TRADE ASSOCIATIONS

IBA LISTENS TO CALLS FOR REGULATION

SAN FRANCISCO—Public issues dominated the Third Annual Meeting of the Industrial Biotechnology Association: patent rights, press coverage, and, above all, regulation.

Feeling among the hundred-odd industry executives and observers here ran heavily in favor of even-handed federal regulation, a consensus perhaps surprising in an organization whose membership consists of 42 biotechnology firms. Most attendees seemed to agree that some sort of regulation is inevitable. If so, as several speakers pointed out, a coherent federal policy that protects both the public and the industry is probably better than a crazy-quilt of local rules, regulation by environmental lawsuit, or a regulatory apparatus based on confrontation between the regulators and the regulated.

Harold P. Green presented a coherent set of analyses and proposals. Green is both an associate dean of George Washington University Law School (Washington, D.C.) and corporate counsel to Genex Corp. (Rockville, MD). He has made a special study of the regulatory issues confronting high-technology enterprises.

First, Green warned IBA members against what nuclear power pioneer Hyman Rickover called "the tendency to treat every attempt to regulate new technology in the public interest as a modern version of the persecution of Galileo." Even if we "stipulate that the biotechnological avenues now open to us present no significant risks," Green said, biotechnology must still recognize four facts. It cannot escape the heritage of a past that has—with the Asilomar Conference and the founding of the National Institutes of Health's Recombinant DNA Advisory Committee (RAC)—established biotechnology in the public mind as a force that needs to be regulated. Nor can the industry forget that "public perceptions are more important than reality" when it comes to the political forces behind regulation. Also, said Green, those in biotechnology should recognize that the issues of regulation are too important to be left to scientists. Finally, Green urged those in the field to acknowledge that the capacity for genetic engineering brings with it inescapable issues of reproductive politics and ethics of genetic modification of human beings.

Green went on to outline four ways biotechnology might be regulated in the near future, ranging the spectrum from *laissez faire* to draconian.

- NIH and the RAC might expand their role to embrace industrial applications as well as research. Green called this "unlikely and undesirable." Such a move would leave biotechnology open to the same charges of conflicting interests that plagued the nuclear power industry under the Atomic Energy Commission (AEC), he noted. Green attributed many of the nuclear power industry's current problems to the AEC's failure to be a credible voice for the public interest. Dedicated anti-nuclear groups filled the resulting void. The same, he warned, could happen to biotechnology. (Later in the meeting, RAC chairman Robert E. Mitchell, a layman and lawyer himself, also warned against expanding the RAC into a regulatory agency. Such a move, Mitchell said, would necessarily sow the seeds of adversary procedures in a group that now serves as a respected advisor.)

Biotech Industry Warned of Plot

By John Eckhouse

Opponents of nuclear power next may target the biotechnology industry and try to tie it up in court, a genetic engineering company's legal counsel warned colleagues yesterday at a meeting in San Francisco.

"It would not surprise me one bit to see some of the anti-nuclear negativists extend their negativism to genetic engineering," Harold Green, George Washington University law professor and counsel to Genex Corp., said at the annual meeting of the Industrial Biotechnology Association.

He said some activists already are using provisions of laws like the National Environmental Policy Act as a basis for filing lawsuits. NEPA, a 16-year-old law, requires federal agencies to make a thorough study of environmental issues before approving any action that significantly affects the environment.

"The litigation could be endless and enormous in cost," Green said. He said that was the strategy that opponents of nuclear power used to delay the industry's expansion.

said that will change quickly.

"Regulation is inevitable," he said, adding it should be relatively easy for the industry to live with regulation as long as the government does not select the wrong agency as a watchdog.

Green said his personal preference would be for the Environmental Protection Agency to assume regulatory oversight. Not only does the EPA have the best fit with the genetic engineering industry, he said, but the agency is exempt from the provisions of NEPA — an onerous law he called "an instrument of the devil."

Later in the conference J. Grant Brewen, director of biosciences at Allied Corp., called on his colleagues to work as closely as possible with the government to develop regulations we can live with rather than let what happened with the nuclear industry." He said, though, that scientists should not let regulatory agencies intrude in their laboratories and tell them how to conduct experiments.

An official of the U.S. Patent and Trademark Office told the 75 executives at the conference that

Meet the Press: Issues of press coverage were the most popular topic of discussion at IBA's San Francisco meeting. An aside by Harold Green, warning that the anti-nuclear movement could pick biotechnology as its next target if the industry does not confront the necessity of regulation rationally, became the next morning's headline.

- Existing agencies could take over regulation of biotechnology. Green noted that the U.S. Environmental Protection Agency (EPA) is beginning to do just that under the authority of the Toxic Substances Control Act (TOSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A relatively small amendment to EPA's charter would be sufficient to solidify the agency's authority, Green said, bringing the industry under a well-established, well-understood, familiar, and predictable regulatory wing. This is the course Green favored. An added benefit is that the EPA is itself exempt from the environmental impact provisions of the National Environmental Protection Act (NEPA), the prime legal weapon of Jeremy Rifkin and his Foundation on Economic Trends (Washington, D.C.) as well as the means by which anti-nuclear groups have delayed construction of nuclear power stations until rising costs made the projects uneconomical. Transferring regulatory authority to EPA would not, however, undermine the authority of other agencies like the U.S. Department of Agriculture or the Food and Drug Administration, Green noted.
- Congress could create a new agency expressly to regulate biotechnology. Green said that inventing a new regulatory apparatus from the ground up is an uncertain business. And the creation of a new agency would send a clear message to the public that biotechnology presents unique problems and needs special scrutiny.
- The federal government could establish a new watchdog commission, perhaps on the ethics of evolutionary issues and human gene therapy. This committee—in a way the mirror of the more technically oriented RAC—might begin as an advisory body answering the hard social questions raised by biotechnology. Once such a body had established its moral authority, Green said, it might find that authority expanding to encompass the regulation of commercial applications. This approach, Green warned, could lead to a damaging confusion between day-to-day commerce and the special cases that illuminate fundamental ethical choices. (The RAC is not without its ethical dimension, however. RAC chairman Mitchell said that his commission expects to see its first applications for research on human gene therapy within six months to a year. The committee has already established a two-tier review for such proposals: one tier will consider technical merits, while the other will take up social and ethical issues.)

—Douglas McCormick