

## The ethical limits of physicians' autonomy and the Brazilian Federal Council of Medicine

Os limites éticos da autonomia dos médicos e o Conselho Federal de Medicina do Brasil

Los límites éticos de la autonomía de los médicos y el Consejo Federal de Medicina de Brasil

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Recently, two facts brought to the spotlight the limits of physicians' autonomy to prescribe medicines and the Brazilian Federal Council of Medicine (CFM). The first fact was a conflict between the CFM and the Brazilian Health Regulatory Agency (Anvisa) regarding the agency's decision to remove amphetamine weight-loss medicines from the market <sup>1</sup>. The second was the widespread prescription of ineffective and potentially harmful medicines during the COVID-19 pandemic. In both cases, CFM stated that professional autonomy – a central tenet of medical practice – ensures physicians the right to prescribe whatever they think is the most beneficial therapy for their patients.

When the results of the Sibutramine Cardiovascular Outcomes (SCOUT) study emerged in 2010, suggesting that the cardiovascular risks of sibutramine outweighed its potential benefits in the treatment of obesity and overweight, the agency's Technical Chamber of Medicines (CATEME) recommended Anvisa to withdraw it as well as three other amphetamine-like anorectics from the market <sup>1</sup>. CATEME's recommendation was debated with CFM and other stakeholders and, in 2011, the Anvisa's board of directors decided to ban three anorectics (fenproporex, mazindol, and diethylpropion) and keep sibutramine on the market under stricter control rules for dispensation. Despite the agency's reasonable decision, CFM and some medical associations continued to pursue the goal of bringing the three amphetamine medicines back to the drugstores shelves. In 2017, a strong advocacy campaign promoted by CFM and some medical associations for the return of amphetamine-like anorectics succeeded when the Brazilian National Congress, overlapping Anvisa's regulatory jurisdiction over the pharmaceutical market, approved a law (*Federal Law n. 13,454/2017*) that authorized the production, sale, and consumption of these drugs. In October 2021, however, the Brazilian Supreme Federal Court (STF) considered the amphetamine anorectics law unconstitutional, bringing the regulatory affairs back on track.

The CFM campaign reiterated many times that, by removing amphetamine-like drugs from the market, the Anvisa would be jeopardizing physicians' professional autonomy to prescribe the drugs they think are the most suitable to meet their patients' clinical needs. The news posted on the CFM website as well as a letter from CFM president to the congressman Rodrigo Maia, then President-in-Office of the Chamber of Deputies, showed their point of view. The letter emphasized that the provisions of the amphetamine anorectics bill to be enacted "*respect the autonomy of physicians and patients to choose recognized and valid therapeutic procedures*" and that Anvisa's decision to prohibit them "*would represent a direct interference with this process*" <sup>2</sup>.

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This argument is fallacious because medical practice regulation and control of the pharmaceutical market are distinct regulatory areas that do not overlap. Ensuring that only drugs with proven effectiveness, safety, and pharmaceutical quality enter and stay on the Brazilian pharmaceutical market is Anvisa's legal duty (*Laws n. 6,360/1976 and n. 9,782/1999*). The agency duties also encompass approval of therapeutic indications and recommended dose regimens listed on the product label, which must be supported by the best evidence from clinical trials, and how products should be dispensed in commercial drugstores or hospital pharmacies. On the other hand, CFM and regional councils are those responsible for regulating the practice of medicine and overseeing if it complies with the current code of medical ethics (*Decree-Law n. 7,955/1945 and Law n. 3,268/1957*).

The strict respect of physicians' autonomy arose as the justification presented by CFM for refraining from acting when a large-scale prescription of ineffective and potentially harmful drugs for COVID-19 took place in the country during the last two years.

On April 16, 2020, CFM issued a technical report making clear that the physicians who prescribe drug therapies with no proven efficacy and safety for COVID-19 will not be punished: "...the physician who uses chloroquine or hydroxychloroquine, under the conditions aforementioned, in COVID-19 patients will not commit an ethical violation" <sup>3</sup>.

In April 2020, only a few weeks after the World Health Organization (WHO) declared that the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outbreak had become a pandemic (on March 11, 2020), there was no vaccine and no antiviral agent with proven clinical efficacy to prevent and/or to treat this viral infection. In this context, the use of the antimalarial 4-aminoquinolines to treat SARS-CoV-2 infection outside of clinical trials could be considered acceptable as it was shown that this drug inhibited viral proliferation in in vitro assays with different cell lines <sup>4</sup>. In July 2020, the mistaken findings of a small, non-randomized, and uncontrolled (single-arm) clinical trial by Gautret et al. <sup>5</sup> may have also misled physicians to prescribe chloroquine/hydroxychloroquine for prophylaxis and/or treatment of COVID-19.

Still in 2020, however, results of well-designed randomized controlled trials (RCTs) and observational studies arose, and the scientific knowledge of this hypothetical usefulness of chloroquine or hydroxychloroquine – often prescribed in association with azithromycin – advanced substantially and evolved from "unproven clinical effectiveness" to "proven ineffectiveness and potential harmfulness" for COVID-19 patients <sup>6,7,8,9,10,11</sup>. Prescription of antibiotics (e.g., azithromycin) for the treatment of non-bacterial infections, such as respiratory viral infections, is a typical example of nonrational use of medication <sup>12</sup>. In this specific case, robust clinical trials and large observational studies showed that chloroquine or hydroxychloroquine – whether as monotherapy or combined with azithromycin – not only were ineffective but also increased mortality of COVID-19 patients (due to their additive pro-arrhythmogenic effects), particularly when chloroquine or hydroxychloroquine were combined with azithromycin <sup>7,8,9,10,11</sup>.

On January 25, 2021, despite the overwhelming evidence of ineffectiveness and potential harmfulness of chloroquine/hydroxychloroquine and azithromycin, the president of the CFM reassured that the council would not change its position of respecting the "physicians' absolute autonomy" to treat their COVID-19 patients with these drugs, and also the patients' autonomy to decide themselves if they accept this prescription or not <sup>13</sup>.

The respect for patients' autonomy is one of the four guiding principles of healthcare and medical research ethics outlined by Tom Beauchamp & James Childress in their treatise on the *Principles of Bio-medical Ethics* <sup>14</sup>. According to Beauchamp & Childress's theory of bioethics, the four principles, namely: respect for autonomy, nonmaleficence, beneficence, and justice, are non-hierarchical principles, and thus they must be equally considered. In other words, when facing a particular case, physicians must balance the demands by these principles to determine which principle carries more weight <sup>14</sup>. Although Principlism is commonly accepted and used, some bioethics scholars discuss the use of it to solve ethical issues in clinical medicine.

Respecting the patient's autonomy to decide to take part in clinical research and/or in selecting the therapy in healthcare interventions is a physicians' prima facie duty. Moreover, avoiding harm and providing a medical benefit to their patients is also physicians' prima facie duty. Although it is far less explored and discussed, physicians' autonomy cannot be considered "absolute" because, as aforementioned, it must be balanced with the four guiding principles of medical ethics.

Obtaining patients' informed consent from is required when the pharmacotherapy is experimental, i.e., efficacy and safety are presumed but not proved yet, and it is given in the context of the clinical study or administered in the medical practice outside of a clinical trial. Informed consent is also required in non-experimental therapies involving health risks, that is, the efficacy has been proven but the therapy presents significant health risks. To obtain a valid consent, physicians should disclose to their patients all relevant information about the therapy effectiveness and safety in an understandable way, and ensure that patients have understood it <sup>15</sup>. Informed consent is primarily intended to protect the patient, and not the physician. If it contains the relevant and updated information in a plain language and is fully understood by the patient, the consent is valid, thus protecting the physician. In healthcare interventions, informed consent should reflect a shared decision-making between physician and patient that complies with the patient's reasonable wishes. However, it is unthinkable to ask for and to obtain informed consent for a therapy with several evidence from clinical trials and observational studies showing that it is ineffective and harmful for COVID-19 patients. In any case, if eventually obtained, the consent would not be valid because the only plausible explanation for obtaining such unreasonable consent would be that the physicians were not aware of the best evidence available, or that they have conflicts of interest and purposely biased the information provided to their patients.

Another limitation of physicians' autonomy is that physicians are committed to act according to their patients' best interests and must observe the combined beneficence/nonmaleficence ethical principles <sup>16</sup>. In other words, physicians must comply with the Hippocratic aphorism found in *Epidemics*: "As to diseases, make a habit of two things – to help [to do good] or at least, to do no harm" <sup>17</sup> (p. 2026). Medical autonomy does not entitle physicians to prescribe ineffective and potentially harmful drugs to their patients. In the most recent version of the Brazilian Code of Medical Ethics <sup>18</sup>, the beneficence/nonmaleficence principle of medical practice is implicit in Chapter II: "The physician has the right to: (...) II - Indicate the appropriate procedure for the patient, observing the scientifically recognized practices (...)"; and in Chapter III: "The physician is forbidden: Article 1. To cause harm to patients, capable of being characterized as malpractice, lack of prudence, or negligence". Prescription of proven ineffective and harmful therapies for COVID-19 is, thus, against the notion of beneficence/nonmaleficence and against the Brazilian Code of Medical Ethics.

CFM was created by *Decree-Law n. 7,955/1945* and became a federal autarchy in 1957 (*Law n. 3,268/1957*). The main legal attributions of CFM are to update the *Brazilian Code of Medical Ethics* and to act in accordance with the regional councils of medicine to oversee the enforcement of professional ethics, to investigate and to judge violations of medical ethics, and to apply penalties.

The advocacy for continue marketing dangerous drugs with questionable effectiveness to treat obesity and overweight overstepped the limits of the legal competence of CFM. On the other hand, stating that prescribing chloroquine/hydroxychloroquine for COVID-19 should not be considered a violation of medical ethics is to give a *carte-blanc* to a large-scale nonrational use of medicines that were proven to be ineffective and harmful. If CFM had timely warned physicians that the notion of medical autonomy does not support the prescription of ineffective and harmful medicines, and that prescribers and disseminators of the so-called chloroquine "early" therapy for COVID-19 violate medical ethics, the organization would have avoided a huge suffering and many deaths in this pandemic. Due to its serious public health consequences, the CFM mismanagement during the pandemic was itself a tragedy within a larger national tragedy with over 650,000 casualties.

## Additional informations

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## References

1. Paumgartten FJR. The return of amphetamine-like anorectics: a backward step in the practice of evidence-based medicine in Brazil. *Cad Saúde Pública* 2017; 33:e00124817.
2. Conselho Federal de Medicina. Ofício CFM nº 4770/2017 – GABIN. [https://portal.cfm.org.br/images/PDF/oficio\\_anorexigenos.pdf](https://portal.cfm.org.br/images/PDF/oficio_anorexigenos.pdf) (accessed on May/2022).
3. Conselho Federal de Medicina. Parecer CFM nº 04/2020. <https://sistemas.cfm.org.br/normas/visualizar/pareceres/BR/2020/4> (accessed on May/2022).
4. Paumgartten FJR, Delgado IF, Pitta LR, Oliveira ACAX. Chloroquine and hydroxychloroquine repositioning in times of COVID-19 pandemics, all that glitters is not gold. *Cad Saúde Pública* 2020; 36:e00088520.
5. Gautret P, Lagier JC, Parola P, Hoang VT, Meddeb L, Mailhe M, et al. Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial. *Int J Antimicrob Agents* 2020; 56:105949.
6. Gérard A, Romani S, Fresse A, Viard D, Parasol N, Granvullemin A, et al. “Off-label” use of hydroxychloroquine, azithromycin, lopinavir-ritonavir and chloroquine in COVID-19: a survey of cardiac adverse drug reactions by the French Network of Pharmacovigilance Centers. *Therapie* 2020; 75:371-9.
7. Nguyen LS, Dolladille C, Drici MD, Fenioux C, Alexandre J, Mira JP, et al. Cardiovascular toxicities associated with hydroxychloroquine and azithromycin: an analysis of the World Health Organization Pharmacovigilance Database. *Circulation* 2020; 142:303-5.
8. Rosenberg ES, Dufort EM, Udo T, Wilberschied LA, Kumar J, Tesoriero J, et al. Association of treatment with hydroxychloroquine or azithromycin with in-hospital mortality in patients with COVID-19 in New York State. *JAMA* 2020; 323:2493-502.
9. Skipper CP, Pastick KA, Engen NW, Bangdiwala AS, Abassi M, Lofgren SM, et al. Hydroxychloroquine in nonhospitalized adults with early COVID-19: a randomized trial. *Ann Intern Med* 2020; 173:623-31.
10. Fiolet T, Guihur A, Rebeaud ME, Mulot M, Peiffer-Smadja N, Mahamat-Saleh Y. Effect of hydroxychloroquine with or without azithromycin on the mortality of coronavirus disease 2019 (COVID-19) patients: a systematic review and meta-analysis. *Clin Microbiol Infect* 2021; 27:19-27.
11. Axfors C, Schmitt AM, Janiaud P, Van't Hooft J, Abd-Elsalam S, Abdo EF, et al. Mortality outcomes with hydroxychloroquine and chloroquine in COVID-19 from an international collaborative meta-analysis of randomized trials. *Nat Commun* 2021; 12:2349.
12. World Health Organization. Promoting rational use of medicines: core components. Geneva: World Health Organization; 2002. (WHO Policy Perspectives on Medicines, 5).
13. Ribeiro MLB. O Conselho Federal de Medicina e a Covid-19. *Folha de S.Paulo* 2021; 24 jan. <https://www1.folha.uol.com.br/opiniaao/2021/01/o-conselho-federal-de-medicina-e-a-covid-19.shtml>.
14. Beauchamp TL, Childress JF. Principles of biomedical ethics. 8th Ed. New York: Oxford University Press; 2019.
15. Murray B. Informed consent: what must a physician disclose to a patient? *Virtual Mentor* 2012; 14:563-6.
16. Varkey B. Principles of clinical ethics and their application to practice. *Med Princ Pract* 2021; 30:17-28.
17. Markel H. “I swear by Apollo”: on taking the Hippocratic oath. *N Engl J Med* 2004; 350:2026-9.
18. Conselho Federal de Medicina. Código de Ética Médica: Resolução CFM nº 2.217, de 27 de setembro de 2018, modificada pelas Resoluções CFM nº 2.222/2018 e 2.226/2019. <https://portal.cfm.org.br/images/PDF/cem2019.pdf> (accessed on May/2022).

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