ScienceScope

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FDA to Ask for Data on Gender Differences

Do drug companies fail to determine how their products affect women? After a report by the General Accounting Office in October 1992 claimed just that, Congress, led by Representatives Patricia Schroeder (D-CO) and Olympia Snowe (R-ME), demanded that the drug industry and the Food and Drug Administration (FDA) stop shortchanging women. Now the FDA is taking action: Within the next few months, it will begin to monitor closely companies that fail to discriminate between the sexes.

The planned guidelines would stipulate that along with new drug applications, companies must include a summary of a drug's efficacy and side effects in men and women separately. If a company refuses to do this, says one FDA official, FDA would consider turning away an application. But that seems an unlikely event, the official says, because "it shouldn't be hard to do these analyses."

Drug company officials agree that such analyses will cost little time and money, but they bristle at the suggestion that they've been negligent. FDA, they point out, didn't even recommend gender analysis until 1988 and still doesn't require it. As a result,

claims Donnica Moore, associate director of medical education for Sandoz Pharmaceuticals, companies often perform gender analyses but withhold the results from FDA unless a drug shows a significant difference in the way it

Did DOE's Happer Fall Into Ozone Hole?

William Happer, the energy research director at the Department of Energy (DOE), is popular enough in the scientific community that he was one of a handful of Bush appointees whom the Clinton Administration specifically retained earlier this year. But now he's leaving—apparently given the boot, that is, because of some of his environmental views.

Happer's fall from grace, according to associates, can be traced to his very public opinion that the health threat of ozone depletion is overstated. Specifically, Happer points

out what he sees as a "discrepancy"

Leading Candidates Reject Top Agency Jobs

Call it a bad week for science appointments. As *Science* went to press, word leaked out that two candidates who had been considered sure bets to head up the National Science Foundation (NSF) and the Office of Technology Assessment (OTA) had each turned down job offers.

Sandra Faber, a University of California, Santa Cruz, astronomer, has withdrawn from consideration for NSF director because, her office says, she's unwilling to leave research. The backing-out epidemic also appears to have claimed another leading candidate for the NSF post, Radcliffe College president Linda Wilson.

Over at OTA, Maxine Savitz, an Allied-Signal Inc. electrochemist, had been considered such a sure bet to take former director John Gibbons' job that OTA had distributed her resume to employees and written a press release. But on the day she was to be announced, she, too, apparently got cold feet, withdrawing for undisclosed reasons.

That leaves OTA in a bit of a bind: Savitz had been the lead choice of both Gibbons (who is now the president's science adviser) and OTA's board chairman, Representative George Brown (D–CA). Staffers worry that the agency will suffer if it goes directorless much longer. With Democrats running both Congress and the White House, lawmakers have been calling OTA less frequently for reports that could be used for political ammunition, leaving the agency short of work—and influence.



Gender bias. FDA wants to see data on how prospective drugs affect women.

affects men and women. Explaining this behavior, a staffer at a Washington, D.C. medical think tank says, "The general rule of thumb is that you don't give FDA more than they ask for, because then they'll ask more questions."

> ⁸ between predicted levels of UV-B, the cancercausing radiation that ozone normally blocks, and levels actually measured on the ground. As a result, he says, "I think there are some questions about how much of a

problem [ozone depletion] is." If anything, he says, "it's mostly a lifestyle problem."

Contrast Happer's views with those of Vice President Al Gore, whose apocalyptic vision of an environmentally ravaged Earth drew the epithet "Ozone Man" during the presidential race last year. Something was bound to give, and that, it seems, was Happer's job. DOE sources say Gore's office made it clear that Happer was no longer welcome to stay. Was the clash due to Happer's ozone views? Happer, a press officer at his side, told Science: "There may have been a little something there." White House officials say they were indeed shocked by Happer's ozone sentiments, but they're mum as to why he's leaving. As one puts it, "We don't need a reason to fire Bush appointees."

Advice to a Lovelorn Super Collider

Loyal champions of the Superconducting Super Collider (SSC) —like Stanford University physicist Sidney Drell—seem to be losing patience with the delays that Congress and the Administration are forcing on the SSC. Drell, for one, is urging his fellow physicists to face up to a difficult choice: Either find a way to move the project ahead at a faster pace or, if that fails, pull the plug.

In a recent talk at Princeton University, Drell discussed the "uncertain and volatile" future of the \$10 billion SSC, which he said "we love...for its scientific potential," but which members of Congress seem to adore for its pork. He said he hates to watch it limp along as a construction project and advocated one of three options for getting the SSC built.

Drell's option one: Persuade the government to commit to finishing the SSC on a "date certain" 10 years from now. (The SSC is, in fact, slated for completion in 2003.) Drell conceded that political support for this choice may now be hard to muster, leading to....

Option two: Mount a "fullcourt press to convert the SSC into a truly international project." Drell asked: "What could be more foolish than to build both the SSC and a large hadron collider at CERN?" Both the European Community and the United States are pressed for cash. So how about setting the hadron collider aside and asking Europe to contribute \$2 billion and Japan to kick in \$1.5 billion to the SSC budget? Of course, this would require "that all the major players are truly equals in a new management organization for the scientific leadership"-a tough proposition, but "there may be no alternative." None, that is, except....

Option three: "Terminate the project." As scientists, Drell said, "we have to seriously face this alternative...if we have neither of the other two choices."

SCIENCE • VOL. 260 • 7 MAY 1993



William Happer