

Integrity in Science Watch

April 24, 2006

Heart-stopping Failure to Balance Cardiovascular Drugs Committee

The Center for Science in the Public Interest has called on the Food and Drug Administration to postpone the April 26 Cardiovascular and Renal Drugs Advisory Committee that has been called to consider controversial [new labeling guidelines](#) for blood pressure control drugs. Fully three-fourths of the 12-member panel received [conflict of interest waivers](#).

Physicians can choose from at least seven classes of drugs to treat the 65 million Americans with hypertension, which is often caused by obesity, excessive salt consumption, and lack of exercise and is a major contributor to heart disease. Many of the 35 million Americans on antihypertensives take more than one drug. Drug labels - and the permissive statements those labels allow drug salespersons to make to physicians - can have a major impact on prescribing patterns.

Guidelines developed by the [National Institutes of Health in 2003](#) suggested cheap, generic diuretics, which have been around since the 1950s, "have been virtually unsurpassed in preventing the cardiovascular complications of hypertension." Those guidelines, which, if followed, could save consumers, insurance companies and the Center for Medicare and Medicaid Services billions of dollars, also state that "diuretics should be used as initial therapy for most patients with hypertension, either alone or in combination with one of the other classes." The guidelines specifically recommend against using calcium channel blockers (Pfizer's Norvasc, a calcium channel blocker, is the world's best-selling anti-hypertensive drug) in patients with congestive heart failure.

The FDA's proposed label, on the other hand, states only that "numerous drugs from a variety of pharmacologic classes, whose only common property is to reduce blood pressure, have been shown to reduce cardiovascular morbidity and mortality." The accompanying discussion does not include congestive heart failure among its primary heart disease endpoints. "This document is written so industry can go out and say that it doesn't matter which drug you use," said Curt Furberg, a hypertension expert at Wake Forest University who sits on the FDA's Drug Safety committee. He wasn't invited to be part of this panel.

Several of the physicians who will play key roles in the committee's deliberations have conflicts of interest that relate directly to the labeling discussion. For instance, committee chair William R. Hiatt, a professor of medicine at the University of Colorado, has [conducted research](#) for Bayer Pharmaceutical showing the benefits of controlling blood pressure in diabetics with peripheral arterial disease. The label guidelines suggest secondary benefits like improved PAD can be used as a basis for recommending one drug

over another. None of the 11 physicians associated with the [National High Blood Pressure Education Program Coordinating Committee](#), which wrote the 2003 peer-reviewed guidelines, was chosen for the FDA panel.

The CSPI letter to acting commissioner Andrew von Eschenbach called on the FDA to balance the panel with experts familiar with the 2003 guidelines and experts on dietary approaches to controlling blood pressure. The group also recommended adding language to antihypertensive drug labels reminding consumers and physicians that "weight loss, diets rich in vegetables and fruits, and diets low in salt are simple ways of treating high blood pressure. Lowering your blood pressure through such changes could save you the cost and side effects of this (and possibly other) medications."

Industry-funded Docs Define Mental Disorders

Nearly a third of the physicians and psychiatrists who define mental illness for the medical profession had undisclosed financial ties to at least one pharmaceutical company, [a new study](#) released last week showed. And panels that defined severe disorders like schizophrenia in the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* were entirely made up of members financially affiliated with drug companies. The manual is used by the almost one-half million mental health professionals in the U.S. Sheldon Krinsky of Tufts University, who co-authored the study in the *Journal of Psychotherapy and Psychosomatics*, concluded that the investigation "demonstrates that there are strong financial ties between the industry and those who are responsible for developing and modifying the diagnostic criteria for mental illness." The authors call for transparency for future DSM panel members.

Allergy Journal Strengthens Conflicts of Interest Disclosure Policy

The *Journal of Allergy and Clinical Immunology (JACI)*, an Elsevier publication, will require greater financial disclosure from authors and automatically publish those disclosures, the editor told the Center for Science in the Public Interest (CSPI) in an email communication. CSPI's Integrity in Science Watch previously (March 31st) reported two mold experts, Dr. Abba Terr and Dr. Andrew Saxon, failed to disclose their roles as defense witnesses in mold exposure liability lawsuits when publishing a review that downplayed the risks from household mold exposure. Editor Donald Leung said future author conflict of interest forms accompanying *JACI* submissions will now include "specific questions" about expert witnessing and the journal will "ensure that all published manuscripts will carry a conflict of interest statement regarding each author."

Industry Consultant on NAS Panel Reviewing OMB Risk Assessment Rules

Claiming the agency was unable to find another qualified candidate, the National Academy of Sciences has included one of the founders of ENVIRON International, a prominent industry consulting firm, on a [new panel](#) that will evaluate the Office of Management and Budget's [proposed risk assessment guide](#) released in January. Six federal agencies including the Environmental Protection Agency have asked the NAS to [review the OMB proposal](#), whose time-consuming data review requirements would make it far more difficult to approve new health and safety regulations. The NAS waiver went to ENVIRON founder Joseph V. Rodricks, who is one of the eighteen members on the committee. NAS is "unable to find another individual with the equivalent combination of scientific credentials and expertise," the waiver stated.

Transcript Shows Bias in CDC Vaccine Study, Parent Group Alleges

Advocates for Children's Health Affected by Mercury has released a [transcript of a conversation](#) between the chair of an Institute of Medicine (IOM) study on the side-effects of vaccines and the study director at the IOM that suggests the study's outcome was predetermined. A [Medscape article](#) (subscription required) reported the transcript, which was posted on an activist group's website earlier this month, includes a statement by Dr. Marie McCormick, Harvard researcher who chaired the IOM committee, to IOM's Kathleen Stratton that "we are not ever going to come down that [autism] is a true side effect." CDC spokesman Tom Skinner said the emails had been taken out of context. The agency takes its scientific credibility very seriously and "in no way" tried to influence IOM experts, he said.

Industry-Funded Scientists Spin Aspirin Debate

A *Wall Street Journal* article today describes the hidden financial ties between big drug companies and researchers involved a debate over "aspirin resistance." Aspirin, the anti-clotting drug taken by millions of Americans, has been shown to help reduce the risk of heart attack and stroke by as much as 25 percent. An article published in *Physician's Weekly* last July by Daniel Simon, associate professor at Harvard Medical school, stated that as many as 30 percent of the 25 million aspirin-taking Americans were aspirin resistant, at higher risk for heart attacks and strokes, and may need other anticlotting drugs. According to the *Journal*, "the article didn't mention that Dr. Simon receives research funding from Accumetrics Inc., a privately held San Diego company that makes a test to measure aspirin resistance, and from pharmaceuticals maker Schering-Plough Corp., which sells a drug being tested as a potential benefit for patients deemed aspirin-resistant." *Physician's Weekly* managing editor Keith D'Oria said he knew about Simon's role with Accumetrics, but the weekly does not tell its readers about contributors' conflicts of interest.

The article also discloses that Dr. Eric Topol, a booster of the aspirin-resistance hypothesis who is now at Case Western Reserve University, consulted for Accumetrics and advised another aspirin resistance-testing firm, Aspirin Works, a division of Creative

Clinical Concepts Inc. of Denver. He previously served as a consultant to companies that make aspirin alternatives including Bristol-Myers, Sanofi-Aventis and Eli Lilly & Co. Topol told the *New York Times* last year that he has since cut his ties to drug manufacturers.

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