U.S. regulators to blame for lack of progress in biopharming

Dr. Henry Miller's *cri de coeur* is well-earned: he was the founding director of the FDA's Office of Biotechnology (too bad he decided to revert to the private sector, now with the Hoover Institution at Stanford). He points out that, although pharmaceutical biotechnology has largely evaded the cold dead hand of hyper-regulation (think of insulin, e.g., marketed in 1982, and such products now account for over one-fifth of U.S. drug expenditures), in other sectors "genetic engineering has failed to realize anything approaching its potential for vertical progress."

Miller tells it like it is when seeking whom to blame: "The reason is plain: In the non-pharmaceutical sectors, federal regulators for years seemingly have done everything they can to prevent U.S. researchers and companies from employing genetic engineering to create the 'next big thing.'

"'Biopharming' — the once-promising biotechnology area that uses genetic engineering techniques to induce crops such as corn, tomatoes and tobacco to produce high concentrations of high-value pharmaceuticals (one of which is the Ebola drug, ZMapp) — is moribund because of the Agriculture Department's extraordinary regulatory burdens. Thanks to EPA's policies, which discriminate against organisms modified with the most precise and predictable techniques, the high hopes for genetically engineered 'biorational' microbial pesticides and microorganisms to clean up toxic wastes have evaporated."

Read full, original article: Henry Miller in the Wall St. Journal: EPA/USDA strangled biopharming in its cradle