based in the recognition of patient as vulnerable and hyposufficient. This recognition yielded searching of mechanisms that would lighten the burden of

proof. It presupposes that there would be, thus, more balance between the parties, mostly when relationships are unequal, and in which one of the parties has more economic power, knowledge, or advantages, as it happens in consumer-supplier relationship. Inversion consists in ascertaining that, in case of proven damage, the obligation to prove a medical error does not fall on the patient but rather the doctor has the obligation to prove that he acted *lege artis* or, at least, that there is not causal nexus between alleged damage and his practice. In several European countries this burden of proof inversion, normally, requested in cases in which the doctor is accused of gross error or when he did not comply with the duty of suitably documenting the patient's health records. In Brazil, as mentioned, judges also tend to consider patient's hyposuffiency in situation in which the patient undeniably would be in disadvantaging in providing evidences.

The law, as state in Consumer Protection Code[25], leaves for the judge the task of establishing when he would use the burden of proof inversion. Despite all reserves mentioned, it is undeniable that if this innovation is well applied, it may mean a great progress to insure a patient, in higher vulnerability status, the possibility to have his rights advocated. However, the excessive increase in number of lawsuits after adoption of this normative device requires a cautioned analysis. It should be remembered that the definition of damage and the nature of accountability in medical error do not allow for a direct equivalence between the increase in the demand of lawsuits for medical errors and an – actual – increase of *proven* medical error.

Additionally, patient's protection for medical error requires preserving patient-physician relationship, not been enough to that end a measure targeted in it, as it seems to be society's interpretation on the formulation celebrated in the Consumer Protection Code.

Obviously, the legal scope itself excludes this interpretative mistake, but despite the fact that this interpretation be only known after a final court ruling, it does not get the same repercussion obtained by the processing in the society. In other words: as final court ruling does not have the same disclosure and impact that reports citing the opening of processes for medical error, the loss remains not only for the doctor's professional image in view, but also for his social role – that society itself clamors that it be rescued. It is correct that here we consider the alleged 200% increase in medical error cases as unprecedented if evaluated under a technically differentiated point of view, which requires a more accurate analysis. Regarding the ethical-professional context of the patient-physician relationship, it is necessary attention so we will not have a society in which social roles, established in a complex network of relationships and values, will not end up with doctors more concerned in how to protect themselves from the patient and in gathering evidences than with the profession's essence: which is "to care for", and not "to render a service".

Medical professional exercise characterizes for having in service rendering a consequence of care and not care as consequence of service rendering. In the exercise of medicine, the established contract is not characterized by "provide me a service: take care of me!", but rather "you cared for me, therefore you rendered me a service!".

The application of normative device in burden inversion

The issue in question is not the burden of proof inversion. It has to do with an opposition stand to its aprioristic setting previously to establishment of a patient-physician relationship, as it seems to be interpreted in instances comprising medical error processing. This opposition standpoint initially bases in findings of unwanted events, directly or indirectly, associated to the normative device in view. The extraordinary increase in the number of medical error conflicts since the institution of Consumer Protection Code; doctors' advocate standpoint that gradually outlines, either by market growth in professional insurance for civil accountability or by other advocacy extraordinary measures, even if difficult to evidence due to lack of records [1,32,33].

The issue is, when and under what situations the normative device of burden of proof inversion will be used in order to achieve targeted balance between involved parties in conflicts and in which situations this same device, within limits intended by Justice, will bring greater collective loss than the individual gain. For example, aesthetical plastic surgery, it is an obligation of results and as such, it mandates the inversion of the burden. Considering that, technological development led to rise of a *productive medicine,* in order to confer a predicate or attribute to someone who does not have it, as it happens not only with the aesthetical medicine but also, in other aspects, in reproductive medicine would the assisted reproduction techniques come to constitute an obligation of results? The line of argument that supports the obligation of results and not of means in any medical procedure, including aesthetical procedures, has a weak argumentative force as everyone looking for medical care searches to achieve only *possible* results, and never guaranteed ones. One must be aware that this reference relates to physician's personal responsibility and not to the legal entity.

Additionally, gross errors cases that often involve aesthetical plastic surgeries would not need the device that inverts the burden. It is understood as part of this group, in addition to classical gross errors, the aesthetical plastic surgeries done by physician without due technical qualification and/or inappropriate environment for the procedure. Additionally, aesthetical surgeries undertaken to fulfill exotic desires, which are incompatible with professional honesty and good sense. Such gross errors imply inclusively not only to aesthetical surgery, but to any medical procedure in any area of practice, which does not comply with basic prerequirements to medical practice and its role in the relationship.

It should be noticed that these basic pre-requirements, in the specificity of the procedure in view, comprise the essential elements for the cost-benefit analysis – in the same way that is applied to gross error characterization in cases of tubal sterilization, hysterectomy, and general surgical procedures undertaken in inappropriate environment, without blood bank or other specific pre-requirements for procedure. In the understanding advocated here, all cases included in the roll of medical act, as programmed intervention in an initial status, aiming a diverse final status and under certain technical predictability (through use of procedures duly recognized by scientific community) are subject to the nature of this act. It should be said, once again, that the approach is limited to patient-physician relationship, and does not state anything regarding objective accountability for legal entities by simple certainty of damage.

In other words: in face of the complexity governing patient-physician relationship, it is only possible to dictate rules to apply the normative device of burden of proof inversion after establishing the relationship and setting of a conflict. It is odd, under this focus, to set medical civil responsibility as having an objective nature, as a rule, for a few specific cases, exemplified by aesthetical plastic surgery. It is maintained the traditional understanding the judge will be committed to designate exceptions and to identify gross errors. Objectivity is not a sufficient condition for truth, even though crucial to Law in enforcing its function in contemporary democratic societies of complex organization: to balance conflicting interests. It suits with Habermas positive Law understanding, which establishes the difference between instrumental and communicative action, conferring preeminence to communicative rationality over strategic or instrumental rationality guided toward result.

It is the same *nature of the medical act* and the *specificities of the patient-physician relationship* – which makes, as José de Aguiar Dias synthesizes, that *neither judiciary nor administrative authorizations free the physician from the subjective responsibility* [24] – that weakens the line of argument of those that, in some cases, insist in not recognizing this nature and specificity, to attribute objective responsibility with obligation of results.

Final considerations

The burden of proof inversion consists in a normative device with legal support in the Consumer Protection Code – that in Brazil also means one of the changes brought in by the 1988 Constitution, a certificate that the country would commit itself in the construction of a *democratic legal state*. To that sense, it implies unarguably in gain not just legal, but political and social.

However, after more than ten years of its celebration that, if in one hand there was

progress in democratic consolidation, in the other hand, the patient-physician relationship may be regretfully threatened and not just by the normative device itself, but by the rule of its application. The legal path in facing social conflicts is not only prescriptive, but also as well behavior configuring. At influencing on specific social behavior, it projects a whole spectrum of future social relations. From there comes both its relevance in maintenance of public order and social security and the awareness of the necessary zeal at times of prompting changes.

Therefore, attention must be paid to adequate the physician to legislation and legislation to physician. In the first option, it is necessary to see if the case is to adequate legislation to a few physicians whose professional attitude is desirable to prevent or to physicians whose professional attitude is desirable to valuate. There are several ways to approach the fact that professionals, who are not really committed to norms governing professional activity in its three dimensions: technical, legal, and ethics seem to proliferate in Brazil.

The patient-physician relationship is the social institution that defined throughout history the role of a physician not only a mere service renderer but as the one technically fit and socially legitimated to exercise the art of medicine. Such exercise does not mean just getting expected results; to exercise this art means predominantly to manage in social relationships the abyss that sometimes is place between the expected and the achieved. Put in other way, physician acts as mediator between knowledge and patient in understanding the gap between foreseen and gotten result through scientifically acknowledged, morally admitted and legally allowed intervention

Supposing that medical error is an exception and not the rule in medicine in Brazil, and supposing, still, that the majority of our physicians comprises professionals committed and engaged in exercising the good medical art, it would be regrettable that the attempt to generate balance in cases, where patient it is seem as minority, would shaken even more the "patient-physician relationship" institution – which cannot be reduced to a cold contract, lacking historical touchstones that defined physician's social role. It is necessary to take care that legal claims, certainly growing with regulation of physician's professional activity, will not bring the legalist character reigning in the USA.

Based in previous statement, the review of lawsuits involving accusations of medical error in Brazil becomes urgent. It aims at searching for mechanism that, whenever necessary, the burden of proof inversion device be effectively a gain in the balance of an unequal relation without, however, to take the chance of a loss that overlays this gain, as it happens in other consolidated democracies. Afterall, Brazilian legislation has mirrored in other advanced democracies aiming at reducing incidence of medical errors, and not increasing it.

Despite the exceptions, the burden of proof inversion application is, within the legal realm, an undeniable instrumental gain.

But, the title itself points to its needed interdisciplinary approach: thus, the medical error topic within the Brazilian legislation context cannot be understood disassociated of democratic consolidation process, which, in its turn, requires reflection about the distinction between what could be called of *legalist state* or *state of the law*.

If the normative device of the burden of proof inversion and the growing wave of legal pursuit of medicine may be seen as indicative of progress in the State democratic consolidation, it is also indicative in parallel to this progress it must be thought about the desired dose of state intervention in social relations, more precisely in patient-physician relationship.

As example of the social relation that cannot be reduced to a mere technical competence (even if *sine qua non* condition) or solely to the implicit contract that governs (despite its historical excellence), nor reduce it to legal setting up (even in face of its importance in protecting subject-matter such as life and health). It should be highlighted, finally, that the current article intends more to promote interdisciplinary discussion in dealing with proposed topic than to advocate unison. Thus, in this discussion, the formulation given to the burden of proof may counter pose other ways of interpretation in order to enrich the still recent debates involving bioethics in Brazil.

Resumen

La inversión del *onus probandi* en la caracterización del error médico por la legislación brasileña

El error médico es uno de los temas más instigadores del debate en torno de la judicialización de la medicina. En Brasil, más de diez años después de la implementación del *Código de Defesa do Consumidor* (Código de Defensa del Consumidor), se puede constatar un enorme aumento en la abertura de demandas jurídicas alegando error médico. El dispositivo normativo de la inversión del *onus probandi*, resultante de los cambios en la legislación en Brasil, advenidas con la Carta Magna de 1988, constituye indubitable ganancia jurídica, política y social. De una óptica ético-profesional el mecanismo normativo interfiere directamente en una institución social que se debe salvaguardar: la relación médico-patiente. La relación médico-patiente es una institución social que ha definido a través del tiempo el papel social del médico, no como un mero prestador de servicios, sino como aquél que está técnicamente apto y socialmente legitimado para ejercer el arte de la medicina.

Palabras-clave: Errores médicos. Testimonio de experto. Defensa del consumidor. Inversión del

onus probandi. Legislación. Constitución. Rol del médico.

Abstract

The *onus probandi* inversion in characterizating medical error by the Brazilian Law

Medical error (malpractice) represents one of the most exciting themes concerning the judiciary status of medicine. In Brazil, more than ten years after the elaboration of the Consumer Protection Code, can be seen an enormous increase in lawsuits trials regarding medical errors. The onus probandi inversion, a normative divice resulting from changes at the Brazilian Law and by the 1988 Constitution, is certainly a juridical, political and social gain. From professional ethics point of view, the normative mechanism interferes directly a social institution that must be preserved: the physician-patient relationship. The physician-patient relationship consists of a social institution, which historically defined physician´s social role not just as a service renderer, but as the one that is not only legally licensed, but technically able and social legitimated to exercise the art of medicine.

Key words: Medical errors. Expert testimony. Consumer advocacy. Onus probandi inversion. Legislation. Constitution. Physician's role.

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