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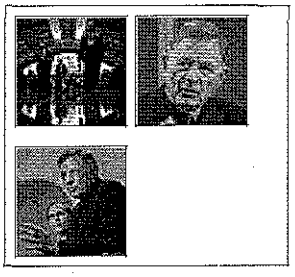
San Francisco Chronicle

The building of biotech 25 years later, 1980 Bayh-Dole act honored as foundation of an industry

Bernadette Tansey, Chronicle Staff Writer
Tuesday, June 21, 2005

Philadelphia -- In 1980, Birch Bayh, a veteran Indiana senator, was defeated after serving 18 years in a job he loved. But in the final hour of a lame-duck session held after the election he lost, he managed to squeak a last bill through Congress.



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Twenty five years later, Bayh is being hailed as a visionary whose hard- won legislation helped create the biotechnology industry by spawning a whole generation of scientist-entrepreneurs.

The Bayh-Dole act allowed universities and their faculty members to stake patent claims on discoveries they made through research funded by such federal agencies as the National Institutes of Health, instead of leaving ownership of the intellectual property with the government.

That change accelerated the use of academic

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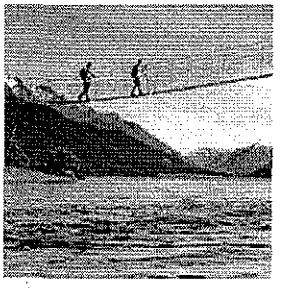

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breakthroughs like gene splicing to develop biotech drugs and other products, giving rise to a three-way partnership of government, universities and startup firms that is "the envy of every nation," said Biogen Idec Inc. Chief Executive Officer James Mullen.

Mullen lauded Bayh on Monday at the Biotechnology Industry Organization's annual conference, BIO 2005. The folksy Bayh, looking out at a sea of faces in the Grand Ballroom of the Pennsylvania Convention Center, said he couldn't have foreseen the full consequences of his 11th-hour victory.

"I don't think any of us who worked so hard to get that passed had the slightest idea we'd be sitting here 25 years later in the birthplace of our country, with all these people created by it," said Bayh.

But while the industry association was celebrating Bayh-Dole's legacy, critics made a case that the 1980 act has had devastating, if unintended, consequences on the integrity of the scientific enterprise.

The unprecedented commingling of the academic and commercial spheres has led to bias in scientific findings, undermined public trust in medical research and tilted universities toward profit-making projects rather than fundamental discoveries, said Sheldon Krimsky, a Tufts University professor and author of the 2003 book "Science in the Private Interest."

"It has resulted in egregious conflicts of interest, especially in the biomedical sciences, and has contributed to the near-extinction of the norm of disinterestedness," he said.

Krimsky points to recent industry controversies over the alleged suppression of drug studies with unfavorable results, and disclosures that academics who serve on influential scientific advisory panels to government agencies like the FDA often have extensive ties to industry.

Manufacturers who fund academic research have sometimes retained the right to veto publication of a university scientist's results, he said.

At BIO 2005 itself, an expert panel grappled with the fallout from accusations last year that manufacturers of certain antidepressants had played down or withheld data showing increased risks of suicide linked to the drugs.

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One drugmaker, GlaxoSmithKline, settled fraud charges by promising to post all data online, and some others followed suit. Prestigious scientific journals are devising rules to guard against selective publication of favorable studies, to the exclusion of negative results.

Bayh, looking back on the genesis of his landmark statute, said it grew out of concerns during the 1970s that the nation was losing its edge in such core industries as automobile and steel production.

At the same time, he recalled, too little commercial use was being made of the thousands of government-owned patents flowing from the billions spent by federal agencies to fund academic research.

"Nobody would spend thousands or millions to get it into your medicine cabinet," said Bayh.

The solution, under the Bayh-Dole act, was to allow universities and their scientists to own the patents and commercialize the inventions themselves.

In what was at the time a revolution in academic culture, faculty members founded their own private firms or granted exclusive licenses to biotech company partners.

Executives on the BIO panel honoring Bayh credited the legislation for academic/industry partnerships that have yielded 60 biotech therapies, including Herceptin, the Genentech Inc. breast cancer drug, and Nupogen, an Amgen Inc. remedy for the dip in infection-fighting white blood cells that can result from chemotherapy.

The BIO panelists conceded that the new world of university-industry collaboration holds the potential for bias or an appearance of bias.

"Conflicts (of interest) are natural products of the system in which we work," said Roger Perlmutter, executive vice president of research and development at Amgen. But such conflicts can be managed by the disclosure of industry connections, he said.

Critics greet that argument with skepticism. They also say Bayh-Dole has achieved the opposite of its stated goals -- that it slows and hampers research toward promising remedies.

Stanford Professor Mildred Cho, associate director of the Stanford University Center for Biomedical Ethics, said genetic research that used to be openly shared is now tied up in patent rights that prevent other researchers from making use of it. Genetic tests that used to be developed quickly from such work are now stymied, one of her research surveys found.

Michael Eisen, a professor of genetics and development at UC Berkeley, said universities are now so eager to reap returns from faculty work that they entangle their researchers in bureaucratic paperwork. Outside firms

seeking to license academic inventions can also be thwarted, he said.

"The companies that are in a position to actually translate academic research into useful therapies or products have trouble negotiating with financially strapped universities who want to recover as much money as they can from their scientists' inventions," said Eisen.

Mining each new scientific technique for royalty fees not only burdens research but also leads to higher health care costs, said Merrill Goozner of the Integrity in Science Project at the Center for Science in the Public Interest.

How far the industry has developed

By 2004, the biotechnology industry that the Bayh-Dole act of 1980 fostered had:

1,444 companies in the United States, 330 of them public

$330 billion in market capitalization

187,500 employees

$42.7 billion in revenue

230 marketed therapeutic products

365 products in late-stage clinical trials.

Source: Ernst & Young

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