International Organization
for Chemical Sciences
in Development

Imperial College
London
Institute of Global Health Innovation

Chemistry and health: the need for a comprehensive approach

School of Chemistry & Molecular Biosciences, University of Queensland: 17 July 2018

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THE GRADUATE INSTITUTE GENEVA

GLOBAL HEALTH CENTRE

The RISE Institute
Institute for Reconstruction and International Security through Education

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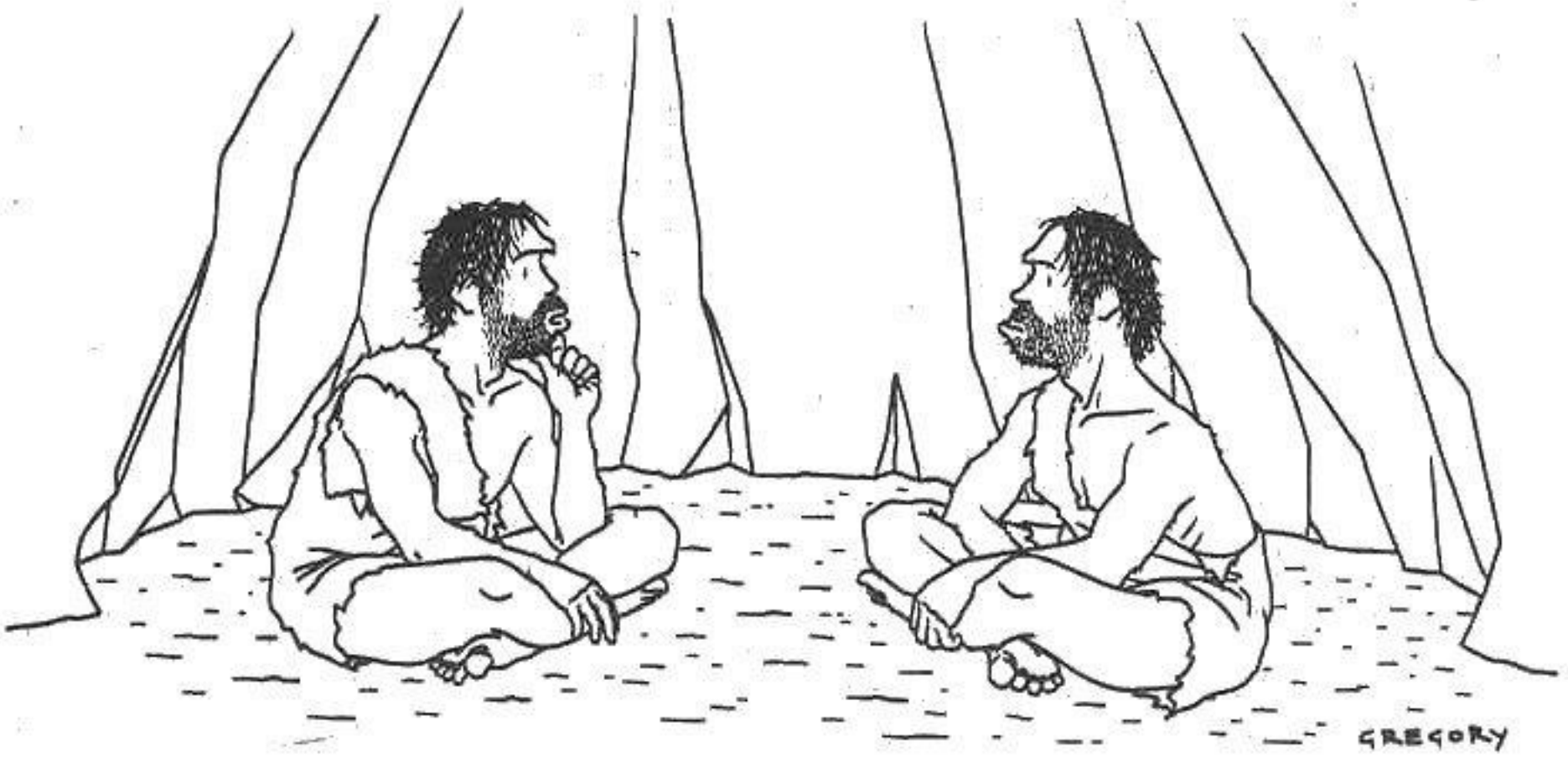
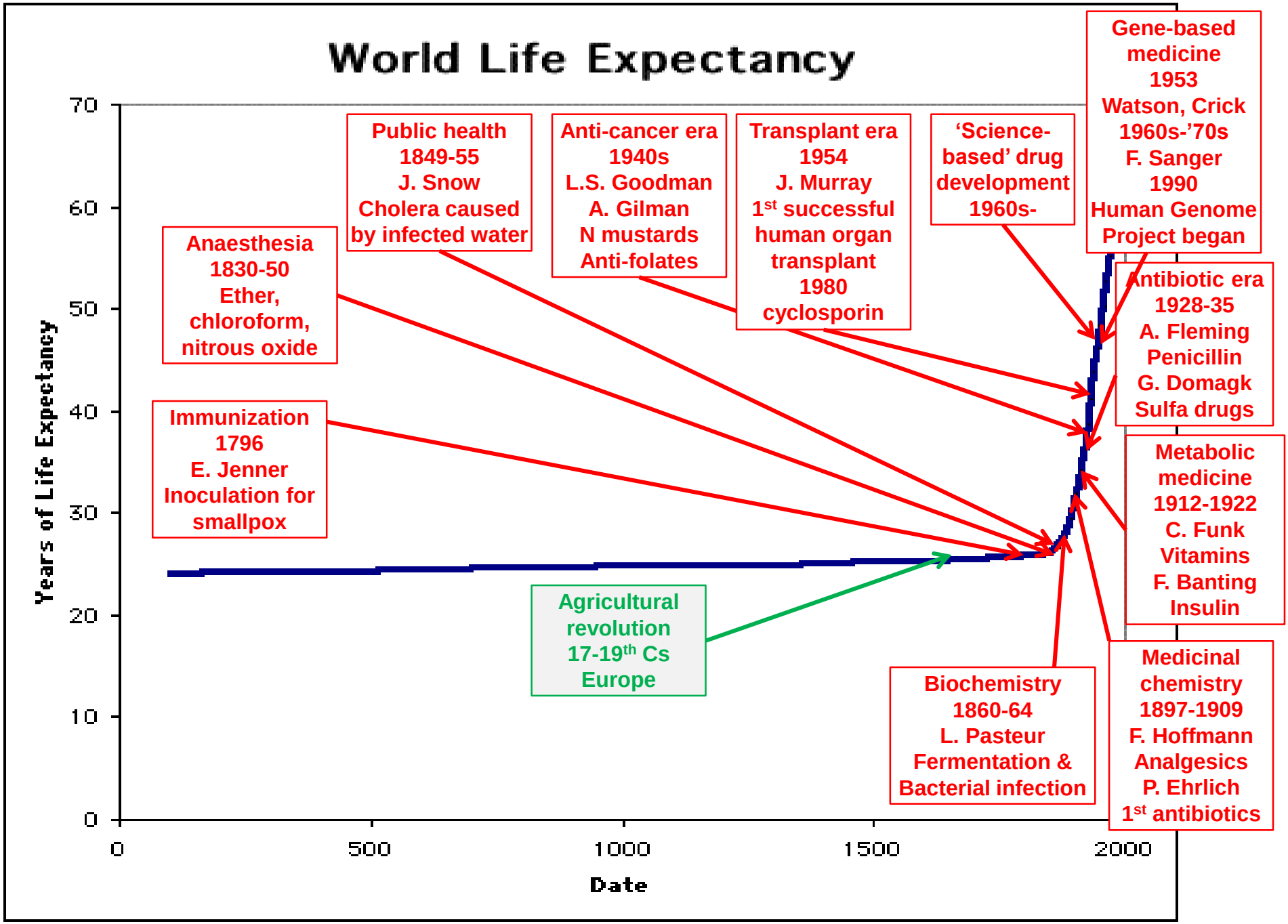


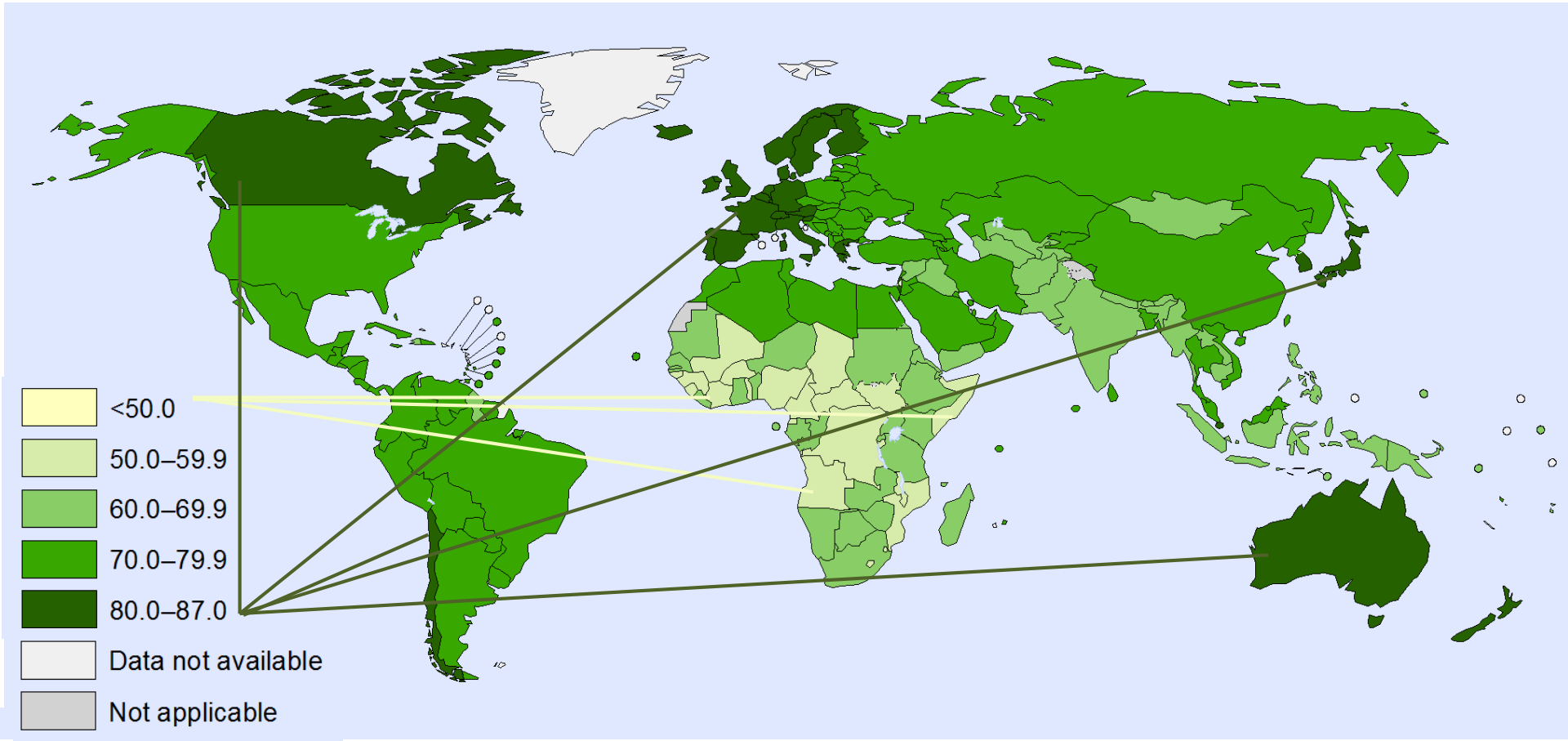
Our air is clean, our water is pure, we all get plenty of exercise, everything we eat is organic and free range,
but something's just not right – nobody lives past thirty!

Alex Gregory. New Yorker, 22 May 2006. www.newyorker.com/cartoons/bob-mankoff/cave-cuisine

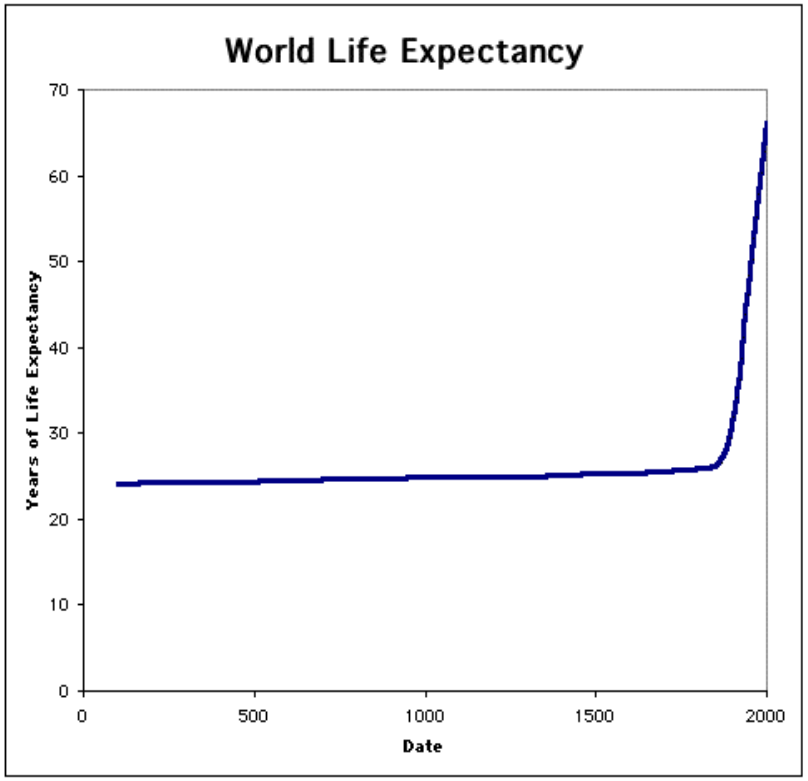


Life expectancy graph from:
www.j-bradford-delong.net/movable_type/images2/Life_Expect_Long.gif

World: Life expectancy at birth, both sexes, 2015

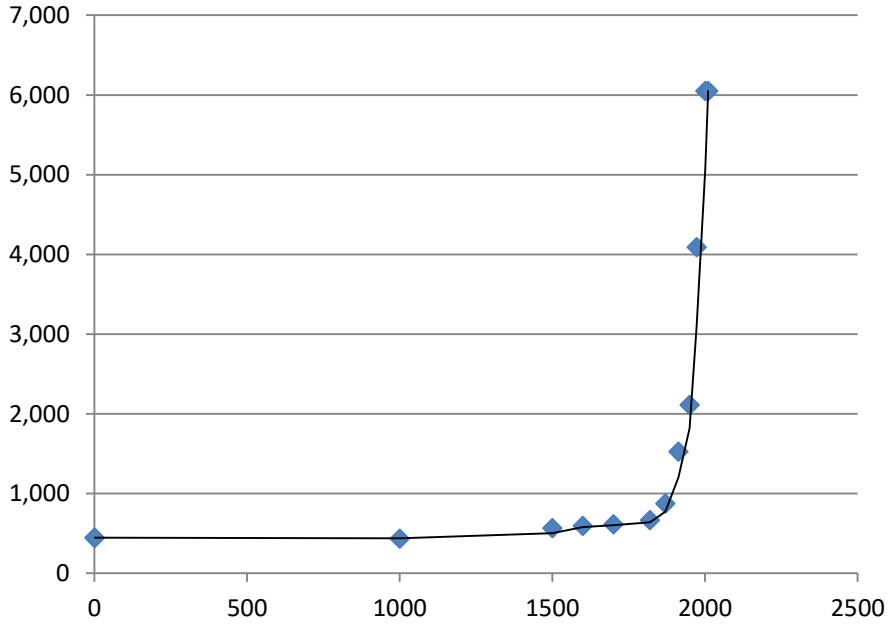


http://gamapserver.who.int/mapLibrary/Files/Maps/Global_LifeExpectancy_bothsexes_2015.png



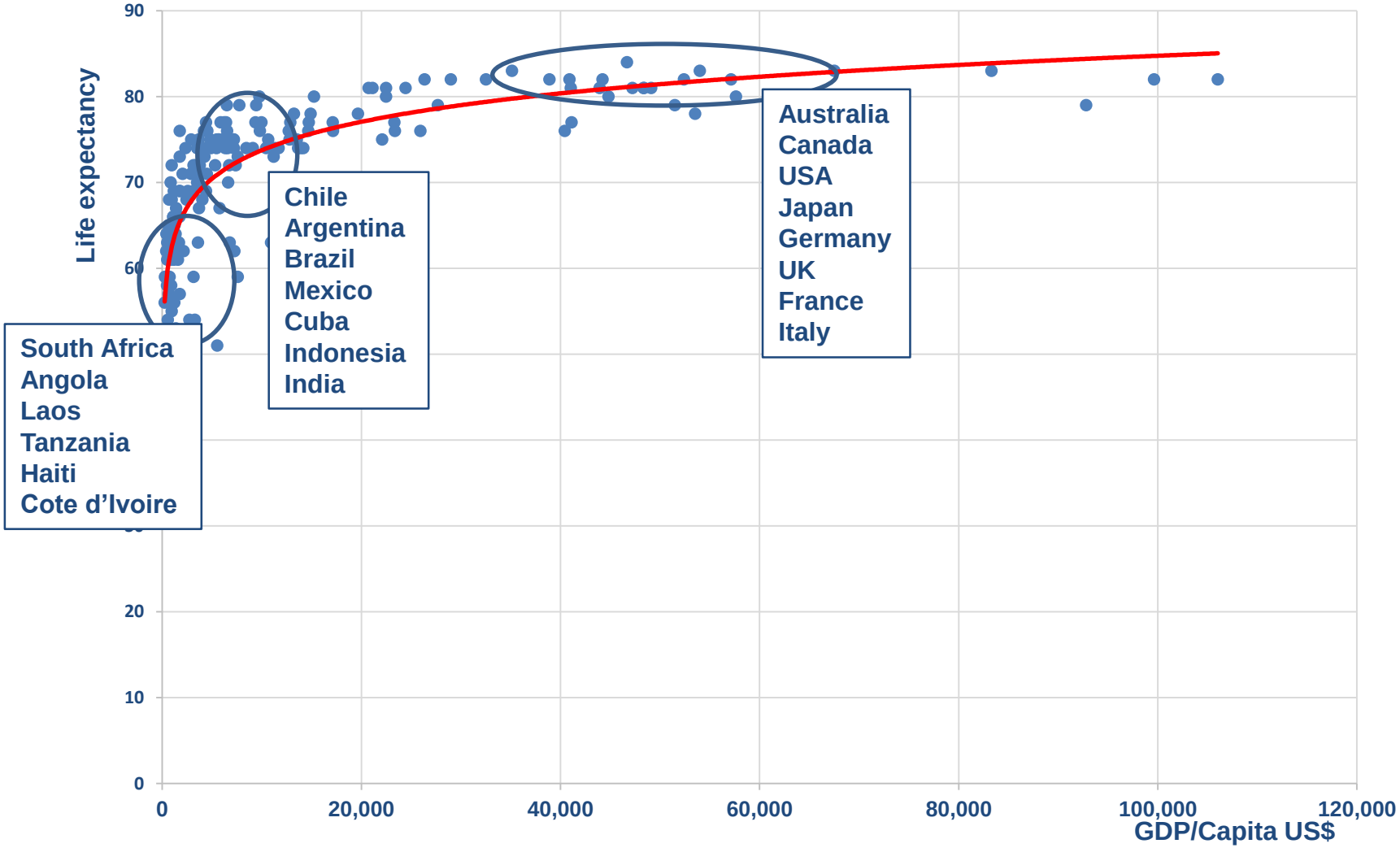
Global GDP per capita

1990 international (Geary-Khamis) dollars



How much health do you get for your wealth?

Preston curve: Life expectancy vs GDP per capita 2012

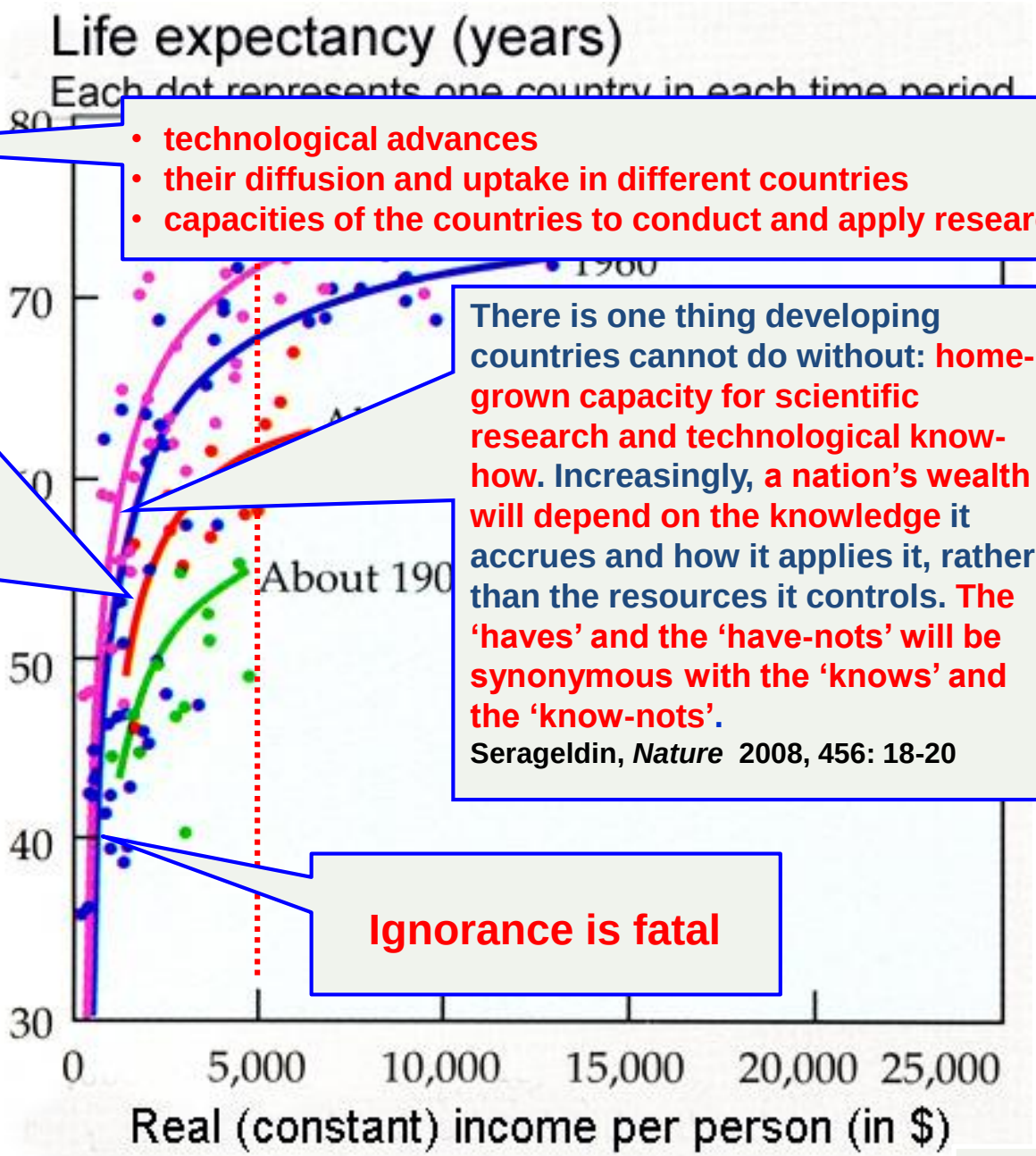


Matlin 2015: GDP data from World Bank 2015; Life expectancy data from WHO World Health Statistic 2014

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*

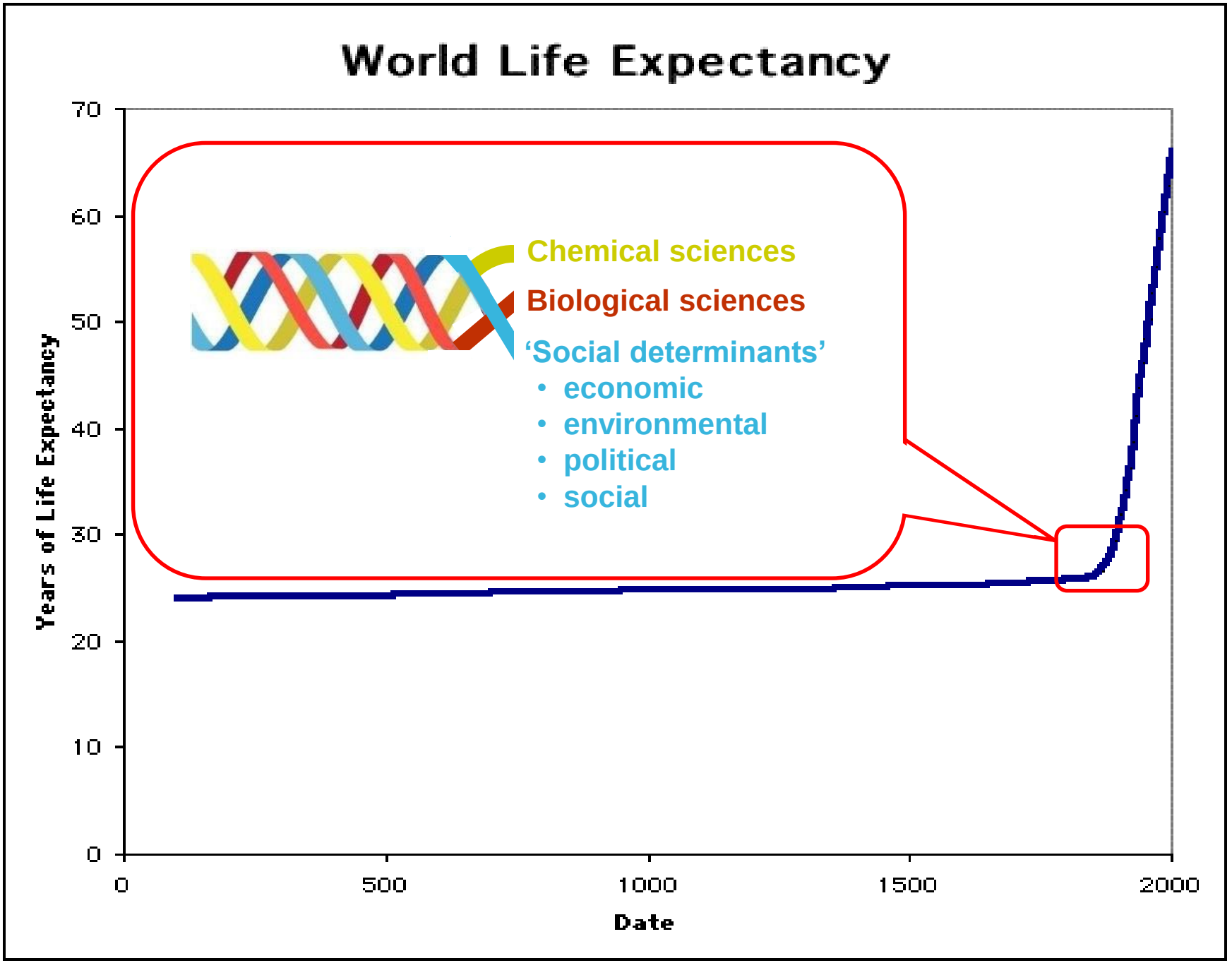


- **technological advances**
- **their diffusion and uptake in different countries**
- **capacities of the countries to conduct and apply research**

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

C. Dye; Preston curves from: www.gresham.ac.uk/lectures-and-events/is-wealth-good-for-your-health



Life expectancy graph from:
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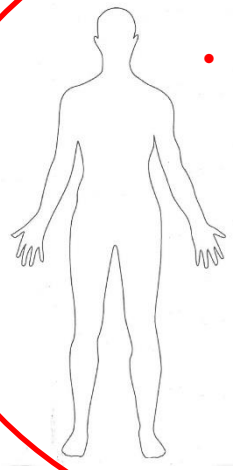
Oncoming global health challenges

State of the body



- **Diseases:**
  diagnosis, prevention, treatment
  - Old, new, re-emerging
  - Epidemics & pandemics
  - Non-communicable diseases
  - Ageing
  - Personalised medicine
  - etc

State of the world

- **Global environment**
  - Pollution: land, sea, air
  - Climate
  - Water
  - Food,
  - etc

- **Economic/political/social factors**
  - Globalization
  - Conflict, violence
  - Health equity
  - Population
  - Urbanization
  - etc

The chemical sciences have been central to global progress and will be essential to meeting oncoming global challenges – especially sustainable development

Matlin, Mehta, Hopf & Krief, *The role of chemistry in inventing a sustainable future..* Nature Chemistry 2015, 7, 941-3

2015 UN Sustainable Development Goals (SDGs) for 2030

"Ensure healthy lives and promote well-being for all at all ages" and *"leave no-one behind"*

www.un.org/sustainabledevelopment/sustainable-development-goals/

Chemistry in the 21st century

‘One-world chemistry’

Aims to be:

- A science for the benefit of society
  - Ethical practice
  - Systems thinking (ST)
  - Cross-disciplinarity

Recognises:

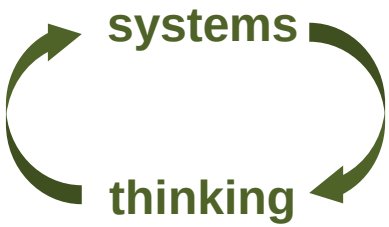
- Earth is a single system in which the health of human beings, animals and the environment are all strongly interconnected: all three must be taken into account in considering the impacts of chemistry

Implications for chemistry and health

- **Need for comprehensive approaches** that see the relationships between chemistry and health in the broad context
  - ➢ **Thinking about systems** and how they function and interact
  - ➢ Using **cross-disciplinary approaches**

Matlin et al, Nature Chemistry 2016, 8, 393-8

Implications for chemistry education



Cross-disciplinary modes

Disciplinary

Working alone in silos

Multidisciplinary

Working ‘side-by-side’: some exchange of knowledge

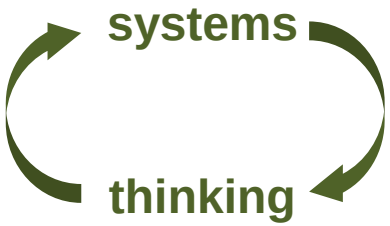
Interdisciplinary

Developing expertise in working across boundaries and transferring methods between disciplines

Transdisciplinary

Creating new synthesis of subjects in which knowledge, methods and solutions are developed holistically: recognizing that valuable knowledge can be found in the spaces between defined disciplines

Implications for chemistry education



System

- an interconnected set of elements that is coherently organized in a way to achieve a function or purpose.

Systems thinking

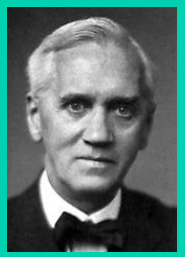
- Using strategies to develop understanding of the interdependent components within and among complex, dynamic systems
- Seeing and understanding systems as wholes rather than as collections of parts – as a web of interconnections that creates emerging patterns which help to identify the leverage points that lead to desired outcomes

adapted from http://watersfoundation.org

Challenges to health

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 and vaccines 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

Challenges in the chemical sciences for global progress

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

- Increasing rates of resistance to a number of antibiotics
- Vancomycin-resistant enterococci have emerged as a major healthcare problem in Australia.

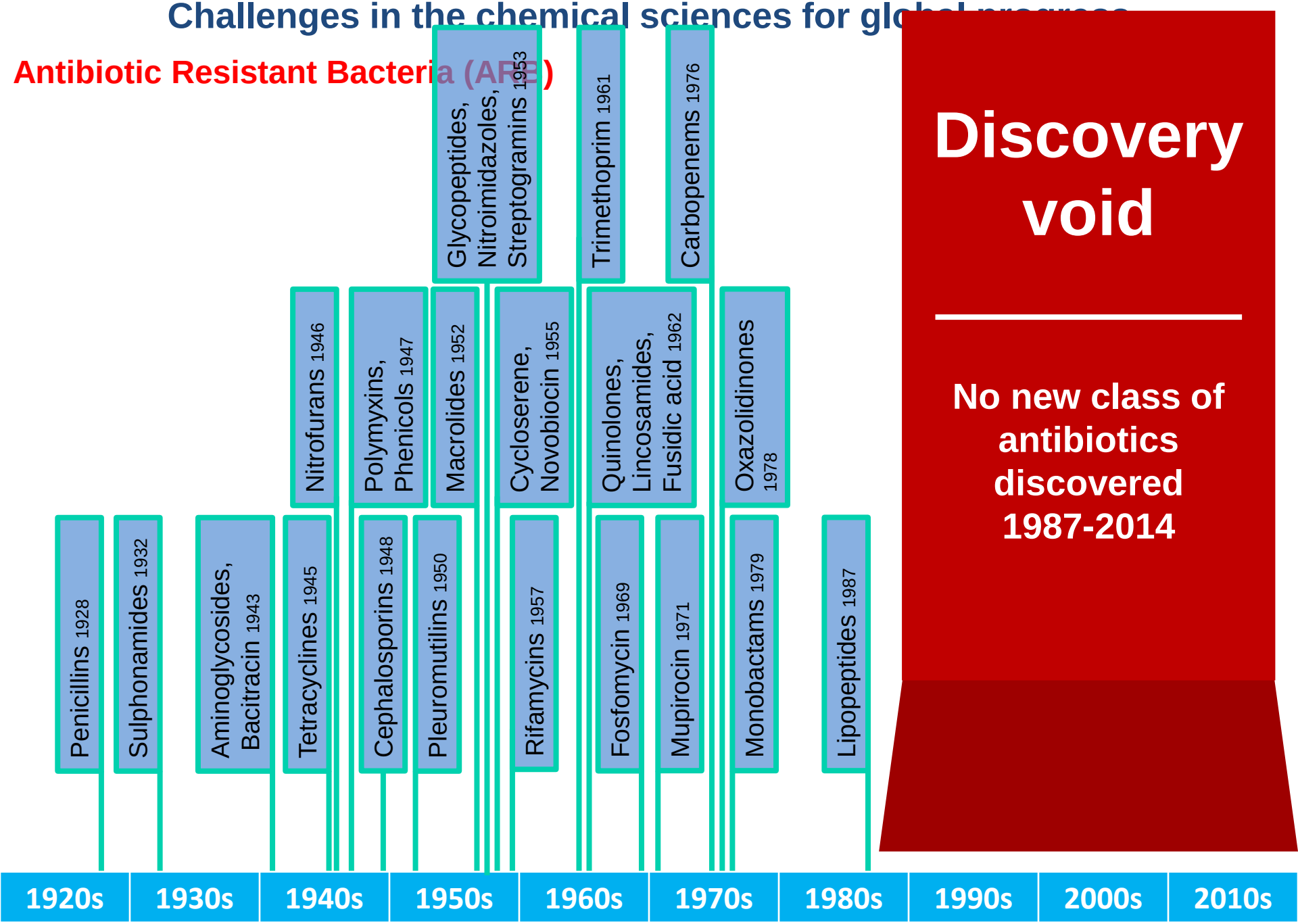
https://www.safetyandquality.gov.au

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

Challenges in the chemical sciences for glo

Antibiotic Resistant Bacteria (ARB)



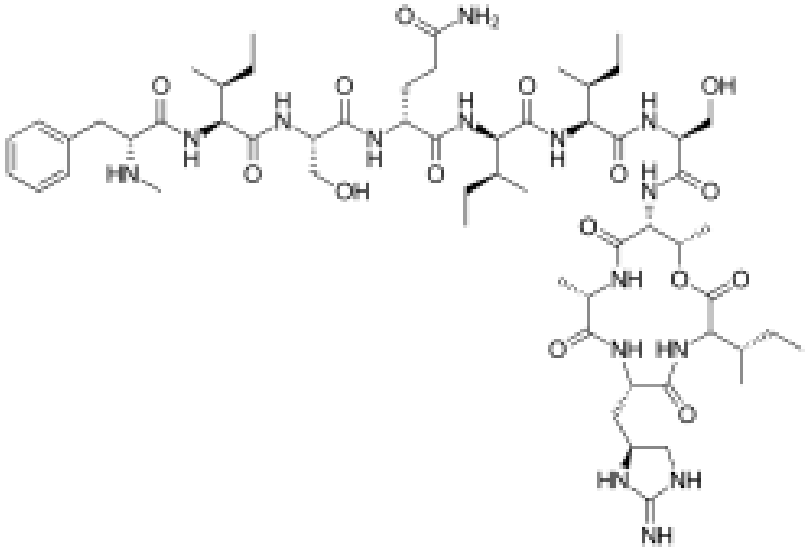
Discovery void

No new class of antibiotics discovered 1987-2014

Professor Dame Sally C Davies, Chief Medical Officer, England

Challenges in the chemical sciences for global progress

Antibiotic Resistant Bacteria (ARB)



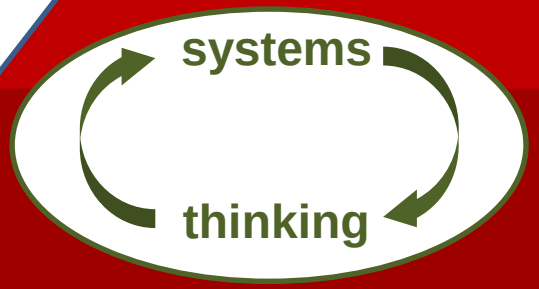
2015 Teixobactin discovered in soil sample (new screening technique for bacteria that cannot be cultured in lab)

- First new class of antibiotics since 1987
- *"Without detectable resistance"* in G+ organisms
- Research was funded by US National Institutes of Health and German research agencies
- Patent owned by early-stage biotech company

2018 Phase II clinical trials funded by NIH

Discovery void

No new class of antibiotics discovered 1987-2014



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

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Challenges in the chemical sciences for gl[illegible]

Antibiotic Resistant Bacteria (ARB)

EDITORIAL

nature biotechnology

Wanted: a reward for antibiotic development

Addressing the commercial failure of the antibiotic market should be a priority for governments seeking to encourage development of new drugs against resistant bugs.

At the end of May, the Nature conference "Countering Antimicrobial Resistance" in Beijing, China, showcased a wide array of discovery approaches focused on combatting drug-resistant bacteria. On the one

Bad Bugs program, the Global Antibiotics Research and Development Partnership, Novo Holdings' REPAIR Impact Fund and the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)

Nature Biotechnology 2018, 36555; https://www.nature.com/articles/nbt.4193

companies

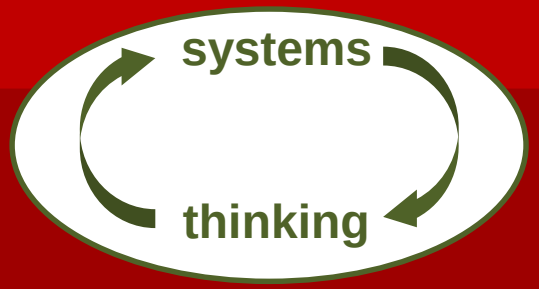
- any new antibiotic is likely to be kept as a last-resort treatment

"Systemic global market failure to incentivize front-end investment in antibiotic development through the promise of longer-term commercial reward"

- **Regulatory burdens**

Discovery void

No new class of antibiotics discovered



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

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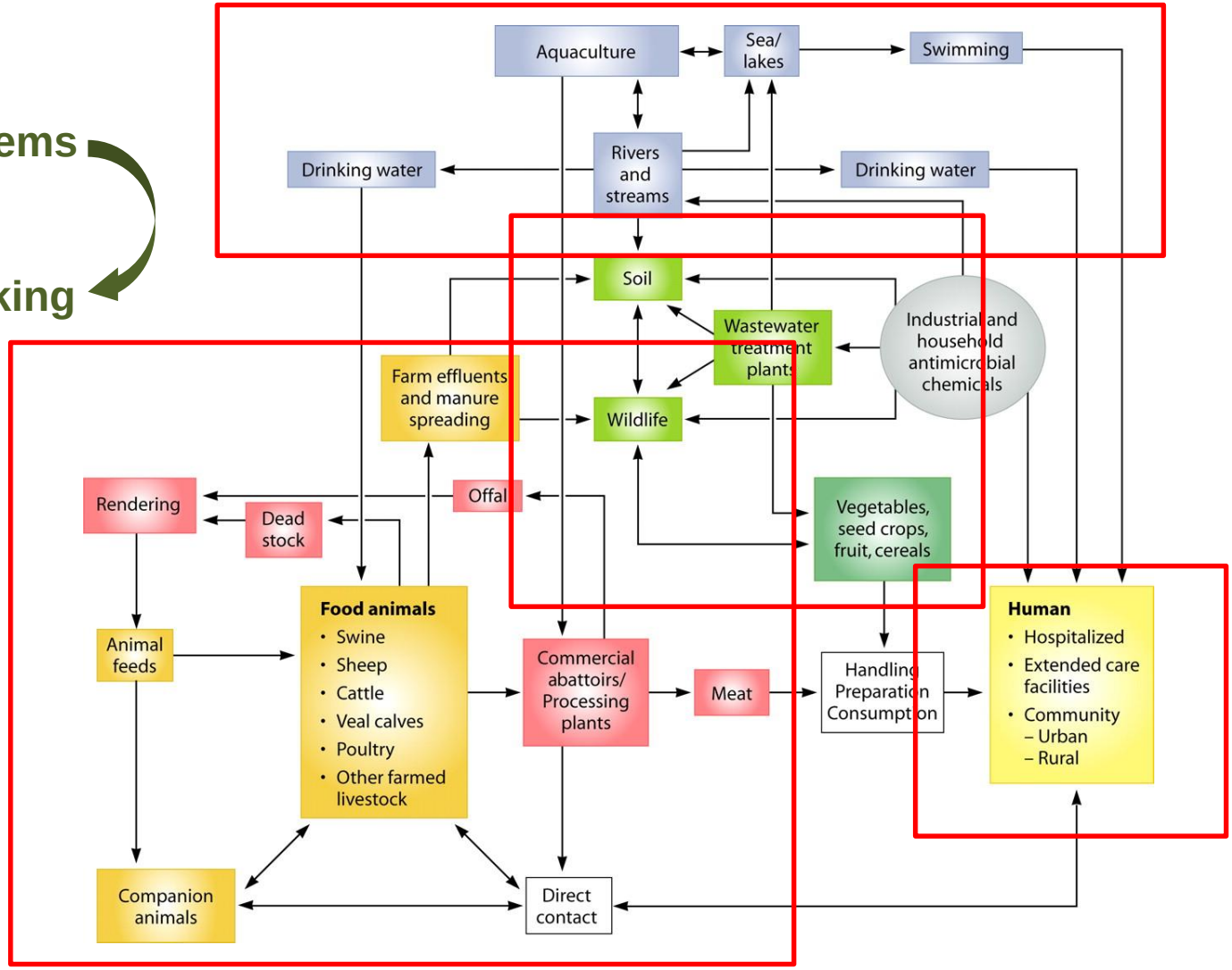
Determinants of antimicrobial resistance

Dissemination of antibiotics and antibiotic resistance within agriculture, community, hospital, wastewater treatment, and associated environments

systems thinking



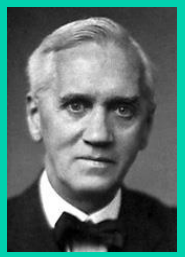
Julian Davies, Dorothy Davies. Microbiol. Mol. Biol. Rev. 2010;74:417-433
http://mmbr.asm.org/content/74/3/417.full

Challenges in the chemical sciences for global progress

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

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Challenges in the chemical sciences for global progress

Antibiotic Resistant Bacteria (ARB)

Need for better tools to recognize resistance

- Especially: cheap, accurate, rapid and easy-to-use point-of-care test kits 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

Need for greater investment in new antibiotics

- US: Obama administration nearly doubled the federal funding to combat antimicrobial resistance to more than $1.2 billion in 2016
- EU: Action Plan against Antimicrobial Resistance launched 2011
- IMI: EU/European pharmaceutical industry 'Innovative Medicines Initiative': *New Drugs for Bad Bugs* programme

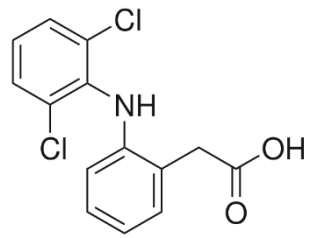
Need for a coordinated global effort to counter antibiotic resistance

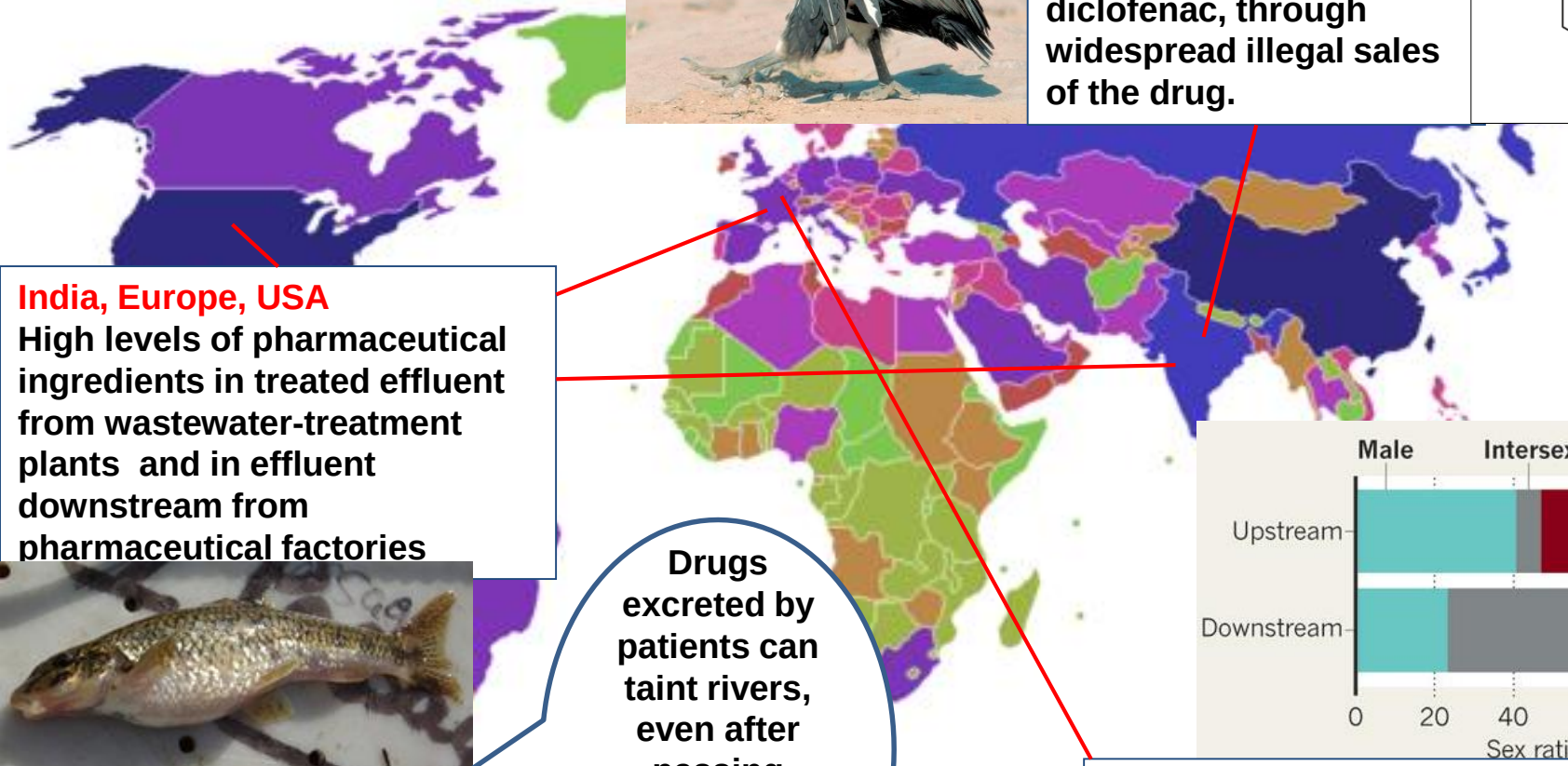
- May 2015 World Health Assembly: *Global action plan on antimicrobial resistance (AMR)*
  - ✓ governments all committed by May 2017 to put in place a national action plan on antimicrobial resistance, aligned with the global action plan
- USA+EU: Trans Atlantic Taskforce on Antimicrobial Resistance
- WHO, UN's Food and Agriculture Organization and World Organisation for Animal Health collaborating closely

Contaminants in environment, food & pharmaceuticals

India

Critically endangered vultures in India are still at risk of exposure to the anti-inflammatory drug diclofenac, through widespread illegal sales of the drug.





India, Europe, USA

High levels of pharmaceutical ingredients in treated effluent from wastewater-treatment plants and in effluent downstream from pharmaceutical factories

Gudgeon downstream of wastewater-processing plant had swollen abdomens and other abnormalities

Drugs excreted by patients can taint rivers, even after passing through wastewater-processing facilities

Fish downstream of a French pharmaceutical factory much more likely to show characteristics of both sexes (intersex) than those upstream

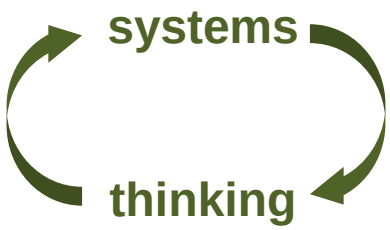
Nature.com August & September 2011

Contaminants in environment, food & pharmaceuticals

High levels of pharmaceutical ingredients found in treated effluent from wastewater-treatment plants and in effluent downstream from pharmaceutical factories.
Examples from India, USA and EU
USA and 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.

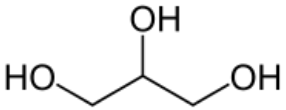
Nature, 15 August 2011.
www.nature.com/news/2011/110815/full/476265a.html

- **Need for better regulation and enforcement**
  – requires understanding and support from public and policy makers
- **Need for rapid, accurate, very sensitive, affordable analytical techniques**
  – preferably that can be applied at, or very close to, the site being inspected

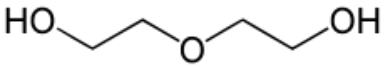


Contaminants in environment, food & pharmaceuticals

Glycerine



DEG



2011 UK

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

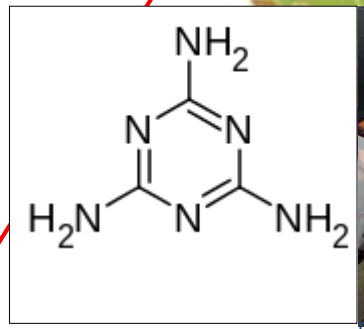
23 September
Man arrested in London and later convicted and jailed

- **Need for better regulation and enforcement**
- **Need for rapid, accurate, very sensitive, affordable analytical techniques**

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 supplies 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

Extent of problem:

- **Toxicoses from 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.**

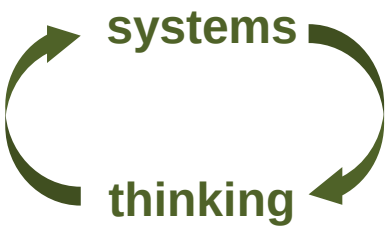
- **Contaminated raw material produced in a poorly regulated market may cross national boundaries and be used in manufacturing processes for numerous products, sometimes in more well-regulated markets.**

Capacity for solutions

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

- **The [relevant 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.**



Global problem needing global solutions

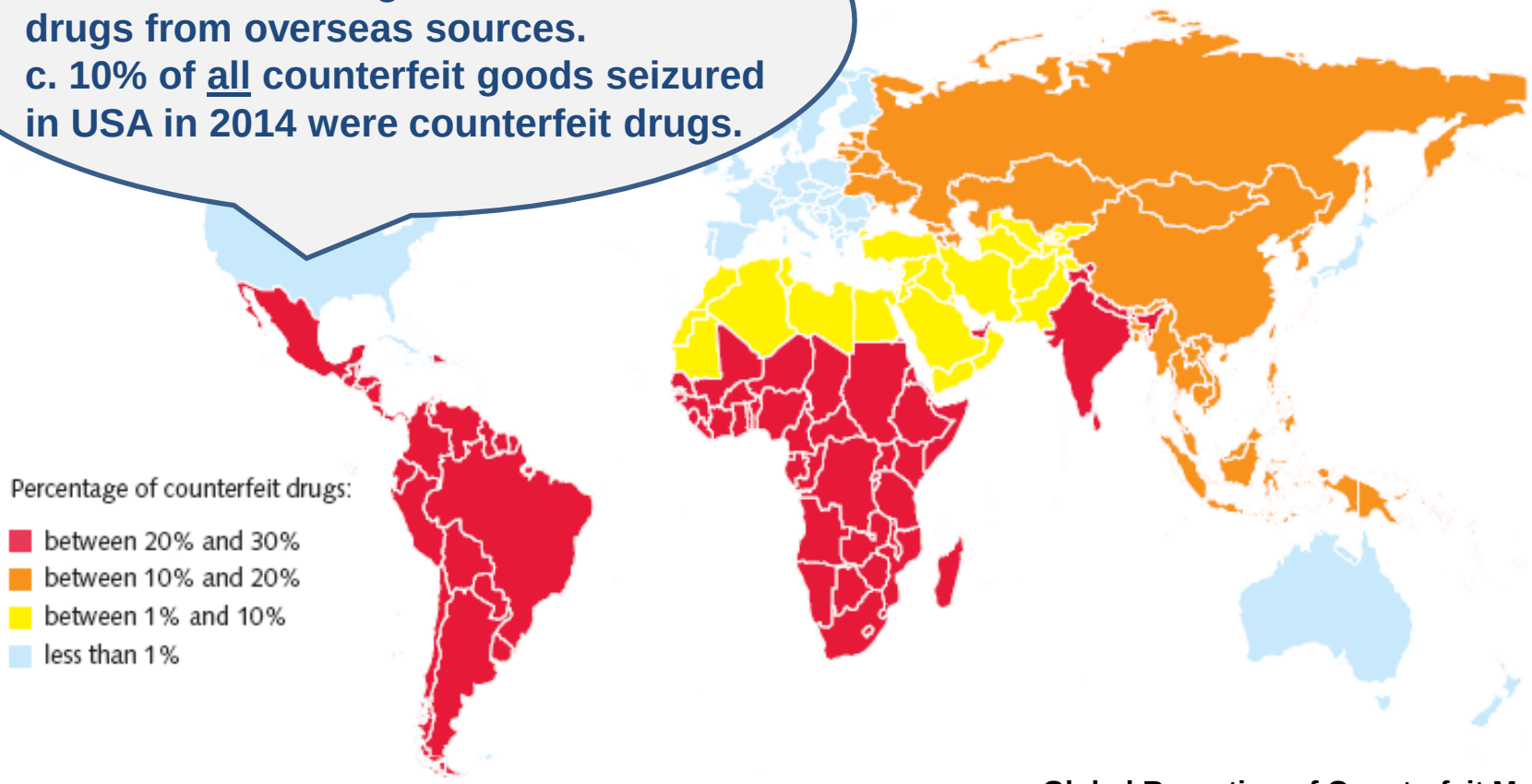
Brown & Brown *Vet Pathol* 2010, 47, 45-52

Counterfeit drugs

Its a fake world: Counterfeit drugs becoming increasingly available

- Estimated counterfeit drug sales worth in the range US$ 75 - 200 billion/year globally
  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.
c. 10% of <u>all</u> counterfeit goods seizured in USA in 2014 were counterfeit drugs.



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 $1.4 million misbranded and counterfeit drugs and controlled substances**
- **An international 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

July 2011

US National Association of Boards of Pharmacy report:
96% of 8,000 internet pharmacy Web sites analyzed operate out of compliance with United States pharmacy laws

www.nabp.net/news/nabp-issues-rogue-online-pharmacy-public-health-alert/

Counterfeit drugs

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

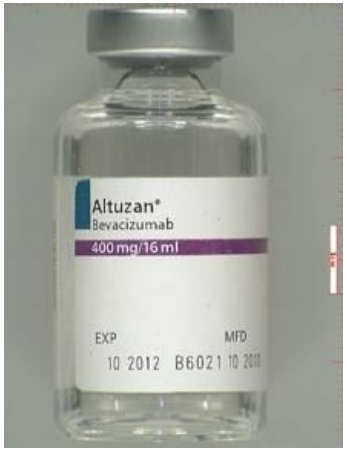
Counterfeit drugs included antibiotics, hormones, analgesics, steroids, antihistamines:

- **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%**

➢ **In 2011, 64% of antimalarial drugs in Nigeria were found to be counterfeit**

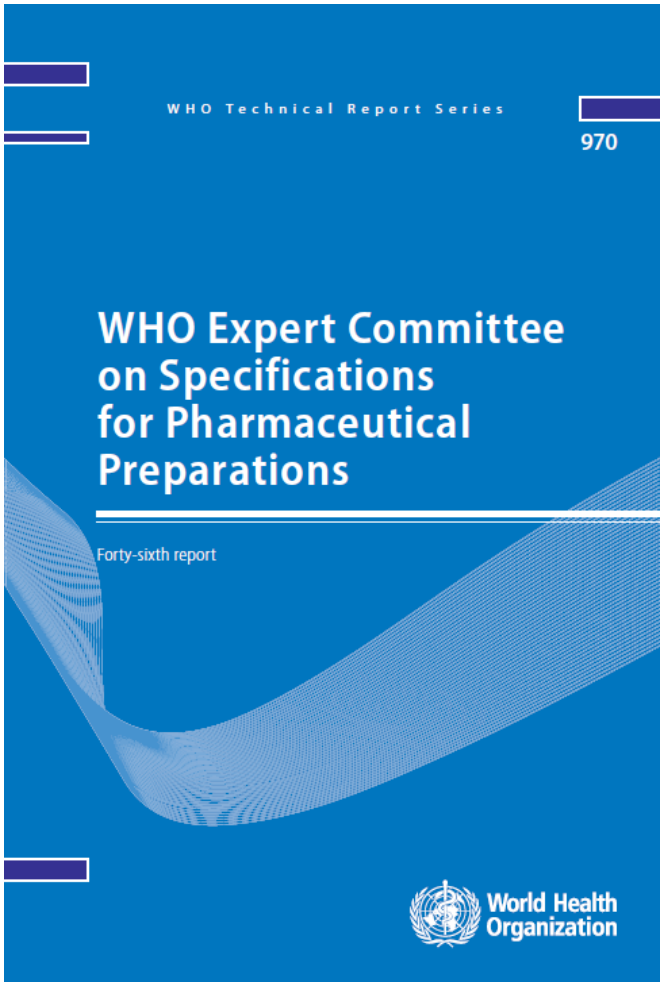
No simple solution

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



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

- **In 2015, of 191 WHO member states c. 20% had well developed drug regulation. Of remainder, c. 50% implemented some drug regulation; another 30% either had no drug regulation in place or a very limited capacity that hardly functioned.**

General Information on Counterfeit Medicines, WHO 2015 www.who.int/medicines/services/counterfeit/overview/en/index1.html
Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products, WHO 2016. /www.who.int/mediacentre/factsheets/fs275/en/

Technologies to prevent/identify counterfeits

- **World market for pharmaceutical anti-counterfeiting technology c. US$ 3.4 billion in 2015**
- **Pharmaceutical + food anti-counterfeiting market may exceed US$ 160 billion by 2020**

www.visiongain.com/Report/1360/Pharmaceutical-Anti-counterfeiting-Technologies-Market-Analysis-and-Forecasts-2015-2025

www.hexaresearch.com/research-report/pharmaceuticals-and-food-anti-counterfeiting-technologies-industry/

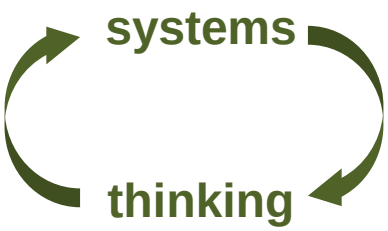
Contaminants in environment, food & pharmaceuticals

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

  - **Public and policy makers need to understand the dangers; and the policies and practices [systems] needed to counter them and to tackle highly ingenious criminals**
    **** Challenges for [chemical] science literacy***

- **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**
    **** Challenges for capacities for [chemical] science literacy, communication, diplomacy***



- **The chemical sciences have been good for health**

- **Faced with the oncoming global challenges, even greater efforts are required**

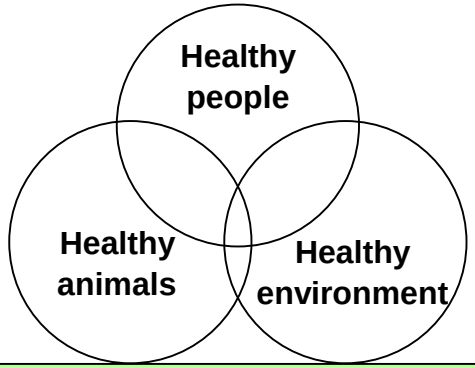
- **The chemical sciences are not able to function optimally in helping to deliver better health and health equity**

Three systemic fragmentations, involving:

1. **the science discipline**
2. **the functioning of industry**
3. **the regulatory systems related to health**

Matlin, Mehta, Krief & Hopf. *ACS Omega*, 2017, http://doi.org/10.1021/acsomega.7b01463

The chemical sciences support health through multiple channels



Sustainable development

Regulatory systems for medicines & medical practice		Regulatory systems for food quality	Regulatory systems for the environment
Safe, effective, affordable pharmaceutical products: drugs, vaccines, drug delivery systems, etc	Other medical products and devices: anaesthetics, prosthetics, diagnostics, medical imaging	Safe, nutritious food from production, processing, preservation	Good quality of land, water, air, global ecosystem

Education, research and practice in 'the chemical sciences for health'	Pharmaceutical and other health science industries; agriculture & fisheries	Environmental monitoring, protection & preservation, cleaning

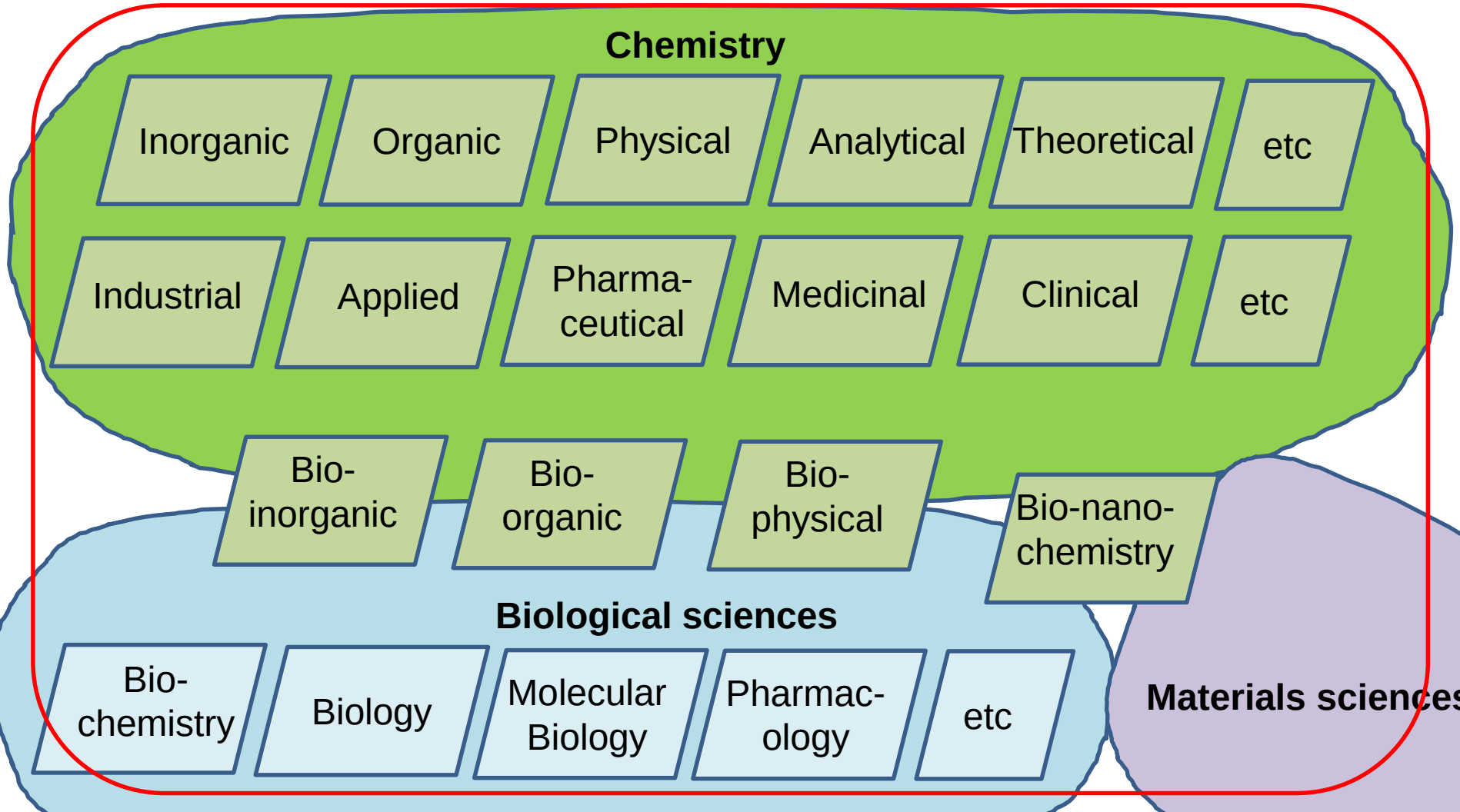
The chemical sciences

Matlin, Mehta, Krief & Hopf. *ACS Omega*, 2017, http://doi.org/10.1021/acsomega.7b01463

One-world chemistry, systems thinking and cross-disciplinarity applied to ‘the chemical sciences and health’

Three systemic fragmentations:

1. **Compartmentalization in the science discipline**



One-world chemistry, systems thinking and cross-disciplinarity applied to 'the chemical sciences and health'

Three systemic fragmentations:

1. **Compartmentalization in the science discipline**

Chemistry and Health

- Creating an overall vision of the multitudinous roles and capacities of the chemical sciences in achieving better health
- Providing the intellectual underpinning for trained graduates and researchers with a solid, broad platform of knowledge and skills to engage in cross-disciplinary work applied to health, related to, eg:
  - ❑ medicinal/pharmaceutical chemistry
  - ❑ biopharmaceutical analysis
  - ❑ clinical chemistry
  - ❑ biomaterials
  - ❑ medical imaging
  - ❑ toxicology
  - ❑ environmental analytical chemistry
  - ❑ nutrition & food analysis
  - ❑ forensic chemistry
  - ❑ regulatory affairs
- Promoting convergence of diverse knowledge streams in the chemical sciences and harnessing these convergences to enhance the innovative contributions of the chemical sciences to health

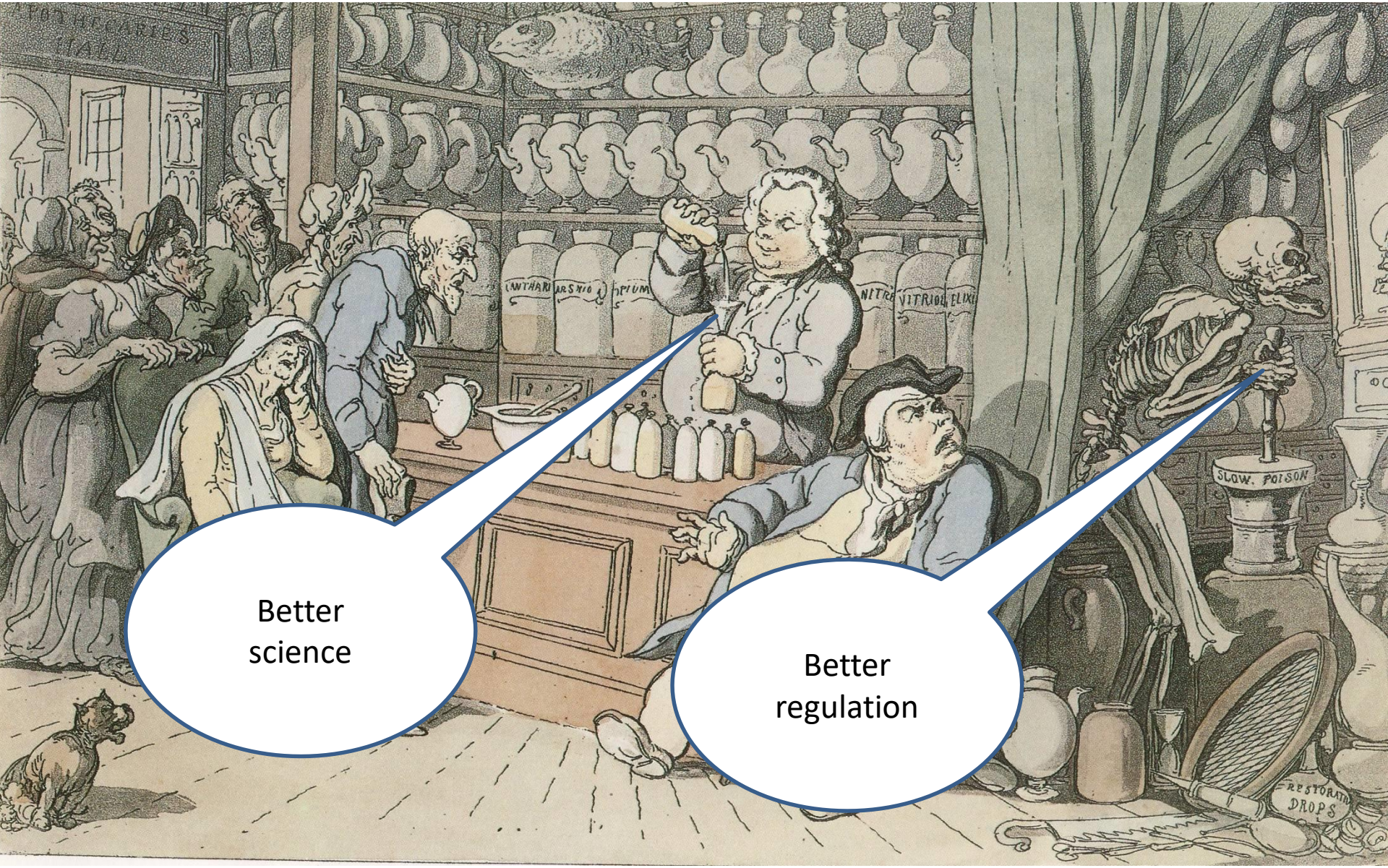
➢ New degrees; changed curricula

One-world chemistry, systems thinking and cross-disciplinarity applied to ‘the chemical sciences and health’

Three systemic fragmentations:

1. **Compartmentalization in the science discipline**
2. **Dis-integration in the pharmaceutical industry**

The pharmaceutical industry



The Quack Doctor, 1814

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

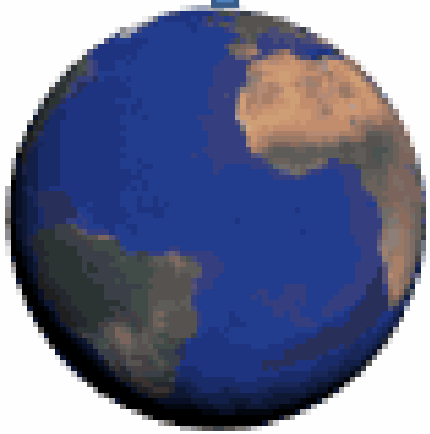
The pharmaceutical industry

Globally:

- **The 20 largest pharma/biotech companies employed over 1.3 million people in 2006**
- **The industry generated global sales > US$ 1 trillion by 2015**
- **Biopharmaceutical research companies are the most research intensive in the world; USA invested US$ 67.4 billion in 2010; in Europe, represents 1/5 of total EU private R&D expenditure**

Australia:

- **The Australian pharmaceutical industry exports products worth AUS$4 billion annually and employs more than 15,000 people**

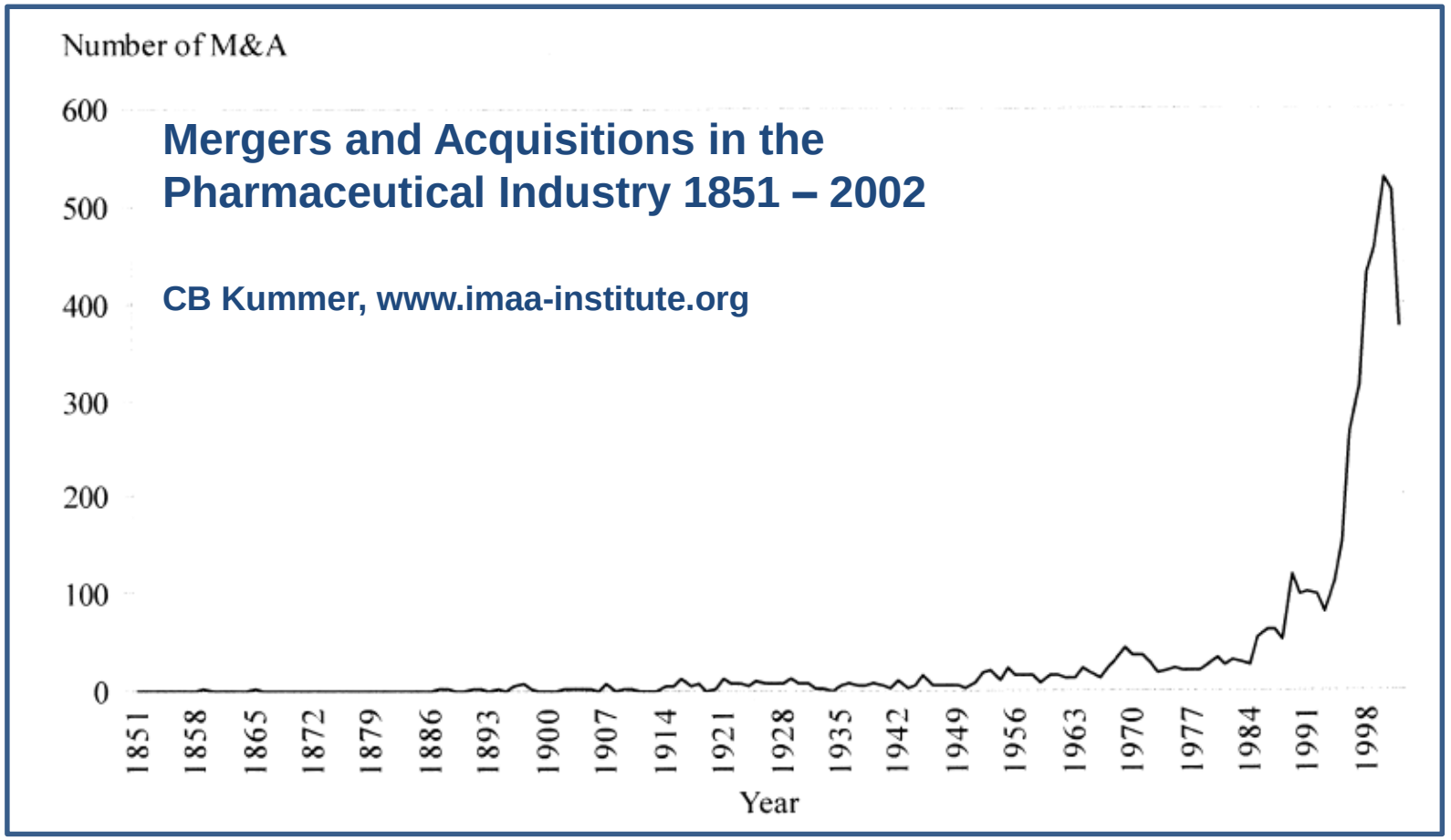


The pharmaceutical industry

- **Moving: sideways, and to East and South Asia**

Paradoxically:

- **Mergers and acquisitions**
- **Shift from ‘vertical’ to ‘horizontal’ structures, including the separation of research from development**



The pharmaceutical industry

- **Moving: sideways, East and South**

Paradoxically:

While mergers apparently have achieved cost reductions and addressed short-run pipeline problems, there is little evidence to date that they increased long-term R&D performance or outcomes. Many of the larger pharmaceutical firms… continue to deal with a persistent R&D productivity problem.

Grabowsky & Kyle 2008
Mergers and alliances in pharmaceuticals: effects on innovation and R&D productivity.
http://margaretkyle.net/G-K%20Merger%20chapter.pdf

the world.

Downey, Greenberg, Kapur. Reorienting R&D for a Horizontal Future
Research-Technology Management, 2003, 46(5): 22-28

The pharmaceutical industry

- Moving: sideways, East and South

Pa

es, including the separation

Without a substantial increase in R&D productivity, **the pharmaceutical industry's survival** (let alone its continued growth prospects), at least in its current form, **is in great jeopardy**.

Paul et al (Lilly Research Laboratories, Eli Lilly and Co)
Nature Reviews 2010, 9, 203-214
www.nature.com/nrd/journal/v9/n3/pdf/nrd3078.pdf

Although **mergers and acquisitions** in the pharmaceutical industry might have had a reasonable short-term business rationale, their **impact on the R&D of the organizations** involved **has been devastating**.

LaMattina (former President of Pfizer Global R&D)
Nature Reviews 2011, 10, 2559-560
www.nature.com/nrd/journal/v10/n8/pdf/nrd3514.pdf

USA, 1970–2002

Lin ng by PhRMA member companies, inflation-adjusted to constant 2002 dollars by the NIH Biomedical R&D price deflator.

IM Cockburn, The Changing Structure Of The Pharmaceutical Industry, *Health Affairs, 23, no.1 (2004):10-22.* http://content.healthaffairs.org/content/23/1/10.full.html

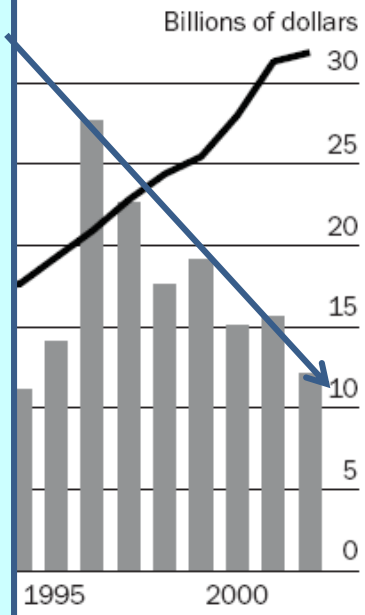
The pharmaceutical industry

- **Pharmaceutical industry** is undergoing fundamental change and its **future is unclear**.
- Emergence of **a handful of companies** that **controls two-thirds of NMEs**.
- **Growth in number of NMEs controlled by marketing organizations** that have little or no internal drug discovery or development activities: increased dramatically since 2000 and could raise **important questions about the future landscape and viability of drug discovery and development**.

Kinch et al (Center for Molecular Discovery, Yale University) An overview of FDA-approved new molecular entities: 1827-2013. Drug Discovery Today 2014, 19, 1033-1039. https://www.ncbi.nlm.nih.gov/pubmed/24680947

es, including the separation

USA, 1970–2002



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R&D price deflator.
tructure Of The Pharmaceutical Industry,
Health Affairs, 23, no.1 (2004):10-22. http://content.healthaffairs.org/content/23/1/10.full.html

One-world chemistry, systems thinking and cross-disciplinarity applied to

ABPI 2016

More organisations overall, particularly large firms, reported a greater increase in their global discovery investment than that in the UK. This could suggest that whilst areas of the landscape may be thriving, overall the UK may be proportionally losing out globally.

Thus the UK needs to consider how it can best maintain its position as a central player in a dynamic global discovery landscape.

www.abpi.org.uk/our-work/library/industry/Pages/The-changing-UK-drug-discovery-landscape.aspx

Does it matter where and how the science gets done, as long as new products are created to meet the growing health needs? Analysts differ:

- **Some: the metamorphosis has had 'mixed results'**
- **Some: it has not been to the advantage of people's health**
  - **decline in numbers of new drug entities coming into use annually**
  - **narrowing of focus on block-buster drugs while 'diseases of the poor' neglected**
  - **may be a shift in job opportunities in the relevant sciences accompanying the geographic relocation of pharmaceutical R&D to South and East Asia;**
  - **and this may decrease the popularity of these sciences in Europe North America, Australia – weakening their traditionally strong capacities in research for health**

One-world chemistry, systems thinking and cross-disciplinarity applied to 'the chemical sciences and health'

Three systemic fragmentations:

1. Compartmentalization in the science discipline
2. Dis-integration in the pharmaceutical industry

The model needs revisiting since the world needs

- more drugs and other health products at more affordable prices for more diseases and conditions
- a system that enables achievement of the SDG goals of health and health equity for all, based on the principle of 'leave no-one behind'.

Solutions will not be straightforward:

- driven by economic forces that do not originate in the pharmaceutical sector itself but in functioning of economic reward and innovation systems at national and global levels.

If the high-income countries with traditionally strong pharmaceutical development capacities wish to retain their industries and their leadership roles in the field, they need to play close attention to systemic elements involved and bolster critical ones, including:

- ensuring strong, robust and well-designed education programmes, including relating to the chemical sciences, that create a pool of talent with skills honed in conducting inter-disciplinary and trans-disciplinary research
- well-funded academic centres that can create new leads to health products
- innovation hubs that foster early-stage drug development
- national innovation systems and innovation financing that encourage the growth of independent middle-size companies that have options beyond buy-out when they create promising candidate products and high-value new licensed drugs

One-world chemistry, systems thinking and cross-disciplinarity applied to 'the chemical sciences and health'

Three systemic fragmentations:

1. Compartmentalization in the science discipline
2. Dis-integration in the pharmaceutical industry
3. Disconnections in the regulatory sector

It's a dirty world and a fake world – affects pharmaceuticals, food and the environment

Need for more effective regulation

- Licencing
- Quality of products procured
- Quality of products in circulation
- Counterfeits
- Contamination of environment
- Contamination of foodstuffs

Regulation = Laws + policing + criminal justice system

- Analytical science feeds into all three
  - Sets position for what is **possible**
  - Sets practical framework/limits for timescale and cost of what is **detectable**
  - Sets limits of what is 'provable' and therefore **enforceable** by courts

Dialogue essential: between scientists, policy makers, legal system, public, media

- Non-technical language
- Effective communication – e.g. about 'certainty' and 'risk'


World Organization for the Regulation of Food, Environment and Drugs
WORFED
Analytical Chemistry Division
Medicines and Medical Devices
ICH
harmonisation for better health
Lyfjastofnun
Icelandic Medicines Agency
KOREA FOOD & DRUG ADMINISTRATION
FOOD AND DRUG ADMINISTRATION
THAILAND
INVIMA
FACSS
EUROPEAN MEDICINES AGENCY
Ministry of
Department of Health and
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Safe Drugs
MINISTRY OF HEALTH

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Thank you

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