

Inside Aging Today

## THE TRUTH ABOUT THE CRITICAL CONDITION OF OVERDOSED AMERICA

By PAUL KLEYMAN

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Recent news about the flu-vaccine shortage, removal of Vioxx from the market and revelations that Paxil and similar antidepressants double the previous incidence of suicidal ideation by teenagers is raising serious questions about the system of prescription-drug development, manufacture and regulation in the United States. These and other revelations are turning up in headlines at a time when the U.S. healthcare system is increasingly under the microscope.

The debate has intensified with the publication of at least six books so far in 2004 by major publishers, all with provocative titles including *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* by Marcia Angell (one of two former editors of the *New England Journal of Medicine* ( *NEJM* ) to write such a book); *Critical Condition: How Health Care in America Became Big Business--and Bad Medicine* by Pulitzer Prize winners Donald L. Barlett and James B. Steele; and *Overdosed America: The Broken Promise of American Medicine* by John Abramson of Harvard Medical School.



Marcia Angell

### INITIATIVES FOR CHANGE

In addition to this surfeit of texts, the editors of the 11 largest and most influential medical journals announced this fall that they will no longer review

a clinical trial for publication unless it has been registered on a new central database. This extraordinary measure comes in the wake of evidence that drug companies were suppressing research showing that some of their drugs are not effective or produce harmful--even fatal--side effects. A growing chorus of experts is clamoring for the government to require pharmaceutical manufactures to enter all studies, positive or negative, on such a database.

Furthermore, Consumers Union, publishers of *Consumer Reports* magazine, is announcing a twin initiative on prescription drugs in November. One aims to educate the public about where best to obtain the best-quality, most effective prescription drugs at the lowest price. A separate initiative is intended to advocate for improvements in related public policy.

Last year, University of Minnesota geriatric researcher Robert Kane, after finding himself frustrated in his efforts to assist his own mother, formed the group Professionals With Personal Experience in Chronic Care. The group's website ( [www.ppecc.org](http://www.ppecc.org) ) states, *Our message to policymakers and health system leaders--If professionals working within the healthcare system are having serious problems with getting care for themselves and their families, then the system is failing in a major way.*

Although prescriptions for change differ widely, nobody believes there isn't a significant problem. Even a conservative think tank, the Pacific Research Institute in San Francisco, published a book this fall titled *Miracle Cure: How to Solve America's Health Care Crisis and Why Canada Isn't the Answer* by the institute's director, Sally C. Pipes. Whether the ultimate remedy lies, as Pipes believes, in free-market remedies, in a Canadian-style single-payer system or in another shade of reform, no changes in the perverse economic incentives now driving the U.S. healthcare and prescription drug system can be enacted without a buy-in from stakeholders ranging from consumer advocates to major players in the business of healthcare.

In the realm of prescription drugs, the potential contribution of the pharmaceutical manufacturers to the future health of older Americans--for treating such debilitating conditions as Alzheimer's, diabetes, incontinence and rheumatoid arthritis--is outlined on the website of the Pharmaceutical Association of America (PhRMA) at [www.phrma.org](http://www.phrma.org). In 2003, reports the PhRMA site, member companies invested an estimated \$33.2 billion on research to develop new treatments for diseases--an estimated 17.7% of domestic sales on research and development--a higher R&D-to-sales ratio than any other U.S. industry. Still, the percentage devoted to marketing and administration was almost double this amount, a point of concern raised by Angell and other authors.

## **UNREASONABLY HIGH**

Major drug makers are hardly unaware that their industry's standing with the American public has slipped severely. A Harris poll last summer found that only 13% of respondents find drug manufacturers to be generally honest and trustworthy--a drop of 35% since 1997--placing the industry with oil companies, managed care organizations and tobacco companies in the public's esteem. In the same poll, 57% of those surveyed called drug prices unreasonably high.

In addition, there are signs of healthy debate within the pharmaceutical industry about its role. In a *New York*

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*A surfeit of provocative new books challenges the U.S. health system.*

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*Times* op-ed article on

Oct. 27, 2004, Peter Rost, a physicians and marketing executive for Pfizer, departed from his firm's corporate leadership by calling for legalizing the reimportation of prescription drugs. He wrote, *Every day Americans die because they can't afford life-saving drugs . . . Americans are dying without the appropriate drugs because my industry and Congress are more concerned about protecting astronomical profits for conglomerates than they are about protecting the health of Americans.*

Also sharply criticizing the pharmaceutical industry's charging what he calls exorbitant prices has been Roy Vangelos, former chairman of Merck and Company. He told *The New York Times* (July 8, 2004), *This industry delivered miracles, and now they're throwing it all away. The article quotes Robert Wittes--a former Bristol-Meyers researcher, now the chief physician at New York's Memorial Sloan-Kettering Cancer Center--who said that skyrocketing drug prices invite government price controls. In response, the Times piece noted, major pharmaceutical executives established a committee chaired by Karen Katen, president of Pfizer's pharmaceutical group, to discuss how to improve the industry's image. Pfizer and other companies have launched discount programs to help uninsured and low-income consumers obtain medications.*

However important cost is--and U.S. consumers will spend \$250 billion on prescriptions drugs in 2004--safety concerns are also amplifying the debate over reforming the U.S. approach to prescription-drug research, development and marketing. Among the many key issues raised in the new books are:

- Much of research and development by drug companies is focused not on needed new drugs, such as vaccines and antibiotics, but on me-too copycat versions of best-selling compounds.
- FDA rules merely require a manufacturer to show that a drug works better than a sugar pill, rather than existing medications for the same condition, and the agency routinely approves drugs that offer no new benefit.
- Federal regulations allow pharmaceutical companies to hide negative data from drug trials that might be bad for sales. Sometimes, as in the case of Vioxx and possibly other Cox-2 painkillers, the new formulations present deleterious and even fatal new side effects.
- Drug manufactures are not obligated to test new compounds on the population segments expected to be the primary users of a drug. For elders, who metabolize molecules at different rates than younger people, the lack of data about proper application or dosing is disturbing.

One of the more strident voices for prescription-drug reform is physician Marcia Angell, a former editor of *NEJM* and author of *The Truth About the*

*Drug Companies (New York City: Random House, 2004). During a nationally broadcast address at San Francisco's Commonwealth Club in October, she challenged industry claims that it needs to set prices high to subsidize innovative research and development by asking, Is that true, do Americans get their money's worth?*

## LARGE PROFITS

Angell, now a faculty member of the Harvard Medical School Department of Social Medicine, noted that for the past two decades, pharmaceutical manufacturers have reaped some of the largest profit margins in U.S. industry. In 2002, the top 10 drug companies netted gains of 17% percent of sales, compared with a median of only 3% for all Fortune 500 companies. Yet, she said, Of the 78 [drugs] approved in 2002, only 17 actually contained new active ingredients, and only seven of those were classified by the FDA as likely to be improvements over drugs already on the market. Most of the others were just minor variations of old drugs. Of those seven innovative drugs, not one came from a major American drug company. The most profitable drugs are variations of top-selling drugs already on the market. These are me-too drugs, such as the cholesterol-lowering compound, Lipitor, the top-selling drug in the world, which is one of six competing medications of this type.

Angell and others stress that even though the pharmaceutical industry turns out whole families of me-too drugs for

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*Viabile solutions will require moving beyond conventional perspectives.*

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relatively mild conditions, it pays almost no attention to less profitable scourges. For example, it has been a long time since pharmaceutical companies have developed a new drug that would help with the growing problem of antibiotic resistance. Vaccine shortages have become common not only for influenza but also for such childhood illnesses as diphtheria and whooping cough, she said.

She added, Big drug companies license or otherwise acquire about a third of all their drugs from universities and NIH-funded small biotech companies. Although the drug industry claims to spend an average of \$802 million to bring each new drug to market, Angell said, independent analysis shows that the true figure is a small fraction of that amount.

Moreover, Angell explained, Drug companies have enormous influence over what doctors are taught and what they prescribe. The companies support a great majority of continuing medical education sources, medical conferences, meetings of professional societies. Wherever doctors gather together, there is drug company money. There's an army of sales representatives to visit doctors and teaching hospitals to tout their wares, hand out free samples and so on. There's ample evidence that this huge investment in medical education has paid off in terms of prescriptions from doctors and hospitals. Doctors are taught a very drug-intensive style of medicine in which for every ailment, no matter how minor, for every discontent, they reach for a drug. And the drug they reach for, those free samples, are left for them by the drug companies. . . . But these drugs are the newest. most

expensive drugs . . . so that when the patents run out, both the patient and the doctors are hooked.

Angell and *Critical Conditions* authors Barlett and Steele, editors at large for *Time Magazine*, are among the writers who urge a shift to a single-payer healthcare system. Others offer different public policy solutions. For example, in *Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs* (New York City: Knopf, 2004), Jerry Avorn of Harvard Medical School criticizes the stale perspectives he sees on both the left and the right.

Avorn writes, When it comes to medications and other aspects of health policy, workable solutions to our problems will require us to move beyond conventional perspectives of conservative and liberal, and instead to build on what will work best in the vision of each--a policy style that's been called ideologically androgynous. Conservatives will need to take a hard look at the waste and inequities that the commercialization of healthcare has created. For their part, liberals will need to keep an open mind about the efficiencies and responsiveness that a pluralistic system could offer, if properly tamed and closely regulated. The left will also have to consider whether a decentralized system of care coupled with gentle economic incentives for doctors and patients to use resources wisely might promote rather than threaten our goal of universal access, affordability and accountability.

One can only hope that the flurry of books featured here and others to come signal that a meaningful new round of debate--and subsequent action--is underway. Healthcare in the United States is a broken mirror, and only leadership from stakeholders in every quarter can begin to reflect a system in rosy health again. The first task is to address the critical issues--the perverse incentives and resulting health disparities--that are raised in these books. Among the stakeholders, those from industry to advocacy need to refocus their efforts on the one interest shared by all, that of the patient. Whatever your political or economic stripe, to borrow a line from the world of politics, It's your mother, stupid.

#### **BOOKS OFFER HEALTHY DEBATE**

Released by major publishers in 2004, the following books by prominent authorities or journalists examine the healthcare and prescription drug system in the United States. Readers can find sample chapters or articles by the authors drawn from some of these texts through an Internet search of the authors or publishers.

**Overdosed America: The Broken Promise of American Medicine** by John Abramson (New York City: HarperCollins), a physician and clinical instructor, Harvard Medical School.

**The \$800 Million Pill: The Truth Behind the Cost of New Drugs** by Merrill Goozner (Berkeley: University of California Press), director, Integrity in Science Project, Center for Science in the Public Interest, Washington, D.C., and former chief economics correspondent, *Chicago Tribune*.

**The Truth About the Drug Companies: How They Deceive Us and What to Do About It** by Marcia Angell (New York City: Random

House). A physician and senior lecturer at the Harvard Medical School Department of Social Medicine, Angell is a former editor of the *New England Journal of Medicine* ( *NEJM* ).

**Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs** by Jerry Avorn (New York City: Knopf), associate professor, Harvard Medical School, and chief of pharmacoepidemiology and pharmacoconomics, Brigham and Women's Hospital, Boston.

**Critical Condition: How Health Care in America Became Big Business--and Bad Medicine** by Donald L. Barlett and James B. Steele (New York City: Doubleday), editors at large for *Time Magazine* , winners of the Pulitzer Prize for *America: What Went Wrong?*

**On the Take: How Big Business Is Corrupting American Medicine** by Jerome P. Kassirer (New York City: Oxford University Press), faculty member, Tufts School of Medicine; adjunct professor, Yale School of Medicine; former editor, *NEJM* .

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