**I Congreso Costarricense de Bioética**

Heredia, 26 de Junio de 2008

# Las convergencias *epistemológicas* entre la Bioética y la MBE

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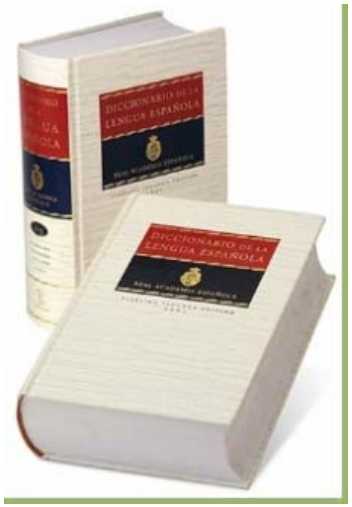
☞ **Epistemology:** the study or a theory of the nature and grounds of knowledge especially with reference to its limits and validity.




**epistemología.**

(Del gr. ἐπιστήμη, conocimiento, y *-logía*).

**1.** f. Doctrina de los fundamentos y métodos del conocimiento científico.

# Epistemology

Epistemology is one of the core areas of philosophy. It is concerned with the nature, sources and limits of knowledge. Epistemology has been primarily concerned with propositional knowledge, that is, knowledge that such-and-such is true, rather than other forms of knowledge, for example, knowledge how to such-and-such. There is a vast array of views about propositional knowledge, but one virtually universal presupposition is that knowledge is true belief, but not mere true belief (see Belief and knowledge). For example, lucky guesses or true beliefs resulting from wishful thinking are not knowledge. Thus, a central question in epistemology is: what must be added to true beliefs to convert them into knowledge?

Sir Francis Bacon
1561 - 1626

# Variación en la Práctica Clínica

Table 1 Directly standardized operation rates per 100 000 people for coronary artery bypass grafting (CABG) and angioplasty (PTCA), cataract surgery, and hip replacement in 66 primary care groups in London

| Procedure | Mean | SD | Minimum | Maximum |
|---|---|---|---|---|
| CABG & PTCA | 80.4 | 36.1 | 28.2 | 192.8 |
| Cataract surgery | 291.3 | 81.3 | 167.3 | 617.9 |
| Hip replacement (65 and over) | 201.5 | 59.4 | 74.0 | 363.0 |

**Majeed**, 2002. *J Pub Health Med* 24:21-26

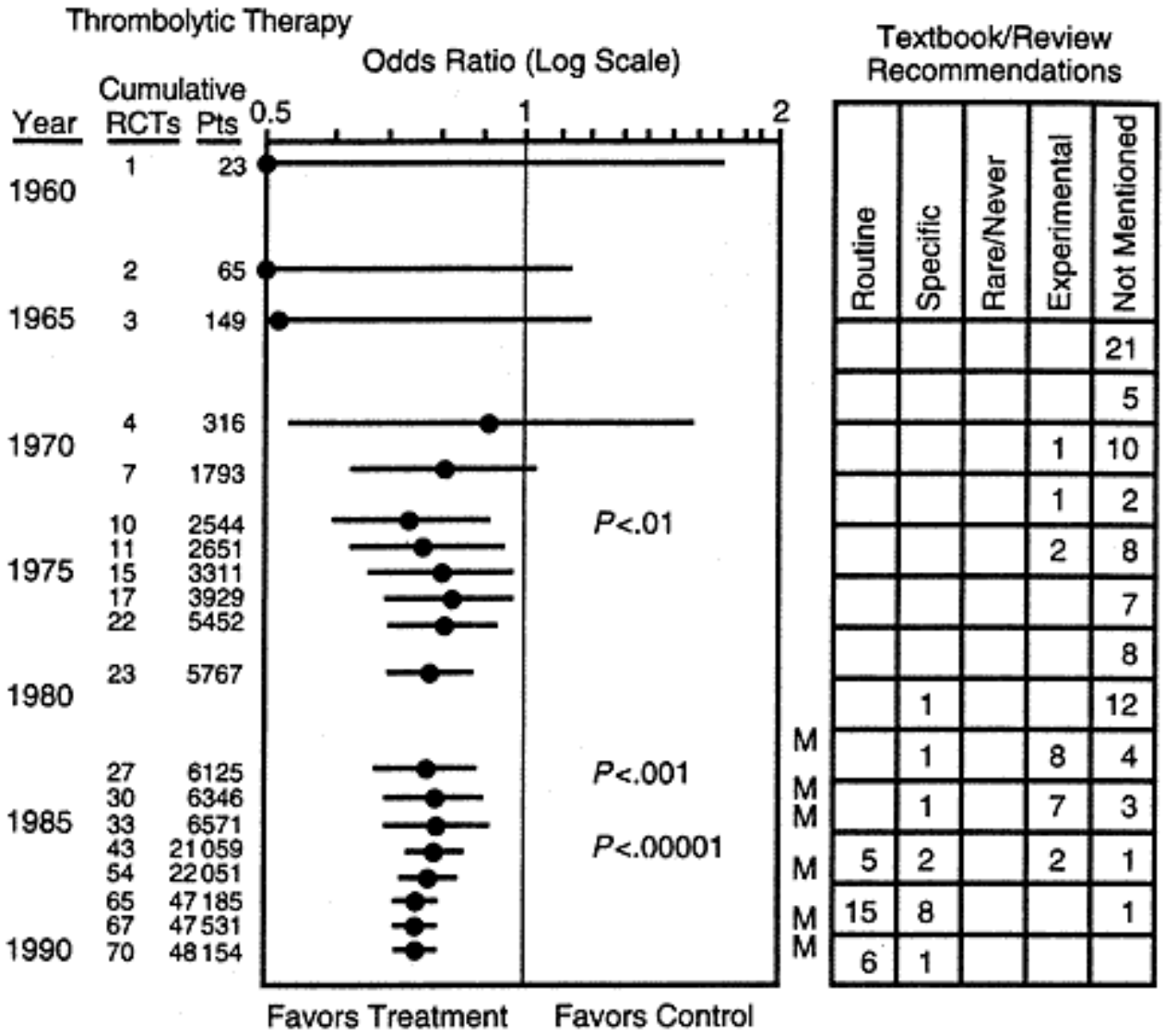



FIG 1. CUMULATIVE META-ANALYSIS OF THE RANDOMIZED TRIALS THAT HAVE INVESTIGATED THE IMPACT OF THROMBOLYTIC THERAPY ON MORTALITY AFTER MYOCARDIAL INFARCTION. SEE TEXT FOR EXPLANATION. RCT = RANDOMIZED CONTROLLED TRIAL. PTS = PATIENTS. (FROM REFERENCE 1, WITH PERMISSION)

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**Antman et al.** *JAMA* 1992; 268:240-248

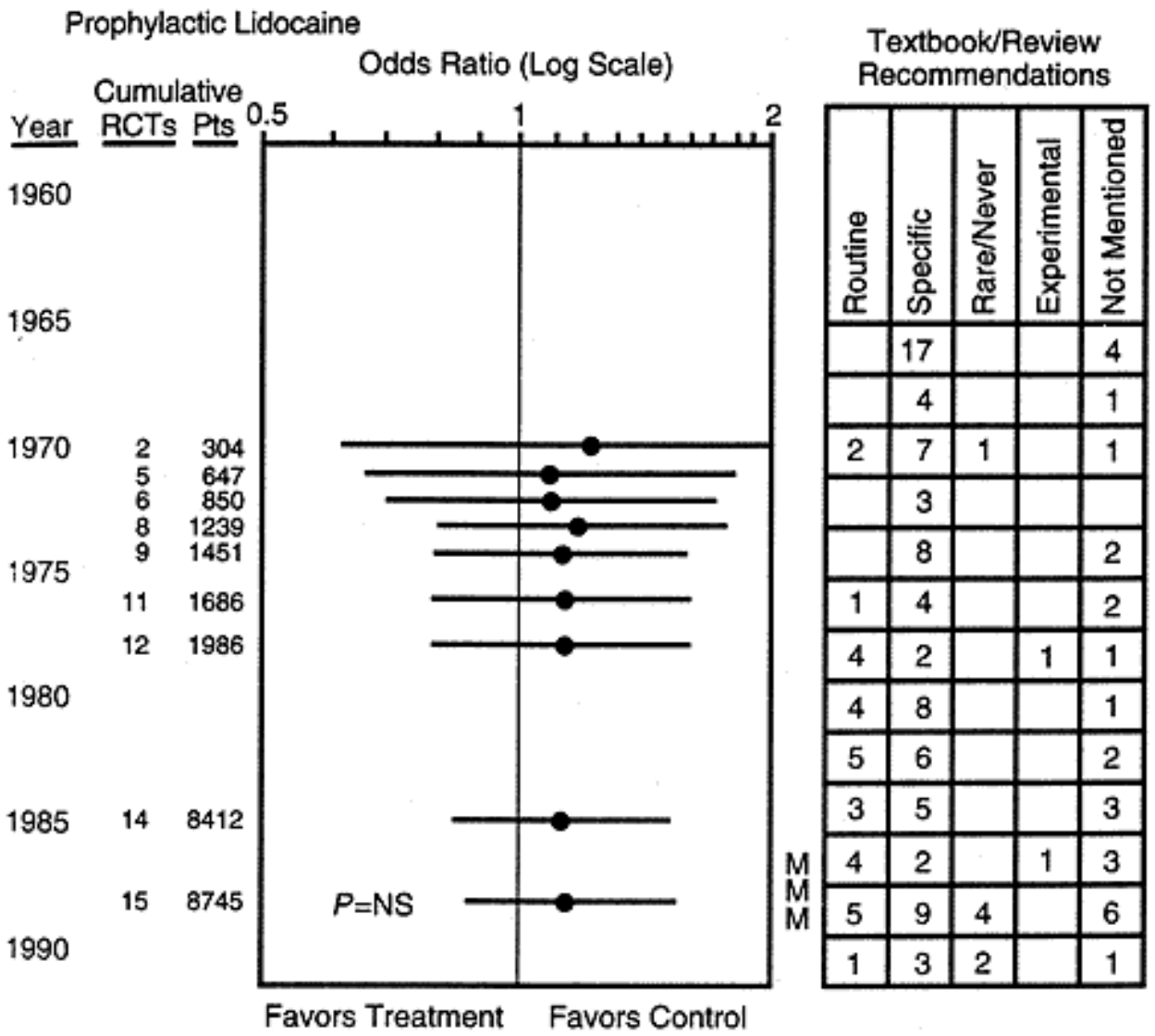


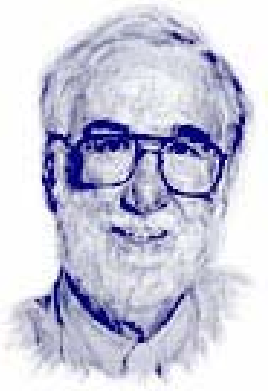

FIG 2. CUMULATIVE META-ANALYSIS OF THE RANDOMIZED TRIALS THAT HAVE INVESTIGATED THE IMPACT OF PROPHYLACTIC LIDOCAINE TO PREVENT LETHAL VENTRICULAR ARRHYTHMIAS IN PATIENTS PRESENTING WITH MYOCARDIAL INFARCTION. SEE TEXT FOR EXPLANATION. M = META-ANALYSIS. NS = NOT SIGNIFICANT. (FROM REFERENCE 1, WITH PERMISSION)



**Antman et al.** *JAMA* 1992; 268:240-248

☞ "It is surely a great criticism of our profession that we have not organised a critical summary, by speciality or subspeciality, adapted periodically, of all relevant randomised controlled trials"

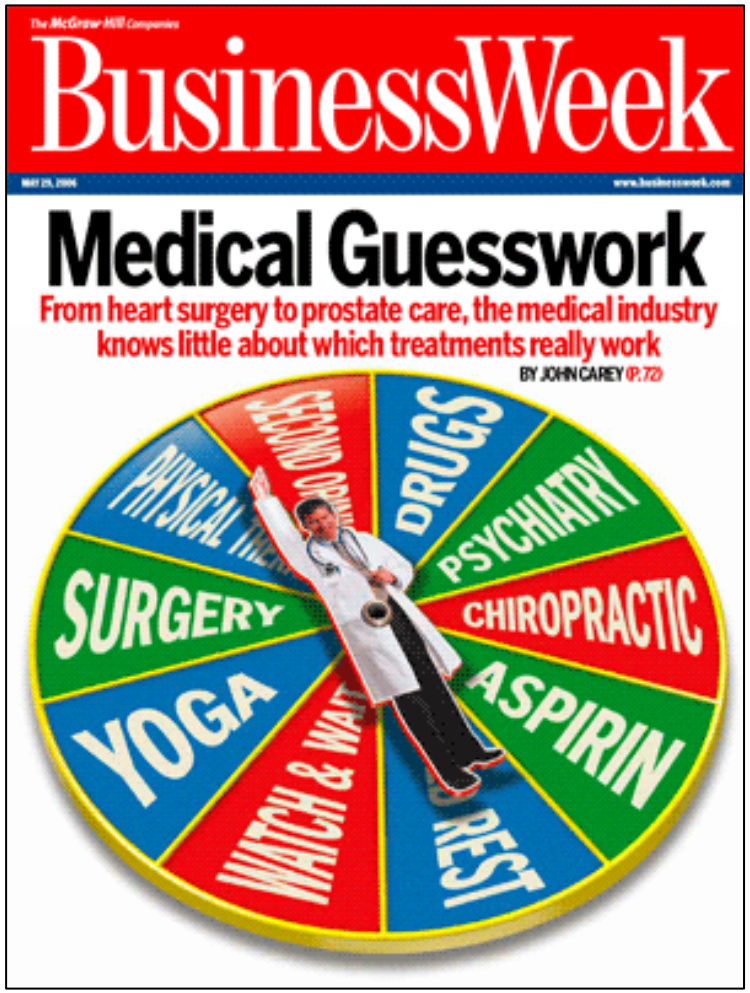
*Archibald Cochrane*



# Medicina Basada en Evidencias

☞ Es el uso consciente, explícito y juicioso, de la mejor información científica disponible, al momento de tomar decisiones en salud

Adaptado de: **Sackett et al.** *BMJ* 1996;312:71-72 (13 January)




May 29th , 2006

Sin embargo…

- ☞ No toda la información es de público acceso.

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

# Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy

Erick H. Turner, M.D., Annette M. Matthews, M.D., Eftihia Linardatos, B.S., Robert A. Tell, L.C.S.W., and Robert Rosenthal, Ph.D.

ABSTRACT

**BACKGROUND**

Evidence-based medicine is valuable to the extent that the evidence base is complete and unbiased. Selective publication of clinical trials — and the outcomes within those trials — can lead to unrealistic estimates of drug effectiveness and alter the apparent risk–benefit ratio.

**Turner E**. *N Engl J Med* 2008;358:252-60.


BRITISH JOURNAL OF PSYCHIATRY (2003), 183, 102–104

**Clinical trials of antidepressant medications**

**are producing r**

GORDON PARKER / IA

2002). A large number of randomised placebo-controlled trials of antidepressants have been carried out over the past decades, mostly funded by the pharmaceutical industry, and it is now recognised that about 50% of negative trials go unpublished (Thase, 1999). Meanwhile, unipolar de-

Sin embargo…

☞ No toda la información es generada con un interés *primario* en su validez.

Reviews and Overviews

# Why Olanzapine Beats Risperidone, Risperidone Beats Quetiapine, and Quetiapine Beats Olanzapine: An Exploratory Analysis of Head-to-Head Comparison Studies of Second-Generation Antipsychotics

Stephan Heres, M.D.

John Davis, M.D.

Katja Maino, M.D.

Elisabeth Jetzinger, M.D.

Werner Kissling, M.D.

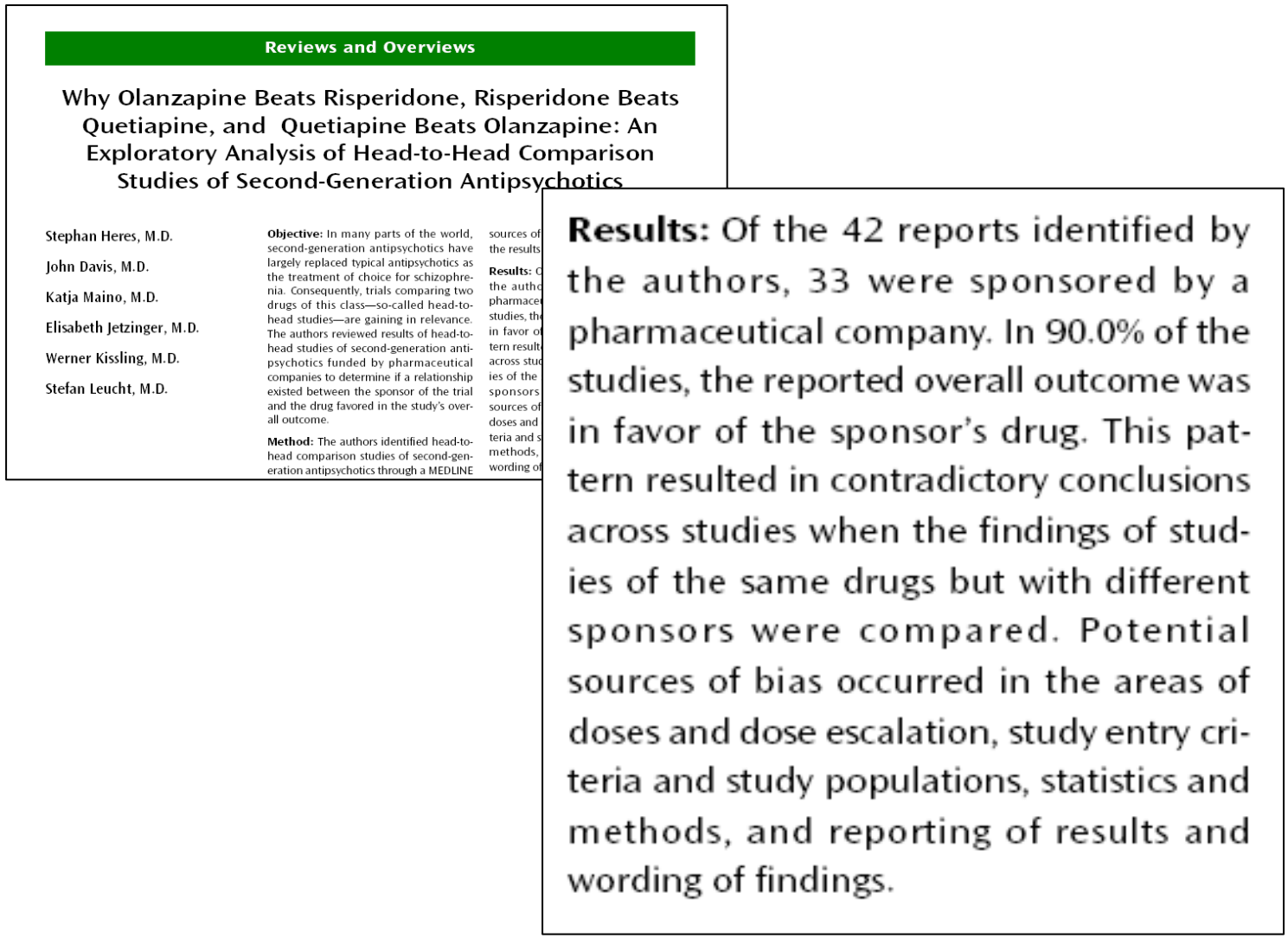
Stefan Leucht, M.D.

**Objective:** In many parts of the world, second-generation antipsychotics have largely replaced typical antipsychotics as the treatment of choice for schizophrenia. Consequently, trials comparing two drugs of this class—so-called head-to-head studies—are gaining in relevance. The authors reviewed results of head-to-head studies of second-generation antipsychotics funded by pharmaceutical companies to determine if a relationship existed between the sponsor of the trial and the drug favored in the study's overall outcome.

**Method:** The authors identified head-to-head comparison studies of second-generation antipsychotics through a MEDLINE sources of bias that could have affected the results in favor of the sponsor's drug.

**Results:** Of the 42 reports identified by the authors, 33 were sponsored by a pharmaceutical company. In 90.0% of the studies, the reported overall outcome was in favor of the sponsor's drug. This pattern resulted in contradictory conclusions across studies when the findings of studies of the same drugs but with different sponsors were compared. Potential sources of bias occurred in the areas of doses and dose escalation, study entry criteria and study populations, statistics and methods, and reporting of results and wording of findings.

**Heres S.** *Am J Psychiatry* 2006; 163:185–194



Reviews and Overviews

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**Heres S.** *Am J Psychiatry* 2006; 163:185–194

Respiratory Medicine (2006) 100, S17–S21

ELSEVIER

respiratoryMEDICINE

# Evidence-based recommendations or "Show me the patients selected and I will tell you the results"

Leif Bjermer*

*Department of Respiratory Medicine & Allergology, 221 85 Lund, Sweden*

**Bjermer L**. *Respiratory Medicine* (2006) 100, S17–S21

**TABLE 1. Use of Exclusion Criteria Designed to Maximize Drug-Placebo Differences in 31 Studies of the Efficacy of Antidepressants in the Treatment of Depressed Outpatients**[a]

| Exclusion Criterion | Frequency (%) |
|---|---|
| Comorbid medical condition | 83.9 |
| Short duration of depressive episode | 41.9 |
| Comorbid personality disorder | 16.1 |
| Mild depression | 96.7 |
| Treatment response during placebo lead-in period | 54.8 |
| Comorbid anxiety disorder | 35.5 |
| Long duration of depressive episode | 12.9 |
| Comorbid substance use disorder | 83.9 |
| Prior nonresponse to treatment | 48.4 |
| Comorbid dysthymia | 19.4 |

[a] Studies were published from 1994 through 1998 in five psychiatric journals (*Archives of General Psychiatry, American Journal of Psychiatry, Journal of Clinical Psychiatry, Journal of Clinical Psychopharmacology,* and *Psychopharmacology Bulletin*).

**Posternak M.** *Am J Psychiatry 2002; 159:191–200*

Sin embargo…

- ☞ No toda la información generada tiene un valor *real* para la sociedad.

BMJ

## Summary points

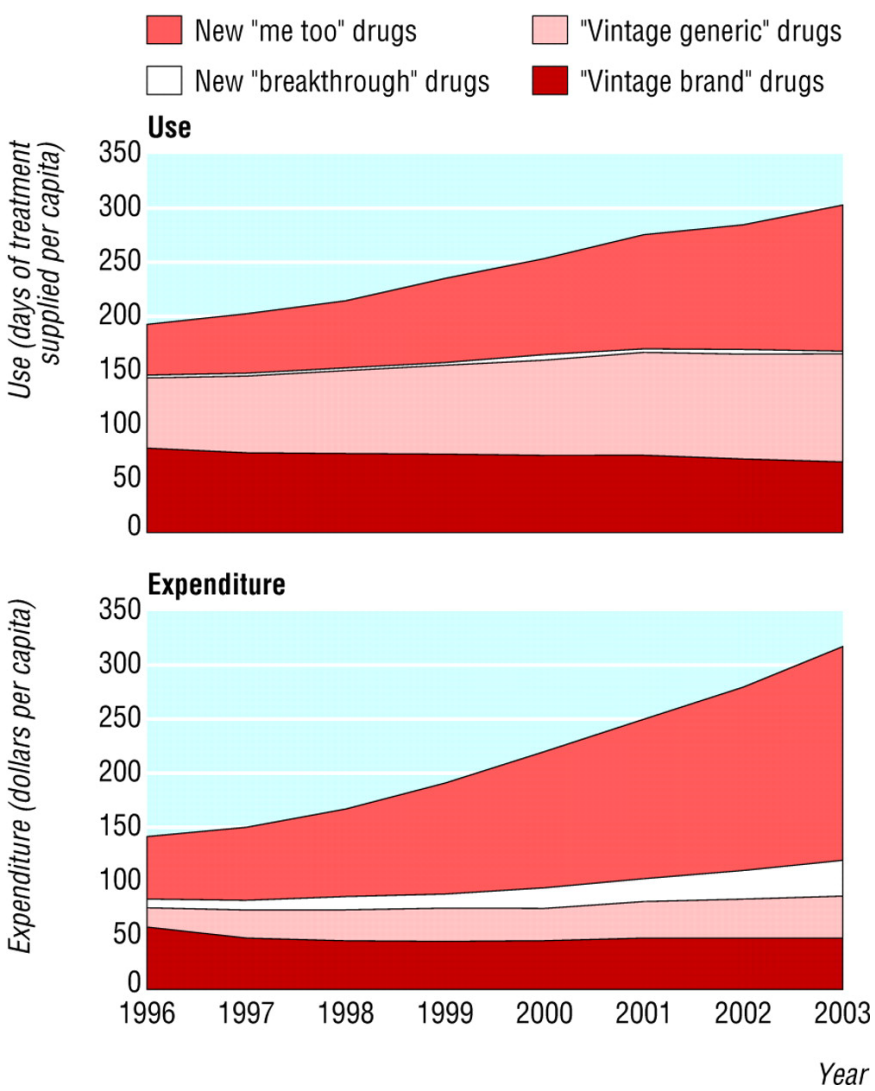
Some forms of "medicalisation" may now be better described as "disease mongering"—extending the boundaries of treatable illness to expand markets for new products

Alliances of pharmaceutical manufacturers, doctors, and patients groups use the media to frame conditions as being widespread and severe

Disease mongering can include turning ordinary ailments into medical problems, seeing mild symptoms as serious, treating personal problems as medical, seeing risks as diseases, and framing prevalence estimates to maximise potential markets

Corporate funded information about disease should be replaced by independent information

**Moynihan R**. *BMJ* 2002;324:886–91




**Morgan S.**. *BMJ* 2005;331:815-816

International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)

## Guideline 3: Ethical review of externally sponsored research *(commentary)*:

- … Committees in the host country have a special responsibility to determine whether the objectives of the research are responsive to the health needs and priorities of that country.

The social worth of a research project is more difficult to determine than its scientific merit but that is not a good reason for ignoring it. Researchers, and ethics review committees, must ensure that patients are not subjected to tests that are unlikely to serve any useful social purpose. To do otherwise would waste valuable health resources and weaken the reputation of medical research as a major contributing factor to human health and well-being.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Multi pertransibunt & augebitur scientia.
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Anno
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