COMMITTEE ON STRONGER FOOD AND DRUG REGULATORY SYSTEMS ABROAD

Session 2.

RAISING THE PROMINENCE OF REGULATORY SYSTEMS

Regulatory Systems and Public Health

National Academy of Sciences, Washington DC. April 3rd 2019

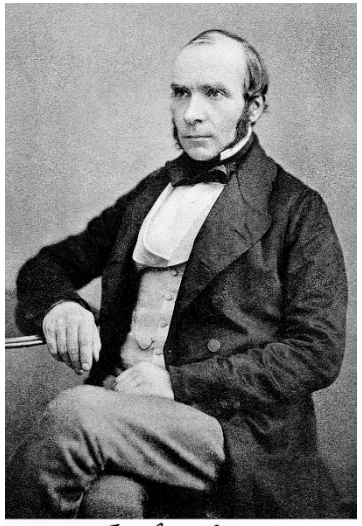
Carlos Santos-Burgoa, MD, MPH, PhD
Professor, Global Health
Milken Institute School of Public Health
The George Washington University

16 effective slides

OUTLINE

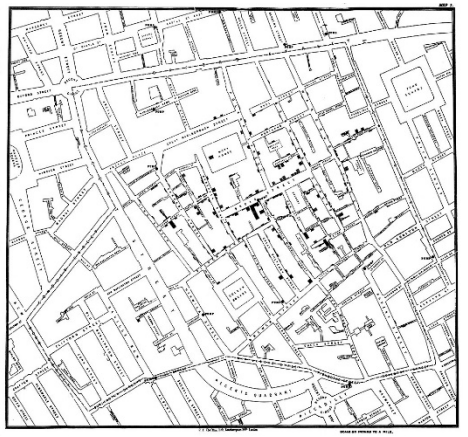
- Regulation as a Public Health Function
- The turnaround on Public Health Regulatory Institutional Capacity
    - Specific emphasis on financing health regulatory institutions
- The future for development

Risk identification and protection: Public Health Regulatory Authority and IMPACT



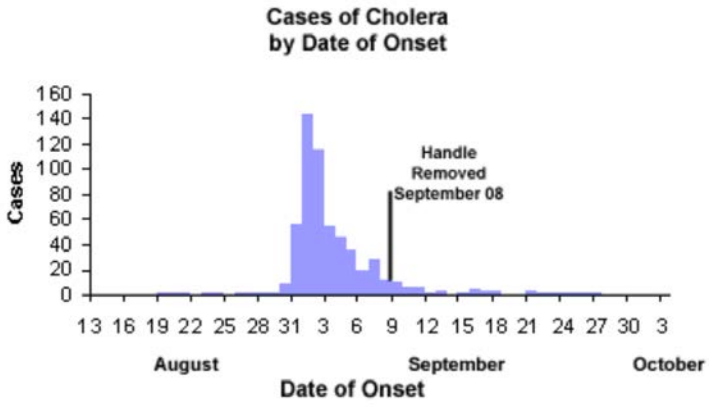
https://commons.wikimedia.org/w/index.php?curid=403227

1854 Soho, London, Cholera epidemic

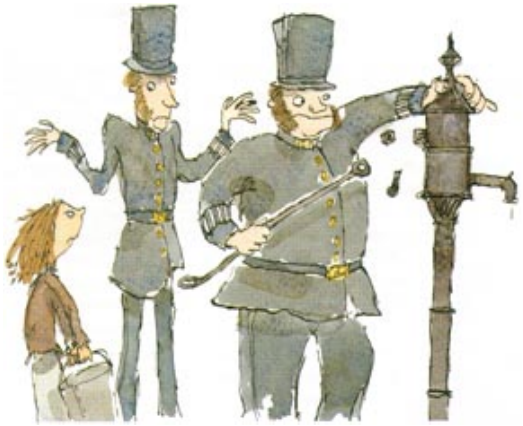


EVIDENCE

Broad Street Pump



IMPACT



Source: *Cricket* 31(3), pp. 23-31, Nov. 2003

HEALTH AUTHORITY

POLICY DEBATE AND DECISION

REGULATION: AN ESSENTIAL PUBLIC HEALTH FUNCTION

Essential public health functions, CDC, CLAISS and PAHO (Americas Region, 2001)

1. Health situation monitoring and analysis
2. Surveillance, research and control of the risks and threats to public health
3. Health promotion
4. Social participation in health
5. Development of policies and institutional capacity for public health planning and management
6. Strengthening of public health regulation and enforcement capacity
7. Evaluation and promotion of equitable access to necessary health services
8. Human resources development and training in public health
9. Quality assurance in personal and population-based health services
10. Research in public health
11. Reduction of the impact of emergencies and disasters on health

Seventeen versions of classifications identified by WHO

6. Strengthening of public health regulation and enforcement capacity

https://apps.who.int/iris/handle/10665/272597

REGULATION: AN ESSENTIAL PUBLIC HEALTH FUNCTION

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https://apps.who.int/iris/handle/10665/272597

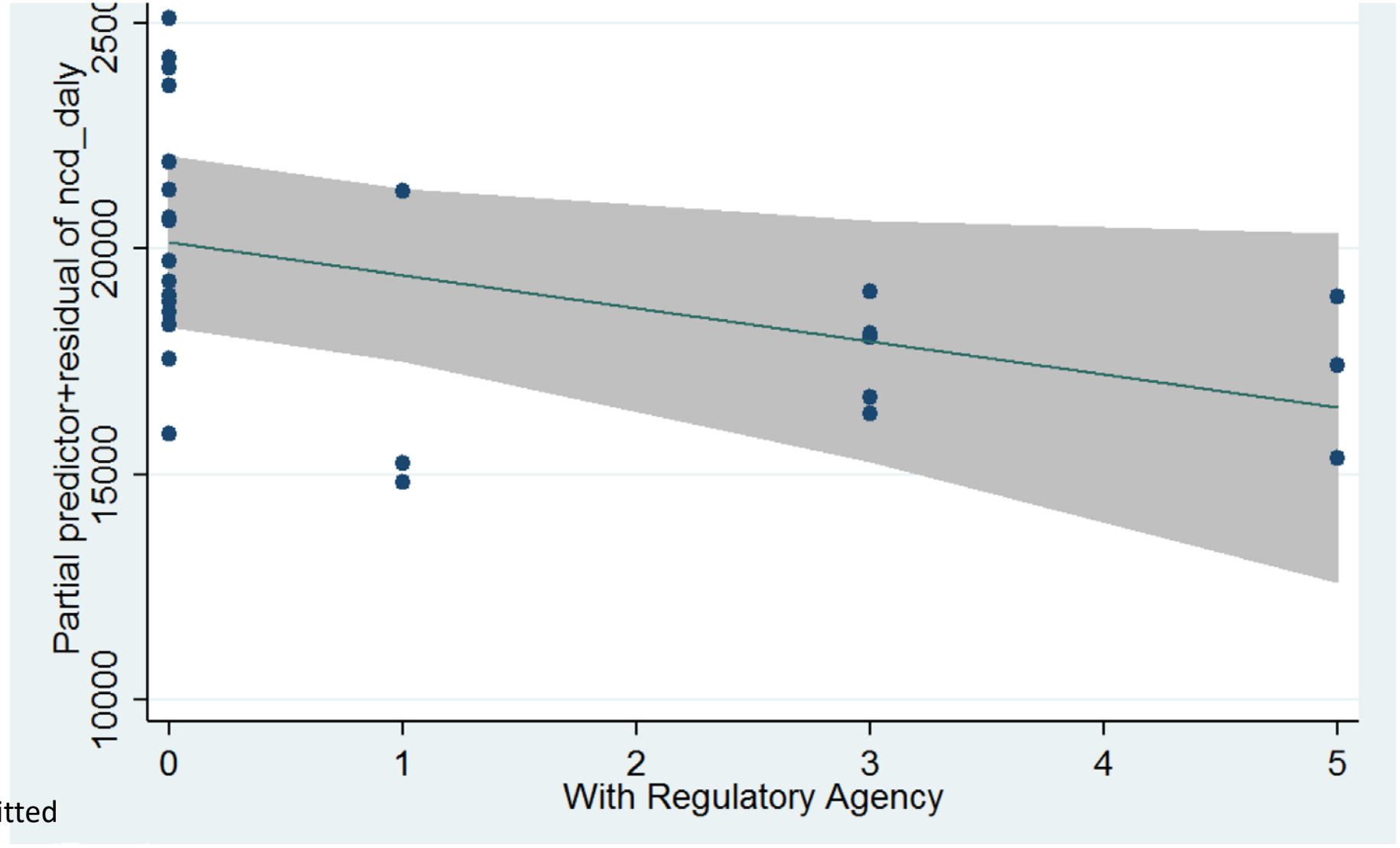
A primary responsibility of Health: TO PROTECT (*Betcher, WHO,1998*)

- In some countries, the protection of Health is a Constitutional right
- Responsibility of the State (*Amartya Sen*)
- Responsibility of Governments on Health, by WHO Constitution (*Treaty*)
- Leading to innovation (*Mazucatto, 2011*)
- Non-delegable
- Producing "Common Public Goods" (non-excludable, non-rival in consumption) (*Moon, Rotingen, Frenk, 2017*)
- ***Results oriented, impact*** (*NAS, 2012*)

VALUE PROPOSITION:

Healthy life years
Reduced Disease Burden
Human and Health Security
Sustainable Health System
Labor productivity
Development growth

IMPACT OF PUBLIC HEALTH REGULATORY CAPACITY ON DISABILITY ADJUSTED LIFE YEARS FROM NONCOMMUNICABLE DISEASES*. THE AMERCIAS, 2014



** Addressing food, tobacco, alcohol, other*

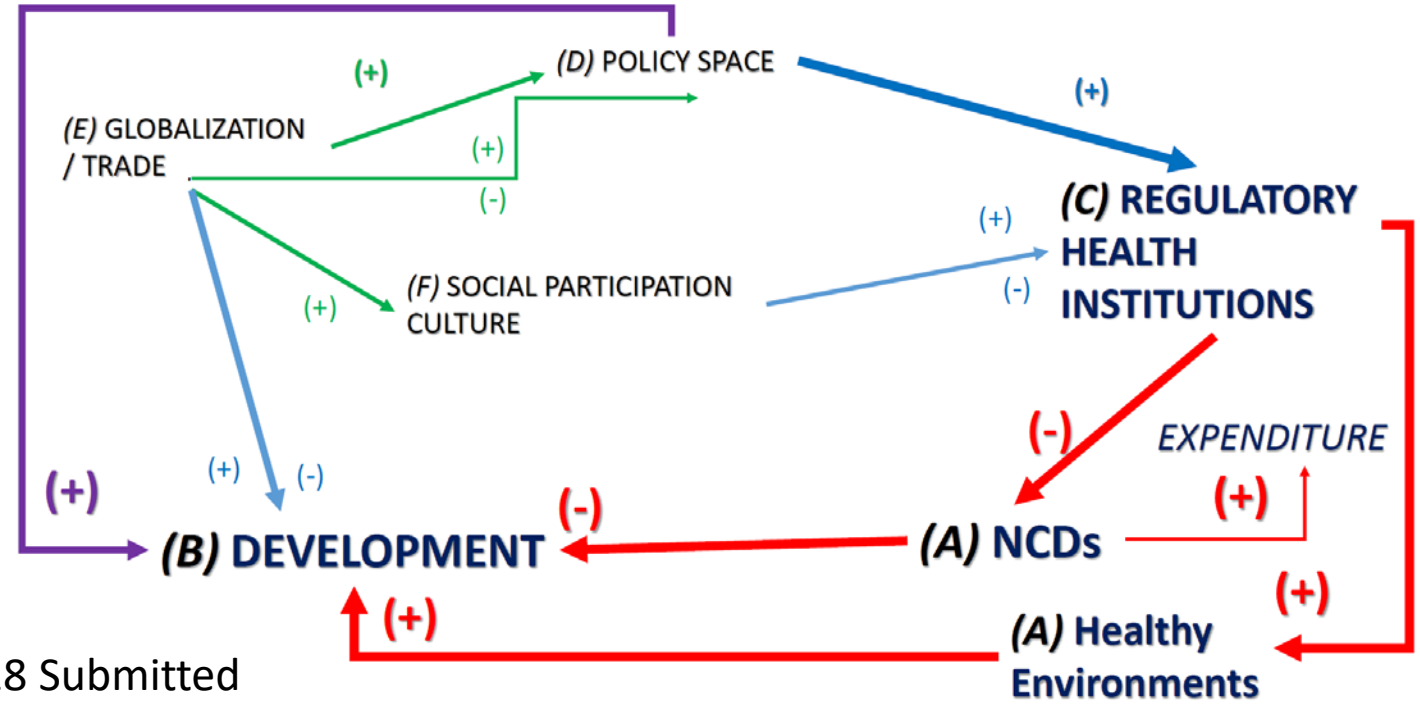
Source: Santos-Burgoa, 2018 Submitted

ROLE IN ECONOMY AND DEVELOPMENT

- Regulation influence on Economy *(Jean Tirole)*
  - In Mexico, 44 cents of each peso of families spent, under Public Health Regulation (Sánchez y Tépoz, 2018)
  - 18% of the commercial NAFTA trade (non-medical) (Santos-Burgoa, 2017)
  - Commerce can be used for leverage; but Health regulation is not at the service of commerce
  - International trade is key
  - Development synergy factor
  - *Equity modulator,* most important in developing countries

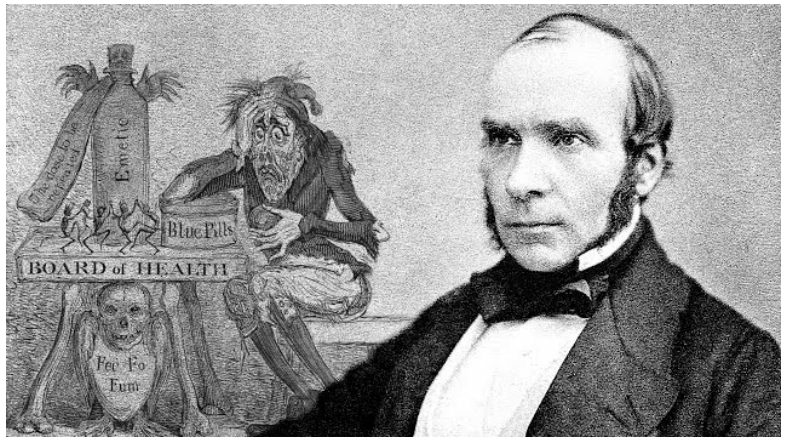
(Santos-Burgoa 2018)

Figure 4. Relational loop diagram NCDs on development and regulatory institutions



Source: Santos-Burgoa, 2018 Submitted

PUBLIC HEALTH REGULATION: Referents for a conceptual framework

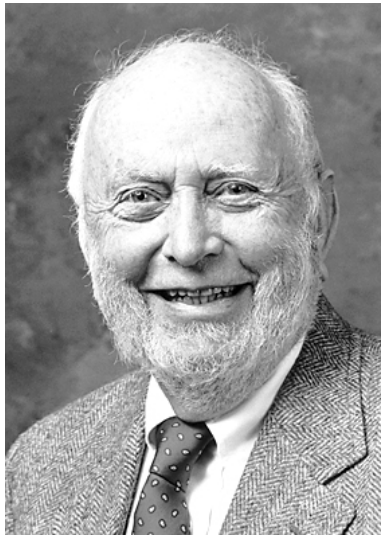


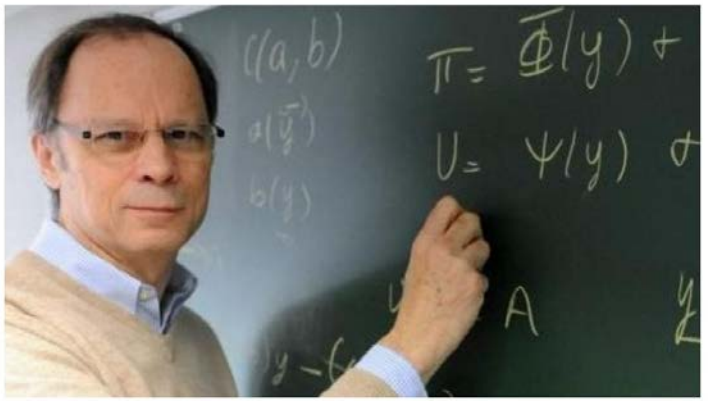
Protection and Risk (John Snow);

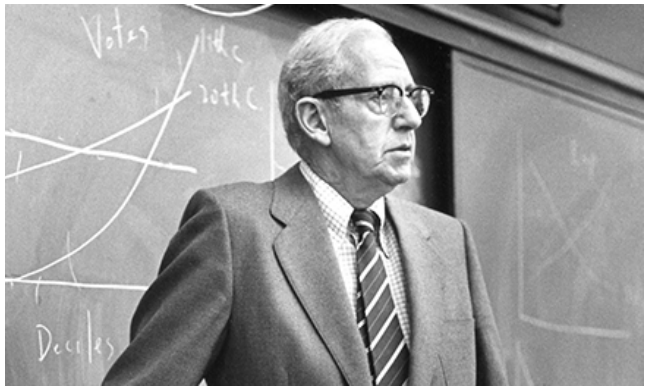
Development and Human Security(Amartya Sen);

Essential Public Health Functions (Douglas Bettcher, WHO)

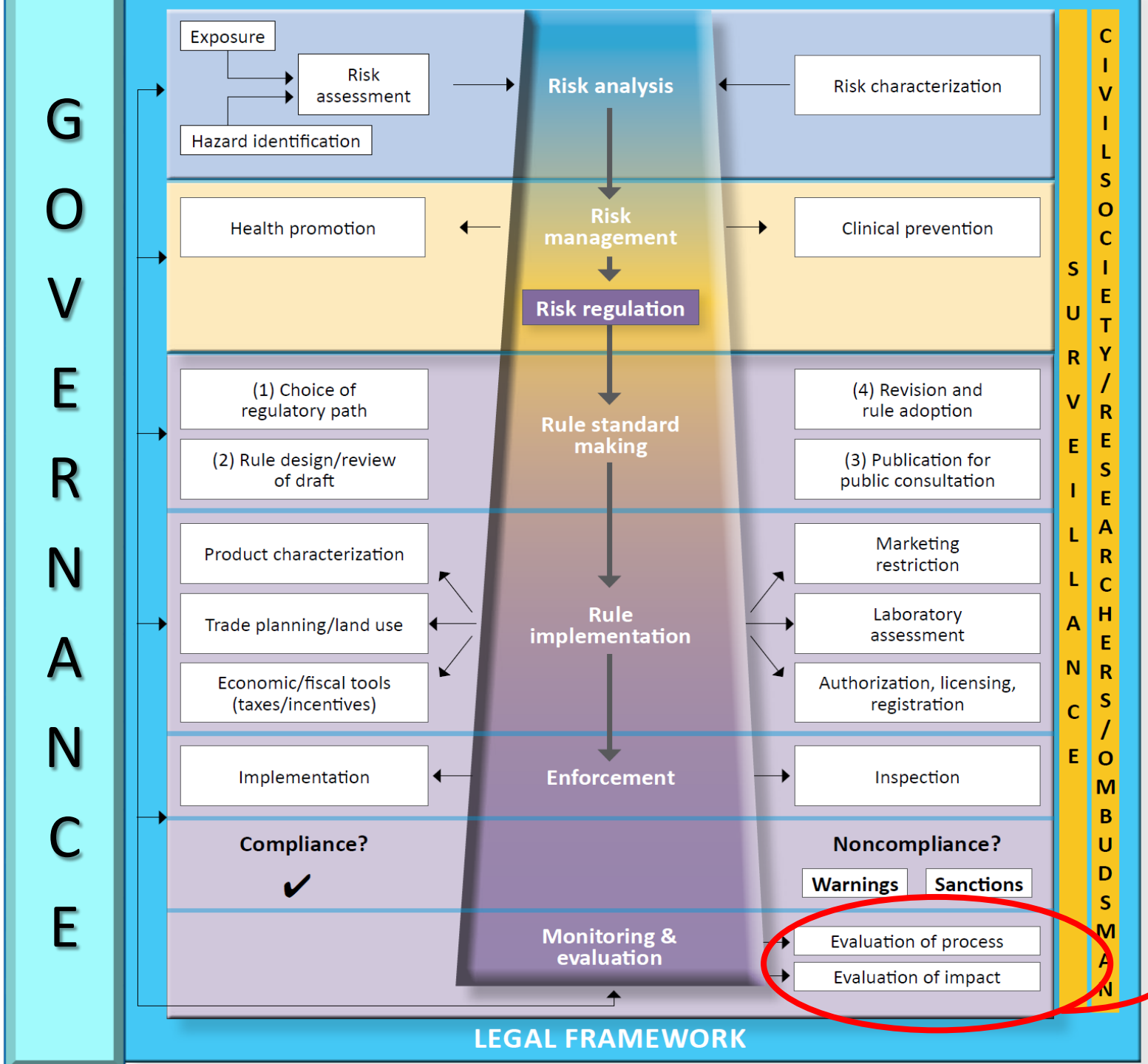
The Value of the State (Marianna Mazucatto)







Regulation and (Jean Tirole y George Stigler - Capture-)
Institutional Economics (Douglass C. North)



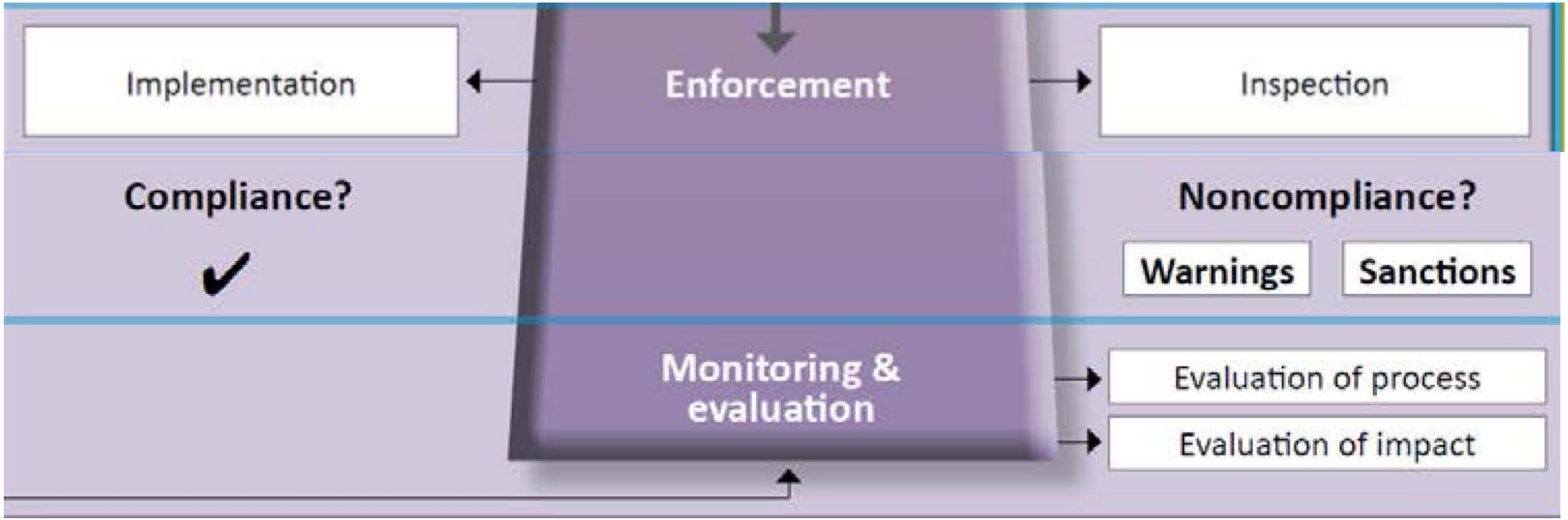
INTEGRATED PUBLIC HEALTH RISK REGULATORY PROCESS (from NCDs REGULA)

Consideration for capacity for evaluation, and for development

Evaluation at implementation for feedback, adjustment and review

Source: Modified from CSB in PAHO 2015

IMPLEMENTATION PERFORMED AT NATIONAL (FEDERAL) AND ALSO AT THE SUBNATIONAL (STATE / LOCAL district municipal)



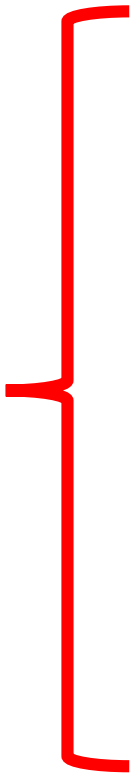
CENTRALIZED AND FEDERAL GOVERNMENTS CHALLENGE FOR ENFORCEMENT, MONITORING AND EVALUATION

- Chile (SEREMIS), Honduras … Districts (need funding, human talent, technology and organization)
- Mexico (CEPRIS, Jurisdictions), Argentina, Brazil … States and Health Jurisdictions
  - Federated follow up for implementation
  - Coordination agreements and technical and $ resources flow
  - Local resources synergy and PH Regulatory infrastructure

35 countries

http://ais.paho.org/phip/viz/nmh_ccs_resultstool.asp

REGULATORY INTERVENTIONS



THE SPREAD OF COMPLEX RESPONSIBILITIES OF PUBLIC HEALTH REGULATION (Mexico's COFEPRIS) (difficult balance)

Comisión Federal de Proteccion Contra Riesgos Sanitarios: atribucion de ejercer la regulación, control, vigilancia y fomento sanitarios

a. Establecimientos: de salud, de disposición de órganos, tejidos, células de seres humanos y sus componentes, de disposición de sangre y los demás establecimientos que señala el citado ordenamiento, con las excepciones a que hace referencia la Ley;

b. medicamentos, remedios herbolarios y otros insumos para la salud;

c. alimentos y suplementos alimenticios;

d. bebidas alcohólicas y bebidas no alcohólicas;

e. productos de perfumería, belleza y aseo;

f. tabaco;

g. plaguicidas y fertilizantes;

h. nutrientes vegetales;

i. sustancias tóxicas o peligrosas para la salud;

j. químicos esenciales, precursores químicos, estupefacientes y psicotrópicos;

k. productos biotecnológicos;

l. materias primas y aditivos que intervengan en la elaboración de los productos señalados en las fracciones b) a k) anteriores, así como los establecimientos dedicados al proceso o almacenamiento de éstos;

m. fuentes de radiación ionizante para uso médico;

n. efectos nocivos de los factores ambientales en la salud humana;

ñ. salud ocupacional;

o. saneamiento básico;

p. importaciones y exportaciones de los productos a que se refiere la fracción II del artículo 17 bis de la Ley;

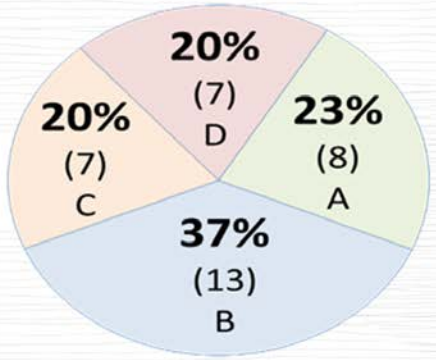
q. publicidad y promoción de las actividades, productos y servicios a que se refiere la Ley y demás disposiciones aplicables;

r. sanidad internacional, salvo en las materias exceptuadas por la Ley, y

s. en general, los requisitos de condición sanitaria que deben cubrir los procesos, productos, métodos, instalaciones, servicios o actividades relacionados con las materias anteriormente descritas, en los términos de la Ley y demás disposiciones aplicables;

PUBLIC HEALTH REGULATORY INSTITUTIONAL CAPACITY, WEAKENESS AND CHALLENGE BY REGULATED SECTORS

Country Regulatory Capacity in the Americas (N=35) [2018]



- **82%** of population covered by **8** NRAr
- **2%** of population have "some or no legal bases and organizational structures (18 million in 14 countries)

- A - States with National Regulatory Authority of Regional of Reference according to CD50.R9 (NRAr)
- B - States that have legal bases and organizational structures for a comprehensive regulatory system
- C - States that have some legal bases and organizational structures for a regulatory system
- D - States that do not currently have legal bases and/or organizational structures for a regulatory system

Source: Barbosa J, 2019

PAHO

WEAK PUBLIC HEALTH REGULATORY CAPACITY

CHALLENGE:

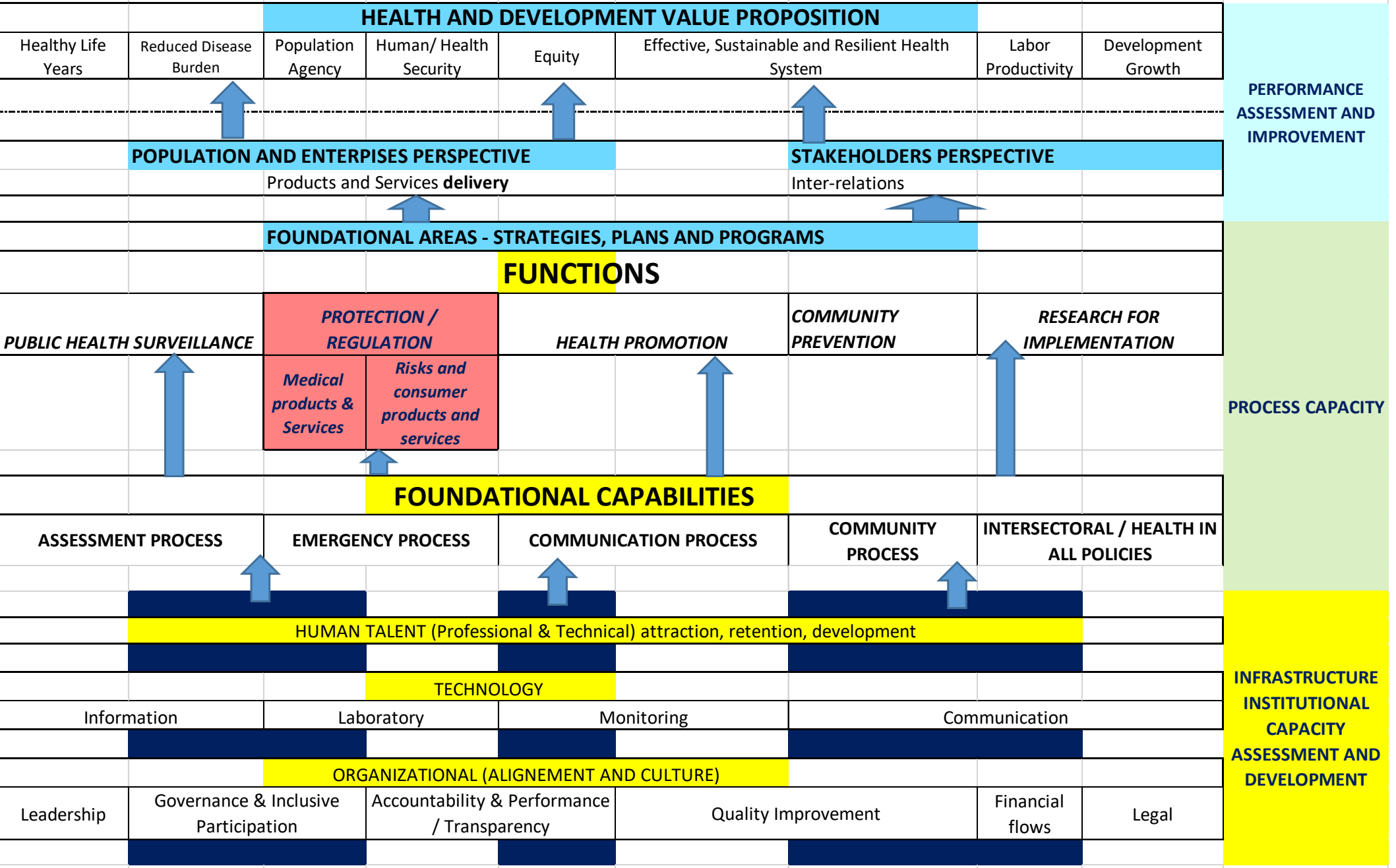
- Widespread informal economy, and large quantity micro-business

AND

- Strong National and Global Corporations
  - Consolidation of Pharmaceutical
  - Chemical, processed food, alcohol, tobacco, others…
- The problem of
  - Interference of industry
  - Regulatory capture

- IMPACT ON GOVERNANCE

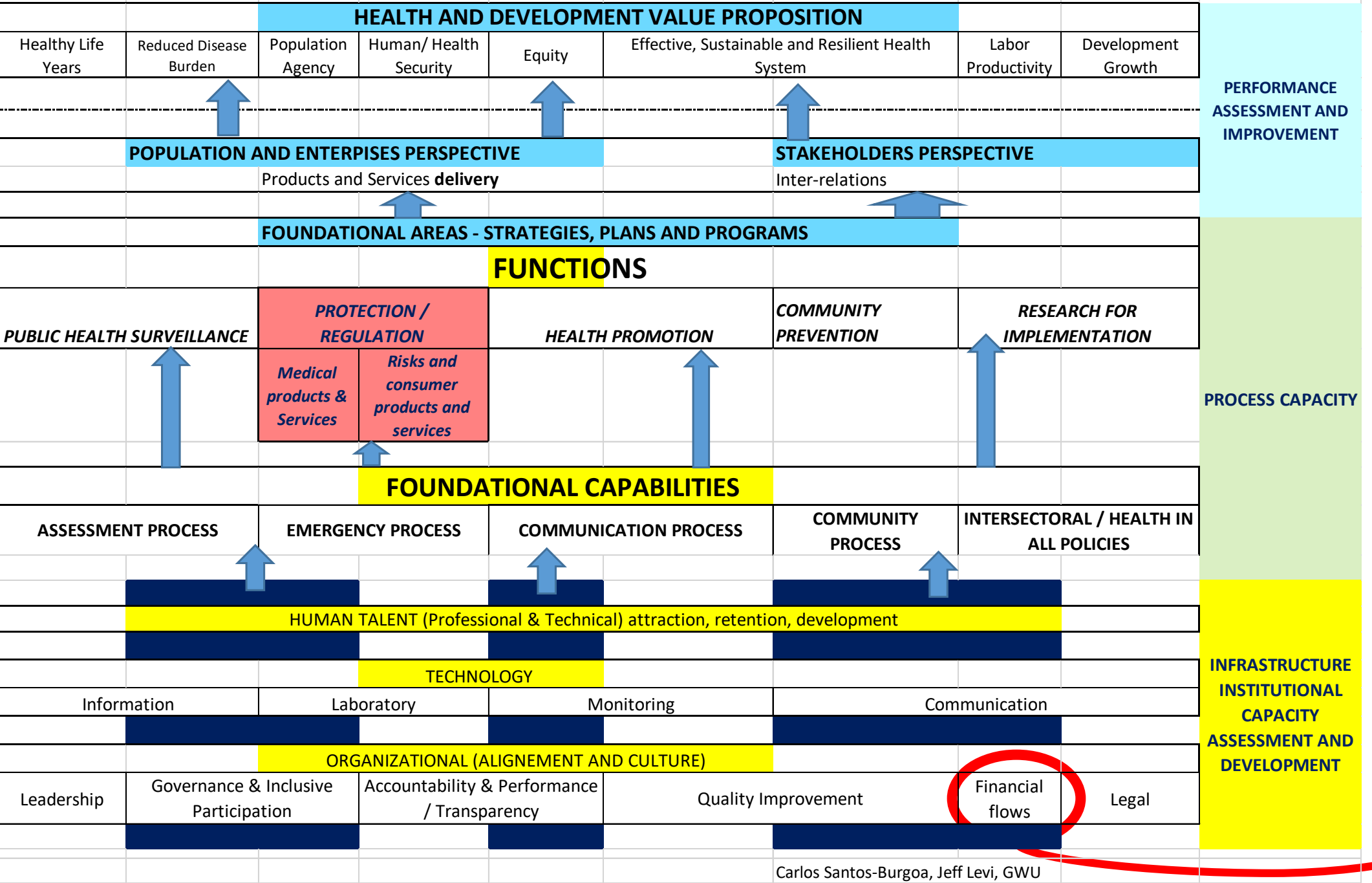
PUBLIC HEALTH FUNCTION INSTITUTIONAL ASSESSMENT (March 6, 2019)



WEAKENESS AT THE BOTTOM LIMITS DELIVERY AT THE TOP

Carlos Santos-Burgoa, Jeff Levi, GWU

PUBLIC HEALTH FUNCTION INSTITUTIONAL ASSESSMENT (March 6, 2019)



Carlos Santos-Burgoa, Jeff Levi, GWU

FOR A STRONG PUBLIC HEALTH REGULATORY CAPACITY

- Ministers of Health are confronted with a “false dilema”
  - *Medical care (fulfill the social expectative), versus*
  - *Health protection (not visible and bothersome action) taking the budget from care*
- Financial flow critical for an effective public health risk protection policy
  - Public common goods (norms, standards, guidance, etc.). → taxes
  - Private godos (licences, certificates, authorization for individual benefit). → fees
    - ***Equity adjusted***

TABLE 7. Potential sources and typical uses of revenue for entities that regulate NCD risks

General taxpayer revenue	Regulated entity fees and fines
• Establishment and organization • Basic science for risk assessment • Development of norms and standards • Laboratory development • Evaluation of regulation • All other activities	• Registration • Registration renewal • Licenses • License renewal • Authorizations and certificates • Laboratory analyses and verifications • Inspection and monitoring • Sanctions

Fuente: Santos-Burgoa en PAHO, 2015

THE CASE OF NEW PHARMA-CEUTICAL PRODUCTS

Table 1 | **Budgets, product approvals, timelines and fees of various regulatory authorities for new pharmaceutical products**

Regulatory authority	Budget for the fiscal years 2015/2016 (in US$ millions)*	Number of technical reviewers in 2016	Number of NDA submissions for new drugs in 2015/2016‡	Number of new therapeutic approvals in 2015/2016‡	Standard review timelines (days)	Median time for approval (days) in 2015	Fees per NDA in 2016 (in US$ thousands)*
European Medicines Agency (EMA)	340/342	~4,500§	61/68	39/27	210	422‖	316
US Food and Drug Administration (FDA)	1,194/1,230	~2,000	35/41	45/22	300	333‖	2,374
Pharmaceuticals and Medical Devices Agency (Japan)	246/241	~560	127/NA	42/48	365	311‖	274
Chinese Food and Drug Administration	199/250	~120¶	NA	72/31#	900	639	862
UK Medicines and Healthcare products Regulatory Agency (MHRA)	438/477	NA§	NA	146**/NA	210	230	120
Health Canada	84/108	~1,570	27/25	20/27	270	361	248
Swissmedic	115/108	~60	295	27/42	365	464	72
Central Drugs Standard Control Organization (India)	26/NA	~130	NA	17/22	270	523	1
Roszdravnadzor (Russia)	55/NA	NA	NA	NA	210	335	8
Health Sciences Authority (Singapore)	146/NA	~300	NA	61/72	295	409	62
Therapeutic Goods Administration (Australia)	104/NA	NA	43	27/NA	255‡‡	373	172
Brazilian Health Surveillance Agency	NA/NA	NA	NA	NA	730	834	69
Comision Federal de Proteccion Contra Riesgos Sanitarios (Mexico)	NA/NA	NA	NA	NA	variable	variable	7

Modified from:
https://www.nature.com/articles/nrd.2017.135

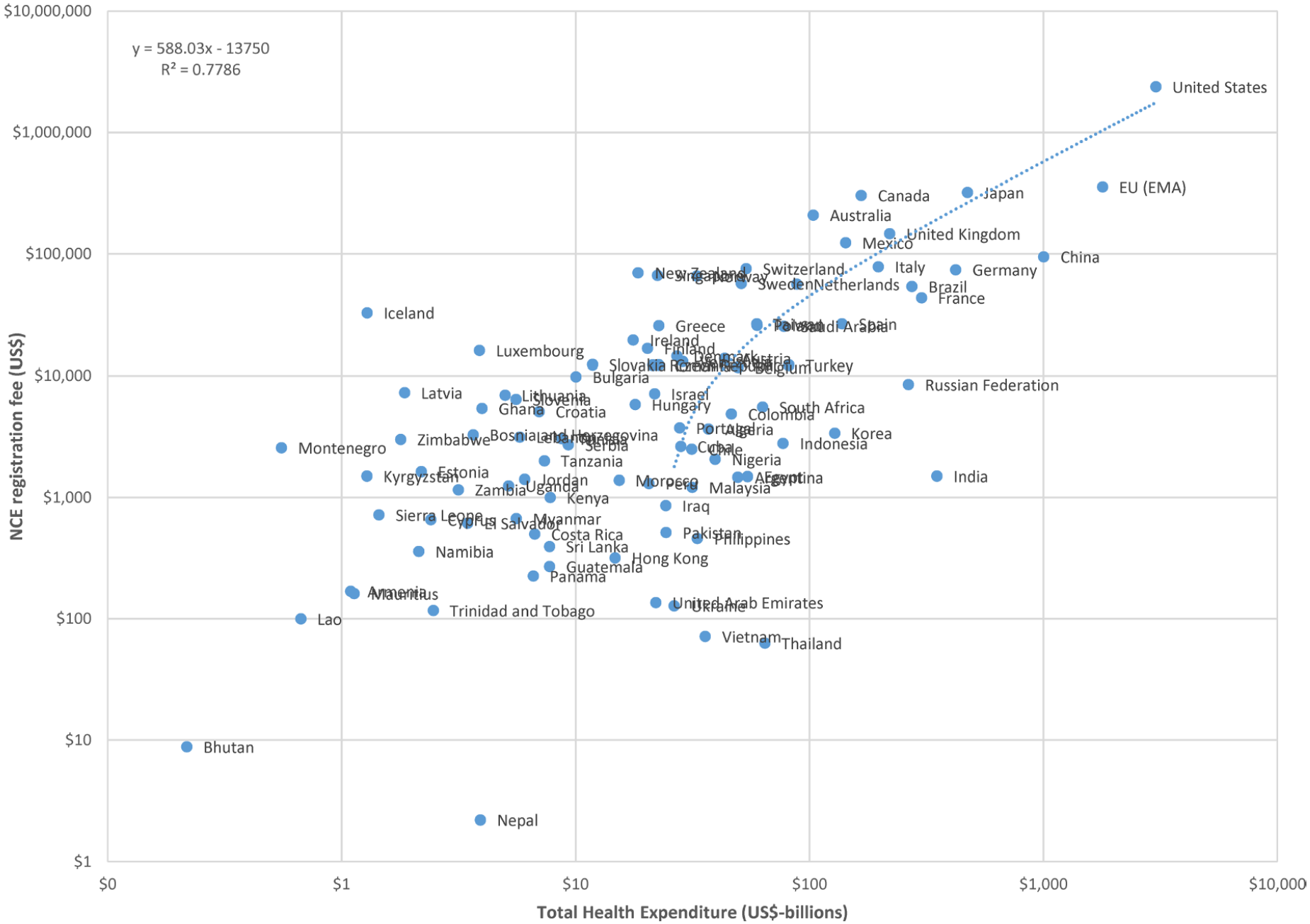


Fig 2. Plot of new chemical entity (NCE) registration fees to billions of US dollars in total health expenditure, logarithmic scale.

https://doi.org/10.1371/journal.pone.0182742.g002

EMERGO by UL

Expertise Services Resources News About

WORLD COMPARATIVE OF COSTS AND PERFORMANCE

MEDICAL PRODUCTS

Market	Device Class	Risk	TIME* from submission to approval	COST** of gaining regulatory approval	COMPLEXITY*** of registration process
South Korea	Class IV	High	6-10 months	$$$$$	$$$$$
Japan	Class III - Highly Controlled	High	9-11 months	$$$$$	$$$$$
Europe	Class III	High	6-9 months	$$$$$	$$$$$
Brazil	Class III Registro	High	8-15 months	$$$$$	$$$$$
Japan	Class IV - Highly Controlled	High	13-16 months	$$$$$	$$$$$
Colombia	Class IIb	High	4-6 months	$	$$
Saudi Arabia	High Risk	High	1-6 months	$$	$$
Brazil	Class IV Registro	High	8-15 months	$$$$$	$$$$$
Colombia	Class III	High	4-6 months	$	$
Taiwan	Class III	High	10-12 months	$$$	$$$
	Class IIb	High	< 1 month	$	$
Hong Kong	Class III	High	8-12 months	$$	$$
Mexico	Class II	High	3-10 months	$$$	$$$
	Class III	High	< 1 month	$	$
Hong Kong	Class IV	High	8-12 months	$$$	$$
Canada	Class III	High	4-5 months	$$$	$$$$
Mexico	Class III	High	3-10 months	$$$	$$$
Singapore	Class C	High	4-6 months	$$	$$$
India	Non-notified IVD	High	<1 month	$	$
Canada	Class IV	High	6-8 months	$$$$	$$$$$
United States	Class III	High	18-30 months	$$$$$	$$$$$
Costa Rica	Class IV	High	2-4 months	$$	$$$

https://www.emergobyul.com/resources/worldwide/global-regulatory-comparison-tool?action=&field_market_tid=All&cost=All&field_device_risk_value=All&order=field_device_risk&sort=desc

HANDLING OF FEES

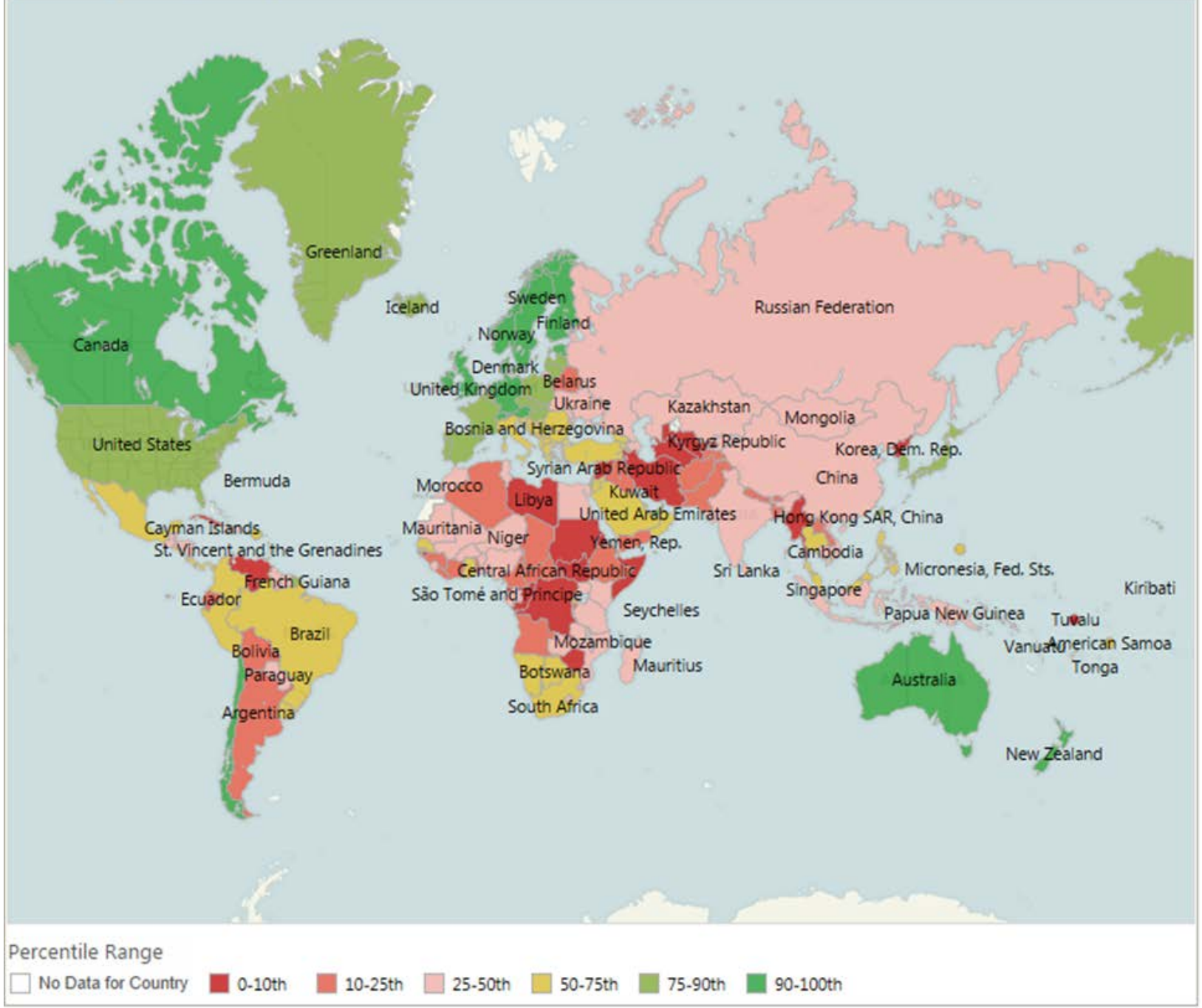
- **Straight into general national revenue**
    - Negotiate the annual budget considering the contribution from fees, but undistinguishable of taxes (ANVISA)
    - Negotiate that a minimum additional budget considering a percent of the fees to complement a major proportion of taxes budget
    - Consider a tax for the general operation AND consider a fraction of the fees returned to the agency (COFEPRIS)
- **Directly into the Agency funds**

ADDITIONAL REVENUES

- Local and State taxes and collected fees

THE CHALLENGE OF COSTING AND USE OF ADDITIONAL REVENUE

- Cost should aim to “internalize” the overall management of the product, from analysis to post-marketing and population surveillance *(Integral Process/Product Cost)*
  - “Explicit” subsidies could be especially designed to foster equity oriented interventions such as reducing entry barriers to those in the informal economy, the poor, others
  - Subsidies to the poor justified by the principle of “Solidarity” and effective public health impact
- The regulated entity should not have to contribute to the general expenditures of the regulatory body
- The benefit for the regulated entity should be
  - A reliable risk analysis
  - An effective levelled field for all actors
  - Performance quality and efficiency
  - Competitiveness and fostering innovation
- The benefit for the regulatory body should aim for the organizational development improving infrastructure and process components



Source: Kaufmann D., A. Kraay, and M. Mastruzzi (2010), The Worldwide Governance Indicators: Methodology and Analytical Issues
The Worldwide Governance Indicators are available at: www.govindicators.org

WORLD REGULATORY QUALITY (Including Public Health Regulation), as of 2013

Within this context, the opportunity / challenge is to assure the delivery of sound drugs, and safe and healthy food regulation, that will effectively impact health, lower communicable and Noncommunicable diseases, support health care sustainability, and contribute to economic growth and development

THE FUTURE FOR THE DEVELOPMENT OF PUBLIC HEALTH REGULATORY INSTITUTIONS

Integrate them to the Health System as an Asset, not a liability

- Positioning the idea, make it feasible, provide the social basis (the demand), the economic rationale, and support the local leadership
- Essential for Health System sustainability

Focus support on the needs for INSTITUTIONAL capacity

- ***Map*** the global capacity
- Integral Process / Product ***Costing*** methods development
- Innovation for monitoring supporting process (informatics), health surveillance, and impact evaluation to ***visualize the Public Health Impact of Regulation*** … more on children and populations ins situation of vulnerability in developing economies (*i.e. leveraging the 2018 UN Secretary-General's Independent Accountability Panel for Every Woman, Every Child, Every Adolescent (IAP))*
- ***Regulatory capture*** awareness, identification, and management approaches
- Identify the opportunities for innovation in ***Regulatory Infrastructure*** (talent, technology, and organization) and ***Process*** including global / regional exchanges and comparative analysis
- Foster ***professional associations*** to reposition the field in developing countries

Carlos Santos-Burgoa, MD, MPH, PhD

Professor, Global Health

Milken Institute School of Public Health

The George Washington University

950 New Hampshire Ave, NW, Room 408

Washington DC

Phone +202-604-1438

Email csantosburgoa@gwu.edu

ADDITIONAL SLIDES

Table 17: Local Health Department‡ Revenue by Sources

Revenue Source	Acton County (MA)	Boston (MA)	Custer (ND)	Fargo Cass (ND)	Fulton Health District (GA)	Jefferson County (AL)	South Health District (GA)
Local	24.7%	42.5%	20.3%	45.8%	39.9%	51.1%	6.4%
State	8.2%	3.7%	11.6%	9.1%	20.0%	2.3%	33.6%
Federal Flow-Through[35]	3.4%	5.8%	45.3%	23.1%	20.8%	9.4%	32.8%
Federal Direct	Not Reported	13.0%	0.0%	0.0%	Not Reported	1.8%	2.5%
ARRA	Not Reported	2.5%	0.0%	0.0%	0.8%	12.1%	0.7%
Medicaid	Not Reported	2.5%	3.3%	5.3%	1.0%	17.9%	6.5%
Medicare	15.1%	4.3%	0.0%	0.2%	<0.1%	0.2%	0.5%
Private Foundations	1.7%	0.6%	1.4%	0.4%	Not Reported	0.0%	0.0%
Private Health Insurance[36]	8.2%	7.9%	6.3%	1.3%	<0.1%	1.5%	2.5%
Fees and Fines	Not Reported	3.0%	12.8%	14.7%	17.4%	9.5%	6.8%
Other	38.7%	14.0%	0.3%	0.1%	Not Reported	5.8%	7.6%
Total	100.0%	100.0%	101.4%†	100.0%	100.0%	111.6%†	100.0%

IN THE USA, FEES AND FINES, AND PRIVATE SOURCES ARE USED FOR PHF

http://www.norc.org/PDFs/PH%20Financing%20Report%20-%20Final.pdf