

# Ethics of Mental Health Research

8th Global Forum on Bioethics in Research

Vilnius, 27 – 29 June, 2007

**Rodrigo A. Salinas**

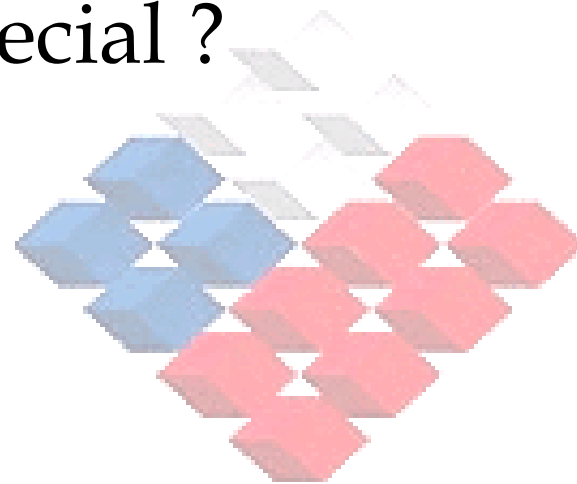
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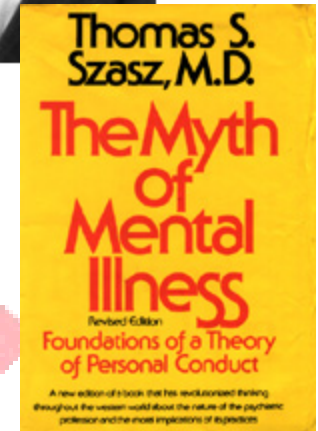
👉 What makes mental health research so special ?



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Psychiatry is conventionally defined as a medical speciality concerned with the diagnosis and treatment of mental diseases. I submit that this definition, which is still widely accepted, places psychiatry in the company of alchemy and astrology and commits it to the category of pseudoscience. The reason for this is that there is no such thing as 'mental illness'.



Thomas Szasz (1920 - )

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# Political abuse of psychiatry

Birley JLT. Political abuse of psychiatry.  
*Acta Psychiatr Scand* 2000; 101: 13–15. © Munksgaard 2000.

The abuse of psychiatry in Nazi Germany 60 years ago was the abuse of the 'duty to care'. Its scale was enormous; 300 000 people were sterilized and 100 000 killed in Germany alone and many thousands further afield, mainly in eastern Europe. This episode occurred in a country with a high reputation for its medicine, including psychiatry, and for its interest in the ethics of medical research. The economic conditions which preceded the violent political upheaval had led to increasing concern about 'the burden on the State' of the mentally ill and disabled. These preoccupations are still with us today. There may still be lessons to be learnt from the Nazi episode.

## **J. L. T. Birley**

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The Netherlands

Key words: abuse of psychiatry;  
human experimentation

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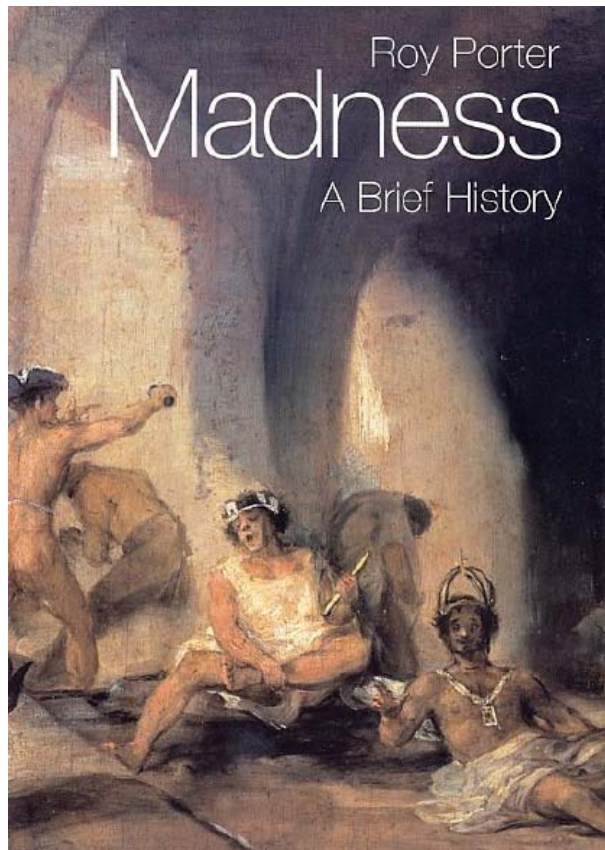


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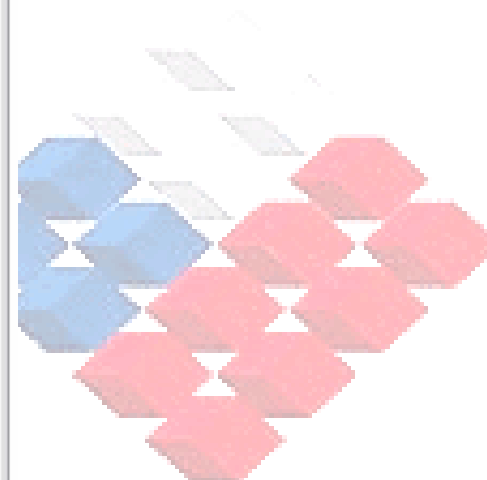
☞ In the late nineteenth century the priority lay, for many psychiatrists, upon establishing their discipline as a truly scientific enterprise, capable of taking its rightful place in the pantheon of the 'hard' biomedical sciences, alongside neurology and pathology, and utterly distinct from such quackish and fringy embarrassments as mesmerism and spiritualism. Providing psychiatry with a sound scientific basis was particularly important at that time, on account of its strong positivistic and Darwinian leanings.

Porter R. *Madness, A Brief History*.



Box 1: Nine beliefs summarising the perspective of the neo-Kraepelinian approach<sup>19</sup>

- **Psychiatry** is a branch of medicine
- **Psychiatry** should use modern scientific methods and base its practice on scientific knowledge
- **Psychiatry** treats people who are sick and need treatment for mental illness
- A boundary exists between normal and sick people
- Mental illness is not a myth; there are many mental illnesses. It is the task of scientific **psychiatry** to investigate the causes, diagnosis, and treatment of these mental illnesses
- The focus of psychiatric physicians should focus on the biological aspects of mental illness
- There should be an explicit and intentional concern with diagnosis and classification
- Diagnostic criteria should be codified, and a legitimate and valued area of research should be to validate such criteria by various techniques. **Psychiatry** departments in medical schools should teach these criteria and not belittle them, as has been the case for many years
- Statistical techniques should be used in research efforts directed at improving the reliability and validity of diagnosis and classification



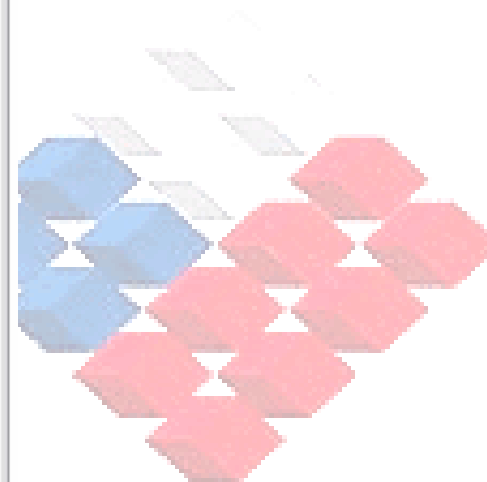
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Double D. *BMJ* 2002;324:900–4



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# WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

## Ethical Principles for Medical Research Involving Human Subjects



### A. Introduction

8. ... Some research populations are vulnerable and need special protection ... **Special attention is also required for those who cannot give or refuse consent for themselves**, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

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# WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

## Ethical Principles for Medical Research Involving Human Subjects



### B. Basic principles of all medical research

24. For a research subject who is legally incompetent, physically or **mentally incapable of giving consent** or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.



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

**Guideline 15:** Research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent.

Before undertaking research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent, the investigator must ensure that:

- ☞ such persons will not be subjects of research that might equally well be carried out on persons whose capacity to give adequately informed consent is not impaired;



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

### Guideline 15:

#### Commentary on Guideline 15

*General considerations:* Most individuals with mental or behavioural disorders are capable of giving informed consent; this Guideline is concerned only with those who are not capable or who because their condition deteriorates become temporarily incapable.



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- 👉 in cases where prospective subjects lack capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with applicable law.



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

### Guideline 15:

#### Commentary on Guideline 15

*Consent of the individual:* ... The agreement of an immediate family member or other person with a close personal relationship with the individual should be sought, but it should be recognized that these proxies may have their own interests that may call their permission into question.



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## Universal Declaration on Bioethics and Human Rights

### Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(b) research should only be carried out for his or her direct health benefit, ... if there is no research alternative of comparable effectiveness with research participants able to consent ...



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**But ...**

- ☞ Regulations and guidelines require interpretation ...

Cannot deduce a particular application  
of a guideline

Florencia Luna, Ruth Macklin, Vilnius 2007

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## 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.





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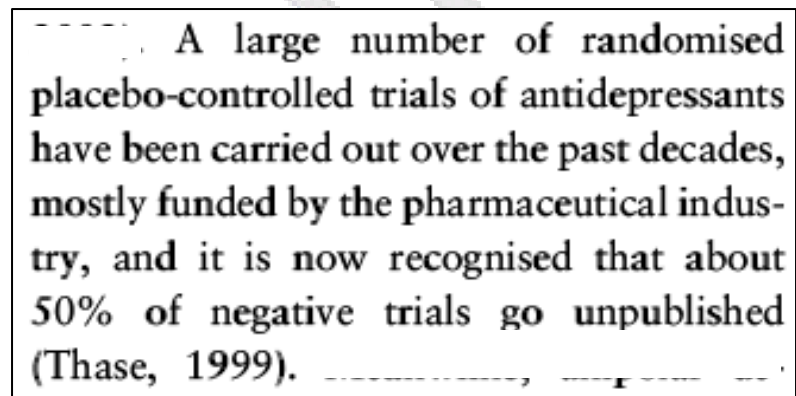
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*Am J Psychiatry* 2006; 163:185-194



## GORDON PARKER / IAN M. ANDERSON and PETER HADDAD

GORDON PARKER / IAN M. ANDERSON and PETER HADDAD



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## **Clinical trials of antidepressant medications are producing meaningless results**

GORDON PARKER / IAN M. ANDERSON and PETER HADDAD



A related question is whether clinical trials provide any evidence that one type of antidepressant therapy is superior to any other. As reviewed earlier (Parker, 2001), very large databases suggest that different classes of antidepressant drugs are equally efficacious. Meta-analyses also report similar response rates for drugs and most non-drug treatments for depression.

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Respiratory Medicine (2006) 100, S17–S21



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## 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

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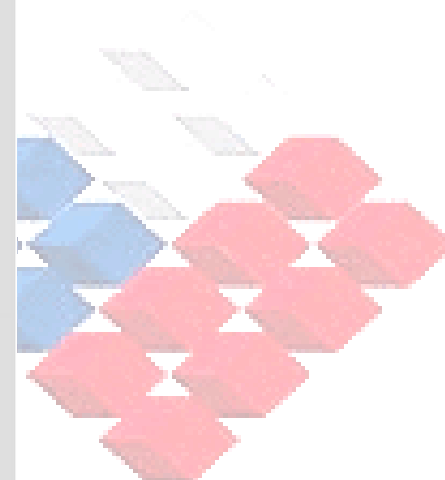
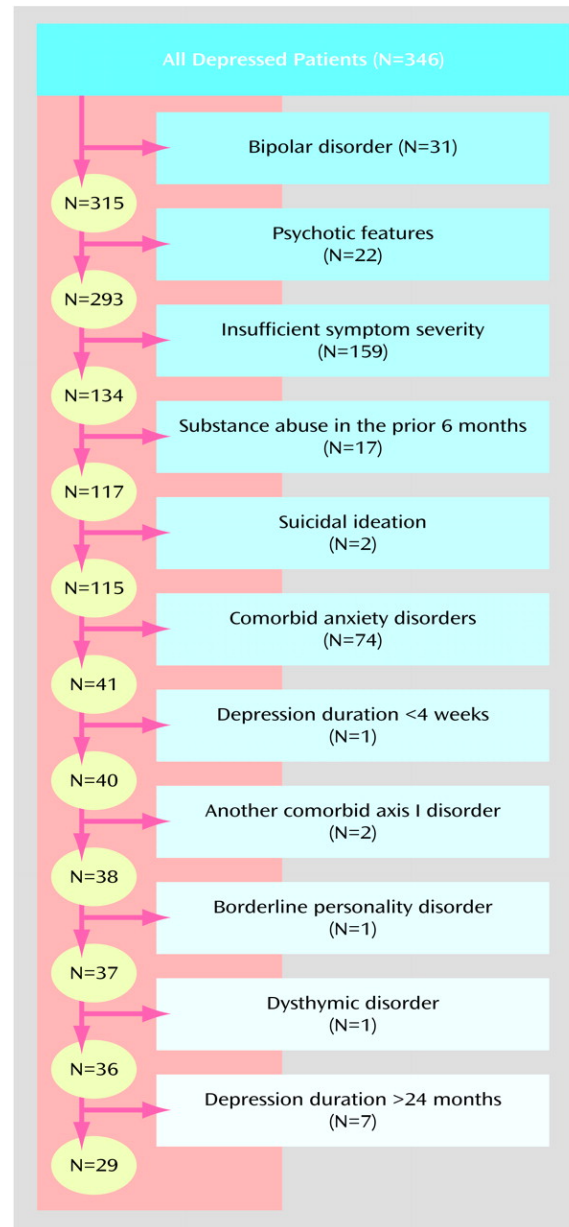


**TABLE 1. Use of Exclusion Criteria Designed to Maximize Drug-Placebo Differences in 31 Studies of the Efficacy of Antidepressants in the Treatment of Depressed Outpatients<sup>a</sup>**

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

<sup>a</sup> 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*).





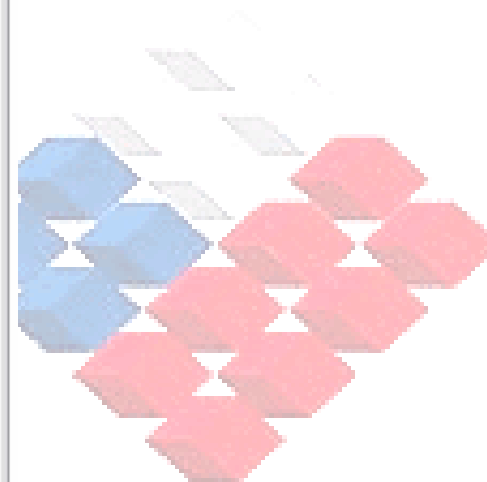
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Zimmerman M. *Am J Psychiatry* 2002; 159:469–473



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Double D. *BMJ* 2002;324:900–4



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Brunsdon B, Prior F (2005) The brain of LB1, *Homo floresiensis*. *Science* **308**: 242–245

Morwood MJ *et al* (2004) Archaeology and age of a new hominin from Flores in eastern Indonesia. *Nature* **431**: 1087–1091

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Tabitha M. Powledge

doi:10.1038/sj.embor.7400471

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## Disease mongering and drug marketing

Does the pharmaceutical industry manufacture diseases as well as drugs?

The late medical journalist Lynn Payer addressed the issue in the early 1990s in her book *Disease-Mongers: How Doctors, Drug Companies, and Insurers Are Making You Feel Sick*. She wrote: "Disease-mongering—trying to convince essentially well people that they are sick, or slightly sick people that they are very ill—is big business.... Disease mongering is the most insidious of the various forms that medical advertising, so-called medical education, and information and medical diagnosis can take." Similarly, Arthur Caplan, Professor of Bioethics at the University of Pennsylvania, Philadelphia, USA, last December told the popular American TV programme *60 Minutes*, "If you want to stir up worry in the public, and you've got the advertising dollars to do it, you can turn almost anything into a disease." The focus of the *60 Minutes* report was the recent emergence of a market for adult attention deficit disorder

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Wolinsky H. *EMBO reports* VOL 6 | NO 7 | 2005





## Summary points

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

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

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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

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Corporate funded information about disease should be replaced by independent information

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Moynihán R. *BMJ* 2002;324:886–91





## Personal or social problems as medical ones: social phobia

When Roche was promoting its antidepressant Aurorix (moclobemide) as a valuable treatment for social phobia in 1997, its public relations company issued a press release, picked up by some of the media, announcing that more than one million Australians had an underdiagnosed psychiatric disorder called social phobia.<sup>11</sup> The release described a “soul destroying condition” and quoted a clinical psychologist strongly endorsing the role of antidepressants in its treatment. At that time, government figures suggested the number of people with the disorder might be closer to 370 000.

Moynihán R. *BMJ* 2002;324:886–91

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TreatmentTeam

## Bipolar Disorder at a Glance

Bipolar disorder is a biological illness that causes extreme shifts in mood, thoughts, energy, and behavior. Moods swing from mania to depression, with occasional periods of normal mood (euthymia) in between. This illness appears in both adults and children, and affects people of all ages, races, and ethnic groups. Unlike major depressive disorder, which affects women more than men, bipolar disorder affects women and men in equal numbers.

*Lilly*



# The Mood Disorder Questionnaire (MDQ)

This questionnaire should be used as a starting point. It is not a substitute for a full medical evaluation. Bipolar disorder is a complex illness, and an accurate, thorough diagnosis can only be made through a personal evaluation by your doctor. However, a positive screen here may suggest that you might benefit from seeking such an evaluation from your doctor. Regardless of the questionnaire results, if you or someone you know has concerns about your mental health, please contact your physician or another healthcare professional.

**INSTRUCTIONS:** Please answer each question as best you can.

	YES	NO
1. Has there ever been a period of time when you were not your usual self and...		
... you felt so good or so hyper that other people thought you were not your normal self or you were so hyper that you got into trouble?	<input type="radio"/>	<input type="radio"/>
... you were so irritable that you shouted at people or started fights or arguments?	<input type="radio"/>	<input type="radio"/>

The Lilly logo is written in a red, cursive script font.



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**INSTRUCTIONS:** Please answer each question as best you can.

**YES    NO**

1. Has there ever been a period of time when you were not your usual self and...

... you were so easily distracted by things around you that you had trouble concentrating or staying on track?

☐ YES    ☐ NO

... you had much more energy than usual?

☐ YES    ☐ NO

... you were much more active or did many more things than usual?

☐ YES    ☐ NO

... you were much more social or outgoing than usual, for example, you telephoned friends in the middle of the night?

☐ YES    ☐ NO

... you were much more interested in sex than usual?

☐ YES    ☐ NO

The Lilly logo is written in a red, cursive script font.



## Brief Report

# Development and Validation of a Screening Instrument for Bipolar Spectrum Disorder: The Mood Disorder Questionnaire

Robert M.A. Hirschfeld, M.D.

Janet B.W. Williams, D.S.W.

Robert L. Spitzer, M.D.

Joseph R. Calabrese, M.D.

Laurie Flynn, B.S.

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Susan L. McElroy, M.D.

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**Objective:** Bipolar spectrum disorders, which include bipolar I, bipolar II, and bipolar disorder not otherwise specified, frequently go unrecognized, undiagnosed, and untreated. This report describes the validation of a new brief self-report screening instrument for bipolar spectrum disorders called the Mood Disorder Questionnaire.

**Method:** A total of 198 patients attending five outpatient clinics that primarily treat patients with mood disorders completed the Mood Disorder Questionnaire. A research professional, blind to the Mood Disorder Questionnaire results, conducted a telephone research diagnostic interview by means of the bipolar module of the Structured Clinical Interview for DSM-IV.

**Results:** A Mood Disorder Questionnaire screening score of 7 or more items yielded good sensitivity (0.73) and very good specificity (0.90).

**Conclusions:** The Mood Disorder Questionnaire is a useful screening instrument for bipolar spectrum disorder in a psychiatric outpatient population.

(*Am J Psychiatry* 2000; 157:1873–1875)





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Supported by an unrestricted educational grant from Abbott Laboratories.

The authors thank David M. Medearis, B.S., for assistance in the preparation of this article.

*Am J Psychiatry* 157:11, November 2000





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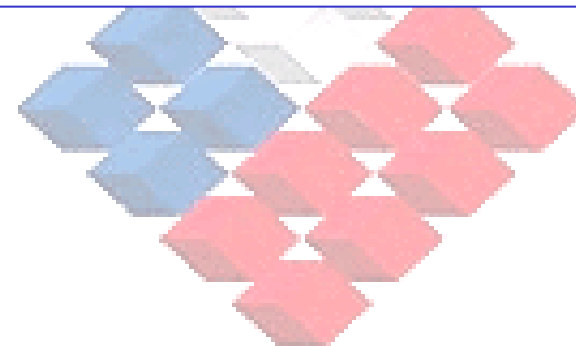
*Robert M. A. Hirschfeld, M.D.*, has received research or grant support from Abbott, Bristol-Myers, GlaxoSmithKline, Organon, and Wyeth; is a consultant to or member of the advisory boards of Abbott, Bristol-Myers, GlaxoSmithKline, Forest, Lilly, Pfizer, Organon, Janssen, Wyeth, Sepracor, and Novartis; and is a member of the speakers bureaus of Abbott, Bristol-Myers, Forest, Lilly, Organon, and Pfizer.



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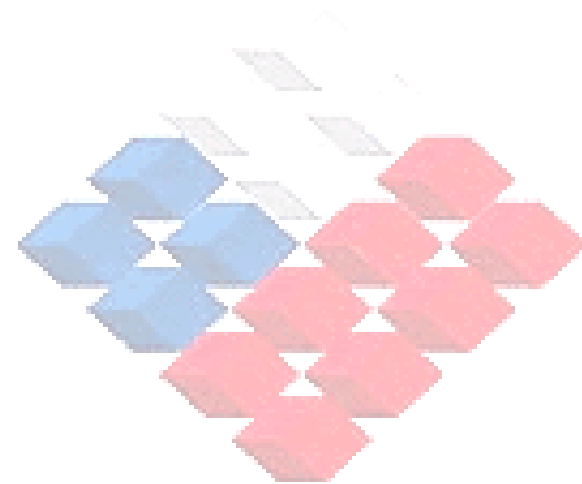
The social worth of a research project is more difficult to determine than its scientific merit but that is not a good reason for ignoring it. Researchers, and ethics review committees, must ensure that patients are not subjected to tests that are unlikely to serve any useful social purpose. To do otherwise 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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👉 ありがとうございます



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