INTERNATIONAL AGREEMENT ON DATA RELEASE

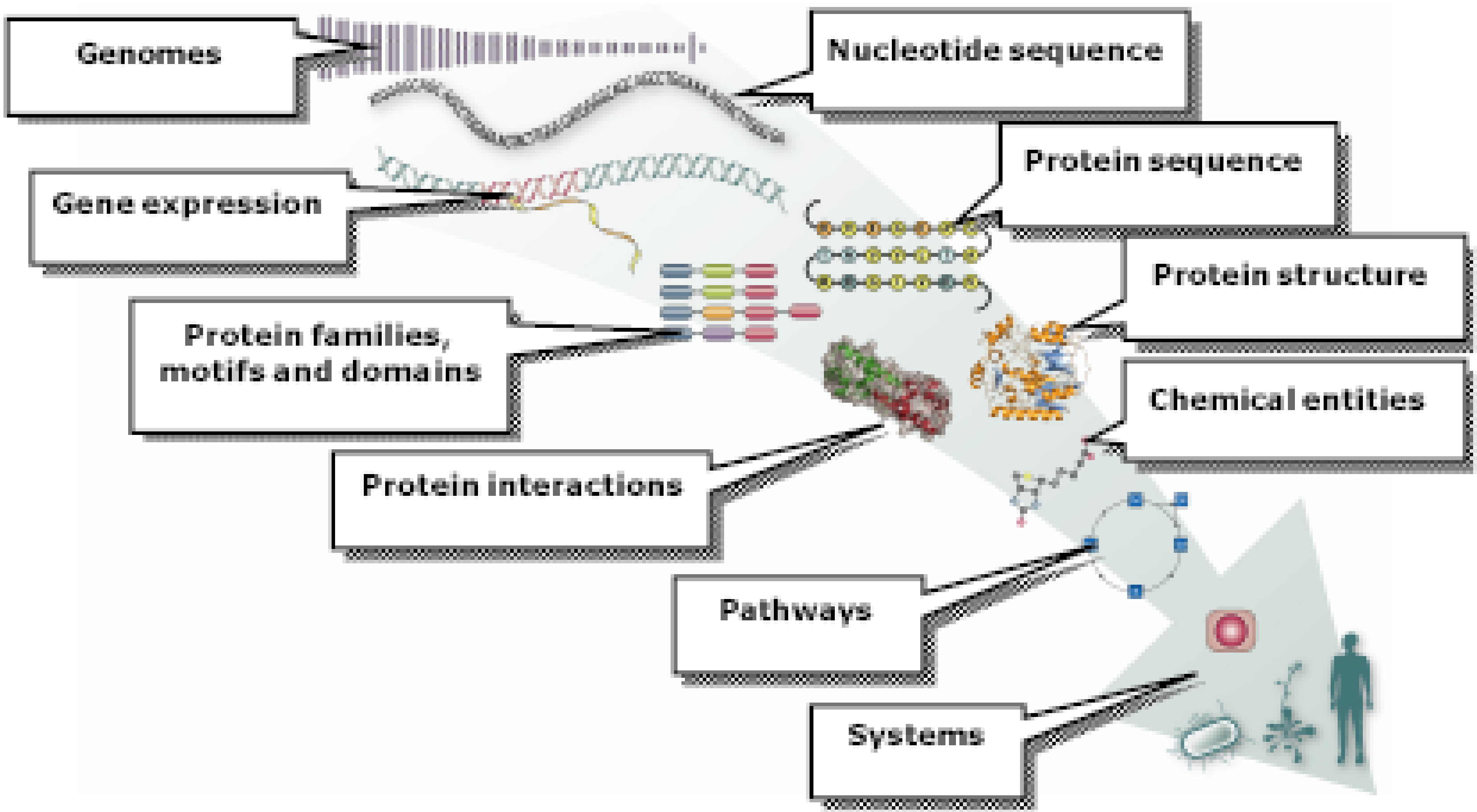
"All human genomic sequence information should be freely available and in the public domain in order to encourage research and development and to maximise its benefit to society."

The Bermuda Statement, February 1996

Assemblies of 1-2 kb are deposited in public database (GenBank, EBI) every 24 hours

No patents are filed

Databases: molecules to systems



Genomes

Gene expression

Protein families, motifs and domains

Protein interactions

Pathways

Systems

Nucleotide sequence

Protein sequence

Protein structure

Chemical entities

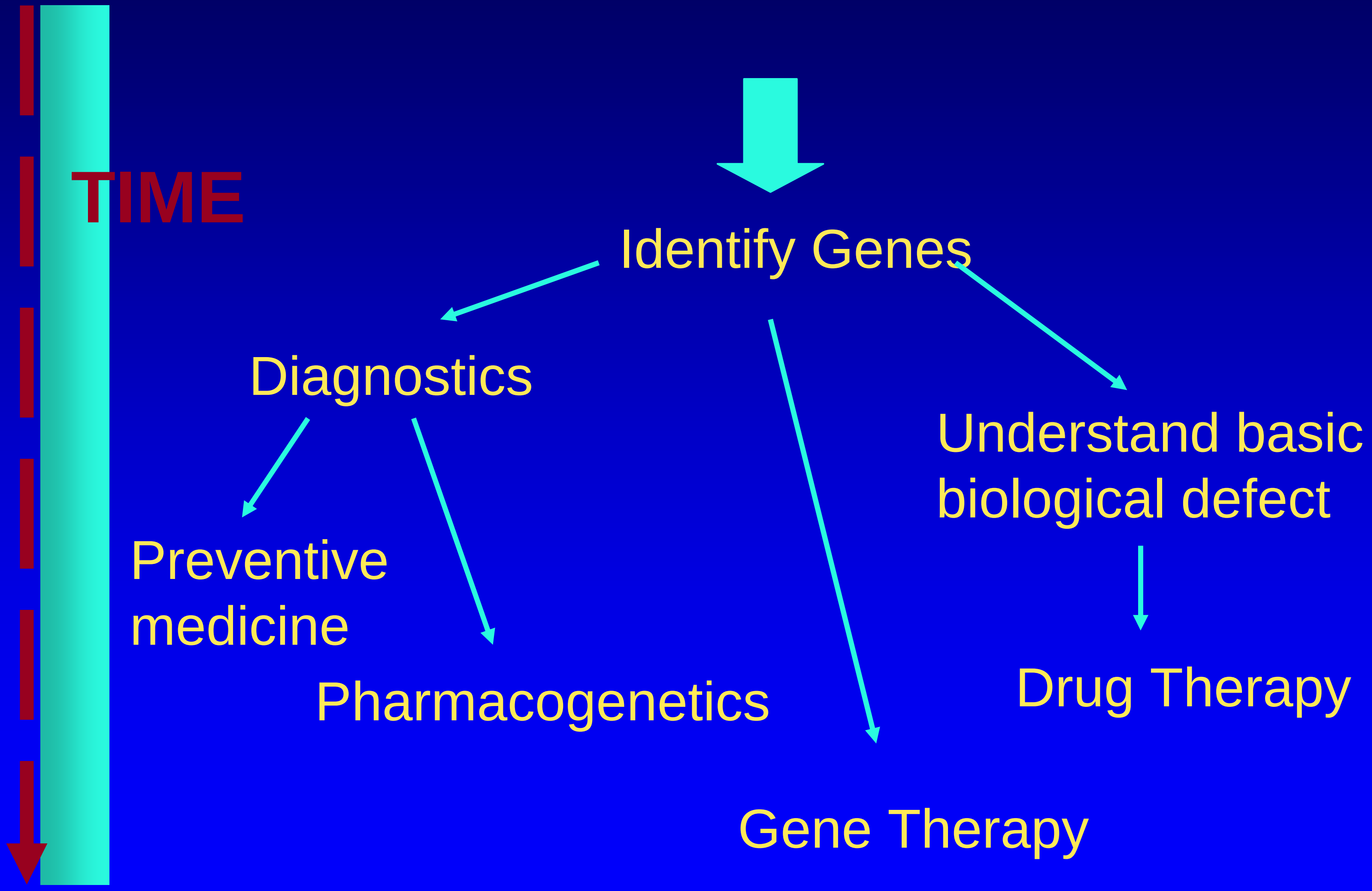
Genetic variation

Once we have a reference sequence the next phase is to characterise all common variation

Important variations are measured in many individuals

- medical importance
- identification and forensics
- understanding development

Disease with genetic component



TIME

Identify Genes

Diagnostics

Understand basic biological defect

Preventive medicine

Pharmacogenetics

Drug Therapy

Gene Therapy

public
revenue

discovery

knowledge

understanding

private
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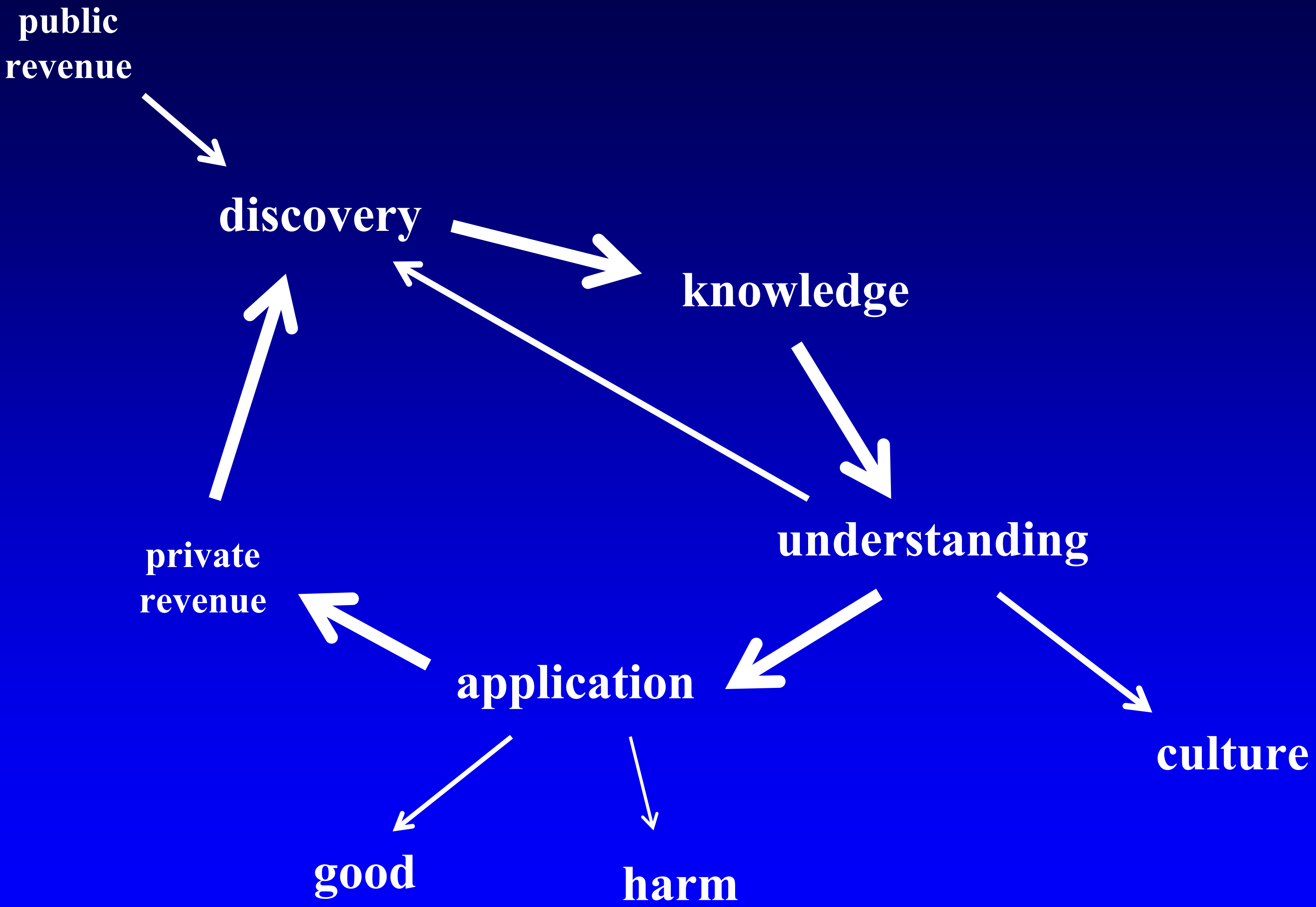
application

culture

good

harm



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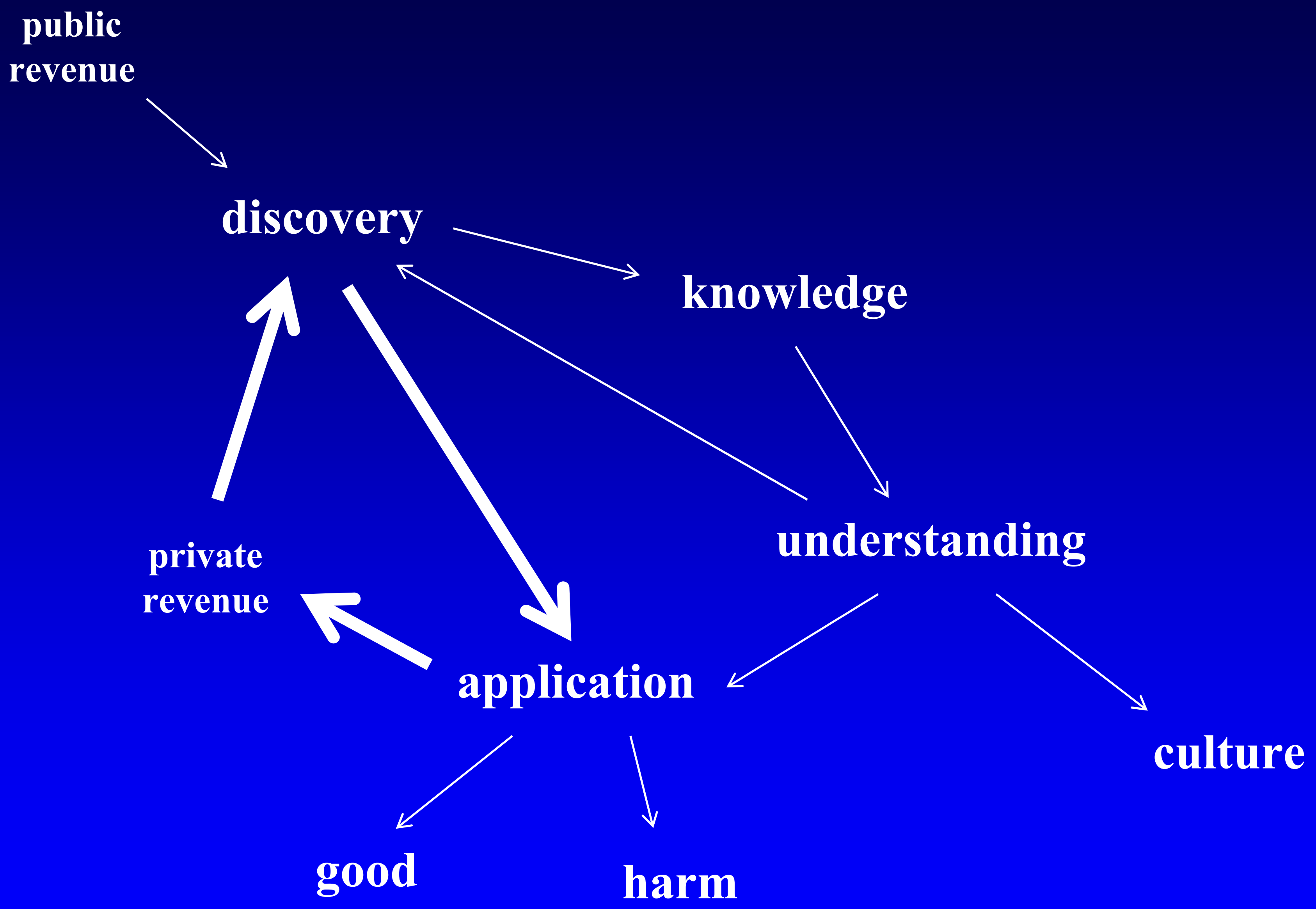

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Marketing issues

Lobbying

Adversarial testing

Ghost publication

Disease mongering

Genetic Equity

Genetic discrimination

- Discrimination already outlawed for ♀/♂ and for skin colour
- It’s time to outlaw all genetic discrimination
- How to apply this principle?

UK agencies

Human Fertilisation and Embryology Authority
Human Genetics Commission
National Screening Committee
Commission for Equality and Human Rights

Nuffield Council on Bioethics

International Centre for Life
Genetics Knowledge Parks
ESRC units

et al . . . .

The Human Genetics Commission

- Acting chair John Sulston
- Individuals - clinical, research and commercial genetics; law, ethics, consumer, sociology and disability rights
- Chief Medical Officers, HFEA

The HGC’s remit

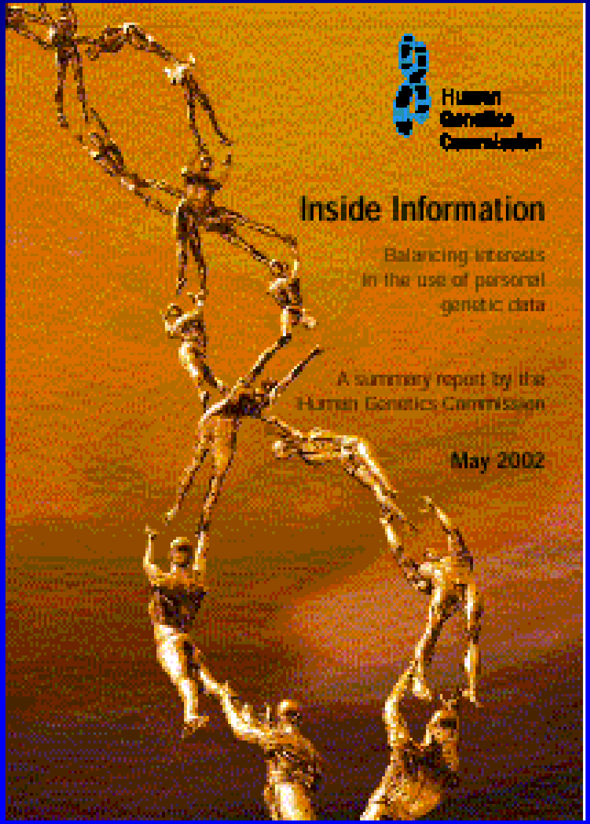
- Analysis of developments in human genetics including:
  - impact on human health and healthcare
  - social, ethical, legal and economic implications
- Informing and consulting the public
- Promoting dialogue and collaboration
- Horizon scanning
- Advising on strategic priorities for research

Inside Information

Balance between “respect for persons” and “genetic solidarity”

Respect for persons:-
- genetic privacy
- genetic non-discrimination

Genetic solidarity:-
- trust and goodwill
- contribution of all to human genetics



Human
Genetics
Commission

Inside Information

Balancing interests
in the use of personal
genetic data

A summary report by the
Human Genetics Commission

May 2002

Genetics and Insurance

- UK: voluntary moratorium until 2011 on use of DNA tests for policies less than £300,000 (£500,000 for life insurance)
  - but family history and other tests still allowed
- Has such insurance become a primary social good?
- Australian experience: insurance not needed for mortgage

Genetics and Employment

- Discrimination not yet a major issue, but sporadic cases reported
- Sometimes specific discrimination may be socially desirable
  - but this should be exceptional, and justified case by case

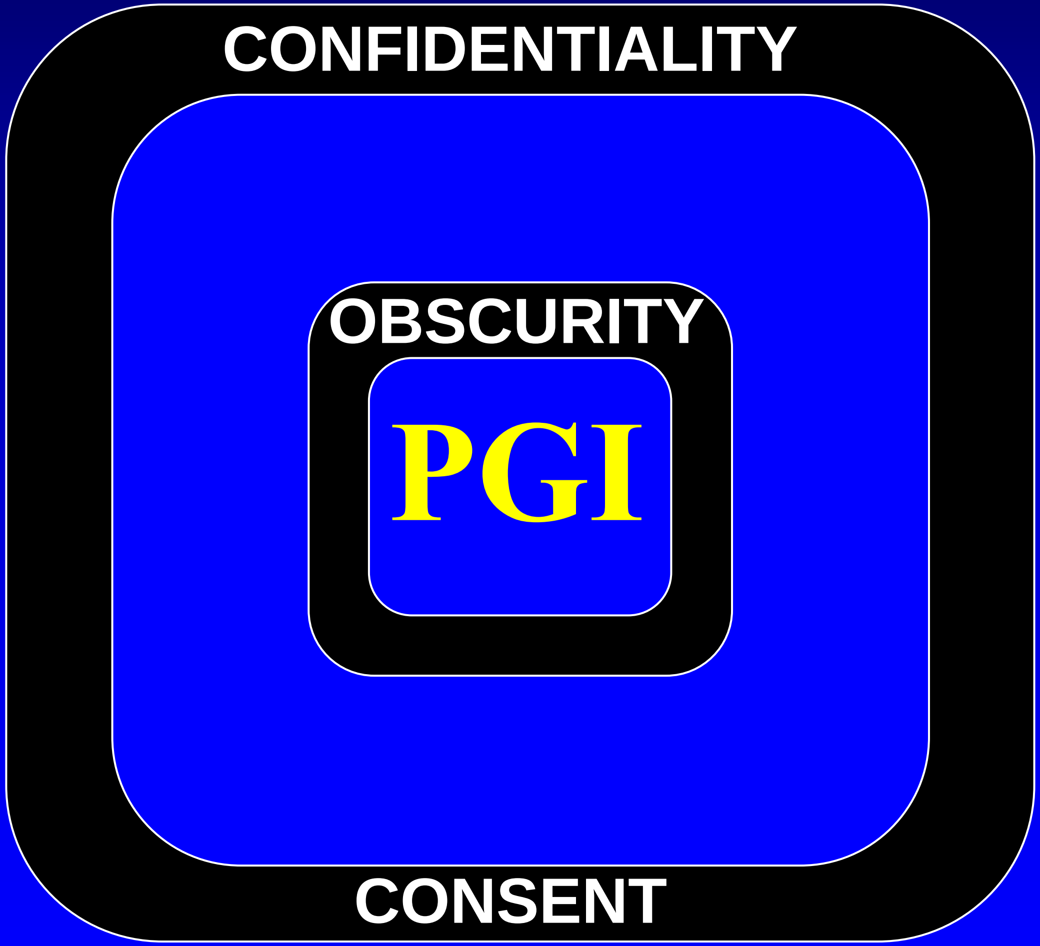
Information Commissioner’s Code on genetic testing (summary)

- Do not test to predict a worker’s future general health
- Do not demand the results of a previous genetic test
- Only use genetic testing to obviate a serious safety risk to the worker or to others
- Only use genetic testing as a last resort, where it is not practicable to make changes to the working environment
- Inform the Human Genetics Commission of proposed genetic testing

Current Issues

- The scope of “genetic testing”
  - DNA (self or relative’s)
  - Family history, proteins, gene expression, metabolites
- The Single Equalities Bill
- Regional variation
- Importance of NICE
- QALY’s
- Over the counter genetic testing

EQUITY



CONFIDENTIALITY

OBSCURITY

PGI

CONSENT

The scope of personhood

- Selecting embryos
- Genetic modification
- Prostheses
- Speciesism: a provisional position

Global Medicine

Healthcare delivery

Infrastructure

UK NHS, using watchdogs for rationing
- equitable, free at point of delivery

US system, based on ability to pay
- growing concerns

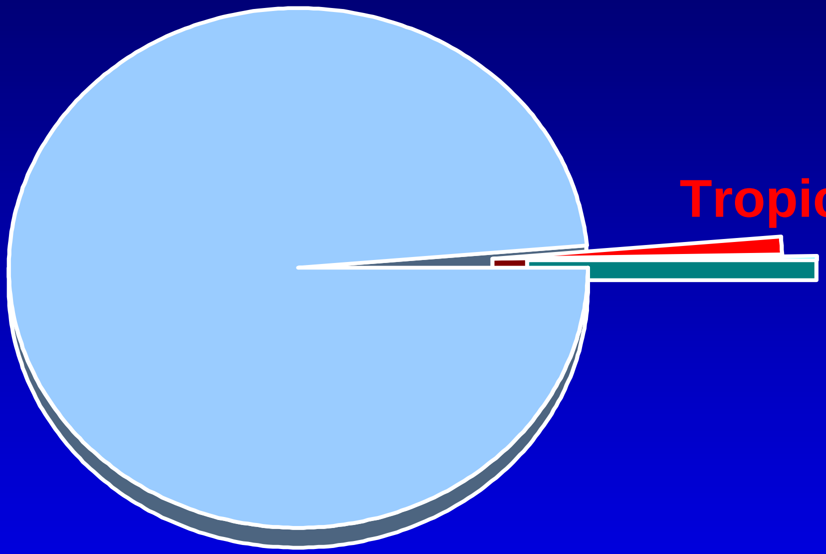
Global ??

The global health gap

Health spending per person per annum is approximately $4,108 in the US, $1,193 in Britain, $23 in India, and $5 in Malawi.

…. reflecting overall differences in wealth

Total number of new drugs developed from 1975-2004: 1,556



Tropical diseases: 18

TB: 3

1.3%

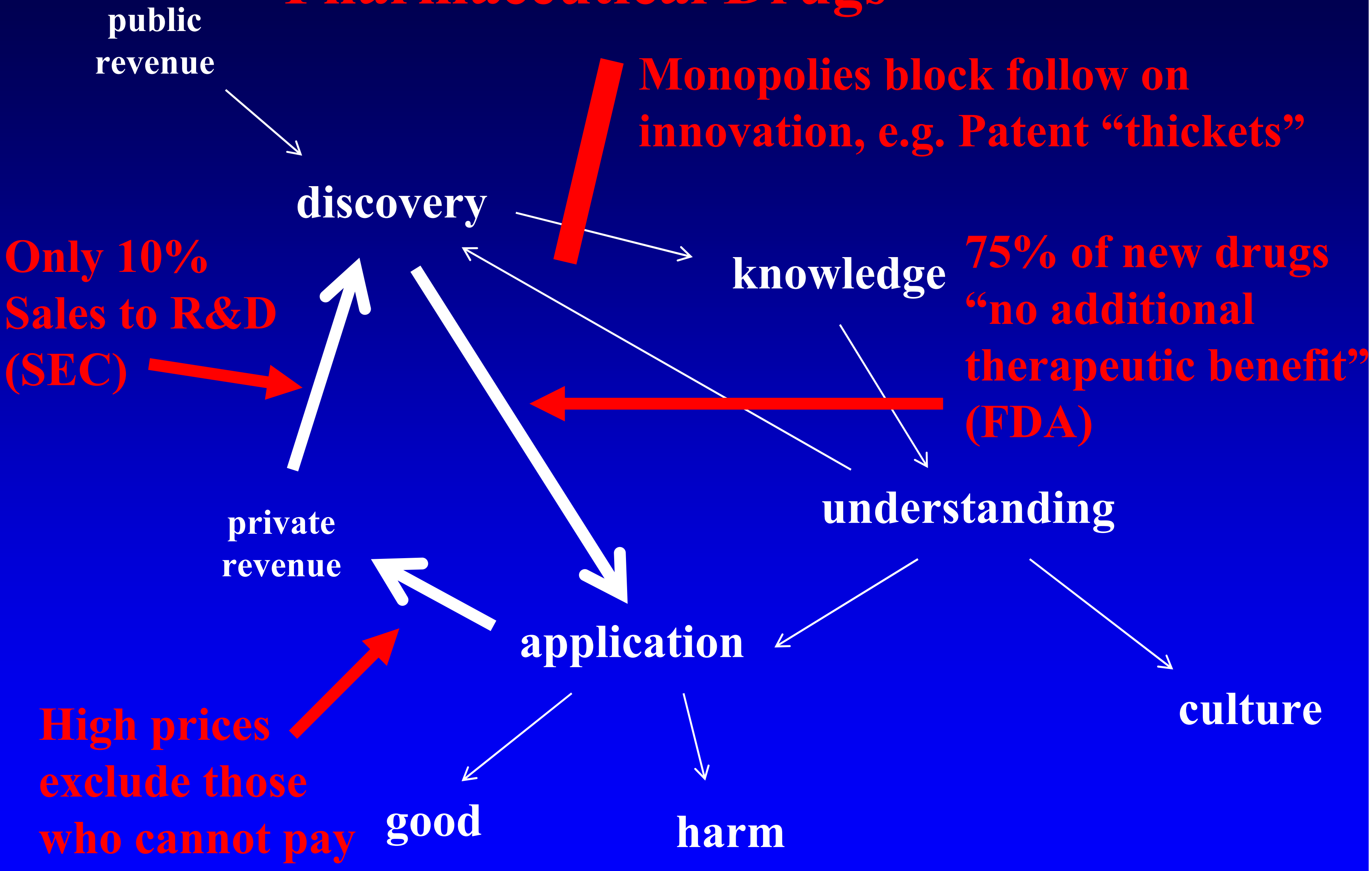
Tropical diseases and tuberculosis account for 12% of the global disease burden but only 1.3% of new drugs developed.

Source: Chirac P, Torreele E. *Lancet*. 2006 May 12; 1560-1561.

The drugs people use must be safe, affordable and available. Medicines are not everything, but without them little can be done.

Source: Lee Jong-Wook, WHO Director-General, April 2006 .

Pharmaceutical Drugs



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Monopolies block follow on innovation, e.g. Patent “thickets”

Only 10% Sales to R&D (SEC)

75% of new drugs “no additional therapeutic benefit” (FDA)

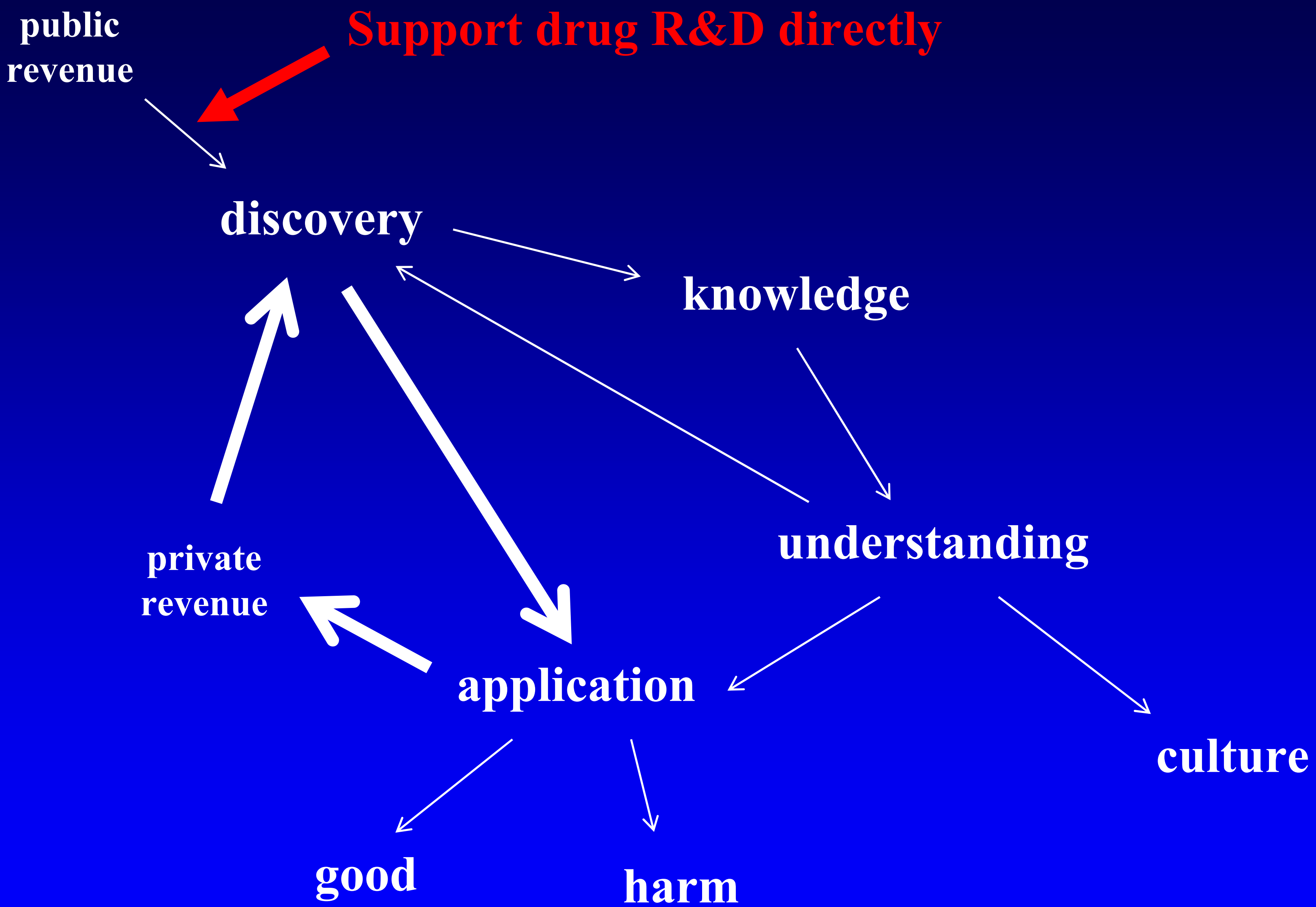
High prices exclude those who cannot pay

Two problems

- Innovation:
  how to support R&D for diseases on basis of need rather than market

- Access:
  how to provide access to medicines at affordable prices while still providing financial incentives for R&D

Support drug R&D directly



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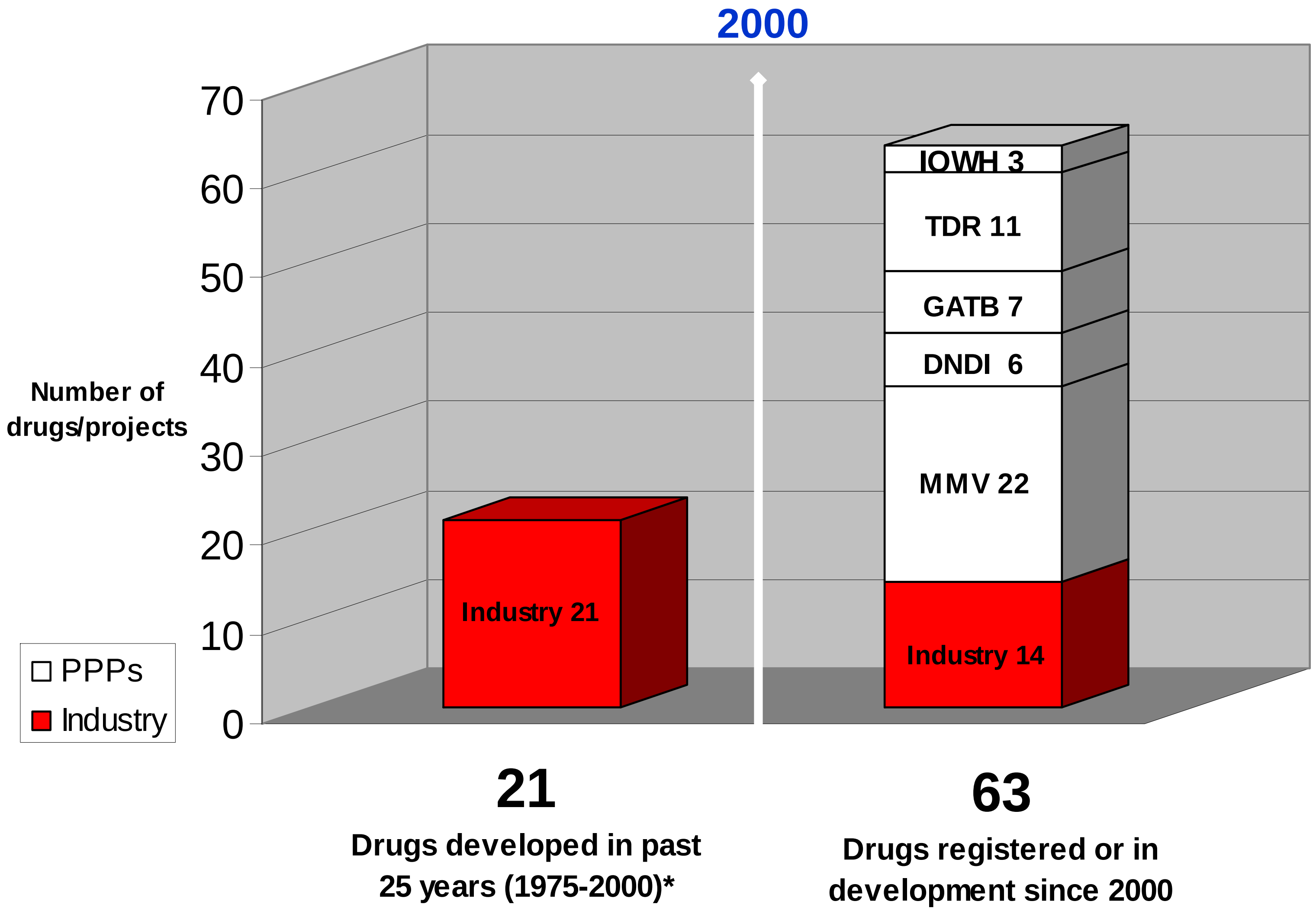
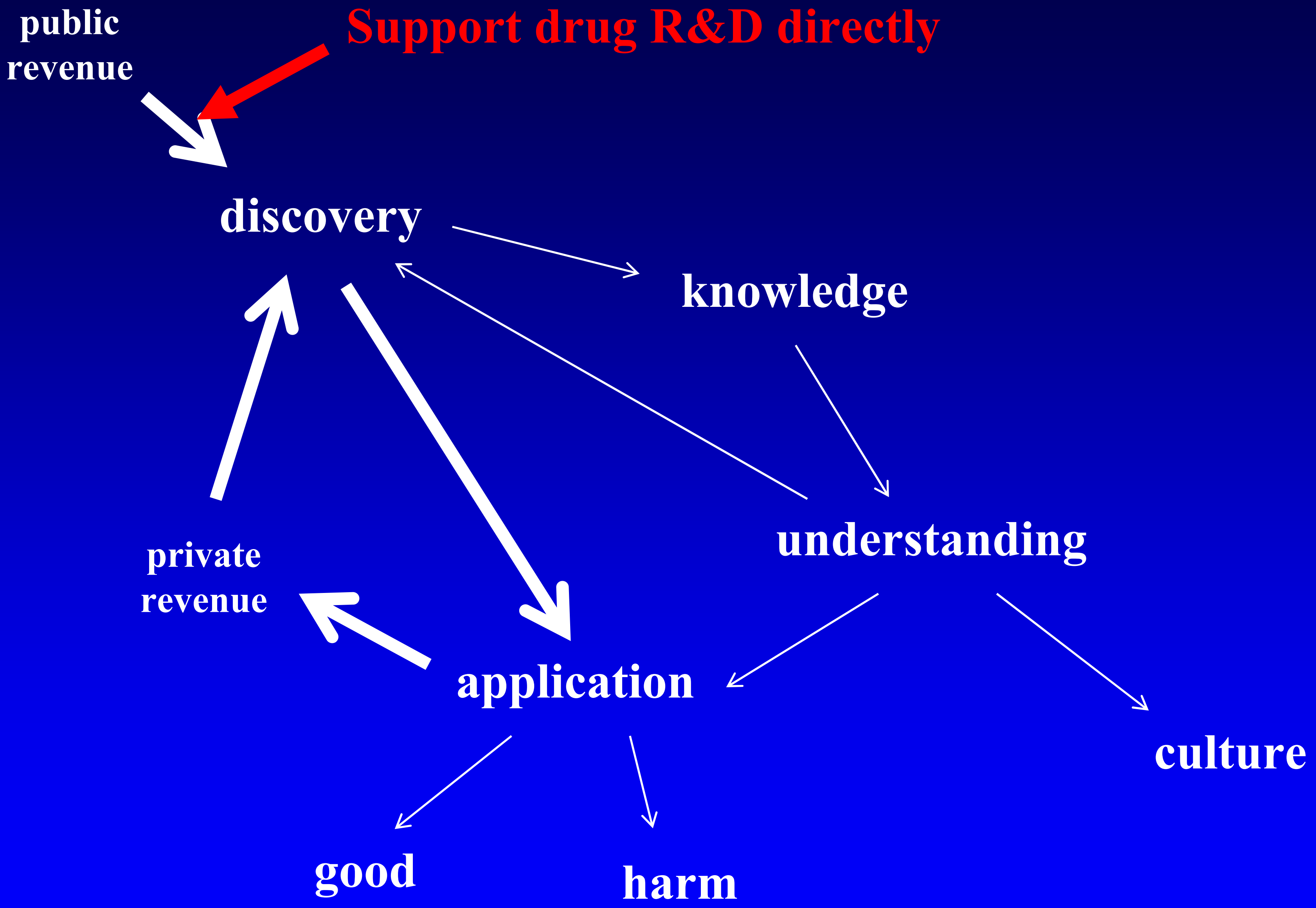
Directly Funded PDPs appear to work



* Some with TDR collaboration

** Further SME in-house activity yet to be included



Support drug R&D directly

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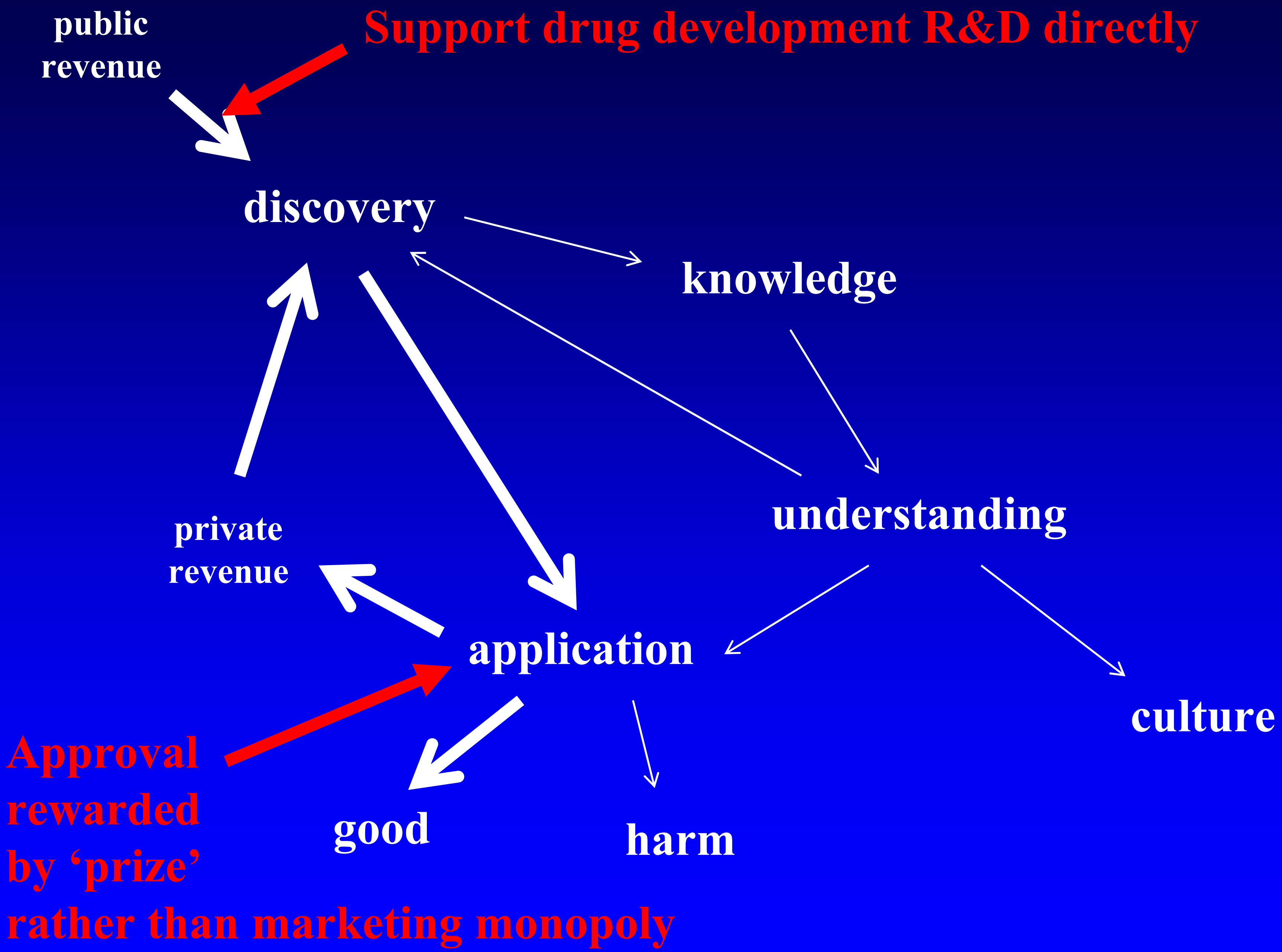

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revenue

Support drug development R&D directly

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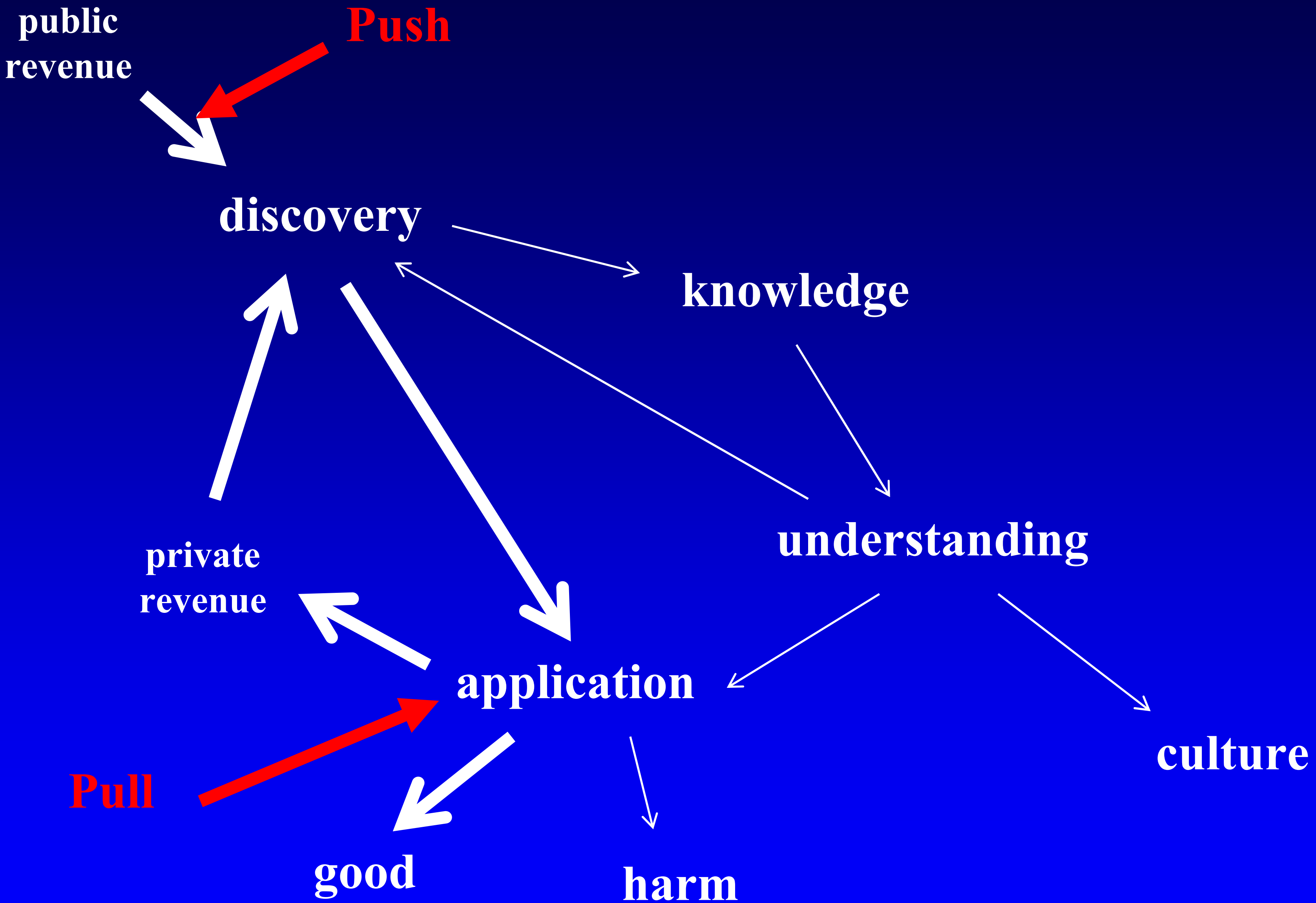
**Approval
rewarded
by ‘prize’
rather than marketing monopoly**

good

harm



public revenue

Push

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Pull

good

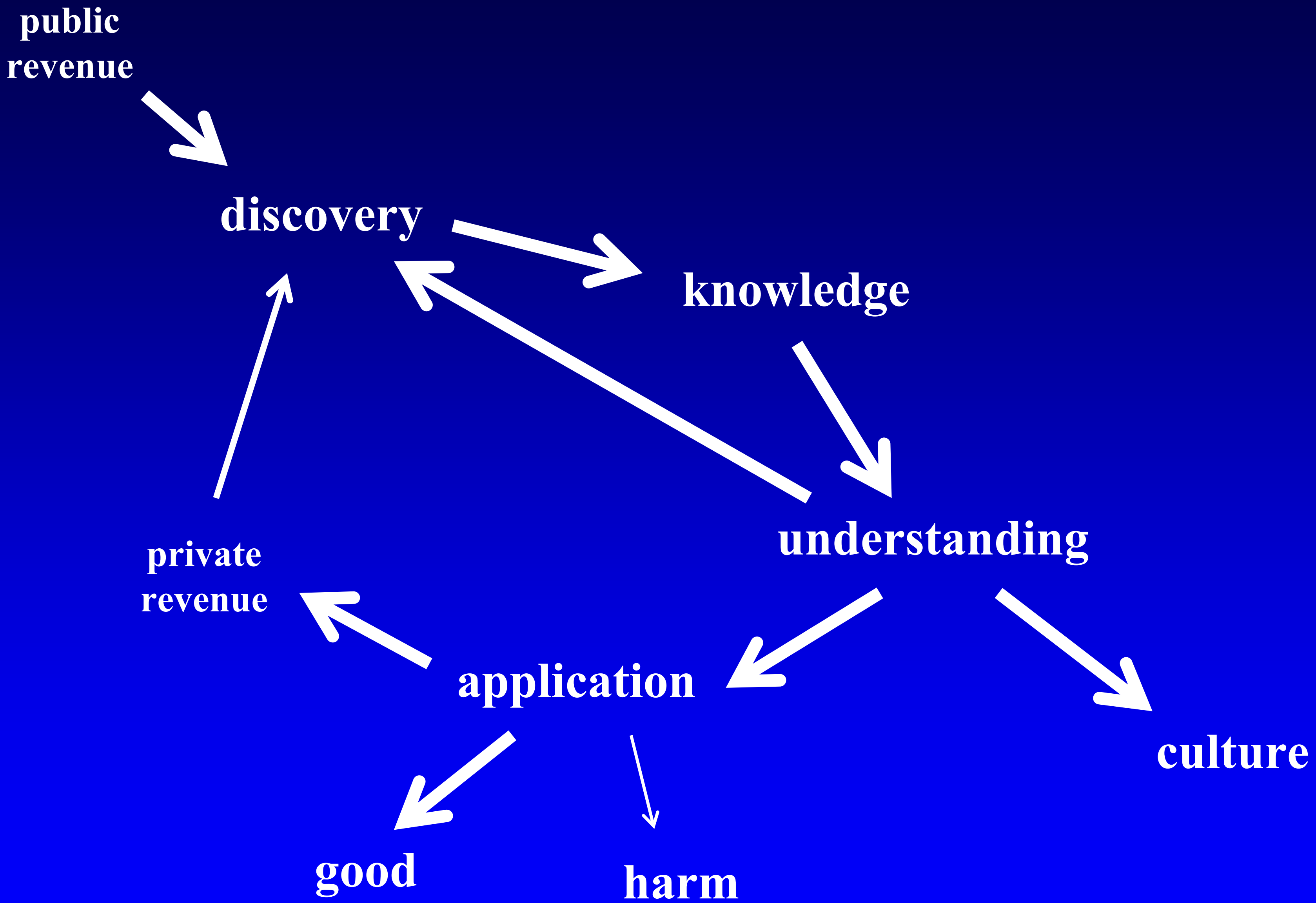
harm

Recent developments in aid

- Global fund has spent \$7 billion in 136 countries
- UNITAID: international air-ticket solidarity levy, collected €300 million in 2007
- Advance Market Commitment (AMC) for vaccines, \$1.5B
- US AIDS fund (increased to \$50B?)

Policy developments

- Role of campaigning NGOs
  - Oxfam, MSF, UAEM, …
- Intergovernmental working group (IGWG) set up by WHO following CIPIH report
- WIPO adoption of development agenda
- Use of compulsory licences
  - Thailand and others
- Bilateral pressures



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Globalisation of justice

- Common goods
    - access to knowledge
    - rational intellectual property
- International funds, instruments, treaties
- Public consultation and safeguards

- Universal healthcare

- Avoiding the tragedy of the nations

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– institute for Science Ethics and Innovation

…. but the opinions stated are my own