The challenging nature of gathering evidence and analyzing the judicialization of health in Brazil

A natureza desafiadora de coletar evidências e analisar a judicialização da saúde no Brasil

La desafiante naturaleza de reunir pruebas y analizar la judicialización del derecho a la salud en Brasil

João Biehl [1]
Joseph J. Amon [2]
Mariana P. Socal [3]
Adriana Petryna [4]

[1] *Princeton University, Princeton, U.S.A.*
[2] *Human Rights Watch, New York, U.S.A.*
[3] *Johns Hopkins Bloomberg School of Public Health, Baltimore, U.S.A.*
[4] *University of Pennsylvania, Philadelphia, U.S.A.*

Correspondence
J. Biehl
Princeton University.
128 Aaron Burr Hall, Princeton, NJ 08544, U.S.A.
jbiehl@princeton.edu

http://dx.doi.org/10.1590/0102-311X0086315

We read with great interest the article *Studies Published in Indexed Journals on Lawsuits for Medicines in Brazil: A Systematic Review*, by Gomes & Amador, published in *Cadernos de Saúde Pública* [1]. We applaud Gomes & Amador's goal of contributing to the effort of "*explain(ing) the judicialization phenomenon, identifying the general profile of lawsuits, drawing inferences on the claims, describing the various issues involved, and proposing alternatives to solve problems*" (p. 2). The review examined 17 studies that looked at lawsuits seeking access to medicines in Brazil, including our analysis of 1,080 lawsuits filed against the state of Rio Grande do Sul and published in *Between the Court and the Clinic: Lawsuits for Medicines and the Right to Health in Brazil* [2]. We are writing to correct two errors in the authors' description of our study. In Table 4 of their article Gomes & Amador (p. 6) state:

1. That the drugs most frequently requested by legal claims in our study were "*teriparatide, clopidogrel, insulin glargine, rituximab, and infliximab*". In fact, they were budesonide, acetylsalicylic acid, formoterol, simvastatin, and hydrochlorothiazide;
2. That the medical prescriptions supporting legal claims in our study originated from public health services. In fact, our results showed that 36.8% of the prescriptions came from private practices.

In addition, Gomes & Amador state that 56% (n = 256) of the different medicines requested in the lawsuits we analyzed were not part of governmental drug formularies. In our article, we presented the information on the 455 different medicines requested to illustrate the broad range of medicines sought by plaintiffs. Gomes & Amador, however, used this information to represent (misleadingly) the general frequency of lawsuits seeking access to off-formulary drugs. The authors did not mention that 65% (n = 1,956) of the 3,008 drugs requested in the 1,080 lawsuits were part of governmental drug formularies, and that 74% of the lawsuits requested at least one drug from these established formularies. Furthermore, we found that, of the 254 drugs on governmental formularies at the time of our study, 78% (n = 198) had been requested at least once.

Beyond these specific issues, we also wish to voice concern about the authors' conclusions. For example, on drug costs, Gomes & Amador state: "*in most cases, the prescribed drugs can be classified as medium to high cost*" (p. 9). This assertion is at odds with the strong evidence in our results that patients often sued for cheap, on-formulary drugs, and that even when they sued for expensive drugs, these also tended to be included in governmental formularies. Moreover, as seen in Table 2 of Gomes & Amador's article (p. 6), only one study under their review actually contained specific drug costs.

More broadly, we believe that Gomes & Amador underemphasized the marked heterogeneity of the various results reported. Such heterogeneity is critically important given the decentralized nature of the Brazilian universal health care system and the significant differences in economy, demography, and administrative capacity within and across the twenty-six Brazilian states. In our view, the judicialization of the right to health in Brazil is not a single phenomenon. Rather, judicialization may be a reflection of regional differences in judiciary strength (especially in terms of the presence of public defender's offices) and the limitations of public health administrations. Failing to acknowledge regional differences and attempting to fit all data into one singular narrative may contribute to a biased interpretation of the nature of judicialization and thus limit the understanding of its drivers and implications. Scholarly analyses of the judicialization of the right to health must be guided by careful consideration of heterogeneous findings from diverse studies, including our own.

Further studies that account for regional differences in population health and right to health demands, as well as differences in state capacity and judiciary presence, are needed. Such studies should also account for, and aim to elucidate, the role of judicialization in holding health care systems accountable to the citizens they aim to serve.

Contributors

J. Biehl, J. J. Amon, M. P. Socal and A. Petryna contributed to the conception and design of the work, acquisition, analysis, and interpretation of data; drafting the work and revising it for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work.

1. Gomes VS, Amador TA. Estudos publicados em periódicos indexados sobre decisões judiciais para acesso a medicamentos no Brasil: uma revisão sistemática. Cad Saúde Pública 2015; 31:451-62.
2. Biehl J, Amon JJ, Socal MP, Petryna A. Between the court and the clinic: lawsuits for medicines and the right to health in Brazil. Health Hum Rights 2012; 14:E36-52.

Submitted on 01/Jun/2015
Approved on 23/Jun/2015

The authors reply

As autoras respondem

Las autoras responden

Vanessa Santana Gomes [1]
Tânia Alves Amador [1]

[1] *Instituto de Estudos em Saúde Coletiva, Universidade Federal do Rio de Janeiro, Rio de Janeiro, Brasil.*

Correspondence
T. A. Amador
Programs de Pós-graduação em Assistência Farmacêutica, Universidade Federal do Rio Grande do Sul.
Av. Ipiranga 2752, sala 602A. Porto Alegre, RS 90610-000, Brasil
tania.alves@ufrgs.br

We wish to thank the authors that sent a *Letter* to CSP based on their detailed reading and identification of imprecisions in the data in Table 4 of our article entitled *Studies Published in Indexed Journals on Lawsuits for Medicines in Brazil: A Systematic Review*, published in *Cadernos de Saúde Pública* [1]. We reviewed the data, found errors, and prepared an errata to be published in the journal, since there was an error in the table's original configuration and other data were revised. Table 4 included percentages of medicines from the list presented in the article *Between the Court and the Clinic: Lawsuits for 14 Medicines and the Right to Health in Brazil* [2]; there was indeed a flaw in the data's presentation, but it was not intentional, nor was it intended to mask the data.

As for the statement that "in most cases, the prescribed drugs can be classified as medium to high cost" [1] (p. 460), we wish to begin by quoting the complete paragraph from which the phrase was extracted: "*Data on the therapeutic indications for the medicines were analyzed by 11 of the 17 articles included in the review and show that in most cases the prescribed drugs can be classified as medium to high cost, while four studies were designed to clarify points on rare diseases. Thus, it is not possible to infer that the high cost of lawsuits is due to the lack of organization in primary care. The data in the studies are specific, and are not able to answer this question*" (p. 460). We feel that the phrase taken out of the paragraph's context does not reflect what we suggested: that only ten of the 17 studies provided data on the most frequent therapeutic indications, and that among these, the majority of the medicines were medium and high cost. By way of example, seven studies found that the drugs with the heaviest demand included immunobiologicals (prescribed for treatment of autoimmune diseases and cancer) like adalimumab, etanercept, and infliximab, among others. Concerning these drugs, the *Boletim Brasileiro de Avaliação de Tecnologias em Saúde* [Brazilian Bulletin on Health Technology Assessment] [3] published a study in 2012 featuring safety and efficacy data, and since it was impossible to differentiate products in relation to efficacy, they also

compared the annual cost of treatment with these products. According to the study, the annual cost of treatment with adalimumab for patients weighing up to 70kg with a diagnosis of rheumatoid arthritis was BRL 29,211.12.

By way of illustration, we conducted a search in the *Consulta Remédios* website (*https://consultaremedios.com.br/,* accessed on Feb/2016) on the current price of a box of adalimumab, not specifically concerned with the dosage, but simply to check the price. The lowest price we found was BRL 6,589.32. The data in the articles were obviously collected in a different time period and under different economic conditions, but we emphasize the need to consider these limitations. The statement in the article is made within this context, but we feel that the phrase taken out of context may give the false impression that the majority of studies on judicialization analyze claims for medium or high-cost drugs.

We also see as a limitation to our article the inference on the disorganization (or lack thereof) of primary healthcare services, without analyzing this question with the necessary depth. In fact, the set of data presented in the articles is not sufficient to draw conclusions on flaws in the management of pharmaceutical care either in Brazil as a whole or in the states, given the studies' widely heterogeneous objectives. Still, we also recall that in the Discussion section we said, "*One limitation to this review is the lack of homogeneity among the studies, since each one focused on a specific aspect of health-related lawsuits, thus hindering a comparative analysis of the articles. The methods adopted in the current review, such as the application of descriptors and the criterion of including articles published in indexed journals, may have led to a loss of relevant studies done in different states of Brazil*" (p. 460).

Concerning medicines selected for distribution in primary care and that are claimed via lawsuits, we call attention to acetylsalicylic acid (ASA; aspirin), listed among the drugs most frequently claimed via legal action. The authors raise hypotheses on the causes, among which "failure in access", but they also suggest that when claiming access, plaintiffs with prescriptions for more than one drug may tend to claim access to all the drugs on that given prescription. Another variable that may influence the analysis and that relates to ASA is the classification used by the Ministry of Health for financing. Since 2009 [4], medicines are classified in components, and the specialized component, characterized as a line of outpatient care and defined by Clinical Protocols and Therapeutic Guidelines, presents (in one of the groups) drugs that are part of the basic component. Thus, when a patient uses a specialized medicine, the prescription may include some adjuvant treatment, and all the components may thus be claimed together. If a given study did not investigate this information, the study has no way of saying anything about the grounds for the legal claim to the respective drug.

In relation to underestimating the results' heterogeneity and considering the statement, "*More broadly, we believe that Gomes & Amador underemphasized the marked heterogeneity of the various results reported. Such heterogeneity is critically important given the decentralized nature of the Brazilian universal health care system and the significant differences in economy, demography and administrative capacity within and across the twenty-six Brazilian states*" [5], we agree that the debate on access to medicines in Brazil via lawsuits should include arguments that take into account the differences between the country's regions and states. Although we believe that Brazil has made progress in all areas, regional differences (social, cultural, economic) can still influence citizens' access to legal relief via the courts, even though the country already has public defender's offices virtually nationwide – according to data from 2013, only four states have still not effectively implemented public defender's offices (two of which in the South, one in the North, and another in the Central-West) (Instituto de Pesquisa Econômica Aplicada. Mapa da defensoria pública no Brasil. http://www.ipea.gov.br/sites/mapadefensoria, accessed on Feb/2016). Still, we emphasize that the diversity of results presented in the review are not due to differences between the regions in which the studies were done. Only one study was performed in the Northeast region, where most of the states have the country's lowest Human Development Indices (HDI), together with the North [6]. The studies included in the review were carried out in the states of São Paulo, Rio de Janeiro, Minas Gerais, Santa Catarina, and Rio Grande do Sul, which have the highest socioeconomic indices and similar characteristics, meaning that they largely resemble (more than differ from) each other. In this context, we can indeed expect that more people in these regions would resort to lawsuits to ensure their rights.

Local and regional differences obviously exist within states, but the differences that we referred to (and which did not allow conclusions on the causes of judicialization) are related specifically to the studies' objectives, which the article highlighted. Our initial perspective when compiling the data, that the review might shed light on non-obvious factors in the judicialization issue that has sparked so much debate, for example, loss of equity in the health system, failed to bear out, due precisely to the heterogeneity in the study approaches. As obvious factors, we identify the maturation of the health system and a longer democratic period in the country and thus the consolidation of citizens' rights.

Despite the current scenario, we do not deny that in this transition involving decentralization of health administration there are still local governments that have not fully assumed their role as administrators; however, this conclusion cannot be drawn from the data in the studies covered by the review. And the article discussed these limitations. However, we take advantage of the opportunity to add that our discussion failed to address all the complex factors that impact the judicialization of health in Brazil (especially in relation to medicines) and which thus sparked the questions addressed in the letter.

1. Gomes VS, Amador TA. Estudos publicados em periódicos indexados sobre decisões judiciais para acesso a medicamentos no Brasil: uma revisão sistemática. Cad Saúde Pública 2015; 31:451-62.
2. Biehl J, Amon JJ, Socal MP, Petryna A. Between the court and the clinic: lawsuits for medicines and the right to health in Brazil. Health Hum Rights 2012; 14:E36-52.
3. Medicamentos biológicos para artrite reumatoide. Boletim Brasileiro de Avaliação de Tecnologias em Saúde 2012; VI:1-35.
4. Ministério da Saúde. Portaria nº 2.981, de 26 de novembro de 2009. Dispõe sobre o componente especializado da Assistência Farmacêutica (revogada pela Portaria nº 1.554/2013). Diário Oficial da União 2009; 30 nov.
5. Biehl J, Amon JJ, Socal MP, Petryna A. The challenging nature of gathering evidence and analyzing the judicialization of health in Brazil. Cad Saúde Pública 2016; 32:e00086315.
6. Programa das Nações Unidas para o Desenvolvimento. Desenvolvimento humano e IDH. http://www.pnud.org.br/IDH/DH.aspx (accessed on Feb/2016).