ISSN: **2764-4006** | www.revistacientificaipedss.com

RELATIONSHIP BETWEEN SUS DOCTORS AND THE PHARMACEUTICAL INDUSTRY: ETHICS, TRANSPARENCY, AND INSTITUTIONAL RESPONSIBILITY IN THE CONTEXT OF RARE DISEASES

Relationship Between Public Healthcare Physicians and the Pharmaceutical Industry: Ethics, Transparency, and Institutional Responsibility in the Context of Rare Diseases

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Date of publi cation: January 30, 2026
DOI: doi.org/10.55703/27644006060104

ABSTRACT

The relationship between doctors of the Unified Health System (SUS) and the pharmaceutical industry raises important ethical questions, especially in the context of rare diseases, characterized by high-cost therapies and a scarcity of therapeutic alternatives. This study aims to analyze the conflicts of interest, ethical challenges, and institutional transparency mechanisms involved in this relationship, in light of Brazilian and international regulations. It is a qualitative study, of a documentary and normative nature, based on the analysis of legislation, ethical resolutions, public health policies, and scientific literature. The results indicate that, although there are regulatory instruments aimed at preventing conflicts of interest, gaps still persist in the oversight and transparency of interactions between health professionals and the pharmaceutical industry. It concludes that strengthening control mechanisms, combined with ongoing ethical education, is essential to ensure the integrity of clinical decisions, patient safety, and equity in access to treatments for rare diseases within the SUS.

Keywords: Medical ethics; Conflict of interest; Rare diseases; Unified Health System; Pharmaceutical industry.

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INTRODUCTION

The interaction between doctors of the Unified Health System (SUS) and the pharmaceutical industry is a sensitive topic of great relevance to medical ethics, especially in the context of rare diseases. These illnesses, characterized by low prevalence and high therapeutic cost, often require innovative medications, many of which are still in the early stages of incorporation into the public health system.

The influence of the pharmaceutical industry on medical prescriptions, clinical guidelines, and public policies can generate conflicts of interest that affect professional autonomy, patient safety, and the sustainability of SUS. In this context, it becomes essential to analyze the ethical limits of these relationships, as well as the mechanisms of transparency and institutional accountability adopted in Brazil.

This study aims to discuss the impacts of the doctor-industry relationship in the treatment of rare diseases, considering the Brazilian regulatory framework and international experiences, especially regarding the control of conflicts of interest and the protection of patients' rights.

METHODOLOGY

This is a qualitative study, of a documentary and normative nature, based on the analysis of legislation, ethical resolutions, institutional documents, and scientific literature related to medical ethics, conflicts of interest, the pharmaceutical industry, and rare diseases.

Documents such as o the Medical Ethics Code, resolutions from the Federal Council of Medicine (CFM), norms from the National Health Surveillance Agency (ANVISA), guidelines from the SUS, as well as international legislation, such as the Sunshine Act, were analyzed. The analysis was conducted through an interpretative approach, seeking to identify principles ethical, institutional responsibilities, and impacts on clinical practice.

NORMATIVE FRAMEWORK AND REGULATION OF CONFLICTS OF INTEREST IN HEALTH

Brazilian Normative Framework On conflicts of interest

The relationship between doctors in the Unified Health System (SUS) and the pharmaceutical industry is regulated by a set of ethical and legal norms aimed at ensuring transparency, professional integrity, and the protection of public interest. Among the main normative instruments are the Medical Ethics Code, the resolutions of the Federal Council of Medicine (CFM), federal legislation on conflicts of interest, and the guidelines of the National Health Surveillance Agency (ANVISA).

Despite the existence of this regulatory framework, it is observed, in scientific events and educational activities, that the obligation to declare conflicts of interest is often fulfilled in a merely formal manner. In many cases, speakers present slides with references to the current norms, such as ANVISA Resolution No. 96/2008, CFM Resolution No. 1,595/2000, and the Medical Ethics Code, but with unreadable text, insufficient time, and lack of contextualization for the audience.

This practice undermines the ethical and pedagogical purpose of conflict of interest declarations, which aim to ensure transparency, preserve the critical autonomy of the audience, and mitigate possible commercial influences on scientific content. By reducing this procedure to a mere protocol act, a relevant opportunity to strengthen ethical education and consolidate a professional culture based on responsibility, integrity, and the protection of patient interests is lost.

This scenario is especially relevant for young doctors, residents, and professionals in training who work in the SUS, for whom transparency should not be understood as an accessory detail, but as an essential component of the principles of beneficence, non-maleficence, justice, and autonomy, which are fundamental pillars of medical practice and social trust in science.

The Brazilian regulatory framework has progressively evolved in this field. The Medical Ethics Code (Resolution

CFM No. 2,217/2018 establishes that the patient's interest must prevail over economic, corporate, or institutional interests. In 2024, CFM Resolution No. 2,386 expanded the transparency requirements in the relationships between doctors and companies in the health sector, bringing o Brazil closer to international models of ethical regulation.

Sunshine Act and International Transparency

In the international context, the Physician Payments Sunshine Act stands out, approved in the United States in 2010 and operationalized from 2014. This legislation requires pharmaceutical companies and medical device manufacturers to publicly declare all payments, benefits, and transfers of value granted to physicians and teaching hospitals.

The information is consolidated in the Open Payments Database, managed by the Centers for Medicare & Medicaid Services (CMS), allowing public access and social control. The goal is not to criminalize the relationship between doctors and industry, but to recognize its potential ethical risk and establish mechanisms for active transparency, making these interactions visible, auditable, and socially trustworthy.

Evidence indicates that the Sunshine Act has increased the visibility of financial relationships in the health sector, strengthened more responsible practices, and contributed to the increase of public trust in clinical and scientific decisions.

Brazil and the United States: regulatory approaches and differences

In Brazil, there is no specific federal law equivalent to the Sunshine Act. The regulation of conflicts of interest is fragmented and distributed among different instruments, such as the Medical Ethics Code, CFM Resolution No. 2,386/2024, Federal Law No. 12,813/2013, ANVISA regulations, and internal ethics and integrity policies of the EBSERH Network.

The Brazilian approach is predominantly ethical-normative, focusing on individual and institutional responsibility, with transparency being heavily dependent on self-regulation and professional requirements.

In the United States, on the other hand, there is specific and systematic federal legislation. The obligation to register falls on companies, not on physicians. The law covers direct and indirect payments, including fees, travel, educational funding, research, royalties, and financial participation.

Information is public, auditable, and inserted into a policy of a preventive, educational, and non-punitive nature.

ANVISA and the Regulatory Health Perspective

The National Health Surveillance Agency has specific regulations aimed at preventing and managing conflicts of interest among its public agents, based on current federal legislation. The Code of Ethics for ANVISA Employees reinforces principles such as integrity, transparency, and defense of the public interest.

Although these guidelines are primarily directed at institutional action, they directly engage with the assistance field by highlighting that health decisions must be protected from commercial interference, especially in contexts of high technological and therapeutic complexity, as occurs in rare diseases.

EBSERH Network, HC-UFU, and Institutional Responsibility

The EBSERH Network has a Code of Ethics and Conduct that establishes commitments to integrity, administrative probity, transparency, and defense of the public interest. In the context of the Hospital de Clínicas da Universidade Federal de Uberlândia (HCUFU/EBSERH), consolidating as a Reference Service for Rare Diseases (SRDR), this dimension assumes expanded relevance.

The vulnerability of patients, the use of extremely high-cost therapies, and the pressures from care, legal, and market forces make the ethical management of conflicts of interest not only a normative requirement but also an institutional and moral duty.

DISCUSSION

Conflict of Interest as an Ethical Risk

The conflict of interest should not be confused with dishonesty. It is a situation of ethical risk that requires recognition, declaration, and proper management. The relationship between industry, science, and care can be legitimate when guided by clear ethical criteria, institutional oversight, and an unequivocal commitment to the public interest.

In the context of rare diseases, where there is a scarcity of therapeutic alternatives and

The high cost of treatments makes the risk of undue influence even more sensitive. The protection of medical autonomy and patient safety depends on effective mechanisms of transparency and regulation.

Transparency and Social Trust

In the contemporary scenario of the SUS, it is not enough for decisions to be technically correct; they need to be understandable, auditable, and socially trustworthy. Transparency protects the physician, strengthens institutions, qualifies public policies, and preserves society's trust in science and medical practice.

The adoption of more robust mechanisms for disclosing conflicts of interest, combined with ongoing ethical education, represents an essential path to strengthen the integrity of the health system and ensure that patient care remains at the center of clinical and institutional decisions.

CONCLUSION

Proper management of conflicts of interest does not threaten medicine; on the contrary, it ethically and institutionally strengthens it. Active transparency, professional responsibility, and public commitment reaffirm the mission of the SUS: to protect life, human dignity, and the collective interest. In strategic services such as the SRDR, this is not only a normative requirement but constitutes an ethical-moral obligation.

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