Concept Article

Evidence-based health and the judicialization of health in Brazil

A saúde baseada em evidências e a judicialização da saúde no Brasil

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With the promulgation of Brazil's Federal Constitution, on October 5, 1988, the outlines of the public health system in the country were established, which sought inspiration from the United Kingdom's National Health Service. Its basic operating guidelines are set out in the clause 196 of the Constitution, in the provisions of Law n. 8.080 / 90, as well as a very expressive number of sparse laws[1].

It is from the institutionalization of a Unified Health System (UHS), with actions and public services organized according to a regionalized and hierarchical network (clause 198 of the Constitution), establishing more clearly, the right to health as a "right for all" and a " duty of the State", the latter being responsible for guaranteeing the entire population residing in Brazil (which, eventually and occasionally, also includes foreigners) ample access to comprehensive, universal and free health, financed with funds from the budgets of the Union, the States, the Federal District and the Municipalities, pursuant to the clause 195 of the Federal Constitution[1].

The system includes, in addition to state political people, who are the most prominent and primary recipients of the prescriptive (and sanctioning) content of the legal rules related to this topic, also the health centers and posts, public hospitals, including university students, laboratories and blood centers, as well as health, epidemiological, environmental surveillance services, as well as foundations and academic and scientific research institutes.

Three decades later, however, what is considered one of the most important milestone of Brazilian citizenship, seen by one of the largest public health systems in the world, has been showing clear signs of exhaustion. The standardization that gives the individual the right to comprehensive, universal, isonomic and free health care, generates, for the individual, the subjective public right to claim the implementation of these public health actions, without going down to greater considerations regarding the possibilities of the purse, generally precarious, but which, due to considerations immanent to the very structure of law, is capable

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of compromising the possibilities of the state to carry out the fulfillment of the obligations granted to it by the Constitution, establishing an impasse that, taken to extreme situations , characterize the impossibility of voluntary compliance, by the state entity, of the obligations established by the legislation.

This situation leads to the questioning of this state inaction with the Judiciary, which examines condemnatory provisions, which, for their assistance, consume resources destined to the health area. The state is no longer able to voluntarily fulfill its obligations, because there are no resources left. So it expects to be condemned, in a vicious circle of judicial demands that compel the public entity to provide health actions, in a phenomenon that, currently, has been called judicialization of health.

The consequences of this institutionalized model of dispute settlement that, at some point, pass through the ineffectiveness of public health management in the country, but which, on the other hand, demonstrate exacerbated voluntarisms registered in extravagant judicial decisions, range from unpredictability from the obligations to which the state will be subjected from decisions rendered in individual concrete cases, to the extreme cost of compliance with some of them, in the absence of any standardization to what may be required[2].

Perhaps the most troubling aspect of this phenomenon, which is certainly the root of the discomfort that has become inherent to the term, lies in the fact that judicial performance develops exclusively from an individual point of view. The judge provides for the plaintiff. The State / Public Administration provides for everyone. Judicialization removes the individual claim from the plexus of collective demands that shape the action of the State / Administration to implement a subjective right singularly identified with the one who filed for civil suit litigation. Therefore, it is seen as an intrusion, an unwanted continuity solution in the implementation procedure of general public health care policies, in favor of only a few beneficiaries, who had their rights recognized in the context of legal proceedings.

The precepts of Evidence-Based Health

With regard to the effectiveness and safety of new health technologies, before making a decision regarding a new treatment, one must ask: Does every new health technology bring health benefits? In other words: is it safe? Is it effective on the most important outcomes from the patient's point of view? Are there alternatives? What is the real benefit?[3]

In terms of safety, for many drugs only in phase IV, when they were already on the market, adverse events were observed that made it impossible to continue on the market. An example was the drug rosiglitazone (Avandia®). Despite the benefit in controlling diabetes, years later, its registration was suspended, as further studies associated its use with heart failure, acute myocardial infarction and death[4]. Another example was the drug rimonabant (Acomplia ®), used to treat obesity, the drug seemed promising for reducing body weight, especially waist circumference, and improving cardiovascular risk. However, after its approval, it had its registration suspended by the main health surveillance agencies in the world due to its association with adverse psychiatric events, such as anxiety, depression and suicide[5].

The best methodological quality of study to assess efficacy is the randomized clinical trial (RCT). Randomization when appropriate and accompanied by a concealment allocation balances the observable and unobservable characteristics of the study participants. Thus allowing the differences found at the end of the study to have an association of chance with the studied technology[6].

In addition to randomization, it is important that the study has sufficient statistical power to detect an effect of a given intervention, when that effect does exist. Small sample size studies are more likely to overestimate the effect of an intervention, sometimes even showing an effect, when, in fact, it does not exist[7,8].

Many health decisions are made based on surrogate outcomes. Those who do this assume that the impact of an intervention on this type of outcome would be the same on the most important outcomes from the patient's point of view. However, this assumption has often proved to be wrong[9].

In relation to risks and benefits, the current recommendation is that the studies should not focus their results on statistical significance or not[10]. This avoids giving too much importance to a statistically significant difference, but which clinically is not, and that the lack of statistical significance is interpreted as not having an effect.

Public Expenditure regarding the Judicialization phenomenum in Brazil

A study recently showed that in the state of São Paulo, from 2016 to 2018, 17% of the total expenses paid for medicines were allocated to lawsuits (R$ 679,935,967.31), and that they competed with the resources originally allocated to politics of pharmaceutical assistance[11]. Within the scope of the union, the expenses are also exorbitant, ranging from R$ 26.37 million in 2007 to over R$ 1.3 billion in 2016. In 2016, ten medications represented almost 91% of the expenses, and among them[12], the drug Soliris® (eculizumab) alone accounted for almost half of these expenses, R$ 624,621,563.43 destined for 364 patients.

Eculizumab is used to treat two rare genetic diseases, Atypical Hemolytic Uremic Syndrome (AHUS) and Paroxysmal Night Hemoglobinuria (PNH).

In 2019, the National Commission for the Incorporation of Technologies in UHS recommended against the incorporation of the eculizumab for the treatment of AHUS, under the justification that RCT's had not been carried out to assess its efficacy and safety in the treatment of AHUS[13]. The available studies, in addition to being uncontrolled, were of small sample size. Regarding PNH, despite to the evidence of the efficacy of the eculizumab using mostly substitute outcomes, the commission ruled to recommend its incorporation, subject to the fulfillment of provisionally established criteria for rare diseases[14].

Strategies to deal with health lawsuits in Brazil

Several strategies have been implemented to minimize the negative impacts of the judicialization of health in Brazil, of which we'll focus on two of them.

The first refers to the NAT-Jus digital plataform, created by Resolution n. 238/2016, a project of the National Council of Justice (NCJ), which provided for the creation of the Technical Support Centers for the Judiciary (TCJ-Jus) branch, linking court circuits across de country, with the scope of subsidizing magistrates in health lawsuits. Upon receiving this type of action, the judge may refer to TCJ-Jus, and depending on the case, the Court's own team may issue a technical opinion, or may refer it to one of the Health Technology Assessment Centers of one of the partner institutions.

The second is the recent decision adopted by the Brazilian Supreme Court (Supreme Federal Court) which, in a specific case brought to trial, established the main guidelines to be observed in actions that postulate the granting of drugs to plaintiffs. This is the Extraordinary Appeal n. 657718, in which, general lines, it has been stablished that[15]:

- The State cannot be compelled to supply experimental drugs.
- The absence of registration in Anvisa (National Sanitary Agency) prevents, as a general rule, the supply of medication by judicial decision.
- It is possible, exceptionally, to grant a judicial drug without a health record, in the event of an unreasonable delay by this agency (Anvisa) in considering the request (a period greater than that provided for in Law No. 13,411 / 2016), when three requirements are met:

  I - the existence of a request for registration of the drug in Brazil, except in the case of orphan drugs for rare and ultra rare diseases;
  II - the existence of registration of the medication in renowned regulatory agencies abroad;
  III - the inexistence of a therapeutic substitute registered in Brazil.

- Civil suits that demand the supply of medicines without registration in Anvisa must necessarily be proposed against the Federal Government, within de jurisdiction of a Federal District Court.

Final considerations

It is hoped that this decision will soon have an important impact on the multiple decisions taken in the country, within the scope of judicialization, in order to slow down the exponential growth os the expenditure curve in this area that has been occurring in the paste years.

However, it is essential that in this process the precepts that guide evidence-based health are followed. Otherwise, exorbitant expenses, aimed at the few, whose effectiveness and safety are uncertain, and which, if evaluated by methodologically adequate studies, may be maintained, results would most likely be different.

Author contributions

Nunes-Nogueira VS and Leite MSF were responsible for the original idea. Both authors participated equally in the conception of the article, writing, review and final approval.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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