Proposed Constitutional Amendment (PEC) No. 10 of 2022: Manifestation of the Scientific Department of Inborn Errors of Immunity of the Brazilian Association of Allergy and Immunology (ASBAI)

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The Brazilian Association of Allergy and Immunology (ASBAI) is composed of medical specialists in Allergy and Clinical Immunology responsible for the diagnosis and care of patients with primary immunodeficiency disorders (PIDs), more recently referred to as inborn errors of immunity. The most common PIDs, according to global experience, are those affecting antibody production. In these cases, the main clinical manifestations are infections, which can range from mild and recurrent to severe, requiring hospitalization for intravenous treatment. These infections can result in pulmonary, auditory, and other sequelae and may even lead to death in many situations.

The primary treatment for these patients is immunoglobulin (Ig), obtained through the collection of human plasma from many donors. For decades, patients, as well as the medical specialists who care for them, have suffered from periodic Ig shortages in Brazil and the dire consequences associated with it. Despite numerous proposals, we remain dependent on the importation of these products, as Brazil does not produce a single drop of Ig.

In recent years, particularly during the pandemic, when Ig became increasingly difficult to acquire, the Brazilian Ministry of Health began procuring products that were not approved by the Brazilian Health Regulatory Agency (ANVISA), arguing that Fiocruz's National Institute of Quality Control could perform the same type of safety and efficacy analysis as ANVISA. Despite the pandemic being under control and the resumption of plasma collection and Ig production in other countries, the Brazilian Ministry of Health maintained this stance. ASBAI, as well as patient associations, expressed opposition to this decision, as this flow could clearly compromise the quality and safety of treatment for patients using Ig. Unfortunately, the arguments presented by the parties responsible for product use and the patients themselves were NOT considered.

Indeed, it is of paramount importance that Hemobrás produces Ig in Brazil and that we stop being completely dependent on imported products. This is expected to happen by the end of 2025, according to information provided by the Federal Government. However, we estimate that production, while welcome, will most likely not meet the demand for Ig, which has been growing worldwide.

Plasmapheresis represents a significant advancement in the collection of plasma, from which many products necessary for the well-being of thousands, perhaps millions, of Brazilian citizens are obtained. It is important to note that although our focus has been on antibody deficiency, patients with neurological, rheumatologic, hematological, and other diseases also require and use human Ig. Additionally, various derivatives such as albumin, coagulation factors, and complement proteins, which are essential for the treatment of various diseases, are obtained from human plasma.

The European community, concerned with ensuring the supply of Ig for a growing number of patients, is revising its legislation. A populous country with continental dimensions like Brazil should do the same. We also share concerns regarding the commercialization of plasma, which is precisely why we believe that the legislation should be reviewed, improved, and meticulously drafted to respect the principles of the 1988 Constitution of Brazil while ensuring that our patients are respected and receive adequate care. We would like to note that our health care model, the Brazilian Unified Health System, is a source of pride and, at this moment, we must demonstrate our ability to provide adequate treatment for our Brazilian patients and citizens.

ASBAI – Scientific Department of Inborn Errors of Immunity

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