International Organization
for Chemical sciences
in Development

I O C D

Imperial College
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Chemical Sciences for Development: Potential and Prospects

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- Head of Strategic Development, IOCD

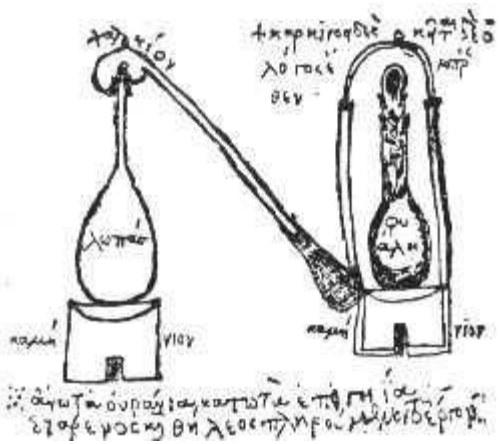
INRS-EMT, University of Quebec, 22 July 2014

Chemical Sciences for Development: Potential and Prospects

1. **The chemical sciences have been good for development (wealth and health) [up to a point, for some]**

2. **International Organization for Chemical Sciences in Development**

3. **Chemical sciences for development: Challenges and potential**

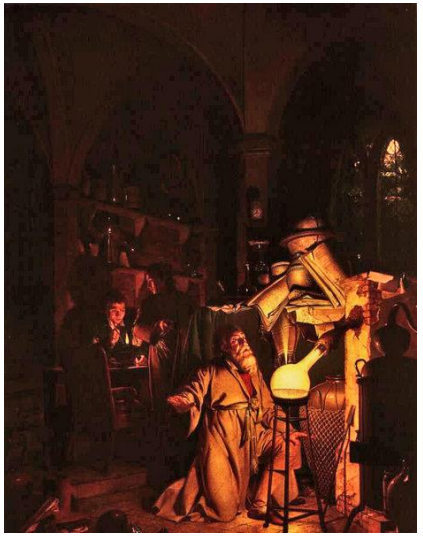


Ambix, cucurbit and retort of Zosimos,
from Marcelin Berthelot,
Collection des anciens alchimistes grecs
(Paris, 1887-1888)

Philosopher's Stone **for metals**

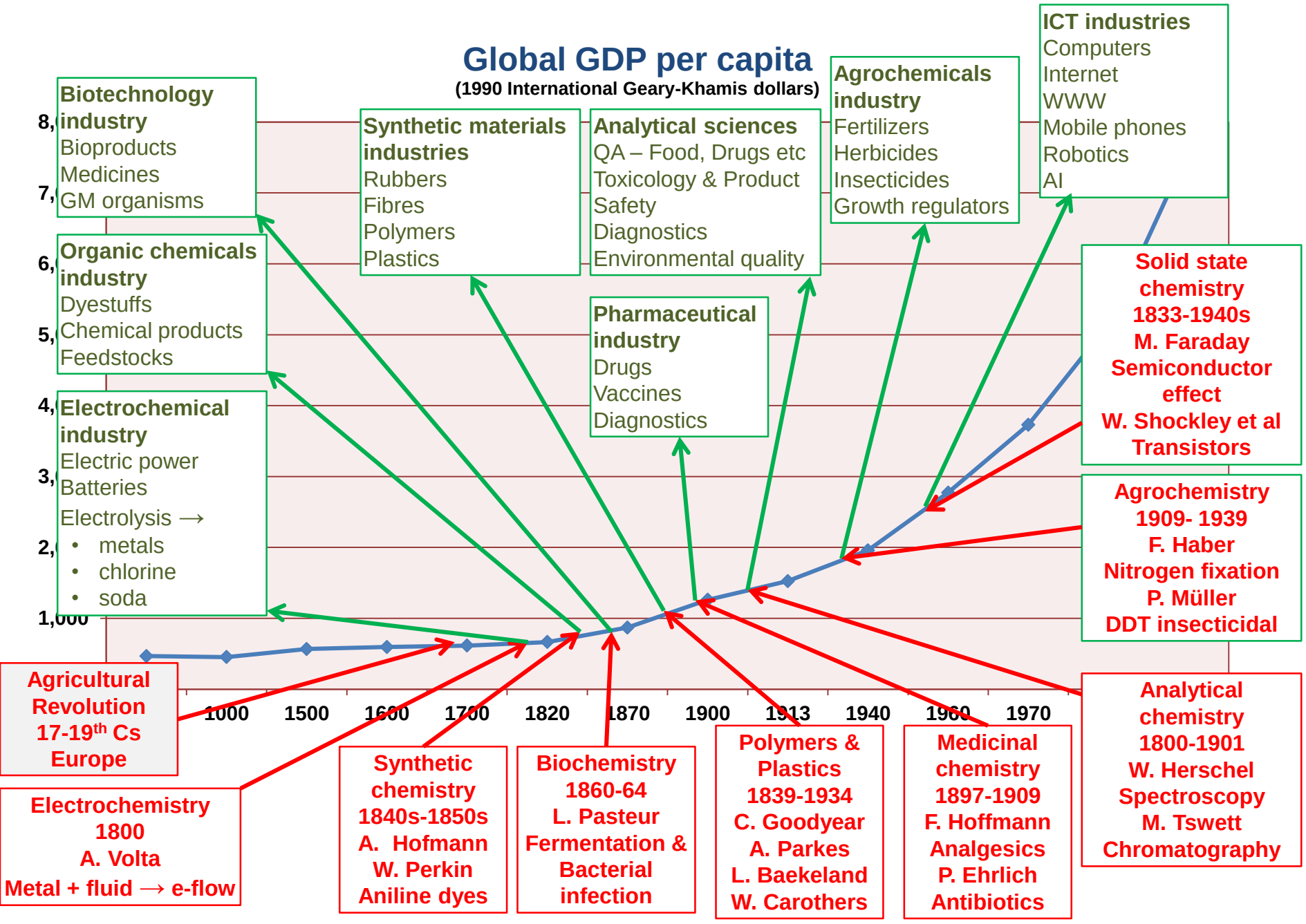
Alchemy

Elixir of Life **for humans**



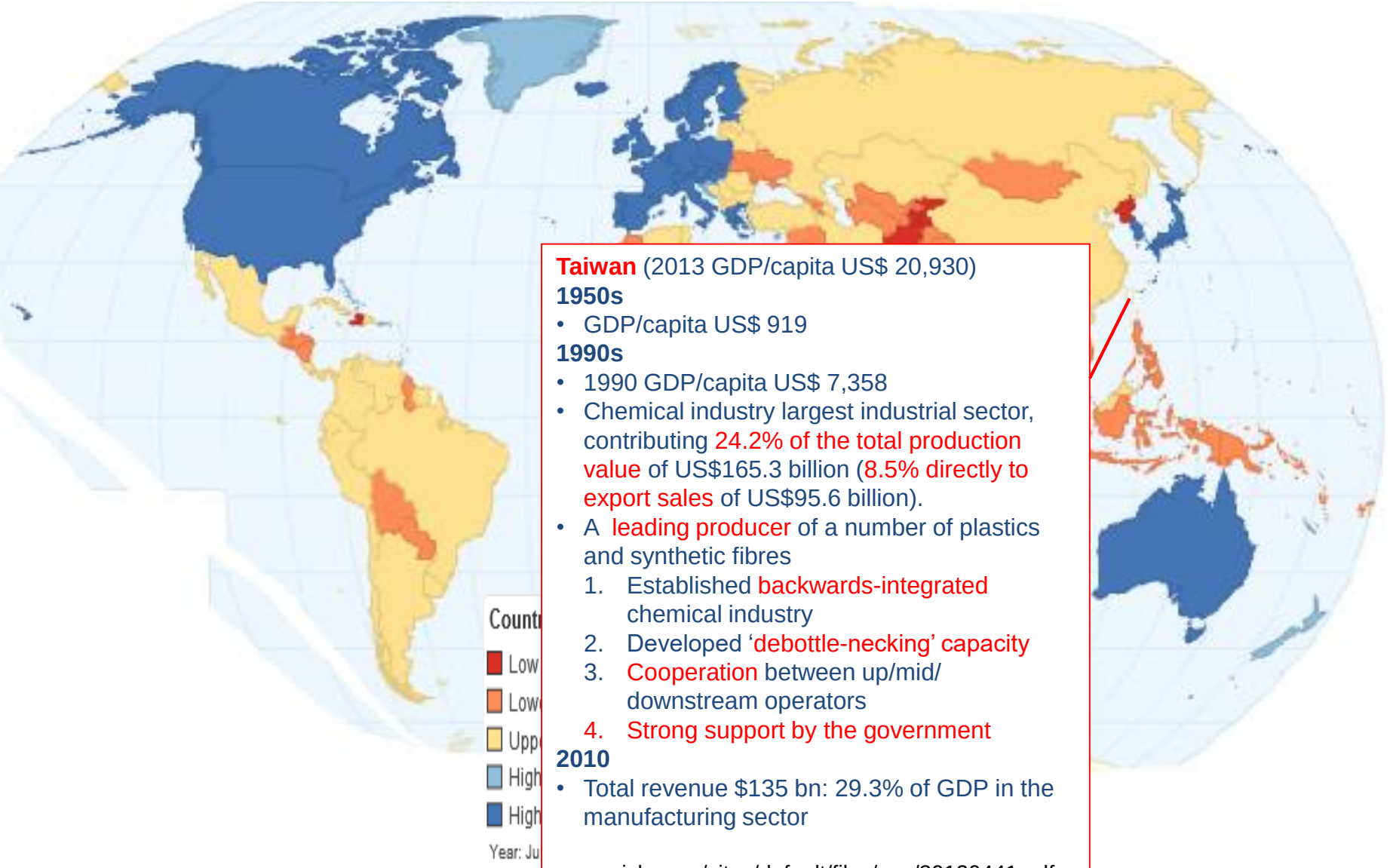
Painting by Joseph Wright of Derby, 1771:
Attempt to distil a substance to transmute lead into gold (discovery of white phosphorus)

Black Powder: S, C, KNO_3 probably invented by Chinese alchemists searching for *Elixir of Life*



GDP data from: A. Maddison, Statistics on World Population, GDP and Per Capita GDP, 1-2008 AD. www.ggdc.net/MADDISON/oriindex.htm

Country Income Groups (GDP/capita) 2011 (World Bank Classification)



Taiwan (2013 GDP/capita US$ 20,930)

1950s

- GDP/capita US$ 919

1990s

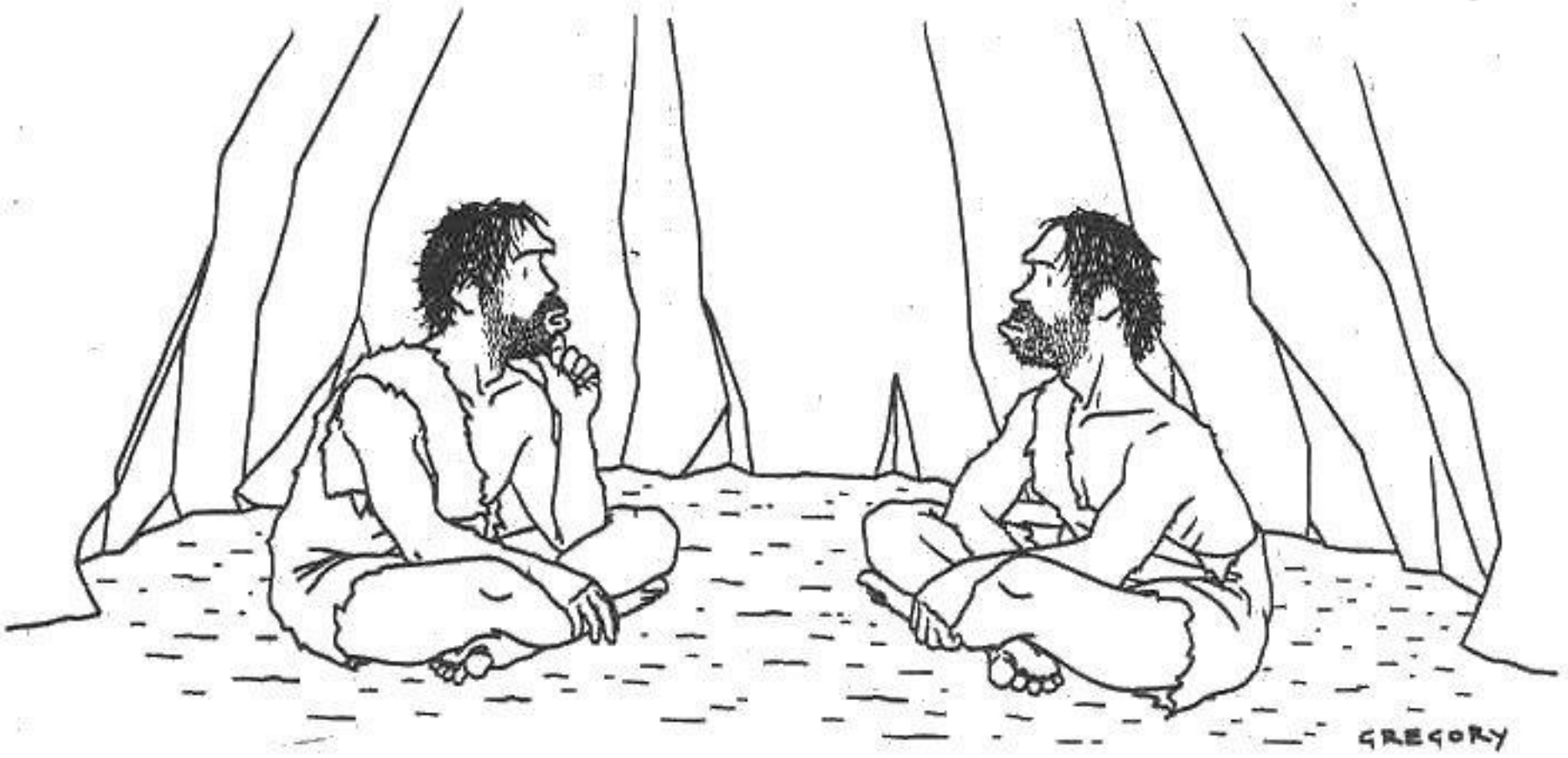
- 1990 GDP/capita US$ 7,358
- Chemical industry largest industrial sector, contributing 24.2% of the total production value of US$165.3 billion (8.5% directly to export sales of US$95.6 billion).
- A leading producer of a number of plastics and synthetic fibres
  1. Established backwards-integrated chemical industry
  2. Developed 'debottle-necking' capacity
  3. Cooperation between up/mid/ downstream operators
  4. Strong support by the government

2010

- Total revenue $135 bn: 29.3% of GDP in the manufacturing sector

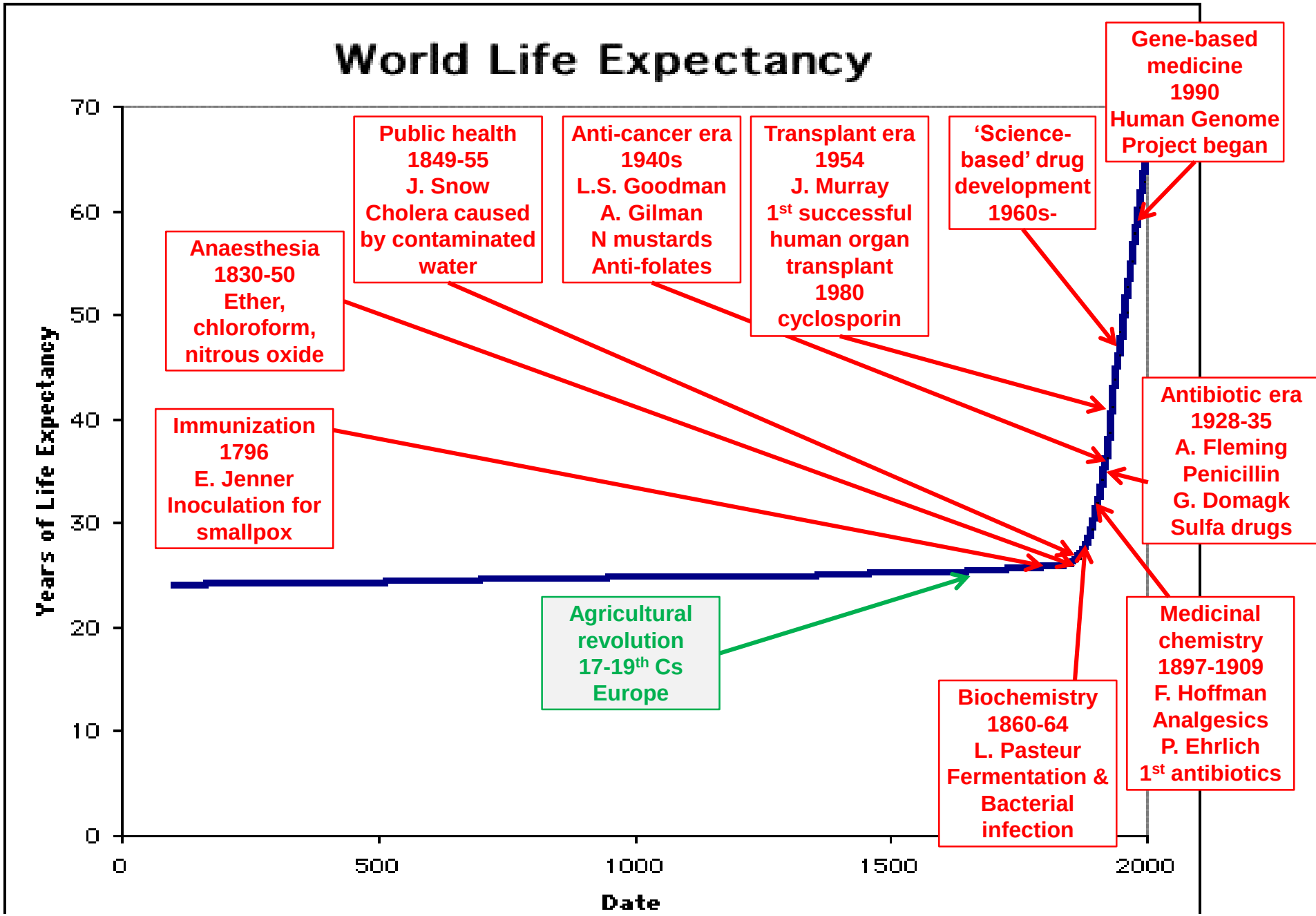
www.aiche.org/sites/default/files/cep/20120441.pdf

http://chartsbin.com/view/2438



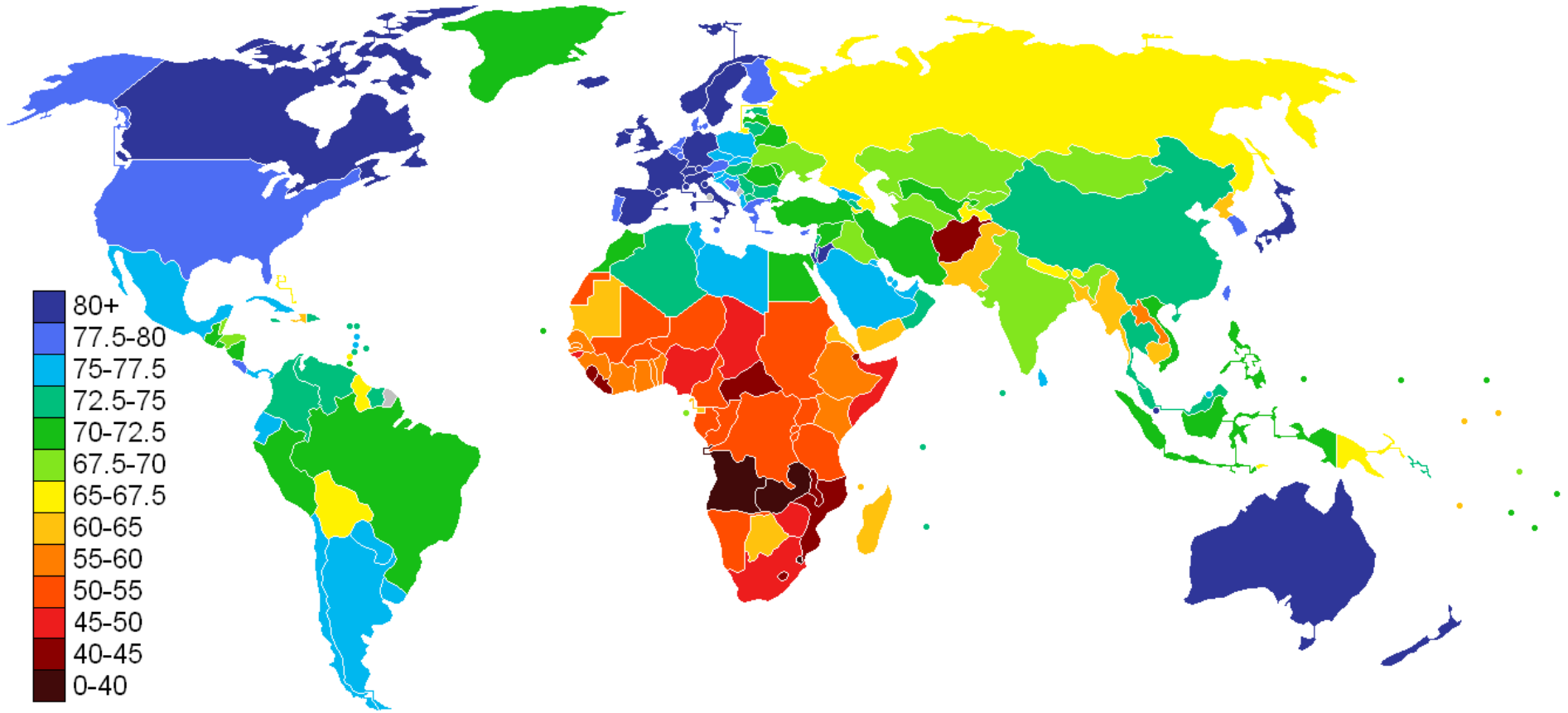
Something's just not right -- our air is clean, our water is pure, we all get plenty of exercise, everything we eat is organic and free-range, and yet nobody lives past thirty.

New Yorker, 2006 and thanks to R Terry, WHO

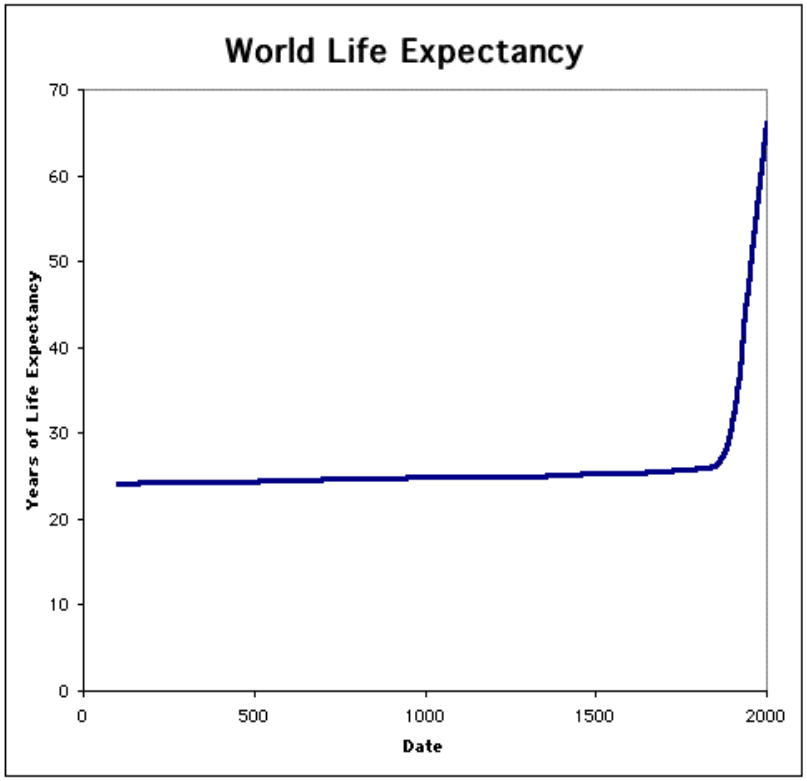


Life expectancy graph from:
www.j-bradford-delong.net/movable_type/images2/Life_Expect_Long.gif

Life Expectancy at Birth by Country: 2011 Estimates

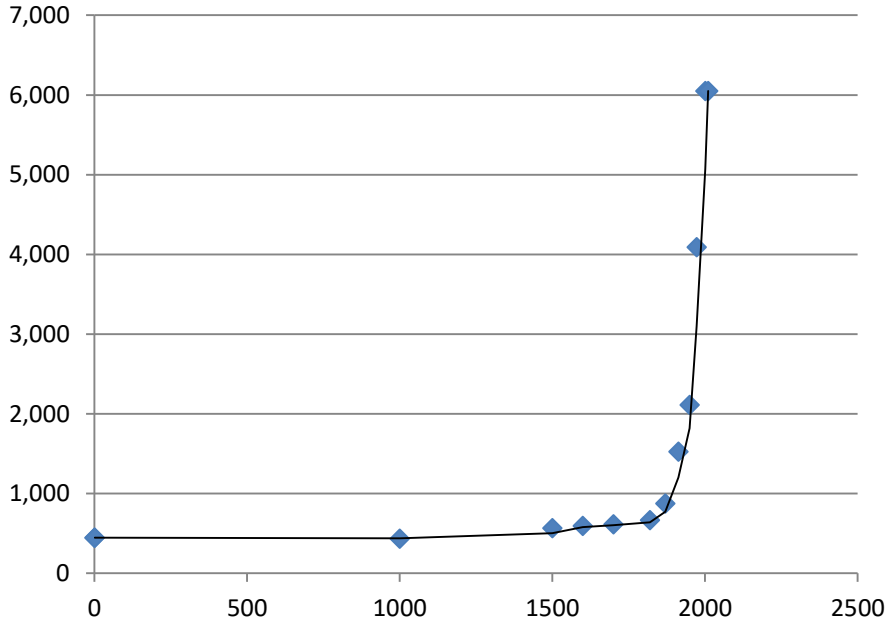


CIA World Factbook 2011; http://en.wikipedia.org/wiki/Life_expectancy



Global GDP per capita

(1990 international Geary-Khamis dollars)



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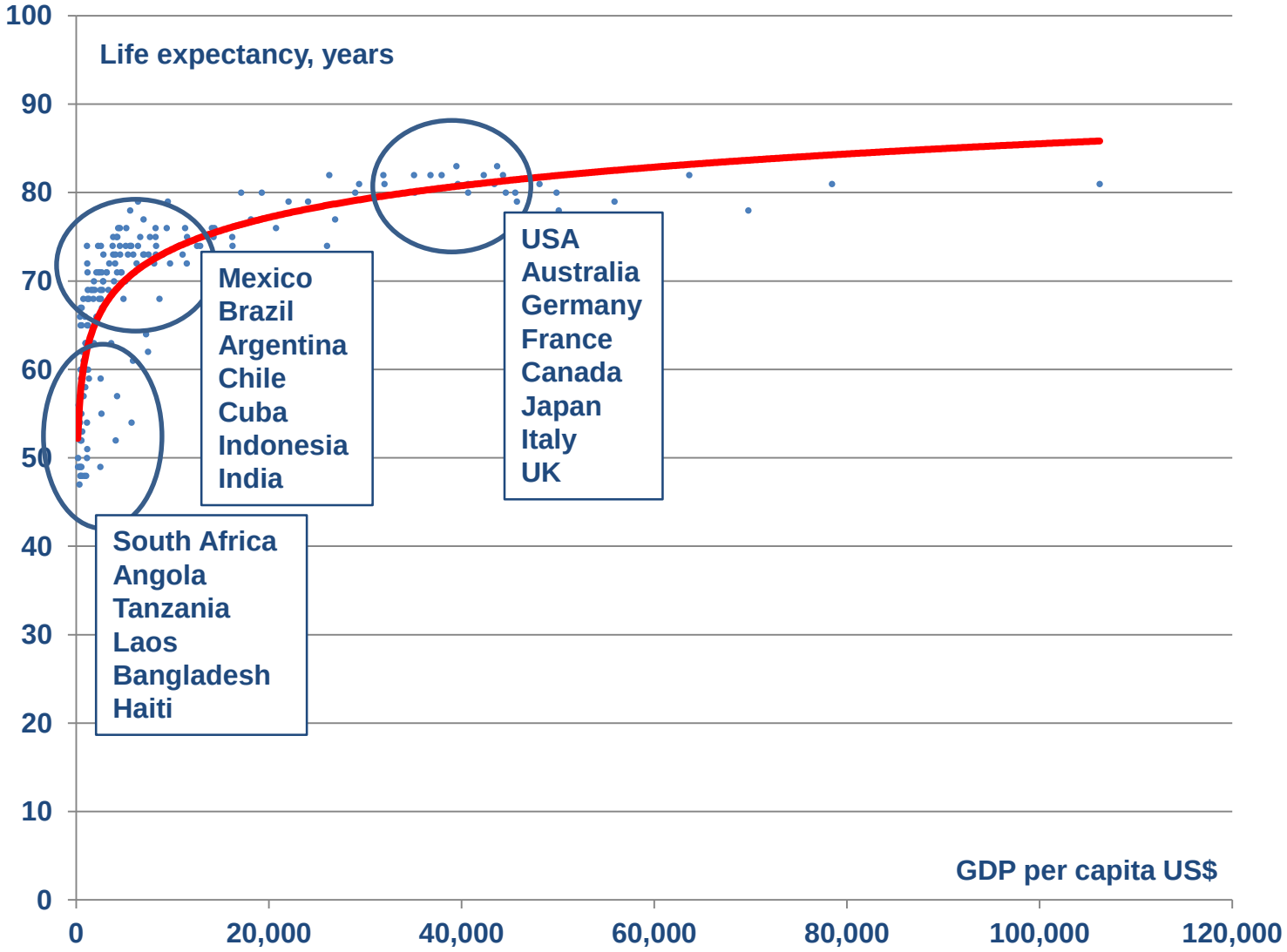
GDP data from:
A. Maddison, Statistics on World Population, GDP and Per Capita GDP, 1-2001 AD. www.ggdc.net/MADDISON/oriindex.htm

How much health do you get for your wealth?

Preston curve: Life expectancy vs GDP per capita 2009

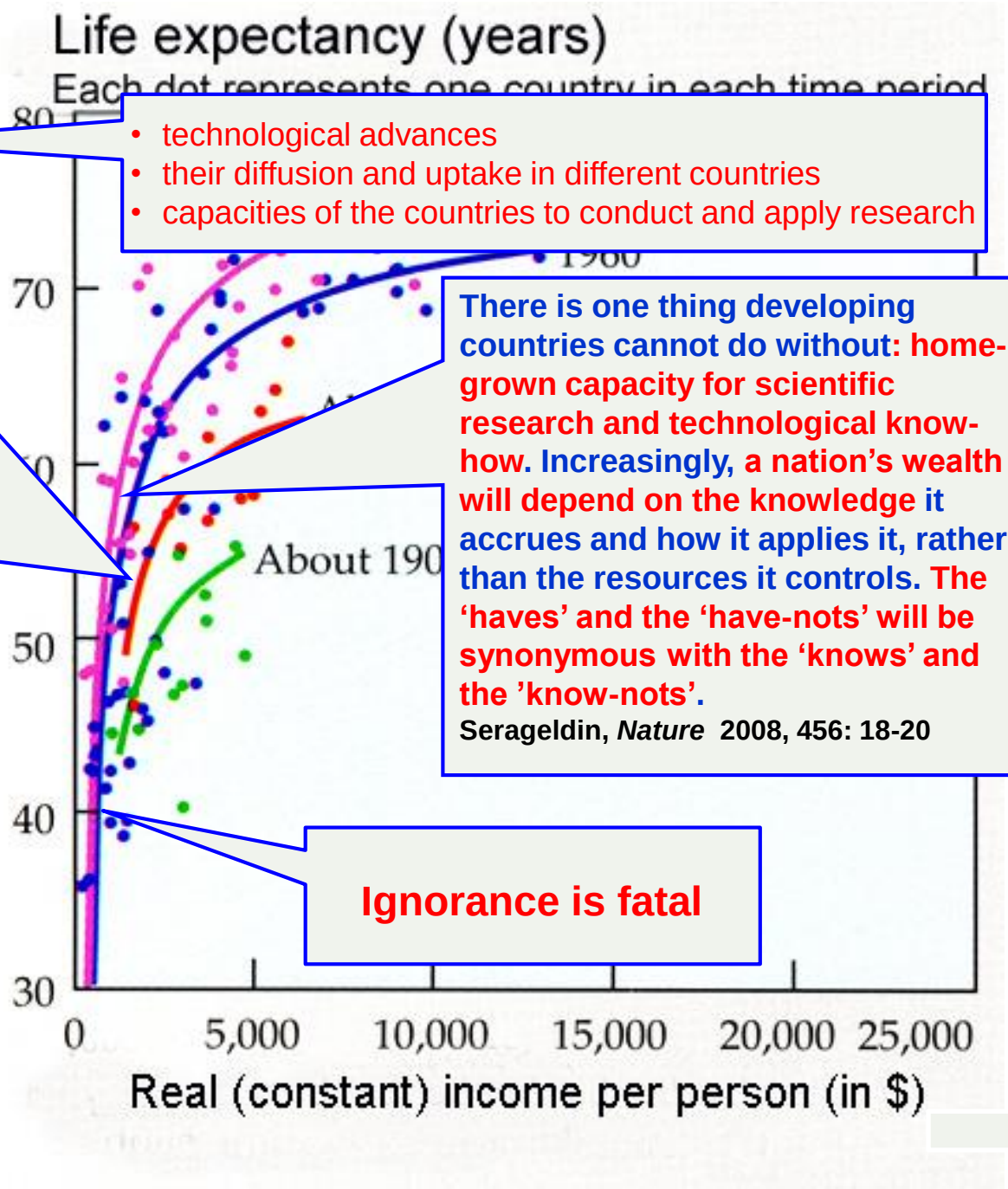


Matlin, *Research for health,* in: *Health G20: A briefing on Health Issues for G20 Leaders,* ProBrook, London, 2011, 116-128.

Preston curves 1900-1990

- **20th century mortality decline had its origin in technical progress**
  Easterlin, *European Review of Economic History 1999*, 3: 257–94

- **Much of the variation in country outcomes results from very substantial cross-country variation in the rate of technical progress**
  Jamison, *Disease Control Priorities in Developing Countries (DCP2), World Bank 2006*



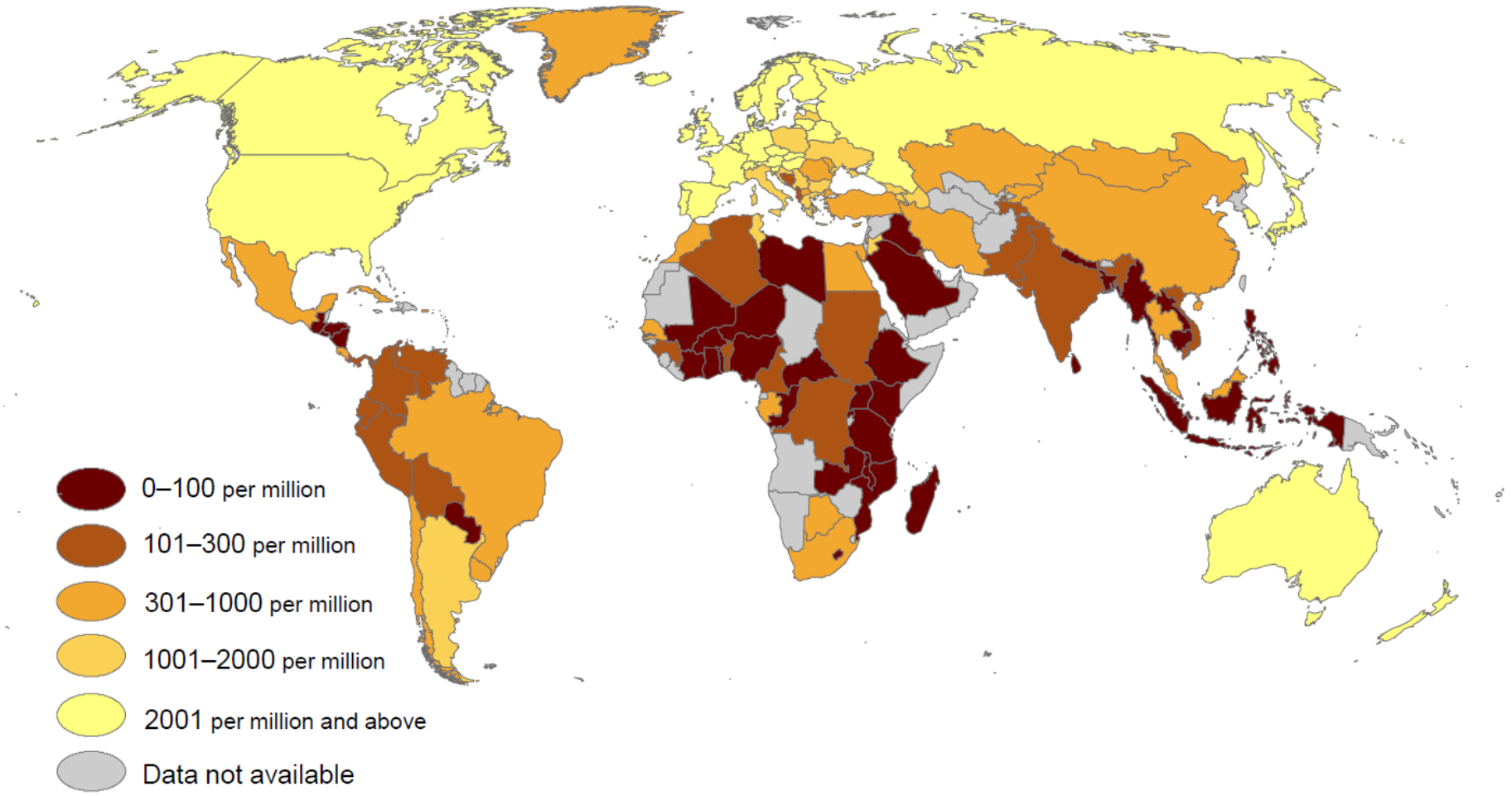
- technological advances
- their diffusion and uptake in different countries
- capacities of the countries to conduct and apply research

There is one thing developing countries cannot do without: home-grown capacity for scientific research and technological know-how. Increasingly, a nation's wealth will depend on the knowledge it accrues and how it applies it, rather than the resources it controls. The 'haves' and the 'have-nots' will be synonymous with the 'knows' and the 'know-nots'.
Serageldin, *Nature* 2008, 456: 18-20

Ignorance is fatal

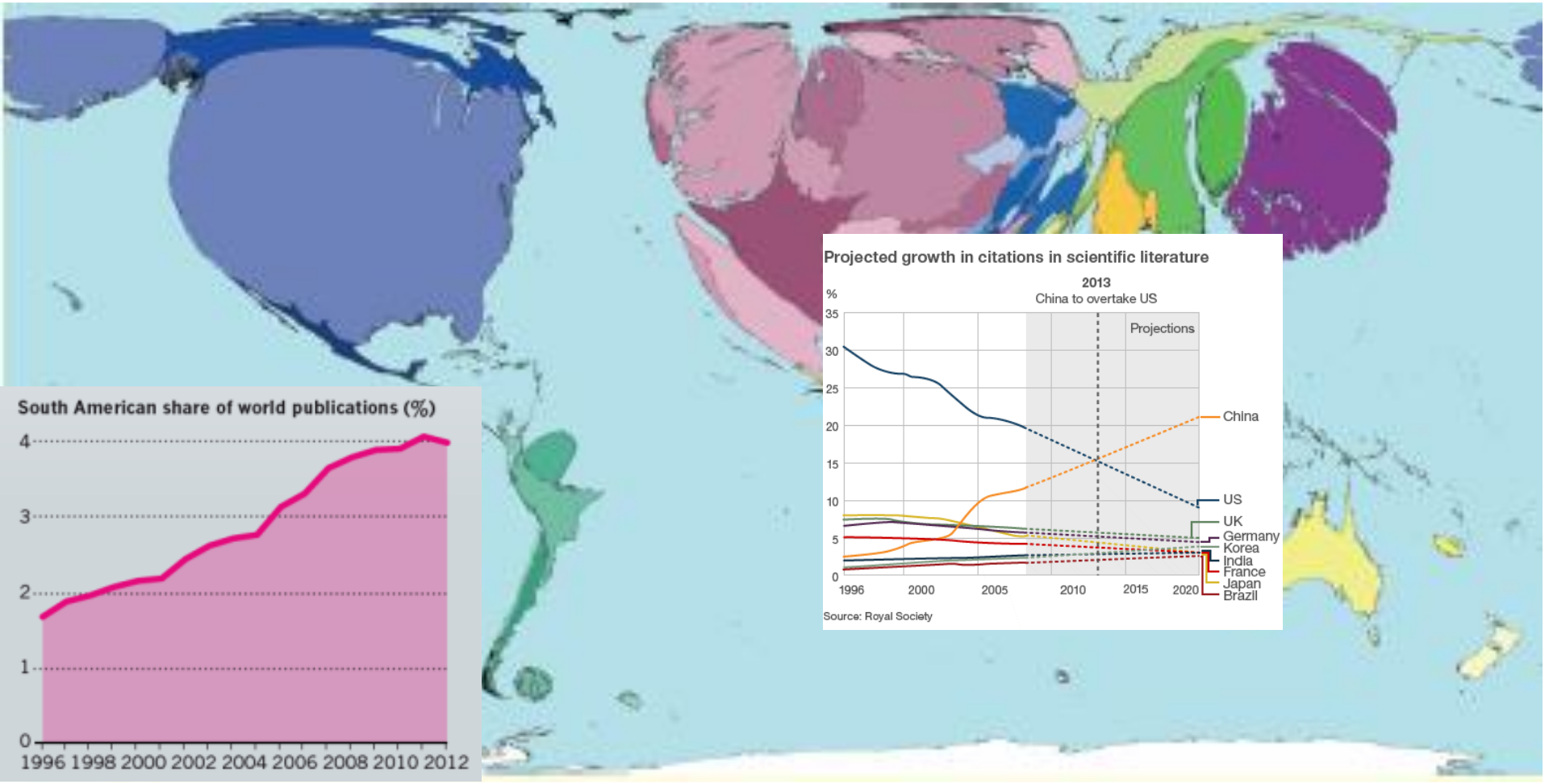
Science capacity: R&D activity

Researchers per million inhabitants: 2010 or latest available year



Human Resources in R&D. UNESCO-UIS Fact Sheet No 21, December 2012
http://www.uis.unesco.org/ScienceTechnology/Documents/sti-hr-rd-en.pdf

Science capacity: Scientific publications by countries, 2001



Territory size shows the proportion of all scientific papers published in 2001 written by authors living there. Scientific papers cover physics, biology, chemistry, mathematics, clinical medicine, biomedical research, engineering, technology, and earth and space sciences.

www.worldmapper.org

International Organization for Chemical sciences in Development

Pierre Crabbé
(Belgium)
1928-1987

Executive Director
1981-1987

1981 IOCD founded at UNESCO, Paris
1983 Registered as NGO, Belgium
1985 Secretariat moved to Mexico
1987 Death of Pierre Crabbé

- Research projects: e.g. medicinal chemistry, natural products
- Research facilitation: e.g. analytical service centres
- Capacity building – mainly individual

Robert Maybury
(USA)

Executive Director
1987-2010

- Shift from research projects to meetings, seminars, workshops
- Capacity building – individual, institutions, networks, policy

IOCD Working Groups & Programmes 2010

- Biotic Exploration Fund
- Environmental Analytical Chemistry
- Plant Chemistry
- Tropical Diseases
- Books for International Development
- Medicinal Chemistry: Open and Distance Learning
- Organic Chemistry: Online Tutorials (Spanish)
- Global Microscience Programme

International Organization for Chemical sciences in Development

Alain Krief (Tunisia)

Executive Director 2010-

World has changed since 1981

- **Economically**
- **Politically**
- **Socially**

- **Moved from ‘international aid’ to ‘development cooperation’; from MDGs to global sustainable development**
- **Concept of ‘developed’ and ‘developing’ countries outmoded: replaced by Wold Bank classification ‘high-income’ and ‘low- and middle-income’ countries (HICs and LMICs)**

New Strategy 2011 – 2020

International Organization for
Chemical sciences in Development

IOCD Strategy 2011 – 2020

Three Strategic Priorities

1. **Chemistry for better health**
2. **Chemistry for a better environment**
3. **Capacity building in chemistry education**

IOCD's strategy:

Support ownership, partnership and capacity building for the use of the chemical sciences globally, but especially in and for the benefit of LMICs

IOCD's approach:

Going beyond scientific aid for LMICs to fostering science applied to equitable global development

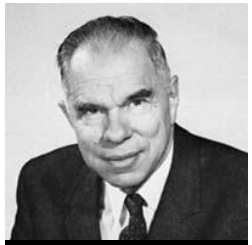
IOCD's function:

Increasingly to serve as an umbrella, facilitator and promoter for programmes and funding for research, education and capacity building in the chemical sciences

International Organization for Chemical sciences in Development

IOCD

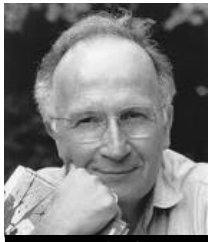
Presidents


Nobel
G Seaborg


Nobel
JM Lehn

Senior Advisory Council

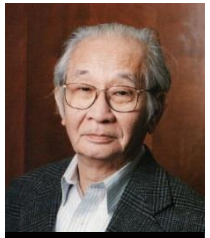

Nobel
N Borlaug


Nobel
R Hoffmann


Nobel
S Bergström


Nobel
R Noyori


CNR Rao


K Nakanishi


A Ur-Rahman


Y Apeloig


B Abegaz

Working Group Leaders and collaborators

3. Chemical sciences for development: Potential and prospects

New challenges in the chemical sciences for development

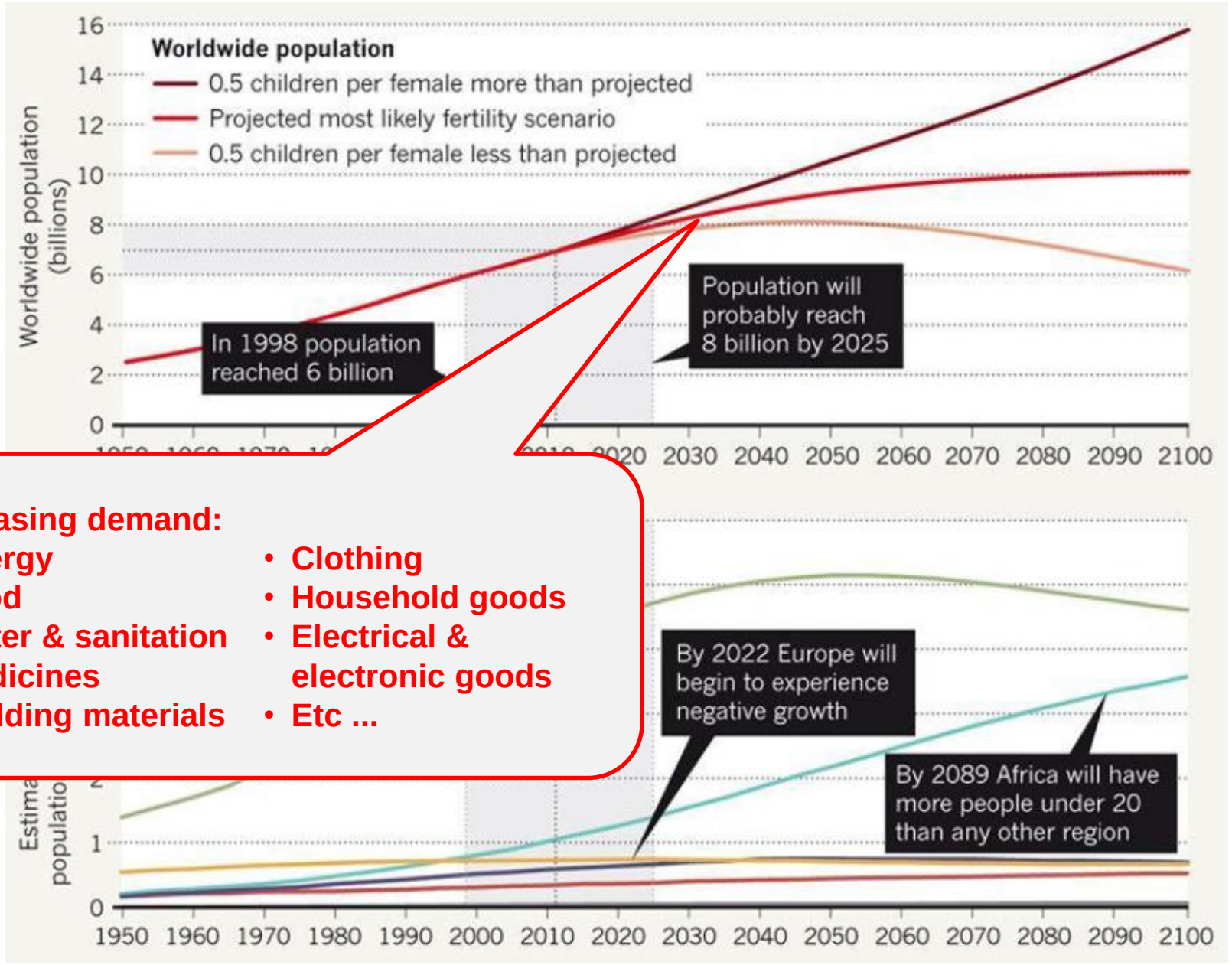
Challenges in:

- **Science**
- **Capacity for science**
- **Governance of science**

New challenges in the chemical sciences for development

1. More people, limited resources
2. It’s a dirty world and a fake world

New challenges in the chemical sciences for development



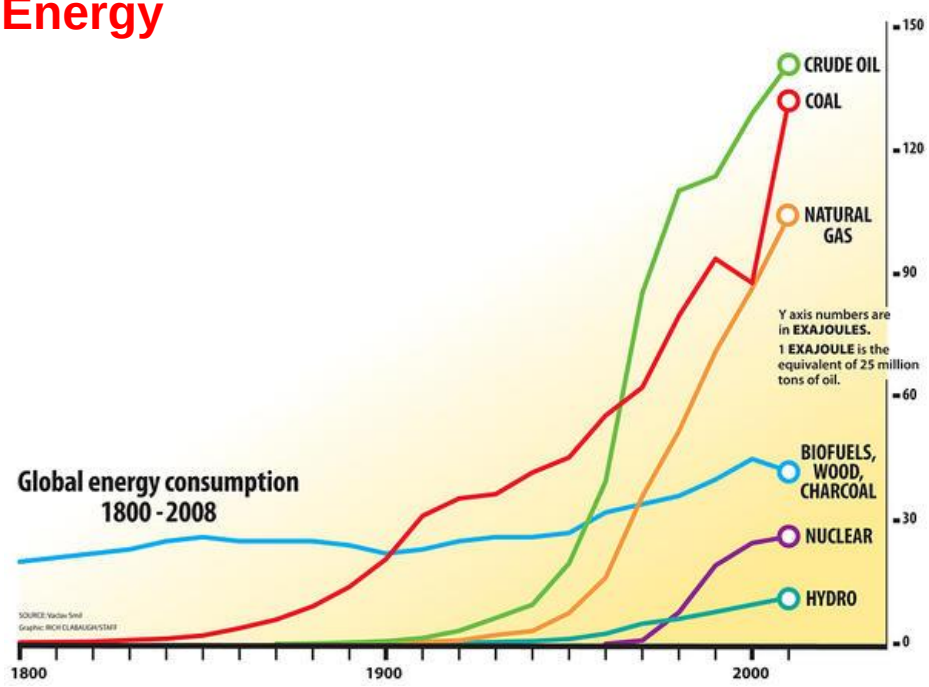
Increasing demand:

- **Energy**
- **Food**
- **Water & sanitation**
- **Medicines**
- **Building materials**
- **Clothing**
- **Household goods**
- **Electrical & electronic goods**
- **Etc ...**

J. Tollefson, Nature 2011, 478: 300. www.nature.com/news/2011/111019/full/478300a/box/1.html

New challenges in the chemical sciences for development

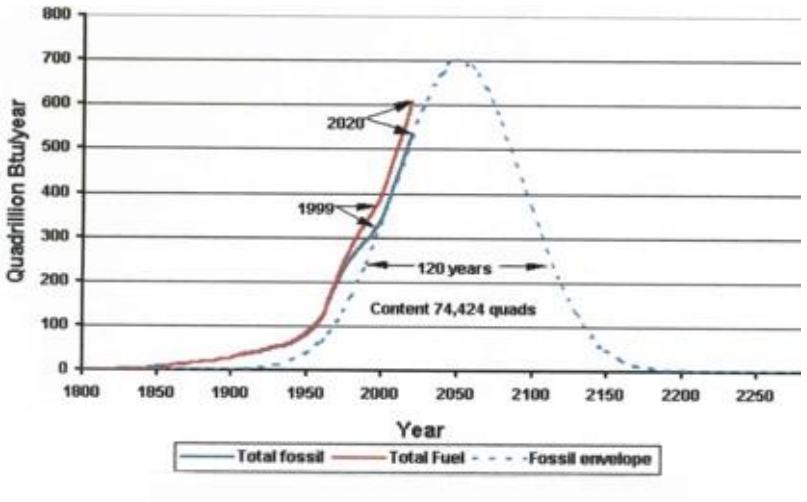
Energy



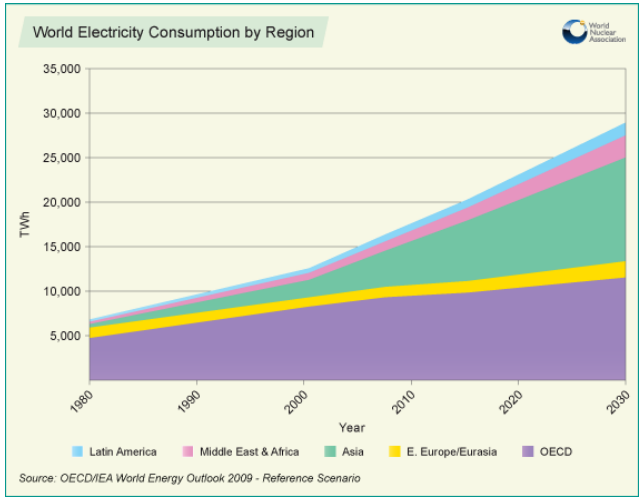
www.thephysicist.co.uk/2010/11/world-energy-consumption/

Global energy consumption: actual and projected

The blue curve represents the actual lifetime of known fossil resources



http://belaliptakpe.com/energy-related-work/energy-free-home-and-the-electric-car/



www.worldenergyoutlook.org/media/weowebsite/2009/WEO2009.pdf

New challenges in the chemical sciences for development

Energy

Science and policy goals

Sustainable energy creation and use in a "low-C economy"

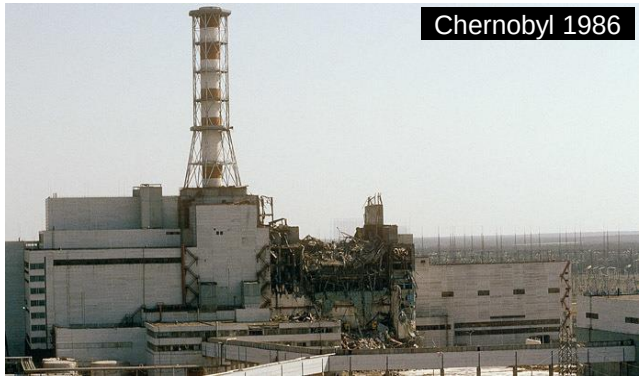
- **Energy security: Reduced dependence on finite supplies of fossil fuels**
- **Environmental security: reduced emissions of greenhouse gases**

Science

Energy generation (low/zero C: e.g. solar; fuel cells; wind, wave; fission, fusion;)
Energy storage
Energy transmission & transportation
Energy for transportation

Policy

Defining goals and targets
Creating enabling conditions and incentives
De-incentivizing non-sustainable and environmentally unfriendly energy sources



New challenges in the chemical sciences for development

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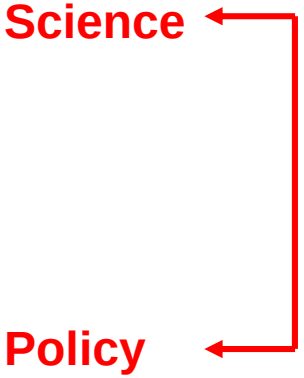
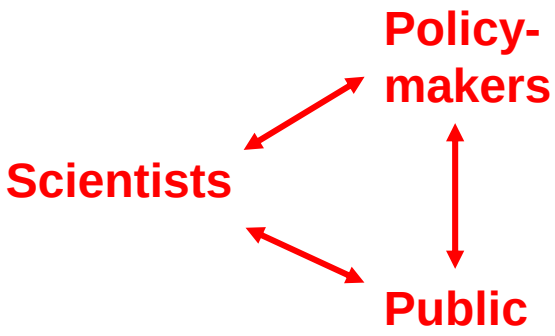




New challenges in the chemical sciences for development

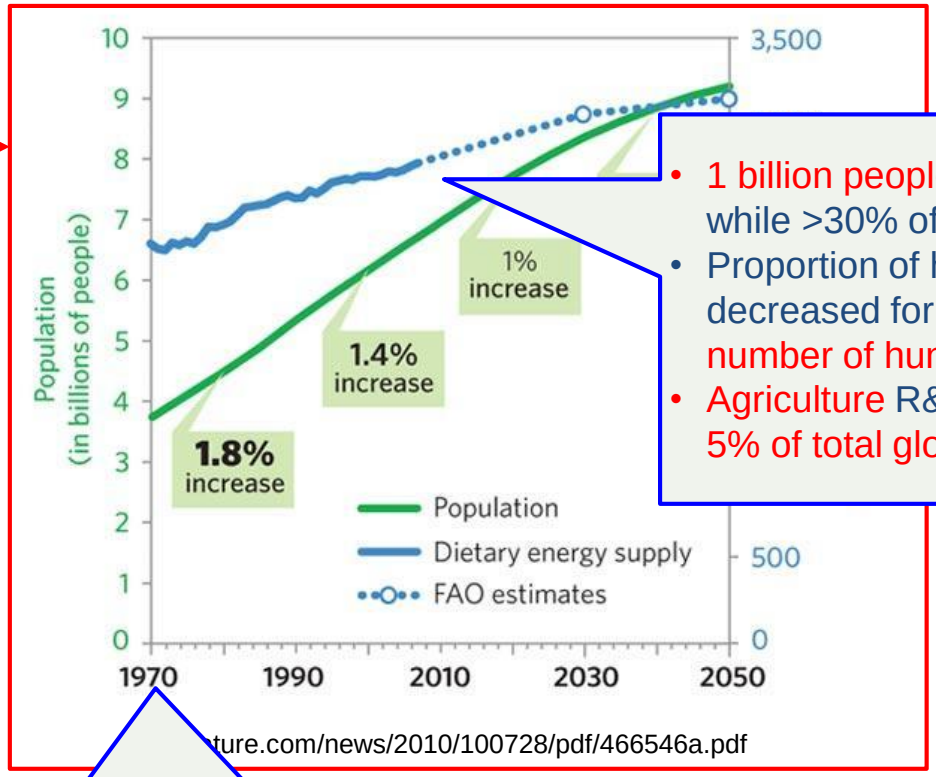
Food

Quantity

Quality

Safety

Sustainability



ture.com/news/2010/100728/pdf/466546a.pdf

- 1 billion people under-nourished in 2009, while >30% of food goes to waste
- Proportion of hungry people in LMICs has decreased for decades, while absolute number of hungry people barely dipped
- Agriculture R&D currently makes up only 5% of total global science R&D

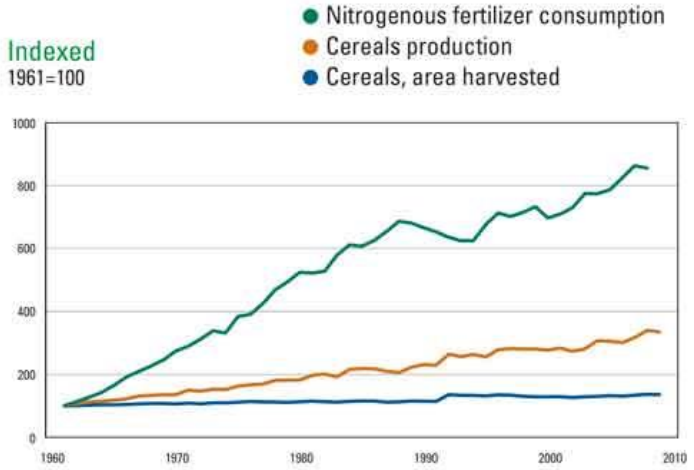
Green Revolution

high-yielding, resilient varieties of plants

+

modern agricultural production techniques

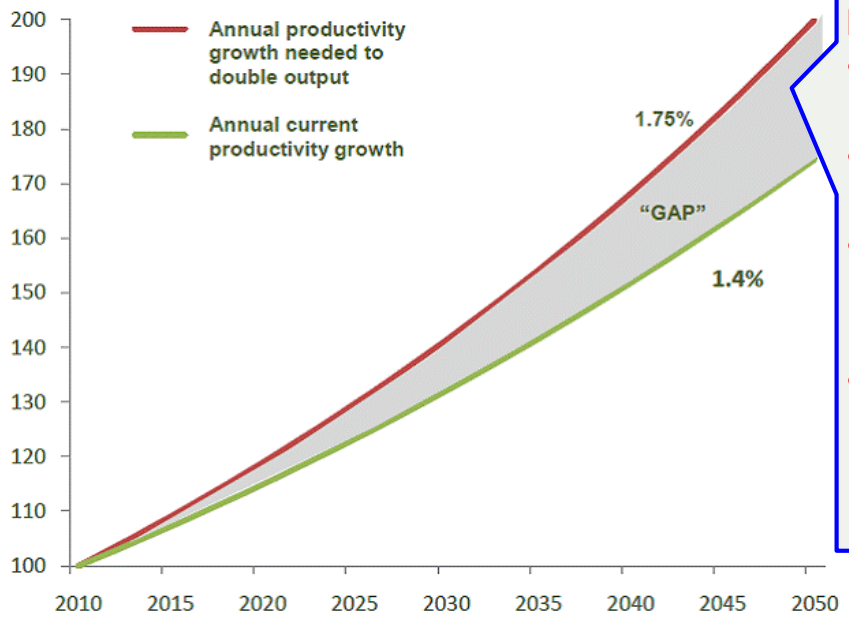
- **Soil chemistry**
- **Irrigation**
- **Fertilizers**
- **Pest control agents**



New challenges in the chemical sciences for development

Food

- **Quantity**
- **Quality**
- **Safety**
- **Sustainability**

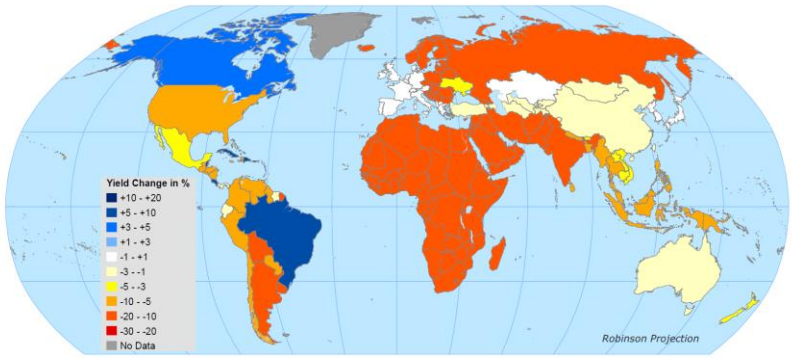


www.globalharvestinitiative.org/index.php/gap-report-gap-index/2010-gap-report/

FAO projections:

- **(2006) 70% increase in food demand by 2050**
- **(2009) global agricultural output needs to double by 2050**
- **Even then, in 2050 nearly 300 million people will remain undernourished**
- **At current rates of growth, agricultural productivity will not double by 2050**

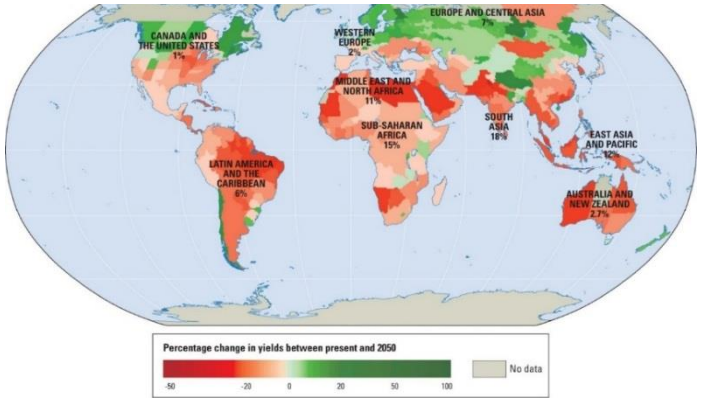
Effects of Climate Change on Global Food Production



Projected Maize Yield Change in %
1970-2000 Baseline to 2080, SRES A2A Scenario

http://sedac.ciesin.columbia.edu/data/set/crop-climate-effects-climate-global-food-production/maps/1

Climate change will depress agricultural yields in most countries in 2050, given current agricultural practices and crop varieties



http://pol-check.blogspot.ca/2012/08/global-warming-what-will-change.html

New challenges in the chemical sciences for development

Food

Quantity

Quality

Safety

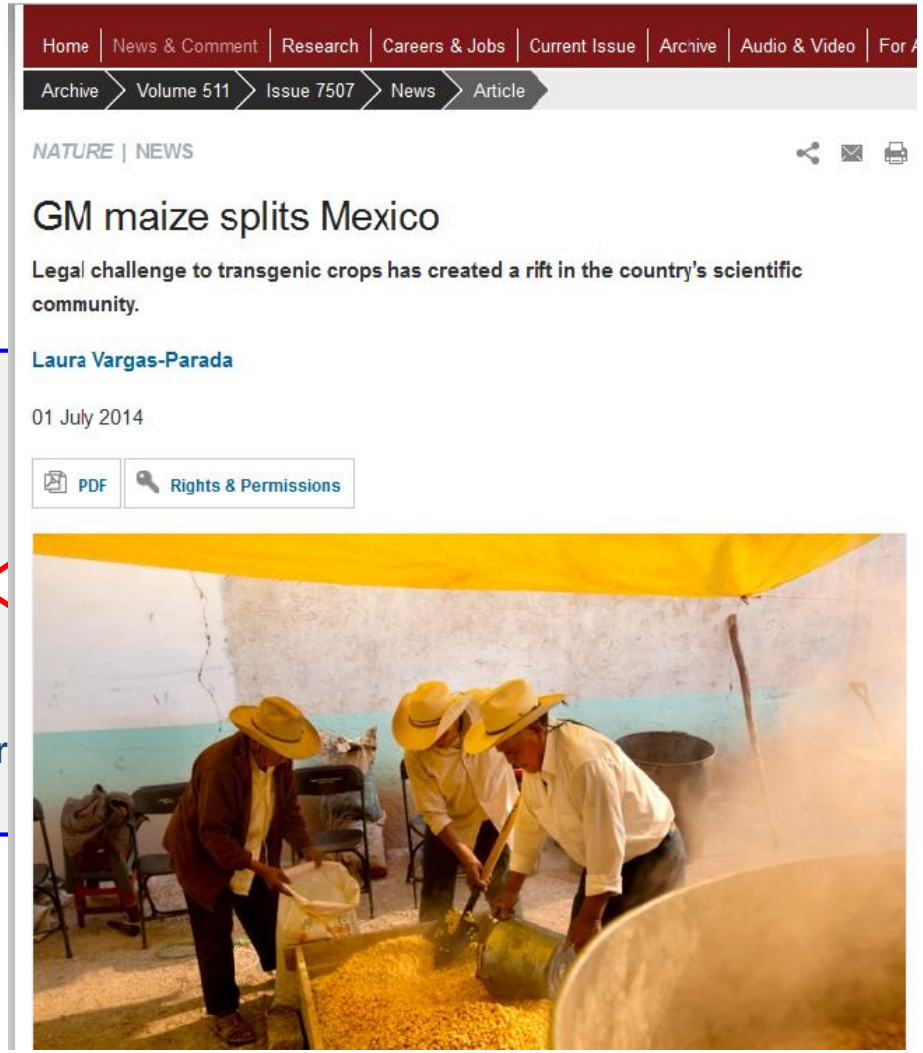
Sustainability

Potential contribution of chemical sciences

- Crop varieties
- Soil
- Water
- Growth promoters
- Pest control agents

Genetically modified crops

- resistance to pests
- resistance to herbicides
- increased nutritional value
- production of valuable goods such as drugs
- thriving in environmentally challenging conditions (e.g. drought, temperature or salt resistance).



www.nature.com/news/gm-maize-splits-mexico-1.15493?WT.ec_id=NATURE-20140703

New challenges in the chemical sciences for development

Food

Quantity

Quality

Safety

Sustainability

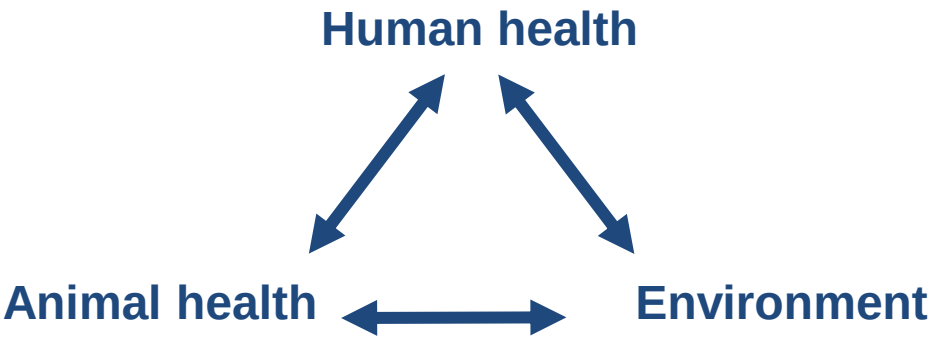
Science and policy goals

Sustainable production and consumption of food that provides adequate nutrition and does not harm health or the environment

One Health initiative

… dedicated to improving the lives of all species – human and animal – through the integration of human medicine, veterinary medicine and environmental science

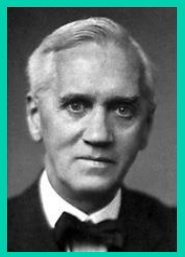
www.onehealthinitiative.com



New challenges in the chemical sciences for development

Antibiotic Resistant Bacteria (ARB)

Early 20th century
Pre-antibiotic era
Infections cause around **43% of deaths**



1928
Fleming discovers penicillin;
First examples of resistant bacteria seen

1945
Fleming wins Nobel Prize

"note of warning … It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them, and the same thing has occasionally happened in the body."

On average antibiotics add 20 years to each person's life

Late 20th century
'Golden age' of antibiotic discovery
By 2000, fewer than **7% of deaths** caused by infections

1920s | 1930s | 1940s | 1950s | 1960s | 1970s | 1980s | 1990s | 2000s | 2010s

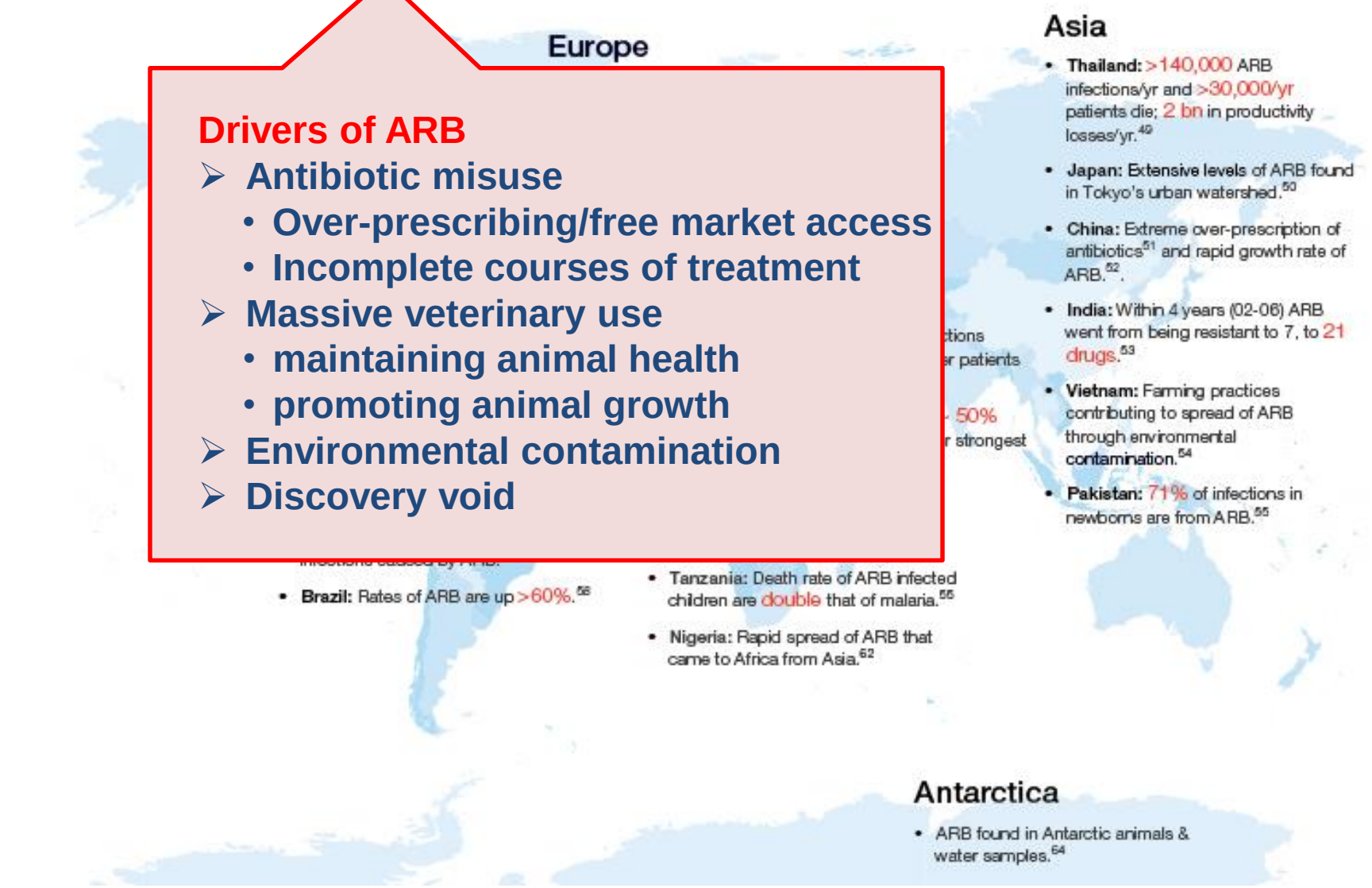
Professor Dame Sally C Davies, Chief Medical Officer, England

New challenges in the chemical sciences for development

Antibiotic Resistant Bacteria (ARB): spread

Drivers of ARB

- Antibiotic misuse
  - Over-prescribing/free market access
  - Incomplete courses of treatment
- Massive veterinary use
  - maintaining animal health
  - promoting animal growth
- Environmental contamination
- Discovery void



1920s	1930s	1940s	1950s	1960s	1970s	1980s	1990s	2000s	2010s

http://reports.weforum.org/global-risks-2013/view/risk-case-1/the-dangers-of-hubris-on-human-health/#read

New challenges in the chemical sciences for development

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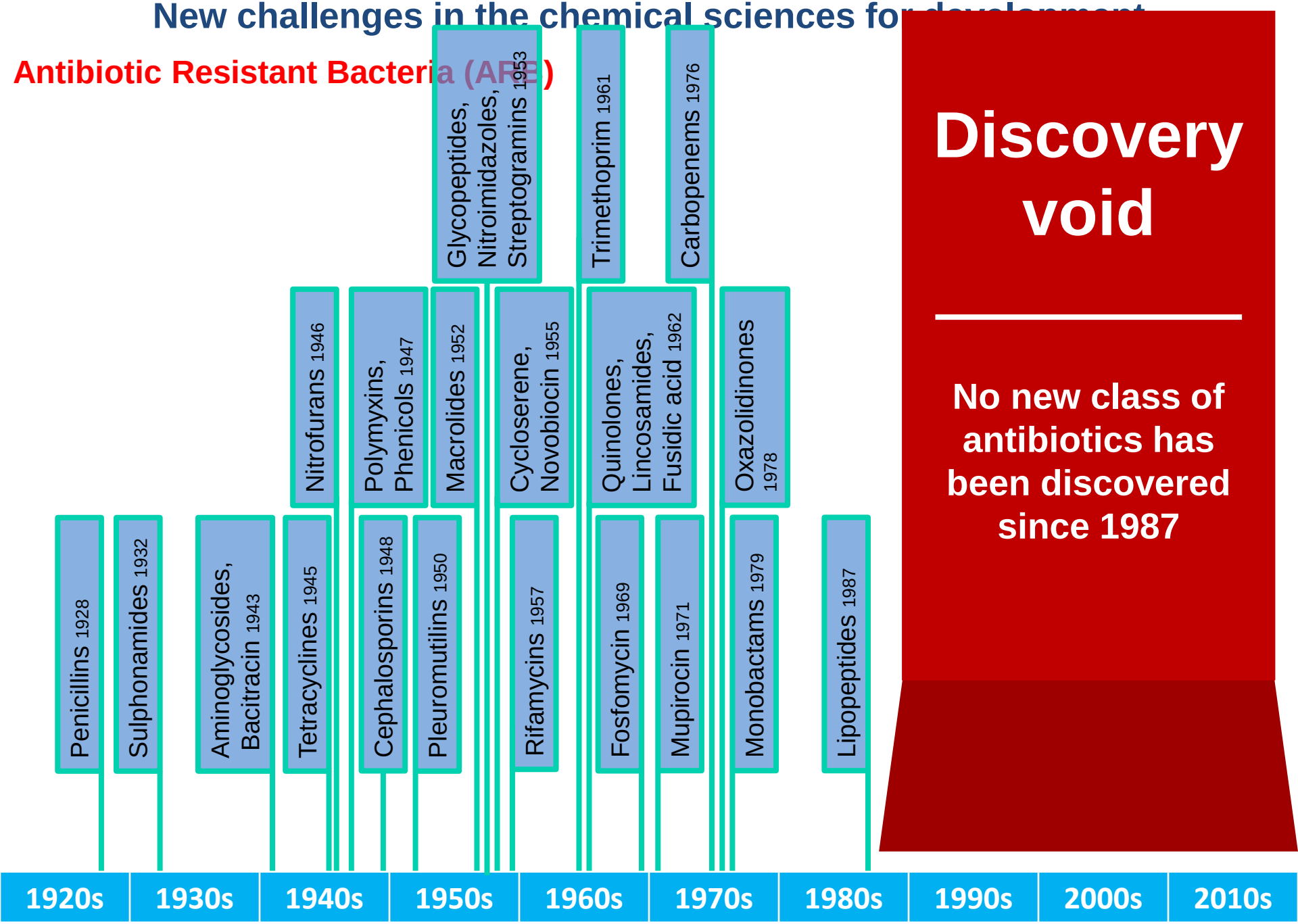

Discovery void

No new class of antibiotics has been discovered since 1987

Professor Dame Sally C Davies, Chief Medical Officer, England

New challenges in the chemical sciences for development

Antibiotic Resistant Bacteria (ARB)

Failures

- **Science**
  - "low-hanging fruit all picked": traditional approach of discovering natural or synthetic compounds to kill bacteria may be getting harder
  - new life science technologies such as genomics, nano-scale engineering and synthetic biology have not (yet) yielded new approaches in the treatment of bacterial disease
- **Economics**
  - drugs for chronic diseases offer a greater potential return on investment for pharmaceutical companies
  - any new antibiotic is likely to be kept as a last-resort treatment
  - "Systemic global market failure to incentivize front-end investment in antibiotic development through the promise of longer-term commercial reward"
- **Regulatory burdens**

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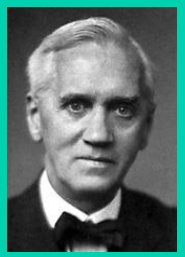
New challenges in the chemical sciences for development

Antibiotic Resistant Bacteria (ARB)

Early 20th century
Pre-antibiotic era
Infections cause around 43% of deaths

Mid 21st century
Without action, infection-related mortality may have returned to pre-antibiotic levels



1928
Fleming discovers penicillin;
First examples of resistant bacteria seen

2013
Lancet Infectious Diseases:
"We stand at the dawn of a post-antibiotic era … virtually all disease-causing bacteria are resistant to the antibiotics commonly used to treat them"

1945
Fleming wins Nobel Prize

"note of warning … It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them, and the same thing has occasionally happened in the body."

Late 20th century
'Golden age' of antibiotic discovery
By 2000, fewer than 7% of deaths caused by infections

1920s | 1930s | 1940s | 1950s | 1960s | 1970s | 1980s | 1990s | 2000s | 2010s

Professor Dame Sally C Davies, Chief Medical Officer, England

New challenges in the chemical sciences for development

Antibiotic Resistant Bacteria (ARB)

Need for better tools to recognize resistance

- **2014 UK Government launch of Longitude Prize £10 million (CDN$ 18 m) "to help solve one of the greatest issues of our time".**

  - **The challenge for Longitude Prize 2014 will be, by 2020, to create a cheap, accurate, rapid and easy-to-use point-of-care test kit for bacterial infections:**
    - ✓ **more targeted use of antibiotics**
    - ✓ **overall reduction in misdiagnosis and prescription**
    - ✓ **part of the toolkit for stewardship of antibiotics in the future**

New challenges in the chemical sciences for development

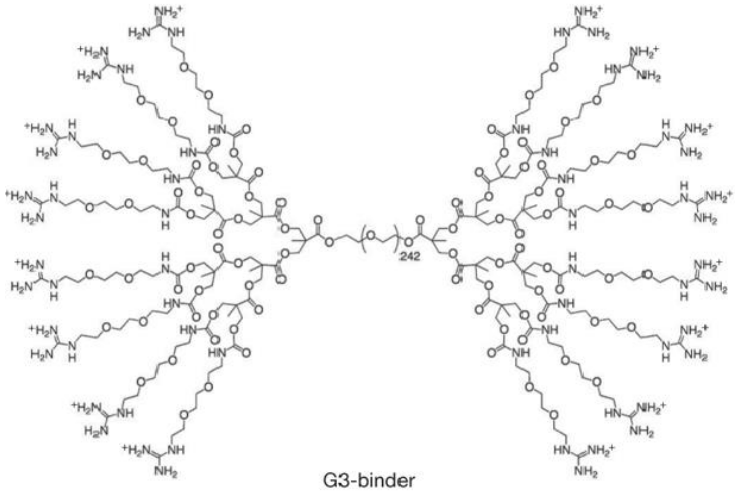
Materials

- **Limited world supplies of many of the elements and natural resources will become a serious constraint during the 21st century**
  - **Challenges for chemical sciences to create new materials with useful properties for a very wide range of applications**
    - **Low-C**
    - **Low-energy footprint**
    - **Environmentally friendly**

New challenges in the chemical sciences for development

Materials

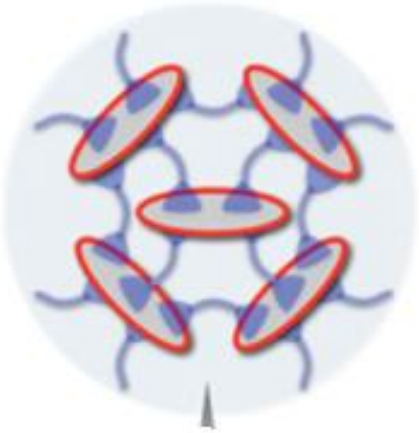
- e.g. replacing plastics with hydrogels



clay nanosheets

H_2O

Sodium polyacrylate



'aquamaterial'
98% water
<0.4% organic components

Non-flammable and environmentally friendly, easy to mould, and with silicone-rubber-like properties.

Takuzo Aida *et al, Tokyo Nature 2010,* 463, 339-343
Journal of the American Chemical Society 2013, 135, 15650-55

New challenges in the chemical sciences for development

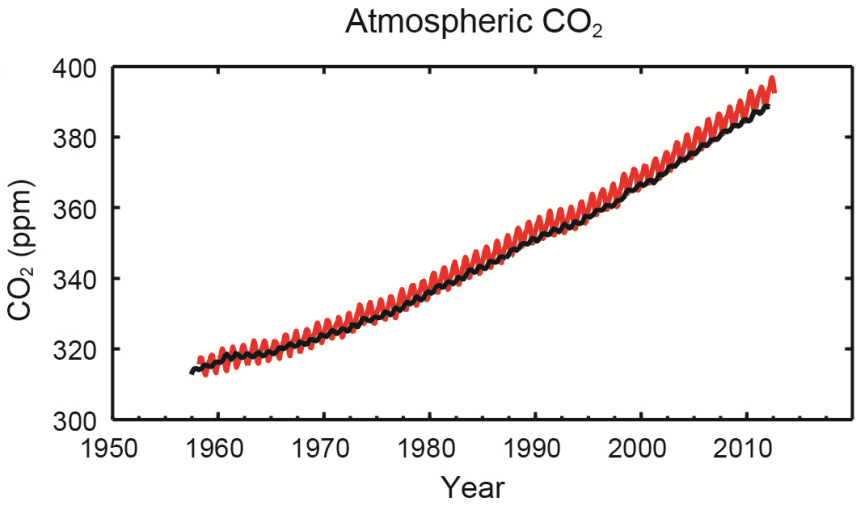
1. More people, limited resorces
2. It's a dirty world and a fake world

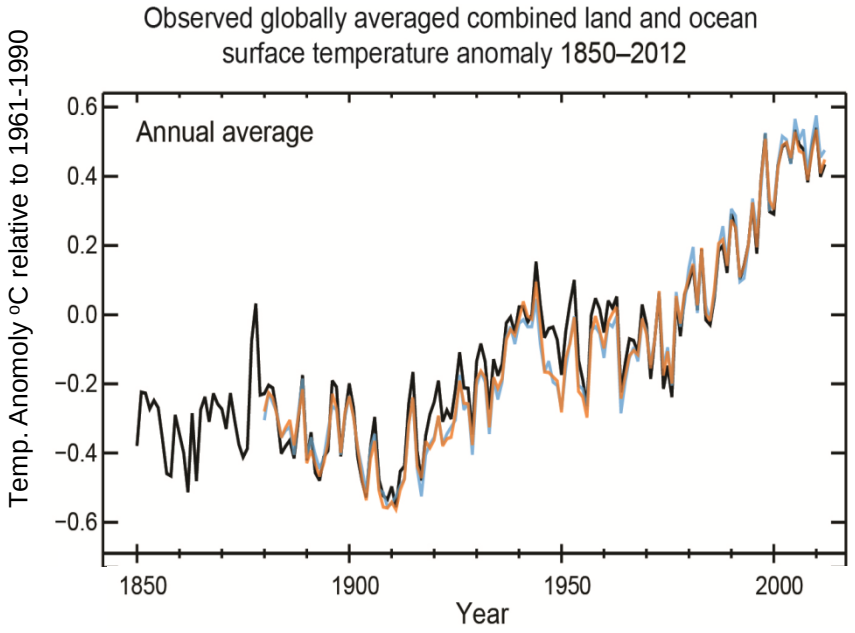
Contaminants in
- Environment
- Food
- Pharmaceuticals

Counterfeit drugs becoming increasingly available

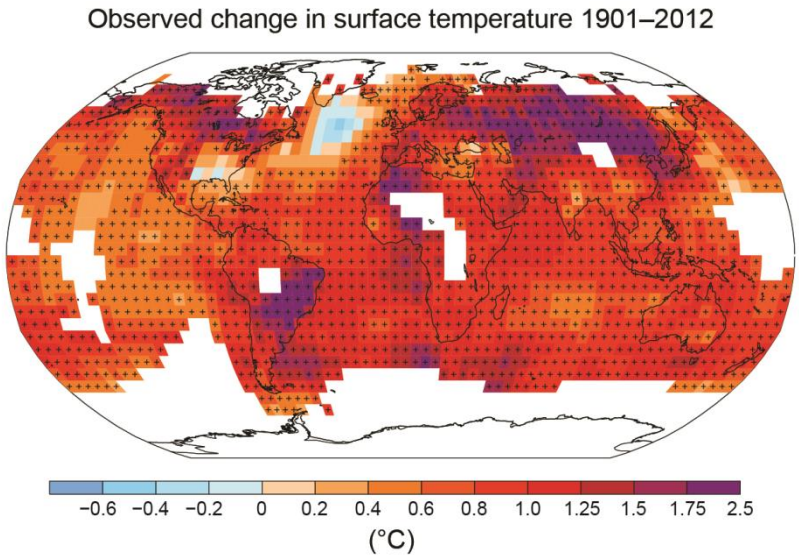
Contaminants in environment, food & pharmaceuticals

Greenhouse gases: Climate change





IPCC 5th Assessment Report, 2013.
www.ipcc.ch/report/ar5/wg1/



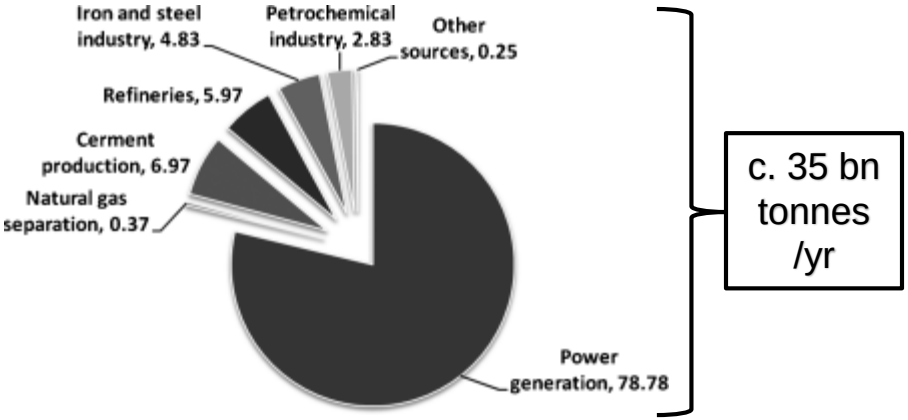
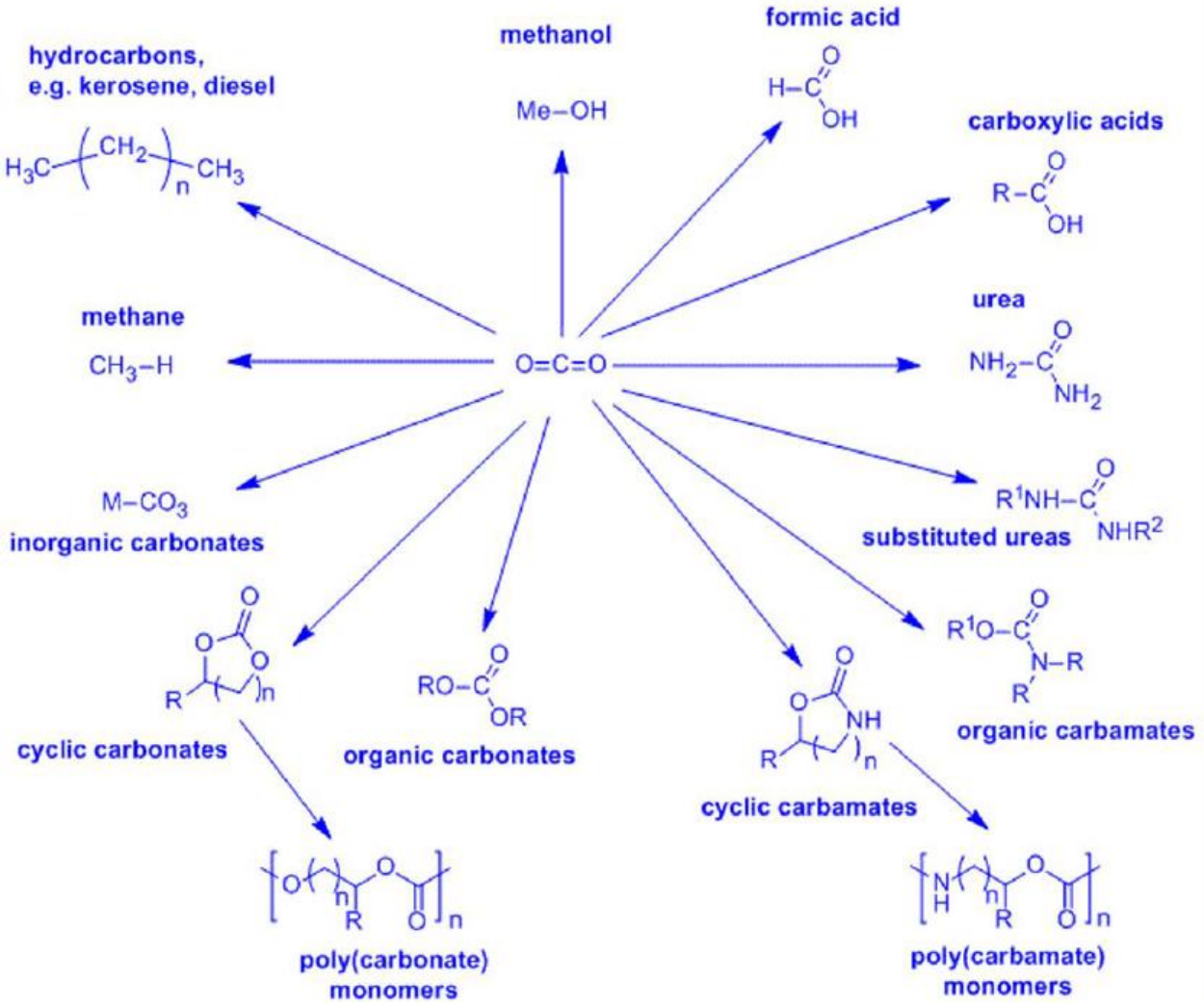


Figure 1. Worldwide stationary CO_2 sources emitting more than 0.1 Mt CO_2 per year

Hunt et al, ChemSusChem 2010, 3, 306-322

Contaminants in environment, food & pharmaceuticals

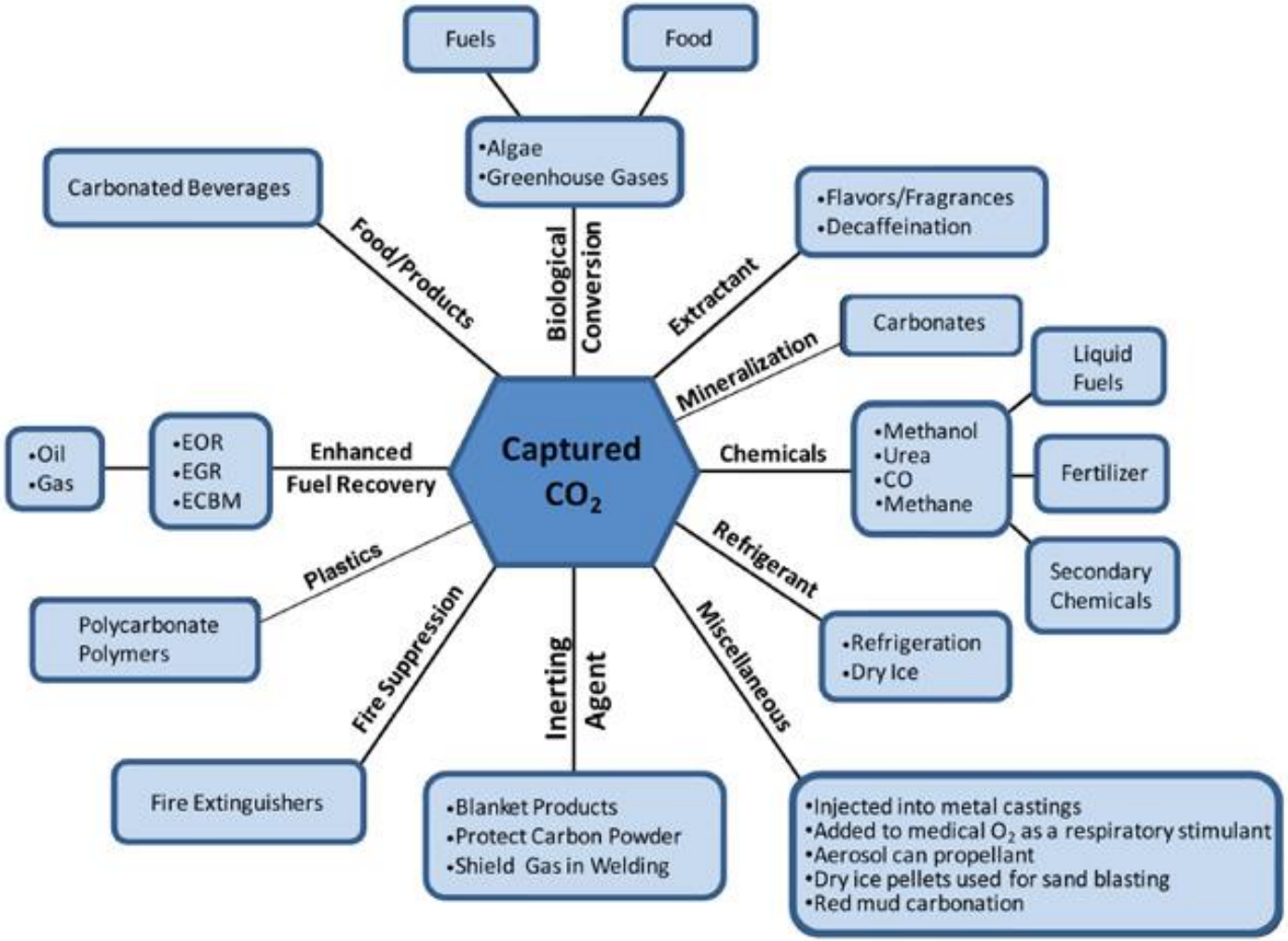
$C0_2$: capture
storage
utilization



http://co2chem.co.uk/wp-content/uploads/2012/06/CCU%20in%20the%20green%20economy%20report.pdf

Contaminants in environment, food & pharmaceuticals

$C0_2$ utilization



US Department of Energy: National Energy Technology Laboratory
www.netl.doe.gov/research/coal/carbon-storage/research-and-development/co2-utilization

Contaminants in environment, food & pharmaceuticals

- High levels of pharmaceutical ingredients in treated effluent from wastewater-treatment plants and in effluent downstream from pharmaceutical factories.
- Examples from India, the USA, and the European Union.
- The USA, EU do not have regulations limiting the concentrations of pharmaceuticals released into the aquatic environment in either municipal wastewater or in effluent from manufacturing facilities.

Nature, 15 August 2011.
www.nature.com/news/2011/110815/full/476265a.html

➢ Need for rapid, accurate, very sensitive, affordable analytical techniques that can be applied at or very close to the site being inspected

Contaminants in environment, food & pharmaceuticals

2011 UK
26 August
Class 1 Drug Alert
Nurofen Plus contaminated with Seroquel XL (antipsychotic) and Neurontin (epilepsy/ painkiller)

23 September
Man arrested in London and later convicted and jailed

2008 Nigeria
Dethylene glycol (DEG) in baby teething mixture
111 victims, 84 deaths reported

- **DEG traced to batch of glycerine from a local unlicensed pharmacy**
- **Last 20 years: hundreds of deaths of children and adults from DEG in medicines in Argentina, Bangladesh, Haiti, India, Nigeria, Panama.**

Premier Wen visits victim at Beijing Children's Hospital

2008 China
Melamine in infant formula
300,000 affected, 53,000 hospitalised, 6 reported deaths

- **Samples from 22 out of 109 suppliers of baby milk powder found to be contaminated with unsafe levels of melamine.**
- **People jailed ; 2 executed.**

Contaminants in environment, food & pharmaceuticals

Impact of globalization on drug and food safety: important lessons

- **Contaminated food and drugs are often identified only when large numbers of people or animals are affected and numerous deaths result**

- **Deliberate contamination may be widespread but escape detection in poorly regulated markets.**

- **Contaminated raw material produced in a poorly regulated market may cross national boundaries and be used in manufacturing processes for numerous products, sometimes in more well-regulated markets.**

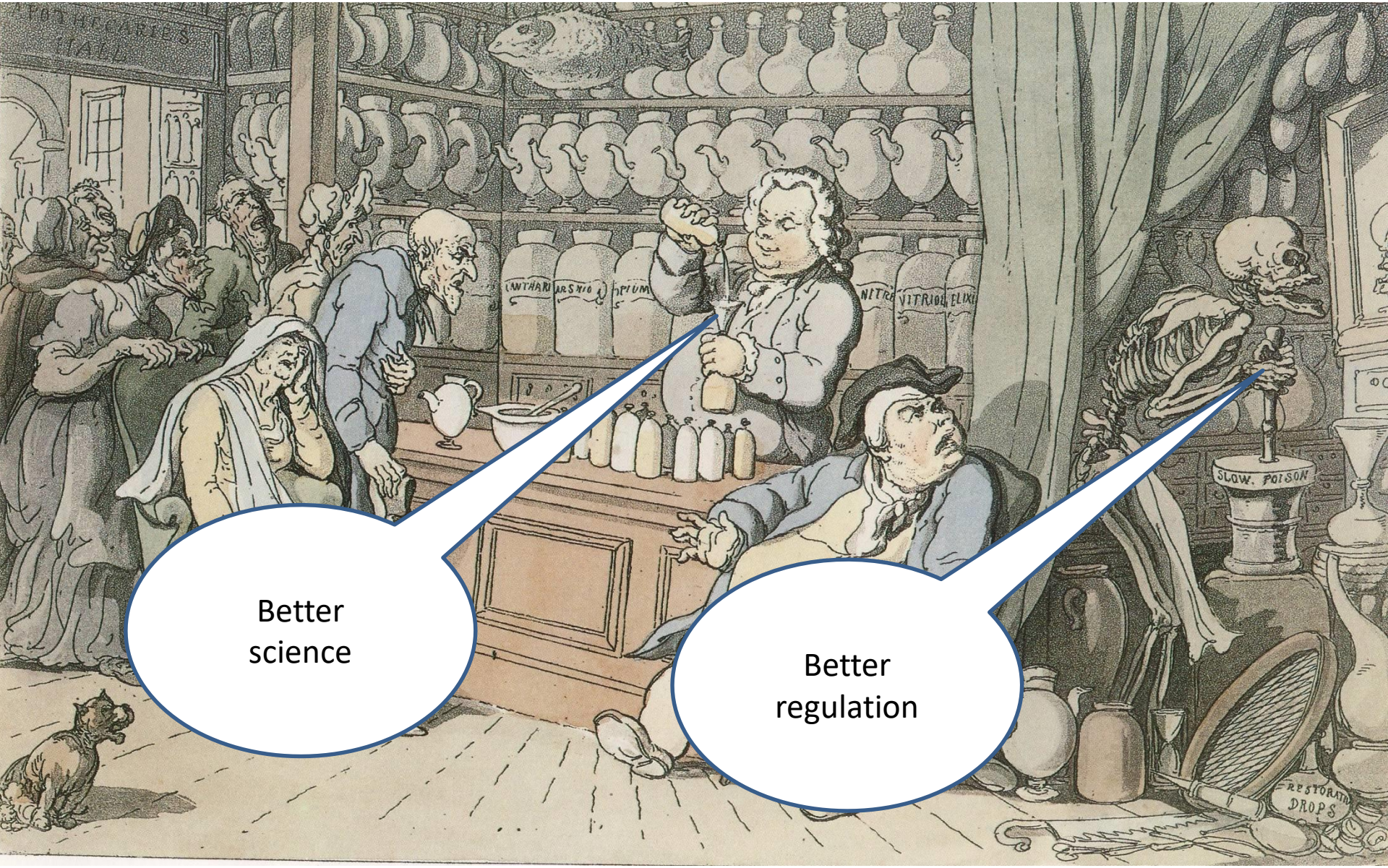
- **It is not clear that regulatory organizations have the capacity to identify significant contaminations despite their best efforts.**

- **The [scientific] communities, in cooperation with regulatory agencies, should develop cooperative programmes designed to detect and limit these global outbreaks.**

- **Although addressing regional or national outbreaks remains an important role for regulatory agencies, the [relevant scientific] communities must develop proactive global approaches to this global problem.**

Brown & Brown *Vet Pathol* 2010, 47, 45-52

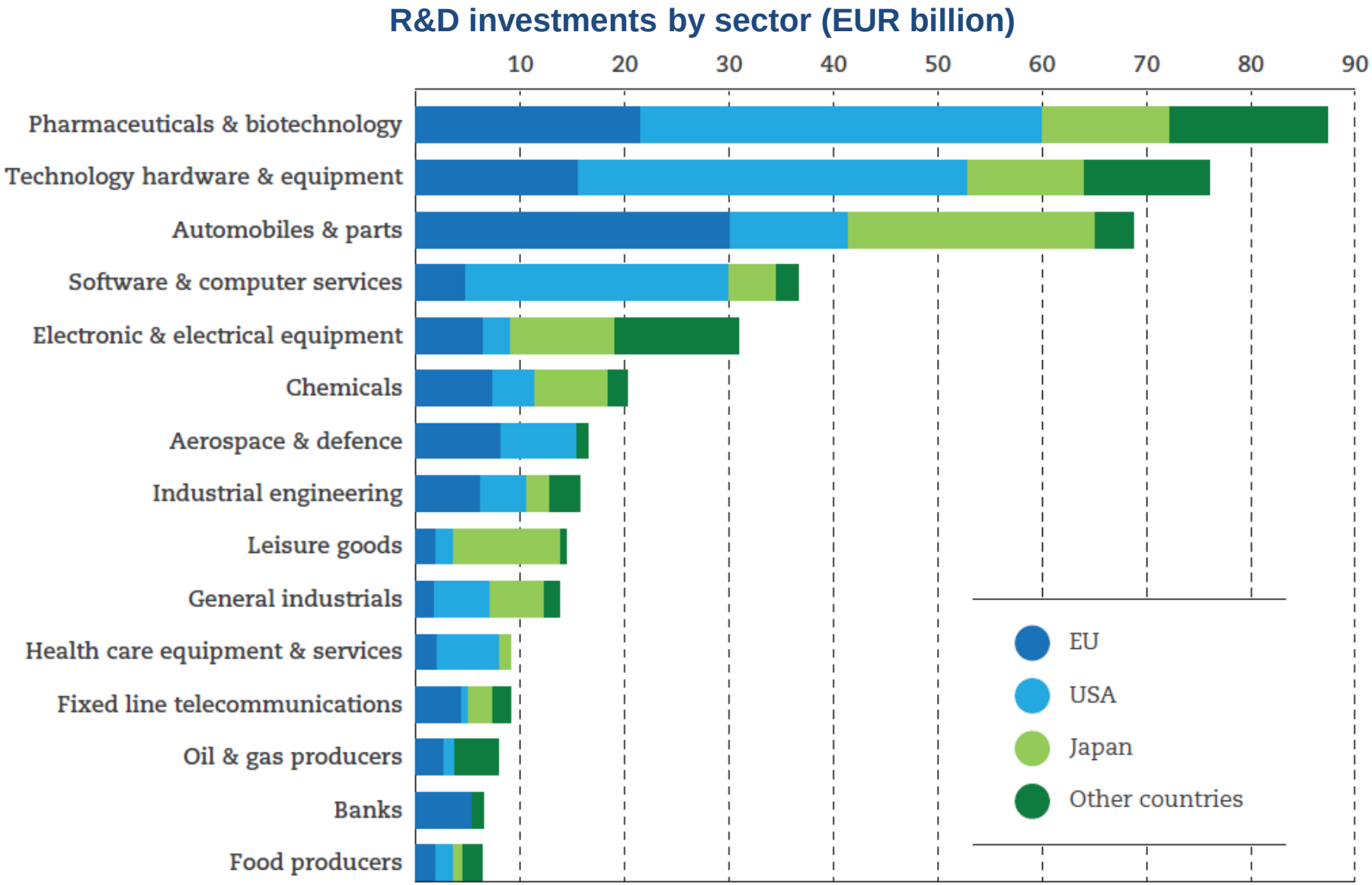
The pharmaceutical industry



The Quack Doctor, 1814

Arnold-Foster & Tallis, *The Bruising Apothecary*, Pharmaceutical Press, 1989

The pharmaceutical industry



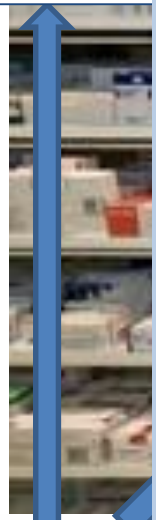
www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf

The pharmaceu

Globally:

- The 20 largest pharma/biotech companies employed >1.3 million people in 2006
- The industry will generate global sales of US$ 1 trillion in 2014: will rise to US$ 1.2 trillion

USA :
biopharmaceutical research companies are the most research intensive in the USA: invested >US$ 65 billion; directly employed >810,00 people and indirectly supported 4 million jobs in 2012



Pharmaceuticals are moving East and South

Canada:

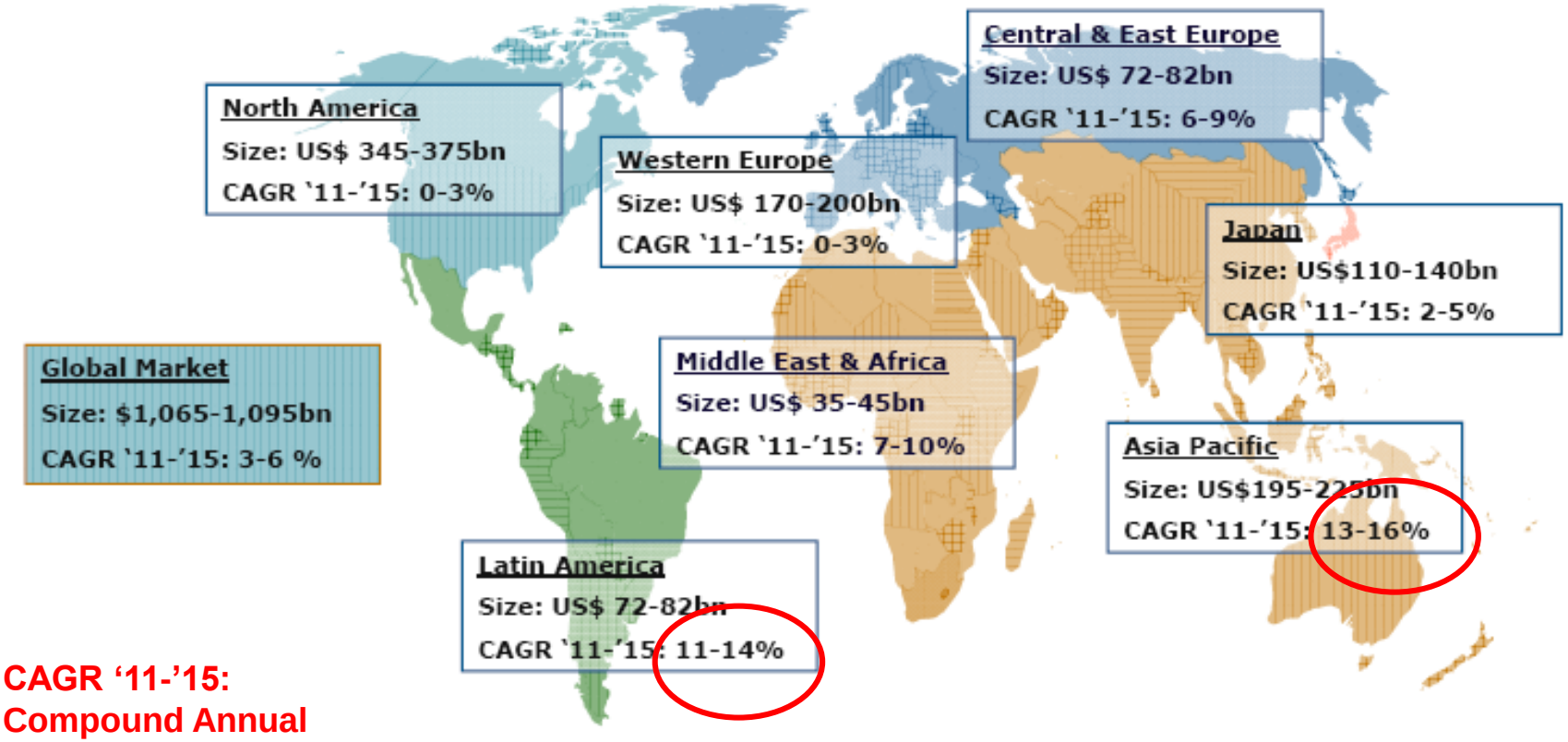
- One of Canada's most innovative industries
- 8th largest global market (2.5% share) and 7th fastest growing
- Employment for 27,000 people in 2013

www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html

Consumption moving East, South

Over the next 5 years, growth opportunities will continue to move away from traditional pharma

Global: IMS Regional Pharmaceutical Outlook in 2015 (US$ Billions)



CAGR '11-'15: Compound Annual Growth Rate 2011-2015

"Pharmerging" markets

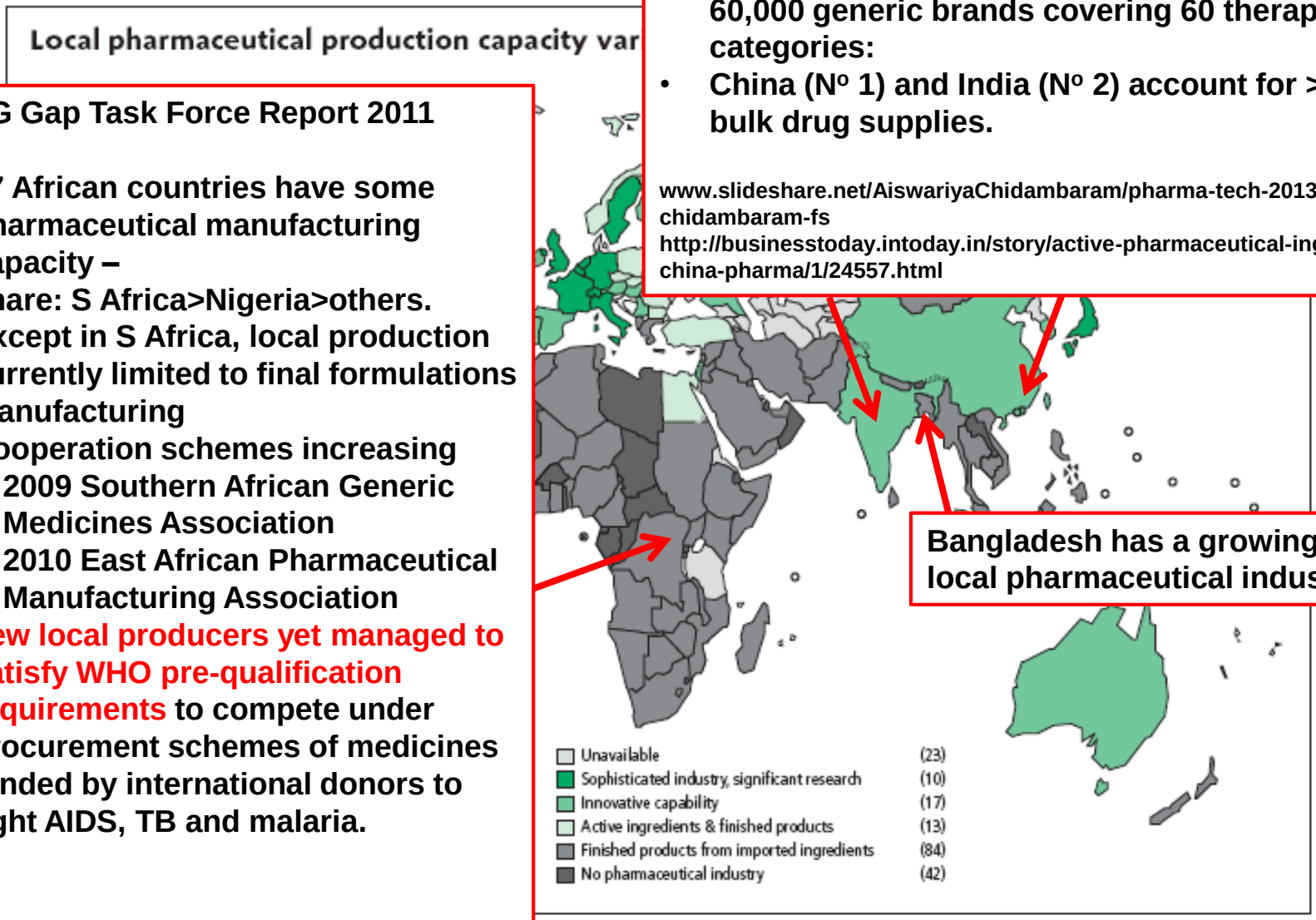
IMS Health, Market Prognosis, Apr 2011. www.bvgh.org/LinkClick.aspx?fileticket=kMaOKGUbqgI%3D&tabid=168

Production

Global Generic Pharma > US$ 150 bn/yr; CAGR > 8%
HIC generic companies dominate production, but India + China growing:

- **India produces > 20% of world's generic drugs (c. 60,000 generic brands covering 60 therapeutic categories:**
- **China (Nº 1) and India (Nº 2) account for > 40 % global bulk drug supplies.**

www.slideshare.net/AiswariyaChidambaram/pharma-tech-2013-aiswariya-chidambaram-fs
http://businesstoday.intoday.in/story/active-pharmaceutical-ingredient-api-china-pharma/1/24557.html



Bangladesh has a growing local pharmaceutical industry.

MDG Gap Task Force Report 2011

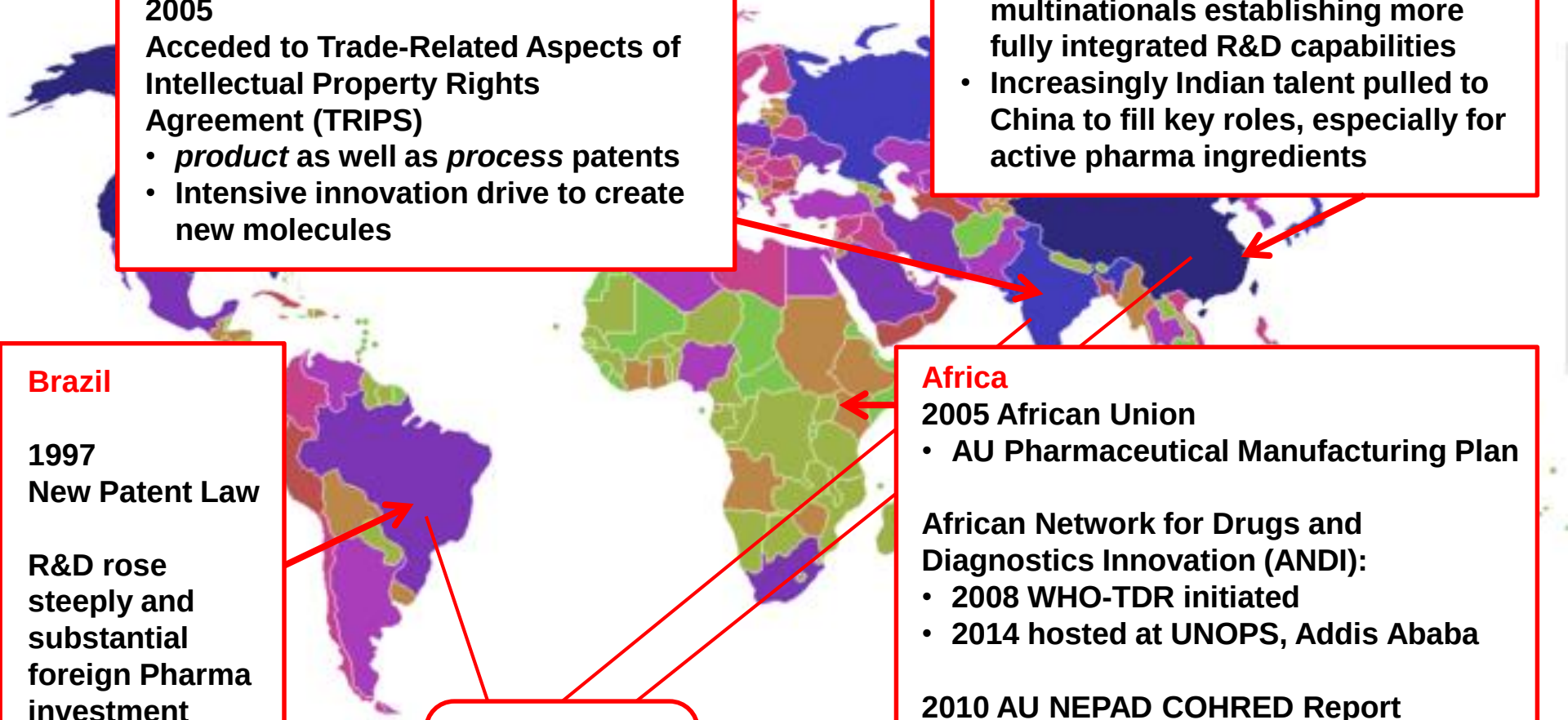
- **37 African countries have some pharmaceutical manufacturing capacity –**
  share: S Africa>Nigeria>others.
- **Except in S Africa, local production currently limited to final formulations manufacturing**
- **Cooperation schemes increasing**
  - **2009 Southern African Generic Medicines Association**
  - **2010 East African Pharmaceutical Manufacturing Association**
- **Few local producers yet managed to satisfy WHO pre-qualification requirements to compete under procurement schemes of medicines funded by international donors to fight AIDS, TB and malaria.**

www.unric.org/en/latest-un-buzz/26954-the-mdg-gap-task-force-report-2011

04. **http://apps.who.int/medicinedocs/en/d/Js6160e/3.html**

R&D moving East, South

Pharmaceutical R&D globalizing



India

"Pharmacy of the developing world"

2005
Acceded to Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)

- ***product*** **as well as** ***process*** **patents**
- **Intensive innovation drive to create new molecules**

China

- **Home-based R&D investment**
- **R&D skills in chemistry, analysis, late stage drug development, clinical trials attracting outsourcing**
- **'Second wave' now in process, with multinationals establishing more fully integrated R&D capabilities**
- **Increasingly Indian talent pulled to China to fill key roles, especially for active pharma ingredients**

Brazil

1997
New Patent Law

R&D rose steeply and substantial foreign Pharma investment attracted

Africa

2005 African Union

- **AU Pharmaceutical Manufacturing Plan**

African Network for Drugs and Diagnostics Innovation (ANDI):

- **2008 WHO-TDR initiated**
- **2014 hosted at UNOPS, Addis Ababa**

2010 AU NEPAD COHRED Report

- **Strengthening Pharmaceutical Innovation in Africa**

"Innovative developing counties"

Small Molecule Drugs and Biomolecul

Prot… …cids, carbohydrates

…ical
…strat

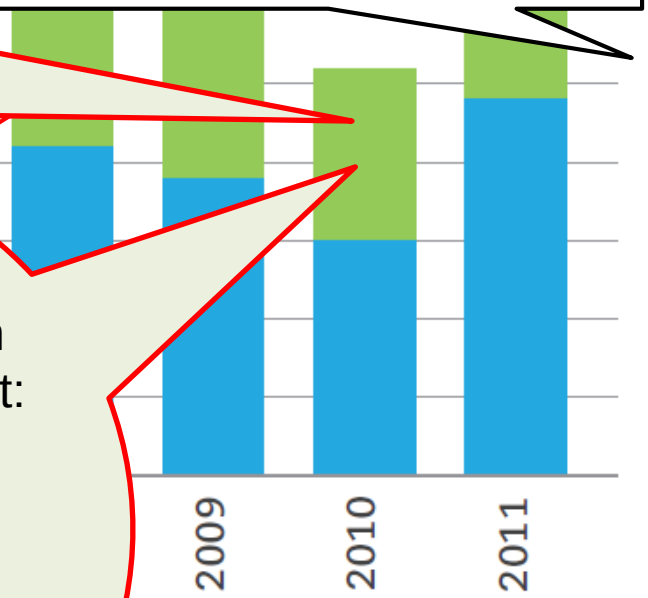
…es
…wth factors
…proteins

- **…**
- **C… an …**
  sub… …que…
  structure, …nation – which can affect biologi…
- **Structure may be strong… influenced by condition… production**

European Union
specially adapted approval procedure for "*similar biological medicinal products*" – demonstrates *"comparability"* of the *"similar"* product to an existing approved product

2012 biologic drug market
US$ 169 bn global revenues
- **Great demand for lower-cost biologics, driving interest in "generic" versions**
  - **"biosimilars"**
  - **"follow-on biologics "**

Need for greater harmonization



USA
2010 Patient Protection and Affordable Care Act: abbreviated approval pathway for biological products shown to be "*biosimilar to, or interchangeable with*", an FDA licensed reference biological product

…CE)

www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf

Small Molecule Drugs and Biomolecular Drugs (Biologics)

How to use analysis to ensure the functional identity of different batches of biologicals, or of successor biosimilars?

No silver bullet

- **No one analytical technique is sufficient** to properly characterize all the ways the structure of a follow-on can vary from that of the innovator product.
- Consensus that **multiple, orthogonal approaches to characterizing a follow-on biologic will be necessary** to construct a portfolio of data demonstrating structural similarity.
- Highly likely that **some form of clinical trial data will be required** to establish that the follow-on product is safe.

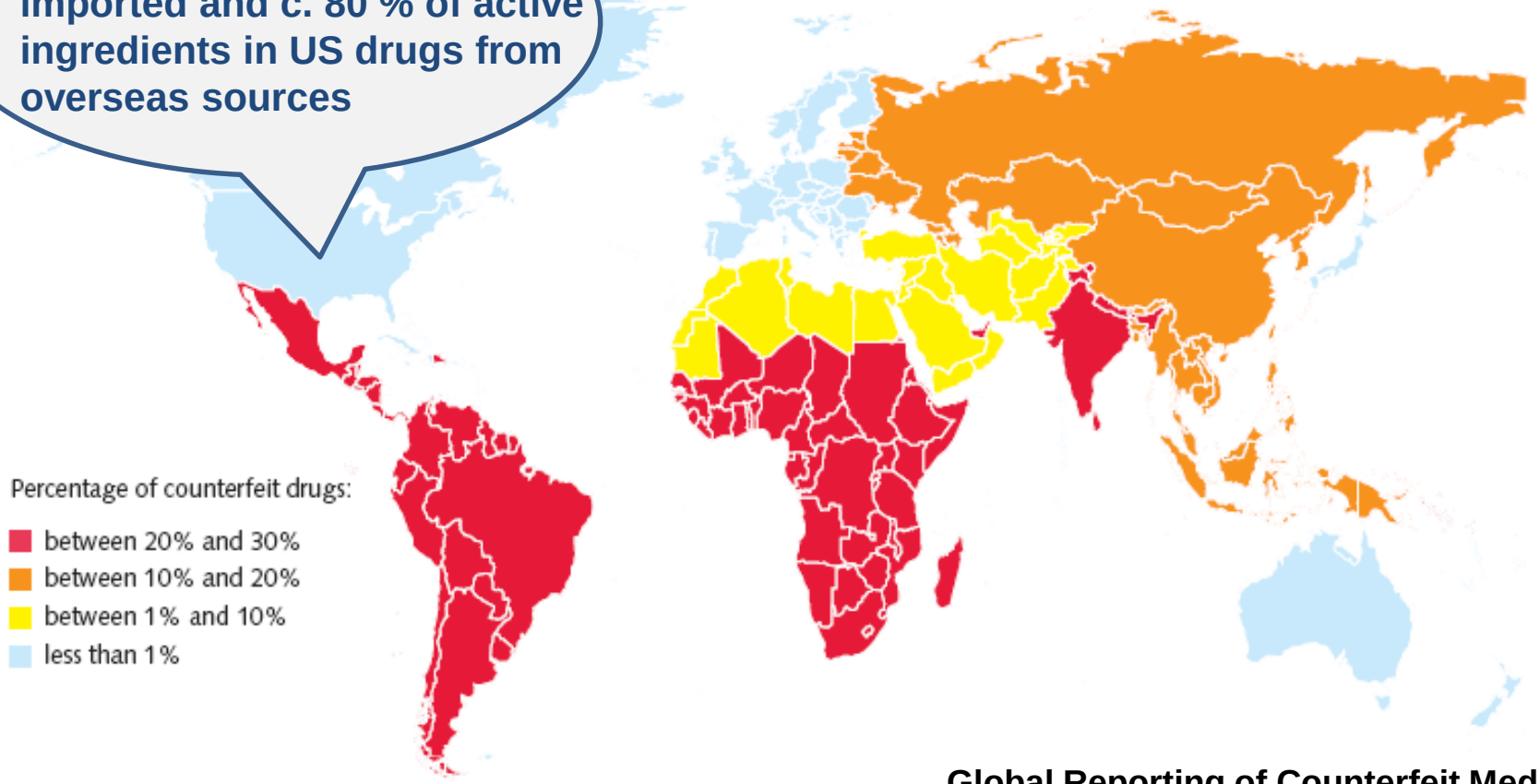
MacNeil & Douglas: Challenges to Establishing a Regulatory Framework for Approving Follow-on Biologics. http://web.mit.edu/cbi/publications/FOB_macneil.pdf

Counterfeit drugs

Its a fake world: Counterfeit drugs becoming increasingly available

- Estimated counterfeit drug sales worth US$ 75 billion globally in 2011
- Counterfeit medicines estimated to constitute >10% of global medicines market: c. 1% in HICs and 10-50% in LMICs

c. 40 % of drugs in USA imported and c. 80 % of active ingredients in US drugs from overseas sources



Global Reporting of Counterfeit Medicines
http://ec.europa.eu/internal_market/indprop/docs/conf2008/wilfried_roge_en.pdf

Counterfeit drugs

June 2011

Belgian man extradited from Costa Rica to USA convicted of operating fraudulent internet pharmacy and jailed for 4 years

- **Sold US$1.4 million misbranded and counterfeit drugs and controlled substances**
- **A global business:**
  - **customer service call centre in Philippines**
  - **Western Union wire transfers via the Philippines, Costa Rica and USA**
  - **credit card processors in the Netherlands**
  - **website hosting service in USA**
- **The Canadian co-defendant remains a fugitive.**

www.fda.gov/ICECI/CriminalInvestigations/ucm257945.htm

Counterfeit drugs

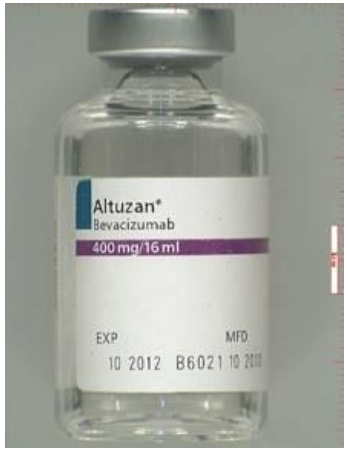
Jan 1999 - Oct 2000 WHO: 46 reports from 20 countries (60% LMICs)

Counterfeit drugs included antibiotics, hormones, analgesics, steroids, antihistamines:

- without active ingredients, 32.1%;
- with incorrect quantities of active ingredients, 20.2%;
- with wrong ingredients, 21.4%,
- with correct quantities of active ingredients but fake packaging, 15.6%;
- with high levels of impurities and contaminants, 8.5%

No simple solution

- Problem has reached a global dimension and needs a global approach
- Absence of, or weak, drug regulation

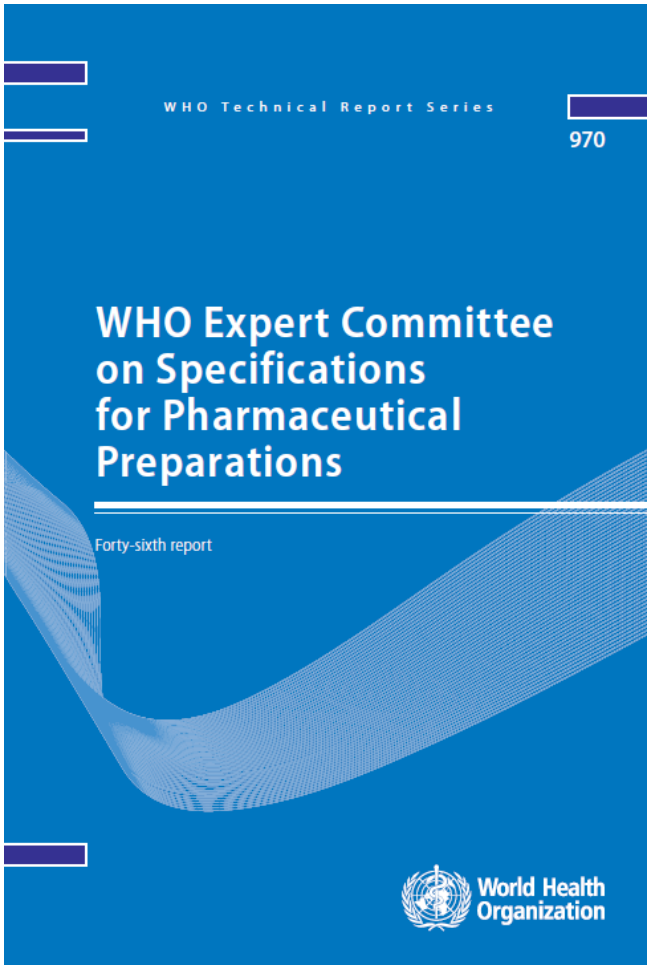


Lipitor (Pfizer) , a statin used to control cholesterol, : counterfeit pills (left); genuine examples (right).

WHO 2011: www.who.int/medicines/services/counterfeit/overview

FDA 2012: www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm298047.htm

Counterfeit drugs



Every country, regardless of its stage of development, should consider investment in an independent national drug quality control laboratory

WHO Expert Committee on Specifications for Pharmaceutical Preparations 29th Report, 1984
http://whqlibdoc.who.int/trs/WHO_TRS_704.pdf

Absence of or weak drug regulation

- At present, of 191 WHO member states **c. 20% have well developed drug regulation**. Of remainder, c. 50% implement some drug regulation; another 30% either have no drug regulation in place or a very limited capacity that hardly functions.
- **Inadequate resources** for drug regulation activities and **absence of training** of national drug regulatory authorities' personnel may also manifest itself as **inefficiency** and **incompetence** of national drug regulatory authorities.

General Information on Counterfeit Medicines, WHO 2014
www.who.int/medicines/services/counterfeit/overview/en/index1.html

Technologies to prevent/identify counterfeits

Predicted: World market for pharmaceutical anti-counterfeiting technology will rise to roughly US$1.2 billion in 2015

Visiongain Report 29 October 2012
www.healthcareitnews.com/news/rx-anti-counterfeiting-technologies-reach-12b-2015

Contaminants in environment, food & pharmaceuticals

- **Challenges/opportunities for the chemical sciences**
  - New chemistry products and processes: Safe, effective, affordable, sustainable

- **Challenges for regulation**
  - Better cooperation and harmonization among analysts in the fields of pharmaceuticals, food, environment
  - Better cooperation and harmonization between analysts in all fields and policy makers


World Organization for Regulation of Food, Environment and Drugs
WORFED
U.S. Food and Drug Administration
FOOD AND DRUG ADMINISTRATION THAILAND
EUROPEAN MEDICINES AGENCY
Ministry of General
SOCIETY for APPLIED SPECTROSCOPY
AACC
ASMS
FACSS
MINISTERIO DE SALUD PÚBLICA
swissmedic
Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration
Analytical Chemistry and Environment Division
Royal Australian Chemic
AOAC INTERNATIONAL
SFDA 国家食品药品监督管理局
State Food and Drug Administration
NAFDAC
ACS Chemistry for Life
Analytical Chemistry Division
PBA 2011 BRAZIL
Health Sciences A
NEW ZEALAN AND MEDICAL SAFETY AUTH
Singapore Integrity • Service
Agência Nacional de Vigilância Sanitária
Lyfjastofnun
Icelandic Medicines Agency
Medicines and Medical Devices
NATIONAL DRUG AUTHORITY
Safe Drugs
ICH
harmonisation for better health
KFDA KOREA FOOD & DRUG ADMINISTRATION

New challenges in the chemical sciences for development

Challenges in:

- **Science**
- **Capacity for science**
- **Governance of science**

Essential to have more effective and productive communication between scientists and policy makers

Policy-makers

- **Evidence-informed policy**
- **Understanding the significance of research results**

Scientists

- **Policy-informed research**
- **Understanding the significance of policy and practical constraints**

- **Non-technical language**
- **Communication about ‘certainty’**
- **Communication about ‘risk’ – including distinction between ‘risk assessment’ and ‘risk management’.**

Thank you

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