The *Constitutional Amendment Proposition 241/2016* and the Brazilian Unified National Health System: impacts on research and on industry

A *Proposta de Emenda Constitucional 241/2016* e o Sistema Único de Saúde: impactos na pesquisa e na indústria

La *Propuesta de Enmienda Constitucional 241/2016* y el Sistema Único de Salud brasileño: impactos en la investigación y la industria

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The *Constitutional Amendment Proposition 241/2016* (PEC 241, in Portuguese), sponsored by the Brazilian Federal Government, has given rise to a broad debate in society. Its slowly revealed radicalness tends to impact practically all public policy components, generating favorable and unfavorable positions which, in general, have differed in the manner in which they are exposed. While favorable points of view habitually approach it in its totalizing aspects – its supposed aggregate macroeconomic effects –, contrary positions have sought to work with a larger resolution, seeking to evaluate its impacts on sectoral policies. Among these, policies connected to social security have been the object of the greatest and most careful scrutiny, due to the obvious impact that PEC 241's effects could have on individuals' quality of life [1,2].

Nonetheless, other, equally relevant sectoral policies affected by PEC 241 are beginning to be an object of concern and debate, and that is the case of science, technology and innovation policies. It is worth remembering that the main federal agency responsible for these policies, the Ministry of Science, Technology and Innovation (MCTI, in Portuguese) had its mission "diluted" when it recently incorporated the agency responsible for the national communications policy.

One of the most important acquisitions in health policy in the past 15 years was the growing incorporation of health research and innovation within the focus of the Ministry of Health and the Brazilian Unified National Health System (SUS, in Portuguese) in general. Though it was conceived to be strongly intersectoral, SUS only embraced health research and innovation in a broad, extramural manner in its second decade (since year 2000), despite the fact that some aspects concerning those issues were established in 1994 in the First National Health Science and Technology Conference. The policy trajectory during its first decade is well documented [3,4,5,6,7,8]. More recently, the Ministry of Health incorporated the proposal to create synergies between broadening access to industrial health products and strengthening the health industrial complex (HIC) in Brazil into its policies. This development opened doors to federal SUS administrators, in partnership with the Brazilian Bank for Economic and Social Development (BNDES, in Portuguese) regarding the issue of strengthening productive capacity and local innovations in health. This was expressed in the Productive Development Policy, which has become the health component of industrial policies in Brazil, something that has also been extensively studied [9,10,11,12]. A discussion of PEC 241's potential impacts on health science, technology and innovation policies must focus on its effects on this 15-year trajectory, particularly on its two components. This is what I shall discuss further ahead.

However, given the importance of human health research on the overall research map in Brazil, we should first discuss impacts of the

amendment on the general federal expenditures on science, technology and innovation. Data extracted from the MCTI website (http://www.mct.gov.br/index.php/content/view/29140/Brasil_Dispendio_nacional_em_ciencia_e_tecnologia_C_T_sup_1_sup__em_valores_correntes_em_relacao_ao_total_de_C_T_e_ao_produto_interno_bruto_PIB_por_setor_institucional.html, accessed on 13/Oct/2016) show that the aggregate increase in expenditures between 2000 and 2013 was 467.6% in current values – BRL 5,795,400.00 in 2000 and BRL 32,897,800.00 in 2013. Considering the 126.5% aggregate inflation rate in that period [13], there was an expressive increase of financial resources.

Unfortunately, the MCTI has not published data on federal expenditures for the years 2014 and 2015. However, there is evidence that the growth trend disappeared, with a reduction in expenditures in those two years. Recently, the presidents of the Brazilian Science Academy (ABC, in Portuguese) and the Brazilian Society for the Advancement of Science (SBPC, in Portuguese) noted this fact in their respective websites [14,15]. Both entities expressed their concerns based on the variation in MCTI's budget, a much more restricted indicator compared with that one we have used here (federal expenditures). Nonetheless, the reduction trends is adequately recorded. ABC's president notes that the Ministry of Health's budget for 2016 is BRL 4.6 billion, against BRL 7.9 billion in 2013.

Taking as indicator the allocation of financial resources, we may evaluate the potential impacts of PEC 241 on federal science, technology and innovation policy by comparing the resources' nominal growth curve between 2000 and 2013 with the hypothetical curve resulting from applying PEC 241's rules during the same period (expenditures in the preceding year minus measured inflation according Gomes & Cruz [13]). As a result, we see that financial resources would heave an aggregate variation that is BRL 79.8 billion smaller that what was effectively allocated during the period. Both curves are presented in Figure 1.

PEC 241's specific impacts on Ministry of Health actions in terms of science and technology policy and the productive development policy are harder to measure quantitatively, though this second component has tangible results in terms of savings for SUS [16]. However, I see no reason to believe that their future scenario will be different, in terms of trends, from what was presented for federal science, technology and innovation expenditures as a whole.

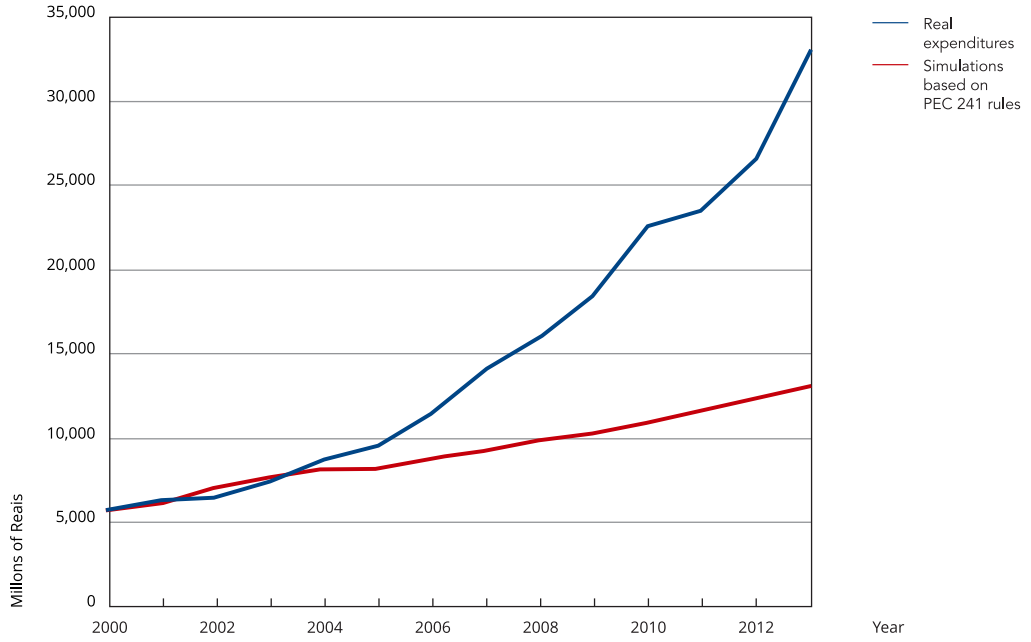
Within a scenario of radical spending cuts, the differences in impact on the different sectoral policy components will obey several factors, to wit: (1) the degree of consolidation of each of these components. More traditional, consolidated policies will tend to suffer smaller impacts; (2) the impact variation according to different time frames for each policy's results to be reached. The longer the time frame and, especially, the more they surpass politicians' reproduction period (electoral periods), the greater the impact. In this hypothesis, more strategic policies, with longer maturation periods, will be most affected; (3) the nature of policies directed more toward national interests versus those serving more localized, shall we say "parochial", interests. In this case, one should note the deterioration in quality of the past few federal legislatures, the most recent expression of which was the agglutination of most representatives around a president of the House of Representatives who soon after was expelled under heavy accusation of ethical violations. Considering these three variables, everything is conspiring to a strong impact on science, technology and innovation and productive development policies coordinated by the Ministry of Health.

As the references of this text show [3,4,5,6,7,8], the construction of the science, technology and innovation policy in SUS was not easy. With the exceptions of the research sectors on Agriculture (Brazilian Agricultural Research Corporation – Embrapa, in Portuguese) and Oil & Gas (Brazilian State Oil Company – Petrobrás), science, technology and innovation policies in Brazil were created transversally, through "generalist" funding agencies that were scantily integrated with targeted sectoral policy demands. In part, this process was a result of the low perception, by the institutions responsible for those policies, of science and technology's contribution to perfecting and advancing their missions. The construction of an extramural science, technology and innovation policy in SUS had to break with this Brazilian tradition. In short, we must question if, within the Ministry of Health itself, a recent policy, whose results are usually expressed in decades and whose construction not infrequently had to face opposition within the Ministry of Health itself, will be bolstered or even preserved in the the scenario inaugurated by PEC 241.

As for the productive development policy, in addition to its novelty, its strategic character and its ties with policies that do not fall strictly within the health sector (industry, technology and innovation policies), the impacts it will suffer due to PEC 241 will follow different paths. One of this policy's constitutive pillars is using the State's buying power both to bolster SUS's pharmaceutical care and, through its strengthening, to

Figure 1

Federal expenditures on science, technology and innovation between 2000 and 2013 in millions of current Reais. Real expenditures and simulations based on PEC 241 rules.



strengthen Brazilian health industries' productive and technological capacity. This pillar's basic tool is partnerships between private companies and official laboratories for developing and producing priority industrial items for SUS (PDP's, in Portuguese). In essence, the partnership offers a guarantee that SUS will purchase the product for a set period of time, with the commitment of providing lower prices than those of international purchases and, moreover, with the commitment that technologies involved with each product will be absorbed by the public partner. Details, achievements and challenges of this policy can be found in publications that have already been mentioned [9,10,11,12].

I understand that the source of PEC 241's impacts on productive development are derived from predictable budgetary-financial restrictions and the subsequent dispute between the several components for their share. The Ministry of Health's expenditures with medicines purchases increased by 53% between 2011 and 2014 and has already reached close to 14% of the federal health budget [17]. It is hard to believe that this rate of growth can be sustained once PEC 241 goes into effect. As a result of this, the policy may be destroyed by abandoning the component of encouraging local fabrication, so long as multinational companies engage in dumping practices and the Ministry of Health starts to buy medications from Indian and Chinese manufacturers, whose gigantic scale of production can offer prices that are unmatchable for official laboratories and national private companies.

Finally, biologics, which currently correspond to half of expenditures with medicines purchases by the Ministry of Health, have been the object of important government funding initiatives, whether through the productive development policy or through obtaining subsidies and credit from BNDES and the Brazilian Innovation Bank (FINEP, in Portuguese). Dumping strategies may be fatal for the development of an industry that manufactures biologics locally.

1. Chernavsky E, Dubeux R. O limite aos gastos públicos na construção do Estado mínimo: algumas simulações. http://jornalggn.com.br/noticia/o-limite-aos-gastos-publicos-na-construcao-do-estado-minimo#.V5YJ7bLfco4.facebook (accessed on 15/Sep/2016).
2. Vieira FS, Benevides RPS. Os impactos do novo regime fiscal para o financiamento do Sistema Único de Saúde e para a efetivação do direito à saúde no Brasil. Brasília: Instituto de Pesquisa Econômica Aplicada; 2016. (Nota Técnica, 28).
3. Santos LMP, Moura EC, Barata RCB, Serruya SJ, da Motta ML, Silva EFT, et al. Fulfillment of the Brazilian agenda of priorities in health research. Health Res Policy Syst 2011; 9:35.
4. Santos LMP, Souza LEPF, Serruya SJ, Guimarães RFN. O papel da pesquisa na consolidação do Sistema Único de Saúde (SUS). Cad Saúde Pública 2010; 26:1666-7.
5. Guimarães R, Santos LMP, Angulo-Tuesta A, Serruya SJ. Defining and implementing a National Policy for Science, Technology and Innovation in Health: lessons from the Brazilian experience. Cad Saúde Pública 2006; 22:1775-85.
6. Guimarães R. Pesquisa em saúde no Brasil: contexto e desafios. Rev Saúde Pública 2016; 40:3-10.
7. Guimarães R. Setting and implementing a health research priority agenda in Brazil. In: Matlin S, editor. Global forum update on research for health. Volume 2: poverty, equity and health research. London: Pro-Book Publishing; 2005. p. 96-8.
8. Guimarães R. Bases para uma política nacional de ciência, tecnologia e inovação em saúde. Ciênc Saúde Coletiva 2004; 9:375-87.
9. Gadelha CAG, Costa LS, Borges T, Maldonado J. O complexo econômico-industrial da saúde: elementos para uma articulação virtuosa entre saúde e desenvolvimento. Saúde Debate 2012; 36:21-30.
10. Gadelha CAG, Costa LS, Maldonado JMSV, Barbosa PR, Vargas MA. The health care economic-industrial complex: concepts and general characteristics. Health 2013; 5:1607-21.
11. Costa LS, Gadelha CAG, Maldonado J, Santo M, Metten A. O complexo produtivo da saúde e sua articulação com o desenvolvimento socioeconômico nacional. Revista do Serviço Público 2013; 64:177-97.
12. Soares SP, Gadelha C, Costa L, Burd P. Globalização, inovação e desenvolvimento: o complexo econômico e industrial da saúde (CEIS) e o papel do Estado nos cenários nacional e internacional. RECIIS (Online) 2013; 7:1-14.
13. Gomes G, Cruz CAS. Vinte anos de economia brasileira 1995/2014. http://docplayer.com.br/220398-Vinte-anos-de-economia-brasileira-1995-2014-gerson-gomes-carlos-antonio-silva-da-cruz.html (accessed on 13/Oct/2016).
14. Academia Brasileira de Ciências. Pesquisadores temem 'desastre' na ciência com aprovação da PEC 241. http://www.abc.org.br/article.php3?id_article=8164 (accessed on 17/Oct/2016).
15. Sociedade Brasileira para o Progresso da Ciência. Nader diz que aprovação da PEC 241 é retrocesso para educação e CT&I. http://www.sbpcnet.org.br/site/noticias/materias/detalhe.php?id=5553 (accessed on 17/Oct/2016).
16. Ministério da Saúde. Medicamentos biológicos lideram lista de novas propostas de PDP. http://portalsaude.saude.gov.br/index.php/cidadao/principal/agencia-saude/18638-medicamentos-biologicos-lideram-lista-de-novos-projetos-de-pdp (accessed on 20/Oct/2016).
17. Conselho Federal de Farmácia. Gasto federal com remédios sobe 53%. http://www.cff.org.br/noticia.php?id=2935 (accessed on 20/Oct/2016).

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