Thanks for sending me this outline. These comments are fairly succinct in light of the turnaround time; I could provide more detail if desired. I bolded my most important points.

1. Overall, I think Prof. Wagner has done a good job of canvassing the issues and focusing on the highest priority ones:

a. Even within the present scope, I suspect that this report will lead to the conclusion that ACUS should commission additional projects to look more deeply into several of these issues.

b. I agree that it makes sense to exclude the role of the legislative and judicial branches for these purposes. The outline is ambiguous, however, about whether its focus is literally on intra-agency processes, or whether the project will encompass executive branch processes, in particular, the role of OMB in implementing EO 12866 and the interagency review process. I'm assuming the latter since (i) she'll be interviewing OMB and OSTP staff and (ii) the reforms listed in Part IV are administered by OMB and OSTP. I think that is the right scope.

2. I also agree generally with the problems identified in Part I.A.2:

a. *Politicization of science* was certainly highlighted in the prior administration and is a chief focus of the new scientific integrity policy statements. I would recommend also looking into the potential for non-political, career managers to direct the outcomes of assessments being conducted by scientists who they supervise. This has been a major issue in the case of EPA's Nat'l Center for Environmental Assessment.

b. *Poor explication* of science-based decisions has also been highlighted repeatedly, most recently and prominently in the National Academy of Sciences' report on EPA's IRIS assessment of formaldehyde (characterizing it as a "roughly 1,000 page draft" containing "long descriptions of the studies" but "little beyond a brief introductory chapter . . . on the methods for conducting the assessment").

c. The NAS formaldehyde report also highlights the extent to which EPA's practice is a *lagging indicator of progress* in the fields of toxicology and epidemiology (EPA did not use a computational fluid dynamics model developed with industry support, even though it would be "useful," or a biologically-based dose response (BBDR) model even though it is "one of the best-developed BBDR models to date").

d. I'm not sure about agencies committing outright "errors" -- that seems a strong statement given the judgmental quality of science-based decisionmaking, but there may be examples here. Certainly, there are concerns about how agencies use peer review panels:

i. Panels run by contractors are exempt from FACA; also, issues of conflict and bias are governed by the relevant acquisition rules rather than by federal ethics rules.

ii. Agencies often issue narrowly-drawn charges to panels that suggest they are using the panels to validate particular decisions rather than to evaluate the work under review.

iii. **Most important, peer review processes -- and indeed most agency scientific evaluation process -- are not interactive, and so outside stakeholders have no**

opportunity to really engage reviewers or agency decision makers (directly or indirectly) in substantive dialogue. The scientific community customarily engages itself via symposia and the like. Agency science processes are much more closed and legalistic, with outsiders permitted brief "comment periods" that function principally to check a due process box.

e. **I would propose adding one additional problem: failure to use *approaches designed to identify and characterize the best available science*. The phrase "best available science" is embodied in the OMB Information Quality Guidelines but also in virtually all Obama Administration pronouncements on relevant topics (e.g., the President's memo on Scientific Integrity). Criticisms that agencies have not always explained their decisionmaking frequently conceal, or are a more polite way of expressing, a concern that agencies actually are not following any explicit frameworks, decision logics, lists of criteria, etc. for making decisions. Agency scientists around the world have collaborated with academic and industry scientists to develop a variety of these, addressing topics like assessing mode of action, conducting evidence-based toxicology, evaluating weight of evidence, etc. Agencies typically pay lip service to them, but rarely do they demonstrate that they have applied them rigorously and systematically.**

3. I agree with Part II.

4. If Prof. Wagner were to look into the "best available science" issue noted above, Part III of the outline would need to be revised accordingly. Also, I am not sure I see the distinction between III.C.1 and III.C.2, since science advisory boards and similar entities are peer review bodies.

5. I agree with Part IV.

6. I would expand Part V.C beyond reviewing and sharing "private science" to look more broadly at how effectively agencies take advantage of it. Most "private science" is intended to address data gaps, but agencies tend not to coordinate with the funders of that work either to ensure that it will meet their needs or to time their assessments so that the work can be used. With steadily diminishing government funding for research and increased expectations that industry should "have the burden of proof" regarding chemical safety, more rational cooperation (designed to avoid agencies being flim-flammed, and transparent) seems an obvious reform.

7. Part VI.A.2 could be expanded to capture the "best available science" issue noted above.

8. **I would propose considering whether to move Part VI.C.1 ("development of additional administrative mechanisms that enable agencies to respond to changing science") to "Highest priority reforms." Agencies like FDA, EPA, etc. face a huge challenge making use of academic research using innovative but ad hoc methods to explore new endpoints of concern (e.g., endocrine effects), because they conventionally make regulatory decisions using internationally agreed test guidelines that have been validated (i.e., they yield reproducible results of agreed significance). EPA has struggled for over a decade to validate test methods for endocrine effects, despite support by both NGOs and industry. All stakeholders are eager to move to a "toxicity pathways" approach to evaluating**

chemical hazards that would avoid having to use animal tests, but face similar standardization and validation challenges.

-- Jamie

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