



Inaugural Richard Titmuss Public Lecture

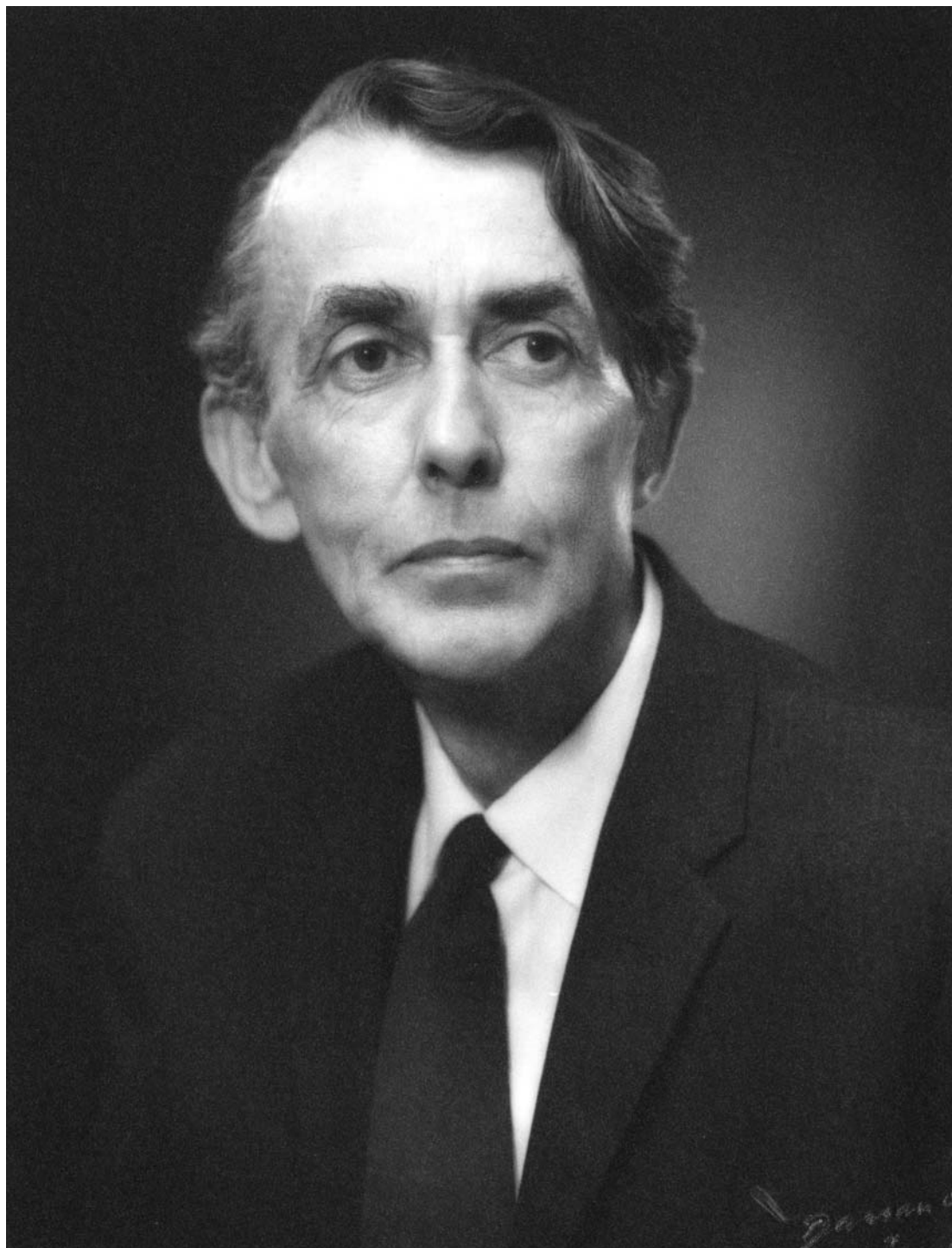
Altruism, Self Interest and Social Solidarity in assessing the effects of healthcare interventions

Sir Iain Chalmers

Editor of the James Lind Library

Professor Alistair McGuire

LSE, Chair



Altruism, self-interest and social solidarity in assessing the effects of healthcare interventions

Iain Chalmers

Editor, *James Lind Library*

www.jameslindlibrary.org

1st Richard Titmuss Annual Lecture
London School of Economics
27 November 2006

THE GIFT RELATIONSHIP

from human blood
to social policy

RICHARD M. TITMUSS
on his social philosophy

GEORGE ALLEN & UNWIN

The Gift Relationship

A comparison of blood transfusion services in Britain and the USA.

An exploration of altruistic blood donation to unidentified strangers, set within the context of the British National Health Service.

Richard Titmuss on the NHS

"We cannot understand the National Blood Transfusion Service without also understanding the National Health Service, its origins, development and values." (p 60)

"The most unsordid act of British social policy in the twentieth century has allowed and encouraged sentiments of altruism, reciprocity and social duty to express themselves; to be made explicit in identifiable patterns of behaviour by all social groups and classes." (p 292)

"Disease must be attacked in the poorest and the richest, in the same way as the fire brigade will give full assistance to the humble cottage as readily as the most important mansion. **Our policy is to create a National Health Service** to ensure that everybody, irrespective of means, age, sex or occupation, shall have equal opportunities to benefit from the best and most up-to-date medical and allied services available."

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Winston Churchill, 1946

Putting my cards on the table

I am committed to the principles of:

- (i) A publicly-funded National Health Service
- (ii) Equitable access to effective health care
- (iii) Efficient use of resources in health care and health research
- (iv) Shared risk in addressing uncertainties about the effects of healthcare interventions

gift

The **gift**
relationship

from human blood to social policy
by **Richard M Titmuss**

Original edition with new chapters

edited by **Ann Oakley**

and **John Ashton**

LSE
BOOKS



Titmuss's objective

"... the study is about the role of altruism in modern society. It attempts to fuse the politics of welfare and the morality of individual wills." (p 59)

Titmuss's conclusions

"In comparing commercialised blood market systems in the United States with a voluntary system functioning as an integral part of the NHS in Britain we have considered four sets of criteria...

(i) economic efficiency, (ii) administrative efficiency, (iii) price (the cost per unit to the patient) and (iv) purity, potency and safety (or quality per unit)...

On all four criteria, the commercialised blood market fails." (pp 269-270)

“Unlike gift-exchange in traditional societies, there is in **the free gift of blood to unnamed strangers** no contract of custom, no legal bond, no functional determinism, no situations of discriminatory power, domination, constraint or compulsion, no sense of shame or guilt, no gratitude imperative....

"...(S)ocial gifts and actions carrying no explicit or implicit individual right to a return gift or action are forms of **'creative altruism'**...They are creative in the sense that the self is realised with the help of anonymous others." (p 279)

"...In not asking for or expecting any payment of money, these donors signified their **belief in the willingness of other men to act altruistically** in the future, and join together to make a gift freely available should they have need of it." (p 307)

“As individuals (donors were) taking part in the creation of **a greater good transcending the good of self-love.**

To ‘love’ themselves, they recognised the need to ‘love’ strangers. By contrast, one of the functions of atomistic private market systems is to ‘free’ men from any sense of obligation to or for other men, regardless of the consequences to others who cannot reciprocate.” (p 307)

Assessments of the book

Blood, Politics, and Social Science

Richard Titmuss and the Institute of Economic
Affairs, 1957–1973

*By Philippe Fontaine**

ISIS 2002;93:401-434

Academia

“Titmuss’s resolutely eclectic approach could appeal to a large audience... but it could also annoy disciplinary specialists who felt uncomfortable with the ongoing redefinition of territories.”

Fontaine, p 424

Alvin Gouldner, a sociologist

"...complained that Titmuss did not provide a clear picture of the 'social worlds of buyers and sellers [of blood]' and therefore missed the most important thing, namely that 'the reifying institutions that have produced them, their need and their greed, are a vastly greater danger to humanity than the tainted blood that they pass on.'"

Fontaine, p 424

Arthur Seldon, co-founder of the Institute of Economic Affairs – a British free market orientated think tank – could not believe that the picture could be as black as Titmuss had presented it, and looked for reassurance from colleagues in the United States. However, *The Gift Relationship* had impressed many respected American economists, including Milton Friedman, whose faith in the market could hardly be doubted.

Fontaine p 427

Edmund Leach, a social anthropologist,
and provost of King's College, Cambridge,
observed in a book review that:

"Titmuss' anthropology may be a bit shaky
[but] his moral case is founded on rock."

Leach 1971

Outside academia

US Department of Health, Education and Welfare: "...the welfare of the United States will be promoted by development of a 100 percent voluntary blood supply as soon as possible."

New York Times: One of the "seven books of special significance published in 1971."

35 years later

Books that have changed health services and health care policy

Nick Black, Duncan Neuhauser¹


Health Services Research Unit, London School of Hygiene & Tropical Medicine, London, UK; ¹Epidemiology & Biostatistics Department, Case Western Reserve University, Cleveland, OH, USA

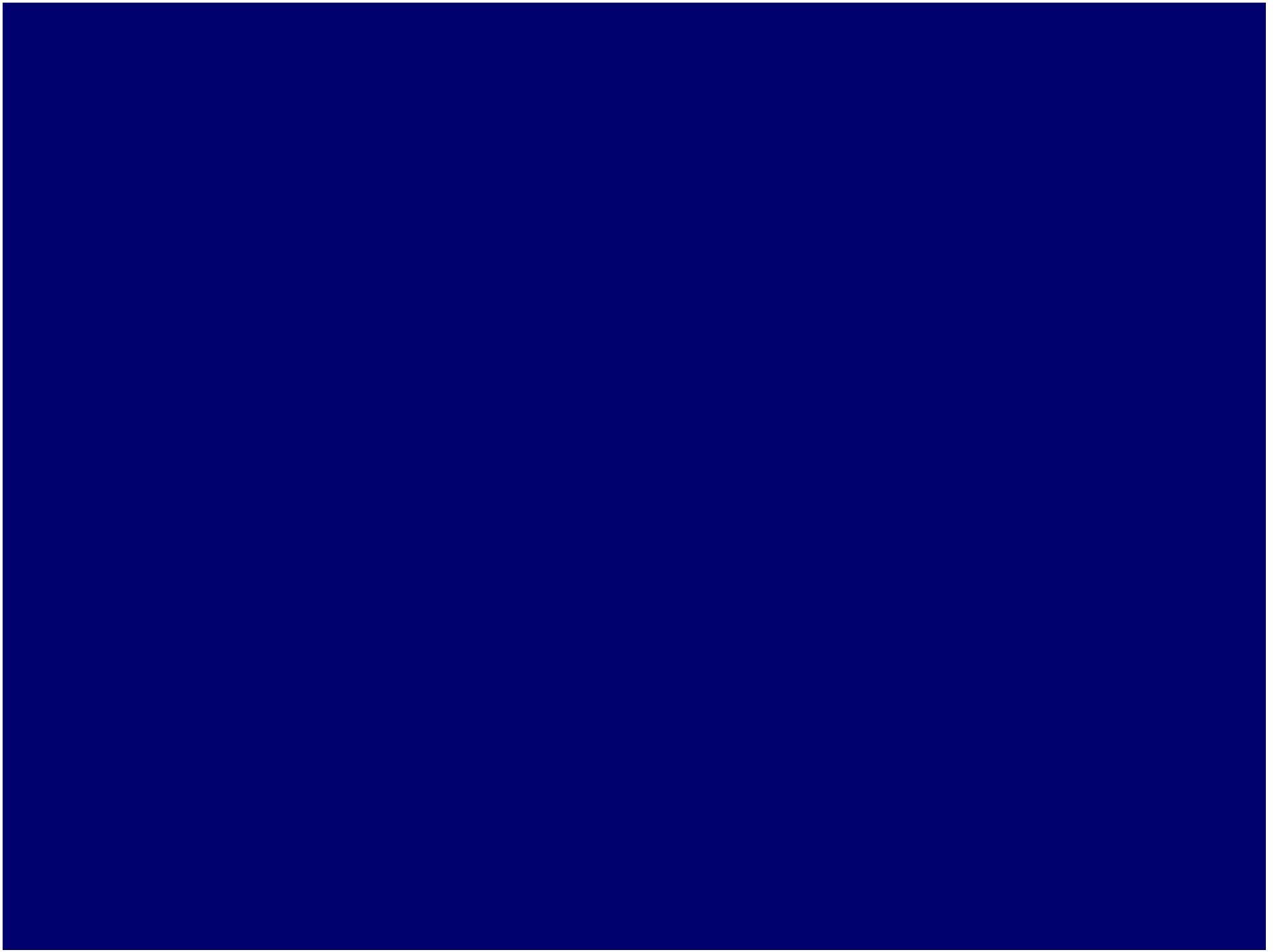
Table 1 The 20% of suggested books considered to have been the most influential

Titmuss RM. *The Gift Relationship. From Human Blood to Social Policy*. London: George Allen & Unwin, 1970

A personal response!

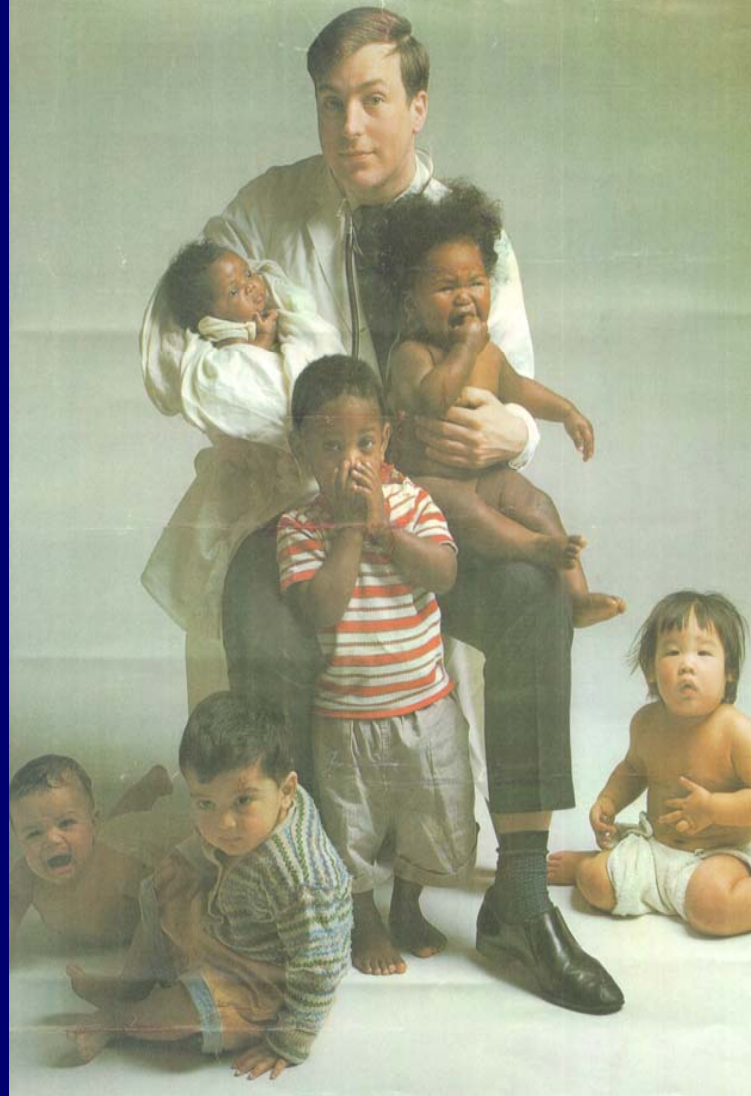
Scottish National Blood Transfusion Service	
Blood Group. O Rh Pos.	Reg. No.
Name Dr. Iain Chalmers,	
Address 22 Leckford Road,	
Oxford.	
Please notify any change of name or address to:—	
BLOOD TRANSFUSION SERVICE	
ROYAL INFIRMARY, FORESTERHILL, ABERDEEN	
Telephone: Aberdeen 681818 Ext. 2321	
Please bring this card with you each time you attend	

The Scottish National Blood Transfusion Service	
	
CERTIFICATE OF BLOOD DONATION	
The Blood Transfusion Service gratefully acknowledges your gift of blood for the benefit of others	
given on	17 AUG 1980
at
	INSCH.
<i>Brodie Lewis</i> Regional Director	



Question 1: *Have health professionals and the NHS made effective, efficient use of altruistically-donated blood?*

**This do-gooder
needs your help**



Fund raising advert for the United Nations Association

50c



GC • 40

DR. BENJAMIN SPOCK

BABY AND CHILD CARE



The most widely recommended hand-
book for parents ever published—
Authoritative, illustrated, indexed

Over 19,000,000 copies sold

The
Complete
Book
POCKET
BOOKS

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- Chalmers I, Enkin MW, Keirse MJ, eds. *Effective Care in Pregnancy and Childbirth*. Oxford: Oxford University Press, 1981
- Cochrane A. *Effectiveness and Efficiency*. London: Nuffield Provincial Hospitals Trust, 1972
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I think it is preferable to accustom a baby to sleeping on his stomach from the start if he is willing. He may change later when he learns to turn over.

“Systematic review of preventable risk factors for SIDS (Sudden Infant Death Syndrome) from 1970 would have led to earlier recognition of the risks of sleeping on the front and might have prevented **over 10 000 infant deaths in the UK and at least 50 000 in Europe, the USA and Australasia.**”

Ruth Gilbert et al. Int J Epidemiol, 2005

A. L. COCHRANE

Effectiveness and efficiency

Random reflections on
health services

THE ROCK CARLING FELLOWSHIP

1971

Cochrane's influential book
set out the case for
effectiveness (including tender
loving care) and **efficiency**, as
well as **equity**, in the National
Health Service.

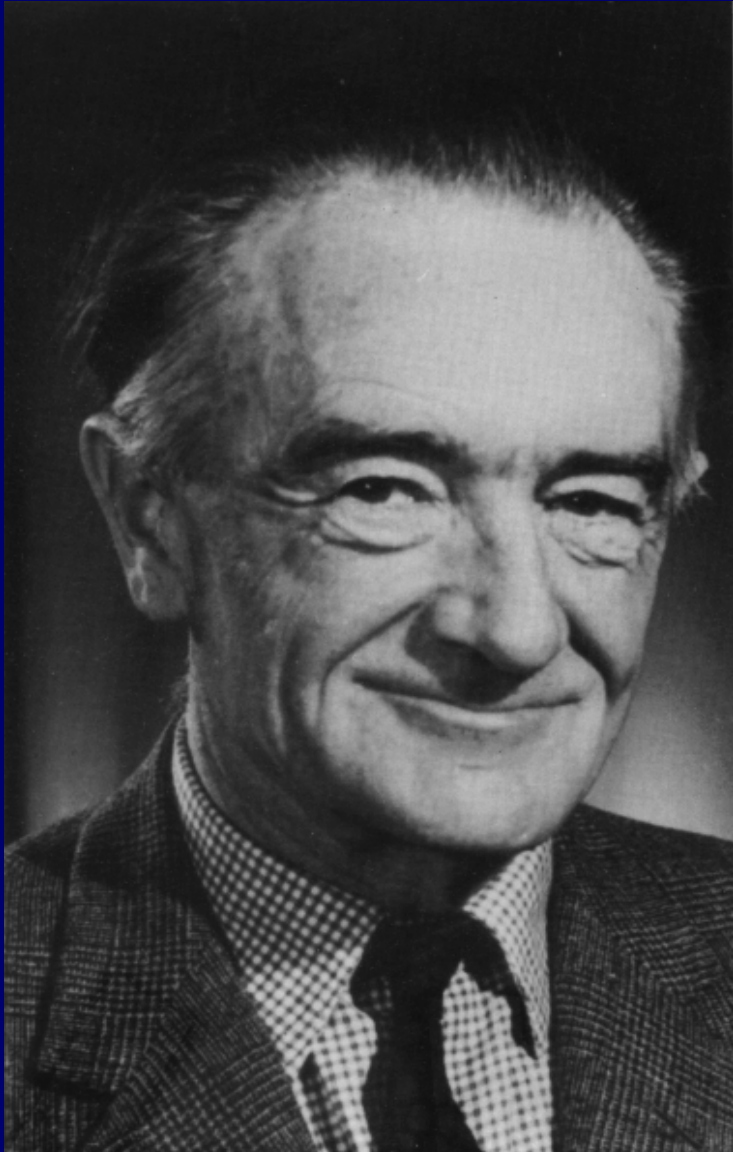
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-



Archie Cochrane, 1979

*"It is surely a great criticism of our profession that we have not organised a **critical summary**, by specialty or subspecialty, adapted periodically, of all relevant **randomized controlled trials**."*

For more information about
Critical summaries
(systematic reviews)
and randomised controlled trials

visit

The James Lind Library
www.jameslindlibrary.org

or read

'Testing Treatments'
Evans et al. British Library, 2006

EFFECTIVE CARE IN PREGNANCY AND CHILDBIRTH

VOLUME 1 • PREGNANCY PARTS I–V

VOLUME 2 • CHILDBIRTH PARTS VI–X and INDEX



OXFORD UNIVERSITY PRESS

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What did Richard Titmuss think about
randomized trials for assessing the
effects of interventions?

HELPING THE AGED
A FIELD EXPERIMENT IN SOCIAL WORK

by
E. MATILDA GOLDBERG

with
ANN MORTIMER
BRIAN T. WILLIAMS

with a Foreword by
RICHARD M. TITMUSS

Goldberg's randomized trial of social work

"...this study represents the first field experiment in Britain in the complex and diffuse area of activities which we call social work."

"...methodologically this study is more advanced than similar social work experiments in the United States and other countries."

Richard Titmuss, 1971

What can the results of systematic reviews of randomised trials tell us about the use of altruistically-donated blood within the NHS?

Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion (Review)

Hill SR, Carless PA, Henry DA, Carson JL, Hebert PC, McClelland DBL, Henderson KM



**THE COCHRANE
COLLABORATION®**

Use of liberal criteria for transfusing blood results in more re-bleeding, more pulmonary oedema and cardiac events, and *increased mortality*.

"... for most patients, blood transfusion is probably not essential until haemoglobin levels drop below 7.0 grammes per decilitre."

Human albumin solution for resuscitation and volume expansion in critically ill patients (Review)

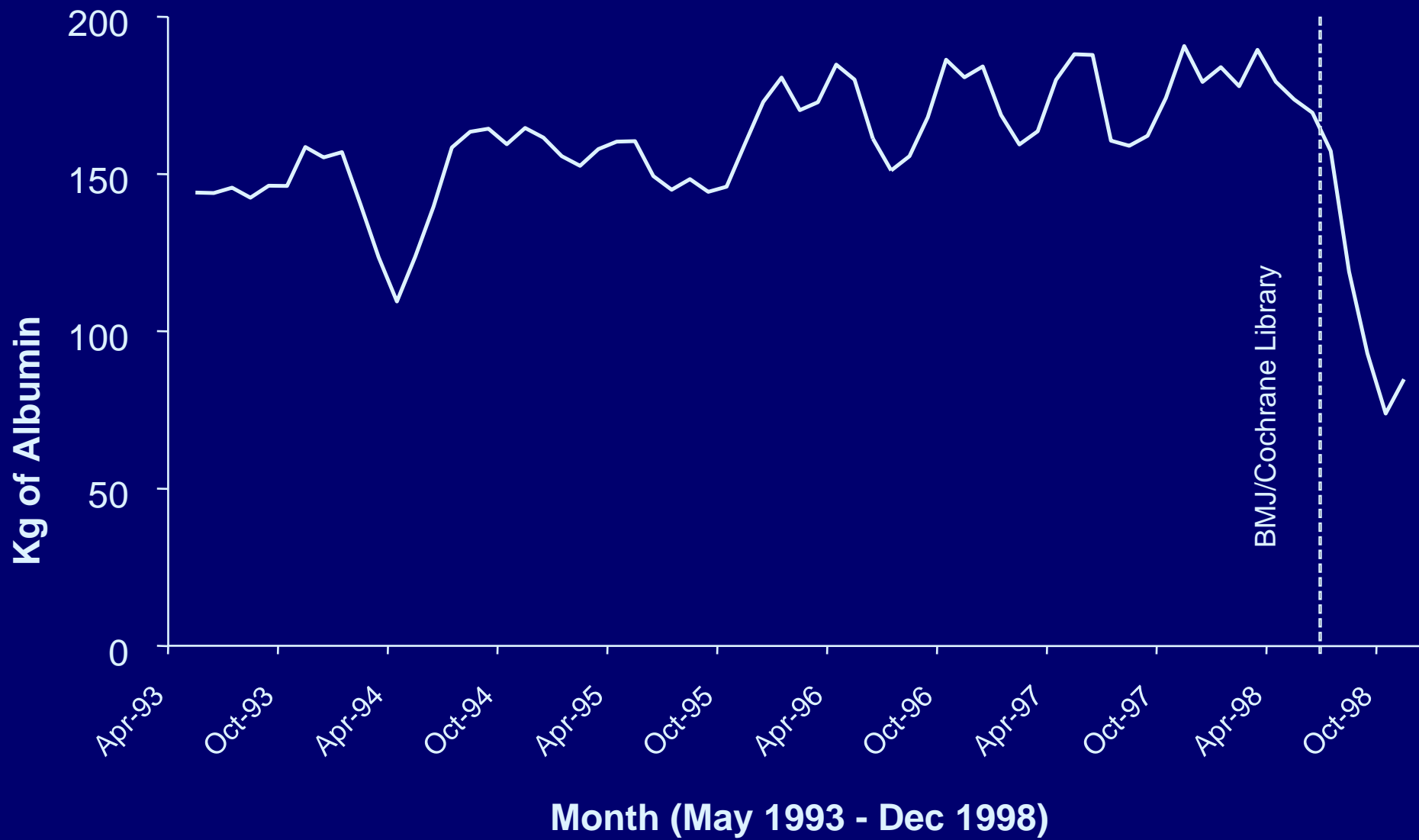
The Albumin Reviewers (Alderson P, Bunn F, Li Wan Po A, Li L, Roberts I, Schierhout G)



**THE COCHRANE
COLLABORATION®**

Mortality among critically ill people resuscitated with human albumin solution was actually somewhat *higher* than among people resuscitated with salt water.

"...albumin should only be used within the context of well concealed and adequately powered randomised controlled trials."



Reactions from industry

Manufacturers allocated \$2.2 million:

- To prepare literature reviews supporting the use of albumin, to be sent to leading regulatory agencies
- To prepare and disseminate a Cochrane critique dossier
- To establish a medical advisory panel to write articles supporting the use of albumin

Brian McClelland, Director, Department of Transfusion Medicine, Edinburgh (*BMJ* 1998).

Albumin: don't confuse us with the facts

*Rather than fulminating,
seek to answer the questions raised*

The SAFE Study Investigators

**A comparison of albumin and
saline for fluid resuscitation in
the intensive care unit.**

New England Journal of Medicine 2004; 350:2247-56.

Saline has
similar effect to
albumin in
critically ill
patients



Critically ill people with low serum albumin

No evidence exists to support the routine use of albumin rather than saline p1029, p1044

Effect of baseline serum albumin concentration on outcome of resuscitation with albumin or saline in patients in intensive care units: analysis of data from the saline versus albumin fluid evaluation (SAFE) study

Saline versus Albumin Fluid Evaluation Study Investigators

Conclusion The outcomes of resuscitation with albumin and saline are similar irrespective of patients' baseline serum albumin concentration.

Trial registration ISRCTN76588266.

Resuscitation using albumin in critically ill patients

Research in patients at high risk of complications is now needed

J L Vincent *professor*

(jlvincen@ulb.ac.be)

Department of Intensive Care, Erasme University Hospital, 1070
Brussels, Belgium

Competing interests: None declared.

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Wilkes MM, Navickis RJ.
Annals of Internal Medicine 2001.

Vincent JL, Dubois MJ, Navickis RJ, Wilkes MM.
Annals of Surgery, 2003.

Vincent JL, Wilkes MM, Navickis RJ.
British Journal of Anaesthesia, 2003

Vincent JL, Navickis RJ, Wilkes MM.
Critical Care Medicine, 2004.

Albumin's own goal.

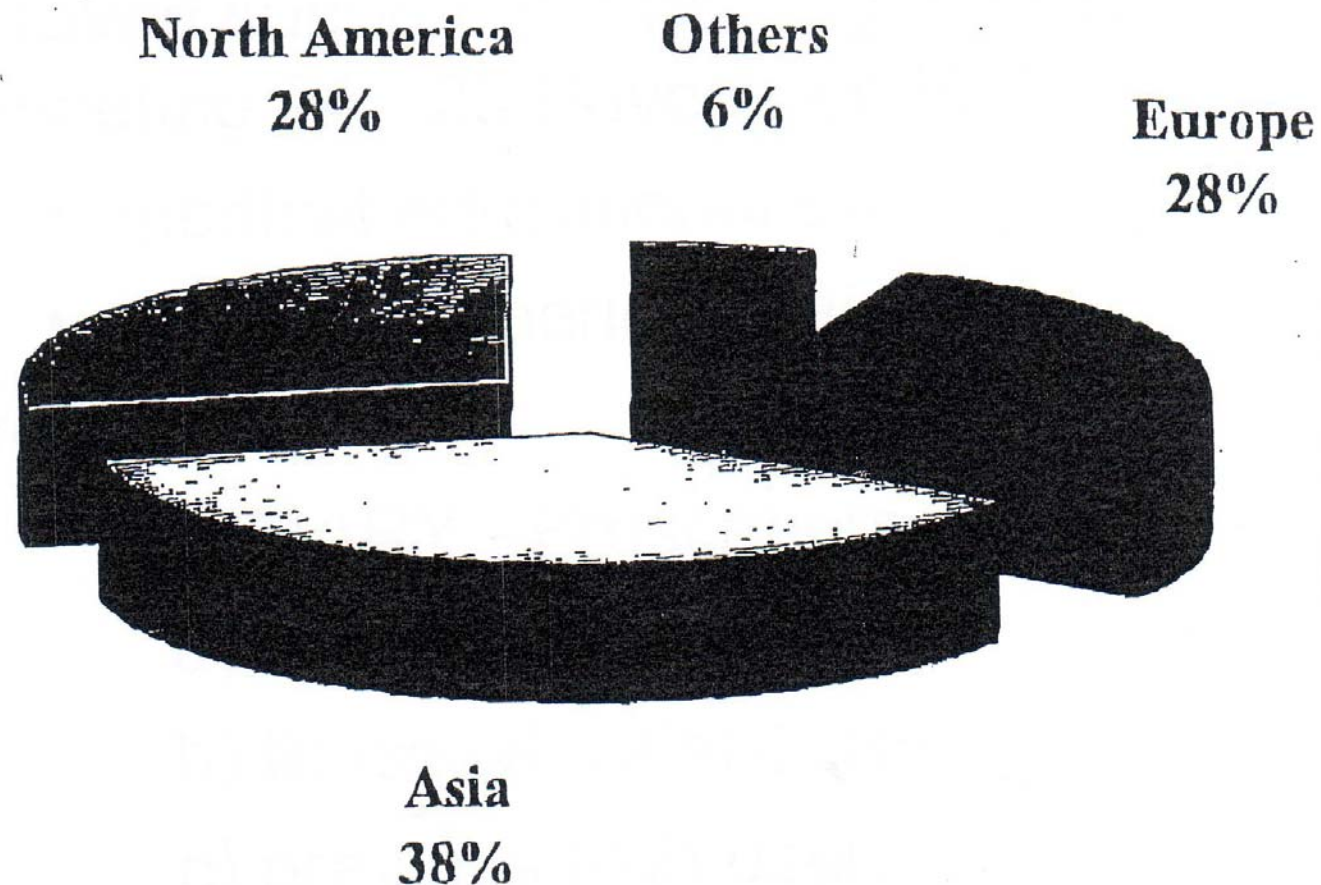
“The author's Conflicts of Interest are widely known. His regrettable oversight may prove more effective than any scientific study in settling any small remaining doubt about Albumin.”

Leopold D. bmj.com, 18/11/06

Until 1998, British patients were
being transfused a total of
8 tons of albumin every year,
a cost of £12 million

GLOBAL ALBUMIN MARKET

1996 - \$1.5 billion (MRB 1998)



Who's looking after the interests of blood donors and the NHS?

A year after the Cochrane reviewers had sent their initial analysis to the Committee on Safety of Medicines (CSM) in 1998, the Committee advised that:

“patients should be reassured if they have received albumin treatment and survived (*sic*)”.

Intellectual property, drug licensing, freedom of information, and public health

Ian Roberts, Alain Li Wan Po, Iain Chalmers

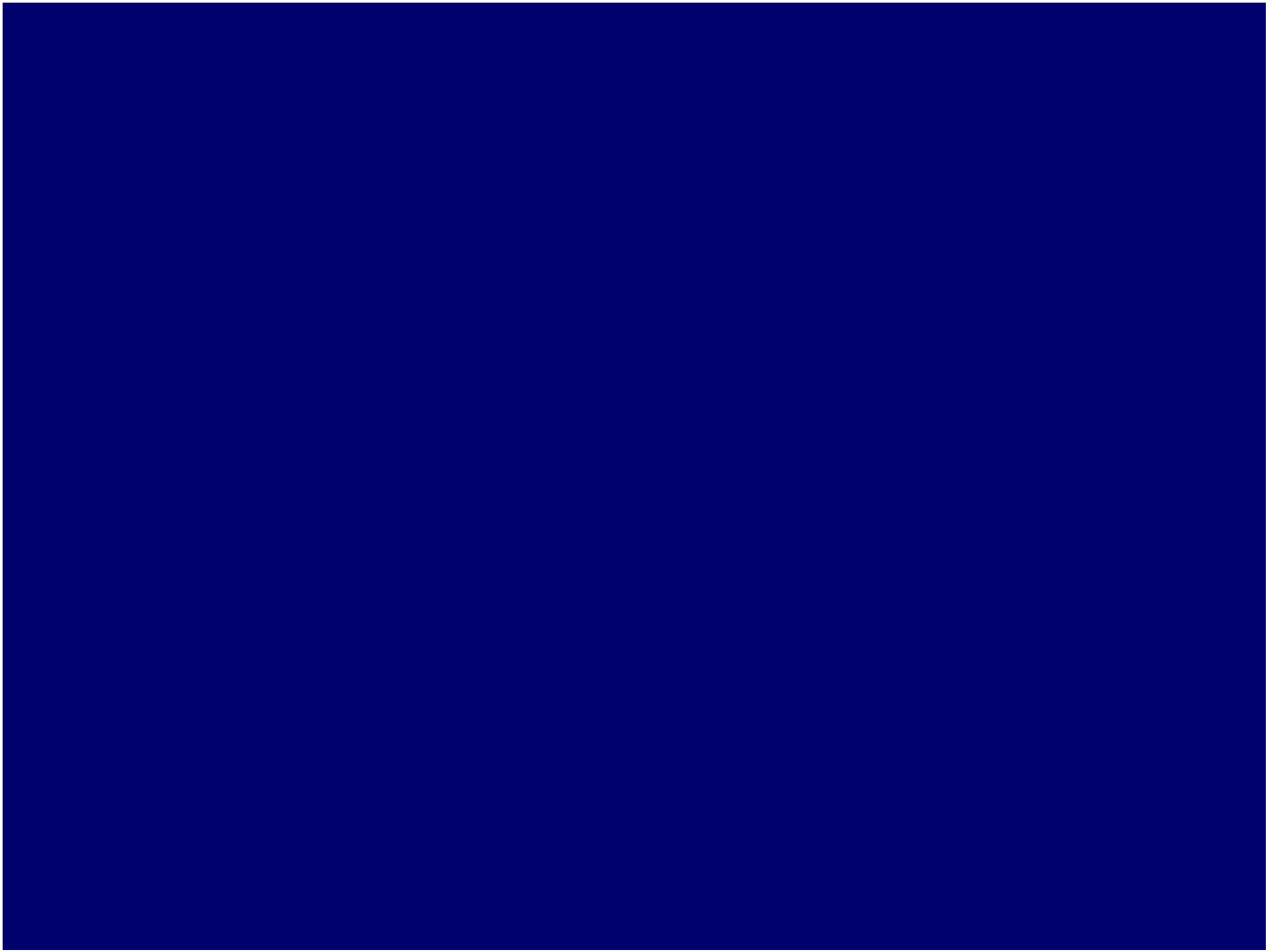
Lancet 1998; 352: 726–29

MCA response to request for information

"If you believe there may be unpublished evidence that the MCA holds, I would be pleased to receive more specific details to help us consider this matter further. If a more specific search were justified [that] uncovered data not in the public domain, we would then consider whether or not it was in the public interest to make [them] available, although **such data may be commercially sensitive and we would not usually release them without the owner's consent.**"

Question 1: *Have health professionals and the NHS made effective, efficient use of altruistically-donated blood?*

Comment 1: Health professionals and the NHS have sometimes failed badly to promote effective, efficient use of altruistically-given gifts of blood.



Question 2: *Do researchers and the NHS make effective use of patients' often altruistic participation in research assessing the effects of healthcare interventions?*

Titmuss: *The Gift Relationship*, pp 281-2

“We could have taken for study the giving role of the patient as research material for experimentation and the testing of new drugs and other diagnostic and therapeutic measures. Millions of people in Western societies every year are expected to give themselves, without price or a contractual reward, in these situations.”

What do I want from health research and researchers when I am a patient?

Chalmers I. BMJ 1995;310:1315-1318.

Wish No. 1

"...systematic reviews of carefully controlled research will be required
to produce the kind of evidence that I
am likely to believe, and that I would
wish those offering me care to take into
account."

The human costs of having failed to prepare systematic reviews of randomised trials

“Advice on some life-saving therapies has been delayed for more than a decade, while other treatments have been recommended long after controlled research has shown them to be harmful.”

Antman et al. JAMA, 1992

**What [else] do I want from
health research and researchers
when I am a patient?**

Chalmers I. BMJ 1995;310:1315-1318.

Wish No. 2

"When the relative merits of alternative forms of care are uncertain, I want to be offered the opportunity to participate in properly controlled research – and the emergency medical card that I carry makes this explicit."



MEDICAL EMERGENCY CARD

supplied by

VOLUNTARY EUTHANASIA SOCIETY

3 Prince of Wales Terrace London W8 5PG 0171 937 7770

My Full name is

IAIN GEOFFREY CHALMERS

If there is no reasonable prospect of recovery I do NOT wish
to be resuscitated or my life to be artificially prolonged

My Advance Directive is lodged with

DR. ANDY CHIVERS
01865 - 558861

1. Medical Information eg. blood group

Invite me to participate in all
randomized controlled trials for
which I am potentially eligible

2. After my death my organs may be used
for medical purposes

YES

3. Next of Kin

JAN CHALMERS
01865 - 554949

Signature

Date

Iain Chalmers 7/12/98

Is this altruism or self-interest?

My wish to be entered into randomised controlled trials when the relative merits of alternative forms of care are uncertain is purely selfish. Patients receiving treatment as participants in such trials seem to fare better than apparently comparable patients receiving the same treatments outside trials. Furthermore, new technologies seem as likely to be inferior as they are to be superior to existing alternatives, so randomisation provides an efficient hedging strategy in the face of these evenly balanced odds. Thirdly, randomised controlled trials help to generate reliable information on which to base future decisions about my health care.

The reasons given by people who have agreed to participate in research often appear to include **altruism**, as Titmuss suggested, but only rarely does it appear to be the only motivating factor.

Other reasons include **hope of access to useful new treatments or better care**; belief in the **altruism of researchers**; and sometimes, particularly in early phase clinical trials, **financial incentives**.

A recurring theme is **patients' trust in medical advice** that it is in their own **self-interest** to participate in research.

Whatever the ratio of altruism and self-interest among people volunteering to participate in clinical research,
it is reasonable to assume that people want to participate in research that is worthwhile.

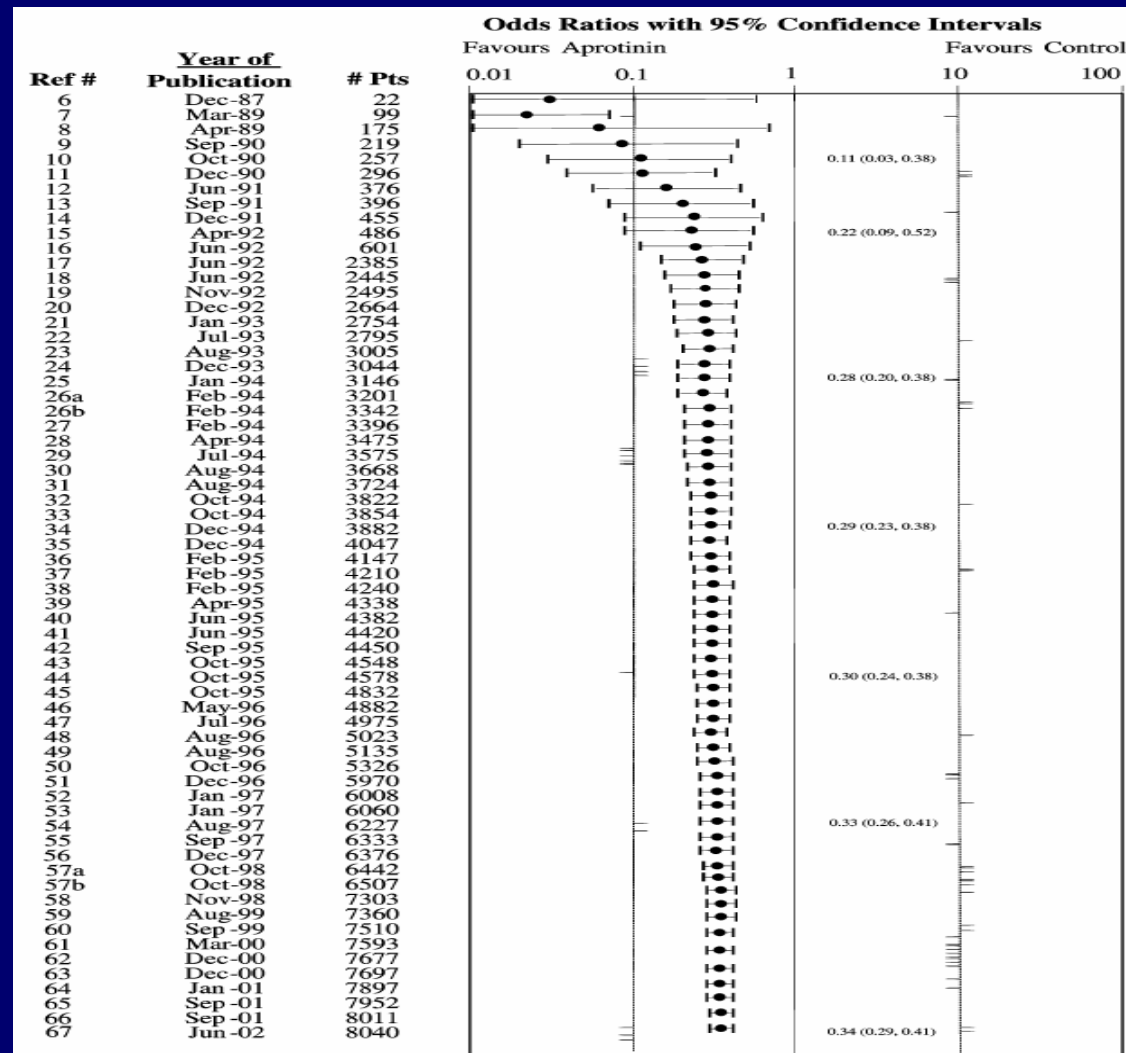
(i) Is the research needed?

Randomized controlled trials of aprotinin in cardiac surgery: could clinical equipoise have stopped the bleeding?

Dean Fergusson^{a,b}, Kathleen Cranley Glass^{b,c}, Brian Hutton^a and Stan Shapiro^{b,c,d}

Clinical Trials 2005; 2: 218–232

Cumulative estimate of the effect of aprotinin on perioperative blood transfusion, 1987-2002.



(ii) Does the research address questions that are important to people using and working in the NHS?

Perceived research needs for treating osteoarthritis of the knee (Tallon 2000)

Focus Groups Results

- **Specialist**
 - Wanted more time with patients
 - Didn't want any more drug trials
- **Physiotherapists**
 - Wanted funding for research
 - Didn't want poor quality research
- **General Practitioners**
 - Wanted education for patients
 - Didn't want drug trials
- **Patients**
 - Wanted information on disease
 - Wanted physiotherapy
 - Didn't want side-effects of drugs

1st choices among research priorities in survey of 67 patients

Knee replacement (35.8)

Education and advice (20.9)

Complementary therapy (6.0)

Tablets (4.5)

Injections in the knee (4.5)

Physical therapy (3.0)

No treatment at all (1.5)

Miscellaneous other priorities (23.9)

Healthcare interventions assessed in 460 randomised trials of treatments for osteoarthritis of the knee

380 trials of drugs

29 trials of complementary therapies

24 trials of physiotherapy/exercise

14 trials of education

13 trials of surgery



House of Commons
Health Committee

The Influence of the Pharmaceutical Industry

Fourth Report of Session 2004–05

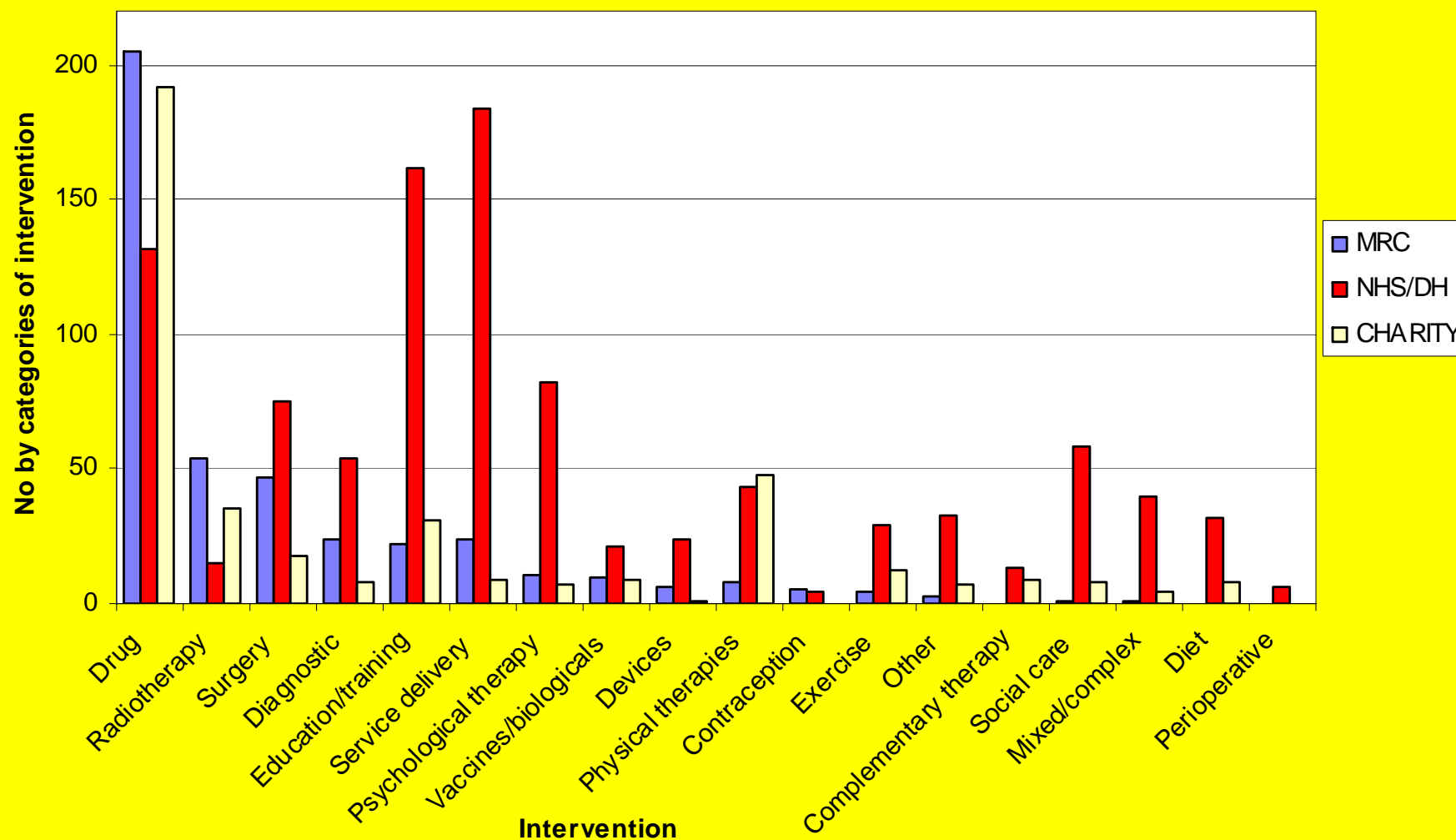
Volume I



House of Commons Health Committee

328. Areas of research that are not of direct interest to the pharmaceutical industry but may significantly benefit patients, such as non-pharmacological treatments, should be funded by Government.

Numbers of randomized controlled trials starting between 1980 and 2002, by main category of funder and type of intervention



Corticosteroids for acute traumatic brain injury (Review)

Alderson P, Roberts I



**THE COCHRANE
COLLABORATION®**

Effect of intravenous corticosteroids on death within 14 days in 10 008 adults with clinically significant head injury (MRC CRASH trial): randomised placebo-controlled trial

*CRASH trial collaborators**

Lancet 2004; 364: 1321-28



THE LANCET

Volume 364 Number 9442 October 9-15, 2004

www.thelancet.com

"The administration of corticosteroids to brain-injured patients has seemingly caused more than 10 000 deaths during the 1980s and earlier."

See Comment page 1291

(iii) Is the research assessing outcomes of treatment which are important to people using the NHS?

OMERACT 7 Workshop

Incorporating the Patient Perspective into Outcome Assessment in Rheumatoid Arthritis — Progress at OMERACT 7

JOHN R. KIRWAN, SARAH E. HEWLETT, TURID HEIBERG, ROD A. HUGHES, MAGGIE CARR, MAGGIE HEHIR, TORE K. KVIEN, PATRICIA MINNOCK, STANTON P. NEWMAN, ENID M. QUEST, ERIK TAAL, and JANNEY WALE

A survey of patients with rheumatoid arthritis revealed that the most important symptom was not pain, **but fatigue.**

New drugs for Alzheimer's disease – A consumer perspective (Cream and Cayton, 2002)

Dementia treatment outcomes

Researchers

- Improvement of 3+ points on the ADCog
- Delay in admission to institutional care
- Maintenance of ADLs

Patients

- Improvements in mood
- Increased confidence
- Reduction in fear and distress

Carers

- Reduction in caring for challenging behaviours
- Reduction in anxiety
- Improved sleep

*(iv) Are all the results of research
to which patients have
contributed being made public?*

Biased under-reporting of research

(Cowley, Skene, Taylor & Hampton 1993)

"... When we carried out our study in 1980 we thought that the **increased death rate** that occurred in the (anti-arrhythmic drug) group was an effect of chance...

....**The development of (the drug) was abandoned for commercial reasons,** and this study was therefore never published; it is now a good example of '**publication bias**'. The results described here ... might have provided **an early warning of trouble ahead.**"

At the peak of their use in the late 1980s, it has been estimated that anti-arrhythmic drugs were causing – *every year* - comparable numbers of deaths to the *total* number of Americans who died in the Vietnam war.

Moore 1995.

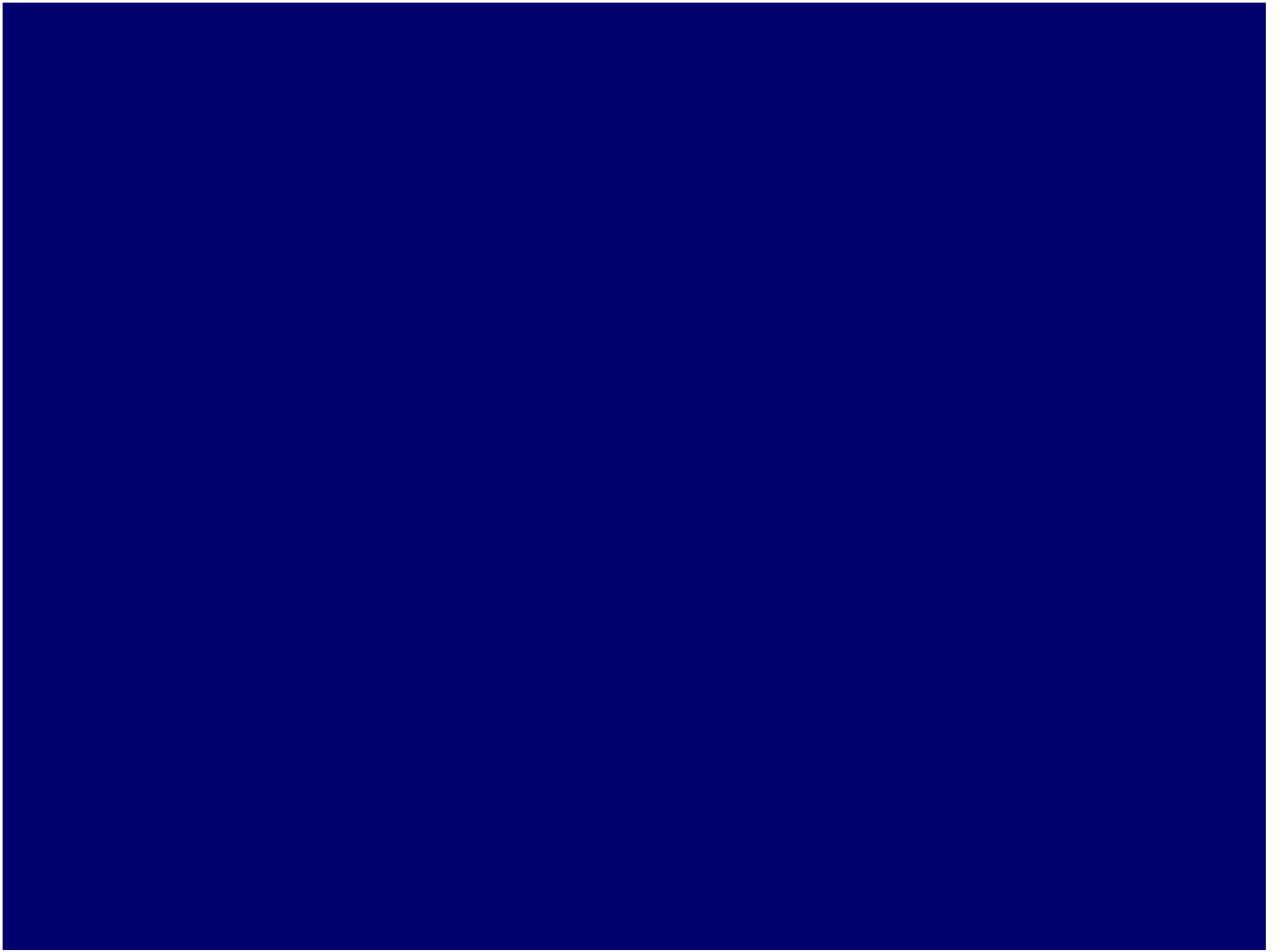


House of Commons Health Committee

We recommend that the clinical trials register be maintained by an independent body and the results of all clinical trials data, containing full trials information, be put on the register at launch as a condition of the marketing licence. (Paragraph 355)

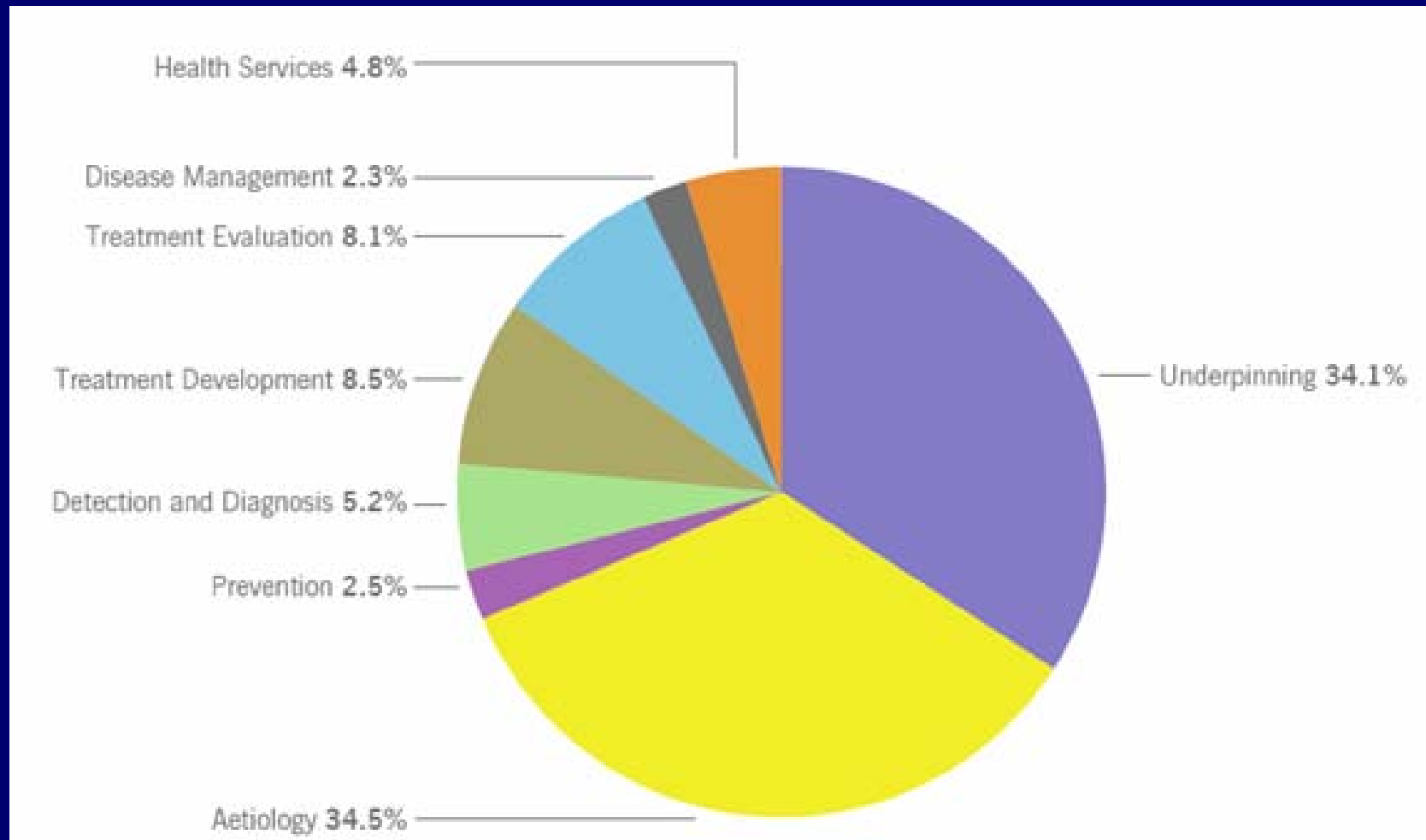
Question 2: *Do researchers and the NHS make effective use of patients' often altruistic participation in research assessing the effects of healthcare interventions?*

Comment 2: Too much clinical research is **redundant** or **irrelevant** to the interests of patients, and a substantial proportion of **relevant research is not published**.



Question 3: *Is industry's dominance of clinical research delivering good value for patients and the NHS?*

Public and charitable investment in biomedical research, UKCRC, 2006



The altruistic medical researcher: gone and forgotten? (von Schroeder 1997)

"... In the economic climate of today's science... selfishness is increasing. Research has become an industry, and virtuous ideals are a romantic notion. If we use altruism as an indicator, then its rarity and fragility indicate research's unhealthy state."

The context: Governments want universities to be profit-making; universities want departments to be profit-making; and departments want individual researchers to be profit-making.

“Science simply ceases to exist”

“In all scientific debates all sides always have their own biases: we have no other way to look at data but to interpret them. However, in usual clinical or epidemiologic research, studies are repeated by others, in different settings and by different means, looking for biases, flaws, and ways of remedying them, endlessly arguing whether the biases are remedied or not. That is the essence of open scientific debate and criticism, which is the only guarantee for progress...”

"...That is no longer possible with pharmaceutical products because the monopoly of the pharmaceutical industry of studies of its own products leads to persistently one-sided studies that can no longer be questioned by studies from other sides. Moreover, the one-sidedness cannot be seen from the public record, that is the published papers. **Without the possibility of open debate, science simply ceases to exist.**"

Vandenbroucke 2006

**What about industry's
economic performance?**



THE R&D SCOREBOARD

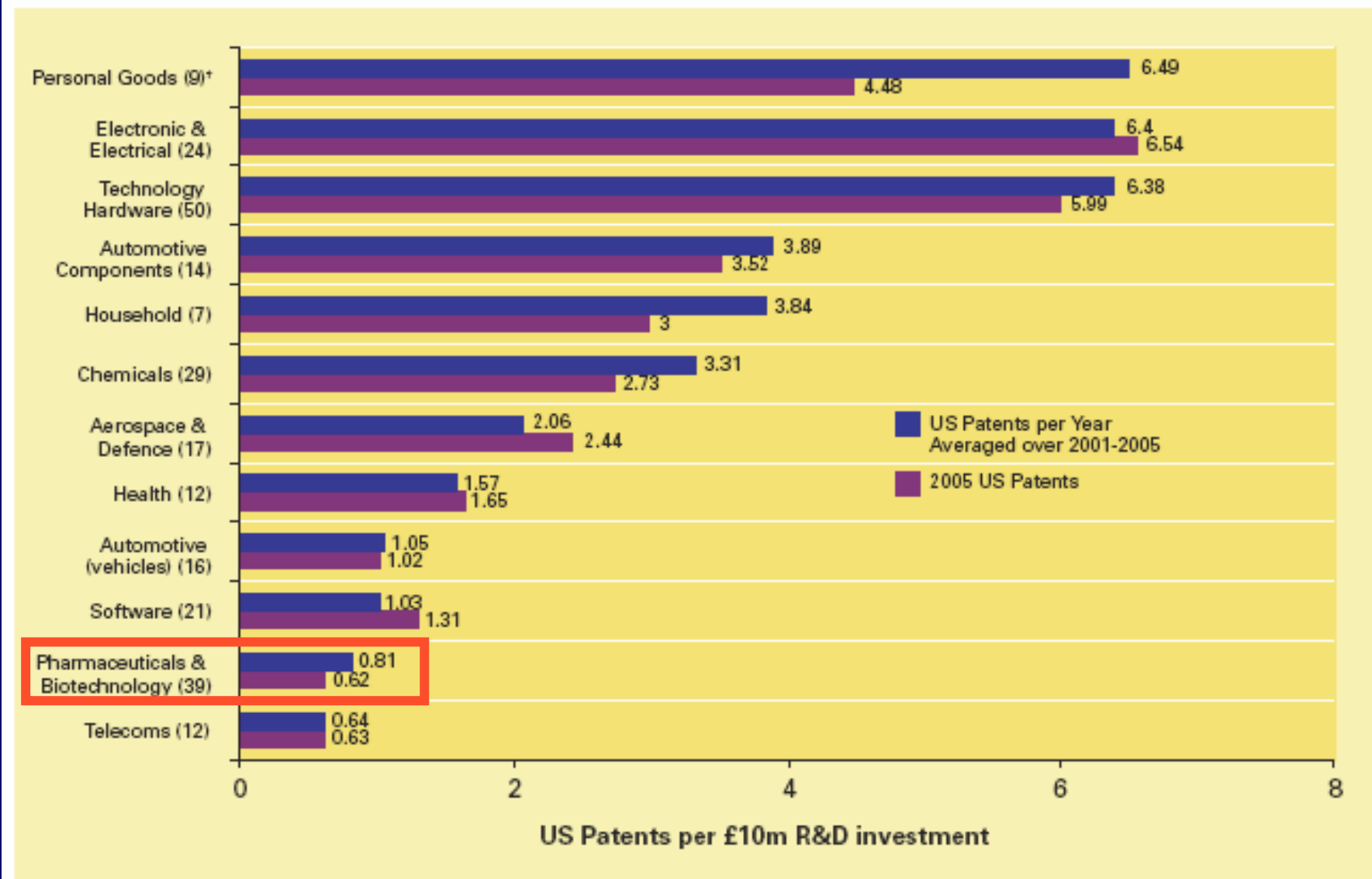
2006

The top 800 UK & 1250
Global companies
by R&D investment

COMMENTARY AND ANALYSIS

Volume 1 of 2

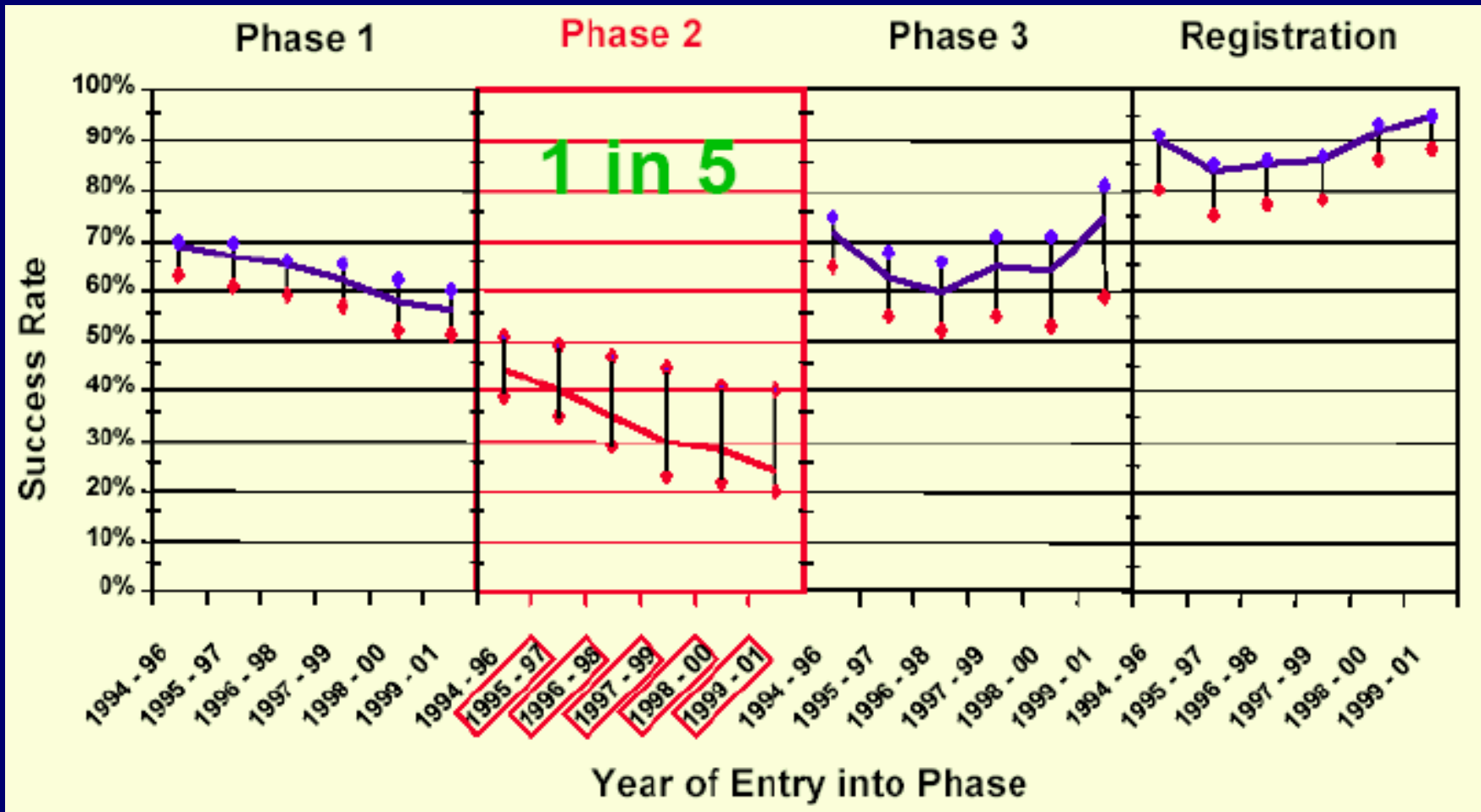
Figure ES7 The patents-to-R&D ratio for 12 sectors



† number of companies used in the calculation

Survival of proposals for new drugs

[Source: 2005 Global R&D Performance Metrics Programme:
Industry Success Rates Report, CMR International, May 2005, p 7]

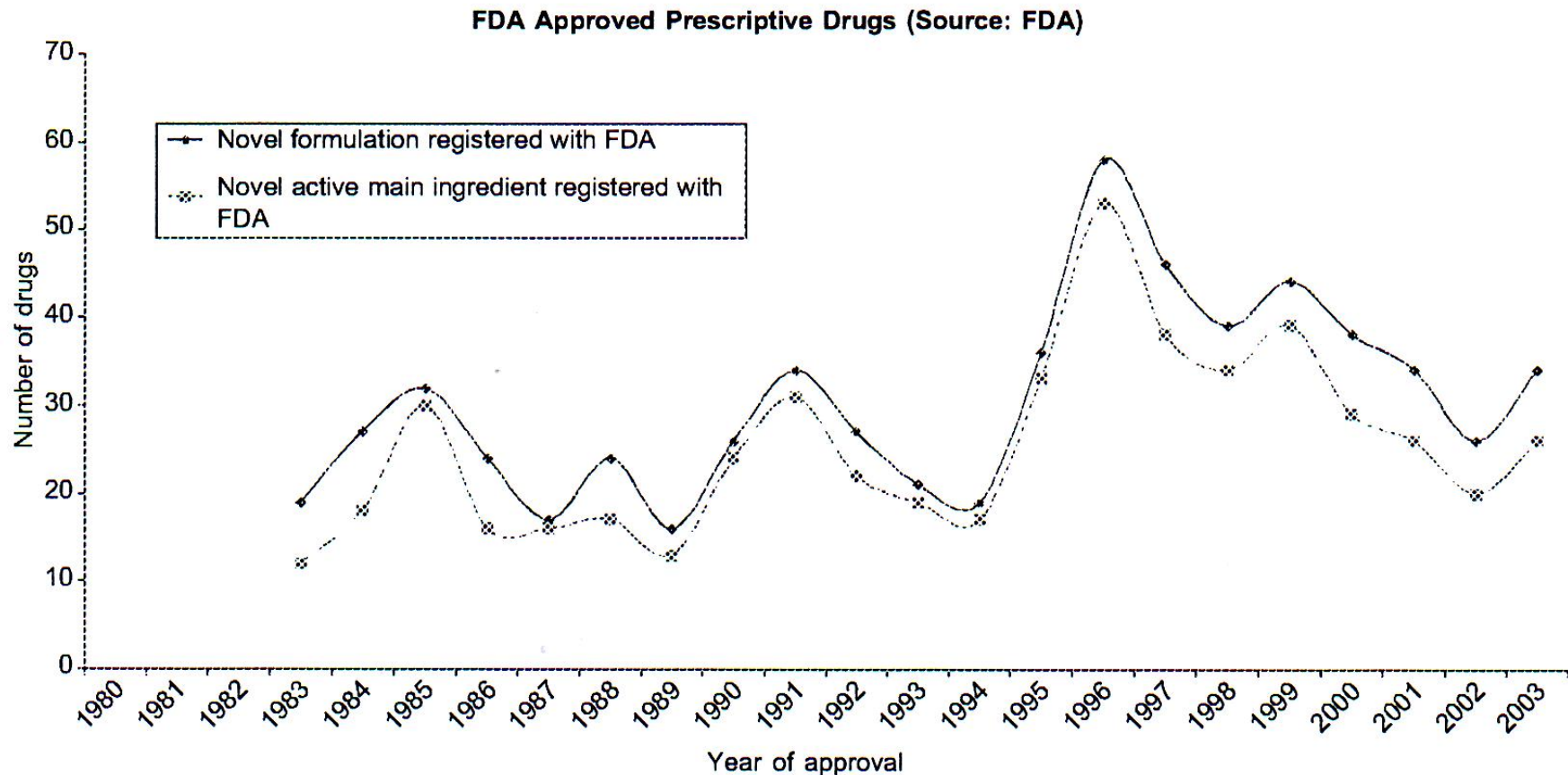


The myth of the biotech revolution

Paul Nightingale¹ and Paul Martin²

¹Science Policy Research Unit, Freeman Centre, University of Sussex, Brighton, BN1, UK

²Institute for the Study of Biorisks and Society (IGBIS) Room B13, Law and Social Sciences Building, University Park, Nottingham, UK, NG7 2RD



“Rather than producing revolutionary changes, medicinal biotechnology is following a well-established pattern of slow and incremental technology diffusion. Consequently, many expectations are wildly optimistic and overestimate the speed and extent of biotechnology, suggesting that the assumptions underpinning much contemporary policymaking need to be rethought.”

Nightingale and Martin 2004

An inefficient industry operating in a dysfunctional market turns to disease-mongering to sustain profits

A Collection of Articles on
DISEASE MONGERING
in
PLOS MEDICINE



Erectile dysfunction
Female sexual
dysfunction
Premenstrual dysphoric
disorder
Restless legs
ADHD
Bipolar disorder
Irritable bowel
syndrome
Osteoporosis
Drapetomania

Drapetomania:

an uncontrollable urge to escape slavery

Question 3: *Is industry's dominance of clinical research delivering good value for patients and the NHS?*

Comment 3: Industry's dominance in clinical research is driving out altruism among researchers, distorting the research agenda in favour of commercial priorities, squandering the contributions of patient volunteers, failing to meet the research needs of the NHS, and yielding poor return on investment.



Question 4: *How might patients ensure that their voluntary, often altruistic contributions to research are likely to help people using and working in the NHS?*

Trust in medical research is breaking down.

There is a danger that the goodwill which leads people to participate voluntarily in research will dry up.

EDITORIALS

Managing allegations of scientific misconduct and fraud: lessons from the “Hall affair”

If we can learn from this, it will have made a contribution to the pursuit of integrity in research

COMMENTARY

Scientists behaving badly

To protect the integrity of science, we must look beyond falsification, fabrication and plagiarism, to a wider range of questionable research practices, argue **Brian C. Martinson**, **Melissa S. Anderson** and **Raymond de Vries**.

Annals of Internal Medicine

MEDICINE AND PUBLIC ISSUES

Research Misconduct, Retraction, and Cleansing the Medical Literature: Lessons from the Poehlman Case

Harold C. Sox, MD, and Drummond Rennie, MD

The Guardian
UK news

Glaxo faces drug fraud lawsuit

Firm accused of keeping back negative trial results



Trials Under Fire

UK News

Horror Drug Trial 'Shouldn't Have Happened'

Friday, 13th October 2006, 07:22

Cracking down on medical trials

Doctors need to have unbiased data on effectiveness of new drugs, says ethicist *Arthur Schafer*

From optimism to disillusion about commitment to transparency in the medico-industrial complex

Iain Chalmers

JRSM 2006;99:337-341

1998



Richard Sykes *Chairman*

GlaxoWellcome

Being a modern pharmaceutical company

Involves making information available on clinical trial programmes

Glaxo Wellcome's new disclosure policy, *inter alia*, is "to help those undertaking systematic reviews of clinical data and **to help reduce the impact of publication bias.**"

Richard Sykes *Chairman*

GlaxoWellcome, Greenford, Middlesex UB6 0NN

BMJ VOLUME 317 31 OCTOBER 1998 www.bmj.com

2004



**Richard Sykes,
Rector, Imperial College London**



House of Commons Health Committee

Recommendations

353. The Committee was impressed by the evidence from Sir Richard Sykes. He acknowledged problems, emphasised the industry's underlying strengths and the commitment of its employees, and defined solutions in terms of greater transparency of data and in relationships:

Today the industry has got a very bad name. That is very unfortunate for an industry that we should look up to and believe in, and that we should be supporting. I think there have to be some big changes.³⁰¹

Framing volunteers'/donors' gifts in economic terms

(Trevor Sheldon, personal communication)

Development of ' **a quasi-market for altruistic gifts**', in which researchers vie for altruistically provided goods.

For any such quasi-market to work, **trustworthy information is needed** to inform potential altruistic donors.

Chronic failure to provide the public with relevant information

None of the 'public engagement in science' organizations in the UK has ever made a sustained effort to increase general knowledge about the research methods needed to obtain reliable information about the effects of treatments.



TESTING TREATMENTS

BETTER RESEARCH FOR BETTER HEALTHCARE

Imogen Evans, Hazel Thornton & Iain Chalmers
with a Foreword by Nick Ross

Caveat donor!

Agree to participate in a clinical trial only on condition (i) that the study protocol has been registered publicly on www.controlled-trials.com; (ii) that the protocol refers to the systematic reviews of existing evidence showing that the trial is justified; and (iii) that you receive a written assurance that the full study results will be published, and sent to all participants who indicate that they wish to receive them.

A patient-led good controlled trials guide

Chalmers Lancet
2000;356:774

Researchers and research sponsors will need to realise that one of the preconditions for consumer endorsement of and partnership in their trials is likely to be that protocols and other trial documents should be made public. Researchers—commercial or non-commercial—who wish to compete successfully for the attention of potential partners must therefore be prepared to be far more open about their activities than they have been in the past.⁵

Question 4: *How might patients ensure that their voluntary, often altruistic contributions to research are likely to help people using and working in the NHS?*

Comment 4: Public trust in research is being eroded by increasing evidence of scientific misconduct and undeclared conflicts of interest. Patients and the public need information to help them to be selective in making altruistic contributions to research.



Question 5: *Assuming the public continues to support a National Health Service based on the principle of social solidarity, how might the research needs of those using, working in and paying for the NHS be served more effectively?*

A DISPATCHES REPORT FOR CHANNEL 4 TELEVISION



SERVING TWO MASTERS

CONSULTANTS, THE NATIONAL HEALTH SERVICE
AND PRIVATE MEDICINE

Dr John Yates

A model clinical trials agreement

The Department of Health's new model agreement raises questions about the NHS's relation with industry

"This model agreement appears at a time when public trust in the drug industry has never been lower. The industry has recently been described as extraordinarily ineffective, and the *BMJ* (among others) has been urging that a firewall be set up between sponsors and research. **The likelihood of guilt by association is therefore considerable.**"

Goodyear, 2006



House of Commons Health Committee

48. We recommend that responsibility for representing the interests of the pharmaceutical industry should move into the remit of the Department of Trade and Industry to enable the Department of Health to concentrate solely on medicines regulation and the promotion of health. (Paragraph 392)

Agenzia Italiana per il Farmaco (AIFA)

First European drug regulatory agency to fund independent clinical research on proprietary and unregistered drugs.

Legislation requires pharmaceutical companies to contribute 5% of their advertising and promotion costs to fund this research.

In March 2006 a budget of 40 million Euros was used to commission 54 clinical research projects evaluating orphan drugs, head to head comparison of drugs in randomized trials, and translational research.

Garattini, personal communication

Taking more seriously the research needs of those using and working in the NHS

Database of Uncertainties about the Effects of Treatments (DUETs): *A resource to help prioritise new research*

Search for (topic **Asthma** which has health condition codes *Respiratory diseases: Asthma*)

Patients' questions (8)	Carers' questions (18)	Clinicians' questions (11)	Research recommendations (41)	Ongoing research (6)
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www.duets.nhs.uk

Minimizing Harm and Maximizing Benefit
During Innovation in Health Care:
Controlled or Uncontrolled
Experimentation?

Chalmers, 1986

Self-interest, social solidarity and shared risk

“...we have frequently spoken out against the use of uncontrolled, unevaluated, and often routine use of invasive techniques and treatments...

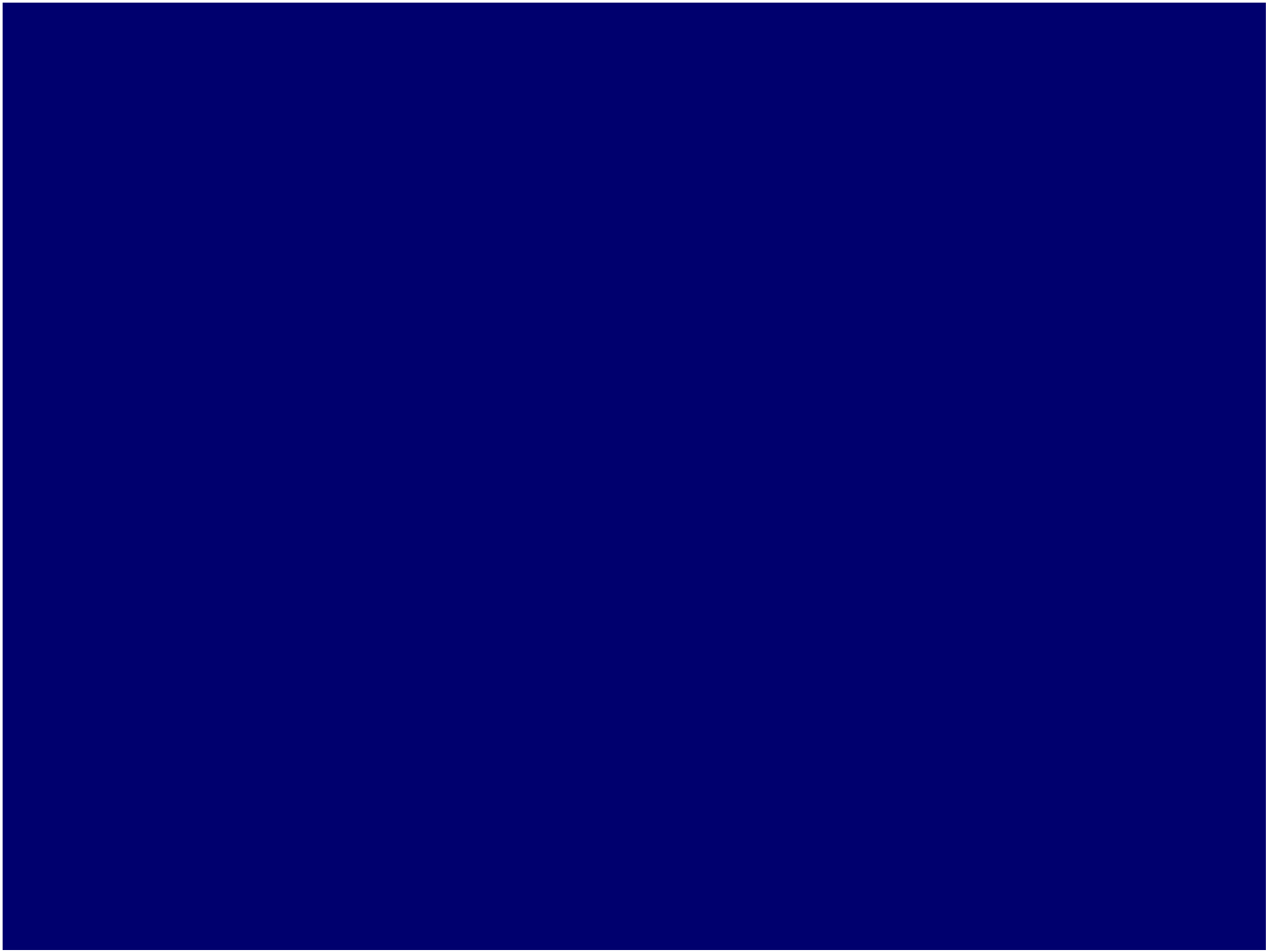
... we appreciate that to press for randomized controlled trials without openly acknowledging the need for participation in those trials is not a tenable position...

“...We recognise that in pursuit of safety, acceptability and high standards of clinical practice it is necessary to conduct such trials, and that these depend on a sufficient number of (people) **voluntarily limiting their own freedom of choice in order that a better service may be provided in the future.**”

Somorjay, National Childbirth Trust, 1987

Comment 5: The NHS should:

- (i) distinguish more clearly between the self-interest of the Service, and the interests of industry and academia;
- (ii) take more seriously the research needs of those using and working in the Service;
- (iii) ensure that adequate information about research done within the Service is publicly accessible;
- (iv) be more ready to restrict the use of inadequately assessed healthcare interventions to the context of research integrated within the Service.



Some concluding reflections on moral and economic incentives

FREAK ONOMICS



'A phenomenon'

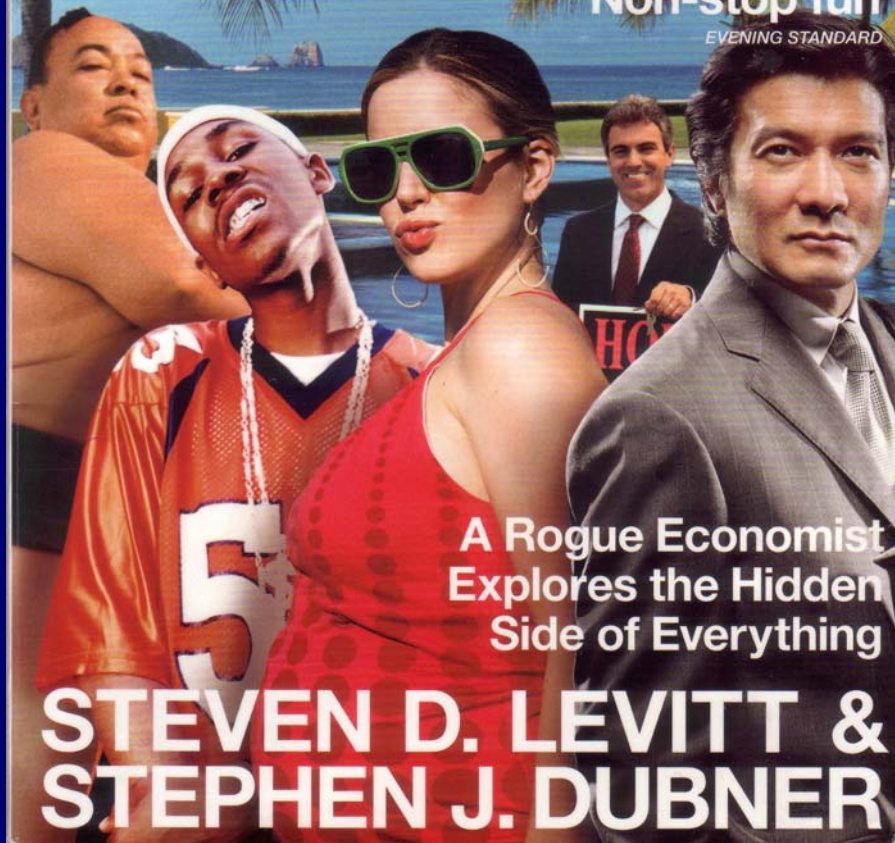
OBSERVER

'Brilliant'

SUNDAY TELEGRAPH

'Non-stop fun'

EVENING STANDARD



A Rogue Economist
Explores the Hidden
Side of Everything

STEVEN D. LEVITT &
STEPHEN J. DUBNER

“When people are given a small stipend for donating blood rather than simply being praised for their altruism, they tend to donate **less** blood...

“What if the blood donors had been offered an incentive of \$50, or \$500, or \$5,000. Surely the number of donors would have changed dramatically...But something else would have changed dramatically as well, for **every incentive has its dark side**... They might steal blood at knife point...pass off pig blood as their own...circumvent donation limits by using fake IDs.” (p 24)

“We have lived so long under **a theocracy of markets, competition, and cost containment** that people may forget that these are driven by an ideology of no more validity than **the ideology behind common cause, collaboration, and social purpose** that it supplanted.”

Grimley Evans, 1997

THE ORIGINS OF VIRTUE



'If my *The Selfish Gene* were to have a Volume Two devoted to humans, *The Origins of Virtue* is pretty much what I think it ought to look like'

— Richard Dawkins in *The Times Literary Supplement*, International Books of the Year



MATT RIDLEY



"Economists, who founded their whole discipline on the question 'What's in it for the individual?', have begun to back away. Much of the innovation in economics in recent years has been based on the alarming discovery by economists that people are motivated by something other than material self-interest." (pp 131-2)

"The virtuous are virtuous for no other reason than that it enables them to join forces with others who are virtuous, to mutual benefit." (p 147)

What would Richard Titmuss have thought today?

He would probably have been appalled by the privatisation of healthcare and health research; but I hope he would have been gratified by the evidence of more sophisticated economic analysis.



Inaugural Richard Titmuss Public Lecture

Altruism, Self Interest and Social Solidarity in assessing the effects of healthcare interventions

Sir Iain Chalmers

Editor of the James Lind Library

Professor Alistair McGuire

LSE, Chair