

Notes regarding the attached paper

Dear Reader –

You will quickly work out that the attached is in an early and rather undersourced state of preparation, although it relates to a general problem and to quite recent American developments in the Obama administration that I hope you may find interesting.

Should you not wish to read the whole, I recommend that you start with pp. 1-3, setting the problem, and have a look at a recent executive order issued by President Obama, wanting to address it, pp. 26-28. Part I of the paper, pp. 4-11, deals with the bending of science by private persons, and Part II, 11-25, addresses its bending by/within government authority, and thus the recent executive order. Much of the detail here is, you may think thankfully, peculiarly American in character. Perhaps Part II(C), pp. 18-25, which addresses central political controls over judgments, presents the matter most likely to be important to our conversation. President Obama has repeatedly promised to restore integrity to governmental science, but how, concretely, should this be reflected in his oversight of activities as significant for the nation's economy as contemporary rulemaking? My sincere hope is to spark some discussion of these problems from an Australian (and parliamentary) perspective. There are notable differences between presidential and parliamentary systems to be explored, but it is submitted that the accommodation of the problem of political will and scientific judgment is a common one. The acceptability of rulemaking practice, that is, inheres in its demonstrable legality as well as considerations of political answerability.

I look forward with pleasure to our time together, and deeply appreciate your kindness in inviting me to be with you.

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Possible Controls over the Bending of Regulatory Science

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“Bellerophon Taming Pegasus,” the monumental statue shadowing the formal entrance to Columbia Law School, states in metaphor the tension that motivates this piece. Nominally it reflects reason taming unreason, which is the role that law claims in society. One knowing a bit of its history sees more. Commissioned in the early ‘60’s, its earliest sketches reflected a proportion and a distance between man the master and the winged horse of unreason suggesting that the outcome was secure. The golden bridle would do its work and reason would prevail. As the early ‘60’s became the late ‘60’s, Pegasus grew in the sketches, Bellerophon shrank, and ultimately the two merged. Now Pegasus was Bellerophon’s own head; the bridle was around his own neck; the horse’s expression of pain and rage was his own. And as Bellerophon could never completely tighten the noose around his own neck if he wished to live, one knew that the struggle could not be resolved. Reason and unreason continuously contend. What a metaphor for the project of law!

In particular, what a metaphor for the continuing tensions between objective (“scientific”) and political inputs to regulatory decisionmaking. For science as for law, the basic call is to “reason,” to analysis as free as it can be of the influence of “man.” And, for science as for law, “man” *cannot* be eliminated. Judgments must be made in inevitable arenas of uncertainty – judgments that will be shaped by human predispositions and heuristics that need hardly correspond to the realities they seek to describe. And beyond these unavoidable human difficulties lie the incentives that in so many contexts twist human behaviors in ways that law seeks to control – greed for profit and lust for power central among them.

The American regulatory landscape has been littered with efforts to distort or suppress information relevant to the responsibilities of federal agencies responsible for protecting health, safety or the environment on the basis of sound science. While these efforts have a long historical pedigree – consider the industrial practices respecting such hazards as silicosis, tobacco and asbestos, or government behaviors in respect of nuclear weapons testing¹ or the Tuskegee experiment² – recent times have seen them take particular prominence. Drug company failures to alert regulators respecting hazards their products created and the like spread across the pages of two recent books describing a variety of means that have been used in the service of distorted outcomes: creation of research to produce intended outcomes; suppression of unwanted information; discrediting reliable research; interfering with the careers of those who produce unwanted information; and public relations campaigns.³ “The editors of our best international scientific and medical journals,” one reports, “are chagrined by their inability to weed out unreliable research emerging from a funding regime that is in-

¹<http://www.hss.energy.gov/healthsafety/ohre/roadmap/experiments/index.html>;
http://historytogo.utah.gov/utah_chapters/utah_today/nucleartestingandthedownwinders.html.

² <http://www.cdc.gov/tuskegee/timeline.htm>.

³ Thomas O. McGarity and Wendy E. Wagner, *Bending Science: How Special Interests Corrupt Public Health Research*. (2008); David Michaels, *Doubt is Their Product: How Industry’s Assault on Science Threatens Your Health* (2008).

creasingly driven by the expectation of future economic gain.”⁴ Within the science community, they suggest, organized insistence on recreating the conditions for honest inquiry will require such measures as mandatory disclosures of all financial interests (conflict of interest reporting) and the development of techniques for data-sharing that permit peer review while diminishing opportunities for harassment and other inappropriate behaviors – along with vigilant self-policing regimes. The situation, one might say, reflects only an ordinary instance of a particular community’s need to identify and suppress deviant behaviors that threaten its integrity and values. Theft and fraud, too, are social problems and we develop law and institutions to secure our sense of social honesty. But it is not, of course, simply an intra-community affair. The public consequences of distortion may be quite severe.

Similar alarms were widespread about the Bush administration’s treatment of scientific issues. In what one journalist-reporter characterized as “The Republican War on Science,”⁵ battles ranged over such disparate issues as global warming, day-after contraception, endangered species protection, environmental hazard regulation and politicized controls of advisory committee membership. Sixty-two prominent scientists issued a remarkable call for “Restoring Scientific Integrity in Policy-Making” in February of 2004.⁶ Thousands more signed it subsequently, and the signatories included 52 Nobel laureates, 63 National Medal of Science recipients, and 195 members of the National Academies.⁷ A more recent journalist’s account, “Undermining Science: Suppression and Distortion in the Bush Administration,”⁸ suggested that little changed in its wake.

Politics certainly infected these alarms. The Union of Concerned Scientists, that catalyzed both the petition and the more recent book, is not a neutral body. Conservative authors and columnists have persuasively pointed to similar episodes in Democrat administrations,⁹

⁴ McGarity and Wagner, at 229-230.

⁵ Chris Mooney, *The Republican War on Science* (2005).

⁶ The text can be found on the web-site of the Union of Concerned Scientists, http://www.ucsusa.org/scientific_integrity/abuses_of_science/scientists-sign-on-statement.html.

⁷ http://www.ucsusa.org/scientific_integrity/solutions/big_picture_solutions/prominent-statement-signatories.html.

⁸ Seth Shulman, *Undermining Science: Suppression and Distortion in the Bush Administration* (2008);

⁹ “For the sake of argument, let’s assume that the Bush administration has done all that UCS accuses it of doing. This problem is not particular to Republican administrations—the very linkage of government and science almost guarantees some chicanery. Let’s recall the halcyon days of the Clinton administration. In 1993, Princeton University physicist William Happer was [fired](#) from the Department of Energy because he disagreed with Vice President Al Gore’s views on stratospheric ozone depletion. In 1994, President Bill Clinton [rejected](#) the finding from the Embryo Research Panel of the National Institutes of Health which declared that the intentional creation of human embryos for genetic research was ethical. Clinton simply banned any federal funding for such research.

And in 1993, the EPA used a meta-analysis of a number of studies to find that second-hand smoke caused lung cancer in adult non-smokers and serious respiratory problems in children. That may well be, but the EPA had to put its [thumb on the scales](#) in order to get the result it wanted. The agency included just 11 out of 30 known studies on second-hand smoke in its meta-analysis, and even then found no increased risk to non-smokers at the 95 percent confidence level that had been the traditional agency standard. So the agency simply moved the confidence level from 95 percent to 90 percent in order to get the result it wanted.

At the time, I talked to a member of the EPA’s scientific advisory board, an epidemiologist working at a

and the literature on science, policy and politics is rich with suggestions that the economic importance and political salience of science and technology issues makes them inevitable.¹⁰ As in the case of stem cell research, disputes may often really be about values (e.g., the sanctity of human life, understood to begin at conception) rather than science as such, although what one author describes as “stealth advocacy” may often invoke ostensible science in their support.¹¹ One may add that a Republican administration encounters a civil service likely to be much less sympathetic to its preferences than a Democratic one. Disregard for the work of the civil service could be seen as an understandable reaction to civil servants’ resistance to legitimate political direction. Still, it is striking that the two administrations prior to this President Bush, one Republican and one Democratic, found about as many occasions to invoke the Endangered Species Act *each year* as the most recent Bush administration did through its whole term in office¹² – and the latter, largely under judicial compulsion. Nor had any prior presidency been so marked by the repeated, anguished phenomena of lifetime government scientists resigning jobs that they had not permitted to serve in integrity, with repeated accounts of muffled reports of scientific views and findings.

President Obama made the issue of “restoring scientific integrity” prominent in his successful political campaign, and an applauded theme of his inaugural address. On March 9, 2009, he issued a memorandum for the heads of executive departments and agencies purporting to address these issues. It appears in full in Appendix A to this paper. It assigns to the Director of the Office of Science and Technology Policy, the White House office responsible for coordinating science matters in government, the task of developing recommendations that will produce merit-based (i.e., not political) appointments, use of scientific methods (including peer review as appropriate) in developing information, heightened transparency, and improved protection for dissidents (“whistleblowers”). And skepticism whether this was a change in the service of science or of politics immediately followed.¹³

I

What are the tools law can bring to improve the chance that “reason” will prevail, to diminish the influence of “unreason”? One may start, however briefly, in the realm of private conduct affecting other persons, and then turn to the additional complications of the regula-

leading east coast university who requested anonymity. He told me that he knew it was inadvisable to change the confidence level. He didn't oppose the change, though, because he was afraid he would be kicked off the board if he didn't go along. "I wanted to remain relevant to the policy process," he explained. He was also an EPA grant recipient.” Ronald Bailey, “Why government isn't the best place to look for unbiased science,” reasononline, www.reason.com/news/show/34774.html, (March 3, 2004), visited March 10, 2009. And see the NY Times columns and posts to this point by John Tierney in the New York Times, e.g. “Politicizing Science,” <http://tierneylab.blogs.nytimes.com/2009/02/27/politicizing-science>, visited March 10, 2009.

¹⁰ Roger Pielke, Jr., *The Honest Broker – Making Sense of Science in Policy and Politics* (2007); Daniel S. Greenberg, *Science, Money and Politics* (2001); Sheila Jasanoff, *The Fifth Branch – Science Advisers as Policymakers* (1990)

¹¹ Pielke, *supra*.

¹² *Id.* at xii-xiii.

¹³ Sheryl Stolberg, “Obama Puts His Own Spin on Mix of Science with Politics,” *NYTimes*, March 9, 2009; John Tierney, “Politics-Free Science?,” <http://tierneylab.blogs.nytimes.com/2009/03/09/politics-free-science>, visited March 10, 2009.

tory sphere.

A. *Criminal law*

Using society's earliest and most stringent control over private behaviors harming others, individual or corporate conduct misrepresenting or suppressing data relevant to health, safety or environmental regulation might be made a criminal offense, with punishments calibrated to the likely harms produced by this action and the level of intentionality involved. Regulatory violations could be similarly treated.

In some cases, such behavior seems readily reachable under the existing general provisions of the criminal law. One whose actions deliberately, intentionally, recklessly, even negligently cause the death of another will be convicted of homicide absent some such justification as self-defense or excuse such as mental incapacity. The degree will vary, and with it the punishment, but law's assurance of civil peace starts here. A deer hunter whose shot kills the human standing near his prey has committed homicide if he saw her, understood he ran a significant risk of killing her instead of the deer, yet so preferred the thought of venison on his table that he was willing to take that risk. That he held no malice toward his victim, that he preferred that his shot kill the deer and not her, will be relevant only to the question of degree.

Severe criminal punishment for regulatory violations likely to cause deaths or serious injury is not unknown in the world, although Americans may have some tendency to regard it as the product of a harsh or primitive legal system. China has recently sentenced to death two corporate officials responsible for the use of a melamine filler in infant formula that caused widespread injury and death; three others were given life sentences.¹⁴ This is consistent with a past practice of reacting to particularly damaging scandals – corruption,¹⁵ lax regulation,¹⁶ etc. – with harsh and widely publicized punishments. One can believe the practice should induce caution among persons responsible for decisions like these. Deterrence, whose effectiveness is often questioned in relation to crimes that occur in an environment of poverty, high emotion, or poor education, has its most intuitive appeal in relation to those whose social misconduct is intelligently calculated – and the decisions of corporate managers meet that test. Given the harsh social consequences of their misbehavior, it is hard to see these individuals as merely scapegoats, condemned for public satisfaction and without real expectation that high-level behaviors generally will change, although spotty enforcement may give some credibility to that characterization.

Society's record is generally poor when it comes to applying the general criminal law prohibitions of homicide in the corporate context. Early in 2009, steel company executives are being prosecuted in Italy for homicide on account of several terrible worker deaths resulting, it is alleged, from a deliberate decision to forgo safety measures of known importance. It is not difficult to characterize this situation as an analogy to the case of the deer hunter, “do-

¹⁴ David Barboza, “Death Sentences in Chinese Milk Case,” *The New York Times* January 23, 2009.

¹⁵ Jim Yardley, “Beijing Olympics Building Chief May be Executed for Corruption,” *The New York Times* October 20, 2008.

¹⁶ David Barboza, “China Sentences Former Drug Regulator to Death,” *The New York Times* May 29, 2007.

lus eventualis” as it is known in European criminal law. Aware of a significant risk that worker death might result from their decisions, but caring more for the corporate bottom line, it is alleged, the executives chose to accept that risk. Whether in this instance the charges are justified or rather, as some have argued, the product of prosecutor grandstanding in the wake of what was certainly a terrible and tragic accident, the principal thing to notice in the present context is that it is the *first* such prosecution ever brought on this theory in that country. In the United States as well, such prosecutions are few. Even in cases arising in smaller companies, where outrageous conduct has had *immediately* fatal results to a few *known* workers *deliberately* put in harm’s way, such prosecutions are rarely brought.¹⁷

To the extent specific legislative judgments about criminality have been made in the health, safety and environmental context, they embody varying assessments of criminality that can perhaps be understood politically, but that are normatively outrageous. Federal environmental laws *and* their enforcement treat regulatory violations endangering human life *or* health (including misreporting and other cover-ups) as important felonies.¹⁸ Under federal workplace safety legislation, however, the deliberate disregard of a safety regulation that results in worker death – what in Italy is now being prosecuted as homicide – is only a misdemeanor; prosecutions are rare and prison sentences unknown.¹⁹ And deliberate disregard that *merely* results in serious injury to a worker is not a federal regulatory crime under the OSHA statute; death must have been caused for a misdemeanor to have been committed.²⁰ Although it promoted coordination of environmental and workplace criminal prosecutions, as one means to improve workplace safety, the Bush Administration “declined to support such steps as making it a felony for employers to commit willful safety violations that cause a worker’s death. ... Instead, the administration has emphasized a more collaborative approach, offering

¹⁷ Compare, for example, *The People of the State of Illinois v. O’Neil*, 194 Ill. App. 3d 79 (1990)(homicide charges sustained where workers were repeatedly sent unprotected into unventilated space known to have large concentrations of cyanide gas) with “Death In The Workplace: Companies Still Getting Away With Murder”, <http://spewingforth.blogspot.com/2006/01/death-in-workplace-companies-still.html> (visited January 4, 2009) and David Barstow, “When Workers Die: U.S. Rarely Seeks Charges for Deaths in Workplace,” *New York Times*, December 22, 2003 (<http://www.nytimes.com/2003/12/22/national/22OS-HA.html?ex=1387429200&en=439ea219cc1cff70&ei=5007&partner=USERLAND>, visited January 4, 2009)(small plumbing company not prosecuted despite second death of employee buried in trench being dug in deliberate non-compliance with OSHA safety regulations). “*O’Neil* was the first prominent prosecution of corporate officials for the death of an employee.” Lisa Heinzerling and Mark Tushnet, *THE REGULATORY AND ADMINISTRATIVE STATE* 124 (2006). The *New York Times* articles was an element in a Pulitzer-Prize-winning investigative series, “Dangerous Business,” published in a series of *Times* articles in the winter of 2002-03 and aired on the PBS program *Frontline*. It centered on the 4,600 injuries and nine deaths since 1995 at foundries owned by *McWane Inc.*, a privately held company based in Birmingham, Ala.

¹⁸ “All federal environmental crimes carry potential prison sentences, including up to 15 years for knowingly endangering workers. ... [The Environmental Protection Agency] has some 200 criminal investigators with extensive experience building cases for federal prosecutors. In 2001 alone, the agency obtained prison sentences totaling 256 years.” David Barstow and Lowell Bergman, “With Little Fanfare, a New Effort to Prosecute Employers That Flout Safety Laws,” *The New York Times*, May 2, 2005.

¹⁹ David M. Uhlman, *Prosecuting Worker Endangerment: The Need for Stronger Criminal Penalties for Violations of the Occupational Safety and Health Act*, issue brief for the American Constitution Society, Sept. 2008, http://www.acslaw.org/files/Uhlmann%20issue%20brief_0.pdf (visited Feb. 6 2009).

²⁰ *Id.*

companies increased technical assistance, for instance, on how to comply with regulations."²¹

Prosecutions are more likely for behavior that results in dramatic, unmistakable results in the short term. The Italian theory is being tested in the context of a fatal fire proceeding directly from disregard of important workplace safety regulations. But it would also reach tobacco company executives or asbestos company executives who participated in the suppression of information about the long-term fatal consequences likely to follow the use of their products, lest profits falter. Yet such executives are in the position of bomber pilots rather than infantrymen. Knowing that their actions will kill, they are unaware even generally of the identity of their prey and harder to prosecute, despite the larger number affected, than someone who knows his particular victim. The difficulties are the greater when, as for tobacco and asbestos, one adds long latency periods and near-impossible questions about causation in each particular instance, if not statistically.

Moreover, acceptance that deaths will occur from a course of corporate conduct, in and of itself, could not properly be taken as a sufficient condition for *any* level of criminalization. Intelligent calculation, that may have to accept the likelihood of *some* deaths resulting from a course of conduct, is affirmatively sought in relation to large-scale actions affecting the public. Health and safety regulations are calibrated to an assessment of how much must be spent to save each statistical life; adoption of a regulation will be sharply criticized if it would cost \$15 million for each life expected to be saved. But of course that means that in deciding not to adopt that regulation, the responsible agency is accepting the likelihood that X people will die from the risk not being responded to. Many industrial activities – the building of a bridge, for example, or the manufacturing of a drug – involve a statistical likelihood that some deaths will occur as a result, however great precautions are taken. These actors are no more or less aware just who is destined to die than the person introducing melamine into the food chain or the suppresser of health information about asbestos or tobacco. They cannot be thought to intend the deaths in a criminal law sense.

This consideration may help us understand in a way why we so dilute the moral dimension of economic or industrial decisions that cost lives. We do not want every executive who plans an enterprise for which there is reasonable certainty that some will die in carrying it out to regard herself as a murderer. She may have violated no norm of revelation or conduct, done her best to reduce what the great Holmes once described as the inevitable industrial toll of arms, legs, and lives. Yet having to think oneself a murderer, too, is an attitude that would be useful at the extremes here under consideration. If we do not want all to quail, we should want that for some.

There is, then, a need for considerable caution in this regard. We might wish the deterrence that we hope would flow from possible criminal liability for callously preferring deaths to loss of profit. At the same time we would not wish to inhibit planning behaviors, governmental or industrial, that we would regard as rational or even preferable.

A further reason for caution may be suggested by the difficulty the public may have in distinguishing calculated indifference, as in the tobacco and asbestos examples, from miscalculation. Among the rare American attempts to apply homicide reasoning to corporate behavior was the reckless homicide indictment of the Ford Motor Company for immolations

²¹ Barstow and Bergman, note 18 above.

allegedly resulting from its deliberate decision to design the Ford Pinto without safety precautions that would have prevented them. (Only the corporation was charged, not “responsible” corporate officers.) This suggests the other side of the *dolus eventualis* argument.²² In reaching the design decision that exposed its customers to the risk of immolation, Ford’s engineers had relied on one of many calculations about the probable frequency of injurious outcomes from the Pinto’s design in relationship to the “value” of those outcomes and to the cost of varying its design. Ford was intending to produce a very affordable car; its calculations, although readily caricatured as outrageous, produced a car whose *overall* safety record was in line with other models in its price range. Ford disregarded no existing regulation or law in acting as it did. Nonetheless, the cost savings of the particular design decision Ford made, about \$12/car, were so slight as to obscure the inevitability, even desirability as a general matter, of calculations such as Ford had made. Although Ford was acquitted of the criminal charges, it lost millions of dollars in damage awards, many “punitive,” returned in civil actions against it by victims or their families.

Yet while these considerations suggest acceptance of justifications different from those we would ordinarily consider in relation to individual acts, it is hard to find in them a reason for inaction. Where existing regulations are deliberately violated, in awareness of the risks entailed, it is hard *not* to find serious criminality in the deaths or serious injuries resulting. And yet (as seems often the case for behavior by those who are the most likely to be deterred by awareness of its criminality, the social and educational elite), use of criminal sanctions is decidedly exceptional. In this context, we have basically suppressed the front-line incentive on which we ordinarily rely for controlling harmful social behavior.

B. Punitive damages

Permitting a jury to assess punitive damages in such a case, as was done against Ford, is not as severe an inhibition on corporate decisionmaking as criminal punishment of the executives responsible for decision would be. The executives may feel a blemish, could even feel required to resign their positions – perhaps followed, however, as has been the recent custom in the face of *financial* mismanagement, by a “golden parachute.” But the verdict will expend itself on insurance companies, on shareholders, on customers who may have to pay higher prices, on employees who may be faced with lessened job security or worse job conditions, or on creditors in the extreme case of induced bankruptcy. Rewarded for corporate profitability, and without corresponding levels of *personal* risk – or, perhaps, balancing corporate survival against workplace hazard – the executive may not think the possibility of punitive damages on some future occasion to be a significant factor. If she is making rational calculations based on her own interests and benefits, the balance will favor inappropriate risk-taking. Probably juries’ retrospective assessment of just how such calculations are made contributes to the remarkable size of many punitive damage awards by American juries.

To be sure, not all executives or corporations will be motivated simply by the maximization of personal or corporate financial well-being. A striking illustration can be found in the American sewer pipe industry. Two firms headquartered in Birmingham Alabama, the American Cast Iron Pipe Company and the McWane Company, are dominant players in the industry. As revealed in a prize-winning story appearing in the New York Times and on

²² Reckless homicide and *dolus eventualis* homicide involve similar, if not quite identical, states of mind.

PBS's program "Frontline,"²³ management styles at the two companies could not have differed more. ACIPCo, its management initially informed by religious principles and eventually committed to employee ownership, has few workplace injuries or regulatory violations; turn-over is very slight, and any job that does open has a long waiting line. At least until the 2003 exposé brought massive publicity and until stiff penalties were subsequently inflicted for its practices, McWane appears to have been run solely for the profits of its owners. As a sequel story remarked about what seems to be the most recent conviction, "Prosecution witnesses, including several former foundry supervisors, depicted a brutal and dangerous workplace at Atlantic States, in Phillipsburg, N.J. They told of rigged smokestack tests, of polluted wastewater dumped under cover of night, of regulators stalled at the front gate while flagrant safety violations were hidden. Workers, they said, were blamed for accidents even when shoddy equipment or inadequate training was the real cause. Prosecutors called it 'the McWane way.'"²⁴ Wages were low, working conditions dreadful, and turnover extraordinarily high.

Of course law does not purport to reward outliers at the saintly end of the range of human conduct; it seeks to constrain the outliers at the other end. Recognition there must be that some risk-taking inheres in the nature of the corporate enterprise – as, indeed, in hunting there is always the risk that one's shot, off-target, will injure a person not known to be in the line of fire. The issue is identifying socially unacceptable levels of risk-taking that greatly imperil the well-being of others, and finding correctives for it. Appropriate levels of criminalization of personal conduct seem more likely than the prospect of punitive damages to accomplish this. The risk that – as perhaps in Ford's case – punitive damages will be used in reaction to decision processes we generally prefer, certainly tolerate, to be employed should stand as a caution against them.

C. *Tort damages*

Any crime is also a tort. One should not doubt that the corporate or personal violator of regulatory provisions may be held to answer for damages ensuing – although, again, the existence of insurance and such difficulties as establishing causality will reduce the resulting signals for caution. Holmes' "bad man," calculating in these circumstances, will again tend to overvalue the profits to himself in relation to the harms to others, as seen through the discounted lens of possible future liability.

Here one encounters the additional rationale, so prominent in contemporary thinking about tort, that tort law should work to reflect the true full costs of social activity to the consuming public. Here violation of standards of conduct is no necessary concern. If a given enterprise will take four lives, the value of those lives should be reflected in the costs of the enterprise just as its other raw materials will be. Placing these costs on the enterprise, it is thought, will encourage steps to avoid them if possible, as well as more accurately inform the public of the true costs of what it is buying.

²³ See note 18 above.

²⁴ David Barstow, "Guilty Verdicts in New Jersey Worker-Safety Trial - New York Times," April 27, 2006, <http://www.nytimes.com/2006/04/27/us/27mcwane.html?scp=6&sq=McWane&st=nyt>, visited Feb. 6, 2009. See also Uhlman, note 19 above. David Barstow was the lead reporter in the Times-PBS investigation, and Mr. Uhlman was the chief federal prosecutor at this trial.

Of course it is possible, and some believe, that this already occurs in the employment context through the payment of a premium to employees who must accept risk as an element of their work.. On this view the employees of McWane should be receiving much higher real and implicit wages than the employees of Acipco, and of course this is not so – actually, real wages at Acipco are higher. The two companies hire from different labor markets, Acipco among skilled blue collar workers, McWane among the desperate.

Such events depend not only on a worker's ability to extract a premium – that she has equivalent alternative employment possibilities and that the labor market is not oversupplied – but also on her knowledge that she is facing risks. A worker might be able to see and evaluate immediate mechanical hazards for herself, although even this presumes a level of knowledge not all will have. But this is not possible for the sorts of risks that have long latency periods, with demonstrable statistical but not personal causality. Employers thus have a cost-saving incentive not to share with their employees the information they may have about such risks. Even if employees are fully aware of risks, optimism and other distorting factors may lead them to undervalue them. And for other settings where suppression of risk information and the like is financially advantageous – apprising customers of the risks of tobacco, for example – there is no other place to put the true cost than in price. And there is every incentive not to do so.

In the particular context of workplace hazards, employer undervaluation is compounded by worker compensation laws that defuse tort liability, substituting schedules of payment that omit important elements of harm (pain and suffering), provide less than full wages (to reduce incentives for worker malingering, certainly also a risk), and may fail to be kept current with levels of inflation and other like economic changes. The employer sees only some, hardly all, the true costs of its safety failures.²⁵

For the long-latency, problematic causality contexts presented by pollution, industrial chemicals, airborne particles (including asbestos), tobacco, pharmaceutical side-effects, and the like, the retrospective and individualized character of tort relief further saps the “true cost” rationale of meaning. Even to the extent liability may be imposed, it reflects itself on current actors, not those whose decisions may have produced the harms complained of. This is hardly to deny that those harmed have suffered a burden from which they deserve to be relieved – although, again, causality issues will make it difficult to say with precision who has been harmed – only to deny that the current liability could have been expected to have a significant bearing on the motivations of those whose behavior resulted in the risks, or on the cost of what they put on the market when they put it there.

D. Regulation

Private law systems cannot be relied upon to generate incentives for disclosure of the risks private actors may impose on others in pursuit of personal gain; if anything they create incentives for concealment, not disclosure. And this is particularly the case for risks that are latent, not immediate in their effects. Criminal law can create deterrence, reinforcing common morality, but only if it is calibrated to the moral seriousness of offenses; and for the behaviors of concern here that calibration is generally missing. Contemporary law's conventional weapon for requiring private persons and corporations to disclose and to constrain risks

²⁵ See generally John Fabian Witt, *The Accidental Republic*.

of this character, rather, has been regulation, backed with requirements to provide regulators with information and sanctions for non-compliance, fines and orders, that are imposed outside the criminal law. *Malum prohibitum* (a characterization which may itself be a symptom of failed courage when it is used in situations in which lives have been deliberately and significantly imperiled, and perhaps taken), not *malum in se*. No jail time.

The proactive nature of regulation, however, has perhaps compensating advantages. In addition to regular disclosure of information – to an agency, to those (such as workers) immediately concerned, or to the public at large – pre-approvals may be required. Specific conduct (such as implementation of safety measures at a worksite) may be required. Here, too, of course, there may be private incentives for non-disclosure, for efforts to suppress or distort information. Compliance remains an issue – and securing that in turn requires public resources for enforcement that have not always been forthcoming. But in prospect, at least, the burden of looking forward has been placed directly on the private actor.

Regulation can have a retrospective quality too, where it depends on inspections to ascertain and sanction past violations of regulatory standards. Here it has its greatest similarity to criminal law, or to tort law in the private sphere, and one may think that it shares their weaknesses. “Command and control” regulation, as the police approach has been characterized, has faced growing criticism in recent decades – for its inefficiency (looking backwards as it generally does), for its heavy requirements on public resources, and for its emphasis on identifying non-cooperators rather than encouraging compliance.

Increasingly one finds reliance on measures that leave more room for individual choice, and that stress incentives rather than disincentives. Cap-and-trade systems for pollution control create positive incentives for plants that can cheaply control their emissions to do so, since that creates a corporate asset that can be sold to others. A toxic resource inventory that merely put in public view data about the materials being released to the atmosphere, land and water created reasons for local industry to protect the local environment.²⁶ Offering to trade eased enforcement for cooperative efforts to identify and control workplace hazards reduced workplace injuries in Maine’s 20 most hazardous workplaces by a staggering __ percent, while also reducing the personnel requirements of the state office *and* transforming state employees from policemen to safety engineers, a more satisfying role.²⁷ In programs like the European REACH regulation, possibly hazardous chemicals cannot be used in quantity without advance clearance; as, in drug manufacture, pharmaceuticals may not be placed on the market without elaborate testing and preclearance regimes.²⁸

Standard-setting is perhaps a middle ground. Until the federal Environmental protection Agency [EPA] establishes the cap for cap-and-trade systems, with perhaps also the future rate of decline in the cap that gives the approach much of its force and attractiveness, no regime is in place – albeit, once a cap is set, the firms acting under it will be free to innovate or purchase “rights.” Until it sets a national ambient air quality standard for a given pollutant, similarly, the atmosphere remains a cost-free commons for that pollutant; subsequently the pri-

²⁶ Karkainen

²⁷ Kelman? Maine 200.

²⁸ Farber

vate firm may choose its own means for compliance. Setting targets, many have come to believe, is preferable to instructing the subjects of regulation exactly how they are to behave. Standards, not rules. But targets cannot be set without information. “Best science” is a typical statutory command for their basis.

All these measures, like “command and control” police enforcement, like license application procedures whether for a new drug or a nuclear power plant, depend at the outset on accurate information – information generally not developed independently by government but to be supplied by those subject to regulation. That is emphatically the case for the newer forms of regulation, that presume submission of a continuing stream of data. “Bending science” and accurate science thus become matters of direct concern.

Directly providing false data to the government is a criminal offense; failure to provide required data, a regulatory one. Here the issues are detection and seriousness of consequent enforcement efforts. Other private techniques for “bending science” or creating unwarranted doubt, as chronicled in the recent book-exposes,²⁹ may keep away data the government does not yet know to require, challenge the validity of data known to be correct, attack the credibility of scientists responsible for proper studies, bankroll public relations campaigns to create an impression of doubt and the need for further study, and so forth. These are unlikely to be regulatory or criminal offenses in themselves, and it must be obvious that people acting in complete good faith will sometimes find reason to behave in all these ways – may yet find no sufficient reason to reveal data still uncertain and in development, may have a solid basis for doubting others’ results or their credibility, etc. The issue is, at root, one of good faith. Engaging, in effect, the adversary process with the knowledge that death or serious harm to others is a likely effect of the delay it will produce is not an innocent activity. When endowed with sufficient knowledge of likely harm to others, those who engage in these tactics to postpone regulation or public knowledge they know to be warranted, albeit potentially harmful to their profits, can be said to fall within the reach of “*dolus eventualis*” reasoning at criminal law.

II

Thus far, the discussion has assumed that government behaviors may be affected but not infected by “bending.” The question for discussion now is how the timeliness and internal integrity of government regulatory decision-making can best be promoted. Here the issues are ones both of procedures employed, and of the place of politics in the determinations made. The focus will be on rulemaking – the generation of regulations that if valid have the force and effect of statutes – rather than adjudication, given the greater centrality of policy issues of broad interest in that context. And the matrix will be that suggested by President Obama’s recent directive on restoring scientific integrity, which focuses in turn on selection and retention of candidates, internal procedures including “well-established scientific processes” such as peer review and transparency, protection for dissidents, and White House relations.

²⁹Note 3 above.

A. Selection and retention of candidates

The executive order directs that selection of candidates “should be based on the candidate's knowledge, credentials, experience, and integrity.” Left off this list of desirable qualities are such typical criteria for political appointment as loyalty, and known predisposition to agreement with the President/agency head's policy preferences. One might find room for these qualities in the interstices of “credentials, experience, and integrity,” and appraisals of President Obama's own appointments to scientific posts have not been lacking in suggestions that they have been used.³⁰ Nor can one imagine than persons possessing “credentials, experience, and integrity” lack political commitments, or predispositions on issues in play in the scientific community respecting which final judgment has yet to be reached. In his short recent book, “The Honest Broker,” Roger Pielke, Jr. valuably distinguishes between the kinds of political issues that can be appropriately resolved by reliable inquiry into observable facts – is a tornado approaching? “tornado politics” – and others that cannot, “abortion politics.”³¹ To the extent reliable inquiry cannot produce uncontested answers – very often the case in situations, say respecting climate change, where politicians are nonetheless moved to act – the engaged scientist is faced with the choice between acting as “stealth advocate,” acting on the basis of personal belief or preference, and acting as “honest broker,” stating clearly the alternatives and their associated uncertainties and implications.

One mechanism that might be thought useful to encourage “honest broker” behaviour is a definition of function to separate, so far as possible, the responsibility for appraising those issues, such as risk, for which scientific inquiry may be helpful from the questions what to do about such matters once identified. Such a separation is explicit, for example, in the standard-setting activities of the Codex Alimentarius Commission under the aegis of the FAO and the WHO. This body undertakes setting international standards for food safety to ensure human health protection, in light of the best available scientific data.³² Overall risk analysis is conceived as comprised of three functionally separated elements: risk assessment, risk management, and risk communication. The allocation is in the service of creating a zone in which “scientific integrity” may be ensured (risk assessment); another in which political judgments are made and from which guidance and standards emerge (risk management); and a third element of systematic, maximally sustainable transparency that may build public trust (risk communication). Risk assessors are encouraged to identify the data, assumptions and uncertainties bearing on their assessments, and the characteristics of the hazards they identify, and to report their conclusions in a manner permitting peer and public review. Risk managers, taking a range of economic and political factors into account, are to respect “precaution” and public attitudes towards risk in deciding how best to respond to the assessments thus received; again, their processes and reports should be “transparent, consistent and fully documented.” Both assessors and managers, while respecting “legitimate concern to preserve confidentiality,” are encouraged to communicate their activities and conclusions with the greatest accuracy and transparency possible, so as to strengthen working relationships and build public trust.

³⁰ E.g., John Tierney, “Findings: Politics in the Guise of Pure Science,” NY Times, D1, February 24, 2009.

³¹ N. 10 above at 40.

³² Its Working Principles for Risk Analysis for Food Safety for Application by Governments, CAC/GL 62-2007, is attached as an appendix.

This intellectual separation is intuitively appealing, and certainly sends useful signals to those minded to heed them. It could be seen to reinforce the “honest broker” vision of scientist function. But as appears amply in the literature, the uncertainties of outcomes and predispositions of analysts confound its reliability.³³ “Stealth advocacy” can readily appear at the level of risk assessment, whether or not risk management is identified as a separate task. Indeed, much of the (frequently industrial) pressure for “risk assessment” as an initial, distinct, preparatory step to “risk management” can be understood as an instrument of delay. The EPA should not be required to coordinate with the Department of Defense in assessing the “toxicity of perchlorate, a component of rocket fuel detected nationally in drinking water, breast milk, and produce,” one activist, consumerist science NGO has been argued, as this “could mean that the DOD and its contractors are liable for potentially billions of dollars in cleanup costs. The DOD has long sought to weaken any scientific standard that would mandate cleanup of perchlorate contamination.”³⁴

The executive order does not, and perhaps could not, take this kind of approach to the “integrity” problem. Some disposition to hear all sides—to enlist “honest brokers”—might be suggested by the President’s appointment to be his Secretary of State of his principal political opponent, and his reputation as a person committed to hearing all sides. His expected nomination of a former colleague, Professor Cass Sunstein, to head the office most directly concerned with domestic regulation, the Office of Information and Regulatory Analysis [OIRA] in the Office of Management and Budget [OMB], puts in that important post an academic whose recent writings have repeatedly stressed the importance of hearing all sides for sound decision.³⁵

Recent years have seen both a significant expansion of agency control mechanisms in the White House itself and much enlarged penetration of “political clearances” into agency bureaucracies. While the controls centered in OIRA, discussed further below, have attracted the most scholarly and congressional attention, Lisa Bressman and Michael Vandenbergh’s groundbreaking account of the EPA-White House interface from the perspective of EPA political appointees dramatically illustrates the number of White House voices (in both Republican and Democratic administrations) purporting to exercise “presidential control.”³⁶ President Obama’s appointments to White House positions—for example, a former EPA administrator, Carol Browner, to a new position as White House Coordinator of Energy and Climate Policy, “climate czarina” – suggests that this reality may persevere. The prompt annulment of President Bush’s Executive Order 13422, on the other hand, withdrew certain personnel requirements for responsibility *within* agencies that might have been seen as additional political con-

³³ E.g., Jasanoff, *The Fifth Branch*, n. 10 above.

³⁴ “Scientific Integrity,” a submission of the Union of Concerned Scientists to the public comment files respecting revision of E.O. 12866, see n. ___ below, <http://www.reginfo.gov/public/jsp/EO/fedRegReview/public-Comments.jsp> (visited March 12, 2009), citing Sass, J. 2004. U.S. Department of Defense and White House working together to avoid cleanup and liability for perchlorate pollution. *International Journal of Occupational and Environmental Health*(abstract). 10:330-334.

³⁵ Citations to, e.g., Republic .com; recent piece on cascades.

³⁶ Lisa Schultz Bressman & Michael P. Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 MICH. L. REV. 47, 47-52 (2006).

trols.³⁷

The increasing scope of political clearance for persons having policy responsibilities has attracted rather less attention, but certainly renders American “administration” more political than might be expected in the strong civil service regimes of many parliamentary democracies. Probably the move in this direction began during the presidency of Jimmy Carter, when a reform of the civil service laws created in the upper echelons of the civil service a Senior Executive Service, those persons responsible for policy direction and other matters involving substantial discretion. In the United States as in European democracies, important federal bureaus, elements perhaps of a cabinet department, might be under the direction of a senior civil servant, a permanent government employee rather than a political appointee.³⁸ The new law made them more subject to reward and punishment, reassignment and direction, than they had previously been. While these persons were still nominally in the civil service (that is, they are permanent employees), it is perhaps not surprising to learn that with the enlarged possibilities of reward and discipline from above, practices of political clearance developed:

- The White House office responsible for vetting appointments within government for, inter alia, political acceptability grew from thirteen to twenty-one during the quarter century between 1982, the second year of the Reagan administration, and 2008, during the second term of the second Bush administration. The office peaked in 2001 with thirty-five employees.³⁹
- A Department of Justice investigation found that Monica Goodling, the DOJ’s White House Liaison and Senior Counsel to the Attorney General, “improperly subjected candidates for career positions [in the Justice Department] to the same politically based evaluation she used on candidates for political positions, in violation of federal law and department policy.”⁴⁰

³⁷ Exec.Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 23, 2007), essentially required every agency to place control over its rulemaking operations in the hands, not of the agency head, but of a staffer directly responsible to the White House.

³⁸ The classic study of their work, written at about the time of this change, is HERBERT KAUFMAN, *THE ADMINISTRATIVE BEHAVIOR OF FEDERAL BUREAU CHIEFS* (1981).

³⁹ Compare *FEDERAL/STATE EXECUTIVE DIRECTORY 1985* (Carroll Publishing Co. 1985) with *CARROLL’S FEDERAL DIRECTORY 2008* (Carroll Publishing Co. 2008).

⁴⁰ U.S. Dep’t of Justice, *Investigation of Allegations of Politicized Hiring by Monica Goodling and Other Staff in the Office of the Attorney General 1*, 135 (2008), available at <http://www.usdoj.gov/oig/special/s0801/final.pdf>.

Similar implications arise from presidential reactions to congressional requirements of relevant expertise for important policy positions. In the wake of the Katrina disaster and the deficiencies in Federal Emergency Management Administration management it revealed, Congress passed statutes requiring that the person appointed to head FEMA be a person experienced in the management of complex institutions and disaster management. Department of Homeland Security Appropriations Act, 2007 § 611(11), 6 U.S.C. § 313 In a later statute, it directed that appointees to high office in the United States Postal Commission have similar experience-related backgrounds. Postal Accountability and Enhancement Act of 2006 § 501, 39 U.S.C. § 202. In signing the lengthy statutes including these provisions into law, the President identified these two provisions in particular, as against many he accepted, as unconstitutional infringements of his authority to nominate or appoint anyone he chose. Statement by President George W. Bush Upon Signing H.R. 5441, 2006 U.S.C.C.A.N S49, S52 (Oct.

All of this, one might understand, is intimately connected with presidential claims to control the work of executive government – then turned not to administrative, but to political ends. And it can be thought a consequence of legislative irresponsibility in Congress, of the increasing practical importance of regulation to the American economy (and hence to politicians), and of the American habit, common in recent decades, of putting one political party in power in the White House and the other in power in Congress. For Presidents facing a politically hostile Congress, the incentive – the need – to take active control of the permanent government bureaucracy is clear. The issue may be the nature of the control; and here the quality and understanding of persons appointed, more than legal rules – the understood ethos of the administration – may be the most important.

One area of personnel control that has long been thought important, in science as in politics, is the subduing of personal financial advantage – not power, now, so much as greed. Both formal conflict of interest requirements and attention to the loyalties likely to persevere from prior activities and commitments operate here. The presuppositions of a civil service that invites transition between public and private life, as the American one does, at both leadership and staff levels, creates inevitable tensions. These are dealt with, but imperfectly, by financial controls and by restrictions on “revolving door” service. One President appoints construction executives to head the Occupational Safety and Health Administration, another industrial safety professionals with union connections. Each on leaving office may return to a post similar to that from which she came; either may be preferable to appointing a skilled administrator who is inexperienced about issues of workplace safety; both may return to private life with increased skills and understanding that in fact serve to aid their clients’ attention to industrial safety realities. And for both questions can be raised about the “objectivity” of their attention to programmatic issues.

Conflict of interest regulation and revolving-door control have been recurrent issues in the US. President Obama made strong commitments to avoiding appointments questionable on such grounds, and some of his initial designees withdrew in embarrassment after compromising connections or lapses came to light; but (as with Secretary of Treasury Geithner) it is not surprising that some of his appointees do bring with them prior commitments or experience that seem likely to influence their judgment. Attention to such issues is perhaps easier, and more readily regularized, at lower levels – as, for example, assurance of balance and lack of conflict in the advisory panels that work with the Food and Drug Administration or the EPA. The literature is replete with examples of settings in which these efforts have not been successful and, indeed, it may be hard even in the academy to find a pharmacological expert who has not had financial dealings with the drug industry. The FAO-WHO Codex Alimentarius process already mentioned commits to having experts involved in risk assessment publicly known, transparently selected, and free of potentially disabling conflicts of interest. The FAO questionnaire on the subject explores in considerable detail, for individuals and also their families and business connections, a wide range of financial and other interests that could raise such questions – seeking explanations where potential conflicts arise, presuming

4, 2006) (“[the statute] purports to limit the qualifications of the pool of persons from whom the President may select the appointee in a manner that rules out a large portion of those persons best qualified by experience and knowledge to fill the office. The executive branch shall construe [section 611] in a manner consistent with the Appointments Clause of the Constitution.”); Statement by President George W. Bush Upon Signing H.R. 6407, 2006 U.S.C.C.A.N. S76 (December 20, 2006) (making an almost identical statement).

consent to disclosure of the document, and suggesting that disqualification may occur if disclosure is refused.⁴¹ But with disclosure, appointments are not disqualified.

⁴¹ The questionnaire is attached as Appendix C.

B. Procedures

The noted American scholar Jerry Mashaw, writing about procedural choices in the context of administrative adjudications affecting individual rights, persuasively argued the point that there is no “best” answer. He identified three perspectives from which this question could be approached: individual fairness, affording maximum attention to the process claims of the individuals whose rights are at stake; professional integrity, considering *both* the arguable contributions made to sound decision by the professional commitments of the deciders *and* the possible interference with these contributions that could be created by procedural details⁴²; and bureaucratic rationality, which would value the confinement of likely error to cases “on the borderline” and efficiency – low cost in relation to the issues to be determined. [Quote]

And, of course, procedural requirements may not only contribute to more accurate or efficient, or fair outcomes. They may also provide “handles” that participants eager to add delay or expense to government determinations can use to achieve that. As long-time American Congressman John Dingell is reported once to have observed, "If you let me write the procedure, and I let you write the substance, I'll screw you every time." Many believe that the notorious slowness and infrequency of rulemaking on issues of occupational safety and health is the product of industrial success in securing cumbersome and expensive procedural requirements in a law whose purpose of improving worker safety they could not directly oppose. Claims to improving fairness and accuracy were a different matter.

So the same kinds of trade-offs as Mashaw remarked for the setting of adjudication may be implicit in providing procedures for standard-setting. Even if we start with the proposition that the standards to be set should reflect as is best possible the state of scientific knowledge, we can identify significant elements that will influence the timeliness, accuracy and acceptability of the outcomes. Rulemaking in American law is a public procedure, with agencies statutorily required to solicit public comment on any proposal before acting on it, and to explain their reasoning in response to comments and other materials when they do act. American caselaw has largely established propositions central to President Obama’s recent executive order, that

- (1) ... (c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;
- (d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions.

⁴² Examples might be teachers or doctors, whose professional commitments have often been relied upon. In the welfare context, the proceduralization of welfare administration in the wake of *Goldberg v. Kelley* [cite] broad a shift in hiring from social workers, professionally committed to the wellbeing of their clients, to case-workers with an eye to the bottom line. [cite]

(e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised ...

And as long as three decades ago, a thoughtful writer celebrated the proposition that judicial review of rulemakings, requiring what our courts have called a “hard look” at matters in controversy, armed those within an agency who cared about reasoned decision-making (i.e., acts of judgment) with a weapon with which to influence those who did not (i.e., prefer acts of will).⁴³ The other side of this, however, has been the plaint recurrent in the American literature that the “hard look” has produced ossification – has made it too costly for agencies to produce regulations, and provided the opponents of warranted regulation with too many tools by which to delay or obstruct it.

Perhaps nowhere in American administrative law have ossification concerns been voiced more loudly than in connection with the issues of peer review and information quality – both issues on which the executive order appears to make commitments. Does peer review add another step to what is already a time-consuming, resource-expensive process? In the realm of “pure science” (or review for publication in science journals), peer review might be characterized as merely the process that happens (assessments and efforts at replication that conduce to validity), and the passage of time is not so relevant as a factor. Add financial or power consequences to truth-seeking, and social consequences to delay, however, and matters become considerably more complex. If it is to be conducted outside government (that is, using scientists whose connection with public service is no more than as a special employee), can adequate assurances be attained that the reviewing peers will not be interested ones? The Bush administration’s efforts to put peer review mechanisms in place were widely criticized for their perceived tendencies to produce delay and to arm regulatory opponents without notably improving regulatory outcomes. A so-called “Information Quality Act” was inserted by stealth in an omnibus budget statute during the Bush administration, and seen by many to have similar tendencies. “More study is required” is notoriously an obstacle to action – appropriate at times, but readily wielded in a wider range of circumstances.

One does not too readily find enforceably mandated procedures like the American ones for the adoption of regulatory measures in other political systems. The European Union engages in advanced public consultations about proposed legislative actions; for subsidiary legislation corresponding to American rulemaking, however, it deploys the somewhat obscure process of comitology, which lacks similar commitments.⁴⁴ In the development of Codex Alimentarius standards, FAO-WHO employs a process resembling American notice and comment rulemaking, with some exposure of data, opportunities for comment by interested persons, and an ostensible commitment to objective, science-based judgment. Adoption, however, is political, by agreement of the member states; the extent to which transparency is actually achieved, by documents or through the Internet, appears uncertain (perhaps especially at later stages); and it does not appear there is any objectivized test of the reasoning that may be employed. In parliamentary democracies the responsibility of ministers to the Parliament is often, if not invariably, accepted as a sufficient basis for their exercise of rule-

⁴³ William F. Pedersen, Jr., *Formal Records and Informal Rulemaking*, 85 YALE L.J. 38, 59 (1975).

⁴⁴ ABA study.

making powers.

Recent, broadly grounded studies by members of the science community have emphasized the positive contributions of embracive participatory processes to the quality as well as the acceptability of judgments made in contexts like these.⁴⁵ Building on the dominant ethic of scientific inquiry – the full reporting of approaches, data, reasoning and results, with open acknowledgment of and attempts to frame uncertainties – these studies stress transparency and candor as root values of the iterative processes they imagine. Of course certain realities intrude when translating the conditions of scientific inquiry to the world of government action. Securing the cooperation of commercial participants, often essential, may depend on effective capacity to assure them that information they provide will not be revealed to competitors or in other respects imperil their interests. Government actors will not be disposed or able to await the definitive resolution of all issues in the face of needs for action, not merely knowledge. Not every participant in a process will be motivated simply by the pursuit of accurate understanding. Concerns for efficiency, and for protection against manipulative uses of opportunities afforded for participation, have consequent force.

A further complication is introduced by the frequently remarked variations between expert and public evaluations of risk – variations which no society committed to democracy can ignore. The observable differences in public willingness to accept risks of varying sorts, even when openly and reliably defined, will produce policy outcomes varying from those that straightforward comparison of objective risk levels would suggest. Motorcycle riders will notice no cognitive dissonance as they campaign vigorously against nuclear power. These are issues that might be addressed by education; but while certainly susceptible of political manipulation, they reflect preferences that cannot be discredited.

C. Central government controls and politics

An entirely separate issue, and the one that initially catalyzed this writing, concerns the place of political controls, and perhaps especially centralized executive political controls, over the outcomes of standard-setting activities. American arrangements for the allocation of executive authority typically place responsibility for science-based decisionmaking in civil-service-dominated agencies rather than the political White House. When the legislature has empowered a particular organ of government to create regulations – subsidiary norms – to carry forward a statutory scheme that imagines technical or scientific judgments being made, what is the appropriate reach of centralized executive oversight or control?

In the spring of 2008, the public became aware of disagreements between the Bush White House and the Environmental Protection Administration [EPA] about the level of ozone exposure appropriate for national ambient air quality standards to protect forest growth and other “secondary” targets of protection from harm by air pollution. (“Primary” standards are set for public health concerns.) Reflecting the differences they understood between the needs and vulnerabilities of human and forest lungs, the various scientific advisory committees and bureaucratic decisionmakers within EPA had settled on an ozone level marginally differing

⁴⁵ Thomas Dietz and Paul Stern, Eds., *Public Participation in Environmental Assessment and Decision Making* (National Research Council 2008); Jason Chilvers, *Deliberating Competence: Theoretical and Practitioner Perspectives on Effective Participatory Appraisal Practice*, 33 *Science, Technology & Human Values* 421 (2008)

from the primary standard. It would have been somewhat more stringent than the primary level but also with a more forgiving measurement interval.

These standards are to be set following the public procedures of the Clean Air Act for rulemaking, procedures building on but somewhat more stringent than those of our Administrative Procedure Act. (In many European countries, the development of similar measures would be described as subsidiary legislation or perhaps ministerial decrees; in the EU, as implementing measures.) Under these procedures as currently understood, the public receives notice of a proposed rule and access to the data and reports underlying it, and any person interested to do is able to submit additional data and to comment on the proposal; the agency must then explain its decision in some detail and, as already indicated, its reasoning is subject to relatively close scrutiny on judicial review.

The EPA's Administrator, a politically responsible official comparable in dignity to a Cabinet Secretary and who by statute is given the authority to decide such matters, was prepared to accept and act on the advice he had received from his staff. Before he could do so, however, contemporary arrangements (established by the President for White House coordination and oversight of regulatory activity) required him to seek clearance from an office in the President's Office of Management and Budget, the Office of Information and Regulatory Affairs [OIRA]. OIRA initially sought reconsideration of the matter, suggesting that the primary and secondary standards would most efficiently be identical – set at the somewhat more permissive level already determined for the primary standard. EPA staff generated a response detailing why, in their judgment, the best scientific evidence available about the differing vulnerabilities of humans and forests required differing standards under their statutory responsibilities. The EPA Administrator indicated to the White House, then, that he intended to stand by his staff's judgment. At this point he was directed – told President Bush had decided – that identical standards must be adopted. The Administrator acquiesced.

The resulting blizzard of newspaper stories and congressional inquiries suggested that something untoward had occurred. The relevant statute, placing the responsibility for this decision in the Administrator and not the President, both assumed and required that the decision would be made in accordance with the best available scientific information. Neither the President nor his agent OIRA has the resources or expertise to do good science on such an issue. Moreover, the relevant statute precludes using economic cost/benefit, as such, as a decisional consideration. (While this proposition might seem questionable as a policy matter, it had underlain our Supreme Court's willingness just a few years earlier to accept the significant law-making authority the statute confers on the EPA's Administrator.⁴⁶ Permitting EPA to make political trade-offs rather than base its actions on ostensibly objective judgments about best science would heighten concerns about the constitutionality of conferring this law-making authority on unelected officials.⁴⁷) Suspicions were rife that the White House judg-

⁴⁶ *Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457 (2001) (“While Congress need not provide any direction to the EPA regarding the manner in which it is to define ‘country grain elevators,’ which are to be exempt from [certain statutory requirements], it must provide substantial guidance on setting air standards that affect the entire national economy.”).

⁴⁷ Cf. *Boreali v. Axelrod*, 71 N.Y. 2d 1 (1987) (New York's Public Health Council authorized to consider only public health factors in adopting a regulation controlling smoking in public places; it lacks the “open-ended discretion” to construct “a regulatory scheme laden with exceptions based solely upon economic and social concerns.”)

ment about ozone was animated by raw political concerns for the well-being of favored industries; or if not that, certainly by the factors of economic cost that the statutes had excluded from the Administrator's consideration. Congressional committees demanded, and the White House adamantly refused to provide, a variety of documentary evidence and testimony on the issue. The standard was issued in the form the White House had insisted upon, and in that form will be subject to judicial review.⁴⁸

That the back-and-forth became public is due in substantial part to the increasing availability of information about governmental regulatory activities on the Internet. The EPA has been one of the leading agencies in developing public Internet data-bases associated with its rulemaking activities. As a matter of the APA's text, the obligations to expose matters concerned with rulemaking appear to be rather slight. Nonetheless, judicial decisions and the realities of our Freedom of Information Act have resulted in thorough agency exposure of the scientific reports or data on which rulemaking decisions may be based, as well as commentary received from outside the agency. The idea that this should happen is uncontroversial, and is strongly voiced in President Obama's recent executive order. To the extent such information is made available and searchable on the Internet, as increasingly it is, citizen monitoring is facilitated. And, responding in part to commitments made in the OIRA mandate, the computerized database for the ozone rulemaking quickly included much material revealing the back-and-forth that had occurred.,

The bureaucratic structures President Bush employed in interacting with EPA did not originate with him, but have been steadily developed by American presidents at least since the administration of Richard Nixon, most notably by Ronald Reagan and William Clinton.⁴⁹ Their current expression is in Executive Order 12,866, an order initially created by President Clinton and then somewhat modified by President Bush. The order, in basic outline, creates three stages for agency consultation with the White House during rulemaking: first, consultation with the White House about their rulemaking priorities (the "regulatory plan," which is published annually in advance of any particular proposals); and then draft and final analyses of particular rules to be proposed and perhaps adopted in carrying out the plan. For the latter stages, it directs agencies, to the extent consistent with law, to engage in structured analyses of the projected costs and benefits of rulemaking proposals, assessing the projected costs and benefits of alternative approaches and choosing that policy which maximizes benefits in relation to costs and in other respects conforms to presidential policy preferences. The intensity of this effort and of OIRA's supervision of it is to vary with the importance of the rule; the greatest effort is required for proposals likely to add \$100,000,000 or more annually to industrial costs or in other respects have a major economic impact.

Although not statutory, the existence and general shape of this regime have been accepted by Congress, which has passed several statutes assuming its existence and continuation, and

⁴⁸ In a similar recent episode, OIRA delayed for years action on a proposed regulation to protect an endangered species, right whales, from collisions with large boats traveling at speeds that made evasion difficult; the regulation was eventually issued in the form the responsible agency had requested but only after more than a year's delay past the action times assured by the order creating the OIRA review regime. See Robbie Brown, "U.S. Requires Ships to Cut Speed in Waters Used by Right Whales," NY Times, Oct. 9, 2008.

⁴⁹ Such a regime was first given formal public shape by President Jimmy Carter (Executive Order 12,044); precursors can be found in the presidencies of Richard Nixon and Gerald Ford.

by the academic community. Rulemaking is understood to be too important to national well-being for there not to be a strong central voice and regime for coordination and settlement of interagency dispute. Through the Clinton administration at least, the disputes that have arisen about it could be characterized as marginal: the nature and extent of its transparency; the precise nature of the inquiry to be conducted; the balance OIRA should strike between supervision of agency processes in general and detailed attention to particular proposals; and the threshold beneath which only superficial OIRA engagement is appropriate.⁵⁰ Probably the most important criticism has been that, as administered, EO 12866 has too often proved not to be a neutral device, but rather a deregulatory device – a source of delay and diversion, a pressure point for reduction of burdens and not actions to protect the public. A narrow focus on monetized “costs” and “benefits,” in relation only to regulatory actions agencies have in fact proposed (and not, then, to their priority choices), has largely been responsible for that.

The public alarm over President Bush’s apparent use of the EO 12,866 procedures to “bend science” led President Obama, at the very outset of his administration, to announce a sweeping reconsideration of the practice. Without awaiting further public input, he revoked changes that President Bush had made in the order, that obscured the role of the Vice President, required the designation in each agency of political officers directly responsible to him to control rulemaking, and expanded the reach and intensity of OIRA’s review. This effectively restored it to the shape it had had during the Clinton administration – but in that administration as well the order did not lack critics of its politicizing and delay-promoting possibilities. Perhaps in consequence, President Obama has invited public as well as agency engagement with the question, how the order should be revised. As of March 11, 37 public comments or meetings (but, as of yet, no agency views) had been memorialized on the White House web site,⁵¹ reflecting both the administration’s commitments to transparency and the wide range of views held on the matter.

In the American context, the controversy about the chief executive’s engagement with rulemaking has a number of elements, some of which are doubtless (and perhaps happily) unique to it. Thus, it may be seen to illustrate ongoing disputes about the nature and extent of the American President’s authority in relation to the decisions of domestic government. Is our President, the one elected official our Constitution vests in a largely undefined way with “the Executive power,” entitled to *decide* every matter the Congress may delegate to cabinet Departments and other governmental agencies? Or is he merely to *oversee* their doing so, accepting that ultimate legal responsibility for action has been placed in them and that his authority is limited to persuasion, to replacing officers whose decisions displease him, and the like?

I have discussed this question at length elsewhere.⁵² In a nutshell, my view is that control and influence are different matters. The President, our one elected executive official with a

⁵⁰ **Error! Main Document Only.**OIRA will doubtless remain a small office, and one lacking the expertise to be found in the operating agencies. This makes it important that effort be focused on the most important rule-makings, and that it be prompt. No more than a few hundred rules annually, as such, should be in strong review.

⁵¹ <http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp>, visited March 12, 2009.

⁵² Peter L. Strauss, Overseer or “The Decider”? The President in Administrative Law, 75 G.W.L.Rev. 695 (2007)

constitutionally defined active role, is entitled to try to influence agencies, and would be shirking if he did not do so. He is the named, elected head of the executive branch, with constitutional authority to demand the "Opinion, in writing" from the leadership of executive departments⁵³ -- for me, this must include the so-called independent regulatory commissions as well as the cabinet departments -- on any matter Congress has assigned to them (that is, their "Duties," to which the same constitutional text also refers). Certainly this supposes that, once informed of their opinion, he will have a chance at least to reason with them. And where responsibilities are shared among several agencies -- to take an example I am a bit familiar with, radiation exposure protections, which concern the Nuclear Regulatory Commission, EPA, Occupational Safety and Health Administration, the Department of Defense, the Department of Energy, the Department of Transportation (hazmats) and probably others -- coordination is certainly part of what he has to do. He should have staff to help him with this, a matter of particular importance where multiple agencies are involved.

Control, in my judgment, is an entirely different matter. Congress has placed decisional responsibility in the EPA, say, not in the President. That placement, no less than the placing of the Forest Service in the Department of Agriculture and National Parks in the Department of the Interior, is a part of the law to whose faithful execution the President has undertaken to see. He is not assuring the faithful execution of the law if he purports to assign decisional responsibility to a place Congress has not put it, or takes on himself decisional responsibility for a matter Congress has delegated to someone else. There are, to be sure, certain questions (foreign policy issues for example) as to which there is "no law to apply," as the courts have said, and federal officials are merely the organs to express presidential will. Chief Justice Marshall famously addressed this setting in *Marbury v. Madison*.⁵⁴ But where legality is central to our very tolerance of governmental authority, as it is for rulemaking decisions like the EPA's, in my judgment, our President's role under the laws, in a government of laws, requires him to respect Congress's placement of duties where Congress has placed them. When the EPA is authorized to adopt rules, it is the head of the EPA who has the responsibility to decide those matters. The President's place is one of oversight, not decision, making sure that she does that well. Which of course includes the agency head's acting only on the basis of those factors Congress has made relevant to her decision -- precisely the issue President Bush's intervention on ozone appeared to compromise.

Of course consultation can often result in pressures, the substitution of judgment in fact. To turn from the presidency for the moment, the courts, too, know that they are responsible to review agency action (oversight) but are not to substitute their own judgments (decision); yet this does not keep them from doing things on occasion that to the observer seem like substitution. The important thing is the attitude -- that agencies know what their responsibilities are,

⁵³ U. S. CONST. art. II, § 2, cl. 1 (The President "may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any subject relating to *the Duties of their respective Offices*[.]") (emphasis added).

⁵⁴ *Marbury v. Madison*, 5 U.S. (1 Cranch) 137 (1803): an official obliged "to conform precisely to the will of the President," Marshall wrote, "is the mere organ by whom that will is communicated. The acts of such an officer, as an officer, can never be examinable by the courts. ... The province of the court is, solely, to decide on the rights of individuals, not to enquire how the executive, or executive officers, perform duties in which they have a discretion. Questions, in their nature political, or which are, by the constitution and laws, submitted to the executive, can never be made in this court."

that courts are aware that they are not supposed to substitute judgment, and that onlookers like myself can point to departures and cry "Shame!" One's impression is that the Obama administration understands this, but the proof will be in the pudding.

The involvement of OIRA reflects only one, perhaps indeed the most regular and (although not completely) transparent, of the means by which political officials may succeed in influencing decisions ostensibly committed to bureaucrats instructed to act on the basis of objective data and limited, stated considerations.⁵⁵ As noted previously, that OIRA's interventions became public owes something to precommitments it had made. These were made as part of the political price exacted by previous Congresses for accepting the role Presidents had established for it; the disclosures also had their source in bureaucratic initiative. And the ensuing proceedings, congressional and judicial, as well as the fact of a searchable Internet database, reflect possible controls on such interventions in the American context. President Obama's apparent taste for other central offices with oversight responsibilities⁵⁶ suggests a possible need to generalize these controls.

It seems at least possible that the new administration will pay more disciplined attention than its predecessors have to the first, priority-setting stage of the executive order process. Priority planning has been a part of the executive order at least since the second Reagan administration, but it has never been seriously used, so far as I have been able to tell. Conversations with agencies about their priorities – where the President believes it is important for them to put their effort – is in my judgment far more likely to be effective in improving government performance and administration than retrospectively checking sums on a series of particular rules. So also, engagement with agencies in how they structure their internal processes to promote sound and efficient analysis and decision, downplaying retrospective analysis of what is already well under way. Retrospective analysis threatens, and has been used to secure, considerable delay of initiatives already established as important priorities. And an emphasis on the regulatory plan element may also increase political responsibility *within* agencies. Chris DeMuth, the progenitor of the regulatory plan element, rationalized it as a way to give the political heads within agencies a mechanism for engaging with their staff at the outset of rulemakings, rather than also find themselves caught in retrospective exercises with effective *fait accompli* perpetuated by staff.

One kind of issue about presidential control with proven implications for "science-bending" concerns presidential control over executive branch communications with Congress. Transparency, and all the contributions to "honest brokering" and effective democracy through the "marketplace of ideas" that go with it, are impaired if the President takes the position that communications with Congress or the public must be pre-cleared politically. One notorious example during the Bush administration was the suppression of projections concerning the cost of certain health-care measures. Some such controls are of long-standing,

⁵⁵ Accounts of Vice President Dick Cheney's behavior in office, for example, have included his repeated forceful and undisclosed interventions on a question concerning the amount of water (that might otherwise be used by farmers for irrigation) to be released from a single western dam in order to protect an endangered species of fish living in the river on which the dam was situated. Under the statute, wisely or not, the farmers' needs were not a relevant consideration; rather, the decision was to be based on a scientific assessment of the survival needs of the endangered species. Jo Becker and Barton Gellman, "Leaving No Tracks," *The Washington Post*, June 27, 2007, p. A01.

⁵⁶ See the text above, following n. 36.

however. Thirty-two years ago, when the author was General Counsel of the US Nuclear Regulatory Commission, the Office of Management and Budget was “coordinating” (i.e., pre-clearing) communications and testimony to Congress about legislative proposals and budgetary matters. The Commission’s nominal independence (it was of course an element of the executive branch, but its statutes provided explicitly for direct communication) softened these controls; but within the Commission itself, its Bureau “executives” sometimes exercised rather rigorous control over what they would permit their staff members to tell the Commission about perceived nuclear power risks. And similar pressures might be brought to bear on utility personnel to suppress safety concerns they might wish to share with the Commission. Such “bending” did not conduce to public protection. The “whistleblower” provisions of President Obama’s directive on scientific integrity reflect one possible response to such problems – hopefully successful in [re]establishing an ethos, if not invariably successful in preventing suppression of data.

The legal basis for sweeping presidential control over communication by others in the executive branch, if not its political reality, can be questioned. To the extent the American Constitution speaks to the matter at all, it merely permits the President to recommend to the Congress such legislation as he regards as expedient. Citizens of parliamentary democracies, inured to the powers of their prime minister over legislative business, will easily grasp the weakness of this provision, which addresses only presidential initiative and does not even suggest that a presidential suggestion must become legislative business. For that to happen, some member of Congress must introduce a bill, whose language the President cannot legally control. There is nothing here about keeping others from making any recommendations they might like. Nonetheless, as indicated, Presidents have long asserted the right to sit astride any such communications, at least outside the “independent regulatory commission” context.

On this issue, the Obama administration appears to be sending somewhat mixed signals. The recent executive order on scientific integrity is explicit that

(3) ... (b) Nothing in this memorandum shall be construed to impair or otherwise affect...:

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

This seems to keep OMB’s existing controls over direct agency communications firmly in place. On the other hand, in a recent statement accompanying his signing of a piece of complex legislation, explaining his reservations about limited elements of the bill he was permitting to become law,⁵⁷ President Obama wrote:

Executive Authority to Control Communications with the Congress. Sections 714(1) and 714(2) in Division D prohibit the use of appropriations to pay the salary of any Federal officer or employee who interferes with or prohibits certain communications between Federal employees and Members of Congress. I do not interpret this provision to detract from my authority to direct the heads of executive departments to supervise, control, and correct employees’ communications with the Congress in cases where such communica-

⁵⁷ On the controversy over “signing statements,” hardly necessary to explore here, see Ronald Cass and Peter L. Strauss, *The Presidential Signing Statements Controversy*, 16 *Wm & Mary Bill of Rights J.* 11 (2007)

tions would be unlawful or would reveal information that is properly privileged or otherwise confidential.⁵⁸

Note that in this statement President Obama, unlike his predecessors, limits his reservation to “cases where such communications would be unlawful or would reveal information that is properly privileged or otherwise confidential.” This is a much more limited, and readily accepted, claim.

One may be certain similar issues about transparency regularly present themselves in *every* administrative law system. The Internet and its ready searchability are global phenomena, so that questions about what information it should contain about governmental policy formation, made available to whom, and on what time schedule, are universal. Questions inviting scientific assessment frequently also involve uncertainties not completely resolvable by objective means, and/or kinds of risk to which the public is particularly sensitive. They may reflect matters of large public concern, on which the public, and politicians representing them, will understandably and acceptably wish to have a voice. The use of nuclear power, or of GMOs in the food chain, and the problems of global warming come readily to mind, and there are many like situations. One easily imagines situations like the more acceptable way of understanding the ozone controversy in the United States, in which generalist politicians are motivated by public interest considerations that may be missing from the particular law governing an agency’s resolution of a matter. Understandable as it may be for them to inject these considerations into the decisional framework, that course nonetheless presents troubling questions of legality. If the inadequacy of the existing legal framework is thus revealed, the proper response appears to be changing, not overriding, that framework. Beyond this lies the possibility that, less acceptably, individual politicians will act covertly in the interest of particular “clients” to influence decision away from the point that an inquiry according to framework laws would determine.

To what extent is the data on which scientific assessments or political judgments may be based provided through the Internet, or in other ways exposed to public view? What are the contexts in which political interventions in an ostensibly objective (scientific) process may arise? To what extent are they transparent, so that the fact of them may be known? What if any controls are available to constrain their impact? Still at an early stage in my inquiries, my hope is to learn further about the means various governmental arrangements employ for mediating and controlling the interface of science and politics -- how these problems are seen and responded to. In the current day, given the high levels of concern about global warming, GMOs, and other matters, finding appropriate space both for the understandings science can bring and for the expression of democratic concerns that do not and need not regard all risks as commensurate, is challenging indeed.

⁵⁸ Press Statement of March 11, 2009, http://www.whitehouse.gov/the_press_office/Statement-from-the-President-on-the-signing-of-HR-1105/, visited March 13, 2009.

Appendix A

THE WHITE HOUSE

Office of the Press Secretary
For Immediate Release March 9, 2009

March 9, 2009

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGEN-
CIES

SUBJECT: Scientific Integrity

Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues, including improvement of public health, protection of the environment, increased efficiency in the use of energy and other resources, mitigation of the threat of climate change, and protection of national security.

The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity.

By this memorandum, I assign to the Director of the Office of Science and Technology Policy (Director) the responsibility for ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes. The Director shall confer, as appropriate, with the heads of executive departments and agencies, including the Office of Management and Budget and offices and agencies within the Executive Office of the President (collectively, the "agencies"), and recommend a plan to achieve that goal throughout the executive branch.

Specifically, I direct the following:

1. Within 120 days from the date of this memorandum, the Director shall develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch, based on the following principles:

- (a) The selection and retention of candidates for science and technology positions in the executive branch should be based on the candidate's knowledge, credentials, experience, and integrity;

(b) Each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;

(c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;

(d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions;

(e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised; and

(f) Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decision-making or otherwise uses or prepares.

2. Each agency shall make available any and all information deemed by the Director to be necessary to inform the Director in making recommendations to the President as requested by this memorandum. Each agency shall coordinate with the Director in the development of any interim procedures deemed necessary to ensure the integrity of scientific decisionmaking pending the Director's recommendations called for by this memorandum.

3. (a) Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

4. The Director is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

Appendix B

WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY FOR APPLICATION BY GOVERNMENTS *CAC/GL 62-2007*

SCOPE

1. The Working Principles for Risk Analysis for Food Safety for Application by Governments are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health.

GENERAL ASPECTS

2. The overall objective of risk analysis applied to food safety is to ensure human health protection.

3. These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner.

4. To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.⁵⁹

5. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.

6. Risk analysis should be:

- applied consistently;
- open, transparent and documented; and
- evaluated and reviewed as appropriate in the light of newly generated scientific data.

7. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission,⁶⁰ each component being integral to the overall risk analysis.

8. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties.⁶¹

9. Effective communication and consultation with all interested parties should be ensured

⁵⁹ It is recognized that national governments will use different approaches and time frames in the application of these principles taking into account national capacities and resources.

⁶⁰ See *Definitions of Risk Analysis Terms Related to Food Safety*, Procedural Manual.

⁶¹ For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations” (see definition of “Risk Communication”).

throughout the risk analysis.

10. The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

11. There should be a functional separation of risk assessment and risk management to the degree practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

12. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

13. National governments should take into account relevant guidance and information obtained from risk analysis activities pertaining to human health protection conducted by Codex, FAO, WHO and other relevant international intergovernmental organizations, including OIE and IPPC.

14. With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective application of risk analysis principles and techniques in their food control systems.

15. National governments should share information and experiences on risk analysis with relevant international organisations, other national governments (e.g. at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate a broader and, where appropriate, more consistent, application of risk analysis.

RISK ASSESSMENT POLICY

16. Determination of risk assessment policy should be included as a specific component of risk management.

17. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

18. The mandate given by risk managers to risk assessors should be as clear as possible.

19. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

RISK ASSESSMENT

20. Each risk assessment should be fit for its intended purpose.

21. The scope and purpose of the risk assessment being carried out should be clearly

stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.

22. Experts, involved in risk assessment including government officials and experts from outside government should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment. Information on the identities of these experts, their individual expertise and their professional experience should be publicly available, subject to national considerations. These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, including disclosure of conflicts of interest in connection with risk assessment.

23. Risk assessment should incorporate the four steps of risk assessment, i.e., hazard identification, hazard characterization, exposure assessment and risk characterization.

24. Risk assessment should be based on scientific data most relevant to the national context. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

25. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

26. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

27. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

28. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

29. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

RISK MANAGEMENT

30. National government decisions on risk management, including sanitary measures taken, should have as their primary objective the protection of the health of consumers. Unjustified differences in the measures selected to address similar risks in different situations should be avoided.

31 Risk management should follow a structured approach including preliminary risk

management activities,⁶² evaluation of risk management options, implementation, monitoring and review of the decision taken.

32. The decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles⁶³ as they relate to decisions at the national level. National Governments should base their sanitary measures on Codex standards and related texts, where available.

33. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

34. Risk management should take into account the economic consequences and the feasibility of risk management options.

35. The risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties.

36. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

37. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

38. Risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, national governments should seek and take into consideration the potential impact of such measures on trade and select measures that are no more trade-restrictive than necessary.

39. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. The relevance, effectiveness, and impacts of risk management decisions and their implementation should be

⁶² For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

⁶³ See *Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to which other Factors are Taken in to Account*, Procedural Manual.

regularly monitored and the decisions and/or their implementation reviewed as necessary.

RISK COMMUNICATION

40. Risk communication should:

- i) promote awareness and understanding of the specific issues under consideration during the risk analysis;
- ii) promote consistency and transparency in formulating risk management options/recommendations;
- iii) provide a sound basis for understanding the risk management decisions proposed;
- iv) improve the overall effectiveness and efficiency of the risk analysis ;
- v) strengthen the working relationships among participants;
- vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
- vii) promote the appropriate involvement of all interested parties;
- viii) exchange information in relation to the concerns of interested parties about the risks associated with food; and
- ix) respect the legitimate concern to preserve confidentiality where applicable.

41. Risk analysis should include clear, interactive and documented communication, amongst risk assessors and risk managers and reciprocal communication with all interested parties in all aspects of the process.

42. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

43. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The decisions taken and the procedures followed to reach them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 28).

Appendix C

DECLARATION OF INTERESTS FOR FAO EXPERTS

The assistance of distinguished authorities knowledgeable in a variety of scientific professions is essential to the work of the Food and Agriculture Organization of the United Nations (FAO). **It is expected that persons qualified to serve as an expert for FAO may have private interests related to the subject of their expertise. At the same time, it is imperative that situations be avoided in which such interests may unduly affect, or may be perceived to affect, an expert's impartiality or the outcome of work in which he/she was involved.**

To assure the highest integrity, and hence public confidence, in the activities of the Organization, FAO's regulations and policies require that all experts serving in an advisory role disclose any circumstances which could give rise to a potential conflict of interest (i.e., any interest which may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). Accordingly, in this Declaration of Interest (DOI) form, you are requested to disclose any financial, professional or other interest relevant to the subject of the work or meeting in which you will be involved and any interest that could be significantly affected by the outcome of the meeting or work. You are also asked to declare relevant interests of others who may, or may be perceived to, unduly influence your judgment, such as immediate family members, employers, close professional associates or any others with whom you have a substantial common personal, financial or professional interest. If you do not provide, where requested, the amount or value of the interest, it will be assumed to be significant.

Kindly complete this form and submit it to FAO Secretariat, well in advance of the meeting or work. You are also asked to inform the Secretariat of any change in this information that occurs before or during the course of the meeting or work. If FAO considers that a potential conflict of interest exists, one of several outcomes can occur, depending on the circumstances involved: (i) you may be invited to continue to participate in the meeting or work, provided that your interest would be publicly disclosed; (ii) you may be asked not to take part in the portion of the meeting, discussion or work related to your interest, or not participate in related decisions; or (iii) you may be asked not to take part in the meeting or work altogether. Non-completion of the DOI form would preclude further consideration of an expert's participation.

Experts are requested to agree that any relevant conflicts may be **publicly disclosed** to other meeting participants and in the resulting report or other work product. The Secretariat will assume that you consent to such a disclosure, unless you check "no" in the space provided on the last page of this form. In addition, the information disclosed by you **may later be made available** to persons outside of FAO if the objectivity of the work or meeting in which you are involved is questioned and the Director-General considers disclosure to be in the best interests of the Organization, although only after discussion with you.

Date and title of meeting or work, including description of subject-matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached):

Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself, your employer and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your minor children). The term "commercial entity" includes -- aside from any commercial venture -- an industry association, research institution or other organization whose funding is significantly derived from commercial concerns having an interest related to the subject of the meeting or work. The term "meeting" also includes a series or cycle of meetings.

EMPLOYMENT AND CONSULTING

Within the past 3 years, have you worked for a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or negotiation for future work.

- 1a Employment Yes No
- 1b Consulting, including service as a technical or other advisor Yes No

RESEARCH SUPPORT

Within the past 3 years, have you or your department or research unit received support or funding from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or award for future research support.

- 2a Research support, including grants, collaborations, sponsorships, and other funding Yes No
- 2b Non-monetary support valued at more than US\$1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.) Yes No

INVESTMENT INTERESTS

Do you have current investments (valued at more than US\$10 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified.

- 3a Stocks, bonds, stock options, other securities (e.g., short sales) Yes No
- 3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures) Yes No

INTELLECTUAL PROPERTY

Do you have any current intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?

- 4a Patents, trademarks, or copyrights (also include pending applications) Yes No
- 4b Know-how in a substance, technology or process Yes No

PUBLIC STATEMENTS AND POSITIONS (*during the past 3 years*) (questions relate to balanced composition of committee or group)

- 5a As part of a regulatory, legislative, judicial, or other governmental process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization? Yes No
- 5b Through your articles, editorials or speeches, could you be perceived as having taken a prominent or well-known position related to the subject of the meeting or work? Yes No
- 5c Do you hold an office or other position, paid or unpaid, where you may be expected to Yes No

represent interests or defend a position related to the subject of the meeting or work?

- 5d Have you served as a principal investigator, as lead expert in an expert committee or scientific or advisory group, and/or a member of a steering committee, an advisory board or equivalent body in relation to the same product or subject matter? Yes No

ADDITIONAL INFORMATION

- 6a *If not already disclosed above, have you worked for the competitor of a product which is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a financial or commercial competitive advantage?* Yes No

- 6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, financial or professional interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes No

- 6c Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? Yes No

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not provide, where requested, the amount or value of the interest, it will be assumed to be significant.

Nos. 1 - 4 Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) <u>and</u> basic descriptive details.	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, assumed significant)	Current interest (or year ceased)

Nos. 5-6: Describe the specific circumstances, parties involved, time frame and other relevant details

CONSENT TO DISCLOSURE. The Secretariat will assume that you consent to the disclosure of any relevant conflicts to the other meeting participants and in the resulting report or work product, unless you check “no” in the space provided here. If you check “no”, the Secretariat will not disclose the information without your prior approval, although this may result in your not being able to participate in the meeting or conference. **No:**

DECLARATION. I hereby declare that the disclosed information is true and complete to the best of my knowledge. I undertake to inform the responsible staff of FAO of any change in this information or any new information that needs to be reported, which occurs before or during the meeting or work itself and through the period up to the publication of the final results.

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