The thalidomide tragedy: the struggle for victims' rights and improved pharmaceutical regulation

Adriana Moro

Doctoral student, Programa de Pós-graduação em Políticas Públicas/Universidade Federal do Paraná.
Avenida Prefeito Lothário Meissner, 632, térreo
80210-170 – Curitiba – PR – Brasil

adri.moro@gmail.com

Noela Invernizzi

Professor, Setor de Educação; Programa de Pós-graduação em Políticas Públicas/Universidade Federal do Paraná.
Avenida Prefeito Lothário Meissner, 632, térreo
80210-170 – Curitiba – PR – Brasil

noela@ufpr.br

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Abstract

The thalidomide tragedy in the late 1950s was a watershed moment for pharmaceutical regulation. New uses for this medication are being researched and implemented today. This article revisits the history of thalidomide and its consequences for regulation and for victims' rights in Brazil, based on a literature review, documentary analysis, and newspaper reports. The events highlighted herein show the lack of strong standards for safe medication use, as well as how the tragedy was transformed into a public problem through its divulgation in the press; the article also shows that the increasing mobilization of victims was essential in pushing for more effective drug regulations.

Keywords: thalidomide; risks; pharmaceutical regulation; media; thalidomide victims.

Thalidomide offers a tragic example of the need for greater regulation to prevent the use of harmful drugs and to adequately communicate the risks of medications. The disaster also provided an essential impetus for expansion of state authority over the pharmaceutical industry in the United States, Germany, and later in other countries.

Thalidomide was presented in the 1950s as a wonder drug, subsequently banned for its harmful effects, and in recent years has returned to treat patients with illnesses such as cancer and Hansen's disease. Because of the tragedy surrounding it, thalidomide was one of the most important drugs of the twentieth century in terms of mobilizing health legislation, marking the starting point for application of the concepts of safety and pharmacovigilance for medications. It also triggered ethical debates about the behavior of the pharmaceutical industry and the living conditions and rights of people with disabilities caused by the drug.

In Brazil, although the disaster took place in the early 1960s, even today there are cases of teratogenesis involving thalidomide. This is explained by the widespread use of the drug to treat Hansen's disease (also known as leprosy); Brazil has the second-largest number of people affected by this illness. Within this scenario where the system is still too fragile to prevent risks from the drug, its use may be extended, given that new uses for thalidomide are being researched and implemented around the world. Consequently, it is appropriate to revisit the history of the thalidomide tragedy and its consequences for regulations and victims' rights. In this article, we reconstruct this history using a literature and document review and reports from Brazilian newspapers. For this latter resource we used the news archive built by members of the Brazilian Association of Thalidomide Syndrome Victims (Associação Brasileira de Portadores da Síndrome da Talidomida), which presents the events that took place in Brazil and abroad, from the viewpoints of the victims. During this process, we emphasize how the lack of strong standards for safe use of medications was evidenced, and show the important role of the media in transforming the tragedy into a public problem, as well as the increasing mobilization of affected groups in order to demand drug regulation.

We begin in the first section with a description of the methodology used and the data sources. In the second section, we use the literature review and Brazilian regulatory documents to accompany the discovery of the drug in the 1950s, its uses, its broad marketing, the signs of the tragedy, and its impact on regulation. The aim of this section is to contextualize the reconstruction of the history of this tragedy based on the news published in the media carried out in the subsequent sections. Next we discuss a more vivid report of the major historical events surrounding thalidomide, which was done by the media in converting it into a public problem. This reconstruction was divided into decade-long periods, which are addressed in sections three to five. In the last section, we present some conclusions about the thalidomide tragedy and its legacy for drug regulation and in relation to victims' rights.

About this study

The first phase of the research involved a review of the literature on the thalidomide tragedy and review of documents on regulation of this substance in Brazil. We performed our document search in the Brazilian public-domain Jusbrasil database, which we accessed on September 6, 2014; we searched the keyword "talidomida" in "laws," "decrees," and

"ordinances" from 1960 to the first half of 2014. We found 29 results. Of these, 12 were laws (eight state and four federal), nine were federal decrees, six were resolutions, one was an interim measure, and one was a board resolution (resolução de diretoria colegiada, DRC). Only the most relevant documents were included in this study.

Information from both sources was organized chronologically, allowing us to follow the emergence of the drug, the commercial strategies that culminated in its widespread use, the first evidences of the tragedy, the withdrawal of the drug, legal action against the company, and the development of regulation.

The second phase consisted of analyzing the press archive from the Brazilian Association of Thalidomide Syndrome Victims (ABPST), which includes broad-circulation Brazilian newspapers and magazines. Although this is not an exhaustive database, it does constitute a relevant source because it contains stories reporting the tragedy selected by the main affected group, according to their perceptions and interests. In this way, the archive itself can be considered a reflection of the way in which the context of the problem was defined by the victims. Even though it is only a partial archive, it is sufficiently large and diverse to show how the problem was addressed in the national media, who the main actors were, and what their demands were.

The information was collected between December 2014 and August 2015, with the consent of the association. Because we only had access to printed copies of these stories, we excluded those which were illegible, as well as stories from the foreign press. The ABPST archive was created by laypeople, and as a result not all the materials were always saved with all the relevant publication data.

We selected 43 articles dating from the early 1960s to the late 1980s (see references). These articles were published in the following newspapers: *Folha de S. Paulo* (13), *O Estado de S. Paulo* (5), *Diário da Noite do Brasil* (1), *Rio do Povo* (1), *Diário do Povo* (1), *Jornal de Campinas* (1), *Jornal do Brasil* (1), *O Brasil* (1), *Zero Hora* (5), *Estado de Minas* (1), *Correio Braziliense* (1), *Diário de Notícias* (1), and *Gazeta Mercantil* (1); they also came from the *Jornal Informativo da ABVT* (3); and the magazines *Manchete* (2), *O Cruzeiro* (2); *Veja* (1), and *Seleções do Reader's Digest* (2).

After analyzing the content, we classified the articles by decade, and each decade was categorized by the topic that was most frequently addressed in the articles. We use these categories as the titles of sections 3, 4, and 5.

From wonder drug to tragedy, from tragedy to regulation

Thalidomide was discovered in 1953 by Wilhelm Kunnz, in what at that time was West Germany. It was first synthesized by the pharmaceutical manufacturer Chemie Grünenthal, to be added to antibiotics (Lima, Fraga, Barreiro, 2001). However, it was recognized worldwide as a treatment for insomnia after Herbert Keller demonstrated its efficient use as a sedative and hypnotic in 1957 (Saldanha, 1994). At that time, the tests showed no toxicity, and a lethal dose was not established. Animal experimentation in science at that time was restricted to rats, and rarely birds, pigs, or mice. Teratological testing was limited; according to Silveira et al. (2001), the literature of the era does not mention that the group of neuroleptic drugs, tranquilizers, sedatives, and antiemetics was tested.

The drug was launched on the market in 1956 as a cold and flu medication, under the trademark Grippex. The possibility that an Asian influenza epidemic might reach Germany in 1957 provided an excellent marketing opportunity (Leandro, Santos, 2015). Despite insufficient studies on its safety in humans, Grünenthal launched the drug Contergan as a sedative in October of 1957; it was one of the most widely sold medications in West Germany that year (Lima, Fraga, Barreiro, 2001).

Grünenthal launched an advertising campaign stating that the substance was innocuous and safe (Oliveira, Bermudez, Souza, 1999). Ads were planned for fifty top-line medical publications, in addition to two hundred thousand letters to physicians and fifty thousand to pharmacists around the world (Mokhiber, 1995). Sales during the first year of production reached 90,000 units per month in twenty countries, and spread across the other continents. The United States was one of the few countries which did not allow this drug to be sold, on the recommendation of Frances Kelsey, a researcher at the Food and Drug Administration (FDA). Even so, the drug was used in off-label applications in this country, as we shall see later.

Thalidomide was marketed under at least 52 trade names worldwide (Bosch, 2012, p.8). It was so successful that in 1958, the beverage distributor Distillers Biochemicals Ltd. (DBCL), which owned the Johnnie Walker label, became a distributor of the drug. DBCL launched an advertising campaign based on replacing barbiturates, which were responsible for countless poisoning deaths, with thalidomide, which was considered nontoxic. In a leaflet sent to thousands of doctors, it claimed that thalidomide was safe for use by pregnant women (Oliveira, Bermudez, Souza, 1999 cited in Mokhiber, 1995, p.373).

In Brazil, the first commercial advertisement for thalidomide appeared in three broad-circulation newspapers in 1959. It was directed at physicians, offering them literature and free samples of Sedalis, the trade name for thalidomide launched by Instituto Pinheiros Produtos Farmacêuticos, Chemie Grünenthal's representative in Brazil. The advertisement emphasized the drug's sedative/hypnotic properties, without barbiturates or side effects, and stated that it was well-tolerated by children and patients with liver damage (Leandro, Santos, 2013). These authors maintain that the sale of thalidomide, which was bolstered by aggressive advertising, came along with the euphoric wave of medication consumption of the 1940s and 1950s, when laboratories expanded their business by launching products that promised well-being, physical strength, and the end of undesired pain and discomfort from busy modern life.

In 1958, the "mother company" behind thalidomide began to receive notifications from laypersons about peripheral neuropathies, represented by cramps, muscle weakness, and loss of motor coordination (Borges, Froehlich, 2003). As sales grew, in 1961 reports that the drug could cause constipation, dizziness, a hangover sensation, and memory loss also increased. An initial study was published in that same year in the *British Medical Journal*; in it, James Murdoch advised against long-term use because no studies had been conducted on long-term effects (Oliveira, Bermudez, Souza, 1999, cited in Mokhiber, 1995, p.372).

Despite the lay reports about possible malformations, the first medical reports of cases of teratogenicity in children in Germany date back to 1959. These described a distinctive type of congenital malformation, caused by faulty development of the long bones in the arms and legs, as well as hands and feet which varied from rudimentary to normal. The first study that drew attention to the increasing incidence of extremity malformations was performed by

Wiedemann in 1961 (Oliveira, Bermudez, Souza, 1999). But it was Lenz (1988), also in 1961, who quoted a study by Pfeiffer and Kosenowa during the North Rhine-Westphalia Pediatric Meeting in Germany and advocated removing the drug from the market until new studies were conducted; these authors associated 34 cases of babies with congenital malformations of the extremities born to mothers who had used thalidomide during pregnancy. This hypothesis was confirmed by McBride in Australia (also in 1961), and by the presentation of other anomalies affecting various systems and organs which were described as teratogenic malformations by Mellin and Katzenstein (Oliveira, Bermudez, Souza, 1999).

The abnormalities caused by thalidomide include hearing loss, ocular alterations, deafness, facial paralysis, malformations in the larynx, trachea, lungs, and heart, and mental retardation in 6.6% of affected individuals. The mortality rate among the victims ranged from 40% to 45%. Around the world, between ten and 15 thousand children were born with the characteristic abnormalities associated with thalidomide, and 40% died during the first year of life (Vianna, Sanseverino, Faccini, 2014).

Chemie Grünenthal withdrew the drug from the market through its distributor DBCL in December of 1961, after publication of the research that linked thalidomide to birth defects. Another distributor of the drug, Merrell Company, withdrew it in March of 1962 (Oliveira, Bermudez, Souza, 1999).

The thalidomide tragedy unfolded differently in two of the major western powers at that time, Germany and the United States, due to their different practices in the area of medicine and pharmaceutical regulation (Daemmrich, 2003). These two countries tried to rewrite their stories of thalidomide, at the center of the struggle for global hegemony in the area of knowledge and the drug market. The US came out stronger, and was an example for the world in drug regulation policy. Thanks to Frances Kelsey, the drug was not approved by the FDA, under the argument that the testing was insufficient. The cases of thalidomide-related teratogenicity recorded in that country resulted from the use of the drug in pregnant women during clinical trials conducted by 1,200 physicians who received the medication directly from the company, since before this episode the government had no control over clinical trials (Appel, 2010).

According to Daemmrich (2003), the Merrell lab was so confident in the safety of thalidomide that it used the testing period to recruit doctors in the United States. According to this author, approximately 16,000 patients received the drug during the experimental phase, and 624 were pregnant women. However, the majority of these received the drug after their first trimester of pregnancy, so only 17 children were born with phocomelia.

Although thalidomide had not been officially approved in the United States, thereby in large part sparing it from its effects, after the disaster drug regulation became the FDA's main focus. This agency established the Investigational New Drug procedure, and came to monitor the development of clinical trials that determine the safety and efficacy of new drugs. The New Drug Application Standard (which was issued in 1938 after an event involving the deaths of more than one hundred children who consumed an elixir containing the solvent diethylene glycol) was replaced by the Harris-Kefauver Amendment in 1962, which provided more severe control after the thalidomide tragedy (Melo, Ribeiro, Storpirtis, 2006). Other standards soon followed: the Bulk Pharmaceutical Chemicals Act of 1963, which established

good laboratory practices for handling raw materials, the Drug Abuse Control Amendment of 1965, and the Fair Packaging and Labeling Act of 1966, which established procedures for packaging and labeling drugs (Melo, Ribeiro, Storpirtis, 2006).

In Europe, which was the epicenter of the calamity, the regulatory issue also took on new dimensions. In 1964, the World Medical Association published the Helsinki Declaration, which established standards for clinical research. Following this declaration, the then European Economic Community (EEC) recognized the need to regulate medications, and approved directive 65/65/EEC of January 26, 1965, which formed the basis of European pharmaceutical legislation (Martins et al., jul. 2014). However, the first comprehensive medication law in Europe was only enacted in 1976 (Melo, Ribeiro, Storpirtis, 2006).

In Germany, where the drug originated, the tragedy stimulated discussions about research agendas, the regulation of pharmaceutical products, and the conditions the country offered to physically disabled people, as well as proposals for laws providing indemnification and support for victims (Dally, 1998). As for Grünenthal, the company's trial began in January 1968 and ended three years later, when prosecutors withdrew the charges, in exchange for which the company agreed to create a fund for the victims (Daemmrich, 2003). Under this agreement, the company and individual defendants were released from civil criminal prosecution related to the event.

The history of thalidomide in Brazil was different from what occurred in other countries. Sales of the drug began in March 1958, almost two years after adverse effects were identified in Germany. Notes on the withdrawal of thalidomide appeared in the *Diário Oficial* and *O Estado de S. Paulo* newspapers in August of 1962. But this only took place in 1965, at least four years after Germany (Oliveira, Bermudez, Souza, 1999), as the media reported.

Even after the official withdrawal of thalidomide, it remained in some Brazilian drugstores, as noted by Leandro and Santos (2015), and continued to be sold by several laboratories because there was no regulation effectively banning its sale. A few years after the tragedy, in 1965, the drug was approved in Brazil for treatment of erythema nodosum leprosum (ENL), as well as in other countries (Penna et al., 2005). The persistence of high rates of the disease in Brazil – in 2013 between 30,000 and 33,000 cases were registered (Brasil, 2014) – spells out the widespread, uninterrupted use of thalidomide across the country.

This virtually continuous use of thalidomide in Brazil was accompanied by the drafting of regulatory measures, but these had demonstrated weakness, considering the occurrence of new cases. In 1961, the National Health Code (Código Nacional de Saúde) was approved; this established general rules on the defense and protection of health, charging the Ministry of Health with adopting preventive measures and also instituting the Central Laboratory for Drug, Medication, and Food Control. Even though this action coincided with the initial phase of the reported events, it did not help avoid the thalidomide disaster in Brazil. The medication was only banned and recalled in August of 1962, without specific legislation for this purpose (Penna et al., 2005; Lenz, 1988). In September 1962, the media announced that the Association of Pharmacists (Associação de Farmacêuticos) had requested that sedative-based medications be controlled through registration and the creation of a "list of sedative-based pharmaceutical drugs," indicating a movement toward more severe regulation. In response, in 1963 the Executive Group of the Pharmaceutical Industry (Grupo

Executivo da Indústria Farmacêutica, Geifar) was created to control the pharmaceutical industry, in an attempt to prevent the occurrence of new tragedies like thalidomide.

The Medication Center (Central de Medicamentos, Ceme) was established by the president, and was charged with procurement and distribution of medications. However, this action focused on sanitary regulation of drug sales, rather than the safety of the medications. The first national law on drug safety was approved in 1973 (Law 5.991).

As for legislation providing reparations to victims, in the state of São Paulo Law 1.653 recognized the ABVT in 1978 as an entity of public utility. After years of pressure on the state from victims, as we will see later, the first legislation specific to thalidomide (Law 7.070) was drafted in 1982, and dealt with the special pension for disabled survivors.[1]

Drug regulations made substantial advances in the country after 1988, with free and high-quality care guaranteed through the Unified Health System (Sistema Único de Saúde, SUS). In this context, thalidomide received its own regulation more than three decades after the disaster occurred (and after being used nearly continuously throughout this period) in 1997, through Decree 354. This decree regulated the registration, production, manufacturing, sale, display, prescription, and dispensing of thalidomide-based products, and also prohibited their manipulation, procurement, and sales displays in pharmacies and similar establishments, with a few exceptions. The distribution of samples or advertising of this drug was also prohibited, along with its use by women of childbearing age.

In 2003, thalidomide became the object of Law 10.651, and the only medication in the country to have its own law. This law presented some progress in relation to the 2003 decree, with more extensive measures for the prevention and control of drug risks, improvement in the distribution process, permitted use in women of childbearing age with the provision of contraceptive methods to avoid pregnancy during treatment, improvements in packaging (and with them, clearer information), and domestic production of the drug at reduced prices.

Other important norms were approved after this date, such as the National Drug Policy (Política Nacional de Medicamentos) in 1998, the Generics Act (Lei dos Genéricos) in 1999, the National Pharmaceutical Assistance Policy (Política Nacional de Assistência Farmacêutica) in 2004, the Program for Strengthening Institutional Capacity for Regulation Management (Programa de Fortalecimento da Capacidade Institucional para Gestão em Regulação) in 2007, and Resolution 54, which regulated drug tracking in 2013. Of paramount importance was the creation of the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, Anvisa) in 1999.

Note that 20 years passed between knowledge of the thalidomide tragedy at a global level and the first Brazilian initiative for legislation specifically about this drug (which focused on the rights of the victims, in 1982), and more than 30 years passed until the 1997 decree on safe use of the drug. During this period, the second generation of victims of this drug appeared in the country.

The 1960s: questions about the tragedy and the need for drug controls

The first press materials available in the archive, from 1962, report the adverse effects of the drug. The *Folha de S. Paulo* newspaper (Mais de…, jul. 1962) ran a headline "More than 3,000 women took the drug in the United States,"[2] and continued by quoting a report:

> The thalidomide ... was provided as samples to 15,904 patients in the United States … 3272 American women who took the pills were of childbearing age. But the investigations indicate that they took the drug in their last months of pregnancy … To the extent of our knowledge, up to this point the medication did not affect the newborns. The report … does not take into account the cases of some women who received the drug when they were abroad and gave birth to deformed children … In Europe the drug has produced thousands of deformations in fetuses.

The pediatrician Vicente Monetti decried the occurrence of malformations caused by thalidomide in the *Diário da Noite do Brasil* newspaper (Talidomida..., ago. 1962), in the article entitled "Thalidomide: responsible for half of the cases of congenital malformations:"

> Reports from scientists from around the world, particularly Europe, repeat with increasing frequency the relationship between congenital malformations and the administration of thalidomide to pregnant women … it has been observed that only children whose mothers took the drug at the beginning of pregnancy are affected … this fact depicts what can happen … with other drugs ... [if] prenatal treatment is not well-managed from the beginning.

Also in 1962, the *Folha de S. Paulo* (Cientistas…, ago. 1962) stressed: "Scientists warn: not only 'Thalidomide' causes birth defects," and included statements from Professor Newton Freire Maia, former president of the Brazilian Genetics Society (Sociedade Brasileira de Genética):

> Not only 'Thalidomide,' but also other drugs may cause children to have birth defects. For this reason, woman who suspect they may be pregnant should avoid taking any type of medication for at least the first two months of pregnancy ... Prof. Newton Freire Maia mused that the painful experience of thalidomide demonstrated that similar drugs must undergo thorough laboratory testing, with special precautions taken before releasing these products on the market.

Freire Maia mentioned research published in England which revealed that thalidomide was responsible for half of severe cases of birth defects, indicating that other tranquilizers used during pregnancy might increase the likelihood of birth defects. This as well as the previous news story underscored the importance of testing medications before sale to ensure their safety, and highlighted the concept of potential risk. During this period, physicians used this opportunity to highlight the importance of prenatal consultations and guidance on medication use.

On May 30, 1962, the first known victim of thalidomide in Brazil was born at the Leonor Mendes Barros Maternity Hospital (Casa Maternal Leonor Mendes Barros), according to *O Cruzeiro* magazine (Continua..., set. 1962): "The 22-year-old [father] and 18-year-old [mother] were struck a blow when they received their greatly-desired first child showing the deformations caused by the drug. It was a girl, with no arms. The hands were atrophied, and grew directly from the trunk, one with 3 fingers and the other with 4."

According to the magazine, the team that examined the case drafted a scientific article that would be sent to the United Nations, which had been studying thalidomide in various countries. The same article also reported that a professor identified only as Hepp had created a system for classifying the cases observed and later developed artificial limbs for these children. The article also shows concern with the living conditions for these children born with the syndrome, some of whom were 3 or 4 years old.

The ban on sales of the drug in Brazil, which took effect in August 1962, was reported by the newspapers. *O Estado de S. Paulo* (Apreensão…, 1962) ran the headline "Thalidomide seized." The *Folha de S. Paulo* (Apreendidos..., ago. 1962) reported that "4 million thalidomide pills were seized," indicating that the drug was widely sold in Brazilian pharmacies. *O Cruzeiro* (Continua…, set. 1962) stated: "Sales of thalidomide continue in Brazil," referring to the slowness of the process.

In September of 1962, the newspaper *Rio do Povo* (Relação..., set. 1962) announced "Relationship with sedative-based pharmaceuticals," highlighting actions to prevent a recurrence of events like the thalidomide tragedy:

> Around the world, news reporting that thalidomide-based drugs were causing defects in children whose mothers had taken this medication during pregnancy had even greater impact. A number of measures have been adopted to withdraw all the pharmaceutical products which have been broadly condemned from the market and from the laboratories.

According to the article, the Association of Pharmacists had requested that sedative-based medications be controlled via a registry. This point in time can be seen as a milestone for the beginning of drug controls, and a precursor to controlled prescriptions for medications, indicating a move toward more rigorous regulation. The article also comments on restricting marketing for the drug, reinforcing pressure from the media to completely remove it from the market.

With the headline "The bottom line of thalidomide is tragic," *O Cruzeiro* (É trágico…, set. 1962) published an interview with professor Widukind Lenz, a geneticist from Hamburg who stated he did not forgive the West German health authorities for not acting immediately when he denounced thalidomide: "They took ten days to ban the drug. And these ten days may cost more than 300 deformed babies."

Lenz stated that at the beginning, he thought it was a localized epidemic. But to be sure, he wrote to many pediatricians in West Germany and observed that the result was worse than he expected; he got to work, suspecting radioactivity and chemical products because the birth defects did not resemble those caused by viruses. He said:

> For some weeks I was convinced that the phocomelia epidemic stemmed from the use of a new chemical cleaner sold for home use in 1959. But I was wrong: that product had been definitively tested and approved by scientists in charge of the manufacture of chemical products for domestic use. I found that there was no such control in relation to the laboratories that manufacture drugs (É trágico…, set. 1962).

In another interview with Lenz, published by the *Folha de S. Paulo* (Apreendidos..., ago. 1962), the scientist resoundingly emphasized that the tragedy resulted not only from a laboratory's negligence, but a broader failure he attributed to "the functioning of society:"

> Lenz does not place all the blame on the laboratories. He thinks that society itself is equally to blame... On the other hand, the free sale and the blatant propaganda cause the public to place themselves in danger from drugs they do not need. And this without even a word of advice from the health authorities. 'Consequently, the tragedy of thalidomide is not only the fault of those who manufactured it, but also the lack of good sense in the society in which we live.'

An article in *O Cruzeiro* (Continua…, set. 1962) again cited Lenz, referring to the feeling of guilt among mothers who took the drug: "Lenz noted that mothers were reluctant to admit they had taken the drug, afraid of their husbands and family." This situation, according to Lenz, caused significant difficulty in studying the new cases that the drug may have generated several months after it was taken off the market.

The press also portrayed (in a sensationalist manner, on occasion) the legal and ethical dilemmas generated by this drama in the affected families, bringing to light issues such as euthanasia and abortion. The *Folha de S. Paulo* (Matou…, 1962) reported a case in Belgium:

> She killed her daughter deformed by thalidomide.
>
> A young woman 25 years of age, after giving birth to a daughter with defects resulting from use of thalidomide during pregnancy, obtained a prescription for barbiturates from a physician and mixed it with honey; she gave this to her daughter and killed her, with consent of her husband and her mother.

Following this event, the *Folha de S. Paulo* (Mãe…, 1962) published the article "Mother held," referring to the same young woman. After some time, the magazine *Manchete* (Após…, 1962) stated: "After lengthy discussions, the jury in Liège acquitted the defendants on trial for killing a child deformed by thalidomide." The story continues:

> What was at stake was more than a family drama: the errors of medicine and the greed of industrialists, who want to make profits at any cost, releasing harmful drugs with terrible consequences for genetics, without being thoroughly tested. And behind all of this there was still the tormenting and serious question: should we let abnormal children live? (Após…, 1962).

The same issue of the paper contained an article on "Legal abortions in Sweden" (Abortos...,1962), referring to seven women who underwent legal abortions after having taken thalidomide while pregnant. Another article in the same newspaper (Drama..., 1962) reported the position taken by the Catholic Church: "Thalidomide drama: Vatican attacks decision by mother of future child with defects," referring to a woman in Arizona who caused a miscarriage so she would not give birth to a creature deformed by the effects of thalidomide.

After the drug was recognized as causing defects and banned in many countries, the subject reappeared in the headlines when the trial of the pharmaceutical manufacturer Chemie Grünenthal began in Germany in 1968. Under the headline "Thalidomide: those responsible begin trial" (Talidomida…, 1968), the *Folha de S. Paulo* reported:

> The trial of Dr. Heinrich Mueckter, head of scientific research at Chemie Grünenthal, and his colleagues began today at 10:00 (5:00 in Brasília), in a rented ballroom. The directors are accused of breaching the German drug law, first recklessly and then deliberately causing physical injury, and are also accused of causing wrongful death by neglect.

The newspaper reports that some three hundred spectators and journalists had gathered to follow the trial, in addition to the five judges and two magistrates. The total cost and potential duration of the trial, according to the report, could only be compared to the trials of the Nazi war criminals.

In 1968, the *Folha de S. Paulo* (Sedativo…, jun. 1968) reported new cases of embryopathy caused by thalidomide under the headline "Sedative led to little monsters" and questioned drug safety: "Thousands of small 'monsters,' victims of congenital malformations, appear today in various countries around the world as a terrible warning against the unknown dangers of modern miracle drugs."

The magazine *Seleções do Reader's Digest* (Isto pode…, jan. 1969) warned "This could happen again," reporting the news that thalidomide was again being tested for use to treat nodules. In this respect, the thalidomide tragedy was reported from the viewpoints of the victims' parents, who in Germany had formed 42 organizations dedicated to the problems faced by these children.

The 1970s: mobilization around victims' rights

In the 1970s, Brazilian newspapers began to disclose reparations received by thalidomide victims around the world. This process was much more delayed in Brazil, as the press stated. However, the articles reported that the victims began to organize themselves and fight for recognition of their rights and for better drug regulation.

In 1973 the newspaper *O Estado de S. Paulo* (Trezentos..., nov. 1973) published news from London: "Three hundred million for thalidomide victims," stating that after 12 years of struggle, 433 British children with birth defects would be compensated by the Distillers company, which had distributed the drug in Great Britain:

> They will be paid 20 million pounds … of this total, six million pounds will be divided among the victims, and the rest will be deposited in a fund to ensure the future of these children. The fund was established because many of the children will not be able to work when they become adults.

Reparations to the victims were also underway in Japan. In 1974, *the Estado de S. Paulo* reported (Japão…, out. 1974) "Japan grants compensation for thalidomide:" "The families of 63 Japanese children, deformed after prenatal use of thalidomide, will receive compensation varying from 28 to 40 million yen."

The article also emphasized the parents' allegation that the government had not taken immediate measures to prohibit the sale of thalidomide after the German physician Lenz warned in 1961 that pregnant women should not take it.

In Brazil, as the drugs continued to be produced and used to treat leprosy, the magazine *Veja* (Ainda…., ago. 1973) reported: "Still thalidomide," arguing that there was negligence on the part of the health authorities and recalling the tragedy:

> It was, without doubt, a tragedy composed of misunderstandings. And, more than anything, absurd acts of negligence. Since 1957, the directors of the Grünenthal … knew that their product … could have adverse side effects on the nervous system.

> Nevertheless, the company continued to produce it, promote it, and sell it for another four years. In 1961, … thalidomide, which up to that point had been sold in 51 countries, was removed from the market … In Brazil, the victims … until now had comprised an unknown legion… The first cases have begun to be notified.

From that point, the search for thalidomide victims began in Brazil, first in Porto Alegre and São Paulo, and then in other locations. The *Folha de S. Paulo* (Vítimas..., ago. 1973) reported: "Thalidomide victims begin their campaign today," describing a gathering in Campinas organized by Mrs. Angelina Nacarato, whose son was affected by thalidomide, and the lawyer Karoly Pichler. Mrs. Nacarato told the newspaper:

> We, who have suffered all these years … we are very passive about the issue. It is incredible that I have only been able to bring together 22 children in the state, when we know that there are many more. This gives the impression that they aren't even interested in the money. But our case is not just about the indemnification. We want all the children in Brazil to be compensated, at least for the non-material losses they have suffered (Vítimas…., ago. 1973).

The article goes on to explain that the gathering would not only be the scene of discussions about deformations or emotional disorders in these children, but also about genetic testing to be done by State University of Campinas Medical School (Faculdade de Ciências Médicas da Universidade Estadual de Campinas), under the coordination of Professor José Fernando Pereira Arena. The meeting was also intended to mobilize the group to demand government compensation, because even though they knew about the deformations caused by thalidomide, the authorities allowed sales of the drug in the country to continue.

The newspaper *O Estado de S. Paulo* (Famílias…, ago. 1973) also reported on the organization of the victims. The article "Rio Grande do Sul families intend to demand pensions from the government" explains: "Obtaining a lifetime pension from the government for children affected by thalidomide is the goal of seven families from Rio Grande do Sul who gathered Saturday in Porto Alegre and decided to form an association."

The note refers to the first association of the families affected by the tragedy, the Association of Parents and Friends of Child Victims of Thalidomide (Associação de Pais e Amigos de Crianças Vítimas da Talidomida, ABVT), created to provide legal, medical, dental, and psychological assistance to these children. To do so, ABVT had university support: PUC-Campinas and Unicamp helped with psychological assistance, and dental evaluations were performed by the pediatric dentistry team at the Piracicaba School of Dentistry. The association also organized support to acquire prostheses and wheelchairs. However, in its newsletter, the ABVT (Dificuldades..., ago. 1974) reported difficulties in getting parents to join the association, which were attributed to problems they faced earlier when were required to prove that their children were victims of thalidomide by showing medical prescriptions of the drug.

From the original headquarters in Porto Alegre, two other regional groups were created in Belo Horizonte and in Campinas. Little by little, victims began to appear in other regions of Brazil. The ABVT bulletin (Surgem..., set. 1974) reported: "Two thalidomide victims appear in Salvador." According to the article, the father of one of the victims had filed a lawsuit and would receive 22,000 cruzeiros in compensation, in addition to the monthly pension granted by a German foundation to help children victims of thalidomide.

The *Folha de S. Paulo* (Vítimas..., jan. 1975) reported on "Victims of thalidomide in Rio." The physician Harold Rocha Portela, director of the São Zacarias Hospital, stated that the exact number of victims was difficult to clarify because of the lack of statistics and absence of communication between the physicians who cared for the patients. The physician, who had published ten articles abroad about the congenital malformations caused by thalidomide, reported that twenty cases had appeared since 1953 in his hospital alone. The *Diário do Povo* (Associação…, mar. 1975) also reported on the association's search for victims across the country.

The press indicated that several lawsuits were filed to demand responsibility from the domestic laboratories that produced the drug, but without much success, according to the headlines of the *Jornal do Brasil*: "Lawsuits on effects of thalidomide challenged" (Contestadas…., nov. 1976) and *O Brasil*: "Laboratories challenge suits by parents of children damaged by thalidomide" (Laboratórios…, jan. 1977). The latter reported:

> Through the lawyer Walkirio Bertoldo, in October of 1976 the parents of children initiated a suit demanding compensation against the three laboratories in São Paulo, because they produced thalidomide-based medications which were taken by the mothers, and also against the government for having allowed the sale of these products in Brazil.

The newspaper *Zero Hora* (Advogados…, maio 1977) also discussed the cases. The article "Lawyers for thalidomide victims file appeals" explains:

> In the coming days Walkirio Ughini Bertoldo, the lawyer representing the 146 Brazilian victims of thalidomide, will file a review appeal against the decision of the 5th federal court judge … who declared himself not competent to judge the case and passed it on to the Federal District court.

This search for support to compensate the victims was also reported by the *Estado de Minas*: "Victims of thalidomide appeal to Geisel" (Vítima..., out. 1977); by the *Correio Braziliense*: "Augusto Frein defends victims of thalidomide" (Augusto..., jul. 1978); by *Zero Hora*: "Figueiredo will hear thalidomide victims" (Figueiredo..., jul. 1978); and by the *Folha de S. Paulo*: "Fund proposed for victims of thalidomide" (Proposto…, 1978). In this last article, the association's legal adviser Walkirio Bertoldo recalled that Brazil was the only country that still had not provided a solution for the greatest tragedy in medicine, and also said: "While the maneuvers of the government and the Sintex, Ceil, and Americano pharmaceutical labs continue, favored by the structure of our slow judicial system, cases of suicide and other dramas increase among the Brazilian victims of this medication" (Proposto…, 1978).

In 1978 the *Diário de Notícias* (Victims…, out. 1978) reinforced: "Thalidomide victims demand compensation" and quoted the complaint filed by ABVT against Sintex do Brazil (formerly Instituto Pinheiros), Laboratório Americano de Farmacoterapia, and Comercial Exportadora and Industrial Ltda. (Ceil), stating: "We call on the public to boycott their drugs, help us, complain."

Although in 1978 ABVT was strengthened by an increase in membership and also was recognized as an association of public utility, the cases it promoted in the courts were losing strength. In 1979, the *Gazeta Mercantil* (Fornecedor…, jul. 1979) stated that the "Supplier of thalidomide [was] excused from indemnification," explaining that the rapporteur of the

proceedings had excluded the German laboratory based on a clause in the contract to supply the product between Grünenthal and Syntex do Brazil (formerly Instituto Pinheiros), which expressly excluded the German company from liability for any damage caused by the drug.

During the same period, in other countries the focus now concentrated on the daily lives of the children. "Thalidomide victims may already face a better life," read an article in *Seleções do Reader's Digest* in 1978 (As vítimas…, 1978): "The world has followed with interest efforts by British, German, and Russian specialists who strive for recovery in children deformed by thalidomide … to do so, they study equipment that allows them to live normally, eating, walking, playing, and even having a profession in the future."

It explained that the performance of these children in school had surprised the teachers, because they learned with ease. The article reported that in the Chailey Heritage School in Sussex, England, children who were victims of thalidomide received therapy for social independence. In terms of mobility, it stated that in Germany gas-powered arms and hands had been developed, and that Russian scientists had invented a bioelectrical arm driven by impulses in the brain, in order to improve the daily lives of these children.

The 1980s: victims reach adulthood, the end of legal wrangling, and Brazil's new health policy

In 1981, the ABVT newsletter (Conquista…, jun. 1981) commemorated the 42 lawsuits that had obtained compensation from the German company for Brazilian children.

Another case was in progress at the national level. *O Estado de S. Paulo* (Figueiredo…, abr. 1982) announced "Figueiredo will decide on thalidomide agreement," referring to a project president João Figueiredo had sent to congress that would create a life-long pension for the victims. The article also reported the expectations of lawyer and president of ABVT at that time, Walkirio Bertoldo, who had been meeting with legal advisers from the Ministries of Health and Social Welfare, as well as with the lawyers defending the laboratories in the case. It states: "In July of last year, thalidomide victims held a national gathering in Porto Alegre to define a strategy to pressure the government and the laboratory to resolve the case, because Brazil is the only country which has not yet made a compensation agreement" (Figueiredo…, abr. 1982).

In the *Jornal de Campinas* (Associação..., jul. 1982) the president of the Campinas Victims' Association, Angelina Nacarato, stated that many families had not yet sought out the association to pursue their rights, whether through ignorance or exhaustion. She estimated that there should be more than 300 victims in Brazil. Nacarato mentioned the compensation agreement under discussion in the congress, and criticized the proposal to pay two to four times the minimum wage at that time to each victim, considering it insufficient: "Unwilling to accept the pension amount specified by the government, Angelina says: 'The authorities need to know how a person affected by this drug … is discriminated against in society. And that this person was a victim, and is not to blame'" (Associação…, jul. 1982).

In December 1982, the government approved Law 7.070, which established a special pension for physically disabled people with thalidomide syndrome; this pension was monthly, life-long, and non-transferable, and was provided to those petitioners who could provide a

doctor's certificate stating they lacked the ability to work, move about, take care of their own personal hygiene, and feed themselves.

In 1983, two articles introduced a new problem: new uses of thalidomide. The newspaper *Zero Hora* (Fantasma…, out. 1983) reported: "A ghost from the past: English physician treats pain with thalidomide," referring to the use of thalidomide to treat Behcet's disease, which causes painful ulcers. It stated that thalidomide victims in London had expressed their willingness to resume the campaign against the drug on a global level.

The *Folha de S. Paulo* (Malformações…, mar. 1983) published a news story about new cases: "Thalidomide malformations in Paraná" and about the first measures related to pharmacovigilance of thalidomide, since it continued to be dispensed to treat leprosy (Hansen's disease): "After five more cases of children born in the last six months with malformations caused by the use of thalidomide by their mothers during pregnancy, the Paraná State Department of Health (Secretaria de Saúde do Paraná) yesterday announced the adoption of stringent measures to control the distribution of this drug to patients with Hansen's disease."

According to the article, around 20,000 people in the state were treated for this disease using thalidomide at Department of Health clinics. It reported that this drug was distributed freely, without adequate medical guidance and without testing for pregnancy before prescription. The newspaper stressed the distribution of information booklets to patients and educational posters at health clinics among the measures adopted by the Department of Health.

The use of thalidomide to treat Hansen's disease was also addressed by *Zero Hora* (Talidomida…, set. 1987), which stated: "Thalidomide, only in Brazil:"

> According to Doctor Thomaz Rafael Gollop, head of the Department of Human Genetics at the São Paulo Maternity Hospital … thalidomide is given indiscriminately to all victims of Hansen's disease, without even any information given to women of childbearing age about how to avoid having children… 'In our service alone over the last seven months we attended six patients who had been treated with thalidomide.'

The renewed use of the drug, still without specific legislation, revived the specter of new cases of teratogenicity. In this context, *Zero Hora* (Defeito…, 1984) reported a study indicating the possibility that the effects of the drug could be inherited: "Thalidomide defect is passed in the DNA:"

> The deformities caused by thalidomide can be transmitted by heredity, said a group fighting for the rights of victims of this substance yesterday in London … the thalidomide victims want Guiness to fund more research on the effects of the drug. In recent studies, McBride and the pathologist Peter Huang perceived that thalidomide can affect the DNA of eggs and sperm.

The results of this research were not confirmed in the following years, but the reporting in the press incited fears that unregulated use of the drug could cause more damage.

In 1985, the magazine *Manchete* (Os filhos…, 1985) announced: "Thalidomide children demand justice," describing the conditions of thalidomide victims in the 1950s and 1960s, and hoping that in Brazil that they would reach adulthood with the hope that the authorities would finally help them. The story characterized the victims in Brazil as politicized and not

trusting the political class, since up that point they had not received effective responses from the government. It also clarified that thalidomide had had no effect on the victims' offspring, reporting a case: "The pregnancy occurred in September 82, after consulting the obstetrician… about possible risks. 'He guided me from the beginning and reassured me completely. There was no reason for the thalidomide to affect my son, because the drug is not present in my body and does not alter the genetic constitution of the victims'" (Os filhos…, 1985).

Finally, the article reported that the victims were preparing to file a lawsuit against the government to readjust their pensions: "We have received two and a half minimum wage [equivalents] from the government, which are adjusted in March. This is not fair, in a country where inflation is rampant. We have to complain. After all, they let the drug enter here, and let it do enormous damage to a number of people. The least they owe us is a decent pension" (Os filhos…, 1985).

This process of growing mobilization among Brazilian thalidomide victims in the 1980s would find a more conducive environment to ensure the population's rights to health and drug safety. In the context of the redemocratization of the country, a new era began in public health with the creation of the Unified Health System (Sistema Único de Saúde), charging it with control and supervision of procedures, products and substances of interest to health, as well as health and epidemiological surveillance activities. With the contribution of social movements, health conferences and councils were established; these were permanent in nature, entrusted with decision-making in formulating strategies and monitoring health policies. These activities made space for social participation in the context of struggles for the right to health. This was also the case for the thalidomide victims' movement.

In 1991, the Associations of Parents and Friends of Child Victims of Thalidomide were merged at the initiative of Claudia Maximiano. These children, who now were adults, founded the Brazilian Association of Thalidomide Syndrome Victims, headquartered in São Paulo. Actions on the part of the association, which had slowed, were renewed, and a new stage in the victims' negotiations for their rights began. The mobilization in the health councils and at Anvisa focused on regulating drugs; Ordinance 354 of 1997 finally regulated the manufacture and registration of thalidomide-based products. The use of this medication was extended to treat Aids, lupus, multiple myeloma, and specific cases of graft rejection.

Final considerations

Reconstructing the thalidomide tragedy by reviewing the literature, documents, and articles in Brazilian newspapers in the ABPST archive showed, first of all, the magnitude of this event amidst the context of the rapid internationalization of the pharmaceutical industry, the post-war baby boom, and the incorporation of drugs into a new standard of consumption stimulated by aggressive advertising. Second of all, this process showed how fragile regulation and the practices of communication between physicians and institutions were, not only permitting the tragedy to occur but also producing a sluggish response in facing it. Third, it proved the tremendous inequality between the power of the companies

that caused the problem, obtaining agreements to avoid criminal accountability for the events, and the victims who took decades (despite their growing organization) to obtain compensation and assistance, which varied from country to country.

We observed that the media became a space for the victims' voices, playing an important role in transforming the drama of families into a public problem. Organizations of victims and family members, as well as doctors, lawyers, and other actors, publicly demanded greater control of the pharmaceutical industry and decried slow responses to the victims. The publicity also helped achieve the objectives of other platforms such as rights for people with disabilities, and promoted the social debate on bioethics issues related to conflicts of interest in health, the right to life, and abortion.

The study shows that the constitution of this disaster as a public problem, increasing mobilization of the affected groups, and restoration of the democratic institutions that provided significant spaces for public control of the healthcare system were necessary for effective progress in regulating drugs in the country and recognizing the rights of victims.

However, despite the almost uninterrupted use of this drug, the country progressed slowly in developing regulations that would protect patients and compensate victims, and that legislation still exhibits difficulties in effective implementation. As a consequence of this lapse, Brazil became the only country with three generations of thalidomide victims.

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NOTES

[1] According to Penna et al. (2005), an international study sponsored by the World Health Organization (WHO) to verify the clinical benefits of thalidomide in treating Hansen's disease was conducted in Brazil, India, Spain, Mali, and Somalia in 1971. Although this study offered evidence about the benefits of thalidomide for treating this disease, it was also questioned because of the diversity of methodologies used.

[2] In this and other citations of texts from Portuguese, a free translation has been provided.

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