



## POLICY FORUM: BIOTECHNOLOGY

# Some History Should Be Repeated

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In the 1970s, a controversial new technology raised specters of Frankenstein's monster, the hatcheries of *Brave New World*, and eugenics. Headlines prompted congressional debate on stringent regulations, moratoriums, and even bans. The "mad science" to which I've alluded is not human cloning, although the same cultural bogeymen have been invoked in that debate, but the science of recombinant DNA. Then as now, critics and politicians feared science was going too far too fast, that we were only the seeming masters of technologies that would overwhelm us and our progeny.

The scientists who discovered and perfected recombinant DNA technology were themselves rightly concerned about safety and ethics. Over the course of several years, they painstakingly wrote protocols by which they could safely and ethically harness the vast potential of the technology to improve the quality of human life. In this journal and others, at the 1975 Asilomar conference, and in discussions with the NIH, thoughtful scientists weighed and debated these issues.

The political debate and media coverage were, however, considerably less measured. "God knows what's going to crawl out of the laboratory!" exclaimed the mayor of Cambridge, MA, in 1976, when the local government passed a moratorium on the technology while a review committee evaluated the danger Harvard's petri dishes might pose to the townspeople.

Of course, what eventually "crawled out of the laboratory" was a series of life-saving and life-enhancing medications and vaccines, beginning in 1982 with recombinant insulin and soon followed by human growth hormone, clotting factors for hemophiliacs, fertility drugs, erythropoietin, and dozens of other additions to the pharmacopeia. Last fall brought the approval of a recombinant product for severe, life-threatening sepsis, the first drug approved for this condition.

We near a critical U.S. Senate policy debate about human applications of somatic cell nuclear transfer (SCNT), or cloning, as it has come to be called. Under threat of an anticloning amendment that would have clogged the legislative works in late Septem-

ber, Majority Leader Tom Daschle (D-SD) promised the Senate's most ardent foe of the technology, Sam Brownback (R-KS), a February or March floor vote on a proposal to criminalize all applications of the technology, whether reproductive or therapeutic. The House last summer passed such a bill, and President Bush commended the action. A Senate vote brings us perilously close to a federal law that would punish scientists who pursue a promising avenue of research with prison terms and large fines.

I am sometimes asked why the Biotechnology Industry Organization (BIO) so passionately supports this research, even though only a handful of our more than 1000 members are engaged in stem cell and SCNT research. We have to be the front line of support research that we consider ethical and in the best interests of patients. Even so, I agree that opposition to some lines of research is appropriate. More than 90% of Americans oppose human reproductive cloning. It is simply too dangerous and ethically questionable. On the day Dolly was unveiled almost 5 years ago, BIO issued a statement opposing reproductive cloning of humans, and we have never wavered from that position.

But therapeutic cloning is another matter. If research succeeds, it could benefit tens of millions of patients worldwide. Research on therapeutic applications of SCNT is an essential extension of basic embryonic stem cell research aimed at generating replacement cells, tissues, and organs. Genetically matched transplants could address some of humanity's most vexing and devastating disorders—Alzheimer's and Parkinson's diseases, diabetes, spinal injuries, liver and kidney failure, and heart disease.

I welcome a thoughtful, reasoned discussion of the ethics and limits of the technology, as well as the appropriate regulation of the research and its eventual clinical applications. But I also hope the media and the Senate will adopt a more reasonable perspective if the eugenics alarm is sounded or if grandiose claims of imminent baby clones are made. The biotechnology community shares the

same goal as most supporters of a ban on human SCNT: the prevention of human reproductive cloning. But where we part company is on the appropriate means of prevention.

Some believe a total ban on the technology is the only way to prevent its misuse. But when it comes to technologies and materials that have both beneficial and harmful uses, laws can be written to distinguish between the two, regulate as necessary and punish violators accordingly. We don't criminalize pain medications because they may be abused by a few, or fertilizer because it can be used to create a bomb. We don't outlaw airplanes because they might be hijacked. We should take the more sensible step of prohibiting only reproductive cloning—that is, implantation of a cloned embryo.

There is another objection to therapeutic cloning experiments, derived from a faith-based belief that the cloned embryo's potential to become a person entitles it to legal and moral status as a person. However, I agree with the opinion that I heard first expressed by Bert Vogelstein in a Senate hearing in December, who reminded his audience of the importance of distinguishing the potential for human life (which is possessed by every cell in a human hair) from actual human life.

To date, biotechnology products have helped more than 250 million people through innovative drugs and vaccines. Twenty-five years ago, when the future of recombinant DNA technology was at stake, hope prevailed over fear, and reasoned debate over sensationalism. We must do our utmost to ensure that history repeats itself in the debate now before us.

## SELECTED RECOMBINANT PRODUCTS FOR DISORDERS AFFECTING LARGE PATIENT POPULATIONS

Product	Company
<b>Diabetes</b>	
Humalog (insulin lispro)	Eli Lilly & Co.
Lantus (insulin glargine)	Aventis
NovoLog (insulin aspart)	Novo Nordisk
<b>Hepatitis B</b>	
Engerix-B (recombinant hepatitis B vaccine)	GlaxoSmithKline
Intron A (interferon- $\alpha$ 2b)	Schering Corp.
Recombivax-HB (recombinant hepatitis B vaccine)	Merck & Co., Inc.
<b>Acute myocardial infarction (heart attack)</b>	
Retavase (reteplase)	Centocor*
TNKase (tenecteplase)	Genentech, Inc.
<b>Rheumatoid arthritis</b>	
Enbrel (etanercept)	Immunex Corp.
Kineret (anakinra)	Amgen
Remicade (infliximab)	Centocor*
<b>Stroke</b>	
Activase (alteplase)	Genentech, Inc.

\*Subsidiary of Johnson & Johnson

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