

# LOCAL PRODUCTION OF DRUGS AND CORPORATE CAPTURE:

## ANALYSIS OF THE BRAZILIAN CASE



GRUPO DE TRABALHO SOBRE  
PROPRIEDADE INTELECTUAL



ABIA  
ASSOCIAÇÃO BRASILEIRA  
INTERDISCIPLINAR DE AÍDAS





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**ORGANIZATION:**

Brazilian Network for Peoples  
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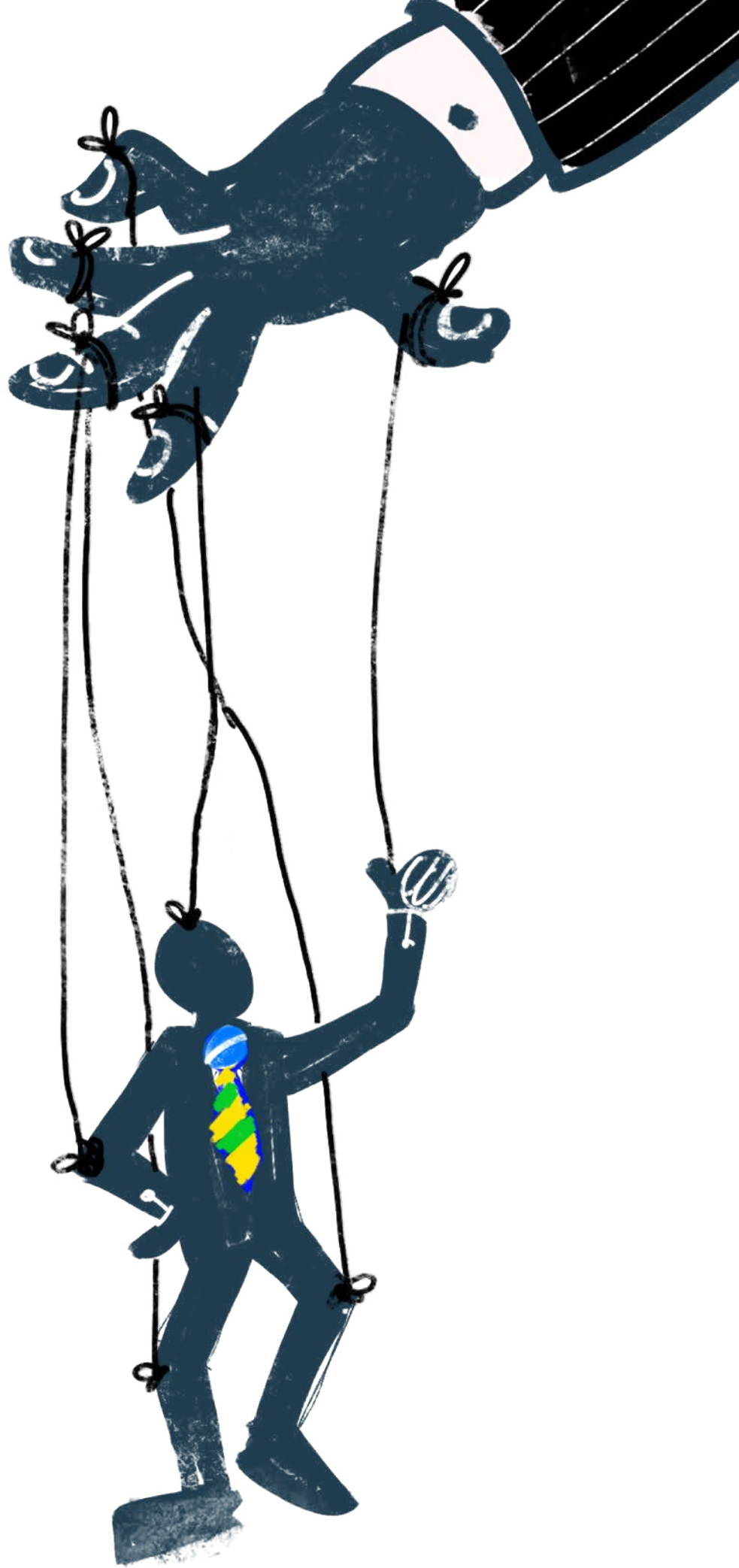
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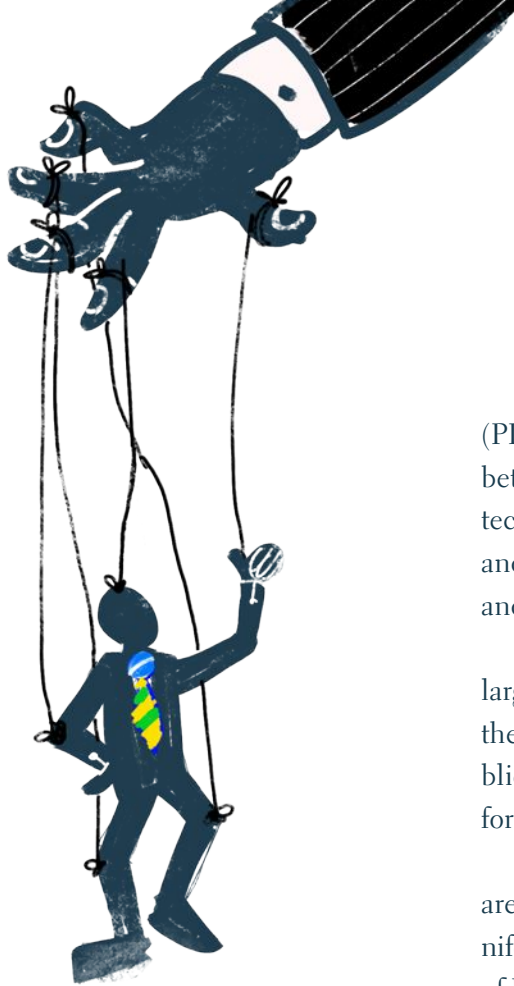
# Executive Summary

**I**n January 2016, Oxfam published its 210 OXFAM Briefing Paper, titled “An Economy for the 1%.” In this report, it is clear how the current economic and development model has produced and continues to produce extreme inequality. According to the document, 1% of the global population holds more wealth than all the rest – the 99% – combined. There are several reasons for this concentration; and consequences as well.

One important consequence is the power to influence political decisions resulting from all this wealth. Capture of public policies by private entities is not rare; nor are the various ways this capture occurs. In a world of extreme inequality, in which companies often have higher revenue than the GDP of a developing country, designing public policies, with regulatory instruments to prevent these companies from capturing public policies, is a Herculean task.

According to the OXFAM briefing paper, one of the ways to deal with the tendency towards increasing concentration of income, and consequently, power, at the global level, is to invest in universal and free public health systems, such as the Single Health System, in Brazil, or the National Health System, in England. Furthermore, the report states that it is necessary to change the way medical research is conducted and establish drug prices that are accessible for the populations that need them.

These two themes – universal health systems and access to drugs and corporate capture of public policies – and their manifestation in Brazil are the themes of this study. This study was conducted within the scope of the Empowering Civil Society Networks in an Unequal Multi-polar World project (ECSN-BRICSAM), which seeks to understand the sources of inequality in health, lack of access and poor quality of health related to the most diverse forms of corporate capture, such as lobbying, privatization, concessions, tax benefits, etc.



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Since 2008, the so-called Productive Development Partnerships (PDPs) have become institutionalized in Brazil. These are partnerships between public and private laboratories (Brazilian and transnational), for technology transfer of drugs and other health technologies, so that public and private Brazilian laboratories can subsequently own the technology and supply the drug (or other input) to the Ministry of Health.

If we consider the current level of inequality and the power of the large multinational pharmaceutical companies, we need to delve into the theme in order to understand the complex relationship between the public and private entities involved in the PDPs, as well as analyze possible forms of corporate capture behind these partnerships.

Thus, we are looking for some analytic parameters to verify if there are cases of corporate capture in the PDPs and how these practices are manifest. The parameters defined were: (a) analysis of the prices the Ministry of Health (MH) pays for PDP products; (b) a brief analysis of the situation of Brazilian public laboratories; (c) a critical analysis of Ordinance 2531 of 2014, that currently sets the rules for PDPs and their ramifications in terms of transparency and participation; and (d) cases of policy implementation. The data was obtained between February and August 2015.

Due to the large amount of data, tables, graphs and other information, it was not possible to include all these elements in the text of this study. Therefore, four annexes were organized. Annex I contains the graphs and tables listed throughout the text; Annex II provides a deeper analysis of the situation of the Ezequiel Dias Foundation; Annex III consists of the requests made by means of the Law of Information Access; and Annex IV presents more information on the live interviews conducted. These annexes are available at:

To prepare the conceptual background of this study – the concept of corporate capture – a brief bibliographic discussion was conducted. With regard to the policy itself, a survey of official documents, articles and books assessing the results of policies to strengthen local drug production was made.

While some data were published on websites, others were not. If was necessary, therefore, to use e-SIC (the Electronic Citizen Information Service) in order to better understand the issues related to the intellectual property, regulation, control and monitoring of technologies targeted by the PDPs. Six requests for clarification of the pharmaceutical forms of

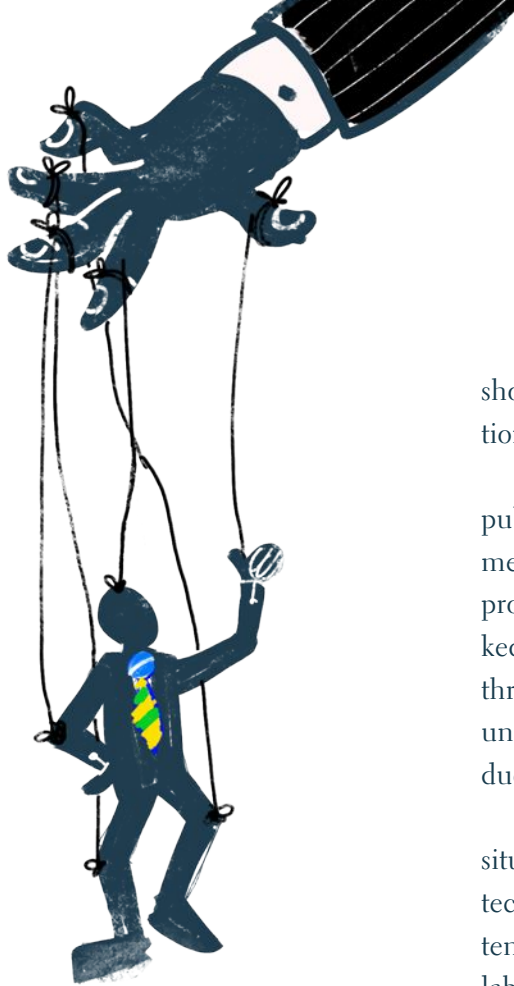
the drugs involved, the patent status of the technologies, details of the fiscal spending on health by the government and on contributions by the population and entities in the public hearing on Ordinance 2531/14, were filed. In addition, three live interviews were conducted with the Ministry of Health, specifically the Secretariat of Health Science, Technology and Innovation (SCTIE), the Cristália Laboratory, a Brazilian private laboratory, and the Ezequiel Dias Foundation, a public laboratory.

After a brief review of the regulatory evolution of the intellectual property system in the global environment, we move on to a more detailed analysis of how the regulatory framework of the Productive Development Partnerships has evolved in Brazil. After a description of how the partnerships are structured, we continue with an analysis of Ordinance 837/12, the first that regulated PDPs, and the change to Ordinance 2531/14, which currently regulates the policy.

To understand how Ordinance 2531/14 came about, we reviewed Public Inquiry No. 8 of 2014 and its contributions. A first finding is the enormous participation of the private sector in contrast to the few contributions by organizations defending the public interest. It is not by chance, in regulatory terms, that Ordinance 2531/14 offers a much more permissive environment for private interests than the prior ordinance: no concern with policy transparency, classifying the information as secret; no measure to encourage equitable participation in execution of the policy, including only representatives of public and private laboratories and public managers and excluding society from the discussion; extension of the technology transfer deadline, generating greater exclusivity and higher prices; and no provision for dealing with the monopolies created by patents.

Then we moved on to an analysis of how the policy is implemented. For this, we reviewed pricing data and how the PDP can end up extending the patent monopoly and preventing Brazil from formulating combinations important for public health, as in the case of the drug for HIV/AIDS, Atazanavir.

With regard to prices, we used the limited data available on websites such as the Transparency Portal, the Federal Official Gazette and those sent in response to requests made by e-SIC. In an internal publication of the Ezequiel Dias Foundation, an annual minimum savings of 5% is forecast, with the advent of PDPs. After analysis of the data for 13 of the 27 products currently in the PDP phase, during the 2010 to 2015 period, six



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showed no reduction in purchase price and another three showed reductions of less than 5%.

We moved on to a consideration of the situation of the FUNED public laboratory. There are various questions that go beyond the implementation of PDPs, related to management and regulation of the drug production policy in Brazil. A one-dimensional approach to the PDPs looked at the laboratory only in terms of the products chosen to be developed through PDPs. In an impressive way, the production of pharmaceutical units considered essential fell drastically, far below the laboratory's productive capacity.

The next topic to be discussed closely related to the prior one – the situation of FUNED – is the non-involvement of the Ministry of Health in technology transfer contract negotiations between public and private, often transnational, laboratories. What is seen is a scenario in which public laboratory administrators do not have effective experience or mechanisms to negotiate contracts of this type with Brazilian or transnational private laboratories. This scenario ends up promoting corporate capture of public policies, to the extent that the existing regulation does not provide means to prevent or avoid it.

Consequently, the following are the recommendations derived from the data and analyses of the present study:

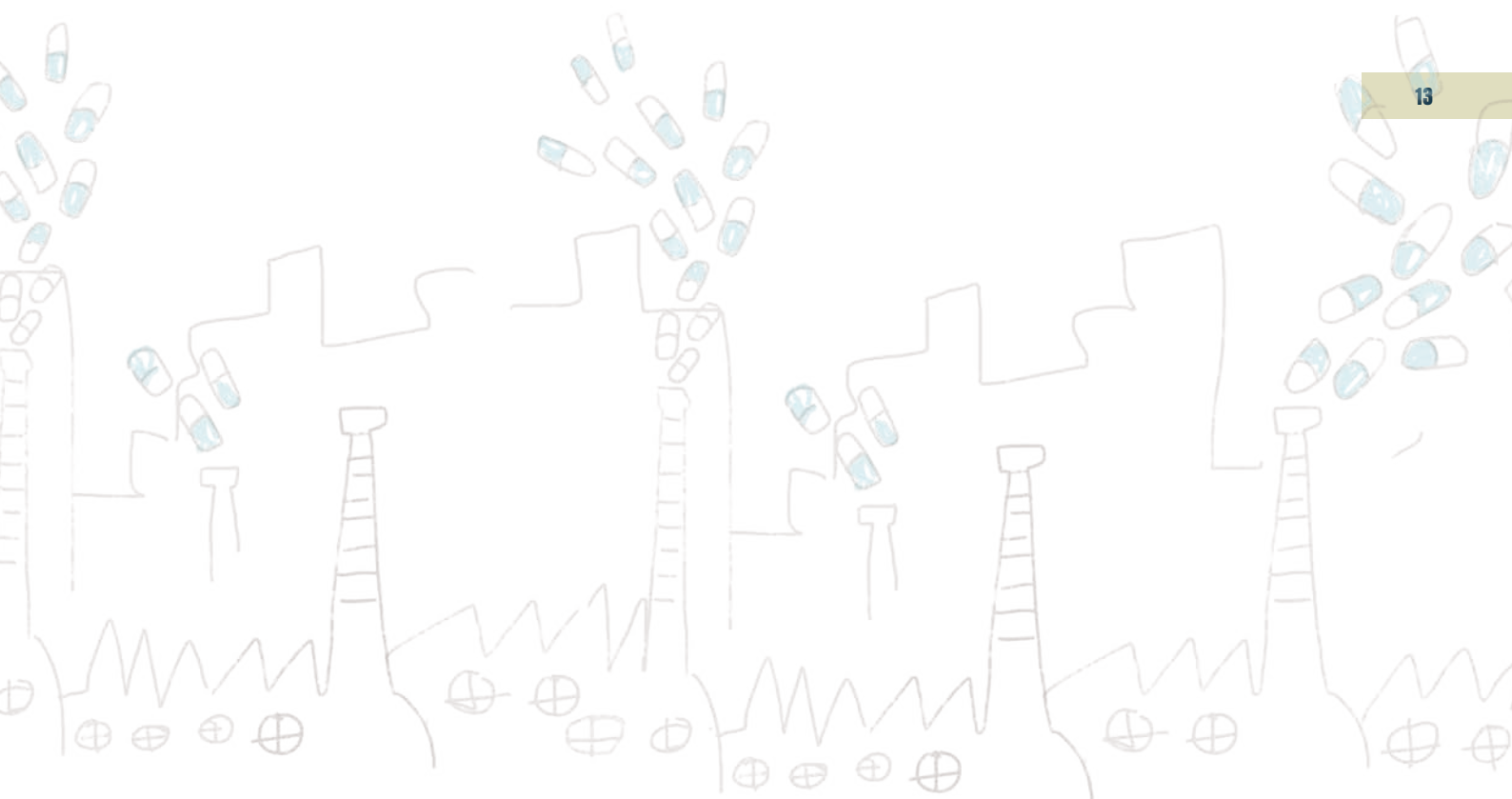
- All documents related to PDPs, which contain data on prices, deadlines, the real impact of projects, and oversight and execution reports, etc. should be published.
- There should be equitable participation of society in the formulation and execution of any public health policy.
- The extension of all types of monopoly through PDPs should be avoided.
- Rules, criteria and objectives for policy, guided by and for public health, should be formulated.
- Every contract that does not solely promote the public interest should be revised.

In this way, rethinking PDP regulation or even rethinking the policy itself is urged. It is necessary that formulation and execution of public health policies really make the public interest the priority, define



the criteria for selection of partnerships, promote dissemination of information, transparency and social participation, and establish punitive criteria and sanctions in case of fraud. In addition, it is essential that the Brazilian government returns to use of the public health safeguards permitted by the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement and provided for in Brazilian law, as in 2007, with the mandatory licensing of the Efavirenz drug, to ensure the right to health and reduction of inequality.

Finally, we can affirm that the practices herein described, which exclude organized civil society from decision making on public policy, increase prices and tax exemption practices and undermine transparency, serve solely the interests of corporations, open the door to capture and corruption, and perpetuate high levels of inequality in Brazil.



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As principal investigator in conducting this study, I would like to thank all of those who contributed to it. I want to thank GTPI/REBRIP for the trust placed in me and for helping us with important documents to complete this study. I also want to thank the managers of the Ministry of Health, of the Cristália drug company, and of the Ezequiel Dias Foundation for having me and for agreeing to being interviewed.

## **Dedication**

I dedicate this work to all Brazilian citizens who need the Unified Health System and to those who are working on a daily basis to strengthen this vital system for well-being of the Brazilian population.







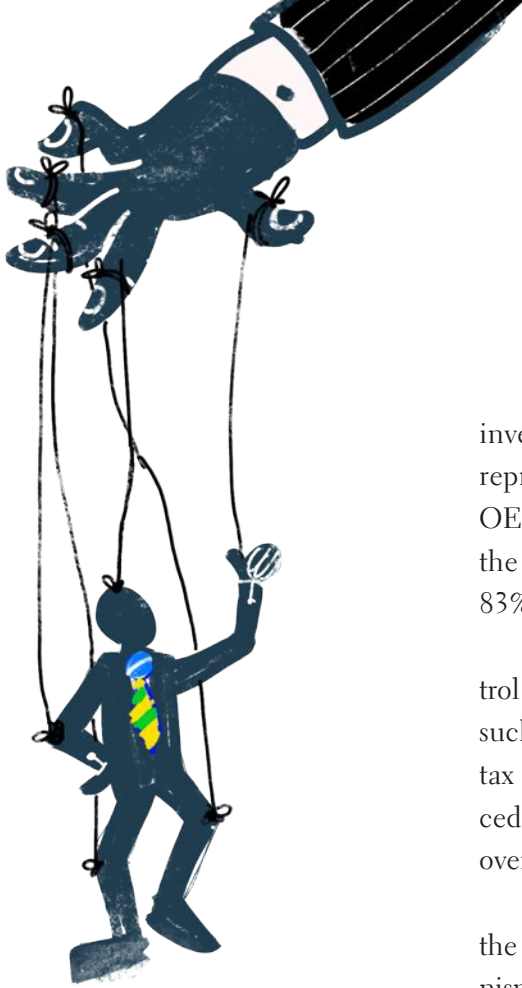
## 1. INTRODUCTION

In January 2016, Oxfam launched its Report No. 210, entitled *An economy for the 1%*. That report clearly shows how the current economic model has led and continues to lead to situations of extreme inequality. According to that report, 1% of the global population may have more wealth than all the rest of it - the bottom 99%. There are several reasons for this concentration of wealth, as well as many consequences.

The power to influence political decisions resulting from all this wealth is a major consequence. Cases of capture of public policies by private entities are not rare; as are the various forms that such capture takes. In an extremely unequal world, where companies often have higher revenues than the GDP of a developing country, drawing up public policies with regulatory tools to prevent such companies from capturing public policies is a Herculean task.

According to Oxfam's report, one way to overcome this trend toward income concentration and, consequently, toward concentration of power globally is to invest in universal and free public health care systems such as Brazil's Unified Health System or the UK's National Health System. More than that, the report states that it is necessary to change the way medical research is being done and to set drug prices at affordable levels for the populations that need them.

In Brazil, the right to health is ensured to all citizens through a universal and integral system that carries out health promotion, prevention and recuperation actions and it is the duty of the State to provide health care services (Federal Constitution of 1988). It is estimated that spending on health care nationwide in 2013 amounted to 8.9% of the Gross Domestic Product (GDP), which is a percentage similar to those recorded in countries of the Organization for Economic Cooperation and Development (OECD), such as the UK, Spain and Australia, namely, 9.32%, 9.44% and 9.03%, respectively.



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However, if we take a closer look at these data, we see that private investments account for 54% of that figure, while public investments represent 46% of it (Brazil, 2013a). In countries such as those of the OECD, public investment in health care exceeds 70% on average and the highest percentage is the one recorded in the UK, of approximately 83% (Brazil, 2013a).

In addition, it is important to consider governmental financial control mechanisms that have an impact on universal access to health care, such as the so-called de-earmarking of federal budget items (DRU) and tax exemptions for health care. Combined, these two mechanisms reduced funds previously earmarked for the Unified Health System (SUS) by over R\$14 billion between 2010 and 2011.

Moreover, private sector participation in health care services is on the rise in Brazil. It is therefore important to rely on independent mechanisms to regulate the private sector with the aim of ensuring transparency in the process of inspecting the participation of private companies in health care, so as to preserve the universal aspect of the Unified Health System (SUS), fight inequity and address situations of lack of access to health care actions and services.

Concerns about the influence of private actors on public policy are not recent. Freitag (1983) pointed out that the American academy demonstrated in the late 1970s the influence of corporations on public institutions through a phenomenon referred to as “corporate dictatorship.” Even back then there were clear concerns about the “capture” of the US government by corporations and about the “revolving doors” phenomenon, which remains so current today.

The corporate capture issue has been discussed at the United Nations for decades, but no major changes have been recorded for the populations and communities affected by it. In recent years, however, the UN Human Rights Council began to make significant progress in this area, mainly as a result of a historic voting session in 2014, when approval was given to set up a working group charged with drawing up a binding treaty designed to punish transnational companies for human rights violations. Globally, a civil society campaign called “Dismantle Corporate Power” and other important actions could benefit from the results of this study.

Several of these events were triggered by a record of obscure and rights violating actions of private companies. Recently, the power of corpo-



rations to influence legislation, regulatory frameworks and even agencies intended to regulate their activities has been drawing attention especially from social movements and civil society organizations, leading them to prepare several reports on the nature of such interference in different fields (FOEI, 2015; Kato & Sá, 2013; *Repórter Brasil*, 2015). It should be noted that academia has also been studying the subject in detail (Monks, 2012; Roland et al, 2013; Dal Bo, 2006, among others)

The corporate capture concept proposes a variable and a dynamic effect under which public policies and institutions become corporate-biased in their objectives. In the health care field, corporate capture leads government agencies to change health policies, disregarding the effects of such changes on people's lives and on public health and favoring only the interests of corporations that should be regulated by these agencies (Abraham, 2009).

Therefore, in this study we bring up some issues related to current Brazilian policies designed to stimulate the domestic production of drugs. We will try and analyze the influence of the drug industry on the regulation of this policy in the context of a highly permissive environment for domestic and foreign private investment in health care.

We also try to understand and demonstrate how these issues relate to the Brazilian public health care system. The SUS system provides perhaps the greatest example of a national public policy implemented horizontally and with social participation. However, this system has been constantly affected by lack of funds and social participation; by outsourcing and privatizations; government after government, by tax exemptions and benefits granted to private companies with funds that should be allocated to financing public health care.

Finally, we will try and expose the means used by large corporations – in this case drug companies – to adapt, change, suppress or approve regulations and public policies to defend their commercial interests. For this purpose, we analyzed ordinances, inputs from public consultations, laws, the production capacity of public drug manufacturers and drug price data. Using the corporate capture concept as a backdrop, we sought to understand which direction major policy decisions are taking in the health care area. The so-called Partnerships for Productive Development (PDP) were a topic of special interest in this study.

For the purposes above, the study was organized as follows. The text itself is divided into eight parts: 1. introduction, 2. access to drugs



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and intellectual property in Brazil: evolution of the regulatory framework, 3. public-private partnerships in health care in Brazil: partnerships for productive development, 4. Anomalies in acquisition prices and lack of transparency in calculations of cost benefits. PDPs as an extension of patent monopoly, 6. situation of public drug companies, cost benefits and technology transfer, 7. non-involvement of the Ministry of Health in negotiations, 8. final considerations.

In these eight sections, the topics we sought to address in detail were the following ones: (a) analysis of acquisition prices paid by the Ministry of Health (MS) under PDPs; (b) a brief analysis of the situation of domestic public drug companies; (c) a critical analysis of Ordinance 2,531 of 2014, which sets out rules for PDPs and their consequences in terms of transparency and participation; and (d) policy implementation cases. The data were collected between March and July 2015.

Due to the large volume of data, tables, graphs and information involved, it was not possible to include all these elements in the text of this study. For this reason, four annexes were included in the study. Annex I contains the graphs and tables mentioned along the text; Annex II provides a deeper analysis of the situation of the Ezequiel Dias Foundation; Annex III contains requests for information filed through the Access to Information Act; and Annex IV provides more information on each face-to-face interview that was held. These annexes are available at:

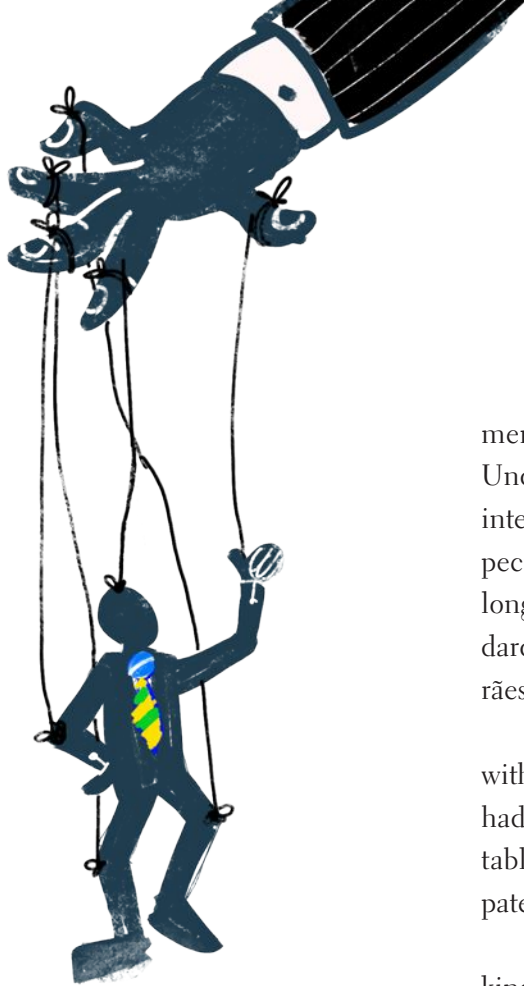
This study was conducted under the Empowering Civil Society Networks in an Unequal Multi-Polar World (ECSN-BRICSAM) project. It is intended to strengthen the collective capacity of multi-thematic civil society organizations (CSOs) in Brazil, Russia, India, Indonesia, China, South Africa and Mexico (collectively referred to as BRICSAM countries). One of the activities contemplated in this project was that of conducting a series of surveys for the purpose of understanding the sources of inequity in health care systems, the lack of access to health care and the bad quality of such systems as a result of several forms of corporate capture, such as lobbying, privatizations, concessions, tax benefits, etc. Haliton Alves de Oliveira Jr. was the principal investigator, supported by Pedro Villardi, Marcela Vieira and Felipe Fonseca.

## 2. ACCESS TO DRUGS AND INTELLECTUAL PROPERTY IN BRAZIL: EVOLUTION OF THE REGULATORY FRAMEWORK

The Paris Union Convention (PUC) was signed in 1883 as the first international legal instrument setting out principles related to intellectual property rights. Under that agreement, each country was free to draft domestic legislation on patents based on three principles: 1) independence between patents and trademarks; 2) equal treatment for foreigners and nationals; and 3) property rights (Nogueira, 2013). For many years, the convention was the benchmark for intellectual property issues. A key aspect of the PUC was the flexibility that it allowed member countries to enjoy in determining the extent of intellectual property protection to be granted within their own territory (Gontijo, 2005). Thus, just like a country had the flexibility not to grant patents on drugs, another one was free to decide that patents would be valid for 5 years. It would even be possible for a country not to allow any field of knowledge to be appropriated by the private sector for any length of time without violating the PUC.

In 1947, the General Agreement on Tariffs and Trade (GATT) was signed and became a milestone for multinational negotiations, mainly favoring the great powers in the post-World War II period. It should be stressed at this point that there was great dissatisfaction on the part of some developing countries, including Brazil and India, over the fact that developed countries could use the GATT to discuss their dissatisfaction over the level of protection of intellectual property rights, which from then on were to be discussed within the World Intellectual Property Organization (WIPO) (Gontijo, 2005).

Given this impasse, the Uruguay Round was held between 1986 and 1994. During that round of negotiations, adjustments were proposed in various provisions of the GATT, including intellectual property provisions (De Andreade Guaracy, 2003). At the end of that round, the World Trade Organization (WTO) was created for the purpose of promoting progressive liberalization of global trade and it was decided that it would concentrate discussions on trade relations and manage international trade agreements from then on (Bermudez et al., 2004).



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To join the WTO, all countries were required to sign all the agreements contained in a single package that became known as the Single Undertaking. This obligation stiffened multilateral agreements involving intellectual property. After signing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), member countries were no longer free as before to enter into agreements providing for lower standards than those established under the TRIPS Agreement (de Sá Guimarães, 2005).

With the signing of the TRIPS Agreement in the 1990s, countries with domestic laws that imposed restrictions on patentable subject matter had to amend them to include all areas of knowledge in their list of patentable subject matter. As a result, all signatory countries had to recognize patents on drugs (Nogueira, 2013; Bermudez et al., 2004).

Recognizing that patents could have negative impacts on the making and implementation of public policies, the TRIPS Agreement allows member countries to include safeguards for public health in their laws. It is important to mention that the TRIPS Agreement does not provide for an exhaustive list of measures, but only for a few options, leaving room for countries that adopted other measures not listed in the agreement, provided that such measures are consistent with its provisions (Article 30).

In fact, since the obligation to conform to the TRIPS Agreement was imposed significant negative consequences on public health and on access to drugs have been recorded in many countries of the Global South. Brazil amended its law on May 14, 1996 to allow for drugs to be patented. Because Brazil has a public, universal and integral health care system, it suffered serious impacts on its health sector, particular on its program to ensure access to antiretroviral drugs (ARVs) for people with AIDS (Corrêa and Cassier, 2010).

This factor led the government to adopt policies to stimulate the domestic production by public manufacturers of drugs whose patents had expired already or had not been granted in Brazil. However, important drugs for the STD/AIDS program were still under patent protection and their prices were high, threatening the program's survival and leading the Brazilian government to invest in the idea of compulsory licensing as a strategy to ensure access to them (Nogueira, 2013).

In the mid-2000s, the Brazilian government decided – or was forced – to tackle the problem of high drug prices by resorting to mechanisms

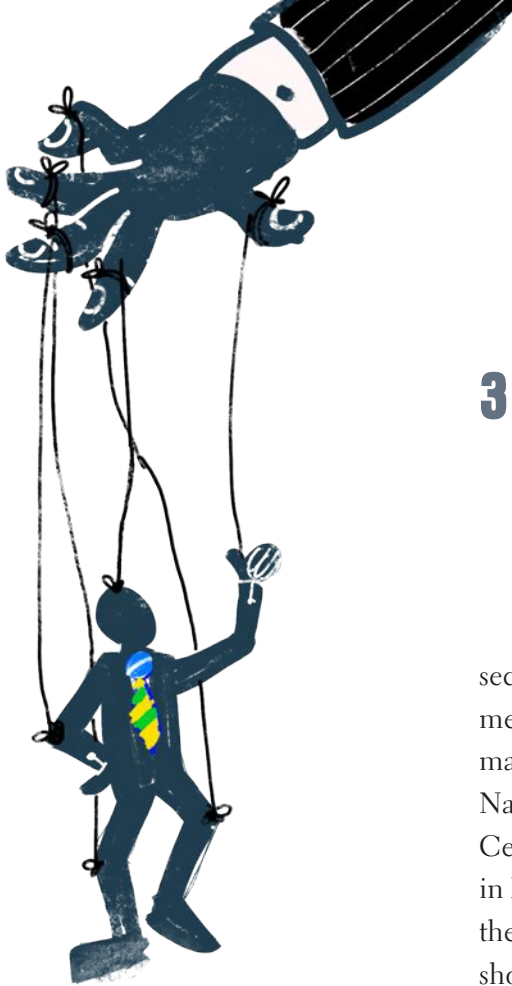
such as the strategic use of public laboratories to support price negotiations and threats to issue compulsory licenses. Compulsory licensing allows for the possibility of exploiting patented products without authorization from the patent holder by government decision in specific cases that justify such measure, as when abusive pricing is detected, when epidemics break out or for reasons of public interest, for example (Nogueira, 2013; Correa, 2001).

Therefore, the Brazilian government began to negotiate price reductions with several multinational manufacturers of ARVs: nelfinavir (Roche), efavirenz (Merck), kaletra (Abbott), among others. In these cases, the negotiations were successful and the government managed to secure reductions in the price of those drugs (Corrêa & Cassier, 2010; Lago & Costa, 2010).

However, after several agreements had been secured without resorting to compulsory licensing, the Brazilian government's bargaining power proved to be not strong enough. At the same time, some drugs were putting disproportionate pressure on the budget. This was the case of efavirenz, which was used by about 75,000 patients in 2007 at a cost of US\$580 per patient/year. The same product was being sold by the patent-holding company in Brazil for about US\$280 per patient/year in other middle-income countries. Given this situation and after many negotiations, the Brazilian government issued a compulsory license for efavirenz on May 4, 2007 (Brazil, 2007a). Since then, the savings made by buying generic versions of efavirenz imported from India and then by producing it in Brazil have exceeded US\$100 million (Viegas, Hallal and Guimarães, 2012).

This was the scenario that characterized the stance of the Brazilian government in relation to the impacts of pharmaceutical patents on policies designed to ensure access to drugs: negotiations with patent holders based on prices charged in other developing countries and on production cost data provided by public drug companies and use of health protection measures under the TRIPS Agreement, such as compulsory licensing. However, there was a shift in 2008 in how the Brazilian government addresses this issue, as we will see below.





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### **3. PUBLIC-PRIVATE PARTNERSHIPS IN THE HEALTH CARE IN BRAZIL: PARTNERSHIPS FOR PRODUCTIVE DEVELOPMENT**

Strategic partnerships between the Brazilian state and the private sector are not new. Since the 1960s, the Brazilian government and domestic private companies have been engaging in partnerships at times formally and at other times with particular dynamics. Examples include the National Immunization Program, the experience of Brazil's Central Drug Center (CEME) and the process of copying and producing the first ARVs in Brazil in the early 1990s. An important feature of these experiences was the understanding that Brazil's technological and industrial development should be guided by the purpose of ensuring better health conditions for the its population (Villard, 2014; Chaves, 2016).

However, an institutional political arrangement was adopted in 2008 that raises doubts about whether the policy continues to focus on public health as a priority. In that year, the so-called Partnerships for Productive Development (PDPs) were established.

PDPs are characterized as partnerships involving cooperation under agreements between public institutions and private entities for developing, transferring and absorbing technology, developing production capacity, and promoting Brazil's productive and technological qualification in connection with strategic products with the aim of meeting the demands of the SUS system (BRAZIL, 2014c). With the aim of promoting PDPs, several ordinances were issued, creating a regulatory framework that would from then on characterize and guide Brazil's technological development in the health sector. Let's take a closer look at this new scenario.

Ordinance No. 374, which was issued in February 2008, established the National Program for Promoting Public Production and Innovation in the Health Industrial Complex, according to its text. What transpires is the opportunity for the State to play a prominent role in promoting and regulating drug production through concerted actions in support of competitiveness, financing, research and development activities in companies, procurement policies, intellectual property protection, partnerships and investment in infrastructure (De Regina, 2013).

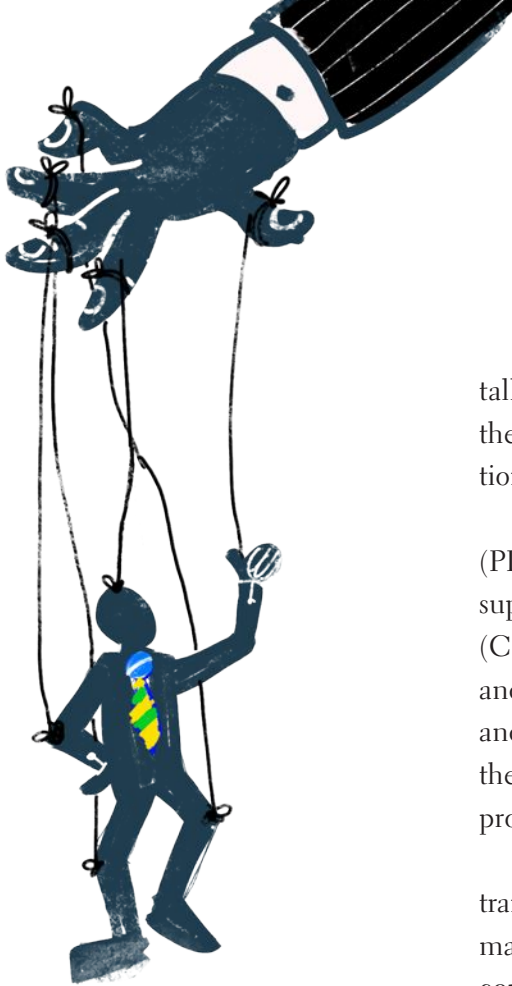
Several other instruments were issued in 2008 to define the legal framework of the policy. The most important ones include a Decree issued in May 12 creating the Executive Group of the Health Industrial Complex, Ordinance No. 978 of May 16 defining a list of strategic products for the SUS system, Ordinance No. 128 of May 29 setting guidelines for hiring manufacturers of health-related products, and Ordinance No. 3,031 of December 16 setting criteria to be considered by official drug companies in their bids for purchasing raw material.

This framework underwent changes throughout 2010. It's important to highlight the passage of Law No. 12,349 of December 15, 2010, which amended the Bidding Law (Law No. 8,666 of June 21, 1993), for the purpose of including among its objectives that of promoting sustainable national development by allowing for margins of preference in public tenders for procuring products manufactured in Brazil. In the health area, this law was subsequently regulated by Decree No. 7,713 of April 3, 2012 (De Regina, 2013).

The biggest step toward defining public-private partnerships involving technology transfer to domestic public drug companies was taken in 2012 with the approval of Ordinance No. 837 of April 18, which set guidelines and criteria for the establishment of Partnerships for Productive Development (PDPs). Later, in 2014, Public Consultation No. 8 was held in August 13 and defined the new Ordinance No. 2,531 of November 12, which provides for some worrying measures, such as a permissive environment for private entities in relation to the establishment of monopolies, participation of companies with patents about to expire, an increase from five to ten years in the patent protection period, and non-distribution of public demand as a means to avoid monopolies.

The Unified Health System (SUS) has been seriously affected by underfunding and, therefore, severe budget constraints, making it imperative for it to be able to buy products at low prices under public policies (Paim, 2010). In 2012, spending on drugs amounted to R\$9.5 billion, corresponding to 13% of the total budget of the Ministry of Health, of approximately R\$73 billion, but this budget still does not ensure full access to drugs to much of the population (Rezende, 2013).

Thus, the weaknesses observed in the field of technological innovation in Brazil underscore the vulnerability of its health system. In short, Brazilian society is exposed to risks derived from the fact that Brazil's ins-



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talled capacity is not sufficient to produce drugs and meet the demands of the population appropriately, making it excessively dependent on international suppliers (Gadelha, 2005).

In this context, the Partnerships for Productive Development (PDPs) constitute a strategic action of the Ministry of Health (MS) in support of the development of the Economic-Industrial Health Complex (CEIS). This initiative is intended to contribute toward the development and innovation of the domestic industrial park of drugs and of chemical and biological inputs for drug production, as well as toward improving the country's trade balance through increased availability of domestically produced drugs (Brazil, 2004).

Between 2009 and 2012, fifty-five PDP proposals for technology transfer processes were approved. Participants include fifteen public drug manufacturers, fifteen private multinationals and sixteen domestic private companies. During this period, the partnership proposals contemplated the manufacture of 55 products (45 drugs, one health product, a diagnosis kit and five vaccines) and three research and development projects.

The R&D partnerships comprised major drug groups such as those of antiretrovirals, cancer drugs, drugs for treating genetic and neglected diseases, antipsychotics, and drugs for treating osteoporosis, Alzheimer's disease and coagulopathies (Rezende, 2013; Brazil, 2015d). Between 2009 and 2014, a further 49 PDP proposals were signed, totaling 104. Altogether, the partnership proposals involved 20 public drug companies and 54 private ones in technology transfer projects related to drugs, equipment and surgical material. Currently, 27 products are in PDP phase (phase III) and are being purchased by the federal government. Only one product is in the final transfer stage (technology internalization phase): a vaccine against influenza developed under a partnership between the Butantan Institute and Sanofi Pasteur (Brazil, 2015d).

According to surveys carried out by the Industrial Complex and Innovation in Health Department (DECIIS) of the Science, Technology and Strategic Inputs Secretariat (SCTIE) of the Ministry of Health, spending on the target drugs developed under these PDPs amounts to approximately R\$4 billion/year. The projects, whose minimum duration is five years, will allow for average savings of R\$1.8 billion/year and for foreign currency savings of approximately US\$1 billion/year upon their completion (Brazil, 2015d).

It should be noted that there's a lot of fanfare by the Ministry of Health around the cost benefits generated by PDPs. However, there is no transparent reporting of how these benefits are being calculated. Moreover, as will be shown later, the acquisition prices of some of the products increased, even disregarding the value added through technology transfer.

One of the pillars of this policy is the commitment made by government to purchase the drugs. This commitment is based on a proposal from the Science, Technology and Innovation Secretariat of the Ministry of Health (SCTIE/MS), according to which PDPs should cover both technology transfer for finished products and for their Active Pharmaceutical Inputs (APIs). The partnership is established between a public drug company, which receives the technology transfer of the finished product, and a domestic private drug company that develops – or receives from an international drug company – technology for producing APIs (Rezende, 2013). It should be stressed that the technology for APIs, which are the most expensive elements and the ones that require the highest degree of technology in the drug manufacturing process, is not appropriated by the public company, as it is only developed and absorbed by the domestic private company. Subsequently, the domestic private company that has the API technology sells the active ingredient to the public company, which then manufactures the product.

Currently, Ordinance 2,531 of November 12, 2014 is the one that governs PDPs. It redefines guidelines and criteria for establishing the list of strategic products to be acquired for the Unified Health System (SUS) and for the establishment of Partnerships for Productive Development (PDPs) and disciplines their respective processes of submission of the respective proposal, presentation of supporting facts, decision, transfer and absorption of technology, procurement of strategic products for the SUS system under PDPs and their respective monitoring and evaluation (BRAZIL, 2014c).

PDPs are divided into four phases: 1) Submission of a PDP project proposal: this phase includes the submission of a project proposal, as well as an analysis of its feasibility, which is evidenced by the signing of a term of commitment between the Ministry of Health (SUS) and the public institution; 2) PDP Project: this is the initial phase of implementation of the approved proposal and of the term of commitment; 3) PDP: initial phase of implementation of the partnerships (product development by



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the private company, transfer and absorption of technology and signing of the contract between the ministry and the public institution); and 4) Internalization of the technology: final phase of the technology transfer to the public institution and its absorption by that institution (Brazil, 2014c) .

### **OBJECTIVES OF PDPs, ACCORDING TO ORDINANCE 2,531/2014**

1) increasing the access of the population's to strategic products and reducing the vulnerability of the SUS system 2) reducing production and technological dependence; 3) rationalizing the purchasing power of the state through selective centralization of spending in the health sector, with a view to ensuring the sustainability of the SUS system and increasing the production of strategic products in Brazil 4) protecting the interests of the Public Administration and of society by ensuring savings and advantages to them, considering prices, quality, technology and social benefits 5) fostering technological development and the exchange of knowledge for innovation within public institutions and private entities, contributing to the development of the Economic-Industrial Health Complex (CEIS) and to making them more competitive and qualified 6) fostering the development and manufacture of strategic products for the SUS system in the national territory; 7) ensuring the technological and economic sustainability of the SUS system in the short, medium and long term, promoting structural conditions to increase the country's production and innovative capacity, contributing to reduce the trade deficit of CEIS and ensuring access to health care; and 8) stimulating the development of Brazil's public production network and its strategic role in connection with the SUS system.

According to information provided by the Industrial Complex and Innovation in Health Department (DECIIS) (Brazil 2014b) in 2015, sixty-two PDP proposals have been approved already. The remaining 42 proposals were rejected for not complying with Ordinance 2,531 or for not submitting the required information. These PDPs involve 42 health pro-



ducts altogether, 38 of which are drugs and 13 are other health products and a vaccine. Currently, there are 19 Brazilian public drug companies taking part in PDPs, considering the proposal phase and PDPs that have been actually approved already.

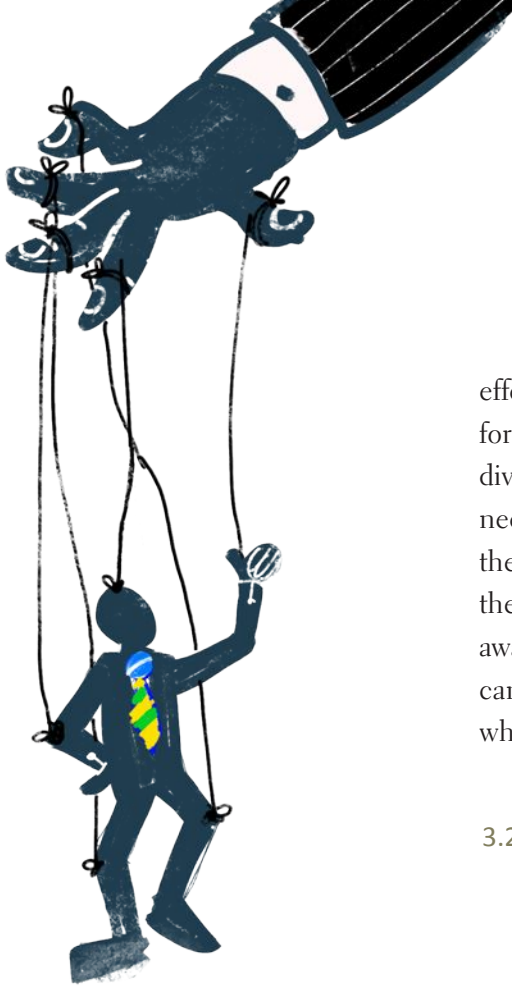
Currently, the Ministry of Health acquires 27 products from 29 PDPs. These products are already in the so-called PDP phase (phase 3) and are being manufactured by private drug companies involved in the partnerships. Subsequently, they are formulated by public drug companies and sold to the Ministry of Health.

Of these products in PDP phase, 14 are currently comprised in the Specialized Component of Pharmaceutical Assistance (Brazil, 2013b), 10 are comprised in the Strategic Component (Brazil, 2007b), two are comprised in the Basic Component (Brazil, 2013c), one is comprised in the basic and specialized components and two are simultaneously comprised in the strategic and specialized components. We can thus see that most products being produced under PDPs are designed for treating chronic diseases and to be used in vaccination campaigns, meaning that they are highly value-added products for continuous use.

Until the first half of 2015, only one PDP product had been internalized, namely, an influenza vaccine transferred from the company Sanofi Pasteur to the Butantan Institute, which now has all the information to ensure the required technological mastery and portability to meet the demands of the SUS system. There may be several reasons why only one PDP of all that were approved has been internalized. There is no doubt, however, that the regulatory framework plays a key role in determining when a technology will be internalized by a domestic drug company and the role that will be played by all the drug companies involved in the process. So let us take a look at a brief comparative analysis between Ordinance 837/2012 and Ordinance 2,513/2014.

### **3.1. From Ordinance 837 of April 18, 2012 to Ordinance 2,531 of November 12, 2014**

Ordinance 837 of 2012 was the first normative instrument to regulate PDPs. That ordinance defined the guidelines and criteria for establishing Partnerships for Productive Development (PDPs). It introduced important regulatory instruments for the private sector that could be



effective for controlling corporate capture. These instruments provided for a ban on partnerships with holders of patents about to expire, for the division of public demand as a way of controlling monopoly power, for the need or not to include (possibility) a margin for the transfer, embedded in the purchase price, and for a maximum period of five years to implement the partnerships to be executed. Many of these instruments were done away with when Ordinance 2,531/2014 was issued. However, it only became effective after public consultation No. 8 was held, in August 2013, whose process and contributions deserve a brief analysis.

### **3.2. Analysis of the contributions to society of Public Consultation No. 8, which was held on August 13, 2013**

With the aim of consolidating the currently in force Ordinance 2,531/2014, Public Consultation No. 8 (CP8) (Brazil, 2013d) was held on August 13, 2013. That public consultation marks the elimination of the guidelines set by Ordinance 837/2012 and clearly reveals strong private interests in proposing a new legislation. Some of those interests were even contemplated in the new Ordinance, indicating the presence of corporate capture and the influence of domestic and foreign private companies. It is important to mention that even before the currently in force Ordinance 2,531 was consolidated, its draft text contained worrying provisions already, such as one that extended the five-year deadline for technology transfer provided for in Ordinance 837/2012 to ten years.

Altogether, 54 organizations provided contributions during the CP8, including domestic and foreign private companies; representatives of the pharmaceutical and pharmachemical industry; natural persons; groups of organized civil society and representatives of patients; public laboratories and their representative entities; and representatives of government agencies. If one considers only quantitative aspects, the discrepancy between the number of contributions from the private sector and, why not say, from transnational drug companies and the number of contributions from sectors linked to the public interest, especially from civil society organizations, jumps to the eye.

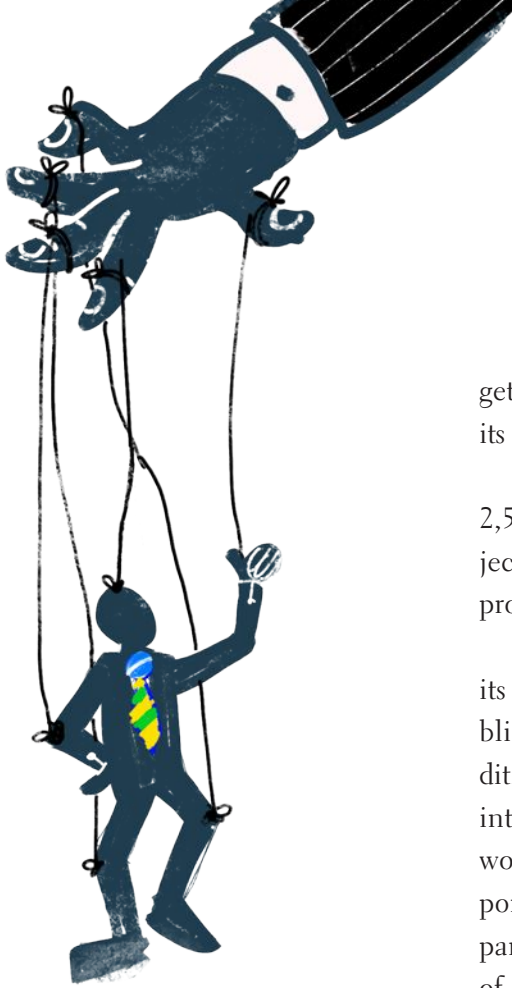
## The contributions

The Intersectoral Science and Technology Committee of the National Health Council – CICT/CNS only requested the inclusion of another modality of strategic product in Article 4 of the draft. It did not even bother to make any comments on the lack of mechanisms for monitoring and evaluating PDPs effectively, which is something one would expect a committee of the National Health Council to do. The contributions from the Unified Health System itself only pointed out the need for centralizing the procurement of products from PDPs at the Ministry of Health. The lack of social participation and interest in promoting access and equity became evident even before the Ordinance was actually issued.

The presence of the private sector in the contributions provided during that public consultation deserves special mention. Most private companies and their professional associations requested permission for the private entity of the partnership to make an oral presentation of the PDP proposal to the Ministry of Health, the right for the private institution to appeal against the rejection of PDP proposals, the precise definition of the deadline for signing the contract and/or acquisition (predictability), and permission for the private entity to take part in defining acquisition prices along with the public entity of the partnership and the Ministry of Health. These requests were not granted in the text of the new Ordinance 2,531/2014.

Few suggestions made during the CP8 that can be seen as contributing to improving access to health products and to promoting equity were incorporated into Ordinance 2,351/2014. Many entities suggested that more than one PDP should be approved for the same product. However, the suggestion that such partnerships should be established by different private partners was not incorporated into the text, although it existed already. This fact would prevent a single private company from enjoying exclusivity during the technology transfer period, thus increasing competitiveness and facilitating price agreements.

Another important suggestion made by ANVISA and by the Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP) was that pending patent applications should be more strictly monitored, including with information about the number of follow-on patent applications included in PDP documents. This would facilitate the management of intellectual property for the tar-



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get product of a PDP, which could prevent monopoly extension even after its conclusion.

An aspect that was suggested and included in the text of Ordinance 2,531/2014 was that the defined list of strategic products should be subjected to public consultation. This is the only form of social participation provided for in the Ordinance.

Even though eight entities requested authorization for society and its representative associations to participate in the process through public debates about the PDPs, this authorization was not granted. In addition, nine entities called for transparency. Their requests were mainly intended to make sure that information about terms of commitment would be publicly disseminated, as well as the quarterly monitoring reports of the policy governing the PDPs, the evaluation reports of the partnerships, and the decisions made at meetings of the GECIS. Lack of transparency and the inclusion of an article specifically defining all information related to PDPs as confidential undermine the credibility of the policy before society, which is left with no means to evaluate and monitor the execution of PDP contracts. Corporate capture and institutional corruption are much more likely to occur in a black box, without any possibility of social control.

It is very possible that this lack of transparency and social participation led to cases of fraud and corruption involving PDPs. Until the first half of 2015, two cases had been reported by the media: the Labogen case and irregularities in the so-called PDP of the Pacemaker. In the case of the PDO of the Pacemaker, a document issued by the Brazilian Court of Audit (TC 011.777/2014-1) reads as follows:

*“the Ministry of Health, through Furp, signed a contract at the end of 2013 amounting to R\$ 80,600,000.00 with the said companies (Medtronic LTDA and Scitech) to supply pacemakers and coronary and arterial stents to the SUS system for a period of five years. Special mention should be made of the fact that there was no public call for submitting projects or a tender for selecting the contractors, meaning that the companies were awarded the contract without proper transparency.”*

This is another worrying issue, which the first ordinance that regulated the PDPs did not address and Ordinance 2,531/2014 failed to cor-

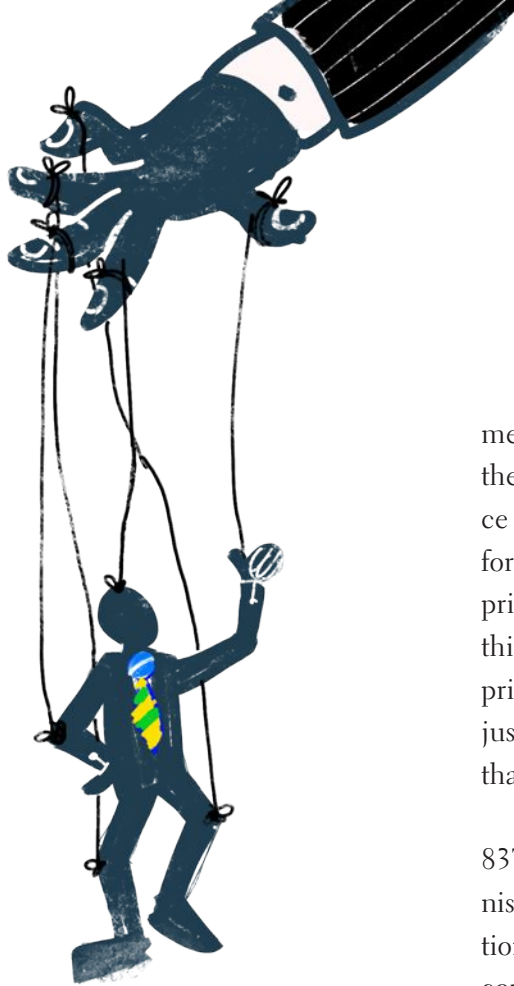
rect: no criteria have been set for selecting private drug companies to take part in the partnerships. Moreover, because clear-cut criteria are lacking, many other partnerships are likely to be investigated for the same reason, generating delays, suspicion, lack of access to strategic products and increasing the vulnerabilities of the SUS system.

Private drug companies continue to be selected for partnerships without proper criteria under Ordinance 2,531/2014. There is no transparency about the characteristics and specializations of private drug companies that make them eligible to participate in PDPs. Some entities have defended the idea of holding tenders or setting criteria for selecting private partners on the basis of competition. This would ensure the principle of publicity provided for in Law 8,666 (public procurement law) and prevent corporate capture, which occurs much more often in the absence of regulation and transparency.

Ordinance 2,531/2014 provides that PDPs must comply with the intellectual property law in force. In addition, the BIO (Biotechnology Industry Organization) even suggested during the CP8 that it would not be necessary to check the patent status of the products involved in other countries. This proposal was not accepted. Analyzing the patent status of health products in other countries is essential for preventing abuses and the extension of monopolies after the end of PDPs. There are PDPs being executed in which the existence of other patent applications for the technology being transferred can lead to the extension of monopolies and favor transnational drug companies.

In addition, Ordinance 2,531/2014 defined that PDP contracts must be multi-annual. This ensures legal certainty for the private institutions involved in the partnerships. This fact alone would not be an aggravating factor. However, it should be stressed that Ordinance 2,531/2014 does not provide for any punitive mechanisms or for means to ensure legal certainty for the public entity if the private one fails to comply with the partnership contract (these contributions were provided during the CP8). Even worse, there is no provision in the Ordinance to ensure the pre-qualification of private and public entities for PDPs and not even a definition of the cost benefits that a partnership can generate. A suggestion to include in the Ordinance provisions defining cost-benefit criteria and how to calculate them was made during the CP8, but it was not accepted.





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Although it defines the multi-year nature of the partnership agreement, Ordinance 2,531/2014 does not set clear-cut criteria for regulating the acquisition prices of products under patent protection. The Ordinance provides that market prices are to be used for this purpose, leaving room for abusive pricing. The GTPI/REBRIP suggested during the CP8 that the price of products under patent protection and procured without tender for this reason should be reduced by 35%. This percentage corresponds to the price reduction of generic drugs in relation to non-generic ones and it is justified by the exclusivity period that patent holders would enjoy beyond that contemplated in the patent during the technology transfer period.

Another important issue that was contemplated in Ordinance 837/2012 and was raised during the CP8 was the need to define mechanisms to prevent PDPs from being used to extend monopolies. A suggestion to this end was not accepted, propitiating a favorable environment for corporate capture.

Some other contributions that were not included in Ordinance 2,531/2014 clearly indicate the intention to allow for corporate bias in public policy-making. For example, the Biomm company suggested that companies without an installed industrial plant should be allowed to take part in a PDP and to even import inputs until the construction of the plant is completed. That was exactly the situation of the Biomm company when the CP8 was held, as it was building a factory in Minas Gerais state that is scheduled to become operational in 2015-2016 .

Another example is the requirement of private sector participation in the Technical Evaluation Committee and in the Deliberative Committee of PDPs, which was even proposed by the Brazilian National Confederation of Industry. In addition, a drug company that did not identify itself requested PDPs with a duration of more than ten years.

It is important to note that in its Chapter IV, Article 10, only paragraph, Ordinance 2,531/2014 indicates that a flowchart for the PDP process was to be made available on a specific website of the Ministry of Health. However, the information available there does not allow for a detailed monitoring of the implementation of such partnerships: no information is available so far on the final dates of technology transfer processes or on the status of implementation of the partnerships.

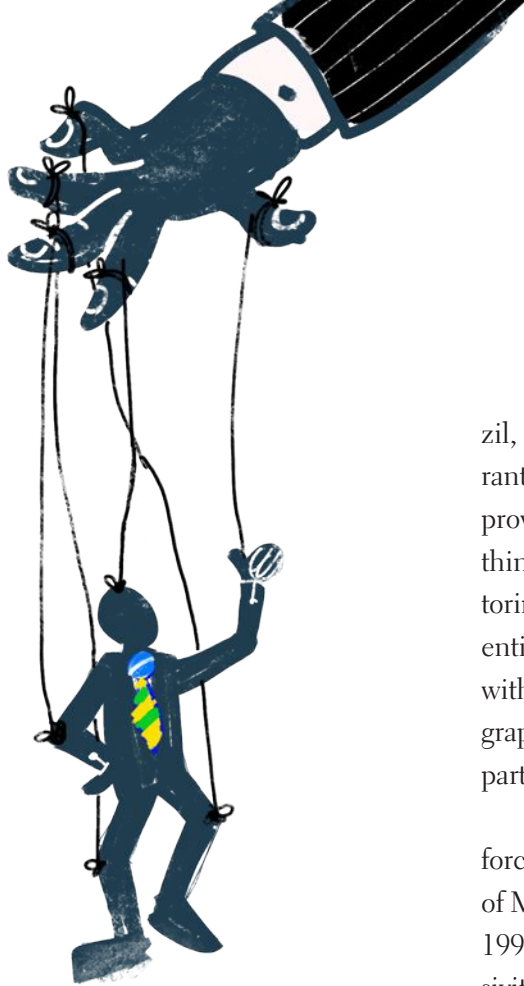
A master's thesis showed that only 40% of seven of the 11 five-year partnerships established in 2009 had been implemented until 2013. The

same thesis calculated a linear rate of success of 67% for the seven PDPs evaluated in it. However, the same study showed that the percentage of execution of the phase of registration by the public drug company of the drug produced by the domestic private partner was 7.5% and that for four of the 11 partnerships analyzed the percentage was 0% (Rezende, 2013).

For the first acquisition, a product developed under a PDP can be registered by the Public Institution receiving the transfer or by the transferring private entity/patent holder (Article 53 of Ordinance 2,531/2014) (Brazil, 2014c). However, after the first acquisition of a product developed under a PDP, the public institution has a deadline of sixty (60) days to submit its registration application to ANVISA and, one year after the first acquisition, the Ministry of Health will only make a new acquisition of the product if it was successfully registered with ANVISA by the public institution (Article 53, paragraph 2; and Article 54 of Ordinance 2,531/2014) (Brazil, 2014c).

It is also important to consider the fact that decisions are made only by the Ministry of Health and by the private and public institutions participating in PDPs, without equal representation of all stakeholders. Representatives of Health Councils and other representatives of civil society are not allowed in any way to take part in discussions on the feasibility of the proposals or in monitoring established PDPs. This fact confirms the reduction in social participation in the SUS system, a demand institutionalized through Law No. 8,142 of 1990, which provides for the Health Councils and Conferences (Brazil, 1990). In turn, Ordinance 2,531/2014, which redefines PDPs, does not provide for any equal representation, transparency or social control.

A decree issued in May 12, 2008, which created the Executive Group of the Health Industrial Complex (GECIS) – a group that participates in actions to define strategic products and evaluate PDP proposals – defines in its Article 4, paragraph 1, that the “Executive Group shall be advised by a Permanent Forum for Civil Society Participation...” (Brazil, 2008). However, when one analyzes the composition of such Executive Group, it is not possible to find not even one representative of civil society in it. On the contrary, and corroborating the fact the group is more focused on strengthening measures to protect intellectual property, it includes representatives of the National Institute for Intellectual Property (INPI) and of the Brazilian Agency for Industrial Development (ABDI). Again, participation is only ensured for corporations and public managers.



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According to the Access to Information Act (Law 12,527/2011) (Brazil, 2011) and to Ordinance 1,583/2012, access to monitoring reports is guaranteed. In particular, Article 4, VII (a) of the above-mentioned ordinance provides as follows: “Article 4. Access to information includes, among other things, the right to obtain: VII information on the implementation, monitoring and results of programs, projects and actions of public agencies and entities, as well their proposed targets and indicators.” It is a known fact that, with the aim of restricting access to and monitoring of PDPs, the only paragraph of Article 26 of Ordinance 2,531/2014 classifies information on these partnerships as confidential.

As for intellectual property, that ordinance provides that the law in force is to be complied with, in this case the Intellectual Property Act (LPI) of May 14, 1996, which provides for the recognition of drug patents (Brazil, 1996). However, the recognition of drug patents, associated with the exclusivity of the Ministry of Health to procure the drugs in question during the technology transfer period, ended up leading to an indirect “extension” of the drug monopoly period, ensuring to the company holding the respective patent a longer period of market exclusivity and higher spending with the purchase of those drugs. This can be true even for companies holding patents set to expire in less than ten years (the deadline set for the technology transfer), making it possible for them to benefit from the exclusive purchasing rights of the Ministry of Health during a PDP via acquisition in public companies.

This ordinance states that the numbers of patents of products being developed under PDPs and their duration must be reported. However, it does not provide in a clear way for any obligation to disseminate information on those patents to the general public, making it impossible to monitor the development of patented products.

Furthermore, it does not clearly indicate the policy that will be applied to dealing with those patents. For example, what measures is government to take if the term of a patent extends beyond the end of a given PDP contract? Will all patents be licensed? What happens if a company does not report all patents related to a particular technology? These questions are not answered by the text of the ordinance. In addition, the deadline for completing the technology transfer process, which used to be five years, was extended. Even worse, after Ordinance 2,531/2014 was issued, the deadline can be set according to the complexity of the transfer, and it can be as long as

10 years, thus increasing the possibility of market exclusivity and monopoly.

As for technological internalization, Ordinance 2,531/2014 provides for the transfer of not only the technology for producing the end product, but also of the drug master file, of the API production technology, of the master cell bank for biological products and of electronic components in the case of health equipment. But the criteria for such transfers are not publicly disseminated, which would allow for checking whether the transferred process is still effective or if the technology became obsolete, as well as whether it will be possible for public institutions to maintain a transferred plant in light of the country's current level of technological development. This impasse generates uncertainties as to the achievement of the objectives of PDPs as defined in the Ordinance, raising questions about whether they can actually contribute to reducing the vulnerability and dependence of the SUS system.

This is the case of the drug tenofovir, which is currently in PDP phase (phase III) and is acquired by the Ministry of Health from the public drug manufacturers FUNED and LAFEPE. According to item 7.6.1 of the Clinical Protocol and Therapeutic Guidelines for AIDS, the first-choice treatment consists in a combination of tenofovir, lamivudine and efavirenz (TDF + 3TC + EFV) ("3-in-1") in a combined fixed dose formulation, whenever available. The so-called "3-in-1" version is already in PDP phase (phase III) under partnerships involving the public manufacturers FUNED, LAFEPE and Farmanguinhos and the private companies Cristália, Blanver/Globe, CYG and Nortec, and it is being acquired by the Ministry of Health. Thus, according to the Ministry of Health, 90 million tablets of the "3-in-1" tenofovir were purchased in 2015.

## CONFIDENTIALITY AS A RULE AND NOT THE EXCEPTION

It is important to note that after defining "observance of publicity as a general rule and secrecy as the exception" in its Article 3 (I), Law 12,527/2011 (the Access to Information Act) indicates the kind of information that can be classified as confidential and of limited access for being considered essential to ensure the security of society or of the state. And precisely because it is the exception, which restricts the fundamental right to access information, information that can be rated as confidential should be interpreted restrictively rather than extensively.



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For conducting this study, six requests for access to information were filed between May 12-22 of 2015 and two of them were denied, one of which under Article 23, item VI, of Law No. 12,527/2011, under Article 25, item VII, of Decree No. 7,724/2012 and under Article 9, section VII, of Ordinance GM/MS No. 1,583/2012, according to which the Ministry of Health classifies terms of commitment of partnerships for productive development as confidential, at the level of secret, as well as other documents related to such partnerships involving technology transfer.

Two other requests were fully granted, one was granted with incomplete information and one was not even answered. It should be highlighted that the requests were not related to information on formulations, synthesis routes and other technical information on drug production or technology transfer, but rather to the terms of the contracts, such as amounts of public fund transfers, duration, criteria for selecting public and private companies to take part in the partnerships, etc.

In 2014, the GTPI/REBIP group checked how many requests for access to information related to PDPs had been filed until then. It saw that 20 requests for access to information on PDP contracts, executive projects, prices, deadlines and monitoring reports had been filed until that year. All requests were denied based on the argument that the requested information was confidential because it could threaten national security.

It should be made clear that public consultations alone cannot satisfy the need for participation and access to information held by the Ministry of Health regarding PDPs. The reticence of that Ministry to provide information that is clearly of a public nature gave rise to situations such as that of the recent case of the LABOGEN drug company, which was accused of influence peddling in a scandal that led to the fall of the then vice president of the Brazilian House of Representatives.

The lack of prior public publicity about the nature of the contracts and of the criteria for selecting drug companies to participate in PDPs exposed the Ministry and led to public distrust of the integrity these partnerships.



## 4. ANOMALIES IN ACQUISITION PRICES AND LACK OF TRANSPARENCY IN CALCULATIONS OF COST BENEFITS.

The objectives of the PDPs include that of ensuring cost benefits for the SUS system, thus strengthening its sustainability, improving the access of the population to essential products, and reducing the vulnerability of the system. However, with regard to price reductions, the PDPs contemplate a reduction of only 5% (FUNED, 2015) in prices in relation to those paid in the last purchase made by the Ministry of Health. As we will see, this reduction is rather small and disregards the natural downward trend in prices, especially in the case of drugs under monopoly.

In the case of the PDP for manufacturing atazanavir, for example, the price set in the contract for buying the product in 2016 (US\$2.28/unit) is 6.5 times higher than the lowest price available on the international market today (US\$0.35/unit) (Medecins Sans Frontieres, 2014). Another example is the case of the PDP for manufacturing tenofovir: the acquisition price of the domestic product manufactured under the PDP in 2014 (US\$1.81/unit) is higher than the acquisition price of the product in 2010 (US\$1.75/unit), when it was still being bought from the company that held the patent application. One of the reasons given is that the price includes the cost of the technology transfer.

What draws attention in this case is the price paid by the Ministry of Health both for tenofovir and for its “2-in-1” and “3-in-1” combinations. According to a study on the appropriation of the production cost of the monodrug tenofovir in “2-in-1” and “3-in-1” formulations conducted by the GTPI/Rebrip, the prices of the drugs purchased by the Ministry of Health are at least three times higher than they should be and the definition of the initial price for the PDP was higher than it could be, taking into account the appropriation of the production cost (Scopel et al, 2016, in press).

Moreover, although the Ministry of Health announced repeatedly that the PDPs would ensure savings of billions of reais for the public treasury, how these savings were calculated was not transparently reported. The GTPI/REBRI/P has filed requests for clarifications from representatives of the Ministry of Health countless times and invariably got no response or evasive and inadequate responses.



## Acquisition prices paid by the Ministry of Health for products developed under the partnerships

According to Ordinance 2,531/2014, the acquisition prices of products developed under the partnerships must decrease during the PDP phase. According to a publication of the public drug manufacturer of the state of Minas Gerais, the Ezequiel Dias Foundation (FUNED), the goal is to reduce the acquisition price by at least 5% each year (Funed, 2015).

Analyzing the purchases made by the Ministry of Health, information about which is available on the website of DECIIS (Brazil, 2014b), one can see that such reduction has not been recorded for some products. Furthermore, an international comparison clearly shows that the acquisition prices charged for some products in Brazil are higher than those charged in other countries.

The way abstracts of these purchases are published in the Official Gazette (DOU) (Brazil, 2014b) make it difficult for civil society to analyze these costs and monitor PDPs. Spending figures are disseminated by substance, in terms of total quantity. For the drug clozapine, for example, the total acquisition amount paid by the Ministry of Health is reported for both concentrations of 25 and 100 mg. For some institutions, such as for the Oswaldo Cruz Foundation and Farmanguinhos, it is impossible to know the exact amount and quantities of each acquired drug, as the abstract only shows the transfer of funds by the Ministry of Health to stimulate the production of drugs, without any definition of the object of the transaction.

This form of reporting makes it impossible to analyze the respective quantities of each concentration and by dosage form. Thus, the analysis method that was used considered, for standardization purposes, the Defined Daily Dose (DDD), which is the average daily maintenance dose for an adult individual for the main therapeutic indication of the drug in question (ANVISA, 2015).

The International Drug Price Indicator Guide 2013 of the MSH (Management Science for Health), which was developed in partnership with the World Health Organization, was used for the price analysis. The international price data disseminated by zenRx Research were also used. Although these figures were not adjusted by the National Consumer Price Index (IPCA), they represent a comparative analysis of the purchases

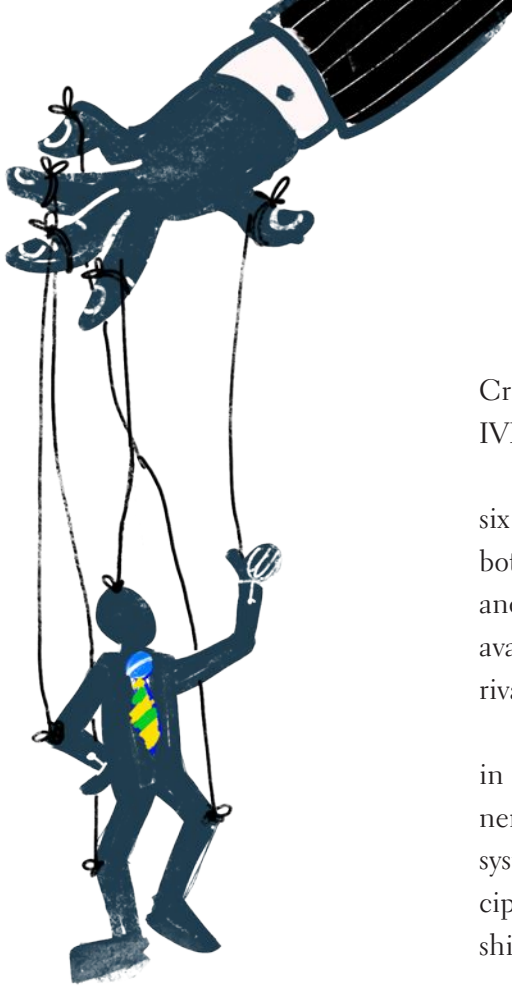
reported by the Ministry of Health. After all, the high price increase observed for most drugs could hardly be offset by that adjustment. Moreover, according to Article 55 (III) of Paragraph of Ordinance 2,531/2014, the technology transfer price is included in the purchase price. As one of the components of the lack of transparency of this Ordinance, no information is provided on the price of such transfer.

We only analyzed 13 products of the 27 ones that are currently in PDP phase. Due to inadequacies in the abstracts published in the Official Gazette, it was not possible to analyze the remaining products. Among all purchases in the 2010-2015 period, no reductions in the acquisition price were observed for six of them and for three others the reductions were seen to be lower than 5% (Table 3). For ten purchases, the acquisition price decreased by more than 5% and some of these decreases were quite significant. The results are shown in Table 3 in Annex I.

Moreover, according to the 2013 edition of the Drug Price Guide of the WHO (the latest version of the price guide), the prices paid for clozapine, recombinant factor VIII, imatinib mesylate, olanzapine, tenofovir and meningococcal C conjugate vaccine were higher than the global average in all periods of the purchases (DRUG PRICE GUIDE, 2013). In this analysis, the prices of the influenza vaccine were lower than the international average (according to the Drug Price Guide) in the purchases made in 2010, 2012, 2013 and 2014. Although the price of that vaccine increased between 2010 and 2011, it was not possible to make a global comparison, as the Drug Price Guide does not provide this price for 2011.

In addition, at more than one point in time the prices of the drugs clozapine, mycophenolate sodium, olanzapine, quetiapine, botulinum toxin and cabergoline were higher than those charged in some countries, such as in the U.S, Canada, Australia, Italy, France, Germany and the UK.

Among PDPs that cannot be seen as economic alternatives based on the analysis made in the preceding paragraphs, four of them are partnerships with private foreign drug companies (recombinant factor VIII: Hemobrás/Baxter; influenza vaccine: Butantan Institute/Sanofi-Pasteur; meningococcal C conjugate vaccine: FUNED/Novartis; and sodium mycophenolate: FURP+Bahiafarma/Novartis) and seven others are partnerships with domestic private companies (quetiapine: LAFEPE/Cristália; cabergoline: Bahiafarma + Farmanguinhos/Cristália; botulinum toxin: LAFEPE/Cristália; olanzapine: LAFEPE/Cristália; clozapine: LAFEPE/



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Cristália; tenofovir: FUNED/Blanver + Nortec; and imatinib mesylate: IVB/E.M.S + Laborvida + Globe + Alfa Rio.

Still with regard to the products manufactured under these PDPs, six drugs are protected by patent: recombinant factor VIII, olanzapine, botulinum toxin, meningococcal C conjugate vaccine, influenza vaccine and mycophenolate sodium. Generic versions of the others are already available in the Brazilian market: Clozapine, Olanzapine, Quetiapine, rivastigmine, tenofovir, cabergoline and imatinib mesylate.

There are currently 11 foreign private drug companies participating in PDPs and this study showed that three of them are taking part in partnerships that failed to reduce the prices of drugs purchased by the SUS system. In addition, the private domestic drug company Cristália is participating in 10 PDPs (largest private participant), five of which are partnerships that either have a low cost-benefit ratio or are not economical at all.

It should also be considered that a partnership for producing the drug donepezil (FURP + FUNED/Cristália) was discontinued in 2010. As a senior manager of the Cristália company stated in an interview held on July 1, 2015, that partnership was discontinued due to its inability to ensure an economically viable price for Cristália. The partnership was thus discontinued by common agreement with the public entities involved. Therefore, even though the transfer to private domestic companies of the technology to produce APIs was ensured, the SUS system remained as vulnerable as before and the access of the population to the drug was not improved.

Article 55 (III)(a) of Ordinance 2,531/2014 provides as follows: the prices set for purchasing drugs developed under PDPs shall take into account the technological inputs associated with the internalization of their production and shall follow a decreasing path in real terms. Moreover, according to interviews held with senior managers of the Ministry of Health, this high price is associated with the price paid for the transfer of technology. This price, however, was not reported by the Ministry of Health and neither how it was calculated.

Thus, although periodic evaluations are carried out (quarterly monitoring reports), some PDPs are not complying with Ordinance 2,531/2014 and the reduction targets set for the public drug companies remain valid. This shows that the policy has been favoring private drug companies, mainly international companies, even when they don't abide by the rules.

## 5. PDPS AS AN EXTENSION OF PATENT MONOPOLIES

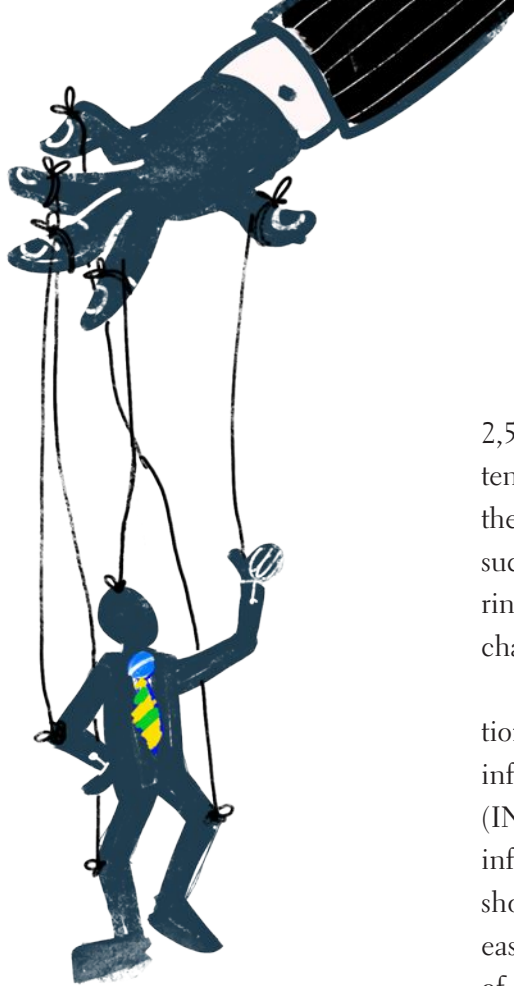
One of the worrying aspects of the regulatory framework established under Ordinance 2,513/2014 is that it extended the maximum duration of PDPs to 10 years. Let us consider the case of the drug atazanavir, which has been used in Brazil since 2004 for treating about 60,000 patients and costs US\$ 830 per patient per year.

The PDP for producing atazanavir is a technology transfer case plagued with problems related to compliance with the deadlines and to the patent status of the drug. The partnership was established in 2011 with the signing of the respective term of commitment, according to which the partnership was scheduled to last until 2017. The contract was signed between the drug companies Farmanguinhos, Bristol and Nortec.

A long delay in the schedule followed due to price negotiations. Then another problem emerged related to regulatory issues, causing further delays in the schedule. The Bristol company closed down its plant in São Paulo and, because a quality control structure was lacking, once again it took longer than scheduled for Farmanguinhos to obtain the required sanitary registration for the drug. If the sanitary registration had been obtained within the set deadline, in 2011, the end of the five-year period would coincide with the expiration of the patent in 2017. However, the sanitary registration was only obtained in January 2014, with a delay of 18 months.

The year in which the PDP would end, 2017, is when the patent on atazanavir expires, meaning that it would fall into public domain then. With the extension of the PDP due to delays in the original schedule, the monopoly situation that could end with the expiry of the patent will continue while the partnership remains in force. In practice, the PDP extends a monopoly over an essential drug for the Brazilian population.

Another issue to be considered is that of follow-on patents. This term refers to pending patent applications that may be approved at any time, including during the implementation of the PDP. In this regard, a fundamental question is: what will happen to the local production if one of the patent applications not contemplated in the contract is granted? Even if the technology transfer is completed, will Brazil face limited possibilities to produce the drug?



In addition, no instruments are contemplated in Ordinance 2,531/2014 to restrict the participation in PDPs of companies holding patents that will expire in less than five years, which is the period defined for the technology transfer process. Companies holding patents expiring within such short period would thus benefit from a “patent extension,” since during the technology transfer process the government is only allowed to purchase the product in question from the company participating in the PDP.

It should be emphasized that it is also difficult to access information on patents related to products developed under PDPs. A request for information was filed with the National Institute for Intellectual Property (INPI) for this purpose. In its response, it failed to provide the requested information and the INPI even suggested that an employee of the Institute should be hired and paid to make such a patent search. It would be much easier to keep track of patents on drugs involved in PDPs if the Ministry of Health made such this information available, as ANVISA did by publishing a guide on drugs under patent in Brazil in 2010 (Brazil, 2010).

Even in the case of the PDP for producing atazanavir, the contract limits production to one formulation, expressly forbidding the production of any other formulation or combination of the drug. However, the World Health Organization recommended recently that atazanavir should be used in combination with ritonavir. This combination is already being used in other countries because of the benefits it provides to patients. In this scenario, Brazil will not be allowed, at least until 2019, to produce this combination even if it has the technology to do so due to a limitation imposed by the company Bristol-Myers Squibb on the PDP contract.

## **6. SITUATION OF PUBLIC DRUG COMPANIES, COST BENEFITS AND TECHNOLOGY TRANSFER**

One of the main objectives of PDPs is to strengthen public and private domestic drug companies. In this part of the study, we will present data on major public drug companies as an additional element for reflecting on such a policy. We also present elements for a discussion on the extent to which the technology transferred to Brazilian public drug companies is up to date.



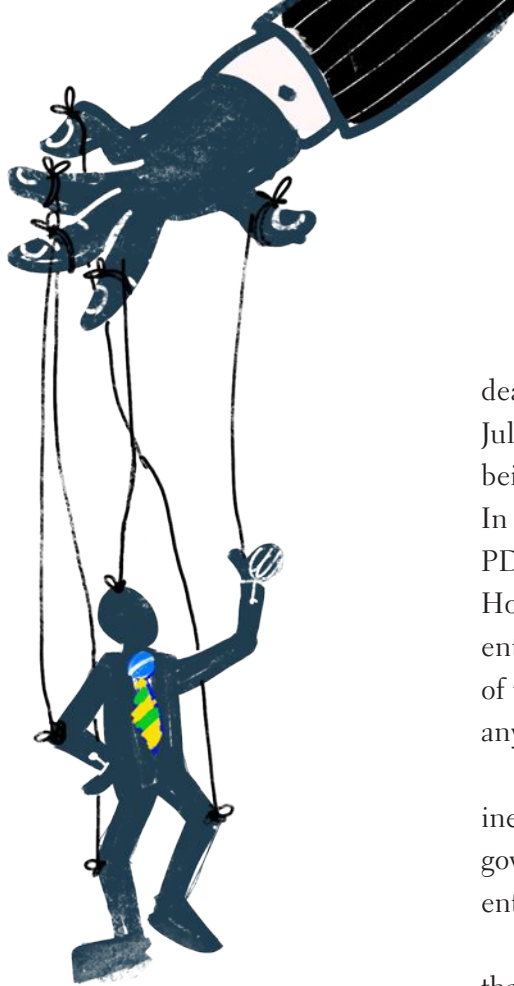
Currently, there are 20 Brazilian public drug companies involved in PDPs. The websites of those companies do not provide clear information about the partnerships they are engaged in. Only the Ezequiel Dias Foundation (FUNED) presented more enlightening data on the PDPs conducted in the institution. One of the institutions, the Bahia Foundation for Scientific Research and Technological Development, Supply and Distribution of Drugs (Bahiafarma), does not even have a website.

Information provided by the public institutions themselves shows very clearly seen that the production capacity of public drug companies has decreased substantially. A 2013 management report is available on the website of Farmanguinhos (Farmanguinhos, 2013) according to which it has the capacity to produce 6.5 billion drug units. However, in 2013, it only produced 668 million units, which is a figure well below its production capacity.

According to the website of the Vital Brasil Institute (Instituto Vital Brasil, 2015), the estimated cost benefits provided to Brazil's Unified Health System by the PDP for producing imatinib mesylate amount to R\$337 million. According to that same source, data disseminated on the website of the Ministry of Health indicate savings of R\$915.500/year with the domestic production of Biotin and of R\$5.8 million in five years with the production by the institute of a solution for preserving organs. However, that estimate is not publicly disseminated and no evidence is provided that these savings are significant for the Unified Health System. In addition, no access is provided to follow-up mechanisms that would allow for such conclusion.

Something similar happens with the Bahiafarma drug company. According to data available on the Fiocruz website and in media reports (Fiocruz, 2014; newspaper Bahia Toda Hora, 2015), cabergoline 0.5 mg, which is being produced under a PDP involving the Bahiafarma drug company in association with Farmanguinhos and Cristália, is being purchased for half its price as a result of the drug being produced in Brazil. As shown in Table 5 in Annex I, in a comparison involving six countries it was seen that the price of cabergoline produced in Brazil is higher than that charged in Italy, France and the UK.

In addition, three products (10-valent pneumococcal vaccine, meningococcal C conjugate vaccine and clozapine) entered the PDP phase in 2010, meaning that the companies involved have a five-year



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deadline to complete the technology transfer process. However, until July 2015 all of these products continued in the PDP phase and were still being produced and distributed by the private entity of the partnership. In 2011, the drugs quetiapine, tacrolimus and tenofovir also entered the PDP and should now be completing the technology transfer process. However, these products continue to be manufactured by the private entities of the partnership and there is no evidence that the construction of the plant for producing it in public drug companies will be finalized any time soon (Brazil, 2014b).

Although this failure to meet deadlines may be associated with the inefficiency of the public drug company or with the lack of investment by government, it may also be associated with delays caused by the private entity itself, as in the case of atazanavir.

Senior managers of FUNED interviewed on July 8, 2015 reported that all the PDPs in which the institution is taking part had to undergo adjustments to meet the requirements set out in Ordinance 2,531/2014. In this regard, they reported that FUNED's partnership projects will basically only have their schedules changed. Moreover, they said that they reported all delays to the Ministry of Health. When asked about whether information related to these partnerships should be treated as confidential, they answered no, but they defended the argument that administrative problems (referring to the delay) should not be publicly disseminated, as this could be harmful. The managers of FUNED also attributed the delay to management problems faced by the Foundation in recent years, as will be discussed below. They said: "This is the great bias of PDPs: If a PDP doesn't work as a policy it's because it cannot be operationalized (referring to hurdles in the public service)."

The senior managers of FUNED reported that its relationship with the private entities involved in the partnership is positive, but they didn't explain exactly why. In an interview with a senior manager of the company Cristália, one of the private entities involved in PDPs, he recognized that delays are likely to happen, especially in partnerships involving biotechnological and nano-structured products. He told us that these are highly technological partnerships that might require more time to yield actual results.

According to him, the change in the duration of the PDP from five to ten years was made in response to a request related to drugs invol-

ving complex technologies. However, he also mentioned that such delays should never occur in partnerships around less technological products (referring to products under wide public domain). Moreover, he told us that the decision to extend the duration of a partnership is not only theirs, “this is a decision agreed upon between the parties” (referring to the public and private entities involved in the partnership and the Ministry of Health). According to him: “Such extensions are assessed in detail, they are not ordinary or usual... Otherwise you end up killing the policy, killing the goose that lays the golden eggs.” This last view shows how the policy is perceived by that private drug company.

Some contributions to CP8 can improve the process of controlling the execution of PDP contracts. Administrative and criminal penalties were suggested if companies fail to comply with those contracts. It was also suggested that the Ministry of Health should publicly disseminate a list of all public drug companies eligible to take part in the partnerships. Something must be done urgently for that purpose, since according to the senior manager of FUNED, “the issue of the five-year period being short or not depends on your (industrial) plant. If you already have the required framework it’s easy, otherwise the period should be longer and you should consider the need for building new plants.” According to that senior manager, they will only start to package and label the meningococcal vaccine vials at the company in the fifth year of the PDP. However, it will be necessary to build a new plant to produce the vaccine.

If we take into account other issues addressed in this study, such as lack of transparency, the substantial cost benefits afforded by the policy and the statements of senior managers of public and private drug companies, we see that a major debate on the actual priority of the policy of the PDPs needs to be held. Despite the argument that the ultimate goal of PDPs is that of reducing the vulnerability of the SUS system and strengthening it, we noticed that these partnerships have a significant economic and developmental bias that has little to do with health perspectives and with the way public health policies are traditionally made in Brazil: with participation, transparency and horizontality. Restricting the debate to private entities and government undermines the concept of inter-sectorality, which was a cornerstone in building the SUS system.



## Analysis of the situation of the Ezequiel Dias Foundation.

The Ezequiel Dias Foundation (FUNED) is located in Belo Horizonte, the capital of Minas Gerais state, and it produces 29 registered drugs of different therapeutic classes, such as antihypertensives, anticonvulsants, antidepressants, among others. These drugs are produced to meet the needs of basic health care programs implemented by the State Health Secretariat of Minas Gerais.

The registered antiretrovirals, serums and vaccines it produces are used in national pharmaceutical care programs such as the STD/AIDS Program and the National Immunization Program (NIP). Thalidomide, which is exclusively produced by FUNED in Brazil, is used by the Ministry of Health to treat leprosy and lupus, but it has a high potential for treating other diseases such as cancer (FUNED, 2015).

Although a list of the foundation's 29 registered drugs is available on its website, we know that FUNED has not been able to maintain its capacity to produce essential drugs for the SUS system at high levels. According to FUNED's website itself (FUNED, 2015), the foundation's production capacity decreased from 1.104 billion units in 2009 to 35.1 million units in 2014, and until March 2015 no figures related to its production had been reported.

However, it can be clearly seen that PDPs have become a high priority for the Foundation, according to an interview with one of its senior managers. According to that manager, the revenue from these partnerships is high (and it is the only source of revenue for the Foundation, as shown in Figure 1, Annex II) and they bring new investment to FUNED.

A problem is that FUNED has lost its Certificate of Good Manufacturing Practices (CGMP). With the PDPs, it is regaining them. What this means is that the Ministry of Health allows a partnership to be established with a public drug manufacturer that lost an important certificate which is then regained with the PDPs. There was no public or political will to regain the CGMP before the PDPs, showing that economic interests played a major role in this regard, even for a public drug company, which should be driven not by profit, but rather by the public health needs of the Brazilian population.

After 2009, a sharp drop was recorded in the production of basic drugs by the institution (FUNED, 2015). On the other hand, according to the Foundation, its production of immunobiological drugs increased exponentially in 2014, hitting the mark of 383.6 million units (Graph 2, Annex II). However, it must be clarified that the product that contributed the most to this increase (meningococcal C conjugate vaccine) is not produced by FUNED itself, but rather by its private partner Novartis. As reported by a senior manager in the interview, FUNED's operations are currently restricted to packaging and labeling the vials of the vaccine and the PDP should be in its final year, according to the deadline set for it (the partnership was initiated in 2010).

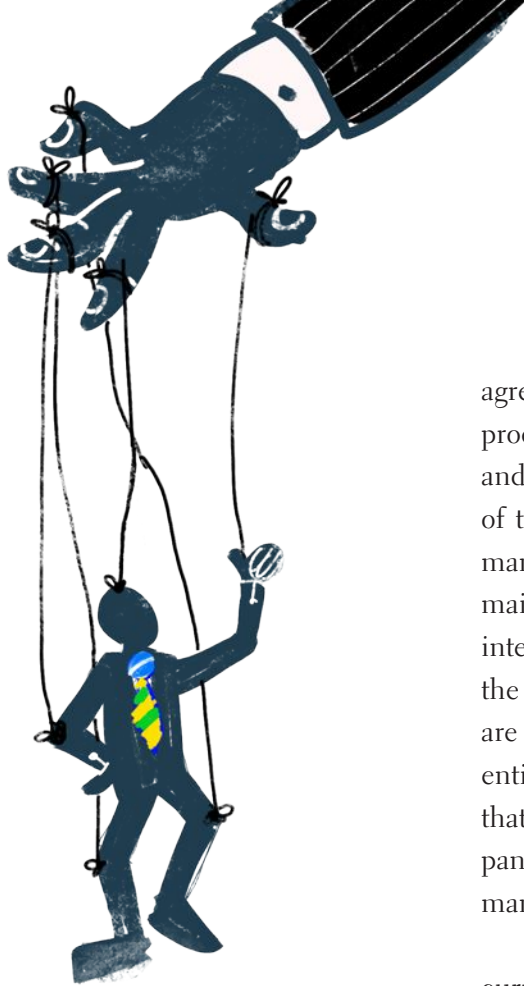
The analysis shows that, in addition to the legal factors set out in Ordinance 2,531/2014 and which regulate PDPs, major structural and administrative factors are having an impact on the production capacity of public drug companies. Who could have any interest in decreasing the production capacity of public drug companies and in having them packaging drugs and vaccines?

## **7. NON-INVOLVEMENT OF THE MINISTRY OF HEALTH IN THE NEGOTIATIONS**

One of the likely reasons for the inefficient negotiation of prices recorded in PDPs is the lack of experience of public drug companies in conducting such negotiations. The Ministry of Health has extensive experience in negotiating prices with private companies, but we were informed that the ministry does not get involved in the negotiations between the public companies and their private partners.

Ordinance 2,531/2014 reinforces the non-involvement of the Ministry of Health. This concern was expressed back in 2013 by the GTPI/Rebrip as it kept track of the PDP for producing atazanavir and became aware of this fact. Despite some reports and warnings, the new regulatory instrument failed to strengthen the capacity of the public sector to negotiate better contractual conditions for technology transfer.

According to Article 45 of 2,531/2014, "Until the start of the PDP phase, the public institution and the private entity shall enter into an



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agreement or contract to develop, transfer and absorb the technology of a product to be produced under a PDP according to the criteria, guidelines and guidance provided for in this Ordinance, without the intervention of the Ministry of Health.” According to an interview held with senior managers of the Ministry of Health, the responsibility for establishing and maintaining PDP agreements lies with the public institution. During that interview, when asked about matters pertaining to public drug companies, the senior managers reported that they have no such information, as PDPs are under the responsibility of the public drug company and of the private entity that owns the technology. During that same interview, he reported that when management was decentralized in 2006 and public drug companies became autonomous in relation to the Ministry of Health, a lot of management difficulties emerged.

Therefore, the wide autonomy enjoyed by public drug companies currently as reported by the senior managers during their interviews is, to say the least, contradictory in light of the possibility of regulatory capture as described by Dal Bó (2006). According to that author, capture “is the process by which special interests affect state intervention” (idem: 2003) by changing macroeconomic policy, tax policies and research and development (R&D) priorities. One must also remember that such capture can occur in environments marked by weak or faulty regulation.

A scenario in which senior managers of public drug companies have no experience or effective mechanisms to negotiate with private – domestic and transnational – companies leaves room for corporate capture of public policies, considering that the regulations in force do not provide for ways to prevent or avoid it.

## **8. FINAL CONSIDERATIONS**

Published in 1984, a book by John Braithwaite entitled “*Corporate Crime in the Pharmaceutical Industry*” pointed out an endemic problem. That book, released over 30 years ago, is more and more up-to-date (Braithwaite, 1984). In an article entitled *Big pharma often commits corporate crime, and this must be stopped*, Peter C. Gøtzsche showed that with a simple search on the web he found a link between the 10 largest drug companies in the world and fraud. According to him, the main ones were



the following: illegal market, due to the recommendation of “off-label” *use of drugs*; misrepresentation of research results; concealment of dangerous data.

As we have seen, the Partnerships for Productive Development, which constitute a development strategy of the Brazilian government, are plagued by several problems in their regulatory framework and implementation from the perspective of public health. In this study, we sought to show that lack of transparency, non-equitable participation, serious regulatory problems and questionable priorities mark one of the main policies of the Brazilian government. All of these factors become even more worrying when one considers that the industry that is operating as a partner of government is the one described above by Braithwaite (1984) and Gøtzsche (2012). During the study, many cases of evident corporate capture of regulatory instruments and public policies were detected.

## Transparency

In Ordinance 2,531/2014, there is not a single mention of the need to ensure public dissemination of data on the monitoring and inspection of PDPs and social participation in them. On the contrary, it classifies all documents that could be used to check the priorities of the policy and even monitor their implementation as confidential. It is essential that all documents relating to PDPs containing data on prices, deadlines, actual impact of the project, monitoring and implementation reports, etc. are publicly disseminated.

## Participation

We have seen that only senior public managers – from government and public drug companies – and representatives of private domestic and transnational companies are allowed to attend formal forums for discussing PDP-related policies. Representatives of civil society and of patients’ and health workers’ associations are completely excluded from them. The principle of participation, which is a constitutional principle and one that forms the basis of the SUS system, is being systematically violated. It is urgently necessary to set up a forum in which the voice of civil society organizations, trade unions and patients’ associations can be heard on an



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equitable basis and actually influence the development and implementation of the policy.

## More and more exclusivity?

As a rule, PDPs ensure procurement exclusivity to a single supplier – a policy that for decades has been the object of debates on domestic and international pharmaceutical assistance and on the need to rely on multiple sources of drugs. Such a policy should be the exception, not the rule. The Brazilian government’s priority should be on putting the largest number possible of drugs in public domain, stimulating the production of drugs by public drug companies. By treating the PDP policy as “the goose that lays the golden eggs” and betting on a one-sided project, the Brazilian government forgets lessons learned in the past that led to major technological developments, such as the copying of drugs, and made it possible to ensure the sustainability of universal access to drugs through mechanisms such as compulsory licensing.

The copying of drugs through reverse engineering, as was done, for example, for producing antiretroviral drugs and ensuring the success of the policy of universal access to HIV/AIDS treatment, is an approach diametrically opposite to how PDPs have been designed to incorporate technology transfer. All the positive externalities – incremental innovation, establishment of non-pharmacopoeial standards, etc. – of copying drugs are not present in a vertical technology transfer process. This is so because, since the way a technology is to be transferred is defined beforehand as a top-down process based on the technology chosen by the patent holder or private partner selected to take part in a PDP, no room is left for domestic drug companies to optimize their production.

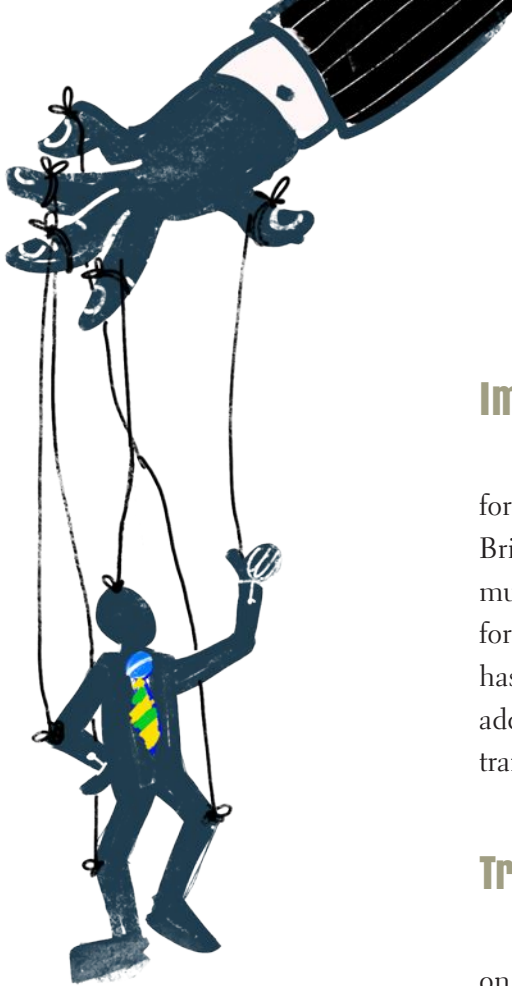
During the interview with senior managers of FUNED, it could be clearly seen how they view private drug companies, particularly transnationals, as technologically and innovatively superior: questions such as “do we know how to do this?” and observations such as “we lack the capacity and technology to do this” were made during the interview. Buse and Walt (2000a) argue that this kind of perception of inferiority of the public sector undermines technological development and increases the vulnerability of Brazilian drug companies that PDPs were allegedly designed to fight.

It is thus important to consider some measures and include them in health care regulations and policies to make sure that the public interest and the goal of reducing inequalities prevail in relation to corporate capture:

- General rules, criteria and objectives clearly designed to improve health care should be established;
- The horizon of policy options based on public health safeguards provided for in the law should be expanded, giving priority to realizing the right to health
- If partnerships for transferring technology are deemed necessary, the terms of the respective agreements should reflect the needs of the population and not, for example, the purpose of showing the “social responsibility of the private sector” as a marketing strategy;
- Intellectual property (IP) issues related to developed end products should be transparent and should not be used to justify high prices;
- Health innovation alternatives should always be clearly linked to ensuring access to new necessary products;
- Each and every contract that fails to meet the public interest should be reviewed.

According to Velasquez (2014), commercial interests do not necessarily coincide with the public interest and combining these two at times contradictory or incompatible interests is not always easy. Thus, it is up to the state to answer the following question: what comes first, business or health? In a permissive environment for corporate interests, in which senior public managers often believe that they depend on the private sector, public health is seldom a priority, as this study has attempted to show.

Thus, considering that PDPs have an economic and developmental bias and are mainly focused on improving trade balance results, such partnerships can hardly be seen as health policies. If we depend only on PDPs to strengthen the SUS system, we will be backsliding in the efforts we made to remove public health from the trade arena during the debates on the Brazilian Constitution of 1988 and on the passage of the Health Organic Law.



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## Implementation problems

We have demonstrated, for example, problems faced in the PDP for producing atazanavir. The contract signed with the multinational Bristol-Myers Squibb (BMS) restricts domestic production to a single formulation of the drug, expressly prohibiting the production of any other formulation or combination, even though the World Health Organization has recommended the use of atazanavir in combination with ritonavir. In addition, delays resulting from actions of BMS itself and chronic lack of transparency call this partnership into question.

## Trade and Public Health

As mentioned above, the Brazilian patent law prohibited patents on drugs until 1996. Even though the TRIPS Agreement provided for a transitional period until 2005 for developing countries to adhere to its rules, Brazil passed its current patent law in 1996 in accordance with the obligations contemplated in the TRIPS Agreement (Law 9,279/1996).

In fact, the WTO TRIPS Agreement has the stated objective of promoting technological innovation in a manner conducive to social and economic welfare (Article 7, TRIPS agreement). Intellectual property protection is still defended as the best mechanism to stimulate private innovation and thus ensure the progress of science and technology for the good of humanity and development of countries. Such reasoning, however, is being increasingly challenged.

Entities such as the Academy of Sciences, the United Nations itself and U.S. Federal Trade Commission have already indicated that the quality of granted patents is deteriorating, affecting the public domain unduly and having negative effects on innovation, even in developed countries. According to them, the patent system, which was originally designed to protect inventions and investment, is becoming an instrument for restraining competition, an obstacle to the development of science and technology and a threat to public health (Santos, 2007).

The TRIPS agreement allows for public health safeguards to be used. However, the effective use of such safeguards depends on their inclusion in domestic laws and on political will to actually apply them, which is something that has not been done so far, considering the privileges

afforded by PDPs and the one-dimensional strategy taken by the Brazilian government.

Timid regulatory actions may be a symptom of the extent to which regulators are encouraged to connive with corporate interests and to see large drug companies as partners (Davis & Abraham, 2013). The interests and motivations that lead to corporate capture range from corruption to the so-called cultural capture (Dal Bó, 2006).

It is thus urgently necessary to review the regulation of PDPs or even the policy itself. It is necessary to regulate public health policies that truly give priority to the public interest, define criteria for selecting entities to take part in the partnerships, set qualification standards for public and private entities, promote public dissemination of information, transparency and social participation and establish punitive criteria and penalties for fraud. Moreover, it is essential that the Brazilian government resumes the use of public health safeguards under the TRIPS agreement and the Brazilian law to ensure the right to health and reduce inequality.

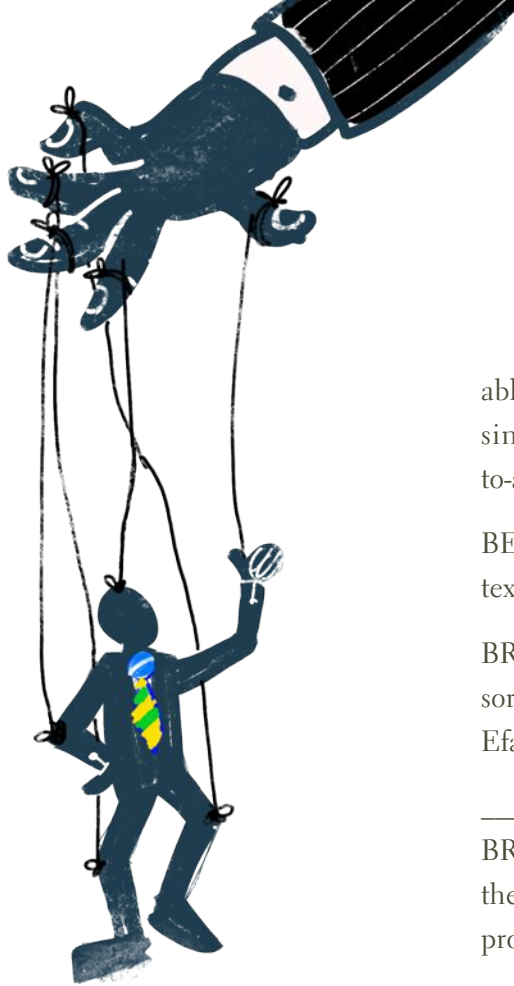
Finally, the practices described here consist in: excluding organized civil society from decision-making on public policy, extending the duration of partnerships, undermining transparency to serve the interests of corporations and leave room for corporate capture and corruption and for keeping inequality in Brazil at its current high levels.

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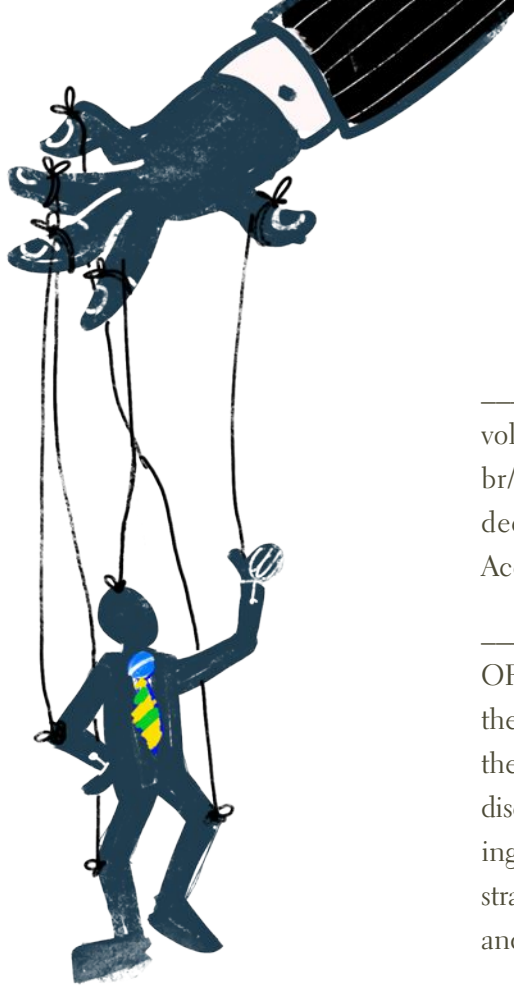
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# ANNEX I





**LOCAL  
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**Table 1: PDP proposals approved and currently in force**

Drug	Class	Public entity	Private domestic entity	Private foreign entity	Joint Venture
Raloxifene	Osteoporosis	LFM	Blanver/ Nortec	-	-
Formoterol + budesonide	Antiasthmatic	Farmanguinhos	-	Chemo	-
Rifampicin + isoniazid + ethambutol + pyrazinamide	Tuberculostatic	Farmanguinhos	-	Lupin	-
Beta interferon 1-a	Multiple sclerosis	Biomanguinhos	-	Merck S. A.	Bionovis
Entecavir	Antiretroviral	Funed	Microbiológica	-	-
Octreotide	Acromegaly	IVB	Laborvida / Hygéia	-	-
Thermostable ritonavir	Antiretroviral	LAFEPE	Cristália	-	-
Sirolimus	Immunosuppressant	Farmanguinhos	Libbs	-	-
Ziprasidone	Antipsychotic	LFM	NPA/E.M.S./ Laborvida	-	-
Raltegravir	Antiretroviral	LAFEPE	Nortec	Merck Sharp Dome	-
Riluzole	Amyotrophic sclerosis	LFM	Cristália	-	-
Sevelamer	Hyperphosphatemia	Bahiafarma, Farmanguinhos	Cristália/ITF	-	-
Etanercept	Antirheumatic	Biomanguinhos, IVB	-	Merck	Bionovis
Rituximab	Antirheumatic	Biomanguinhos, IVB	-	Merck	Bionovis
Olanzapine - reformulation	Antipsychotic	Nuplam	CYG	-	-
Mycophenolate sodium	Immunosuppressant	LQFEx	EMS / Globe / Nortec	-	-
Ritonavir in capsules Soft-gel capsules	Antiretroviral	LAFEPE	Cristália	-	-
Lopinavir + Ritonavir	Antiretroviral	Farmanguinhos, FURP, IQUEGO	Cristália	-	-
Entacapone	Antiparkinsonian	Iquego, FURP, LIFAL	EMS/Nortec	-	-
Leuprolide	Hormonal disorders	FURP, LQFEx	Cristália	-	-
Glatiramer	Multiple sclerosis	FURP, LQFEx	-	-	Supera
Goserelin	Hormonal disorders	FURP, LQFEx	Cristália	-	-
Selegiline	Antiparkinsonian	Lifal	Cristália	-	-
Tolcapone	Antiparkinsonian	Lifal	Cristália	-	-

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Drug	Class	Public entity	Private domestic entity	Private foreign entity	Joint Venture
Liposomal amphotericin B	Visceral leishmaniasis	LAFERGS	Cristália	-	-
Darunavir	Antiretroviral	Farmanguinhos	Globe	Apotex/ NT Pharm/ Pharmchem	-
Deoxycholate amphotericin B	Leishmaniasis, co-infected Leishmania HIV	LAFERGS	Cristália	-	-
Chloroquine diphosphate	malaria	LAFERGS	Cristália	-	-
Galantamine	Alzheimer's disease	FURP	EMS/Nortec	-	-
Hearing aid	Assistive technology	FURP	Politec	-	-
Platinum coils	Aneurism	FURP	First Line	-	-
Adalimumab	Rheumatoid arthritis	Bahiafarma	Libbs	Mabxience	-
Adalimumab	Rheumatoid arthritis	Biomanguinhos	-	-	Orygen
Bevacizumab	Oncological	Biomanguinhos	-	-	Orygen
Bevacizumab	Oncological	Butantan	Libbs	Mabxience	-
Bevacizumab	Oncological	IVB	-	Merck Serono	Bionovis
Bevacizumab	Oncological	Tecpar	-	Biocad	-
Certolizumab	Rheumatoid arthritis	Biomanguinhos	UCB Pharma/ Meizler	-	-
Etanercept	Rheumatoid arthritis	Bahiafarma	-	-	Orygen
Etanercept	Rheumatoid arthritis	Butantan	Libbs	Mabxience	-
Rituximab	Rheumatoid arthritis/oncological	Butantan	Libbs	Mabxience	-
Somatropin	Growth hormone	Biomanguinhos	Cristália	-	-
Somatropin	Growth hormone	FUNED	-	Pfizer	-
Filgrastim	Oncological	Biomanguinhos	Eurofarma	-	-
Trastuzumab	Oncological	Bahiafarma	Libbs	Mabxience	-
Trastuzumab	Oncological	Biomanguinhos	-	-	Orygen
Trastuzumab	Oncological	IVB	-	Merck Serono	Bionovis
Single-Chamber Pacemaker and Permanent Endocardial Electrode	Cardiology	FURP	-	Medtronic Comercial Ltda	-
Double-Chamber Pacemaker and Permanent Endocardial Electrode	Cardiology	FURP	-	Medtronic Comercial Ltda	-
Coronary Stent and Balloon Catheter for Coronary Stent	Cardiology	FURP	Scitech	-	-
Arterial Stent and Balloon Catheter for Arterial Stent Cardiology	Cardiology	FURP	Scitech	-	-

Drug	Class	Public entity	Private domestic entity	Private foreign entity	Joint Venture
Linear Surgical Stapler	General surgery	FURP	-	Johnson & Johnson	-
Refills for Linear Surgical Stapler	General surgery	FURP	-	Johnson & Johnson	-
Coronary Stent System	Cardiology	IQUEGO	-	Medtronic Comercial Ltda	-
Cardioverter-Defibrillator	ICU/Emergency	NUTES/UEPB	Lifemed	-	-
Multiparameter monitor	Diagnosis and Monitoring	NUTES/UEPB	Lifemed	-	-
Ophthalmology Equipment Set	Ophthalmology	CTG/UFPE	Opto Eletrônica S.A	-	-
Hemodialysis Machine and Dialyzing Filter	Hemodialysis	LAFERGS	Lifemed	-	-
Solution for organ preservation	Organ transplantation	IVB	-	IGL Group	-
Biotin	Biotinidase deficiency	IVB	Laborvida	-	-
Adsorbed Vaccine against Diphtheria, Tetanus and Acellular Pertussis	Diphtheria, Tetanus and Whooping Cough Prevention	Butantan	-	Glaxo Smith Kline	-
Sildenafil Citrate - REFORMULATION	Pulmonary Arterial Hypertension (PAH)	LFM	EMS	-	-

## Chart 1

### Name of the Drug Manufacturer

Fundação Baiana de Pesquisa Científica e Desenvolvimento Tecnológico, Fornecimento e Distribuição de Medicamentos (Scientific Research and Technological Development Foundation of the State of Bahia, Drug Supply and Distribution) (Bahiafarma);

Farmanguinhos;

Biomanguinhos;

Vital Brazil Institute (IVB);

Butantan Institute (Butantan);

Technology and Geoscience Center - Engineering School of the State of Pernambuco (CTG-EEP);

Fundação Para o Remédio Popular (Affordable Drug Foundation) (FURP);

Chemical Industry of the State of Goiás (IQUEGO);

Ezequiel Dias Foundation (FUNED);

Chemical and Pharmaceutical Laboratory of the Army (LQFEx);

Industrial Pharmaceutical Laboratory of the State of Alagoas (LIFAL);

Governor Miguel Arraes Pharmaceutical Laboratory of the State of Pernambuco (LAFEPE);

Pharmaceutical Laboratory of the State of Rio Grande do Sul (LAFERGS);

Pharmaceutical Laboratory of the Navy (LFM);

Center for Research into Food and Drugs of the Federal University of the State of Rio Grande do Norte (NUPLAM);

Center for Strategic Health Technologies of the University of the State of Paraíba (NUTES);

Technological Institute of the State of Paraná (TECPAR);

Brazilian Company for Blood Products and Biotechnology (Hemobrás);

Oswaldo Cruz Foundation (FIOCRUZ).

**Chart 2: PDP products being acquired by the Ministry of Health currently**

Drug	Class	Public entity	Private entity	Component of Pharmaceutical Assistance	Clinical Protocol and ordinances
Clozapine	antipsychotic	LAFEPE	Cristália	Specialized	CPTG for schizophrenia and schizoaffective disorder
10-Valent pneumococcal vaccine	immunobiological	Biomanguinhos	Glaxo Smith Kline	Strategic	NA
Meningococcal C conjugate vaccine	immunobiological	Funed	Novartis	Strategic	NA
quetiapine	antipsychotic	LAFEPE	Cristália	Specialized	CPTG for schizophrenia and schizoaffective disorder
Tacrolimus	immunosuppressant	Farmanguinhos	Libbs	Specialized	CPTG for Primary Nephrotic Syndrome in Children and Adolescents CPTG for Immunosuppression in Pediatric Liver Transplantation and CPTG for Immunosuppression in Renal Transplantation
Tenofovir	antiretroviral	FUNED	Blanver/Nortec	Strategic and Specialized	HIV infection (Ordinance SVS/MS No. 27 - December 2, 2013 and Ordinance SVS/MS No. 12 – April 28, 2014); CPTG for Chronic Viral B Hepatitis and Coinfections
Tenofovir	antiretroviral	LAFEPE	Cristália	Strategic and Specialized	HIV infection (Ordinance SVS/MS No. 27 December 2, 2013 and Ordinance SVS/MS No. 12 – April 28, 2014); CPTG for Chronic Viral B Hepatitis and Coinfections
Olanzapine	antipsychotic	LAFEPE	Cristália	specialized	CPTG for schizophrenia and schizoaffective disorder
Rivastigmine	Alzheimer's Disease	IVB	Laborvida, E.M.S. / Nortec, Globe	Specialized	CPTG for Alzheimer's Disease



Drug	Class	Public entity	Private entity	Component of Pharmaceutical Assistance	Clinical Protocol and ordinances
MMRV vaccine (measles, mumps, rubella and chickenpox)	immunobiological	Biomanguinhos	Glaxo Smith Kline	Strategic	NA
Alphataliglucerase	Gaucher's disease	Biomanguinhos	Pfizer/Protalix	Specialized	CPTG for Gaucher's Disease
Recombinant Factor VIII	Hemophilia	Hemobrás	Baxter	Strategic	NA
Recombinant Human Insulin	Diabetes	Farmanguinhos	Indar	Basic	NA
Imatinib mesylate	oncological	Farmanguinhos/ Fiocruz	Cristália/Alfa Rio	Specialized	ORDINANCE No. 312 OF MARCH 27, 2013 (leukemia) and ORDINANCE No. 783 OF AUGUST 29, 2014 (hypereosinophilic syndrome)
Imatinib mesylate	oncological	IVB	EMS, Laborvida/ Globe, Alfa Rio	Specialized	ORDINANCE No. 312 OF MARCH 27, 2013 (leukemia) and ORDINANCE No. 783 OF AUGUST 29, 2014 (hypereosinophilic syndrome)
Botulinum toxin	Muscle relaxant	LAFEPE	Cristália	specialized	CPTG for Focal Dystonias and Hemifacial Spasm and CPTG for spasticity
Atazanavir	antiretroviral	Farmanguinhos	Bristol/Nortec	Strategic	HIV infection (Ordinance SVS/MS No. 27 - December 2, 2013 and Ordinance SVS/MS No. 12 - April 28, 2014),
Leflunomide	Antirheumatic	LFM	Cristália	specialized	CPTG for Psoriatic Arthritis, CPTG for Rheumatoid Arthritis
Pramipexole	antiparkinsonian	Farmanguinhos, FURP	Boehringer/ Nortec	specialized	CPTG for Parkinson's Disease
Hepatitis A Vaccine	immunobiological	Butantan	Merck Sharp Dome	strategic	NA
HPV vaccine	Papillomavirus prevention	Butantan	Merck Sharp Dome	strategic	Immunization, according to the Manual for vaccination standards and procedures (2014) and Technical standards and documents of the PNI

Drug	Class	Public entity	Private entity	Component of Pharmaceutical Assistance	Clinical Protocol and ordinances
Everolimus	Immunosuppressant	FURP, Bahiafarma	Novartis	specialized	CPTG for immunosuppression in kidney transplantation
Mycophenolate sodium	immunosuppressant	FURP, Bahiafarma	Novartis	specialized	Heart transplant (without CPTG), CPTG for Immunosuppression in Pediatric Liver Transplantation and CPTG for Immunosuppression in Renal Transplantation
Micronutrients	Profound anemia in children	LFM	EMS/ NPA, DSM	strategic	Prevention of nutritional deficiencies, according to WHO's guideline on use of multiple micronutrient powder formulations for home fortification of food consumed by infants and children in the 6 to 23 month age bracket (2013).
Tenofovir Lamivudine Efavirenz	antiretroviral	Farmanguinhos, FUNED, LAFEPE	Cristália, Blanver/ Globe, CYG, Nortec	strategic	HIV infection (Ordinance SVS/MS No. 27 - December 2, 2013 and Ordinance SVS/MS No. 12 – April 28, 2014)
Tenofovir + lamivudine	antiretroviral	Farmanguinhos, FUNED, LAFEPE	Cristália, Blanver/ Globe, CYG, Nortec	Strategic	HIV infection (Ordinance SVS/MS No. 27 December 2, 2013 and Ordinance SVS/MS No. 12 – April 28, 2014)
Infliximab	Rheumatoid arthritis	IVB, Biomanguinhos	Bionovis/ Janssen-Cilag	Specialized	CPTG for Psoriatic Arthritis, CPTG for Rheumatoid Arthritis, CPTG for Crohn's Disease, CPTG for Ankylosing Spondylitis and CPTG for Inflammatory Spondylopathy
IUD	contraceptive	Furp	Injeflex	Basic	NA
Cabergoline	Prolactin inhibitor	Bahiafarma, Farmanguinhos	Cristália	Basic and Specialized	CPTG for Acromegaly and CPTG for Hyperprolactinemia

NA: Not applicable or does not exist. CPTG: Clinical Protocols and Therapeutic Guidelines



**Table 2: Main differences between Ordinances 837/2012 and 2,531/2014**

Ordinance 837/2012	Ordinance 2,531/2014	Notes
Article 4, Subsection I (c).	Article 14, Subsection VIII, Item 7 (e); Article 55, Subsection III (b).	Text of Ordinance 837/2012: “whenever feasible from a technical and economic point of view, <b>PDPs involving only holders of exclusive rights about to expire or that expired recently should be avoided</b> with the aim of ensuring the participation, as a priority, of more than one bidder, so as to keep the market competitive; and...”  This text was suppressed in Ordinance 2,531/2014, which contemplates the possibility of participation in PDPs of holders of exclusive rights, considering market price estimates of products under patent as a regulation.
Article 4, Subsection II (e).	No regulation	Text of Ordinance 837/2012: “The acquisition of goods and products manufactured under PDPs shall contemplate a <b>balanced distribution of public demand with the aim of avoiding the formation of monopoly</b> and of ensuring the internalization of their technology and production, provided that the technological scale, economic scale and specific quality of each PDP are respected, due to the uniqueness, nature and relevance of the production of strategic products and goods for the SUS system and to the need to ensure full observance of all conduct set forth in items XIV and XIX do paragraph 3 of article 36 of Law No. 12,529 of 2011; and...”  Ordinance 2531/2014 does not contemplate any regulation whatsoever for avoiding the formation of monopoly.
Article 4, paragraph 1	Article 55, Subsection III (a).	Text of Ordinance 837/2012: “ <b>Exceptionally</b> , under the PDP regime, <b>prices may include</b> a margin on negotiated costs for the purpose of integrating strategic technology for the SUS system, <b>provided that it is justified by the technological inputs associated with the internalization of production</b> and with the relevance of the good or product for public health.”  Text of Ordinance 2,531/2014: “the prices set for purchasing drugs developed under PDPs <b>shall take into account</b> the technological inputs associated with the internalization of their production and shall follow a decreasing path in real terms...”  Ordinance 837 defines the inclusion of the transfer price in the acquisition price to be paid by the Ministry of Health as an exception, while Ordinance 2,531 defines such inclusion as an obligation. This factor is important because some technologies are already widely mastered in Brazil and have many suppliers. This is the case, for example, of the drugs in phase III of PDPs (acquisition by the MS) clozapine (one generic version), olanzapine (13 generic versions), and quetiapine (14 generic versions) <sup>1</sup> , excluding those manufactured by public drug companies.
Article 4, Item III (d).	Article 14, Item IV (a).	Text of Ordinance 837/2012: “the duration of <b>PDPs shall not exceed five (5) years</b> , except in cases where the technological development process requires a period that is <b>admittedly longer</b> than that duration and the PDP results in nationalization of a highly important product for the country.”  Text of Ordinance 2,531/2014: “the duration of a PDP shall be <b>proposed according to the technological complexity</b> involved in internalizing the technology of its products in the country, <b>but it shall not be longer than ten (10) years</b> .”  The two ordinances allow for the duration of PDPs to be extended. However, ordinance 837/2012 makes it clear that this extension for technology transfer purposes is only allowed when the required period for such transfer is admittedly longer. The fact that Ordinance 2,531/2014 provides that PDPs can be extended according to their technological complexity allows private bidders for a PDP to classify their technology as complex.

## BOX 1: THE LABOGEN CASE

The Labogen case became publicly known in the middle of a Federal Police investigation carried out early last year. Lawful interception showed that a drug company had been favored in a competitive tender for a PDP for producing sildenafil citrate for treating pulmonary hypertension. The investigations suggested that federal representative André Vargas, the then Vice President of the House of Representatives, had brokered a contact between the company - which did not have the capacity to produce the drug, not even under a partnership - and the Ministry of Health. After this situation was reported, the agreement for the PDP was cancelled and an internal inquiry was carried out at the Ministry of Health. Although no favoritism was identified by the team in charge of the inquiry, some weaknesses were detected and changes in the format of PDPs were suggested<sup>1</sup>.

- 1 Information obtained on the websites of the newspapers Jornal de Pernambuco, Valor and Globo: [http://www.diariodepernambuco.com.br/app/noticia/brasil/2014/11/12/interna\\_brasil,542461/ministerio-da-saude-anuncia-novas-regras-para-pdp-de-medicamentos.shtml](http://www.diariodepernambuco.com.br/app/noticia/brasil/2014/11/12/interna_brasil,542461/ministerio-da-saude-anuncia-novas-regras-para-pdp-de-medicamentos.shtml); <http://www.valor.com.br/politica/4005014/caso-labogen-esta-encerrado-diz-ministro-da-saude>; <http://g1.globo.com/politica/noticia/2014/04/labogen-bateu-na-porta-errada-diz-padilha-sobre-lobby-na-saude.html>; <http://noticias.uol.com.br/politica/ultimas-noticias/2014/07/02/vargas-fez-contato-entre-labogen-e-ministerio-da-saude-diz-socio-de-laboratorio.htm>

**Table 3: Analysis of acquisition prices paid by the Ministry of Health**

Drug	Period	% of increase in the acquisition price	% of reduction lower than 5 %	% of reduction > 5 %
Clotting factor VIII	2013 - 2015	14.3	-	-
Rivastigmine	2012 - 2015	88.7	-	-
Rivastigmine	2013 - 2015	-	-	90.54
Influenza vaccine	2010 - 2011	19.6	-	-
Influenza vaccine	2011 - 2012	9.7	-	-
Influenza vaccine	2012 - 2013	13.15	-	-
Influenza vaccine	2013 - 2014	-	2.9	-
Meningococcal vaccine	2010 - 2011	-	2.6	-
Meningococcal vaccine	2010 - 2011	36.3	-	-
Quetiapine	2011 - 2012	-	4.6	-
quetiapine	2012 - 2014	-	-	34.60
Clozapine	2010 - 2011	-	-	5.23
Clozapine	2014 - 2015	-	-	40.40
Imatinib mesylate	2013 - 2014	-	-	5.00



Drug	Period	% of increase in the acquisition price	% of reduction lower than 5 %	% of reduction > 5 %
Imatinib mesylate	2014 - 2014	-	-	24.20
Mycophenolate sodium	2014 - 2015	-	-	5.18
Tenofovir*	2011 - 2014	-	-	20.36

Source: Acquisition report, available at: <http://portalsaude.saude.gov.br/images/pdf/2015/maio/26/Aquisi----es-de-produtos-de-PDP-26052015.pdf>

\*Tenofovir manufactured by FUNED: comparison between acquisitions in 2011 and 2014. Annual comparisons were not possible, as the abstracts published in the Official Gazette do not allow for an analysis of prices between 2013 and 2013.

**Table 4: Comparison between the acquisition prices of PDP products and the average world price.**



Drug	Price per DDD in US\$ (PPP*)	Average international price/DDD in US\$	Year	Difference between the price per DDD and the international average (in times)
Clozapine (25 and 100 mg)	3.70	0.76	2010	4.87
	3.34	0.76	2011	4.39
	3.08	0.76	2012	4.05
	1.84	0.76	2015	2.42
Recombinant Factor VII	0.46	0.34	2013	1.35
	0.44	0.34	2014	1.29
	0.50	0.34	2015	1.47
Imatinib mesylate (100 and 400 mg)	41.72	3.82**	2013	10.92
	38.24	3.82**	2014	10.01
	30.51	3.82**	2014	7.98
Olanzapine (5 and 10 mg)	6.03	0.15	2012	40.2
	5.38	0.15	2013	35.87
	1.95	0.15	2015	13
Tenofovir 300 mg	2.23	0.215	2011	10.37
	1.78	0.138	2014	12.89
Meningococcal C conjugate vaccine	13.55	1.75	2010	7.74

\*PPP: Purchasing Power Parity; \*\*Price well below those recorded in OECD countries.

**Table 5: Comparison between the acquisition prices paid for PDP products and acquisition prices in other countries**

Drug	US\$/DDD								Year
	Brazil	Australia\$	Canada\$	France\$	Germany\$	Italy\$	United Kingdom\$	USA\$	
Clozapine	3.70	5.18	9.05	3.14*	4.14	3.51*	1.59*	2.86*	2010
	3.34	5.18	9.05	3.14*	4.14	3.51	1.59*	2.86*	2011
	3.08	5.18	9.05	3.14	4.14	3.51	1.59*	2.86*	2012
Mycophenolate sodium	16.00	17.94	22.14	-	20.22	18.44	8.96*	15.80*	2014
Olanzapine	6.03	5.08*	7.00	5.03*	7.03	4.76*	3.12*	-	2012
	5.38	5.08*	7.00	5.03*	7.03	4.76*	3.12*	-	2013
	1.95	5.08	7.00	5.03	7.03	4.76	3.12	-	2015
Quetiapine	7.72	6.25*	1.52*	-	11.57	6.50*	7.39*	-	2011
	7.23	6.25*	1.52*	-	11.57	6.50*	7.39	-	2012
	4.31	6.25	1.52*	-	11.57	6.50	7.39	-	2014
	4.09	6.25	1.52*	-	11.57	6.50	7.39	-	2015
Type A Botulinum Toxin ¥	2.47	4.16	-	-	-	-	1.38*	3.91	2014
Cabergoline	5.10	6.68	10.40	4.76*	10.20	3.79*	4.12*	-	2015

\*Countries with lower prices than those charged in Brazil; \$Figures obtained from ZenRx: <http://www.zenrx.org/rawdata.asp?c=IA&o=M&s=1&w=y>; ¥Price per Unit (U) .

**Table 6: Total tax relief figures and by health area in the 2009–2014 period**

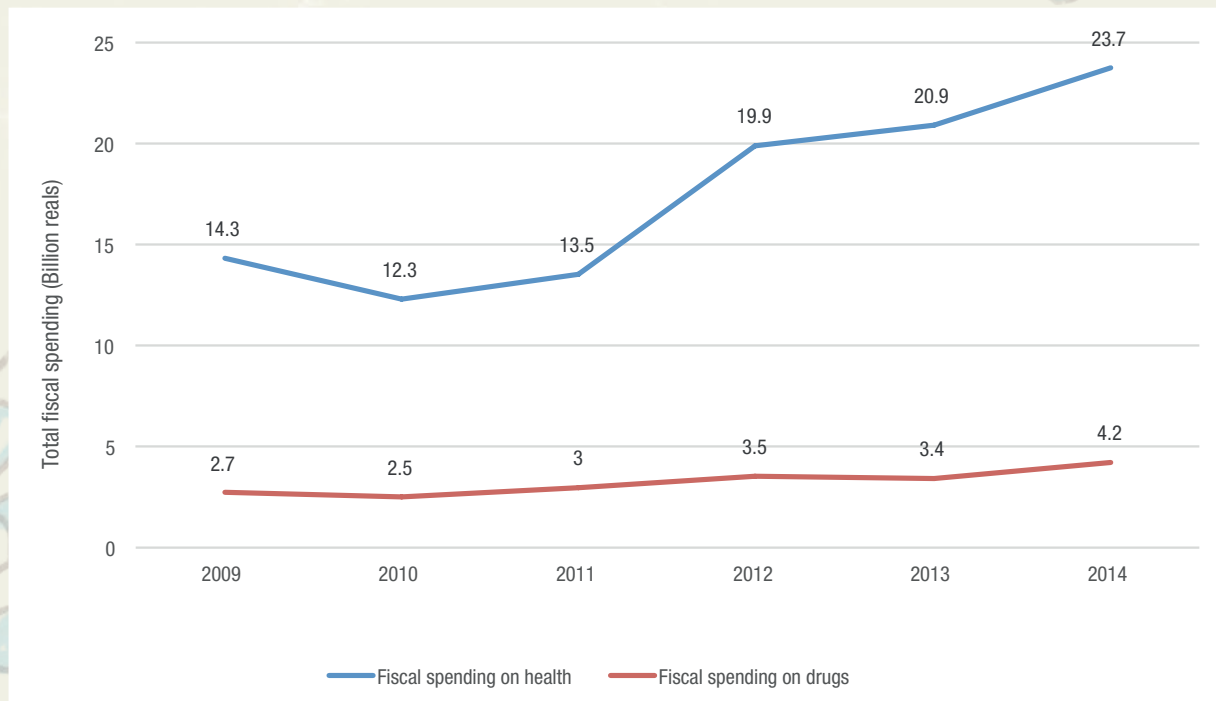
Area	2009 (R\$)	2010 (R\$)	2011 (R\$)	2012 (R\$)	2013 (R\$)	2014 (R\$)
Medical expenses (IRPF)	6,794,095,789	3,325,339,605	4,408,890,042	9,715,107,620	9,874,206,268	10,724,947,105
Medical assistance (IRPJ)	2,276,769,701	2,961,314,044	2,936,021,268	3,149,139,314	3,450,713,531	3,724,879,007
Chemicals and pharmaceuticals	782,595,116	951,436,417	1,037,903,141	943,127,396	807,366,174	808,262,654
Social assistance (ESFL)	1,851,105,864	2,587,115,721	2,158,614,364	2,560,377,647	2,739,357,300	2,863,824,120
Drugs	2,673,019,699	2,507,225,995	2,959,319,355	3,483,855,904	3,433,259,589	4,187,129,321
Pronas/PCD	-	-	-	-	305,871,005	674,430,273
Pronon	-	-	-	-	-	674,430,273

Area	2009 (R\$)	2010 (R\$)	2011 (R\$)	2012 (R\$)	2013 (R\$)	2014 (R\$)
Mineral water	-	-	-	-	-	64,100,000
Total fiscal spending on health	14,377,586,168 (3.05)	12,332,431,782 (2.20)	13,500,748,169 (2.08)	19,851,607,880 (2.71)	20,916,644,873 (2.66)	23,722,002,753 (1.96)
Total fiscal spending	100,991,607,532 (21.45)	113,875,428,613 (20.34)	116,082,902,877 (17.84)	145,977,475,125 (19.96)	170,015,969,718 (21.66)	249,761,192,255 (20.66)

IRPF: Income tax on natural persons; IRPJ: Income tax on corporations; ESFL: Non-profit entities; Pronas/PCD: National health care program for disabled people; Pronon: National program in support of cancer care.

Source: Brazil's Internal Revenue Service (<http://www.receita.fazenda.gov.br/arrecadacao/renunciafiscal/DemonsRenunciaFiscal.htm>).

**Graph 1: Evolution of fiscal spending on health and drugs in the 2009–2014**



1 List of Generic Drugs already registered with ANVISA. Available at: [http://portal.anvisa.gov.br/wps/wcm/connect/7c-6c5b80453b5b67bb94fbc6167d5085/00C%C3%B3pia+de+Gen%C3%A9ricos+Registrados+de+acordo+com+o+refer%C3%Aancia+registrado+\(3\).pdf?MOD=AJPERES](http://portal.anvisa.gov.br/wps/wcm/connect/7c-6c5b80453b5b67bb94fbc6167d5085/00C%C3%B3pia+de+Gen%C3%A9ricos+Registrados+de+acordo+com+o+refer%C3%Aancia+registrado+(3).pdf?MOD=AJPERES). Accessed on: April 13, 2015.







# **ANNEX II**



## Annex II – A more detailed analysis of the situation of the public drug manufacturer FUNED

The Ezequiel Dias Foundation (FUNED) is located in Belo Horizonte, the capital of Minas Gerais state, and it produces 29 drugs of different therapeutic classes, such as antihypertensives, anticonvulsants, antidepressants, among others. These drugs are produced to meet the needs of basic health care programs implemented by the State Health Secretariat of Minas Gerais.

The antiretrovirals, serums and vaccines it produces are used in national pharmaceutical care programs such as the STD/AIDS Program and the National Immunization Program (NIP). Thalidomide, which is exclusively produced by FUNED in Brazil, is used by the Ministry of Health to treat leprosy and lupus, but it has a high potential for treating other diseases, such as cancer (FUNED, 2015)<sup>1</sup>.

Although a list of the foundation's 29 registered drugs is available on its website, we know that FUNED has not been able to maintain its capacity to produce essential drugs for the SUS system at high levels. According to FUNED' website itself<sup>2</sup>, the foundation's production capacity decreased from 1.104 billion units in 2009 to 35.1 million units in 2014, and until March 2015 no figures related to its production had been reported.

According to a publication of the Foundation itself<sup>3</sup>, PDPs help to expand its playing field and ensure increased turnover to it. However, when one analyses the current situation of FUNED, it can be noticed that the figures reported in that publication are in contradiction with that statement. According to Chart 3 (Annex II)<sup>4</sup>, the drug purchase figures for a contract with the Ministry of Health during the 2008-2013 period were, respectively, R\$18,731,525.75; R\$17,175,447.23; R\$163,462,776.5; R\$388,893,833.6; R\$231,275,619.8 and R\$55,487,698.9.

Specifically in relation to PDP products, there was also a reduction: tenofovir (R\$116,309,896.20, R\$76,155,634.20 and R\$ 48,908,365.20

1 <http://funed.mg.gov.br/institucional/>

2 <http://funed.mg.gov.br/institucional/funed-em-numeros/resultado/>

3 Parcerias para o desenvolvimento produtivo na política do desenvolvimento do complexo econômico-industrial da saúde (ceis). Available at: <http://funed.mg.gov.br/institucional/parcerias-para-o-desenvolvimento-produtivo-pdp/>

4 <http://funed.mg.gov.br/institucional/funed-em-numeros/resultado/>

in 2011, 2012 and 2013, respectively); meningococcal C conjugate vaccine (R\$129,733,121.00, R\$246,535,909.50, R\$135,133,113.00, R\$118,592,124.00 in 2010, 2011, 2012 and 2013, respectively). There was clearly a major decrease in revenue after 2011. Moreover, according to the abstracts of purchases published in the Official Gazette, the production of Tenofovir in units amounted to 28,800,000, 19,800,000 and 16,500,000 in 2011, 2012 and 2013, respectively, showing that it decreased by 12.3 million units in two years. The figures for the production of meningococcal vaccine were 8,000,000, 14,000,000 and 12,000,000 in 2010, 2011 and 2012, respectively, with a decrease of 2,000,000 units in the last period.

According to the Foundation, its production of immunobiological drugs increased exponentially in 2014, hitting the mark of 383.6 million units (Chart 2). However, it must be clarified that the product that contributed the most to this increase (meningococcal C conjugate vaccine) is not produced by FUNED itself, but rather by its private partner Novartis. As reported by a senior manager in an interview, FUNED's operations are currently restricted to packaging and labeling the vials of the vaccine and the PDP should be in its final year, according to the deadline set for it (the partnership was initiated in 2010).

According to a publication of the Foundation itself<sup>5</sup>, PDPs help to expand its playing field and ensure increased turnover to it. However, when one analyses the current situation of FUNED, it can be noticed that the figures reported in that publication are in contradiction with that statement. According to Chart 3<sup>6</sup>, the drug acquisition figures for a contract with the Ministry of Health during the 2008-2013 period were, respectively, R\$18,731,525.75; R\$17,175,447.23; R\$163,462,776.5; R\$388,893,833.6; R\$231,275,619.8 and R\$55,487,698.9.

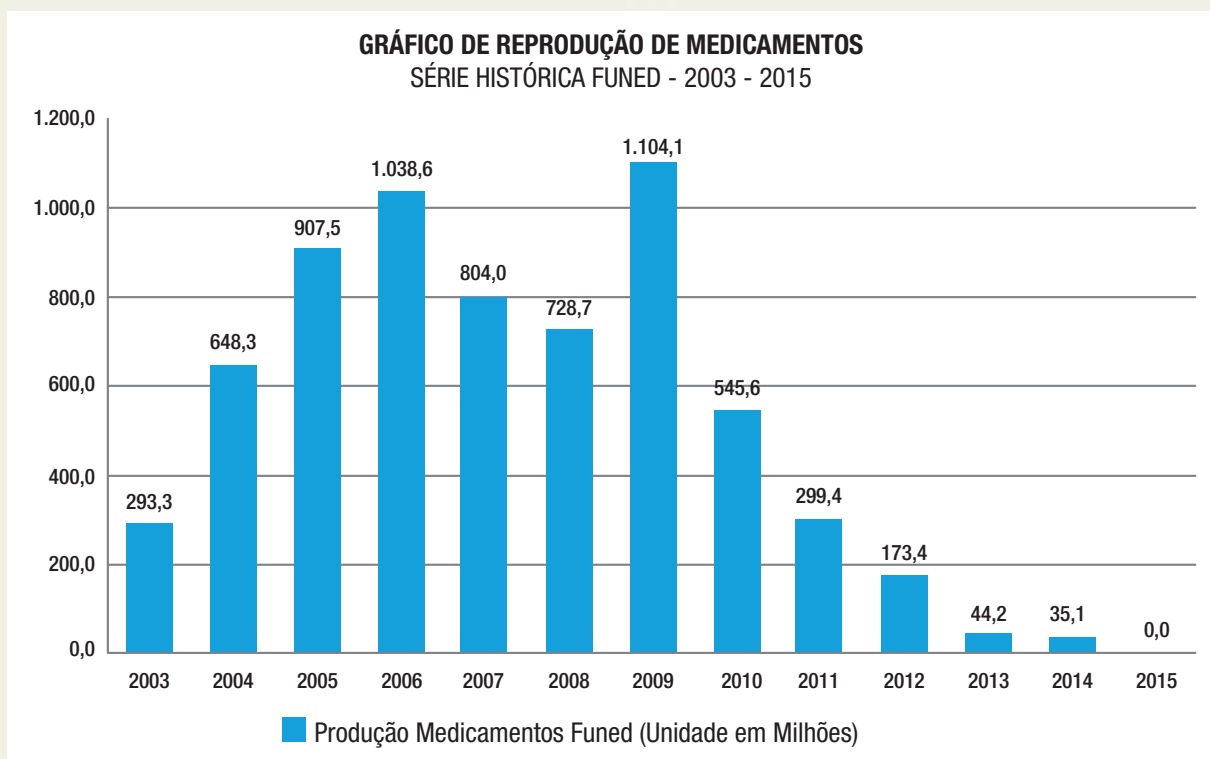
According to a document of the Union of Public Health Workers (SIND-SAÚDE), FUNED is not being properly represented in technical discussions held by the Ministry of Health, resulting in loss of investments and of registrations for producing basic drugs for the SUS system, leading to a sharp decrease in their production. This fact is confirmed in Chart 1, which shows the decrease in production recorded in the Foundation in recent years.

5 Parcerias para o desenvolvimento produtivo na política do desenvolvimento do complexo econômico-industrial da saúde (ceis). Available at: <http://funed.mg.gov.br/institucional/parcerias-para-o-desenvolvimento-produtivo-pdp/>

6 <http://funed.mg.gov.br/institucional/funed-em-numeros/resultado/>



**Chart 1: Evolution of drug production by the Ezequiel Dias Foundation – FUNED**



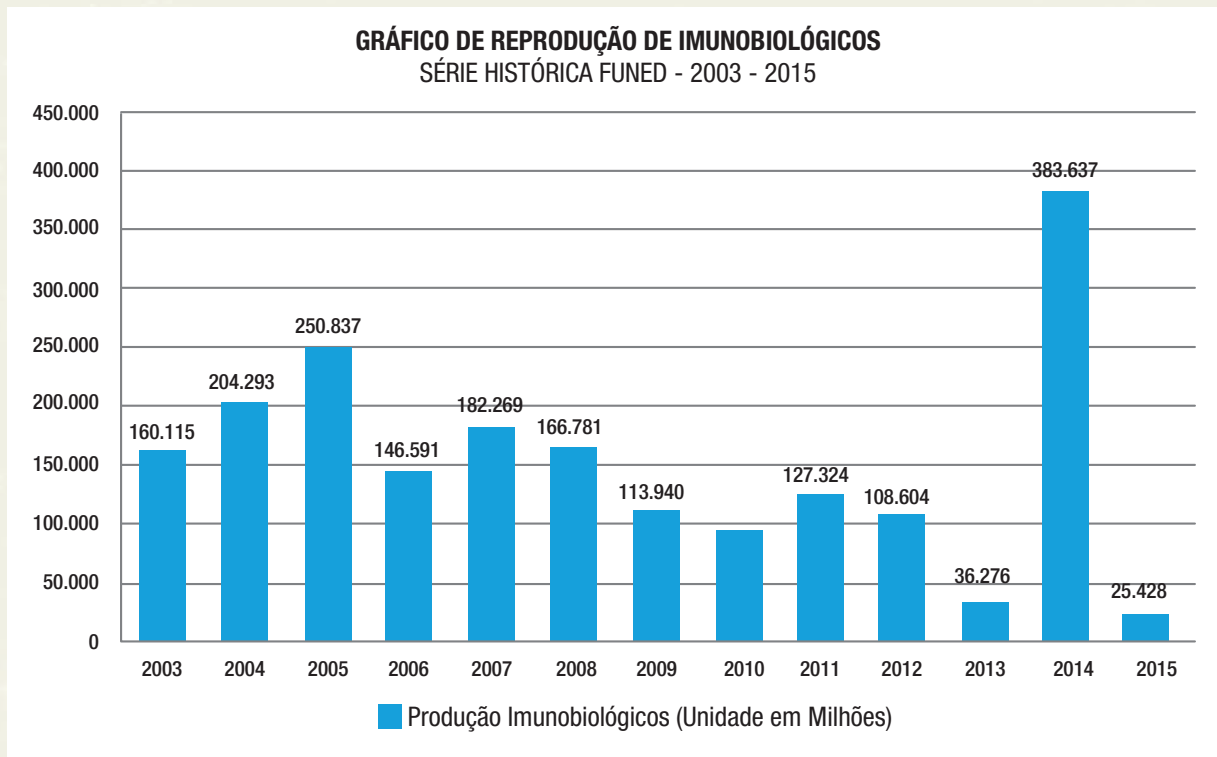
Source: <http://funed.mg.gov.br/institucional/funed-em-numeros/resultado/>

According to the union, FUNED's Industrial Board, the largest producer of drugs and serums and the main source of revenue of the institution, has been deteriorating as a result of the drop in production and loss of pharmaceutical inputs.

According to the document, most manufacturing units of the Industrial Board are not compliant with legal requirements, do not have a CBPF (Certificate of Good Manufacturing Practices) and, consequently, are not producing anything. This was confirmed by senior managers of the Foundation in interviews. They even reported that PDPs were responsible for encouraging the institution to obtain those certificates in 2015. This means that as a manufacturer of basic drugs for the SUS system the Foundation was not required to have those certificates, but to engage in partnerships with private companies that would increase its revenues significantly it was necessary to obtain them.



**Chart 2: Evolution of drug production by the Ezequiel Dias Foundation – FUNED**



Source: <http://funed.mg.gov.br/institucional/funed-em-numeros/resultado/>

The senior managers of the Foundation reported that PDPs are not just about technology, as they change how the institution is organized completely. When asked whether the institution had plans to become autonomous after the partnerships, they reported that getting rid of the private initiative is a “difficult task.” They said that the partnerships provide a certain degree of autonomy that enable them not to have to enter into partnership contracts for every new investment. But they recognized that this does not mean that new partnership contracts will not be signed. According to them, “in today’s globalized world, if you don’t engage in new partnerships... other things will come up, new partnerships for you to take part in.”

They also highlighted that innovative and technological competence is lacking in Brazil, generating the need for partnerships with the private sector. One of the senior managers raised issues related to Brazil’s participation in the TRIPS agreement, mentioning that Brazil lacks an

appropriate domestic framework for that purpose. He said that many of the drugs contemplated in PDPs have no patent protection, but we lack the necessary framework to produce them. In response to a question about compulsory licensing as an alternative provided for in the TRIPS agreement, he said: “can we produce the drug? Are we prepared to issue compulsory licenses? ... How can you issue a compulsory license if you can’t produce (the drug or health product) ... as in the case of efavirenz with Fiocruz... They had a very hard time with that! Brazil lacks the technology to issue compulsory licenses.” In the case in question, that of the compulsory licensing of efavirenz, it took 21 months for the drug to be developed and produced, a much shorter period than that of a PDP.

According to a 2014 publication of the Union of Public Health Workers of Minas Gerais State (SIND-SAÚDE)<sup>7</sup>, FUNED had several presidents since it was established who in most cases lacked the technical knowledge to understand its interfaces and unique characteristics, and therefore failed to realize the importance of the Foundation to the public health care network and of its capacity to contribute toward improving it. This situation was also reported by senior managers of FUNED in interviews. They even said that the non-participation of the Ministry of Health in defining private partners for PDPs is harmful for these partnerships.

Not to mention that the registration of some products has been lost. Unit V (which is in charge of producing biopharmaceuticals under PDPs), whose construction is behind schedule, has several equipment items that have not been installed yet, whose warranty has expired and which are about to become obsolete. Furthermore, even though specific details were not provided, the document of SIND-SAÚDE mentions that technology transfer agreements and contracts signed with private companies for producing biopharmaceuticals under PDPs are seriously flawed and will not be complied with.

The union also reported that the institution has been extensively engaged in deceptive marketing and that the following facts need to be considered:

- A technology transfer agreement between FUNED and the BIORIO Foundation for producing erythropoietin, interferon and pegylated interferon expired in 2011 before the technology transfer was completed. Audit Report No. 2260.4179.13

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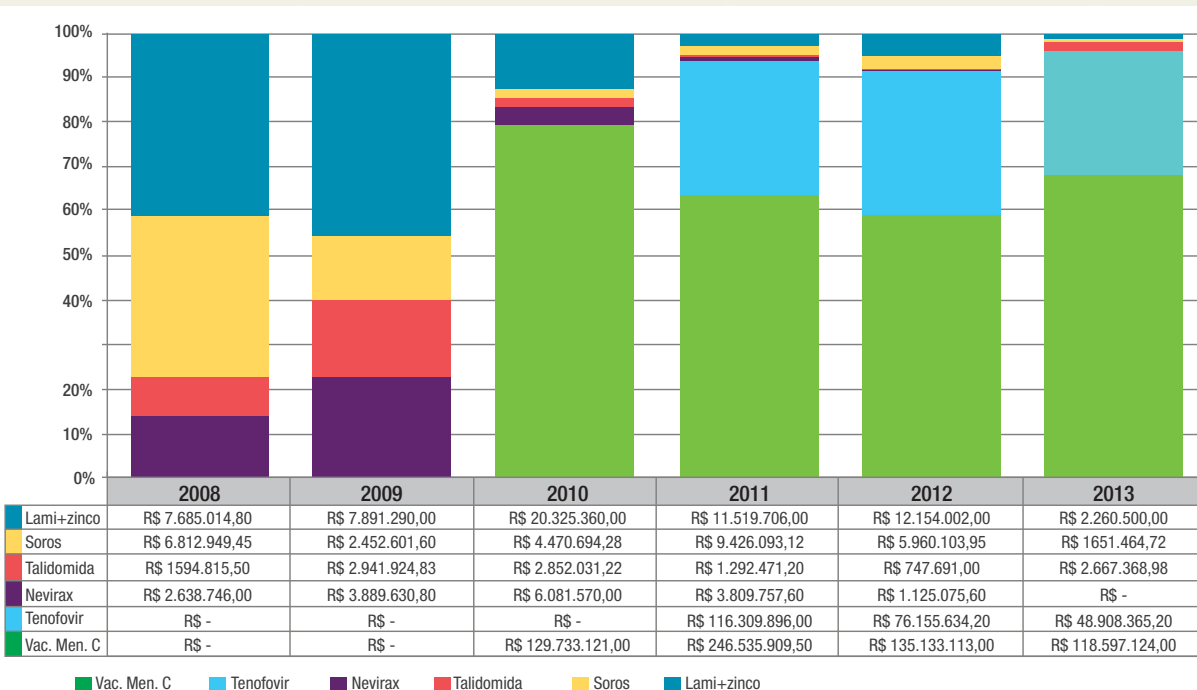
<sup>7</sup> Diagnóstico FUNED. Available at: <http://www.sindsaudemg.org.br/index.php/sindicato/documentos.html>

related to that Agreement shows that not all stages contemplated in the agreement were actually implemented, even though FUNED paid for all of them;

- A plant for producing liquid drugs built with funds from the Ministry of Health is not in operation because, due to project errors and other problems, it failed to meet the requirements contemplated in the good manufacturing practices provided for in specific laws;
- Drug production was virtually halted in 2014. After Unit I had its operations suspended by the Health Surveillance Agency at the end of 2013 for lack of the certificate of good manufacturing practices, virtually no drugs were produced in 2014. Unit III does not have the certificate of good manufacturing practices either;
- A technology transfer partnership between FUNED and BLANVER for producing the drug Tenofovir has been plagued with problems and irregularities from the outset, facts which are being investigated by the Public Prosecutor's Office. An Administrative Inquiry has been ordered through Ordinance 035/2014 to investigate the non-compliance with the technology transfer schedule agreed upon for producing Tenofovir, which has been seriously affected;
- A technology transfer schedule for producing a meningococcal C conjugate vaccine through a strategic alliance with NOVARTIS has been plagued by delays from the outset. The initial contract expired in October 2014 and it was extended for another year, which was not sufficient to complete the technology transfer. In 2013, a decision was made that the vaccine would not be produced in freeze-dried form any longer, but rather in liquid form. As a result, a large lyophilizer bought by FUNED stopped being used altogether. An administrative Inquiry was initiated to investigate who is responsible for the non-compliance with the technology transfer schedules for producing the vaccine.



**Chart 3: FUNED's turnover with drugs in partnership with the Ministry of Health**



Source: <http://funed.mg.gov.br/institucional/funed-em-numeros/resultado/>









**LOCAL  
PRODUCTION  
OF DRUGS AND  
CORPORATE  
CAPTURE:**

**ANALYSIS  
OF THE  
BRAZILIAN  
CASE**



**GRUPO DE TRABALHO SOBRE  
PROPRIEDADE INTELECTUAL**

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