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EMMA ROTHSCHILD: THE DECLINE OF THE AUTO-INDUSTRIAL SOCIETY



Zadie Smith: Speaking in Tongues

Darryl Pinckney: What He Really Said

TIM FLANNERY: 'THE SUPERORGANISM'



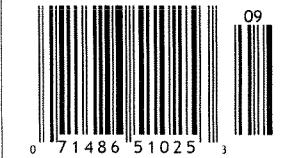
Norman Mailer: The 'Deer Park' Letters

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ALBERT ROSENBERG



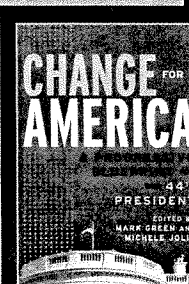
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ALLAN M. BRANDT

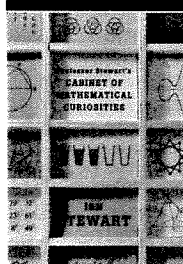
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'Drug Companies & Doctors': An Exchange

To the Editors:

In her article ["Drug Companies & Doctors: A Story of Corruption," *NYR*, January 15], Dr. Marcia Angell incorrectly implies that Dr. Alan Schatzberg and Stanford University did not address a conflict of interest issue until US Senator Charles Grassley made inquiries into the matter. In fact, extensive documentation sent to Senator Grassley and available online to the public since June 2008 (ucomm.stanford.edu/news/conflict_of_interest_schatzerg_grassley.html) shows that both Stanford University and Dr. Schatzberg did comply with all rules regarding disclosure and management of Dr. Schatzberg's conflict. The National Institute of Mental Health (NIMH) was informed about the potential conflict before any federal funds were expended on Dr. Schatzberg's grant. The requirements established by the National Institutes of Health were met, and appropriate notice was given to the NIMH. Stanford's reviews and management of the potential conflict were extensive and well documented. The integrity and safety of the research were assured by Data Safety Management Boards at both Stanford and the NIMH.

Dr. Angell also took misleading liberties with a letter I wrote to Dr. Jane Steinberg of the NIMH by quoting selective phrases out of context. Her review says that "the university's [general] counsel announced that it was temporarily replacing Schatzberg as principal investigator 'to eliminate any misunderstanding.'" Dr. Angell's selective quote leaves a negative impression not justified by the fuller explanation in my letter. Dr. Schatzberg had already requested that the grant for which he was principal investigator be restructured to eliminate any appearance of conflict. I noted that Stanford University, with the concurrence of Dr. Schatzberg, would temporarily appoint another faculty member as principal investigator while working with the NIMH to restructure the grant, to eliminate any misunderstanding of Dr. Schatzberg's role in mifepristone research for those not familiar with the grant and federal oversight process. This step was taken to put to rest any confusion about the integrity of the research and to allow important mental health research to continue.

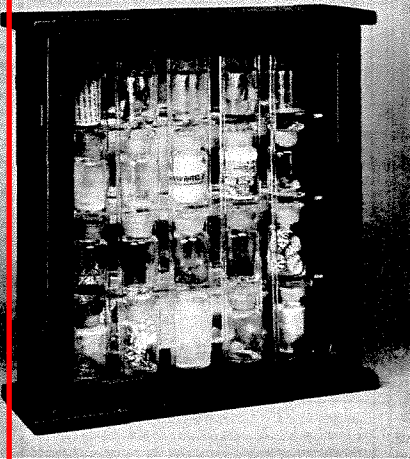
It may be that Dr. Angell does not agree with the federal requirements for management of conflicts of interest; however, she should not allege misconduct or corruption where there is none.

Debra L. Zumwalt

Vice President and General Counsel
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cholesterolemia, migraine—exist on a spectrum of normal-abnormal and are defined as diseases when they cause significant distress or are associated with bad outcomes in the long term. The distinction between a normal cell and a cancerous or potentially cancerous cell is not always clear. Similarly, there are people who are "shy" and people who are unable to eat a meal with friends, make a presentation required in the course of their work, or stand up in church to announce that money is being collected to buy food for the hungry.

As Angell notes, the provision of money and other valuables by pharmaceutical companies to medical schools, medical societies, and individual physicians has been



Joseph Cornell: Untitled (Grand Hotel Pharmacy), circa 1947

widely accepted for many years. Some of the effects, such as the development of effective new treatments, have been positive. It is good that society and the profession are finally paying attention to the consequences that are negative. But standards—of diagnosis, research, and behavior—change over time. It is unfair to suggest physicians are "corrupt" for activities that were virtually universal when they occurred. The diagnostic manual of psychiatric disorders to which Angell refers was produced fifteen years ago.

The American Psychiatric Association is currently engaged in an inclusive, wide-ranging, transparent, and science-based process of diagnostic classification: the fifth edition of that manual. That process began in 1999, will involve over 160 experts from all over the world, all of whom have agreed to disclose and limit their income from the pharmaceutical industry, and is slated to end with publication in 2012. The public is invited to read reports on that process and to send comments and suggestions via a dedicated Web site, www.dsm5.org. We are aware of no parallel process in any other branch of medicine.

There has been an explosive increase in the development and marketing of new medications over the last ten or fifteen years, and physicians are and have always been eager to adopt new interventions that hold promise for relieving the suffering of our patients.

Our concern is that the majority of people with painful, disabling, and too often fatal psychiatric conditions are not diagnosed and not treated. According to the World Health Organization, clinical depression is the primary cause of disability worldwide in terms of years lost due to disability. Suicide was the third leading cause of death in the United States in 2004 for children, adolescents, and young adults, ages 10–24. Much of that suffering, disability, and death can be avoided with expert diagnosis and treatment. Psychiatric diseases have been recognized and categorized since the time of

the ancient Greeks. Sadly, prejudice against psychiatric diseases, those who suffer from them, and those who treat them, has lasted centuries as well. Much of what stands between those who are ill and the treatment that could help them is stigma. We hope that open-minded examination and appropriate limitation of the sometimes cloudy relationships between physicians and the pharmaceutical industry will clear the air without contributing to that stigma.

Nada L. Stotland, M.D., M.P.H.

President
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Chicago, Illinois

Marcia Angell replies:

The above letters, as well as the letter from Dr. Schatzberg's legal representative that was the subject of the editors' "Note to Readers" in the February 12 issue of *The New York Review*, mischaracterize my position. My article was about the conflicts of interest that permeate medicine, not failures to disclose them. And nowhere did I state or imply that they were unlawful, as Schatzberg's lawyer charges. My point was that pervasive conflicts of interest corrupt the medical profession, not in a criminal sense, but in the sense of undermining the impartiality that is essential both to medical research and clinical practice. That use of the word "corruption" is supported by every dictionary I have checked (e.g., "a change for the worse of an institution, custom, etc.; a departure from a state of original purity" in the *New Shorter Oxford English Dictionary* of 1993). It is used in that way by many writers, including the author of one of the books I reviewed. A recent example occurs in "Money and the Changing Culture of Medicine," an article in the January 8 issue of *The New England Journal of Medicine*, which states: "... evidence indicates that drug promotion can corrupt the science, teaching, and practice of medicine."

My short paragraph concerning Dr. Schatzberg focused entirely on the fact that he was principal investigator in a research project funded by a National Institute of Mental Health grant that included testing a drug (mifepristone) to treat psychotic depression that was developed for this use by a company (Corcept Therapeutics) he cofounded and partly owned. He also served as a member of the company's board of directors and chairman of its scientific advisory board. All of this surely constitutes a conflict of interest, and it was longstanding. He initiated a patent application on mifepristone to treat psychotic depression in 1997 (Stanford, where he is on the faculty, owns the patent); he cofounded Corcept Therapeutics in 1998, and, in 1999, extended the National Institute of Mental Health grant for the study of psychotic depression to include testing mifepristone. Stanford also had equity interest in the company. Later the university divested itself of the stock, but still receives royalties for licensing the patent to Corcept Therapeutics. Contrary to the letter from Debra L. Zumwalt, I did not imply that Stanford and Dr. Schatzberg did not "comply with all rules regarding disclosure and management of Dr. Schatzberg's conflict." However, I believe those rules are entirely too lax, and in my article, I was just as critical of the institutions that make the rules as of individuals who follow them.

Stanford believes it adequately managed Dr. Schatzberg's conflict of interest, but I disagree. As an example of its "management" of the conflict of interest, Stanford said in a statement released on June 25, 2008, that although Dr. Schatzberg was principal investigator on the National Institute of Mental Health grant, he "has not had

responsibility for any aspect of the conduct of the grant's research related to mifepristone." Yet he remained principal investigator until July 31, 2008, and was coauthor of published papers on mifepristone in 2001, 2002, and 2006, all favorable to the drug.

Dr. Stotland is incorrect in stating that very few medications of any kind have been tested in children. Many have been tested and found not to warrant FDA approval; others have been tested in poorly designed trials for marketing purposes, not to gain FDA approval. Although it is illegal to promote drugs for use in children if the FDA has not approved them for that use, the law is frequently circumvented by disguising marketing as education or research. Eli Lilly recently agreed to pay \$1.4 billion to settle civil and criminal charges of marketing the anti-psychotic drug Zyprexa for uses not approved by the FDA (known as "off-label" uses). Zyprexa, which has serious side effects, is one of the drugs frequently used off-label to treat children diagnosed with bipolar disorder. I don't deny the serious effects of psychiatric conditions, but it is still necessary to show in adequate clinical trials that the drugs used to treat them do more good than harm.

Dr. Stotland says that many medical conditions exist on a spectrum from normal to abnormal, but those she mentions present different problems in diagnosis. Unlike migraines or shyness, hypertension or high cholesterol can be defined by an objective measurement—a blood pressure or cholesterol level. One can dispute the threshold chosen as abnormal, but the measurement is easily verifiable. The fact that psychiatric conditions are not objectively verifiable underscores the necessity for both diagnosis and treatment to be as impartial as possible. That is why conflicts of interest are more serious in this field than in most others, and why it is so important that the authors of the *Diagnostic and Statistical Manual of Mental Disorders*, which is now the standard reference for defining and diagnosing psychiatric conditions, be free of them. Yet, as was the case with the authors of the current edition of the manual (DSM-IV), most members of the task force now working on DSM-V have financial ties to industry. Dr. Stotland seems to think that it is enough to disclose those ties and to limit the amount of money members may receive, but I am far less sanguine.

Most conflicts of interest in medicine can and should be eliminated, not "managed." One of Dr. Stotland's predecessors as president of the American Psychiatric Association, Dr. Steven S. Sharfstein, warned his colleagues in a column published in *Psychiatric News* on August 19, 2005: "Drug company representatives bearing gifts are frequent visitors to psychiatrists' offices and consulting rooms. We should have the wisdom and distance to call these gifts what they are—kickbacks and bribes." While industry sponsorship of research may be acceptable, it should be for work of scientific, not just commercial, importance. Academic researchers should have no other financial ties to companies whose products they are evaluating and should bear full responsibility for the way the research is conducted and reported.

Judges do not hear cases in which they have a financial interest. Reporters do not write stories about companies in which they have a financial interest. By the same token, doctors should not have a financial interest in treatments they are evaluating or accept gifts from the makers of drugs they prescribe. In a January 5 editorial supporting legislation to require disclosure of industry payments to doctors, *The New York Times* ended with this sentence: "Better yet, the medical profession needs to wean itself almost entirely from its pervasive dependence on industry money." I agree, and I suspect a growing part of the public does too.

To the Editors:

We appreciate the concerns expressed by Marcia Angell in her review of several books addressing the activities of pharmaceutical companies, their relationships with physicians, and the significant impact of those relationships on pharmacologic research and the prescribing of medications. The exchange of money or other items of value between the medical community and medically related industries should be transparent and limited to payment for legitimate services. Some of the statements in the review, however, are misleading and prejudicial. For example, because research on children is fraught with ethical challenges, very few medications of any kind have been tested on children and thereby approved for pediatric use by the Food and Drug Administration. Psychiatric medications are not at all unique in that respect.

Many of the most commonly treated medical conditions—hypertension, hyper-