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Elize Massard da Fonseca, [Kenneth Shadlen](#), Francisco Inácio Bastos

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**Integrating science, technology and health policies in Brazil:
Incremental change and public health professionals as reform agents**

Elize Massard da Fonseca^{1*}

Kenneth Shadlen²

Francisco Inácio Bastos³

1. Visiting Research Fellow at the Institute of Education and Research (INSPER), Sao Paulo, Brazil. Her research agenda focuses on the political economy of pharmaceutical regulation. She holds a PhD in Social Policy, University of Edinburgh (UK) and a PhD in Public Health, National School of Public Health (Brazil).

2. Professor of Development Studies at the London School of Economics, United Kingdom. He researches the comparative and international political economy of development, with a special focus on the politics of intellectual property.

3. Senior researcher at the Oswaldo Cruz Foundation (Fiocruz), Ministry of Health, Rio de Janeiro, Brazil. His research focuses on epidemiology, the prevention of drug abuse and HIV/AIDS. Recently, he has published in areas of philosophy and the history of biology and health sciences.

*Corresponding author

Rua Quata, 300 #700
São Paulo, SP, Brazil
emassard@gmail.com

Contributions

EMF, KS and FIB have contributed equally to the conceptualization, data analysis and writing of this manuscript. EMF was responsible for data collection.

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Abstract

Brazil has encouraged an ambitious set of policies toward the pharmaceutical industry, aiming to foster technological development while meeting health requirements. We characterize these efforts, labeled the “Health-Industry Complex” (*Complexo Industrial da Saúde*, CIS), as an outcome of incremental policy change backed by the sustained efforts of public health professionals within the federal bureaucracy. As experts with a particular vision of the relationship between health, innovation, and industry came to dominate key institutions, they increasingly shaped government responses to emerging challenges. Step by step, these professionals first made science and technology essential aspects of Brazil’s health policy, and then merged the Ministry of Health’s new focus on science, technology, and health, with industrial policy measures aimed toward private firms. We contrast this depiction of these policy changes with a conventional view that relies on partisan orientation of the Executive.

Key words: Pharmaceutical Industry; Science and Technology; History of Public Health; Health Policy

Latin American countries have historically treated policies for organizing and managing health systems and policies regarding science and technology as distinct areas, with limited integration between the two. Health policymakers have been concerned with health services provision, while officials in development ministries and agencies have focused on investments related to the promotion and use of technologies. In Brazil, however, running contrary to this tendency, the two dimensions of public policy have become fused, with the alignment of health policy with measures to promote scientific and technological development of the pharmaceutical industry. This paper examines the process of transformation of health policy in Brazil.

Prior to the 1990s, health policies and science and technology policies in Brazil bore little relationship to each other; in fact often they were in conflict and undermined each other.

And to the extent that health-related innovation and production were on the public policy agenda, the main focus was on public production of medicines, with little concern for or engagement with the activities of private industry. However, since the mid-2000s the Brazilian Ministry of Health (MoH) has adopted a series of initiatives for the establishment and expansion of the “Health-Industry Complex” (*Complexo Industrial da Saúde*, CIS). These initiatives have included, for example, incentives for production and technological development in the biomedical sector, mechanisms to promote technology and knowledge transfers from large multinational pharmaceutical companies to Brazilian companies, and coordination among various ministries and state agencies involved with promoting science and technology (S&T). The integration between public policies in health, science and technology, and industry is unprecedented in Brazil.

The array of new science and technology and industrial policy initiatives that contribute to the CIS respond directly to the needs of Brazil’s health system. The country has one of the world’s largest universal public health systems, called the National Health System (*Sistema Único da Saúde*, SUS).¹ Coverage includes substantial expenditures on medicines (for example, the high-cost treatment of diseases like cancer, HIV/AIDS, and hepatitis) and other health products and services. The demands created by so many obligations in health led to the urgent need for a more vibrant industrial sector, and the CIS, a pioneering step that greatly expands the volume of resources dedicated to health-oriented industrial policies, is envisioned and designed as a package of measures to reform the country’s science and technology and industrial bases in order to satisfy the large and ever-expanding needs of the SUS.

Not only does the CIS invest in industry for the sake of health, but it also treats investments in health as a driving force of economic development. In doing so, the logic of the CIS differs from the traditional public health model, which focuses on identifying the most efficient ways to improve “health.”² The CIS model understands the health sector as involving a wide range of interconnected industries and activities (e.g. pharmaceuticals, diagnostics, healthcare services, medical devices,) which jointly, in addition to contributing to the delivery of healthcare, can be the source of broader technological change and economic development. CIS speaks directly to an emerging global health agenda that calls for enhanced

¹ Though available to all Brazilians, in effect the SUS serves approximately 75% of the country’s population, with roughly 25% of the population opting for private health insurance.

² Marco Di Tommaso and Stuart Schweitzer, *Health policy and high-tech industrial development: learning from innovation in the health industry* (Cheltenham: Edward Elgar Publishing, 2005).

integration between health and industrial objectives, and also supports local production of pharmaceuticals in low- and middle-income countries.³

Our analysis of the CIS builds on a substantial body of research.⁴ Various authors have endeavored to understand the expansion of Brazil's health-oriented science and technology and industrial policies in the 2000s, under the governments of Presidents Luís Inácio Lula da Silva (Lula) and Dilma Rousseff of the Workers Party (PT), but few have discussed the underlying motivations in the decision to foment actions for the CIS. One explanation might be the emergence of political movements situated on the left of the political spectrum and the “developmentalist” orientation of the PT governments of the early 2000s.⁵ Yet explanations that attribute the CIS to the orientation of the incumbent government and the general thrust toward renewed industrial policies of the 2000s are problematic from a temporal perspective: the Health-Industry Complex has its roots in the period *prior* to the Lula government. To be sure, the choices made by the post-2003 PT governments are of major importance, but the process did not start with these governments. In order to understand the policy options available to the PT governments in the 2000s, it is essential to understand the trajectory of science and technology in health over time and how past choices facilitated the initiatives that ultimately produced the CIS.

³ United Nations, ‘*Transforming our world: The 2030 agenda for sustainable development*’, (New York: United Nations, 2015); United Nations Conference on Trade and Development, ‘*Local production of pharmaceuticals and related technology transfer in developing countries: A series of case studies by the UNCTAD secretariat*’, (Geneva: United Nations Conference on Trade and Development, 2011).

⁴ Lia Hasenclever, Maria Auxiliadora Oliveira, Julia Paranhos, Gabriela Chaves (eds.), *Desafios de operação e desenvolvimento do complexo industrial da saúde*, (Rio de Janeiro: e-papers, 2016); Ana Luiza Viana, Aylene Bouquat, Nelson Ibanez (eds.), *Saúde desenvolvimento, ciência, tecnologia e inovação*, (São Paulo, Hucitec, 2012); see also the special edition of the journal *Cadernos de Saúde Pública/Reports in Public Health* 32:supl.2 2016; Kenneth Shadlen and Elize Fonseca, 'Health Policy as Industrial Policy: Brazil in Comparative Perspective', *Politics and Society*, 41:4 (2013), pp. 560 - 86

⁵ Antoine Metten, Laís Costa, Carlos Gadelha and José Maldonado, 'A introdução do complexo econômico industrial da health na agenda de desenvolvimento: uma análise a partir do modelo de fluxos múltiplos de Kingdon', *Revista de Administração Pública*, 49:4 (2015), pp. 915-36; Ana Luiza Viana & Paulo Elias, ‘Saúde e desenvolvimento’, *Ciência e Saúde Coletiva*, 12: Suppl (2007), pp.1765-1777; Carlos Gadelha & Laís Silveira, ‘Saúde e Desenvolvimento Nacional: a gestão federal entre 2003 e 2010’, in Cristiani Machado, Tatiana Vargas, Luciana Lima (eds.), *Políticas de Saúde no Brasil: continuidades e mudanças* (Rio de Janeiro: Editora Fiocruz, 2012). Although the main objective of the studies by Viana & Elias and Gadelha & Silveira was not to explain the political process in the formation of the CIS, they attribute to the incumbent Administration the option for pro-development policies that backed the policies for the pharmaceutical sector.

Emphasis on the Executive's ideological orientation also risks overlooking the relevant role of the federal bureaucracy. There are sound reasons to expect the state bureaucracy to matter for the development of the CIS, consistent with studies of industrial development in Brazil that show state actors' crucial roles in industrial policymaking.⁶ Since many analyses of industrial development in Brazil examine events that occurred during the military regime (1964-1985), the experience of the CIS also provides an opportunity to explore the role of the bureaucracy in the recent period. Matthew Flynn, one of the few authors to mention the federal bureaucracy's role when examining contemporary health and industrial policies, attributes the emergence of Brazil's industrial policy for medicines for HIV/AIDS to an alliance between the bureaucracy, local industry, and civil society.⁷ Flynn, like many other analysts of the CIS, emphasizes the role of a group of intellectuals, public health professionals, and leftist politicians – collectively referred to as *sanitaristas* – working within the federal bureaucracy to promote sweeping reforms such as the creation of a national public health system and policies to respond to HIV/AIDS.⁸ The *sanitaristas*' role in the federal bureaucracy dates to the military regime, when these actors were invited to join the Ministry of Health in order to expand the legitimacy of a government which until then had been impervious to civil society's interests, and then grew substantially in the 1990s.⁹ Our analysis complements and builds on this research by extending the analysis of the role of public health professionals in the formulation of public policy beyond health per se, examining instead their role in creating a coalition for a broader industrial policy related to health, the CIS.

We argue in this article that a process of institutional change occurred incrementally, over a long period of time. The Health-Industry Complex, launched in 2007 and implemented in the following decade, resulted from gradual changes in science, technology, and health

⁶ Ben Ross Schneider, *Politics Within the State: Elite Bureaucrats and Industrial Policy in Authoritarian Brazil*, (Pittsburgh, PA: University of Pittsburgh Press, 1991).

⁷ Matthew Flynn, *Pharmaceutical Autonomy and Public Health in Latin America: State, society and industry in Brazil's AIDS Program* (New York: Routledge, 2015).

⁸ Sarah Escorel, *Reviravolta na saúde: origem e articulação do movimento sanitário* (Rio de Janeiro, Ed. Fiocruz, 1999); Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (New York: Springer, 2008); Jessica Rich, 'Grassroots Bureaucracy: Intergovernmental Relations and Popular Mobilization in Brazil's AIDS Policy Sector', *Latin America Politics and Society*, 55:2 (2013), pp. 1-25.

⁹ Tulia Falletti, 'Infiltrating the State: The evolution of health care reforms in Brazil, 1964-1998', in James Mahoney and Kathleen Thelen (eds.), *Explaining Institutional Change: ambiguity, agency, and power*, (New York: Cambridge University Press, 2010); Nunn, *The Politics and History of AIDS Treatment in Brazil*.

policies that were initiated soon after the democratic transition of the late 1980s. We identify points of policy “layering” over time, as new initiatives were introduced, and we show that these gradual changes were spearheaded by groups of public health researchers gaining space within the federal bureaucracy.¹⁰ By the the mid-2000s, a segment of these researchers, occupying central positions in health policy decision-making, provided important impetus for the CIS. The initiatives advanced by this group, anchored in the premise that innovation in health technologies was essential and that the relationship between the state and private groups was critical for achieving these goals, differ substantially from Brazil’s public health tradition.

Our analysis is rooted in the literature on gradual institutional change.¹¹ A fundamental premise of this approach is that institutional change reflects perceptions of rules’ inadequacy, processes of reinterpretation, and the establishment of new social and political coalitions, all of which can culminate in transformation but occur gradually.¹² This can be thought of as a change-by-layering model, by which institutions undergo modifications via the processes of amendment and revision of existing rules. However, in addition to minor alterations occurring over long periods of time, the accrued weight of small changes can also create moments of opportunity for policymakers to promote more sweeping changes.¹³

Another premise for this literature is the role assigned to social and political actors in processes of institution-building and and institutional change. Previously, the literature on institutionalism assigned greater historical weight to structure and design, with political actors’ agency only considered important during moments of institutional rupture or crisis. Thelen and Mahoney, challenging this perspective, present a typology of actors that can drive different types of incremental change. In the case of layering, changes are usually introduced

¹⁰ Kathelen Thelen and James Mahoney (eds.), *Explaining Institutional Change: Ambiguity, Agency, and Power* (New York: Cambridge University Press, 2010). Faletti, ‘Infiltrating the State.’

¹¹ Wolfgang Streeck and Kathelen Thelen, 'Institutional Change in Advanced Political Economies', in Wolfgang Streeck and Kathelen Thelen (eds.), *Beyond Continuity: Institutional change in advanced political economies* (Oxford / New York: Open University Press, 2005), pp. 1-39.

¹² Thelen and Mahoney, *Explaining Institutional Change*; Giovanni Capoccia, 'When Do Institutions “Bite”? Historical Institutionalism and the Politics of Institutional change', *Comparative Political Studies*, 49:8 (2016), pp. 1-33.

¹³ Jan Olsson, 'Politics as Institutional Subversion: a neglected mechanism in explaining institutional change and continuity', *International Conference on Public Policy (1-4 July)*, (Milan, 2015); B. Guy Peters, Jon Pierre, and Desmond S. King, "The Politics of Path Dependency: Political Conflict in Historical Institutionalism," *The Journal of Politics* 67, no. 4 (November 2005): 1275-1300.

by “subversive” actors, labelled as such because they promote changes within institutions and on the fringes of existing rules, rather than through more obvious mobilizations against the status quo.¹⁴ Subversive actors introduce their agendas gradually, without breaching existing rules, but building or promoting minor alterations that accumulate over time and lead to incremental change; they initiate processes of change from the periphery until finding pathways leading to core. The evolution of the CIS in Brazil illustrates these dynamics.

The remainder of the article is organized in four sections. The next section explores the emergence of a new agenda science and technology policy in coordination with national health policies. For decades there was little dialogue between actions in health, industry, and science and technology in Brazil. Although they dealt with related issues, the management and development of these policies were distinct realities. Gradually, health policy integrated science and technology issues on the federal agenda, which served as the basis for actions in the Health-Industry Complex. The second part discusses the role of a group of public health professionals as agents of change. We present the development of their positions and specific experiences with technology transfer in a research institution affiliated with the Ministry of Health. Finally, the third part analyzes the alignment of science and technology policies as related to health, with industrial policies. Here, in contrast to the past when health professionals were averse to working with private industry, now we see health professionals embracing an approach to health and industrial policies that include an important role for private firms. All of these changes illustrate processes of layering, in that we witness the overlaying of new initiatives on existing practices, than deconstruction and replacement of past policies and practices. In the conclusion, we summarize the principal findings, the article’s contributions, and suggestions for further research.

The study is based on data collected from 2012 to 2016, including government documents (legislation, official speeches, documents from ministries and other government agencies) and newspaper articles, as well as thirty interviews held with key informants representing government, the private sector, academia, and civil society groups, selected according to their participation in this process and/or their ability to comment on the evolution of science and technology and health in Brazil. To increase the information’s validity, we used the following protocols: we revised the context and the policies before each interview in order to identify possible incoherencies and inconsistencies during the interview; we

¹⁴ Thelen and Mahoney (eds.), *Explaining Institutional Change: Ambiguity, Agency, and Power*.

triangulated primary data with other document sources and interviews; we contacted some informants more than once in order to clarify inconsistencies.

Building a science and technology agenda in health

In the late 1980s, following the demise of the military regime, Brazil's health system underwent profound reform, with a highly centralized model based on social contributions replaced by a decentralized and universal model. The health reform movement advocating these changes consisted of physicians and intellectuals who sought to expand access to health and to promote an understanding of health as a social right. Science and technology were secondary issues on the agenda, overshadowed by more urgent issues such as the expansion of free access to health services and the financial stability of the new universal healthcare system, the SUS.¹⁵ To the extent that science and technology emerged on the agenda, this tended to be limited to state investments in public laboratories and government production of medicines. Research reveals a handful of events and publications on science and technology related to health produced by researchers at the Oswaldo Cruz Foundation (*Fiocruz*), the leading biomedical research institution in Latin America, affiliated with the Brazilian Ministry of Health and birthplace of the country's health reform movement.¹⁶

It is important to take a step back and contextualize that Brazil experienced different cycles in terms of the interaction between health policy and its industrial base without a formal agenda or clear objectives on what might constitute a science and technology policy appropriate for health.¹⁷ The production of medicines in Brazil dates to the early 20th century, financed largely by the state for the development of vaccines for the health system, to prevent and combat major endemics. There was a limited presence of private pharmaceutical manufacturers, and they were largely ignored by public policy (even in health regulatory policy, which focused on inspecting ports and controlling endemics). After the 1930s, with

¹⁵ Nilson Costa, 'Inovação Política, Distributivismo e Crise: A Política de Saúde nos Anos 80 e 90', *Dados*, 39:3 (1996), pp. 423-78.

¹⁶ Sergio Arouca, 'Política de imunobiológicos e tendências atuais da política de saúde', in Fundação Oswaldo Cruz (ed.), *1o Seminário: Qual política tecnológica para que política de saúde?*, (Rio de Janeiro, 1987); Marília Marques, *Ciência, Tecnologia, Saúde e Desenvolvimento Sustentado* (Rio de Janeiro: Fiocruz, 1991), Marília Marques, *Por uma política de ciência e tecnologia em saúde no Brasil* (Rio de Janeiro: Fiocruz, 1998).

¹⁷ Ana Luiza Viana, Hudson Silva, Nelson Ibanez, Fabiola Iozzi, 'A política de desenvolvimento produtivo da saúde e a capacitação dos laboratórios públicos nacionais', *Cad. Saúde Pública*, 32:suppl.2 (2016), pp.s1-s14.

the emergence of the international pharmaceutical industry, the context in Brazil was marked by entry and dominance of foreign firms as suppliers of health products (e.g. equipment, medicines). Indeed, in the post-World War II period, the academics and public health professionals began to call attention to the “de-nationalization of the pharmaceutical industry,” which, they contended, could pose threats to the country’s financial situation and also public health.¹⁸ These researchers recommended various measures to build and strengthen the country’s production capacities, including initiatives to stimulate local production of medicines by state laboratories and the creation of a state pharmaceutical company.¹⁹ At this stage, however, public health researchers tended to be hostile to the private sector, particularly the multinational pharmaceutical companies that dominated the sector but domestic firms as well. To the extent that the health researchers concerned themselves with production, their focus was on state production.

Some steps to strengthen the domestic production of medicines, both by government and private manufacturers, were taken during the military regime. These included, for example, further reforms to the intellectual property law to limit patents on pharmaceuticals, the creation of the *Central de Medicamentos* (CEME) with the responsibilities of regulating and distributing medicines produced by public laboratories, and an array of tariff and tax incentives to stimulate the local production of drugs by private, Brazilian pharmaceutical firms. Driving these changes was a nationalist group in the Armed Forces that viewed domestic production of medicines as a national security issue,²⁰ but subsequent initiatives were typically spread across different government agencies, and their effects were thus limited. As one public health official declared in the early 1980s, “there is no Brazilian pharmaceutical industry, but only a pharmaceutical industry in Brazil” (p. 169).²¹

Brazil’s science and technology framework with regard to health was built slowly. The democratic transition of the 1980s created opportunities for building a health agenda that was linked to science and technology, and some incipient steps were taken in this period, but for the most part policy remained disarticulated across these realms. An important event, for example, was the first National Conference on Science and Technology in Health, organized in 1994 by the Ministry of Health, with the support of the Association of Researchers in

¹⁸ Ediná Costa, *Vigilância sanitária: proteção e defesa da saúde* (São Paulo: Sobravime, 2004).

¹⁹ Madel Luz, *As instituições médicas do Brasil* (Porto Alegre: Rede Unida, 2014)

²⁰ Costa, 'Vigilância sanitária: proteção e defesa da saúde'

²¹ José Saraiva, 'Política nacional de medicamentos', *Revista Brasileira de Educação Médica*, 7:3 (1983): pp.167-178.

Collective Health (ABRASCO). This event focused attention on the relationship between health policy and science and technology policy, and, importantly, created a platform for actions to be taken. In order to institutionalize science and technology in the Ministry of Health, for example, the final report of the Conference recommended the creation of a Secretariat of Science and Technology in Health.²² Yet, despite these efforts, little interaction followed between the MoH and other government agencies to promote a broad and cohesive agenda in science, innovation, and health; different actors in the state continuing to work on their own agendas, separately, remained the order of the day. Indeed, the demand for a specialized unit on Science and Technology within the Ministry of Health was only partially met with the creation of a department responsible for science and technology at the MoH, as we will discuss below. The lack of coordination was so serious that in 1996, after a controversial period of negotiation, the Brazilian National Congress not only passed a new intellectual property law which, as required by the World Trade Organization, meant that the country would begin to grant patents medicines, consequently increasing the price of the original name brand drugs, but it also enacted a law that guaranteed universal access to AIDS drugs – many of which would be made more expensive precisely because of the new intellectual property law.²³ In short, significant and impactful decisions were still being made seemingly without in-depth discussions or debates on relationships between various laws and their potential implications and contradictions.²⁴

We observe the Ministry of Health focusing more explicitly on science and technology later in 2000, as indicated by the establishment of the Department of Science and Technology (DECIT). This change, which we can regard as an instance of “layering,” with the addition of new roles for an existing institution, were motivated by public health emergencies that were regarded as evidence of the incipient nature of actions in health-related science and technology in the country. First, international agencies like the U.S. National Institutes of Health began to refuse to fund Brazilian researchers, citing gaps in the ethical review of

²² C Roitman, A Fagundes, G Penna and N Garrido, 'Relatório submetido à plenária final', *I Conferência Nacional de Ciência e Tecnologia em Saúde*, (Brasília, 1994); Associação Brasileira de Pós-Graduação em Saúde Coletiva, 'I Conferência Nacional de Ciência e Tecnologia em Saúde', *Boletim Abrasco* vol. 54 (Rio de Janeiro: Abrasco, 1994).

²³ Amy Nunn, *The Politics and History of AIDS Treatment in Brazil*; Kenneth C. Shadlen, *Coalitions and Compliance: The Political Economy of Pharmaceutical Patents in Latin America* (Oxford University Press, 2017).

²⁴ Indeed, parallel to these changes, in the 1990s Brazil also embarked on an accelerated process of integration into the global economy, including trade liberalization measures that could potentially harm domestic pharmaceutical firms.

multicenter protocols.²⁵ As a result, Brazilian researchers began to demand that the MoH improve its calls for health research projects and that it urgently improve the ethical regulation of studies enrolling human subjects in clinical trials. In the absence of changes, Brazil's participation in projects with major implications for world science, like the Genome Project, would be impossible in a context of insufficient regulation of research ethics. The second event that triggered the creation of the DECIT was an episode of environmental contamination in Rio de Janeiro. The Federal Attorney's Office requested a technical report from the MoH on the contamination, and the Ministry's report stated that prior studies had been incomplete and inadequate, signaling another shortcoming in health research in Brazil.²⁶ The creation of the DECIT thus marks an important landmark in the gradual introduction of science and technology policies within the MoH, and an effort at better coordination of such activities.²⁷

We also witness the integration of health and industry under the direction of Health Minister José Serra (1998-2002), with the public production of antiretrovirals medicines encouraged as a way to meet the demands of the National AIDS Program.²⁸ In this period we also observe reformulation of the institutions and rules for regulation of medicines and other health products, with the creation of an independent regulatory agency (ANVISA), and following that requiring drug manufacturers to adapt their manufacturing processes and plants to the new rules. Again, these changes should be regarded as incipient, the incremental integration of health and science, technology, and production policies. As important as the efforts to increase local production of antiretrovirals were, for example, they did not yet form part of a broad discussion on an industrial policy oriented toward the health sector, but rather were limited to responding to health needs in a single therapeutic class.

The next incremental step on the path to building was the change in the leadership of the National Economic and Social Development Bank (BNDES) in 2003, following the election of President Luiz Inácio Lula da Silva. At this point, the pharmaceutical industry

²⁵ Interview with Beatriz Tess, former director of DECIT, Ministry of Health, September 12, 2014.

²⁶ Ministério da Saúde, *Exposição Humana a Resíduos Organoclorados na Cidade dos Meninos, Município de Duque de Caxias, Rio de Janeiro* (Brasília: Ministério da Saúde, 2003).

²⁷ Importantly, the decisions were made in a context of economic stabilization in Brazil after decades of recession, which allowed expanding investments in S&T in general. The Ministry of Science and Technology also considerably expanded funding for research in various sectors and launched a discussion on a National Policy for Science and Technology.

²⁸ Matthew Flynn, "Public Production of Anti-Retroviral Medicines in Brazil, 1990–2007," *Development and Change*, Vol. 39, No. 4 (2008), pp. 513–536.

began to occupy a more privileged position in discussions of industrial policy, signaled as a key sector in the Industrial, Technological, and Foreign Trade Policy (PITCE). The BNDES began debating the sector's needs for the first time, as explained by Pedro Palmeira, Head of the Health Products Department at BNDES:

[...] when Carlos Lessa took office at BNDES, we began to hear about the health sector as something in which the bank could play some role. The departments began to grow, and in the chemical industries department Lessa demanded a core group of people to focus on the health industry. There wasn't anything at all, no systematic knowledge on the health sector. There was only a group of three people. We had a program from the previous Administration that was to try to develop the generics industry.²⁹

Palmeira's remarks illustrate the moment in which the bureaucracies in the health and industrial fields began to move in unison. As further illustrations, two seminars were held in 2003 that aimed at identifying bottlenecks in the pharmaceutical industry that were problematic for the health sector.³⁰ These events were important in that they drew together a segment of public health researchers who were sensitive to the issues of the production of medicines, technological development, and industrial policy. The BNDES invited groups of collective health researchers to participate in these events, and they prepared situational diagnoses that contributed to the elaboration of the Program to Support the Development of the Pharmaceutical Production Chain. This program, known as *Profarma*, and especially the component of the program oriented toward "innovation," mark a milestone in investment management by the BNDES, which was now moving far beyond a traditional focus on financing manufacturing infrastructure processes. Many of the BNDES loans were to help firms command reverse engineering technology, for example by studying the path for

²⁹Interview with Pedro Palmeira, former head of the Industrial Area Department / Health Products Department, BNDES, October 23, 2014.

³⁰Ministério do Desenvolvimento, Indústria e Comércio Exterior, *Fórum de Competitividade da Cadeia Produtiva Farmacêutica* (Brasília, Ministério do Desenvolvimento, Indústria e Comércio Exterior, 2003).

synthesizing reference products in order to manufacture generics, investments that were interpreted as innovation at the time.³¹

In parallel, and still in the early years of the Lula Governments, an “Innovation Law” was passed in 2004, decisively introducing innovation on the policy agenda. With some amendments to the original bill submitted in Congress during the Fernando Henrique Cardoso Administration, the Innovation Law updated the legal framework to encourage cooperation between science and technology institutions and the private sector, besides regulating the use and negotiation of the intellectual property produced through these collaborations. Previously, Brazil had no formal regulation allowing researchers from public universities and research institutes to engage in formal collaboration with private companies. Again, we observe a layer of science and technology policies initiated under the previous Administration and added to the government agenda under President Lula.

When Luiz Inácio Lula da Silva took office as President of Brazil in 2003, in addition to the reorganization of the BNDES, the Ministry of Health also underwent fundamental restructuring. Various Secretariats were created in Ministry (Secretariats are the second echelon below the Ministry itself, and within Secretariats are Departments). This reorganization created various possibilities for what might happen to DECIT: eliminating it altogether, retaining it as a third-echelon department, or promoting it to the status of secretariat. The third of these options would indicate the importance that the Ministry as taking science and technology matters, and it was public health researchers invited to participate in the government’s transition team that suggested this option – converting DECIT into the SCTIE.³² The transition thus provided an opportunity for reclaiming a longstanding demand by experts in the area of science and technology and health, namely the creation of a Secretariat that could better coordinate the research activities applied to the health sector and create a science and technology policy for the National Health System. As discussed, this demand had already been voiced at the ABRASCO Conference on Science and Technology in Health in 1994, but it had been only partially met to that point, with a third-echelon Department. The creation of SCTIE would help the MoH take a strategic role in conducting science, technology, and innovation policy in health, coordinating activities across

³¹ L.X. Capanema, P.L. Palmeira Filho, and J.P. Pieroni, “Apoio do BNDES ao complexo industrial da saúde: a experiência do Profarma e seus desdobramentos,” *BNDES Setorial* 27 (2008), pp. 3-20; Shadlen and Fonseca, “Health Policy as Industrial Policy.

³² Interview with Reinaldo Guimarães, former director of DECIT and former secretary of SCTIE, Ministry of Health, October 23, 2014, and interview with Moises Goldbaum, former secretary of SCTIE, Ministry of Health, September 30, 2014.

these realms and doing so in a focused way from a single important division of the Ministry. Accordingly, SCTIE would become responsible for, among other things, the procurement of medicines, decisions on the incorporation and evaluation of new technologies by the health system, and the health research agenda itself.

In sum, the agenda for S&T in health was built gradually from the late 1980s through the early 2000s. Science and technology policies and health policies became more integrated in the wake of democratization, then further integrated under the leadership of Health Minister Serra, and then the agenda was moved to the next level in the 2000s under President Lula. Despite these changes, however, while private industry became targeted by other policy instruments and state agencies, as discussed above, the private sector remained excluded from the Ministry of Health's agenda. That next step in integration was yet to occur.

Scientists as political agents:

The experience with technology transfer and agenda-building in the Health-Industry Complex

Historically, the bureaucracy of the DECIT, and of the Secretariat of Science, Technology, and Strategic Inputs (SCTIE) that succeeded it, was largely occupied by public health researchers working in the area of science and technology in health, and who provided crucial impetus for these actions.

The new staff of federal administrators in the SCTIE involved mostly researchers or administrators with experience in science and technology and health. One of the leading research clusters on science and technology in Brazil was at the Oswaldo Cruz Foundation (Fiocruz), a research institution linked to the MoH. And it was a group of researchers from Fiocruz, particularly those affiliated with the research group on “Development, Economic Industrial Complex, and Innovation in Health,” now occupying positions in the Ministry, that spearheaded initiatives in science and technology and health toward what would eventually become the “Health-Industry Complex.” In order to understand this reformist group's agenda and proposals, it is important to contextualize the work by Fiocruz and, within Fiocruz, the role of this particular research group.

One of the most important missions of Fiocruz is the production of inputs (medicines and vaccines) for the federal government's health programs. Complementing the creation of the Secretariat within the MoH and the Profarma program at BNDES, Fiocruz launched a Four-Year Plan (2005-2008) which determined, as a priority, actions for the Health-Industry Complex and innovation chains. In doing so, researchers called attention to the need for

greater involvement by Fiocruz in the decisions made at the MoH; and it defined strategies to improve the production process for inputs for the National Health System.³³ In this context, the “Development, Economic Industrial Complex, and Innovation in Health” research group launched a project called “Innovation in Health” with the objective of identifying support for the formulation of a multi-sector policy involving production, management, and technological development.³⁴ The project was coordinated by researchers José Gomes Temporão (later Minister of Health from 2007 to 2011), Carlos Gadelha, Eduardo Costa, and Reinaldo Guimarães (all later secretaries of the SCTIE), and Paulo Buss (president of Fiocruz from 2000 to 2008).

The “Innovation in Health” Project and the production of inputs at Fiocruz had important consequences for developing an agenda for the Health-Industry Complex in the MoH.³⁵ The coordinators drew on a conceptual base combining public health with economic development, and expecting the strategic use of the state’s purchasing power to shape industrial development. Gadelha emphasizes the systemic nature of Brazil’s approach to industrial policy in this area, marked by the focus on various sectors in the Health-Industry Complex and their relationships to the state and the international context, as well as on service providers (hospitals, outpatient clinics, etc.).³⁶ Guimarães highlights the particular relevance of health for generating innovation, since it is one of the world’s prime areas of investment in research and development (R&D), in a context in which innovation is a key differential for national competitiveness in a globalized environment.³⁷ For this group of researchers, the health sector was a key factor for economic development and innovation – and now this group had privileged access to corridors of power within the Ministry of Health.

With Fiocruz researchers occupying important positions in upper echelons within the MoH, the role of science and technology on the Ministry’s agenda became consolidated. The 2nd National Conference on Science, Technology, and Innovation in Health, for example, was followed by the National Policy on Science and Technology in Health, the National Agenda

³³ Fundação Oswaldo Cruz, 'Plano Quadrienal 2005-2008', (Rio de Janeiro: Fiocruz, 2005).

³⁴ Fundação Oswaldo Cruz, 'Projeto Inovação em Saúde', *Revista Rio de Janeiro*, 11, (2003), pp. 1-19.

³⁵ Interview with José Gomes Temporão, former Health Minister, September 29, 2014.

³⁶ Carlos Gadelha, 'Política industrial: uma visão neo-schumpeteriana sistêmica e estrutural', *Revista de Economia Política*, 21:4 (2001), pp. 149-71.

³⁷ Reinaldo Guimarães, 'Pesquisa em saúde no Brasil: contexto e desafios', *Revista de Saúde Pública*, 40: No Esp (2006), pp. 3-10; Carlos Gadelha, 'Desenvolvimento, Complexo Industrial da Saúde e Política Industrial', *Revista de Saúde Pública*, Vol. 40, (2006), pp. 11-23; Carlos Gadelha, 'Saúde e desenvolvimento: uma nova abordagem para uma nova política', *Revista de Saúde Pública*, 46:suppl 1 (2012), pp. 5-8.

on Research Priorities in Health, the creation of an agency to assess new health technologies, and the creation of a Policy for Technological Management for the National Health System.³⁸ The procurement of high-cost medicines was also re-centralized, whereas it had previously been the responsibility of the country's 27 states, a move was important for improving the efficiency of government purchases of patented products and crucial for increasing the Ministry of Health's bargaining power with the suppliers of these products.³⁹ All these initiatives had the support of, and were monitored by, the Working Group of Health, Science and Technology of Abrasco, the network of public health scholars that had been active since the early 1990s.⁴⁰

Driven by researchers within SCTIE, the Ministry of Health became increasingly concerned about the production of medicines and technology transfer in the 2000s. A critical event that inspired state activism here were the events around Minister Temporão's decision to issue a compulsory license on the patent of efavirenz (EFV), an important antiretroviral drug that was in high demand by the National Aids Program. The decision came in 2007, following years of negotiations with the patent-holder (Merck), some of which had yielded price reductions but left the drug at a price that, because of the increased demand for the drug, was continuing to place substantial burdens on the health budget. This event underscored weaknesses in the production of medicines and the need to consider new alternatives for the production of ARVs.⁴¹ After all, the consortium of three companies that stepped up to supply the AIDS Program with EFV experienced difficulties producing the drug, and it was necessary to import a generic version from Indian companies (where there was no patent). Ministry of Health officials agree that this situation was crucial for advancing initiatives for the industrial development of medicines.⁴² For the first time, the MoH sponsored a partnership between private Brazilian pharmaceutical and pharma-chemical companies and the public laboratory Farmanguinhos with the guarantee of purchase of EFV production.

³⁸ Ministério da Saúde, "Decit 10 anos".

³⁹ Elize Fonseca & Nilson Costa, 'Federalismo, Complexo Econômico da Saúde e Assistência Farmacêutica de Alto custo no Brasil', *Ciência e Saúde Coletiva*, 20:4 (2015), pp. 1165-76.

⁴⁰ Comissão de Ciência & Tecnologia em Saúde, '*Comissão de Ciência & Tecnologia em Saúde e propostas para a nova diretoria (2006-2009)*', (Rio de Janeiro: Abrasco, 2009). The Working Group was converted as a Commission and later into a Comitê of Abrasco.

⁴¹ Shadlen & Fonseca, "Health Policy as Industrial Policy: Brazil in Comparative Perspective".

⁴² Interview with Reinaldo Guimarães, former director of DECIT and former secretary of SCTIE, Ministry of Health, October 23, 2014; interview with José Gomes Temporão, former Minister of Health, September 29, 2014.

The involvement of private firms constitutes an important change. Prior to this period, though Brazilian firms had been the subject of some industrial policy measures, as discussed above regarding PITCE and BNDES lending, they were not regarded by health officials as central to the country's health agenda. Yet the conflict over drug patents and the experience of the compulsory license triggered a greater dialogue between the MoH and the pharmaceutical companies. In fact, the experience of using the Ministry of Health's purchasing power to promote the Brazilian consortium for the local production of efavirenz served as an embryo for subsequent policies for the Health-Industry Complex, as explained by Minister Temporão, who led the process:

The experience with compulsory licensing confirmed a view I already had, that we needed to develop a new path to what I call technological sustainability. In other words, it's impossible to conceive of a system that's intended to be universal, with quality, meeting all the needs and demands of Brazilian society, without addressing the issue of technological sustainability, without reducing Brazil's degree of dependence on technologies in relation to cutting-edge knowledge produced by science, in medicines, vaccines, reagents, diagnostic equipment, and treatment.⁴³

To conclude this section, we have seen that action by a group of researchers from Fiocruz that were working in SCTIE facilitated the fusing of the health and industrial policy agendas. A counterfactual effort suggests that if this group of researchers interested in the industrial development of health had not been occupying key positions in the federal bureaucracy, it is unlikely that the health policy agenda would have embraced the private sector and become integrated with industrial policy as it did. The measures taken by the BNDES for the pharmaceutical industry date to the end of the Cardoso Administration, with major expansion at the beginning of the Lula's Presidency, but both were strikingly dissociated from health policy. It was not until the action by the group of researchers working within the SCTIE that these activities in science and technology, innovation, and industrial policy were aligned with health policy. This shows the crucial role of these reformist administrators in the process of building the Health-Industry Complex and illustrates the

⁴³ Interview with José Gomes Temporão, former Health Minister, September 29, 2014.

layering process, while the science and technology and health institutions were evolving gradually.

*Layering in science and technology and health:
Public-private cooperation for the development of medicines*

Throughout the remainder of the Lula Presidency and continuing in the administrations of Dilma Rouseff, the fusion of science and technology, health, and industrial policies became yet more accentuated. Health was treated as an economic development activity, and promoting industrial development in pharmaceuticals was regarded as critical for health. Drawing on the experience with efavirenz, the Ministry of Health expanded the consortium model to include the production of strategic medicines for the SUS. In contrast to bargaining with international pharmaceutical firms under the threat of issuing compulsory licenses, the SCTIE began to engage these firms and encourage them to establish partnerships and technology transfer agreements with Brazilian companies, at the same time further aligning health policy measures with the activities of the BNDES and the array of state agencies promoting innovation. This marked an unprecedented shift in Brazil's health policy, with measures to promote science and technology for health aligned with industrial policy and, together, the consolidated initiatives targeting public and private actors throughout the pharmaceutical production chain. This section examines these changes.

A number of policy and institutional reforms serve to illustrate the alignment of health and industrial policies in Brazil. Regarding policies per se, the Ministry of Health's adoption of a coordinated approach to industrial policy was reflected by the signing in December 2007 of an agreement on Cooperation and Technical Assistance with the BNDES for the development of activities, programs, and studies with a view towards the development of the Health-Industry Complex.⁴⁴ Linked to this, the "More Health" program was launched by Minister Temporão in December 2007, with a budget of BRL 5.1 billion (US\$ 2.6 billion) from 2008 to 2011. Based on the Fiocruz Innovatoin Project, the "More Health" program aimed to improve the industrial and innovative capabilities of private Brazilian pharmaceutical companies.⁴⁵

⁴⁴ Ministério da Saúde, 'Relatório de Gestão 2007 da Secretaria de Ciência, Tecnologia e Insumos Estratégicos'.

⁴⁵ Gadelha, "Desenvolvimento, Complexo Industrial da Saúde e Política Industrial"; Gadelha, "Saúde e desenvolvimento: uma nova abordagem para uma nova política."

Completing policy measures were institutional reforms within the Ministry of Health. The Ministry created a Department of the Industrial Complex and Innovation in Health (DECIIS), within the SCTIE, to coordinate the new focus on a wider array of “health-related” areas, such as technological development, production, and innovation.⁴⁶ Reflecting the Ministry of Health’s concerns with these broader areas, the official appointed as Director of the DECIIS was a career civil servant from the Ministry of Development, Industry, and Commerce, chosen precisely to help SCTIE improve its competence in industrial policy. And the Ministry of Health created an Executive Group of the Health-Industry Complex (GECIS), also within SCTIE, to facilitate dialogue with different government agencies and the private sector. The GECIS had the ambitious objective of better coordinating the various government initiatives to increase the sector’s competitiveness, besides assuming the responsibility for executing the pharmaceutical sector’s industrial policy.

Not only did industrial policy gain a larger profile in the Ministry of Health’s activities, but the Ministry of Health became a key player in the design and implementation of Brazil’s industrial policy. In addition to the PITCE, discussed above, Brazil had two more major industrial policy plans in this period, the Policy for Productive Development (2008-2010) under Lula and the Greater Brazil Plan (2011-2016) under Rousseff. Both of these, like the PITCE before them, targeted pharmaceuticals as a key sector.⁴⁷ With regard to the Greater Brazil Plan, the Executive sought to coordinate and induce the stakeholders through (i) vertical action by executive committees responsible for specific sector agendas and (ii) horizontal measures to address inter-sector problems (measures to bolster exports, etc.). And it was GECIS that was designated as the body in charge of managing the health and pharmaceutical dimensions of this program. Not only did this designation reinforce the leadership of the SCTIE team in conducting health industry policy, but it also facilitated the coordination of actions in science and technology in health and industrial policy with the MoH. Groups of business representatives and government agencies which had previously engaged in little dialogue with each other now had a common channel for dialogue and for

⁴⁶ Ministério da Saúde, *Relatório de Gestão 2007 da Secretaria de Ciência, Tecnologia e Insumos Estratégicos* (Brasília: Ministério da Saúde, 2008).

⁴⁷ The Productive Development Policy launched during the Luiz Inácio Lula da Silva Administration in 2008 was a comprehensive proposal that converged with macroeconomic and other government policies, but markedly diferente from the PITCE, which selected only three priority sectors of the economy.

negotiating the conduction of health industry policy. This is evidenced by the minutes of the meetings of the GECIS, which are public and available on the Ministry of Health website.⁴⁸

As for the execution of the components of the Health-Industry Complex in the Greater Brazil Program, an important observation is in order. Two main criticisms of this regarded (1) governance, with the decision to segment industrial policy and turn its execution over to government departments which purportedly lacked expertise in activities to promote industry and (2) fragmentation, in that the executive committees were broad and difficult to coordinate.⁴⁹ However, our research on industrial policy for health suggests exactly the opposite. As we have shown thus far, the SCTIE had already developed important expertise on the health industry, and the MoH staff consisted of industrial policy experts capable of coordinating the execution of the Greater Brazil Program. In addition, allowing the inclusion of different groups in the executive committee not created a channel for dialogue among different stakeholders in the pharmaceutical sector for the first time. Such dialogue led to the creation of new industry associations, such as *Grupo FarmaBrasil*, which represents Brazil's leading pharmaceutical firms, and *Mobilização Empresaria pela Innovation* (MEI), a network of business actors interested in collaborating to develop pro-innovation policies in Brazil.

Perhaps the most important illustration of the alignment between health policy and industrial policy is the establishment of a new form of public-private partnerships in Brazil, known as Partnerships for the Productive Development of Medicines (PDP). The SCTIE established partnerships between multinational research companies, public laboratories, and domestic industry for technology transfer in strategic medicines. Agreements were established for the production of medicines for AIDS, cancer, neglected diseases, and others. As of mid-2017, 86 PDPs had been established that include biotech drugs.⁵⁰ The incentive comes from the guarantee of purchase from the original manufacturer and later from the company that internalizes the technology.

⁴⁸ <http://portalsaude.saude.gov.br/index.php/o-ministerio/principal/leia-mais-o-ministerio/581-sctie-raiz/deciis/12-deciis/12076-grupo-executivo-do-complexo-industrial-da-saude-gecis> (accessed June 13, 2017).

⁴⁹ Shapiro, Mario, 'Ativismo estatal e industrialismo defensivo: instrumentos e capacidades na política industrial brasileira', in Alexandre Gomide e Roberto Pires (eds.), *Capacidades Estatais e Democracia: Arranjos institucionais de políticas públicas*, (Brasília: Ipea, 2014), pp. 239-266.

⁵⁰ Ministério da Saúde, '*Relação de Parcerias para o Desenvolvimento Produtivo (PDP) segundo fases do processo*', Retrieved December 07, 2017 from <http://portalms.saude.gov.br/ciencia-e-tecnologia-e-complexo-industrial/complexo-industrial/parceria-para-o-desenvolvimento-produtivo-pdp>

The expression “Health-Industry Complex” also began to be used in the BNDES. Profarma, for example, was no longer regarded as “the program to support the pharmaceutical chain, but the program to support the development of the Health-Industry Complex.”⁵¹ Indeed, we witness the reformulation and reorganization of Profarma too, with two new component programs were created: Profarma Exportation and Profarma Public Producers, with the objective of stimulating exports in the Health-Industry Complex (especially pharmaceutical chemicals) and support for the public laboratories.⁵² The process illustrates the gradual way these regulatory decisions were made and the coordinated action by SCTIE, marked by extensive dialogue with the Office of the President, government agencies in innovation management and industrial policy, and members of industry.

Importantly, the policies for the Health-Industry Complex were not immune to criticisms and setbacks. First, pharmaceutical industry associations and civil society groups questioned the partnerships’ transparency, since it was not clear which criteria had been used to determine the list of priority products for the MoH or how the partners were selected.⁵³ In addition, a possible fraud in the PDP contracts was exposed while national elections were in progress, thus revealing weaknesses in the program’s governance.⁵⁴ In response, the SCTIE launched a public consultation to draft a regulatory framework for the PDPs. According to Carlos Gadelha, Secretary of the SCTIE in 2014, the new regulatory framework is more detailed, forming a kind of shield to protect new contracts, and open to monitoring and evaluation.⁵⁵

To conclude this section, and in light of recent political economic changes in Brazil, it is worth pointing to four observations which suggest that the measures aligning science and technology, innovation, industry, and health are consolidated and likely to persist. First, in the context of political instability, featuring the impeachment of President Dilma Rousseff and her replacement by Michel Temer, business associations from the state-owned and private pharmaceutical industry mobilized jointly to demand continuity in MoH policy.⁵⁶

⁵¹ Ibid.

⁵² Luciana Capanema, Pedro Palmeira and João Pieroni, 'Apoio do BNDES ao complexo industrial da saúde: a experiência do Profarma e seus desdobramentos', *BNDES Setorial*, 27:Mar. (2008), pp. 3-20.

⁵³ DCI, 'Setor farmacêutico pede maior transparência em parcerias', (December 9, 2014)

⁵⁴ O Globo, 'Labogen: Ministério da Saúde abriu mão de exigência', (May 3, 2014).

⁵⁵ Ministério da Saúde, 'Ata da Sétima Reunião Ordinária do Comitê Executivo do Complexo Industrial da Saúde – GECIS', (Brasília: Ministério da Saúde, 2014).

⁵⁶ “Manifestação conjunta Interfarma e Alfob sobre PDPs,” 3 August 2016 (<https://www.interfarma.org.br/noticias/1011>)

An industry analysis published in October 2016 suggests that the technology transfer projects have been kept on hold since 2015 due to the country's political crisis, but that they still enjoy strong support from the Brazilian and multinational pharmaceutical companies.⁵⁷ Second, following the replacement of Dilma, further investments in the Health-Industry Complex were included in the federal government's Four-Year Plan (2016-2019) that sets the MoH budget.⁵⁸ Third, in spite of the strategic changes in financing from BNDES, the pharmaceutical industry is still a priority and enjoys specific financing in the area of the Bank's horizontal lines.⁵⁹ And fourth, outside of government, health institutions and researchers that had long supported the traditional public health model, in which the private sector played only a supporting role in the health system, are now publishing formal notes of support for the Health-Industry Complex and Ministry of Health after the transition to the Temer Administration.⁶⁰ The civil society organizations associated with AIDS patients and their leaders and representatives, who have a history of struggle with multinational pharmaceutical companies, do not disapprove of the policies for the Health-Industry Complex – despite their strong criticism for the lack of broad channels for dialogue and greater transparency in the technology transfer negotiations.⁶¹

Conclusion

This article analyzed the gradual integration of science and technology, industrial, and health policies in Brazil. Focusing on the role of health researchers and professionals as agents of change within the state, we examined this process of integration as occurring gradually and incrementally beginning in the early 1990s.

⁵⁷ Valor Econômico, *Valor Setorial: Saúde* (São Paulo, Valor Econômico, 2016).

⁵⁸ Ministério do Planejamento Orçamento e Gestão, 'Plano Plurianual 2016–2019: Desenvolvimento, produtividade e inclusão social', (Brasília: Ministério do Planejamento Orçamento e Gestão, 2015).

⁵⁹ Telephone interview with Carla Reis, Sector Manager of the Department of the Industrial Complex in Health and Health Services, BNDES, on January 17, 2017.

⁶⁰ Centro Brasileiro de Estudos de Saúde, *Manifesto em Defesa das PDPs*: <http://cebes.org.br/site/wp-content/uploads/2014/08/Manifesto-entidades-CIS-jun-2014.pdf> (acessado em 10 de novembro de 2016) e Abifina, *ABIFINA mostra benefícios das PDPs em audiência na Câmara*: http://www.abifina.org.br/noticias_detalhe.php?not=2795 (accessed on November 10, 2016).

⁶¹ Hailton Jr et al, 'Produção Local de Medicamentos e Captura Cooperativa: Uma análise do caso brasileiro'.

Historically, science and technology hardly recorded on the Ministry of Health's radar screen – it was a peripheral issue and, to the extent that these topics were ever addressed, there was little coordination with other activities being undertaken by the Ministry. Yet in the late 1980s and early 1990s, a group of health researchers began holding events on the links between science and technology and health, and subsequently developed a research agenda on the theme. As some of these actors then obtained positions in the federal bureaucracy, they were able to begin implementing measures to heighten the profile of science and technology in the Ministry of Health and join together these different policy areas. This constitutes an initial instance of layering.

In the 2000s, in the context of the Lula Government's more explicit industrial policy agenda, public health professionals within the state were able to push for both organizational changes and policy reforms that would establish the seeds of a "Health-Industry Complex." And, following the conflict with an international pharmaceutical firm over the price of a patented drug that was important to the National Aids Program, placing significant strain on the health budget, and revealing weaknesses in the country's industrial base, these actors in the Ministry of Health exploited the the opportunity to adapt and expand a new model for technology transfer and the use of the state's purchasing power to include other health inputs. Now the Ministry of Health was collaborating with the national development bank and other agencies in the state that worked directly with private industry, tying together science and technology, health, and industrial policy. This constitutes yet further layering.

These changes took place gradually, and over a considerable period of time. The researchers driving the Health-Industry Complex had worked within Brazil's health bureaucracy for years. José Temporão, for example, an important health professional who would become Minister of Health at a critical moment in the 2000s, had conducted research on vaccines and pharmaceutical production for decades. The broad trajectory is nicely captured by Carlos Gadelha, then-secretary of the SCTIE:

Many people initially criticized the conceptual and political progress of science and technology in the health area, but much of what took place over these 20 years is due to the issue's grasp by the Collective Health field, when the issue assumed a leading position on the agenda of the CNS [National Health Council]. We need an Economic Industrial Complex that serves the SUS as a whole, instead of only developing three "little niche products" for the global market. Either we agree that building the SUS requires a national

policy for science, technology, and innovation, or public health will not be possible for us.⁶²

Based on these findings, three points merit attention. First, a notable aspect of the Health-Industry Complex is the focus on engaging with the private sector to meet the country's health policy objectives, witnessed in terms of encouragement and subsidy of private firms as well as establishing the framework for partnerships. This marks a fundamental shift away from both the traditional approach of the Brazilian health community, which did not envision an important role for private industry, and public policy. Indeed, under José Serra's term as Minister of Health under Cardoso witnessed a strictly state-led production agenda for ARVs, much closer to the traditional public health model.

Second, the research suggests that traditional ideologies may be of little use in understanding health policy changes in Brazil. As we have seen, it was the "center-right" Cardoso Government that pursued a state-led strategy for the production of AIDS medicines exclusively by public laboratories, while it was the "center-left" Lula and Rouseff Governments that embraced private industry and even went so far as to adopt an approach to technology transfer from leading international.

Third, the gradual and incremental nature of these changes should be underscored. It is common to regard the shifts discussed in this paper as resulting from a change in the President of Brazil, with the emergence of the PT Governments that promoted a broad industrial policy for the pharmaceutical sector.⁶³ Yet by starting the analysis in 2003, after Lula's inauguration, such an approach misses the incremental changes within the state bureaucracy that occurred previously, and that allowed the CIS to emerge, ultimately, in the 2000s. As we have seen, the researchers driving the Health-Industry Complex had worked within Brazil's health bureaucracy for years. Our study suggests that the actions of reformist groups working within the Ministry of Health, and in particular their ability to gain increasing authority and exploit moments of crisis to engineer further changes, provides a stronger explanation for the Health-Industry Complex and, more generally, the fusing of Brazil's policies on health, science and technology, and industrial development.

⁶² Carlos Gadelha in *Chamamento para Coalizão em Nome da Ciência e Tecnologia em Saúde* goo.gl/xbDKPX (accessed August 8, 2014).

⁶³ Metten et. al., 'A introdução do complexo econômico industrial da saúde na agenda de desenvolvimento: uma análise a partir do modelo de fluxos múltiplos de Kingdon'.

Our study also contributes to the literature on industrial development in Latin America. We emphasize that policies for science and technology and innovation are crucial elements of an industrial policy. There is a consensus that one of the main challenges for industrial policies is their linkage to macroeconomic policies, but with little attention to the importance of aligning initiatives to foment innovation, science and technology, and local industries. The Brazilian case suggests that science and technology policy and industrial policy are may be regarded as two sides of the same coin, requiring coordinated action. Indeed, with the Pan American Health Organization reiterating the need for coordination among science and technology, pharmaceutical, and industrial policies to promote innovation and access to medicines⁶⁴, Brazil's case can provide important lessons for the countries of the region about the potential paths and their challenges.

Further studies are needed to understand whether the Brazilian experience is virtuous in its effects in both the industrial sector and access to medicines. Successful industrial policies in late developing countries depend on disciplining and “reciprocal control mechanisms,” for example, and further research is needed to understand how such instruments are functioning in the case of Brazil's new policies toward the pharmaceutical sector.⁶⁵ At this point assessments of the impact of these policies are premature. There are some reports of important investments by Brazilian pharmaceutical companies that have increased their research portfolios motivated by the PDPs;⁶⁶ studies that question this instrument as a way to reduce the cost of medicines;⁶⁷ and analyses that question whether there is actual coordination between industrial policy and health policy.⁶⁸ One of the main policy strides in the Health-Industry Complex is the establishment of a collaborative network for the production of medicines in the country. Important management instruments have been improved: (i) the consolidation of the commission to assess new health technologies, (ii) the

⁶⁴ Pan American Health Organization, ‘Access to High-Cost Medicines in the Americas: Situation, Challenges and Perspectives’, (Washington DC: Pan American Health Organization, 2010).

⁶⁵ Alice Amsden, *The Rise of “The Rest”: Challenges to the West from Late-Industrializing Economies* (Oxford University Press, 2001); Shadlen and Fonseca, “Health Policy as Industrial Policy.”

⁶⁶ Valor Econômico, 'Libbs antecipa conclusão da fábrica e inicia produção piloto de biossimilar', *Valor Econômico* (São Paulo, 2016).

⁶⁷ Gabriela Chaves, Lia Hasenclever, Claudia Osorio-de-Castro & Maria Oliveira, 'Estratégias de redução de preços de medicamentos para Aids em situação de monopólio no Brasil', *Revista de Saúde Pública*, 49:86 (2015), pp. 1-11.

⁶⁸ Lia Hasenclever, Maria Auxiliadora Oliveira, Julia Paranhos, Gabriela Chaves (eds.), *Desafios de operação e desenvolvimento do complexo industrial da saúde*.

improvement of procurement mechanisms for high-cost medicines, with the centralization of these processes, and (iii) inter-ministerial coordination in a crucial sector for the country's development. Thus far, the main publications and assessments on these activities have been produced by the government departments themselves and the researchers affiliated with them.⁶⁹ Further studies by independent researchers will be essential, particularly in light of the serious crisis of confidence in the public sphere that currently marks Brazilian politics and society.

⁶⁹ For example: Capanema et al., 'Apoio do BNDES ao complexo industrial da saúde: a experiência do Profarma e seus desdobramentos'; Gadelha & Costa, 'Saúde e desenvolvimento no Brasil: avanços e desafios'. In 2015 the Ministry of Health presented the preliminary results of the technology transfer programa. However, thus far there has been no specific report on this evaluation. The information can be accessed at: <http://portalsaude.saude.gov.br/images/pdf/2015/outubro/01/Apresentacao-Parcerias-para-o-Desenvolvimento-Produtivo-29-10-15-Gecis.pdf> (accessed November 10, 2016).