Regulators unreasonably stifling ‘biopharmed’ life-saving drug development from genetically engineered plants

Obtaining medicines from plants is not new.

Aspirin was first isolated from the bark of the willow tree in the 18th 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”, this technology emerged showing great promise about 15 years ago, with clinical trials of vaccines and drugs produced in bananas, tomatoes and tobacco.

Unfortunately, progress has since stalled, owing to the vehement risk aversion of regulators.

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 for use in an oral rehydration solution for treating diarrhea, which is surpassed only by respiratory diseases as the leading infectious killer of children under the age of five in developing countries.

Research in Peru showed that fortifying an oral rehydration solution with the proteins extracted from Ventria’s rice substantially lessens the duration of diarrhea and reduces the rate of recurrence – a near-miraculous advance for people in the developing world.

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.

Biopharming has much to offer us.

If we are to reap what we can sow, however, we will need reasonable, science-based policies from regulators worldwide.

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion and analysis. Read full, original post: Are regulators too cautious about biopharming?