Price Caps Threaten NIH Drug Deals

Two of President-elect Bill Clinton's top priorities—slashing health care costs and directing fed-

eral research to help industry—may be headed for a head-on collision at the National Institutes of Health (NIH).

Officials there are worried that Congress may dust off a little-used clause in NIH's cooperative research and development agreements (CRADAs) with pharmaceutical companies and use it to force firms to limit the price of the drugs they develop in cooperation with NIH. That, NIH officials fear, could derail the agency's growing technology transfer efforts if companies were to forgo research cooperation in order to charge what they want.

Last week, at a meeting of NIH Director Bernadine Healy's advisory panel, drug industry representatives told NIH that the very existence of the "reasonable-pricing" clause is scaring off companies who fear the clause might be enforced in the future (though it rarely has

been in the past). And they complained that NIH has neither the statutory authority nor the necessary expertise to establish fair prices for drugs. No conflict exists on that point: NIH officials agree with industry, and they worry that any move to arm NIH for such a task would erode its research links with companies.

But Congress is once again gearing up to battle the pharmaceutical industry over drug prices, and this time NIH is likely to be dragged into the fray. Bolstered by a report last month from the Office of Technology Assessment that found that treatments with Ceredase, a drug developed with help from NIH, could cost a patient as much as \$500,000 a year, Senator David Pryor (D-AR) has called NIH's deals with industry a "license to price gouge."

Now, along with Representatives Henry Waxman (D–CA) and Ron Wyden (D–OR), Pryor is planning legislation in 1993 that, among other things, may force NIH to invoke the pricing clause routinely. One mechanism has already surfaced: an independent board to negotiate the price of drugs developed under CRADAs with NIH. That may answer one NIH concern—

the agency doesn't want to be forced into the accounting business—but it leaves the question of what the role of price policeman may do to NIH's budding relationship with industry.

Ethical Pickle at Lawrence Livermore

The job of general counsel at the Lawrence Livermore National Laboratory includes reviewing ethical issues, and you would assume the occupant was an expert on ethics and the law. Hence lab staffers are puzzled about the fix the lab's top legal officer, general counsel William C. DeGarmo, has gotten himself into. According to a consent decree filed by the Securities and Exchange Commission (SEC) in Denver, DeGarmo has agreed to "disgorge" to the SEC \$27,332 in profits he made last year and pay an additional penalty of \$27,000 for making questionable transactions in the stock of the Cray Computer Corp. of Colorado Springs, Colorado.

A complaint released last week by the SEC alleges that DeGarmo had access to "material nonpublic

Transition Talk II

After expecting to meet President-elect Bill Clinton at the altar, it appears that the biotechnology industry just got jilted at least for the time being.

Last month, Clinton's aides invited 20 high-profile biotech researchers—including gene therapy pioneer W. French Anderson and such genome project luminaries as Leroy Hood, Eric Lander, and David Botstein—to an educational "roundtable" on biotech research issues in Little

horse, Berkeley geneticist Mary-Claire King.

But that was before the budget cut. Now Healy is scrambling for money to skim from other NIH programs—she says even a million or two will do for starters to begin assembling a laboratory by mid-1993. But unless she is willing to wait until then for a genome chief, the money crunch may require her to at least temporarily hire an off-campus director—and face a rerun of Watson's divided loyalties and potential conflicts of interest. information" enabling him to profit from stock deals. Specifically, the SEC charges that DeGarmo was aware on 20 December 1991 that Livermore had canceled its contract to purchase a \$30 million Cray computer, and that 3 days later, he "sold short" 5000 shares of Cray common stock before Cray issued a press release. Although he agreed to pay the penalty, DeGarmo told Science he merely made "an error": He assumed the press release had already been issued before he sold the stock. He reported the "error" to the SEC in January.

Livermore, according to a spokesman, has put DeGarmo on "investigatory leave" while considering what action to take, and DeGarmo's co-employer, the University of California, "has made no decision" on the case, according to a spokesman.

Rock, Arkansas, on 16 December. But last week Clinton's staff canceled the meeting; it was too early to get into such details of science policy, they explained.

But then why schedule the meeting in the first place? Apparently some of Clinton's aides thought that a biotech roundtable would assist them with policy planning on health care and technology issues. But the science and technology team, headed by Greg Simon, an aide to Vice President-elect Al Gore, had its own agenda—that left an in-depth discussion of biotechnology policy off the first page.

Clinton intends to reschedule the meeting in a few months, a transition source says. But the episode has left some of the wouldbe participants with a bad taste, especially because they're stuck with tickets purchased with their own money. Krishna Dronamraju, the president of the Foundation for Genetic Research in Houston, says when Clinton's staff originally asked him to help set up the roundtable, "I saw a lot of hope for science and technology in the new administration. But we started off on the wrong foot."

Congress Foils NIH Genome Plans

When James Watson resigned under pressure as director of the National Institutes of Health's (NIH) Human Genome Project in April, NIH Director Bernadine Healy swore that things would be different with the next genome czar. No more deals like the one that allowed Watson to split his time between NIH and Cold Spring Harbor Laboratories, which he continued to direct during his NIH tenure. But now a little-noticed congressional budget cut is forcing Healy to rethink her promise.

In October, Congress cut nearly half of a special \$20 million NIH fund that Healy can use without jumping through too many bureaucratic hoops. Healy had hoped to use the fund to outfit a new genome laboratory on the NIH campus with which to attract her ideal candidate for genome director—a high-profile scientist actively engaged in research, such as hotly pursued Francis Collins of the University of Michigan or this week's dark

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