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Public Comment upon the OMB Peer-Review Standard For Range of Studies
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PLEASE REPLACE THE COMMENT SENT ON DECEMBER 12th WITH THIS

Since the public comment period was extended to December 15th 2004, a number of articles critical of the proposal have appeared in the press that are either wrong or misleading. I feel that it is important for me to comment further. One complaint is that there are no concrete examples where Peer Review by external experts would have helped. For example Michael Taylor of Resources for the Future is quoted as saying that "It offers peer review as a solution, but nowhere defines the problem" . So let me give a few examples from my personal experience over the last 25 years where it seems to me that the country would have been better served by peer review and the transparency it demands.

(1) The first is the 1980 report by the National Highway Transportation Safety Administration. Which concluded that the potential benefit of air bags "greatly outweighs the small possible risk of injury" to children. A correct statement as far as it goes. But it does not go far enough. The small risk to children could have been avoided without sacrifice to the main objective. NHSTSA misused the English language and used rhetoric which was patently false. The principal problem in this case was Joan Claybrook. She talked about "passive restraints". On several occasions I commented that air bags were among the more active things I could think of. (I have regularly told this to my risk analysis class at Harvard). It is that very failure to insist on seat belts whether or not air bags were used that killed 144 children since 1993. This unfortunate use of language stopped people thinking. Peer review would certainly have saved many of these children. The main issue is air bags without seat belts. Seat belts do most of the work of saving lives, but Joan Claybrook implied that they were superseded by air bags. You cannot save someone who does not want to save himself, or his own children. He or she could do so by fastening seatbelts. Attempts to do save people who do not want to be saved often fail, since they are often made without thought. Certainly my very public comments would have had to have a response.

(2) The report on saccharin on April 15th 1977 by FDA was a model of clarity. That had no peer review but needed none. Donald Kennedy had no illusions - he could have, but declined to use emergency powers, deliberately leaving time for Congress to make an exception to the law if it wished (which Congress did)

(3) The Wall Street Journal has a fake scenario in which lives would be lost if an emergency arose. Quoting the Wall Street Journal "If the FDA concludes that alerting the medical community will save lives. No go: A new federal rule requires that the FDA first assemble outside experts to meet, review the evidence and write a report." Nonsense. Emergency powers

exist and would be protected under the new rules. Who would decide what is an emergency? Normally the agency, although OMB might reasonably be given 24 hours to respond. Maybe the proposal should be modified to make this clear.

(4) The famous example where the acting administrator of EPA , Jack Moore, complained on "60 minutes" that he lacked emergency powers to ban ALAR is false. There the Science Advisory Board explicitly had told him (correctly in my view) that the science was not there to justify an emergency ban. What he feared doing was issue an emergency ban when scientists disagreed with him. Certainly there was no emergency. But if Jack Moore had been sure of the science there would have been no reason to fear a lawsuit.

(5) One public policy professor at my own University is quoted as complaining that because science entails judgment, she doubts that peer review such as OMB envisions would produce better regulatory science. That is sheer nonsense. It is akin to the nonsense by the Texas Appeals court in *Kumho tire*. That court argued that Engineering is an art rather than a science and that therefore the Supreme court's words in Daubert and Joiner dis not apply. The Supreme Court, led by its liberal members, held that the more the subject issue is closer to an art than a science, the more a judge must be cautious about accepting expert testimony. But the more uncertain the scientific issue, the more one needs peer review, and peer review by someone not involved with the agency. Peer review is not now necessary for a statement that 2+2 = 4. It might have been a couple of thousand years ago.

(6) NASA has routinely declined to have its activities reviewed by outsiders. Yet NASA has a classic example of the top administrators refusing to accept the caution of its engineering and science contractors - the Challenger disaster. It is likely that an outside review of the circumstances of the launch would have urged caution. It certainly would have urged caution if Nobel Laureate Richard Feynman had been one of the reviewers. Feynman has eloquently described, as only Feynman could, the problems he had in getting the subsequent investigating committee to take the criticisms of NASA seriously. Even after the Challenger disaster, when it was proposed that NASA have an external safety review committee, NASA opposed the suggestion vehemently. Only in the last 3 years have NASA even undertaken a proper risk analysis of their operations.

(7) One must not pooh-pooh procedural questions. NASA has a tendency to do so. On the launch of the Galileo space probe, which had a plutonium powered thermoelectric generator, Congress and a Presidential directive insisted that he sign off on it. I was one of the 4 people asked to advise the President. NASA and DOE had three subcommittees. We 4 met in the executive office building with the Chairman of the 3 subcommittees and 20 - 30 others. I asked whether anyone on their committees or anyone else to their knowledge had any qualms because I wanted to know about them before offering any advice. Without exception they said that everyone was fully supportive. A week later I was shown a letter just received by the President. It came from one of the subcommittee members - Dr Richard Cuddihy- who suggested that Galileo not be launched. Richard Cuddihy who had raised several issues of concern a year before had been ignored largely because in the intervening time he had had a heart attack and not attended meetings. Dr Cuddihy's issues were all sensible, and NASA should have responded.

To the best of my knowledge neither NASA nor DOE ever responded. It was left, by NASA, to us 4 last reviewers to respond. This was obviously incorrect procedure. I should have been reviewing NASA,s work not doing it myself. How else can one be sure that NASA understood the problems? I wrestled with this issue and discussed it with Nobel Laureate Ed Purcell who agreed on the importance of procedure. If Dr Cuddihy had not signed off on the subcommittee report 2 days before launch, I might well have recommended postponement.
(8) Andrew Robbins writing in the Boston Globe objects to the requirement that outside reviewers should be used when possible, and not always the same ones. Robbins argues that anyone with an EPA contract would be excluded. He argues further that would only leave industry scientists. In detail he is wrong. It would, for example still leave me, Not only NASA but EPA frequently break this obvious rule. That need not be so. What is crucial is *transparency*. All contracts and potential conflicts of interest should be disclosed *publicly in writing and on the record.* An agency would be free to reject the comment or peer review. But since outside scientists would do the review, the agency would have to address any concerns they raise.

(9) Apparently the American Public Health Association announced its opposition to OMB's proposal, arguing that "public-health decisions must be made in the absence of scientific certainty, or in the absence of perfect information." Of course. But, as noted above, the less perfect the information, the more necessary is peer review. AND not just peer review of the underlying scientific data, but review of the applicability of the data to the decision at issue. Agencies do not do too badly in collecting all the relevant data. EPA in particular does a good job here and gets it reviewed. But the analysis of the data and the applicability to the decision at issue is typically *not* reviewed. It should be. It is more important. Scientists will do their own peer review of the science. Scientists do not automatically do peer review of the applicability of the science to a prudent public health policy.

(10) Cancer bioassays by the National Toxicology Program are reviewed by in house people and a regular caste of reviewers. Yet two very important issues have been ignored or over a decade. These would have come to light if better peer review were accepted by NIEHS. Many good scientists have said this, and when said to NTP there is a strong suggestion that NTP refuses to ask their advice again. (i) the pathologist knows which animals were in the control group and which in the dosed group before he submits his report. No modern epidemiology study would be accepted in such a way. Yet it is harder to do a double blind epidemiology study that a double blind animal study. (ii) There is strong, almost overwhelming, evidence that failure to control diet increases cancer. Yet in the NTP studies animals are fed *ad libitum*. There is strong evidence that a failure to control diet leads to serious indications of carcinogenicity. Indeed, I believe that none of these studies should be used as a basis for regulation until these weaknesses are corrected.

(11) Peer review need not result in a lack of caution. Indeed the opposite is the case. The Atomic Energy Commission at one time proposed to accept the siting of a nuclear power plant on the east river. The “outside” committee, the Advisory Committee on Reactor Safeguards” objected and was overruled. That was later reversed. What would the citizens of New York think now about the Indian Point Power Station next to the UN?

(11) The EPA regulation on arsenic is one which would have benefitted by proper peer review of the applicability of the science to the regulatory issue. The proposal was discussed in 1990 at a whole afternoon session of the San Diego arsenic conference. But the detail was not discussed. Indeed I failed to find any arsenic expert outside EPA who understood exactly how they arrived at their proposed regulation. I only realized it somewhat later and was able to explain it to others. In this case the way in which the EPA arrived at the rule was sufficiently bizarre that few people believed it. (Although experts such as Dr Allan Smith agreed with the final conclusion). In this case there was plenty of time. The basic problem - that arsenic laden water taken regularly was more dangerous at low doses than previously realized - was published in English in US journals in 1986.

(12) One of the more frustrating features of the US agencies is a refusal to acknowledge - let along comment upon- public comments. A frustrated scientist finds it hard to be helpful. In the last 25 years I have made almost as many public comments to the EPA. *Not one has been acknowledged*. I believe that if my comments were heeded public health would have been improved. I have raised this personally (usually orally) to every EPA administrator in the last 20 years. EPA should take a leaf out of the books of NRC and NASA who publish every comment and the agency response to those comments.

(13) Enough public interest foundations exist that it is unlikely that a dangerous situation could continue - *provided that there exists the transparency that this proposal recommends.* For example, one such foundation, the Atlantic Legal Foundation, has regularly represented distinguished scientists in egregious misuse of science. But ALF has regularly declined to consider cases where distinguished scientists are divided such as whether there is a man made hazard of global warming, or whether fine particles at ambient levels pose a risk to health. They implicitly consider that regulations on such matters where science is uncertain, can reasonably err on the side of caution. But by their nature these are not emergency situations and there is ample scientific discussion.

(14) I do not suggest that any US agency is deliberately distorting science and public policy. None of the agencies is perfect (including OMB) but none is completely on the side of the devil either. What tends to happen is a refusal to listen to, and respond to, criticism - they are too busy. They should not be. For example, in 1979 at a meeting of the Toxicology Forum, an EPA official discussed many risks and the regulation of these to below a one in a million (10E-6) lifetime risk. I pointed out that by EPA's own calculation chloroform standard still left a risk of 1 in 10,000 per lifetime. The EPA official said that they could not regulate chloroform to the same level because to do so would shut down 80% of the water systems in the country. I went further and asked why the EPA did not clearly explain this to the American public. The shocking, elitist, response was "They would not understand." Peer review would bring this elitism into the open. (The chloroform risk assessment was later to be shown inaccurate because it was based upon a gavage study which was almost certainly improper.)

(15) All agencies are politically sensitive to some degree. The adverse effects of this sensitivity will be less if open, transparent, peer review is the norm. The EPA is normally excellent at summarizing data and making the summaries available. But in one case EPA wrote

a report about the exposure of Americans to benzene. The draft correctly stated that the biggest integrated exposure was through smoking cigarettes. This was removed from the table in the final report to avoid senators from the tobacco states voting against the EPA budget. No knowledgeable peer reviewer would ever let that pass.

(16) As I write this, I note that most of my research funding since 1955 came from the Navy, the Atomic Energy Commission and the Department of Energy under contract to Harvard University. That has not stopped me criticizing these agencies. But I had the luxury of academic tenure at a good University which is unlikely to fire me. Now I have officially retired, the chance of being fired drops from small to zero. This gives me a freedom of talk and action - and of course a duty that goes along with that freedom. People in the agencies have no such freedom of action, and this proposal of OMB may help those in the agencies who put science ahead of politics. I would be happy to explain the above points in detail to anyone who asks.