BOUNDARIES IN SCIENCE POLICY MAKING: Bovine Growth Hormone in the European Union

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We simultaneously explore the history of European Union policy on the commercialization of recombinant bovine growth hormone and the sociology of boundary drawing. We argue that, to understand why some boundary-drawing efforts succeed and others fail, we need to be attentive to the relatively stable discursive, organizational, and institutional factors that shape boundary construction. We suggest that attention to two discourses (scientism and social welfarism), the structure of policy making in the European Union, and the institutionalization of particular discourses in World Trade Organization regulations shed light on the E.U.-rbGH case.

In December 1999, after over a decade of debate, study, and stopgap measures, the European Council established a permanent ban on the commercial use of recombinant bovine growth hormone (rbGH) in E.U. countries. Injections of rbGH, the first recombinant DNA product of the agricultural biotechnology industry, increase milk production in dairy cows. Since its introduction, rbGH has been controversial because some argue that its safety for humans and animals is uncertain and that its commercialization will hurt already struggling small-scale dairy producers (e.g., Hallberg 1991). In Europe, perhaps the most contentious element of the rbGH debates was the consideration of a so-called "fourth hurdle" or "fourth criterion," a requirement to evaluate the possible socioeconomic impacts of new veterinary technologies prior to commercialization. Some E.U. policy makers wished to institute this yardstick as part of the evaluation process for growth promoters and products of biotechnology, such as rbGH. Opponents of the fourth hurdle argued for placing socioeconomic considerations outside the boundaries of legitimate consideration in the regulation of veterinary technologies. They argued that the fourth hurdle and other efforts to ban rbGH on socioeconomic grounds were illegitimate because they were unscientific, subjective, and political.

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The history of the debate over the fourth hurdle and the regulation of rbGH in the E.U. provides an opportunity to (re)conceptualize the boundary-drawing process in the making of science and technology policy. Recent studies of boundary drawing in science focus primarily on identifying and describing the processes of boundary construction. They are concerned with *what* happened and *how*. By contrast, we are interested in *why* boundaries get drawn in particular ways and in *why* some boundary-drawing initiatives are successful and others fail. Unlike most studies on boundary drawing in technoscience, our interest is in relatively stable factors that constrain and shape both boundary construction and, ultimately, science and technology policy. In this context, we are especially concerned with the conditions under which the claims of advocates for nonscience—in this case, knowledge claims that fall outside the accepted boundaries of experimental-natural science—are treated as credible in policy disputes.

Our basic contention is that to understand the outcome of boundary struggles in the science and technology policy arena we cannot examine only the relatively fleeting rhetoric used by actors engaged in boundary drawing. In addition, we must look at relatively stable or obdurate factors that constrain boundary drawing and make some efforts at boundary drawing more legitimate than others. In this context, we are centrally interested in the extent to which the established discursive terrain shapes a particular boundary between science and nonscience and, furthermore, defines science as the sole legitimate factor in assessments required in science and technology policy making. In addition, we are attentive to the role of organizational factors in shaping the character of boundary confrontations in technoscience policy making.

Much scholarship on boundary drawing in technoscience focuses on what Thomas Gieryn (1999, pp. 4, 5) terms boundary work: the drawing of rhetorical boundaries "between science and some less authoritative residual nonscience." In the present case, opposing groups generally agreed on the location and nature of the border between science and nonscience. The matter at stake was the legitimacy of nonscientific criteria for evaluating and regulating new technologies. On several occasions during the E.U. debate over rbGH and the fourth hurdle, policy makers treated so-called nonscientific considerations as legitimate. Most E.U. policy makers did not view the socioeconomic effects of a new technology as matters that could be evaluated scientifically or objectively. Yet for over ten years, "nonscientific" issues were of equal, if not greater, concern to policy makers than "scientific" questions about rbGH. Here, we seek to explain both why this was possible and why, in the end, the final ban on rbGH constituted a compromise.

We argue that the outcomes of these boundary-drawing episodes in the debate over rbGH and the fourth hurdle can be understood best through consideration of (1) the relatively stable and historically resonant discourses that shaped the debates, (2) the established organizational characteristics of E.U. policy making, and (3) the institutionalized discursive terrain of the international policy making arena. We focus especially on two countervailing discourses that we call scientism and social welfarism. We also pay attention to the organization of policy making in the European Union, which at least partially explains the character and outcome of the rbGH controversy. Finally, we consider the role of international trade agreements in constraining the range of concerns that EU policy makers may use to justify banning a technology.

THE HOW, WHEN, AND WHY OF BOUNDARY DRAWING

Concern with the sociology of boundary drawing is widespread (Lamont and Molnar 2002). It is the focus of work on the reproduction of social class (Bourdieu 1984), analysis of the professions (Abbott 1988), and the study of culture (DiMaggio 1992). Boundaries are also a central issue in a broad range of work in the sociology of science and technology. Especially prominent is research that explores the construction and maintenance of boundaries between science and nonscience and investigations of the lines drawn between science and politics. The literature is vast, and this is not the place for a comprehensive review. Here, instead, we profile a small sample of work that addresses these issues. One way to categorize this scholarship is in terms of whether the work attends to the rhetorical construction and functions of boundaries or is more interested in the role that organizations play in developing and maintaining borders and resolving contradictions.

We begin with the work of Thomas Gieryn, probably the most prominent analyst of boundaries in technoscience. As we have noted, his work focuses on the concept of boundary work. Boundary work is centrally about how "people contend for, legitimate, or challenge the cognitive authority of science" (Gieryn 1995, p. 405). Gieryn has studied topics as varied as boundary struggles in Victorian science, mid-twentieth-century U.S. policy debates about whether the social sciences are legitimate sciences, the cold fusion controversy, and the "science wars" of the mid-1990s. In one essay, Gieryn explores the Victorian John Tyndall's effort to gain public support and resources for science through double-boundary work: Tyndall sought simultaneously to demarcate science from religion and mechanics, hoping to thereby show its intellectual superiority to the former and technical superiority to the latter. In this effort, Tyndall expressed contradictory rhetorics. To separate science from religion, Tyndall pointed to its empirical basis, but to distinguish science from engineering, he stressed the abstract, theoretical character of science.

In investigating boundary work in the policy realm, Gieryn traces the debates surrounding the genesis of the National Science Foundation in the 1940s and the prospects for the creation of a National Social Science Foundation in the 1960s. He shows how rhetorics of similarity (to science) and difference (from science) were used by social scientists and natural and physical scientists in different and contradictory ways depending upon their political aims. In following these debates, Gieryn shows that the occasion, form, and content of boundary work in these struggles were shaped by professional and political interests and not by any innate characteristics associated with social science or science.

Sheila Jasanoff's work covers a broad, but related, range of science and technology policy topics. In a 1987 essay, for example, she explores how actors, including public interest groups, public officials and scientists, use "boundary defining language" to separate science from policy and to specify who can interpret science. Jasanoff looks specifically at carcinogen regulation and at the contested definitions of such notions as transcience versus science and risk management versus risk assessment. Specific terms are used, according to Jasanoff, (1987, p. 226) to "advance particular views about the nature of science and its relation to policy." Furthermore, Jasanoff argues that the ways these boundaries are drawn have important implications for how "decisionmaking authority is allocated among scientific and political or legal institutions" (p. 224).

In their study of the risk/ethics boundary in biotechnology regulation in the European Community (E.C.), Les Levidow and Susan Carr (1997) are similarly concerned with the role of language in boundary construction and with the impact of the boundaries established. Levidow and Carr show how critics and supporters of precautionary legislation for the intentional release of genetically engineered organisms in the E.C. differently drew boundaries around what would count as a risk. The authors argue that despite differences in the boundary drawn around risk, all players' notions of risk were tied to an implicit ethics.

Whereas Gieryn, Jasanoff, and Levidow and Carr focus on what we might call the linguistic realm, Kelly Moore's (1996) work analyzes the role of organizations in negotiating the science/politics boundary. Looking at the involvement of scientists in the political realm in the mid-twentieth-century, Moore shows that, by creating public interest science organizations separate from professional scientific societies, scientists were able to protect the idea of science as independent of values and politics while simultaneously engaging in explicitly value-driven action. According to Moore (1996, p. 1594), these organizations "made serving the public interest relatively permanent and durable, obfuscated how political interests affect scientific knowledge, and helped preserve the organizational representations of scientific unity: professional science organizations."

Like Moore's essay, David Guston's work looks at the role of organizations in boundary drawing. Guston (1999, p. 88) is interested in what he terms boundary organizations: entities that "help stabilize the boundary between science and politics by participating in a set of principal-agent relations." Guston studied the U.S. National Institutes of Health's Office of Technology Transfer (OTT), and his work shows how boundary organizations such as this help mediate the relationship between actors with distinctive interests in defining the science/policy boundary. According to Guston, the OTT "gives both the policy-makers and the scientists an opportunity to construct the boundary between their enterprises in a way favourable to their own perspectives" (p. 106).

We engage work in this research area—what might be termed boundaries of technoscience literature—at two levels. In one sense, our work is synthetic. We draw together two strands of the boundaries literature. While work such as Gieryn's primarily emphasizes the importance of language in understanding boundaries in technoscience, work such as Moore's and Guston's stresses organizations. We believe both are important and contend that to understand *why* boundaries are constructed in particular ways depends on understanding the realm of language *and* organizational structures in relationship to one another.

At a second level, our work poses a friendly challenge to the constructivist approach taken in much of this work. In all, this literature shows that the boundary work concept is a powerful tool, analytically useful across a wide range of realms. Through the study of episodes of boundary work, Gieryn and others have demonstrated that there is no essential, transcendent, universal definition of science. Rather, scientists and other actors with a stake in how science is perceived engage in boundary work in local, historically bounded contexts. These boundary workers attempt to separate science from nonscience and to attribute desirable qualities to science that contrast with those of nonscientific entities. While some boundaries may be repeatedly reinforced, science is often re-mapped and redefined in diverse and contradictory ways.

Gieryn's (1995, p. 394) central concern is with *how, when, and to what end* boundaries in science are drawn. In this regard, Gieryn's work fits in with the broad social constructivist

tradition in science and technology studies (STS) that focuses on processes of construction rather than the effects of already constructed phenomena (Kleinman 1998; 2003). Unlike much work in the social constructivist tradition, Gieryn is sensitive to the existence of "enduring cultural spaces" (1995, pp. 420, 440) and discursive legacies from previous conflicts (1995, p. 431) that shape new boundary struggles, but in general he is more interested in the *contingent* than the *enduring*.

Generally, Gieryn appears more concerned with the broad effects of boundary work and boundaries on the cognitive authority of science than with the outcomes of the individual boundary-work episodes he examines.[1] For individual cases, he discusses boundaries being accepted but generally says little about the conditions under which acceptance occurs. He tends to *describe* boundary-work successes and failures but avoids *explaining* them. He is cautious, asserting that there are no "general determinants" of successful boundary work (Gieryn 1995, p. 406). Still, even if there are no general determinants of success, it may be possible to specify why boundary struggles result in particular outcomes in specific cases.

In this article, we show that it is precisely by paying attention to the enduring features of the discursive (and to a lesser extent organizational) terrain—the already constructed rather than the process of construction—that it is possible to understand why boundary struggles turn out the way they do. Our attention to the enduring features of the social world in which boundaries play a role points to three related ways in which our work differs from Gieryn's. First, while along with Gieryn we focus on what might be termed the linguistic realm, we are interested in historically established discourses and the effects they have in boundary-related struggles. Gieryn is more interested in rhetoric, which might be seen as a contingent linguistic practice often premised in action on strategic objectives. Second, and relatedly, the historically established character of the discourses with which we are concerned often means they are utilized by actors in an unexamined taken-for-granted manner—quite the opposite of the strategic use of rhetoric emphasized by Gieryn. Finally, and again relatedly, while one might say that Gieryn is centrally concerned with the goals of individuals and groups in boundary struggles, we are more concerned with the structures within which actors engage in struggle and work to realize their goals.

THE DEBATE OVER rbGH AND THE FOURTH HURDLE IN THE EUROPEAN UNION

The central story of rbGH and the fourth hurdle in Europe begins in 1987, when both Monsanto and Eli Lilly requested marketing authorization of their rbGH products in Europe. Following E.U. guidelines, these products were sent for review by a central evaluation body, the Committee for Veterinary Medicinal Products (CVMP). Traditionally, the European Union regulated new veterinary technologies—the category under which rbGH falls in the E.U. policy-making arena—along three dimensions: safety, efficacy, and quality. According to E.U. documents and statements by proponents of rbGH, new technologies can be evaluated on a strictly scientific and objective basis only if evaluation is limited to these three dimensions. Both proponents and opponents of rbGH appeared to agree that these criteria were indeed scientific, objective, and free of values. In this context, there appears to have been an ongoing, but implicit, conflation by all parties to the debate of the "objectivity" of measures of safety, efficacy, and quality and

what would count as acceptable levels according to these measures. Thus, although actors with different values and interests might have argued over the acceptable levels of safety, quality, and efficacy and fought over the values underlying different levels of acceptability, they did not. As a result, what counted as acceptable levels themselves seemed to take on an aura of objectivity.

Critics of rbGH, including farmers, consumers, environmental activists, and policy makers, raised a variety of concerns about the hormone's effects. Many asked about the impact of rbGH on human and animal health. In both the United States and the European Union, significant opposition to the drug was also based on a concern that its use would force an increased number of small-scale dairy farmers out of business. It was an inauspicious time to introduce a drug that would increase milk production: both Europe and the United States were in the midst of major milk surpluses, and small-scale dairy farmers were suffering financially.[2]

Some opponents of rbGH, while not challenging the scientific status of the three existing evaluation criteria, argued that they were not sufficient for regulating new growth promoters and products of biotechnology. A number of members of the European Parliament, most prominently a Member of Parliament (MEP) named Ken Collins, sought the inclusion of a fourth criterion of evaluation: an assessment of the likely socioeconomic impacts of rbGH would have if commercialized. This consideration was dubbed the "fourth hurdle." Proponents of the fourth hurdle asked what effect the hormone would have on the social organization of the dairy industry, on ownership patterns, consolidation, and control of dairying (EP 1988b; 1991a; 1996).

As the debates over the approval of rbGH and the possibility of introducing a fourth hurdle unfolded, participants on both sides drew boundaries around science and the standards by which they believed it was appropriate to regulate science and technology. Unlike the kinds of cases of boundary work studied by Gieryn, in the case of the fourth hurdle the boundaries around, and attributes of, science were generally agreed upon by the contending parties. Science was widely understood to be objective and value-free. Debate participants, both for and against rbGH, typically viewed the existing three criteria as scientific and thus thoroughly apolitical. The content of terms such as objective, value-free, and technical was generally not interrogated by either side but remained abstract. Measures of socioeconomic impacts and not just acceptable levels according to such measures, on the other hand, were understood by all to be value-laden. As the European Commission (CEC 1992) acknowledged early on: "By their nature, socioeconomic aspects need to be considered in a different way" than the traditional three hurdles. The central struggle over the fourth hurdle and rbGH was over whether it was legitimate to include nonscientific criteria of evaluation in the assessment of new technologies.[3] Here again, an implicit conflation seemed to be accepted by both sides in the debate. There was clearly no agreement on the level of socioeconomic impact that would justify a refusal to commercialize rbGH or any other veterinary technology—such a *decision* was obviously value-laden—so, in turn, both sides seemed to agree that the *measures themselves* also would be inevitably value-laden.

Supporters of socioeconomic evaluation of new veterinary technologies pointed to the need to rely on nonscientific factors in undertaking assessments. One member of the European Parliament argued that "the use of the [rbGH] hormone ... increase[s] unfair competition and social inequality, both between producers and between regions." As a consequence, according to this MEP, the "technology should be judged primarily in

qualitative, not quantitative terms" (Ulburghs, quoted in EP 1988a, p. 17). The implication here is that quantitative evaluation is scientific, but qualitative assessment is not. A 1989 report from the European Commission called for going beyond scientific criteria of evaluation. According to the report: "Apart from the purely scientific aspects, the considerable uncertainty in relation to consumer reaction and consequences for the market requires that the Community's approach be based on the fullest awareness of all the implications" (CEC 1989). Again, the sense here is that consumer reactions and market consequences are not scientific matters.

Opponents of the fourth hurdle, and particularly those with interests in the commercialization of rbGH, presented a variety of arguments against the use of nonscientific criteria in the drug evaluation process. The Secretary-General of a biotechnology lobby group argued that "a rigorous, objective and non-political regulatory and control system is the best guarantee of the integrity of the food chain." He went on to suggest that adding a fourth hurdle would inhibit innovation, because manufacturers would fear that their products would be banned for "non-objective" reasons ("FEDESA: Veterinary drugs" 1991). Another industry lobbyist made a similar argument. June Grindley of the U.K. BioIndustry Association argued that "product approval should be on the basis of the assessments of safety and effectiveness rather than upon judgments of its benefits to society." According to Grindley, "Only a regulatory system based on sound scientific principles will allow European industry to maintain its competitive position" (quoted in "Conference Report: UK industry group" 1991).[4] Apparently, Grindley did not believe that socioeconomic criteria could be included in a scientific regulatory system.

In another example of opposition to the fourth hurdle, the British Ministry of Agriculture's biotechnology unit worried that socioeconomic criteria are "essentially speculative and to a large part dependent on political considerations." Evaluation on such grounds are "unlikely to be reproducible" ("Conference Report: BST's 'Fourth Hurdle'" 1991), with reproducibility implicitly viewed as a crucial feature of authentic scientific practice.

This general position was taken in E.U. parliamentary debate as well. Early on, one member of the European Parliament argued, "The only sound way forward is to have a regulatory framework . . . that is scientific, objective and based on clear criteria . . . The European Community should without question develop a rational, predictable and objective system" (Chistopher Jackson, quoted in EP 1988a, p. 13). In a debate three years later, another MEP argued that the European Union should not introduce "social criteria which are not relevant to the scientific research" (Lord Plumb, quoted in EP 1991b, p. 295). Statements like these were common both in the debates in Parliament and in newspaper coverage throughout the 1990s.

While the fourth hurdle as a matter of policy remained unresolved, E.U. policy makers took action on the immediate problem of rbGH, passing the first ban on the hormone on April 25, 1990. Over the following decade, the European Council passed a series of moratoria on the production and use of rbGH in the European Union, culminating in a permanent ban that began in January 2000. The stated justifications for each of these six successive moratoria varied, but as a growing number of non-E.U. nations approved the use of rbGH, and the E.U.'s drug assessment body (CVMP) approved the drug on the grounds of quality, safety, and efficacy, the socioeconomic motivations for the ban became more obvious. The 1990 ban was instituted for one year on the grounds that more time was needed to study the problem, particularly because "products arising from

milk production occupy a very important place in the Community; . . . they represent an essential source of income for part of the agricultural population" (EC 1990). Following worries expressed in the European Parliament and in the Economic and Social Committee, the moratorium document pointed to concerns about the possible socioeconomic effects of commercializing rbGH. In 1991, the ban was extended until the end of that year, pending further research (EC 1991).

The prohibition was extended again until 1993, based on the need for "further deliberation . . . regarding some aspects of consistency with other Community policies," namely, the concern that commercialization of rbGH might contradict the mandate to protect the existing structure of agriculture as embodied in the Common Agricultural Policy (CAP) (EC 1992). At that time, the E.U.'s Agriculture Commissioner was pushing for a permanent ban on rbGH on the grounds that it would have socioeconomic impacts inconsistent with E.U. policy ("Hormones" 1993), and in fact, when in 1993 the Commission proposed a permanent moratorium on rbGH, it did so on socioeconomic grounds, acknowledging that the drug had already passed the three criteria of quality, safety, and efficacy (CEC 1993). The Council again extended the ban through 1994, arguing that not all issues had been resolved (EC 1993).

A fourth extension of the moratorium passed in 1994, this time until the end of the decade, and again recognized concern about the likely socioeconomic effects of rbGH (EC 1994). However, the Council's decision also referenced international trade issues, particularly the approval of rbGH in the United States. Still committed to a ban on rbGH, European opponents of the substance turned to the accepted "scientific" dimensions of evaluation in search of justification for a moratorium. Responding to a concern that international trade partners would demand a scientific rationale for the ban, the Council decision called for a "Working Party of independent scientists, in collaboration with the Member States" to assess the effects of using rbGH (EC 1994). At least one newspaper reported that this turn to a "scientifically measurable" justification for the rbGH ban came as a response to World Trade Organization (WTO) pressure (Riley 1999).[5] Following that decision, the European Commission used studies that found that the use of rbGH results in "painful and debilitating" conditions for cows regularly injected with the substance, "leading to significantly poorer welfare of the animals" as a "scientific" justification for a final, permanent ban ("Agriculture" 1999; CEC 1999; "Commission proposes ban" 1999; HCP 1999; SCAHAW 1999).

The outcome of this decade-long controversy was mixed and ambiguous. On the one hand, opponents of rbGH who were also the supporters of a fourth hurdle saw their position reflected in many of the temporary bans and in initial consideration of a permanent ban. In fact, some proponents of rbGH viewed the ongoing ban as "the fourth hurdle by the back door" ("Hormones/Veterinary Drug" 1991; "BEUC" 1994). Sustained concern with the social impacts of rbGH and interest in social criteria of assessment point to the relative success of rbGH opponents in extending the boundary around what would count as legitimate criteria for evaluating veterinary technologies to include "nonscientific" factors.

In addition, rbGH opponents successfully achieved a permanent ban on the commercialization of rbGH in Europe. Although the Commission's official stance was that the proposed permanent ban was "exclusively motivated by reasons of animal welfare and health" (ostensibly objective, scientific concerns) ("Commission proposes ban" 1999), some opposed to the moratorium argued that the report on animal welfare effects was a

"thinly-veiled attempt" to justify extending the ban for socioeconomic reasons (Riley 1999). A spokesman for Monsanto argued that "the E.U. moratorium has nothing to do with food safety or welfare, and everything to do with the supply and demand for milk" (Horton 1999). Despite these protests, with the support of the Economic and Social Committee and the European Parliament, E.U. ministers voted to approve a permanent prohibition on rbGH in December 1999 ("Council and Parliament" 1999; EC 1999; ESC 1999).

At the same time, this success for rbGH opponents was limited. After a decade of banning rbGH because of its anticipated impacts on rural economies, the European Union ultimately used a "scientific" rationale for passing a permanent moratorium, thus reasserting the uniquely legitimate place of scientific criteria in assessing new technologies. Furthermore, the fourth hurdle was never institutionalized as a general criterion for evaluating new veterinary technologies. While the concept underlying the fourth criterion was reintroduced on occasion (e.g., EP 1996),[6] it never regained momentum at the policy level. This certainly can be viewed as a success for the biotechnology industry and its allies who opposed the fourth hurdle.

Overall, proponents of rbGH could take heart in two facts. First, no fourth hurdle was institutionalized as a permanent criterion for evaluating new veterinary technologies. Second, the use of a "scientific" rationale for the permanent ban—although not what rbGH proponents would have wished—meant that no precedent for the use of "nonscientific" criteria was established. "Nonscientific" measures of assessment in the evaluation of new veterinary technologies were not institutionalized as rules.

UNDERSTANDING THE FOURTH HURDLE IN EUROPEAN DECISION MAKING

To understand why the rbGH/fourth hurdle controversy in the European Union proceeded as it did and was resolved as it was, we address three main questions: (1) Why did both sides assume that the fourth hurdle was unscientific (subjective) and that the first three were scientific (objective)? (2) Why was the fourth hurdle, nevertheless, a legitimate policy consideration (both explicitly and implicitly) in discussion of the rbGH moratoria? (3) What organizational and institutional factors help to explain the policy outcomes for the fourth hurdle and rbGH? To answer these questions, we argue that attention has to be paid to three categories of obdurate and constraining factors: discourses with powerful historical resonance, the organizational structure of policymaking, and discourses that are institutionalized in global trade rules.

Scientism and the Standard Three Criteria

A crucial piece of the explanation for why the virtues of the traditional three criteria were taken-for-granted by both sides is the belief that these hurdles were scientific.[7] Here, matters of science were viewed as uncontentious. This state of affairs is in keeping with what we call *scientism.* In essence, this is the notion that facts and values are distinct entities and that facts, unlike values, are beyond dispute (Daniels 1967; Bruce 1987; Proctor 1991; Gieryn 1999). Common extensions on this position include (1) the assumption that facts are superior to values, (2) the idea that because science is based on facts and not values (i.e. science is value-free), it provides a superior basis for decision

making, and (3) the belief that policy decisions and policies themselves should be based on objective facts and that scientific experts should shape public policy.

The ideas that facts and values are distinct and that facts are superior to values have deep and diverse roots.[8] For the most part, explicit discussion of the virtue of "value-freedom" has been restricted to scholars and intellectuals. One can find the notion in the radical separation Plato sought between the pure (and presumably value-free) realm of contemplative thought and the tainted sphere of practical action. Early modern philosophers worked to exclude ethical matters from natural philosophy. And in the seventeenth century, as a new and fragile science in Europe sought autonomy from church and state, science advocates stressed its apolitical character.

In the early twentieth century, advocates of value-free science, such as Max Weber, sought autonomy from "moralistic subservience to the government" (Proctor 1991, p. 105). Value neutrality was also a way to defend social science against "charges of socialism" (p. 134). The threat of Nazism strengthened the ideal of value-free science, and by the second half of the twentieth century, the virtues of value-freedom were firmly entrenched in the dominant work in the philosophy of science (p. 159).

In the present day, natural and social scientists alike have observed that the authority of science and scientists rests "on assumptions about scientific neutrality. The interpretations and predications of scientists are judged to be rational and immune from political manipulation because they are [assumed to be] based on data gathered through objective procedures" (Nelkin 1995, p. 452). Importantly, although the virtues of value-free science are widely accepted in public debate in the United States and Europe, the meaning of the idea and its implications for the practice of science and policy is typically not interrogated in public discussion. It remains amorphous—a signifier without a precise signified. This allows for its flexible use across a wide array of policy and other debates.

In many cases—the rbGH controversy in the United States, for example[9]—the discursive dominance of scientism contributes to preventing the legitimate entry of so-called nonscientific concerns into technoscientific decision making. The general argument in such cases is that decisions based strictly on scientific facts are unambiguous, indisputable, and therefore preferred. Indeed, in the U.S. case, commercialization for rbGH was justified based on studies that regulators said showed that the substance was safe for cows and humans. While regulators viewed socioeconomic concerns as nonscientific (that is, value-laden), they did not consider the possibility that what counts as an acceptable level of safety might also be a nonscientific matter. In the European case, the status of scientism meant that there was little controversy about the traditional three criteria or the acceptability of particular levels across measures for each criterion. Their basis in science—and hence fact—put them beyond dispute. However, the question remained whether it was, nevertheless, appropriate to regulate rbGH on social (and thus presumably value-based), as well as scientific, grounds.

Social Welfarism and the Status of the Fourth Hurdle

The values underlying the socioeconomic assessment of new technologies were contentious and obvious for all to see. The issue was not whether the fourth hurdle was scientific, but whether there was a legitimate place for a nonscientific standard in determining whether to permit commercialization of new technology. Illustrating this concern, a European Commission document stated: "The Commission will normally follow scientific

advice. *The Commission reserves the right, however, to take a different view in light of its general obligation to take into account other Community policies and objectives*" (CEC 1992; emphasis in original). The Commission seems to be suggesting that at times values, not value-free science, will be the basis on which it makes decisions.

Unlike in the United States, for example, where there was no significant countervailing discourse to scientism in the debate over the commercialization of rbGH, in Europe, actors contended with a counterbalancing discourse that we call *social welfarism.*[10] We see social welfarism as multifaceted. Indeed, to call it a single discourse is somewhat misleading, since, of course, Europe (for our purposes, primarily Western Europe) is made up of a number of countries, each with a distinct history. In each Western European country, social welfarism certainly has a distinct coloration, and as clearly, the relative dominance of this element varies by country. At the same time, we believe there is enough overlap that we can describe social welfarism as a single discourse that operated in the E.U. rbGH policy debate.

Social welfarism does not constitute a direct contrast to scientism. It is not the position that knowledge or policy should be based on values instead of facts. Rather, it encompasses a broad set of values on which policy can be based. It is the idea that the market and private mechanisms cannot solve all social and economic problems and that, therefore, it is often appropriate for the state to intervene on the basis of implicitly agreed social values. By and large, while this element probably has roots in the late nineteenth century, its development is primarily a product of the decades on either side of World War II. Roughly speaking, state action occurred along two dimensions. On the one hand, some European states in the post-WWII period developed a practice of intervening in the economy to promote national economic development objectives. On the other hand, in some form, most states developed a social safety net, involving components such as a right to health care, unemployment insurance, and old age pensions.

Until recently the Common Agricultural Policy (CAP), the feature of the European policy landscape most directly relevant to the case of rbGH, had a fundamentally social welfarist character. The majority of western European countries have elected to preserve economic and social features of rural and agricultural life that are "quite at odds with the usual social and economic structure of an industrial urbanized society" (Rieger 1996, p. 98). The European Union aims to insulate the farming economy from industrialization and urbanization, a desire clearly manifest in CAP. The premise of CAP is that agricultural communities of member nations ought to be guaranteed a fair standard of living. Price guarantees are a central feature of this program. According to one analyst, CAP should be viewed as "an integral part of the west European welfare state and its particular moral economy" (Rieger 1996, p. 100). CAP's underpinnings are viewed not as science (as objective) but as shared values (as subjective).

The history in many European countries of state intervention in the economy with the aim of promoting economic growth and of insulating citizens from the vagaries of the market through social welfare provision provides the foundation for social welfarism as an element of legitimate discourse. We believe this history made it possible for some E.U. politicians to articulate criteria for evaluating technology that would theoretically prohibit the development of certain technologies if they did not meet the social goals of the Union. It was legitimate to explicitly assert that the traditional three "scientific" criteria for evaluating veterinary technology are not encompassing enough. Social welfarism allowed proponents of the fourth criterion to be taken seriously when they

asserted that the ostensibly scientific (and hence fact-based) criteria commonly used to assess veterinary technologies—measures on which criteria for evaluating health, safety, and efficacy were agreed—provided an insufficient basis for assessing rbGH. Because of the legitimacy of social welfarism in Europe, opponents had to seriously engage the issues raised by advocates of the fourth hurdle.

Organizational Structures, Institutionalized Discourse, and the Fourth Hurdle/rbGH Debate

It seems fair to say that neither side had a clear upper hand in this controversy, and there were no clear winners and losers. Understanding the policy outcome as a compromise, we can turn to the structure of policy making for at least a partial explanation. Many analysts of policy making argue that structures that are fragmented with multiple points of entry, where political parties are not programmatic and lack discipline, are associated with compromise decisions and delays in decision making (Skowronek 1982; Skocpol 1985; Weir and Skocpol 1985; Kleinman 1995). This certainly describes the structure of E.U. policy making. The Parliament has never had a majority party and views among MEPs on this controversy varied considerably. Specific policy determinations during the decade-long controversy depended on who happened to hold committee rapporteurships. Rapporteurships are determined by a system of points allocated to political parties on the basis of their number of members in the Parliament (Abels 1998, p. 50). This means that even small parties can hold rapporteurships, and that rapporteurships are not necessarily stable over time. Thus, although Collins, an MEP supporter of instituting a fourth hurdle and of banning rbGH, was the rapporteur on this issue throughout most of the period, the position of the E.P.'s Committee on the Environment and Consumer Affairs changed abruptly when Collins was replaced as rapporteur by Juan Luis Valverde Lopez, who fervently opposed the fourth hurdle idea. Under Lopez's rapporteurship the Environment Committee reversed itself in 1991, opposing Commission proposals for a fourth hurdle, and indeed, this marked the end of widespread efforts in the Parliament to institute a fourth criterion as a general rule.

Like the Parliament, the European Commission is also fractured. The Commission is made up of over twenty directorates general (DGs), and each of these is responsible for a specific policy domain. During the decade-long struggle over the socioeconomic assessment of rbGH, the DG for Agriculture came out consistently in favor of a fourth criterion, while the DGs responsible for the Internal Market and for Science Research and Development opposed the idea. This division pointed clearly to the need for a compromise policy.

Final determination on policy is made by the European Council, whose deliberations are not publicly available. However, decisions on temporary bans and the ultimate moratorium are consistent with the character of the Council, which must balance divergent national interests (as there certainly were in this case), and Council members were surely aware of divisions in both the Parliament and the Commission.

It seems plausible that the substantial delay in passing the final ban and the decision to drop pursuit of a fourth hurdle for all veterinary technologies can be explained by the fragmentation of the E.U. policy-making structure. Indeed, in this regard the European Union and the United States are similar. In the United States, where policy making is famously fragmented and where political parties lack discipline, there is evidence of at

least one compromise decision regarding rbGH. A brief temporary moratorium on the hormone was passed in 1993. Unlike the European Union, however, the United States finally approved rbGH for use, and a fourth hurdle was never seriously considered as a matter of policy.

To explain the distinctive outcome in the E.U. case, we believe that attention must be paid to policy-making structures *in combination with* the character of the discursive terrain. Unlike in the European Union, socioeconomic considerations lacked a legitimate place in U.S. congressional debate on rbGH, and the U.S. decision to permit commercialization of the substance was made on the basis of criteria assumed to be scientific. Significantly, *scientism* was clearly the dominant discourse in debate over rbGH in the United States. Moreover, in U.S. science and technology policy debates, *social welfarism* generally lacks legitimate grounding. Thus, we conclude, albeit tentatively, that while the E.U. policymaking structure constitutes part of the explanation for the compromise outcome in the fourth hurdle/rbGH debate, the outcome would likely have looked very different if social welfarism did not confront scientism as a countervailing discourse. A social welfarist discourse gave rbGH opponents legitimate grounds for argument and positioned them to settle for a compromise—a ban without a generally applicable fourth hurdle.

Finally, and not insignificantly, in order to understand the decision to ban rbGH, the role of international trade agreements must be taken into account. Trends toward a globalized economy and rules for governing it exert increasing influence on E.U. policy. In the late 1990s, the European Union was under pressure from the World Trade Organization (WTO), following complaints by the United States and Canada, to lift its prohibition on the use of beef hormones (a separate, but not unrelated hormone ban). The beef hormone case was the first major dispute involving the WTO Agreement on Sanitary and Phytosanitary Standards (SPS), bringing attention to the requirement that decisions to limit the flow of trade be based on science (Ziegler 1998). The SPS agreement allows countries to take the measures they deem necessary to protect animal, human, or plant health, but requires those measures to be based on "scientific principles."

Around the same time, in a case brought by Eli Lilly, the European Court ruled that milk produced using rbGH was safe for human consumption. The Court stated that "it is clear from the case file that the moratorium on [rbGH] was introduced for socioeconomic reasons" (CFI 1998). These events heightened concerns that the WTO would challenge the E.U. ban on rbGH ("Court undermines" 1998; Horton 1999). Thus at the end of the 1990s, the European Commission turned its attention to human safety and animal welfare issues (included under the "safety" criterion) and denied that the permanent moratorium on rbGH had anything to do with the socioeconomic concerns that motivated the ban throughout the 1990s. In this way, E.U. policy makers avoided possible repercussions for creating "barriers to trade" while continuing to ban a hormone that many believed to be socially and economically destructive. The structure of E.U. policy making notwithstanding, were it not for the WTO and the strength it lent to scientism, it seems likely that rbGH would have been banned in the European Union on socioeconomic grounds. Social welfarism served as a source for multiple temporary bans on rbGH, but WTO trade rules that institutionalized a kind of scientism ultimately meant that, while proponents of the fourth hurdle were able to prohibit the commercialization of rbGH, they were not able to make "nonscience" a legitimate basis for technology regulation.

CONCLUSION

Empirically, one of the most curious aspects of the rbGH/fourth hurdle debate in the European Union is the apparent conflation taken for granted by rbGH opponents and proponents alike. Actors on both sides appeared to assume not only that the traditional three criteria of evaluation were scientific, but that the thresholds set as acceptable across these three dimensions were also matters of fact, objective matters. In the case of the fourth criterion, opponents and proponents made a similar conflation but in reverse. They appeared to assume that, because what would count as an acceptable level of social impact was clearly a matter of values, any measurement of such criteria must also be value-laden.

We do not know for certain what explains these two parallel conflations. We do, however, have some speculations. In the matter of the traditional three criteria, it may be that widespread consensus on what counts as acceptable levels of safety, quality, and efficacy (according to agreed measures) has led to the conflation. Because there is such consensus, the value basis of determining acceptable levels may have become hidden. By contrast, because opponents and proponents would clearly disagree about what would count as acceptable levels of, for example, social dislocation resulting from the introduction of new technologies, the value-laden basis of any measure of social impact is widely assumed.

At a conceptual level, our study makes several contributions to the literature on boundaries in technoscience. First, we illustrate the virtues of examining the role of both linguistic *and* organizational features of the social world in order to understand boundaries in technoscience policy making. Second, our study shows the importance of paying attention not only to highly context-dependent and fleeting rhetorics, but also to deeply rooted historically resonant discourses. Finally, we focus on actors' use of taken-for-granted and unexamined discourses rather than assuming all uses of rhetoric are self-consciously strategic.

In the rbGH/fourth hurdle case generally, three explanatory factors stand out:

1. The historical resonance and the respective statuses of discourses: The power of scientism and social welfarism in the E.U. debate over rbGH came from their long histories and their respective statuses as taken-for-granted common sense. E.U. officials accepted both as legitimate premises for debate, if not for policy.
2. The structure and organization of decision making: The power and stability granted by historically resonant discourses should be considered in combination with the rules of debate and policy making as these are structured by policy-making institutions.
3. Institutionalization of discourses: The institutionalization of discourses in laws and regulations, as was the case of scientism in the WTO, can make those elements more powerful still.

It is not clear the extent to which the kinds of factors we focused on are broadly applicable to understanding boundaries in technoscience policy making. However, we believe our study suggests the virtue of attention to concerns in addition to processes of construction and related questions of *how* boundaries are drawn in particular ways. In future research, understanding the role of enduring and stable attributes of the social world may help explain *why* boundaries are drawn in particular ways and *why* some actors are more successful in boundary drawing than are others.

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NOTES

1. In this context, Gieryn (1999, p. xi) notes: "There are winners and losers of course, but through it all and over historical time, the connection is reproduced between science (a fuzzy set if there ever was one) and the legitimate power to define the real."

2. For some early discussions of these issues, see Roush (1991), Hallberg (1991), and USC-OTA (1991).

3. There were some who suggested or implied that the socioeconomic effects of commercializing rbGH could be the subject of "objective" and, therefore, scientific study (EP 1996). There were, however, few, if any, explicit statements of intent to consider socioeconomic effects "scientifically."

4. The language of "competitive position" points to the importance of the rhetoric of the "free market" that, along with the discourses on which we focus here, played a part in the fourth hurdle/rbGH debate in the European Union. We develop this point in Kleinman and Kinchy (2003).

5. Politicians and bureaucrats on both sides of the debate generally appeared to accept that the traditional three criteria of assessment are "scientifically measurable" while the socioeconomic impacts of a new technology are not. However, an array of social scientists who have studied the likely impacts of new biotechnologies in agriculture appear to believe that socioeconomic impacts can be scientifically measured (e.g., Fetrow 1999). In this context, it is worth noting that our study focuses centrally on politicians and civil servants. We do not discuss the roles of scientists, social scientists, or social movements.

Significantly, in a thorough review of E.U. documents, press coverage, and our correspondence with a key member of the European Parliament, we found no evidence that any of these actors had a direct impact on the trajectory or outcome of the struggle over the commercialization of rbGH and the fourth hurdle in the E.U. It may be that the thinking of politicians and civil servants involved in the debate was shaped by what they heard from scientists, social scientists, or social movements, but this is not clear from the historical record. On the matter of social movements, in particular, in Europe, nongovernmental organizations (NGOs) (environmental groups, animal rights groups, and the like) began to take a sustained interest in genetic engineering and agriculture only in the mid-1990s (Schweiger 2001). Of course, discussion of the social impacts of veterinary technologies and rbGH began in E.U. governmental bodies in the late 1980s. Moreover, although groups and alliances in Europe began organizing in 1991 to oppose the commercialization of rbGH in the European Union, and sometimes mentioned the effect on small-scale farming of commercialization, this was typically not central to their messages, and we found no evidence that these organizations were interested in the fourth hurdle in particular ("BST" 1991; "COPA and COGECA" 1994; "Hormones" 1994). All this said, in the United States some opponents of rbGH did oppose the technology on the grounds of its likely social impacts, and it seems possible—perhaps even likely—that those in the European Parliament and Commission supportive of the fourth hurdle and opposed to the commercialization of rbGH on socioeconomic grounds were influenced by U.S. NGOs. In the end then, while it seems possible that social movement organizations *indirectly* influenced E.U. policy makers, we found no concrete evidence of this. As importantly, we found no

evidence of a *direct* impact of social movements on E.U. policy making on this matter, and, given the timing of European NGO interest in agricultural biotechnology and the focus of their opposition, we have reason to doubt that NGO influence on this policy matter was significant.

6. In its 1996 "Own-Initiative Opinion," the European Parliament repeated "its proposal for adding a fourth criterion to the present three—safety, quality and effectiveness—in the procedure for the approval of non-therapeutic veterinary medicaments, requiring an objective study of the social and economic consequences and an environmental impact assessment" (EP 1996).

7. Here again, we remind readers that both sides in the rbGH/fourth hurdle debate seemed to conflate the objectivity of *measures* of safety, quality, and efficacy with the perceived objectivity of decisions about *acceptable levels* across these dimensions.

8. Much of our discussion here relies on the work of Robert Proctor (1991).

9. For a comparative analysis of the rbGH debate in the United States and Europe, see Kleinman and Kinchy (2003).

10. Of course, in some debates in the United States over the development of science and technology, actors are able to draw on a quasi-theological discourse to bolster their position. Such discourses are usually adopted in cases in which humans and potential humans are directly subject to the treatment of the product of technoscience (e.g., fetal research, stem cell research, and certain types of cloning).

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