

nication with FDA reviewers, who often ask for additional time-consuming tests late in the approval process. The fear of such requirements, says Lasagna, leads to "real or imagined perceptions of what FDA will demand," which in turn lengthen the process.

Lasagna praises Kessler "for moving the agency in the direction of a collegial relationship with the regulated communities." Kessler calls this change "one of the most important things the agency has done" to try to shorten drug development times. But the real test of this relationship is whether drug companies

will still be required to provide data on demand. The FDA is not known for its flexibility in arguments over data requirements. "It's like fighting a 600-pound gorilla in its cage," Lasagna says. "You aren't going to win."

The next commissioner must balance the need to keep FDA's staff scientifically up to date with the need to review new drugs even more quickly. Friedman says the agency can do a better job in seeking advice from scientists at universities and other government branches, such as the National Institutes of Health, adding that "we need more effective

linkages with scientists outside the agency."

Those who support FDA's research program realize that they must find new ways to demonstrate why science is vital to a regulatory agency. "It's hard to show that better science is giving the public more bang for the buck," says Noguchi. But Friedman thinks the case can be made. "These are very difficult times for science and regulatory activities," he says. "What's essential is that we find more effective ways for science to be the engine that drives the agency."

—Richard Stone

ETHICS

Draft Research Code Raises Hackles

Scientists in Canada who do research with human subjects have spent the past several months worrying—and complaining—about a proposed new ethics code that many say would needlessly restrict good research while making funding decisions more vulnerable to political pressures. The proposal, first unveiled in the spring, was put together by the Tri-Council Working Group on Ethics, formed by the country's three top research funding agencies* to devise a uniform code for government-funded research with human subjects. Made up mostly of doctors, ethicists, and lawyers, the group originally set a 15 July deadline for feedback from the professional community. But that has gone by the boards. The committee's chair, Jean Joly, an infectious-diseases expert at the University of Montreal, says the mail is still arriving. About 260 letters, "most [of them] single-spaced," have come in, he says. Although many are "laudatory," some are "absolutely explosive." A second draft now isn't expected to be ready until spring.

One major sticking point for the critics, who include many experimental psychologists, is a redefinition of the role of an institution's Research Ethics Board (REB). Under the new guidelines, REBs would review not just the ethics but the "scientific validity" of proposed studies with human subjects. This sets up a process that threatens to "confuse ethics with experimental design," argues psychologist John Furedy, president of Canada's Society for Academic Freedom and Scholarship (SAFS). Because

only two of the five board members would be required to be knowledgeable about the science, board decisions on sensitive research—such as a study comparing AIDS prevalence and promiscuity in different ethnic groups—could be swayed by local political sensibilities, critics say.

Critics have also reacted to the draft's emphasis on ensuring a "subject-centered perspective" in research. One provision in particular stipulates that in studies where at the outset subjects are either deceived or not fully informed about the purpose of the research, "If the subject decides he or she does not want to participate following [a postexperiment] debriefing, the subject's data must be removed from the study." Doreen Kimura, a psychologist at the University of Western Ontario in London, Ontario, and a founding mem-

ber of SAFS, says that allowing subjects to back out of a research project after the data have been collected would complicate the type of research she does. For example, she says, the results of a study comparing old and young people on a cognitive task could be biased if old people who felt they had performed poorly often withdrew.

Both SAFS and the Canadian Society for Brain, Behaviour, and Cognitive Science also say that the working group has put too much emphasis on the need for research to be of moral benefit to society. "What are the 'moral benefits' of knowing whether a particular configuration of lines on paper produces a visual illusion?" asks the brain society in a draft response to the proposed code. The society's president, psychologist Vincent DiLollo of the University of British Columbia (UBC) in Vancouver, also says that the working group's concern about avoiding "coercion" of research subjects is so extreme that

many psychologists worry that the final version of the code will prohibit them from paying or giving course credit to students for being research subjects.

The draft code has also raised a shower of objections from historians and social scientists with a proposal that in research with people who belong to a "collectivity," such as a family or community, "the researcher may not begin until permission has been obtained from the appropriate authorities for that collectivity." Critics maintain that this could be interpreted to mean, for example, that one would have to get permission from the head of a neo-Nazi gang to interview a disaffected member.

Tricouncil group members acknowledge that they have gotten some people very rattled, but insist that they are listening to all comments. Indeed, in some instances—including the matter of consent for members of collectivities, and a proposal that would prohibit clinicians from recruiting their own patients into their trials—the working group is promising to back off. In other cases, members say that their critics have overreacted. For instance, Michael McDonald, director of the Center for Applied Ethics at UBC, says that there is no need to worry about the REBs turning down good science for political reasons: Because funding agencies do scientific reviews of proposals, "I don't expect REBs themselves to be really much concerned about scientific validity other than making sure some kind of review has taken place."

Chair Joly admits that the working group has a "very, very difficult" task before it. Ultimately, he says, "the document that we produce we hope will be a living document ... always under revision." Furedy, for one, is not reassured. "That ... is always the case with vague, totalitarian documents," he claims.

But as McDonald points out, most reactions to the draft have been positive. "This is the first time we've had a discussion all across the country on the subject of research ethics," he says. "I think it's marvelous ... terrific."

—Constance Holden



Concerned psychologist. Doreen Kimura.

* The Medical Research Council, the Social Sciences and Humanities Research Council, and the Natural Sciences and Engineering Research Council. The draft report can be found on the Internet at <http://www.ethics.ubc.ca/code/>