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In the name of public health: misoprostol and the new criminalization of abortion in Brazil

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ABSTRACT

This article explores the criminal regulation of misoprostol as a controlled drug in Brazil as a new form of abortion criminalization. A qualitative analysis of Brazilian case law shows how the courts use a public health rhetoric of unsafe abortion to criminalize the distribution of misoprostol in the informal sector. Rather than an invention of the local bench, this judicial rhetoric reflects global public health discourse and policy on unsafe abortion and the double life of misoprostol as both an essential medicine and a controlled drug. In contrast to previous studies, the article shows that abortion criminalization is not the cause, but rather the consequence of misoprostol's double life. In the last section, it draws on an outlier judgment of the case law to chart a regulatory future for misoprostol and its supply in the informal sector as a site of harm reduction and safe abortion in public health policy.

KEYWORDS: abortion, drug control, misoprostol, new criminalization, public health

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I. INTRODUCTION

In¹ the 1990s, Brazilian researchers were among the first to document the informal use of misoprostol as a harm reduction measure.² Contra-indicated for use in pregnancy, but widely known by word-of-mouth, Brazilian women with the support of health care providers creatively misused the drug in a highly restrictive legal environment to have safer abortions.³ Brazil is credited as the birthplace of self-managed abortion, the sourcing of abortion drugs and their use to end a pregnancy outside of formal health care systems, or in the informal sector⁴—today, a worldwide practice.⁵ This experiential knowledge circulated from homes and streets to laboratories and hospitals worldwide, later leading to scientific confirmation of misoprostol's abortifacient properties. Formulated as a tablet, thermostable and with a shelf life of several years, misoprostol causes cramping and bleeding akin to heavy menstruation or early miscarriage.

Indeed, many of the working-class women first recorded using misoprostol in north-eastern Brazil did not associate the drug with abortion, but used it as a preventative measure against the risk of pregnancy.⁶ As such, the consumption of the drug had the purpose of regulating menstruation, that is, 'to re-balance the body, release "curdled" blood, and start menstrual flow without the moral judgment associated [...] with abortion.'⁷ Researchers have documented a similar use of misoprostol today among Peruvian working-class communities, where the drug lives its social life as part of a larger family of pharmaceuticals, including combined oral contraceptives and

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- 1 The authors are grateful to Leticia Ueda and Carla Vitória for their help in collecting and organizing the case law discussed in this paper.
 - 2 M. Klitsch, *Antiprogestins and the Abortion Controversy: A Progress Report*, 23 FAM. PLANN. PERSPECT. 275–282 (1991); Regina Maria Barbosa & Margareth Arilha, *A Experiência Brasileira com o Cytotec*, 2 REV. ESTUD. FEM. 408–417 (1993); Helena Lutécia Coêlho et al., *Misoprostol: The Experience of Women in Fortaleza, Brazil*, 49 CONTRACEPTION 101–110 (1994); S. H. Costa, *Commercial Availability of Misoprostol and Induced Abortion in Brazil*, 63 in INTERNATIONAL JOURNAL OF GYNECOLOGY AND OBSTETRICS (1998).
 - 3 MARGARETH ARILHA, THAÍS DE SOUSA LAPA & TATIANE PISANESCHI, *ABORTO MEDICAMENTOSO NO BRASIL* (2010).
 - 4 The terms 'formal' and 'informal' sector distinguish between a set of actors, markets, and sectors in the use and supply of misoprostol. The 'formal sector' generally refers to a set of actors and arrangements that are officially authorized to use and supply misoprostol by written state policy, and which are usually confined to the formal health care system. The 'informal sector,' in turn, refers to the use and supply of misoprostol, and related activities, which do not have the explicit authorization of the state and may even be prohibited by it, but enjoy some degree of legitimacy by virtue of social practice and acceptance (Hans-Joachim Lauth, *Formal and Informal Institutions*, in ROUTLEDGE HANDBOOK OF COMPARATIVE POLITICAL INSTITUTIONS 56–69 (Jennifer Gandhi and Rubén Ruiz-Rufino, 2015). The term 'informal sector abortion' is widely used in the field, and generally refers to abortion activities undertaken outside of the formal health care system. See Sonia Chemlal & Giuliano Russo, *Why Do They Take the Risk? A Systematic Review of the Qualitative Literature on Informal Sector Abortion in Settings Where Abortion is Legal*, 19 BMC WOMEN'S HEALTH 55 (2019).
 - 5 Joanna N. Erdman, Kinga Jelinska & Susan Yanow, *Understandings of Self-Managed Abortion as Health Inequity, Harm Reduction and Social Change*, 26 REPRODUCTIVE HEALTH MATTERS 13–19 (2018); Heidi Moseson et al., *Self-Managed Abortion: A Systematic Scoping Review*, 63 BEST PRACTICE AND RESEARCH: CLINICAL OBSTETRICS AND GYNAECOLOGY 87–110 (2020); Mariana Prandini Assis & Sara Larrea, *Why Self-Managed Abortion is so Much More Than a Provisional Solution for Times of Pandemic*, SEX. REPROD. HEAL. MATTERS (2020).
 - 6 Marilyn K. Nations et al., *Women's Hidden Transcripts About Abortion in Brazil*, 44 SOC. SCI. MED. 1833–1845 (1997).
 - 7 *Id.* at 1842.

emergency contraception pills.⁸ For many of the women using the drug in the impoverished neighborhoods of Lima, it is not an abortifacient. Ideas of time and of when life begins, widespread in Andean culture, allow the interpretation that misoprostol is rather a thing that prevents pregnancy from happening. Such understanding of the drug, shared by both Peruvian and Brazilian women, is compatible with their moral values and religious beliefs: By taking the pills, they are not performing a sin or any moral wrong, but rather maintaining their health, blood flow, and overall wellbeing. In other words, they exercise some control over their reproductive lives.⁹

This was not the intended purpose of misoprostol, originally developed and marketed by G.D. Searle & Company under the brand name Cytotec, and approved by national drug regulatory agencies across the world for the biomedical indication to treat gastric ulcers.¹⁰ Yet misoprostol has proven an effective, safer, and increasingly popular drug in many low-resource settings where abortion laws are restrictive.¹¹ Cheap generic misoprostol products are today ubiquitous and informal supply channels continue to grow, including drug sellers, online services,¹² feminist initiatives,¹³ and community-based networks.¹⁴

In 1986, misoprostol was first registered under the brand name Cytotec in Brazil for use in the treatment of gastric ulcers and sold in pharmacies and drug stores without prescription.¹⁵ With the ease of availability, the sale and use of misoprostol for abortion, or more generically to prevent pregnancy, was widely practiced, but also well publicized, and eventually coverage in the Brazilian press of misoprostol's 'misuse' sparked a heated debate about greater regulatory controls, including withdrawal from the market.¹⁶

In 1991, the Brazilian government enacted regulations that limited misoprostol sales to authorized pharmacies with a double-copy prescription¹⁷ under the justification that

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- 8 Rebecca Irons, *Post-Coital Pharmaceuticals and Abortion Ambiguity: Avoiding Unwanted Pregnancy Using Emergency Contraception and Misoprostol in Lima, Peru*, in *CRITICAL MEDICAL ANTHROPOLOGY: PERSPECTIVES IN AND FROM LATIN AMERICA* 90–115 (Jennie Gamlin et al., eds., 2020).
 - 9 Nations et al., *supra* note 6; Irons, *supra* note 8.
 - 10 Paul W. Collins, *Misoprostol: Discovery, Development, and Clinical Applications*, 10 *MED. RES. REV.* 149–172 (1990).
 - 11 Nina Zamberlin, Mariana Romero & Silvina Ramos, *Latin American Women's Experiences with Medical Abortion in Settings where Abortion is Legally Restricted*, 9 *REPRODUCTIVE HEALTH* 1–11 (2012); Jennifer Conti & Erica P. Cahill, *Self-managed abortion*, 31 *CURR. OPIN. OBSTET. GYNECOL.* 435–440 (2019).
 - 12 Chloe Murtagh et al., *Exploring the Feasibility of Obtaining Mifepristone and Misoprostol from the Internet*, 97 *CONTRACEPTION* 287–291 (2018).
 - 13 Mariana Prandini Assis & Sara Larrea, *supra* note 5.
 - 14 RJ Gomperts et al., *Using Telemedicine for Termination of Pregnancy with Mifepristone and Misoprostol in Settings where there is no Access to Safe Services*, 115 *BJOG AN INT. J. OBSTET. GYNAECOL.* 1171–1178 (2008); Kinga Jelinska & Susan Yanow, *Putting Abortion Pills into Women's Hands: Realizing the Full Potential of Medical Abortion*, 97 *CONTRACEPTION* 86–89 (2018); Naomi Braine, *Autonomous Health Movements: Criminalization, De-Medicalization, and Community-Based Direct Action*, 22 *HEALTH HUM. RIGHTS* 85 (2020).
 - 15 Helena L.L. Coelho et al., *Selling Abortifacients over the Counter in Pharmacies in Fortaleza, Brazil*, 338 *THE LANCET* 247 (1991).
 - 16 Katherine Wilson, Sandra G. Garcia & Diana Lara, *Misoprostol Use and its Impact on Measuring Abortion Incidence and Morbidity*, in *METHODOLOGIES FOR ESTIMATING ABORTION INCIDENCE AND ABORTION-RELATED MORBIDITY: A REVIEW* 191–201 (Susheela Singh, Lisa Remez, & Alyssa Tartaglione eds., 2010).
 - 17 A double-copy prescription is a prescription issued in two copies, one of which must be retained by the pharmacy and later subjected to formal inspection by a body of regulation and control.

Cytotec was being misused for illicit purposes.¹⁸ While these restrictions limited the availability of the drug, with declining pharmacy inventories, and created new barriers to access, sales of the drug nevertheless increased.¹⁹ Throughout the 1990s, a parallel increase in abortion-related hospitalizations, clinical case reports associating informal misoprostol use with fetal malformations,²⁰ a targeted campaign orchestrated by newly created Brazilian Society for the Surveillance of Medicines (SOBRAVIME)²¹ and an ecofeminist mobilization against the pharmaceuticalization of women's health spurred continued debate over the need of greater regulatory control.²²

Eventually, misoprostol became subject to a brutal regime of criminal enforcement in Brazil through the 1998 restructuring of the National Health Surveillance System and the creation of a list of controlled substances, to which it was added. *Portaria n° 344/1998* (a federal ordinance) restricted the possession and use of misoprostol to registered hospitals for narrowly prescribed uses, and required special authorization for the production, import, distribution, and packaging of the substance or any medicine containing it.²³ More recently, the National Health Surveillance Agency (ANVISA hereafter), responsible for enforcing the ordinance, restricted any publicity or dissemination of information about misoprostol on the internet or social media.²⁴ Although these are administrative regulations, breach of them constitutes a criminal offense.

This article explores the criminal regulation of misoprostol in Brazil as a new form of abortion criminalization, which reflects global public health discourse and policy on unsafe abortion and the double life of misoprostol as an essential medicine and controlled drug. A growing biographical literature on misoprostol, since its development in a northern Chicago suburb laboratory in the 1970s, all share a preoccupation with the drug's 'social life,' and, particularly, its 'double life' as an illegal abortifacient and a life-saving essential medicine.

Most previous studies on the social life of misoprostol treat criminalization as the independent variable, a cause of misoprostol's double life.²⁵ This article, in contrast, shows how new forms of abortion criminalization are emerging as consequence rather

18 Brasil. Ministério da Saúde. Secretaria Nacional de Vigilância Sanitária. *Portaria n° 101* (Brasília, 1991); Brasil. Ministério da Saúde. Secretaria de Vigilância Sanitária. *Portaria n° 27* (Brasília, 1986).

19 Costa, *supra* note 2.

20 Ilana Löwy & Marilena Cordeiro Dias Villela Corrêa, *The 'Abortion Pill' Misoprostol in Brazil: Women's Empowerment in a Conservative and Repressive Political Environment*, 110 AM. J. PUBLIC HEALTH 677–684 (2020).

21 Mariana Prandini Assis, *Misoprostol on Trial in Brazil: A Descriptive Study of the Criminalization of an Essential Medicine*, CAD. SAUDE PUBLICA (2021).

22 Mariana Prandini Assis, *Liberating Abortion Pills in Legally Restricted Settings: Activism as Public Criminology*, in THE ROUTLEDGE INTERNATIONAL HANDBOOK OF PUBLIC CRIMINOLOGIES 120–130 (Kathryn Henne & Rita Shah eds., 2020).

23 Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Portaria n° 344* (Brasília, 1998), https://bvsms.saude.gov.br/bvs/saudelegis/svs/1998/prt0344_12_05_1998_rep.html.

24 Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Resolução n° 911* (Brasília, 2006); Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Resolução n° 1050* (Brasília, 2006); Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Resolução n° 1534* (Brasília, 2011); Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Resolução n° 753* (Brasília, 2017).

25 Silvia de Zordo, *The Biomedicalisation of Illegal Abortion: The Double Life of Misoprostol in Brazil*, 23 HIST. CIENCIAS, SAUDE—MANGUINHOS 19–35 (2016).

than cause of misoprostol's double life through an elective affinity²⁶ between the progressive global public health agenda to end unsafe abortion and the ideology of biomedical drug control systems.

Part I of the article introduces the theory of the social lives of medicines and describes key aspects of misoprostol's double life. By reference to a case law analysis on criminal misoprostol-related charges in Brazil, Part II shows how the courts have interpreted and applied the 'crime against public health' to the informal supply of misoprostol. The analysis focuses on the public health rhetoric of the judicial reasoning, in particular, the assumed truth of illegal abortion as unsafe abortion. Rather than an invention of the Brazilian bench, Part III explores how this judicial rhetoric reflects global public health discourse and policy on unsafe abortion and the double life of misoprostol within it. Part IV then draws on an outlier case from the Rio Grande do Sul Court of Justice to chart a regulatory future for the supply of misoprostol in the informal sector as a site of harm reduction and safe abortion in public health policy.

II. THE DOUBLE LIFE OF MISOPROSTOL

While medicines are material things, whose specific chemical structures produce discernible biological effects in a living organism, they are much more.²⁷ As mobile things, medicines move from hands to hands and across contexts, regulatory regimes, and borders. They are exchanged between an array of social actors, in an equally diverse set of transactions, having biomedical, economic, political, social, and religious value. Many medicines are used in ways that were never intended by their developers or manufacturers, and thus acquire different meanings for different people in different moments, while also affecting social understandings about events, processes, and time. In sum, medicines have social lives: They themselves are actors, tangible things living multiple lives with and between people through acts of manufacturing, trading, advertising, prescribing, buying, caring, and consuming. Medicines 'use people as much as people use them.'²⁸

As social things, whose socialization and interpretation reach beyond any pharmaceutical truth, medicines can also have their biographies written.²⁹ The biographies of medicines can be written from the perspectives of those who interact with them and each other, the different stages of their making, distribution, use and afterlife, and the surrounding environments thereof.³⁰ Such approach follows the thing as it evolves in relation to the contexts and interacting actors. The biographies of misoprostol are many. Since its discovery in 1973 by a large pharmaceutical company,³¹ the drug has had complex and multiple social lives in laboratories and pharmacies, clinical and clandestine settings, and national and global regulatory regimes.

26 J. I. Hans Bakker, *Elective Affinity*, in THE BLACKWELL ENCYCLOPEDIA OF SOCIOLOGY 1352 (George Ritzer ed., 2007).

27 SUSAN REYNOLDS WHYTE, SJAAK VAN DER GEEST & ANITA HARDON, SOCIAL LIVES OF MEDICINES (2002).

28 *Id.* at 157.

29 Anita Hardon & Emilia Sanabria, *Fluid Drugs: Revisiting the Anthropology of Pharmaceuticals*, 46 ANNU. REV. ANTHROPOLOGY 117–132 (2017).

30 *Id.*

31 Collins, *supra* note 10.

A myriad of social actors has interacted, shaped, and transformed the value of misoprostol: manufacturers, scientists, researchers, physicians, pharmacists, traffickers, abortionists, feminist activists, and those seeking some control over their reproductive lives. Misoprostol has also shaped and transformed key concepts in reproduction, understandings of contraception and abortion, and their regulatory regimes. Misoprostol has materially and actively engaged in a range of social events that today are pivotal for local and global reproductive law and policy.

The biographies of misoprostol continue to be written, forming a young but growing literature of diverse disciplines and localities.³² Yet, these biographies all share a common thread: misoprostol's double life. Though born as a treatment for gastric ulcers, misoprostol has since lived a remarkable double life (largely) off-label in the field of reproductive health. On the one hand, misoprostol lives as an essential medicine used in formal health care systems for multiple indications, including abortion, management of miscarriage, induction of labor, and treatment of postpartum hemorrhage. On the other hand, misoprostol lives and thrives underground, creatively sourced and repurposed in the informal sector, outside authorized practice, for clandestine abortion. As misoprostol moves between these lives, a lifesaving medicine and a clandestine abortifacient, it inhabits strikingly different regulatory worlds. This article explores the legal consequences of that double life, specifically the way in which abortion has been newly criminalized in Brazil through biomedical drug control systems premised on a rhetoric of public health protection.

III. A CRIME AGAINST PUBLIC HEALTH

Relatively, little legal research exists on the criminalization of abortion as a function of drug-related offenses, or drug regulation. A recent comprehensive case law review on all decisions of appellate level courts in Brazil concerned with the informal supply and use of misoprostol fills this gap.³³ The review consists of 331 judicial decisions in criminal cases between July 1988 and June 2019 which include the key words 'cytotec'—'citotec'—'misoprostol'—'abortifacient medication'—'medication for abortion'—'abortifacient pill.' Based on case law in this review, as translated from Portuguese to

32 de Zordo, *supra* note 25; Seydou Drabo, *A Pill in the Lifeworld of Women in Burkina Faso: Can Misoprostol Reframe the Meaning of Abortion*, 16 INT. J. ENVIRON. RES. PUBLIC HEALTH 1–13 (2019); Margaret E. MacDonald, *Misoprostol: The Social Life of a Life-Saving Drug in Global Maternal Health*, XX SCI. TECHNOL. HUM. VALUES 1–26 (2020); Sydney Calkin, *Transnational Abortion Pill Flows and the Political Geography of Abortion in Ireland*, TERRIT. POLIT. GOV. 1–17 (2020); Irons, *supra* note 8; I. H. Solheim et al., *Beyond the Law: Misoprostol and Medical Abortion in Dar es Salaam, Tanzania*, 245 SOC. SCI. MED. 1–9 (2020); Ilana Löwy & Marilena Cordeiro Dias Villela Corrêa, *The 'Abortion Pill' Misoprostol in Brazil: Women's Empowerment in a Conservative and Repressive Political Environment*, 110 AM. J. PUBLIC HEALTH 677–684 (2020).

33 Assis, *supra* note 21. This review included a comprehensive case law search in the official online databases of all appellate courts—state and federal—as well as high courts. The 331 judicial decisions were identified and read and analyzed in their entirety. A quantitative and qualitative database was created using Excel, containing the following variables: '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.' While there are limitations related to the fact that only appellate decisions were included, the percentage of cases that, in general, reaches appellate courts in Brazil is high. In 2019, 23 per cent of the cases reached state courts and 25 per cent, federal courts. CONSELHO NACIONAL DE JUSTIÇA, *Justiça em números 2019* (2019).

English by one of the co-authors, a native speaker of the language, this section explains how Brazilian appellate courts have used a public health rhetoric of unsafe abortion to criminalize the distribution of misoprostol in the informal sector.

While all the cases in the review have as their object one or more criminal offenses, they are unevenly distributed by time and offense which reflect the features of abortion criminalization through drug regulation. Of the 331 judicial decisions reviewed, only six are dated before 2000 (one decision in the 1980s, and five decisions in the 1990s). After the enactment of *Portaria n° 344/1998*, which restricted the possession and use of misoprostol to registered hospitals and required special authorization for its production, import, distribution, and packaging, the cases increase dramatically—and the nature of the offense involved shifts too. Most of the 331 decisions date from after 2000 (63 decisions in the 2000s, and 266 decisions in the 2010s).

Of these decisions, only 26 cases (8 per cent) involve a charge under Articles 124 and 126 of the Penal Code, the abortion offenses.³⁴ In these cases, misoprostol is mentioned at trial only as the method used and revealed during criminal investigation. A further 56 cases (17 per cent) involve contraband or trafficking offenses, a class of crimes concerned with the illegal movement and trade in prohibited drugs.³⁵ The contraband cases generally involve the import of small quantities of misoprostol: an individual with four or six tablets found in the home, assumed for personal use. Rarely in the case law are the accused individuals who purchased or used the drugs with the intention to end their own pregnancies. Rather 195 cases (59 per cent) involve subjects directly implicated in the commercialization of misoprostol. In the trafficking cases, the accused is often found with large quantities of misoprostol, or misoprostol among large quantities of other illicit drugs as part of a generalized drug trade.³⁶ Moreover, these suppliers are often arrested in large operations orchestrated by the Federal Police, in which firearms, ammunition, and money are also involved.³⁷

34 Article 124 of the Penal Code: To cause an abortion on oneself or to consent that another cause. Penalty—Imprisonment of 1–3 years. Article 126 of the Penal Code: To cause an abortion with the consent of the pregnant person. Penalty—Imprisonment of 1–4 years.

35 Article 33 of *Lei n° 11.343*: To import, export, remit, prepare, produce, manufacture, acquire, sell, exhibit for sale, offer, have in deposit, transport, bring with it, store, prescribe, administer, deliver to use or provide drugs, even if free of charge, without authorization or in violation of legal or regulatory determination. Penalty—Imprisonment of 5 (five) to 15 (fifteen) years and payment of 500 (five hundred) to 1500 (one thousand five hundred) days-fine. Paragraph 1. The same penalties apply to those who: I—import, export, ship, produce, manufacture, acquire, sell, expose for sale, offer, supply, have in deposit, transport, bring with it or keeps it, even free of charge, without authorization or in disagreement with legal or regulatory determination, raw material, supply, or chemical product for drug preparation; II—sow, cultivate or harvest, without authorization or in disagreement with legal or regulatory determination, of plants constituting raw materials for drug preparation; III—use a place or property of any nature that own, possess, administer, guard or supervise, or consent that others use it, even free of charge, without authorization or in disagreement with legal or regulatory determination, for illicit drug trafficking. Two offenses can be described as contraband: Articles 334 and 334-A of the Penal Code. They include the circumventing of tax due on entry, exit or consumption of goods and their commercialization (Article 334) and the import or export of illicit goods and their storage or commercialization (Article 334-A).

36 While most cases (61 per cent—203 cases) is not related to misoprostol only, but also involve other substances, the number of misoprostol-only cases is not irrelevant (39 per cent—128 cases).

37 Debora Diniz & Rosana Castro, *O comércio de medicamentos de gênero na mídia impressa brasileira: Misoprostol e mulheres*, 27 CAD. SAUDE PUBLICA 94–102 (2011).

The overwhelming majority of the misoprostol cases—238 (72 per cent)³⁸—concern the offense of Article 273 in the class of *Crimes Against Public Health* in the Penal Code. In its original 1940 wording, Article 273 targeted counterfeit or adulterated medicines, by prohibiting tempering with a medicinal substance to modify its quality or reduce its therapeutic value, suppress any element of its normal composition, or substitute for one of inferior quality.³⁹ The offense captured anyone who sold or otherwise delivered an adulterated substance for consumption.

In 1998, the same year the National Health Surveillance System was restructured, Congress reformed Article 273 in response to an alleged large-scale drug counterfeiting scheme.⁴⁰ The provision now targets not only those who counterfeit or adulterate medicines, but also captures whoever imports, sells, exhibits for sale, has in deposit to sell or, in any way, distributes or delivers for consumption, the counterfeit or adulterated substance. In addition, the offense encompasses medicines under any of the following conditions:

- without registration, when required, with the competent health surveillance body;
- without the identity and quality characteristics accepted for its commercialization;
- with reduction of its therapeutic value or its activity;
- of unknown origin; or
- acquired from an establishment not licensed by the competent health authority.

After the adoption of *Portaria n° 344/1998*, Brazilian courts began treating any medicine containing misoprostol outside the formal system—that is, not produced by authorized laboratories and/or circulating outside authorized facilities—as without registration or of unknown origin. By labeling these medicines as ‘non-registered with ANVISA,’ the courts thereby justified the application of Article 273 to cases involving misoprostol.⁴¹

The public health crime of Article 273 is more punitive than the drug offenses of contraband or trafficking. The reform of the provision in the late 1990s recategorized the offense as a heinous crime—that is, a person convicted of the crime cannot receive amnesty, mercy, or pardon, neither can they be granted bail or provisional release⁴²—with an increased penalty from 1–3 years to 10–15 years imprisonment. By comparison, abortion offenses under the Penal Code carry a maximum penalty of 4 years, or 8 years if the illicit abortion causes death. Article 273 now carries a minimum penalty higher than drug trafficking, making the informal supply of misoprostol, a controlled

38 In another 19 cases (6 per cent), Article 273 appears in association with other criminal offences.

39 Brasil. Presidência da República. *Decreto-Lei 2.848 (Código Penal)*, de 07 de dezembro de 1940, http://www.planalto.gov.br/ccivil_03/decreto-lei/del2848.htm.

40 Brasil. Congresso Nacional. *Lei n° 9677*, de 02 de julho de 1998, http://www.planalto.gov.br/ccivil_03/LEIS/L9677.htm.

41 It is interesting to note that until 2005, Cytotec—the most common version of misoprostol that appears in the case law—was still registered with ANVISA for the treatment of gastric ulcer, thus not technically ‘without registration’ for the purpose of Article 273. Since 2001, Prostokos is registered for obstetrical and gynecological use, and from 2005 onward, it became the only version of misoprostol authorized in the country by ANVISA.

42 Brasil. Congresso Nacional. *Lei n° 8.072*, de 25 de julho de 1990, http://www.planalto.gov.br/ccivil_03/leis/18072.htm.

medicine, an offense more reprehensible than illicit drug trade. Indeed, in the case law, some defenders seek to substitute a drug trafficking charge to avoid this extraordinary penalty.

Under prevailing doctrinal interpretation, Article 273 is also a crime of *abstract nature*; that is, the mere performance of the prohibited action regardless of intent or effect is sufficient for conviction. Article 273 creates a class of public health crime in the mere possession or supply of misoprostol. In the 1990s, Cytotec was available through pharmacy or drug store venues and used off-label. The presence of the drug was not itself prosecutable, or a criminal offense. This changed after 1998. As a crime of abstract nature, the offense is not consequence-based. It does not matter whether the supply poses any actual health risk or harm,⁴³ as in the cases of counterfeit or adulterated medicines where the crime is ‘of concrete danger.’⁴⁴ Rather conviction tends to follow expert evidence that the product contained misoprostol, a controlled substance, and some evidence of its unknown origin, being a foreign medicine or otherwise unregistered in the national health surveillance system. This also became easier after 2000, when the manufacturer of Cytotec left the Brazilian market, and local production began of a dedicated misoprostol brand, Prostokos, with restricted distribution in hospitals.⁴⁵ As the Superior Court of Justice explained in one case, ‘the intrinsic harmfulness . . . the injurious potentiality of the drug [is presumed by the law] . . . and does not require demonstration.’⁴⁶ The simple supply of misoprostol outside health surveillance control, in violation of *Portaria nº 344/1998*, constitutes a heinous public health crime and raises the prospect of a minimum of 10 years imprisonment.

The severity of the penalty against the abstract nature of the crime raises a constitutional question of proportionality. In some of the misoprostol cases involving Article 273, the judges expressly consider whether the act should be treated as a heinous crime. In the majority of these cases, the judges answer affirmatively for the reason that misoprostol is misused in clandestine and illegal abortion.⁴⁷ Sometimes they cite the mere abortifacient property of misoprostol as reason to consider its illicit trade heinous.⁴⁸ More often, the heinousness of the crime comes from the specific intended use of the drug in ‘*clandestine and illegal abortion*,’ cited in the case law as a major

43 GUILHERME DE SOUZA NUCCI, *MANUAL DE DIREITO PENAL* (15 ed. 2019).

44 Thiago Bottino & Alexandre Ortigão Sampaio Buarque Schiller, *Aspectos penais e regulatórios da venda de medicamentos sem registro*, 14 *REV. ELETRÔNICA DO CURSO DIREITO DA UFSM* 1–33 (2019).

45 Maria M. Fernandez et al., *Assessing the Global Availability of Misoprostol*, 105 *INT. J. GYNECOL. OBSTET.* 180–186 (2009).

46 Brasil. Superior Tribunal de Justiça. Habeas Corpus 100502/SP. Relator Napoleão Nunes Maia Filho—Quinta Turma. *Diário de Justiça Eletrônico*, Brasília, 29 mar. 2010, https://ww2.stj.jus.br/processo/revista/inteiroteor/?num_registro=200800363515&dt_publicacao=29/03/2010.

47 Brasil. Tribunal Regional Federal (4. Região). *Processo ACR 5001587–05.2010.4.04.7006 PR*. Relator Márcio Antônio Rocha. Porto Alegre, 5 jul. 2016, https://jurisprudencia.trf4.jus.br/pesquisa/inteiro_teor.php?orgao=1&documento=8351796.

48 For instance, a Federal Regional Court denied the accused’s plea to apply the principle of insignificance, given small number of pills apprehended (50 pills) because the ‘nature of the medicine, potentially harmful given its illegal use as an abortifacient, does not allow the use of that principle’ (Brasil. Tribunal Regional Federal (4. Região). *Processo ACR 0007216–28.2008.4.04.7002 PR*. Relator Luiz Carlos Canalli. Porto Alegre, 12 dec. 2012, https://jurisprudencia.trf4.jus.br/pesquisa/inteiro_teor.php?orgao=1&documento=5356588).

cause of maternal death and disability.⁴⁹ The judges tend to focus on the scale of the impact, the ‘significant number of people’ endangered by the ‘irregular importation’ and ‘unlawful commercialization’ of large quantities of misoprostol of unknown origin.⁵⁰ The heinousness of the crime resides in its public health harm.⁵¹

A case from the state of Paraná illustrates well how the courts invoke illegal abortion as a public health harm to justify the application of Article 273. In 2010, a man and a woman driving a car from Paraguay into Brazil were stopped by the police in the small town of Garapuava. The police found in their possession 50 pills of Cytotec, in addition to many erectile dysfunction pills and anabolic steroids. In upholding their conviction under Article 273, a Federal Regional Court described the criminal provision as having the purpose of preventing the country from becoming an uncontrolled market of ‘open air pharmacies’ in the form of ‘street vending.’⁵² The defendants argued for their crime to be reclassified as contraband given the small amount of the medicine in their possession. The Court denied their plea, reasoning that their conduct exposed many people to the health risk of using an unregistered medicine without medical supervision in the course of an illegal abortion.

The Minas Gerais Court of Justice applied similar reasoning to a case of a street vendor, caught by police while selling Cytotec in a busy public square in Belo Horizonte.⁵³ At the time of his arrest, the defendant had with him only 4 pills of the medicine. In denying the habeas corpus requested by his defense, the judges argued that the defendant’s action called for a ‘more incisive response from the repressive state

49 Brasil. Tribunal Regional Federal (4. Região). *Processo ACR 5002552–58.2011.4.04.7002 PR*. Relator João Pedro Gebran Neto. Porto Alegre, 31 ago. 2016, https://jurisprudencia.trf4.jus.br/pesquisa/inteiro_teor.php?orgao=1&documento=8464614; São Paulo. Tribunal de Justiça. *Processo ACR 0012100–36.2006.8.26.0047*. Relator Farto Salles. São Paulo, 21 set. 2018, https://esaj.tjsp.jus.br/cjsg/imagens/saj/ico_pdf.gif. Brasil. Tribunal Regional Federal (2. Região). *Processo ACR 0008299–35.2002.4.02.5001*. Relator Messod Azulay Neto. Rio de Janeiro, 21 out. 2011, http://jurisprudencia.trf2.jus.br/sm/download?name=siapro-download-juris&id=192566_200250010082996_2007-08-21.

50 In an outlier case from the state of Rio de Janeiro, the Court rejected the abortifacient property of misoprostol as sufficient for the conviction of a pharmacist, arrested with 8 pills: ‘The expert report confirmed that the substance is CYTOTEC MISOPROSTOL 250 mg. I understand that the simple fact that the substance found in the pills has abortifacient effect is not sufficient, in this case, to subsume to the crime for which the accused has been convicted, considering, in addition, the very high penalty for this crime’ (Rio de Janeiro. Tribunal de Justiça. *Processo ACR 0004413–29.2011.8.19.0014*. Relator Cairo Ítalo França David. Rio de Janeiro, 25 out. 2018, <http://www1.tjrj.jus.br/gedcacheweb/default.aspx?UZIP=1&GEDID=0004537E59A36C47F963CB11126EBF8D369EC5091C285ASD>).

51 When the medicine is imported in small amount, courts sometimes choose to avoid Article 273, reasoning that because of the small number of pills, there is ‘low exposure of society to possible damage to health,’ or the pills represent no ‘social hazard,’ or generate ‘no or negligible harm to public health.’ These cases do not ‘represent conduct of a high degree of objection’: there is minimum or no risk to public health (Brasil. Superior Tribunal de Justiça. Habeas Corpus 411316/MG. Relator Antonio Saldanha Palheiro—Sexta Turma. *Diário de Justiça Eletrônico*, Brasília, 4 out. 2017, https://ww2.stj.jus.br/processo/revista/inteiro_teor/?num_registro=201701962380&dt_publicacao=04/10/2017).

52 Brasil. Tribunal Regional Federal (4. Região). *Processo ACR 5001587–05.2010.4.04.7006 PR*. Relator Márcio Antônio Rocha. Porto Alegre, 5 jul. 2016, https://jurisprudencia.trf4.jus.br/pesquisa/inteiro_teor.php?orgao=1&documento=8351796.

53 Minas Gerais. Tribunal de Justiça. *Processo HC 0014762–96.2014.8.13.0000*. Relator Paulo Calmon Nogueira da Gama. Belo Horizonte, 6 fev. 2014, https://www5.tjmg.jus.br/jurisprudencia/pesquisaNumeroCNPJEspelhoAcordao.do;jsessionid=A063DF43F59F0E5F99B396101FDE4B35.juri_node2?numeroRegistro=1&totalLinhas=1&linhasPorPagina=10&numeroUnico=0014762-96.2014.8.13.0000&pesquisaNumeroCNPJ=Pesquisar.

apparatus,' because he was selling a 'controlled drug indiscriminately used for abortion.' For the Court, the defendant 'directly and severely endangered public health,' and 'diffusely threatened the health of potential victims,' in addition to providing the means for 'the practice of another crime, that is clandestine abortion.'

The São Paulo Court of Justice denied an appeal for a more lenient sentence consideration by two men arrested for transporting 10 blisters of Cytotec and 7 blisters of a drug for erectile dysfunction from Paraguay to Brazil. In denying the appeal, the Court reasoned that the seriousness of their conduct resulted not only from 'the intention of commercializing a large number of controlled medicines,' but because the drugs were used in clandestine abortion, by the commercialization of this drug, the defendants effectively contributed 'to the increase of maternal mortality rates in the country.'⁵⁴

In another case, a Federal Regional Court denied the defendant's plea for application of the principle of insignificance on the reasoning that carrying 100 pills of misoprostol from Asunción, Paraguay, to be sold in Salvador, Northeastern Brazil, could not be considered insignificant as it resulted in the irregular introduction of a drug that allows individuals to engage in the commission of a crime that endangers public health.⁵⁵

The new criminalization of abortion in Brazil is not primarily justified by the religious or moral offense of abortion. Rather, in the Article 273 case law, Brazilian courts use a public health rationale rooted in the assumed truth of clandestine and illegal abortion as unsafe abortion to criminalize the illicit sourcing of a controlled drug, but also the critical supply of an essential medicine.

IV. GLOBAL ABORTION DISCOURSE AND POLICY

Unsafe abortion, the basis on which the Brazilian courts explain the *heinousness* of the misoprostol offenses, has long been a major cause of maternal mortality in the country, and the subject of sustained advocacy. Beginning in the 1980s, a strong public health narrative of clandestine abortion as unsafe abortion dominated local advocacy efforts to reform the criminal provisions on abortion.⁵⁶ This narrative became particularly strong in the 1990s, when Brazilian feminists acquired a new shared global framing of unsafe abortion through the U.N. development agendas of the Cairo and Beijing Conferences.⁵⁷ This section explores how the public health rhetoric of the Article 273 case law, rather than a simple invention of the Brazilian bench, reflects global abortion discourse and policy and the double life of misoprostol within it. It introduces this context to the judicial reasoning in the Article 273 case law in an effort to explain the curious contradiction of a public health argument in the service of abortion criminalization.

The heinousness of 'unsafe abortion' is a convention of global abortion discourse. About 25 million unsafe abortions occur every year in low- and middle-income countries worldwide, and 7 million people are admitted to hospitals every year as a

54 São Paulo. Tribunal de Justiça. *Processo ACR 0012100-36.2006.8.26.0047*. Relator Farto Salles. São Paulo, 21 set. 2018, https://esaj.tjsp.jus.br/cjsg/imagens/saj/ico_pdf.gif.

55 Brasil. Tribunal Regional Federal (3. Região). *Processo ACR 0000425-80.2006.4.03.6116 SP*. Relator Hélio Nogueira. São Paulo, 15 set. 2015, <http://web.trf3.jus.br/acordaos/Acordao/PesquisarDocumento?processo=00004258020064036116>.

56 Thais Medina Coeli Rochel de Camargo, *Pro-abortion Rights Narratives in Brazil, 1976 to 2016*, 36(Suppl 1) CAD. SAUDE PUBLICA 1-13 (2020).

57 Lucila Scavone, *Políticas feministas do aborto*, 16 REV. ESTUD. FEM. 675-680 (2008).

consequence.⁵⁸ The *silent scourge of unsafe abortion*, the *preventable pandemic of unsafe abortion* are titles of landmark publications in the field, with opening statements on the magnitude of unsafe abortion and its devastating impacts registered by these measures of death and disability.⁵⁹ Global abortion activism labored for this recognition. In 1994, abortion was accepted onto the global development agenda but only as a major public health concern of unsafe abortion with the goal of eradication.⁶⁰ For decades, the public health harms of unsafe abortion were the habitual basis for abortion law reform, that is, the assumption that illegal abortions are unsafe abortions.⁶¹

This conflation of illegality and public health harm can be attributed in part to the World Health Organization (WHO, hereafter), which beginning in 1990, defined illegal abortion as unsafe abortion, or rather relied on the legality of abortion as a basis for distinguishing safe from unsafe abortion. Similar to the reasoning of the Brazilian courts in the Article 273 case law, WHO's definition of *unsafe abortion* focused only on the circumstances of an abortion, not its actual outcomes. Unsafe abortion was defined as the termination of pregnancy by untrained persons in an environment that failed to conform to minimal medical standards.⁶² For decades, this approach worked well enough because abortion outside of these circumstances presented unreasonable risk, often involving invasive or other unsafe methods. The informal use of misoprostol was seen or constructed as among these methods.

While today global declines in abortion-related morbidity and mortality since 1990 are credited to the informal use of misoprostol,⁶³ this was not always the case. Early in the documentation of the practice, there was a reported increase in women presenting to hospitals with incomplete or failed abortions, either real or feared, or simply because they wanted to safely complete the abortion through legal post-abortion care. Hospital-treated complications are an important data source for indirectly calculating unsafe abortion, which increased with the reported informal use of misoprostol.⁶⁴ Public health discourse did not always reflect the fact that misoprostol use, by replacing more dangerous methods, also decreased the severity of abortion-related complications (uterine perforation, infections, and sepsis) for those who did present to hospitals and thus made abortion safer.⁶⁵ Studies from Brazil in the 1990s, for example, documented

58 Bela Ganatra et al., *Global, Regional, and Subregional Classification of Abortions by Safety, 2010–14: Estimates from a Bayesian Hierarchical Model*, 390 LANCET 2372–2381 (2017); S. Singh & I. Maddow-Zimet, *Facility-Based Treatment for Medical Complications Resulting from Unsafe Pregnancy Termination in the Developing World, 2012: A Review of Evidence from 26 Countries*, 123 BJOG 1489–1498 (2016); Lale Say et al., *Global Causes of Maternal Death: A WHO Systematic Analysis*, 2 LANCET GLOB. HEAL. e323–e333 (2014).

59 David A. Grimes, *Unsafe Abortion: The Silent Scourge—PubMed*, 67 BR. MED. BULL. 99–113 (2003); David A. Grimes et al., *Unsafe Abortion: The Preventable Pandemic*, 368 THE LANCET 1908–1919 (2006).

60 United Nations, *Programme of Action of the International Conference on Population and Development* 118 (1994).

61 Marge Berer, *National Laws and Unsafe Abortion: The Parameters of Change*, 12 REPROD. HEALTH MATTERS 1–8 (2004).

62 WORLD HEALTH ORGANIZATION, *THE PREVENTION AND MANAGEMENT OF UNSAFE ABORTION: REPORT OF A TECHNICAL WORKING GROUP* (1993).

63 Singh and Maddow-Zimet, *supra* note 58; SUSHEELA SINGH ET AL., *ABORTION WORLDWIDE 2017: UNEVEN PROGRESS AND UNEQUAL ACCESS* (2018).

64 Wilson, Garcia, and Lara, *supra* note 16 at 191.

65 Ilana G. Dzuba, Beverly Winikoff & Melanie Peña, *Medical Abortion: A Path to Safe, High-Quality Abortion Care in Latin America and the Caribbean*, 18 EUR. J. CONTRACEPT. REPROD. HEAL. CARE 441–450 (2013).

a decreasing number of severe abortion-related complications in public hospitals due to the use of misoprostol,⁶⁶ but they also recorded an increase in the number of women hospitalized for induced abortion and deemed all these abortions as ‘unsafe.’⁶⁷

The informal use of misoprostol as an abortifacient presented a further complication in global policy discourse by virtue of its political rather than public health risk. Researchers, development agencies, health authorities, and advocates wanted to expand access to misoprostol as an essential medicine for its many other reproductive health indications, but they faced the complication of its informal and even off-label use for abortion.⁶⁸ While the drug has few contraindications and was widely known to be safe and effective for use early in pregnancy, with serious adverse events rare thereafter, the manufacturer of Cytotec, G.D. Searle & Co (and then Pfizer) actively suppressed this knowledge and refused to research or register misoprostol for any reproductive health indication for the lifetime of its patent.⁶⁹ Package warnings clearly stated that misoprostol was contraindicated in pregnancy, and Searle publicly warned of acute risks of off-label use for ‘mother and fetus,’ with repeated emphasis that the drug was not approved for abortion.⁷⁰

In 1991, the company published a Letter to the Editor of *The Lancet* strongly condemning the reported misuse of the drug in Brazil ‘to interfere with the course of pregnancy.’⁷¹ The Letter was printed on the same page of a study showing that Brazilian pharmacies had been selling Cytotec over the counter for termination of pregnancies.⁷² The company’s warning was unusual because the off-label use of medicines is practiced worldwide. Lack of commercial registration or licensing for a particular indication is not equivalent to dangerous or unsafe use, and regulators can make a product available for a particular indication if it has a public health benefit. In this case, however, Searle’s protests were seized upon by drug regulators as a reason to restrict the off-label use of misoprostol for abortion. Searle went one step further by refusing to include package inserts or manufacturer doses for safe reproductive use, which led to wide and indeed dangerous variations in practice.⁷³ Labor induction requires 25 µg of misoprostol, but tablets manufactured for ulcer treatment contain 4 or 8 times that dose, which can rupture the uterus.⁷⁴ During this time, concerns about fetal exposure to misoprostol

66 Walter Fonseca et al., *Determinantes do aborto provocado entre mulheres admitidas em hospitais em localidade da região Nordeste do Brasil*, 30 REV. SAUDE PUBLICA 13–18 (1996); Walter Fonseca et al., *Características sócio-demográficas, reprodutivas e médicas de mulheres admitidas por aborto em hospital da Região Sul do Brasil*, 14 CAD. SAUDE PUBLICA 279–286 (1998); S. H. Costa & M. P. Vessey, *Misoprostol and Illegal Abortion in Rio de Janeiro, Brazil*, 341 LANCET 1258–1261 (1993); Costa, *supra* note 2.

67 A retrospective study in Brazil with 1840 women who obtained hospital-based post abortion treatment found the incidence of infection among women who had used misoprostol to be almost one-twelfth that of women who had used other methods (A. Faúndes et al., *Post-Abortion Complications after Interruption of Pregnancy with Misoprostol*, 12 ADV. CONTRACEPT. 1–9 (1996)).

68 MacDonald, *supra* note 32.

69 Andrew D. Weeks, Christian Fiala & Peter Safar, *Misoprostol and the Debate Over Off-Label Drug Use*, 112 BJOG 269–272 (2005).

70 Yap-Seng Chong, Lin-Lin Su & Sabaratnam Arulkumaran, *Misoprostol: A Quarter Century of Use, Abuse, and Creative Misuse*, 59 OBSTET. GYNECOL. SURV. 128–40 (2004).

71 W. Wilson Downie, *Misuse of Misoprostol*, 338 LANCET 247 (1991).

72 Coelho et al., *supra* note 15.

73 Chong, Su, and Arulkumaran, *supra* note 70.

74 Jessica L. Morris et al. *FIGO’s Updated Recommendations for Misoprostol used Alone in Gynecology and Obstetrics*, 138(3) INT. J. GYNECOL. & OBSTET. 363–366 (2017).

and its teratogenic effects also began to surface.⁷⁵ From 1991 to 2011, 68 mostly anecdotal studies were published in Brazil on the association between the failed use of misoprostol to end a pregnancy and Moebius Syndrome, a rare condition.⁷⁶ None of the few epidemiological studies showed a statistically relevant correlation, yet the fetal risks of *in utero* exposure garnered public and media attention, further supporting an association between informal and unsafe use.^{77,78}

This double life of misoprostol—as a lifesaving medicine and a life-threatening drug—led to its controlled distribution in global policy, specifically the *WHO Essential Medicines List* (WHO EML hereafter). Essential medicines are defined as those ‘that satisfy the priority health care needs of the population . . . selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.’⁷⁹ Yet the WHO EML reports show that an evidence-based assessment of misoprostol repeatedly blended public health and political risk.

In 2003, WHO rejected an application to add misoprostol as an essential medicine for obstetric and gynecological indications given limited country level registration despite extensive study and off-label use for these indications. In its report, the reviewing Expert Committee observed that misoprostol ‘is also an effective abortive agent’ and that various countries justified non-registration by ‘concern about the widespread use of misoprostol as a self-medication . . . mainly where abortion is considered illegal.’⁸⁰ In 2005, an application to add misoprostol in a combined regimen with mifepristone⁸¹ for medical abortion was successful.⁸² The Expert Committee, however, recommended that mifepristone and misoprostol be included on the complementary list, medicines for which specialized facilities, care or training are needed, and that the following note be further added to the entry: ‘requires close medical supervision.’⁸³ Even this cautious recommendation created controversy with media reports that the United States attempted to block the addition.⁸⁴ The WHO recommendation was

75 Chong, Su, and Arulkumar, *supra* note 70.

76 Löwy and Villela Corrêa, *supra* note 20.

77 *Id.*

78 It is important to clarify though that, in a collaborative project between the Population Council and Gynuity Health Projects on Misoprostol and Teratogenicity, it was found that ‘there is an association between birth defects and *in utero* exposure to misoprostol,’ which, however, has low risk. The most commonly cited defects are ‘equinovarus’ (clubfoot), cranial nerve anomalies (affecting nerves V, VI, VII, and XII), and absence of the fingers.’ (NEENA M. PHILIP, CAITLIN SHANNON & BEVERLY WINIKOFF, *Misoprostol and Teratogenicity: Reviewing the Evidence* 17 (2003)).

79 WHO EXECUTIVE BOARD, REVISED PROCEDURES FOR UPDATING THE WHO MODEL LIST OF ESSENTIAL DRUGS: A SUMMARY OF PROPOSALS AND PROCESS 4 (2001).

80 WHO EXPERT COMMITTEE ON THE SELECTION AND USE OF ESSENTIAL MEDICINES, WHO TECHNICAL REPORT SERIES 920: THE SELECTION AND USE OF ESSENTIAL MEDICINES 16 (2003).

81 Mifepristone, also referred to as RU486, is a medicine that blocks the reception of progesterone, a hormone needed for pregnancy to continue. In the combined regime of medication abortion, mifepristone is the first step of the sequence, followed by misoprostol.

82 WORLD HEALTH ORGANIZATION, *Model Lists of Essential Medicines* (2005), http://whqlibdoc.who.int/cgi-bin/repository.pl?url=/hq/2005/a87017_eng.pdf.

83 WHO EXPERT COMMITTEE ON THE SELECTION AND USE OF ESSENTIAL MEDICINES, *WHO Technical Report Series 933: The Selection and Use of Essential Medicines* 37 (2005), <https://archives.who.int/medicines/services/expertcommittees/essentialmedicines/TRS933SelectionUseEM.pdf>.

84 The Editors of the Lancet Group, *Abortion Drugs Must Become WHO Essential Medicines*, 365 THE LANCET 1826 (2005).

approved, but in another unprecedented act, the WHO Director General qualified the entry with the black box text, ‘where permitted under national law and where culturally acceptable,’ language never before used in the EML.⁸⁵

The WHO EML was taken as an endorsement of the strict regulatory controls on misoprostol enacted in countries such as Brazil, and as a warning against market—or community based distribution and use. Throughout Latin America and the Caribbean, misoprostol remains subject to prescription controls, and in a few countries, the medicine is restricted to institutional use.⁸⁶ More fundamentally, the WHO EML inscribed into policy the double life of misoprostol as both a controlled drug and essential medicine, and its black box text then delegated the full authority to balance control and access to national authorities.

Brazil was one of the first countries to register misoprostol for reproductive health indications, including the legal termination of pregnancy, and began local generic production soon after the patent for Cytotec expired. Brazil also includes misoprostol on its *National List of Essential Medicines*, but only for approved indications.⁸⁷ The risks of off-label or informal use of misoprostol, however, continue to be publicized with clinical practice guidelines mentioning the teratogenic effects of misoprostol use in the first trimester of pregnancy,⁸⁸ By regulation, package inserts for the product must also contain a risk warning for use during pregnancy (Article 83 of *Portaria no 344/1998*).

Over time, with the generic production of misoprostol globally, and an increasing supply and availability of products, public health research on the use of misoprostol for early pregnancy termination eventually led to improved and standardized regimens and protocols, and significantly decreased safety concerns.⁸⁹ In 2019, an application to the WHO EML successfully moved mifepristone and misoprostol for medical abortion to the core list of essential medicines—the minimum medicine needs for a basic health care system—and removed the requirement for close medical supervision.⁹⁰ WHO guidelines and systematic reviews now widely support a less medicalized delivery, generally requiring access to quality medicines, instructions on how to use them and

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- 85 Liza Gibson, *WHO Puts Abortifacients on its Essential Drug List*, 331 *BMJ* 68 (2005); Katrina Perekhodoff, Lucía Berro Pizarrossa & Jelle Stekelenburg, *Realising the Right to Sexual and Reproductive Health: Access to Essential Medicines for Medical Abortion as a Core Obligation*, 18 *BMC INT. HEALTH HUM. RIGHTS* 1–7 (2018).
- 86 Luis Távora Orozco & Susana Chávez Alvarado, *Regulación del uso obstétrico del misoprostol en los países de América Latina y El Caribe*, 59 *REV. PERU. GINECOL. Y OBSTET.* 85–94 (2013).
- 87 Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Resolução—RDC n° 36*. (Brasília, 2008), http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2008/res0036_03_06_2008_rep.html; Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. *Relação Nacional de Medicamentos Essenciais*. 7.ed. (Brasília, 2010), <https://www.saude.gov.br/images/pdf/2014/setembro/29/Rename-2010.pdf>.
- 88 Brasil. Ministério da Saúde. Secretaria de Atenção à Saúde. *Protocolo Misoprostol*. (Brasília, 2012), http://bvsms.saude.gov.br/bvs/publicacoes/protocolo_utilizacao_misoprostol_obstetricia.pdf.
- 89 Elizabeth G. Raymond, Margo S. Harrison & Mark A. Weaver, *Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review*, 133 *OBSTET. GYNECOL.* 137–147 (2019).
- 90 WORLD HEALTH ORGANIZATION, *Model Lists of Essential Medicines* (2019), <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf>; WHO EXPERT COMMITTEE ON THE SELECTION AND USE OF ESSENTIAL MEDICINES, *WHO Technical Report Series 1021: The Selection and Use of Essential Medicines* (2019), <https://apps.who.int/iris/bitstream/handle/10665/330668/9789241210300-eng.pdf>.

information about when and where to seek help.^{91,92} The use of misoprostol is regarded as a safe and effective method to end an early pregnancy.⁹³ Importantly, the research base that supports this view includes studies of informal use in legally restrictive countries.⁹⁴ Indeed WHO has also acknowledged that the increasing informal use of misoprostol has made abortion safer and reworked its classification scheme of safe and unsafe abortion to accept a gradient of risk.⁹⁵ While keeping the binary of safe and unsafe abortion, WHO now divides unsafe abortion into two further categories: less and least safe. Abortion with misoprostol is characterized as a safe and effective method, even if the sourcing and use of the drug outside the formal health care system makes the method less safe. With this change, WHO acknowledges that more than a service delivery environment matters to safe abortion and has expressly named the legal environment as a condition of safe abortion.

Nonetheless, the 2019 WHO EML retains the black box text. Misoprostol is an essential medicine for basic health care systems to prevent leading causes of maternal mortality and morbidity but only '[w]here permitted under national law and where culturally acceptable.' In its report, the Expert Committee explained its role and responsibility as 'provid[ing] WHO with technical guidance in relation to the selection and use of essential medicines . . . its mandate does not extend to providing advice on the statement.'⁹⁶

V. A FUTURE FOR MISOPROSTOL IN PUBLIC HEALTH POLICY

This section draws on an outlier case from the Rio Grande do Sul Court of Justice to chart a regulatory future for misoprostol. In this case, the Court turned away from the dominant view of misoprostol as a controlled drug under a punitive criminal policy and reengaged the discourse of unsafe abortion to secure access to misoprostol as an essential medicine through public health policy.⁹⁷ The Court accepted the realities of

91 WORLD HEALTH ORGANIZATION, HEALTH WORKER ROLES IN PROVIDING SAFE ABORTION CARE AND POST-ABORTION CONTRACEPTION 81 (2015); WORLD HEALTH ORGANIZATION, MEDICAL MANAGEMENT OF ABORTION 54 (2018).

92 WHO recommendations for induced medical abortion under 12 weeks gestation include the use of a misoprostol-alone regimen using repeated doses of 800 mcg buccally, vaginally, or sublingually. Where there is access to a source of accurate information and to a health-care provider (should one be needed or wanted at any stage of the process), the abortion process can be self-managed with pregnancies < 12 weeks of gestation without the direct supervision of a health-care provider. This can be contrasted with early WHO guidance on the use of misoprostol alone in 2012, which stressed the importance of access to post-abortion care. (Jennifer Tang et al., *WHO Recommendations for Misoprostol Use for Obstetric and Gynecologic Indications*, 121 INT. J. GYNECOL. OBSTET. 186–189 (2013)).

93 Raymond, Harrison, and Weaver, *supra* note 89.

94 Silvina Ramos, Mariana Romero & Lila Aizenberg, *Women's Experiences with the Use of Medical Abortion in a Legally Restricted Context: The Case of Argentina*, 22 REPROD. HEALTH MATTERS 4–15 (2015); Caitlin Gerds et al., *Second-Trimester Medication Abortion Outside the Clinic Setting: An Analysis of Electronic Client Records from a Safe Abortion Hotline in Indonesia*, 44 BMJ SEX. REPROD. HEAL. 286–291 (2018).

95 Bela Ganatra et al., *From Concept to Measurement: Operationalizing WHO's Definition of Unsafe Abortion*, 92 BULL. WORLD HEALTH ORGAN. 155 (2014); Ganatra et al., *supra* note 57; Gilda Sedgh et al., *Insights from an Expert Group Meeting on the Definition and Measurement of Unsafe Abortion*, 134 INT. J. GYNECOL. OBSTET. 104–106 (2016).

96 WHO EXPERT COMMITTEE ON THE SELECTION AND USE OF ESSENTIAL MEDICINES, *supra* note 90 at 426.

97 Rio Grande do Sul. Tribunal de Justiça. *Processo ACR 70020896791*. Relator Marco Antônio Bandeira Scapini. Porto Alegre, 11 out. 2007, https://www.tjrs.jus.br/buscas/jurisprudencia/exibe_html.php.

informal supply and focused rather on the actual harms of clandestine markets and humane evidence-based interventions to address them.⁹⁸

The case concerned a charge under Article 180 of the Penal Code, which criminalizes buying and selling the products of a crime. The accused bought misoprostol from a street vendor, and then resold it in his own ‘street store’ to an adolescent on her ‘great insistence.’ The Court acquitted the accused on the lack of evidence as there was no report that misoprostol, the controlled substance, was found in the product bought and sold. However, before issuing an acquittal, the Court made a general comment on the facts giving rise to the case. On the one hand, the Court explained, the case presents the undeniable reality of an ineffective prohibition. Misoprostol continues to be sold openly in Brazil, such that a quick search on the internet shows how easy it is to buy unregistered products. To the benefit of many, the Court provided an example: a full listing with the selling price, contact information, and website of Cytotec suppliers.

On the other hand, the Court observed, there is the undeniable reality of demand, ‘hundreds of thousands of poor women—usually very young—who each year seek clandestine abortions.’ While measuring misoprostol demand and use is methodologically challenging because of the illicit context,⁹⁹ the 2010 and 2016 National Abortion Surveys in Brazil show that almost half of those who end their pregnancies every year do so with medicines.¹⁰⁰ Supporting qualitative research shows that Cytotec is the medicine most often used either alone or in combination with teas, liquids, and herbs.¹⁰¹

With these two realities—of supply and demand—the Court acknowledged not only the futility of drug control laws in eradicating unsafe abortion, but also their dysfunction. It is not the informal supply of misoprostol that makes abortion unsafe, but the criminalized conditions of its distribution and use.

Research supports the intuition of the Court. Studies from Brazil highlight the insecurity, risk, and violence that people both fear and experience with the informal supply and use of misoprostol.¹⁰² In clandestine markets, people are concerned about the quality of misoprostol tablets, which are often repackaged differently than advertised or resold as single pills.¹⁰³ Studies based on the random sampling of misoprostol products from informal markets show that most contain misoprostol, and even if less than labeled

98 Alyson Hyman et al., *Misoprostol in Women's Hands: A Harm Reduction Strategy for Unsafe Abortion*, 87 *CONTRACEPTION* 128–130 (2013); Diniz and Castro, *supra* note 37.

99 Wilson, Garcia, and Lara, *supra* note 16.

100 Debora Diniz & Marcelo Medeiros, *Aborto no Brasil: Uma pesquisa domiciliar com técnica de urna*, 15 *CIEN. SAUDE COLET.* 959–966 (2010); Debora Diniz, Marcelo Medeiros & Alberto Madeiro, *National abortion survey 2016*, 22 *CIEN. SAUDE COLET.* 653–660 (2017).

101 Debora Diniz & Marcelo Medeiros, *Itinerários e métodos do aborto ilegal em cinco capitais brasileiras*, 17 *CIEN. SAUDE COLET.* 1671–1681 (2012).

102 Adriane Roso et al., *Relatos de aborto medicamentoso na internet: ilegalidade restringindo os direitos das mulheres*, 16 *CONEX.—COMUN. E CULT.* 65–96 (2017), <http://www.uces.br/etc/revistas/index.php/conexao/article/view/4966> (last visited June 28, 2020); Nanda Isele Gallas Duarte, Lorena Lima de Moraes & Cristiane Batista Andrade, *Abortion Experience in the Media: Analysis of Abortive Paths Shared in an Online Community*, 23 *CIEN. SAUDE COLET.* 3337–3346 (2018).

103 Hyman et al., *supra* note 96; Margit Endler, Amanda Cleve & Kristina Gemzell-Danielsson, *Online Access to Abortion Medications: A Review of Utilization and Clinical Outcomes*, 63 *BEST PRACT. RES. CLIN. OBSTET. GYNAECOL.* 74–86 (2020).

or falsified, the drugs are rarely dangerous but simply ineffective.¹⁰⁴ Yet such research is beyond the common knowledge of most people, leaving them only with trust and faith, and word of mouth. Moreover, the law precludes the very assurance that people seek, namely some evidence that the product contains misoprostol, for such evidence is the very condition that attracts criminal liability under Article 273.¹⁰⁵ Research also shows that the informal supply of misoprostol leaves many people without evidence-based instruction on safe and effective use, what to expect during the process and when to seek help, while the threat of criminal liability leaves others reluctant to acquire, ask or provide such information.¹⁰⁶ Product package inserts, for example, may be of limited assistance especially if they are outdated or restricted to the original indication for the drug, or provide contradictory information such as advising against use during pregnancy, while instructing on use for pregnancy termination.¹⁰⁷ These inserts themselves are a documentary testament to the double life of misoprostol. Without access to information on safe informal use, people may delay or forgo seeking care when they need it, and health care providers may know little about misoprostol or its use affecting the quality of post-abortion care.¹⁰⁸ The current regulatory regime in Brazil ‘keeps women hostage between the risk of counterfeit product and fear of denunciation if they seek medical help, perpetuating endless stories of fear and silent torture.’¹⁰⁹

In understanding criminalization as the greatest public health threat in unsafe abortion, this outlier Brazilian court called not only for the legalization of abortion, but equally for ‘a public health policy that ensures all . . . the ideal conditions for termination of an unwanted pregnancy.’ In this single sentence, the court gave voice to a view of informal misoprostol suppliers, users, and the markets they form as sites of critical public health intervention.¹¹⁰ In the judgment, there is an impulse to understand these markets and to make them safer, rather than to eradicate them.

For example, in the case, the Court specifically named the accused as a neighborhood street vendor,¹¹¹ the differences in drug sellers being an important feature of

104 Veronique Berard et al., *Instability of Misoprostol Tablets Stored Outside the Blister: A Potential Serious Concern for Clinical Outcome in Medical Abortion*, 9 PLOS ONE 1–13 (2014); World Health Organization, *Quality of Medicines: Quality of Misoprostol Products*, 30 WHO DRUG INF. 35–39 (2016); Murtagh et al., *supra* note 12.

105 In the Brazilian case law, judges applied the lesser offense of contraband in cases where the pills did not contain misoprostol, in effect awarding sellers for counterfeit drugs. (Brasil. Tribunal Regional Federal (4. Região). *Processo ARGINC 5001968–40.2014.4.04.0000*. Relator Leandro Paulsen. Porto Alegre, 19 dez. 2014, https://jurisprudencia.trf4.jus.br/pesquisa/inteiro_teor.php?orgao=1&documento=6506662)

106 Kate Reiss et al., *Knowledge and Provision of Misoprostol Among Pharmacy Workers in Senegal: A Cross Sectional Study*, 17 BMC PREGNANCY CHILDBIRTH 1–8 (2017); Solheim et al., *supra* note 32; Timothy Powell-Jackson et al., *Delivering Medical Abortion at Scale: A Study of the Retail Market for Medical Abortion in Madhya Pradesh, India*, 10 PLOS ONE 1–14 (2015).

107 Laura J. Frye et al., *A Cross-Sectional Analysis of Mifepristone, Misoprostol, and Combination Mifepristone-Misoprostol Package Inserts Obtained in 20 Countries*, 101 CONTRACEPTION 315–320 (2020).

108 Debora Diniz & Alberto Madeiro, *Cytotec e aborto: A polícia, os vendedores e as mulheres*, 17 CIEN. SAUDE COLET. 1795–1804 (2012).

109 *Id.* at 1803.

110 Karen Marie Moland et al., *The Paradox of Access—Abortion Law, Policy and Misoprostol*, TIDSSKR. DEN NOR. LAEGEFORENING (2018).

111 Medicine sellers such as storekeepers and drug peddlers are well-known characters in anthropological studies of pharmaceuticals. In performing the role of prescribing medicines (though not in writing),

the misoprostol caselaw (doctors and pharmacists, drug dealers, internet suppliers). A known intermediary of clandestine markets in Brazil, street vendors usually sell small quantities of medicines, and tend to live and work in communities without connection to drug trafficking (which tend to operate via the internet with larger drug inventories).¹¹² Not only do these vendors sell misoprostol, they also often know and inform buyers about its safe use.¹¹³ Indeed, people may even trust these intermediaries more than actors in formal health care systems because they speak a shared dialect and experience a mutual need for discretion and a common sense of lived circumstance. In these markets, neighborhood street vendors form part of a network of care along with partners, friends and family,¹¹⁴ and increasingly activist networks and community groups who provide information and mutual support through hotlines, online forums and accompaniment services to make informal markets safer and more secure.¹¹⁵ Studies from Burkina Faso¹¹⁶ and Tanzania¹¹⁷ document the ways in which misoprostol has been repurposed for pregnancy termination in the informal sector through a material network inhabited by drug vendors in pharmacies, health workers and sex workers. These studies note that misoprostol takes on a life of its own within these networks, producing novel social relations that facilitate access to the drug and information on safer use thus creating an informal nurturing web.

From this viewpoint, informal markets of misoprostol information and supply can be a powerful site of collective action and support safer abortion practices through a dynamic interaction of informal and formal sectors of abortion care.¹¹⁸ Viewed in this light, the role for the state is neither to ignore nor eliminate these markets, but to support safe supply, information and use within them.¹¹⁹ There are, in other words, alternative ways to ensure that misoprostol as an essential medicine is available within health systems in 'adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford,' as the WHO Essential Medicines List promises.¹²⁰

More than 20 years ago researchers advocated that making misoprostol available for safe abortion at the community level would do more than any other realistically

particularly in low resources context, they are described as 'closer to their customers than doctors and pharmacists geographically, financially, and socially' and often treat their customers more respectfully than formal health care professionals. (WHYTE, VAN DER GEEST, AND HARDON, *supra* note 27 at 159).

112 Diniz and Madeiro, *supra* note 108.

113 *Id.*

114 Diniz and Medeiros, *supra* note 101; Duarte, de Moraes, and Andrade, *supra* note 102.

115 Susan Yanow, Joanna Erdman & Kinga Jelinska, *D.I.Y. Self-Managed Abortion*, CONSCIENC. MAG. (2019).

116 Drabo, *supra* note 32.

117 Solheim et al., *supra* note 32.

118 de Zordo, *supra* note 25; Duarte, de Moraes, and Andrade, *supra* note 102; Sandra Fernández Vázquez & Lucila Szwarc, *Aborto medicamentoso: transferencias militantes y transnacionalización de saberes en Argentina y América Latina*, 12 *REVIISE* 163–177 (2018).

119 For example, with informal supply, package inserts are a critical source of safer use information and therefore interventions to improve the quality and accessibility of information within them, is a critical harm reduction intervention. (Jamie Cross & Hayley Nan MacGregor, *Knowledge, Legitimacy and Economic Practice in Informal Markets for Medicine: A Critical Review of Research*, 71 *SOC. SCI. MED.* 1593–1600 (2010); Gerald Bloom, Hilary Standing & Robert Lloyd, *Markets, Information Asymmetry and Health Care: Towards New Social Contracts*, 66 *SOC. SCI. MED.* 2076–2087 (2008)).

120 WHO Executive Board, *supra* note 79 at 1.

achievable, sustainable, large-scale intervention to save lives.¹²¹ They also noted that such interventions depend more on state policy than on the will of people to help themselves. Though likely unknowingly, a lone Brazilian court acting against the case law recited almost verbatim the calls of these researchers, who declared: ‘We have the evidence. Our challenge now is to use the evidence of misoprostol’s efficacy and safety to ensure that every[one] has access.’¹²² In the end, the Court acquitted the accused because in its words, the criminalization of a street vendor who sells medicine requested by a young woman in need is no measure of justice.

VI. CONCLUSION

The new criminalization of abortion in Brazil is a function of drug control laws enforced against the informal supply of misoprostol in the name of public health. It is a curious turn given misoprostol’s other life as an essential medicine for reproductive health. Yet this local practice is consistent with the double life that misoprostol has long lived within global abortion discourse and policy, and with the single reality that the meaning of drugs and medicines depend as much on context as any intrinsic property.¹²³ A willingness to see and act on the informal supply and markets of abortion drugs as not a criminal threat to public health, but a critical intervention to protect the health and lives of people may yet be misoprostol’s future life.

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121 Ndola Prata et al., *Saving Maternal Lives in Resource-Poor Settings: Facing Reality*, 89 HEALTH POLICY (NEW YORK). 131–148 (2009).

122 Ann Stars & Beverly Winikoff, *Misoprostol for Postpartum Hemorrhage: Moving from Evidence to Practice*, 116 INT. J. GYNECOL. OBSTET. 1–3, 1 (2012).

123 WHYTE, VAN DER GEEST, AND HARDON, *supra* note 27.