A. LOPES MUNIZ
Advogados Associados

Latin America Healthcare Compliance Certification Program

Judicialization of Health

(and Other Hot Topics)

THE DEVIL LIES IN THE DETAILS

ONE HOT TOPIC

INCLUSION OF DRUGS IN GOVERNMENT FORMULARY

INCLUSION OF HIGH COST DRUGS FOR RARE DISEASES IN GOVERNMENT FORMULARY

- Definition of Rare Disease: Condition affecting 65 individuals in 100,000.
- Present Regulation on Rare Diseases – Ordinance GM-MS 199/2014 – does not provide for the supplying of drugs.
- Bill of Law 1.606/2011 approved in the House still pending approval in the Senate
- Today inclusion in Government list depends on the budge what generates judicialization.

LIST OF DRUGS AVAILABLE IN THE SUS
(Integrated Health System)

- The National Commission for the Adoption of Technologies by the System (CONITEC) was created only in 2011 by Law 12.401*. This Commission decides on what items - including new drugs - will be covered by SUS.

- The System issues a list (since its creation) of the products that are available for free supply to patients.

- The updates of the list, until 2010 were rare. Now they are more frequent but high cost/high complexity drugs still take a long time to be added.

- Between 2016 and 2017, in average:
  - 50% of private suggestions were added
  - 85% of government (public) suggestions were added
  - 08% of other (medical associations…) suggestions were added

* Before that a department in the Ministry of Health was responsible but very little changed for many years.

JUDICIALIZATION

THE POLITICAL ENVIRONMENT AROUND THE CONSTITUTION OF 1988

&

THE COST OF RIGHTS

(or: the perception that rights are free)

"Our Constitution is a blend of a dictionary of utopias and the meticulous regulation of the ephemeral."

Roberto Campos

(250 articles; 111 transitional provisions; and 105 amendments)

LEGAL FRAMEWORK

FEDERAL CONSTITUTION (The Genesis of the Good, the Bad and the Ugly)*

- **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.

*Oxford comma dropped on purpose

JUDICIALIZATION MAY INVOLVE PRODUCTS THAT ARE REGISTERED AND PRODUCTS THAT ARE NOT 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."**

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) **(this is not what the law says)**

(In May/2017 – Resp 1657.156- Court Suspended ongoing Proceedings but allows examination of new injunctions by lower courts)

"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)

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 Barrosos**

   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)

ACTIONS OF THE GOVERNMENT

Different Spheres in the Government Started Investigating the Issue

- **One of the indicators of such a concern, is stated in an interview given by the State of São Paulo General Attorney:**

  "... multinational laboratories which are trying to register the drug in Brazil ... and start to foster the access to the drug via judicial injunctions to force the registration. There is also the question of the interest of such multinationals in selling very expensive drug to replace existing similar drugs with almost the same efficacy."

- **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 idea is to create pressure and stress to reduce prescriptions.

- **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.**

NATIONAL JUSTICE CONCIL (CNJ)

RECOMMENDATION 31, March 30, 2010

Recommends that the States' Courts of Appeals and Federal Circuits' Courts of Appeal:

- avoid authorizing the supply of drugs not yet registered at ANVISA, or still in clinical trials except in the cases provided for in the law.

- verify with the National Council of Ethics in Clinical Trials (CONEP), whether the plaintiffs are subjects in clinical trials in which case the sponsors must be responsible for the continuation of the treatment.

NATIONAL JUSTICE CONCIL (CNJ)

RECOMMENDATION 43, August 20, 2013

Recommends that the States' Courts of Appeals and Federal Circuits' Courts of Appeal:

- foster the specialization of Courts to process and judge cases which object is the right to public health.

- give orientation to the competent Courts so that they prioritize the judgment of cases related to supplementary health. (private health plans)

CHANGE IN CLINICAL TRIAL REGULATIONS:

RESOLUTION CNS – 466/2013 – Section III.3 (d)

Clinical trials sponsors must:

Assure to all trial subjects, for as long as they need, free access to the best prophylactic, diagnostic, and therapeutic methods that have demonstrated to be efficacious:

This access shall also be guaranteed during the interval between the end of the participation of each subject in the study and the end of the study, through the proper extension study procedure.

PHARMACEUTICAL INDUSTRY ASSOCIATION

(Research Based)

- **Section 2.1 Companies and adherents do not defend or accept judicialization as a positive policy for** public health in Brazil. They understand that it is, rather, a consequence of the public system's gaps and problems. Therefore, they must contribute to structural solutions that help the population have effective access and oppose any undue recurrences to Justice. In this sense, companies and adherents must meet the criteria set out in this Section.

- **Section 2.2 Companies and adherents in their relationship with Healthcare professionals, Healthcare related** professionals, patients and patient associations, **are prohibited from any actions, whether direct or indirect, that promote or encourage patients to prosecute lawsuits seeking access to treatment and therapies.**

WHAT ABOUT PRIVATE HEALTH PLANS?

- Courts would generally rule in favor of the patient;
- Superior Court of Justice seems to be changing its understanding;
- Change is based on the plan contracts that exclude the supply of non-registered drugs;
- This may foster the increase in lawsuits filed against the government

ANOTHER HOT TOPIC

TRANSFERENCE OF PRODUCT REGISTRATION

TRANSFERENCE OF REGISTRATION

- Until 2001 ANVISA allowed the transference of product registration from the holder to other third parties with no other requirements.

- In December 2001 ANVISA decide to allow the transference only as a result of mergers, acquisitions or spin-offs.

All other "transferences" were made by the kafkanian procedure of: **(i)** cancelling the old registration, and **(ii)** filing for a whole new registration.

TRANSFERENCE OF REGISTRATION

- In August 2016 ANVISA, in an effort to correct the situation, issued a new Resolution allowing the transference in case of commercial operations of SALES of assets. **(RDC 102/2016)**
- The RDC defines "commercial operation" as those that result in the sale of assets, or group of assets, not linked to an M&A operation.
- The new Resolution ignored that a considerable number of transferences of registration result from licensing operations.
- So, we may need to go back to Kafka.

A. LOPES MUNIZ
Advogados Associados
DESDE 1975

mfl@almlaw.com.br
www.almlaw.com.br
Av. Brigadeiro Faria Lima, 1656 – 5º andar
Telefone (phone) 55-11-3038-0723

MILESTONE CASES

- **2011** – Criminal Investigation 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)

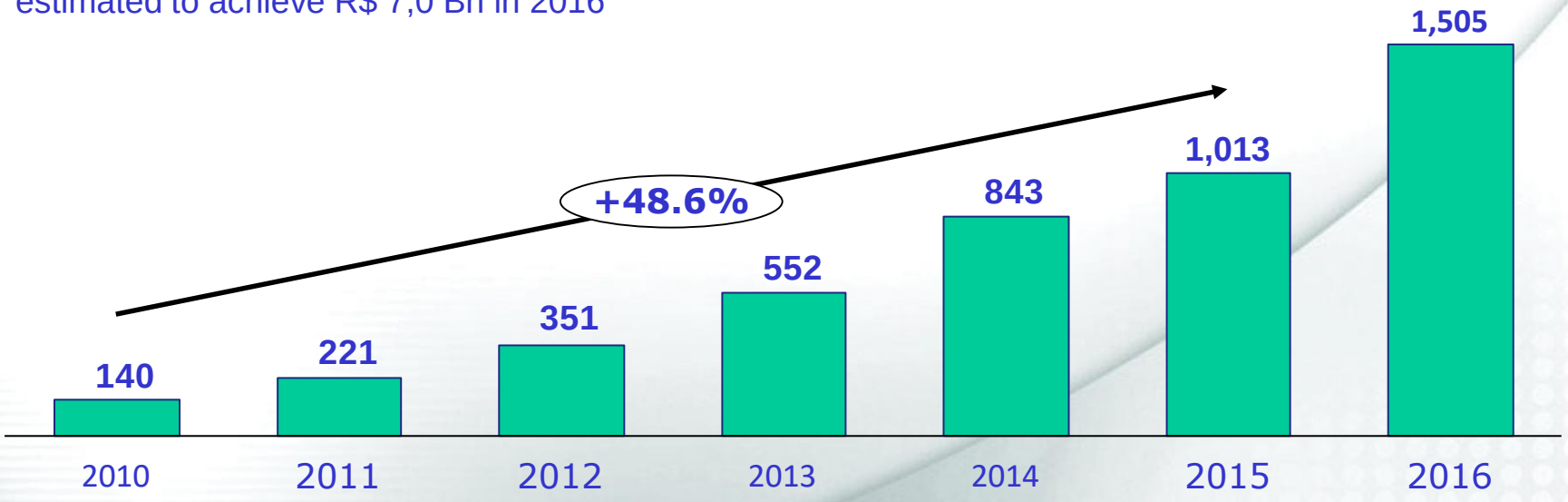
- **2017** – Criminal Investigation on prescription high cost drugs for Rare Circulatory Disease. Involvement of NGO, doctors and reps. (Alexion)

BACK-UP

Federal expenditure with judicialization grew 49% between 2010 and 2015

Ministry of Health[1] expenses to attend court decisions (R$, in millions)

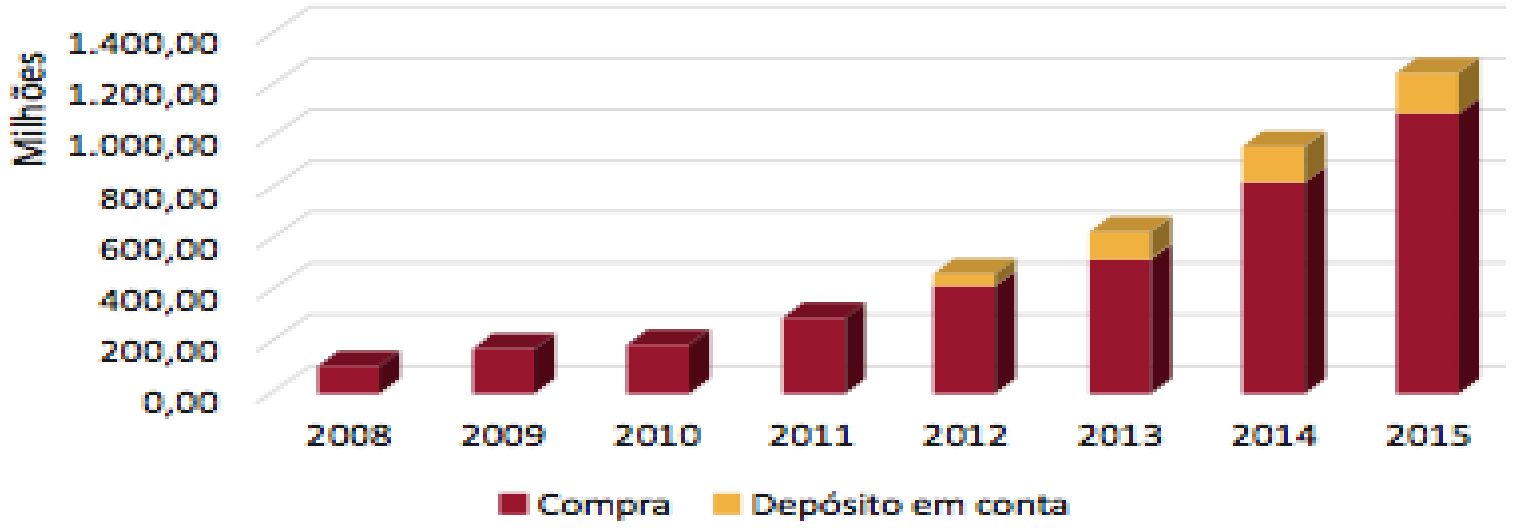
- **The amount is even higher,** since it refers only to actions brought against Federal Government and most demands are against states or municipalities
- Considering federal, states and municipalities, total legal actions is estimated to achieve R$ 7,0 Bn in 2016



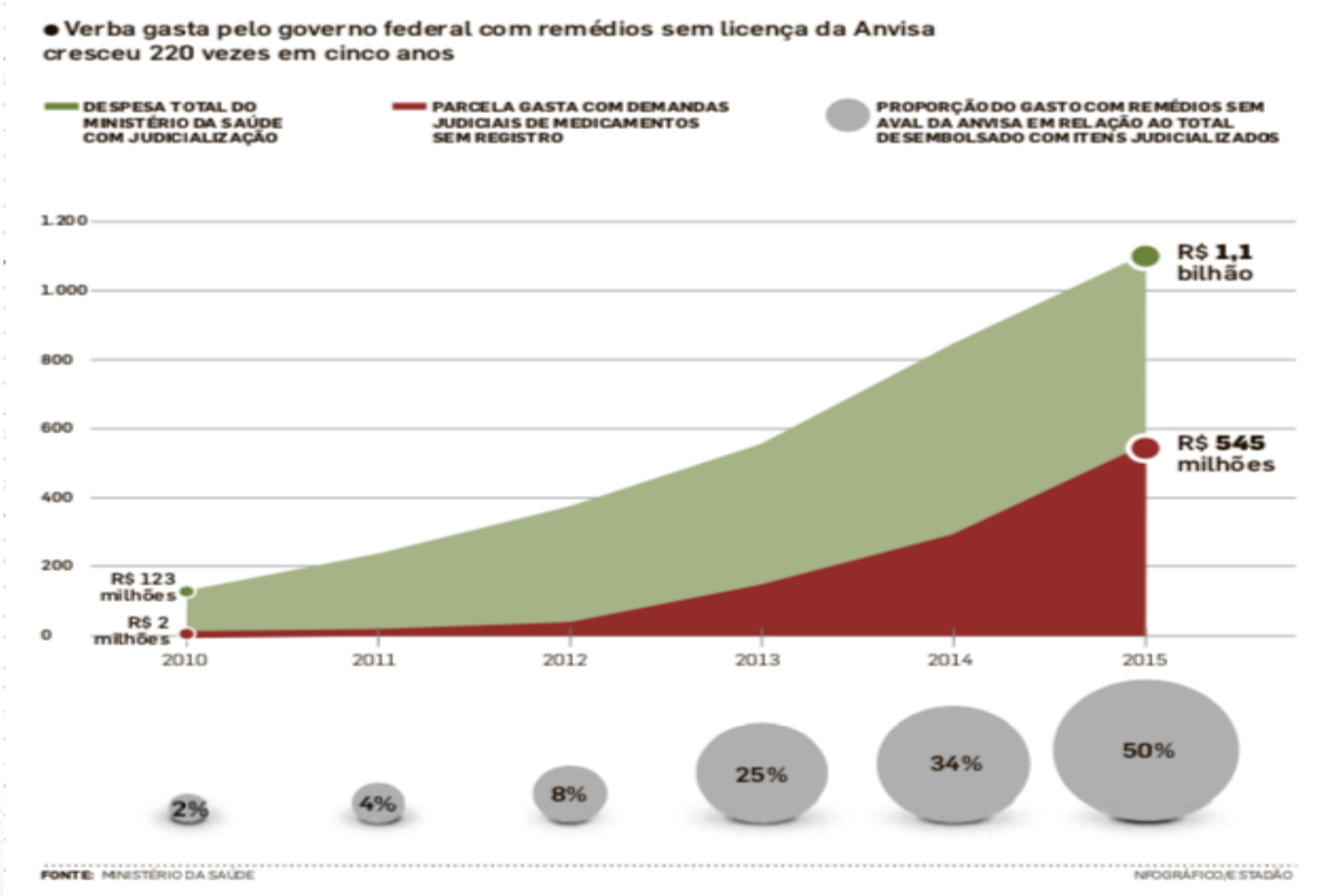
Source: Gazeta do Povo Journal and Ministry of Health
[1] Considers only Federal expenses
Includes: drugs, treatments, surgeries and equipments judicially secured

A. LOPES MUNIZ
Advogados Associados

Gráfico 20: Orçamento de Medicamentos do Ministério da Saúde – Despesas totais com demandas judiciais, de 2008 a 2015



Fonte: SCTIE e FNS.
Elaboração própria.
* Valores atualizados pelo IPCA com valores de março de 2016.


Verba gasta pelo governo federal com remédios sem licença da Anvisa cresceu 220 vezes em cinco anos
DESPESA TOTAL DO MINISTÉRIO DA SAÚDE COM JUDICIALIZAÇÃO
PARCELA GASTA COM DEMANDAS JUDICIAIS DE MEDICAMENTOS SEM REGISTRO
PROPORÇÃO DO GASTO COM REMÉDIOS SEM AVAL DA ANVISA EM RELAÇÃO AO TOTAL DESEMBOLSADO COM ITENS JUDICIALIZADOS
1.200
1.000
800
600
400
200
0
R$ 1,1 bilhão
R$ 545 milhões
R$ 123 milhões
R$ 2 milhões
2010
2011
2012
2013
2014
2015
2%
4%
8%
25%
34%
50%
FONTE: MINISTÉRIO DA SAÚDE
INFOGRÁFICO/ESTADÃO

NUMBER OF LAWSUITS FILED IN 2016

- São Paulo – 28,000
- Rio Grande do Sul – 28,000
- Rio de Janeiro – 15,000
- Minas Gerais – 8,000

JUDICIALIZATION OF HEALTH

A. LOPES MUNIZ
Advogados Associados

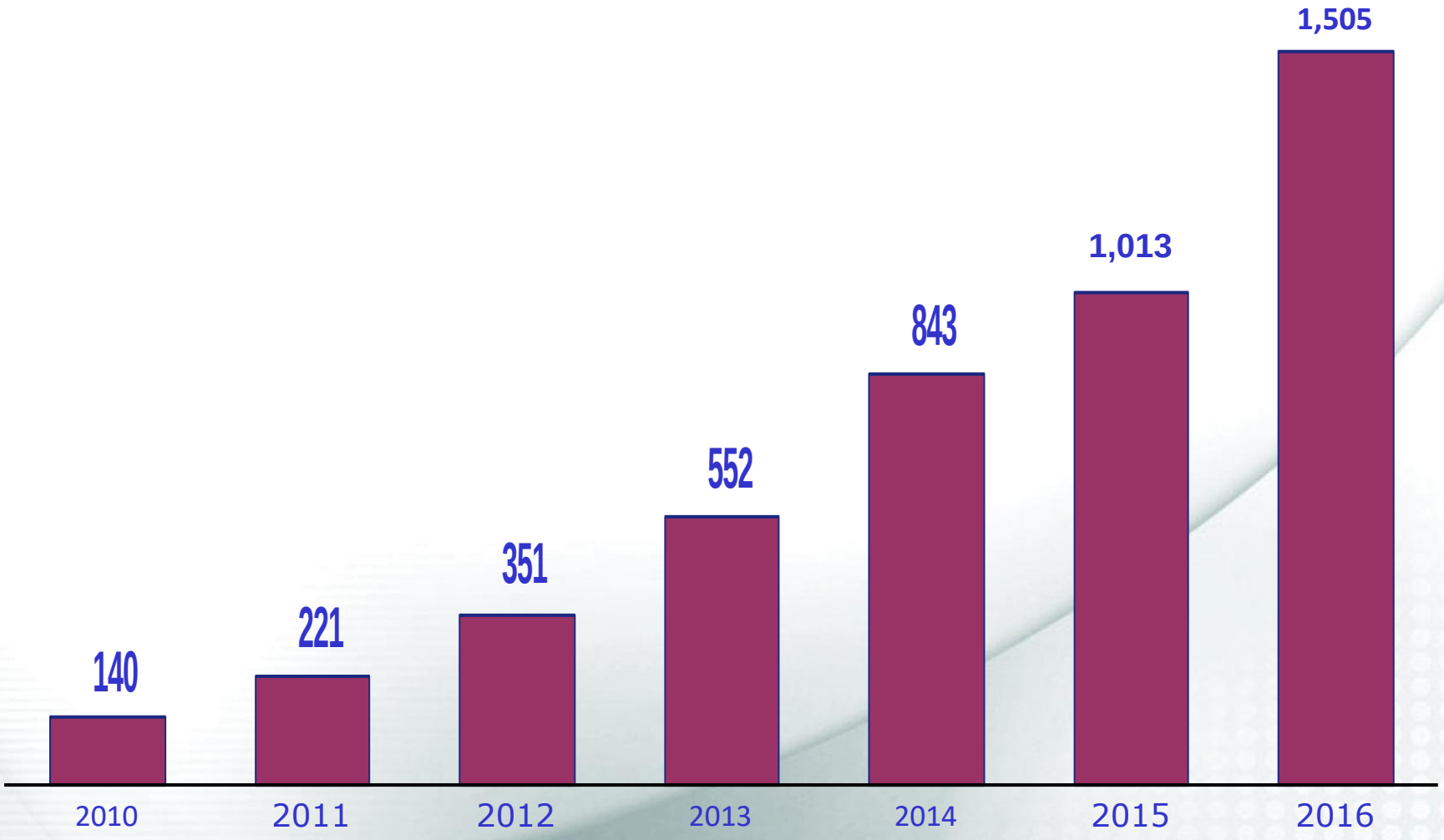
However

Decisions of CONITEC signal that the Commission is somewhat biased. CONITEC seems to work favoring the incorporation of technologies that are requested by the Ministry of Health and "ignoring" requests made by the industry and/or other sectors of the Government. (According to the law CONATEC must decide in 180 + 90 days)

Source of Request	Number	Incorporated	Not Incorporated	Under Examination
Industry	101	11	30	60
Ministry of Health	96	35	3	58
Government Other	11	1	6	4
Medical Societies / NGO	13	0	1	12
Other	6	0	0	6

Source – Interfarma - 2015

Federal Government Spending
Judicialization - 2010 and 2016



Amounts in Reais - Millions

GENERAL INTERPRETATION OF THE COURTS

- "The Federal Government, the States and the Municipalities have the obligation for the promotion, prevention and recovery of health. **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 (Public Power) to promote the actions necessary to implement the right to health." (Civil Appeal – 70051801585 – Court of Appeals –RS on 12/12/2012)

- "As per the terms of article 196 of the Constitution, it is an obligation of the State (Union, States and Municipalities) to assure access to health to people that do not have sufficient financial resources: "health is a right of the people and obligation of the State..." (Interim Appeal – 38106 RS 2009.04.00.038106-0 – Federal Court of Appeals - fourth circuit - 01/26/2011)

- "Supply of imported drug not registered at ANVISA for treatment of grave disease Myelodisplasitc Syndrome. Right to life. Legal and constitutional duty of the government to supply the necessary drugs to ensure life and health for all. Understanding of articles 5, 196 and 198 of the Constitution." (Interim Appeal – 132515-82.2012.8.26.0000 – Court of Appeals – SP)

- Sexta-feira, 24 de fevereiro de 2017 **Mantida decisão que determina fornecimento de medicamento a portadora de doença rara no Acre**
- A presidente do Supremo Tribunal Federal (STF), ministra Cármen Lúcia, manteve a decisão que determinou o fornecimento, pelo Estado do Acre, do medicamento Soliris (eculizumab) a uma portadora da Síndrome Hemolítico Urémico Atípica (SHUa), doença rara caracterizada por uma anemia hemolítica crônica, causada provavelmente por uma mutação genética das células-tronco da medula óssea.
- A ministra indeferiu o pedido de Suspensão de Liminar (SL 1053) feito pelo estado, que pretendia suspender os efeitos da decisão sob o argumento de que tal obrigação causaria grave lesão aos cofres públicos, já que cada frasco do medicamento, produzido por um laboratório francês, custa em torno de R$ 11 mil. A decisão do Tribunal de Justiça do Acre determina o fornecimento de 54 frascos, ao custo de R$ 594 mil.
- No pedido ao STF, o Estado do Acre alegou não ser razoável exigir-se que o poder público arque com tamanho gasto para fornecer um medicamento que sequer possui comprovação científica nem registro na Agência Nacional de Vigilância Sanitária (Anvisa). Outro argumento foi o alto custo do remédio, destacando que uma pretensão individual não pode se sobrepor às normas que tutelam as políticas públicas de fornecimento de medicamentos.
- De acordo com os autos, o Soliris é o único medicamento para o tratamento da enfermidade e seu uso é medida de imperativa necessidade, sob pena de perda irreparável da função renal e, em última análise, de morte. O medicamento é aprovado por agências sanitárias da Europa e dos Estados Unidos.
- **Decisão**
- Em sua decisão, a ministra Cármen Lúcia afirma que pedidos de suspensão de decisões pelos quais se reconhece o dever de fornecimento desse remédio, prescrito para o tratamento da Síndrome Hemolítico Urémico Atípica e da enfermidade denominada Hemoglobinúria Paroxística Noturna pelos entes federados, não são novos no STF, e citou inúmeros precedentes nos quais a obrigação foi mantida pelo Tribunal.
- Segundo a ministra, para demonstrar a existência de grave lesão à ordem econômica, o Estado do Acre apresentou dados referentes ao orçamento de 2016, apontando déficit que lhe impediria de dar cumprimento à ordem judicial impugnada. Mas não juntou aos autos comprovação de não ter condições financeiras no exercício de 2017 de se organizar para cumprir a decisão relativa ao fornecimento do medicamento.
- A ministra afirmou que não se pode desconsiderar a medida cautelar na Ação Direta de Inconstitucionalidade (ADI) 5501, em que o STF suspendeu a eficácia da lei que autoriza o uso da chamada pílula do câncer, nem as questões relativas ao fornecimento de medicamento não registrado na Anvisa (Recurso Extraordinário – RE 657718) e de alto custo (RE 566471), ambas ainda pendentes de julgamento de mérito. Essas hipóteses, explicou a ministra, poderiam justificar a suspensão da decisão impugnada, porém “a negativa de tratamento à interessada configura dano inverso que pode levar a óbito”.