Public Values and Risk Assessment

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I want to begin by discussing Henny Penny.[1] To the best of my knowledge, she has not been patented nor is she a registered trademark, but as is appropriate for my presentation, she is eminently in the public domain. This story may be one of the first encounters most of us have had with the values relevant to risk assessment and since most public presentations about risk are in the form of stories, albeit television or newspaper, it may help to remind ourselves how well this childhood pastoral legacy fits present day circumstances.

You know the story. Henny Penny is in the barnyard when suddenly she is hit on the head by an acorn. She immediately assumes the sky is falling and that she must hurry to tell those in authority. She recruits a number of her companions to join in the mission. On the way she and her friends are seduced by a wily fox to take a short cut from which she and her friends are never heard from again.

It presents a role model which derides conclusions based upon a foolish reaction to Nature because this response leads to even greater disaster. Nature is very regular; she does not play tricks such as sending the sky to fall like rain and we can depend on that when we try to figure out what is going

[1] Presently there are 10 listings for this story in Canada and 8 in the United States in current *Books in Print.*

on around us. True natural events which can be very destructive are not ruled out, but we can deal with these precisely because they are a part of common sense understanding of what the world is about. We must respect and can trust nature in its untampered state.

The presence of technology has altered this picture. Based on science, it tries to harness nature's regularity and tame her power to produce predictable outcomes upon which a host of human activities can be formed. On this view, animal domestication maybe one of the earliest examples of a technological change being imposed upon the natural world. Bronowsky (1973) has argued that the discovery of a cultivatable form of wheat is one of the primal discoveries of civilization. But there is a slight caveat to which I would like to call your attention. Most people do not view the domestication of animals or the discovery of wheat as technology. They see it as an example of human ability to exploit natural abundance, fundamental to the Story of Creation which gives biblical authorization to pastoral goodness. A contemporary example of how pervasive this attitude is, is found in Michael Fox's introduction to his book, *Superpigs and Wondercorn: The Brave New World of Biotechnology...and Where It All May Lead* (1992). In it he describes the need to repair "this dispoiled planet" and the need to "dress and keep" the Garden of Eden.

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The views just presented are not easily reconcilable. They offer conflicting approaches to the course of human life. Most Americans know little of the history of science and technology. What for the average North American resident symbolizes the state of contemporary agriculture as well as what to expect from biotechnology consists of a brew of naivete and skepticism—Arcadia or the Monster. It is not hard to find vestiges of this style of moral understanding in current conflicts over the licensing of agricultural products having biotechnological modifications.

Here are three illustrations which I believe represent current versions of this state of Americana: First, there is the belief that if you grow something, it represents contact with a reality absolutely fundamental for human existence. Apartment dwellers with their three tomato plants 30 stories above the street can really get into this business of growing things. (Of course, it may also be a last desperate attempt to find a replacement for the wooden tomatoes which adorn the average salad.) At this level, these plants can signify a desire to maintain one of the last vestiges of the pastoral dream from which most of life has been wrenched—roots, if you will.

Second, there is the paradox inherent in the abundance which North American agriculture exemplifies. On the one hand, the industry remains one of the major unsolvable problems for modern governments, far outstripping the complications currently posed by the challenge to transform our defense industry. On the other hand, this politicalization of agriculture has succeeded in disillusioning the very people who wallow in its largess. The difference in the effectiveness of the pork barrel in determining agricultural policy, while at the same time the failure of legislators to protect the consuming public from the risks inherent in the raising and preparation of food for consumption, has not gone unnoticed, *viz* federal inspection of the meat packing industry.

Third, the effects of biotechnology as it applies to agriculture are a source of concern both rational and irrational. There is a real ignorance of science and how it works especially as related to probability. There is a belief that the effects of biotechnological manipulation pose a risk for a possible but unknown catastrophe. To the extent that the changes biotechnology proposes initiate an element of risk to those who use its products, they demand a form of control unknown to the simple morality of a pastoral ideal in conflict with an apocalyptic vision of a mechanical universe which would destroy the Garden. To the extent that the present effectiveness of the protective role of government has a high failure rate with no attribution of responsibility, there is real fear as to what Food and Drug Administration (FDA) approval means in terms of protecting the consumer. This view of the failure to protect from risk can be dismissed as the continual failure of moral politics to understand and regulate the new face of agriculture. Finally, the extent to which contemporary patterns of food distribution make it difficult for the average person to chopse on the basis of accurate information—increases the paranoia of a public ignorant of science and fuels the notion that current regulatory procedures controlling agricultural biotechnology are untrustworthy.

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That Americans were far from being prepared for a change of moral climate was suggested in 1964 by Leo Marx in his monograph, *The Machine in the Garden.* His review of American literature from the colonial period to the present day suggests that we are stunned by the magnitude of the protean conflict figured by the machine's increasing domination of the visible world. This recurring metaphor of contradiction makes vivid, as no other figure does, the bearing of public events upon private lives. It discloses that our inherited symbols of order and beauty have been divested of meaning. It compels us to recognize that the aspirations once represented by the symbol of an

ideal landscape have not, and probably cannot be, embodied in our traditional institutions. It means that an inspiriting vision of a humane community has been reduced to a token of individual survival. To change the situation we require new symbols of possibility, and although the creation of these symbols is in some measure the responsibility of artists, it is in greater measure the responsibility of society. The machine's sudden entrance into the garden presents a problem that ultimately belongs not to art, but to politics (Marx, 1964).

CLUES FROM BIOETHICS: INFORMED CONSENT

As I see it, the challenge presented by the new age is to transform our simplistic view of moral conflict with a nuanced theory of ethical accounting. It requires vocabulary which reflects awareness of the content of the public values just presented and a theoretical structure that incorporates the reason of science into our political reality. The paradigmatic instance of this change is played out in the history of bioethics over the last quarter century. Now a mature enterprise, lessons from what has happened in medicine may provide some clues as to how traditional moral responses to biotechnology might be recast in a mold which will resolve current social deadlock.

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The history of bioethics has been covered elsewhere (Clouser, 1970). For our purposes, I would emphasize its source in the awareness that *individuals* have the *right* to be protected from exploitation by those who are offering them medical care and treatment. Over the years, a series of cases have helped delineate the circumstances under which this protection should apply (NIH, 1980). The result has been the creation of a working system whereby technology is supported at the same time protecting those who would be its beneficiaries or its victims (e.g., Halushka vs. University of Saskatchewan, 1965). In the center of this system has been FDA. There are three tiers to this system which are indispensable to its functionality: Tier One—the establishment of ethical principles which must be realized in action; Tier Two—the demand that all activity must be backed by data which has been subject to the statistical demands demanded by contemporary science; and Tier Three—the development of a process whereby the first two criteria may be acted upon. In addition, and indispensable to the working of the system, is a definition of roles which separate the function of regulatory as opposed to developmental responsibilities. Let me describe in more detail the constituents of this practice:

Tier One

The establishment of ethical principles which provide a moral arena for action

Here the dominant normative force has been autonomy. Functionally, this has led to the enshrinement of informed consent as its most important ex-

pression. Subject to a caveat covering emergency treatment for children and the mentally incompetent, every act with its costs and benefits must first be understood before being accepted by an individual patient. The extension of risk to patients other than mentally competent adults is severely restricted to those interventions for which the benefit is clearly demonstrable. As it has developed, the practice of principled action has been most completely explored as it applies to individuals. Principles governing society, such as justice and fairness, have only recently been the subject of more sophisticated attention, particularly as it applies to the availability of health care. Here it is obvious that notions such as that of "the common good" are highly controversial and the sharing of both costs and benefits has proved highly difficult to implement in a socially acceptable manner.

Tier Two

The requirement that all projected actions must be the subject of investigations which produce data conforming to current scientific practice as regards statistical probability is essential to developing a meaningful cost/benefit analysis. Of more than a little interest to those concerned about the effects of biotechnology are the practices which cover the development and use of new drugs. The three-phase trial system which moves from animals to human subjects is used to determine general parameters of risk and efficacy (NIH, 1977). Only after passing all three phases can a drug be licensed for the task for which it was tested. This system is not perfect, but its shortcomings have not prevented it from working. Of some concern is the practice of using only adult males in the Phase 3 trials, the final step before licensing. The failure to include children, women and the elderly in these protocols has led many to question the conclusions, particularly about dosage and side effects which are included in the approval documentation. The practice of asking physicians to report adverse effects as they occur in the "field" has only been partially successful in developing a more complete dossier about each drug.

Tier Three

The development of a process through which principles may be combined with data to produce a distribution system which is safe within defined limits acceptable to the consuming public is the final component in the practice Institutional Review Boards (IRBs) must review all trials using human subjects for both scientific merit and ethical responsibility (Levine, 1961). The record has been neither incident nor scandal free.[2] There was the famous thalidomide affair and perhaps more to our concern, the cancer risks to the daughters of mothers who had been prescribed diethylstilbestrol (DES) during

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[2] The most outspoken of recent critics has probably been Ivan Illich. c.f. *Limits to Medicine: Medical Nemesis: The Expropriation of Health.* McClelland and Stewart, Toronto, Ont. 1976.

pregnancy as an attempt to avoid early miscarriages (Potter, 1991). There have been detractors who insist that the present system is far too conservative in a time of crisis such as that produced by AIDS. Nonetheless, it is critical not to lose sight of the core process. It is the principle of informed consent. This has allowed for the implementation of such widely differing practices as giving bioengineered growth hormone to children, gene therapy for cancer, and xenografts from hogs with transgenically altered immune systems. Each individual can in theory and in practice, supported by social consensus, assume risk because each is free to choose whether or not to receive defined benefits. Consent is also understood as a process with several gradations—with increased risk in relation to benefit requiring more awareness of what is being accepted.

The additional element in the practice just described is what, I believe, accounts for its level of public acceptance. This is the attempt to separate regulatory responsibilities from developmental functions—the role of government as distinct from that of industry. Jane Jacobs in her recent book, *Systems of Survival-a Dialogue on the Moral Foundations of Commerce and Politics* (1992), argues that these groups represent two distinct modes or syndromes, the Guardian and the Commercial, which are essential to the functioning of human society. The first, guardianship, arises from the behavior which we share with animals—foraging for food and protecting our territories. Guardians work in the armed forces and police, government ministries and their bureaucracies, legislatures, courts and organized religions. The second, Commercial, arises from trade and production of goods and is an endeavor unique to human beings. These two modes of survival have produced two discrete and contradictory ethical systems and are the source of conflict when the precepts appropriate to the guardian system are imposed on the commercial and vice versa. In its everyday functionality, this means that drug companies are free to be as inventive as possible—expressed as profitability—so long as they operate within the structures and regulations designed to protect society. But, and this is a major qualifier, the individual (a patient in this case) is still free to determine whether he or she accepts the risks and benefits made available by this symbiotic structure. In the case of health care, the point where this assumption of risk and benefits occurs is not in terms of a market relationship, but as informed consent. As we turn to the matter of agricultural biotechnology, we encounter a significant difference in the risk/benefit struc-

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ture. There is great difficulty in exercising informed consent because, as we have previously noted, the monolithic distribution system tends to restrict action to all or nothing. You either buy the product available or you do without it. In practical terms, consumers are left with what appears to be an irrational response—massive group threats of boycott—to what is more reasonably viewed as a need for rational discussion and understanding.[3]

CURRENT CONTROVERSIES: AN ETHICAL ANALYSIS

In this final section I would like to review a number of current controversies involving bioengineered agricultural applications, subjecting them to the three-tiered structure I have proposed and which has been developed in the course of bioethics as well as the survival ethics proposed by Jane Jacobs (1992).

I will begin with the Tier Two of the structure. This is the requirement that all projected actions must be the subject of scientific investigation. I think that what is most upsetting to the scientific community is the fact that on this criteria, agricultural biotechnology has performed quite well. Let me begin by comparing the cases of bovine and porcine somatatropin. The evidence would suggest that, from the point of animal welfare, bST is acceptable—the review of testing seeming to indicate that there is no increased risk of mastitis in animals given the hormone, as well as attesting that there is no contamination of the milk by bST. The effect upon hogs by bST has not been so benign and until the adverse effects on the animals can be controlled, on the basis of animal welfare alone, scientific evidence would tend to support withholding acceptance of this method of enhancing lean qualities of pork. In both of these examples, there does not appear to be serious objection to *in vivo* investigations. When it comes to Bf-toxin in food crops to control insects, the issue is more complex. Recent field tests of corn involving transgenic manipulation of an insecticidal protein derived from *Bacillus thuringiensis (Bt)* has proved it to be highly resistant to heavy field infestation of the European corn borer (Koziel et al., 1993). Here, I believe, our experience from medical history may be helpful in delineating the issues. Are the long-term effects of *Bt*-toxin similar to what has happened to the effectiveness of our recent treatments for tuberculosis or to the eradication of small pox? Or to put the problem in another way, what is the evidence that the long-term effects of Bf-toxin on pest control will be more successful than produced by the heavy use of insecticides? Then, there is the controversy of the Flavr Savr™ tomato. The likelihood that its use of the kanamycin-resistance gene

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[3] Compare the campaign waged by Jeremy Rifkin against the Flavr Savr™ tomato which involved threated boycott of McDonald's and Campbell's products as well as the enlistment of prominent chefs to refuse their use.

as a marker in the reverse-RNA antisense process will produce human side effects by hooking up with the wrong bacteria during the digestive process is highly remote (Hoyle, 1992). The evidence appears to be at a level of certainty which would be perfectly acceptable had this been a drug being considered for licensing. It is not an overstatement to suggest that the level of scientific research and testing involved in biotechnology is at least as good as that available in the health care field. If we want to understand what may be the problem, we must turn to the other tiers which round out the consumer protection package available to the user of health care.

How can government regulate with one hand when its other hand is in the business of agriculture?

This brings us to another look at Tier One—the establishment and implementation of ethical principles to provide a normative element that protects the user/consumer from exploitation. I do not believe that different principles apply here from those which are used in our evaluation of health care. But our previous examination does suggest that informed consent by the individual to the risk/benefit involved in food product use has a more complex ethical application. [4] Furthermore, the nature of risk is such that the specific instance in which it will appear cannot be determined, so that concepts of common good may unwittingly but unfairly single out victims. Theoretically it could be possible to establish a compensation system to help ease the morbidity/mortality of victims, but the multisource of present risk for disease such as cancer would make the application of this worthy idea almost impossible. So, I believe the resolution of our ethical case must take into account the general insistence of the American consumer that the decision to assume risk must be an individual one, even if there are notable instances when the actual rational weighing of outcome is honored more in the breach as, for example, in deciding to get a driver's license.

Can the process powers of Tier Three produce a distribution system which is safe and accountable by reworking the ways in which we apply our ethical principles? We may get a better sense of what this orientation is up against by asking some leading questions. Is McDonald's likely to give customers a choice of Flavr Savr™ tomatoes or regular ones? What about Campbell's? Labeling is one possible response, but it is ethically acceptable as reflecting the existence of choice only if alternatives are readily available. Merely spelling out contents is not enough because what is of paramount im-

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[4] For a different approach see: MacLean, D. "Social Values and the Distribution of Risk." In *Values at Risk.* D. MacLean, ed. Rowman & Allanheld, Totawa, NJ. 1986. p 75-93.

portance is some indication of risk. Is there the equivalent available to us of a Phase 3 drug trial which could produce acceptable accounting of risk? (It would of course add considerably to the cost of food in the short run.) Who could run a large trial of 10,000 to 20,000 randomized participants? For what period of time? Most carcinogens are notoriously slow in producing symptoms of disease so we would probably have to accept animal evidence here. Possibly a consensus conference, something like the Presidential Commission on Bioethics (1980) that produced the original ethical guidelines for health care could, in addition to offering insight as to the relationship of autonomy to common good, clarify the roles of government and industry. For example, only government in the exercise of its guardianship role could extend the common good to include the ecosystem and produce the regulations to which development must conform. Certainly we need less of the kind of argument presented by Michael W. Fox (as cited by Johnson, 1993) that implies that eliminating profit motives is in the public interest, because it confuses even further the difference between protection and innovation, both of which are vital to our future welfare. This discussion has also shown that the social interaction we have called "process" is all too often subsumed under the term *politics.* Nowhere is this more true than in that paradoxical enterprise of our society called agriculture.

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Jane Jacobs (1992) offers the vision that the human past and future is tied in quite absolute ways to the proper use of both guardian and commercial enterprise. The application of biotechnology to agriculture seems destined for more of the same unproductive confusion and mistrust by our citizenry unless we can sort out the current confusion as to which is responsible for what. How can government regulate with one hand when its other hand is in the business of agriculture? Since the time frame of all living creatures is from the human perspective, is it nonetheless a fitting human response to expect that profitability take a somewhat longer perspective than the next two to five years? I would offer, as one possibility, that the combination of values which currently drives American skepticism about the future promised by biotechnology is demanding a standard of accounting closer to a view of time expressed by the evolution of natural life than the short term perspective that plagues both government and industry. *Sub specie aeternitatis* indeed!

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