edited by DAVID P. HAMILTON

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Spoiled milk? A GAO report has fueled a furor over animal drugs.

New Pressure on "Off-Label" Animal Drugs

Researchers beware: If, like many of your colleagues, you administer therapeutic drugs in animal studies that aren't specifically approved for the species you're studying, you could soon wind up in trouble with the Food and Drug Administration (FDA), which has recently come under pressure to enforce a federal law that prohibits "off-label" use of veterinary drugs.

Suppose, for instance, you're working with the spiny anteater, an animal highly valued by researchers interested in studying how sleep evolved. Your big problem is that there's no FDA-approved anesthetic for these prickly beasts. And unlike doctors, who can legally prescribe drugs for uses other than those for which they were originally approved, you're prohibited from using an anesthetic that's been approved for another species, like dogs.

Until now, the FDA has turned a blind eye to the off-label use of veterinary drugs. But, driven by concerns over the safety of food products, the regulatory agency has come under increasing pressure from Congress and public interest groups who want it to crack down on the use of drugs in animals other than the ones for which they were specifically approved. A recent General Accounting Office report helped fan the flames: It concluded that off-label use of drugs in cows "could cause potentially unsafe residues in milk" and recommended that FDA restrict such use, at least for dairy cows.

Researchers and veterinarians have already warned that a widely applied crackdown could hamper their work, and legislators in both the House and Senate have introduced bills that would allow veterinarians to use off-label drugs in animals when there are no approved alternatives. Sponsors don't expect action on the legislation before the election but say Congress is likely to take up the issue next year.

Smithsonian Faces the Big Squeeze

Caught in a budget vise for the second year in a row, the Smithsonian Institution may soon have to take drastic action to balance its books—including layoffs of staff at the Museum of Natural History, which carries out much of the institution's research.

Officially, Smithsonian administrators say it's far too early to speculate on whether layoffs are in the offing. But the news from Congress so far bodes ill for the institution's prospects. Both houses have passed spending bills that fall well short of the Administration's spending request—the House by $12.3 million, the Senate by $20.4 million. While both houses support raising the institution's overall budget from this year's level, the Smithsonian's "uncontrollable" expenses in salaries and health insurance will easily swallow these increases. As a result, congressional reductions in the request translate directly into cuts in the institution's program budget.

The natural history museum has already begun to plan for the worst. After the Senate Appropriations Committee voted on 23 July to cut $7 million from the institution's 1992 program budget, museum deputy director Stanley Shetler estimated in a memo that the museum's share might come to $1.4 million, assuming the Smithsonian pro-rated the $7 million reduction across its various programs. "That almost certainly means firing some people," says Donald Ortner, director of the museum's anthropology department, mainly because 97.3% of the museum's operating budget is tied up in staff costs.

FDA to Form New Science Board

In its latest attempt to integrate industrial and academic science more thoroughly into its decision making, the Food and Drug Administration (FDA) will soon form a new science advisory board—the first time in recent memory that the agency has called on top-level outside advice to help set research strategy and smooth its relations with industry.

FDA senior science adviser Elkan Blout says he is looking for 8 to 10 accomplished scientists to advise the agency on emerging scientific and technical matters in industry and academia and to serve as the agency's liaison with the outside scientific community. In particular, he says, he wants the new science board to serve as a conduit between FDA and the pharmaceutical industry that will perform the dual role of sensitizing the agency to companies' interests while helping them to understand better FDA's regulatory objectives.

Blout is courting some high-powered talent from the biotech industry for the new board: He says he is reaching out to such luminaries as Merck president Roy Vagelos; former Yale Medical School dean Leon Rosenberg, now a vice president at Bristol-Myers Squibb; and Chiron president Bill Rutter. An FDA statute also requires him to look for at least one member to represent "consumer interests," he says. But Blout insists that no one without proper scientific credentials will have a seat on the board.

EPA Enforcement to Get the Dingell Treatment

Fresh from raking the Environmental Protection Agency (EPA) over the coals last month for allegedly mismanaging research contracts with industry, Representative John Dingell (D–MI) will haul a new set of EPA officials before his oversight subcommittee on 10 September—just 2 months before the presidential election. This time, however, he'll be on EPA's side, probing allegations that the Department of Justice has prevented EPA lawyers from fully prosecuting environmental lawbreakers.

In a 6 July letter to U.S. Attorney General William Barr, Dingell revealed allegations that the department's Environmental Crimes section had "disrupted and undermined the EPA's criminal enforcement program." Some of the allegations Dingell has dug up since his staff began an investigation in January include "apparently preferential treatment of certain large and powerful corporations," "closed door meetings with defense counsel without the knowledge of the EPA," and "agreement to trivial financial penalties in cases involving serious and long-standing environmental violations."

The hearing is also likely to produce some fireworks over charges that Justice has been "stonewalling" Dingell's investigation. Dingell complains that Barr hasn't allowed his staffers to interview three assistant U.S. attorneys, two of whom previously worked in the Environmental Crimes section. In a 20 July letter, the Justice Department agreed to allow Dingell's staff to interview one of the attorneys but hasn't yet given her written permission for the interview, a Dingell staffer says. "They'll be disappointed if they think their stonewalling tactics are going to work," the staffer adds.