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Regulating Genetic Engineering

The Limits and Politics of Knowledge

For many people based in the United Kingdom, as we are, memories of bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, remain vivid. We recall, in particular, that during the decade after the identification of the disease in 1986, the British government and representatives of the cattle industry asserted that BSE was, in effect, substantially equivalent to the familiar disease of sheep and goats called scrapie, which was then widely assumed to be harmless to humans. Although some control measures were taken, BSE infectivity was allowed to remain in our food supply. And as we tragically learned, BSE could be transmitted to humans, in a brain-wasting form called variant Creutzfeldt-Jakob disease. According to government statistics, 177 Britons died of this lingering disease through June 2014.

We have also subsequently learned that if adequate precautionary measures had been taken in time, and the BSE pathogen had been eradicated from cattle and their feed chain, such measures would have cost about £20 million. (Given the exchange rate in 1990 as a mid-range value, that amount would have equaled approximately $33 million in U.S. currency.) But lacking such preventive efforts, the eventual costs to the UK government of this regulatory failure exceeded £20 billion, not to mention the massive commercial losses that occurred. The loss of life, of course, overshadows all.

Moreover, we know that if the BSE pathogen had been eradicated during this period, evidence to show that the expenditure of £20 million had been prudent and had provided a thousandfold return on the investment, would never have emerged. It is in the light of this knowledge, and other examples of a similar kind, that we approach the current assaults on critics of genetic engineering (GE), such as the broadside by Drew L. Kershen and Henry I. Miller in their article, "Give Genetic Engineering Some Breathing Room," in the Winter 2015 *Issues in Science and Technology*.

As typified in their article, charges against critics of GE often take four general forms. But all of them, we argue, are unsupported by facts. First, scientific and policy debates are not, as claimed, polarized in black and white, divided simply into two contending camps. Second, there is no genuine consensus within the scientific community about the safety and acceptability of innovations produced using GE. Third, allegations of costly overregulation presuppose that there is reliable and complete foreknowledge of benefits as well as any and all possible risks, but such scientific hubris should never be treated as an adequate substitute for systematic investigations. Fourth, common representations of GE as an incremental, innocuous innovation that poses no special risks and requires no special regulation is inconsistent with the biotechnology corporations' insistence that GE is a radical innovation that deserves special protection and incentives.

One pivotal error underpins most misrepresentations. It is often implied that policy judgments about, for example, the regulation of GE can and should be based on, and only on, scientific considerations. This ignores a longstanding body of analysis that argues that science on its own can never determine policy decisions. Mountains of evidence show that regulatory policies have never been based solely on science. Nor could they be; as analytic philosophers like to say, you cannot derive an "ought" from an "is."

Supporters of GE repeatedly characterize the challenges presented by GE as "risk." This implies that it is always possible to confidently assign probabilities for all potential problems and benefits of GE. Yet even if this were the case, Nobel prize–winning work on rational choice theory, which underlies risk assessment, has established that problems involved in comparing the "apples and pears" of differently viewed impacts and benefits mean that there can be no single, definitive, overall ordering of risks from the point of view of society as a whole. GE proponents, however, seldom acknowledge the more intractable state of uncertainty, in which there exists no confident basis for estimating probabilities. For their part, Kershen and Miller mentioned this possibility only once. But this they applied to corporate complaints about the regulatory process, not to potential safety concerns or ecological impacts. This failure to acknowledge the problematic status of relevant knowledge demonstrates the partisan nature of analyses by GE supporters—and their departure from scientific balance.

This is not to suggest that facts about the world are irrelevant to policy. It is, however, important to recognize that facts, even if known for certain, can never on their own settle normative policy questions. Political and normative considerations are not just second-order supplements to science that are required only when significant uncertainties are evident. Values and interests are inseparably constitutive of the judgments that frame the choices scientists make about which questions to ask and their assumptions about what data are relevant and how they are to be interpreted. This is no less true of the three of us than it is of those who wholeheartedly support GE. The difference is that while we acknowledge our normative commitments, they pretend to a disinterested fact-focused neutrality.

Let's take the typical arguments one by one:

Polarization. The scientific and policy debates about GE do not take the form of a binary polarization. In reality, there is a broad, diverse spectrum of views on a wide range of pertinent issues. Just because some GE supporters choose to locate themselves at one extreme end of an axis does not justify their classification of anybody who raises questions about GE as if they all belonged together at the opposite end.

As one of us (Stirling) has recently argued, there are too many protagonists in these debates who behave as if the only positions available are simply to be "for" or "against" a single family of innovations; as if GE can be interpreted only as either absolutely indispensable or uniquely unacceptable. But modern biotechnology offers diverse innovation pathways and it is possible to adopt reasonable political perspectives on their respective pros and cons. Alternative approaches to a given breeding problem, such as transgenics, cisgenics, apomixis, gene editing, and genomic and marker-assisted selection, could each create different patterns of benefits and risks (social, political, economic, and cultural, as well as biophysical and ecological), depending on how and where they might be applied.

Consensus. Kershen and Miller asserted that "The seminal question about the basis for regulation of genetic engineering in the 1970s was whether there were unique risks associated with the use of recombinant DNA techniques. Numerous national and international scientific organizations have repeatedly addressed this question, and their conclusions have been congruent: There are no unique risks from the use of molecular techniques of genetic engineering." The plausibility of this narrative rests on the assertion that there is a consensus in the scientific

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community around this position, but that is a misrepresentation.

For example, the European Network of Scientists for Social and Environmental Responsibility gathered more than 300 signatures from independent researchers endorsing a statement rejecting the claim that there is a consensus on the safety of genetically modified organisms (GMOs). The statement held that "the claimed consensus is shown to be an artificial construct that has been falsely perpetuated through diverse fora. ... [T]he scarcity and contradictory nature of the scientific evidence published to date prevents conclusive claims of safety, or of lack of safety, of GMOs. Claims of consensus on the safety of GMOs are not supported by an objective analysis of the refereed literature."

Although it may be easy to gather supportive narratives from selected organizations and individuals, that does not constitute a consensus across the scientific community. Moreover, given the incompleteness, equivocality, and uncertainties in the evidential base, it would be disingenuous to claim to be able to definitively judge the safety of particular products of GE, or of GE technologies, as a uniform taxonomic category.

Overregulated. Kershen and Miller asserted that: "…the most comprehensive and unequivocal analysis, the 1989 National Research Council report, *Field Testing of Genetically Modified Organisms*, on the risks posed by genetically engineered plants and microorganisms, concluded that '…modern molecular techniques are more precise, circumscribed, and predictable than other methods. …With organisms modified by molecular methods, we are in a better, if not *perfect, position to predict* the phenotypic expression' " (emphasis added).

This casual piece of reasoning implies that the knowledge now available to scientists approaches perfection, being almost complete and entirely reliable; sufficient, at any rate, to confidently pass judgment on the safety not only of the GE products that have already been marketed but also of any and all GE products that might be developed at some time in the future. This claim is then interpreted as if it implies that the safety of GE products should *not* be tested. That line of argument aspires to automatically rule out entire ranges of investigations; such studies are supposedly unnecessary because it is already known what the results will show.

In this way, the essentially antiscientific quality of this argument is exposed. Scientific hypotheses are supposed to be testable and tested, not excuses for insisting that no tests should be conducted. The safety or risk profiles, or both, of particular products of GE can be established only empirically; to claim perfect or even sufficient foreknowledge for any or all products, in any or all contexts, constitutes a profoundly unscientific and antiscientific perspective.

As well as claiming that the products of GE can pose no novel or unanticipated risks, some GE advocates also insist that the benefits will be substantial, and assume that those benefits will be widely available and shared. Given those assumptions, they insist that almost all regulatory institutions adopt approaches that are, in Kershen and Miller's words, "not 'fit for purpose'…they are unscientific [and] anti-innovative…" They repeatedly allege that GE is subject to costly overregulation, not only in the United States, but also in other countries. They suggest that the key question to ask is: "What will be the regulatory costs, time, and energy required to capture the public benefits of the new technologies?", but they do not pause to reveal who will be doing the capturing or what it is that will be captured.

They insist that regulatory policies are just "inhibiting innovation," and they do so by ignoring the fact that regulations can influence the direction of technological trajectories, toward, for example, providing safer, more useful, and more sustainable products and processes. Such influencing is the essence of precaution, which is not about being hostile to technology or innovation, but is about being serious about scientific uncertainties and conscientious about social choices. Unblinking GE proponents similarly fail to acknowledge that it may be important also to ask: What will be the

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biophysical, ecological, social, and economic costs of failing to regulate innovative novelties adequately?

Incremental and innocuous. Proponents of GE insist that all innovative GE products and processes constitute incremental rather than radical changes in technology, and that in respect of issues of risk and safety they are entirely innocuous. They insist that, as Kershen and Miller declared: "…the newest techniques of genetic modification are essentially an extension, or refinement, of older, less precise, and less predictable ones..."

Such insistence that GE provides only incremental rather than radical innovations is very difficult to reconcile with corporations' insistence that they require or deserve special protection for their "intellectual property." Corporations active in GE have long insisted collectively that their products must be covered by patents, rather than by, for example, traditional forms of protection, such as those provided to plant breeders by the International Union for the Protection of New Varieties of Plants under the so-called UPOV Convention.

In this way, the corporations active in the GE field try to have it both ways. With respect to innovativeness, GE is radically different from traditional methods in R&D, necessitating special protection of intellectual property. With respect to safety, harm, or risks, the companies insist that GE is not remotely special or distinctive. They cannot maintain such an inconsistent perspective, which is essentially unscientific.

The case for special protection for intellectual property was premised on claims that their R&D costs would be particularly high, and without patent rights, commercial returns could not reasonably be anticipated. Strangely, however, Kershen and Miller insisted that modern GE-based methods are "…more precise and versatile than ever…," opining that "… the use of the newest genetic engineering techniques actually *lowers* the already minimal risk associated with field testing." If those statements are true, then the R&D costs should have fallen, not risen. In other words, such claims about the technological superiority of GE techniques and the corporate argument for patent rights over transgenic organisms are mutually inconsistent.

So where are we left? Sadly, the polarizing effects of these various kinds of arguments have resulted in an unpromising state of public debate about GE and its regulation. As a coda, we are not suggesting that GE is invariably unsafe or unacceptable. On the contrary, we envisage several conditions under which GE technology could potentially contribute to global food security, environmental sustainability, and other valuable public outcomes. This is even more true of wider (relatively neglected) applications of advanced biotechnology. However, we are critical of the corporate strategies of some of the large firms that, motivated by the particular private benefits they anticipate, have invested heavily but selectively in GE trajectories.

Genetic engineering does not need "breathing room," but thoughtful reevaluation and careful redirection toward important public goods, such as improved food security and environmental sustainability. We find it ironic that while Kershen and Miller, along with many other GE proponents, insist that regulatory and policy judgments about GE should be based on science alone, their arguments are typically articulated with exaggerated emotional intensity.

We do not pretend to be value-neutral; rather, we acknowledge our concerns to prioritize the needs of poor and hungry communities over those of corporations that have invested heavily in GE. We also maintain that helping those communities means directing the application of available and innovative technologies, as well as socioeconomic institutions and policies, toward the sustainable reduction of poverty. We certainly should not be unquestionably promoting anything that risks aggravating socioeconomic inequalities and inflicting great harm on those who are most vulnerable.

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