No stranger to controversy

***Policy Controversy in Biotechnology: An Insider's View* by Henry I. Miller. R. G. Landes Company, Austin, TX, 1997, pp. 221. $69.95 (hardcover).**

Harold Schmeck

Early in 1985, a public health disaster erupted that fit almost exactly the "worst case scenario" hypotheses of the anti-recombinant DNA activists. A young man who had taken human growth hormone as a child to prevent pituitary dwarfism died after developing a fatal, incurable degenerative disorder of the brain. In short order several other cases were found, all linked to the growth hormone treatments. Then still other cases appeared in the United States and in other countries. Dozens of such fatalities developed over the next decade before preventative measures choked off the disasters. A few cases have continued to occur recently because of the years-long incubation period of the infections.

But the "activists" never cited that deadly outbreak in their drive to outlaw gene-splicing and related biotechnology because the human growth hormone that produced the tragedies was *not* a product of genetic engineering. The cause of the disaster was the natural human substance harvested from pituitary glands of people who had died, usually in accidents. One or more of the pituitaries had been taken, unknowingly, from people already infected with the causative agent of the "slow virus infection" called Creutzfeldt–Jakob disease. It was nobody's fault—there was no practical way of detecting the agent in the pituitary tissue.

There is a useful irony to this story. Despite all the dire warnings and predictions from its opponents, recombinant DNA work was not the problem at all. In fact, it was the solution. It has come to the rescue of children all over the world who were threatened with pituitary dwarfism. The artificial, genetically manipulated product was, and is, safe. It was use of the natural biological product that caused deaths. Human growth hormone produced by the biotechnology industry was approved by the US Food and Drug Administration (FDA; Rockville, MD) less than six months after the Creutzfeldt–Jakob cases first came to public attention. The FDA had been debating the approval for many months. The product was produced by recombinant DNA technology. At that time many people saw that fact as a political hot potato. There was a small, but highly vocal, group of opponents of gene splicing work who tried to promote the idea that it was all fundamentally dangerous because DNA manipulations were involved in the production process.

In his book, Henry Miller argues persuasively that the key issue in all such debates is the purity and safety of the product itself, not the process used in its production.

The book is a series of essays on the nation's long efforts to draft policies to govern research and development of products through the new biotechnology processes variously called recombinant DNA technology, gene-splicing and genetic engineering. Basically, he thinks there has been far too much governance and that much of it has been irrational, unscientific, unnecessarily costly, and destructive of the common good.

Miller is a former officer of the FDA. He has indeed been an insider, as the title of his book states. He was the FDA's primary reviewer for the first therapeutic drug produced by molecular genetic techniques for human use. That product was human insulin, which won FDA approval in 1982. He was also the agency's representative for a decade on the RAC, the Recombinant DNA Advisory Committee of the National Institutes of Health. For a long time, the RAC was the main federal overseer of this revolutionary new kind of biotechnology. He is now at Stanford University's Hoover Institution (Palo Alto, CA).

While Miller would no doubt agree that the new biotechnology is revolutionary in its effects and potential, he denies that the process confers any extra risk on its products. They are simply as good or better than the same products produced by more primitive means that are often less predictable in their effects.

Biotechnology itself is one of mankind's oldest enterprises. It goes back at least 6,000 years to the ancient Sumerians and Babylonians who used yeast to brew beer. One could even define it to include most of the food crops and domestic animals on which the world has depended since the Paleolithic age. What is new in the new process of biotechnology is the ability to make the changes deliberately and with hitherto unimaginable precision and predictability of result.

As to the risk that a harmless organism will become dangerous because of the addition or removal of a specific gene through DNA manipulations, he says that kind of transformation is about as likely as it would be for a squirrel monkey to turn into King Kong just by gobbling a bottle of hormones.

He says the seminal issue in the nation's policies on biotechnology is that very "product versus process controversy." Is human insulin or human growth hormone rendered potentially hazardous simply because gene splicing techniques were part of the production process, or should safety be assessed on the nature of the actual product itself?

He credits the FDA with focusing on the product and notes that this rationale has been "validated by near-unanimous scientific consensus and a decade of success" with innumerable safe and effective products that are presently on the market.

Even though the biotechnology industry is demonstrably thriving today, Miller's essays assert that the decades-long fanning of controversy—and the self-defensive responses of bureaucrats—has caused serious and unnecessary delays in the progress of industry and public health, and is still costing the American people a lot of money that could better be spent otherwise. He considers it a harmful and unfair tax on innovation and human ingenuity.

Miller has strong biases and doesn't hide them. It is clear that he considers the Clinton Administration collectively to be the Great Satan. While he concedes that bureaucratic fumbling and stupidities have occurred during both Republican and Democratic administrations, he seems happiest, by far, when denouncing the current regime.

Miller also comes very close to equating the performance of US Vice President Albert Gore with that of Trofim Lysenko, the notorious Soviet agricultural bureaucrat and theorist whose scientifically preposterous ideas fit nicely with Marxist ideology, but came close to ruining all of the USSR's agriculture during the Stalin era.

The book calls for major reforms in the handling of biotechnology matters at the Environmental Protection Agency (Washington, DC), the US Department of Agriculture (Washington, DC) and, to lesser extent, at the FDA and the US National Institutes of Health (Bethesda, MD). But Miller does not seem particularly hopeful that meaningful changes will ever be made.

Some of his denunciations might best be taken with an aliquot of NaCl, but the volume is certainly thought-provoking and well worth reading ///

Harold Schmeck, previously a member of the Commission on Life Sciences of the National Research Council, is retired from the New York Times, and currently lives in Chathamport, MA.