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REGULATORY FRONTIERS

Integrating Social and Ethical Concerns Into Regulatory Decision-Making for Emerging Technologies

Gary Marchant, Ann Meyer & Megan Scanlon*

I. INTRODUCTION

Many emerging technologies—including advances in genetic medicine, animal and plant biotechnology, nanotechnology, stem cells, robotics, synthetic biology, and neuroscience—raise important ethical and social issues. These issues are intensively debated in a variety of contexts by stakeholders, scholars, and the researchers themselves during the research stage of technology development. Discussion appears in academic research projects and publications; regional, national and international conferences; professional associations; Congressional debates and reports; and governmental advisory bodies such as the President’s Council on Bioethics, the Secretary of Health and Human Services (HHS) Advisory Committee on Genetics, Health and Society, or the HHS Secretary’s Advisory Committee on Human Research Protections. With a few relatively narrow exceptions for requirements such as human subjects protection,¹ however, the

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1. While Institutional Review Boards (IRBs) are required to review most research involving human subjects, IRBs are expressly prohibited from considering the longer-term ethical implications of proposed research. 45 C.F.R. § 46.111(a)(2) (2008) (“The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible

impact of these debates on the direction and performance of research is primarily hortatory and voluntary, with few mandatory legal requirements or restrictions relating to ethical and social concerns imposed at the research stage.

Ethical and social concerns may also animate market forces in the form of consumer demands, as well as objections once the technologies are commercialized. But between the research and commercialization stages in the development of emerging technologies, the regulatory-approval step provides perhaps the best opportunity to expressly and formally consider the ethical and social impacts of new technologies. Yet, when confronted with making regulatory decisions that raise such ethical and social concerns, federal regulatory agencies often seem prevented by legal and practical restraints from addressing those very issues.

This article considers the issue of whether and how regulatory agencies should give more express consideration to the ethical and social impacts of technologies they regulate. Part II demonstrates that current practice and law generally exclude the explicit and open consideration of ethical and social issues. Part III sets forth the arguments for giving greater weight to those issues in regulatory decision-making. Part IV raises some potential concerns and pitfalls associated with giving more express consideration to ethical and social implications. Finally, Part V evaluates two potential models for more explicitly incorporating ethical and social concerns into regulatory decision-making.

II. EXCLUSION OF ETHICAL AND SOCIAL CONCERNS IN CURRENT PRACTICE

While current U.S. regulatory regimes usually address issues such as costs and impacts on health, safety, and the environment, such regimes are generally structured to ignore the social and ethical issues that arise in response to emerging technologies. Yet, the concerns expressed by many members of the public tend to be centered in the ethical and social realms, whether presented as the “yuck” factor or repugnance in response to technological developments that cause discomfort or unease, or in more concrete and articulated moral or societal

effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.”).

concerns.² Examples of such concerns include the distributional impacts of new technologies, their potential use for enhancing humans, the “unnatural” nature of some of the interventions made possible by new technologies, and the commoditization or destruction of human or animal “life,” however defined.³

A recent example of a regulatory agency’s inability and failure to address the public’s social and ethical concerns is the decision by the Food and Drug Administration (FDA) to approve the marketing of milk and meat from cloned animals.⁴ Thousands of members of the public took the time to prepare and submit comments to the FDA raising social and ethical concerns about the FDA’s proposed decision on cloned animals.⁵ While the substantive merits of these comments are certainly debatable, the FDA refused to engage the issues altogether, instead dismissing such claims with a cursory statement that “the agency has not been charged with addressing moral, religious, or ethical issues associated with animal cloning”⁶ Yet, a public opinion poll found that 63% of respondents felt (53% felt strongly) that “[g]overnment regulators should

2. E.g., Kristen Kulinowski, *Nanotechnology: From “Wow” to “Yuck”?*, 24 BULL. SCI. TECH. & SOC’Y 13, 17 (2004); Leon R. Kass, *Defending Human Dignity*, COMMENTARY, Dec. 2007, at 53, 54; Editorial, *Beyond the Yuck Factor*, NEW SCIENTIST, June 25, 2005, at 5, 5.

3. See, e.g., Anne Chapman, *Genetic Engineering: The Unnatural Argument*, 9 TECHNÉ 81, 81–92 (2005) (arguing that genetic engineering is unnatural and hence morally suspect); Kass, *supra* note 2, at 54 (discussing nanomechanical implants that enhance sensation or motor skills and the emerging science of producing man-machine hybrids).

4. See generally John F. Murphy, *Mandatory Labeling of Food Made From Cloned Animals: Grappling with Moral Objections to the Production of Safe Products*, 63 FOOD & DRUG L.J. 131 (2008) (recounting the origins of cloned food, the FDA’s decision to approve products from cloned animals as safe, and the legislative response to the FDA’s decision).

5. U.S. FOOD & DRUG ADMIN., FDA’S RESPONSE TO PUBLIC COMMENT ON THE ANIMAL CLONING RISK ASSESSMENT, RISK MANAGEMENT PLAN, AND GUIDANCE FOR INDUSTRY, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055491.htm> [hereinafter U.S. FOOD & DRUG ADMIN] (stating that the FDA received approximately 30,500 comments); see also Rick Weiss, *FDA is Set to Approve Milk, Meat from Clones*, WASH. POST, Oct. 17, 2006, at A1 (noting that surveys showed that 60 percent of the U.S. population was uncomfortable with the idea of cloning animals for milk and food); Zahra Meghani & Immaculada de Melo-Martin, *The U.S. Food and Drug Administration’s Evaluation of the Safety of Animal Clones: A Failure to Recognize the Normativity of Risk Assessment Projects*, 29 BULL. OF SCI. TECH. & SOC’Y 9, 9 (2009) (questioning the FDA’s stated mission and the adequacy of the public comment process).

6. U.S. FOOD & DRUG ADMIN., *supra* note 5, at 4.

include ethical and moral considerations, in addition to scientific evaluation of risks and benefits, when making regulatory decisions about cloning or genetically modifying animals.”⁷

The FDA’s refusal to consider such concerns is undoubtedly correct in a legal sense. Congress charged the agency only with ensuring that products are “safe” and “effective,”⁸ criteria that do not seem to incorporate broader ethical or social concerns. Nonetheless, it is problematic to dismiss as “out-of-bounds” the deeply-felt views of many Americans who comment on a proposed government action simply because their concerns are outside the agency’s stated mission.

Many other examples of this problem exist. The approval of drugs such as human growth hormone that have enhancement as well as therapeutic applications proceeds without significant consideration of the ethical concerns, and despite many concerns among experts and the public about potential misuse for enhancement purposes.⁹ As the number of available drugs addressing cognitive performance (e.g., Alzheimer’s treatments) is expected to expand over the next decade,¹⁰ the inability of FDA to consider factors other than safety and efficacy will become increasingly problematic and limiting. Similarly, much of the opposition to genetically modified crops and foods is based on ethical, social, and religious concerns,¹¹ yet regulatory agencies including the FDA, U.S. Department of Agriculture (USDA), and Environmental Protection Agency (EPA) have not given any explicit consideration or weight to such concerns.¹²

7. Memorandum from the Mellman Group to the Pew Initiative on Food and Biotechnology, *Recent Findings*, at 7 (Nov. 7, 2005), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press_Releases/Food_and_Biotechnology/PIFB_Public_Sentiment_GM_Foods2005.pdf.

8. Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 393(b) (2009).

9. See, e.g., Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, MICH. ST. L. REV. 1135, 1159-60 (2005).

10. See Robert E. Becker & Nigel H. Greig, *Alzheimer’s Disease Drug Development in 2008 and Beyond: Problems and Opportunities*, 5 CURRENT ALZHEIMER RES. 346, 346-47, 356 (2008).

11. Lynn Frewer et al., *Societal Aspects of Genetically Modified Foods*, 42 FOOD & CHEMICAL TOXICOLOGY 1181, 1183 (2004); Immaculada de Melo-Martin & Zahra Meghani, *Beyond Risk*, 9 EMBO REP. 302, 302 (2008).

12. Melo-Martin & Meghani, *supra* note 11, at 305.

III. THE CASE FOR INCLUSION OF SOCIAL AND ETHICAL CONCERNS

As the ethical and social issues raised by new biomedical and other emerging technologies continue to expand in the future with growth in the capabilities and power of new technologies, the current inability to consider ethical and social issues in the context of regulatory decision-making will become increasingly problematic. To be sure, there are other social mechanisms including governmental ethics advisory bodies, scholarly and public deliberations, and the new focus on upstream engagement, available to address the social and ethical impacts of new technologies.¹³ Notwithstanding such forums and mechanisms, there remains a problem when ethical or social issues are raised (often by the public) in specific rulemaking proceedings, as agencies often lack the legal jurisdiction or political wherewithal to respond on the merits. Given that many of the public concerns about such technologies are ethical or social in nature, it seems inappropriate from both a normative and instrumental perspective for regulatory agencies to continue to disregard such concerns because they are outside of their stated regulatory missions.

The straightforward normative argument for regulatory agency consideration of social concerns is that in a democratic society, citizens should have the right to comment on whatever issues concern them regarding government decisions. Moral and social concerns are often deeply-felt and strongly-held by many members of society, and in their perception such issues cannot be divorced from the scientific, economic, and other policy issues that regulatory agencies do consider.¹⁴ Thus, in a democracy, citizens should have the right to raise moral and social concerns about a proposed government action, and to have those concerns considered and addressed by government decision-makers.¹⁵

13. See JAMES WILSDON & REBECCA WILLIS, *SEE-THROUGH SCIENCE: WHY PUBLIC ENGAGEMENT NEEDS TO MOVE UPSTREAM* (2004); Tee Rogers-Hayden & Nick Pidgeon, *Moving Engagement "Upstream"? Nanotechnologies and the Royal Society and Royal Academy of Engineering's Inquiry*, 16 *PUBLIC UNDERSTANDING SCI.* 345 (2007).

14. See Sheila Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 *MINERVA* 223, 243 (2003) (arguing that public discussion of science and technology should include ethical analysis).

15. See Marcy Darnovsky, *Political Science*, *DEMOCRACY*, Summer 2009, at 36, 37, available at <http://www.democracyjournal.org/pdf/13/Darnovsky.pdf> (last visited Jan. 23, 2010).

There is also an instrumental value to agencies expressly considering ethical and social concerns raised by the public. The public is much more likely to accept a government decision if its views have been accorded respect and consideration, even when they do not agree with the ultimate decision substantively, than if the government does not provide an opportunity to air and consider those dissenting views.¹⁶ Thus, regardless of the ultimate outcome of the decision-making process, government decisions will be more credible if regulators expressly consider the ethical and social issues that concern members of the public.¹⁷

An additional instrumental argument is that ethical and social issues are so central to decisions on many emerging technologies that if they are not addressed explicitly, they will inevitably be addressed implicitly or covertly. An example is the recent FDA debacle over the Plan B emergency contraceptive, where ethical and social concerns appeared to motivate the agency's reluctance to approve the product for over-the-counter availability, yet the agency declined to be explicit about these concerns and instead tried to camouflage its decision on scientific and policy grounds that it perceived were more legitimate.¹⁸ This ruse fooled no one—not the critics, the media, Congress, or even scientists within the agency. The FDA's recalcitrance to approve the product was eventually struck down by a federal court on the grounds of improper decision-making criteria and procedure.¹⁹ The entire incident left a blemish on the agency's credibility and reputation.²⁰

A final instrumental argument is that if the public's ethical and social concerns are not addressed now, those concerns will fester and build up over time until they burst forth with potentially devastating consequences for the scientific and technological enterprise. As Leon Kass warned almost forty years ago: "If attempts are not made early to detect and diminish the social costs of biomedical advances by intelligent

16. NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 81–82 (Paul C. Stern & Harvey V. Fineberg eds., 1996).

17. Frewer et al., *supra* note 11, at 1190.

18. *See id.* at 392–94.

19. *Tummino v. Torti*, 603 F. Supp. 2d 519, 547–48, 550 (E.D.N.Y. 2009).

20. *See* Frank Davidoff, *Sex, Politics and Morality at the FDA: Reflections on the Plan B Decision*, HASTINGS CENTER REP., March 2006, at 20, 24–25.

institutional regulation, the society is likely to react later with more sweeping, immoderate, and throttling controls.”²¹ We may already be experiencing the first waves of such pent-up public frustrations as a result of past failures to adequately address the public’s concerns. Those concerns, and the potentially devastating long-term consequences of ignoring them, will expand dramatically with the growing impact and intrusiveness of emerging technologies.

In short, for both normative and instrumental reasons, there is a strong presumptive case for allowing agencies to give express consideration to ethical and social concerns in regulatory decisions.

IV. CONCERNS ABOUT INCORPORATING ETHICAL AND SOCIAL ISSUES

There are some reasons to be cautious about explicitly incorporating ethical and social issues into regulatory decision-making. Unlike safety and efficacy, where people can fairly easily reach consensus on what is a good or bad result (e.g., causing tumors is bad), there is more room for disagreement on what is a good or bad moral or social effect.²² For example, people may disagree on whether the alleged impact of genetic engineering in promoting the consolidation of small family farms into larger, more efficient industrial farms is a favorable or unfavorable outcome.²³ In the same vein, social and ethical risks are more intangible, as well as harder to define and quantify, and thus do not lend themselves to the same type of quantitative analyses and validation that are common for safety or efficacy determinations by regulatory agencies.²⁴

21. Leon R. Kass, *The New Biology: What Price Relieving Man’s Estate?*, 174 SCI. 779, 787 (1971).

22. See Harold T. Shapiro, *Reflections on the Interface of Bioethics, Public Policy, and Science*, 9 KENNEDY INST. ETHICS J. 209, 209 (1999) (“[W]e continue to lack a moral consensus on some of the most profound ethical claims that some believe ought to be more fully reflected in actual public policies.”).

23. See, e.g., Daniel Lee Kleinman et al., *Local Variation or Global Convergence in Agricultural Biotechnology Policy? A Comparative Analysis*, 36 SCI. & PUB. POL’Y 361, 365 (2009).

24. Such factors produce trepidation about the government wading into ethical and moral issues. Thus, in one poll, approximately two-thirds of respondents favored basing governmental regulatory decisions on scientific factors alone, while only one-third favored decisions based on ethical and social concerns. George Gaskell et al., *Social Values and the Governance of Science*, 310 SCI. 1908, 1908 (2005). As the authors of this study note,

Finally, ethical and social views are not fixed in time, but tend to shift rapidly with changes in technological capabilities and other societal factors.²⁵

Other problems also justify caution in making regulatory agencies the arbiters of moral correctness. The professional staff of regulatory agencies consists primarily of scientists, engineers, economists, and attorneys. Should these agencies be staffed much more heavily with ethicists, social scientists, and, perhaps, even theologians? Would we accept such a government agency explicitly making moral and social decisions about products such as the Plan B emergency contraceptive, especially when the outcome might shift dramatically with a change in administration?²⁶ Given that ethical and moral concerns are closely tied to religious beliefs for many people, might allowing explicit moral and social decisions create a risk of violating the First Amendment's required separation of church and state? Finally, regulatory agency officials have expressed concern that requiring express consideration of moral and ethical issues in regulatory actions would jeopardize the perceived scientific basis and credibility of their decisions.²⁷

Given the intangible and subjective nature of ethical and social concerns, there is also a risk that government agencies empowered to consider such concerns might publicly justify regulatory decisions based on such factors, when protectionist or other improper motives are the true rationale for the decision.²⁸ For example, several European Union (EU) member

however, alienating the significant minority who favor consideration of ethical and social implications could adversely affect overall societal trust in new technologies. *Id.* at 1909.

25. See Shapiro, *supra* note 22, at 210.

26. See Jonathan D. Rockoff, *Critics Weigh in on FDA's Decisions: Some Say Ethics, Finances Should be Factors for Product Approval*, BALTIMORE SUN, Jan. 9, 2006 (quoting bioethicist Daniel Callahan opposing giving agencies such as FDA authority to consider moral considerations in regulatory decisions because "[a]ny solutions would, I think, reflect the position of the party in power.").

27. See *id.* (citing the argument of a former FDA official that "the agency's hard-won credibility would suffer if it abandoned its scientific focus").

28. See LINDA NIELSEN & BERIT A. FABER, NAT'L CONSUMER AGENCY OF DENMARK, ETHICAL PRINCIPLES IN EUROPEAN REGULATION OF BIOTECHNOLOGY – POSSIBILITIES AND PITFALLS 22 (2002) ("Since ethical concerns are difficult to document and might be perceived as a paving the way for ulterior national interests . . . it is difficult to take account of these concerns.").

states recently proposed that the EU regulatory approach to GM foods should be revised to allow a member state to ban or restrict genetically modified (GM) foods based on factors such as social-economic and moral objections of the public.²⁹ While many EU citizens have genuine social and moral objections, public opinion studies show that the primary concern is that GM foods are unsafe.³⁰ Yet, every major scientific organization that has addressed the issue, including the EU's own scientific advisors, has concluded that GM foods are as safe, if not safer, than conventional non-GM foods.³¹ Thus, ethical and social concerns could act as a Trojan horse used to hide invalid or inappropriate rationales that cannot stand up to public scrutiny but which are nevertheless the true drivers of a regulatory decision.

V. NEW APPROACHES FOR CONSIDERING ETHICAL AND SOCIAL CONCERNS

The concerns described in the previous section suggest that it might be problematic to give regulatory agencies direct and express authority to make ethical or social judgments about emerging technologies. On the other hand, it may be even more objectionable to avoid these ethical and social considerations altogether. Innovative new mechanisms or approaches are needed to incorporate ethical and social concerns into regulatory decisions on emerging technologies. Concurring in this view, the Secretary's Advisory Committee on Genetic

29. Memorandum from the General Secretariat, Council of Europe to the Delegations, Annex (June 24, 2009), available at <http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re02.en09.pdf> (last visited Jan. 23, 2010).

30. See, e.g., Montserrat Costa-Font et al., *Consumer Acceptance, Valuation of and Attitudes Towards Genetically Modified Food: Review and Implications for Food Policy*, 33 FOOD POLY 99, 107–108 (2008); Gunjan Sinha, *Up in Arms*, 27 NATURE BIOTECHNOLOGY 592, 592–593 (2009).

31. See, e.g., European Commission, *A Review of Results: EC-sponsored Research on Safety of Genetically Modified Organisms*, <http://ec.europa.eu/research/quality-of-life/gmo/index.html> (compiling the results of over 80 European Commission-sponsored research projects on the safety of GM food); see also, e.g., NATIONAL RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS 49 (2002) (“the transgenic process presents no new categories of risk compared to conventional methods of crop improvement”); NATIONAL RESEARCH COUNCIL, REPORT IN BRIEF: SAFETY OF GENETICALLY ENGINEERED FOODS (2004) (“Genetic engineering . . . poses no unique health risks that cannot also arise from conventional breeding and other genetic alteration methods.”).

Testing recommended in 2000 that:

In the future, [genetic] tests may be developed that raise major social and ethical concerns. Because FDA's review will focus on assuring the analytical and clinical validity of a test, the agency's capacity to assess the ethical and social implications of a test may not be sufficient. The Secretary should consider the development of a *mechanism* to ensure the identification and appropriate review of tests that raise major social and ethical concerns.³²

Another group of experts likewise endorsed the creation of mechanisms to explicitly consider the public's social and ethical concerns:

[I]t is becoming very apparent that institutional transparency, coupled with the integration of public concerns into policy development and implementation, will facilitate the introduction of emerging technologies and their applications . . . into society. In order that this strategy might be successful, it is important to understand what is driving public concern, and to integrate this into policy development rather than dismiss it as irrational as has sometimes happened in the past.³³

In designing mechanisms to better analyze and deliberate on the moral and social dimensions of proposed regulatory decisions, we must recognize that in the morally pluralistic society in which live, consensus on these issues is highly unlikely.³⁴ Thus, the goal should not be to make any final decision on these ethical and social issues, but to provide a process whereby differing perspectives and interests can be presented, discussed, and considered in a transparent and explicit manner.

What might a new institutional approach look like? In the remainder of this paper, we consider two possible models: (1) the requirement for an ethical impact statement to accompany regulations, and (2) the creation of an ethics review board to review specific regulatory decisions. As analysis of real-world examples will show, both models allow more explicit and formal consideration of ethical and social issues in regulatory decision-

32. Public Comments on Preliminary Final Recommendations on Oversight of Genetic Testing, 65 FED. REG. 21,094, 21,095 (July 2000); *see also* Kass, *supra* note 21, at 787 ("Concepts of 'risk' and 'cost' need to be broadened to include . . . social and ethical consequences.").

33. Frewer et al., *supra* note 11, at 1191.

34. *See* Lonneke Poort, *Consensus or Dissensus in the Legislative Approach to Complex Policy Problems?: Animal Biotechnology as an Example* 15 (Tilburg Working Paper Series on Jurisprudence and Legal History, No. 08-03, 2008), available at <http://ssrn.com/abstract=1284924>.

making.

A. ETHICAL IMPACT STATEMENT

A regulatory agency could be required to issue an “Ethical Impact Statement” (“EthIS”) to accompany any significant regulatory decisions. This EthIS would have to identify and evaluate the ethical and social impacts of the agency’s proposed decision and the efforts (if any) the agency was undertaking to mitigate those impacts. This model is analogous to the Environmental Impact Statement (EIS) that federal agencies must issue under the National Environmental Policy Act (“NEPA”) for any federal actions that will significantly affect the human environment.³⁵ Although NEPA does not have any substantive impact in terms of limiting or directing an agency’s decision,³⁶ it does have a beneficial impact in forcing the agency to be aware of the environmental impacts of its actions, and informing the public of those impacts.³⁷ An EthIS could operate

35. 42 U.S.C. § 4332 (2006). Various types of other impact statements are required in other contexts, primarily in jurisdictions outside the United States, which provide additional bodies of empirical evidence that could also be used as models for an ethical impact statement. See, e.g., Roger Clarke, *Privacy Impact Assessment: Its Origins and Development*, 25 COMPUTER L. & SECURITY REV. 123, 123 (2009) (discussing privacy impact assessments); Janet Collins & Jeffrey P. Koplan, *Health Impact Assessment: A Step Toward Health in All Policies*, 302 JAMA 315, 315 (2009). (discussing proposals for health impact assessments “to examine the effects that a policy, program, or project may have on the health of a population”); Elin Palm & Sven Ove Hansson, *The Case for Ethical Technology Assessment (eTA)*, 73 TECHNOLOGICAL FORECASTING & SOC. CHANGE 543, 543–44 (2006) (proposing requirement for an ethical technology assessment).

36. *Marsh v. Ore. Natural Res. Council*, 490 U.S. 360, 371 (1989) (“NEPA does not work by mandating that agencies achieve particular substantive environmental results.”).

37. See *Inland Empire Pub. Lands Council v. U.S. Forest Serv.*, 88 F.3d 754, 758 (9th Cir. 1996) (“NEPA’s goal is satisfied once . . . information is properly disclosed; thus, NEPA exists to ensure a *process*, not to ensure any result.”); see also James M. McElfish, Jr., *NEPA and Liberty, Now and Forever*, 39 ENVTL. L. REP. 10629, 10629 (2009) (“The result of these procedures is that *alternatives* are considered that the government would not have identified on its own, that *data* are discovered that the government would not have otherwise identified, and that *environmental issues* are studied that the government would not have identified or studied. Bad decisions are sometimes avoided and good decisions made even better. Mitigation measures are identified; some of them are even adopted.”). Despite its many positive impacts, the NEPA EIS requirements has been criticized for the amount of time and resources needed to complete an assessment, the low quality of information and analysis often included, and the “ritualization” of the process within agencies, stimulated by a desire to make litigation-proof

in a similar manner with respect to a regulation's ethical implications.

Another precedent for an EthIS is the World Bank's requirement for a Poverty and Social Impact Analysis ("PSIA"). The origins of the PSIA can be traced back to the 1995 World Summit for Social Development in Copenhagen, which adopted the Declaration on Social Development.³⁸ As subsequently articulated by the World Bank, the new approach to social policy outlined by the Declaration involved a "political, economic, ethical and spiritual vision [that is] based on human dignity, human rights, equality, respect, peace, democracy, mutual responsibility and cooperation, and full respect for the various religions and ethical values and cultural backgrounds of people."³⁹ This represented a significant broadening of the Bank's decision-making criteria beyond traditional economic considerations. By the end of the 1990s, the World Bank had revised its social development strategy to more explicitly consider and give more weight to social norms, values, and institutions, using "a holistic approach" that replaced the Bank's fixation on increasing income.⁴⁰ One mechanism adopted for implementing this strategy was a requirement to conduct a PSIA of proposed policy reforms.⁴¹

A PSIA utilizes a multidisciplinary approach, integrating both social and economic analytical tools, to perform an ex-ante analysis of the social impacts of proposed policy reforms.⁴² A

decisions. See generally Bradley C. Karkkainen, *Toward a Smarter NEPA: Monitoring and Managing Government's Environmental Performance*, 102 COLUM. L. REV. 903, 917-23 (2002).

38. See Antje Vetterlein, *Economic Growth, Poverty Reduction, and the Role of Social Policies: The Evolution of the World Bank's Social Development Approach*, 13 GLOBAL GOVERNANCE 513, 527 (2007); see also SOC. DEV. DEP'T, WORLD BANK, PAPER NO. 27, SOCIAL DEVELOPMENT UPDATE: MAKING DEVELOPMENT MORE INCLUSIVE AND EFFECTIVE 1 (1998).

39. Vetterlein, *supra* note 38, at 527.

40. *Id.* at 518.

41. See *id.* at 528.

42. See INT'L BANK FOR RECONSTRUCTION & DEV., WORLD BANK, A USER'S GUIDE TO POVERTY AND SOCIAL IMPACT ANALYSIS 1 (2003), [http://siteresources.worldbank.org/EXTTOPPSISOU/Resources/1424002-1185304794278/4026035-](http://siteresources.worldbank.org/EXTTOPPSISOU/Resources/1424002-1185304794278/4026035-1185386760315/PSIA_English.pdf?resourceurlname=PSIA_English.pdf)

1185386760315/PSIA_English.pdf [hereinafter PSIA USER'S GUIDE]. Although there is no fixed template for analyzing the poverty and social impacts of policy, "it is possible to identify a number of elements that make for good-practice PSIA." *Id.* at 9. The ten elements of a PSIA are: (1) asking the right questions, (2) identifying

successful PSIA tends to have four characteristics: (1) it helps to promote the use of a wider range of evidence in policy making; (2) it “increases the extent to which distributional equity is considered in the policy process by ensuring that policies are not judged purely on aggregate economic efficiency grounds;”; (3) it combines analysis with process to understand and manage the political economy of reform, and (4) it “supports inclusive policy making by providing evidence with which policy makers and other stakeholders can inform their discussions through existing or emerging policy processes.”⁴³

An effective PSIA, thus, has two major impacts. First, it informs policymakers about the likely societal implications of different policy options to facilitate better and more socially-conscious decision-making. Second, it informs and mobilizes various constituencies in the affected jurisdiction with respect to the probable social impacts of policy interventions, thereby empowering such constituencies to engage with and influence the policy-making process. For this to occur, it is important that the information in the PSIA be collected and communicated in a transparent manner, and opportunities be afforded to stakeholders to participate in the policy-making process.⁴⁴

Identifying and engaging stakeholders early in the process of a PSIA is essential to its success. The World Bank PSIA procedure therefore calls for a “stakeholder analysis” to identify “people, groups, and organizations that are important to take

stakeholders, (3) understanding transmission channels, (4) assessing institutions, (5) gathering data and information, (6) analyzing impacts, (7) contemplating enhancement and compensation measures, (8) assessing risks, (9) monitoring and evaluating impacts, and (10) fostering policy debate and feeding back into policy choice. *Id.*

43. JEREMY HOLLAND, TOOLS FOR INSTITUTIONAL, POLITICAL, AND SOCIAL ANALYSIS OF POLICY REFORM 11 (2007).

44. INT’L BANK FOR RECONSTRUCTION & DEV., WORLD BANK, GOOD PRACTICE NOTE: USING POVERTY AND SOCIAL IMPACT ANALYSIS TO SUPPORT DEVELOPMENT POLICY OPERATIONS 17–20 (2008), http://siteresources.worldbank.org/INTPSIA/Resources/GPN_August08_final.pdf [hereinafter GOOD PRACTICE NOTE]; see also PSIA USER’S GUIDE, *supra* note 42, at 35. (“One way to approach this is to disseminate information about the proposed reform and the results of the PSIA to the public, especially to key stakeholders, and then to organize a policy forum where stakeholders can discuss the tradeoffs involved. . . . Insights gained through dialogue may be technical (for example, academic research) or social (for example, the perspectives and concerns of groups that typically do not participate in the formal policy debate process.”).

into account.”⁴⁵ The World Bank PSIA User’s Guide advises splitting stakeholders into two primary groups, the first being beneficiaries and those who suffer adverse impacts, and the second consisting of organized groups such as unions, business associations, donors, and civil society organizations.⁴⁶ Once the groups are identified, stakeholder analysis is used, going beyond analyzing the interests of actors in relation to a policy to requiring “key informant interviews” to evaluate interests, and engaging appropriate stakeholders in the policy-making process.⁴⁷ The Bank also recognizes that the interests of stakeholders who are less organized or lacking representation may require the use of special surveys or focus groups.⁴⁸ For example, in Sri Lanka, a stakeholder analysis of the PSIA on land reform showed that “groups likely to be affected by the reform had not yet been consulted nor the impacts they would face considered. By identifying these previously overlooked stakeholder groups, the PSIA enabled their integration into a facilitated consultation process around the reform proposal.”⁴⁹

The PSIA requirements appear to have been successful in promoting greater explicit consideration of social and ethical impacts of World Bank decisions. For example, PSIA findings regarding the social impacts of land and fertilizer reform in Zambia sparked public debate among stakeholders.⁵⁰ Eventually, PSIA disclosure and discussions led to broader reforms in support of the land programs, including improved road access, especially in remote areas, greater access to fertilizer and functioning agricultural extension services.⁵¹ The end result was that “[t]he PSIA seems to have had a major impact on rethinking the need for and speed of a land reform of the kind proposed by the government. Enough evidence was produced through the PSIA analysis to lead policymakers to

45. PSIA USER’S GUIDE, *supra* note 42, at 10.

46. *Id.* at 11.

47. *Id.*

48. *Id.*

49. GOOD PRACTICE NOTE, *supra* note 44, at 15.

50. INT’L BANK FOR RECONSTRUCTION AND DEV., WORLD BANK, TOOLS FOR INSTITUTIONAL, POLITICAL AND SOCIAL ANALYSIS OF POLICY REFORM: A SOURCEBOOK FOR DEVELOPMENT PRACTITIONERS OR TIPS 38, 87–88 (2007), <http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTSOCIALDEVELOPMENT/EXTTOPPSISOU/0,,menuPK:1424015~pagePK:64168427~piPK:64168435~theSitePK:1424003,00.html> (hereinafter TIPS SOURCEBOOK).

51. *Id.* at 89.

rethink the necessity of such a comprehensive reform.”⁵²

Both the EIS and PSIA examples demonstrate the potential impact that a requirement for an analysis of otherwise neglected or under-emphasized dimensions of a decision can have in promoting greater awareness and emphasis on those issues in decision-making. A requirement for an agency to study and discuss the ethical and social impacts of its regulatory decisions could bring greater scrutiny to such issues. The EIS and PSIA examples demonstrate the need for transparency, outreach, and public engagement to ensure full ventilation of the ethical and social concerns of all sectors of society in an EthIS.

Such an approach would also have its limitations. A requirement to study and describe the ethical impacts would not necessarily ensure that those factors are appropriately incorporated into actual decisions. One major criticism of NEPA is that it is only procedural and does not directly affect the substance of regulatory decisions.⁵³ Another issue in the implementation of such a requirement would be the need for some type of threshold and guidance criteria for when an EthIS would be required and how much detail would be required.⁵⁴ Many regulatory decisions may raise few, if any, ethical and social issues, while other decisions may raise substantial ethical and social concerns. A requirement for EthISs would need a way to distinguish these situations through some sort of threshold or tiered approach.

B. ETHICS REVIEW BOARD

A second potential model would be to create an ethics review board (“ERB”) to evaluate and provide recommendations regarding the ethical aspects of specific agency proposals. The ERB could be situated within each agency, or could be government-wide and centralized in the White House. Most federal regulatory agencies already have similar advisory committees to provide scientific advice; the proposed Ethics

52. *Id.*

53. See Matthew J. Lindstrom, *Procedures Without Purpose: The Withering Away of the National Environmental Policy Act’s Substantive Law*, 20 J. LAND RESOURCES ENVTL. L. 245 (2000).

54. For example, NEPA limits the application of the requirement to prepare a full Environmental Impact Statement to only those government actions “significantly affecting the quality of the human environment.” 42 U.S.C. § 4332(2)(C) (2000).

Review Board would provide comparable advice on the ethical and social dimensions of the agency's actions. An ERB outside of the agency might have greater independence and credibility by being immune from any real or perceived control or influence by the agency making the regulatory decision. It would also promote consistency across federal agencies.

A centralized ERB would differ from existing structures such as the President's Council on Bioethics in that, instead of considering ethical issues associated with biomedical technologies in general,⁵⁵ the ERB would review the ethical and social dimensions of specific proposed regulatory actions by agencies. One possible analogy to this review authority is the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), which conducts an independent review of the economic analyses underlying proposed and final substantial regulatory decisions by agencies.⁵⁶

A precedent for a centralized ethical review body is provided by the European Group on Ethics in Science and New Technologies (EGE). This entity was originally constituted in 1991 as the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB), composed of six experts drawn from law, science, medicine, philosophy, and theology.⁵⁷ The group and its responsibilities have continually expanded since its creation.⁵⁸ When the GAEIB's mandate expired in 1997, the European Commission replaced the group with the EGE.⁵⁹ The Commission enlarged the group to twelve members, and the term for individual members was extended to from two to three years.⁶⁰ In 2005, it was further enlarged to fifteen members.⁶¹ EGE members are appointed by the E.U. Commission, and include professors of philosophy, theology, medical and health

55. Exec. Order No. 13,237, 3 C.F.R. 821 (2001), *reprinted in* 5 U.S.C. § 14 app. 2 (2006).

56. Exec. Order No. 12,866, 58 FED. REG. 51,735 (1993); *see also* Office of Management and Budget, Information and Regulatory Affairs, http://www.whitehouse.gov/omb/regulatory_affairs/default/ (last visited Oct. 22, 2009).

57. Helen Busby et al., *Ethical EU Law? The Influence of the European Group on Ethics in Science and New Technologies*, 33 EUR. L. REV. 803, 806 (2008).

58. *Id.* at 806–807.

59. *Id.* at 806.

60. *Id.*

61. *Id.*

care ethics, genetics and public health, clinical pharmacology, plant molecular genetics, food safety, information management, and law who currently serve five-year terms.⁶² The EGE and its predecessor, GAEIB, were created to address the perception that the European Commission lacked the resources, expertise, and authority to address the ethical implications of emerging technologies such as biotechnology.⁶³

There is no specific provision concerning ethics in the Treaty of Europe, the convention creating the EU and its various institutions and authorities.⁶⁴ The EGE, therefore, operates with little or no statutory or other legal authority or requirements. The group creates its own rules for procedure.⁶⁵ It has considerable autonomy; members provide their own perspectives and judgments with no specific obligation to follow or adhere to EU policies or interests.⁶⁶

The EU Parliament and Council of Ministers may request Opinions of the EGE, but the EGE can also initiate its own opinions.⁶⁷ The EGE is under a formal obligation to establish close links with Commission departments involved in the issue under consideration.⁶⁸ The EGE has no other formal obligation to consult other institutional actors, stakeholders, or the public, although the EGE has established the practice of consulting with outside experts to inform and support its opinions.⁶⁹

Notwithstanding the perceived need for such a body to provide expertise in ethics on emerging technologies, the EGE has been subject to extensive debate regarding its legitimacy and democratic accountability. Because technical experts who make up the EGE and its various committees do not have any political or social responsibilities to elected representatives or EU citizens, their accountability is questionable.⁷⁰ Despite these ongoing questions about the legitimacy of the EGE, it plays an influential role in EU law making and policy making. It serves to validate EU-level legislation, provides an interpretive reference point for policy, and serves as a forum for

62. *Id.* at 806, 835–36.

63. *See id.* at 807–808.

64. *See id.* at 837–38.

65. *Id.* at 839.

66. *See id.* at 838–39.

67. *See id.* at 808, 839.

68. *See id.*

69. *Id.*

70. *Id.* at 805.

airing ethical concerns raised by various civil society constituencies.⁷¹ In all of these roles, the EGE must balance economic growth and public acceptance.⁷² Increasingly the role of the EGE is to mediate among the EU legislature and executive, stakeholders such as industry seeking to enhance the regulatory environment for the development of new biotechnologies, and the citizenry who are suspicious of the ethical adequacy of the regulatory environment.⁷³ The courts, including the European Court of Human Rights, have relied on EGE opinions on such issues as ownership of unimplanted embryos.⁷⁴

The EGE is also influential in the adoption of EU Directives. For example, Directive 98/44⁷⁵ regarding legal protection of biotechnological inventions was proposed in 1988, but not passed for ten years because of controversial ethical debates.⁷⁶ The ethical principles outlined in EGE and GAEIB opinions are reflected in the Directive, and it names the EGE and acknowledges that their published opinions were taken into account.⁷⁷ Other EGE opinions identify ethical criteria that should be considered in legislation, advocate for certain positions, or set agendas for policy and legislation.⁷⁸

EU directives not only reflect and endorse many EGE recommendations, but occasionally also cite EGE opinions, and state that additional opinions will be sought in the future.⁷⁹ Commission press releases note that EGE opinions are taken into consideration along with the EU Charter for Fundamental Rights and documents of the Council of Europe, placing the EGE on the same level as long-standing authoritative bodies.⁸⁰ The EGE's recommendations are not always accepted, however, and some regulatory proposals may leave ethical concerns to

71. *See id.* at 805, 837–39.

72. *Id.* at 834.

73. *Id.* at 835.

74. Aurora Plomer, *The European Group on Ethics: Law, Politics and the Limits of Moral Integration in Europe*, 14 EUR. L.J. 839, 839–40 (2008).

75. Council Directive 98/44, 1998 O.J. (L213) 13.

76. Busby, *supra* note 57, at 810.

77. *Id.* at 814.

78. *See id.* at 819.

79. *See id.* at 813–14.

80. *Id.* at 820.

the individual EU member states.⁸¹

While the EGE has its limitations and controversies, it does demonstrate that an ethics review board can be effective in identifying, evaluating, and injecting into regulatory decisions the ethical and social dimensions of emerging technologies. The United States should consider adapting and adopting a similar body for injecting ethical and social concerns into regulatory decision-making.⁸²

VI. CONCLUSION

Ethical and social issues are an inherent and unavoidable aspect of many emerging technologies that will be entering the regulatory pipeline over the next decade. Current regulatory schemes are unable to adequately consider the ethical and social concerns associated with such technologies. It is no longer politically sustainable to ignore these ethical and social concerns in regulatory decision-making, yet giving regulatory agencies direct authority to evaluate and decide ethical issues on their own is likely to over-extend their expertise and legitimacy. Two alternative possible models to facilitate attention to ethical and social issues are requiring an ethical impact statement or creating an ethics advisory board to identify, evaluate, and publicize the ethical and social implications of proposed regulatory decisions. Both models should be considered.

81. *Id.* at 821.

82. It should be noted that this model does not directly engage the public to bring their social, ethical and religious concerns into the debate. Rather, the ethics body (whether it is the EU's, EGE, or the ERB proposed here) would serve as a conduit for expressing such concerns in the regulatory context, even though the relationship with the public would only be indirect.