Law 13,269/2016: clamor by society trumps the scientific method!

Lei nº 13.269/2016: a comoção da sociedade vence o método científico!

Ley n. 13.269/2016: ¡la conmoción de la sociedad gana el método científico!

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Synthetic phosphoethanolamine (the "cancer pill") recently made the news again, when then-President of Brazil signed *Law 13,269/2016* [1], authorizing use of the substance by patients diagnosed with cancer, despite insistent appeals to the contrary by the scientific community.

The law, with only five articles, not only allows use of the substance, but also authorizes its production, manufacture, importation, distribution, prescription, dispensing, and possession or use, despite the fact that it has not been registered with the national health authority and lacks clinical trials attesting to its efficacy.

Notwithstanding the humanistic tone surrounding the issue, *Law 3,269/2016* ignores the scientific tools – clinical trials – that are widely used to prove the quality, safety, and efficacy of medicines before releasing them for use by the population. The law also disrupted Brazil's historically consolidated national health regulatory system and the rules on health surveillance and registration of medicines [2,3,4], innovating creatively in legal terms, but without a proper scientific basis.

The registration of new drugs – and the stages that precede it – involves an important public health issue and not merely a technical and administrative requirement. During the process, the product's quality, efficacy, and safety criteria are assessed, weighing its risks and benefits. In other words, the State guarantees and takes responsibility over the product's marketing and consumption, based on the scientific evidence resulting from clinical trials.

Following a product's registration with the Brazilian National Agency for Sanitary Surveillance (ANVISA), government can monitor its wide-scale use, observing its adverse effects. In complementary fashion, but always aimed at guaranteeing the population's right to health, the agency can cancel a drug's registration, suspending its marketing and use when the health risks are observed to outweigh the benefits. Such decisions are always based on the scientific paradigm.

We should never lose sight of the fact that the efficiency of these control measures is what allows making quality medicines available for consumption by the population [5].

Based on all of the above, it is strange that the law transfers the responsibility for the consumption of synthetic phosphoethanolamine to the patients themselves or their legal representatives (article 2), a clear sign of the lack of scientific evidence to support the drug's use.

Another fact that illustrates the hasty treatment by Congress and the President is that the approval of *Law 13,269/2016* (unintentionally?) shifts the surveillance of phosphoethanolamine outside the scope of the prevailing health authority. After all, if phosphoethanolamine is not a drug, if it did not follow the established procedures for its approval and commercialization, nothing is known about which parameters will

be used to oversee its production, manufacture, distribution, dispensing, etc., leaving meaningless the sole paragraph in article 4 [6].

To claim public relevance as grounds for the use of synthetic phosphoethanolamine (article 3) does not mean to elevate it to a threshold beyond any type of health regulation. However, legislators are poorly equipped to define public relevance, because the expression neither reflects nor constitutes a legal concept. Not even this country's jurisprudence has achieved the feat of conceptualizing public relevance. The important concept is that of a Publically Relevant Service, because "*any debate on the concept of public relevance alone would be senseless*" [7] (p. 73). The dimension proposed by the legislators that drafted the 1988 Constitution when defining health services as publically relevant was to create an imperative of social solidarity, defining health services as essential, as priorities, which is inconsistent with approving a drug while disregarding research and clinical trials.

If *Law 13,269/2016* was signed into law to respond to "clamor by society", as claimed by Emília Curi, then-interim Minister of the former Ministry of Science, Technology, and Innovation, since transformed by *Executive Act 726/2016* into the Ministry of Science, Technology, Innovation, and Communication, the act represents a throwback reminiscent of the Dark Ages, when questions were answered by dogma and faith.

What is left for Brazil now is to await the Supreme Court to issue its ruling on the Direct Claim of Unconstitutionality (ADI 5501) filed by the Brazilian Medical Association (AMB) two days after enactment of *Law 13,269/2016*: will the scientific paradigm prevail again?

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