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Misoprostol on trial: a descriptive study of the criminalization of an essential medicine in Brazil

O misoprostol nos tribunais: um estudo descritivo da criminalização de um medicamento essencial no Brasil

El misoprostol en juicio: un estudio descriptivo de la criminalización de un medicamento esencial en Brasil

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Abstract

Misoprostol is a medicine with a "double" social life recorded in several places, including Brazil. Within formal and authorized health facilities, it is an essential medicine, used for life-saving obstetric procedures. On the streets, or in online informal markets, misoprostol is treated as a dangerous drug used to induce illegal abortions. In the Brazilian case, despite a rich anthropological and public health analysis of the social consequences of misoprostol's double life, there are no studies on the legal implications. This article offers such descriptive analysis, presenting and examining a comprehensive dataset of how Brazilian courts have treated misoprostol in the past three decades. It consists of an encompassing mapping of the "when, where, how, and who" of misoprostol criminalization in Brazil, pointing to the unjust consequences of the use of criminal law for the purpose of protecting public health.

Misoprostol; Jurisprudence; Control

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Introduction

Misoprostol is a synthetic prostaglandin E1 analog developed in the early 1970s, by the pharmaceutical company Searle for the prevention and treatment of gastric ulcer [1]. The drug arrived in Latin America in the 1980s under the brand name Cytotec. Registered in Brazil in 1986, Cytotec was widely available for purchase in pharmacies without prescription. With the assistance of health care workers [2], Brazilian women discovered [3,4] that the medicine caused uterine contractions, followed by cramps and heavy bleeding, sufficient to induce a miscarriage. The use of Cytotec for clandestine abortion, substituting invasive methods, led to a drastic reduction in the number of women seeking medical care due to abortion complications [5]. The practical knowledge about the medicine, developed in the context of severe criminalization of abortion, was disseminated across borders and through an informal network that included pharmacists, physicians, the manufacturer, the media, and women [3]. The social experiment also led to extensive research on the several uses of misoprostol in the fields of gynecology and obstetrics [6].

Today, abortion with pills (or medication abortion) is recognized as an efficient, safe, and inexpensive method of terminating an unwanted pregnancy [7]; with high levels of users' satisfaction [8], including outside the formal health system [9] and without the involvement of health professionals [10]. The decrease of unsafe abortion rates across low- and middle-income countries is associated with the availability and use of misoprostol in the informal sector [11]. However this medicine is not only used for abortion. A watershed discovery in the field of reproductive health, misoprostol is also indicated for management of miscarriage and post-abortion care, induction of labor, cervical ripening before surgical procedures, and treatment of post-partum hermorrhage [1,6].

Since 2005, the World Health Organization (WHO) recognizes misoprostol as an essential medicine [12], and in 2014, the organization reworked its classification of unsafe abortion to include degrees of less and least safe [13]. Misoprostol is acknowledged as a safe method, while the sourcing and use of drugs outside the formal system makes it less safe, according to the WHO, but not totally unsafe. Despite registration for obstetric use worldwide, including in Brazil [14], access to misoprostol continues to be a challenge for women and pregnant people across the world, particularly in Latin America and the Caribbean, a region with some of the most restrictive abortion laws [15].

The Brazilian case is perhaps the most dramatic. In the course of the 1990s, four concomitant events contributed to a heated public discussion about the need for greater national control over misoprostol. Firstly, the scientific documentation of greater numbers of abortion-related hospitalizations [16]. Secondly, the media dissemination of clinical case reports associating failed use of misoprostol with fetal malformations [17]. Also, the ecofeminist mobilization against the pharmaceuticalization of women's health, in the context of the 1992 Rio de Janeiro Earth Summit [18]. And, finally, the establishment of the Brazilian Society for the Surveillance of Medicines (SOBRAVIME, in Portuguese), a civil society organization whose first target was the informal supply of misoprostol [19].

In 1998, following the restructuring of the National System of Health Surveillance, the Department of Health Surveillance (SVS, in Portuguese) of the Brazilian Ministry of Health began regulating substances and medicines subject to special control in *Ordinance n. 344* [20]. Misoprostol, which had first been widely available for purchase in pharmacies and, in 1991, limited to sale by authorized pharmacies with a double-copy prescription [21], was now included in the long list of *Ordinance n. 344*, periodically updated by the Brazilian Health Regulatory Agency (ANVISA, in Portuguese). As a result, outside of authorized health facilities – that is, those expressly and previously licensed for the use of misoprostol – access to the medicine today happens in the informal market [22], where its circulation is considered illegal.

Previous studies described misoprostol as a drug with a double life in several contexts with restrictive abortion laws [4,23,24]. This approach, suggesting that medicines are things with social lives, pays more attention to their social uses and repercussions rather than their chemical structures and biological reactions [25]. Misoprostol lives a social life within formal and authorized health facilities, where it is an essential medicine used for life-saving obstetric procedures. On the streets or in online informal markets, it is treated as a dangerous drug used to induce illegal abortions. In the Brazilian case, despite a rich anthropological and public health analysis providing insights on the social consequences of misoprostol's double life, there still lacks clarity into the exact legal implications of the use,

commercialization, distribution, possession, transportation, and marketing of the drug outside the formal system. Aiming to fill this gap, a team of legal researchers produced a comprehensive dataset of how Brazilian courts have treated misoprostol in the past three decades. In this paper, by presenting and analyzing information retrieved from this dataset, I describe and explain four key dimensions: the "when, where, how and who" of misoprostol criminalization. This is the first study to analyze misoprostol in the context of criminal trials in Brazil. By providing a comprehensive picture of the regulatory framework in action, this study complements previous ones that documented the impact of criminal and public health regulation on individual experiences of engagement with the double life of the medicine [22,26].

Materials and methods

During the first semester of 2019, a team of lawyers conducted a search in the electronic case law databases of the two high courts – the Federal Supreme Court (STF, in Portuguese) and the Superior Court of Justice (STJ, in Portuguese) – and all the appellate courts, namely the 26 states and one Federal District Courts of Justice and the five Regional Federal Courts (TRF, in Portuguese). The research team searched for the keywords "cytotec" – "citotec" – "misoprostol" – "medicamento abortivo" – "medicamento para aborto" – "pílula abortiva" and found 331 judicial decisions, containing one or more of these words, issued between 1988 and 2019, all of them of criminal nature.

The research team retrieved all the existing 331 judicial decisions, which were read and analyzed in their entirety. A quantitative and qualitative database was created using Excel (https://products.office.com/). The following information was extracted from each decision: "Court" – "Casefile number" – "Decision-making body/Rapporteur judge" – "Year of decision" – "Summary of the case, as provided in the decision" – "Criminal offense" – "Subject prosecuted" – "Amount of the medicine apprehended" – "Other substances apprehended" – "Main arguments of the opinion on the merits of the case" – "Judgment". The research did not require ethical approval because all the documents retrieved and analyzed are in the public domain.

This paper presents and explains four key features of misoprostol criminalization in Brazil. Criminalization here is understood as a form of social control that leans on threatened criminal offenses, criminal prosecution, and punishment [27]. The analysis focuses on the process whereby criminal law is deployed by public prosecutors and judges to misoprostol-related activities in the context of judicial proceedings. Therefore, it is not concerned with the outcome – acquittal or conviction – but rather with the association of one or more criminal offenses to misoprostol-related actions. The paper provides a quantitative analysis of part of the information retrieved through documentary research; and then discusses these findings in light of the historical development of public health regulation in Brazil, as well as with findings from previous studies that examined some of those dimensions, either quantitatively or qualitatively.

Firstly, the paper examine "when" the criminalization of misoprostol happens by providing a quantitative analysis of the distribution of the decisions across time.

Secondly, the paper shows "where" criminalization occurs, with a quantitative analysis of the location of the judgements based on courts' jurisdiction. Jurisdiction is the authority to hear and to decide a legal case. The Federal Justice system processes and decides, among others, crimes against the assets, services or interests of the Union and its related bodies [28]. It is organized in five geographically defined regions, each served by an appellate court. The first region embraced by the TRF-1, includes the states of Acre, Amapá, Amazonas, Bahia, Federal District, Goiás, Maranhão, Mato Grosso, Minas Gerais, Rondônia, Pará, Piauí, Roraima, and Tocantins. The states of Espírito Santo and Rio de Janeiro compose the second region, under the jurisdiction of the TRF-2. The third region encompasses the states of Mato Grosso do Sul and São Paulo and is under the jurisdiction of the TRF-3. The TRF-4 has jurisdiction over the fourth region, which includes the states of Paraná, Rio Grande do Sul, and Santa Catarina. Finally, the fifth region corresponds to the states of Alagoas, Ceará, Paraíba, Pernambuco, Rio Grande do Norte, and Sergipe and is under the jurisdiction of the TRF-5.

The jurisdiction of the Federal District and State Courts of Justice, in turn, is determined by exclusion: Everything that is not under the jurisdiction of the specialized justices (military or electoral),

or the Federal Justice, is processed and decided by state judicial bodies, according to their territorial jurisdiction. There are 27 of such courts, one in each state and one in the Federal District.

Finally, the STF hears appeals on constitutional matters and the STJ, on federal legal issues. The STF also has exclusive jurisdiction over certain types of habeas corpus and jurisdictional conflicts [28], while the STJ is responsible for processing, in ordinary appeal, habeas corpus decided by State Courts of Justice and TRFs and, originally, jurisdictional conflicts between State and Federal Courts [28]. Along with the number of cases processed by each court, the paper also offers a projection on the number of cases by the population of states and regions, using the latest data on population size provided by the Brazilian Institute of Geography and Statistics (IBGE. http://www.ibge.gov.br).

Third, the paper shows "how" misoprostol is criminalized, presenting the criminal offenses associated with misoprostol by the courts. To do this, only the criminal offenses directly referred to misoprostol-related actions were isolated by examining each decision in full, since many of the cases involve other actions also categorized as criminal. The criminal offenses are all described in the Brazilian Penal Code [29], except for drug trafficking, regulated in special legislation [30].

Finally, the paper describes "who" is criminalized for misoprostol-related actions. Using an inductive method, all of the cases were reviewed, and the categories used by the courts to describe the subjects were identified. Then, identifying the similarity of the activities developed by individuals loosely described as "street vendors", "drug dealers", "door-to-door sales", "bar owner", "seller", "internet dealer", the category "supplier" was created. Supplier (including via Internet) encompasses anyone who commercially supplies the medicine and is not included in any of the other specific categories used by the courts, which are "abortion provider", "assistant in the abortion", "buyer" (including via Internet), "carrier", "counterfeiter", "importer", "patient", "pharmacist", "physician", "pregnant women", "website administrator", "woman in possession of the medicine", and "woman who received the pills by mail". There are also a number of cases where the prosecuted subject was not characterized, which is also indicated in the results.

The when, where, how and who of misoprostol criminalization in Brazil

The analysis of "when" misoprostol is criminalized shows that the 331 decisions were issued between July 1988 and June 2019. Only 1 case was decided in the 1980s and 5 cases (1.5%) in the 1990s, on both occasions by the São Paulo Court of Justice (TJ-SP). In the 2000s, the number of cases grew considerably – 63 cases (19%), while in the 2010s, it increased dramatically – 262 cases (79.1%).

The analysis of "where" misoprostol is criminalized shows that 189 (57%) decisions were issued by State and Federal District Courts of Justice, 116 (35%) by TRFs, and 26 (7.8%) by Superior Courts (STF and STJ). Table 1 shows the number of cases each court decided in the 1980s, 1990s, 2000s and 2010s, therefore allowing for a combined analysis of "when" and "where" the criminalization of misoprostol occurs.

Figure 1 below shows the Courts of Justice, located in the states and Federal District, which were most active in misoprostol-related prosecution, providing the number of cases processed per 100,000 of inhabitants in the federative unit. The states where the number was equal to or smaller than 0 were excluded from the graph. This information is relevant inasmuch as the absolute numbers presented in Table 1 can be misleading of how active courts really are. For example, TJ-SP is the court with the highest absolute number of cases, but is not among the most active courts when the proportion between the number of cases and the state population is considered. As shown in Figure 1, the most active courts are the ones with jurisdiction over the Federal District and territories (TJ-DFT), Mato Grosso do Sul (TJ-MS) and Santa Catarina (TJ-SC).

Figure 2 shows the most active TRFs in misoprostol-related prosecution, providing the number of cases per one million of inhabitants in the regions. The regions where the number was equal to or smaller than 0 were excluded from the graph. In the case of the TRFs, the trend observed in absolute numbers is confirmed in the proportional analysis. The TRF-4 was the most active court, followed by the TRF-3 and the TRF-2.

Table 1

Number of cases by court per decade in Brazil.

Courts	1980s	1990s	2000s	2010s	%
STF	-		-	12	3.6
STJ	-	-	2	12	4.2
TJ-Acre	-	-	-	3	0.9
TJ-Amazonas	-	-	-	1	0.3
TJ-Bahia	-	-	-	1	0.3
TJ-Ceará	-	-	-	5	1.5
TJ-Federal District and territories	-	-	3	12	4.5
TJ-Goiás	-	-	-	3	0.9
TJ-Minas Gerais	-	-	1	6	2.1
TJ-Mato Grosso do Sul	-	-	3	7	3.0
TJ-Pará	-	-	1	2	0.9
TJ-Paraíba	-	-	-	1	0.3
TJ-Pernambuco	-	-	-	2	0.6
TJ-Paraná	-	-	1	5	0.9
TJ-Rio de Janeiro	-	-	1	6	2.1
TJ-Rondônia	-	-	-	6	1.8
TJ-Roraima	-	-	-	2	0.6
TJ-Rio Grande do Sul	-	-	2	5	2.1
TJ-Santa Catarina	-	-	3	25	8.4
TJ-Sergipe	-	-	-	3	0.9
TJ-São Paulo	1	5	26	44	22.9
TJ-Tocantins	-	-	-	3	0.9
TRF-1	-	-	1	1	0.6
TRF-2	-	-	-	6	1.8
TRF-3	-	-	6	38	13.2
TRF-4	-	-	13	50	19.0
TRF-5	-	-	-	1	0.3
Total	1	5	63	262	100.0

STF: Federal Supreme Court; STJ: Superior Court of Justice; TJ: Court of Justice; TRF: Regional Federal Court.

Table 2 shows "how" misoprostol is subjected to criminalization, outlining the wide range of criminal offenses applied by courts in misoprostol-related cases. It is important to note that in the majority of the cases (305 = 92.1%) only one criminal offense was associated with misoprostol-related actions. However, there are a few cases (26 = 7.9%) in which more than one offense was applied. Because of this, the total number of appearances of offenses in Table 2 is slightly larger than the absolute number of cases.

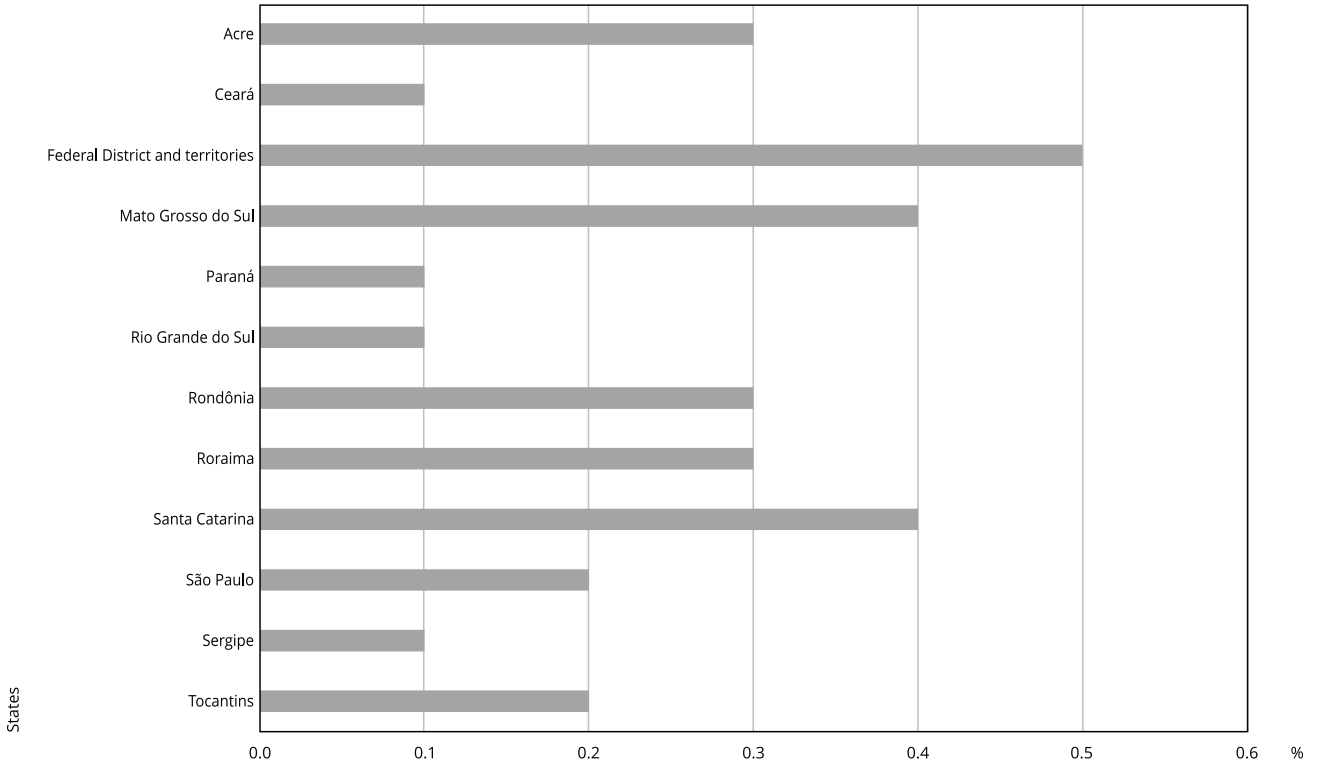
In the vast majority of the cases, the crime associated with misoprostol was a crime against public health, described in Article 273 of the Penal Code [29]. This crime was the only one associated with misoprostol in 238 cases (71.9%). Adding to this number the cases where Article 273 was combined with other criminal offenses, it appears in 257 cases (77.6%).

The second criminal offense most frequently applied to misoprostol-related actions was drug trafficking, which is defined in special legislation [30]. The crime of drug trafficking was applied in total to 33 cases (9.9%): "alone" it appeared in 25 cases (7.5%) and "in association with other offenses", in 8 cases (2.4%).

The third criminal offense most associated with misoprostol was contraband, described in Article 334-A of the Penal Code [29]. Alone, this criminal offense was applied to 18 cases. Combined with other criminal offenses, it appeared in another 5 cases. Therefore, in total, contraband is "how" misoprostol-related offenses are characterized in 23 cases (6.9%)

Figure 1

Number of cases processed by courts per 100,000 inhabitants in the states of Brazil (1988-2019).



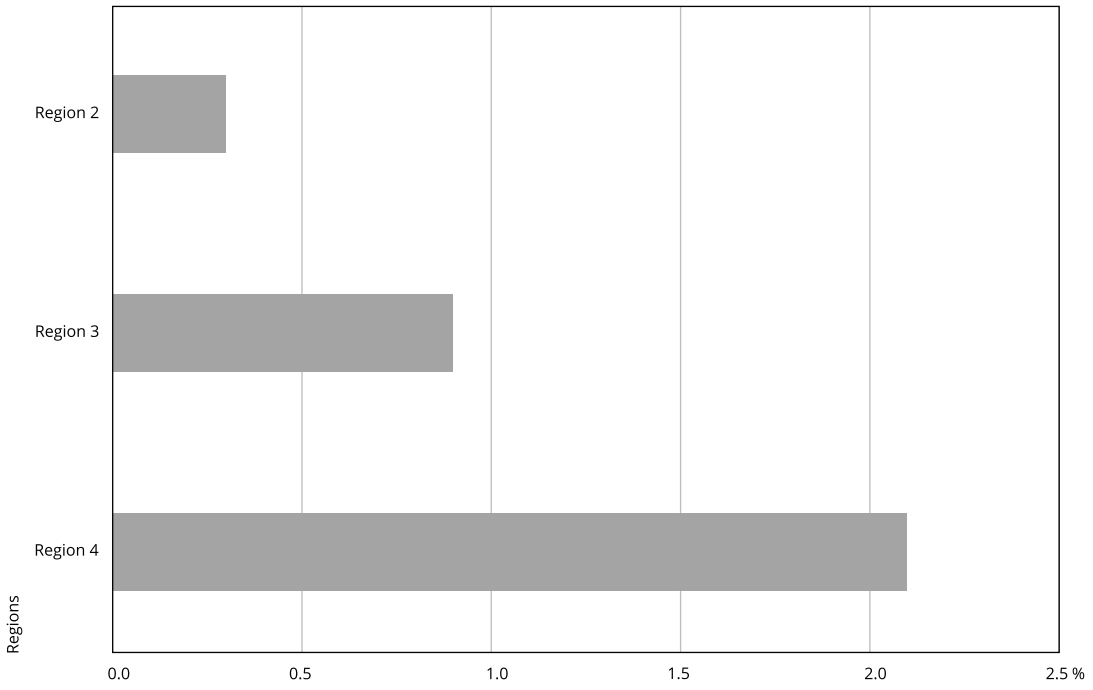
Finally, the crime of abortion was associated with misoprostol in three ways. First, Article 124 of the Penal Code [29], where the crime consists in performing an abortion on oneself or allowing another to do it, appeared alone in 12 cases (4%), and combined with other offenses in 20 cases (6%). Article 126 of the Penal Code [29] – to perform abortion with the consent of the pregnant person – was applied alone to 4 cases (1.2%) and to another 2 cases in combination with Article 127, which determines an increase of the penalty in case of serious injury or death of the pregnant person. In total, abortion offenses were associated with misoprostol in 28 of the cases (8.4%).

Another important finding is "who" figures as the active actor, that is the prosecuted subject, in misoprostol-related criminal cases. The actor most commonly prosecuted was the supplier. Table 3 shows that in 171 cases (51.6%) suppliers were prosecuted, the majority of them found with other substances besides misoprostol (110 cases = 33.2%). If we sum up the cases against all actors directly participating in the chain of commercialization, namely suppliers, carriers, and importers, we have 207 cases (62.5%) in which the prosecuted subject was involved with misoprostol commerce in one way or another. After the supplier, the pharmacist was the second most common prosecuted actor; however, in a considerably smaller number of cases (38 cases = 11,4%). It is relevant to note that the number of subjects reflected on Table 2 is larger than the absolute number of cases because in some of these, more than one person was prosecuted. In addition, in around 20% of the cases, the prosecuted subject was not characterized in the decision.

The final relevant finding is that the majority of the cases (61% – 203 cases) was not related to misoprostol alone, but also to several other substances. This finding is also reflected on Table 3, which shows the number of prosecuted actors found with misoprostol alone and those found with misoprostol and other substances.

Figure 2

Number of cases processed by courts per 1,000,000 inhabitants in the regions of Brazil (1988-2019).



Note: Region 2 (Rio de Janeiro and Espírito Santo); Region 3 (São Paulo and Mato Grosso do Sul); Region 4 (Paraná, Rio Grande do Sul and Santa Catarina).

Table 2

Number of cases in which each criminal offense is applied to misoprostol and other substances in Brazil (1988-2019).

Criminal offenses *	Cases applied alone		Cases applied in association	
	n	%	n	%
Article 124	12	3.6	8	2.4
Article 126	4	1.2	2	0.6
Article 127	0	0.0	2	0.6
Article 129	0	0.0	4	1.2
Article 158	0	0.0	1	0.3
Article 180	1	0.3	1	0.3
Article 211	0	0.0	1	0.3
Article 272	0	0.0	1	0.3
Article 273	238	71.9	19	5.7
Article 278	1	0.3	2	0.6
Article 282	0	0.0	1	0.3
Article 334	1	0.3	4	1.2
Article 334-A	18	5.4	5	1.5
Drug trafficking	25	7.5	8	2.4

* Articles from the Brazilian Penal Code [29].

Table 3

Number of prosecuted subjects by category, found with misoprostol-only and misoprostol and other substances in Brazil (1988-2019).

Prosecuted subjects	Misoprostol-only		Misoprostol + other substances	
	n	%	n	%
Abortion provider	0	0.0	1	0.3
Assistant in the abortion	2	0.6	0	0.0
Buyer (including via Internet)	5	1.5	1	0.3
Carrier	3	0.9	30	9.0
Counterfeiter	0	0.0	1	0.3
Importer	3	0.9	0	0.0
Not qualified	28	8.4	44	13.2
Patient	0	0.0	1	0.3
Pharmacist	21	6.3	17	5.1
Physician	3	0.9	0	0.0
Pregnant women	5	1.5	1	0.3
Supplier (including via Internet)	61	18.4	110	33.2
Website administrator	1	0.3	0	0.0
Woman in possession of the medicine	2	0.6	0	0.0
Woman who received the pills by mail	1	0.3	0	0.0

Discussion

The vast majority of the decisions analyzed were issued in the 2010s and had misoprostol-related actions framed as a crime against public health, described in Article 273 of the Penal Code [29]. The data reflects the relevant criminal impact of the regulatory framework of controlled substances and medicines, first introduced in the country in the late 1990s, on the informal supply of misoprostol.

In May 1998, the SVS issued *Ordinance n. 344* [18] that *"approves the Technical Regulation on substances and medicines subjected to special control"*. The regulation determines that a special authorization from the SVS is required to *"extract, produce, fabricate, improve, distribute, transport, prepare, manipulate, disaggregate, import, export, transport, package, and/or repackage for any purpose"* any controlled substance and their *"updated versions, or medicines that contain it"* [18] (Article 2). In addition, regulatory provisions specific to misoprostol establish that the drug can only be purchased by and used in health facilities previously registered with ANVISA (Article 25) and both the medicine's package and package insert must contain a risk warning for pregnant women (Article 83). More recently, ANVISA also prohibited any form of publicity or dissemination of information about misoprostol on the internet or any social media [31,32,33].

While the regulation alone does not invoke the application of criminal law, the criminalization of misoprostol and any other controlled substance or medicine – included on the list annexed to *Ordinance n. 344* – happens, in most of the cases, through its association with Article 273 of the Penal Code [29]. In the original wording of the 1940 Penal Code [29], Article 273 criminalized *"tempering with food or medicinal substance"*. For medicines, this means modifying their quality or reducing their therapeutic value, as well as suppressing or substituting any element of their composition. The offense carried a penalty of one to three years imprisonment, applied also to anyone who sold, exposed to commerce, had in deposit, or delivered for consumption the tampered medicine.

However, in June 1998, following a public demand to address a large-scale scheme of counterfeiting medicines in the country [34], the Federal Executive, in a joint initiative of the Ministries of Health and Justice, submitted to Congress, in an emergency proceedings, a legislative proposition. According to the ministries [35], the target of the new criminalization would be counterfeited medicines that, having circumvented the control of the health surveillance system, looked legit but had no efficacy.

Under the proposed legislation would also be medicines not registered with the SVS, entering the national, entering the national market through smuggling. Not only the individuals responsible for the counterfeiting and/or tempering would be under the purview of the new law, but also every person involved in any step of the process, from production to dispensation.

The new law, known as the "Medicines Act", was approved by Congress less than a month later, modifying the content and extending the reach of Article 273 of the Penal Code [29]. In its new configuration, this crime targets counterfeiting, corrupting, tampering, or altering medicine; and applies to anyone who imports, sells, exhibits for sale, has in deposit to sell, distributes, or delivers the medicine to consumption. The reform not only increased the penalty to 10-15 years imprisonment – thus, higher than murder or drug trafficking – but also included the offense in the category of heinous crime, along with rape, sexual assault, and genocide. A person convicted under Article 273 does not qualify for receiving amnesty, mercy, or pardon, neither can be granted bail or provisional release [36].

Additionally, the scope of criminalization of Article 273, §1-B reaches anyone who practices any of the actions described above in relation to medicines without registration with ANVISA or in disagreement with the registered formula; without the identity and quality characteristics accepted for its commercialization; with reduced therapeutic value or activity; of ignored origin; or acquired from a non-licensed establishment. It is through this specific provision that misoprostol, when found outside the regulatory scheme established by *Ordinance n. 344* comes under the charge of a serious crime against public health.

The fact that the vast majority of the court decisions analyzed were issued from the 2000s onward points to the effective mobilization of the new and severe regulatory framework by public prosecutors and judges, and progressively so. The increase in number of cases decided on the appellate-level from 2010 onward reflects that a much larger number of criminal investigations and prosecutions into the informal supply and use of misoprostol had been conducted on the trial-level in the previous decade. The courts becoming more active one decade after the legislative change suggests that a timespan is required for the justice system to become fully aware of the new regulatory regime and produce its own interpretation of it.

The larger number of cases processed by State Courts of Justice is explained by the fact that their jurisdiction is the general rule. However, in the misoprostol-related cases, the discussion about jurisdiction acquires some specific contours. Whenever there was "*evidence of the international character of the criminal offense*" [37], for example, that misoprostol had been imported or smuggled from overseas, the case fell under federal jurisdiction. The question of "where" misoprostol-related offenses were prosecuted acquires yet another twist when it becomes also about "how" these offenses were prosecuted.

Indeed, the second offense most commonly associated with misoprostol-related actions was drug trafficking. Such association took place in cases where misoprostol was just one substance among several other controlled substances and goods, including, for example, cocaine, marijuana, guns, ammunition, and money. In these cases, the courts did not make a distinction between the apprehended substances, avoiding the question if they were medicine or drug, the latter defined by special legislation as "*substances or products that can cause addiction*" [30]. If interpreted literally, the definition of drugs does not allow for the enforcement of the drug trafficking offense to cases involving misoprostol, given that the medicine is not addictive. However, as relevant as the discussion about the legal boundaries of the categories "drug" and "medicine" might be for these cases, these questions were not pursued in any of the 331 decisions examined. Importantly, however, is that from the point of view of the defendant, it is better to have the case prosecuted under the drug trafficking offense rather than the public health (Article 273), given that the minimum penalty for the former is much lower than for the latter (5 years versus 10 years imprisonment). For this reason, in some cases the courts declared the unconstitutionality of the penalty established in Article 273, for its disproportionality in relation to the seriousness of the crime, then applying the penalty of drug trafficking [38].

The third criminal offense most associated with misoprostol was contraband. This offense, which is charged with a much lower penalty of 2 to 5 years imprisonment, was applied when there was indisputable evidence that the medicine had been imported, but in small amount. For example, in a case of importation of 20 pills of Cytotec, the court decided that the action was irrelevant for criminal persecution because "*(a) it does not represent a social danger; (b) it does not represent a conduct with a high degree of reprehensibility; (c) it presents a minimum degree of danger; and (d) generates minimum or no risk to*

public health" [39]. Similarly, in another case where the defendant was found with 750 pills of Cytotec, the court reasoned that the amount fell under the threshold established to withdraw the application of Article 273 of the Penal Code [29], invoking, instead, the crime of contraband [40]. Noteworthy, however, is the fact that such discussion can only take place within Federal Courts, because they are the only ones with jurisdiction over contraband cases. Due to the nature of the crime, contraband involves the interest of the Union in protecting its borders against illegal importation of goods.

The rationale behind the mobilization of the criminal rule defining contraband, read alongside the specific wording of the crime against public health (Article 273), suggests that the Federal Courts, different from State Courts, are after large-scale commercialization of the medicine outside of the regulatory frame. That is to say, the extensive evasion of the public health regulation is the target of prosecutors and judges, who are willing to declassify the action to contraband if the amount of medicines does not reveal that a large commercial operation is in place.

Finally, only in few of the cases examined (8.4%) the medicine was associated with abortion offenses. In these cases, the prosecution did not target the medicine as such, but rather the practice of abortion with pills. Misoprostol was cited by the courts only because it was the method revealed in the course of criminal investigation.

The findings about "how" the judiciary tackles misoprostol-related actions as a crime against public health, or as drug trafficking, contributes to understanding previous research finding that the Brazilian media frames misoprostol as police news, in the category of illegal commerce of gender-related drugs [41]. The media is, indeed, not generating its own framing about misoprostol-related criminal cases, but rather merely reporting how the justice system – police, public prosecutors and judges – approaches misoprostol: as a controlled substance, largely commercialized in evasion of the existing public health regulatory framework. In this framing, vendors, laboratory, quantity, and quality of the drugs are more relevant than the stories of individual people who might purchase them for inducing an abortion.

The last finding concerns "who" is most commonly criminalized for misoprostol-related actions. This discovery again speaks to previous research on the matter. In more than half of the cases examined (51.6%), suppliers were the prosecuted subjects, the majority of them found with other controlled substances and illegal goods besides misoprostol (110 cases = 33.2%). In the media coverage analyzed by Diniz & Castro [41] similarly to the criminal investigations and judicial cases examined by Diniz & Madeiro [22], the majority of misoprostol vendors are men, categorized in two profile groups. Rarer in appearance in the media coverage, but common in the case law examined in this paper, the supplier is someone with large stocks of the medicine, who offers a diversified menu of gender-related drugs, such as anabolic steroids, appetite suppressants, and fat burners, most of which not registered for commercialization with ANVISA.

The second most commonly prosecuted subject, according to my data, is the pharmacist (38 cases = 11,4%), whose profile matches the one described by Diniz & Madeiro [22] as an intermediary, someone who helps circulating the medicine either at the local pharmacy or in nearby areas. Known as the vendor of medicines, this person lives in the community and has no connection to organized crime. Not only does this person sell the medicine, but also informs people about its use, regimens, and doses, suggesting preventive therapeutic measures to control infection and other complications. The pharmacist is someone who has been present throughout the entire social life of misoprostol in Brazil. The first sales of the medicine for the purpose of abortion documented in the 1990s happened in pharmacies. On the other hand, in the judicial proceedings here examined, similarly to what Diniz & Castro [41] identified in their research, women only appear when the framing changes from illegal commerce of medicines to medication abortion, that is, in less than 10% of the cases.

The data examined suggests, nonetheless, that the justice system is not so much interested in the small-scale provision of drugs maintained by the pharmacist. Summing up the cases prosecuted against actors participating in the chain of large-scale misoprostol commercialization – namely suppliers, carriers, and importers – there are 207 cases (62.5%) in which the prosecuted subject is involved with misoprostol commerce, in one way or another. The pharmacist, on the other hand, only makes up for less than 15% of the cases.

Also, the finding that misoprostol prosecution occurs alongside other substances corroborates an earlier research finding, misoprostol is only another drug in a large catalogue of controlled substances

and medicines commercialized outside the regulatory regime [41]. However, the number of misoprostol-only cases identified is not irrelevant. They make up 39% of the sample. This number points to the need of further qualitative research into a possible institutional investment in dismantling the existing informal market that allows for misoprostol to live its social life as an abortifacient outside the formal system, thus fulfilling a life-saving role and allowing people access to an essential medicine.

Conclusion

Previous research on the social life of misoprostol in Brazil examines its use for clandestine abortion [2,3,5,22,26], its portrayal by the media [41] and in public health research [17], and its location in an intricated regulatory framework [4]. However, one important site of misoprostol's social life is the justice system, responsible for enforcing the regulatory framework that produces of its double identity as both a highly controlled and putatively dangerous substance, and a life-saving essential medicine.

The justice system criminalizing the informal supply of misoprostol, an important harm reduction measure [42] in the context of great restrictions to abortion, reveals something relevant for the future of public health policy. Courts need to be educated about the role and importance of essential medicines, and the urgency of access to them. A different interpretation of the breach of *Ordinance n. 344* in misoprostol-related actions could emerge if prosecutors and judges were conscious of the life-saving character and safety of the drug [43]. Rather than a crime against public health, the informal supply of misoprostol could indeed be framed as a bottom-up harm reduction measure, one that reveals both the need to remove misoprostol from the scope of *Ordinance n. 344*, and the injustices produced by the use of criminal law for the rhetorical protection of public health [44].

Additional information

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Resumo

O misoprostol é um medicamento com uma "dupla" vida social registrada em vários lugares, inclusive no Brasil. Nos serviços de saúde formais e autorizados, é considerado um medicamento essencial, utilizado para procedimentos obstétricos que salvam vidas. Nas ruas ou nos mercados informais online*, o misoprostol é tratado como um medicamento perigoso, usado para induzir abortos ilegais. No caso brasileiro, apesar de uma rica análise antropológica e de saúde pública das consequências sociais da vida dupla do misoprostol, não há estudos sobre as implicações jurídicas. O artigo oferece essa análise, apresentando e examinando um amplo banco de dados sobre o tratamento dado ao misoprostol pelos tribunais brasileiros nas últimas três décadas. Ele consiste em um mapeamento. Consiste em um mapeamento amplo do "quando, onde, como e por quem" da criminalização do misoprostol no Brasil, apontando as consequências injustas do uso do direito penal em questões de saúde pública.*

Misoprostol; Jurisprudência; Controle

Resumen

El misoprostol es una medicina con una "doble" vida social registrada en varios países, incluyendo Brasil. En los centros de salud formales y autorizados, es una medicina esencial, usada en procedimientos obstétricos que salvan vidas. En las calles o en las tiendas en línea informales, el misoprostol está considerado como una peligrosa medicina usada para inducir abortos ilegales. En el caso brasileño, a pesar del rico análisis antropológico y de la salud pública sobre las consecuencias sociales de la doble vida del misoprostol, no existen estudios de sus implicaciones jurídicas. Este artículo ofrece este análisis, presentando y examinando un banco de datos completo de cómo las cortes brasileñas de justicia han tratado el misoprostol en las últimas tres décadas. Consiste en un exhaustivo mapeo del "cuándo, dónde, cómo y quién" respecto a la criminalización del misoprostol en Brasil, señalando las injustas consecuencias del uso del derecho penal en cuestiones de salud pública.

Misoprostol; Jurisprudencia; Control

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