Intellectual Property's Impact on Global Health & Life-sciences Innovation

Stephen Ezell
Vice President, Global Innovation Policy
ITIF

Dept. of International Health
Georgetown University

Washington, DC

February 6, 2020

ITIF | INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

@ITIFdc

Stephen Ezell, VP, Global Innovation Policy, Information Technology and Innovation Foundation (ITIF)

GEORGETOWN UNIVERSITY

SFS | GEORGETOWN UNIVERSITY
Walsh School of Foreign Service

brivo
simply better security

Nasdaq
Ignite your ambition

Peer Insight

Peer Insight partners with visionary leaders to inspire and architect breakthrough innovation that matters.

ITIF
INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

The Information Technology and Innovation Foundation is a non-partisan research and educational institute - a think tank - whose mission is to formulate and promote public policies to advance technological innovation and productivity internationally, in Washington and in the states.

About ITIF

- The world's leading science and technology policy think tank.
- Supports policies driving global, innovation-based economic growth.
- Focuses on a host of issues at the intersection of technology innovation and public policy across several sectors:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Clean energy, manufacturing, life sciences, and ag biotech

University of Pennsylvania
ScholarlyCommons

TTCSP Global Go To Think Tank Index Reports | Think Tanks and Civil Societies Program (TTCSP)

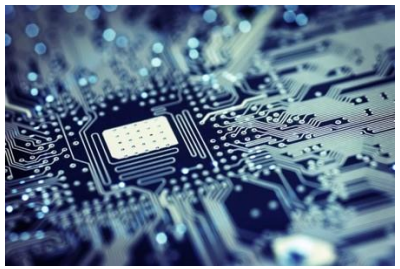
1-27-2020

2019 Global Go To Think Tank Index Report

James G. McGann
University of Pennsylvania, jmcgann@wharton.upenn.edu

Innovation Industries Share Three Distinct Characteristics

1. They compete by inventing next-generation products or services.
2. They are characterized by very high initial fixed costs (e.g., R&D and design), but low marginal costs.
3. They fundamentally embody and depend on intellectual property.





Necessary Conditions for Global Innovation to Flourish

1. Access to large markets (e.g., economies of scale).
2. No excess, non-market-based competition (e.g., subsidies).
3. No forced localization requirements that unnecessarily fragment global production systems.
4. Protection of intellectual property rights.

State of Global Life-Sciences Innovation Activity

- Almost 1,000 new active substances have been introduced globally over the past 25 years.
- America's FDA has approved 500 new drugs since 200 alone.

Source: PhRMA, *Chart Pack: Biopharmaceuticals in Perspective, Spring 2017; IMS Institute for Healthcare Informatics, "Global Medicines Use in 2020: Outlook and Implications"*

Global Health Challenges Increasingly Commonly Shared

- 70% of fatalities in developing world from non-communicable diseases.
- Citizens of low- and middle-income countries bear 80% of the world's death burden from cardiovascular disease.
- 85% of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.

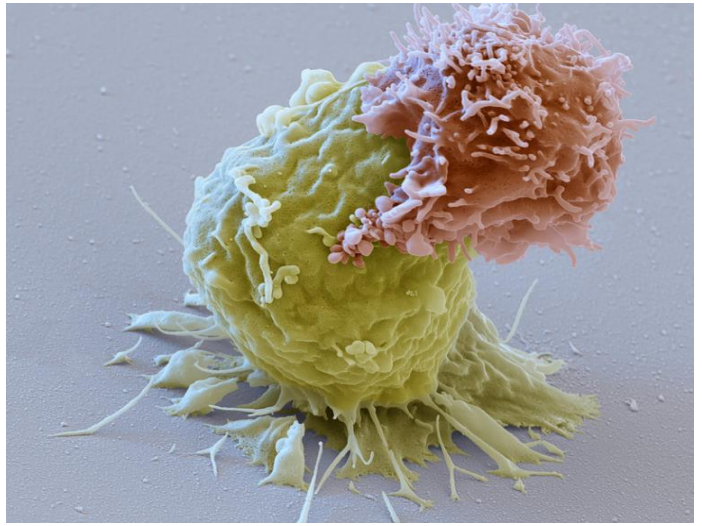
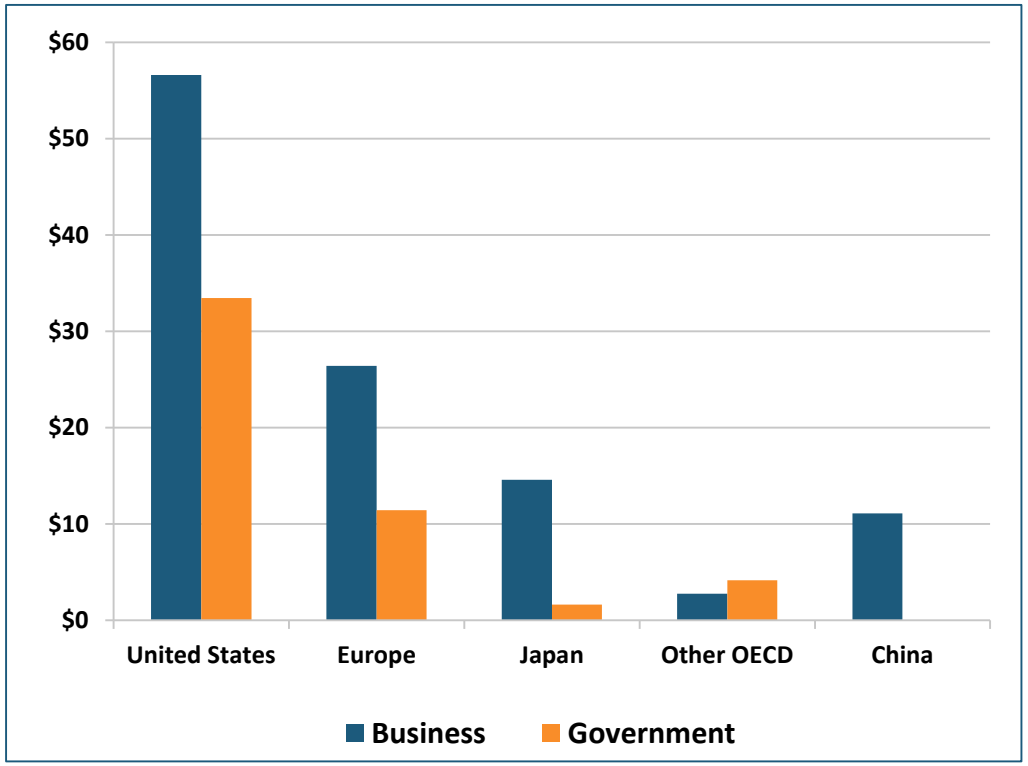


Image of a CAR-T cell (reddish) attacking a leukemia cell (green).

Source: Mark Schultz, Stephen Ezell, and David Lind, "Innovate 4 Health: How Innovators Are Solving Global Health Challenges"

U.S. Leads in Global Life-sciences R&D and Innovation

Business and Government Investment in Pharmaceutical R&D (in Billions), 2017

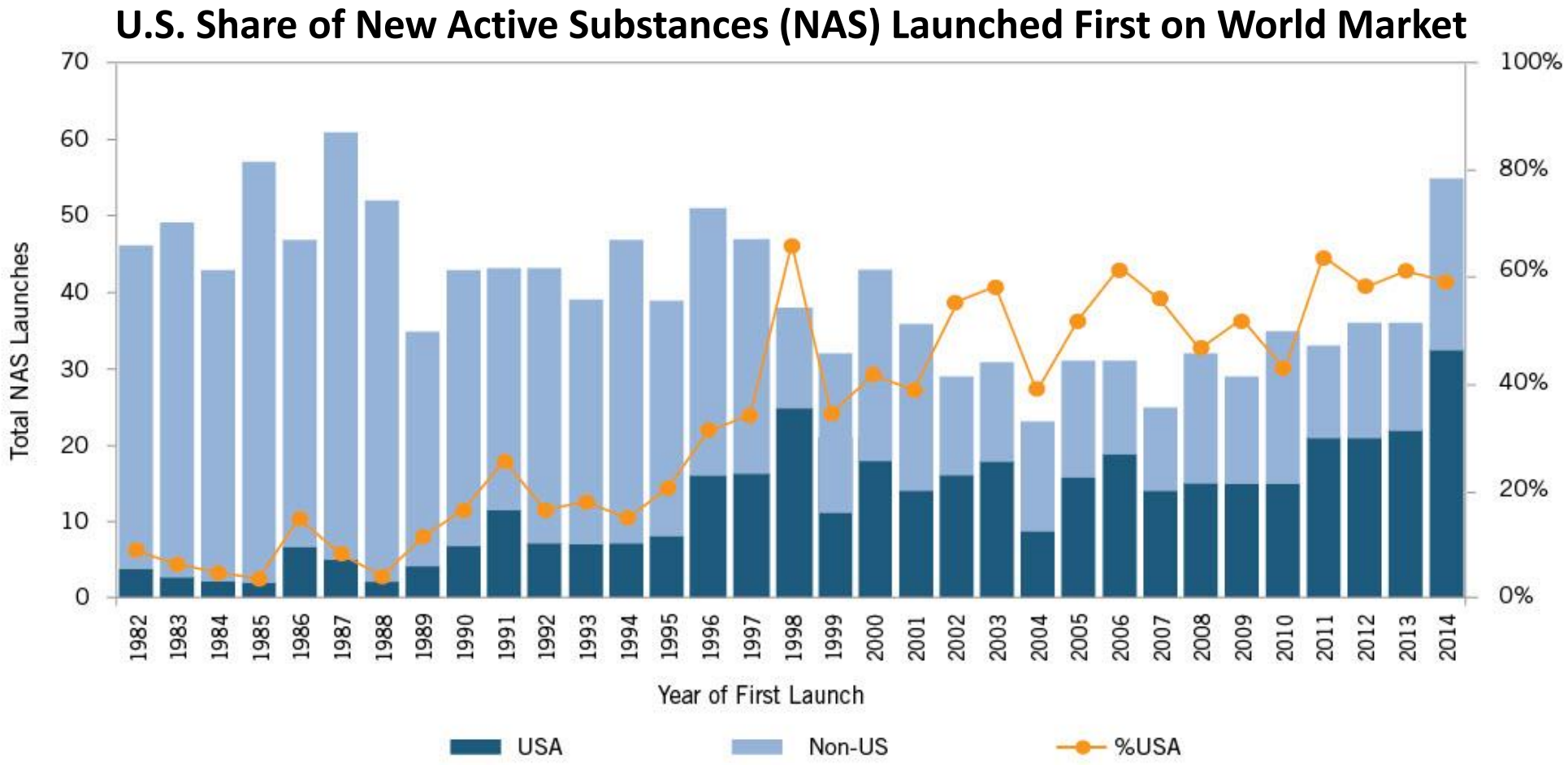


Number of New Chemical or Biological Entities Produced, 1997-2016

Region	1997-2001	2002-2006	2007-2011	2012-2016	Total
U.S.	84	67	65	88	304
Europe	79	46	52	75	252
Japan	29	21	20	32	102
Other	4	14	12	38	64

Source: ITIF, "How to Ensure That America's Life-Sciences Sector Remains Globally Competitive"

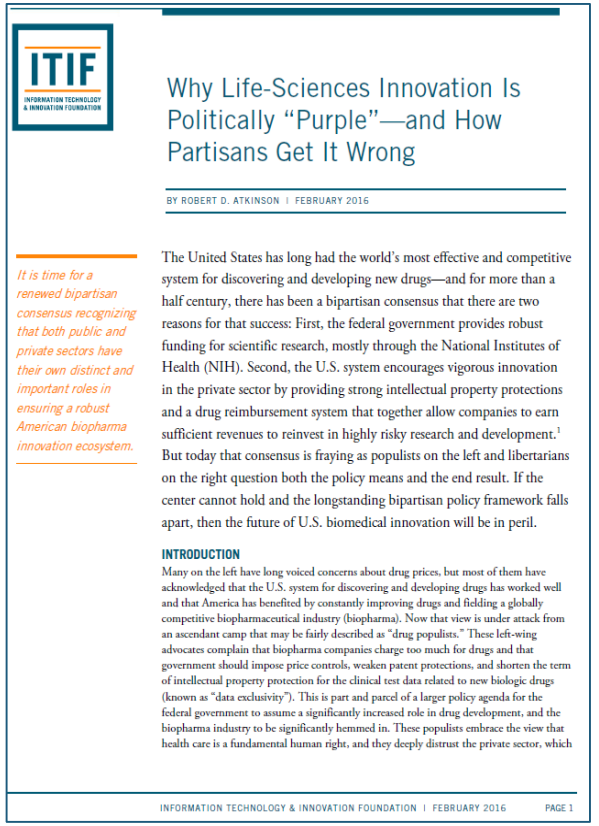
But It Wasn't Always That Way



Source: John K. Jenkins, M.D., "CDER New Drug Review: 2015 Update"

Keys to Life-Sciences Innovation Leadership

1. World-leading public/private investment in biomedical research.
2. Aggressive incentives to encourage investment (E.g. R&D tax credit, Orphan Drug Tax Credit).
3. Effective regulatory/drug approval system (E.g., PDUFA).
4. Pricing/reimbursement system allowing innovators to earn sufficient revenues to reinvest in innovation.
5. Robust intellectual property protections.



ITIF
INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

Why Life-Sciences Innovation Is Politically "Purple"—and How Partisans Get It Wrong

BY ROBERT D. ATKINSON | FEBRUARY 2016

It is time for a renewed bipartisan consensus recognizing that both public and private sectors have their own distinct and important roles in ensuring a robust American biopharma innovation ecosystem.

The United States has long had the world's most effective and competitive system for discovering and developing new drugs—and for more than a half century, there has been a bipartisan consensus that there are two reasons for that success: First, the federal government provides robust funding for scientific research, mostly through the National Institutes of Health (NIH). Second, the U.S. system encourages vigorous innovation in the private sector by providing strong intellectual property protections and a drug reimbursement system that together allow companies to earn sufficient revenues to reinvest in highly risky research and development.[1] But today that consensus is fraying as populists on the left and libertarians on the right question both the policy means and the end result. If the center cannot hold and the longstanding bipartisan policy framework falls apart, then the future of U.S. biomedical innovation will be in peril.

INTRODUCTION

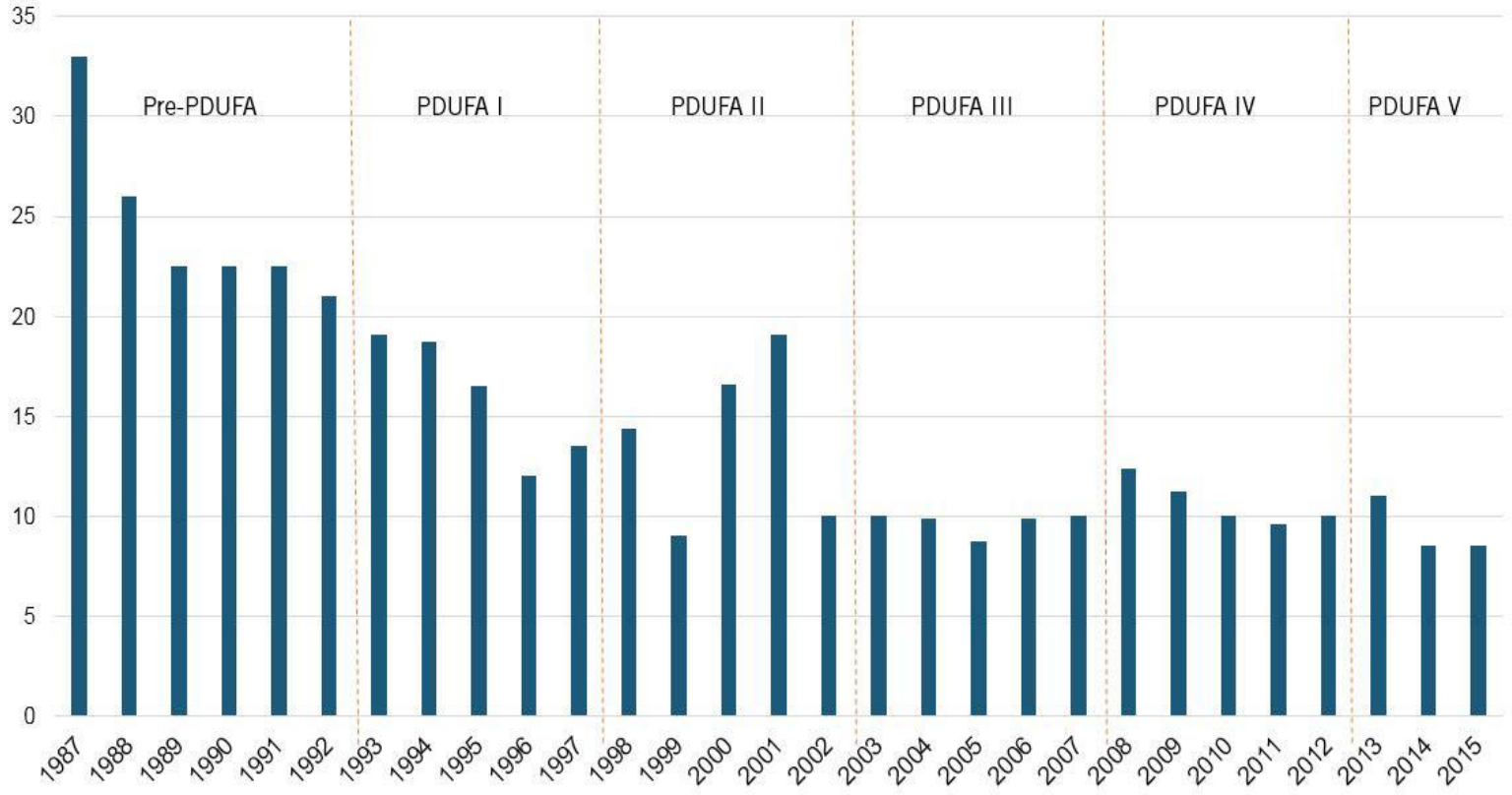
Many on the left have long voiced concerns about drug prices, but most of them have acknowledged that the U.S. system for discovering and developing drugs has worked well and that America has benefited by constantly improving drugs and fielding a globally competitive biopharmaceutical industry (biopharma). Now that view is under attack from an ascendant camp that may be fairly described as "drug populists." These left-wing advocates complain that biopharma companies charge too much for drugs and that government should impose price controls, weaken patent protections, and shorten the term of intellectual property protection for the clinical test data related to new biologic drugs (known as "data exclusivity"). This is part and parcel of a larger policy agenda for the federal government to assume a significantly increased role in drug development, and the biopharma industry to be significantly hemmed in. These populists embrace the view that health care is a fundamental human right, and they deeply distrust the private sector, which

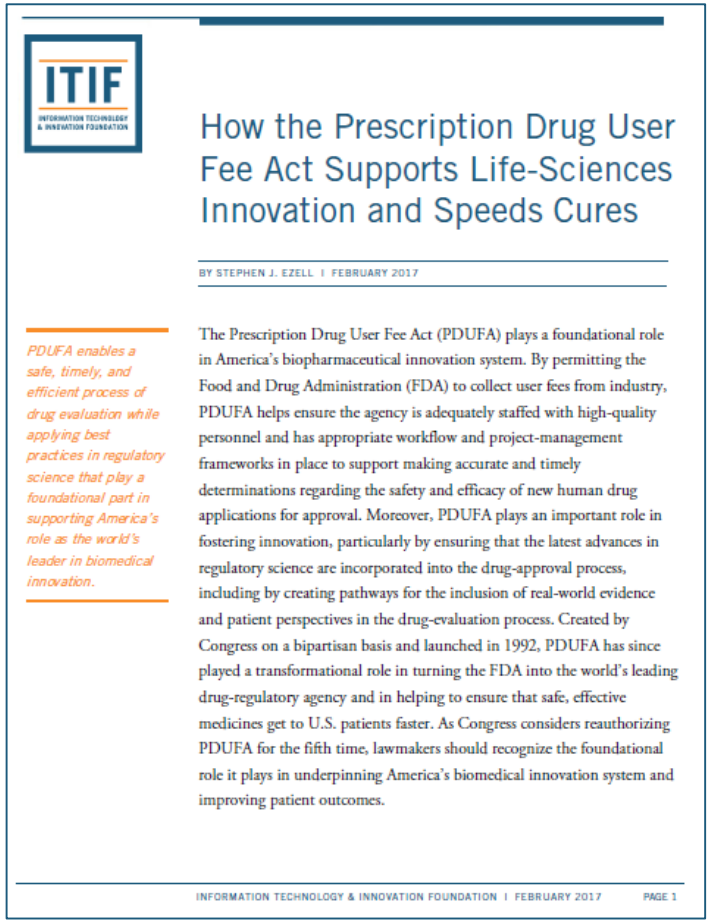
INFORMATION TECHNOLOGY & INNOVATION FOUNDATION | FEBRUARY 2016 PAGE 1

Source: ITIF, "Why Life-Sciences Innovation is Politically "Purple"-And How Partisans Get It Wrong"

Effective Regulatory Policies Make a Difference

Median Approval Times for New Medicines, Months (CDER, NME NDAs/BLAs)





ITIF
INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

How the Prescription Drug User Fee Act Supports Life-Sciences Innovation and Speeds Cures

BY STEPHEN J. EZELL | FEBRUARY 2017

PDUFA enables a safe, timely, and efficient process of drug evaluation while applying best practices in regulatory science that play a foundational part in supporting America's role as the world's leader in biomedical innovation.

The Prescription Drug User Fee Act (PDUFA) plays a foundational role in America's biopharmaceutical innovation system. By permitting the Food and Drug Administration (FDA) to collect user fees from industry, PDUFA helps ensure the agency is adequately staffed with high-quality personnel and has appropriate workflow and project-management frameworks in place to support making accurate and timely determinations regarding the safety and efficacy of new human drug applications for approval. Moreover, PDUFA plays an important role in fostering innovation, particularly by ensuring that the latest advances in regulatory science are incorporated into the drug-approval process, including by creating pathways for the inclusion of real-world evidence and patient perspectives in the drug-evaluation process. Created by Congress on a bipartisan basis and launched in 1992, PDUFA has since played a transformational role in turning the FDA into the world's leading drug-regulatory agency and in helping to ensure that safe, effective medicines get to U.S. patients faster. As Congress considers reauthorizing PDUFA for the fifth time, lawmakers should recognize the foundational role it plays in underpinning America's biomedical innovation system and improving patient outcomes.

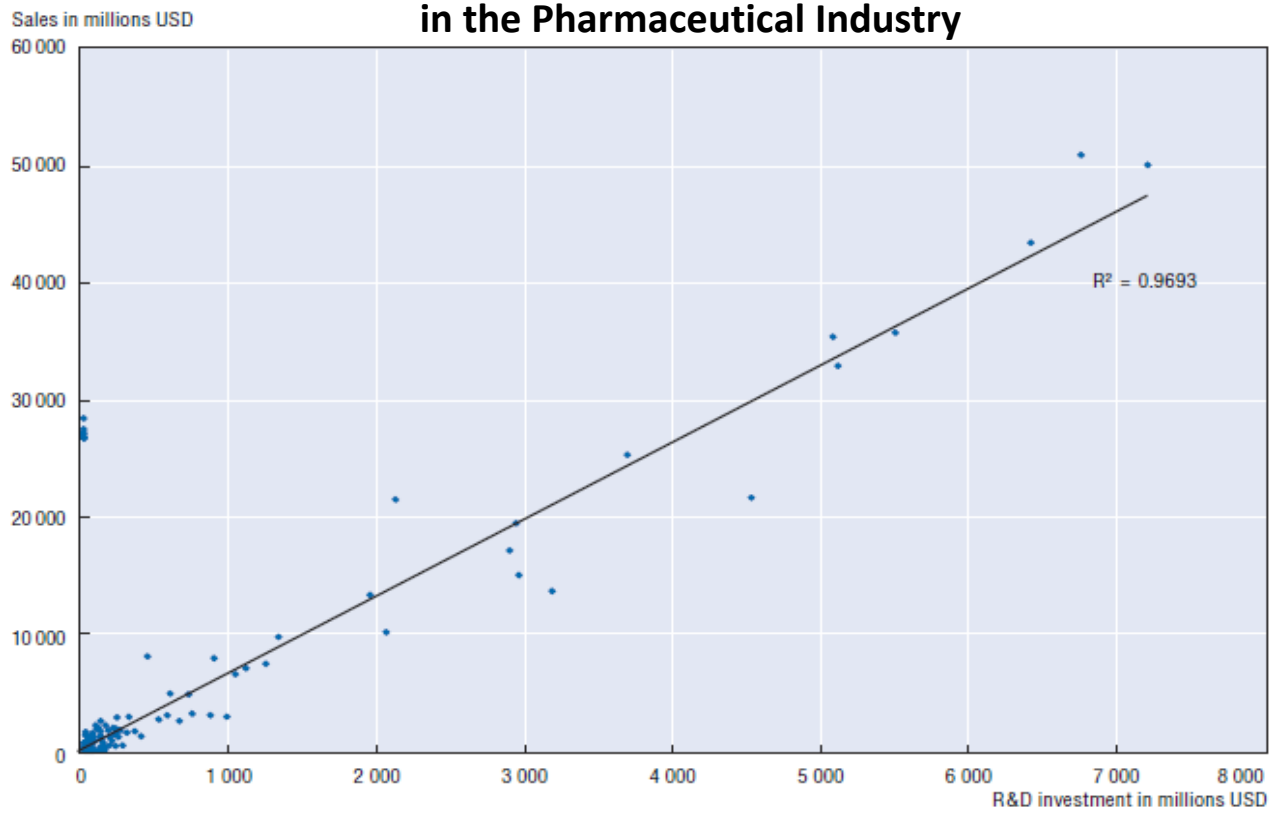
INFORMATION TECHNOLOGY & INNOVATION FOUNDATION | FEBRUARY 2017 PAGE 1

Source: Jenkins, "CDER New Drug Review: 2015 Update"; ITIF, "How the Prescription Drug User Fee Act Supports Life-Sciences Innovation and Speeds Cures"

Reasonable Prices Are Vital for Life-Sciences Innovation

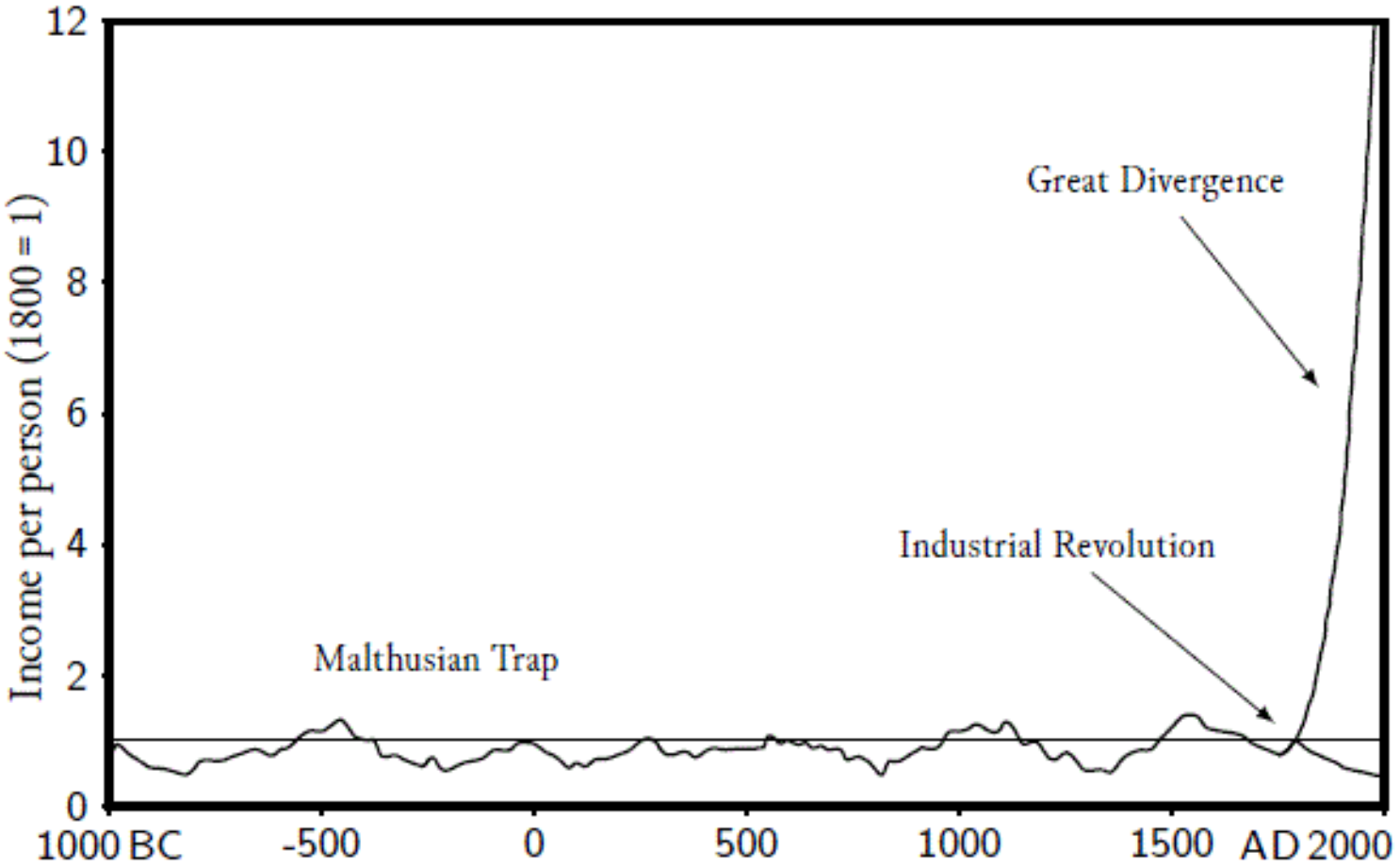
- OECD: “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.”
- A statistically significant relationship exists between a bio-pharma enterprise’s profits from the previous year and its R&D expenditures in the current year.
- A 50% drop in U.S. drug prices would result in the number of drugs in the development pipeline dropping up to 24%.

Relationship Between Sales and R&D Expenditures in the Pharmaceutical Industry



Sources: OECD, *Pharmaceutical Pricing Policies in a Global Market*; Maloney and Civan, “The Effect of Price on Pharmaceutical R&D”

Creation of IP Rights Pivotal Driver of Global Economic Growth



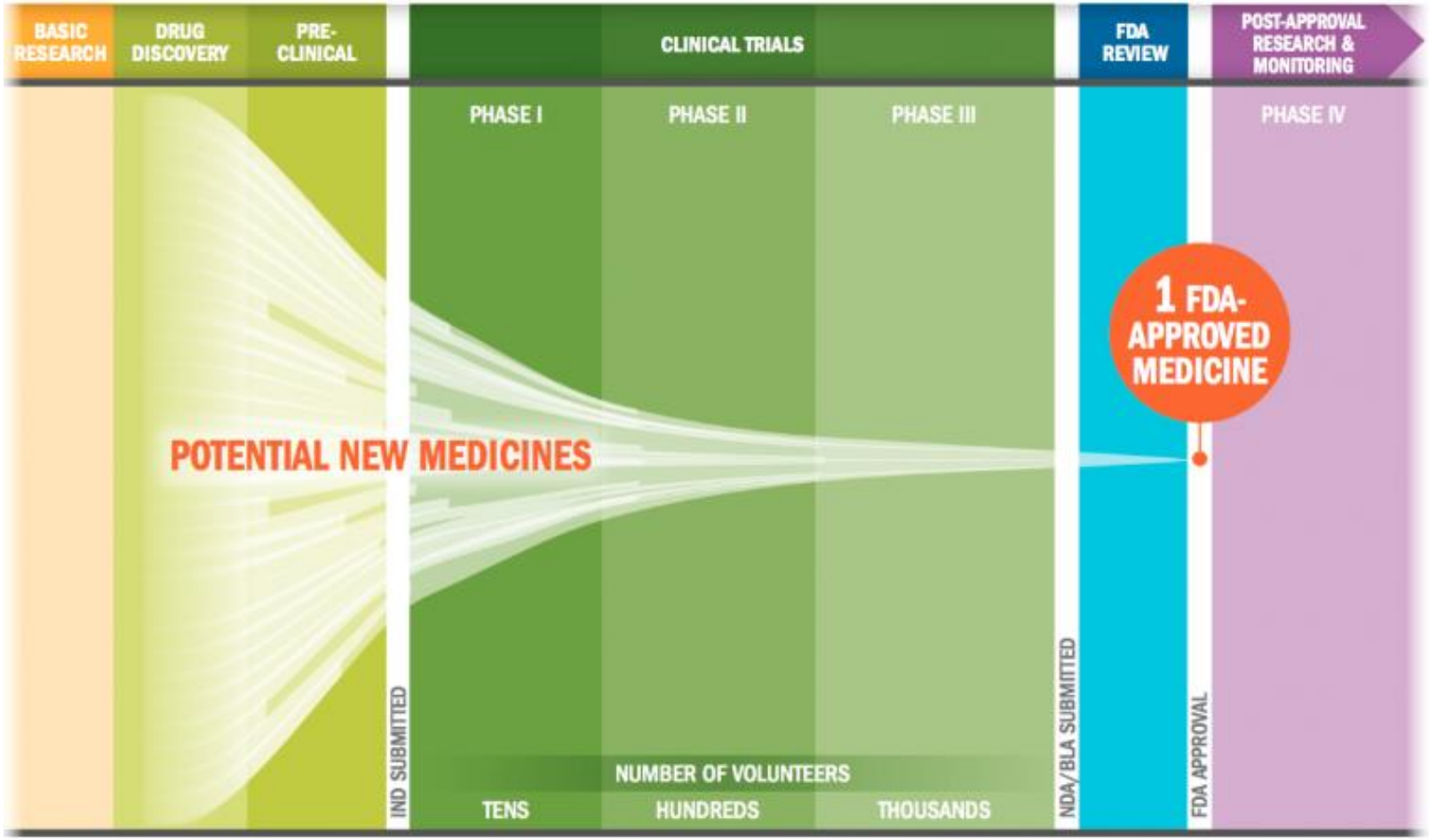
Source: Gregory Clark, *Farewell to Alms: A Brief Economic History of the World* (Princeton, N.J.: Princeton University Press, 2007); Mark Schultz

IPRs Are Vital to Innovation, As They:

1. Create incentives that empower domestic innovation.
2. Enable a virtuous cycle of innovation.
3. Induce knowledge spillovers that help others to innovate.
4. Boost domestic levels of R&D, exports, and FDI.
5. Facilitate the international diffusion of technology, innovation, and knowhow.

The Biopharmaceutical Research and Development Process

- "The average cost to develop a new drug, including the cost of failure, has increased in six out of eight years."
- "The average cost in our 2018 drug cohort rose to $2.2 billion, almost double the $1.2 billion required in 2010."



Source: PhRMA, *2015 Biopharmaceutical Research & Development* Report; Deloitte, "Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 20018"

IPRs Create Incentives for Life-Sciences Innovation Globally

Ryan: "Patents provided incentives for biomedical technology entrepreneurs to make risky investments into innovation in Brazil."

cordia verbenacea

Acheflan

World Development Vol. 38, No. 8, pp. 1082–1093, 2010
© 2010 Elsevier Ltd. All rights reserved
0305-750X/$ - see front matter

www.elsevier.com/locate/worlddev

doi:10.1016/j.worlddev.2009.12.013

Patent Incentives, Technology Markets, and Public–Private Bio-Medical Innovation Networks in Brazil

MICHAEL P. RYAN *
The George Washington University Law School, DC, USA

Summary. — Contested is whether patent laws promote indigenous technology invention and innovation in developing countries. Brazil reformed its patent laws in 1996 to permit pharmaceutical product patents. Study of five post-patent law reform bio-medical technology invention and innovation projects in the state of Sao Paulo supports the propositions that patents provide incentives to Brazilian bio-medical technology entrepreneurs to make risky investments into innovation and that patents facilitate technology markets among public–private technology innovation networks, both Brazilian collaborations and North-South collaborations. Brazil enacted a technology law in 2005 that encourages public–private technology innovation through patent incentives and patent-facilitated technology markets.
© 2010 Elsevier Ltd. All rights reserved.

Key words — technology innovation, technology networks, patents, intellectual property rights, bio-medical technology, Brazil

1. INTRODUCTION

The 1994 World Trade Organization Agreement regarding Trade-Related Intellectual Property Rights obliges all WTO members to meet certain minimum standards of intellectual property law and enforcement and this means that scores of developing countries must provide higher levels of protection than has been their policy and practice in the past. Contested is whether patent laws promote indigenous technology innovation in developing countries. Runge (2006) rejects enclosure through intellectual property protections to promote technology progress in the North and says that the countries of the South have even more to lose from patent-based enclosure. Evans (2005) calls for an open science model for technology progress in developing countries. The development model should be non-proprietary and non-intellectual property-oriented. A developing country-based scholar says that stronger intellectual property rights in countries such as her Colombia will inhibit scientific research (Forero-Pineda, 2006). She argues that developing country scientists should participate in international professional networks to achieve science and technology advancement.

Though these scholars do not provide empirical evidence to support their arguments, they do ask important questions for development studies. Research universities, scholarly journals, and science conferences are the institutions that drive scientific progress (Pyenson & Sheets-Pyenson, 1999), but are these institutions sufficient to drive national technology innovation in developing countries (or developed countries, for that matter)? Technology innovation drives long-run national economic growth (Romer, 1986, 1990). Technology stasis leads to national economic stagnation; technology progress leads to national economic growth (Grossman & Helpman, 1991), so it is important to identify the institutional frameworks that best promote national technological innovation in developing countries. Do patent laws provide incentives to entrepreneurs in developing countries to make risky investments into technology innovation? Do patent laws facilitate the development of technology markets among public–private technology innovation networks? Do patent laws facilitate North-South technology innovation collaborations?

This is a study of invention and innovation in national technology development.

> "Invention is the first occurrence of an idea for a new product or process, while innovation is the first attempt to carry it out into practice. . . . While inventions may be carried out anywhere, for example in universities, innovations occur mostly in firms, though they may also occur in other types of organizations, such as public hospitals. To be able to turn an invention into an innovation, a firm normally needs to combine several different types of knowledge, capabilities, skills, and resources" (Fagerberg, 2005, p. 4).

Post-patent law reform bio-medical technology invention and innovation in Brazil is studied here. Brazil has a long-established pharmaceutical industry, but Brazilian bio-medical R&D traditionally meant that their public and private drug-makers reverse-engineered international pharmaceuticals so that they could manufacture and market medicines and vaccines innovated in the North to the Brazilian marketplace. Brazilian pharmaceutical makers were at liberty to reverse-engineer, manufacture, and market products under patent in the United States and Europe because pharmaceutical compositions were not patentable subject matter in Brazil. But, in 1996 the Cardoso administration led the Brazilian congress to amend the patent laws with Law No. 9,279 to allow for the patentability of pharmaceutical product patents so that, subject to procedural processes and some restrictions, only patent-holders or their licensees would be permitted to market under-patent medicines.

Bio-medical technology invention and innovation in the state of Sao Paulo is the focus of study. The state of Sao Paulo is the wealthiest state of Brazil, representing some 40% of the gross domestic product of the country, and is the main scientific and business center of the country. Federal research support and "the strong support by the state government makes the state

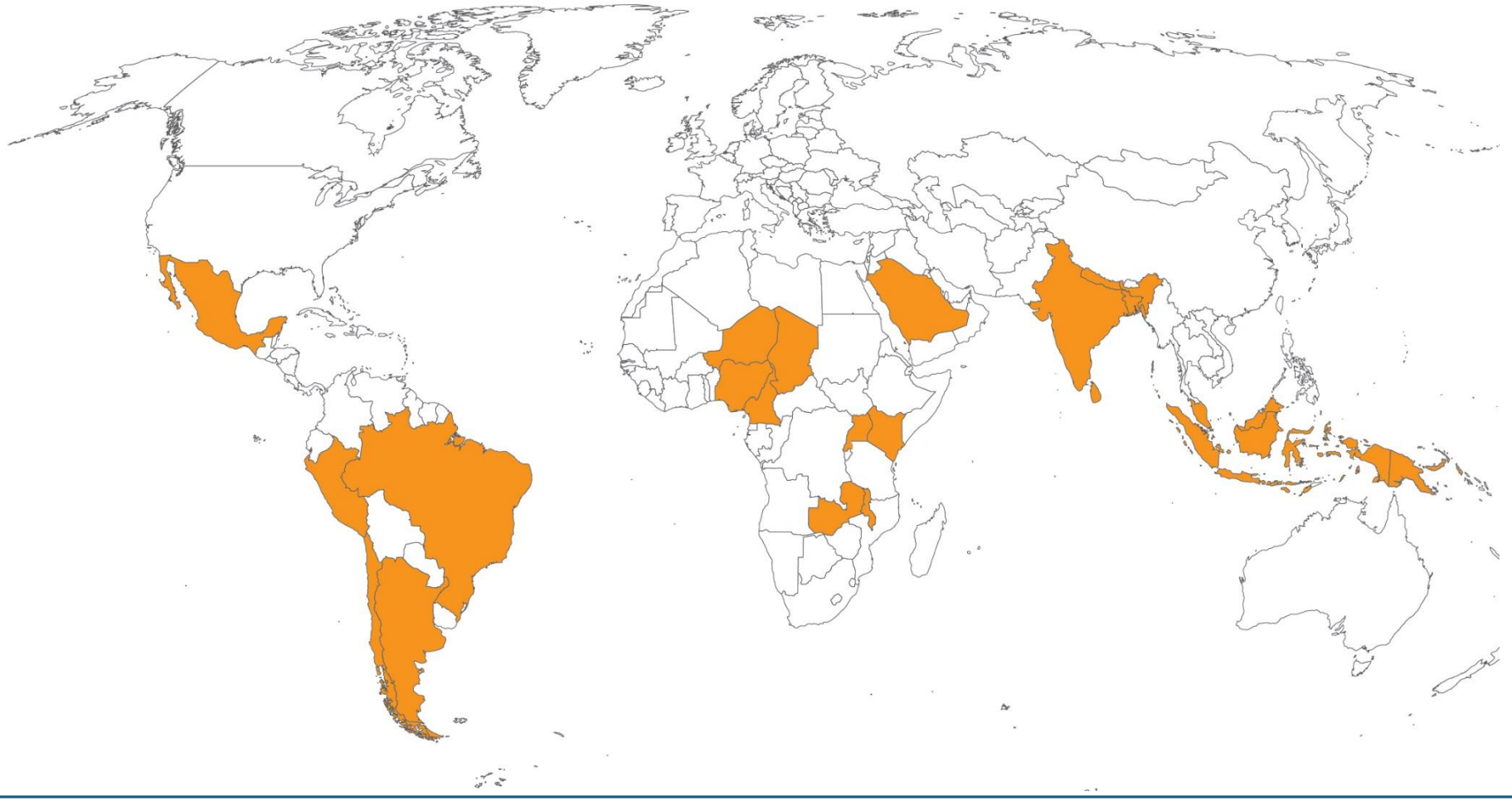
* The author gratefully acknowledges, without responsibility for arguments, University of Sao Paulo Center for Science and Technology Policy director Professor Ary Plonski and PhD student Juliano Froehner, this journal's thoughtful reviewers, and George Washington University research assistant Thomas Lee. Final revision accepted: December 7, 2009.

Source: Michael Ryan, "Patent Incentives, Technology Markets, and Public-Private Bio-Medical Innovation Networks in Brazil"

Innovate4Health Initiative

https://medium.com/innovate4health/case-studies/home

IP-driven Innovation in Healthcare is Happening Everywhere



Innovate4Health: Five Key Challenges

1. Adapting healthcare interventions for environments where resources and infrastructure are challenging;
2. Providing affordable and robust tests for diagnosing diseases;
3. Improving HIV diagnosis and care;
4. Developing affordable interventions to meet basic needs in challenging environments;
5. Getting healthcare to the people in places where access is difficult.

Source: Mark Schultz, Stephen Ezell, and David Lind, "Innovate 4 Health: How Innovators Are Solving Global Health Challenges"

Challenge: Getting Healthcare to People Where Access is Difficult

- 1 billion people lack access to essential health care.
- Global shortage of 7 million public healthcare workers, with that number expected to rise to 13 million by 2035.

Arktek: Passive Vaccine Cooler

Peek Eye Exam Kit (PEEK)

Miroculus Portable Cancer Screener

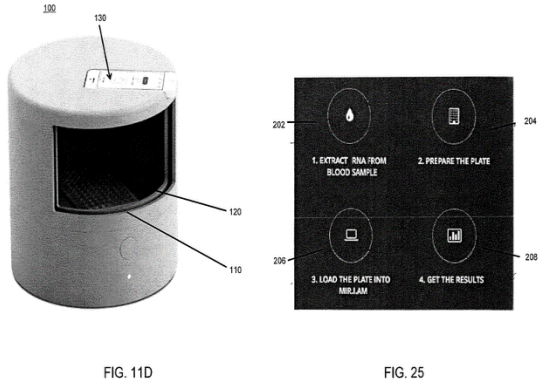


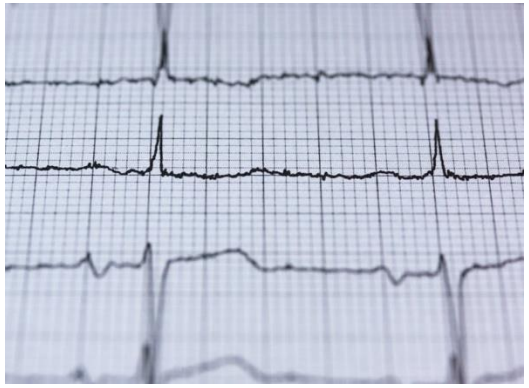
FIG. 11D FIG. 25

Source: Mark Schultz, Stephen Ezell, and David Lind, "Innovate 4 Health: How Innovators Are Solving Global Health Challenges"

Challenge: Getting Healthcare to People Where Access is Difficult

- Cardio-Pad: World's first medical tablet facilitating remote heart examinations/ diagnosis.
- Tackled lack of specialists in Cameroon while dramatically raising affordability.

Arthur Zang



"Patents enable you to protect yourself against rivals who simply want to copy your work."

Source: Mark Schultz, Stephen Ezell, and David Lind, "Innovate 4 Health: How Innovators Are Solving Global Health Challenges"

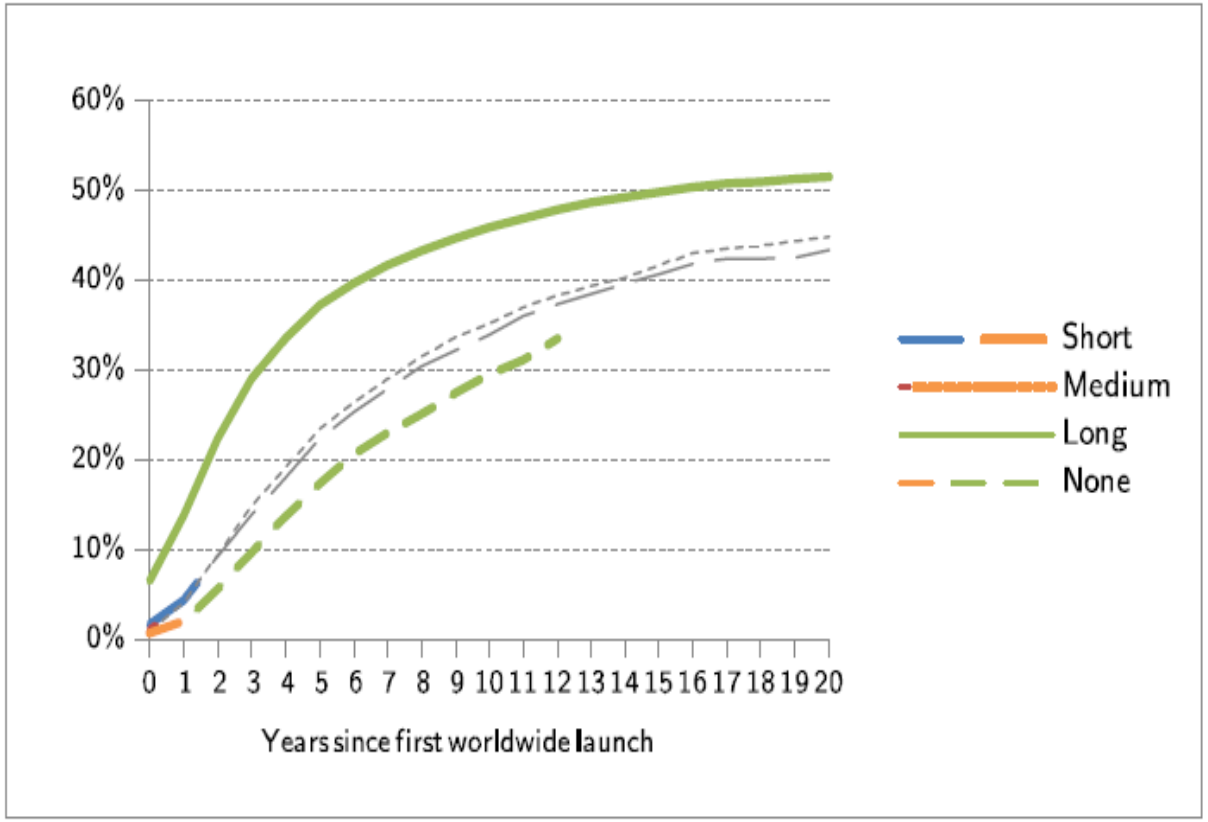
Innovate4Health

ITIF | INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

Stronger Patent Rights Encourage Drug Launches

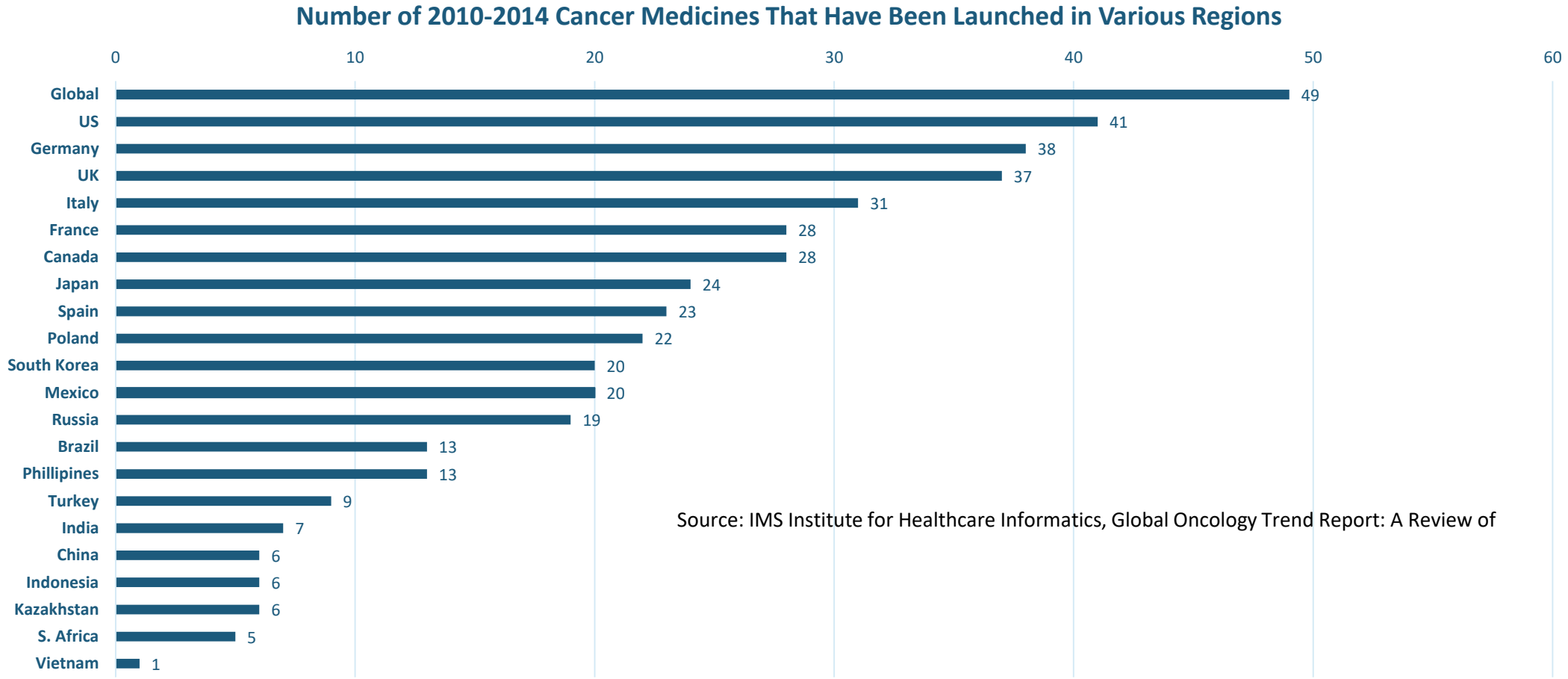
- Study of 642 new drug launches in 76 countries from 1983 to 2002.
- Finds speed/extent of diffusion strongly associated with countries' patent and price regulation schemes.
- Moving from a regime of no product patents to long product-patent terms reduces drug launch lags by 55%.

Fraction of Drugs Launched by Patent Regime



Source: Cockburn, Lanjouw, and Schankerman, "*Patents and The Global Diffusion of New Drugs, 2016*"

Regulatory Policy Significantly Affects Drug Launches

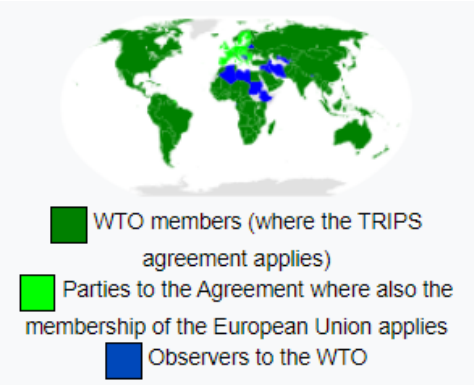


Source: IMS Institute for Healthcare Informatics, Global Oncology Trend Report: A Review of

Source: Frank Lichtenberg, *"The impact of pharmaceutical innovation on cancer mortality in Mexico, 1998-2014"* (Presentation, Mexico City, Mexico, March 30, 2017)

TRIPS and Public Health

- 1995 WTO Trade-Related Aspects of Intellectual Property Agreement (TRIPS).
- Commits members to provide 20 years of patent protection in all fields of technology, including drug patents/processes, and to protect test data.
- Countries may exclude from patentability inventions that would be damaging to human, animal, or plant life and diagnostic, therapeutic, surgical methods.
- “Bolar exemption” permits generic companies to study patents.
- Developing countries given until 2005 to comply.



Doha Declaration on the TRIPS Agreement/Public Health

- Extended until 2016 LDC TRIPS phase-in period to enact drug patenting.
- Clarified and extended TRIPS' compulsory license (CL) provisions:
  - CLs permitted in cases of extreme national emergency;
  - CLs permitted if efforts of licensees to gain access to technology on commercial terms have failed, but licensors should receive adequate renumeration;
  - CLs generally meant to supply domestic markets, but countries with generic drug capacity may issue CLs for export at the request of countries without facilities.
- Ecuador, Malaysia, Rwanda, Chile, and Peru have used or are considering CLs.

Developing Needed Medicines & Access to Medicines

Type 1 Diseases	Type 2 Diseases	Type 3 Diseases
Cardiovascular Diseases	HIV/AIDS	Malaria
Diabetes	Tuberculosis	Chagas disease
Cancers	Meningitis	River blindness
Liver ailments	Dengue fever	African sleeping sickness
Tobacco-related diseases	Hookworm	Leprosy

- The predominant market/IP-based system appears to be effective for diseases impacting large populations or conditions affecting better-off individuals.

- But market failures exist for rare/orphan diseases and neglected tropical diseases that affect smaller populations and citizens of low-income countries.

Source: Keith Maskus, *Private Rights and Public Problems: The Global Economics of Intellectual Property in the 21st Century*; World Health Organization

Developing Needed Medicines & Access to Medicines

- Product Development Partnerships (PDPs): Nonprofits convening PPPs to research and develop treatments to diseases mostly affecting developing countries.
  - Typically grant royalty-free licenses for use in low-income countries or share IP among research partners.
  - Examples: Global Alliance for Tuberculosis Drug Development, WIPO Re:Search, Drugs for Neglected Diseases Initiative (DNDI), International AIDS Vaccine Initiative.
- Advanced Market Commitments (AMCs): Guaranteed minimum purchases for new medicines/vaccines that meet predefined safety and efficacy standards.
  - Example: GAVI's pneumococcal AMC has been introduced in 57 countries, protecting 76 million children through vaccinations.

Source: Keith Maskus, *Private Rights and Public Problems;* Research America, Product Development Partnerships Factsheet

Developing Needed Medicines & Access to Medicines

- Prizes: Award prizes to first successful inventors of new drug/vaccine in exchange for IP disclosure.
- E.g., U.K. Longitude AMR Prize; ALS Prize
- Complement to or replacement for market/IP-based system?

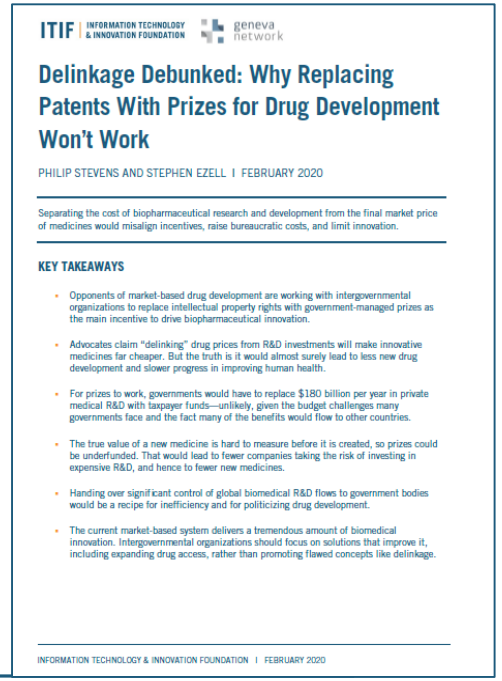
R&D Prizes

		Disease/ Research focus		Design option			Participation		Selectivity		Approach to IP rights	
		Unmet medical needs	Beyond neglected diseases	End prize	Interim prize	Open source dividend	Mandatory	Voluntary	Single (or few) winner	Multiple winners	Replaces IP	Maintains IP
Implemented	EC prizes on better use of antibiotics and vaccines	X		X				X	X			X
	UK Longitude Prize on AMR	X		X				X	X			X
	US AMR Diagnostic Challenge	X		X	X			X		X		X
	Prize4Life ALS prizes	X		X	X			X	X			X
	SUDEP institute challenge		X	X	X			X	X			X
	Archon Genomics XPRIZE		X	X				X	X			X
Proposed	Medical Innovation Prize and Prize Fund for HIV/AIDS (Sanders bills)	X	X	X	X	X	X			X	X	
	Health Impact Fund	X	X	X	X	X		X		X	X	
	TB Diagnostic Prize Fund and Chagas Prize Disease Fund	X		X	X	X		X	X		X	
	Global Health Innovation Quotient Prize	X			X			X	X			X
	HIV Prize Fund	X		X				X		X	X	

Source: IFPMA, "Charting the Course to Sustainable Innovation in Neglected Diseases Globally: An "Optimization Model" for the Use of R&D Incentives"

Developing Needed Medicines & Access to Medicines

- Global Medical R&D Treaty (MRDT): Treaty would place R&D spending obligations on all nations; intl. orgs. like WHO would direct health R&D investment.
- E.g., In 2013 WHO created a Global Observatory on R&D to monitor spending, set priorities, and undertake global health R&D demonstration projects.
- "Delinkage" proponents call for wholesale replacement of market/IP-based drug development system with MRDT & prizes approach.
- Sen. Sanders: Would create an $80 billion Medical Innovation Prize Fund.



ITIF | INFORMATION TECHNOLOGY & INNOVATION FOUNDATION geneva network

Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won't Work

PHILIP STEVENS AND STEPHEN EZELL | FEBRUARY 2020

Separating the cost of biopharmaceutical research and development from the final market price of medicines would misalign incentives, raise bureaucratic costs, and limit innovation.

KEY TAKEAWAYS

- Opponents of market-based drug development are working with intergovernmental organizations to replace intellectual property rights with government-managed prizes as the main incentive to drive biopharmaceutical innovation.
- Advocates claim "delinking" drug prices from R&D investments will make innovative medicines far cheaper. But the truth is it would almost surely lead to less new drug development and slower progress in improving human health.
- For prizes to work, governments would have to replace $180 billion per year in private medical R&D with taxpayer funds—unlikely, given the budget challenges many governments face and the fact many of the benefits would flow to other countries.
- The true value of a new medicine is hard to measure before it is created, so prizes could be underfunded. That would lead to fewer companies taking the risk of investing in expensive R&D, and hence to fewer new medicines.
- Handing over significant control of global biomedical R&D flows to government bodies would be a recipe for inefficiency and for politicizing drug development.
- The current market-based system delivers a tremendous amount of biomedical innovation. Intergovernmental organizations should focus on solutions that improve it, including expanding drug access, rather than promoting flawed concepts like delinkage.

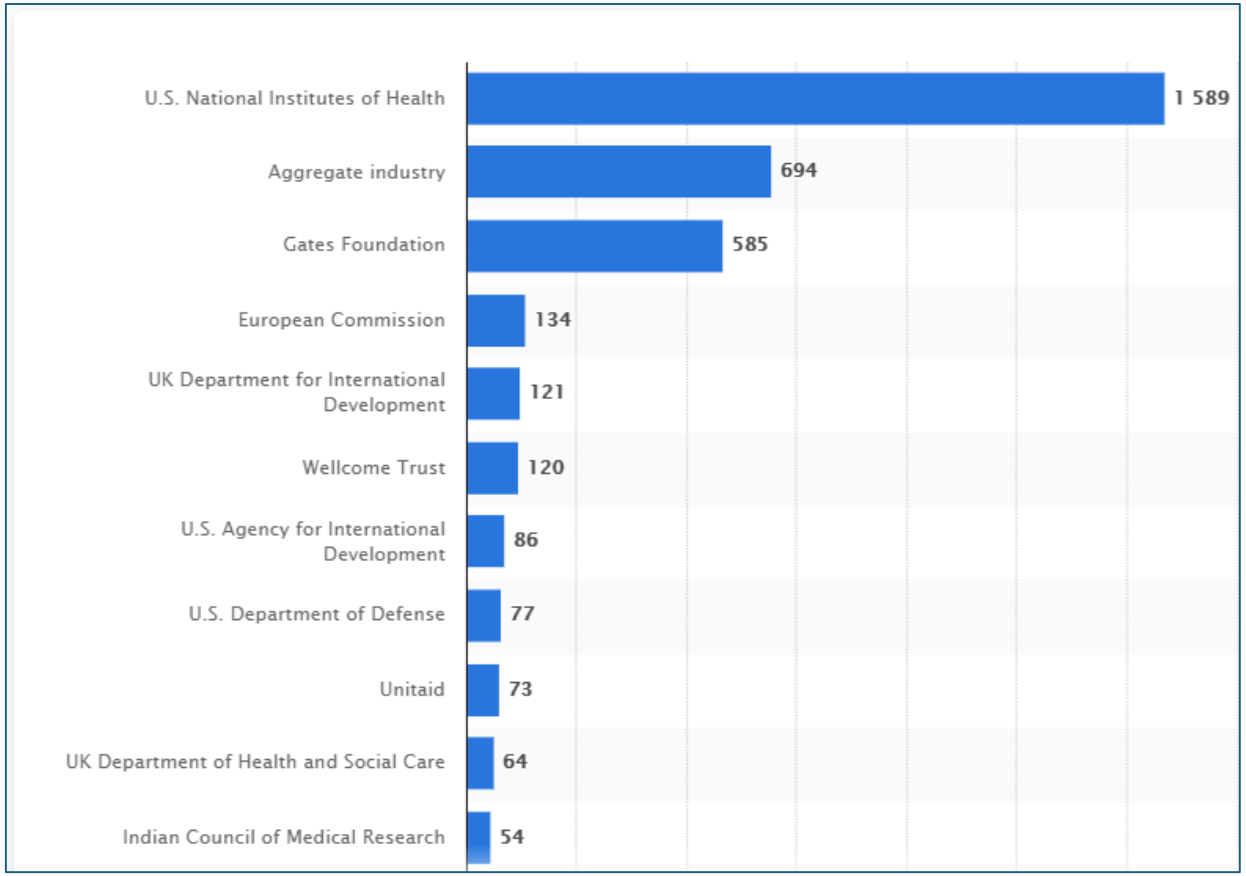
INFORMATION TECHNOLOGY & INNOVATION FOUNDATION | FEBRUARY 2020

Sources: Philip Stevens and Stephen Ezell, "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won't Work"; James Love, "Inside Views: Delinkage of R&D Costs From Product Prices"

Developing Needed Medicines & Access to Medicines

- Many governments, aid agencies, intl. orgs contributing.
- Innovative life-sciences sector actually #2 global funder of research into NTDs.

Leading Organizations Funding NTD R&D in 2018 ($ millions)



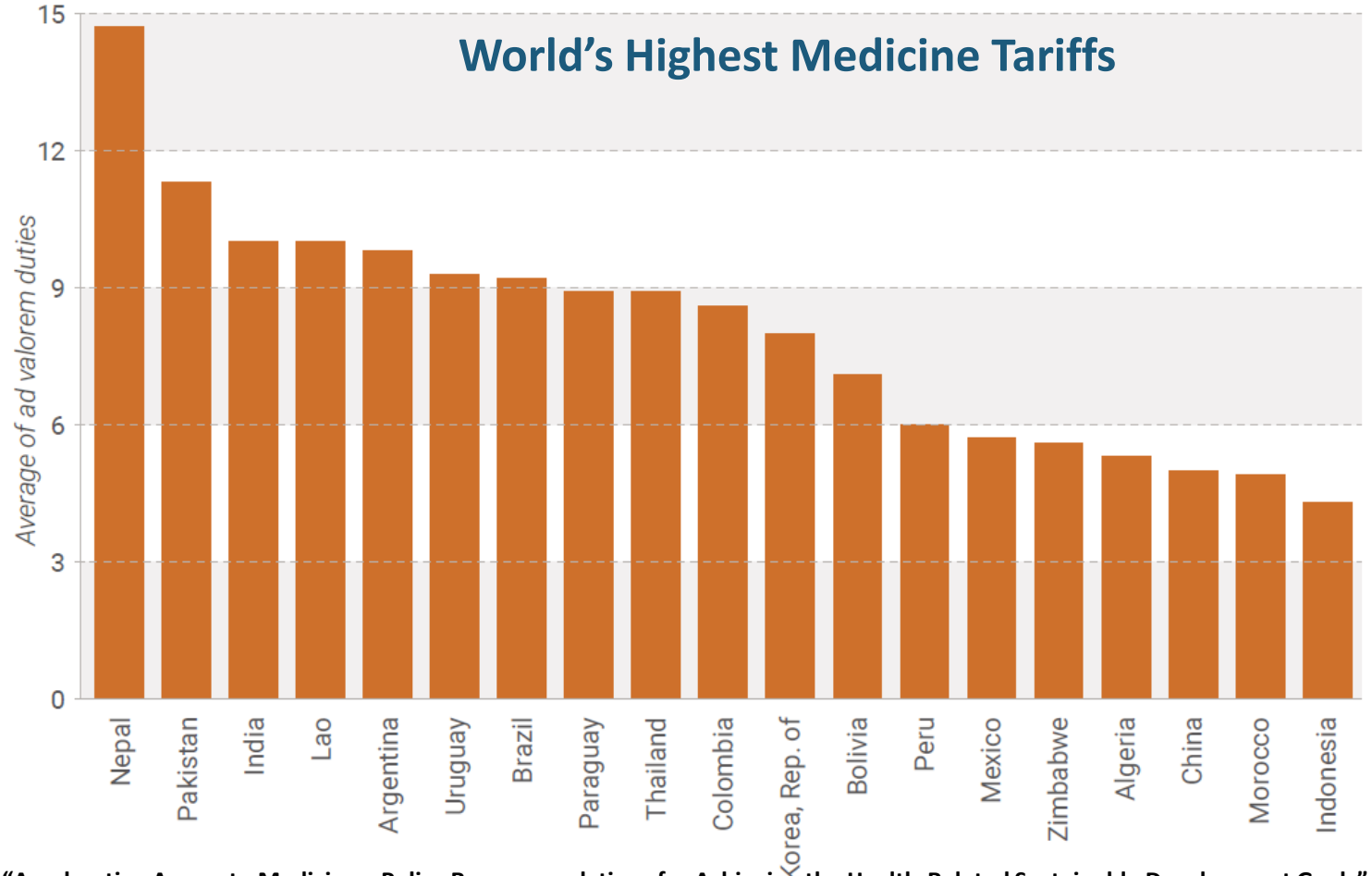
Source: Statista, "Top funders for R&D on neglected diseases by organization 2017"

Ensuring Access to Existing Medicines

- Underdeveloped healthcare systems, underinvestment in public health, lack of skilled professionals, and high taxes/tariffs impede access to medicine.
- 90% of WHO essential medicines are off patent, but available in public-sector facilities in developing countries only 40% of the time.
  - Regional availability ranged from 29% in Africa to 54% in Asia.
- When combined with VAT taxes on medicines, government-imposed levies account for an additional cost increase of: 55% in India; 40% in Sierra Leone; 34% in Nigeria; and 29% in Bangladesh.

Sources: A. Cameron et al., "Medicine Prices, Availability, and Affordability in 36 Developing and Middle-Income Countries: A Secondary Analysis"; World Health Organization, "Medicine Prices and Availability (2011)"

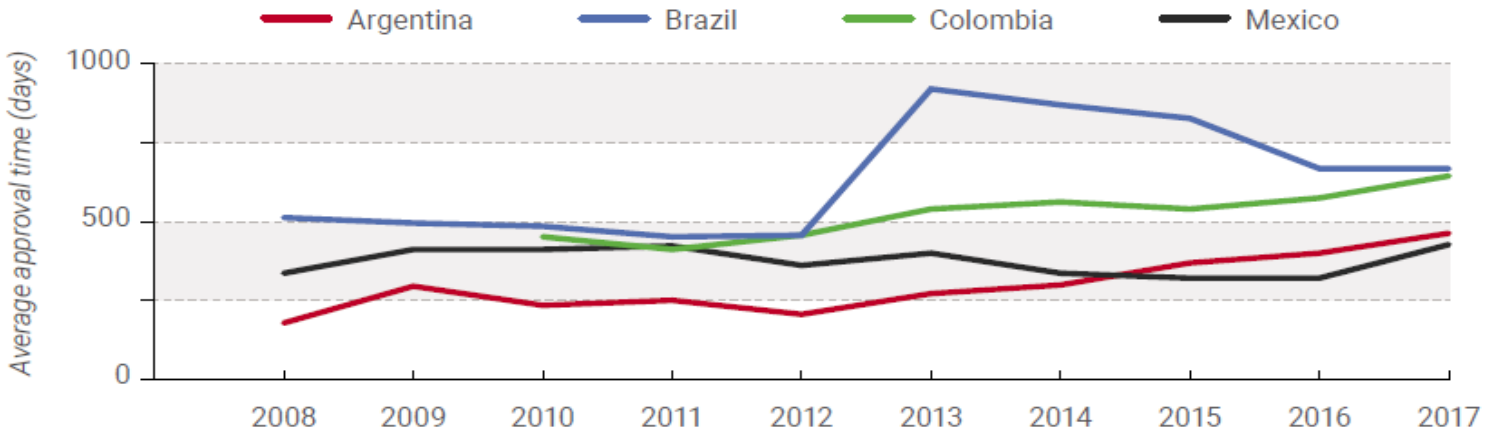
Eliminate High Tariffs on Medicines: Join “Zero for Zero”



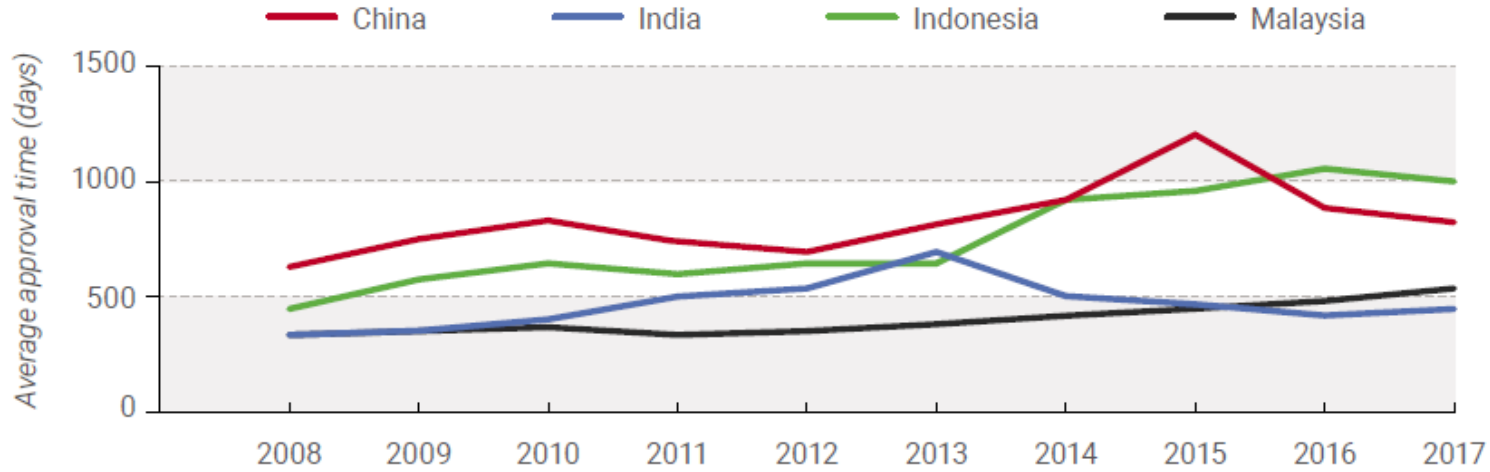
Source: Geneva Network/ITIF, “Accelerating Access to Medicines: Policy Recommendations for Achieving the Health-Related Sustainable Development Goals”

Accelerate Drug Approval Timelines

Average Drug Approval Time, Latin America



Average Drug Approval Time, Asia



Source: Geneva Network/ITIF, "Accelerating Access to Medicines: Policy Recommendations for Achieving the Health-Related Sustainable Development Goals"

IPRs and the Price of Medicines

- Dutta estimated TRIPS introduction would increase price of medicines 18% in India, with effects on various drugs ranging from 3.5 to 80%.*
- Duggan et al. assessed 6,000+ products consisting of 1,000+ molecules in India.**
- Estimates molecules receiving patents saw average price increase of just 3–6 percent.

"Our results demonstrate that the implementation of product patents for India did not cause either the large increases in pharmaceutical prices or the dramatic consolidation of the market that some predicted prior to its enactment."

The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India†

By Mark Duggan, Craig Garthwaite, and Aparajita Goyal*

In 2005, as the result of a World Trade Organization mandate, India implemented a patent reform for pharmaceuticals that was intended to comply with the 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS). Exploiting variation in the timing of patent decisions, we estimate that a molecule receiving a patent experienced an average price increase of just 3–6 percent, with larger increases for more recently developed molecules and for those produced by just one firm when the patent system began. Our results also show little impact on quantities sold or on the number of pharmaceutical firms operating in the market. (JEL K33, L11, L13, L65, O14, O34, O38)

Intellectual property (IP) protection for pharmaceuticals in the developing world is a heavily discussed issue. The debate has only grown more contentious as many formerly poor countries have experienced rapid economic growth and now represent potentially profitable markets for foreign pharmaceutical firms. Partly because of the growing importance of developing countries as consumers for many products, in 1994 all members of the World Trade Organization were required to adopt the Trade Related Intellectual Property Standards (TRIPS). TRIPS was intended to establish uniform IP standards across countries including a product patent system for pharmaceuticals. Many developing countries were given ten years to implement a TRIPS-compliant regime and have only recently created these systems. As a result, little is known about the effects of these policies in developing countries. In this paper, we

*Duggan: Department of Economics, Stanford University, 579 Serra Mall, Stanford, CA 94305, and NBER (e-mail: mgduggan@stanford.edu); Garthwaite: Kellogg School of Management, Northwestern University, 2001 Sheridan Road, Evanston, IL 60208, and NBER (e-mail: c-garthwaite@kellogg.northwestern.edu); Goyal: The World Bank, 1818 H Street, NW, Washington, DC 20433 (e-mail: agoyal3@worldbank.org). We are grateful to Preethi Rao for excellent research assistance and to Jen Brown, Meghan Busse, Leemore Dafny, Pascaline Dupas, Amy Finkelstein, Margaret Kyle, Grant Miller, Neale Mahoney, Petra Moser, Matt Notowidigdo, Emily Oster, Bhaven Sampat, Heidi Williams, seminar participants at Northwestern University, the Bates White Life Sciences Conference and the 60th Anniversary Congress of the Yrjö Jahnsson Foundation for helpful comments. Duggan thanks the Dean's Research Fund and the Global Initiatives Fund at the Wharton School for support of this research and Goyal thanks the DECRG Research Support Budget grant of the World Bank. We also thank Bhaven Sampat for providing data on patent strength for a sample of products in the Indian market. The views expressed in this paper are solely those of the authors and do not represent the views of any of the institutions mentioned above. The statements, findings, conclusions, views, and opinions contained and expressed in this article are based in part on data obtained under license from IMS Health Incorporated and MIDAS™ (2003–2011). All rights reserved. The statements, findings, conclusions, views, and opinions contained and expressed herein are not necessarily those of IMS Health Incorporated or any of its affiliated or subsidiary entities.

†Go to http://dx.doi.org/10.1257/aer.20141301 to visit the article page for additional materials and author disclosure statement(s).

99

Sources: *A. Dutta, "Intellectual Property Rights and Innovation in Developing Countries, Evidence From India" (2008)
**** Duggan, Grathwaite, and Goyal, *The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India***

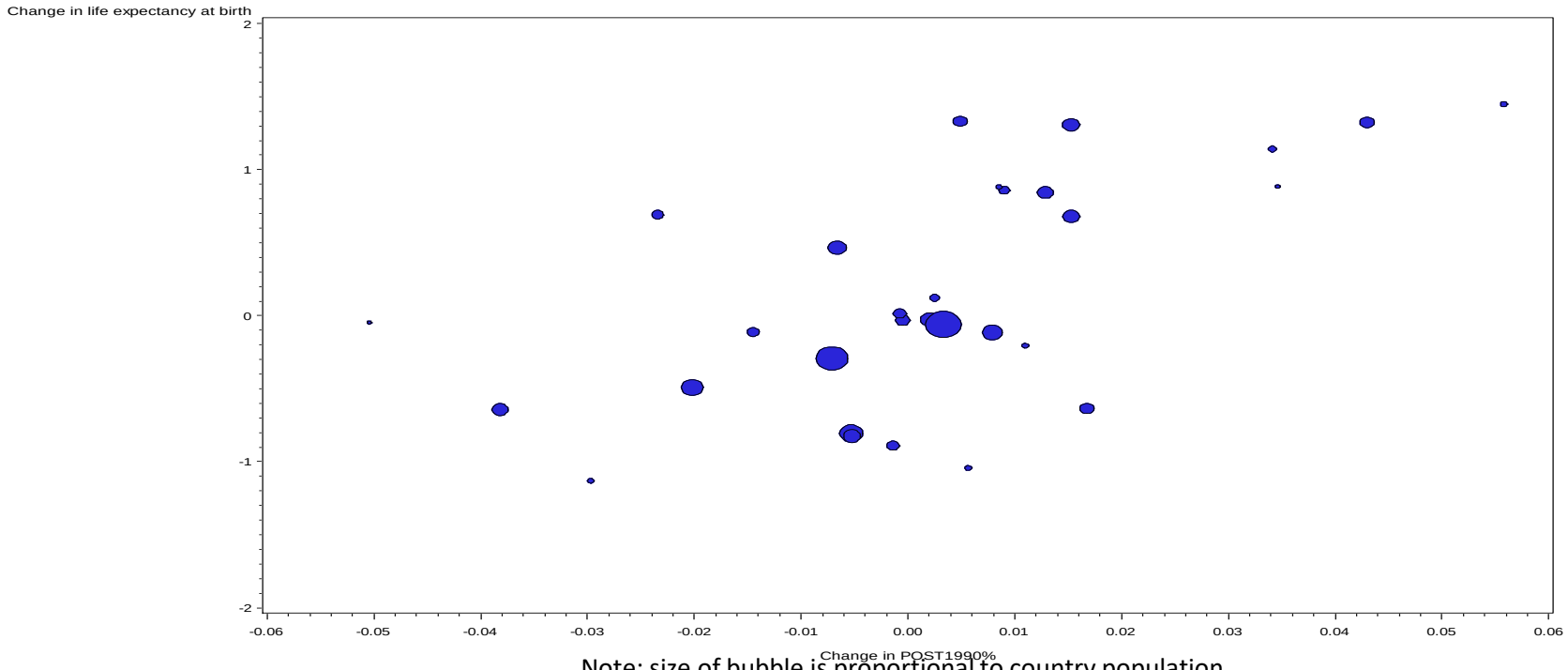
Keys to Developing-Country Life-Sciences Innovation Leadership

1. Leverage country's unique strengths for biomedical innovation.
2. Recognize there are many opportunities to make value-added contributions throughout the drug development process (e.g., clinical trials).
3. Invest in and incentivize biomedical research.
4. Turn universities into engines of innovation.
5. Align drug approval system between safety administration/public heath system.

Conclusion: Why Life-Sciences Innovation Matters

Correlation across countries between 2000-2009 change in life expectancy at birth and change in drug vintage

controlling for changes in income, unemployment rate, education, urbanization, health expenditure, immunization rate, HIV prevalence and tuberculosis incidence



Note: size of bubble is proportional to country population.

Pharmaceutical innovation accounted for 73% of the 2000-2009 increase in life expectancy at birth in 30 countries (1.27 years of the 1.73 year increase).

Source: Frank Lichtenberg, *Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009 Health Policy and Technology* 3(1), March 2014

Conclusion: Why Life-Sciences Innovation Matters

- Helping citizens live longer, healthier lives generates economic benefits.
  - Increase in U.S. life expectancy added $2.8 trillion to U.S. economy, 1970-1990.
  - Tuberculosis and malaria cost worst-hit African countries up to 8% GDP annually.
- Opportunity cost of missing work (especially for chronic diseases).
  - 40% of Mexicans applying to work in auto sector *aren't physically able to do so*.
  - Poor health in working-age adults costs countries (avg.) 7.4% of GDP annually.
- Eliminating heart disease valued at $48 trillion, curing cancer $47 trillion; Alzheimer's disease will cost $1 trillion annually by 2050.

Thank You

Stephen Ezell | sezell@itif.org | 202.465.2984