



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Committee on Regulation

Minutes

March 4, 2013

Members Attending

Russell Frisby, Chair	Michael Fitzpatrick, Public Member	Peter Robbins, Alternate
Michelle Borzillo, Alternate	Carl Malamud, Public Member (by telephone)	Jonathon Rose, Senior Fellow (by telephone)
Bridget Dooling, Government Member	Charles Maresca, Liaison Representative	Carol Ann Siciliano, Government Member
Susan Dudley, Public Member	Alan Morrison, Senior Fellow	Christy Walsh, Government Member (by telephone)
Don Elliott, Senior Fellow	Connor Raso, Alternate	Richard Wiley, Senior Fellow (by telephone)

ACUS Staff Attending

Paul Verkuil, Chairman	Gretchen Jacobs, Research Director	Reeve Bull, Staff Counsel
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Samantha Aster,
Intern

Invited Guests Attending

Wendy Wagner,
Consultant

Members of the Public Attending

Jessica Bell
Patricia Casano
Jamie Conrad
Chuck Elkins
Silvia Ellis
Robert Fensterheim
Chris Granberg



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Francesca Grifo
Ryan Hager
Beth Law
Amit Narang
Michael Patoka
Pat Rizzuto

The meeting commenced at 1 pm in the conference room of the Administrative Conference.

Meeting Opening

Chairman Frisby asked the committee whether they approved the minutes from the September 24, 2012 meeting. Ms. Dooling offered some revisions, and with the revisions added, the committee approved the minutes.

Chairman Frisby opened the meeting and everyone introduced him or herself. ACUS Chairman Verkuil welcomed everyone to the new space and explained that this meeting represents the culmination of nearly two years of work on this project. Chairman Frisby detailed some of the workshops that addressed the science in the administrative process project and how the information from those workshops was incorporated into the recommendations.

Initial Discussion of Draft Recommendation and Revised Consultant's Report

Ms. Jacobs explained that the recommendation pulls together several sources and different perspectives, and that the recommendations were in 3 main parts: best practices, agency disclosure, and peer review.

Professor Wagner explained that she made many changes to her consultant report since the last meeting, including changes to address concerns voiced in the last committee meetings and to incorporate information from the NAS workshop. She also distinguished her recommendations from those circulated in the draft recommendation. She felt that many of the draft recommendations were either not supported by the report or were beyond the scope of the report. She also commented on the recommendation drafting procedure.

Chairman Frisby and ACUS Chairman Verkuil explained that in this case, as in many previous projects, the Committee used a drafting subcommittee to prepare a draft recommendation and that the Committee would have an opportunity to discuss and revise the draft over the next three meetings.

Discussion of Peter Strauss' Comment

Peter Strauss had provided a written comment expressing his concern that the draft recommendation did not fully grow out of consultant's report, and that it should more directly resemble the report. Mr. Bull explained that the committee process has historically involved multiple points of input in addition to the consultant report. The draft recommendation does not



always directly reflect the consultant report – indeed, it would be unprecedented to have a draft recommendation that fully restates the recommendations in the report. ACUS Chairman Verkuil further explained that this is how the Conference has always operated. Chairman Frisby reminded everyone that nothing is final until voted on by the full Assembly in plenary session.

Discussion of the Draft Recommendation

Mr. Elliott suggested that this section be labeled “Practices Worth Considering,” and the Committee agreed.

Discussion of Recommendation 1

There was some confusion over the meaning of “a priori analytical sources.” Ms. Dooling suggested striking “a priori,” and Mr. Elliott agreed. Mr. Elliott also suggested striking out the last sentence, which reads “Agencies should maintain a clear distinction between assessment of risks and review of risk management alternatives.” Mr. Elliott also suggested that the Conference should not articulate a particular approach, but should say that the “agency should explain the relationship between its science and policy approaches.” Mr. Fitzpatrick proposed deleting everything after the word “assess” and replacing it with language from the recommendation contained in Professor Wagner’s report. Ms. Dudley did not agree that the language should be included. Mr. Morrison suggested the differences between the recommendations in the report and draft recommendation be addressed in the preamble.

Discussion of Recommendation 2

Mr. Elliott inquired as to what problem was being resolved in the recommendation. Mr. Bull explained that the recommendation provided a process for conducting meaningful systematic review and was based on input received from the GW workshop and outside reports. Chairman Frisby and Mr. Fitzpatrick expressed concern over including recommendations that are outside the scope of report, though the recommendations might highlight additional topics to be explored.

Discussion of Recommendation 3

Professor Wagner stated that the recommendation in her report focused solely on literature review. Mr. Morrison expressed concern over the lack of detailed parameters in the recommendation. Mr. Elliott stated that it was unrealistic to recommend that all scientific data used be put online by the agency because of the cost of the endeavor and the copyright issues that it could raise. Mr. Elliott and Mr. Fitzpatrick suggested that the language read that unused data should be posted online “to the extent practicable and/or lawful.” In regard to how to handle studies of literature that were rejected, Ms. Dooling explained the similarity to the IQ Bulletin, which looks at whether the information was substantial. Mr. Elliott suggested that in regard to scientific and technical data, the recommendation should say “what was considered,” not “what was accepted or rejected.” Mr. Fitzpatrick further suggested that it should read “considered, including everything rejected.”



Discussion of Recommendation 4

Professor Wagner stated that the findings of her report support a recommendation on “stopping rules” but do not address when agencies might re-open their consideration of a scientific issue. Mr. Elliott suggested looking at the specific statutory procedure in the Clean Air Act. Mr. Morrison stated that he liked the part of Professor Wagner’s report that said agencies need to get on with their business with knowledge that there will always be later emerging information. Ms. Dudley suggested that the recommendation might read “should consider establishing checkpoints.” Ms. Jacobs suggested adding “consistent with law.” The committee agreed to strike the language referring to external peer review bodies. Mr. Elliott suggested adding the word “significant” prior to “ongoing research” in the final sentence, and the Committee supported this approach. The Committee agreed to strike the phrase “external deliberations” and replace it with “other relevant data.”

Discussion of Recommendation 5

Mr. Elliott suggested striking the words “specific types of” and just using “identify future research.” Mr. Morrison and Mr. Elliott agreed that the language should not be “regulatory issue” but “regulatory options.”

Discussion of Recommendation 6

Ms. Dudley was unsure of whether there is a need to address authorship rights or create dissent policies but that the recommendation should be reviewed by the affected agencies in any event.

Discussion of Recommendation 7

Chairman Frisby and Ms. Dudley were troubled with the language distinguishing disagreements over science and policy because it is not always pure science at issue. Mr. Fitzpatrick stated that there should be diversity and vigorous debate within the agency, and no reprisals for that debate, and the recommendation should not encourage scientists to express dissenting views in public. He further stated that the issue was addressed in the Holdren memo.

Chairman Frisby proposed that the first and last sentence be retained and the language in between be stricken. Ms. Grifo explained that FDA and NRC have good dissenting opinion rules. Ms. Walsh suggested the second to last sentence should say “dissenting scientific work in peer reviewed literature.” Mr. Morrison explained that two agencies are doing this and have policies in place, and the recommendation should simply say that agencies should think about doing this. Additionally, it should not be limited to peer reviewed journals, because not everyone has the means and access to these journals. Mr. Elliott agreed with Mr. Morrison, and suggested that the heading should be “dissent policies.”

Mr. Elliott further suggested that both FDA and NRC should be discussed in the preamble, which should refer to at least 3 different approaches. Mr. Fitzpatrick suggested



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referencing the President's scientific integrity memo, and Chairman Frisby agreed. Chairman Frisby further stated that more time is needed to look at the notion of differentiation between approaches. Mr. Elliott also suggested that this may be a good area for a study at a future date.

Discussion of Recommendation 8

Mr. Morrison suggested either deleting this recommendation entirely or picking up additional detail from Professor Wagner's report. Mr. Fitzpatrick suggested taking it out entirely, and Ms. Dudley agreed. Mr. Elliott suggested referencing this in the preamble, since it could be something that the Conference considers in the future. Chairman Frisby suggested adding into the preamble that this is an important subject that may warrant a further study. ACUS Chairman Verkuil explained that the committee has capacity to recommend further study, but ACUS has never put something like this in the preamble before. Mr. Elliott suggested describing aspects of Professor Wagner's report in the preamble, and acknowledging that there was a long discussion on the issue and it was outside the scope of this project.

Discussion of Professor Wagner's First Recommendation

Professor Wagner noted that her first recommendation, which generally addressed how agencies explain their scientific work, was deleted and proposed that it be folded into recommendation 9 or someplace else. Chairman Frisby agreed that it should be included, and Mr. Elliott said he would work with Professor Wagner to change the language.

Discussion of Recommendation 9

The committee agreed to remove the language regarding the President.

Discussion of Recommendation 10

Ms. Dudley felt that the recommendation needed more clarification, and Chairman Frisby suggested adding clarifying language to the preamble.

Discussion of Recommendation 11

Many committee members and meeting attendees expressed concerns over the clarity of the language regarding federally funded research. There was a consensus that the staff should add clarifying language and merge recommendations 11 and 12.

Discussion of Recommendation 12

Professor Wagner stated that the recommendation does not convey that over-claiming of confidential business interaction (CBI) is a problem. Mr. Morrison stated that this may be an area to examine in a future study. Mr. Elliott suggested adding a sentence at the end that includes the notion of over-claiming of CBI in Professor Wagner's report. He further stated that rigorous oversight and penalizing agencies is too command-and-control, and suggested starting with the



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notion that public transparency should be the rule and that claiming protections (CBI, trade secrets, etc.) be the exception, and Chairman Frisby agreed.

Discussion of Recommendation 13

Chairman Frisby stated that ACUS should leave the recommendation in place for now. Ms. Siciliano suggested sending the draft recommendation to agencies with science-focused missions before the next committee meeting.

Discussion of Recommendations 14 and 15

The committee decided to remove both recommendations because they warrant further study and review.

Meeting Closing

Chairman Frisby thanked everyone for coming, and explained that the next step is a new draft for the next meeting. Chairman Frisby concluded the meeting shortly before 3:45pm.