Regulating Biotechnology: Science, Ethics, Law, and Governance Meet Head on in the Age of Informed Ignorance

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REGULATING BIOTECHNOLOGY: SCIENCE, ETHICS, LAW AND GOVERNANCE MEET HEAD ON IN THE AGE OF INFORMED IGNORANCE

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I. INTRODUCTION

It has been five years since the cloning of 'Dolly' the sheep and only two years since the unveiling of the completed map of the human genome. In that short time, these and dozens of other major breakthroughs in the biotechnology industry promise to revolutionize not only the business of applied science as we know it, but our understanding of the world around us. Yet, as new biologic technologies explode into new industrial and agricultural applications, governments fall further behind in terms of their understanding of these technical innovations and their confidence to regulate them. As the Age of the Machine slowly gives way to the Age of the Gene, there is scarcely time to consider the larger possibilities, risks, and implications these new technologies present for all of us. Yet nothing is more essential for regulators, consumers, and the biotechnology industry itself.

Governments have been ill-equipped (and understandably reluctant) to engage the difficult technical and ethical issues presented by biotechnological innovations such as cloning, stem cell research, agricultural transgenics, and the like.[5] Thus, technological innovation has been stymied by bad public relations, understaffed regulatory authorities lacking clear mandates, uninformed legislatures, and miscommunication on all sides.

Governmental regulation of biotechnology will expand as the industry grows and applications for new technologies become increasingly universal. Currently, lawmakers and regulators are highly *reactive* to advances in technologies that appear strange (*i.e.* have a high "weird quotient") or that promise to offer biological drug applications —especially those that might benefit only a small number of whom many anti-biotech activists prefer to describe as "wealthy elites." As biotechnologies evolve, regulators will be forced to become more *proactive* and anticipate how to address breakthroughs which could lead to broader applications.

II. FARMACEUTICALS OR FARMAGEDDON? MOLECULAR FARMING: TREMENDOUS POTENTIAL AND TREMENDOUS OPPOSITION

One of the most promising examples of a growing new sector in the biotechnology industry is molecular farming (or "biopharming"). Molecular farming has garnered increased attention from the media after a string of breakthroughs over the past year.[6] These breakthroughs, however, have increased awareness of the technology and increased corresponding levels of

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[5] *See America's Next Ethical War*, ECONOMIST, Apr. 14, 2001, at 10.

[6] *See* Sharon Begley, *Cloned Calves May Offer Cures for Many Ills*, WALL ST. J., Aug. 12, 2002, at B1; Ken Belson, *Using Corn-Based Plastic, A Laptop Starts To Go Green*, N.Y. TIMES, Aug. 1, 2002, at G3; M.E. Malone, *Scientists Focus On The Tobacco Plant As A Possible Cancer-Fighter*, BOSTON GLOBE, Feb. 5, 2002, at C1; Aaron Zitner, *Fields of Gene Factories*, L.A. TIMES, June 4, 2001, at A1.

opposition from consumer activist groups that attempted to thwart the agricultural biotechnology advances of the 1980s and 1990s.[7]

Regulators need industry to answer the following questions:

(1) What is this new technology, and how would it be used?

(2) What potential benefits does this technology offer?

(3) What risks might it pose?

Molecular farming offers a timely case study as to how the answers to these questions may be presented to regulators and other law makers for any new biotechnology. The biggest risk to the molecular farming industry is that it will fall into the same trap the food biotechnology industry fell – underestimating potentially hostile public reaction.

III. NEGOTIATING THE PUBLIC POLICY MINEFIELD

A. The Importance of the "Public" Part of Public Policy

The entire chain of commerce must be aware of emerging trends in biotechnology, be informed of the consequences of using or not using the technology, and be aware of public opinion surrounding those technologies. To thrive, industry must control the message with a firm, sure, confident hand, and with an offensive, rather than defensive posture. Agricultural biotechnology has been subjected to successful, sustained attack for the better part of the past decade, not because science has rendered any negative verdict as to safety (in fact, quite the opposite is true), but because the activist community reached the public first with a far more persuasive and, this is critical, a more passionate and "user-friendly" argument than has industry.

B. Identify the Appropriate Administrative Bodies

When regulations are established for a new technology, the innovating industry must police itself in order to maintain its regulatory good standing. If even one company in the chain of commerce fails to follow the regulations, it can tarnish the credibility and the image of an entire industry. In the U.S., products are regulated according to their intended use, with some products being regulated by more than one agency.[8] State counterparts of these

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[7] *See* Alan Simpson, *A First Victory Against Those Who Want To Play God*, EVENING STANDARD, Feb. 10, 1999 ("Across the world there are citizens' movements kicking against [genetically modified (GM)] grain. I've just come back from India where the 'cremate Monsanto' campaigns of farmers and peasants are burning down fields of GM crops. In France, farmers in the Farmageddon Movement ploughed up GM fields.").

[8] *See* United States Regulatory Oversite in Biotechnology, *at* http://www.aphis.usda.gov/biotech/OECD/usregs.htm#usdalaws (last visited Apr. 10, 2003)

agencies also may regulate biotechnology.

i. FDA

The FDA governs the safety and labeling of drugs, food and feed, excluding meat and poultry. The FDA ensures that foods derived from new plant varieties are safe to eat, holding them to the same high standard of safety as traditional food products. The FDA may impose restrictions on commercial growing conditions for pharmaceutical and biologic products derived from plants as part of its enforcement of current Good Manufacturing Practice (cGMP) requirements.[9] The mechanism to prevent contamination of food crops is imperfect, but the FDA's authority to act against any regulated products that may become "adulterated" as a result of activities relating to field-testing is not in question.[10]

ii. USDA

The USDA's Animal and Plant Health Inspection Service (APHIS) requires permits for the movement and release of any genetically engineered organism that is a potential plant pest.[11] Applications must receive the concurrence of the department of agriculture in the State in which the environmental release is planned. The permit designates conditions for environmental release.[12] "Risk mitigation" measures are applied according to crop (*e.g.*, barley, rice, corn) because of the unique properties associated with different plants.[13] On August 2, 2002, the USDA announced the creation of a biotechnology unit within APHIS to focus on the USDA's role in regulating

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(providing a chart showing the types of products which are regulated by each agency and sources for more information); *see also* United States Department of Agriculture, *Agricultural Biotechnology*, http://www.usda.gov/agencies/biotech (last visited Apr. 10, 2003).

[9] 21 U.S.C. § 351(a)(2)(B) (2000).

[10] 21 U.S.C. § 342. This provision generally refers to a state in which the quality of a food article is impaired by the introduction of a foreign substance to an extent that makes it unacceptable, in fact, or as a matter of law.

[11] *See* 7 C.F.R. § 340.0 (2003) ("Restrictions on the introduction of regulated articles"); 7 C.F.R. § 340.1 ("Definitions"); 7 C.F.R. § 340.4 ("Permits for the introduction of a regulated article").

[12] *See* Animal and Plant Health Inspection Service, *Information on Field Testing Pharmaceutical Plants in 2002*, May 21, 2002, *available at* http://www.aphis.usda.gov/ppq/biotech/pdf/pharma_2000.pdf.

[13] For example, to minimize movement of transgenic pollen and possible physical mixing of transgenic corn crops, applicants are required to: (1) plant the transgenic corn at sites that are at least 1 mile away from corn seed production (*e.g.*, breeders, foundation, certified, and registered); (2) ensure that any corn from previous seasons is harvested and removed in a radius of 0.25 mile of the transgenic corn plot, before the transgenic corn is sown; and (3) the land within 25 feet of the transgenic plant area must remain uncultivated during the test. Additional requirements for corn and other crops include the employment of buffer strips, bagging the floral structures of the plants, and post-harvest land use restrictions.

biotechnology.

iii. EPA

The EPA approves new herbicidal and pesticidal substances and issues permits for large scale testing of herbicides and biotechnology-derived plants containing new pesticidal substances. In deciding whether to register a new pesticide, the EPA considers human safety, the fate of the substance in the environment, the safety for humans, its effectiveness on the target pest, and any effects on other "non-target" species.

iv. State Laws

States may inspect and monitor field tests of genetically engineered crops. Currently, there are no specific state laws concerning field-testing of pharmaceutical crops, although some states have adopted anti-crop destruction legislation (*e.g.*, Arkansas, Idaho, Iowa, Mississippi, Missouri, Montana), which heightens the penalties for the vandalizing and willful destruction of agricultural facilities or products, including those intended for research purposes.[14] Civil liability in tort may also attach for injury caused to food crops by contamination with genetic material not approved for use in food.

v. Laws in Other Markets

If a food is in compliance with the Federal Food, Drug, and Cosmetic Act, there are no restrictions to its movement in interstate commerce, including for export. Unfortunately, many countries do not accept imported foods solely on the basis that they are in compliance with U.S. law when exported.[15] Approximately 20% of all corn grown in the U.S. is exported. If the major trading partners of the U.S. are unwilling to accept shipments of corn that contain detectable quantities of genetic material from crops modified to produce pharmaceuticals, demand for U.S. corn will decrease with negative consequences for farm income. At the very least, expensive testing protocols would be required to assure foreign purchasers that the commodity offered for import is not adulterated under their legal standards.

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[14] Information obtained from the Pew Initiative on Biotechnology, a project of the University of Richmond, *available at http://pewagbiotech.org/.*

[15] The Federal Food, Drug, and Cosmetic Act (FDA's governing statute) permits the export of adulterated and misbranded food under certain conditions. Key among those conditions is that the substance is not in conflict with the laws of the country to which it is intended for export. 21 U.S.C. § 381(e)(1).

C. Engage Likeminded Actors for Additional Input

Industry can control the public's reaction to a new biotechnology by obtaining an independent scientific analysis of the crop in order to reassure the government of a product's safety. While biotechnology companies are well advised to engage independent bioethics experts, in-house bioethics advisory boards can be seen as biased by their corporate paycheck. The real danger, however, is that the corporation will be perceived has having used bioethics experts as window dressing.[16]

D. Consumers

Consumers will embrace biotechnology only if and when they are convinced that it is beneficial, ethical, and safe.[17] One of the principal difficulties with which the biotechnology industry must contend is the widespread lack of public understanding of the benefits of genetically modified crops. Industry must persuade the public that a new biotechnology will benefit them in a variety of important ways. These benefits should be communicated to the consumers through a credible, and preferably independent, source.[18] The biotechnology industry must take the public's perception of even hypothetical risk seriously. Industry should accept the reality that ensuring public support is a two-front war, and winning the science while losing the public relations battle is worse than a pyrrhic victory, it is a defeat.[19] The introduction of stem cell research and human cloning has added another dimension to this increasingly high-stakes game, the question of whether or not a new technology is ethically and culturally acceptable and appropriate. Consequently, whether we like it or not, viable market analysis must necessarily take into account these issues.

Only through open communication will public concerns be properly heard, interpreted, understood, and addressed. One of the major flaws in the industry and government strategy toward food biotechnology was assuming that a flurry of polls proved beyond doubt that consumers mistrusted biotechnology and wanted labels. The industry cannot afford a repetition of the dynamic we have seen the past decade, where activist groups successfully portrayed industry's marketing of transgenic food as a cynical effort to turn

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[16] *Bioethicists Fall Under Familiar Scrutiny*, N.Y. TIMES, Jan. 8, 2002.

[17] *See* Thomas Jefferson Hoban IV, *Education Required for Animal Biotechnology*, NC State University, *available at* http://www4.ncsu.edu/~hobantj/biotech/Education%20Required..pdf (last visited Apr. 10, 2003).

[18] *Id.*

[19] *See* Peter A. Singer & Abdallah S. Daar, *Avoiding Frankendrugs*,18 NATURE BIOTECHNOLOGY 1225 (Dec. 2000), *available at* http://www.biotech-info.net/frankendrugs.html.

consumers into guinea pigs.

E. Activists' Interests

Much to the chagrin of many a well-meaning policy maker and corporate strategist, it has been demonstrated with depressing clarity that some activist groups are not concerned with facts and engage in intellectual (and not so intellectual) jujitsu to obfuscate, confuse, and distort reality beyond recognition. Some of these groups, predictably, have already begun to attack biopharming. Warning against another StarLink™ incident, a report prepared by the Genetically Engineered Food Alert coalition details the threats that biopharmaceutical and biochemical crops pose, the extent to which they have been planted across the U.S., the failure of regulatory agencies to serve the public, and a set of recommendations.[20] Friends of the Earth called for a ban on biopharming of food crops before the facts were out regarding the Prodigene biopharming episode in November 2002. Many of these groups are concerned (not without some justification) that once planting and production begins, the transgenic plants may find their way into the food supply. It is far better that industry and government get in front of this issues and take this opportunity to publicize facts and explain to the public how potential risks will be addressed.

IV. GOING GLOBAL: THE PAST IS THE KEY TO THE FUTURE FOR PHARMACEUTICAL BIOTECHNOLOGIES IN EUROPE AND ASIA

Chinese policies toward products directly processed from transgenic agricultural products are notoriously opaque. While the regulations do list what tests must be completed and what approvals must be obtained, the regulations do not specify what the tests entail or what information must be supplied to obtain the necessary approvals. Further regulation and legislation is "under development."

Americans are familiar with European Union reticence to embrace new biotechnological innovations. After a string of food safety scares, including mad cow disease, European public opinion is wary of gene-altered crops and has supported a three-year de-facto ban on approvals of new "GM" varieties.[21] The "precautionary principle" frequently requires these new technologies to

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[20] *See, e.g.*, Bill Freese, *Manufacturing Drugs and Chemicals in Crops: Biopharming Poses New Threats to Consumers, Farmers, Food Companies and the Environment*, FRIENDS OF THE EARTH, July 2002, *available at* http://www.gefoodalert.org/library/admin/uploadedfiles/Manufacturing_Drugs_and_Chemicals_in_Crops.doc; *see also* Aaron Zitner, *Fields of Gene Factories*, L.A. TIMES, June 1, 2001, at A-1, *available at* http://www.centerforfoodsafety.org/inthenews/latimesjune4.htm.

[21] Veronica Brown (Reuters, London), *Aventis Sees Swift Restart for UK Gene Crop Trial*, AUSTRALIAN BIOTECHNOLOGY NEWS, Aug. 29, 2002.

be suppressed until they can be tested for unexpected, unknown risks.[22] The logical conclusion, of course, is that European hyper-caution could lead to the indefinite postponement of new marketable technologies.

Molecular farming straddles the line between food and pharmaceutical biotech, so it could easily fall victim to a pandemic of preemptive caution unless the biotechnology industry develops and pursues international strategies for harmonizing legal, ethical, and regulatory principles conducive to the responsible development of these revolutionary technologies around the globe. The realities of globalization and increased market integration, coupled with the explosive growth in biotechnological advances, however, demand some shorter-term strategies.

A. Strategic Partnerships

Developing strategic partnerships with European and Asian biotech interests may smooth the path for introducing new technologies in these regions. It is essential to develop these relationships, otherwise less inviting markets may be more favorably disposed to doing business with foreign biotech companies. One of the major reasons many countries outside the U.S. are wary of biotechnology imports is the potential for "crowding out" local agriculture or industry. Soliciting strategic partnerships neutralizes this concern.

B. Controlling the Message from the Beginning Is Essential

When citizens' reactions in 25 developed and developing countries were surveyed by a Canadian public environmental policy firm, many people had favorable attitudes toward the use of biotechnology to grow pest resistant crops that require fewer chemical pesticides or to develop new medicines and treatments for human diseases.[23] Educating the people and the governments of these countries about biotechnology and its benefits can greatly increase its acceptability. As noted earlier, it helps to get your message out unfiltered, rather than attempting do so in a defensive, reactive mode after the damage has been done.

V. WHERE DO WE GO FROM HERE?

There are no quick and easy solutions to the public policy quagmire that has

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[22] Robert L. Paarlberg, *African Famine, Made in Europe*, WALL ST. J., Aug. 23, 2002, at A12.

[23] *See* Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L. J. 47, 88 (Winter 2001) (citing the Environics study).

developed over the course of years and which has engendered angst, anger, and fear. That said, there are some straightforward recommendations that should at the very least help animate the thought processes of the key actors in this bioethical, sociopolitical psychodrama.

The biotechnology industry stands on the cusp of some of the most inspiring and far reaching technological developments in human history. What it must now do is establish a dialogue with consumers, the end users, and persuade them that the technology brings with it tangible benefits, to health and the environment.

The food and related industries will eventually have to appreciate the fact that activist-driven objections to biotechnology are not unique, and placating opponents on this issue will bring no long-term benefit. Quite the opposite; the template used by Greenpeace, Friends of the Earth and others to discredit biotechnology can be replicated for any innovation that the creative mind can conjure.

The anti-biotechnology activist community is a divided lot. There are groups with legitimate concerns, and these deserve to be addressed. The more vehement of the groups are chameleons, changing their rationale for opposition to suit the circumstances, public relations and otherwise. What is so profoundly frustrating is that there are far nobler causes out there, crying for their seemingly boundless energy. One of them has poignancy here. It turns out that, if the famine situation in sub-Saharan Africa is not resolved soon, the continent can kiss goodbye the potential of effective antiretroviral therapy (ART) for AIDS. There are numerous credible accounts of HIV-infected people in Africa who receive ART (amazing in and of itself, given how expensive and scarce these drugs are) but who, one month later, return with nearly full containers of pills. When their doctors ask why they haven't taken their pills, the patients point to the drug usage label that says, "take with food."[24]

The European Union, which is the front of most of the regulatory ferment surrounding biotech foods, presents an exceedingly difficult set of problems. In its zeal to placate the powerful anti-biotech constituency in Europe, the European Commission developed a food labeling and traceability proposal that manages to create a bright line between American-made snack foods containing ingredients that contain no detectable transgenic protein or DNA (labelable), and wines, cheeses, beers and other delicacies, made in Europe, that might just as likely have been the product of equally undetectable transgenically produced enzymes used as processing aids (not required to be labeled).

The problem with Commission's logic is that, if there exists an ethical responsibility on the regulatory apparatus to ensure that the consumer is allowed to make an informed choice about transgenic foods, where is the line

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[24] In an unfortunate irony, one of the reasons the famine in southern Africa is so severe is because many African nations have felt pressure to refuse food aid from the United States because it may be genetically modified. *See* Robert L. Paarlberg, *African Famine, Made in Europe*, WALL ST. J., Aug. 23, 2002, at A12.

drawn at the right to know? Between soybean oil in a corn product made in the U.S., and a block of cheese manufactured via recombinant chymosin?

The American regulatory system, thought not without its flaws, enjoys a greater degree of public confidence than any other in the world, and will have to remain consistently grounded in a commitment to impartial scientific evidence in order to maintain that credibility.

Regulatory bodies in the developing world are well advised to study carefully both the successes and the mistakes of their counterparts in the U.S. and Europe. For the rest of the world, which is viewing this debate at a distance, it is past time to become actively engaged and involved. This is one of those once-in-a-generation issues that involves far more in its intricate web than the mundane questions of agriculture, food and politics. It is, in a very real sense, a debate about whether we choose to live in ignorance while we are drowning in information, or whether we will wake up and realize that within our grasp are miracles as well as risks, and that a civilization blessed with the genius to conceive and realize such wonders has the capacity to properly regulate and manage those risks, and in doing so leave for its posterity a greater legacy than that left by the past century.