Ministry of Health & Family Welfare

2019 World Conference on Access to Medical Products:
Achieving the SDGs 2030
19-21 November 2019, New Delhi, India
Global Partnerships for Drug Discovery, Innovation, Technology Development:
Scaling up Adaptive Technology Solutions for Medical Products

World Health Organization India

Changing Landscape of Health Innovation Networks and Other Collaborations to Foster Research and Development

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Networks and Other Collaborations

World Health Organization India

Health networks: Webs of individuals and organizations linked by a shared concern to address a particular health problem

Shiffman 2016
https://doi.org/10.1093/heapol/czw019

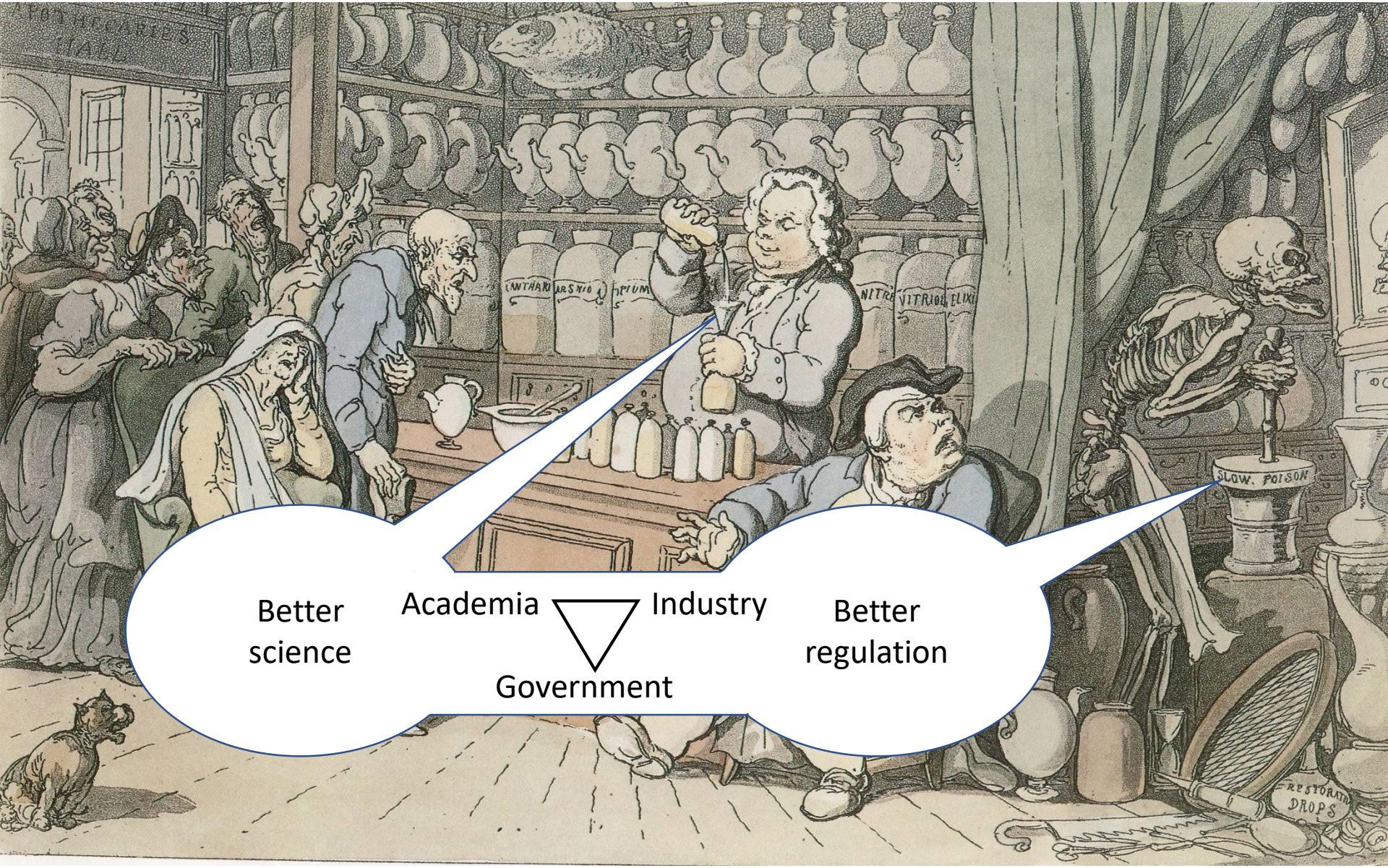
Networks **Alliances** **Consortia** **Initiatives**

Projects **Partnerships** **Ventures**

Collaborations with diverse

- goals
- methods of working
- degrees of formalization, rules, governance
- degrees of openness
- sources and levels of funding

The pharmaceutical industry



The Quack Doctor, 1814

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

The pharmaceutical industry

Global industry:

- >1,500 New Molecular Entities approved as drugs by FDA
- >4 million jobs globally
- The industry generated global sales of US$ 1.2 trillion in 2018

The pharmaceutical industry

- Mergers and acquisitions
- Shift from 'vertical' to 'horizontal' structures, including the separation of research from development
- Buying intellectual property rather than creating it (in many cases, buying the innovative small companies that create the candidates)

- Manufacturing across the industrial sector is "going horizontal,"
  - vertically integrated supply chains are breaking apart into component layers dominated by horizontal specialists and reconfigured regularly to create more cost-effective combinations.
- This seismic shift is reshaping the future of R&D around the world.

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

The pharmaceutical industry

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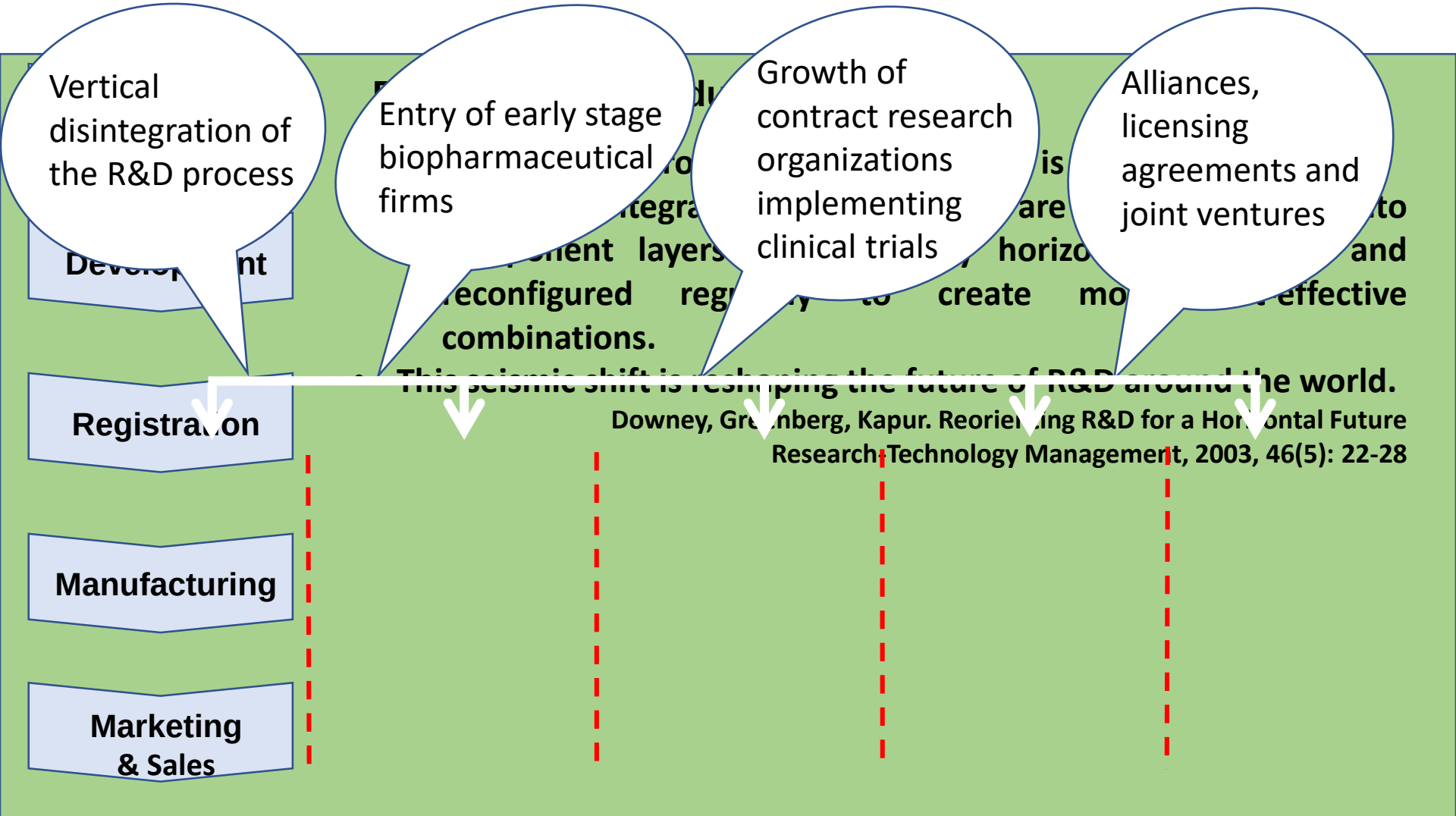

combinations.

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The pharmaceutical industry

- **Mergers and acquisitions**
- **Shift from 'vertical' to 'horizontal' structures, including the separation of research from development**
- **Buying intellectual property rather than creating it (in many cases, buying the innovative small companies that create the candidates)**

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.**

Grabowski & Kyle 2008
http://margaretkyle.net/G-K%20Merger%20chapter.pdf

Pharma mergers are **"bad for science, bad for patients, bad for medicine"**.

LaMattina 2014
https://www.pharmaceutical-technology.com/features/featurepharma-mergers-big-business-bad-science-4467897/

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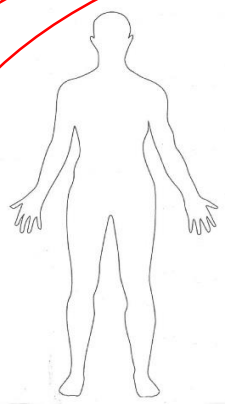
Oncoming global health challenges

World Health Organization India

Health R&D



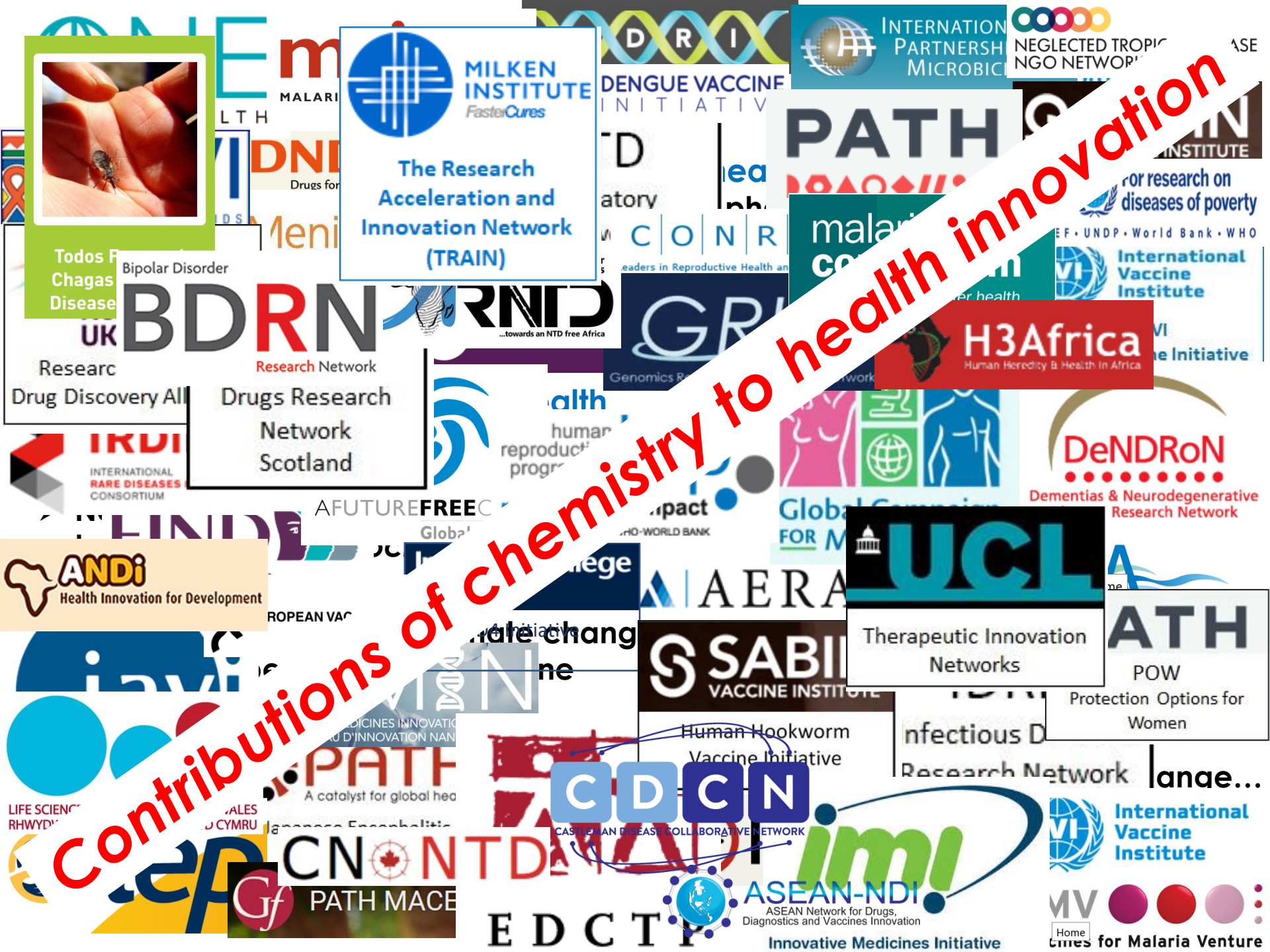
State of the body

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

State of the world

- **Global environment**
  - Pollution: land, sea, air
  - Climate
  - Water
  - Food
  - etc
- **Economic/political/social factors**
  - Globalization
  - Conflict, violence
  - Population
  - Urbanization
  - SDGs: UHC, Health Equity
  - etc

R&D for health


Contributions of chemistry to health innovation
MILKEN INSTITUTE
FasterCures
The Research Acceleration and Innovation Network (TRAIN)
Bipolar Disorder
BDRN
Research Network
Drugs Research Network Scotland
Drug Discovery All
RND
...towards an NTD free Africa
DRI
DENGUE VACCINE INITIATIV
PATH
malari
CONR
eaders in Reproductive Health an
GRI
Genomics R
H3Africa
Human Heredity & Health in Africa
International Vaccine Institute
for research on diseases of poverty
F • UNDP • World Bank • WHO
DeNDRoN
Dementias & Neurodegenerative Research Network
INTERNATIONAL RARE DISEASES CONSORTIUM
AFUTUREFREEC
ANDi
Health Innovation for Development
AERA
UCL
Therapeutic Innovation Networks
SABIN
VACCINE INSTITUTE
Human Hookworm Vaccine Initiative
POW
Protection Options for Women
CDCN
CASTLEMAN DISEASE COLLABORATIVE NETWORK
CNTD
PATH MACE
EDCTP
ASEAN-NDI
ASEAN Network for Drugs, Diagnostics and Vaccines Innovation
Innovative Medicines Initiative
International Vaccine Institute
Home

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Contributions of chemistry to health

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Chemistry

Prevention
- Vaccines
- Antiseptics
- Nutritional factors, e.g. vitamins, trace elements
- Gene editing
- etc

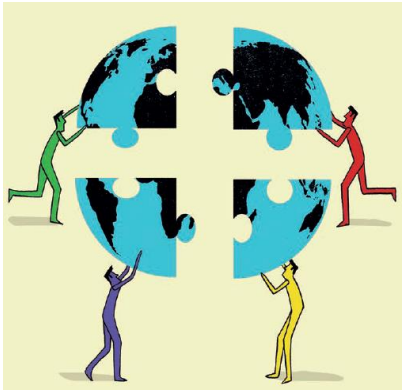
Diagnosis
- Analysis: body fluids, tissues, excretions
- Imaging
- Identification of pathogens
- Gene sequencing
- etc

Treatment
- Pharmaceuticals: cure, control, management
- Anaesthetics
- Medical materials, e.g. in-dwelling
- Prosthetics
- etc

The chemical sciences have been central to global progress and will be essential to meeting oncoming global challenges – especially sustainable development – with 'one-world' chemistry

Matlin, Mehta, Hopf & Krief, *"One-world' chemistry and systems thinking.* Nature Chemistry 2016, 8, 393-6

'One-world' chemistry



Recognises 'one-health':

- Human and animal health and the environment are intimately inter-connected systems

Aims to be:

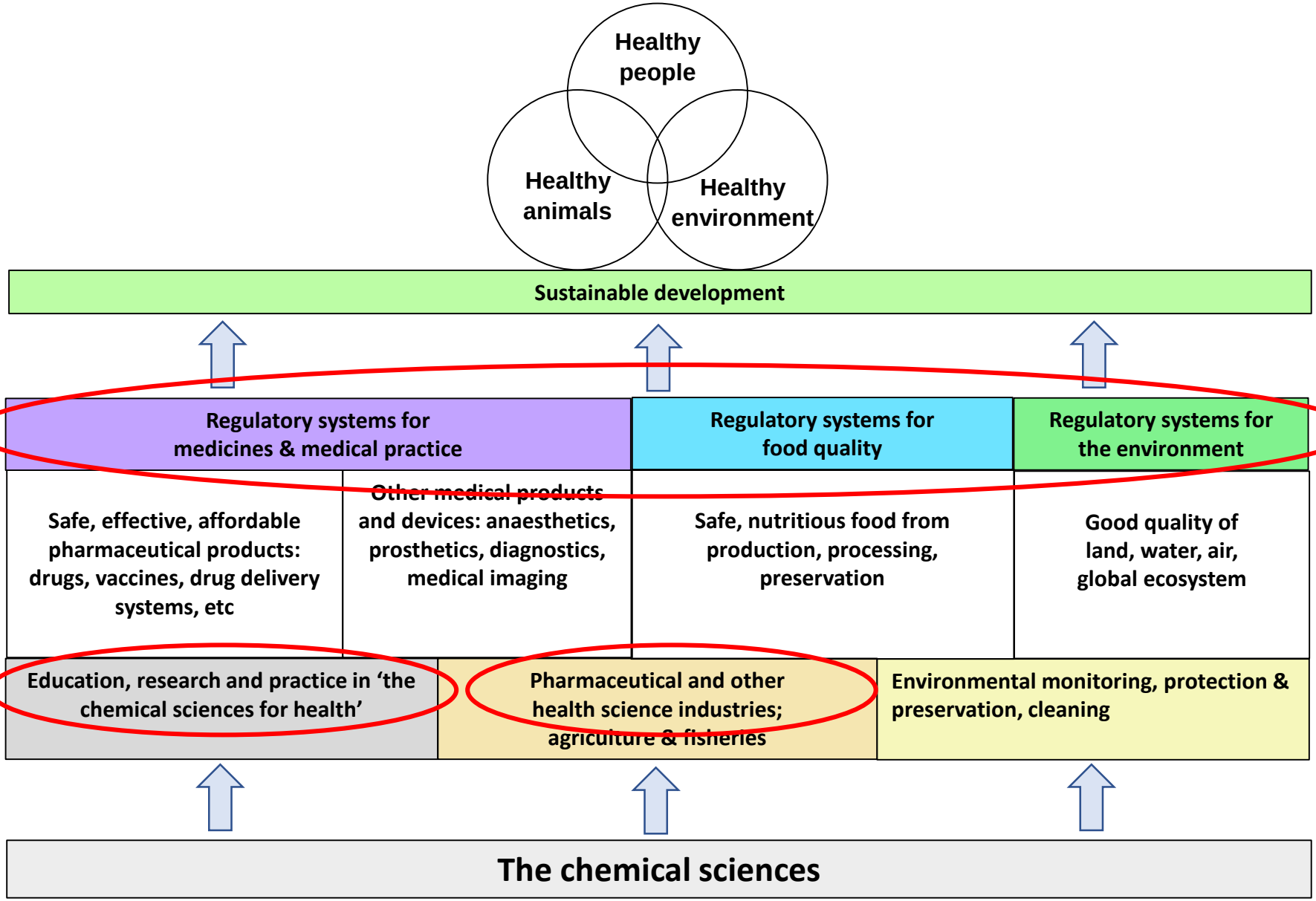
- A science for the benefit of society

Requires

- Systems thinking
- Cross-disciplinary approaches

www.iocd.org/OWC/intro.shtml

The chemical sciences support health through multiple channels



Matlin et al. *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

For health, core chemistry (inorganic, organic, physical, analytical, theoretical) needs to interface with:

- **Biological sciences**
  - biochemistry
  - biology
  - genetics
  - molecular biology
- **Pharmaceutical sciences**
  - medicinal/pharmaceutical chemistry
  - biopharmaceutical analysis
  - pharmaceutical formulation
  - pharmacology
  - pharmacy
  - toxicology
- **Medical sciences**
  - pharmacology
  - clinical chemistry
  - medical imaging
- **Forensics**
  - forensic chemistry
- **Bioengineering science**
  - biomaterials
- **Environmental science**
  - Environmental chemistry
  - analytical chemistry
- **Food**
  - nutrition
  - agricultural chemistry
  - food analysis
- **Legal & regulatory affairs**
  - intellectual property, patents
  - regulation of pharmaceuticals
  - regulation of food
  - regulation of environment

➢ **No single platform to prepare chemistry graduates to work across *'Chemistry and 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**

'Chemistry and Health'

- **Creating an overall vision of the multitudinous roles and capacities of the chemical sciences in contributing to 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 in chemistry applied to health, related to, eg:**

  - ❑ Biological sciences
  - ❑ Pharmaceutical sciences
  - ❑ Medical sciences
  - ❑ Forensics
  - ❑ Bioengineering science
  - ❑ Environmental science
  - ❑ Food
  - ❑ Legal & 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 partnerships of chemistry with health and environmental disciplines**
  - ➢ **New networks of collaborating Departments/Institutions in teaching & research**
  - ➢ **New degrees in 'Chemistry and Health'; 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 model needs revisiting since the world needs

- more drugs and other health products at more affordable prices for more diseases and conditions
- a system enabling achievement of the SDG goals of health and health equity for all

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 countries wish to have strong pharmaceutical development capacities and play leadership roles in the field, attention needed to systemic elements, including:

- ensuring **strong, robust and well-designed education programmes**, including in the chemical sciences, to create a pool of talent with skills 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

  - Across all these areas: **Foster and support networks/initiatives/alliances/partnerships** to encourage research, development and innovation 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
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 – BETTER COORDINATED AND ALIGNED – regulation

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

Regulation = Laws + investigation + 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

Health innovation R&D across pharmaceuticals, food and the environment

- Foster and support networks/initiatives/alliances/partnerships to better align and coordinate regulation – including laws, standards, methods
- 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
U.S. Food and Drug Administration
FOOD AND DRUG ADMINISTRATION
THAILAND
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICI
INVIMA
ISA
FACSS
MINISTERIO DE SALUD PÚBLICA
Ministry of
General
Department of Health and
Therapeutic Goods Adminis
Analytical Chemistr
Environmental Div
Royal Australian Chem
PBA 2011
BRAZIL
Servic
Russian
Analytical Chemistry Division
dicines and
Medical Devices
NATIONAL DRU
Medicines &
Healthcare products
Regulatory Agency
ICH
harmonisation
Lyfjastofnun
Icelandic Medicines Agency
KFDA
KOREA FOOD & DRUG
ADMINISTRATION
CDSCO
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