

BEFORE THE FOOD AND DRUG ADMINISTRATION

In the Matter of)
Food Labeling: Nutrition Labeling of Standard Menu)
Items in Restaurants and Similar Retail Food) **Docket No. FDA-F-0172**
Establishments: Extension of Compliance Date;)
Request for Comments)

COMMENTS OF DR. MARK COOPER

**THE DELAY OF MENU LABELING FOR STANDARD MEALS
FAILS THE COST-BENEFIT TEST**

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I. INTRODUCTION¹

A. PURPOSE AND SUMMARY OF FINDINGS

The 2010 Patient Protection and Affordable Care Act (“ACA”) required the FDA to promulgate a nutrition labeling rule.² On December 1, 2014, the Food and Drug Administration (FDA) issued a final rule requiring Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, with an initial compliance date of December 1, 2015.³ On July 10, 2015, the compliance date for the final rule was extended to December 1, 2016. Due to an appropriations measure, the compliance date was thereafter extended to May 5, 2017. On May 4, 2017—one day before the Final Rule was to go into effect—the FDA announced that it was planning to delay the compliance date for the Rule.

FDA later published, on July 3, 2017, an Interim Final Rule proposing an extension of the compliance date, until May 7, 2018. In its Interim Final Rule (IFR), FDA indicates that a primary reason for the extension is to provide flexibility for businesses, but the decision to delay the compliance date was made without new evidence being cited or new comment being taken.

Upon review of the data, this paper concludes that the Interim Final Rule’s extension of the compliance date is irrational from an economic point of view.

Economic analysis and a review of the evidence in the regulatory record demonstrate that the rule should not have been delayed, and any recourse to economic arguments for such delay are spurious. Indeed, while the final rule adopted previously by FDA demonstrated high net benefits in the range of \$8 billion dollars over 20 years,⁴ the delay does damage to these laudable results. Even FDA’s flawed analysis makes clear that the (IFR) reduces the benefits enjoyed by the public by two dollars for every one dollar that it purportedly saves businesses. Furthermore, this analysis shows that applying a more realistic set of assumptions than did FDA about benefits and costs indicate that the IFR will reduce the public benefits by fifteen dollars for every dollar that it saves businesses.

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²Pub. L. No. 111-148, § 4205, 124 Stat. 119, 573-576 (2010) (codified in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(q)(5) (H)).

³ Food and Drug Administration, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments: Extension of Compliance Date; Request for Comments, *Fed Reg.* 82, 85, 20825, May 4, 2017 (hereafter, “Extension of Compliance Order”) and the supporting Interim Final Regulatory Impact Analysis, April 2017, p. 20827, describes this history.

⁴ Food and Drug Administration, “Final Regulatory Impact Analysis,” Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, FDA – 2011-F-0172, November 2014, pp. 9-1, (hereafter, Final Label Regulatory Impact Analysis)

It is demonstrably the case that the delay imposes costs, rather than delivering benefits to the public, as shown in Section II. Covered establishments that were on the verge of compliance have likely spent 85% of the initial costs of labeling already, and would save only on recurring costs (around 15% of total costs).

Moreover, the vast majority of the top restaurant, supermarket, and convenience store chains already are labeling calories. A survey by the non-profit Center for Science in the Public Interest (CSPI) found that all of the top 50 restaurants had calorie information already.⁵ If the rule is substantively changed subsequent to the IFR notice-and-comment period, the cost to industry will only increase. Covered establishments would need to redesign their menus, menu boards and signs (which the FDA estimated to cost \$250 million), retrain staff (costing \$30 mil), and reconduct legal reviews (estimated at \$1.64 mil).⁶

At the same time, as shown in Section III, benefits to the public will be reduced by additional delay in enforcement, or by any weakening of the rule. Weakening the rule would almost certainly reduce benefits by billions of dollars, although the exact magnitude of the harm imposed on the public will be determined by the extent of the changes.

As discussed below, this analysis indicates that the decision to reopen the final rule to consider whether to diminish its scope is misguided. Relaxation of the rule was already examined fully on this record by FDA—and rejected because the agency found that a reduction in coverage lowers the net benefit for consumers. There have been no relevant changes in the marketplace that could support a decision by FDA to narrow the rule’s scope. If anything, the evidence developed since that decision was made shows that the coverage should be expanded, not reduced.

B. OUTLINE

This report is divided into two Sections:

Section II briefly reviews the key principles of benefit-cost analysis and the design of policies in force under existing executive orders and applies them to the decision to delay enforcement of menu labels. It shows that the delay fails the benefit cost test.

Section III deals with the broader review of the benefit and cost assumptions of the final rule. It concludes that the rule was justified based on the record and scientific knowledge available at the time.

Section IV presents a brief review of the literature since the rule was adopted concludes that the evidence in support of menu labels has become much stronger and that identified weaknesses in the earlier research have been addressed by subsequent research.

⁵ Center for Science in the Public Interest. Supplemental Comment on Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments; Docket No. FDA–2011–F–0172. August 2, 2017., Examples of the labels can be found at <https://www.pinterest.com/cspinutrition/menu-labeling/>

⁶ Final Label Regulatory Impact Analysis, pp. 100-103.

II. BENEFIT-COST ANALYSIS OF DELAY

There has been a long and intense debate about the use and value of benefit-cost analysis in the context of regulatory impact assessment.⁷ In this paper I side-step such controversies because the proposed delay and reopening of the decision to require menu labeling do not withstand scrutiny when FDA's own standards are applied. The IFR fails on its own terms.

A. THE LEGAL MANDATE AND REGULATORY CONTEXT FOR EVALUATING FDA'S IFR

The Congress explicitly mandated the implementation of a labeling program for standard menu items in restaurants and other similar establishments. The IFR recognizes that this mandate falls under the guidance of the Executive Orders in force, including E.O. 12866 (Clinton) and 13563 (Obama) which "direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select approaches that 'maximize net benefits (including potential economic, environmental, public health and safety, and other advantage; distributive impact; and equity.'"⁸ Appendix A shows that these two orders can trace their lineage back to Ronald Reagan's Executive Order (12291), which established the framework for this type of analysis.

The essential elements of the analytic framework that span almost four decades include an extensive and comprehensive number of elements. The specific mandates in the law are paramount, but the agency is required to adopt specific approaches in exercising its discretion in writing rules. The framework declares the goal to be promoting the public interest and maximizing net benefits, including both benefits and costs that can be measured quantitatively and those that must be addressed qualitatively. Alternatives are to be considered only in furtherance of those overarching goals.

I have argued elsewhere, that this legal framework is consistent with traditional economic analysis,⁹ and I have shown that there are numerous questions and concerns that can be raised about this analytic structure.¹⁰ This paper takes as a given that FDA performed such an analysis to judge the impact of the rule as required by Executive Order.

⁷ General critiques can be found in Hiezlerling and Ackerman, 2002; Shapiro and Schroeder, 2008; Rose-Ackerman, Susan, 2011, Sinden, 2014, 2016; I have offered a broad framework for mapping the terrain of knowledge in which complex ambiguity constraints the use of quantitative and statistical methods (offered Cooper, 2017a, Chapters 10, 11). As shown in Appendix B, the benefit-cost approach is suited for only one region (quadrant) of knowledge, where the nature of outcomes and their probabilities are known. The other three regions, vagueness, uncertainty and the unknowns require different analytic methods and approaches to policy.

⁸ Extension of Compliance Order, p. 2028.

⁹ See Cooper, Mark, 2014, Cooper Mark, 2016, Cooper, Mark, 2017b; Cooper, Mark, 2017c

¹⁰ Beyond the general critique, (see Cooper, 2017a, Chapters 3, 10, 11), introducing the consideration of qualitative factors, as the Executive Orders do, poses a basic challenge benefit-cost analysis, but there are additional challenges, as shown in Appendix B. Even within the quantifiable approach, there are challenges stemming from the maximization principle chosen. The Executive Order favor net benefits, but statutes frequently adopt other principles. There are also outcomes that challenge the basic paradigm. Intergenerational consideration raise questions about the discount rate, which is one of the cornerstones of benefit-cost analysis. Incommensurable outcomes require entirely different approaches to the analysis.

B. EVALUATION OF FDA’S INTERIM FINAL RULE TO DELAY THE NUTRITION LABELING OF STANDARD MENU ITEMS

Costs of the Extension Exceed Benefits by a Wide Margin and Diminish Net Benefits

The analysis of the delay contained in the IFR shows that the delay fails to meet the operative standard of cost benefit analysis discussed above for two reasons.

First, without conducting any additional analysis of the record, FDA proposed a one-year delay in implementation of a rule with an extensive evidentiary record that shows a strongly positive benefit-cost ratio and large net benefits, as discussed in Section III. FDA’s own analysis demonstrates that delay is costly and unwarranted. Under all sets of assumptions that FDA considered (showing the magnitude of the benefits and costs and several discount rates), the cost of the delay (defined as foregone benefits) exceeds the benefits of the rule (defined as cost savings for businesses) by more than two-to-one.

Second, a closer examination of FDA’s IFR reveals that it fails to meet the basic standards of benefit-cost analysis in ways that were not identified in the record. In preparing for the final rule and prior extensions, FDA studied compliance costs and timelines in detail. Then, via the IFR, the agency granted a delay to afford affected chain food establishments more time to prepare to comply. Oddly, FDA’s Regulatory Impact Analysis (RIA) for the delay in the IFR assumes that half of covered establishments had made no effort to comply with the final rule that had been published for more than two years (December 1, 2014) and was within one day of going into effect. Assuming that 50 percent of covered establishments would be in violation of the law at such a late hour for compliance, in the absence of any evidence of such, is not a reasonable assumption.

A more reasonable assumption would be that the virtually all covered establishments had taken most steps to comply with the final rule. Such an assumption—that covered establishments were going to comply—yields a very different economic analysis than the RIA for the IFR provides. This assumption would be far more consistent with FDA’s own prior assumptions. In FDA’s compliance cost analysis for its December 2015 final rule, the agency determined that over 85% of the cost of compliance would be sunk costs long before the rule went into force.¹¹ The analysis for the final rule also assumes that slightly less than 15% of the costs were assumed to be recurring.

The vast majority of the top restaurant, supermarket, and convenience store chains already are labeling calories. In a recent scan of the top 50 restaurant chains in 2016 (by revenue according to National Restaurant News), CSPI found that **all 50** provided calorie information either online (*e.g.*, posted per menu item, provided in PDF or other format, or via an online nutrition calculator) or in the restaurant.¹² Numerous examples can be found from covered establishments, including supermarkets and convenience stores that are complying with the menu

¹¹ Final Label Regulatory Impact Analysis, pp. 100-103.

¹² Center for Science in the Public Interest, 2017.

labeling regulations as finalized, showing that posting calories as currently required is both feasible and already widely prevalent.¹³

Therefore, any reasonable and consistent analysis must assume that covered establishments were on the verge of compliance and that they will have spent 85% of the initial costs of labeling already. They will only save the recurring costs, which are around 15% of the total costs. Thus, the delay only “saves” covered establishments a small fraction of the amount FDA assumes. Table 1 shows the re-analyzed impact of the delay under two sets of assumptions.

TABLE 1: THE NEGATIVE BENEFIT-COST IMPACT OF DELAYING NUTRITION LABELING OF STANDARD MENU ITEMS (IN MILLION \$)

<u>Interim Delay</u>	FDA	With full Sunk Costs
Savings from delay	+4	+0.6
Lost benefit of delay	-9.0	-9.0
Net cost	-5	-8.4
Benefit Cost Ratio	-2.25	-15

Sources: See text for the discussion of the derivation of these results.

In the short term, the FDA’s analysis claims that the savings (benefits, applying FDA’s 3% discount rate) due to delay will be \$4 million.¹⁴ This is likely incorrect: instead, given the above discussion of sunk costs, we assume that only 15% of the costs of labeling, which are recurring, may be saved (\$0.6 million). The cost of delay one-year (benefits that will be foregone), remain the same. Therefore, the real cost to consumers of the delay in the IFR remains \$9 million, which is 15 times the benefits to industry.

Additional Future Costs

Not only will the disruption caused by the delay impose immediate costs that are much larger than the benefits of the decision, but if the stated purpose of the review is to change the rule, then much larger costs and a much larger reduction in net benefits will be imposed on the public as a result of delay. The magnitude of these net costs to the public would be determined

¹³ Center for Science in the Public Interest, 2017.

¹⁴ The Interim Final Rule Regulatory Impact Analysis (p. 19) assumes that half the covered establishments are already complying, therefore assuming half the costs of compliance can be saved. However, it recognizes that a higher percentage might be complying (p. 19). “Thus, annualized benefits at 3 percent are an estimated \$4 million: the reduction in total cost between the menu labeling final rule with the published compliance date and the menu labeling final rule with a May 7, 2018, compliance date (\$4 million=\$74 million - \$70 million). To the extent that more than 50 percent of covered establishments have already incurred start-up costs, these benefits are overestimated because firms have not delayed costs. At the limit, for illustration, if 100 percent of covered establishments have already incurred costs of compliance, the estimated cost savings of this interim final rule would be small, possibly zero, because we would expect most or all complying covered establishments to continue to obtain calorie information for newly introduced menu items and add it to menus in anticipation of the new compliance date.” In this analysis, we accept the assumption that half the establishments are complying, but argue that the remainder have already incurred the fixed cost. Therefore, \$3.4 billion has been sunk (.85 * \$4), so the savings is only \$0.6 billion (\$4.0 - \$3.4).

by the rule that is adopted. A decision to change the rule would impose two changes that would reduce the net benefit.

First, to the extent that the rule is changed and requires new compliance effort from covered establishments, sunk costs would be wasted and new costs would have to be incurred. Because most costs are demonstrably already sunk, if the rule is substantively changed, the cost to industry will substantially increase. Covered establishments would have to redesign their menu, menu boards and signs (which the FDA estimated to cost \$250 million), retrain their staff (\$30 million), and conduct a legal review once again (\$1.64 million).¹⁵ Changing the rule significantly will render most of these sunk costs wasted and they would have to be incurred again to comply with a different rule.

Second, there is likely to be additional delay in implementing the rule, further delaying and, therefore diminishing, the flow of benefits. Assuming it takes a year to write a new rule and a year to implement it, a significant part of the sunk costs will be permanently lost and as much as \$280 million in additional costs will be imposed, while benefits will be further reduced.

Enforcement and Flexibility

Since the discussion of delay is driven by concerns about the burdens on businesses to comply and it raises the issue of enforcement, a brief discussion of the enforcement mechanism in the Final Rule is necessary. A further delay in implementing the rule is unjustified for several reasons.

First, as noted above, the implementation of the rule had already been delayed; it has been seven years since Congress passed the national menu labeling policy. Implementation of menu labeling had been delayed from December 1, 2015 to December 1, 2016, and then to May 5, 2017, due to lobbying from supermarkets, convenience stores, and Domino's Pizza. The delay notice was published in the Federal Register just one day before the Final Rule was to go into effect. The only way covered establishments might not be ready is if they had no intention of complying with the regulation.

Second, covered establishments were given flexibility in determining how to comply. They have control over the preparation of the analysis of their standardized menus and menu items. They have flexibility in the form in which information is presented—electronic, menu, menu board, and signs—and how it will be presented, as long as it is in close proximity to the point at which the consumer choice is made.

Third, FDA offers support to promote compliance with assistance and education. Enforcement actions will be on a case-by-case basis, allowing for flexibility to comply and not issuing fines.¹⁶

¹⁵ Final Label Regulatory Impact Analysis, Section II.

¹⁶ https://www.washingtonpost.com/lifestyle/food/pizza-chains-are-making-a-desperate-push-to-avoid-posting-calories-on-menus/2017/04/06/080a8d5e-18b0-11e7-bcc2-7d1a0973e7b2_story.html?utm_term=.8bdc32ab8519

III. EVALUATION OF FDA’S DECISION TO REVIEW THE NUTRITION LABELING OF STANDARD MENU ITEMS

In the previous section, I examined the incremental decision to delay enforcement and concluded that is not supported by either FDA’s or a corrected benefit-cost analysis. In this section, I examine the second issue raised by the Notice, the justification for adopting the rule in the first place.

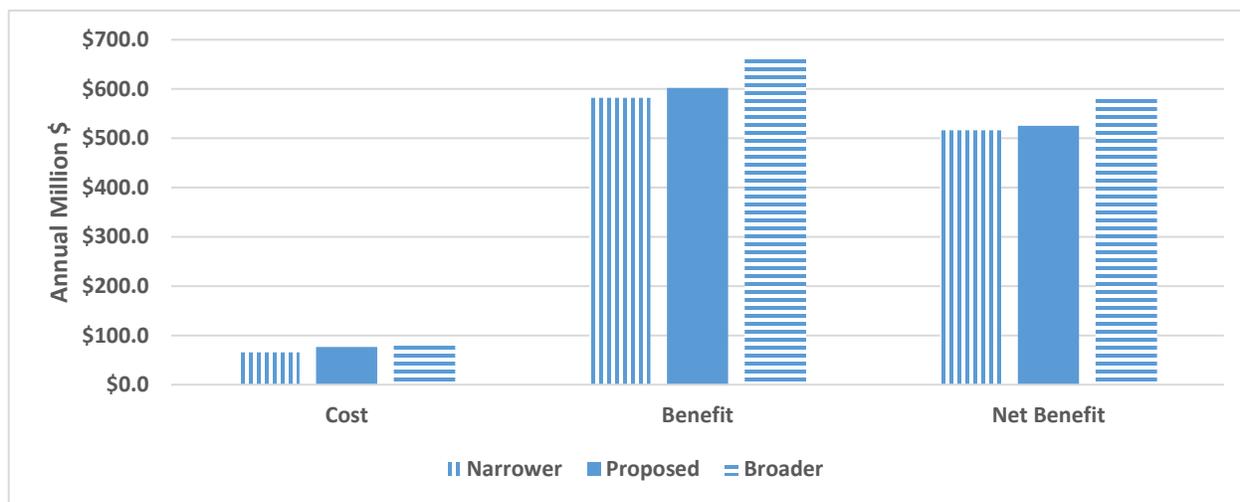
The two issues overlap in the sense that the delay and reopening of the underlying decision are both based on a faulty reading of the record. The record supports the adoption of the rule. The justifications offered for reopening are insufficient. Above all, the complaints of the covered entities were considered by FDA and properly rejected. They were certainly insufficient to override the clear intent of Congress to require the rule.

A. SUPPORT IN THE RECORD: THE POSITIVE BENEFIT-COST OF THE FINAL RULE

Benefits Far Exceed Costs and Broader Coverage Increases Net Benefits

The negative benefit-cost impact of the delay stands in sharp contrast to the positive benefit-cost impact of the Final Rule. The FDA’s analysis of the original Final Rule showed that the benefits are over seven times the cost. Moreover, as shown in Figure 1, although the interim notice seeks review of the Final Rule, the FDA had considered alternatives in the rulemaking. Beyond considering the timing of enforcement, which was discussed above, they considered greater and lesser coverage of the labeling standard.

FIGURE 1: BENEFITS AND COSTS OF NARROWER AND BROADER RULES



Source: Food and Drug Administration, “Final Regulatory Impact Analysis,” Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, FDA – 2011-F-0172, November 2014, pp. 100-103.

The FDA analyses suggested that, if anything, the rule should have been broader, not narrower. The broader the coverage, the higher the net benefit. While there is certainly a declining marginal return to expanding the coverage of the rule, the benefit-cost ratio remains

strongly positive, so its net benefits increase.¹⁷ The graph makes clear that the evidence supporting the benefits of expansion of the scope of the rule is much stronger than is evidence for narrowing its scope.

Market Imperfections Creating the Need for the Rule

The Final Regulatory Impact Analysis on which the rule was based identifies the market failures addressed by the rule as follows:¹⁸

- Endemic factors including inadequate information available to consumers at the point of decision making.
- Transaction costs where collecting information is costly and time consuming.
- Behavioral factors including bounded rationality influenced by suboptimal discounting of future benefits, private demand differing from the socially optimal demand reflecting time-inconsistent preferences, present-biased preferences, visceral factors, lack of self-control.
- Market structural factors including supply-side driven environmental factors like salience and cues and the hidden nature of nutrition content exploited by sellers to increase profits that may drive poor decisions.

The list of potential market imperfections could be readily expanded,¹⁹ but the agency has identified a more than adequate set to justify the adoption of the rule. The presence of these market imperfections strongly supports the FDA's original final rule.

B. UNDERESTIMATED BENEFITS

FDA based its conclusion on very cautious assumptions about the impact of the rule. In addition to the very cautious assumptions made by the FDA in its detailed analysis of costs and benefits, we believe that the FDA underestimated the magnitude of the benefits.

Willingness-to-Pay

The cornerstone of the analysis is based on a willingness-to-pay study of the benefits of nutrition information on menus. Willingness-to-pay studies have been extensively criticized for underestimating the value of public policies that correct market imperfections (see Table 2). The willingness-to-pay observed in survey analysis and derived as implicit through econometric analysis reflects opinions and decisions offered or made by individuals in the context of all the

¹⁷ When the benefit-cost goal is the maximization of net benefits, standards will generally be set at the point where the marginal benefit of a tighter standard just equals the marginal cost. The next step will not be taken where the marginal benefit are less than the marginal costs, since this will lower net benefits. There are instances, however, where the goal is the maximization of a specific outcome at no net cost to society, in which case the rule could set at the point where total benefit equals total cost. An even more rigorous standard could set at the maximum that all technologies could deliver. Here a precautionary principle would justify incurring net costs to achieve higher levels. See Appendix B.

¹⁸ Final Label Regulatory Impact Analysis, pp. 11-13.

¹⁹ Cooper, 2017a, Appendices II and III present comprehensive reviews of several literatures with respect to market imperfections and failures.

imperfections that afflict the market.²⁰ They reflect the market structure the policy is intended to correct more than the “true” value of correction.

TABLE 2: QUESTIONS ABOUT THE CONCEPT OF WILLINGNESS-TO-PAY

<u>Conceptual Problems</u>	<u>Methodological Problems</u>
<p>Individual</p> <ul style="list-style-type: none"> Lack of (sufficient & appropriate) information Willingness v. Capacity to pay Inherent discrimination (value) Risk aversion Marginal v. average Respondent Characteristics <ul style="list-style-type: none"> SES Experience v. Hypothetical <p>Market Structure</p> <ul style="list-style-type: none"> Information asymmetries Availability in market Aggregation of preferences Lack of competition <p>Externalities</p> <ul style="list-style-type: none"> Positive effects Importance of public (social) value 	<ul style="list-style-type: none"> Internal and External validity <ul style="list-style-type: none"> Representativeness Variability Generalization Surveys <ul style="list-style-type: none"> Questions <ul style="list-style-type: none"> Order & presentation of Open v. Closed Provision of information <ul style="list-style-type: none"> Response sets Choice Set Emphasis on costs, not benefits

4Sources: Mark Sagoff, What does willingness to pay measure? University of Maryland; Frank Ackerman, 2008 *Critique of Cost-Benefit Analysis, and Alternative Approaches to Decision-Making*, Report to Friends of the Earth England, Wales and Northern Ireland; Amy, Sinden, 2014, Cost-Benefit Analysis, Ben Franklin, and the Supreme Court, *UC Irvine Law Review*, 4 (4); Crespi, Gregory Scott, 2013, Correcting For the Wealth Bias Of Cost-Benefit Analysis Through Use of "Percentage of Wealth"-Based Valuations," *Creighton Law Review*, 46, Gregory S. Crespi, 2009, *A Brief Reflection on the Problem of Person-Altering Consequences*, 2 J. APP. ECON. 13; Joaquin F. Mould Quevedo, et al., "The Willingness-to-Pay Concept in Question," *Rev. Saude Publica*: 43(2), for health care; Benjamin Leard, et al., 2017, Tisdell, Clem, 2008, "Contingent valuation as a dynamic process," *The Journal of Socio-Economics*, 37. Breffle, William S., et al. 2015, "Understanding how income influences willingness to pay for joint programs: A more equitable value measure for the less wealthy," *Ecological Economics*, 109.

FDA notes that “willingness-to-pay estimates for mechanisms that shift consumers toward healthier diet based on revealed preference data reflect... parameters of a consumer’s utility function, such as age and cultural norms, may not fully reflect their underlying preferences because of time-inconsistent behavior, problems of self-control, addiction, or poor information.”²¹ The author of the main study on which FDA relies notes that the “disparity” between a normative benchmark based on expert opinion” reflect “many possible explanations ranging from incomplete understanding... to the distrust of expert information, time inconsistency, and other contextual and framing effects.”²²

²⁰ Tisdell, 2008, notes the dynamic nature of willingness to pay, which particularly affects policies intending to change perceptions and behaviors. Crespi, 2009, raises similar fundamental issues. Breffle, 2015, and Crespi, 2013, note the problem of differences in valuation across income groups.

²¹ Final Label Regulatory Impact Analysis, p. 65. This short list of consumer “biases” does not do justice to the full array of behavioral factors that call willingness to pay studies into question. Hilbert, 2012, notes that a basic text (Baron, 2007), lists 53.

²² Abaluck, 2011, p. 36, for example, Breffle, et al., 2015, notes the problem of difference willingness to pay across income groups.

The problems with willingness-to-pay analysis are not limited to survey (contingent valuation) based studies. They also apply to econometric studies that base their estimates on econometrically identified implicit willingness-to-pay. Table 2 identifies the problems with willingness-to-pay studies identified in the literature.

As shown in Figure 2, the FDA's analysis based on a willingness-to-pay approach yields a higher benefit-cost ratio than several other approaches the FDA considered, but did not use. Most importantly, the benefit-cost ratio is substantially greater than one for all three approaches to estimating benefits (proposed, morbidity, existing data). Moreover, a more recent study in Health Affairs²³ examined the benefits of reducing childhood obesity through labeling based on expert estimations of benefits. FDA scaled up the estimates to cover the entire population. The fact that the Harvard study found much larger benefits for children suggests an even higher benefit-cost ratio than the FDA found with its willingness-to-pay approach.²⁴

As a general proposition, the supply-side does not play a large role in willingness-to-pay studies in the health policy space. For example, as one critique of willingness-to-pay studies in healthcare put it,

[M]ost of these investigations still do not differentiate the economic factors that might be distorting the market, centering the investigation on a hypothetical aggregate demand when whoever defines the price and amount offered of a particular medication or medial intervention in the health sector generally comes from the supply-side.

An instructive example can be found in a study of Medicare Part D drug purchase decisions by the same author whose willingness-to-pay estimate was used by FDA to calculate the benefit cost characteristics of menu labeling.²⁵ His results show that the supply-side is much more important in determining foregone welfare than the demand side. Consumers are not very good decision makers and sellers exploit them by constraining choices and raising prices.

Overestimated Costs

It further appears that the cost estimates might be overstated. The regulated establishments have had a long time to prepare for the Final Rule and a lot has changed in the landscape since the initial cost estimate was formulated.

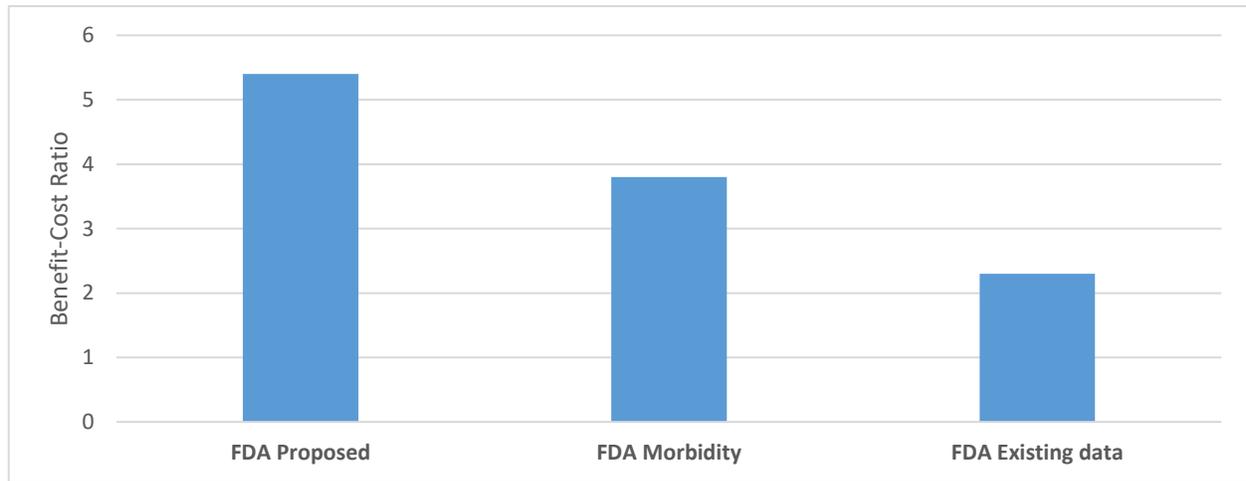
²³ <http://content.healthaffairs.org/content/34/11/1932.full?ijkey=lnFXpx4AIM506&keytype=ref&siteid=healthaff>, <http://content.healthaffairs.org/content/34/11/1932/T2.expansion.html>

²⁴ Gortmaker, et al., 2015, The study involved only children (less one fifth the total in the FDA analysis), assumed a treatment effect that was one-fifth of a study it cited (almost one-tenth the willingness-to-pay effect used by FDA), and included only 10 years. Scaling the results to the FDA parameter, discounting a second 10 years, and deflating yields an estimate of benefits from a menu labeling program that is just under 40% higher than the FDA evaluation.

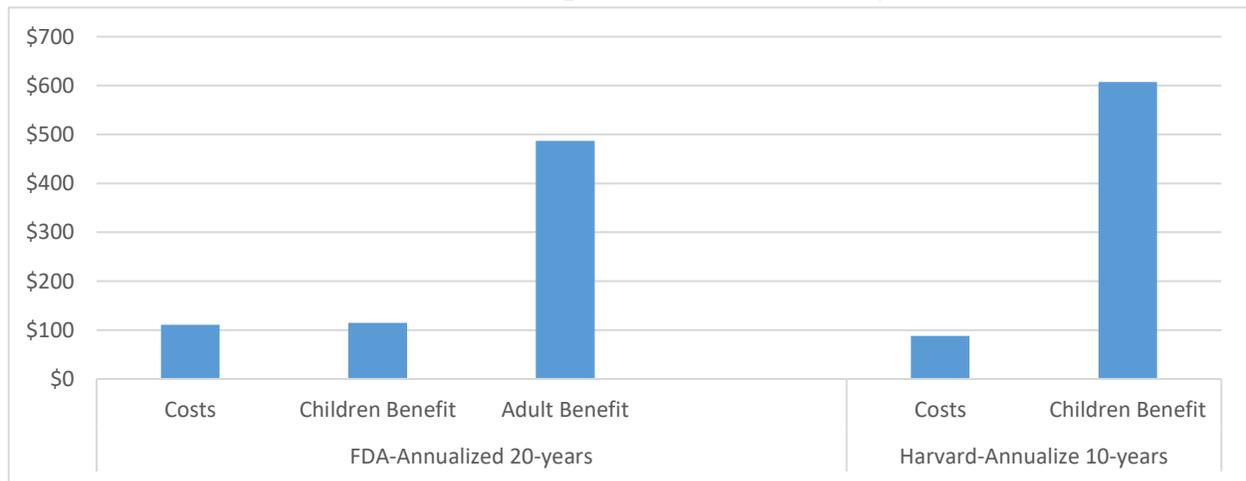
²⁵ Abaluck, 2015.

FIGURE 2: BENEFIT COST RATIOS OF MENU LABELING

FDA, Alternative Measures of Benefits



Estimated Benefits and Costs: FDA Compared to Harvard Study of Interventions



Source: Food and Drug Administration, “Final Regulatory Impact Analysis,” *Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments*, FDA – 2011-F-0172, November 2014, Proposed, p. 10, Existing Data, p. 87, Morbidity, p. 92; Steven L. Gortmaker, *et al.*, 2015, “Cost Effectiveness of Childhood Obesity Interventions Evidence and Methods for Choices, *Am J Prev Med*, 49(1).

In its RIA for the Final Regulations, the FDA relied on a 2004 assessment of which restaurant chains had nutrition information. Since 2004, more than 20 states and localities have passed menu labeling policies, with about a dozen of those policies implemented.²⁶ Most national chain restaurants have an outlet in one of those jurisdictions, and thus likely already have nutrition information.

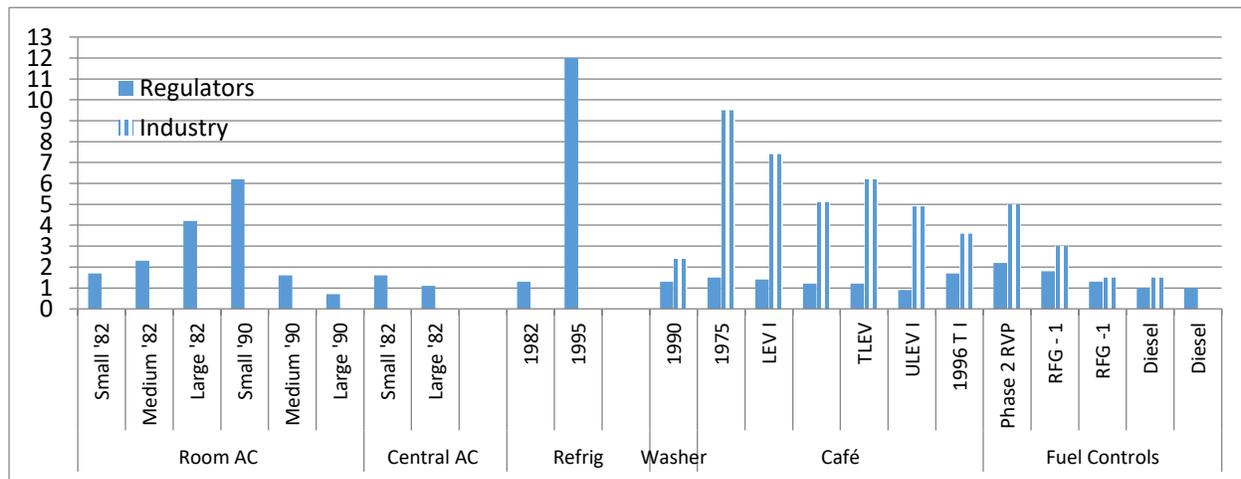
Importantly, while the goal is precisely defined—provision of accurate nutritional information on the menu at the point of choosing the meal—the processes by which the covered

²⁶ Center for Science in the Public Interest. *State and Local Menu Labeling Policies*. Accessed at < <https://cspinet.org/resource/state-and-menu-labeling-policies>>.

establishment achieve that goal is not fixed. Covered establishments have the flexibility to do so in a manner that minimizes their costs, for example by menu analysis software (which the FDA estimated would cost \$280 per item; though even that cost is high given that many chains have registered dietitians on staff and already own food analysis software²⁷) rather than by laboratory analysis (estimated at \$1,030 per item).

Often, compliance costs are much lower than agencies project—averaging about half of the initial projection. Figure 3 shows the systematic overestimation by regulators of the cost of efficiency improving regulations in consumer durables.

FIGURE 3: THE PROJECTED COSTS OF REGULATION EXCEED THE ACTUAL COSTS: RATIO OF ESTIMATED COST TO ACTUAL COST BY SOURCE



Sources: Winston Harrington, Richard Morgenstern and Peter Nelson, “On the Accuracy of Regulatory Cost Estimates,” *Journal of Policy Analysis and Management* 19(2) 2000, *How Accurate Are Regulatory Costs Estimates?*, Resources for the Future, March 5, 2010; ; Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation: A Review of Reviews*, Resources for the Future, 2006; Roland Hwang and Matt Peak, *Innovation and Regulation in the Automobile Sector: Lessons Learned and Implications for California’s CO₂ Standard*, Natural Resources Defense Council, April 2006; Larry Dale, et al., “Retrospective Evaluation of Appliance Price Trends,” *Energy Policy* 37, 2009.

The cost for household appliance regulations was overestimated by over 100% and the costs for automobiles were overestimated by about 50%. Estimates of the cost from industry were even farther off the mark, running three times higher for auto technologies.²⁸ Broader studies of the cost of environmental regulation find a similar phenomenon, with overestimates of cost outnumbering underestimates by almost five-to-one, with industry numbers being a “serious overestimate.”²⁹

²⁷ Center for Science in the Public Interest, 2012, *Informed Eating: Calorie Labeling for Ready-to-Eat Food at Supermarkets and Convenience Stores*. CSPI: Washington, DC.

²⁸ Roland Hwang and Matt Peak, 2006, *Innovation and Regulation in the Automobile Sector: Lessons Learned and Implications for California’s CO₂ Standard*, Natural Resources Defense Council, April.

²⁹ Winston Harrington, 2006, *Grading Estimates of the Benefits and Costs of Federal Regulation: A Review of Reviews*, Resources for the Future, 2006; p. 3.

IV. STRONG AND INCREASING SUPPORT FOR THE RULE IN THE LITERATURE

Since the extensive literature review underlying the rule was completed in 2011 and subsequent considerations dealt with delays in implementation, I focus herein on research findings that have come to light since 2011.

The record evidence in 2011 was adequate to support the rule. In an important sense, the record was positive. Few, if any studies showed that a policy of menu labeling would have a “negative” effect, and virtually every study found a positive effect of providing information, although such findings did not always rise to the level of statistical significance. As one review of 25 studies put it, “no interventions reported an average negative impact on outcomes.”³⁰ The finding of positive, but not significant effects raises the question of research design. Sample sizes were frequently small with low response rates and some studies recognized these limitations.³¹ Models were under-specified in the sense that they did not include important covariates that might be masking or dampening the effect of policy.

In this section, I briefly review the literature on the effectiveness of labeling from three perspectives – an overview of systematic reviews, the recognition of the complexity of the process of influencing consumer nutrition choices at the point of sale, and the importance of the supply-side.

A. SYSTEMATIC COMPARATIVE REVIEWS

The evidence available at the time of the issuance of the rule was more than adequate to support it. Still, in response to the early mixed findings, a great deal of effort was expended to improve the quality of research. The evidence in the academic literature has become stronger since 2011.

The outcome is a vast improvement compared to the earlier review, which described the effects of Menu Labelling as “small but meaningful...”

Overall, the apparent impact of menu labelling on consumers food choices is progressively becoming more positive and more consistent.

The number and quality of findings that support the impact of information has grown in size and quality relative to those that do not find statistically significant support for the rule....

When paralleling these results with those from the literature review conducted in 2012, using the same methodology, the most notable and progressive shift is in the increased proportion of overall positive results with a corresponding reduction in positive results which only applied to some sub-groups.³²

Similarly, a study based almost entirely on analyses from 2013-2104 noted that “There is growing evidence supporting the ability of POP (Point of Purchase) information, particularly

³⁰ Espino, et al., 2015, found 25 studies that met their criteria between 1979 and 2013, of which 22 were prior to 2012. The later studies found large positive impacts.

³¹ Platkin, et al., 2014; Elbel, et al., 2009; Sinclair, et al., 2014.

³² Littlewood and Olsen, 2014, pp. 4...8.

FOP [Front of Package] nutrition labels, to enable consumers to better determine the healthiness of food.”³³ It continues to be the case that there are virtually no negative findings. Moreover, the proportion of studies that finds statistically significant positive results has increased.³⁴ The review of studies in the updated 2012-2014 data period calculated the ratio of studies in three categories -- findings fully supporting labeling, finding supporting labeling in an important subgroup, and those that did not support labeling. The ratio was 4 full, 2 partial and 1 non-supporting. The ratio applied to both field and experimental studies.

Another study that included a literature review that covered a greater diversity of interventions concluded the following:

[W]e find efficacy of in-store/point of purchase healthy food interventions. Increase in purchase and consumption of healthy foods reported by the majority of the reviewed studies, including some with high methodological quality, indicated that in-store intervention strategies may hold a promise in the fight against obesity...Most interventions use a combination of information (e.g. awareness raising through food labeling, promotions, campaign, etc.) and making healthy foods available for consumers. Few used price interventions.³⁵

B. COMPLEXITY

In terms of consumer need, the magnitude of the problem is undiminished since the FDA reached its conclusion.³⁶ The theoretical model that connects information and decision making to nutrition and health has been supported,³⁷ particularly in identifying the role of socio-demographics.³⁸ Simply put, the Congress pointed the FDA in the right direction, but the provision of point-of-purchase information is one input into a complex decision making process. As a review from the Robert Wood Johnson concluded, based largely on press 2012 studies put it.

Menu labeling is likely to cause small, but meaningful reductions in calories purchased at chain restaurants and cafeterias overall, and particularly for patrons who see and use the labels (potentially millions of people once labeling is required nationwide). Menu labeling is a strategy with the potential for broad reach. However, factors other than nutritional and health concerns, including taste, prices, and convenience, may shape choices to a greater extent than nutrition information provided at point of purchase for many customers.³⁹

The literature finds that the manner of presentation of information matters a great deal, which is a reason to improve the labels, not abandon them.⁴⁰ The integration of information into

³³ Volvkova, 2015, p. 27.

³⁴ Littlejohn and Olsen, 2014; Long, 2015; Soideberg and Cassady, 2015; AbdulFatah, and Jensen, 2016; Hiller-Brown, 2017;

³⁵ Abdulfatah and Jensen, 2016, pp. 15-16.b.

³⁶ García-Romero, Geller, and Kawachi, 2015; Ogden, 2015.

³⁷ McDermott, 2015; Reuble, 2015.

³⁸ Azman, 2013; Green, 2015, Bleich, 2014, Breck, 2014.

³⁹ Krieger and Saelens, 2013, p. 2.

⁴⁰ AbdulFatah, and Jensen, 2016; Sinclair, et al., 2014.

the context of decision-making is important.⁴¹ Format is very important.⁴² We have a clearer picture of the complex behavioral process into which menu labeling fits. Consumers want the information. Combining information with other behavioral cues (presentation, education) improves their performance. Thus, information is a sufficient condition, justified in its own right, but it is also a necessary condition for other interventions to be more effective.

C. SUPPLY-SIDE

There is also a supply-side effect that yields a positive result of the policy.⁴³ There is evidence that some restaurants have reduced or are reducing the caloric content of their meals, which yields a positive impact on nutritional choices. This effect was not extensively studied in the earlier research but is an expected marketplace response to increased transparency.

The study in Health Affairs included in Figure 2 provides insight into the importance of various factors that influence the market outcome (childhood obesity, in the case of the study). The intervention with the highest benefit-cost ratio is an elimination of the tax subsidy for advertising to children, a supply-side intervention that alters the incentive of suppliers to influence the decision-making environment.

While the Harvard study presents a derived approach to estimating the potential supply-side impact (derived from empirical estimates of elasticities), there is empirical evidence that mandatory labeling can induce supply-side changes. One comprehensive review that included 42 studies turned up five interventions involving price put it, “the one component that people respond most strongly to seems to be the economic incentive.”⁴⁴ Another five had a combination of information and price interventions. Thus price was the policy variable in less than a quarter of the studies. While price was the most potent intervention, the study also found that non-price interventions had an impact.

Demand shifts, or the fear of them, induced by changes in behavior associated with labeling can alter the offering of menu choices.⁴⁵ This can include the reduction in calories in existing menu items,⁴⁶ taking the opportunity to introduce healthier new items,⁴⁷

The recognition that the supply-side of the market plays a large role reinforces the conclusion that effective menu labeling is an attractive policy, particularly in light of the high benefit cost ratio. Labeling uses a simple demand side nudge to attempt to alter behavior that confronts powerful demand and supply-side forces. The positive impact is large, relative to the cost, but the other forces remain operative. Moreover, labeling is the lynchpin for several other demand-side policies that could magnify its impact. In the absence of policies that eliminate

⁴¹ Webb, et al., 2011.

⁴² Thorndike, et al., 2012, 2014; Escaron, et al., 2013; Newman, C.L., et al., 2014; Sonnenberg L, et al., 2013; James, 2015; Temple and Fraser, 2014.

⁴³ Noted by Abaluck and Gruber, 2015 and Mould-Quevedo, 2009. Empirical studies include Bruemmer, et al. 2012, Namba A, et al. 2011.

⁴⁴ Abdulfatah and Jensen, 2016, p. 12.

⁴⁵ Examples of products that quickly left the market after they were recognized as harmful include trans fats and food colors. Food and Drug Administration, 2015, Lefferts, Jacobson, and MacCleery, 2016.

⁴⁶ Bleich, et., al, 2015a, 2015b.

⁴⁷ Bleich, et, al., 2016.

choices in the marketplace, labeling is a key response in its own right and a building block for other demand-side policies.

D. CONCLUSION

The Executive Orders discussed above outline the goals and approach for benefit-cost analysis by federal agencies. The FDA decision to delay enforcement of the menu labeling rule and the decision to reopen the rule fail to pass muster by those standards. The evidence is strong and growing that labeling has a positive effect that has a high benefit cost ratio. That benefit cost ratio has probably been underestimated and will grow as familiarity and use of the information grows.

There are numerous ways that presenting the information in menu labels will increase its effectiveness, including experience and learning, reinforcement by combination with other information, and ultimately nudging the supply-side to positive responses. Delaying or weakening the rule not only has a direct, negative effect on public health in the short term, it postpones and weakens the processes that can magnify the benefits of labeling. Above all delay and weakening diminish the ability of a basic, low cost demand-side intervention to trigger supply-side responses.

APPENDIX A: THE EVOLUTION OF EXECUTIVE ORDERS GOVERNING RULEMAKING

Obama (13563)

Overall Goal

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. As stated in that Executive Order and to the extent permitted by law, each agency must

Benefit - Cost Analysis Principles

propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify);

It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends.

It must take into account benefits and costs, both quantitative and qualitative. Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

In applying these principles, each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. It must be based on the best available science.

Clinton (12866)

The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need,

Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

[I]n choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider

Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

Reagan (12291)

General Requirements. In promulgating new regulations, reviewing existing regulations, and developing legislative proposals concerning regulation, all agencies, to the extent permitted by law, shall adhere to the following requirements:

Administrative decisions shall be based on adequate information concerning the need for and consequences of proposed government action;

Regulatory action shall not be undertaken unless the potential benefits to society from the regulation outweigh the potential costs to society;

Agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.

Unless covered by the description required under paragraph (4) of this subsection, an explanation of any legal reasons why the rule cannot be based on the requirements set forth in Section 2 of this Order.

To permit each proposed major rule to be analyzed in light of the requirements stated in Section 2 of this Order, each preliminary and final Regulatory Impact Analysis shall contain the following information... A description of the potential benefits of the rule, including any beneficial effects that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits

Regulatory Design

select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and

identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations;

When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective.

Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt. Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively. In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity. Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies. Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

Regulatory objectives shall be chosen to maximize the net benefits to society; Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society shall be chosen; and

A description of the potential costs of the rule, including any adverse effects that cannot be quantified in monetary terms, and the identification of those likely to bear the costs; A determination of the potential net benefits of the rule, including an evaluation of effects that cannot be quantified in monetary terms;

A description of alternative approaches that could substantially achieve the same regulatory goal at lower cost, together with an analysis of this potential benefit and costs and a brief explanation of the legal reasons why such alternatives, if proposed, could not be adopted; and

Openness and Oversight of Process

It must allow for public participation and an open exchange of ideas.

It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements. It must promote predictability and reduce uncertainty

Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

In order to implement Section 2 of this Order, each agency shall, in connection with every major rule, prepare, and to the extent permitted by law consider, a Regulatory Impact Analysis. Such Analyses may be combined with any Regulatory Flexibility Analyses performed under 5 U.S.C. 603 and 604. Except as provided in Section 8 of this Order, agencies shall prepare Regulatory Impact Analyses of major rules and transmit them, along with all notices.

**APPENDIX B:
 AMBIGUITY DEFINED BY FOUR REGIONS OF KNOWLEDGE ADAPTED TO COST-BENEFIT ANALYSIS**

AMBIGUITY DEFINED BY FOUR REGIONS OF KNOWLEDGE

		Knowledge of nature of outcomes	
		<u>Low</u>	<u>High</u>
Knowledge of probabilities of outcomes	High	<p><u>Vagueness:</u> Condition: The decision maker may <u>not</u> be able to clearly identify the outcomes, but knows the system will fluctuate. Strategy: Fuzzy Logic Action: Avoid long-term paths that are least controllable. Minimize surprises by avoiding assets that have unknown effects. Create systems that can monitor conditions and adapt to change to maintain system performance.</p>	<p><u>Risk:</u> Condition: The decision maker can clearly describe the outcomes and attach probabilities to them. Strategy: Hedge Action: Identify the trade-offs between cost and risk. Spread risk by acquiring assets that are uncorrelated (do not overlap).</p>
	Low	<p><u>Unknowns:</u> Condition: In the most challenging situation, knowledge of the nature of the outcomes and the probabilities is limited. Strategy: Diversity & Insurance Action: Buy insurance to build resilience with diverse and redundant assets. Diversity requires increasing the variety, balance, and disparity of assets. Fail small and early. Avoid relying on low-probability positive outcomes and betting against catastrophic negative outcomes.</p>	<p><u>Uncertainty:</u> Condition: The decision maker can clearly describe the outcomes but <u>cannot</u> attach probabilities to them. Strategy: Real Options Action: Buy time to reduce exposure to uncertainty by choosing sequences of hedges that preserve the most options. Acquire small assets with short lead times and easy exit opportunities.</p>

IMPLICATIONS OF CHALLENGES FOR COST-BENEFIT ANALYSIS

		Knowledge of nature of outcomes	
		<u>Low</u>	<u>High</u>
Knowledge of probabilities of outcomes	<u>High</u>	Qualitative	Cost benefit analysis Maximization rules Net Benefit: Maximum @ zero cost Technology limit Marginal Benefit = Marginal Cost Total Benefit = Total Cost All technologies, regardless of cost
	<u>Low</u>	Incommensurable Precautionary Principles Holistic evaluation Cost effectiveness analysis	Intergenerational discount rate = 0

Sources: Framework adapted from, Mark Cooper, *The Political Economy of Electricity: Progressive Capitalism and the Struggle to Build a Sustainable Sector* (Santa Barbara, Praeger, 2017). Chapters 10 and 11. Cost Benefit critique from, Frank Ackerman, 2008, *Cost-Benefit and alternative Critique of Cost-Benefit Analysis and Alternative Approached to Decision-Making: A Report for Friends of the Earth England, Wales and Northern Ireland,*

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