Potentially lifesaving GMO-derived medicines face regulatory roadblocks

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion and analysis.

Obtaining medicines from plants is not new. Aspirin was first isolated from the bark of the willow tree in the eighteenth century. And many other common pharmaceuticals, including morphine, codeine, and the fiber supplement Metamucil, are purified from the world's flora.

More recently, scientists have developed techniques that take this process a step further, using genetic engineering to induce agricultural crops to synthesize high-value pharmaceuticals. Known as "biopharming," the great promise of this technology emerged about 15 years ago, with clinical trials of vaccines and drugs produced in bananas, tomatoes, and tobacco.

One early example of biopharming was the production by the biotech company Ventria Bioscience of rice that contained two human proteins, lactoferrin and lysozyme. Once grown and harvested, the rice kernel is processed to extract and purify the proteins – which are identical to those found in natural breast milk – for use in oral rehydration solution for treating diarrhea, the second leading infectious killer of children under the age of five in developing countries.

But regulators can undo miracles, and they regularly do. When Ventria approached the US Food and Drug Administration in 2010 for recognition that these proteins are "generally recognized as safe" (a regulatory term of art), it received no response. Without an endorsement by the FDA, the company was unwilling to market the product, and so it remains unavailable, tragically depriving children in developing countries of a life-saving therapy.

Read full, original post: Revolution and Reaction in Biopharming