Podcast: Former FDA scientist Henry Miller says misguided regulation keeps safe biotech products off the market

In 1982, the U.S. Food and Drug Administration (FDA) approved the first “GMO” pharmaceutical drug in the world, a new kind of insulin synthesized in genetically engineered bacteria known as Humulin. Insulin demand began to climb rapidly in the 1970s and manufacturers feared they couldn’t produce enough to keep up. Humulin, therefore, was a major step forward for medicine, providing diabetics with a relatively cheap, abundant supply of the hormone.

The new drug was even more significant because it demonstrated the “scientific and commercial viability” of recombinant DNA technology, according to Henry Miller, the FDA biologist who led the agency’s abnormally rapid 4-month review of Humulin. Indeed many drugs, vitamins and food ingredients have been produced with the help of genetic engineering since 1982.

henry miller
Image not found or type unknown
Henry Miller

But “government regulation hasn’t aged as gracefully as genetic engineering technology,” Miller recounted in a 2018 article for the GLP. 37 years after it approved Humulin, the FDA remains extremely risk averse; getting a new drug through FDA approval can take over a decade and cost more than $1 billion. The agency has an even worse record when it comes to regulation of genetically engineered animals, Miller says:

> Regulators have made a horrendous mess of the regulation of genetically engineered animals, which FDA chose to regulate as ‘new animal drugs,’ including a grotesquely prolonged, 20-plus year review of a faster-growing Atlantic salmon …. As a result, the entire biotech sector of genetically engineered animals is moribund.

On this episode of the Biotech Facts and Fallacies podcast, Miller joins GLP editor Cameron English to recount his time at the FDA, detailing his concerns about the agency’s approach to biotechnology regulation. Miller also breaks down the ongoing controversy surrounding GMO food labeling, and explains why the ferocious legal battle over the weed killer glyphosate may have some “tragic” implications for farmers and consumers.

Henry I. Miller, a physician and molecular biologist, is a Senior Fellow at the Pacific Research Institute. He was the founding director of the Office of Biotechnology at the U.S. Food & Drug Administration. Follow him on Twitter @henryimiller

Cameron J. English is the GLP’s senior agricultural genetics and special projects editor. Follow him on Twitter @camjenglish

The GLP's Biotech Facts and Fallacies podcast is produced by Sauce Auxiliary and available for subscription on iTunes and Spotify.