

# Judicialization of post-vaccinal adverse events

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## Abstract

Science has made important contributions to improving people's well-being, achieving remarkable advances that protect them from illnesses. Vaccines are one such example, and serve as a tool to improve the lives of the global population. Vaccines have risks the consequences of which are not fully known, however, making surveillance systems that neutralize or reduce adverse events vital. In Brazil, vaccination policy is "compulsory", restricting the autonomy of the individual, who as a "victim" of adverse events then needs to seek redress through legal action, as the State does not have a national compensation policy. With the support of Bioethics and human rights, this article aims to analyze Brazilian judicial decisions, demonstrating that judicialization is not the best way to solve problems arising from adverse events caused by vaccines, and that there is a lack of preparation among the professionals involved, as well as contradictions, insecurities and injustices in decisions.

**Keywords:** Bioethics. Vaccines. Cost-benefit analysis. Legal responsibility. Human Rights.

## Resumo

### Judicialização de eventos adversos pós-vacinação

A ciência trouxe importantes contribuições para a melhoria do bem-estar do ser humano, surpreendendo com criações que buscam protegê-lo das enfermidades. Vacinas são exemplo, funcionando como instrumentos de melhoria de vida da população mundial. Entretanto, vacinas apresentam riscos cujas consequências não são completamente conhecidas, sendo importante a presença de sistemas de vigilância que neutralizem ou diminuam os eventos adversos delas provenientes. No Brasil, a política de vacinação é "compulsória", restringindo a autonomia do indivíduo, que, quando "vítima" dos eventos adversos, precisa judicializar suas demandas, pois o Estado não possui política nacional de compensação de danos. Este artigo visa, com o apoio da bioética e dos direitos humanos, analisar as decisões judiciais brasileiras, demonstrando que a judicialização não é o caminho mais justo para dirimir problemas surgidos pelos eventos adversos das vacinas, havendo despreparo dos profissionais envolvidos, contradições, inseguranças e injustiças nas decisões.

**Palavras-chave:** Bioética. Vacinas. Análise custo-benefício. Responsabilidade legal. Direitos humanos.

## Resumen

### Judicialización de eventos adversos post-vacunación

La ciencia ha aportado importantes contribuciones a la mejora del bienestar del ser humano, llegando a sorprender con creaciones que buscan protegerlo de las enfermedades. Las vacunas son un ejemplo de ello, funcionando como un instrumento de mejora de la vida de la población mundial. Sin embargo, las vacunas presentan riesgos cuyas consecuencias no se conocen por completo, siendo importante la presencia de sistemas de vigilancia que neutralicen o disminuyan los eventos adversos provenientes de éstas. En Brasil, la política de vacunación es "obligatoria", restringiendo la autonomía del individuo, que cuando es "víctima" de los eventos adversos, necesita judicializar sus demandas, pues el Estado no posee una política nacional de compensación de daños. Este artículo procura, con el apoyo de la Bioética y de los Derechos Humanos, analizar las decisiones judiciales brasileñas, demostrando que la judicialización no es el camino más justo para dirimir los problemas surgidos a partir de los eventos adversos de las vacunas, existiendo una falta de preparación de los profesionales involucrados, contradicciones, inseguridades e injusticias en las decisiones.

**Palabras clave:** Bioética. Vacunas. Análisis costo-beneficio. Responsabilidad legal. Derechos humanos

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Scientific development has enabled health in Brazil and in the world to greatly advance in quality, allowing improvements in the life and health of the population. Vaccines are one of the most important technological advances in fighting diseases worldwide. However, they can also cause harm to some people, such as paralysis, orchitis, generalized injuries, encephalitis and convulsions, thus generating moral conflicts that need to be discussed and resolved.

The risk of damage caused by adverse events following immunization (AEFI) is much lower than the risk of contracting the target disease. However, when this damage occurs, it entails civil liability of the administration and, consequently, the need to repair the so-called moral and material damages. Vaccines are essential for the development of humanity, but it can not be allowed that people have their personal and fundamental rights to autonomy, physical integrity and health restricted or harmed. In addition, it is necessary to combat the lack of State assistance to victims of AEFI.

Vaccines, due to various economic interests, end up being placed in the market without exhausting all possibilities of tests for product safety. They go through procedures that are faster than they should<sup>1</sup> and without due concern for compensation policies for adverse events. With this, the vaccines end up causing harm to some individuals, who need to request the intervention of the Judiciary so that their rights are guaranteed. This article questions whether judicialization would be the most appropriate way to reach a fair and effective decision and promote social welfare.

Bioethics as an impartial tool proves to be elemental to this question, contributing to an equitable, critical and perhaps moral analysis of vaccination and its judicialization, especially in relation to issues related to AEFI, with reference to the Universal Declaration on Bioethics and Human Rights (UDBHR)<sup>2</sup>.

### Vaccines and bioethics

The compulsory vaccination policy increased the responsibility of the individual for his health and, indirectly, for the health of the community, characterizing utilitarian politics. Although utilitarianism is paramount in public health, it affects the autonomy of people and thus generates conflicts, which need to be analyzed and discussed and, above all, solved. Moral conflicts involving

vaccination became more visible and questioned after the focus of attention of the population, earlier on rare diseases and now on the safety and risks of vaccines, making uniform and absolute vaccination positioning difficult.

A more detailed study of the possible negative effects of vaccines on human beings is of paramount importance, as well as educating the population about these issues, so that people search for their rights and demand from the State a fair vaccination policy, from the legal and bioethical point of view. By protecting the whole society, vaccines at the same time overburden too few vulnerable people who, by obligation, end up being victims of AEFIs and abandoned by the State, even though they also hold the right to health. Thus, ethical and moral conflicts between the individual and the collective, benefit and damage, autonomy and the welfare State, must be analyzed, which need to be analyzed critically, including in relation to the judicial processes that deal with the subject and are processed in the courts Brazilians.

This is the role of bioethics: to contribute to the analysis and discussion of these conflicting ethical issues, such as vaccination and its adverse events, seeking outlets that strengthen citizenship, human rights and social justice, seeking to prevent harm, cautious with the unknown, prudent with and committed to the vulnerable. The occurrence of AEFI may lead to civil liability of the administration and, consequently, the need to pay the so-called moral damages. Thus, since all are part of the same society, it is not fair that few are sacrificed to benefit the majority, without there being a compensation policy that protects their rights.

In Brazil, the responsibility deriving from AEFIs is still generically disciplined, with the other demands involving health issues, being governed by the Civil<sup>3</sup> and Consumer Defense<sup>4</sup> codes. In addition, disciplinary and ethical codes related to each category professional still argue to what extent they are sufficient to achieve fair reparation from a moral and legal point of view<sup>5</sup>. In law, liability represents the obligation to make a financial compensation for the damage arising from an act or omission of which one is guilty, directly or indirectly<sup>6</sup>. This limited concept of responsibility is not enough to achieve the goals of bioethics, because it dissociates itself from moral reasons.

For bioethics, responsibility must represent the knowledge of what is fair and necessary, within the standards set by the moral law, observed by the conscience of the members of the society to which it governs and respecting the human dignity of all<sup>7</sup>.

And it is this responsibility that this article will use to work with the vaccination policy in Brazil and its adverse events. The new concept of responsibility must have eyes for the future, for prevention<sup>8</sup>, thinking not only of the financial compensation of harm, but also of protecting inherent human rights, with the principles of human dignity and solidarity<sup>9</sup> as two of its main parameters.

Therefore, the bioethical analysis of vaccination is fundamental, because the moral conflicts that are arising are being judicialized and brought to the discussion of people who do not have the necessary technical knowledge to solve them. This can cause incalculable damage to the individual for violation of basic principles of bioethics - of paramount importance for the realization of equitable social justice - such as human dignity, autonomy, benefit and harm, solidarity, justice and social responsibility, provided for in UDBHR<sup>2</sup>.

### Health, vaccines and judicialization

Health is an indispensable right to the maintenance of human life and dignity. In vaccination policy, this right should be extended to all users of vaccines, including those affected by adverse events. The State can not protect the health of the community with vaccinations and exempt itself from its responsibility to the life, physical integrity and health of this small part of the population.

The Federal Constitution of 1988 brings health as the right of everyone and the duty of the State<sup>10</sup>, expressing the desire of the constituent legislator, and hence of the Brazilian people, to provide every citizen with the full and effective right to health. According to the World Health Organization, health is a state of complete physical, mental and social well-being, not only in the absence of disease or infirmity<sup>11-13</sup>. To have health as a universal right is a considerable step forward, but it does bring some issues that need to be debated from an ethical, bioethical, legal, political and social point of view, so that this right can be equitably accessible and used by all. Such a perspective is quite delicate in Brazil, due to the scarcity of resources, high treatment costs and deficiencies in public policies<sup>14</sup>.

The concept of justice in bioethics is linked to the idea of equity, that is, distributive justice that allots social benefits and costs in a fair and socially cost-effective manner, in a true pact of social cooperation<sup>15</sup>. In Brazil there is no distributive justice in the vaccination policy, since the burden

is borne only by a vulnerable minority of adverse events victims, who must resort to the Judiciary to see their rights enforced. Even this is not always possible, because some courts understand that post-vaccine adverse reactions are inherent damages to the vaccination itself, which is a lawful activity of the State and therefore not subject to liability<sup>16</sup>.

In Brazil, the culture of the judicialization of health, understood as the search for the action of the Judiciary Power in favor of the realization of the right to health, has been growing in strength. "Judicializing" means taking the decision on matters of broad social and political repercussion from the traditional political instances to the hands of the Judiciary, in a transference of power that influences the language, the argument and the model of social participation<sup>17</sup>.

There is no doubt about the legal legitimacy of this movement of health judicialization, since the petition to the Judiciary is the fundamental right of the individual<sup>18</sup>, guaranteed constitutionally, as a form of making effective their rights of citizenship. However, it is necessary to analyze whether the judiciary is prepared to receive and decide these moral and legal issues that involve the right to health, specifically regarding vaccination policy, since it does not only involve legal but also political, social, ethical and sanitary aspects. It is also necessary to verify the preparation of the Judiciary to act, through its decisions, as an instrument for the formation of public policies<sup>19</sup>.

The lack of technical knowledge of legal practitioners working in the Courts of Justice on the subject of health and vaccines can cause incalculable harm to the individual for violation of basic precepts of bioethics, important for the realization of equitable social justice, such as autonomy, benefit and harm, solidarity, justice and social responsibility.

Law professionals are legally well-trained and capable, but most are not qualified to perform their duties in health-related claims of a much more complex dimension involving not only the law, but also ethics, bioethics, politics and technoscience, which can lead to injustice rather than justice. The interest of the Judiciary and legal practitioners regarding the safety of vaccines and the individuals who use them is still recent, especially c the interdisciplinary approach and the way in which law and judicial decisions can contribute to improving such safety, decreasing and even extirpating adverse events.

Dialogue between the Judiciary, the Public Prosecutor's Office, the Public Defender's Office, Brazilian Bar Association (Ordem dos Advogados do

Brasil - OAB), the society and the State is urgently necessary to try to reduce this overvaluation of judicial dynamics. This is because this demand, for the most part, can not exercise true justice<sup>14</sup> and offer an effective process of citizenship construction, in which human rights and bioethical precepts can be discussed, analyzed and performed in a fairer way<sup>20</sup>.

## Objectives

The article has the general purpose of analyzing, in a systematic way and in the light of bioethics, the effectiveness of the judicialization of health as a way to resolve possible conflicts arising from vaccination and its harmful events to the health of the population, taking the UDBHR as reference. The specific objectives are to present the judicial panorama involving the AEFI and their social consequences, identifying the victims of harmful events, those responsible for damage compensation, the content of the lawsuits and the respective decisions regarding their standard of coherence and rationale. Finally, it proposes practical measures, based on bioethics and the UDBHR, to make the vaccination policy, the control and compensation of the damages arising from the vaccines morally correct and socially fair.

## Method of analysis of the judicialization of adverse events following immunization

For the analysis of the topic under discussion, a survey was carried out on the websites of Courts of Justice of all the states of the country<sup>21-47</sup> on decisions related to AEFI, using the keywords “vacinação” (“vaccination”), “vacina” (“vaccine”) and/or “eventos adversos” (“adverse events”), with selection criteria lawsuits already decided by the Collegiate of Courts by means of judgments. A delimitation was determined, limiting this study to judicial decisions on AEFI that occurred from the beginning of 2001 until the end of 2014, and only 43 decisions were found, which became the main corpus of this article.

Then, a quantitative and qualitative study of these decisions was carried out, emphasizing the number of legal actions in each Brazilian region, the quality, effectiveness and fairness of the judicial decisions on the matter and to whom responsibility for the damages caused by the vaccination was

imputed. The methods used here will have their findings presented separately in the discussion, which will be interwoven so as to allow a better understanding and contextualization of the complex phenomenon of the judicialization of the AEFI in the light of bioethics, in order to respond to the proposed objectives. The information used is public and available on the internet. For the analysis, organization and quantitative representation of the data, the resources of the Microsoft Excel 2013 software were used, when necessary.

## Analysis of court decisions on adverse events following immunization

According to the Brazilian National Council of Justice, there are a large number of lawsuits in the judiciary related to health, reaching o 300,000 according to data of 2014 48. However, there are still few cases regarding AEFI, considering the great quantity of vaccines applied in the Brazilian population. Table 1 shows that, in addition to few, actions are poorly distributed among the regions of the country, as in the Northeast region, where no decision was found on the issue in the courts of justice of their states.

**Table 1.** Number of lawsuits by Brazilian region.

Region	Events	(%)
North	2	5%
Northeast	0	0%
South	8	19%
Southeast	30	70%
Center-West	3	7%
<b>Total</b>	<b>43</b>	<b>100%</b>

Despite being few, these events are important, as they serve as a model for science, as well as material for ethical discussion on moral, political and juridical responsibility of the State and society concerning the AEFI. In the decisions, there was a vast source of information that contribute to the questioning of the judicialization of the issues involving the AEFI. Among the lawsuits there were incomplete applications, with no unit in the passive pole, with merely technical decisions, without any bioethical analysis, and many contradictory deliberations, including in the same Court of Justice, which renders a fair compensation policy for damages caused by vaccines unviable. The analysis of the decisions showed that judicialization for compensation of damages arising from AEFI is not

the most appropriate way for the promotion of social justice, as it disrespects the UDBHR for treating similar situations differently and not guaranteeing the protection of the human rights of all.

### *Victims of adverse events*

From the data collected in court decisions, 58% of the people who were affected by AEFI were in the age group with the highest number of compulsory applications of vaccines. That is, they are individuals under the age of 18, incapable of carrying out the acts of civilian life, dependent on parents, guardians, the Office of the Public Defender or the Public Prosecutor's Office to trigger the State in seeking compensation for damages suffered after vaccination. Children do indeed bear the *burden of the occurrence of an AEFI for the general benefit of the population*<sup>49</sup>. To be sure, such a proposition is true, since vaccines are not fully safe and effective<sup>50</sup>. However, such immunizing procedure is compulsory, to which children and caregivers are equally obliged, each in their social role.

Considering that compulsory vaccines are mostly applied at the stage of childhood and adolescence, there is a small difference between the numbers of actions for the benefit of minors and adults as victims of AEFI. This demonstrates that parents have not been seeking the State, either to communicate the event or to seek compensation for the damages suffered, remaining helpless and vulnerable, suffering alone the effects of vaccine damage, for lack of knowledge and support of the State.

### *The passive pole of the demand*

The decisions also showed that the victims of the AEFI and their legal representatives did not reach consensus on whom to request compensation for the damage suffered. This demonstrates that in addition to being unaware of their rights, the victims are not adequately legally advised. Considering the joint responsibility in health between the federated entities, they could trigger all those legitimated to respond for the damage suffered, but they do not, limiting themselves, in most cases, to petition only one of them, be it the municipality, the state or the Union.

The decisions analyzed also demonstrated that laboratories with good assets and that could respond for the compensation for the damages suffered by AEFI victims are usually never called to the responsibility, being excluded from the passive poles of the demands, even being manufacturers

and distributors of the product that caused the damage. Of the actions found, only one was active on the laboratory, equivalent to approximately 2% of the demands. This is a very small number, especially considering that Articles 13 and 18 of the Consumer Defense Code<sup>51</sup> dictate that producers and suppliers should be given greater responsibility, since they are aware of the adverse events that are generally stated in the vaccine's package insert.

An example is the Civil Appeal 0217366-21.2007.8.26.0100, of the Court of Justice of São Paulo (TJSP)<sup>52</sup>, filed by an adult against a medical clinic and a pharmaceutical company, with the purpose of repairing moral, material and aesthetic damages caused by vaccination against the flu, which reports having caused allergic reaction characterized by sores on the face. The action in the first degree of jurisdiction was dismissed, but it was reformed by the TJSP, which, despite this, mistakenly and without plausible reasoning, excluded the pharmaceutical company from its judgment, claiming the absence of guilt.

Without the aid of expert evidence, the TJSP decided to exclude the pharmaceutical company because it stated that the damage occurred was not related to components of the vaccine, despite stating that the said adverse event was foreseeable, and is included in the package leaflet written by the company itself. Thus, although judges can form a conviction and not be required to judge according to expert reports, it is not understood how the court could have removed the vaccine manufacturer from its moral and legal responsibility without conclusive evidence. This harms the victim of the adverse event, a vulnerable part of the process and of the entire vaccination policy.

According to the principle of rational persuasion, judges have the right to freely establish their conviction, according to critical and rational criteria to be indicated in the decision<sup>53</sup>. Therefore, in legal terms, the expert report, although cooperating with the court, is not binding on the judge, who is free to decide - including contradicting that opinion. This principle may be legally correct, but for bioethics, in cases involving AEFI, it is not always morally fair - which is defended in this article - the expert's help being essential.

The liability for the damages caused by the AEFI is joint, since health is the duty of the State, and the Union, state and municipality must repair the damage suffered, especially considering that the vaccines are part of the public health policy, attributed to all federative entities. Ideally, in order

to guarantee the fundamental right of the party and to be fair from the legal and bioethical point of view, it would be necessary to bring all those responsible together. This increases the possibility that the victim of the adverse event will benefit and that justice will be effective, which could not be observed in the decisions analyzed.

Most of the lawsuits are only against the State, others are against the municipality and others against both, demonstrating that there is no standard or uniformity between lawyers and public defenders in the search for the responsible for the damage. With this, the victim, already very vulnerable, remains in loss, because they are not having their right sought in amplitude. A legal compensation system for AEFI, such as the one existing in Germany, Japan and France<sup>54</sup>, and preferably an extra-judicial one, could make a difference, as it would avoid such distortions and distinctions, bringing responsibility to State and laboratories and keep the vulnerable group from depending on the greater or lesser knowledge of their legal representatives to trigger the correct liable subject. Nowadays, since there is no standard system of compensation for post-vaccination damages, the individual is subject to the defense strategy of his/her lawyer or public defender, which is sometimes incomplete and not always the most adequate, causing insecurity, which, according to the UDBHR, is unacceptable and unfair.

### **The claims of the lawsuit**

The decisions analyzed reflected another problem that makes it difficult to protect the rights of AEFI victims: the lawsuits do not follow a standard in claims, either by requesting reparation for moral damages, sometimes material damages, in other cases both, and in others, aesthetic damage. The lack of standardization of claims creates an imbalance between compensations, since some subjects have their damages repaired to a greater degree than others, even when the adverse events are the same, preventing equal decisions.

For the victim of the post-vaccination adverse event, the compensation of damage under Article 10 of the UDBHR, which deals with equality, fairness and equity, must be carried out in its completeness. Therefore, the correct and complete request is of paramount importance, since, by the principle of inertia of the Judiciary, the part can not be compensated for unsolicited damage. Most AEFIs end up resulting in at least moral and material damages. However, we found actions that did not

include any of these requests, ultimately harming the victim. This again demonstrates the insecurity and lack of global protection of AEFI victims, which is not provided judicially.

The appeal made to the Court of Justice of Minas Gerais exemplifies the issue. At the time, in addition to the moral damage, there was material damage recognized, including by the judicial body, but that could not be granted because it was not requested by the victim's defender. According to the judgment, *there is no doubt as to the existence of material damage caused by the expenses that the appellant had with his son, in the face of the reactions that he had, however, those had not been pleaded by them*<sup>55</sup>.

This demonstrates the importance of establishing a unified and out-of-court legal system of compensation for damages, with its own rules and principles, based on the UDBHR, which would identify the adverse events, those responsible for the damages and compensation. Such system would avoid judicialization and situations such as the one reported, bringing more effectiveness and justice to the solution of moral conflicts involving health and vaccines.

### **Judicial provisions and the contents of decisions**

Judicial decisions were also analyzed in order to classify them as "favorable", "unfavorable" or "partially favorable". Of the 43 cases analyzed, 14 had unfavorable decisions to the proposer of the action, representing approximately 33% of the cases, while 42% were favorable and 25% were partially favorable. This situation reflects the unpredictability of the security of effective social and moral justice in cases as complex as those of the AEFI, which is called into question.

The analyzes showed that similar cases had contradictory and conflicting decisions and that those responsible/convicted for adverse events of the same nature were sometimes different, evidencing an irregular sequence of decisions. The differences between the deliberations are found, even between judges of the same state and within the same process. Of the decisions examined, it was found that approximately 74% of them differed from each other in the decisions of the first and second degrees, that is to say, they were modified when they came to the Court on appeal.

The appeal of the Court of Justice of Paraná (TJPR)<sup>56</sup> portrays the situation well. In the first-degree decision, the judge dismissed the action as unfounded

because he found that the plaintiff did not have a proven causal link between the harm and the vaccine. According to the judge's understanding, *there is no evidence that the author had reports proving his fertility prior to the event cited, in order to make it possible to establish that there is a causal link between his vaccination and his subsequent infertility*<sup>56</sup>.

The TJPR, on appeal, took the opposite view, basing its decision on a technical expert report, disregarded by the first degree court, which mentioned that *the documents attached to the case file by the plaintiff with the initial piece are in perfect nexus of temporal development, in days, preceding the vaccination campaign and succeeding the predictive and complicating event (orchitis) known in scientific circles. The treatment received by the author went to orchitis*<sup>56</sup>.

Also from the expert's report, there is the following excerpt: *3.2) is it possible to determine with precision the time in which such injuries were contracted? Expert's response: he data available data point to the event of compatible orchitis as a result of post-vaccine mumps. 3.3) What are the common causes of such injuries? Expert's response: post-vaccinal mumps. 3.4) is it possible to state, without any margin for error, that there is a causal link between the application of the vaccine and the lesions presented by the applicant, that is to say, that the direct and immediate cause is the use of that vaccine? Expert's answer: yes*<sup>56</sup>. Thus, the TJPR reformulated the decision, granting compensation for damages, ending the decision stating that *it is impossible to overlook a causal link between the vaccine and the orchitis that attacked the appellant, provoking their infertility, as also extracted from the expert's' conclusions*<sup>56</sup>.

The analysis of this decision made it possible to verify that there are still judges who decide without considering the expert report, despite its importance. Of the analyzed cases, 21% did not have an expert report, and in 38% of the cases that had it, the decisions were presented contrary to the report. The data show that the judges do not always listen to the experts before making their decisions, causing injustices to the parties involved and generating decisions contrary to the bioethical precepts of integral protection of the individual, in some cases.

Worsening the situation and fortifying the injustice and insecurity that the absence of a unified, preventive and extrajudicial system of compensation of adverse events can cause to society, it was verified, through the material analyzed, that divergences among decisions also occur between courts of justice

of different states, which judge similar cases and involve the same vaccine in contradictory ways. The Court of Justice of Rio Grande do Sul judged a petition for compensation for moral and material damages as a result of an adverse event following immunization with the Bacillus Calmette Guérin (BCG) vaccine. The court considered the action to be unfounded, considering it to be a case of subjective responsibility, in which no fault of the public administration or causal link between damage and vaccine was shown, even contradicting the opinion of the Public Prosecutor's Office on the merits of the complaint.

**Table 2.** Number of lawsuits by the presence of expert's report.

Presence of expert's report	Events	(%)
Yes	34	79%
No	9	21%
<b>Total</b>	<b>43</b>	<b>100%</b>

**Table 3.** Number of lawsuits by the use of expert's report in the decision.

Use of expert's report in the judgment	Events	(%)
Judged according to the report	21	62%
Did not judge according to the report	13	38%
<b>Total</b>	<b>34</b>	<b>100%</b>

According to the Court's decision, *the plaintiff was not successful in demonstrating the wrongful act imputed to the defendant, thus discharging its burden of proof, ex vi legis of article 333, item I, of the CPC, since in it was incumbent upon the requesting party to prove the existence of guilty conduct, especially since the responsibility of the defendant depended exclusively on the analysis of the guilty conduct of the physician, and it is incumbent on the plaintiff to prove the wrongful act occurred due to the fault of the professional doctor, causal link and the damage suffered*<sup>57</sup>.

On the other hand, the civil appeal to the Court of Tocantins<sup>58</sup>, with a similar request, resulted in an action considered to be appropriate because it was a case of strict liability, and the causal link was duly established between the harm and the BCG vaccine. According to the decision, *it is incontrovertible fact in the records that the child died due to an adverse reaction to the BCG vaccine (...). The country law adopted the objective responsibility of the State, for acts of its agents that in this quality cause damage to third parties. That is to say that it is enough to*

*cause the unjust damage perpetrated by the public agents and the proof of the causal link to generate the obligation of the State to repair the injury suffered by the individual*<sup>58</sup>.

The legal uncertainty facing the victims of AEFI is evident. It is not possible to speak of justice, the basic moral precept of bioethics, when, in the same judicial system, similar demands, motivated by similar adverse events caused by the same vaccine, have opposite results. This is almost a game of Russian roulette, infeasible to adequately resolve moral conflicts.

### Vaccination and national system of compensation of post-vaccination adverse events

The Brazilian National Immunization Program was created in 1973, contributing to the reduction and control of infectious diseases. Concerned with the maintenance of vaccination coverage rates, in 1992 the State also included the National Post Vaccine Adverse Event Surveillance System (Sistema Nacional de Vigilância de Eventos Adversos Pós-Vacinação - SNVEAPV), systematized in 1998 in the "Manual of Post-Vaccination Adverse Events Epidemiological Surveillance" (Manual de Vigilância Epidemiológica dos Eventos Adversos Pós-Vacinação), seeking to avoid the loss of society's trust in vaccines<sup>59</sup>.

The benefits of SNVEAPV are reduced because Brazil does not have a national compensation system for adverse events after vaccination. Citizens who are victims of the AEFI remain unprotected in their right to health, obliged to seek help from the Judiciary, which arbitrates without adopting an adequate system of accountability for this type of demand.

The analysis of the contents raised in the actions involving requests for reparations for damages caused by AEFI, which were processed in courts of justice of the Brazilian states until 2014, made it possible to identify that the judicialization is not the most appropriate means to obtain justice in these cases. This is because, in addition to not allowing universal access, it does not present standard procedures, being long and costly, being not isonomic and presenting conflicting decisions, it still lacks correlation with the principles of bioethics, which causes legal and moral injustice to the victims of adverse events.

The judicialization of health becomes insufficient to ensure that citizens' rights are enforced, especially when the justice system is not fully prepared to analyze certain types of demands, such as those discussed here. It is thus necessary to have real means of realizing the human rights of citizens. Thus, it is necessary for the State to see people as subjects of rights, recognizing their dignity and protecting them from any action that affronts them, there being a duty to create the ideal conditions to make that dignity feasible<sup>60</sup>.

In this way, the State can no longer wait for large-scale lawsuits related to the AEFI, more victims being harmed by the justice system, the country's immunization policy being deficient and the Brazilian population's distrust of vaccines to create a compensation system for damages. The government must act as a protector of fundamental rights and human dignity and preventively guarantee the well-being of all.

It is necessary to bring the discussion to the field of morality, of bioethics, demonstrating the importance of creating a policy of compensation for post-vaccination adverse events in place of judicialization, the State and the whole of society taking responsibility for adverse events in favor of the health of the whole community, in a type of collective moral responsibility<sup>61</sup>. In Brazil, we live in a society of solidarity, and the individual can not afford the risks of vaccination alone and, in being a victim of adverse events, one is dependent on judicialization to see one's right protected.

The victims of the AEFI, in the name of justice and solidarity defended by the UDBHR, need to be embraced by the State and society as a whole, with a compensation policy that respects human rights and socializes the risks with vaccines, providing, among other things, the removal of complex, painful and costly judicialization. Valid suggestions would be the creation of a universal and compulsory compensation and indemnity fund for the compensation of damages; regulation and standardization of compensation procedures; assistance to victims through public institutions, such as the Public Defender's Office; and creation of projects focused on education about rights.

Another suggestion to improve the compensation system for damages caused by vaccines in Brazil, bringing more security and justice to the population, would be the creation of a Court of Mediation and Conciliation of Health and Vaccination, in the manner of the Argentinian one<sup>62</sup>. It would have the function of preventing conflicts generated in the provision of the vaccination health service and to assist in



their resolution, with conciliators, mediators, public defenders, social workers and psychologists duly trained to deal with the matter, including with a background in bioethics. This would avoid further emotional exhaustion and provide a faster, humane and fair solution to the demands of this nature. Regardless of the solution adopted, the victims of the AEFI should not be left to fend for themselves in long, unequipped and unfair lawsuits in the search for their human right to health and dignity, in total disagreement with the various precepts described by the UDBHR.

The system for compensation of post-vaccination adverse events represents the realization of the State's constitutional function of protecting and promoting the human dignity of individuals by reducing the pain of victims of harm and providing them with minimum decency<sup>63</sup>. The vaccination policy, by protecting the whole collective from infectious diseases, becomes obligatory and ethically just. Likewise, it would be the compensation system for victims of post-vaccination adverse events, both for systematizing and facilitating victims' access to compensation, which has not been achieved with judicialization, and for guaranteeing the fulfillment of their rights as recommended by the UDBHR<sup>2</sup>.

### Final Considerations

Brazil needs to adopt a legal, uniform and, preferably, extrajudicial policy for the compensation of post-vaccination adverse events so that the population feels protected by the State and is willing to contribute to collective health. Judicialization has proved to be inefficient in order to equitably seek compensation for damages caused by adverse reactions to vaccines. People need to be aware of

their human right to dignity and demand from the State effective means of guaranteeing it.

Brazil can not have one of the best immunization programs in the world, with free vaccination for all, and continue without a compensation plan for damages from vaccines, leaving a portion of the population, including children, adolescents and adults, vulnerable and subjected to the fate of a judicial decision to assert their right to health. Vaccination in Brazil is the main public policy to combat infectious diseases, and without a fair compensation policy it will be increasingly difficult for the State to maintain confidence in vaccines, and now is the time for the country to face this ethical dilemma, fostered by vaccination, between collective and individual.

With the support of bioethics, it will be possible to create a compensatory policy as a corollary of the precept of justice, following the examples of others, such as the Compulsory Personal Injury Insurance for Land Vehicles (Seguro Obrigatório de Danos Pessoais por Veículos Automotores de Via Terrestre), those of the environmental field and those of the military in the reserve, based on the bioethical precepts of solidarity and human dignity. The creation of this compensatory policy of post-vaccination adverse events will bring much more social benefits than its costs, as it will increase confidence in vaccines, maintaining and even expanding vaccine coverage, thereby reducing health spending.

This way, the act of solidarity of the one who was prepared to vaccinate for the benefit of the whole community, but was a victim of AEFI, must be compensated, in the name of the bioethical precepts of human dignity, solidarity, justice and social responsibility, being the judicialization, in the bioethical view, as demonstrated by the judicial decisions analyzed, an unfair means of solving these conflicts.

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