Minnesota Nice?

Some Perspective on Protecting Vulnerable Human Subjects and Conflict of Interest in Healthcare Research

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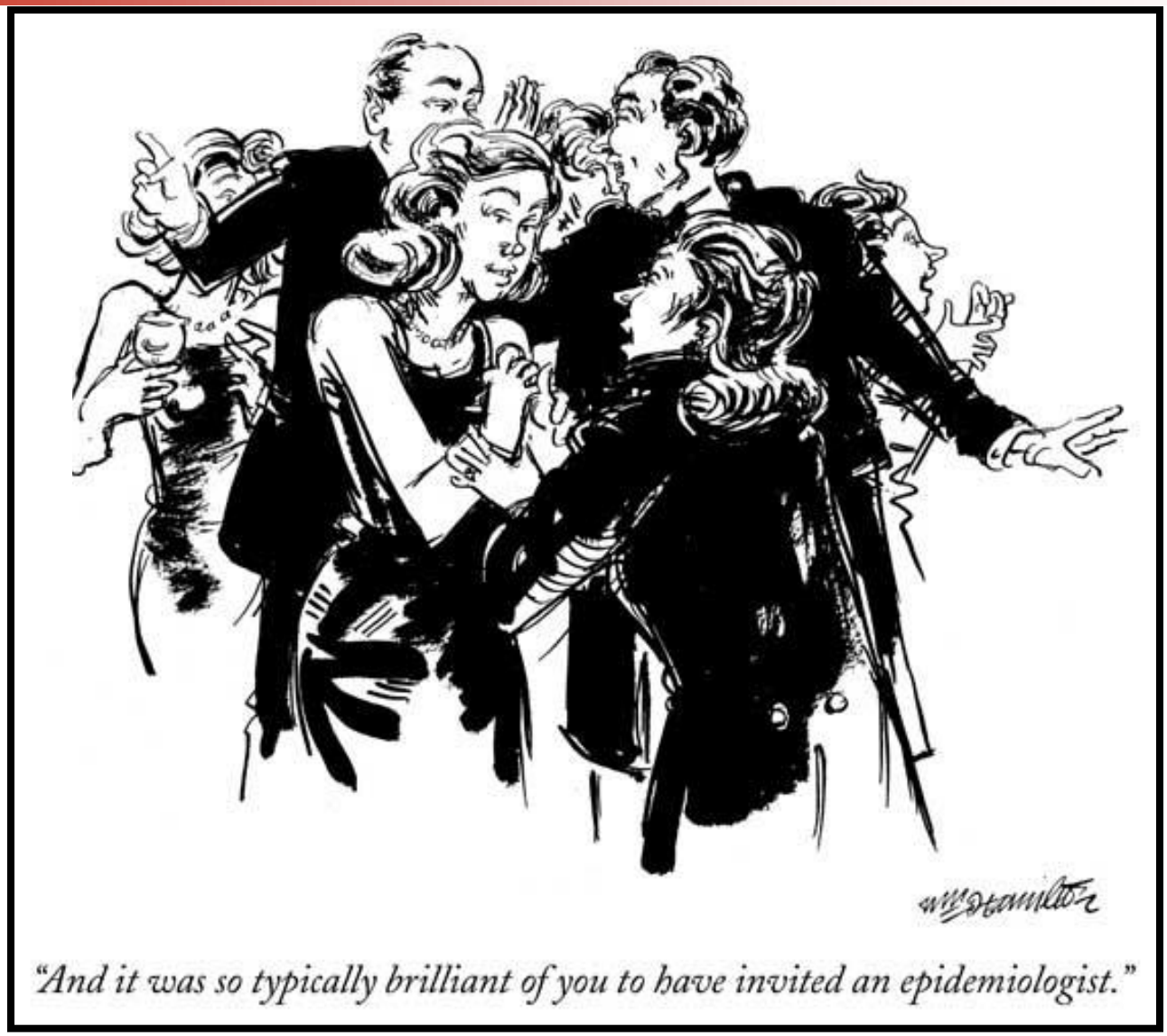
Minnesota nice is the stereotypical behavior of people born and raised in Minnesota to be courteous, reserved, and mild-mannered. The cultural characteristics of Minnesota nice include a polite friendliness, an aversion to confrontation, a tendency toward understatement, a disinclination to make a fuss or stand out, emotional restraint, and self-deprecation.



"And it was so typically brilliant of you to have invited an epidemiologist."

I aim to offer a perspective on recent troubles and discussion at UMN.

This is the perspective of a long-time IRB Chair and a Professor.

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This is the perspective of a long-time IRB Chair and a Professor.

Not a physician or trained ethicist.

I aim to offer a useful perspective on recent troubles and discussion at UMN.

This is the perspective of a long-time IRB Chair and a Professor.

Not a physician or trained ethicist.

Or a lawyer!

My goal is not to offer a novel or definitive account.

But rather to share my perspective in hopes that we learn some things together

The New York Times

The Opinion Pages | OP-ED CONTRIBUTOR

The University of Minnesota's Medical Research Mess

By CARL ELLIOTT MAY 26, 2015

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MINNEAPOLIS — IF you want to see just how long an academic institution can tolerate a string of slow, festering research scandals, let me invite you to the University of Minnesota, where I teach medical ethics.

http://www.nytimes.com/2015/05/26/opinion/the-university-of-minnesotas-medical-research-mess.html

Dan Markingson

http://www.motherjones.com/environment/2015/04/dan-markingson-university-minnesota-clinical-trials-astrazeneca

This story began in 2003, when Dr. Stephen Olson, a psychiatrist at the University of Minnesota used the threat of involuntary commitment to coerce a psychotic young man named Dan Markingson into the so-called "CAFÉ" study: an AstraZeneca-funded trial of antipsychotic drugs aimed at patients experiencing their first psychotic episode. His mother, Mary Weiss, objected to her son's enrollment and tried desperately for months to get Dan out of the study, warning Olson and his co-investigator, Charles Schulz, that her son's condition was deteriorating and that he was in danger of committing suicide. Her warnings were consistently ignored. On May 8, 2004, five months into the CAFÉ study, Dan died after trying to decapitate himself with a box-cutter.

http://www.motherjones.com/environment/2015/04/dan-markingson-university-minnesota-clinical-trials-astrazeneca

What has all of this been about?

Critics believe some University of Minnesota researchers have coerced vulnerable patients into participating in studies, and then neglected their welfare during the research. Much of the focus has been on a few researchers in the Department of Psychiatry, which often conducts clinical drug trials sponsored by drug companies. Critics say university officials have ignored years of requests to look into the matter.

http://www.mprnews.org/story/2015/05/26/faq-drug-trials-patient-safety

Issues – Subject Consent

Not Easy in this Case

"Two high-level government advisory bodies have considered whether special research protections should be provided to people with mental health disorders who participate in research… [I]n neither case were regulations implemented..."

DuBouis 2008, p.5

Consent in Mentally Ill Persons

"…[R]especting the self-determination of participants with mental health disorders can be tricky... The capacity to make decisions may wax and wane, they [subjects] want to retain a voice. Their family members may have strong feelings about being included in the informed consent process, yet may lack legal guardianship."

DuBouis 2008, p.5

Consent for Vulnerable Populations

The first major question regarding Dan Markingson's participation in this clinical trial was whether the consent was informed and properly obtained. The US Common Rule directs Institutional Review Boards (IRBs) "to include 'additional safeguards...to protect the rights and welfare' of 'mentally disabled persons.'" There certainly appears to have been none here. After all, Markingson had just been involuntarily committed to psychiatric treatment. A look at the time course related to Dan's participation raises disturbing questions.

SCIENTIFIC AMERICAN™ **A Clinical Trial and Suicide Leave Many Questions: Part 1: Consent?**
By Judy Stone | December 11, 2012 | 5

Consent? Really?

On November 21—just two days after being deemed incapable of consenting to Risperdal (antipsychotic treatment), he was suddenly determined by Jeanne Kenney, his social worker, to be capable of consenting to a clinical trial of antipsychotic medications. The 10 page CAFÉ study "consent form was read to him verbatim." Dan then signed the consent, witnessed by Kenney, who also had responsibility for study recruitment. Curiously, he remained on Risperdal until December 5.

SCIENTIFIC AMERICAN™ **A Clinical Trial and Suicide Leave Many Questions: Part 1: Consent?**

By Judy Stone | December 11, 2012 | 5

Consent is NOT
Just a signature
on a form!!!!

Key questions surround the case. Let us focus on the issue of consent here:

How can a "volunteer" consent to participate when he has been deemed incompetent to make decisions? How well did he understand the risks of the study?

How voluntary was Dan's consent, given that his alternative was commitment to a state institution?

SCIENTIFIC AMERICAN™ **A Clinical Trial and Suicide Leave Many Questions: Part 1: Consent?**
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The social worker, Jeanne Kenney, did the evaluation that determined that he was capable of consenting—but she was certainly not unbiased, being the study coordinator working under Dr. Olson and responsible for study recruitment.

The study was on probation for poor enrollment, so there was also considerable pressure on her to boost enrollment.

SCIENTIFIC AMERICAN™ **A Clinical Trial and Suicide Leave Many Questions: Part 1: Consent?**
By Judy Stone | December 11, 2012 | 5

Consent & Withdrawal

Could Mr. Markingson have actually withdrawn from the study?

Capacity to withdraw is just as important as capacity to enroll.

Further, he was never re-consented after evidence of dangerous side-effects of the medicine were revealed.

SCIENTIFIC AMERICAN™ **A Clinical Trial and Suicide Leave Many Questions: Part 1: Consent?**

By Judy Stone | December 11, 2012 | 5

Recall the history of consent…

http://www.ushmm.org/wlc/en/article.php?ModuleId=10007035

The Nuremberg Code

(1) The voluntary consent of the human subject is absolutely essential.

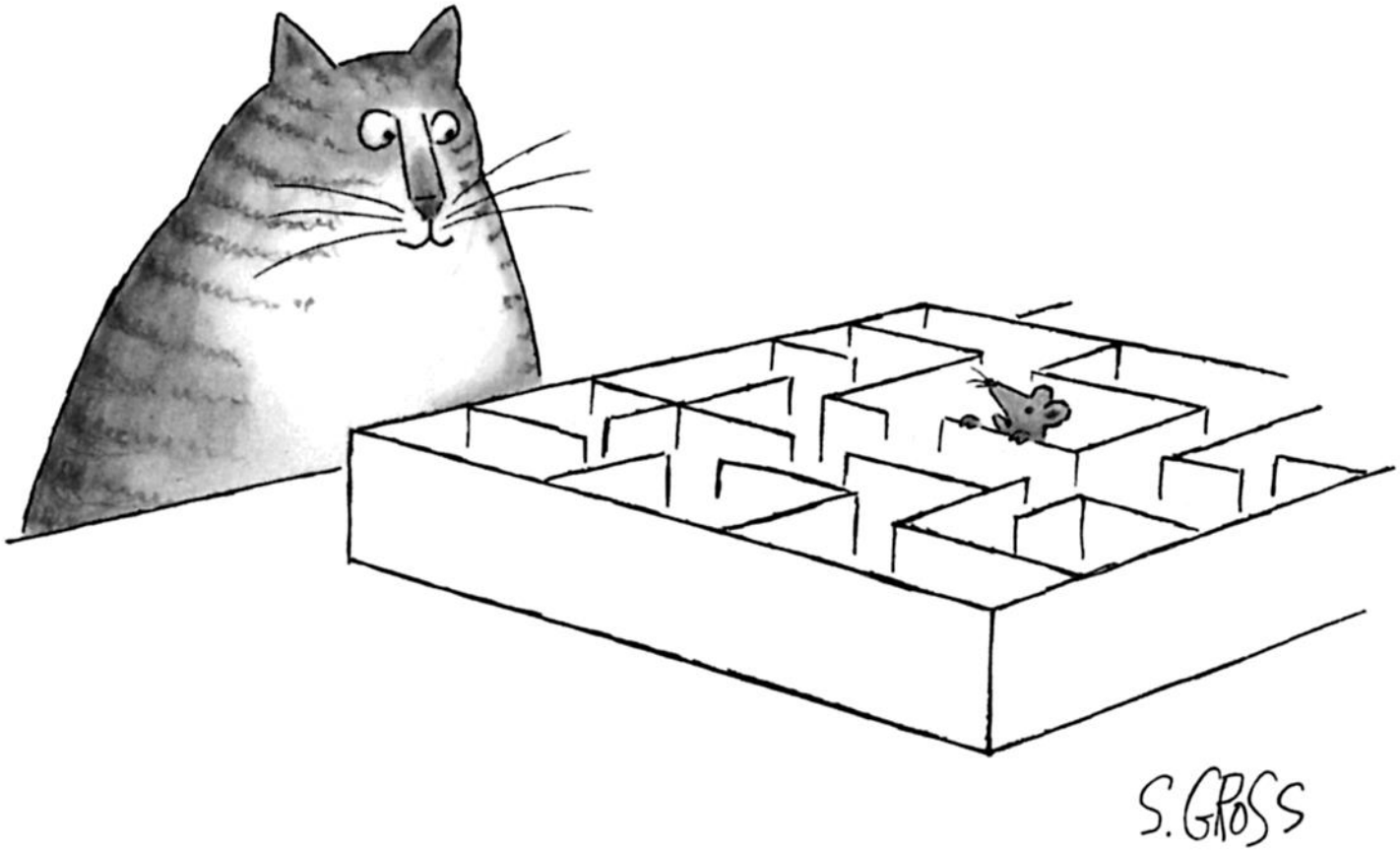
(2) The experiment should be such as to yield fruitful results for the good of society…


DAVISVILLE
Dr. Swett's
ROOT BEER

Tuskegee Syphilis Experiment

"… the study fell short from the very beginning insofar as recruitment was deceptive and manipulative..."

DuBouis 2008, p.16



"Well, you don't look like an experimental psychologist to me."

Issues – Subject Recruitment

When, exactly, is it appropriate to cross-line from treatment to research?

Which hat are you wearing?

Issues – Phase IV study

What constitutes an ethical research design?

Post-approval marketing studies?

Test article. Sure. Compared to what?

Oh, I forgot…

there’s some icky history, too

The UMN Psychiatry Department is no stranger to ethics scandals.

In 1993, the head of child psychiatry, Dr. Barry Garfinkel, was convicted of criminal charges for falsifying data in a clinical trial.

Also in 1993, Professor James Halikas was accused of coercing Hmong refugees into participating in a clinical trial of gamma hydroxybutyrate (GHB) and reportedly refusing to give them methadone instead. They were considered a vulnerable population due to their addiction problems and language barriers. Halikas admitted to not having gotten consent from these individuals. Yet he—a member of the university's IRB—egregiously violated basic research ethics.

SCIENTIFIC AMERICAN™ **A Clinical Trial and Suicide Leave Many Questions: Part 1: Consent?**

By Judy Stone | December 11, 2012 | 5

The UMN Psychiatry Department is no stranger to ethics scandals.

And there was David Adson, chair of the IRB overseeing the CAFE trial and responsible for investigating Dan's death. Despite also receiving money from AstraZeneca and being in the same department as Olson and Schulz (his department chair), Adson claimed that he had no conflict of interest (COI). His actions in regards to Lilly's Zyprexa and COI have also come under criticism.

SCIENTIFIC AMERICAN™ **A Clinical Trial and Suicide Leave Many Questions: Part 1: Consent?**

By Judy Stone | December 11, 2012 | 5

Organizational Culture

It matters….

Institutional Response

Initial Reviews/Investigation

- MN Medical Board
- FDA
- UMN IRB

Finally, External Reviews

- Hired consultants from AAHRPP
- Office of Legislative Auditor
- UMN IRB’s own investigation

SCIENTIFIC AMERICAN™

UMN: How many deaths have occurred during your clinical trials?

By Judy Stone | May 8, 2014 | 1

Eric Kaler, President of the UMN, responded by making a mockery of the "investigation," putting it out on bid on the same web site the U uses to solicit cleaning bids "or a request to supply light bulbs" from vendors. Further, he is insisting that any recommendations be only "forward looking," and ignore past travesties. Kaler's RFP notes that the U will have the "sole discretion" in selecting the Respondent, who will be the one "whose Proposal is the most advantageous to the University." So Kaler will pick the person to investigate human subjects research, specifically excluding the administration and its handling of problems, and that contractor will report back directly to Kaler. What could possibly go wrong?

Lemmens et al. have responded to Kaler, "The RFP is in our opinion so flawed as to preclude any chance the resulting report will be seen as legitimate, except perhaps by those vindicated by it."

An External Review of the Protection of Human Research Participants at the University of Minnesota with Special Attention to Research with Adults Who May Lack Decision-Making Capacity

Final Report

February 23, 2015

In conclusion, in spite of considerable evidence of programmatic strength in many of the domains examined, the University's efforts with regard to human subjects protections do not consistently reflect "best practices" and are not, at this point, "beyond reproach." Many weaknesses in policy and practice were evident and require attention. Indeed, in the context of persistent internal and external criticism of University research involving populations of patients in which the likelihood of impaired consent capacity is high, the external review team believes the University has not taken an appropriately aggressive and informed approach to protecting subjects and regaining lost trust. A major objective of this report is therefore to identify areas of weakness and to suggest remedial steps that could strengthen the University's human subjects research protections and rebuild community and institutional trust.

University officials have, however, repeatedly insisted that the Markingson case has been fully reviewed, with University personnel cleared of any wrongdoing, and that further examination is unnecessary. For example, in a 2011 letter, the then Board of Regents chair said that the University's General Counsel had provided the Board with the "extensive reviews" previously conducted of the Markingson case, and "we do not believe further University resources should be expended re-reviewing a matter such as this…."[4] In a 2013 letter, University President Eric Kaler repeated that position; he said, "I do not believe additional review [of the Markingson case] is warranted."[5]

OFFICE OF THE LEGISLATIVE AUDITOR
STATE OF MINNESOTA • James Nobles, Legislative Auditor

2008

Finding 7. The Minnesota Board of Medical Practice's review of Dr. Stephen Olson was compromised because the expert consultant the Board hired to analyze the case had numerous conflicts of interests.[68]

The FDA report found no evidence of misconduct or significant violation of the research protocol or regulations.[80] But the review never discussed the potential coerciveness of obtaining consent from an individual under a stay of commitment. The FDA said: "There was nothing different about this subject [Markingson] than others enrolled to indicate he couldn't provide voluntary, informed consent per review of his medical records or the approved study protocol." But there was something different—Markingson, unlike others, was under a stay of commitment. That order required him to "cooperate with the treatment plan at [FUMC] until medically discharged and follow all the aftercare recommendations of the treatment team." The FDA did not explicitly discuss how the stay of commitment might have influenced Markingson's ability to freely consent. Markingson consented, but the FDA report did not provide convincing evidence that he was given sufficient information about his options.

OFFICE OF THE LEGISLATIVE AUDITOR
STATE OF MINNESOTA • James Nobles, Legislative Auditor

We are especially troubled by the response of University leaders to the case; they have made misleading statements about previous reviews and been consistently unwilling to discuss or even acknowledge that serious ethical issues and conflicts are involved.

CONCLUSION

We do not think it is possible to know whether Dan Markingson's suicide was connected to his participation in the University clinical drug study; the suicide of a person with serious mental illness may involve many contributing factors. However, the Markingson case raises serious ethical issues and numerous conflicts of interest, which University leaders have been consistently unwilling to acknowledge. They have repeatedly claimed that clinical research at the University meets the highest ethical standards and dismissed the need for further consideration of the Markingson case by making misleading statements about past reviews. This insular and inaccurate response has seriously harmed the University of Minnesota's credibility and reputation.

What did the investigations find?

In February, the external panel hired by the university said the university had weak oversight of research. The reviewers noted that personnel didn't feel the U's leaders were committed to protecting test subjects, and they expressed special concern over a "culture of fear" in the psychiatry department they said kept people from raising safety concerns. It suggested dozens of reforms.

In March, Minnesota Legislative Auditor Jim Nobles criticized the U for its handling of the Markingson case.

Nobles said it was impossible to link Markingson's death to the drug study, but said he found "serious ethical issues and numerous conflicts of interest." He said the conditions under which researchers recruited Markingson were potentially coercive, and that researchers ignored repeated warnings about Markingson's deteriorating condition.

http://www.mprnews.org/story/2015/05/26/faq-drug-trials-patient-safety

The report noted multiple potential conflicts of interest among the researchers and subsequent investigators. Nobles said the FDA investigation had been "limited," and that the U's own investigation had been "superficial." He said university leaders had repeatedly made misleading statements about the thoroughness of past reviews, and that they'd damaged the university's reputation by rejecting calls for further investigation.

Since those reports, more information about university researchers has surfaced.

This month, an internal review found some Fairview Health Services personnel held a "profound" distrust of some U of M psychiatric researchers working there, and it blamed leadership at Fairview and the U for ignoring it.

http://www.mprnews.org/story/2015/05/26/faq-drug-trials-patient-safety

"Had the U not behaved the way it behaved, we might not be talking about this at all," said Misha Angrist, a Duke University professor who has taught the case to students of public policy. "You can't ignore the institutional response to what happened, and a large part of what makes this case so outrageous was the U's stonewalling."

http://www.mprnews.org/story/2015/04/23/university-of-minnesota-markingson-case

External Forces &

Social Movements &

Other Conflicts?

Scientology vs. Psychiatry: A Case Study

FORD VOX | JUL 2, 2012 | HEALTH

Just because one doctor failed to follow the rules doesn't invalidate the entire field of psychiatry.

SCIENTOLOGY Twin Cities

Twin Cities 27°/37° Partly Cloudy 25°

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THE CHURCH OF SCIENTOLOGY OF TWIN CITIES

+ VIEW SLIDESHOW

Welcome to the Church of Scientology of Twin Cities.

Since 1965, we have served a growing congregation in Minneapolis and St. Paul. It is with great pride today we extend our help to communities across Minnesota from our new home in downtown St. Paul.

Our Church realizes Scientology Founder L. Ron Hubbard's vision that all Churches of Scientology become what he termed *Ideal Organizations* (Orgs).

NEWS FROM OUR TWIN CITIES CHURCH
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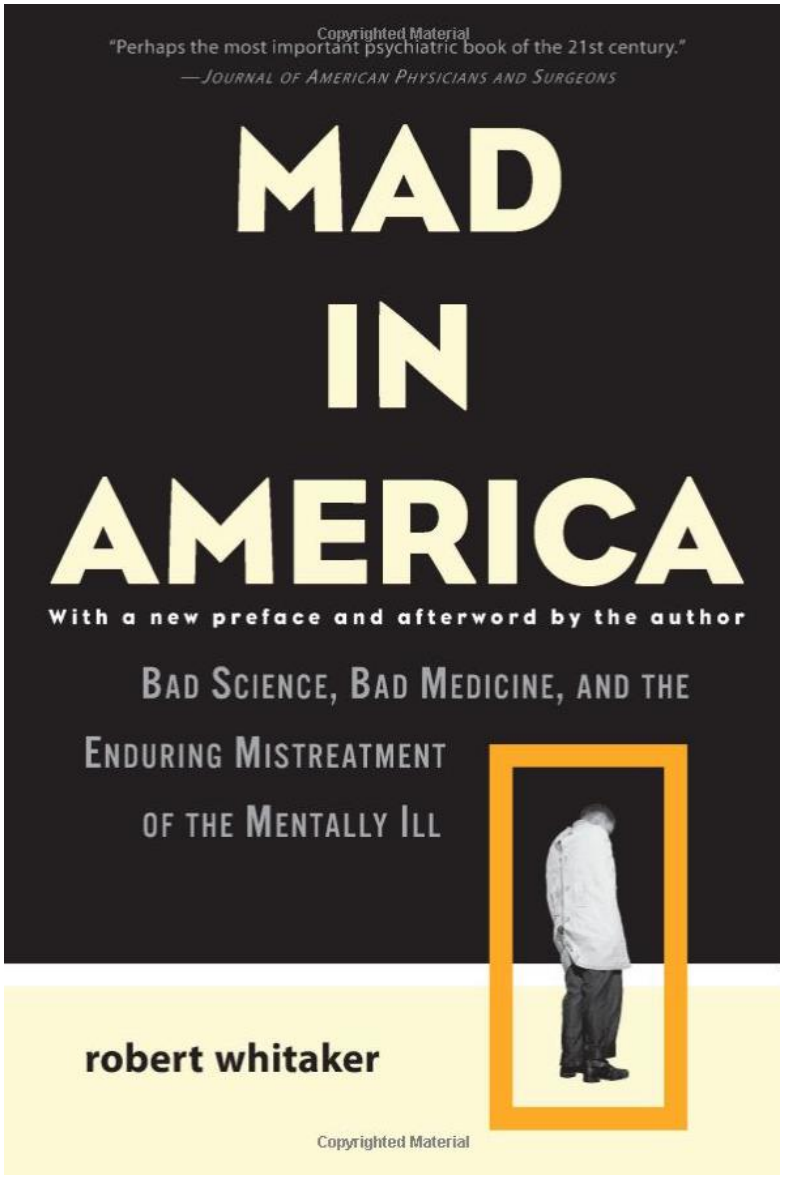
- **What is the Concept of God in Scientology?**
- **What are the Fundamental Practices of the Religion?**
- **What is Auditing?**
- **Who was L. Ron Hubbard?**

see all FAQs ▶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MAD IN AMERICA
With a new preface and afterword by the author
Bad Science, Bad Medicine, and the Enduring Mistreatment of the Mentally Ill
robert whitaker
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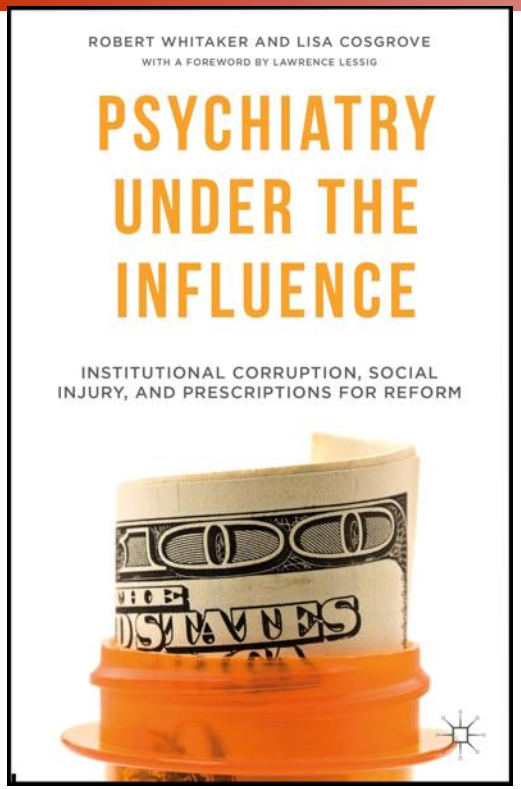
PSYCHOLOGY / SCIENCE

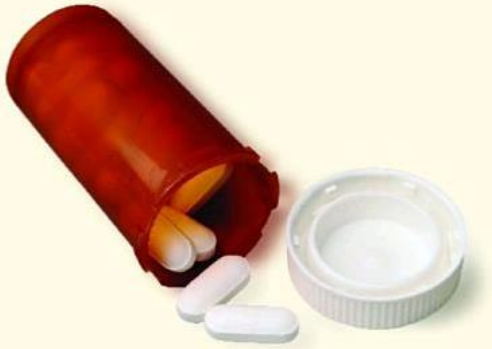
Schizophrenics in the United States currently fare worse than patients in the world's poorest countries. In *Mad in America*, medical journalist Robert Whitaker argues that modern treatments for the severely mentally ill are just old medicine in new bottles, and that we as a society are deeply deluded about their efficacy. The widespread use of lobotomies in the 1920s and 1930s gave way in the 1950s to electroshock and a wave of new drugs. In what is perhaps Whitaker's most damning revelation, *Mad in America* examines how drug companies in the 1980s and 1990s skewed their studies to prove that new antipsychotic drugs were more effective than the old, while keeping patients in the dark about dangerous side effects.

A haunting, deeply compassionate book—now revised to reflect the latest scientific research—*Mad in America* raises important questions about our obligations to the mad, the meaning of "insanity," and what we value most about the human mind.



Psychiatry Under the Influence investigates how the influence of pharmaceutical money and guild interests has corrupted the behavior of the American Psychiatric Association and academic psychiatry during the past 35 years. The book documents how the psychiatric establishment regularly misled the American public about what was known about the biology of mental disorders, the validity of psychiatric diagnoses, and the safety and efficacy of its drugs. It also looks at how these two corrupting influences encouraged the expansion of diagnostic boundaries and the creation of biased clinical practice guidelines. This corruption has led to significant social injury, and in particular, a societal lack of informed consent regarding the use of psychiatric drugs, and the pathologizing of normal behaviors in children and adults. The authors argues that reforming psychiatry will require the neutralization of these two corrupting influences—pharmaceutical money and guild interests—and the establishment of multidisciplinary authority over the field of mental health.

The Truth About the Drug Companies



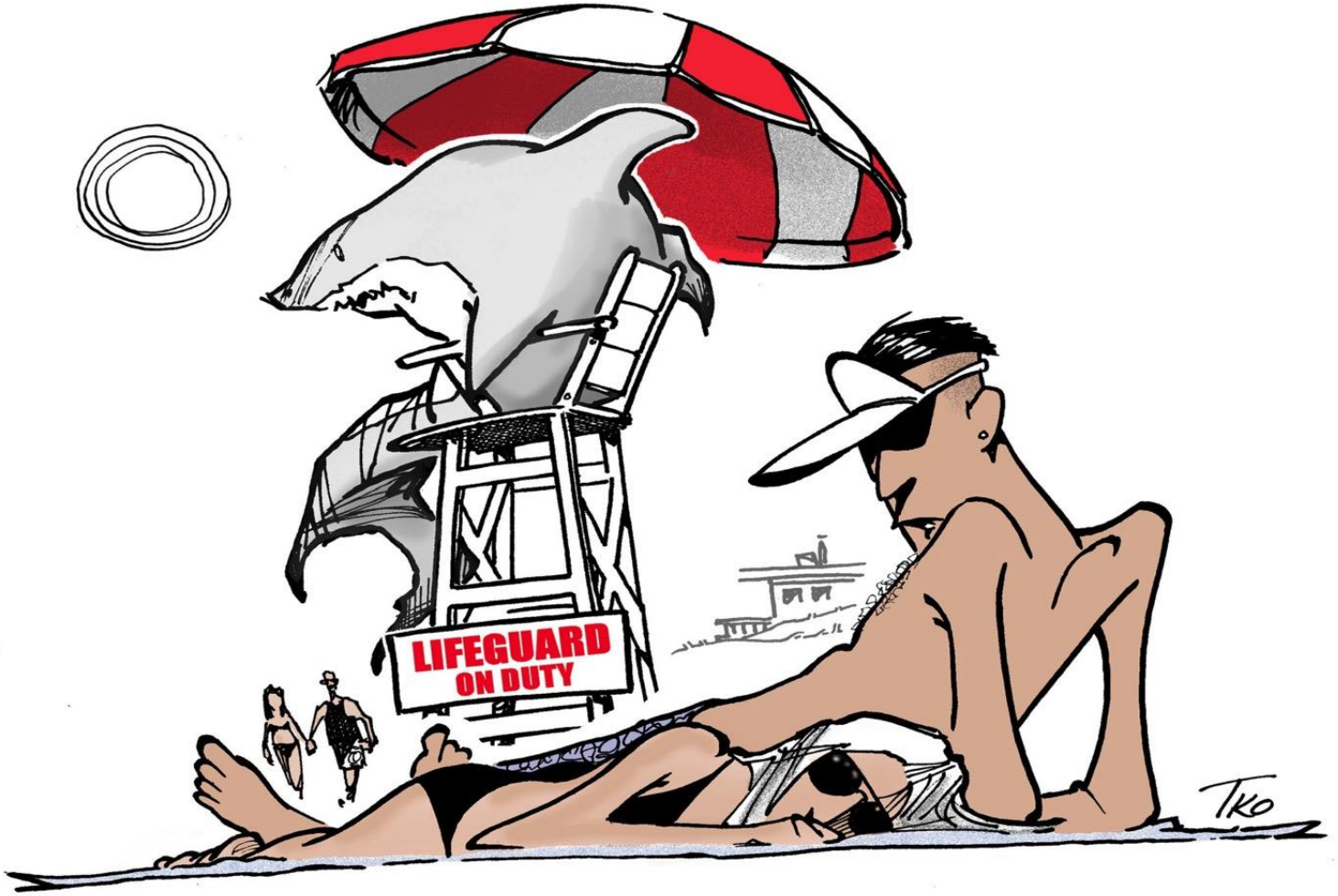
HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT

MARCIA ANGELL, M.D.

Former editor in chief of *The New England Journal of Medicine*
Winner of the Polk Award

CONFLICT OF INTEREST
IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES



"So, I'm the only one who sees a conflict of interest here?"

Conflicts of interest arise when one's institutional task (e.g., patient care, science) is altered/biased due to competing interests.

The *appearance* of a COI is often just as important as suspicion undermines credibility and diminishes our reputation.

nature International weekly journal of science

NATURE | NEWS

Industry ties remain rife on panels for psychiatry manual

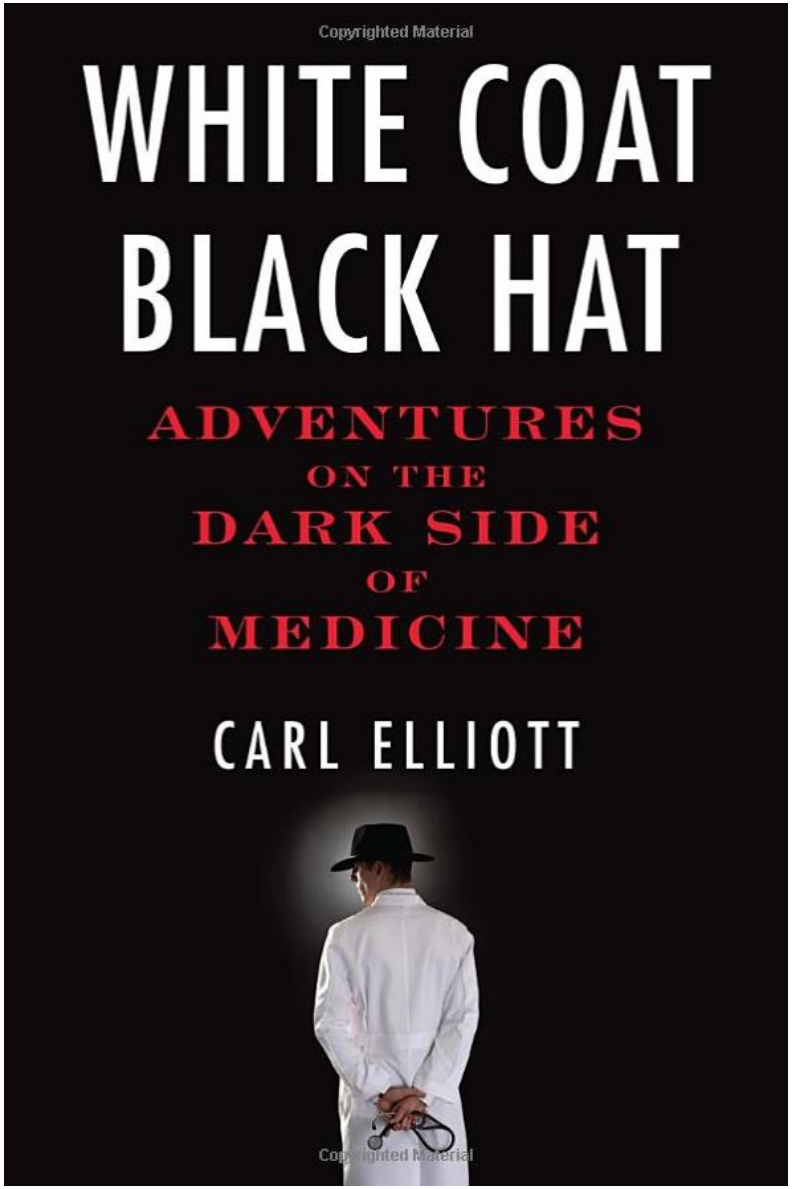
Review identifies potential conflicts of interest among those drawing up *DSM-5*.

Heidi Ledford

13 March 2012 | Updated: 16 March 2012

Potential conflicts of interest among the physicians charged with revising a key psychiatric manual have not declined despite changes to the rules on disclosing ties to industry, says a study published today[1].

The *Diagnostic and Statistical Manual of Mental Disorders* (*DSM*) is used to diagnose patients, shape research projects and guide health-insurance claims. The fifth edition of the manual, *DSM-5*, currently being prepared by the American Psychiatric Association (APA) in Arlington, Virginia, is scheduled for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PHARMAPHOBIA

HOW THE CONFLICT OF INTEREST MYTH UNDERMINES AMERICAN MEDICAL INNOVATION

THOMAS P. STOSSEL

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COI review is viewed by some like “new scientific McCarthyism” that assumes that researchers with industry ties are “tainted and untrustworthy”

Are conflicts only a result of industry funding?

Are NIH/CDC/NSF supported investigators conflicted?

What about RWJF, AHA, ACS?

Disclosure is the solution?

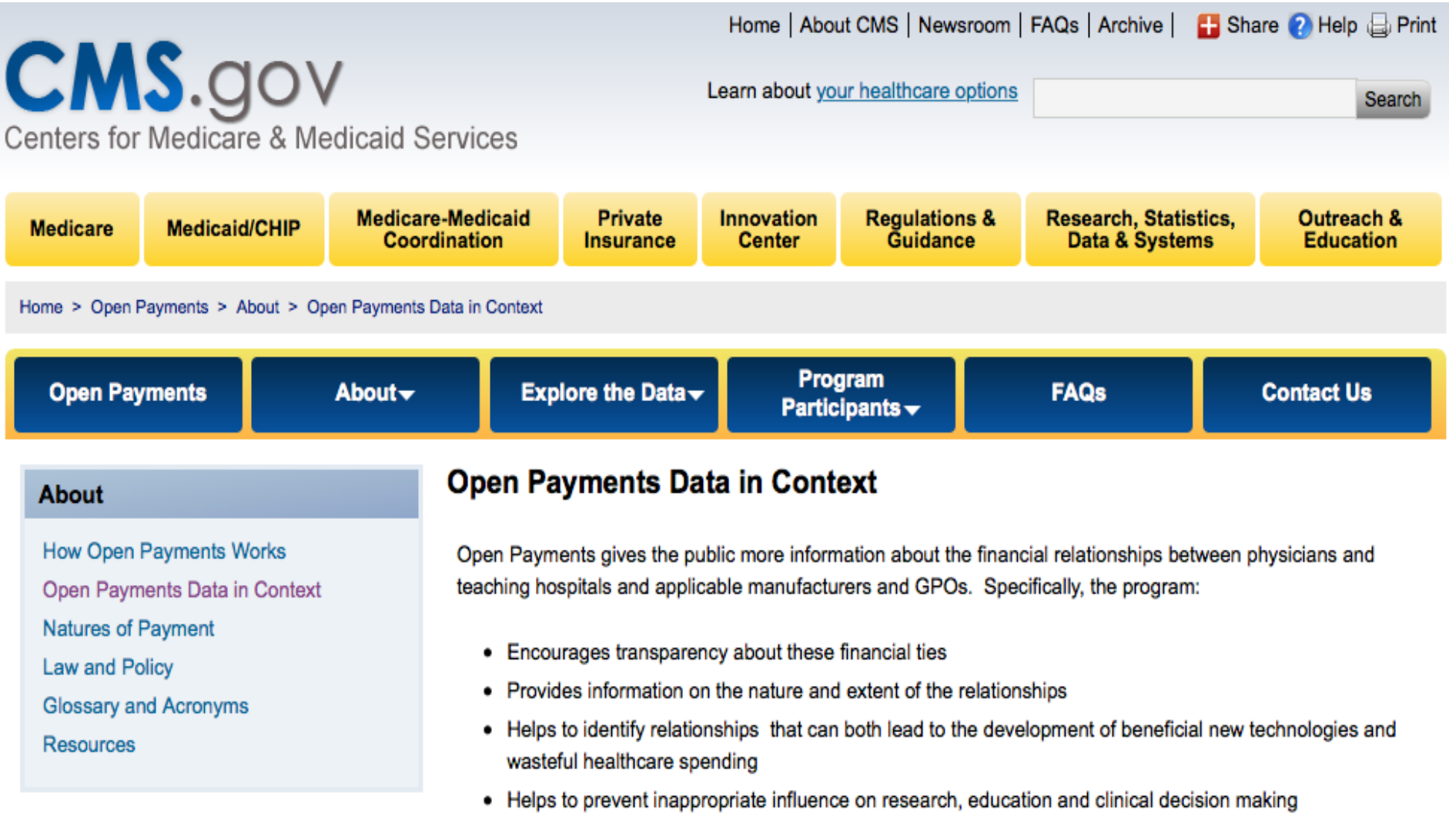
“Sunshine is said to be the best of disinfectants.”

Justice Louis Brandeis (1914)

The central goal of conflict of interest policies in medicine is to protect the integrity of professional judgment and to preserve public trust rather than to try to remediate bias or mistrust after it occurs.

Conflict of interest policies are attempts to ensure that professional decisions are made on the basis of primary interests and not secondary interests.

IOM 2009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Open Payments Data in Context
Open Payments gives the public more information about the financial relationships between physicians and teaching hospitals and applicable manufacturers and GPOs. Specifically, the program:
Encourages transparency about these financial ties
Provides information on the nature and extent of the relationships
Helps to identify relationships that can both lead to the development of beneficial new technologies and wasteful healthcare spending
Helps to prevent inappropriate influence on research, education and clinical decision making

The disclosure of individual and institutional financial relationships is a critical but limited first step in the process of identifying and responding to conflicts of interest.

IOM 2009

NEJM Standards

Financial Associations/Conflict of Interest

The *New England Journal of Medicine* is committed to publishing the highest quality research and reliable, authoritative review articles that are free from commercial influence.

For all research articles we publish, NEJM lists study sponsorship and all relevant financial information as disclosed by the authors. The disclosure forms of all authors are available online with the full text of each article. Additional information about the contributions of authors may also appear in the Methods section of research articles.

A separate policy applies to Review Articles and editorials, which comment on published articles but do not present new research. NEJM expects that authors of such articles not have any significant financial interest in any biomedical company relevant to the topics and products discussed in the article. When a prospective author does have financial ties to disclose, the editors decide whether they are relevant to the topic and whether they are *de minimus*.

None of the NEJM editors has any financial relationship with any biomedical company.

For more information:

Integrity Safeguards

Uniform Format for Disclosure of Competing Interests in ICMJE Journals (November 5, 2009)

Financial Associations of Authors (our current conflict of interest policy; June 13, 2002)

Full Disclosure and the Funding of Biomedical Research (April 24, 2008)

Clinical Trial Registration

In 2005, the **International Committee of Medical Journal Editors** (ICMJE) initiated a policy requiring investigators to deposit information about trial design into an accepted clinical trials registry before the onset of patient enrollment. This policy aims to ensure that information about the existence and design of clinically directive trials is publicly available.

Further discussion can be found in past editorials written on this topic:

Clinical Trial Registration — Looking Back and Moving Ahead (June 28, 2007)

Is This Clinical Trial Fully Registered? (June 9, 2005)

Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors (September 16, 2004)

How Should Doctors Disclose Conflicts of Interest to Patients?

A Focus Group Investigation

BY J. MICHAEL OAKES, PHD, HILARY K. WHITHAM, MPH, ALICEN BURNS SPAULDING, PHD, LYNN A. ZENTNER, JD, AND SETH R. BECCARD, JD

The focus group participants did not dwell on conflict of interest disclosure requirements. But during the discussions, one participant said she was certain that a federal law required physicians to disclose any and all conflicts of interest (an incorrect belief that was corrected after the group ended). In terms of clinic requirements, the participant went on to state, *"I am absolutely sure that [my doctor's] practice already requires disclosure ... the doctor would not want his professional judgment tainted ... [the disclosure] is already out there."*

The issue of trust was critical to all participants. One said, "*If I trust the doctor, the conflict is not a big deal.*" There was near unanimous agreement that when clinicians did not voluntarily disclose a conflict of interest when one existed, they put their relationships with patients in jeopardy. When discussing the issue of not disclosing a potential conflict of interest, one participant stated that even if the doctor was his long-time physician, he would wonder, "*What else didn't he tell me?*"

The following are the two specific recommendations that emerged from our research on *how* disclosures should be made: 1) Give patients an up-to-date, easy-to-read paper document about the conflict of interest; 2) When discussing specific treatment plans for which a conflict is relevant (eg, a drug or device), take the time to discuss the conflict with the patient and offer an assessment of alternatives.

But…

Do Policies Work?

Medical Care:
April 2015 - Volume 53 - Issue 4 - p 338–345
doi: 10.1097/MLR.0000000000000329
Original Articles

Antipsychotic Prescribing: Do Conflict of Interest Policies Make a Difference?

Anderson, Timothy S. MD, MA*; Huskamp, Haiden A. PhD†; Epstein, Andrew J. PhD‡; Barry, Colleen L. PhD, MPP§; Men, Aiju MS‖; Berndt, Ernst R. PhD¶; Horvitz-Lennon, Marcela MD, MPH#; Normand, Sharon-Lise PhD†,**; Donohue, Julie M. PhD‖

SDC

Conclusions: Psychiatrists exposed to strict conflict of interest policies prescribed heavily promoted antipsychotics at rates similar to academic psychiatrists and nonacademic psychiatrists exposed to less strict or no policies.

The American Journal of
Psychiatry

Previous Article

Volume 162 Issue 10, October 2005, pp. 1957-1960

Next Article

Article

Industry Sponsorship and Financial Conflict of Interest in the Reporting of Clinical Trials in Psychiatry

Roy H. Perlis, M.D., Clifford S. Perlis, M.D., M.Be., Yelena Wu, B.A., Cindy Hwang, B.A., Megan Joseph, B.A., Andrew A. Nierenberg, M.D.

http://dx.doi.org/10.1176/appi.ajp.162.10.1957

pharmaceutical industry-funded studies. **CONCLUSIONS:** Author conflict of interest appears to be prevalent among psychiatric clinical trials and to be associated with a greater likelihood of reporting a drug to be superior to placebo.

VIEWPOINT

Conflict of Interest Policies for Academic Health System Leaders Who Work With Outside Corporations

Etta D. Pisano, MD
College of Medicine, Medical University of South Carolina, Charleston.

Robert N. Golden, MD
School of Medicine and Public Health, University of Wisconsin-Madison.

Laura Schweitzer, PhD
Union Graduate College, Schenectady, New York.

New "Sunshine Act" requirements for disclosure by pharmaceutical and medical device companies of payments to faculty have led to increased conversation about conflict of interest (COI).[1] Conflict of interest is defined as "circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest."[2] Conflict of interest is particularly relevant for those in the upper echelons of academic health system leadership—presidents, vice presidents, provosts, deans, chief executive officers, and the senior administrators who report to them.

Unlike most faculty and staff, senior institutional officials are involved in financial and business decisions, indirect business inappropriately to the outside company on whose board he or she sits? Will the leader inappropriately use information about the institution he or she leads to influence decisions by the outside corporation? It is difficult to separate these types of activities and decisions. In addition, there are administrative costs associated with the management of this level of conflict, and such relationships might have a "chilling effect" on other companies that could do business with the academic health system. Beyond service on fiduciary boards, undertaking any paid role (consulting, participation on advisory boards, etc) with an outside entity with interests that overlap those of the leader's institution raises the same issues.

In summary, fiduciary board memberships and compensated roles for academic health system senior leaders with outside entities that have overlapping interests with the system missions should not be permitted, except when there is a clear and compelling institutional interest for the system or when the external role falls outside the scope of the leadership position. All such roles should fall under the purview of a committee consisting of at least superiors, individuals who do not report to the leader, or individuals appointed from outside the organization; this committee should preapprove and manage potential conflicts. In addition, additional compensation for such roles should be provided through a contract with the entity, with payment to the academic health system for the leader's time and effort.

But…

We regulate what we measure

Change is coming.

Perhaps.

Notice of Proposed Rule Making (NPRM)

Conclusions

- Research with very vulnerable people is ethically very difficult, but we must do better
- IRBs must be more vigorous when reviewing such studies
- Conflicts of interest abound: at least disclose
- Institutions must respond fully and thoughtfully; dismissal is dangerous
- Disclosure is not simple
- The protection pendulum can swing too far back

IRBs or Investigators?

"In truth, investigators are much better positioned during the course of their study to protect the interests of individual research subjects than are IRBs. Paradoxically, the person most likely to do something to harm a subject, the investigator, is also the person most capable of preventing such harm… the only true protection afforded research subjects comes from a well-trained, well-meaning investigator."

Greg Koski (former director of OHRP)

"AS THEY SAY, 'DO THE RIGHT THING.'"