# A Strategy to Improve Knowledge about Health Policies and Evidence Based Medicine for Federal Magistrates in Health Litigation

*Bruno Barcala Reis,*[1,2] *Marcus Carvalho Borin,*[2] *Marcelo Dolzany da Costa,*[3] *Renato Luís Dresch,*[4] *Osvaldo Oliveira Araújo Firmo,*[4] *Melissa Cordeiro Guimarães,*[2] *Carla Barbosa Morais Alves,*[2] *Nelio Gomes Ribeiro Junior,*[2] *Ludmila Peres Gargano,*[2] *Túlio Tadeu Rocha Sarmento,*[2] *Pâmela Santos Azevedo,*[2] *Isabella de Figueiredo Zuppo,*[2] *Carolina Zampirolli Dias,*[2] *Vania Cristina Canuto dos Santos,*[5] *Juliana Alvares-Teodoro,*[2] *Francisco de Assis Acurcio,*[2] *Augusto Afonso Guerra Junior*[2]

1: PUBLIC DEFENDERS OFFICE OF THE STATE OF MINAS GERAIS, BRAZIL; 2: CCATES – SUS COLLABORATING CENTER FOR HEALTH TECHNOLOGY ASSESSMENT AT UFMG, BRAZIL; 3: FEDERAL REGIONAL COURT OF THE 1ST REGION, STATE OF MINAS GERAIS, BRAZIL; 4: TJMG – COURT OF APPEALS OF STATE OF MINAS GERAIS, BRAZIL; 5: DGITIS – DEPARTMENT OF MANAGEMENT AND INCORPORATION OF TECHNOLOGIES AND INNOVATION IN HEALTH, SCTIE, MINISTRY OF HEALTH, BRAZIL

**Keywords**: Academic Detailing, Health Litigation, Health Authority, Universal Health Coverage, Health Law

**Abstract**: Several countries maintain universal health coverage, which implies responsibility to organize delivery formats of healthcare services and products for citizens. In Brazil, the health system has a principle of universal access for more than 30 years, but many deficiencies remain and the country observes a day practice for those seeking judicial decisions to determine provision of healthcare.

## Right to Health and the Phenomenon of Judicialization in a Universal System

Several countries maintain universal health coverage, which implies the state's responsibility to organize health care for citizens as well as the respective definitions of the delivery formats for these services and products. The financing of these systems must be planned for sustainability from their sources of funds.[1]

In Brazil, the Unified Health System (SUS) was created by the 1988 constitution, with the principles of universal and equal access, and SUS benefits place it as a huge social evolution for Brazilians, given its essential characteristic of inclusive public policy.[2]

In view of the principles and guidelines defined by the constitutional order through which the determination to promote social advancement is demonstrated, in terms of universal public policy, the Brazilian system has deficiencies, including gaps in organization and governance, regional and social inequalities and suboptimal resource allocation.[3] However, more than 30 years later, many deficiencies and challenges in health care remain contrary to the rights established in the 1988 federal constitution. This significant increase in judicialization became known as the phenomenon of the judicialization of health.[4] This phenomenon consists of the daily practice of seeking, individually or collectively, judicial decisions that determine the provision of health treatment in some way not ensured by public services.[5]

The lawsuits over health care access express legitimate claims of the people and their doctors to enforce citizenship rights enshrined in national and international standards. From the physicians' perspectives, critics report that state regulatory systems may produce corrosion of the medical-professional authority and its autonomy.[6] Thus, health disputes allow to maintain authority over the treatment of particular conditions, reinforcing the scientific basis of medicine, improving the quality of care provided and restoring



*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)
DOI: https://doi.org/10.1017/jme.2023.22

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

public confidence in the doctor. Another argument in litigations in Brazil discusses the use of evidence-based medicine strategies used in public regulatory systems to link clinical decision-making to fiscal imperatives, decreasing physician autonomy and reallocating power to health system managers.

Such litigation, even if legitimate and aimed at seeking to meet health needs from the perspective of the people, imposes on health system managers the responsibility for the effective fulfillment of issued judicial orders. Often, the resulting judicial conflict, sometimes of an individual nature, may end up allocating public resources disproportionately in certain situations, contrary to the principle of equality.[7] Data presented in a research report released by the National Council of Justice of Brazil (CNJ) show that in seven years, there was an increase of approximately 13 times in the expenses of the Ministry of Health with legal claims, reaching (BRL1.6 billion) USD 711 million in 2016, using the purchasing power parity (PPP) conversion factor from the World Bank.[8]

However, there are studies that have registered social increases resulting from the exercise of health litigation against the health system. As an example, the advent of legislation that structured a program with attention to treatments for sexually transmitted infections (STIs) and acquired immunodeficiency syndrome (AIDS). The performance of the judiciary on issues that affected the executive induced the Brazilian legislative power to produce standards to ensure that the medicines and treatments provided by SUS included high-cost products. This situation led to an expansion of the exercise of citizenship, although restricted to organized groups in society.[9]

The growing volume of litigation cases involving the health system has resulted in proactivity by the higher levels of the judiciary to implement solutions to promote the direction of judicial provision that tends to alleviate the possible distortions caused by the judicialization of health. In this context, the CNJ has supported the production of a parallel system to produce information. The aim is to contribute to judicial decisions based on scientific evidence, despite the already organized efforts of the national health services, such as the Brazilian health regulatory agency for medicines and other health technologies (Anvisa); the National Commission for the Incorporation of Technologies (Conitec) in Brazilian health services; and the Brazilian regulatory agency for private health insurance market (ANS).

A study published in 2016 by the CNJ recorded in its final considerations the influence of the judiciary on public policies. Such judicial interventions can have positive or negative results, and their activities decisively influence public policies from the point of view of the budget, management, and risks to citizens' health, among other elements. This interference led the CNJ to define three areas of concentration of efforts, called "challenges," envisaged in qualifying the exercise of jurisdiction provision regarding access to public health: 1) Challenges in conceiving the right to health; 2) Institutional challenges; and 3) Challenges of everyday decision-making.[10]

In line with the CNJ and aiming to improve the jurisdictional provision about judicial requests for medicines not incorporated by the union, the Superior Court of Justice (STJ), the federal appeals court, issued a decision to regulate this significant portion of the lawsuits on health. The appeals court determined that magistrates, when receiving judicial requests for medicines not incorporated in the national health services, must analyze the adequacy requirements expressed in the judgment of the Special Representative Dispute Appeal (n.1,657,156) of the Federal Regional Court of Rio de Janeiro, whose decision is reflected in the so-called Theme 106 STJ, which are:

I. Evidence, by means of a reasoned and detailed medical report issued by a physician who assists the patient, of the indispensability or necessity of the medication, as well as the ineffectiveness, for the treatment of the disease, of the medicines provided by SUS;
II. Financial inability to afford to pay the cost of the prescribed medication;
III. Anvisa approval of the medicine for marketing in Brazil.[11]

The strategy to clarify magistrates about the health evidence and the functional organization of the health services usually occurs through courses and seminars. Thus, academic detailing emerges as an element for promoting information aimed at greater harmony between the powers of the republic through the search for better-informed decisions in health litigation.

## Academic Detailing

Academic detailing is a teaching method that combines interactive industry outreach with noncommercial, evidence-based information from academia, and it may be carried out by a university or nonprofit institution. The team has no conflicts of interest or financial relationships with the industry and aims to bridge the gap between the best available science and the prescription in practice.[12] This instrument is a strategy used in several countries, with the aim of achieving a


*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

more qualified use of the health technologies available, promoting knowledge to the health professionals involved. Some countries that have used this strategy include Australia, with the "National Prescribing Service"; the United States, with the initiative of Harvard University's "National Resource Center for Academic Detailing" in partnership with the "Aloosa Foundation"; Canada by "The Canadian Academic Detailing Collaboration, Cross-province: British Columbia (BC), Alberta, Saskatchewan, Manitoba, Nova Scotia, Canada"; and Brazil with CCATES "SUS Collaborating Centre for Technology Assessment and Excellence in Health."[13]

Academic detailing presents itself as an educational activity that takes place through face-to-face interaction between two professionals. Active methodologies are used to promote behavioral change, through direct interaction with an objective supply of information, in a service-based approach, instead of a focus on sales, using the clinical situations experienced in the daily lives of professionals.[14]

Studies indicate that visits to academic details are very positive in bringing knowledge and key messages. The results from its application can also lead to resource savings.[15] Its effectiveness as a method of intervention in the exercise of professional activities provided positive results with regard to the positioning adopted by the professionals visited.[16] The use of this strategy could contribute to health litigation to harmonize knowledge about health decision-making.

Thus, this work sought to evaluate the use of the visit strategy for academic detailing aimed at federal magistrates disseminating concepts adopted in public policies, evidence-based medicine and health technology assessment to identify and map messages and issues that could meet the knowledge needs of federal magistrates in the health litigation area and describe their perception of the authority of the prescribers in the context of the regulation carried out by Anvisa and Conitec in Brazil.

## Methods

This is an academic detailing intervention combined with an exploratory study describing the magistrates' perceptions of the health authority of prescribers and Anvisa and Conitec. We measure a score of satisfaction with the activities as a response variable of the intervention to reflect the perception of effectiveness and acceptability of the academic detailing. The intervention methodology for this study was based on the Methodological Guideline for Academic Detailing.[17]

The strategy to clarify magistrates about the health evidence and the functional organization of the health services usually occurs through courses and seminars. Thus, academic detailing emerges as an element for promoting information aimed at greater harmony between the powers of the republic through the search for better-informed decisions in health litigation.

The academic detailing for magistrates began with a search and review of publications on the phenomenon of "judicialization of health" and academic detailing practices. Based on our review, we developed a specific academic detailing project for federal magistrates who deal with judicial health demands. The steps taken in conducting the study were as follows:

- Workshop to define key messages;
- Identification of the target population and the definition of a sample of magistrates to be visited;
- Elaboration of visit support materials;
- Training of the "detailers";
- Visit of the magistrates by "detailers" and a case study survey;
- Satisfaction survey with magistrates and "detailers";
- Summary of results and assessment.

*Definition of Key Messages for the Support Materials*

To define the key messages for academic detailing with federal magistrates, we planned a workshop using didactic methods, such as small group discussion and problematization, through case studies about medicines lawsuits. We invited professionals with experience in health litigation to participate in the workshop, such as judges and lawyers, researchers and public health services managers. Finally, we proposed to the participants to assign a score from 1 to 10 for the key messages formulated in each of the small groups to establish the priority messages to be


*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

used in the materials and content used in the visits. A team specializing in graphic design was responsible for formatting the materials.

*Population and Sample*

To define the population of judges to be visited, we collected information on the federal magistrates of Brazil by searching websites and official documents and by telephone contact with each of the Regional Federal Courts (TRF). We identified 1,631 judges and confirmed them by the respective courts. However, after direct contact with the CNJ and TRF, we observed that only a small number of federal judges received ordinary health demands. From this scenario, we sought to identify the magistrates to be visited.

We defined a sample of magistrates, at the end by convenience, but looking for a balanced distribution among the municipalities and regions among all the TRFs in Brazil. Initially, we selected magistrates by randomization, among those referenced by the respective TRFs with expertise in health disputes. In cases where there was no interest and/or availability on the part of the magistrate, we selected another, preferably in the same region, as long as he agreed to receive the visit. As we contacted the magistrates, we chose to adjust the sample using a "snowball" strategy. We invited each magistrate to suggest others who could contribute to the research.[18]

*Procedures*

After preparing the support materials and defining the sample, we trained the "detailers." These were university-level professionals, most of whom were pharmacists with experience in health technology assessment. The training had a workload of 8 hours and consisted of exhibitions and debates about the key messages to the magistrates. We provided standardized instructions about how to fill out the form with information about the visit, as well as guidance on how "detailers" should approach and behave. The training also included a practical activity simulating a visit to one of the three magistrates who participated in the organization of the research. After this activity, we gave feedback to the prospective "detailers," aiming that the whole team would adopt the same procedures.

We carried out visits with the presentation of the three bulletins and boards containing the flow and algorithm from registration to the incorporation of technologies in SUS. At the end of the visit, we presented a case study on decision-making scenarios in view of the evidence and resolutions of health authorities about a hypothetical drug demanded in court.

With the advent of the COVID-19 pandemic, magistrates began to exercise their functions remotely. For this reason, we adapted the planning for virtual visits through videoconferences, carried out with the "Google Meets" application. To make them feasible, we also adapted the material to a virtual format, keeping the same images and layout for the forms and case studies presented and answered.

*Instruments and Data Treatment*

The case study sought to understand the opinion of the magistrates in four decision-making scenarios based on problem situations. In all scenarios, we created a narrative in which the patient presented the court with a prescription for a medication with an urgent decision request, namely:

- In the first scenario, the authority of Anvisa in the prior approval of what can be prescribed in the country;
- In the second scenario, the medical prescriber's authority to define off-label use of a product already registered by Anvisa in the country;
- In the third scenario, the health authority of Conitec to define what can be prescribed with public funding, considering that the product has not yet been assessed;
- In the fourth scenario, the health authority of Conitec to define what can be prescribed to citizens with public funding, considering that the product had a final decision, denying incorporation into the health system.

In addition to the case study, we invited the magistrate to respond to an electronic form containing a satisfaction survey with the academic detailing. In addition, the "detailers" completed a survey about their perception of the visit. Finally, we anonymized records and organized the quantitative and qualitative data in frequency distribution charts and graphs using Microsoft Excel 2010. To carry out the analysis, we grouped the different responses and observations according to the categories and concepts identified in each question. The study is centered on the limits of obtaining information from the interviewees, the data collection forms and the researcher's observations. We sought, in the fieldwork, the cooperation of the interviewees. Thus, we pursued knowledge construction within a field that has been little explored by academia but that has social and economic relevance. This study was approved by the Research Ethics Committee of the Federal University of Minas Gerais (No. 3,742,680).



*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

Table 1
**Key messages addressed by bulletins.**

| BULLETIN 1 | BULLETIN 2 | BULLETIN 3 |
|---|---|---|
| • Explain medicine approval in Brazil — the role of Anvisa;<br>• Explain why certain medicines are not approved in the country;<br>• Explain how the efficacy and safety of a medicine are assessed;<br>• Explain supply of medicines not yet approved in Brazil;<br>• Explain what off-label use is and whether it is prohibited;<br>• Explain how medicines are priced in the country — the role of CMED Authority;<br>• Explain what the FDA and EMA are — relevance of medicine approval in other countries. | • Explain evidence-based medicine and what scientific evidence means;<br>• Explain how the process of incorporating technologies to SUS is carried out — the role of Conitec;<br>• Explain why Conitec does not recommend the incorporation of a certain medication;<br>• Explain where to obtain Conitec's decisions;<br>• Explain the Clinical Protocol and Therapeutic Guidelines of the Ministry of Health, the process of elaboration and updating;<br>• Explain the criteria for Conitec's decisions;<br>• Explain what RENAME (National List of Essential Medicines ) is and what its usefulness is;<br>• Explain what to do when there is no Clinical Protocol and Therapeutic Guidelines;<br>• Explain the relevance to the judicial decision over the incorporation of technologies in countries with a universal health system. | • Discuss individuality versus collectivity in judicial decisions — the budgetary impact of the decision;<br>• Discuss individuality versus collectivity in judicial decisions — the impact of similar successive decisions;<br>• Explain economic evaluation, its relevance and how to interpret the phrase "the drug is not cost-effective." |

## Results

*Design*

We conducted the workshop with the distribution of participants (n = 31) in small working groups and plenary discussions. The participants in the workshop had direct or indirect engagement in health litigation in Brazil and included professionals from the judiciary, federal lawyers, state lawyers, philanthropy and private health lawyers, public prosecutors, public defenders, health system managers (state and federal), regulatory agency personnel and academics.

The workshop functioned in a similar way to a focus group, allowing us to observe the interactions between the participants, expression of opinion with the expression of different ideas, small working groups and plenary sessions. Through the 5 case studies produced to guide the work, we divided the participants into small groups to propose key messages to be used in academic detailing. Finally, we invited all participants to assign scores from one to ten on the key messages proposed in the groups to establish priority. Next, we extracted 25 messages for the magistrates.

After the workshop, we used the main key messages defined for the preparation of three bulletins as support material for "detailers" (Table 1). Based on these messages, health professionals, such as pharmacists, doctors and dentists, as well as lawyers and magistrates, contributed to the preparation of the final texts of the bulletins distributed.

We developed two boards as reference materials. One of them contained a flowchart and algorithm for judicial requests for medicines, and the other contained the flow of registration and incorporation of technologies in the SUS. We prepared a case study delivered at the end of the visit to learn about the magistrates' perceptions about the health authority of prescribers Anvisa and Conitec.

*Academic Detailing Visits*

From October 2019 to November 2020, we made 61 visits to federal judges, 44 of which were in person and 17 virtual, through videoconferences. Of the magistrates visited, 64% were men and 36% women. We observed an average age of 45 years, ranging from 29


*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

Table 2
**General perceptions of magistrates about academic detailing activities.**

| Questions | Magistrates' responses | | | |
|---|---|---|---|---|
| Did the visit add any knowledge about evidence-based medicine concepts and health policies adopted in Brazil? | Yes 81% | | | No 19% |
| Was there anything you did not like about the visit? | Yes 3% | | | No 97% |
| Could this activity be improved? | Yes 54% | | | No 43% |
| At what intensity was the academic detailing effective in deepening knowledge compared to participation in events, such as conferences? | Much more effective 8% | More effective 22% | Equally effective 62% | Less effective and Much less effective 8% |

to 60 years, and for the length of service, we observed 14 years of magistracy, varying from 2 to 26 years.

The average wait time for assistance from the time scheduled for face-to-face visits was 9 minutes, and the average visit duration was 50 minutes. After adapting the visits to the virtual format, the average wait time was 3 minutes, with visits lasting an average of 37 minutes. The magistrates visited were in 16 states: AL, AM, BA, CE, DF, ES, MA, MG, PA, PE, PR, RJ, RN, RO, RS, SP. We cover all five TRFs, with visits to at least one state from each regional federal court.

*Case Study*

After each visit, we made contact by telephone and email with judges, requesting responses to the case study and satisfaction survey. We received 70.5% (43) responses regarding the case study. In the first scenario — judicial demand for a prescription medicine, without prior marketing approval of Anvisa — we sought the perception of the agency's authority for prior approval of what can be prescribed in the country. Considering the responses to the statements, there was a certain recognition of the national regulatory agency's authority. In view of the medical prescription presented to the court, 72% fully agree — "One must know the reasons and justifications that led to the nonapproval" before a decision.

However, we observed a tendency for magistrates to make this authority more flexible in light of specific cases. They expressed it in full disagreement or partial agreement, even when "without approval of Anvisa..." there could be a prescription and supply of the drug with public funding for 65% of the magistrates ("partially agree" and "fully disagree" with the request), and for that purpose there should be at least justifications from the prescriber. In the same vein, 62% stated that if there is authorization by foreign agencies (FDA — Food and Drug Administration, United States and EMA — European Medicines Agency, Europe) approving the drug in other countries, it would be feasible to grant an injunction authorizing the prescription of the drug with public funding.

In the second scenario, we informed the magistrate that the aforementioned medication demanded in the medical report did not fit the indications in the package authorized by Anvisa, configuring off label use. We sought here the magistrates' perception of the prescriber's authority to define clinical indications, in addition to those approved by the health regulatory agency. In view of the statements, we observed a tendency of magistrates to consider the prescriber's authority to define off-label use. In view of the statement "the off-label use shows that there is no basis for the use of the medication", it was observed that 89% of the magistrates disagree or partially agree (70% partially agree and 19% disagree completely). This perception was confirmed by the responses to the statement "If the off-label use is substantiated and justified by the doctor, I must consider it", in which 76% of magistrates agree with the prescriber's authority (16% fully agree and 60% partially agree).

In the third scenario, we informed the magistrate that the medicine demanded in the medical prescription had not been evaluated by Conitec. We sought the magistrates' perception of Conitec's authority in defining, in advance, which medicines can be financed with public resources. In view of the three statements, we observed the relevance of having scientific evidence to support the prescription when the product has not been previously approved to be financed by public funds. The statements "I must understand why this medicine was not evaluated by Conitec" and "In


*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

the absence of evaluation by Conitec, I must request an opinion on the evidence" presented full or partial agreement of 88% and 82%, respectively.

In turn, in the fourth scenario, we informed the magistrate that the aforementioned medication demanded in the medical prescription was evaluated by Conitec but had a negative recommendation for its incorporation into the health system. In this case, we sought the magistrates' perception of Conitec's authority to define incorporation boundaries based on the effectiveness or cost-effectiveness of medicines financed with public resources. However, for 60% of magistrates, when assessing the reliability of technology incorporation, they only partially agreed or even disagreed that "the incorporation assessment carried out by Conitec is reliable and covers all the criteria necessary to evaluate medicines" (58% partially agree and 2% strongly disagree.) The perception was reinforced by 84% of magistrates' full agreement responses that "I need to understand why the doctor prescribed a drug with a negative recommendation from Conitec".

*Satisfaction Survey*

We received 60.7% (37) responses regarding the satisfaction survey (Table 2). The responses presented in the satisfaction survey, with the judges' perception of academic detailing, suggest the use of this information dissemination strategy is effective and acceptable. We highlighted that the items: "The content of the visits was relevant," "The bibliography used in the material is reliable," and "The material distributed will be useful for my professional practice" had good evaluations in the satisfaction survey. Considering the maximum possible score in this section of the satisfaction survey, the academic detailing intervention achieved an average score of 66% (54% to 76%, with a standard deviation of 7%) of the possible points.

When the magistrates answered whether the visit had added some knowledge about evidence-based medicine concepts and health policies adopted in Brazil, 81% responded favorably. However, 54% reported that improvements could further improve this type of action. When asked "at what intensity the academic details made by the visits were effective in deepening knowledge compared to participation in events such as congresses," 92% considered the academic detailing were equal or more effective, and for 30% of the magistrates the action may be more effective.

The magistrates visited emphasized the relevance of the content presented in their professional practice. As these magistrates used to judge health demands, they already had some knowledge related to health concepts but agreed that it would be important information for magistrates with less experience in this legal field. Despite that, most magistrates reported that the visit increased their understanding of the concepts of evidence-based medicine and health policies adopted in Brazil. Questions about Anvisa and Conitec's performance and competences, in addition to the flow of drug approval and incorporation in SUS, were indicated as the main knowledge improved as a result of the academic detailing activity

We observed from the point of view of the "detailers" a very receptive environment in most meetings (89%), while 7% classified it as "receptive," 3% "neutral" and only one visit was considered "not very receptive" (2%). Detailers also noticed a great deal of interest from the magistrates, with the restriction of available time indicated as the main limiter for the presentation of all the planned content.

The "detailers" did not report any differences in the receptivity of the magistrates visited, considering the face-to-face meetings and those that took place virtually. The use of virtual communication strategies during the pandemic made it possible to perceive the feasibility of developing this type of strategy with potential savings and speed, ensuring quality despite technical limitations. Face-to-face visits make it possible to establish interaction and communication with greater clarity when compared to the remote process due to the perception of complete body language.

## Discussion

The work presented here with academic detailing seems to be unprecedented, since in our bibliographic review, no published specific studies focusing on this strategy with magistrates and health litigation, or even any academic detailing actions aimed at magistrates, were found. The studies found for both themes are heterogeneous in terms of study designs, populations studied, target actions and formats for implementing strategies. In general, academic detailing is one of the approaches that can produce good results, especially when performed as part of a multifaceted intervention.[19]

Some studies support the practice by using academic detailing to disseminate evidence and as an educational strategy to qualify health professionals. It is also one of the preferred strategies of the pharmaceutical industry to promote key messages about their products to physicians.[20] There is evidence of the effectiveness of academic detailing as a qualified strategy to modify the behavior of health professionals. This situation led to research questions about the possibilities of using these techniques in the context of health disputes. In this sense, this study sought to


*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

present the results and consolidate them to understand the potential feasibility of using this knowledge dissemination strategy among judiciary operators.

One of the challenges of developing academic detailing that we faced was the definition of what content related to evidence-based medicine and the complex organization of health and medication policies would be the object of formulating key messages. To solve this problem, we designed a workshop with magistrates, lawyers, researchers and public health managers. This workshop allowed us to observe the interactions between the participants and their opinions about the case studies. Finally, the key messages to magistrates that we developed in the workshop received a positive evaluation in the satisfaction survey.

Regarding the participating federal magistrates, although our choice was made by convenience sampling, it was possible to obtain the participation of judges distributed in different municipalities in all five regions of the federal courts. An inherent limitation in the use of the "snowball" mechanism is the fact that the research subjects have, potentially, homogeneous profiles. At least with regard to gender and age, this does not seem to have compromised the results. The participating magistrates, with respect to gender, were 64% men and 36% women and had an average age of 45 years (ranging from 29 to 60 years). In the end, the sample reflects the results of the national sociodemographic survey carried out by the CNJ, which indicates 32% of women magistrates in the Federal Court and 38% of the magistrates in general. Likewise, the aforementioned report points out that the average age of a Brazilian magistrate is 47 years old, with a median of 46 years old, and in the Federal Court, 49% are between 35 and 45 years old.[21]

Another challenge of the study was to adapt visits to the virtual format through videoconferences. For this type of visit, the average wait time was much shorter compared to face-to-face visits, an average of three minutes versus 37 minutes. Although the visitors did not perceive great differences in the receptivity of the magistrates, the face-to-face visit allows the interlocutors to have a more comprehensive interaction, mainly in the aspects of nonverbal communication, such as in the complete body language. In the study by Smart et al.[22] on the viability and acceptability of virtual academic detailing, the results slightly favored face-to-face visits and suggest that virtual detailing visits need to incorporate strategies that minimize any technical difficulties.

Regarding the perspectives that we gathered from the magistrates in the decision-making scenarios of the case study, they seem to recognize the authority of the national regulatory agency. The results go in the same direction as several court decisions that discussed the supply of medicines not registered with Anvisa and, therefore, not incorporated into the health system. The granting of drugs without registration with the regulatory agency seems to be an exception as objects of lawsuits; however, these decisions embrace the principle of the prescriber's authority and supremacy in defining the treatment to be financed by SUS, as long as it is minimally based on evidence. This decision-making perspective is also manifested when the demanded product, still without registration in the country, is already authorized by foreign regulatory agencies.[23]

In the same sense, we perceived the prescriber's authority in situations that refer to "off label" use. The responses collected point out that even when Anvisa grants registration and establishes an indicated use for the medicines, according to demand and the studies presented by the manufacturer, the magistrate tends to consider the opinion of the prescriber. Most magistrates disagree that the use "off label" indicates a lack of evidence for the use of the drug, as long as justified by the prescriber. Although controversial, Conitec itself published in a respected international scientific journal in 2012 that the use of the term "off label" should be applied only for unrestricted and unsafe use when there is no scientific evidence. "When the absence of registration is due to market reasons, the incorporation or prescription may be made, provided that it is scientifically based."[24]

For those who advocate greater autonomy for the physician, regulatory activities by the state could potentially undermine the authority and erode the autonomy of these professionals. Regarding the changes in the dynamics of power among health actors, Senier and collaborators discussed the strategic defense of the doctor's autonomy in the face of health regulation by public health agencies. In this study, public agencies would work to disseminate clinical guidelines and recommendations to physicians to compensate for commercial practices based on marketing and incentives from certain companies. Therefore, state regulations should act synergistically with doctors.[25]

We observed that magistrates tend to make decisions in the sense of preserving medical authority, when in opposition to the regulatory activity of the State. Regarding physician performance, the study by Senier et al. also revealed that in the absence of authority capable of compelling the prescriber to follow evidence-based recommendations, "they somehow improvised ways of voluntarily promoting some compliance, for example, emphasizing the physician's


*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

role as guardian, thus affirming the importance of the physician's autonomy and his clinical judgment". In Brazil, the CNJ recommended to the courts the creation of a voluntary compliance system to support judicial decisions, known as Judicial Branch Technical Support Centers — NATJUS, similar to Senier et al. for analyzing and producing health evidence as the base of the decisions of the magistrates.[26]

In the study "Medical compliance as an ideology," Trostle reports that the popularity of compliance systems could be better understood if analyzed as an "ideology," that is, "a system of shared beliefs to legitimate behavioral values and norms." In this sense, different groups adopt ideologies because they help to "transform power and potential influence into authority and legitimate control". According to Trostle, this is a problematic concept when observing its assumptions and its influences in clinical practice. Hence, it is observed that medical societies create their own systems of evidence, and companies seek to finance studies and activities to influence these systems. Public regulatory authorities in different countries have also created compliance systems, such as Nice (The National Institute for Health and Care Excellence) in England, Cadth (Canadian Agency for Drugs and Technologies in Health) in Canada, and Conitec in Brazil. In our study of academic details, we observed that the Brazilian judiciary itself seems to adopt the idea of compliance for the same reasons indicated by Trostle.[27]

We observed that magistrates tend to make decisions in the sense of preserving medical authority, when in opposition to the regulatory activity of the State.

Nevertheless, unlike criticisms of loss of autonomy, the study reports that state agencies sought a variety of strategies to promote scientific evidence, but at the same time, preserving the doctor's role was a critically important element. Senier and collaborators concluded, "although this structure of compensatory powers has conventionally emphasized the state's power to limit professional autonomy, we see that these projects affirm the clinical judgment of doctors.[28]

In a context of limitations imposed by the court of authority to compel physicians to adhere to evidence-based protocols, public agencies need to use dissemination and persuasion strategies aimed at these professionals, with a view of voluntary adherence. Physicians who are well informed about recommendations based on the best evidence are less subject to the influence of corporate marketing.[29]

Nevertheless, the results of the case study show that the magistrates seem to recognize the authority of Conitec but only partially agree or even disagree with the criteria adopted in the decisions. The magistrates also highlighted the need to understand the reasons for prescribing the drug, especially when it has been previously evaluated with a negative recommendation by Conitec. The perspectives adopted by the magistrates seem to align with the national effort of the CNJ to prepare and disseminate statements that contribute to more qualified judicial decisions through multiprofessional health committees in all states of Brazil.[30] The problem of access to medicines without favorable recommendations by agencies for incorporating health technologies is not unique to Brazil. Groth and Hodin report that some patients in Europe are unable to access the medicines they need due to delays in incorporation into the health systems of the respective countries after approval by the EMA. They also report delays, on average, of 400 days after approval by the European health authority and may even extend for years.[31]

There is a certain international consensus on the importance of adopting public policies that establish an adequate and efficient regulatory environment involving the development of new drugs to the scientific and recommendable limits for the prescription and use of these health technologies. In this sense, the accessibility and financing of new drugs represent challenges worldwide, as there is a search for equitable and comprehensive health care at the same time that the global economic crisis imposes restrictions on public budgets. Nevertheless, it is necessary to address the aging of the population and the resulting increase in the prevalence of chronic and degenerative diseases. The environment is aggravated by the continuous introduction of new drugs at astronomical prices, without sometimes enough evidence for incorporating these products.[32]

It constitutes an additional challenge for policy makers in this area to optimize the entry of new drugs and at the same time ensure the financial sustainability of health systems and encourage the development of new treatments to address areas of unmet clinical need. This is an international problem, and the value of new technologies has contributed strongly to inflating costs in the health sector, increasing the copayments of families and health systems.[33]


*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

Thus, it is important that magistrates understand public health policies, especially in the context of universal health systems based on the principles of socialized medicine. In these systems, it is necessary to make day-to-day decisions in the context of the various restrictions on economic resources, sometimes prioritizing collectivity over the individual. The magistrates responded to the satisfaction survey that the visits had added knowledge about concepts of evidence-based medicine and health policies adopted in Brazil, with 81% responding favorably. For the vast majority (92%), this type of strategy can be as or more effective in bringing knowledge than participating in events such as congresses.

In the satisfaction survey, the magistrates' perceptions of the academic detailing indicated that the use of this educational strategy was acceptable, highlighting the importance of the content and reliability of the support material to contribute to the decision-making of these professionals. Considering the maximum possible score in this section of the satisfaction survey on detailing, the intervention achieved an average of 66% (54% to 76%, with a standard deviation of 7%). In previous studies of academic detailing for physicians focusing on SUS clinical protocols for Alzheimer's disease, an average of 79% satisfaction was obtained (67% to 98%, standard deviation of 10%). In another study carried out with physicians specializing in rheumatology focusing on SUS clinical protocols for rheumatoid arthritis, an average of 57% (36% to 76%, standard deviation 15%) was obtained. All studies cited used the same final instrument for assessing satisfaction. The average value of 66%, obtained from the magistrates, suggests a good acceptability of the detailing strategy for these professionals when compared to previous studies, although the studies worked with different messages and scopes.[34]

We have not found academic detailing studies for magistrates. Physicians and other prescribers have experience dealing with academic detailing, as it is one of the preferred strategies of the pharmaceutical industry for disseminating information about their new drugs; obviously, the same is not true of magistrates. More frequent use of academic detailing strategies for these professionals could bring improvements to the methods, contributing to better results, including eventually disseminating and dialoguing "in person" statements and decisions of higher courts and other areas of knowledge such as health.

In Brazil, we had an increase of approximately thirteen times in federal spending on health lawsuits between 2008 and 2017, without adding municipalities and states frequently demanded in court.[35] The health issues, financial volume and number of people involved in litigations suggest the importance of strategies that can contribute to more informed decisions. Harmonizing concepts adopted seems to be favorable both on the judicial side and for the prescribers and managers of the health system. In this sense, educational actions, such as visits to academic detailing, have economic potential and can promote dialogue between actors and the dissemination of information about evidence-based medicine and health policies. Studies with economic evaluations are desirable for understanding the costs and effectiveness of this type of action in relation to the adoption of other strategies to increase knowledge and promote dialogue between those involved in decisions.

## Conclusion

Academic detailing has shown potential as an instrument for harmonization and qualification between judicial system and public health services. The results obtained with this study allowed us to perceive positive indications regarding the effectiveness and acceptability of this strategy. It is a strategy aimed at the spread of knowledge in the midst of a specific professional universe with the unique and exclusive features of federal judges. The magistrates emphasized the relevance of the content and agreed with the effectiveness of this strategy to deepen knowledge. Most reported that the visits increased their understanding of the concepts of evidence-based medicine and health policies adopted in Brazil. Consequently, the potential of this strategy presents itself as an element of opportunity for the production of informed decisions in relation to the technical criteria that involve the sanitary regulation exercised by the state.

One of the unique features of academic detailing is the dialogue that always takes place during visits. This allows the exchange of knowledge, mainly listening directly to the professionals, in our study, the magistrates. Returning this information to political formulators and public managers is important for the improvement of their actions in the field of health services. When listening to magistrates, we observed that they tend to make decisions in the sense of preserving medical authority and providing medicines with public funds, even when in opposition to the regulatory activity of the state. Thus, as evidence-based medicine has become an ideology, the judiciary has implemented a way of voluntarily promoting some compliance. In this way, these professionals try to avoid criticism as they try to adhere to using scientific health evidence in their decisions in an area considered, in the past, exclusive to health professionals.



*The Journal of Law, Medicine & Ethics*, 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press

## References


1. F. C. J. Stevens and J. van der Zee, "Health System Organization Models (Including Targets and Goals for Health Systems)," *International Encyclopedia of Public Health* (London: Elsevier, 2008): 247–256, doi.org/10.1016/B978-012373960-5.00309-9.
2. A. L. Chieffi, R. D. C. B. Barradas, and M. Golbaum, "Legal Access to Medications: A Threat to Brazil's Public Health System?" *BMC Health Services Research* 17 (2017): 499, doi.org/10.1186/s12913-017-2430-x; J. de O. Costa, C. C. Almeida-Brasil, B. Godman, M. A. Fischer, J. Dartnell, A. Heaney, C. G. B. dos Santos, F. de A. Acurcio, J. Álvares, and A. A. Guerra, "Implementation of Clinical Guidelines in Brazil: Should Academic Detailing be Used?" *Journal of Pharmaceutical Health Services Research* 7 (2016): 105–115, doi.org/10.1111/jphs.12133.
3. A. Massuda, T. Hone, F. A. G. Leles, M. C. de Castro, and R. Atun, "The Brazilian Health System at Crossroads: Progress, Crisis and Resilience," *BMJ Global Health* 3 (2018) e000829, doi.org/10.1136/bmjgh-2018-000829.
4. F. R. de S. Machado, "Contribuições ao Debate da Judicialização da Saúde no Brasil," *Revista de Direito Sanitário* 9 (2008): 73, doi.org/10.11606/issn.2316-9044.v9i2p73-91; M. A. de Á. Machado, F. de A. Acurcio, C. M. R. Brandão, D. R. Faleiros, A. A. Guerra Jr, M. L. Cherchiglia, and E. I. G. Andrade, "Judicialização do Acesso a Medicamentos no Estado de Minas Gerais, Brasil," *Revista de Saúde Pública* 45 (2011): 590–598, doi.org/10.1590/S0034-89102011005000015.
5. M. Ventura, L. Simas, V. L. E. Pepe, and F. R. Schramm, "Judicialização da Saúde, Acesso à Justiça e a Efetividade do Direito à Saúde," *Physis: Revista de Saúde Coletiva* 20 (2010): 77–100, doi.org/10.1590/S0103-73312010000100006; R. N. Sant'Ana, "A Judicialização Como Instrumento de Acesso à saúde: Propostas de Enfrentamento da Injustiça na Saúde Pública (2017).
6. L. Senier, R. Lee, and L. Nicoll, "The Strategic Defense of Physician Autonomy: State Public Health Agencies as Countervailing Powers," *Social Science & Medicine* 186 (2017): 113–121, doi.org/10.1016/j.socscimed.2017.06.007.
7. See Machado, *supra* note 4; See Ventura, *supra* note 5; See Sant'Ana, *supra* note 5; See Senier, *supra* note 6; E. I. G. Andrade, C. D. Machado, D. R. Faleiros, D. A. C. Szuster, A. A. G. Júnior, G. D. da Silva, M. L. Cherchiglia, and F. de A. Acúrcio, "A Judicialização da Saúde e a Política Nacional de Assistência Farmacêutica no Brasil: Gestão da Clínica e Medicalização da Justiça," 18 (n.d.) 46–50.
8. Conselho Nacional de Justiça – CNJ, Relatório Anual do Conselho Nacional de Justiça 2016. (2016).
9. See Machado, *supra* note 4.
10. See *supra* note 8.
11. Superior Tribunal de Justiça – STJ, Repetitivos e IACs. (n.d.).
12. M. A. Fischer and J. Avorn, "Academic Detailing Can Play a Key Role in Assessing and Implementing Comparative Effectiveness Research Findings," *Health Affairs* 31 (2012): 2206–2212, doi.org/10.1377/hlthaff.2012.0817; J. Avorn, "Academic Detailing: "Marketing" the Best Evidence to Clinicians," *JAMA* 317 (2017): 361, doi.org/10.1001/jama.2016.16036.
13. M. C. Borin, Avaliação de Viabilidade de Técnicas de Visitação Médica Para Detalhamento Acadêmico na Artrite Reumatoide, (2018); CCATES – Centro Colaborador do SUS Avaliação de Tecnologias e Excelência em Saúde, Diretriz – Detalhamento Acadêmico. (2015).
14. See CCATES, *supra* note 13.
15. S. B. Soumerai and J. Avorn, "Economic and Policy Analysis of University-based Drug "Detailing" *Medical Care* 24 (1986): 313–331, doi.org/10.1097/00005650-198604000-00003.
16. M. A. O'Brien, S. Rogers, G. Jamtvedt, A. Oxman, J. Odgaard-Jensen, D. T. Kristoffersen, L. Forsetlund, D. Bainbridge, N. Freemantle, D. Davis, R. B. Haynes, and E. Harvey, "Educational Outreach Visits: Effects on Professional Practice and Health Care Outcomes," *Cochrane Database of Systematic Reviews* (2007), doi.org/10.1002/14651858.CD000409.pub2.
17. See CCATES, *supra* note 13.
18. L. A. Goodman, "Snowball Sampling," *The Annals of Mathematical Statistics* 32 (1961): 148–170.
19. See Costa, *supra* note 2.
20. See Fischer, *supra* note 12; See Avorn, *supra* note 12; H. Brax, R. Fadlallah, L. Al-Khaled, L. A. Kahale, H. Nas, F. El-Jardali, and E. A. Akl, "Association Between Physicians' Interaction with Pharmaceutical Companies and Their Clinical Practices: A Systematic Review and Meta-Analysis," *PLOS ONE* 12 (2017): e0175493, doi.org/10.1371/journal.pone.0175493.
21. Conselho Nacional de Justiça – CNJ, Perfil Sociodemográfico dos Magistrados Brasileiros 2018 (2018).
22. M. H. Smart, M. R. Mandava, T. A. Lee, and A. S. Pickard, "Feasibility and Acceptability of Virtual Academic Detailing on Opioid Prescribing," *International Journal of Medical Informatics* 147 (2021): 104365, doi.org/10.1016/j.ijmedinf.2020.104365.
23. See Machado, *supra* note 4; Superior Tribunal Federal – STF, Acórdão Recurso Extraordinário 657.718/MG. Relator: MELLO, Marco Aurélio Mendes de Farias. Publicado no DJ de 30/06/2017 (2017); I. D. Catanheide, E. S. Lisboa, and L. E. P. F. de Souza, "Características da Judicialização do Acesso a Medicamentos no Brasil: Uma Revisão Sistemática," *Physis: Revista de Saúde Coletiva* 26 (2016): 1335–1356, doi.org/10.1590/s0103-73312016000400014.
24. Uso Off Label: Erro ou Necessidade? *Revista de Saúde Pública* 46 (2012): 395–397, doi.org/10.1590/S0034-89102012000200026.
25. See Senier, *supra* note 6.
26. Conselho Nacional de Justiça – CNJ, Resolução Nº 238 de 06/09/2016 (2016).
27. J. A. Trostle, "Medical Compliance as An Ideology," *Social Science & Medicine* 27 (1988): 1299–1308, doi.org/10.1016/0277-9536(88)90194-3.
28. See Senier, *supra* note 6.
29. See Senier, *supra* note 6.
30. Conselho Nacional de Justiça – CNJ, "Judicialização da Saúde no Brasil: Perfil das Demandas, Causas e Propostas de Solução," (2019); I. R. Zimmermann, E. F. de Oliveira, Á. T. Vidal, V. C. C. Santos, and C. A. Petramale, "A Qualidade das Evidências e as Recomendações Sobre a Incorporação de Medicamentos no Sistema Único de Saúde: Uma Análise Retrospectiva," *Revista Eletronica Gestão & Saúde* 6 (2015): 3043, doi.org/10.18673/gs.v6i4.22099.
31. H. Groth and M. Hodin, "How the EU Fails Patients Trying to Access Critical Medicines View," *Euronews* (2019), *available at* <https://www.euronews.com/2019/04/09/how-the-eu-fails-patients-trying-to-access-critical-medicines-view> (last visited November 29, 2022).
32. WHO – Europe, *Access to New Medicines in Europe: Technical Review of Policy Initiatives and Opportunities for Collaboration and Research* (2015).
33. A. Dunn, B. Whitmire, A. Batch, L. Fernando, and L. Rittmueller, "High Spending Growth Rates for Key Diseases In 2000–14 Were Driven by Technology and Demographic Factors," *Health Affairs* 37 (2018): 915–924, doi.org/10.1377/hlthaff.2017.1688.
34. M. C. Borin, A. M. Kakehasi, J. Dartnell, N. Gomes Ribeiro Junior, F. de A. Acurcio, A. A. Guerra Junior, and J. Alvares-Teodoro, "Academic Detailing Program for Rheumatoid Arthritis: A Contribution to Brazilian Public Health System Sustainability," *Journal of Pharmaceutical Health Services Research* 11 (2020): 249–254, doi.org/10.1111/jphs.12365.
35. See Conselho Nacional de Justiça – CNJ, *supra* note 30.




*The Journal of Law, Medicine & Ethics,* 50 (2022): 807-817. © 2023 The Author(s)

https://doi.org/10.1017/jme.2023.22 Published online by Cambridge University Press