CLINICAL TRIALS

CONFLICT OF INTEREST: ROUND TWO

WASHINGTON, D.C.—A year after the U.S. research community shouted down an initial set of proposals for strict guidelines on conflict of interest in publicly funded clinical trials (*Biol Technology* 8:103, Feb. '90), a revised version is up for discussion. The National Institutes of Health (NIH, Bethesda, MD) recently previewed kinder, gentler proposals covering Public Health Service (PHS)-sponsored research, which place most of the responsibility for maintaining integrity on the institutions themselves.

Speaking at a session on this topic at Biotech USA, held here last November, Alicia Dustira, senior policy analyst in the White House Office of Science and Technology Policy, said she believes managing conflict of interest is "a personal responsibility. You cannot mandate ethics." She supports a system to encourage full disclosure of potential conflicts. Other speakers agreed that disclosure is the key element in preventing abuses.

But disclosure alone may not satisfy the regulators. According to Pamela Bridgen, executive director of the Association of Biotechnology Companies (Washington, DC), there has been concern on Capitol Hill about

whether the NIH comments are now strong enough. The new proposals seem to have incorporated some of the objections raised to the first set, cautioning against restrictions that would frustrate the intent of the Federal Technology Transfer Act by making federally funded research unattractive for commercialization.

Since the first proposed guidelines came out in June 1989, the biotech community has feared they could lead to broad mandates against such common practices as trading scientific expertise for equity or stock options in a fledgling company. Alan Tuck, vice president of marketing and business at Biogen (Cambridge, MA), noted that such public/private sector collaboration is what keeps biotech going. He cautioned that restrictive guidelines not only puts the U.S.'s current leadership in this area at risk, but could limit health-care advances and small-company development. He questioned the need for guidelines, noting that faking or skewing clinical results is "just plain stupid."

True instances of conflict of interest have been rare, but the headlines they produce feed public distrust of

science. According to Marion Osterweis, vice president of the Association of Academic Health Centers (Washington, DC), the concern, "seems overblown. It's not immediately apparent why all the current fuss." But in this climate, official guidelines may be needed as much to protect investigators from the taint of suspicion as to discourage actual wrongdoing.

Another reason for encouraging guidelines is to remove the uncertainty that now exists. "We find it increasingly difficult to make arrangements [with researchers]," noted Brian Dovey of Domain Associates (Princeton, NJ), a venture capital firm. "They see a cloud, and are not interested in working with us until it is lifted." Existing policies covering conflict of interest are fragmented, occurring at both state, local, and institutional levels and ranging from voluntary disclosure to forced divestment.

The general principles cited in the new proposals suggest using internal review boards to examine potential conflicts on a case-by-case basis and informing PHS of all financial arrangements made with pharmaceutical companies whose drugs are being tested.

—Pamela Knight

PUBLIC OPINION

BIOTECH A PLUS ACCORDING TO EUROPEAN POLL

LONDON—Biotechnology will make life better, according to 63 percent of people questioned in Britain, France, Germany, and Italy in a survey conducted by the Gallup Organization and financed by Eli Lilly (Indianapolis, IN). Only 13 percent of respondents feel that life would become worse as a consequence of biotechnology.

Carried out in tandem with a new report, *The Case for Biotechnology* (see "No More Shallow Alarums," this issue), the study also shows that only four percent of the population on average in the four European countries want a total ban on biotechnology. Forty-nine percent believe work should be regulated through standards and practices agreed upon jointly by industry and government; 38 percent think it should be strictly controlled by government regulation alone. The findings are based on a representative sample of 1,048 adults in Britain, 1,001 in France, 605 in Germany, and 512 in Italy.

Reflecting the activities of opposition groups in their country, six percent of the German participants want biotechnology to be prohibited com-

pletely. This compares with two percent in France, three percent in Italy, and five percent in Britain. While at least half of the respondents overall (and as many as 65 percent in France) rate new cures for serious diseases as the most important of four possible benefits of biotechnology, only 16 percent of those in Germany choose "reducing our dependence on pesticides and chemical fertilisers" as most important, compared with 26 percent in Italy, 24 percent in France, and 22 percent in Britain.

The most striking finding was the very low proportion of "don't knows" in the French sample. No French participants gave this reply to the question about perceived benefits (compared with 11 percent of the German sample). The corresponding French figures were one percent when asked about concerns regarding biotechnology (Germany, 10 percent), and three percent when asked about regulation (Germany, 11 percent). Eugenics emerged as the principal danger thought to be associated with biotechnology. Forty percent of French respondents, 35 percent of Germans, and 25 percent of the U.K.

participants rate this as their main anxiety. Overall, eugenics was closely followed in the survey by environmental harm as a subject of concern. But 32 percent of participants feel that biotechnology is "ethical," the same percentage see it as "unethical," and 33 percent think it is neither.

"These poll findings demonstrate conclusively that the hysteria which surrounds biotechnology in some parts of the European Community is unrepresentative of public opinion, at least in the major Member States," said Dick Taverne, launching both the poll results and his companion report. "Even in Germany the optimists about biotechnology outnumber the pessimists by more than three to one."

Taverne pointed, however, to "legitimate fears" revealed by the poll in all four countries. "These need to be dealt with in the cool, rational way that is both urged in the report and shown by the poll to be in tune with public opinion. I hope that European politicians and policy-makers, when confronted by specific issues in future, will respond in this spirit."

—Bernard Dixon