
Pharmaceutical Industry

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The purpose of the workshop was to discuss each of the issue areas, determine what impact they may have on the successful development of pharmaceutical applications of agricultural biotechnology, and suggest mechanisms to overcome any identified obstacles. Although most of the participants had little pharmaceutical industry background or direct experience with the applications for human health care through agricultural biotechnology, there were a few participants with direct pharmaceutical industry experience. The participants provided “top of mind” contributions to each of the questions and issues raised.

NEW MARKET OPPORTUNITIES

The workshop explored potential applications of agricultural biotechnology to areas such as health care products, test models, nutraceuticals and functional foods, organs and tissues for transplant, high value proteins and complex molecules.

While it was expected that pharmaceutical applications of agricultural biotechnology may provide biotechnology with an improved reputation, a number of serious barriers to development could be forecast. These include the high cost of development and long lead times, multiple regulatory oversight for the products and processes, poor international regulatory standardization, overly broad patent claims (in the US, Japan and Europe), and the genetic source material being located off-shore.

In order to seize the opportunities, it was generally agreed that the educational system and media must be encouraged to raise the level of awareness in the public. Partnerships will have to be created between the marketing and scientific communities as well as between the numerous groups involved in the research, development, production and sales of the products. The North American public is both poorly informed and skeptical about biotechnology, presenting problems and opportunities. Low levels of trust continue to plague the biotechnology industry; however it was felt that a skeptical public will force the industrial and research communities to improve communications skills and develop more suitable messages.

To create successful market opportunities, it was felt that the initial focus should be on preventative versus curative products. The university research community should consider establishing multidisciplinary teams, as is done in industry, to ensure cross-fertilization of ideas and the development of non-traditional solutions to barriers. Information provision was seen as a priority, with a need for immediate development of education programs to raise the level of public awareness.

SOCIETAL ISSUES, REGULATIONS, AND ETHICS

Much of the workshop discussion revolved around the public concerns of biotechnology such as the safety of products for the environment and human health, the perceived lack of public/individual control over product development and consumer choice. It was noted that pharmaceutical applications of agricultural biotechnology will likely be seen as beneficial for human health but, at the same time, may be seen as detrimental for animal welfare or environmental impact. The public was seen as supportive of crop and income diversification for the primary producers yet concerned about multinationals controlling both the genetic material and farmers growing the proprietary strains under contract.

While there were only minor regulatory gaps recognized by the workshop, such as the premarket regulation for foods, additives, and supplements in the US, several important regulatory issues were identified. The regulatory scene lacks international harmonization and approval times appear excessive. Since health claims cannot be made on food products (except physiological claims such as dietary fiber), North American regulations are not as supportive of functional foods as other jurisdictions in Europe or Asia. Regulatory change should be considered to meet the increasing consumer demands for access to the functional food category.

Ethical considerations raised related mainly to special-interest groups involved in animal welfare. Animals used as factories for production of complex proteins as well as organ donors for transplant were considered the most likely targets for activist concern. The farmers involved will probably be subjected to increased interest from media as such products become more widely known.

Access to and compensation for countries that own useful genetic resources (mostly the developing nations) was seen to be an issue; however, no specific recommendations were tabled. The Convention on Biological Diversity addresses this issue. The existing agreement between Merck and Costa Rica was considered one possible approach.

ECONOMIC AND STRUCTURAL ISSUES

Pharmaceutical applications of agricultural biotechnology are expected to increase rural job creation, diversify farm incomes with high value crops, and introduce new domestic and export market opportunities. However, in comparison with other applications of agricultural biotechnology, only a small segment of the farm community will be affected by the development of pharmaceutical applications. Relatively few farmers will be required to supply the worldwide market for such pharmaceutical products. Those farmers who are involved will be subject to increased tracking, monitoring and evaluation, and may become closely aligned with, if not employees of, large multinationals.

The development of unusual alliances will result as the traditional lines between agriculture and health care begin to erode. Pharmaceutical, seed, food distribution and food processing companies will work together with health care professionals and farmers. Also, health care funding may begin to be accessed by the agricultural research community. New partnerships will develop for research, education, communications, and marketing. The structure of farms will change with vertically integrated "high tech" small farms. The farming profession will become management intensive with unusual market regulations for farm products such as vaccines and nutraceuticals. The main challenge will arise from quality control product issues.

Information provision was seen as a fundamental requirement to ensure the eventual success of agricultural biotechnology applications. The entire biotechnology community must become communicators by developing concise messages in lay terms, delivering these messages at every opportunity and, where possible, through credible organizations. Mass and electronic media, local government representatives and the educational establishment should be utilized to get the message out. The development of a continuous educational system with credits, similar to the one existing for physicians, should be established for pharmaceutical farmers. Additionally, a group called "Brokers for Communication" should evolve to distribute information not only to the public, but also to the pharmaceutical farmers, educators and others. And, finally, the information materials must include details on the intent of the application or product, how it will benefit the user, the risks associated with its use and the mechanisms in place to manage the risks.

The group's recommendations include:

- Develop educational instruments to improve the level of awareness in the public, the media, the farming community, and the pharmaceutical, food processing, and retailing industries.*
- Information materials must describe the intent, benefits, risks, and risk management mechanisms.*
- Regulatory change should be considered to meet increasing consumer demands for access to the functional food category.*
- NABC member institutions should promote workshops and other related activities for dialogue between the agri-food and health care communities, academics, and the public.*
- Participation of industry representatives at NABC meetings should be encouraged.*
- NABC member institutions should encourage graduate students and post docs to attend NABC meetings by covering their costs.*