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On Mandatory Labeling, With Special Reference to Genetically Modified Foods

Cass R. Sunstein*

As a result of movements for labeling food with genetically modified organisms (GMOs) Congress enacted a mandatory labeling requirement in 2016. These movements, and the legislation, raise recurring questions about mandatory product labels: whether there is a market failure, neoclassical or behavioral, that justifies them, and whether the benefits of such labels justify the costs. The first goal of this essay is to identify and to evaluate the four competing approaches that agencies now use to assess the costs and benefits of mandatory labeling in general. The second goal is to apply those approaches to the context of GM food.

Assessment of the benefits of mandatory labels presents especially serious challenges. Agencies have (1) claimed that quantification is essentially impossible; (2) engaged in breakeven analysis; (3) projected various endpoints, such as health benefits or purely economic savings; and (4) relied on private willingness to pay for the relevant information. All of these approaches run into serious normative and empirical challenges. In principle, (4) is best, but in practice, (2) is sometimes both the most that can be expected and the least that can be demanded.

Many people favor labeling GM food on the ground that it poses serious risks to human health and the environment, but with certain qualifications, the prevailing scientific judgment is that it does no such thing. In the face of that judgment, some people respond that even in the absence of evidence of harm, people have "a right to know" about the contents of what they are eating. But there is a serious problem with this response: there is a good argument that the benefits of such labels would be lower than the costs.

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Consumers would obtain no health benefits from which labels. To the extent that they would be willing to pay for them, the reason (for many though not all) is likely to be erroneous beliefs, which are not a sufficient justification for mandatory labels. Moreover, GMO labels might well lead people to think that the relevant foods are harmful and thus affirmatively mislead them.

Some people contend that GMOs pose risks to the environment (including biodiversity), to intelligible moral commitments, or to nonquantifiable values. Many people think that the key issue involves the need to take precautions in the face of scientific uncertainty: Because there is a non-zero risk that GM food will cause irreversible and catastrophic harm, it is appropriate to be precautionary, through labels or through more severe restrictions. The force of this response depends on the science: If there is a small or uncertain risk of serious harm, precautions may indeed be justified. If the risk is essentially zero, as many scientists have concluded, then precautions are difficult to justify. The discussion, though focused on GM foods, has implications for disclosure policies in general, which often raise difficult questions about hard-to-quantify benefits, the proper use of cost-benefit balancing, and the appropriate role of precautionary thinking.

I. Introduction

When should government mandate labels? When would mandatory labels have desirable consequences for social welfare? How can those consequences be measured? Under Executive Order 12866, binding on federal executive agencies, some kind of market failure is ordinarily required to justify regulation, including mandatory labels (either a standard, neoclassical market failure or a behavioral market failure).[1] And even in the presence of a market failure, Executive Order 12866 allows a mandatory label to be imposed only if the benefits justify the costs[2] – an issue that presents unusual challenges in light of the immense difficulty of quantifying both the benefits and the costs of labels.

My principal goal here is to attempt to show how agencies can make progress in surmounting that difficulty. Sometimes they can do so by quantifying both benefits and costs, or at least significant subsets of them. Sometimes they can point to human dignity, equity, or distributional concerns.[3] To anchor the analysis, I focus in particular on mandatory labels for food that contains genetically modified organisms (GMOs), because the topic has become significant in light of recent legislation,[4] and because it raises a number of general puzzles from which broader lessons can be drawn.

In Europe, and increasingly in the United States, there is considerable public concern about GMOs and about food that contains them (GM food).[5] As a matter of science, the principal claims are that GM food poses, or might pose, public health risks. and that GMOs endanger, or might endanger, the environment.[6] (As we shall see, there are other claims as well.) In response to these claims, the most modest proposal is that GM food should be labeled as such, so that consumers can know what they are buying.[7]

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[1] *See* Executive Order 12,866, 3 C.F.R. 638 (1994) (signed Sept. 30, 1993), *reprinted in* 5 U.S.C. § 601, at 802–06 (2012).
[2] *Id.*
[3] *Id.*
[4] National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216 (2016) (codified at 7 U.S.C. § 1621 *et seq.* (2016)). Note that the requirement allows considerable flexibility for the regulated class, and the flexibility should significantly reduce compliance costs: Food producers can comply with a symbol or with text, but also with a barcode consumers can scan to obtain information on ingredients. Implementing regulations will be required to specify this requirement.
[5] See Ben Popken, *Obama Signs Controversial GMO Food Label Law*, NBCNEWS (Aug. 1, 2016, 9:51 AM), http://www.nbcnews.com/business/consumer/obama-signs-controversial-gmo-food-label-law-n620796. On movements in Congress, see Dan Flynn, *Just Label It Takes a Victory Lap After Losing; Opts to Move On*, FOOD SAFETY NEWS (July 10, 2016), http://www.foodsafetynews.com/2016/07/128725/#.V4I0pc5i5FJ. On various issues, see LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE (Paul Weirich ed., 2008).
[6] For an instructive discusson, see Alan McHughen, Pandora's Picnic Basket (2000).
[7] *See* LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE (Paul Weirich ed., 2008).

In its simplest form, the argument is that people have a right to know the ingredients of their food, at least when they fear that those ingredients pose risks to health or the environment. In 2016, Congress embraced that argument, enacting legislation to require labeling of GM food.[8] The new legislation directs the Secretary of Agriculture to promulgate implementing regulations within two years; under existing Executive Orders, those regulations will have to be accompanied by some kind of formal cost-benefit analysis.[9]

The seemingly modest arguments in favor of mandatory labels for GM food raise fundamental questions about product labeling in general. For GM food in particular, a market failure is not simple to demonstrate, and it is even more challenging to show that the benefits of labels justify the costs. The first reason is that GM foods do not pose health risks at all, and the standard (though hardly uncontested) reading of the science appears to be that the environmental risks are somewhere between nonexistent and highly speculative. To that extent, GM labels might confer no benefits on consumers. The second reason is that GM labels may affirmatively mislead some or many consumers, by leading them to believe, falsely, that the government thinks that they do pose risks to health or the environment. Because it is not easy to show that the benefits of mandatory GM labels would justify the costs, there is a strong argument that such labels would run into serious difficulty during the process of scrutiny undertaken by the Office of Information and Regulatory Affairs under Executive Orders 12866 and 13563, and may potentially face legal objections as well.[10]

On welfare grounds, a tempting argument for GM labels is straightforward: Many consumers want them, and they would be willing to pay something in return for them. Labeling is required because people demand them; in surveys, the overwhelming majority of American do favor mandatory labels.[11] But this argument runs into two objections. The first is the fact that the market is not, on its own, producing such labels.

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[8] National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216 (2016) (codified at 7 U.S.C. § 1621 *et seq.* (2016)). Note that the requirement allows considerable flexibility for the regulated class, and the flexibility should significantly reduce compliance costs: Food producers can comply with a symbol or with text, but also with a barcode consumers can scan to obtain information on ingredients. Implementing regulations will be required to specify this requirement.

[9] *See* Executive Order 13,563, 3 C.F.R. 215 (2012) (signed Jan. 18, 2011), *reprinted in* 5 U.S.C. § 601, at 816–17 (2012).

[10] *See supra* notes 4–5. Note, however, the important qualification that the requirement of a cost-benefit justification applies only "to the extent by law," and hence the disclosure mandate might, in this context, fall in the small category of cases in which executive agencies issue a rule, under legal compulsion, for which benefits do not justify costs. On the potential legal objections -- possibly available in the event that the cost-benefit analysis is arbitrary or does not demonstrate that the benefits justify costs -- see note infra.

[11] *See, e.g.*, Cass R. Sunstein, *Do People Like Nudges?*, 68 ADMIN. L. REV. (forthcoming 2016).

This objection that is not fatal in light of potential market failures, but it does raise questions about the basic claim: People's responses to survey questions may not reflect what they really care about, as reflected in their general lack of interest in the topic at the grocery store or in restaurants.

The second and more fundamental objection is that the consumer demand for labels (to the extent that it exists) appears to be based largely on the groundless belief that GM food is dangerous to human health. If that belief is indeed groundless, public officials should correct it, rather than cater to it. But it is possible to ask whether that conclusion is too simple. Those who embrace technocratic conceptions of government will have little interest in public fear as such. But those who favor certain forms of populism might insist that if people are fearful, officials should respond, not least because they need to maintain public trust (and should themselves be humble about how much an evolving science can establish).

A separate argument relies on difficult-to-quantify values and scientific uncertainty. Perhaps GM food would threaten biodiversity; perhaps it would have adverse distributional effects in poor nations; perhaps it endangers widely held moral commitments. If there is a risk that GM food would cause serious and irreversible environmental harm, it is appropriate to take precautions, and labels are a modest way of doing that.[12] Perhaps it will be discovered, in the fullness of time, that the environmental risks (such as the risks to biodiversity) are serious and potentially even catastrophic; perhaps existing research cannot rule that possibility out of bounds.

The force of at least some of these concerns depends on the science. It is clear that if the best reading of the science suggests a certain kind of irreducible uncertainty, the argument for labeling gains force, and it can be fit with a justification that agencies have sometimes given under the general rubric of cost-benefit analysis. But if the risk is vanishingly small or too speculative to be worth taking seriously, as many scientists have concluded, then precautions (including labels) are difficult to justify. With reference to these various points, I sketch the most plausible arguments that the Department of Agriculture (USDA) might make in defending the labeling requirement on cost-benefit grounds and suggest that some form of "breakeven analysis" is probably the best that it can do.

Mandatory labels for GM foods raise pervasive questions about the use of cost-benefit analysis in the context of labeling requirements in general. As we shall see, that context poses distinctive challenges. The costs of labels may be much higher than is readily apparent, because they may produce subtle decreases in consumer welfare (as, for example, when calorie labels lead people to buy goods that are lower-calorie but less delicious, or when energy efficiency labels lead people to purchase appliances that cost less to operate but that are less attractive). At the same time, the benefits of labels are often exceptionally difficult to quantify and monetize, which may lead agencies to make

[12] See Nabil Al-Najjar, *A Bayesian Framework for the Precautionary Principle*, 44 J. LEGAL STUD. S337 (2016).

a flat declaration that they cannot be turned into dollar equivalents at all. Alternatively, agencies may rely on anticipated economic savings or health gains, which may be highly speculative, and which will not, in any case, provide anything like an adequate picture of the actual benefits.

The remainder of this Article comes in three parts. Part II, the heart of the Article, offers general remarks on mandatory labels, with particular reference to the four approaches that agencies have taken to specifying the benefits of such labels. These highly disparate approaches, which imposing varying levels of information-gathering demands on agencies, have yet to receive serious attention in the academic literature, and Part II explores their vices and virtues. Part III applies the analysis to GM foods, concluding that a mandatory label is not simple to justify on cost-benefit grounds, even if agencies use creative approaches to attempt to monetize the benefits. Part III also specifies the best (or least bad) approach that the government might use in attempting to show that the benefits of GM labels justify the costs.

Part IV investigates uncertainty and the precautionary principle. It emphasizes that there is room for precautions in the face of small or uncertain risks of catastrophe, but urges that on current readings of the science, mandatory GM labels are not straightforward to defend on that ground. Part IV also discusses the claim that the precautionary principle is best understood not in decision-theoretic terms, but as a response to democratic imperatives.

II. Product Labeling In General

A. Market Failure?

When should government require products to be labeled? Suppose that we care about social welfare, suitably specified, and answer that labels should be required when they would do more good than harm. It is easy to imagine labels that are unnecessary, that are costly to impose, that are widely ignored by consumers, or that promote the interests of powerful private groups, not of the public as a whole. It is also easy to imagine labels that help consumers to save money, to avoid serious risks, to protect third parties, or to register their deepest moral commitments. Under the standard economic approach, the initial question is whether there is a market failure. In many cases, we expect the market to produce the necessary information on its own.[13] In other words, sellers are expected to disclose relevant information voluntarily. Mandatory disclosure is needed only when voluntary disclosure fails.

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[13] *See* Howard Beales et al., *The Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491, 502 (1981) ("The economic incentive for consumers to gather information is strong. Increases in the efficiency of purchase decisions made are equivalent to increases in real income, and, given the diversity of choices available in a modem economy, improved choices can lead to a large gain. In many markets, price dispersion is substantial for identical or similar products.").

1. *Consumer demand and incomplete information*. When offering accounts of market failure under the requirements of prevailing executive orders, agencies usually ask about what consumers demand.[14] A standard market failure, often invoked by agencies themselves, involves *incomplete information*. Sometimes consumers lack the information that would enable them to make (sufficiently informed) choices, and government provides that information in order to make the market work efficiently.

It is true, of course, that consumers sometimes insist on product-related information, and hence the market will provide it; there is no need for a mandate. But consumers might not have the information that would put them in the position to demand disclosure of (further) information – and it might not be rational for them to attempt to acquire that information. Consider the health risks posed by trans fats, which raise highly technical questions.[15] Rational ignorance on the part of consumers might lead them not to acquire information from which they would ultimately benefit. Without that information, they might lack the knowledge that would lead them even to ask for labels. For that reason, a government response might be appropriate.

A further problem stems from the fact that information has the characteristics of a public good, which means that the market will not generate enough of it.[16] Acting on his or her own, each consumer might not seek information from which all or most consumers would benefit. Mandatory labels overcome a collective action problem.

Yet another problem arises when the point of disclosure is to protect third parties. Often consumers want to know whether products are harming people, and even if they do not, disclosure might be required in order to reduce that harm. Suppose, for example, that disclosure of information is designed to reduce the risks of second-hand smoke, to prevent harms to animals (such as elephants or dolphins), protect vulnerable groups (as with disclosure of "conflict minerals"[17] or labels for products from companies that have frequently violated occupational safety laws[18]), or to protect American jobs (as with "country of origin"[19] or "made in America" labels). If third parties are at risk, we have a standard argument for government intervention. To the extent that GM food is thought to pose risks to the environment, a market failure seems to be involved. It is true, of course, that the preferred response to such risks is some kind of corrective tax, not disclosure. But if a tax is unavailable, for political or other reasons, then disclosure might seem to be a reasonable second-best.

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[14] *See* STEPHEN BREYER, REGULATION AND ITS REFORM 26–29 (1982).
[15] *See* SARAH CONLY, AGAINST AUTONOMY (2013).
[16] Beales et al., *supra* note 10, at 503.
[17] National Association of Manufacturers v. SEC, 748 F.3d 359 (D.C. Cir. 2014).
[18] Cf. https://www.whitehouse.gov/the-press-office/2014/04/08/presidential-memorandum-advancing-pay-equality-through-compensation-data
[19] See 7 U.S.C. §§ 1638, 1638a; American Meat Institute v. USDA, 760 F.3d 18 (DC Cir. 2014).

There are behavioral issues as well. If risks are not sufficiently salient, then consumers might not demand relevant information about them, even if those risks are not exactly trivial. In principle, disclosure could therefore increase consumer welfare.[20] Or suppose that health risks are long-term; if so, then "present bias" might lead consumers not to demand information about them.[21] It is true that in the face of present bias, disclosure might not do much good; present-biased consumers might not care about what they learn. But perhaps information could be provided in a way that would reduce present bias. For example, labels might be graphic or specifically focus people on what might happen in the long-term.

2. *Producer behavior*. Notwithstanding these points, a standard unraveling argument predicts voluntary disclosure even if consumers do not demand it. Assume that for whatever reason (rational or not), consumers would choose non-GM foods if they were given the information that would enable them to do so. Specifically, assume that consumers are willing to pay $10 for genetically modified salmon and $20 for salmon if it is not genetically modified. Further assume that genetically modified salmon costs $5 to produce, whereas non-GM salmon costs $7 to produce. Finally, assume that, initially, half the salmon on the market is genetically modified and half is not. Without any labeling, the consumer would not know what kind of salmon she is buying and would, therefore, be willing to pay $15 (= 0.5*$10 + 0.5*$20). This state of (consumer) ignorance benefits the producers of GMO salmon and harms the producers of non-GM salmon.

But this state of ignorance is not an equilibrium. The non-GM sellers will voluntarily add a "No GMOs" label, so that they can charge $20, rather than $15 per salmon (as long as the cost of adding such a label is less than $5 per salmon). The GM salmon will not be labeled, but GM labeling would not be necessary – rational consumers would infer that non-labeled salmon is genetically modified. As Bar-Gill and Board explain, "An implication of this result is that mandatory disclosure of product-attribute information is often unnecessary."[22]

In the example just given, the relevant quality dimension is binary (GMO or non-GMO). A similar argument predicts voluntary disclosure when the relevant quality dimension is continuous: Assume that different microwave ovens in the market emit radiation in the range of 0-10 mW/cm^2, with levels of radiation distributed uniformly (such that, e.g., the number of microwave ovens emitting no radiation is equal to the number of ovens emitting $1mW/cm^2$ of radiation, and equal to the number of ovens emitting $2mW/cm^2$ of radiation, and so on). Without any labeling, consumers would not be able to distinguish low-radiation ovens from high radiation ovens and would attribute

[20] *See* Xavier Gabaix & David Laibson, *Shrouded Attributes, Consumer Myopia, and Information Suppression in Competitive Markets*, 121 Q.J. ECON. 505, 511 (2006).
[21] Ted O'Donogue and Matthew Rabin, Present Bias: Lessons Learned and to Be Learned, 105 Am Econ Review 273 (2015).
[22] Oren Bar-Gill & Oliver Board, *Product-use Information and the Limits of Voluntary Disclosure*, 14 AM. L. & ECON. REV. 235, 237 (2012).

the average radiation level, 5mW/cm^2, to any oven they consider purchasing. Producers of low-radiation ovens, with radiation levels below 5mW/cm^2, would be harmed by this state of consumer ignorance. These producers would voluntarily disclose their ovens' radiation levels.

Now consumers would know the radiation levels of all ovens with levels below 5mW/cm^2. And when considering a non-labeled oven, the consumer would assume an average radiation level of 7.5mW/cm^2. But then producers with radiation levels between 5 – 7.5mW/cm^2 will voluntarily disclose. Only producers with radiation levels between 7.5 – 10mW/cm^2 will remain silent, and so consumers would attribute an average radiation level of 8.75mW/cm^2 to a non-labeled oven. Now producers with levels between 7.5 – 8.75mW/cm^2 will voluntarily disclose. And so on, until complete unraveling is achieved and all information is voluntarily disclosed.[23]

As a real-world example, analogous to the question of GM food, consider the example of gluten-free foods. Some people (including those with celiac disease) are allergic to food that contains gluten. At least to date, we do not observe statutory disclosure requirements ("warning: this product contains gluten"). Instead we see voluntary labels, saying (for example) that products are "gluten-free." The FDA has issued guidance for such labels.[24] On optimistic assumptions, voluntary labels provide sufficient information.

3. *Markets that do not unravel*. This happy unraveling story, however, does not always play out. Failure of voluntary disclosure occurs for several reasons – some neoclassical and some behavioral. Starting with the standard, neoclassical reasons, note that the unraveling result assumes that voluntary disclosure is truthful. But imperfect enforcement might lead to false disclosures, which government must correct – and once government is in the business of correction, it is essentially mandating a label.

In addition, voluntary disclosure might fail when there is no standardized format or metric for disclosing information.[25] Without standardization, consumers might not be able to make the required distinctions, in which case voluntary disclosure will be insufficient. And if the point of disclosure is to protect third parties, the unraveling story might not work, because consumers might not care enough about third party effects to respond to the various informational signals. True, consumer indifference would also mean that mandatory labels would be ineffective. But it is plausible to think that consumers care some – enough to make mandatory labels work but not enough to promote unraveling.

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[23] *See id.*

[24] For a summary from the FDA itself, see *Gluten and Food Labeling*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm367654.htm (last updated May 2, 2016).

[25] For discussion, see Beales et al., *supra* note 10.

Behavioral economics suggests an additional and perhaps stronger reason for skepticism about voluntary disclosure. The unraveling result assumes that consumers attend to and draw rational inferences from silence – from the absence of a label. But attention is limited,[26] and such inferences can be quite difficult to draw, especially when consumers are receiving numerous signals at the same time (as is true for food) and when there are multiple quality levels or continuous quality dimensions. Suppose, for example, that some products come with labels saying "low fat" or "low sugar." Would consumers necessarily infer that products lacking such labels are high in fat or sugar? Or would many of them not think much or at all about the question of fat or sugar?

A standard neoclassical argument is that in a generalization of the "lemons equilibrium,"[27] competition might occur over easily observed characteristics, such as price, and less or not at all over less observable characteristics, such as ingredients.[28] The behavioral suggestion (or exclamation point) is that in view of the scarcity of attention, this limited kind of competition is highly likely.[29] And even if consumers pay attention to the relevant ingredient (salt, sugar, fat), they might be unable to draw the rational inference from the absence of disclosure.

For example, those who are purchasing cereal or milk might attend to a variety of product attributes, and unless high fat or high sugar content is brought to their attention, many of them might not consider those ingredients at all. If many consumers would not pay attention or draw a negative inference (or a sufficiently negative inference) from the absence of a label, voluntary disclosure might fail. Such failure justifies the consideration of mandatory disclosure, at least in principle. The Affordable Care Act, for example, mandates calorie labels,[30] and there is a plausible argument on their behalf, based on the considerations just sketched.[31]

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[26] *See* DANIEL KAHNEMAN, ATTENTION AND EFFORT (1973); SENDHIL MULLAINATHAN & ELDAR SHAFIR, SCARCITY (2013).

[27] George A. Akerlof, *The Market for "Lemons": Qualitative Uncertainty and the Market Mechanism*, 84 Q.J. ECON. 488 (1970).

[28] Beales et al., *supra* note 10, at 510.

[29] *See* Gabaix & Laibson, *supra* note 14.

[30] Patient Protection and Affordable Care Act § 4205, 21 U.S.C. § 343(q)(5)(H) (2012).

[31] The agency's own explanation disregarded the economic literature on unraveling and spoke instead of how the rule might help consumers: "The final rule may also assist consumers by making the long-term health consequences of consumer food choices more salient and by providing contextual cues of food consumption. The behavioral economics literature suggests that distortions internal to consumers (or internalities) due to time-inconsistent preferences, myopia or present-biased preferences, visceral factors (e.g., hunger), or lack of self-control, can also create the potential for policy intervention to improve consumer welfare." U.S. Food & Drug Admin., Final Regulatory Impact Analysis, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Establishments 11 (FDA-2011-F-0172, Nov. 2014), http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf [hereinafter Calorie Labels].

4. *"Does not contain" labels vs. "contains" labels*. There are many differences between a system in which products without some characteristic say "does not contain x" and one in which products with some characteristic say "contains x." As we have seen, "contains x" offers far more salient information to consumers with bounded attention. In addition, "contains x" might have a distinctive signal, suggesting that private and public institutions think that something is wrong with x.[32] "Does not contain x" might also promote a desirable form of sorting. Suppose that 10 percent of the population is troubled by x, whereas 90 percent is not; suppose that both groups are informed and rational. If so, there is no need for "contains x." Those who want to avoid x can easily do so, and those who have no interest in avoiding x need not be troubled by the issue.

On a certain view of the facts, "does not contain x" is the right approach both to gluten-free and to GM food. People who are allergic to gluten should know what to look for. The principal problem is that if they are inattentive, they might become sick simply by virtue of the fact that the issue has not been brought to their attention. (Compare labels saying "contains peanuts" or "contains shellfish," which may be especially important if consumes are inattentive or if it is not self-evident that the relevant food contains either.) With "does not contain" labels, consumers can easily avoid GM food if that is what they want to do. But this approach is not a solution if GM food threatens has harmful systemic effects or threatens to cause environmental harm (or if relevant interest groups want to stigmatize GM food).

B. Costs and Benefits

Even if there is a market failure, the question remains: Do the benefits of labels justify the costs? If it would be expensive to comply with a labeling requirement – say, $800 million annually – the question whether the benefits are sufficient would be put in stark relief. We could easily imagine disclosure requirements that do little good, perhaps because consumers pay no attention to them.[33] If so, such requirements would be unjustified on cost-benefit grounds. Those who are skeptical of the benefits of disclosure requirements, in general or in particular cases, are not merely making a point about public policy. Whether or not they intend to do so, they are also making a provocative claim about how regulatory review should occur within the executive branch and potentially about judicial review as well. (Recall the limited nature of attention, which raises the possibility that many disclosure requirements could not survive scrutiny under Executive Orders 12866 and 13563, and possibly could not survive judicial review under the Administrative Procedure Act.[34]) We could also imagine disclosure requirements from

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[32] See infra.

[33] *See* OMNI BEN-SHAHAR & CARL SCHNEIDER, MORE THAN YOU WANTED TO KNOW: THE FAILURE OF MANDATED DISCLOSURE (2014); George Loewenstein et al., *Disclosure: Psychology Changes Everything*, 6 ANN. REV. OF PSYCHOL. 391 (2014); Archon Fung et al, Full Disclosure" The Perils and Promise of Transparency (2008).

[34] On the relevance of the APA and the possibility that a failure to demonstrate cost-benefit justification can be a form of unlawful arbitrariness, see Cass R. Sunstein, Cost-Benefit Analysis and Arbitrariness Review, Harv. Env. L. Rev. (forthcoming 2016);

which consumers and third parties would benefit greatly.[35] But assessment of costs and benefits can produce significant challenges.

As we will see, agencies have not always responded well to those challenges, especially for valuing benefits. In fact they have adopted four distinctive approaches to that question, imposing increasingly severe information-gathering demands on agencies. It is not always easy to explain why they choose one or another in particular cases. The first approach, and it may be the most candid, is to confess a lack of knowledge, by acknowledging that in light of existing information, some costs and (especially) benefits simply cannot be quantified.[36] The problem with this approach is that it suggests that the decision to proceed is essentially a stab in the dark. The second strategy involves "breakeven analysis," by which agencies describe what the benefits would have to be in order to justify the costs – and suggest that the benefits are indeed likely to be of the requisite magnitude. The problem with this approach is that involves a high degree of guesswork, and may be a mere conclusion, a kind of ipse dixit, masquerading as an analytic device. Without a great deal of discipline, it too may be closely akin to a confession of ignorance.

National Association of Manufacturers v. SEC, 748 F.3d 359 (D.C. Cir. 2014). To the extent that a statute requires an agency to proceed whether or not the benefits justify the costs – as does the GM labeling statute under discussion here – it is exceedingly unlikely that an inability of offer such a justification would render a regulatory decision legally vulnerable. See id. It is possible, however, that the choice of a particular approach to labeling, as opposed to legally permissible alternative, would be vulnerable if the latter has higher net benefits. And as discussed in text, there will be considerable attention, within the executive branch, to the question whether the benefits justify the costs.

[35] *See* Partha Deb & Carmen Vargas, *Who Benefits from Calorie Labeling? An Analysis of Its Effects on Body Mass* (Nat'l Bureau of Econ. Research, Working Paper No. 21,992, 2016), http://www.nber.org/papers/w21992; Archon Fung et al, Full Disclosure" The Perils and Promise of Transparency (2008).

[36] For an important decision upholding a refusal to quantify benefits, on the ground that quantification is not feasible, see Inv. Co. Inst. v. Commodity Futures Trading Comm'n, 720 F.3d 370, 372–75 (D.C. Cir. 2013). In the context of disclosure, the leading decision is National Association of Manufacturers v. SEC, 748 F.3d 359 (D.C. Cir. 2014), upholding against arbitrariness review a regulation that would require disclosure of use of "conflict minerals":

> An agency is not required 'to measure the immeasurable,' and need not conduct a 'rigorous, quantitative economic analysis' unless the statute explicitly directs it to do so. v. Here, the rule's benefits would occur half-a-world away in the midst of an opaque conflict about which little reliable information exists, and concern a subject about which the Commission has no particular expertise. Even if one could estimate how many lives are saved or rapes prevented as a direct result of the final rule, doing so would be pointless because the costs of the rule—measured in dollars—would create an apples- to-bricks comparison. Despite the lack of data, the Commission had to promulgate a disclosure rule.

The third approach is to attempt to specify outcomes in terms of (say) economic savings or health endpoints. One problem with this approach is that agencies may lack anything like the information that would enable them to venture such a specification. Another problem is that for reasons I will explore, even an accurate specification will not give a complete picture of the actual benefits, and in crucial respects, it will almost certainly overstate them. The fourth approach is to identify consumers' willingness to pay. In principle, that approach is (mostly) the right one, but it runs into normative objections and also serious and often insuperable empirical challenges.

1. *Costs*. On the cost side, some of the questions are relatively straightforward. Regulators may well be able to learn the total cost of (for example) producing fuel economy labels and placing them on new vehicles. The principal difficulty arises *when the information itself imposes costs on consumers*. In current accounts by the federal government, those costs are generally ignored. That is a mistake, even if they prove difficult to quantify, and even if consumers benefit on net.[37] Those costs come in several different forms.

First, a cost is involved in reading and processing the information. For each consumer, that cost is likely to be low, but across a large number of purchasers, it might be significant. Information disclosure is, in a sense, akin to a paperwork burden. To be sure, consumers are not compelled to read and process what is disclosed. But even for those who seek to ignore it, its very presence may operate as a kind of cognitive tax.

Second, and more importantly, the cost may be hedonic, not cognitive. Suppose that smokers are given information about the adverse health effects of smoking or that visitors to chain restaurants are given information about the caloric contents of food. Many members of both groups will suffer a hedonic loss. Consider smokers who cannot quit and customers who choose high-calorie foods notwithstanding the labels. In hedonic terms, such people will lose, rather than gain, if they are miserable at the time of purchase. To be sure, there is a serious normative question whether regulators should count, as costs, the adverse hedonic effect of truthful information. (Is it cost, or a benefit, if people learn, truthfully, that they have diabetes or cancer? Is it a cost as well as a benefit, even if the net effect is positive?) But if we are operating within a consequentialist framework, the hedonic loss must be treated as a cost.

Even if people might be able to quit smoking or to choose lower-calorie items, and will hence benefit greatly on net, they will incur a cost on seeing something that inflicts pain. In principle, that cost should count, even if it is greatly outweighed by benefits. The point, then, is not that the hedonic cost is a trump card; if people make different choices once they are informed, the presumption should be that they are better off. But *by how much*? To answer that question, the hedonic cost must be taken into account. For many people, a calorie label imposes a serious cost, simply because it

[37] For a useful discussion in an especially controversial area, see Helen Levy et al., *Tobacco Regulation and Cost-Benefit Analysis* (Nat'l Bureau of Econ. Research, Working Paper No. 22,471, 2016), http://www.nber.org/papers/w22471.pdf.

informs them that the delicious cheeseburger that they are about to eat is also going to make their belly bulge. (As a friend remarked to me after hearing that the calorie labeling requirement in the Affordable Car Act would be applied to movie theaters: "They just ruined popcorn.")

There is an additional loss, in the form of foregone consumer surplus. Suppose that people decide that on balance, they should have a salad rather than a cheeseburger, on the ground that the latter has many more calories. If they choose the cheeseburger notwithstanding the label, they are better off on balance – and in a sense, they are sadder but wiser (and healthier). They are sadder to the extent that they enjoy their meal less. Assessment of the magnitude of the loss poses serious conceptual and empirical challenges,[38] but there is no question that it exists, and that it might turn out to be a significant fraction of the benefits. In principle, a decision to choose the hamburger might make people only modestly better off, because the hedonic loss is almost as high as the health gain.[39]

Suppose, for example, that consumers are choosing between two essentially equivalent cars; that one would cost $2000 less annually because of its fuel efficiency; and that because of the fuel economy label, they select the fuel-efficient car. For each such consumer, we might be tempted to say that the label has produced $2000 in gains. But in actual practice, the effects of a fuel economy label will be much more complicated to assess. Some consumers will end up purchasing cars that are more fuel-efficient but inferior along some dimension, so that they will gain $2000 minus X, where X refers to the desirable features of the unchosen car that they otherwise prefer. It is hard for public officials to know whether X is, on average, $100, or $1000, or $1950.[40]

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[38] For a framework, see Hunt Allcott & Cass R. Sunstein, *Regulating Internalities*, 34 J. POL'Y ANALYSIS & MGMT. 698 (2015).

[39] I am bracketing here the possible endogeneity of preferences. See Preference Change (Till Grüne-Yanoff and Sven Ove Hansson eds. 2009). Suppose that at Time 1, people enjoy hamburgers a lot and enjoy salads only a little. Now suppose that people switch at Time 2, because they want to eat healthier. At Time 3, people might come to dislike hamburgers (disgusting!) and to love salad (fresh!). In principle, preference change must be taken into account by the considered cost-benefit analyst, though doing so presents serious challenges: It might be difficult to know the magnitude of the change and even the sign (perhaps those who switch to salad will crave hamburgers and grow to despise salad).

[40] Note that this claim does not depend on the objection that a fleet-wide fuel-efficiency requirement will impose costs in the form of a less attractive fleet (with, for example, less powerful vehicles). *See* Ted Gayer & W. Kip Viscusi, *Overriding Consumer Preferences with Energy Regulations* (Mercatus Center, George Mason University, Working Paper No. 12-21, 2012), http://mercatus.org/sites/default/files/Energy_regulations_GayerViscusi_WP1221_1.pdf. All that is necessary is that consumers choose more fuel-efficient vehicles over vehicles that are better along some dimension.

2. *Benefits*. On the benefits side, the assessment is even more challenging.[41] If the government mandates a fuel economy label, agencies should project the economic and environmental benefits from the mandate. But to do that, they have to know the effect of labels on behavior. In principle, a randomized controlled trial would be valuable and perhaps necessary for that purpose. If one group sees a particular label and a similar group sees a different label (or no label), regulators should be able to specify the effect of the label on purchasing decisions. Armed with that information, they could estimate economic and environmental consequences (at least if they could generalize from the trial).

Unfortunately, it is sometimes difficult or impossible to run randomized controlled trials. In these circumstances, making any kind of projection of how consumers will respect to a label is difficult enough, but an additional problem is that for the reasons given thus far, the projection would not give an adequate estimate of the (net) benefits. We have seen that if people are buying cars that are more fuel-efficient but otherwise highly undesirable, there will be a welfare loss. For that reason, regulators might explore the issue from another direction.[42] Rather than asking about the economic savings from the fuel-efficient car, they might ask an entirely different question: *How much would consumers be willing to pay for a fuel economy label*? Under ideal conditions, the right question for regulators to ask involves willingness-to-pay; they

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[41] According to the Environmental Protection Agency and the Department of Transportation, speaking of new fuel economy labels:

> The agencies recognize that Executive Order 13,563 directs agencies 'to use the best available techniques to quantify anticipated present and future benefits as accurately as possible.' In this context, however, quantitative information is not available, and the agencies have therefore chosen instead to continue with a qualitative assessment of benefits. It is difficult to develop a good baseline for the fleet using the existing label, partly because the existing label is not designed to incorporate advanced technology vehicles. It is even more difficult to develop a comparison for the fleet with the new labels, because the effects of label designs on vehicle purchases are not known. Thus, any assessment of quantitative effects of label design on vehicle sales involves a great deal of speculation. The agencies believe that informed choice is an end in itself, even if it is hard to quantify; the agencies also believe that the new labels will provide significant benefits for consumers, including economic benefits, though these benefits cannot be quantified at this time."

Revisions and Additions to Motor Vehicle Fuel Economy Label, 76 Fed. Reg. 39,478, 39,517 (July 6, 2011) (to be codified at 40 C.F.R. pts. 85, 86, 600; 49 C.F.R. pt. 575) [hereinafter Fuel Economy Labels]. In short: "The primary benefits associated with this rule are associated with improved consumer decision-making resulting from improved presentation of information. At this time, EPA and NHTSA do not have data to quantify these impacts." *Id.*

[42] *See* Hunt Allcott & Judd B. Kessler, *The Welfare Effects of Nudges: A Case Study of Energy Use Social Comparisons* (Nat'l Bureau of Econ. Research, Working Paper No. 21,671, 2015), http://www.nber.org/papers/w21671.

should not focus on the economic benefits that consumers might receive if (for example) they purchase more fuel-efficient cars.[43] The reason is that the willingness-to-pay question ought to capture everything that matters to consumers.[44] (Of course it is true that the question will not fully capture third-party effects.)

As an empirical matter, however, it is not easy to obtain a reliable answer to that question, or anything close to it. We might simply ask people, but for the answers to be relevant, it would be important to provide pertinent information[45] – for example, about the potential benefits (purely economic and otherwise) of labels. Providing that information is no simple endeavor, not least because offering numbers would be important, and any numbers might "anchor" consumers and hence bias their answers. Suppose that the problem of anchoring could be overcome and that informed consumers would be willing to pay (say) $10, on average, for fuel economy labels. If so, we might have some sense of the benefits, at least if behavioral biases are not distorting people's answers. Unfortunately, however, survey evidence is imperfectly reliable, in part because

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[43] *See id.*

[44] Id. As noted in text, I am assuming that the answers to the question are not a product of an absence of relevant information or behavioral biases; I am also bracketing some questions about the difference between subjective and objective welfare. See Matthew Adler, Well-Being and Fair Distribution (2011); Martha Nussbaum, The Capabilities Approach (2011); Jon Elster, Sour Grapes (1983). That difference might turn out to be relevant in some contexts that involve health. For agency invocation of willingness to pay, see the elaborate treatment in Calorie Labels, *supra* note, and in particular the summary at 62:

> We begin by describing a study (Abaluck 2011) that estimates the welfare gains from increased nutritional information provided by the Nutrition Labeling and Education Act of 1990 (NLEA) and additional labeling (i.e. extending nutritional information provided by the NLEA to include food away from home, fresh produce, and meats); our primary estimate of the benefits of the final rule uses the willingness-to-pay for nutrition information from that study to estimate welfare gain that serves as our estimate of the benefits of the final rule (Ref. 43). Next, we provide a thorough review of the literature on the potential effects of interventions similar to the final rule on consumer behavior. We then compare the main benefit estimate with two supplemental, illustrative examples of benefits using the literature's average reduction in calories consumed at restaurants due to menu labeling. These supplemental estimates are not included in the final reported values. Last, we conduct a sensitivity analysis and discuss the sources of uncertainty in our estimates.

[45] This is an objection to the particular numbers produced in Allcott and Kessler, supra note, in their valuable paper on the welfare effects of nudges: Information is not provided to participants in their study (involving the economic benefits from energy conservation), and so people's elicited willingness to pay for energy conservation notices is insufficiently informed. Nonetheless, Allcott and Kessler convincingly argue that in principle, willingness to pay is the right question (subject to the qualifications in note supra).

of the familiar problems with contingent valuation studies,[46] in part because of the immense difficulty of informing consumers in a sufficiently neutral way.[47]

For health-related disclosures, the problem is even harder. One goal of calorie labels, for example, is to reduce obesity, which causes an assortment of health problems, including premature mortality.[48] Regulators have established ways to turn health-endpoints into monetary equivalents. For example, a statistical death is now valued at about $9 million.[49] But how many premature deaths would be prevented by calorie labels? And what would be the effect of such labels on adverse health outcomes short of death?

To answer such questions, regulators have to undertake two tasks.[50] First, they must begin by making some prediction about the effect of calorie labels on what people choose to eat. Second, they have to follow that prediction by specifying the health consequences of lower levels of caloric intake. At least it can be said that if they can

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[46] *See* Jerry Hausman, *Contingent Valuation: From Dubious to Hopeless*, 26 J. ECON. PERSPECTIVES 43 (2012).

[47] Researchers might want to inform consumers about the economic savings from a fuel-efficient car, but that number is highly likely to serve as an anchor, biasing judgments. See Nicholas Epley and Thomas Gilovich, The Anchoring-and-Adjustment Heuristic, 17 Psych. Science 311 (2006).

[48] *See* Calorie Label Rule, 21 C.F.R. § 101 (2016); U.S. Food & Drug Admin., Final Regulatory Impact Analysis, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Establishments (FDA-2011-F-0172, Nov. 2014), http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf. Note that § 101.78 discusses obesity and its relationship to cancer risk and high blood pressure, http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_12

[49] *See, e.g.*, Memorandum from Kathryn Thomson, Gen. Couns., and Carlos Monje, Assistant Secretary for Pol'y, to Secretarial Officers and Modal Administrators, Guidance on Treatment of the Economic Value of a Statistical Life (VSL) in U.S. Department of Transportation Analyses—2015 Adjustment (June 17, 2015), https://www.transportation.gov/sites/dot.gov/files/docs/VSL2015_0.pdf. On the underlying theory, see CASS R. SUNSTEIN, VALUING LIFE (2004).

[50] *See* Food Labeling Final Regulatory Impact Analysis, supra note: "Since the potential benefit from the final rule stems from the effect that decreasing the consumption of calories from standard menu items has on mitigating the obesity rate in the U.S. population, we estimate benefits as the direct medical costs and total burden of lost quality adjusted life years (QALYs) that could be averted from an improved diet among the U.S. adult population minus the value of lost utility from reduced or altered consumption."

accomplish those tasks, they will have some sense of the benefits of the labels, once (and this is a third task) they turn the various consequences into monetary equivalents.[51]

Alternatively, we could (again) ask how much people would be willing to pay for calorie labels.[52] As before, asking that question is, in principle, preferable to an effort to assess health-states, because the answer will capture all variables that matter to consumers.[53] Also as before, there are formidable challenges in using surveys to elicit reliable numbers, free from biases of various kinds.

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[51] *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,719 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141), http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM339834.pdf [hereinafter Graphic Warnings for Cigarettes]:

> We estimate the benefits of the final rule by comparing expected life-cycle events of smokers with those of nonsmokers. Nonsmokers tend to live longer and develop fewer cancers, cardiovascular, pulmonary, and other diseases, so the benefits in our analysis include the discounted value of life-years gained, health status improvements and medical services freed for other uses. We also include an estimate of the monetary value of the property and lives saved as a result of the rule-induced reduction in the number of accidental fires caused by smoking. There are other benefits, such as reductions in nonsmokers' morbidity and mortality associated with both passive smoking and mothers smoking during pregnancy, that are likely generated by the final rule, but FDA has been unable to obtain reliable data with which to quantify them. In particular, we were not able to project future levels of exposure to secondhand smoke from historical trends, nor predict future decreases in maternal smoking during pregnancy.

[52] Maria L. Loureiro et al., *Do Consumers Value Nutritional Labels?*, 33 EUR. REV. AGRIC. ECON. 249, 249 (2006), http://erae.oxfordjournals.org/content/33/2/249.abstract, (finding "the mean willingness to pay (WTP) for a box of cookies with a nutritional label is estimated to be about 11 per cent above the price of the box of cookies without a nutritional label. Consistent with prior expectations, our results also indicate a difference between the WTP of individuals suffering from diet-related health problems (estimated mean 13 per cent) and those who do not suffer any diet-related health problems (estimated mean 9 per cent).").

[53] In the words of the FDA:

> To our knowledge, Abaluck (2011) is the only study that translates the potential effect of increasing nutrition information on consumption into estimates of welfare gains using willingness-to-pay based on revealed preferences (Ref. 43). This study uses the variation in nutrition information generated by Nutrition Labeling and Education Act (NLEA) as a method to determine how changes in individuals' beliefs about nutrient content affect consumption decisions. The differential changes in nutrition information across food categories, measured in units of calories per gram, allow the study to identify a general model of food demand as a function of nutrient characteristics that accounts for the total daily diet, prior beliefs about nutrient content, and preferences, including willingness to substitute across food categories.

In light of these challenges, regulators have two reasonable options. First, they can work on the two relevant tracks to try to produce answers: exploring end-points and enlisting surveys. On prominent occasions, they have tried the former.[54] Second, they can acknowledge the difficulties, confess that they cannot surmount them, and use "breakeven analysis," by which they ask what the benefits would have to be, in order to justify the costs, and then do what they can to generate a reasonable lower bound.[55] Suppose, for example, that an energy-efficiency label for refrigerators would cost $10 million annually and that 8 million refrigerators are sold in the United States every year. Even if the average consumer saves only $0.50 annually as a result of the label, the cost will be made up in just three years. Breakeven analysis can be crude, but in some cases, it will suggest that the argument for labels is either very strong or very weak.[56]

U.S. Food & Drug Admin., Final Regulatory Impact Analysis, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Establishments 64 (FDA-2011-F-0172, Nov. 2014), http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf. As before, however, the willingness-to-pay criterion may run into normative objections, even from the standpoint of welfare. See note supra; John Bronsteen et al., Happiness and the Law (2014) (raising questions about willingness-to-pay in view of people's occasional failure to know what will promote their welfare).

[54] *See* Graphic Warnings for Cigarettes, *supra* note; Fuel Economy Labels, *supra* note 31; Improve Tracking of Workplace Injuries and Illnesses, 81 Fed. Reg. 29,624 (May 12, 2016) (to be codified at 29 C.F.R. pts. 1904, 1902) [hereinafter OSHA Reporting Requirement]; Calorie Labels, *supra* note.

[55] *See* Cass R. Sunstein, *The Limits of Quantification*, 102 CAL. L. REV. 1369 (2014). The FDA ultimately chose an approach of this kind in an important regulation involving tobacco products. For an outline and a discussion of the context, see Levy et al., *supra* note 28, at 8:

> A more recent rule issued by the FDA in April 25, 2014 proposes deeming tobacco products such as cigars and e-cigarettes subject to FDA regulation. Although the regulatory impact analysis accompanying this proposed rule avoids even using the term 'consumer surplus' (referring instead to 'full welfare gains'), the approach is conceptually similar to the regulatory impact analysis accompanying the final rule for the graphic warning labels, with foregone consumer surplus offsetting 67 to 84 percent of the value of smokers' private health gains. The regulatory impact analysis accompanying the final version of this rule, released in May 2016, backed away from this estimate. Instead, the May 2016 analysis took a 'breakeven' approach that did not quantify the rule's benefits but instead calculated how large the benefits of the rule would have to be to justify the costs (which are quantified), effectively sidestepping the question of how large the consumer surplus offset should be.

[56] *See* OSHA Reporting Requirement, supra note, at 29,686 (stating that "if the final rule leads to either 1.5 fewer fatalities or 0.025 percent fewer injuries per year, the rule's benefits will be equal to or greater than the costs. Many accident-prevention measures will have some costs, but even if these costs are 75 percent of the benefits, the final rule

3. *Third parties – and morality*. Some actual or imaginable labels are meant to protect third parties, not consumers as such. Suppose that some or many consumers are concerned about the use of certain minerals to finance mass atrocities, and they favor labeling, or some kind of disclosure requirement, so that consumers can decline to purchase products that contain such minerals.[57] Or suppose that consumers care about where goods were made, perhaps because they want to purchase products from their own nation, or perhaps because they do not want to purchase products from nations that do not respect human rights. They might seek "country of origin" labels for that reason.[58] Or suppose that some or many consumers care about the welfare of animals in general or certain animals in particular; because they do, they seek labels to reflect how animals were (mis)treated.

In some of these cases, the third-party effects are not obscure, and the real challenge is how to quantify them. As before, it is necessary to begin by making some projection about consumer behavior. To what extent would consumers change their purchasing habits in response? Even if that question can be answered, it would be necessary to tie any such changes to reduced harm or increased benefit for third parties. And even if that problem can be resolved, it would be necessary to quantify and monetize the resulting effects. It is no wonder that in the context of conflict minerals, the agency concluded that quantification was not possible.[59] Perhaps it should have engaged in some form of breakeven analysis, explaining that the requirement was likely to survive cost-benefit analysis even if its effect were modest. But perhaps it lacked the information that would allow it to make that analysis plausible.

Some disclosure requirements, including mandatory labels, are not simple to defend within a standard cost-benefit framework, not for the reasons I have been sketching, but because considerations of equity, distributional effects, or human dignity are involved. When values of this kind are involved, it is perfectly legitimate to consider them.[60] Under the prevailing executive order,[61] it might well be sufficient for agencies simply to point to such considerations and not to fold them into a cost-benefit analysis. Agencies are authorized to give independent consideration to equity and human dignity. If the goal is to respect distributional goals, then cost-benefit balancing is not the rule of

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will have benefits exceeding costs if it prevented 4.8 fatalities or 0.8 percent fewer injuries per year. OSHA expects the rule's beneficial effects to exceed these values.").

[57] See NAM v. SEC, F.3d (Aug. 15, 2015), available at https://www.cadc.uscourts.gov/internet/opinions.nsf/7677C9E435244EC985257EA50054F3D4/$file/13-5252-1568402.pdf

[58] See American Meat Institute v. USDA, F.3d (DC Cir 2014), available at https://www.cadc.uscourts.gov/internet/opinions.nsf/A064A3175BC6DEEE85257D24004FA93B/$file/13-5281-1504951.pdf

[59] See note supra.

[60] See Executive Order 13563. I am bracketing some theoretical issues here. See Louis Kaplow and Steven Shavell, Fairness Versus Welfare (2009).

[61] Executive Order 13563.

decision, and it is not all that matters. A rule might have costs in excess of benefits, in the sense that the losers lose more than the winners gain, but perhaps the winners have a special claim to attention.[62]

If quantification is required, the question might be: How much would (informed) consumers be willing to pay for such labels? Within a certain framework, that question is the right one. But it is not at all clear that the framework is the right one. If the issue involves human dignity, equity, or distributional considerations – or any kind of harm to third parties -- why should the proper analysis depend on how much people are willing to pay for it? It seems senseless to say that labels that are motivated by distributive goals should be imposed to the extent that people are willing to pay for them.

To say this is not to say that consequentialist considerations do not matter at all. Insofar as harms to third parties are involved, cost-benefit analysis can be used, acknowledging the empirical problems sketched above. Insofar as the issue involves equity or dignity, breakeven analysis might be useful.[63] To the extent that distributive goals are involved, a key question is whether such goals would, in fact, be promoted by labels or disclosure. That question would seem relevant to the "conflict minerals" problem. Some kind of means-ends analysis would seem indispensable to an evaluation of labels that are designed to promote distributive goals (or for that matter equity or human dignity). Agencies should be expected to undertake that analysis – or to explain why they cannot.

5. *Risk-risk tradeoffs*. Some labels might reduce risks, but also and simultaneously create risks. Suppose, for example, that consumers are concerned about Omicron Z (a hypothetical ingredient) and the government responds with a mandatory label. Suppose too that if consumers shift from products with Omicron Z, they will purchase products that contain higher risks. If so, labels will increase risks on balance. As we shall see, the problem is not hypothetical: Products that are GMO-free create risks of their own.

III. GM Foods

I now turn to the question of mandatory labels for GM foods. As we shall see, all of the points discussed thus far – and especially the question of valuing benefits – must be taken into account by the USDA when it produces a regulatory impact analysis to accompany implementing regulations. I offer two general conclusions. The first is that it will not be easy for USDA to claim that the benefits of the mandate justify the costs. The second is that of USDA's various options, the best (or least bad) is probably to use breakeven analysis, accompanied by an account of consumers' desire to be informed or by reference to the remaining uncertainties about environmental risks. In view of the highly technical nature of some of the underlying questions, and the existence of

[62] On the complexities here, see W. Kip Viscusi, Risk Equity, 29 J Legal Stud 843 (2000); Cass R. Sunstein, Valuing Life (2012).

[63] For an explanation with examples, see Sunstein, The Limits of Quantification, supra note.

reasonable disputes among specialists. my goal is less to offer final conclusions about cost-benefit analysis for GMO labels than to outline the considerations that must be taken into account by those who must produce such an analysis.

A. A Little Science

1. *Definition and pervasiveness*. The World Health Organization defines GMOs as "organisms . . . in which the genetic material (DNA) has been altered in a way that does not occur naturally . . . ."[64] According to a common understanding, a GMO is "one that is deliberately created to contain a piece of 'foreign' DNA, usually a full-length 'foreign' gene incorporated in its genome."[65] As a result of the underlying technology, sometimes called "recombinant DNA technology" or "genetic engineering," certain individual genes are transferred into one organism from another.[66] The magnitude of the benefits of GM foods is disputed, but they can potentially grow faster, taste better, resist diseases, lower reliance on pesticides, cost less, and prove more nutritious.[67]

In the United States, GM food has become pervasive. According to the UDSA, adoption of GM crop varieties by American farmers has reached about 90 percent of the total planted acres of corn, soybeans, and cotton.[68] American consumers eat many products derived from these crops—including cornmeal, oils, and sugars— even though they are generally unaware of that fact.[69] As much as 90 percent of corn, sugar beet, and soybean crops are now genetically modified. In American supermarkets, genetically modified ingredients can be found in about 70 percent of processed foods. Among them are pizza, cookies, ice cream, salad dressing, corn syrup and chips. Consider the following figure[70]:

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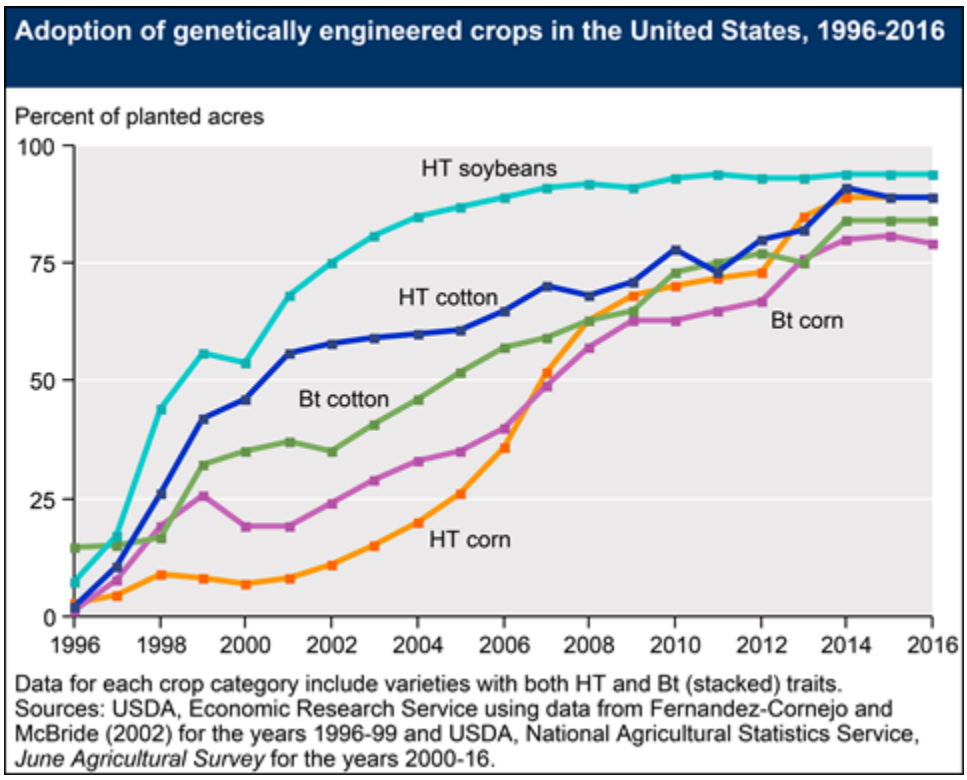
[64] *Frequently Asked Questions on Genetically Modified Foods*, WHO, http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/ (last visited Aug. 9, 2016).
[65] *See* R. Michael Roberts, *Genetically Modified Organisms for Agricultural Food Protection*, *in* LABELING GENETICALLY MODIFIED FOOD 11 (Paul Weirich ed., 2008).
[66] *See* Roberts, *supra* note, at 11–15.
[67] *See* Hans De Steur et al., *Status and Market Potential of Transgenic Biofortified Crops*, 33 NATURE BIOTECHNOLOGY 25 (2015); L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088 (2000).
[68] Jorge Fernandez-Cornejo et al., Genetically Engineered Crops in the United States **2** (2014), available at http://162.79.45.195/media/1282246/err162.pdf
[69] Id.
[70] Jorge Fernandez-Cornejo and Seth James Wechsler, *USDA ERS – Adoption of Genetically Engineered Crops in the U.S.: Recent Trends in GE Adoption*. United States Department of Agriculture, Economic Research Service. (Last updated July 2015). http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx



2. *Benefits*. Do GM foods have significant benefits? The answer is disputed, but standard arguments on behalf of GM ingredients are that they can produce superior foods with not only more nutritional value and greater resistance to herbicides (requiring less use of pesticides) but also improved texture and taste.[71] Scientists have also been able to isolate proteins that cause allergic reactions, in one instance developing a hypoallergenic peanut.[72] GM food is often engineered for longer shelf-life, furthering the reach of shipping fresh food. For example, the Innate potato has been engineered to prevent bruising and browning, as well as a reduction in the amounts of the possible carcinogen acrylamide.[73]

The most famous nutritional supplementation may be Golden Rice, a variety engineered to provide vitamin A.[74] In hopes of combatting protein malnutrition, cereals

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[71] *See* Peter Celec et al., *Biological and Biomedical Aspects of Genetically Modified Food*, 59 BIOMEDECINE & PHARMACOTHERAPY 531 (2005).
[72] *See* Steven Norello, *CRIPSR and a Hypoallergenic Peanut*, NEUROLOGICA BLOG (Oct. 18, 2015), http://theness.com/neurologicablog/index.php/crispr-and-a-hypoallergenic-peanut/.
[73] *See* Andrew Pollack, *U.S.D.A. Approves Modified Potato. Next Up: French Fry Fans*, N.Y. TIMES (Nov. 7, 2014), http://www.nytimes.com/2014/11/08/business/genetically-modified-potato-from-simplot-approved-by-usda.html.
[74] Xudong Ye et al., *Engineering the Provitamin A (ß-carotene) Biosynthetic Pathway into (Carotenoid-free) Rice Endosperm*, 287 SCIENCE 303 (2000); *see also* Robert E. Black et al., *Maternal and Child Undernutrition and Overweight in Low-income and*

such as maize canola and soybean have been engineered for greater amounts of lysine, an essential amino acid. [75] Some products are alternatives to unhealthy foods, such as the sweet protein brazzein, developed in maize as an alternative sweetener to unhealthy sugar.[76] Scientists have also been able to reduce harmful effects of food products, in one instance isolating proteins that cause allergic reactions in the development of a hypoallergenic peanut.[77] In addition, GM foods have been engineered to act as inexpensive vaccines. For example, Applied Biotechnology Institute has developed a hepatitis B vaccine in maize.[78] It remains possible, of course, that techniques will be developed to produce the relevant benefits with reduced reliance on GMOs, especially in wealthy nations.

3. *Health*. With respect to safety, the consensus of the scientific community is unambiguous: GM foods do not present health risks.[79] In 2012, the American Association

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Middle-income Countries, 382 THE LANCET 427 (2013) (finding Vitamin A deficiencies responsible for 157,000 deaths of those 5 years and younger in 2011).

[75] Martina Newell-McGloughlin, (2008). Nutritionally Improved Agricultural Crops. *Plant Physiology*, *147*(3), 939–953. http://doi.org/10.1104/pp.108.121947 McGloughlin provides an overview of techniques and products of GM nutritional supplementing—with carbohydrates, fiber, vitamins, and more—as well as for reduced antinutrients, allergens, and toxins.

[76] Lamphear, B. et al. Expression of the sweet protein brazzein in maize for production of a new commercial sweetener. Plant Biotechnology Journal, 2005. 3(1): p. 103-114.

[77] Dodo, H. W., Konan, K. N., Chen, F. C., Egnin, M., & Viquez, O. M. (2008). Alleviating peanut allergy using genetic engineering: the silencing of the immunodominant allergen Ara h 2 leads to its significant reduction and a decrease in peanut allergenicity. *Plant biotechnology journal*, *6*(2), 135-145.

[78] Hayden, C.A. *et al.* (2015). Oral delivery of wafers made from HBsAg-expressing maize germ induces long-term immunological systemic and mucosal responses. *Vaccine*, 33(25): p. 2881-2886.
See also: Hayden, C.A. et al. *Production of highly concentrated, heat-stable hepatitis B surface antigen in maize.* Plant Biotechnology Journal, 2012. 10(8): p. 979-984.
Hayden, C.A. et al. *Bioencapsulation of the hepatitis B surface antigen and its use as an effective oral immunogen.* Vaccine, 2012. 30(19): p. 2937-2942.

[79] For a helpful discussion of scientific judgments in the United States, see Fred H. Degnan, *Biotechnology and the Food Label*, *in* LABELING GENETICALLY MODIFIED FOOD 17, 24-27 (Paul Weirich ed., 2008). For a more recent overview, see U.S. Food & Drug Admin., Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants (Nov. 2015), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm [hereinafter Labeling Guidance]:

> In the 1992 Policy, FDA stated that it was not aware of any information showing that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding (Ref. 5). Further, FDA concluded that the method of development of a

for the Advancement of Science summarized the consensus, writing that "the World Health Organization, the American Medical Association, the U.S. National Academy of Sciences, the British Royal Society, and every other respected organization that has examined the evidence has come to the same conclusion: Consuming foods containing ingredients derived from GM crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques."[80]

In 2016, the National Academies of Sciences, Engineering, and Medicine issued a book-length report,[81] strongly reaffirming what American and European scientists have long found: Food from genetically modified crops is no more dangerous to eat than food produced by conventional agriculture. In the words of the report, there is "no substantiated evidence" that genetic modification of crops produces less safe foods.[82] In the United States, Canada, the United Kingdom and Western Europe, "no differences have been found that implicate a higher risk to human health safety" from genetically engineered foods.[83] In its summary, the report states, "On the basis of its detailed examination of comparisons between currently commercialized GE and non-GE foods in compositional analysis, acute and chronic animal toxicity tests, long-term data on health of livestock fed GE foods, and epidemiological data, the committee concluded that no

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> new plant variety (including the use of new techniques such as rDNA technology) is generally not material information within the meaning of section 201(n) of the FD&C Act, and would not usually be required to be disclosed in the labeling for the food. This determination was reviewed and upheld by the court in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 178–79 (D.D.C. 2000) (finding that FDA's determination that genetic engineering, alone, is not a material fact that warrants food labeling was entitled to deference) (Ref. 10). Labeling provided by manufacturers on a wholly voluntary basis regarding whether a food was or was not bioengineered as described in this guidance is acceptable to FDA, provided that such labeling is truthful and not misleading. Some consumers are interested in the information provided in such labeling.

[80] *Labeling of Genetically Modified Foods*, AM. ASS'N ADVANCEMENT SCI. (Oct. 20, 2012), http://archives.aaas.org/docs/resolutions.php?doc_id=464.

[81] NAT'L ACAD. SCI., ENGINEERING & MEDICINE, GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS (2016), http://nas-sites.org/ge-crops/2016/05/17/report/ [hereinafter GENETICALLY ENGINEERED CROPS REPORT].

[82] *Id.* at xvii.

[83] *Id.* at 10; *see also Labeling of Foods Derived From Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodScienceResearch/GEPlants/ucm346858.htm (last updated Nov. 19, 2015) ("The agency is not aware of any valid scientific information showing that foods derived from genetically engineered plants, as a class of foods, differ from other foods in any meaningful way. GE (genetically engineered) foods don't present greater safety concerns than foods developed by traditional plant breeding.").

differences have been found that implicate a higher risk to human health safety from these GE foods than from their non-GE counterparts."[84]

This conclusion tracks that of many others.[85] In 2015, the American Association for the Advancement of Science spoke unequivocally. In its words, "the science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe."[86] The European Commission has similarly proclaimed, "The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies."[87] The World Health Organization, the National Academy of Sciences, and the Royal Society in the United Kingdom are in agreement.[88]

4. *Ecology*. There would also be an argument for labeling if GMOs created ecological risks, rather than dangers to human health. Here is the answer is less unambiguous. The 2016 report of the National Academies of Sciences, Engineering, and Medicine finds no clear evidence that genetically modified crops cause environmental harm.[89] At the same time, the report is written with considerable caution. It does

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[84] GENETICALLY ENGINEERED CROPS REPORT , *supra* note, at 10.

[85] See McHughen, supra note, suggesting that it "is not a simple matter to dichotomize between rDNA technology and all others. Nor is it wise, if the distinction is based solely on safety concerns. GM varieties undergo far greater scrutiny for safety and environmental risks than, say, varieties developed from mutation breeding."

[86] *Labeling of Genetically Modified Foods*, *supra* note. The full context: "There are several current efforts to require labeling of foods containing products derived from genetically modified crop plants, commonly known as GM crops or GMOs. These efforts are not driven by evidence that GM foods are actually dangerous. Indeed, the science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe. Rather, these initiatives are driven by a variety of factors, ranging from the persistent perception that such foods are somehow 'unnatural' and potentially dangerous to the desire to gain competitive advantage by legislating attachment of a label meant to alarm. Another misconception used as a rationale for labeling is that GM crops are untested." *Id.*

[87] EUR. COMMISSION, A DECADE OF EU-FUNDED GMO RESEARCH (2001–2010) 16 (2010), http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf.

[88] See note supra.

[89] *See* GENETICALLY ENGINEERED CROPS REPORT, *supra* note, at 8: "Overall, the committee found no conclusive evidence of cause-and-effect relationships between GE crops and environmental problems. However, the complex nature of assessing long-term environmental changes often made it difficult to reach definitive conclusions. That is illustrated by the case of the decline in overwintering monarch butterfly populations. Studies and analyses of monarch dynamics reported as of March 2016 have not shown that suppression of milkweed by glyphosate is the cause of monarch decline. However, there is as yet no consensus among researchers that increased glyphosate use is not at all

acknowledge the importance of continuing monitoring, but pointedly declines to embrace the widespread view that those crops have been responsible for declines in monarch butterfly populations.[90]

Other studies are less equivocal, finding no special risks to the environment from genetically modified agriculture. In 1988, the National Academy concluded that the environmental hazards associated with GMOs are not essentially different from those associated with unmodified organisms.[91] It found that assessment of the risks should be based not on whether the organism is genetically modified, but on the nature of the organism and the environment into which it is introduced.[92] The American Medical Association has endorsed this finding.[93]

At the same time, it must be acknowledged that in some circles, the prevailing scientific judgments are intensely disputed, especially with respect to environmental risks.[94] Some people believe that the scientific consensus is influenced by powerful private interest groups, who have an interest in denying both health and environmental

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associated with decreased monarch populations. Overwintering monarch populations have increased moderately in the last 2 years. Continued monitoring will be useful."

[90] *See id.*

[91] NAT'L ACAD., BIOTECHNOLOGY AND THE FOOD SUPPLY: PROCEEDINGS OF A SYMPOSIUM (1988).

[92] Id.

[93] *See* AM. MED. ASS'N, LABELING OF BIOENGINEERED FOODS (2012). In the same vein, see Philip Dale et al., Potential for the Environmental Impact of Transgenic Crops, 20 Nature Biotechnology 565 (2002), http://www.nature.com/nbt/journal/v20/n6/full/nbt0602-567.html, and in particular this conclusion: "From the current state of knowledge, the impact of free DNA of transgenic origin is likely to be negligible compared with the large amount of total free DNA. We can find no compelling scientific arguments to demonstrate that GM crops are innately different from non-GM crops."

[94] A brisk and helpful statement of relevant risks can be found in NASSIM NICHOLAS TALEB ET AL., THE PRECAUTIONARY PRINCIPLE (WITH APPLICATION TO THE GENETIC MODIFICATION OF ORGANISMS) (2014), available at http://www.fooledbyrandomness.com/pp2.pdf. Consider in particular this suggestion: "More generally, engineered modifications to ecological systems (through GMOs) are categorically and statistically different from bottom up ones. Bottom-up modifications do not remove the crops from their long term evolutionary context, enabling the push and pull of the ecosystem to locally extinguish harmful mutations. Top-down modifications that bypass this evolutionary pathway unintentionally manipulate large sets of inter-dependent factors at the same time, with dramatic risks of unintended consequences. They thus result in fat- tailed distributions and place a huge risk on the food system as a whole."

concerns.[95] In their view, any such consensus is not trustworthy; they do not necessarily that scientists are unconcerned, but they offer a second-order reason to discount that lack of concern. With respect to environmental risks in particular, a number of observers point to what they see as a series of ecological risks, including toxicity to nontarget organisms (such as butterflies and bees), invasiveness in natural settings, and threats to biodiversity.[96] Some scientists and regulators have also expressed grave concern that if it is widespread, GMOs will lead to resistance and the loss of a "public good" -- susceptibility of insect pests to certain proteins.[97] It should be acknowledged that some people fear long-term effects, not only ecological in nature, but also cultural and distributional, including the effects of GM products on small farmers. It is hardly impossible that over time, some of their concerns will be vindicated. For present purposes, the central point is that the prevailing scientific judgment appears to be that the health risks are nonexistent and that the standard environmental concerns are highly conjectural and have not been demonstrated to be serious.

5. *Risk-risk tradeoffs*. It should be clear in this light that if GM labels are effective, there will be a risk-risk tradeoff. On one view, such labels might help diminish ecological risks. At the same time, they might create risks to health and to the ecology. Longer shelf lives save resources and may (modestly) mitigate climate change. GM food reduces use of pesticides, which create hazards of their own. The point is not to reach a final judgment about the magnitude of these effects, but to signal the fact that risks are not only on one side of the equation,

B. What People Want, and Why

1. *Labels for health*? The public opinion evidence is at least as clear as the science: People do not believe that GM food is safe, and they strongly favor mandatory

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[95] See, e.g., Tim Schwab, Pro-GMO Database: Monsanto is the Most Common Funder of GMO Research (2014), available at http://www.foodandwaterwatch.org/insight/pro-gmo-database-monsanto-most-common-funder-gmo-research

[96] See, e.g., Emily Glass, The Environmental Impact of GMOs (2013), available at http://www.onegreenplanet.org/animalsandnature/the-environmental-impact-of-gmos/. On biodiversity in particular, see World Conservation Union, CURRENT KNOWLEDGE OF THE IMPACTS OF GENETICALLY MODIFIED ORGANISMS ON BIODIVERSITY AND HUMAN HEALTH (2007), available at https://cmsdata.iucn.org/downloads/ip_gmo_09_2007_1_.pdf. For a good overview, see McHughen, supra note. For a cautious presentation, see Heather Landry, Challenging Evolution: How GMOs Can Influence Genetic Diversity (2015), available at http://sitn.hms.harvard.edu/flash/2015/challenging-evolution-how-gmos-can-influence-genetic-diversity/ and in particular: "Although there is little evidence that GMOs have impacted genetic diversity in today's environment, scientists and ecologists are very aware of the potential influence that GMOs have on biodiversity. Therefore, researchers are investigating how to better prevent crossbreeding and spreading of GMOs . . . ."

[97] See Sarah L Bates et al., Insect resistance management in GM crops: past, present and future, 23 Nature Biotechnology 57 (2005).

labels. It is not easy to find a domain in which public opinion is so unambiguously at odds with the scientific consensus. A typical survey finds that only 37 percent of Americans believed that genetically modified food is safe to eat (as compared with 88 percent of members of the American Association for the Advancement of Science).[98] According to my own recent survey, 86 percent of Americans favor labeling of GM food—89 percent of Democrats, 80 percent of Republicans, and 86 percent of independents.[99]

What explains such high levels of support for mandatory labels? The simplest answer is that people favor labels because they think that GM food is harmful, and they believe that consumers should be allowed to make an informed choice about whether to consume it. To that extent, the judgment in favor of labels for GM food is quite similar to the corresponding judgment with respect to products that contain high levels of salt or that otherwise are taken to create health risks.[100] Without carefully engaging questions about costs and benefits, people make an intuitive judgment that government should mandate labels in order to allow consumer to avoid, if they wish, products that might be dangerous.

2. *Disgust and naturalness*. On the basis of existing research, the simplest answer appears to be correct, but Sydney Scott and Paul Rozin of the University of Pennsylvania and Yoel Inbar of the University of Toronto, offer some important complications.[101] Scott et al. asked a representative sample of Americans whether they supported or opposed genetically engineering plants and animals. They also asked them to register agreement or disagreement with this statement: "This should be prohibited no matter how great the benefits and minor the risks from allowing it."

Consistent with previous studies, 64 percent of participants opposed genetic engineering. In fact, 71 percent of the opponents, and 46 percent of the entire sample, were absolutists: They want to ban genetic engineering *regardless of the benefits and risks*. To that extent, their opposition to GM foods is not consequentialist, or based on an assessment of costs and benefits at all. To explain the psychology behind that apparently puzzling finding, Scott and her coauthors presented their participants with a scenario in which a random person ends up eating genetically modified tomatoes (either knowingly or unknowingly). They asked people how angry or disgusted they were when imagining the scenario. Opponents of genetic modification were angrier and more disgusted than its supporters. But the absolutists were especially disgusted. Controlling for demographic

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[98] Sydney E. Scott et al., *Evidence for Absolute Moral Opposition to Genetically Modified Food in the United States*, 11 PERSPECTIVES ON PSYCHOL. SCI. 315, 316 (2016).
[99] *See* Sunstein, *supra* note 8. Similar findings have been made in Europe. See Lucia Reisch & Cass R. Sunstein, Do Europeans Like Nudges?, 11 Judgment and Decision Making 310 (2016).
[100] *See* Sunstein, *supra* note 8.
[101] Scott et al., *supra* note.

and other differences, Scott et al. found that disgust was the best predictor of whether people would proclaim absolute opposition to genetic modification.[102]

Their conclusion is simple: People who most strongly oppose genetic modification are not weighing consequences. Their opposition is a product of the fact that they find the idea disgusting. That idea requires its own exploration. By itself, the idea of genetically modified food does not seem to be the sort that would trigger disgust; it is not as if we are speaking of bodily fluids or the ordinary sources of something like nausea.[103] In this context, disgust would seem to be a placeholder for some kind of intense emotion, signaling disapproval. We might speculate that many people have an immediate, intuitive sense that what is healthy is what is "natural,"[104] and that efforts to tamper with nature will inevitably unleash serious risks—so-called Frankenfoods.

This speculation raises two puzzles of its own. First, we might question whether and what extent people really are absolutists about GM food. It is one thing to say, in the abstract, that GM foods should be regulated or banned regardless of the benefits and risks. It is another thing to favor regulation or prohibition after receiving concrete information about benefits and risks. If, for example, people are asked to assume that GM food reduces costs by 20 percent, or promises to save thousands of lives annually, and that it poses no risks to health or the environment, would they really favor regulation or prohibition? Many of those who purport to be absolutists in the abstract, or in response to general questions, tend to become more consequentialist, and more amenable to some form of cost-benefit balancing, when they are presented with concrete numbers.[105]

Second, it is not obvious how regulators should respond to regulatory intuitions of the kind that existing surveys seem to capture. If people are using a heuristic ("unnatural is unsafe"), and if that heuristic is producing an error ("GM food is unsafe"), then regulators should correct the error, so that consumers can make informed decisions. But if consumers are simply disgusted, then they are registering a taste, not an erroneous judgment. Consider a purer case of disgust: Some people are disgusted by Jello. They can decide to avoid Jello; but should regulators mandate labels in the fact of such a taste ("this product contains Jello")? Even if no health issues are involved? In such circumstances, there would not seem to be a compelling argument for mandatory labeling (to say the least). I will return to these issues shortly.

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[102] Id.

[103] *See* Paul Rozin & April E. Fallon, *A Perspective on Disgust*, 94 PSYCHOL. REV. 23 (1987).

[104] *See* JAMES P. COLLMAN, NATURALLY DANGEROUS 29–33 (2001); DIETER BIRNBACHER, NATURALNESS: IS THE "NATURAL" PREFERABLE TO THE "ARTIFICIAL"? (David Carus trans., 2014); Fern Lin, The Impact of Naturalness on Perceived Risk (Spring 2009) (unpublished manuscript), http://opim.wharton.upenn.edu/risk/ackoff/Ackoff2009/Lin2009.pdf.

[105] See Jonathan Baron and Sarah Leshner, How Serious Are Expressions of Protected Values? 6 J Experimental Psychology: Applied 183 (2000).

C. GMO Labels: Normative Considerations

1. *Market failure*. With respect to GM food, is there a market failure, behavioral or otherwise? Consumers can, of course, refuse to purchase GM food – if they know that that is what it is. And if consumers care, we should see a degree of market sorting, in which some companies label their foods as not containing GMOs, some companies acknowledge that their foods contain GMOs, and some companies are silent. In fact, that is exactly what the American market has observed, with the help of FDA guidance on the matter.[106] Where, then, is the market failure, justifying the disclosure mandate? The Department of Agriculture will be required to give some kind of answer to that question.[107]

Consistent with the previous discussion, one response points to behavioral science. Even though some people will infer that food without a "GMO-free" label does in fact contain GMOs, many will not. Most consumers are not thinking about GMOs at all when they are purchasing food. And even though most consumers support GMO labeling in surveys, the issue probably lacks much salience when people are making choices at restaurants or grocery stores.[108] An alternative argument for a market failure involves the environmental consequences, which amount to third-party effects.[109] If GM foods pose nontrivial environmental risks, or even if it merely might do so, labeling can be seen a legitimate way of reducing the relevant risks. A label based on third-party effects would seem unobjectionable in principle, even though as noted, a disclosure mandate is not the preferred way to counteract such effects.[110]

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[106] Labeling Guidance, *supra* note.
[107] See note supra.
[108] *Cf.* Wallace E. Huffman et al., *Consumer Willingness to Pay for Genetically Modified Food Labels in a Market with Diverse Information: Evidence from Experimental Auctions*, 28 J. AGRIC. & RESOURCE ECON. 481 (2003).
[109] See Benoit Morel et al., Pesticide Resistance, the Precautionary Principle, and the Regulation of Bt Corn: Real Option and Rational Option Approaches to Decisionmaking, in Battling Resistance to Antibiotics and Pesticides 184 (Ramanan Laxminarayan ed.) (Washington D.C.: Resources for the Future, 2003) (proposing option theory as an analytical framework for the Precautionary Principle and applying that framework to the issue of commercializing Bt corn); Justus Wesseler, Resistance Economics of Transgenic Crops under Uncertainty: A Real Options Approach, in id. at 214 (discussing pest resistance as an irreversible cost of transgenic crops). See also Nassim Nicholas Taleb et al., The Precautionary Principle (with Application to the Genetic Modification of Organisms) (2014), available at http://www.fooledbyrandomness.com/pp2.pdf (discussing potential risks of GMOs and exploring reasons to be precautionary with respect to them).
[110] On the idea of "mismatch" between market failure and regulatory tool, see BREYER, *supra* note.

2. *Costs and benefits*. Some people argue that they have a "right to know" what they are eating.[111] On this view, consumers are entitled to be informed about the ingredients of their food – salt, sugar, fat, or GMOs. The initial answer to this suggestion is that there is no freestanding "right" to mandatory labels, simply because some or many consumers would favor them. Unless there is a market failure of some kind, the market provides the knowledge to which consumers have a right. We have explored some reasons why there might be a market failure here. The second answer is that even in the face of an actual market failure, whether consumers have a right to know, in the form of a mandatory label, depends on the costs and the benefits.[112]

(a) *Costs*. To assess costs, USDA must begin by projecting the costs of labeling itself. The projection is likely to be disputed,[113] but it does not present serious conceptual difficulties; the only issues are ones of fact. As we have also seen, there are costs as well to consumers who see the label (and are less happy when they do) and also to consumers who, having seen the label, buy goods that are either more costly or inferior (the lost consumer surplus). The latter costs will be extremely difficult to specify, and the USDA might be forced simply to produce some upper or lower bound or even to say that they are not quantifiable. It might also be reasonable for it to conclude that they are unlikely to be large. Merely seeing the label would not impose high costs on consumers. To project the lost consumer surplus, agencies would need to project the likely effect of the label on consumer behavior and the monetized loss. Undertaking that projection might well turn out to be daunting, even impossible, and the agency might be unable to produce specific numbers or even a reasonably bounded range.

(b) *Millions of labels, in search of benefits*. If we focus, as agencies frequently do, on health benefits from mandatory labels, GM labels would seem to be difficult to defend. As we have seen, the health benefits appear to be zero, and so they are not sufficient to justify even modest costs. We have also seen that on one view, environmental benefits cannot be ruled out, but on the basis of the existing science, they would be impossible to quantify. I will return to that issue; for the moment, the simple conclusion is that it would not be so easy to argue that they would justify a significant expenditure.[114]

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[111] See, e.g. http://www.justlabelit.org/right-to-know-center/right-to-know/

[112] It follows that the welfarist approach of the "right to know" asks whether mandatory disclosure passes some kind of cost-benefit test. On some of the complexities with the idea of welfare, see Matthew Adler, Welfare and Fair Distribution (2011). Some of those complexities bear on important regulatory problems – as when a regulation that fails cost-benefit analysis has desirable distributional consequences – but for GM foods, they do not seem to arise and so can be fairly bracketed.

[113] See note supra.

[114] But see NASSIM NICHOLAS TALEB ET AL., THE PRECAUTIONARY PRINCIPLE (WITH APPLICATION TO THE GENETIC MODIFICATION OF ORGANISMS) (2014), available at http://www.fooledbyrandomness.com/pp2.pdf (arguing that GMOs pose risks that are worth taking quite seriously).

In this respect, agencies would have a difficult challenge using their conventional approach to benefits estimates to justify the conclusion that mandatory labeling would survive a cost-benefit test, as required by Executive Order 12291 and 13563.[115] As compared to the case of calorie labeling, for example, it would be hard to specify health or environmental end-points, or even ranges, that could make their way into a conventional regulatory impact analysis.

(c) *Options*. Confronted with this problem, the USDA has several options. First, it might simply announce that the benefits of GM labels are not quantifiable. As we have seen, agencies have taken that route in the past, and it has survived judicial scrutiny, at least under statutes that require agencies to act.[116] The problem with this approach is that when agencies have imposed disclosure mandates without quantifying benefits, they could usuully say that they expect significant benefits (in terms of money or health), but can only speculate about their magnitude. If the expectation of significant benefits is reasonable, a failure to quantify may not be objectionable, at least if quantification is not feasible.[117]

In this context, by contrast, the problem is that there would seem to be no benefits at all (bracketing the question of environmental harm, to which I will return). When benefits are essentially zero, it is not enough, or even reasonable, to say that they are speculative. Because the statute requires the USDA to act, the inability to project benefits is unlikely to be objectionable purely as a matter of law,[118] but it does require serious challenges for the agency when it attempts to produce a regulatory impact analysis and to survive scrutiny within the executive branch. The closest analogy may well be the conflict minerals controversy, where the SEC was not able to project benefits and candidly confessed to that fact.[119] Because GM labels are required by law, such a confession likely be enough to survive judicial review, but it would encounter hard questions under the process of OIRA review.

Faced with that problem, USDA might engage in some form of breakeven analysis, especially if the costs of mandatory GM labels can be described as low.[120] We can easily imagine creative efforts in this vein, asking (for example) about whether it

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[115] As noted, the existing requirements apply, as they must, only "to the extent permitted by law," which means that agencies would be required to proceed even if the benefits do not justify the costs. Nonetheless, it is awkward for an agency to announce that it is proceeding in the face of costs that greatly exceed benefits – though it has happened. See Cass R. Sunstein, Valuing Life (2014).

[116] See note supra.

[117] See Sunstein, Cost-Benefit Analysis and Arbitrariness Review, supra note.

[118] See note supra.

[119] See note supra.

[120] For one estimate, see JOHN DUNHAM, COST IMPACT OF VERMONT'S GMO LABELING LAW ON CONSUMERS NATIONWIDE (2016), http://corn.org/wp-content/uploads/2016/02/Cost-Impact-of-Vermont's-GMO-Labeling-Law-on-Consumers-Nationwide.pdf.

would be worthwhile to charge the average American $X annually (where $X is very little) in return for GM labels.[121] Suppose, for example, that the cost of a label is $2.30 per person per year.[122] It might well be suggested that the mandate obviously survives breakeven analysis. Isn't that modest cost worth incurring, given widespread consumer preference for labels and good-faith concerns about ecological risks? Perhaps so. But one problem is that on that assumption about the per-person cost, the aggregate number is over $700 million—hardly a trivial amount. It would be easy, and misleading, to say that *any* annual $700 million expenditure is justified because for all Americans, the annual per-person cost is merely $2.30. The real question is what people are obtaining for that $700 million.

As an independent method of valuation, or as part of some breakeven analysis, it might seem reasonable to put a spotlight on consumers' willingness to pay for GM labels. On the basis of survey evidence, suggesting that consumers favor such labels, it would not be implausible to think that the amount would be significant, population-wide—and per-person, at least $2.30 per year.[123] Ideally, regulators would actually have some evidence of people's willingness to pay, which they could compare with some estimate of costs. In the absence of such evidence, they might nonetheless engage in breakeven analysis. Would an approach of that kind be sufficient to ground a reasonable cost-benefit analysis under prevailing executive orders? At first glance, it should be, but as we shall now see, any approach of that kind turns out to raise some quite fundamental questions about regulatory policy.

(d) *What consumers want*. We can easily imagine cases in which the law should not mandate labels even if consumers would be willing to pay for it. Suppose, for example, that consumers want to know whether African-Americans or Jews were involved in the production of some commodity. To the extent that the consumer demand reflected racism or prejudice, it should not be honored. But the call for GM labels does not run afoul of this principle, because no invidious discrimination is involved.

Consider a much more relevant comparison: Suppose that consumers are alarmed about some ingredient in food—call it Omega P—even though there is no reason for alarm. Suppose that there is an online health scare about Omega P and that people at least want to know whether the food they are eating contains it. In principle, a label is not a good idea. It would cater to public ignorance, and it would have no benefits. For government, the right response is to inform people that Omega P is in fact safe. Note that

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[121] Compare the approach of the Department of Justice in the context of building accessibility, discussed in Sunstein, The Limits of Quantification, *supra* note.

[122] *See* ANDREW DYKE & ROBERT WHELAN, ECONORTHWEST, GE FOODS LABELING COST STUDY (2014), http://www.justlabelit.org/about-ge-foods-center/ge-labeling-and-food-prices/ (finding as much). With the flexibility of the national law, permitting compliance with the use of bar codes, the costs should be significantly lower than they would otherwise be – but the $2.30 figure, produced by an interested party, might not be credible.

[123] *See id.*

in this case, the standard argument for use of willingness-to-pay is decisively undermined. People might be willing to pay something, perhaps even a great deal, for Omega P labels, but because such labels would not promote their welfare, there is no sufficient reason for them. Note in this regard that 80 percent of Americans have been found to favor a label for foods that contain DNA (!).[124] The challenge for USDA will be to show that labels for GM food are relevantly different from labels for Omega P; perhaps uncertainty and irreversibility can help the agency to show relevant distinctions.[125]

3. *But morality*? For some people, arguments about health and the environment miss the central points. On one view, the objection to GM foods is theological: GMOs tamper with God's creation. On another view, it is moral: There is something wrong with treating nature in this way. On a third view, GM food benefits large corporations, and the wealthy, at the expense of small farmers, poor nations, and the poor in general. The third view can easily be translated into an argument about adverse effects on third parties. Under all three views, GM labels are a modest step in the right direction, by allowing consumers to know what they are buying and to register their preferences and their values.

At the very least, we should be willing to agree that if labels do have some kind of moral motivation, they might be well-justified, even if quantitative cost-benefit analysis turns out to be challenging, impossible, or beside the point.[126] We have seen analogies, in the form of labels designed to protect people form unsafe working conditions or to prevent cruelty to animals. Could GM labels be defended on some such ground? It should not be sufficient merely to point to the *fact* of moral concern; the question is whether the moral concern has some plausible basis. In the abstract, an affirmative answer can hardly be ruled out. Many people hold such concerns in good faith.

The difficulty is to specify some intelligible moral principle that does in fact call for labels. It is not at all clear that there is a plausible religious objection to GM foods (and if there were, it could not easily be invoked by the Department of Agriculture without raising first amendment issues). It is hard to make sense of the argument that GM

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[124] JAYSON LUSK & SUSAN MURRAY, OKLA. ST. U., FOOD DEMAND SURVEY (2015), http://agecon.okstate.edu/faculty/publications/4975.pdf.

[125] See, e.g., Benoit Morel et al., Pesticide Resistance, the Precautionary Principle, and the Regulation of Bt Corn: Real Option and Rational Option Approaches to Decisionmaking, in Battling Resistance to Antibiotics and Pesticides 184 (Ramanan Laxminarayan ed.) (Washington D.C.: Resources for the Future, 2003) (proposing option theory as an analytical framework for the Precautionary Principle and applying that framework to the issue of commercializing Bt corn); Justus Wesseler, Resistance Economics of Transgenic Crops under Uncertainty: A Real Options Approach, in id. at 214 (discussing pest resistance as an irreversible cost of transgenic crops).

[126] See supra.

foods are "mistreating nature."[127] Nor is it clear that GM labels can be plausibly defended on distributional grounds in light of the considerable difficulty in demonstrating that GM foods are objectionable on such grounds and in showing that even if they are, labels are helpful in meeting that challenge.[128] But I do not mean to reach a judgment on the particulars here -- only to suggest the form of a possible justification and the serious challenges that the USDA, or anyone else, might face in offering it.

4. *Drawing False Inferences***.** There is an additional concern: The signal contained in a mandatory label might affirmatively mislead consumers.[129] If the government requires Omega P labels, many consumers will infer that public officials are worried about Omega P, and believe that consumers should think carefully before consuming food that contains it. Whatever the government is seeking to convey, the disclosure mandate might well contain this signal: "Omega P is a legitimate cause for concern." To the extent that public officials provide such signal, they are affirmatively misleading people. Whether the mandate is heard to offer that signal is, of course, an empirical question.

The FDA is plainly concerned with the risk that consumers might be misled in this context. In 2015, it stated that[130]

> a statement may be false or misleading if, when considered in the context of the entire label or labeling . . . it suggests or implies that a food product or ingredient is safer, more nutritious, or otherwise has different attributes than other comparable foods because the food was not genetically engineered. For example, the labeling of a bag of specific type of frozen vegetables that states that they were "not produced through modern biotechnology" could be misleading if, in addition to this

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[127] See Alan McHughen, Pandora's Picnic Basket (2000); Naturally Dangerous, supra note.

[128] McHughen, supra note. One possible defense would point to the fact that consumers might be willing to pay for labels to promote distributional concerns. As before, the question is whether the fact is sufficient, independent of its basis. Recall also that a distributional argument rests on its own; it need not be defended in terms of consumers' willingness to pay.

[129] With Oren Bar-Gill and David Schkade, I am now engaged in a project to test this question. Our preliminary findings support the concern. For an excellent discussion, see Juanjuan Zhang, Policy and Inference: The Case of Product Labeling (unpublished manuscript 2014), available at http://jjzhang.scripts.mit.edu/docs/Zhang_2014_GMO.pdf; Colin A. Carter & Guillaume P. Gruère, *Mandatory Labeling of Genetically Modified Foods: Does It Really Provide Consumer Choice?*, 6 J. AGROIOTECHNOLOGY MGMT. & ECON. 68 (2003) ("Mandatory labeling provides food processors and retailers a choice, but it does not facilitate consumer choice. Because of rational food processor decisions, mandatory labeling acts as a market barrier, and GM products do not appear at the retail level."). *Compare* Charles Noussair et al., *Do Consumers Really Refuse to Buy Genetically Modified Food?*, 114 ECON. J. 102 (2004).

[130] Labeling Guidance, *supra* note.

statement, the labeling contains statements or vignettes that suggest or imply that, as a result of not being produced through modern biotechnology, such vegetables are safer, more nutritious, or have different attributes than other foods solely.

Some evidence suggests that consumers would indeed draw an inference, from a label, that the government believes that GM food is unhealthy.[131] In one study, "respondents consistently believed that foods labeled GMO are less healthy, safe and environmentally-friendly compared to all other labels," suggesting that "a disconnect may exist between the meaning associated with the label and the scientific consensus for GMO food."[132] Nor is it irrational for consumers to infer, from a label, that public officials believe that GM foods pose some kind of risk. Ordinarily, labels are required for that reason; they are essentially warnings and taken as such.

In the implementation of the new GM labeling law, we could imagine creative responses by the private or public sector. The government might allow or require the warnings to be accompanied by a disclaimer: "The FDA has determined that GM foods do not pose a health risk of any kind." Producers of GM foods might be allowed or encouraged to embark on an educational campaign, offering exactly that message. For fully rational consumers, clarifying steps of this kind should correct any misimpression.

But for many consumers, such steps might not work. On the contrary, they might even backfire. In view of public opposition to GM foods, a statement to the effect that they "do not carry risks" might instead focus public attention on the possible association between GM foods and the whole idea of risks. Many consumers might think: "Where there is smoke, there is fire; why not buy something else?" Of course the existence and extent of this reaction present empirical questions, but existing evidence suggests that many consumers will make a false inference, and that it will not be easy to correct that inference.

If labels mislead (some or many) people, the issue is not at an end. It is necessary to ask what kind of welfare loss that imposes. A key question is whether consumers will end up purchasing GMO-free food that is inferior along some dimension – say, it is more expensive, less nutritious, or less costly. If they do so, that is a welfare loss, and it may be substantial.

4. *A summary*. I have covered numerous issues in a relatively short space, and a summary may be useful. With respect to costs, the USDA must calculate the expense of producing the labels themselves. The calculation will undoubtedly produce some dispute, but the analysis should be reasonably straightforward. There are also costs to consumers who see the label (and are less happy when they do) and also to consumers who, having seen the label, buy goods that are more costly or inferior. The latter costs are more important but will be extremely difficult to specify; the USDA might do best simply to

[131] Joanna K. Sax & Neal Doran, *Food Labeling and Consumer Associations with Health, Safety and Environment*, 44 J.L. MED. & ETHICS (forthcoming 2016).
[132] *Id.* at 1.

say that they are not quantifiable. It might be reasonable for it to conclude that they are unlikely to be large, though informed conjecture or (better) evidence would of course be necessary to support that conclusion.

The benefits issue is far more challenging. It is not possible to identify health endpoints that would justify mandatory labels. Nor is it simple to specify environmental risks or to connect a disclosure mandate to reduction of those risks. In principle, the willingness to pay figure is the right one, but it is highly doubtful that USDA could produce reliable estimates. Even if it did, the numbers would be mostly a product of consumer errors, in the form of a mistaken belief that GM food produces health risks.

In these circumstances, USDA will not have an easy time in demonstrating that the benefits of mandatory labels justify the costs. As I have noted, the law requires it to proceed even if it cannot make that demonstration; but under prevailing executive orders, no agency likes to proceed when costs plainly exceed benefits, and the process of scrutiny within the executive branch will produce a serious demand for some kind of plausible cost-benefit justification. For the USDA, the best option is probably to offer a breakeven analysis, invoking consumers' wishes, the risk of irreversible environmental harm (perhaps with special attention to biodiversity[133]), or both. If the per-person cost of labels is indeed very low, a breakeven analysis might turn out to be plausible. That claim brings us to our final topic.

IV. Precautions, Irreversibility, and Uncertainty

When a product or activity creates some kind of risk, even a small one, many people argue in favor of precautions, and in particular in favor of the precautionary principle. Some of the central claims on behalf of that principle involve uncertainty, learning over time, irreversibility, and the need for epistemic humility on the part of scientists. Any consensus might be turn out to be wrong; today's assurance might be tomorrow's red alert.[134] In particular, GMOs are often thought to trigger the precautionary principle, with special emphasis on the need for continuing monitoring, residual uncertainty, and the existence of potentially irreversible[135] or catastrophic

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[133] See McHughen, supra note.

[134] THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY: LATE LESSONS FROM EARLY WARNINGS (Paul Harremoës et al. eds., 2002)

[135] See generally Benoit Morel et al., Pesticide Resistance, the Precautionary Principle, and the Regulation of Bt Corn: Real Option and Rational Option Approaches to Decisionmaking, in Battling Resistance to Antibiotics and Pesticides 184 (Ramanan Laxminarayan ed.) (Washington D.C.: Resources for the Future, 2003) (proposing option theory as an analytical framework for the Precautionary Principle and applying that framework to the issue of commercializing Bt corn); Justus Wesseler, Resistance Economics of Transgenic Crops under Uncertainty: A Real Options Approach, in id. at 214 (discussing pest resistance as an irreversible cost of transgenic crops). On irreversibility more broadly, see Kenneth Arrow and Anthony Fischer, Environmental Preservation, Uncertainty and Irreversibility, 88 Q. J. Economics 312, 313-14 (1974);

environmental risks.[136] This is no mere theoretical point. As one commentator explains, European "legislation that governed GMOs used a precautionary approach, and precaution was one basis for the de facto moratorium on authorizations of GM varieties."[137]

A. Worst Cases

Whatever we think about the particular application, the precautionary principle has deep roots in international law.[138] As long ago as 1982, for example, the United Nations World Charter for Nature gave the first international recognition to the principle, suggesting that when "potential adverse effects are not fully understood, the activities should not proceed."[139] The 1992 *Rio Declaration on Environment and Development* asserts: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." [140] The widely publicized *Wingspread Declaration*, from a meeting of environmentalists in 1998, goes further still: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not established scientifically. In this context the proponent of the activity, rather than the public, should bear the burden of proof."[141]

In its various forms, the precautionary principle has been subject to a great deal of analysis, some of it quite skeptical[142] and some of it highly supportive.[143] A central

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Anthony C. Fisher, Uncertainty, Irreversibility, and the Timing of Climate Policy 9 (2001), available at http://are.berkeley.edu/courses/IAS175/Spring2006/pdfs/Fisher.pdf; Scott Farrow, Using Risk-Assessment, Benefit-Cost Analysis, and Real Options to Implement a Precautionary Principle, 24 Risk Analysis 727, 728 (2004); Cass R. Sunstein, Irreversibility, 9 Law, Probability, and Risk 227 (2010).

[136] *See* Margaret Rosso Grossman, *European Community Legislation for Traceability and Labeling of Genetically Modified Crops, Food, and Feed*, *in* LABELING GENETICALLY MODIFIED FOOD 32, 35–36 (Paul Weirich ed., 2008).

[137] *Id.* at 36.

[138] See note supra; Joel Tickner, The Precautionary Principle in Action (1999); Caroline Foster, Science and the Precautionary Principle in International Courts and Tribunals: Expert Evidence, Burden of Proof and Finality (2013).

[139] G.A. Res. 37/7, annex, World Charter for Nature (Oct. 28, 1982).

[140] Rio Declaration on Environment and Development, U.N. Conference on Environment and Development, annex I, princ. 15, U.N. Doc. A/CONF.151/5/Rev.1 (1992) [hereinafter Rio Declaration], *reprinted in* 31 I.L.M. 874, 879 (1992).

[141] *Precautionary Principle*, SCI. & ENVTL. HEALTH NETWORK (quoting the *Wingspread Statement on the Precautionary Principle*), http://www.sehn.org/precaution.html.

[142] INDUR GOKLANY, THE PRECAUTIONARY PRINCIPLE: A CRITICAL APPRAISAL (2001); Cass R. Sunstein, Laws of Fear: Beyond the Precautionary Principle (2005).

question involves the appropriate approach to "worst-case" thinking. This is not the place for a full analysis, which would require investigation of some complex issues in decision theory,[144] but three points seem clear (bracketing hard questions about quantification). *First*: If a product or activity has modest or no benefits, the argument for taking precautions is far stronger than if its benefits are significant. *Second*: If a product or activity creates a trivially small risk (taking account of both the probability and the magnitude of a bad outcome), then it should not be banned or regulated (including through labels) if it promises significant benefits. *Third*: If a product creates a small (but not trivial) risk of catastrophe, there is a strong argument for banning or regulating it (including through labels) if the benefits are very modest and so do not justify running that risk. Some of the most difficult cases arise when (1) a product or activity has significant benefits and (2) (a) the probability of a bad outcome is difficult or impossible to specify (creating a situation of "uncertainty" rather than risk[145]), *and* (a) the bad outcome is catastrophic *or* (b) the harms associated with the bad outcome cannot be identified (creating a situation of "ignorance"[146]). In such difficult cases, it is not simple to balance the two sides of the ledger, and there is a real argument for eliminating the worst-case scenario.[147]

Let us bracket the most complicated questions here and simply note that in this light, a precautionary argument for labeling GM foods (or otherwise for regulating them) depends in large part[148] on answers to questions of fact. Is this a difficult case or an easy one? The answer turns largely on two further questions. Do such foods promise modest benefits, or instead large ones? With respect to harm, are we speaking of risk, uncertainty, or ignorance? The scientific consensus appears to be risk—and that the

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[143] THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY: LATE LESSONS FROM EARLY WARNINGS (Paul Harremoës et al. eds., 2002); Nabil Al-Najjar, *A Bayesian Framework for the Precautionary Principle*, 44 J. LEGAL STUD. S337 (2016); Foster, supra note.

[144] An especially good discussion is Al-Majjar, supra note. Also valuable is Daniel Steel, Philosophy and the Precautionary Principle (2014).

[145] *See* FRANK H. KNIGHT, RISK, UNCERTAINTY, AND PROFIT 215 (London Sch. of Econ. & Pol. Sci. 1948) (1921); Paul Davidson, *Is Probability Theory Relevant for Uncertainty?A Post-Keynesian Perspective*, 5 J. ECON. PERSPECTIVES 129, 129 **(**1991); Cass R. Sunstein, *Irreversible and Catastrophic*, 91 CORNELL L. REV. 841 (2006). For a technical treatment of the possible rationality of maximin, see Kenneth J. Arrow & Leonid Hurwicz, *An Optimality Criterion for Decision-making Under Ignorance, in* UNCERTAINTY AND EXPECTATIONS IN ECONOMICS 1 (C.F. Carter & J.L. Ford eds., 1972). For a non-technical overview, see JON ELSTER, EXPLAINING TECHNICAL CHANGE app. 1, at 185–207 (1983).

[146] PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY, *supra* note.

[147] See the discussion of maximin in JOHN RAWLS, A THEORY OF JUSTICE (1971). For complications, see Adrian Vermeule, Rationally Arbitrary Decisions, 44 J. Legal Stud. 475 (2015); ELSTER, supra note. Relevant discussion can also be found in Martin Weitzman, 5 Review of Environmental Economics and Policy 275 (2011).

[148] Though not exclusively. Some of the conceptual issues are discussed in Vermeule, supra note; Cass R. Sunstein, Worst-Case Scenarios (2008); ELSTER, supra note.

underlying danger is very low.[149] The consensus may or may not prove correct, but however important, its correctness raises no interesting conceptual questions for our purposes. At the same time, it is true that those who favor a kind of epistemic humility, even for scientific consensus, will be drawn to a precautionary approach.

It should be added that if GM foods really do create a potentially catastrophic risk, and if a sensible version of the precautionary principle is therefore triggered, GM labels are hardly an obvious response. In the abstract, they seem far too weak. Indeed, they might do no good at all On the other hand, they might be able to diminish the risk, on certain assumptions about the likely consumer response, and so might count as one reasonable step. I have raised a question about whether the science justifies invocation of precautionary thinking here, but if it does, labeling might be a justified if partial response.

A distinctive argument, ventured by Nassim Nicholas Taleb et al. in an illuminating discussion of the precautionary principle, is that genetically modified crops pose a "ruin" problem, involving a low probability of catastrophically high costs.[150] Taleb et al. contend that for such problems, it is best to take strong precautions -- in this case, placing "severe limits" on genetically modified food. The discussion is technical, but let us suppose that it is correct. If so, the question is whether genetically modified crops really do create ruin problems. Perhaps they do, but it is certainly possible to read the most recent science to suggest that they do not; if the probability of catastrophic harm is vanishingly low and essentially zero, rather than merely very low, we can fairly ask whether Taleb's argument applies.

B. Precautions and Democracy

On one view, the precautionary principle is not only or even fundamentally about irreversibility, catastrophe, and decision theory.[151] It has an insistently democratic foundation. Its goal is to assert popular control over risks that concern the public. It is about values, not facts. If members of the public are concerned about GMOs, nuclear power, or nanotechnology, then the precautionary principle provides them with a space for them to assert those concerns. It ensures democratic legitimation of the process of risk regulation.

For those who embrace the precautionary principle on this ground, efforts to speak of costs and benefits will fall on deaf ears. And for those who believe that in this domain or others, scientists are in the grip of powerful private interests, and that the "system is rigged," a precautionary approach will seem especially appealing, not least for

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[149] *See supra* note.

[150] NASSIM NICHOLAS TALEB ET AL., THE PRECAUTIONARY PRINCIPLE (WITH APPLICATION TO THE GENETIC MODIFICATION OF ORGANISMS) (2014), available at http://www.fooledbyrandomness.com/pp2.pdf.

[151] See note supra.

democratic reasons.[152] If the science is compromised and hence unreliable, it should hardly be decisive. For those who believe that popular concerns often turn out to be justified even if scientists discount them, the democratic justification for the precautionary principle might even turn out to be appealing on epistemic grounds.

No abstract argument can rule out the possibility that scientists are mistaken or that they have been compromised. It is correct to emphasize that a scientific consensus in favor of safety can be wrong[153]; the same is the case for a scientific consensus in favor of danger.[154] For those who favor the precautionary principle on democratic grounds, and believe that popular concerns about GM foods are a legitimate basis for invocation of the principle, the arguments offered here cannot be decisive. The only response is that some form of welfarism, embodied in the executive branch's self-conscious efforts to catalogue the human consequences of regulation,[155] should not be trumped by baseless fear – and that cost-benefit analysis, understood as a form of applied welfarism,[156] should not be abandoned merely because people are needlessly worried.

V. Conclusion

My goals in this Essay have been twofold. First, I have attempted to make progress in understanding the distinctive challenges, both conceptual and empirical, that agencies face in cataloguing the costs and (especially) the benefits of mandatory labels, and in demonstrating that the benefits of such labels justify the costs. Second, I have tried to show that those challenges are especially acute in the context of labels for GM foods.

In the abstract, the argument for labeling GM food seems appealing, perhaps even irresistible. Many people are concerned about what they see as the associated risks; it might appear obvious that they should have a right to know what they are eating. Partly in response to these claims, there has been a growing movement in favor of mandatory labeling; the movement has now resulted in federal legislation. That legislation requires implementing regulations from the USDA, and hence some kind of cost-benefit analysis.

I have suggested that it will not be easy for the USDA to show that the benefits of GM labels justify the costs. To the extent that the health risks are nonexistent, and the environmental risks are highly speculative, the benefits might fail to support regulatory action, even if the costs are relatively low. To be sure, consumers do appear to support labeling, at least in surveys. But in their actual behavior, most consumers do not show much evidence that they care, as reflected in the fact that the countless foods without a

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[152] As one commentator noted in response to an argument against mandatory labels: "So God is wrong and Monsanto is right?"

[153] See note supra for many examples.

[154] Alan Mazur, True Warnings and False Alarms: "Evaluating Fears about the Health Risks of Technology, 1948-1971 (2004).

[155] See Adler, supra note.

[156] See Matthew Adler and Eric A. Posner, New Foundations for Cost-Benefit Analysis (2006); Sunstein, Valuing Life, supra note.

"GM free" label have not exactly been losing market shares. Moreover, consumer concerns about GM foods appear to be rooted in some combination of baseless fears of health risks and generalized disgust—hardly a sufficient basis for mandatory labels. There is also a risk that GM labels will, for a significant part of the population, end up producing a misleading signal, to the effect that the government believes that GM foods impose significant health risks.

Some regulatory initiatives are justified as precautions in the face of either risk or uncertainty. There are good reasons to consider regulation of products that impose a small risk of imposing irreversible or catastrophic harm, and if the risk cannot be quantified, it might make sense to eliminate the worst-case scenarios.[157] On one view of the science, precautions are justified against GM food, because of the environmental risks, and those precautions might include labels (and possibly more). The best response is that the scientific consensus does not justify that conclusion. So long as the consensus is as it is, the argument for a precautionary approach is difficult to defend—at least if GM food promises significant benefits.[158]

In these circumstances, USDA will face difficulty in demonstrating that the benefits of implementing regulations justify their costs. To be sure, the law requires labels, and hence the inability to make such a demonstration will not prevent implementing regulations from being issued. But within the executive branch, there will be a substantial effort to explore costs and benefits, and to show, if at all possible, that the benefits provide a sufficient justification. USDA's best (or least bad) option may be emphasize that the costs are quite low[159] and to use breakeven analysis, either invoking consumers' desire to have labels or pointing to the existence of potentially serious or even catastrophic environmental risks that cannot be ruled out of bounds. If the per-person cost is very low – say, $2 per year – then a breakeven analysis would not be implausible.

My focus throughout has been on mandatory labels for GM foods, but my real topic has been far broader. In numerous contexts, Congress requires or authorizes federal agencies to impose disclosure requirements.[160] In all those contests, executive agencies are required, by executive order, to set out the benefits and costs of disclosure

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[157] *See* Elster, *supra* note.

[158] For various views, *see, e.g.*, Graham Brookes & Peter Barfoot, *GM Crops: The Global Economic and Environmental Impact—The First Nine Years 1996–2004*, 8 AGBIOFORUM 187 (2005); K.H. Engel et al., *Current and Future Benefits from the Use of GM Technology in Food Production*, 127 TOXICOLOGY LETTERS 329 (2002); Randall Lutter & Katherine Tucker, *Unacknowledged Health Benefits of Genetically Modified Food: Salmon and Heart Disease Deaths*, 5 AGBIOFORUM 59 (2002).

[159] See note supra, suggesting that this is possible in light of the flexibility that the law affords to companies.

[160] For a detailed catalogue and a highly skeptical account, see OMNI BEN-SHAHAR & CARL SCHNEIDER, MORE THAN YOU WANTED TO KNOW: THE FAILURE OF MANDATED DISCLOSURE (2014).

requirements, and to demonstrate that the benefits justify the costs.[161] As we have seen, agencies face persistent challenges in projecting benefits, and they use four different approaches, including a refusal to do so on the ground that quantification is not feasible[162]; breakeven analysis[163]; projection of end-states, such as economic savings or health outcomes[164]; and estimates of willingness to pay for the relevant information.[165]

Each of these approaches raises serious questions and runs into strong objections. In principle, the right question involves willingness to pay[166]; but in practice, agencies face formidable problems in trying to answer that question. If answers are unavailable, a breakeven analysis is the very least that should be required, and it is sometimes the most that agencies can do. If it is accompanied by some account of potential outcomes, acknowledging uncertainties, a breakeven analysis will often show that mandatory disclosure is likely to be justified on welfare grounds – and often likely to show that it is not.

[161] Note that current executive orders do not apply to the so-called "independent" agencies, though they sometimes produce cost-benefit analyses under statutory compulsion or on their own. *Business Roundtable v. SEC*, 647 F3d 1144 (DC Cir 2011). Recall once more that whenever the law requires agencies to proceed, they must do so even if benefits do not justify costs; the requirements in relevant executive orders are imposed "to the extent permitted by law."
[162] See note supra.
[163] See note supra.
[164] See note supra.
[165] See note supra.
[166] Subject to the qualifications in note supra.