Chair of FDA Committee Evaluating ADHD Drug Has Ties to Competitors

The chairman of the Food and Drug Administration advisory committee that will consider a Cephalon, Inc. drug for pediatric attention deficit hyperactivity disorder is head of a university department that receives hundreds of thousands of dollars a year in research support from other ADHD drug manufacturers. Wayne Goodman, chairman of the psychiatry department at the University of Florida, disclosed his department receives major grants from two of Cephalon's direct competitors. Another member of the Psychopharmacologic Drugs Advisory Committee, Andrew Leon of Cornell University, owns less than $25,000 in stock in a Cephalon competitor.

Cephalon's Provigil (modafinil) is a non-amphetamine stimulant for adult sleep disorders. The company now wants to sell it in the booming ADHD drug marketplace, which already has six approved drugs for nearly 700,000 patients, including a half million children. Earlier this week, FDA reviewers recommended stronger mental health warnings for all ADHD drugs because numerous adverse events like mania and psychosis were reported in clinical trials, including those for modafinil. Last month, the FDA's Drug Safety advisory committee recommended by an 8-7 margin that all ADHD drugs carry a black box warning because of increased risk of heart attacks. The FDA has so far rejected the recommendation, including head of the psychiatric drugs division, Thomas Laughren, who said he felt the warning was not necessary.

Cephalon gets nearly half of its $1.2 billion in annual sales from modafinil, whose original patent ran out last December. Late last year, the company agreed to pay four generic manufacturers over $200 million to postpone marketing generic versions of the drug until October 2011. The company will get a six-month extension of that agreement if it wins a pediatric designation for the drug, according to documents filed with the Securities and Exchange Commission earlier this week. Last October, the FDA issued an "approvable" letter to Cephalon for the pediatric use of modafinil pending the March 23 advisory committee meeting.

FDA Advisory Committee website, March 15, 2006. (http://www.fdaadvisorycommittee.com/FDC/AdvisoryCommittee/Committees/Psychopharmacologic+Drugs/032306_Sparlon/032306_SparlonA.htm)
FDA website, March 14, 2006
"Memo: Psychiatric Adverse Events in Clinical Trials of Drugs for Attention Deficit Hyperactivity Disorder (ADHD)," Andrew Mosholder, MD to Thomas Laughren, Director, Division of Psychiatric Products, Office of New Drugs, FDA
Majority of CMAJ Board Quits Protesting Lack of Independence

Only four of nineteen Editorial Board members of the Canadian Medical Association Journal remain today after members decided to resign their positions in solidarity with their colleague Joreome Kassirer who resigned earlier this week. Board members began to question the journal's publisher, the Canadian Medical Association, last month, after it fired the journal's top editors, John Hoey and Anne Marie Todkill regarding a published article revealing an offensive procedure requested by the pharmaceutical industry to question buyers of the morning after pill about their sexual history. The Editorial Board members have written CMA president Ruth Collins-Nakai that they have lost "trust in CMA leadership" because CMA's "efforts at promoting independence at the journal are 'cosmetic.'"


NRC Panel Backs Stricter California Air Emission Standards

A National Research Council panel has concluded states like California can set air emission standards that go beyond federal rules. The unit of the National Academies of Science also said California's proposal to require catalytic converters on lawnmower engines makes sense. The 11-member panel's conclusions represent a setback for Missouri Republican Kit Bond, who wanted support for his efforts to get the EPA to veto the lawnmower rule on behalf of Briggs & Stratton, a major employer in his state. The environment-friendly report comes despite the presence of former auto industry lobbyist Gary Marchant on the NRC panel. The benefits of having California set cutting-edge standards for the nation "outweighed the costs" to manufacturers and consumers, said Marchant, who is now a law professor at Arizona State University.


WHO Bird Flu Data Policies Challenged by Italian Scientist

Pressure is building on the World Health Organization to open its database of more than 2,000 genetic sequences of avian influenza to scientists around the world. Opening the database would give scientists a better understanding of the potential pandemic threat and
allow more rapid development of a human vaccine. In February Italian veterinarian Ilaria Capua refused to give her bird flu data to WHO because it would only be accessed by a "select group of scientists." Instead, she released her virus sample to GenBank, a publicly accessible database run by the National Center for Biotechnology Information in Maryland. WHO claims it developed the closed system because scientists and governments often keep their data hidden to boost their own careers. "I understand you have post-docs, and I understand you have to keep yourself going," Capua said. "But for heaven's sake, you don't have to publish a paper every two months. Let other people look at this data."


Rooting Out Scientific Fraud a Joint Responsibility

Responsibility for the investigation and prevention of misconduct must be shared by all parties involved – the research institution, co-authors and journal editors, a forthcoming article in the Annals of Internal Medicine concludes. In the wake of the Hwang Woo-Suk-Korean stem cell scandal, journal editors around the world are scrambling for new ways to prevent fraudulent articles from appearing in the scientific literature. The Annals article describes the case of Dr. Eric Poehlman, former faculty member of the University of Vermont, whose editors failed to catch his defective research, failed to withdraw it after publication and failed to warn other authors his articles contained faked data. In 2003, the University of Vermont notified three journals that they had published Poehlman's fraudulent research. But, according to the federal Office of Research Integrity, only one of the three journals retracted Poehlman's work. Meanwhile, authors continued to cite the retracted article.


Financial Motive May Be Why Negative Clinical Trials Go Unpublished

Published clinical trials funded by industry are more likely to demonstrate positive conclusions than trials supported by non-profit or government, a Nature article revealed this week. Since clinical researchers are not required to publish their findings, many unfavorable results "languish in filing cabinets," said Christine Laine, editor of Annals of Internal Medicine. In 2005 a group of French scientists showed that over an 18 year span, only 40 percent of the country's registered trials were published, although twice that many had been completed. Because inconclusive or negative data in the drug industry can be vital to "informing decisions about the licensing of drugs," the WHO and other groups want more clinical trial disclosure, including a "list of mandatory entries for trial data,
including primary outcome." The WHO will issue a policy statement in April on the issue.


**Revolving Door Keeps Swinging At FDA**

The day before President Bush appointed Andrew von Eschenbach as permanent head of the Food and Drug Administration, the one-time cancer surgeon asked former Biotechnology Industry Organization lobbyist David W. Boyer to run the FDA's legislative shop. While at BIO, Boyer lobbied Capitol Hill on health care and biodefense issues. He's also worked on Capitol Hill and at the Health and Human Services department headquarters, where he was a special assistant reviewing legislation.


**Correction:** In last week's item: "Proposed EPA Standards for PM Challenged by Outside Scientists," the March 17 deadline for comment on the PM proposal is incorrect. The EPA is open for comment until **April 10, 2006.** *(http://www.epa.gov/air/particlepollution/actions.html)*

*The Integrity in Science Database of Scientists and Organizations With Ties to Industry can be found at:* [www.integrityinscience.org](http://www.integrityinscience.org).

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