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Subject: Comments on Draft Guidelines

Please see attached.

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- OIRA Draft Guidelines - JBW comments.wpd

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Subject: Comments on Draft Guidelines

Dear John,

Thank you for the opportunity to comment on OIRA's Draft Guidelines for Regulatory Analysis and related matters.

Guidelines for Regulatory Analysis.

The Draft Guidelines make several helpful improvements over the 1996 statement of best practices (issued in 2000 as guidelines). The comments below suggest additional ways to improve the Guidelines. The comments are organized in the order the issues arise in the Guidelines.

Varying methodologies. The Report notes that different methodologies across agencies -- for example, different monetized values for effects, different baselines, different treatments of uncertainty -- are "embedded" in OIRA's aggregate assessments of regulatory benefits and costs. 68 Fed. Reg. at 5494. It states that therefore "this aggregation involves the assemblage of benefit and cost estimates that are not comparable." 68 Fed. Reg. at 5499. Other differences across agencies may include different methods for extrapolating dose-response functions from animals to humans, or from high to low doses, even for the same chemical substance. In the Guidelines, OIRA should consider requiring more uniformity across agencies in the methodologies used to assess benefits and costs. Or at least the Guidelines should explicitly

require sufficient transparency so that OIRA and the public could recalculate benefits and costs using consistent methodology across agencies.

Countervailing risks and ancillary benefits. The Guidelines should instruct agencies to forecast and account for the full portfolio of effects caused by the regulation, including in particular the countervailing risks (substitution risks, undesirable side effects) of the regulation, and the ancillary benefits (auxiliary benefits, cobenefits) of the regulation. The Guidelines mention these effects briefly at 68 Fed. Reg. at 5514 (bottom of first column), but thereafter give them little attention. Ideally, in order to emphasize the importance of countervailing and ancillary effects and to ensure that agencies do not neglect them, the Guidelines should instruct agencies to assess a separate category of "side effects" or "countervailing and ancillary effects" or "risk tradeoff analysis," distinct from the discussion of "costs" and "benefits" and BCA and CEA (discussed at 68 Fed. Reg. at 5517-5518). These separate categories of countervailing risks and ancillary benefits should also be included as line items in the Accounting Statement (68 Fed. Reg. at 5525-5526).

The Guidelines (68 Fed. Reg. at 5514, bottom of first column) say that countervailing and ancillary effects should be "added to the direct costs and benefits as appropriate." I suggest the Guidelines instead instruct agencies to evaluate these effects separately, and then put both of these effects on benefits side, not on the costs side. That is, agencies should treat countervailing risks as disbenefits (not as costs), and ancillary benefits as additional benefits. There are several reasons for this approach. First, countervailing risks are distinct from costs; they are disbenefits, not financial or compliance costs of regulation.[1] Often countervailing risks are quite independent of compliance costs. For example, decreasing tropospheric ozone levels would help lungs but expose skin to greater UV, and this would be so even if industry's compliance cost to reduce ozone were zero. Second, costs and countervailing risks can be inversely related. Greater ease of substitution of new products for banned products is likely to reduce compliance costs but increase countervailing risks. Third, the analysis of countervailing risks and ancillary benefits will often be done by agency staff other than those who estimate costs. Economic analysis may help identify the prospects for countervailing or ancillary effects, but the same agency staff who conducted the risk assessments used to forecast target benefits are likely to then conduct the risk assessments of the countervailing and ancillary effects (although if these effects are outside the regulatory agency's domain, different staff will likely conduct such analyses; but still these will not typically be the analysts of cost). Fourth, countervailing risks and ancillary benefits will initially be measured in units that are the same as or similar to the units of measurement for target benefits, such as mortality, morbidity, and ecological effects. And issues of quantification, such as how to discount future lives, will apply equally to target benefits, countervailing risks and ancillary benefits. It will therefore typically make more sense to keep these measures together under the rubric of overall benefits, so that they can be

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[1] So-called "health-health" analysis, assessing the mortality costs of income reductions, is really just a translation of the cost side of benefit-cost analysis into risk terms. See e.g. Ralph Keeney, "Mortality Risks Induced by Economic Expenditures," 10 RISK ANALYSIS, 147 (1990); and the symposium in 8 JOURNAL OF RISK & UNCERTAINTY (1994). By contrast, countervailing risks are distinct new risks created by regulation; they are not just a translation of ordinary regulatory costs.

calculated, added and subtracted in like units. This is especially so when monetization is difficult or unavailable, in which case putting all the non-monetized health and environmental effects together will facilitate analysis of the overall impact of the regulation. Fifth, several statutes prohibit agency consideration of cost in making regulatory decisions. In such cases, it will improve analysis and regulatory decisions to put countervailing risks (disbenefits) and ancillary benefits on the benefits side, so that they may still clearly be considered in shaping policy.[2] See J.D.Graham & J.B.Wiener, RISK VS. RISK (Harvard Univ. Press, 1995); Wiener, "Managing the Iatrogenic Risks of Risk Management," 9 RISK: HEALTH SAFETY & ENVIRONMENT 39-82 (1998); Rascoff & Revesz, "The Biases of Risk Tradeoff Analysis: Towards Parity in Regulatory Policy," 69 U. CHI. L. REV. -- (2002).

Performance standards. The Guidelines instruct agencies to choose performance standards over design standards "if performance can be measured or reasonably imputed" (68 Fed. Reg. at 5515, last paragraph). This phrasing suggests an unrealistic binary criterion -- either performance can be measured, or not -- that could lead agencies to choose performance standards too seldom. The reality is that performance can be monitored increasingly accurately at some increasing cost, and that monitoring performance also yields greater effectiveness because it reveals actual performance whereas monitoring the installation of design standards may be less costly but does not reveal actual performance. Thus, monitoring costs and their contribution to greater effectiveness should be included in an overall cost-effectiveness analysis of the performance standard compared to the design standard. A better phrasing in the Guidelines would instruct agencies to choose performance standards over design standards "if the performance standard would be more overall cost-effective than the design standard, taking into account both the cost savings of affording regulated parties flexibility in compliance options and the costs (and improved effectiveness) of monitoring or imputing performance rather than monitoring design changes."

Optimal analysis; BCA or CEA. The Guidelines instruct agencies to use BCA or CEA in certain situations (68 Fed. Reg. at 5516, Part III). These situations appear to be: use CEA for all regulations, and also use BCA where outcomes can be monetized. But there is a much wider range of circumstances that may influence the choice of analytic rigor and information acquisition. For example, how hard should an agency work to develop monetized values? How far should the agency go in analyzing follow-on effects and side effects? How far should the agency go in assessing sensitivity analyses of alternative assumptions and scenarios? Most fundamentally, when would additional analysis improve the regulatory decision enough to warrant the delay needed to perform that analysis, and when would the disadvantage of delay outweigh the potential improvement in the decision? And, what constraints on the agency's

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[2] Even if countervailing risks were placed on the costs side, there would be a strong argument that they are not the kind of costs meant to be excluded from consideration by statutes that prohibit consideration of costs. The courts have indeed held that under sections 108 and 109 of the Clean Air Act, the countervailing risks of reduced ozone concentrations due to tighter NAAQS *must* be considered even while the costs of such standards *must not* be considered. See Whitman v. American Trucking Associations (ATA), 531 U.S. 457 (2001); American Trucking Associations v. EPA, 175 F.3d 1295 (D.C. Cir. 1999).

analysis are imposed by statute? The Guidelines should therefore instruct agencies to "use the most desirable analysis permitted by law," and to "conduct a brief value of information vs. cost of information (VOI vs. COI) analysis of the degree of regulatory analysis that is most desirable." That is, agencies should conduct a brief BCA of additional information and analysis. OIRA states in the Guidelines that "While these proposed guidelines include some additional requirements on the agencies in performing RIAs, we believe that adherence to the proposed revisions will yield improvements in the information provided by these analyses. Improved analyses will strengthen the regulatory development process, resulting in better designed regulations and potentially large net benefits to society as a whole." 68 Fed. Reg. at 5498. But OIRA could direct agencies to analyze this question more carefully, using BCA methods and criteria. The costs of better analysis and information would include not just agencies' out of pocket expenses and staff time, but the opportunity costs of such time, including delay in regulating the target risk. The benefits of better information and information would be the improved policy outcome, that is, the increased net benefits of regulation compared to the net benefits of regulation without such information. This VOI/COI or BCA-of-analysis approach can help the agency select the method (type, degree, rigor, and information-intensity) of the analysis it employs. And this approach can help OIRA exercise meaningful supervision and review of the analysis method choices that agencies make. See Wiener, "Managing the Iatrogenic Risks of Risk Management," 9 RISK: HEALTH SAFETY & ENVIRONMENT 39-82 (1998). Later in the Guidelines, OIRA suggests this VOI/COI approach for weighing whether to collect additional data, 68 Fed. Reg. at 5523 (second column).

BCA as a cognitive tool. The Guidelines state that the "distinctive feature of BCA is that both benefits and costs are expressed in monetary units," whereas in CEA the costs are monetized but the benefits are not. 68 Fed. Reg. at 5516 (middle column). This seems to be a narrow version of BCA. A more general and robust view of BCA is that its "distinctive feature" is the comparison of pros and cons to arrive at an optimal level of action, whereas CEA seeks to maximize the benefits of a given level of investment or minimize the investment needed to achieve a given level of benefit. Thus, CEA does not monetize both costs and benefits, but more fundamentally it does not identify the optimal level of action: it takes either the level of cost or the level of benefit as given. Also, CEA does not assess countervailing risks or ancillary benefits. The fundamental feature of BCA is that it collects all important consequences of a decision and evaluates them holistically. This "cognitive" feature of BCA is as or more important than its ability to achieve an economically efficient outcome through mathematical calculations of monetized units. See Benjamin Franklin, "**Letter to Joseph Priestley," London, September 19, 1772, in *Benjamin Franklin: Representative Selections, with Introduction, Bibliography and Notes* (Frank Luther Mott and Chester E. Jorgenson, eds., New York: American Book Company, 1936), pp. 348-349**; Cass Sunstein, "Cognition and Cost-Benefit Analysis" (2001).

Using CEA to select policy instruments. The Guidelines state that agencies "also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved" (68 Fed. Reg. at 5517, first full paragraph). The Guidelines should go further, to instruct agencies to "use CEA to identify and select the most cost-effective alternative to achieve the level of benefits indicated in the statute, whenever the statute affords the agency such

discretion, or else explain to OIRA the reason(s) why the agency has chosen an alternative other than the most cost-effective one."

Metric of "effectiveness." The Guidelines are correct to note that CEA is sensitive to the metric used to quantify effectiveness (68 Fed. Reg. at 5517, Part III.C). The Guidelines ask agencies to provide the underlying data so that OIRA can construct a single effectiveness metric on which to make "apples-to-apples comparisons between rulemakings that employ different measures." This is useful. But OIRA should not assume that one single effectiveness metric can be chosen to compare all regulations without loss of analytic insight. The Guidelines should therefore ask the agencies to generate several parallel CEA estimates, each using a different effectiveness metric (as relevant to the regulation), such as lives saved, life-years saved, quality-adjusted life years saved, measures of health utility, and non-human-life benefits such as visibility and aesthetics, species saved, species-years saved, overall ecological health and biodiversity conservation, and willingness to pay for species or biodiversity saved. The different effectiveness metrics illuminate different aspects of the regulation.

Baselines. The Guidelines should focus more attention on the counterfactual baseline forecast of what would have happened without the regulation (the "no action" baseline), discussed at 68 Fed. Reg. at 5517. The analysis of a regulation's benefits and costs does not imply a comparison of the world after the regulation to the world before the regulation. Instead, it requires a comparison of the world after the regulation to what would have happened otherwise, i.e. comparing the future world with and the future world without the regulation. The counterfactual baseline forecast of what would have happened without the regulation is pivotal to the assessment of the regulation's effects, benefits and costs. The suggestion in the Guidelines that "You may often find it reasonable to forecast that the world absent the regulation will resemble the present" is misleading: the world without the regulation will not resemble the present, but rather the extrapolation of present trends into the future. The suggestion to analyze "alternative baselines" is useful, but the Guidelines focus on alternatives that may result from other agencies' regulations; the Guidelines should also instruct agencies to conduct sensitivity analyses of alternative future scenarios for major variables in the baseline (e.g. economic growth rates, prices, consumer tastes). Alternative baselines should also account for policy choices at other levels of government besides federal regulation, such as what states would do or what other countries would do. Agencies should also be asked to identify key uncertainties in the baseline forecast. And agencies should be asked to validate their baseline forecasts over time, to revise their regulatory analyses retrospectively (years after the regulation was adopted) to reflect the revised baselines in light of actual experience, and to use this exercise to generate more accurate baselines for subsequent regulations.

Retrospective analysis. More generally, the Guidelines should instruct agencies to perform and take account of retrospective analysis of ex ante benefit and cost estimates. See Harrington, Morgenstern & Nelson, "On the Accuracy of Regulatory Cost Estimates," Journal of Policy Analysis and Management (2000).

Interpreting WTP. The Guidelines note that market prices provide "the richest data" on WTP "if the goods and services ... trade in well-functioning free markets." 68 Fed. Reg. at 5518 (middle

column). This phrasing may suggest that if the markets are "well-functioning" then market prices are ideal measures of value, but if the markets are not "well-functioning" then market prices may be ignored. Neither of these implications would be correct; and no guidance is provided on what constitutes "well-functioning." It would be better for the Guidelines to instruct agencies to refer to market prices in most cases, while appropriately taking account of the market imperfections and related factors that may make market prices a useful but approximate indicator of value. Market imperfections include limits on workers' and consumers' mobility, information, and choices (which may depress observed WTP); ability to pay (which may affect observed WTP depending on the relative wealth of those observed); and cognitive heuristics that bias workers' and consumers' choices (which may depress or exaggerate observed WTP). These factors, and self-selection by those observed, may also undercut the accuracy of transferring benefits estimates from one context (such as the value of a statistical life derived from compensating wage differentials paid to workers who accept higher workplace risks) to estimate benefits in a different context (such as the value of a statistical life saved from unknowing exposure to toxic substances outside the workplace) -- as noted at 68 Fed. Reg. at 5519 (middle of first column) and at 68 Fed. Reg. at 5521 (second column). Moreover, even perfect market prices are only a plausible lower bound on consumers' WTP for product attributes, because consumers would not pay the market price if they did not value the product more than the market price (hence, consumer surplus). Further, people may put more value on public goods (such as clean air) in public decisions than the WTP they reveal in private markets for such goods. In particular contexts, these factors may mean that market prices will understate or overstate true valuations. The next section of the Guidelines is titled "How To Use Market Data Directly," 68 Fed. Reg. at 5518-5519, but it does not discuss that point; instead it discusses problems when markets are distorted and market data do not reflect social values. This discussion is useful, but the section limits itself to situations in which government programs distort prices. The section would be strengthened by changing the title to "How to Adjust Market Data to Reflect Market Imperfections," and by incorporating the factors mentioned above in this paragraph of comments.

Contingent Valuation. In the discussion of Contingent Valuation, 68 Fed. Reg. at 5519, it would be useful to add a sentence to the effect that "Although contingent valuation methods may not be as accurate as revealed preference methods, the value of resources not traded in markets (such as the existence value of rare ecosystems) is often clearly greater than zero, and therefore the use of appropriately designed contingent valuation methods can often yield estimates that are more accurate than not using such methods or than ignoring such benefits." Also, it might be useful to suggest that the Survey Instrument Design (p.5519, third column) should employ graphical (visual) depictions of incremental probabilities or units of the good, rather than purely numerical measures of probabilities or units, because research by James Hammitt and others suggests that respondents presented with graphical depictions are more sensitive to scope (displaying increasing total WTP but declining marginal WTP for larger amounts of the good) than are respondents presented with purely numerical measures.

Discounting. In the discussion of the rationales for discounting future benefits, 68 Fed. Reg. at 5521 (third column, last full paragraph), the text refers the foregone returns of current expenditures, and to the "impatience" people feel about receiving benefits. Later (p.5522,

second column), the text suggests that money and lives may be discounted for different reasons -- money because of its investment value, and life because people would prefer immediate to future health gains (and the perverse result of discounting costs but not benefits). The two passages may be somewhat confusing to readers seeking a basic understanding of why future events should be discounted. The text could be strengthened by explaining or evaluating the standard intuition behind both kinds of discounting, namely that a return on investment can be earned from having an asset earlier than later. Thus it might be useful to add something like: "Receiving a benefit today (or deferring a cost to later) is more valuable than receiving the benefit later (or incurring the cost today) because the benefit (or cost not yet expended) can yield a stream of productive returns during the interim time between today and later. This is true of both money and life. Money received (or not yet spent) can be invested, so the same dollar amount of money in the future is worth less than that amount in hand today. Life lived (or not yet lost) can be invested in myriad fulfilling and productive activities, so the same number of statistical lives (or years of life) saved in the future is worth less than that number saved today; or, put another way, people would generally prefer to live longer." And, if OIRA believes that this standard intuition is flawed or incomplete, it should explain this point.

The Guidelines make a constructive improvement (68 Fed. Reg. at 5521-5523) by encouraging agencies to use both a 3 percent and a 7 percent discount rate, and perhaps a variety of lower and higher discount rates as well, for longer-term impacts.

Quantitative uncertainty analysis. The Guidelines require quantitative uncertainty analysis of rules costing more than $1billion per year. But why the $1 billion threshold? Why not require such analysis of all rulemakings, subject to the VOI/COI analysis of the appropriate degree of analysis (see discussion above)? The $1 billion threshold could be underinclusive (omitting some rules for which quantitative uncertainty analysis would yield net benefits) and overinclusive (including some rules for which quantitative uncertainty analysis would not yield net benefits).

Analysis and Management of Emerging Risks - Precaution.

Decisions under uncertainty. OIRA states that "Regulators often must decide on an appropriate course of action to protect public health, safety or the environment before science has resolved all the key factual questions about a potential hazard." 68 Fed. Reg. at 5498. But that is not just "often" the case; it is always the case. We never have "resolved all the key factual questions about a potential hazard." We never know the future with certainty. Decisions must always be made in the face of uncertainty. OIRA should recognize and address degrees and types of uncertainty, not certainty versus uncertainty. This recognition is important as a response to claims that precautionary action is automatically warranted in (and yet reserved for) situations of uncertainty, as if uncertainty were a special case and most situations did not involve uncertainty (sometimes described as a purported distinction between "uncertain" and "known" risks -- as if any risks of future events could be "known" beforehand). By the same token, this recognition is important as a response to claims that precautionary action is automatically unwarranted in situations of uncertainty, on the ground that "the science is uncertain, so we should (just) wait for better science." And it is also important in educating policymakers and the public about the

inescapable uncertainties and therefore errors that surround regulatory decisions – and yet the inescapable need to make regulatory decisions in the face of uncertainty.

Degrees of Precaution. Binary classifications such as "precautionary or not" are more misleading than useful. There are so many different definitions of "the precautionary principle" that such binary classifications are more semantic than substantive. Instead, OIRA and the Interagency Work Group on Risk Management (IWGRM) should develop a measure of precaution as a continuous variable that can be measured by degrees: a combination of stringency and earliness (how anticipatory and aggressive in the face of uncertain future risks). See Wiener, "Precaution in a Multirisk World," in Dennis Paustenbach, ed., HUMAN AND ECOLOGICAL RISK ASSESSMENT (John Wiley & Sons, 2002).

Precaution and decision science. OIRA and the IWGRM should use decision science to make sense of "precaution" and to deal with risks characterized by uncertainty, latency, potential extreme consequences. See Stewart, "Environmental Regulatory Decisionmaking Under Uncertainty," 20 RESEARCH IN LAW AND ECONOMICS 71–152 (2002); Wiener, "Precaution in a Multirisk World," in Dennis Paustenbach, ed., HUMAN AND ECOLOGICAL RISK ASSESSMENT (John Wiley & Sons, 2002). For example, OIRA and the IWGRM should develop a decision framework and retrospective research that account for both errors of insufficient precaution (false negatives) and errors of excessive precaution (false positives).

Provisionality and Adaptative Regulation. OIRA and the IWGRM should make regulation of emerging risks adaptable over time and as knowledge improves. That is, make precautionary restrictions provisional, to be revised after additional research. This is easier said than done. The European Commission's Communication on the Precautionary Principle (Feb. 2000) calls for such provisionality, but does not say how it will be achieved in practice. Incentives need to be provided for research by the least-cost provider of such research, and a process needs to be developed to incorporate that research into revisions of regulations. One concern is that the regulatory ratchet may be asymmetric, such that it is easier to tighten than to relax a regulation. There are many examples of regulations tightened over time (CAA NAAQS, CWA effluent guidelines, lead phasedown, CFC phaseout). But there appear to be few examples of precautionary regulations imposed and then relaxed when research found lower risk than initially feared (perhaps saccharine, silicone breast implants). If so, it would be important to understand why. Perhaps regulation confers "technological stigma" which cannot easily be shed. Or there may be asymmetric revelation of false negatives versus false positives: that is, underregulation of real risk becomes apparent once the false negative risk actually occurs, thereby spurring (belated) regulation; but overregulation of a non-risk does not become apparent because the non-occurrence of the risk is indistinguishable from the success of the (unnecessary) regulation.

Evaluate precaution in practice. Even though the US has not formally adopted "the precautionary principle," there has been widespread use of precaution in US regulation. See John Applegate, "The Precautionary Preference: An American Perspective on the Precautionary Principle," 6 HUMAN & ECOLOGICAL RISK ASSESSMENT 413 (2000). OIRA and the IWGRM should evaluate approaches to precaution across major statutes and across federal agencies, e.g. EPA, FDA, OSHA, NHTSA, NRC, CPSC. Assess the roles of Congress, agencies, courts, and

other actors in producing precautionary approaches. Evaluate successes and failures in these approaches.

Compare US and European uses of precaution. OIRA and the IWGRM should compare US and European experience with precautionary regulations. The claim that Europe has become more precautionary than the US is not borne out by a broad analysis of numerous and diverse risks; the reality appears to be frequent use of precaution in both the US and Europe, but against different risks. Why different risks invite precaution in each polity remains an important question for further research. See Wiener & Rogers, "Comparing Precaution in the United States and Europe," 5 JOURNAL OF RISK RESEARCH 317-349 (2002); Wiener, "Convergence, Divergence and Complexity in US and European Risk Regulation," in Norman Vig & Michael Faure, eds., GREEN GIANTS: ENVIRONMENTAL POLICIES OF THE UNITED STATES AND EUROPE (MIT Press, forthcoming 2003).

Relatedly, OIRA and the IWGRM should compare the criteria for regulation under EO 12866 and related authorities, vs. the European Commission's February 2000 "Communication on the Precautionary Principle." What common ground is there? What differences are there? How can each approach learn from the other?

Prompt letters. OIRA should consider using its "Prompt" letters to spur agencies to adopt precautionary regulations that yield expected net benefits, when the agencies are not doing so.

OIRA's specific requests for comment. OIRA requested comments on the following (see 68 Fed. Reg. at 5499):

- Ways in which precaution is embedded in risk assessments:

Risk assessment may overstate risks because of:
- Choice of most sensitive test species
- Linear high-to-low-dose extrapolation
- Animal-to-human extrapolation
- Extrapolation from one site/organ/tissue to others
- Safety factor for interindividual variability
- Exposure assumptions such as Maximum Exposed Individual
- Selective attention to new risks; assuming natural = safe
- Incentive to overstate risks because revelation of a false negative is more damaging to the risk assessor/agency than is revelation of a false positive

But risk assessment may also understate risks because of:
- Sensitive subpopulations (variability; equity) (e.g. children, elderly, genetic predispositions)
- Mixtures and multiple simultaneous exposures, with synergistic effects
- Cumulative exposures and risks over time
- Unforeseen sources of risk
- Strategic risk actors whose behavior may be difficult to predict (e.g. pathogens, terrorists)

The result may be simultaneous paranoia about some risks and neglect of other risks.

- Ways in which precaution is embedded in explicit protective measures in management decisions as required by statutory requirements or agency judgments:

- Margins of safety (e.g., CAA sec. 109, 112)
- Requirements to ignore cost or countervailing risks (e.g., ESA sec. 7)

- Examples of approaches in US risk assessment and management which appear unbalanced:

- Among others, one "precautionary measure" of recent interest is US FDA, "Guidance for industry: revised precautionary measures to reduce the possible risk of transmission of Creutzfeldt-Jakob disease (CJD) and new variant Creutzfeldt-Jakob Disease (vCJD) by blood and blood products," 64 Federal Register 44739 (August 17, 1999) (and subsequent further restrictions). In August 1999 the US FDA instructed blood banks (such as the American Red Cross) to reject blood from any donor who had spent more than 6 months cumulative in the UK during the years 1980–1996 (the period of the BSE epidemic). In June 2001 the FDA proposed to go further, rejecting any donor who had spent 3 months or more in the UK or 5 years or more anywhere in Europe since 1980. (The American Red Cross, which collects about half the blood donated in the US, has adopted an even more restrictive policy, excluding donors who have spent 3 months or more anywhere in Western Europe.) These restrictions on blood donations by people who have spent time in the UK and Europe may reduce the risk of BSE/vCJD in blood recipients in the US, but the risk of transmission through blood donations (as opposed to consumption of contaminated meat and bone meal) is very speculative. FDA recognized that there have been no studies showing human blood transmission of CJD, only conflicting animal data, and no cases yet of vCJD in the US; that the 'transmissibility of vCJD by blood or blood products is unknown' and the 'transmissibility [of vCJD] cannot confidently be predicted from studies of CJD'; and that 'No transmission of CJD or vCJD by human blood components or plasma derivatives has been documented to date' (id.). Further, the restrictions are based simply on time spent in Europe and do not target those who might actually have been exposed to BSE/vCJD, making the restrictions both underinclusive and overinclusive of persons who might carry disease agents. And the risk from blood donations may be declining as the presence of BSE has been minimized in UK and European beef. Moreover, FDA did not conduct a risk assessment before adopting the restrictions. Meanwhile, the countervailing public health losses from the restrictions on blood supply may be quite significant and immediate. The American blood supply is already very tight. The Red Cross testified to the FDA that the 1999 policy would likely reduce the pool of eligible blood donors by about 2% (see US FDA Advisory Committee on Transmissible Spongiform Encephalopathies, Hearings of 2 June 1999, SAG Corp. Transcript, p.46 (Statement of Dr. Williams) (downloaded from <http://www.fda.gov/cber> under Minutes of 1999 Conferences/Meetings). The 2001 policy has been forecast to reduce the blood supply by 5–8% nationwide and more in New York, which imports about 25% of its blood from Europe (see John Tagliabue, "US plan to halt blood imports worries Europe," NY Times, July 17, 2001, p.A1).

- How the US balances precaution with other interests such as economic growth and technological innovation:

    - Many statutes require or authorize BCA
    - Many statutes require or authorize consideration of countervailing risks
    - EO 12866 and OIRA oversight

Analysis of Regulations Related to Homeland Security.

Generally speaking, it is constructive for OIRA to analyze all regulations and government policies, not just those directed at promoting health, safety and environmental quality. (Of course, homeland security regulations are directed at safety.) OIRA should also be analyzing the benefits and costs of financial sector policies, transportation policies and projects, forest management policies and timber sales (including under NFMA 6(k)), land management policies, watercourse and coastal policies and projects, Army Corps of Engineers policies and projects, dam policies and projects, and other federal policies and projects. BCA and CEA were applied in the 1950s and 1960s to evaluate dam construction projects and military strategies; the use of BCA and CEA should not be limited to environmental regulations. And OIRA should consider analyzing the benefits and costs of proposals for legislation (perhaps in cooperation with the GAO or CBO) before Congressional enactment.

Difficulty in quantifying some costs and benefits, such as those related to homeland security, should not preclude thoughtful analysis of the pros and cons. See Benjamin Franklin, Letter to Joseph Priestley, *supra*; Sunstein, "Cognition and Cost-Benefit Analysis" (2001).

Evaluating the benefits of homeland security regulations will require forecasts of terrorism risks. But risk assessment of terrorism will require game-theoretic models of strategic behavior. Unlike earthquakes or volcano eruptions, the risk of terrorist attack depends on preventive measures. It may be difficult to model terrorists' decisionmaking. Standard rational actor assumptions may be inaccurate, e.g. if terrorists are not averse to their own deaths. Yet terrorists may still behave strategically to achieve their objectives. If so, the risk of terrorist attack may depend on potential victims' preventive measures ("hardening"). Hardening of one facility or system may motivate terrorists to choose softer targets (an external cost of hardening). Or, hardening of one facility or system may protect other related facilities or systems (an external benefit of hardening). These features complicate efforts to forecast the risk of terrorist attacks. They may also induce private actors to invest in too much or too little hardening.

It may be quite difficult to assess and attribute the indirect effects of terrorism. For example, highway deaths may rise because people drive instead of flying (e.g. after an airplane hijacking); or highway deaths may decline because people stay home instead of driving (e.g. after sniper attacks).

Evaluating the costs of homeland security regulations will imply measuring the value of foregone privacy and liberty. This may be controversial and difficult. One approach is to

quantify and monetize these losses, perhaps using revealed preference or stated preference methods to assess the monetary value of privacy and liberty. A different approach is to use cost-effectiveness analysis (CEA), keeping privacy and liberty measured in their own non-monetized units, and comparing them directly to the privacy and liberty losses that would result from terrorism itself.

I hope these comments are useful to you.

Sincerely,

Jonathan B. Wiener
Professor