



BIO NEWS

APRIL / MAY 2002

Science Fiction or Scientific Need?

The Case for Plant-Made Pharmaceuticals

By Lisa J. Dry

"Drugs and chemicals will contaminate food supply..." reads the headline for a recent press release from the anti-biotechnology group Genetically Engineered (GE) Food Alert. Scary words intended to incite fear among consumers and concern in the agricultural community.

For more than 15 months a group within BIO's food and agriculture section has been working to prevent the dire event naysayers predict. But even BIO's own members and allies within the food community have been asking why in the world should we grow pharmaceuticals in plants, particularly plants that may also be used for food production? This sounds like science fiction. But in fact, the technology is based on scientific need.

These questions and others were explored at a mid-July conference in Washington, D.C., called "Pharming the field: A look at the benefits and risks of bioengineering plants to produce pharmaceuticals." The meeting was sponsored by the Pew Initiative on Food and Biotechnology, the FDA and USDA.

Speakers made it clear that economics, efficiency and safety are driving the advance of this technology. Biological plants are the most efficient protein producers on the planet, and with research under way on more than 100 monoclonal antibodies (MAbs) as potential therapies, the industry faces a critical manufacturing shortage. Today, just four molecules consume 75 percent of production capacity. The addition of such plants as rice, corn, tobacco and safflower as production facilities can alleviate this shortage.

When capital costs for traditional pharmaceutical products are compared to those of biologics, the need becomes even clearer. Consider that:

- Fourteen percent of treatments in clinical trials today require monoclonal antibodies.
- It takes five to seven years to build a biologics plant (biotech) vs. one to three years for a conventional pharmaceutical plant.
- Today just four molecules consume 75 percent of existing biologics capacity.
- Biotech firms contract out 90 percent of biologics production vs. 55 percent of conventional pharmaceuticals.

As Centocor Vice President for Medical Research Richard McCloskey stated, the top four reasons to make MAbs in transgenic plants are capital avoidance, capital avoidance, capital avoidance and capital avoidance.

But besides economic factors, consider what may be even more important in terms of safety: By creating MAbs in transgenic plants there is no propagation of human pathogens or other mammalian contaminants; no other mammalian contaminants *de novo*; asepsis can begin at purification, not inoculation; and the scale-up utilizes the same technology used in agriculture today.

EpicYTE President Mich Hein predicts 20 to 30 approvals by 2010; his own firm plans clinical trials for a herpes treatment next year. Future applications in development at other BIO member companies include products to address clinically unmet needs in cancer, infectious disease, cardiovascular disease, central nervous system disease, metabolic disorders and inflammatory disease.

The potential benefits of plant-made pharmaceuticals

seemed to impress many at the Pew conference, including industry critics such as the Union of Concerned Scientists, whose representative acknowledged this application has the potential to benefit consumers.

A critical factor in gaining acceptance of this technology is to understand that production methods for plant-made pharmaceutical crops in no way mimic traditional agricultural practices. Comparing production of corn to express a therapeutic protein to corn raised for food consumption is like comparing the careful cultivation of a bonsai plant to large-scale timber production: no resemblance at all.

To this end, BIO and its working group have created a white paper outlining guiding principles to ensure containment of these crops within proper pharmaceutical channels completely outside of agricultural production. This paper is available at BIO's Web site in the food and ag section on www.bio.org.

A webcast of the Pew program is available at www.pewag-biotech.org. ■

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