costly R&D that leads to innovative products to curb diseases that can not now be controlled.

Anticipation of the administration's health-care reforms alone has already hurt the biotechnology industry, according to BIO president Carl Feldbaum. "The ongoing discussion of price controls has had a serious impact on the availability of capital for our research," he says. "We are seeing biotechnology companies postpone or cut back clinical trials, lay off scientists, freeze employment levels, and forgo building new facilities."

Yet funding for biotechnology has by no means dried up, although public funding has fallen off. According to Ernst & Young (San Francisco, CA), biotech firms raised $5.2 billion from July 1992 through June 1993, 20 percent less than the $6.5 billion raised in the year-earlier period. Firms raised $2.9 billion through strategic alliances, $1.1 billion through public offerings, $459 million through venture-capital financings, $385 million through creative financings, and $356 million through other private financings.

Such funding will peter out, though, if real pharmaceutical price controls materialize, says Stelios Papadopoulos of Paine Webber (New York). "If you want to kill this industry, put price controls on drugs," he says. "They will definitely drive investors into different industries."

—Jeffrey L. Fox

Do U.K. regulations of GMOs hamper industry?

OXFORD, U.K.—European industrialists who complain that European Community (EC, Brussels) regulations are hurting the development of genetically modified organisms (GMOs) have found a new ally in Britain's House of Lords, the upper, unelected chamber of the U.K. parliament. After months of investigation, the Lords' Science & Technology Select Committee has concluded that U.K. regulation of GMOs—which is based on the EC's contained-use and deliberate-release directives—is hampering British efforts to commercialize these organisms. The committee, in a report entitled "Regulation of the United Kingdom Biotechnology Industry and Global Competitiveness," calls for fundamental changes in U.K. regulation of GMOs.

"U.K. regulation of the new biotechnology of genetic modification is excessively precautionary, obsolescent, and unscientific. The resulting bureaucracy, cost, and delay impose an unnecessary burden to academic researchers and industry alike," the Lords' report concludes. Not surprisingly, Europe's biotech sector has enthusiastically welcomed this conclusion.

Industry played a big role in putting together the committee's report, though. In hearings, most of the testimonies were given by industrialists and proindustry academics. Moreover, Brian Richards, chairman of British Bio-technology (Oxford, U.K.) and a well-known critic of the existing GMO regulations, served as the committee's official scientific adviser.

The committee's report comes at a time when GMO regulation is the focus of much discussion in Brussels and Britain. EC officials are currently considering easing GMO regulations. In the U.K., the ruling Conservative Party has established a number of deregulation task forces, including one targeting biotechnology, to cut through the regulatory red tape allegedly holding back industry.

In particular, the Lords' committee is calling on the British government to press for amendment of the EC's contained-use directive "so as to substitute a risk-assessment system in place of the current classification system of risk according to size of operations and pathogenicity." In the short term, the committee recommends that work with GMOs known to be safe should only be subject to notification, "whatever the scale of operations," and that GMO applications should be processed well within the 90 day limit.

Concerning the EC deliberate-release directive and the U.K. regulations based on it, the Lords' committee argues that reforms should be introduced that enable certain activities, as selected by a group of EC national experts, to be exempted from the directive. In the interim, the committee recommends that the number of questions in the risk-assessment applications should be reduced by making them specific to the type of organism involved. Moreover, applications should be processed in not more than 30 days, and universities and research councils should be exempt from paying fees on their applications.

The Lords' committee also believes that the principle of product-based regulation should replace the existing process-based laws. "As a matter of principle, GMO-derived products should be regulated according to the same criteria as any other product," states the committee report. "The present process-based system should be retained only for the limited areas where regulation is required—that is to say, all work involving pathogenic organisms and for deliberate release of GMOs outside the low-to-negligible risk category."

For its part, Britain's Advisory Committee on Releases to the Environment (ACRE, London) is proposing GMO-regulatory measures that are less dramatic. ACRE recently unveiled plans to establish a three-tier system to evaluate GMO-release applications more efficiently. It is proposing that those organisms considered to be potentially the most hazardous receive the most stringent assessments. GMOs not thought to be a hazard, but not so well characterized, will be assessed as they are now. And organisms that are very well understood, characterized, and known not to pose any environmental risks will be assessed by the ACRE secretariat. In fact, ACRE will establish a subcommittee to recommend which organisms can be put through this accelerated approval process.

The proposed system, says ACRE Chairman John Beringer, should allow more resources to be focused on assessing the applications of the potentially most hazardous organisms, while allowing benign or duplicate applications to be processed within 30 days of receipt.

—Mike Ward

"U.K. regulation of the new biotechnology of genetic modification is excessively precautionary, obsolescent, and unscientific."