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Latin America Healthcare Compliance Certification Program

Judicialization of Health in Brazil

Industry Interaction with Patient Organizations

JUDICIALIZATION OF HEALTH

GENESIS

THE FEDERAL CONSTITUTION

- **Article 6.**

  Education, **health**, food, work, housing, leisure, security, social security, protection of motherhood and childhood, and assistance to the destitute **are social rights**, as set forth by this Constitution.

- **Article 196.**

  Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.

GENESIS

- **When the Constitution says that :**

  "health is a social right and that it is a right of all and a duty of the State"

Is it referring to collective rights or individual rights?

- Could the principle of "Reservation as Possible" to limit the payment of contingencies be applied to these cases?

  - Should claims be limited by what an individual may reasonably request from society?

JUDICIALIZATION MAY INVOLVE PRODUCTS THAT ARE NOT INCLUDED IN THE GOVERNMENT LIST AND, ALSO, PRODUCTS THAT ARE NOT EVEN REGISTERED BEFORE THE REGULATORY AGENCY.

IS IT POSSIBLE TO IMPORT PHARMACEUTICAL PRODUCTS THAT ARE NOT REGISTERED AT ANVISA?

LEGAL FRAMEWORK

LAW 6360/76

Art. 10. The importation of drugs, active ingredients and other products regulated by this law for industrial and commercial purposes is prohibited, without the previous express authorization from the Ministry of Health.

DECREE 08.077/13

Art. 10. The importation of products subject to sanitary surveillance is subject to previous opinion of ANVISA that will define, in a specific regulation the technical requirements to be followed.

§ 2o The importation, by individuals, of the products regulated by this decree and not subject to special control regimen, in quantities sufficient for individual use, does not require previous authorization provided they are not destined to resale or commerce, and provided applicable ANVISA regulations are observed.

MAIN BASIS FOR LOWER COURT DECISIONS

- "**The lack of inclusion of drugs in pre-approved lists shall not be an obstacle for it being supplied** by any for the members of the federation. It is a right of all and a duty of the State."

- **"Health is a right of the people and obligation of the State..."**

- **"It's a legal and constitutional duty of the government to supply the necessary drugs to ensure life and health for all."**

PREVIOUS INTERPRETATION OF THE SUPERIOR COURT

"The fact that the drug is not registered means it cannot be commercialized and so, the plaintiff's right is not unquestionable and cannot be discussed by means of a Writ of Mandamus." (Appeal. RMS 35434PR2011/0192002-0 - STJ) **(judicialization is not for internal commercialization)**

"The government cannot allege that the drug is not included in the list of essential drugs. Until further evidence the drug prescribed is the one better suited for the plaintiff's condition. Similar decisions have been awarded by this Court."- The lack of registration at ANVISA does not hinder the supply of the drug when it is demonstrated efficacy in the control of the disease. AgRg in Ag 1329352 (2010/0122439-0 - STJ)

NEW DECISION OF THE SUPERIOR COURT

REsp 1.657.156 (April 25, 2018)

The court decided that the supply of drugs by the government will depend on the following cumulative requirements:

- **1 –** Medical report, signed by the patient's doctor, clearly demonstrating that the prescribed drug is necessary and that the drugs already available are not effective;
- **2 -** That the patient does not have the financial resources to pay for the drug prescribed;
- **3 –** That the drug is duly registered before the Regulatory Agency (Anvisa).

This is a judgment of a "repetitive appeal" meaning it will affect all similar cases. However, the court has modulated the effected to say that this decision would not affect the cases that were stayed waiting for the judgment of this appeal.

DECISION OF THE SUPERIOR COURT

REsp 1.657.156 (April 25, 2018)

Basis for the decision:

1- the drug requested is not registered at ANVISA, and its importation would be a violation of article 273, paragraph 1B – I of the Brazilian Penal Code. (pg.52 and 54 – Voto Vista)

2- The SUS cannot pay/reimburse drugs not authorized by ANVISA,

Counter Arguments?

DECISION OF THE SUPERIOR COURT

REsp 1.657.156 (April 25, 2018)

Counter Arguments:

1- Violation of the penal code:

The code expressly says that ANVISA approval is only required “if applicable” and the fact is that, since these imports are made on a patient name basis, they do not require approval, as set forth in paragraph 2 or article 10 of Decree 8.077/2013.

2- The SUS cannot pay/reimburse drugs not authorized by ANVISA,

This means that individuals that cannot pay for their own treatment would not be able to receive the same treatment as those who can and this would somewhat “dent” article 196 of the constitution that expressly mentions that everyone should have the right to universal and equal access .

JUDGMENT AT THE SUPREME COURT

("General Repercussion")

1. **Justice Marco Aurélio Melo**

   Government must supply if patient (and family) have no means. If not registered in Brazil must be registered in another country

2. **Justice Edson Fachim**

   If not in the government list must demonstrate the treatment is the only alternative. If not registered only due to delay in the registration or denial in registration is unlawful.

3. **Justice Luís Roberto Barroso**

   Government must supply if patient (and family) have no means. If not registered only due to delay in the registration .

Judgment Suspended since September 2016 (Justice Teory Zavascki)

"ADVERSE EFFECTS"

JUDICIALIZATION OF HEALTH

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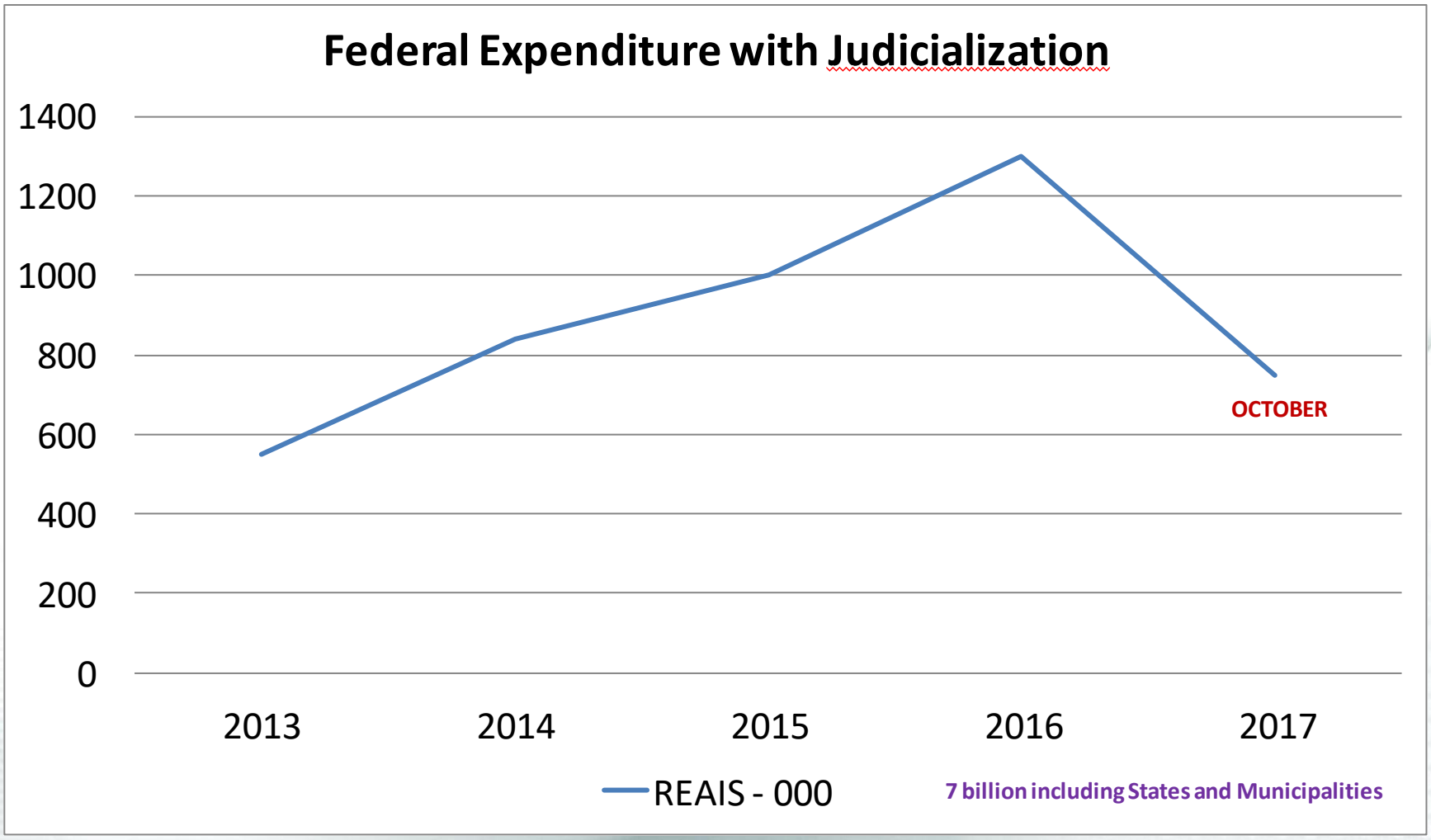

Source – SUS - MoH

1- Different Spheres in the Government Started Investigating the Issue

- Federal and State Prosecutors' offices started to investigate lawyers representing plaintiffs in judicialization cases, as there were lawyers individually representing a large number of patients in different states;

- Investigations also included possible relationship of lawyers with patient organizations and the relationship between patient organizations and the pharmaceutical industry; (QUESTION FOR DISCUSSION) 

- The Federal Police and Federal and State Public Attorney's Offices have started a series of investigations having as their main target prescribing physicians.

- The S-CODE System:

  The State Attorney's Office for the State of São Paulo, created the S-CODE SYSTEM, now being licensed to other states and to the Federal Government. The System compiles data related to health judicialization proceedings and allow fast research on: Plaintiffs, diseases, products, source of product, doctor's issuing medical support reports, plaintiffs' lawyers, etc.

2- The Investigations led to:

- **2011** – Criminal procedures on prescription high cost drugs for Psoriasis. Involvement of NGO, doctors and reps. The State of São Paulo is also seeking indemnification of R$ 100M or US$45.5M (US$1 = R$ 2,3). (Serono/Mantecorp/Wyeth/and others)

  In 2016 Criminal Court convicted 90% of the individuals involved (Doctors, Lawyers and Reps)

- **2015/2016** – Criminal Investigation on prescription high cost drugs for hypercholesterolemia. Involvement of NGO, doctors and reps. (Aegerion)

- **2017** – Criminal Investigation on prescription high cost drugs for Rare Circulatory Disease. Involvement of NGO, doctors and reps. (Alexion)

3- The Public Bid Feud:

The high amounts involved in the purchase of high cost drugs to comply with judicial decisions has called the attention of "birds of prey".

- "Independent" distributors started bidding to supply products they do not have.
- The are offering prices that are just below those of authorized distributors and getting paid in advance by the Ministry of Health.
- They do not have the authorization from registration holders to import the product.
- Some do not have Operating Licenses from **ANVISA.**
- **ANVISA** was denying the license to import.
- After a court order to issue the import license, **ANVISA** published several notes stating that it would not be responsible for the quality and/or the efficacy of the drugs.
- Manufacturers informed the courts and the Ministry of Health that they would not be responsible for the quality and/or the efficacy of the drugs.

PATIENT ORGANIZATIONS INVOLVED IN POLICE INVESTIGATIONS IN BRAZIL

- **Associação Nacional de Doenças Raras e Crônicas - ANDORA**.
  Hypercholesterolemia – Interaction with Aegerion;

- **Associação dos Familiares e Amigos de Portadores de Doenças Graves - AFAG**.
  Paroxysmal nocturnal hemoglobinuria – Interaction with Alexion;

- **Associação do Portadores de Vitiligo e Psoríases no Estado de São Paulo - APVPESP**.
  Psoriasis – Interaction with Merck-Serono/Wyeth/Mantecorp;

Industry Interactions With Patient Organizations

PATIENT ORGANIZATIONS

- Where they come from.
- What they are.
- Snapshot.
- Relationship with Pharmaceutical Industry: **(IFPMA, EFPIA, PhARMA, INTERFARMA, CAEME)**
- Case for Discussion.

GENESIS

- Patient Organizations appeared, in the beginning of the 20th century, as a result of the shortage of resources for public health and the increase of the "number" of chronic diseases.
- After World War II, communities started taking increased interest in the health sector.
- Real growth in their number came from the perception of patients of some diseases that they were being isolated and stigmatized.
- In the area of genetic diseases Patient Organizations direct a lot of effort to pressure governments and health plans to supply drugs, as these types of drugs are, as a general rule very expensive.

PATIENT ORGANIZATIONS SNAPSHOT

- Mostly related to Rare Diseases or High Cost Treatment.
- A considerable number has been started and are managed by family members of people affected by a rare disease. **(emotional involvement)**
- Low degree of professionalism. Very small management structure.
- Although some “collective” effort exists, this is rare.
- Lack of compliance guidelines and/or codes of conduct.
- Funding is always a difficult task, especially in times of crisis.
- Very little knowledge of public policies and lobby practices.

INTERACTION DRIVERS

- Organizations have difficulties in funding and in finding even ad-hoc sponsors;
- Industry has difficulties in finding patients for clinical trials and in getting co-payment/reimbursement status for their products;

Interaction Basic General Rules

(IFPMA – PhRMA – EFPIA – INTERFARMA – CAEME)

- Interactions must be ethical and respect the independence of the organizations.
- The nature of that involvement must be clear from the outset.
- Financial support must be documented and inform the nature of support.
- There can be no promotion of prescription drugs.
- Support if primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization.
- Organizations cannot depend on contribution of one sponsor.

CASE FOR DISCUSSION

Industry Interactions With Patient Organizations

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- A company organizes a two-day event in Miami to discuss challenges to improve the diagnosis of a rare disease.
- For the meeting the company will invite one doctor (KOL) and senior directors of patient organizations from different LATAM countries.
- One of the directors is on vacation in New York with his wife and asks the company to pay the air fare (for both) from NYC to MIA and back.
- Would you authorize it?

Industry Interactions With Patient Organizations

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- What if the director is an individual that has special needs and cannot travel alone?

INTERACTION IN A NUTSHELL

- Nature of interaction must be absolutely clear;
- Components of interaction should be documented. If financial or economic, MUST be documented;
- Independence of parties must be respected.
- Essentially scientific and/or educational;
- No product promotion and no “quid-pro-quo”;
- No sole sponsoring of entity;
- In Europe disclosure of organizations and nature/value of support.

- **Perception is Reality or: “Caesar’s Wife”**

THANK YOU

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- The pharmaceutical company , you work for, wants to openly fund patient organizations to supply legal counseling for suing the government requesting payment for treatment.

- Would that be legal in your country?

- If yes, would you agree with the intention?