

**Summary Minutes of the
U.S. Environmental Protection Agency Science Advisory Board
Public Teleconference
August 27, 2019**

Date and Time: Tuesday, August 27, 2019, 1:00 – 5:00 p.m.

Location: By teleconference

Purpose: To conduct a consultation with EPA on mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed rule “Strengthening Transparency in Regulatory Science” (83 FR 18768).

Participants:

Members of the EPA Science Advisory Board (SAB)

Dr. Michael Honeycutt, Chair

Dr. Hugh Barton

Dr. Barbara Beck

Dr. Deborah Bennett

Dr. Frederick Bernthal

Dr. Todd Brewer

Dr. Joel Burken

Dr. Janice Chambers

Dr. John Christy

Dr. Tony Cox

Dr. Otto Doering

Dr. Susan Felter

Dr. Joseph Gardella

Dr. John Graham

Dr. John Guckenheimer

Dr. Steven Hamburg

Dr. Robert Mace

Dr. Clyde Martin

Dr. Sue Marty

Mr. Robert Merritt

Dr. Thomas Parkerton

Dr. Robert Phalen

Mr. Richard Poirot

Dr. Kenneth Portier

Dr. Robert Puls

Dr. Kenneth Ramos

Dr. Tara Sabo-Attwood

Dr. Anne Smith

Dr. Richard Smith

Dr. Jay Turner

Dr. Donald van der Vaart

Dr. Kimberly White
Dr. Mark Wiesner
Dr. Richard Williams
Dr. Stanley Young
Dr. Matthew Zwiernik

For a complete list of members of the SAB see Roster¹

EPA Science Advisory Board Liaisons

Dr. Barbara Morrissey, EPA Children's Health Protection Advisory Committee

EPA Science Advisory Board (SAB) Staff:

Thomas Armitage, Designated Federal Officer
Thomas Brennan, Director, SAB Staff Office

EPA Representatives:

Maria Doa, EPA, ORD

Other Attendees (See Attachment A)

Teleconference Summary:

Convene the Meeting

Dr. Thomas Armitage, Designated Federal Officer (DFO) for the SAB convened the teleconference at 1:00 p.m., Eastern Time. He noted that the chartered EPA Science Advisory Board was meeting by teleconference to conduct a consultation on mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) under the proposed rule *Strengthening Transparency in Regulatory Science*. He identified EPA Science Advisory Board (SAB) members and SAB Liaisons who were on the call and provided introductory remarks in his capacity as DFO. He stated that the EPA Science Advisory Board (SAB) is an independent Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA). He indicated that the SAB is empowered by law to provide scientific and technical advice to the EPA Administrator. He stated that summary minutes of the teleconference would be prepared and certified by the SAB Chair and he noted the SAB's compliance with ethics requirements. Dr. Armitage also indicated that all meeting materials were available on the SAB web site. These meeting materials included: the Federal Register Notice announcing the meeting,² meeting agenda,³ and SAB roster. Dr. Armitage noted that, as required by FACA, time had been included on the meeting agenda to hear public comments and that requests to speak had been received from 9 individuals. In addition, Dr. Armitage noted that written public comments had been received, posted on the SAB website, and made available to SAB members. He noted that preliminary comments⁴ of SAB members in response to charge questions had also been posted on the SAB website. Dr. Armitage also indicated that public access to the meeting had been provided through a conference line.

Purpose of the Teleconference and Review of Agenda

Dr. Michael Honeycutt, Chair of the SAB, welcomed members of the SAB and other attendees to the teleconference. He indicated that the SAB was holding the teleconference to conduct a consultation with EPA on mechanisms for secure access to personally identifying information and confidential business information under EPA's proposed rule *Strengthening Transparency in Regulatory Science* (the Science and Transparency Rule). Dr. Honeycutt noted that the EPA Administrator had requested the consultation. Dr. Honeycutt also noted that, at a meeting held in June, 2019, the SAB had received a briefing from EPA on the Science and Transparency rule. Dr. Honeycutt indicated that, because the SAB was conducting a consultation, a consensus report of findings and recommendations would not be developed, but SAB members would discuss responses to the EPA's charge questions and provide a report containing the individual written comments of SAB members.

Dr. Honeycutt reviewed the teleconference agenda. He indicated that the Board would first hear remarks from Dr. Maria Doa of EPA's Office of Research and Development. He stated that Dr. Doa would review EPA's charge questions⁵ for the consultation. Dr. Honeycutt indicated that after Dr. Doa's presentation, the SAB would hear public comments. He noted that public comments would be limited to three minutes per speaker and there would be time for questions from SAB members after each speaker's comments. Dr. Honeycutt noted that after hearing public comments, the SAB would discuss responses to the charge questions and members would develop individual written responses to the charge questions following the teleconference. Dr. Honeycutt indicated that before adjourning, there would be time for the SAB to hear additional clarifying comments from EPA staff or members of the public. He indicated that persons who wanted to provide brief clarifying public comments should send an email to the Designated Federal Officer at the email address listed on the meeting webpage.

Remarks from EPA

Dr. Maria Doa of EPA's Office of Research and Development summarized the requirements of the proposed Science and Transparency Rule. She indicated that the proposed rule would require EPA to ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation. This requirement would apply to all significant regulatory actions. Dr. Doa noted that, in meeting this requirement it will be necessary for EPA to make data available in a manner that protects personally identifiable information and confidential business information. Therefore, EPA had requested this consultation with the SAB on existing mechanisms for secure access to personally identifying information and confidential business information.

Dr. Doa presented the following two charge questions to the SAB for the consultation: (1) Other agencies, e.g., National Institutes of Health (NIH) and U.S. Department of Health and Human Services (HHS), use a tiered approach for access to PII data. Please comment on whether such an approach would be a good model for EPA to apply; (2) Given the laws protecting CBI and PII, as well as the proposed requirements for data availability in the Strengthening Transparency in Regulatory Science proposed rule, please comment on how EPA could use studies involving CBI and/or PII to make regulatory decisions.

Dr. Doa discussed the tiered approach for providing access to PII data. She noted that protected data sets could be coded as "non-public," or guidance issued by the Department of Health and Human Services could be followed to de-identify information. Dr. Doa discussed two methods that were available to protect information, the "safe harbor" method and the "expert determination" method. She noted that when applying the "safe harbor" method, a proscribed list of identifiers of the individuals who were part

of a study (or of relatives, employers, or household members of the individuals) are removed. She noted that when applying the “expert determination” method, protected health information is de-identified by a person with appropriate knowledge of and experience with general accepted statistical scientific principles and methods. Dr. Doa also indicated that EPA was currently gathering information about managing public access to human subjects research data sets. Dr. Doa indicated that a tiered approach would provide access to the research data using different strategies based upon disclosure risk, and that access to information and data would vary by tier. Dr. Doa also discussed regulations that protect CBI. She noted that these regulations established basic rules governing business confidentiality claims.

Dr. Doa responded to questions from SAB members. Members asked whether other Federal agencies were conducting analyses of how to protect personally identifying information. A member noted that in responses to previous SAB questions on the proposed Science and Transparency rule, EPA had indicated that the Agency had been working with the National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC) to conduct a pilot study using a secure data enclave to host EPA datasets in a restricted use environment. The member asked whether EPA would be conducting analyses under this pilot project to determine whether personally identifying information could be detected after deidentification. An EPA staff member on the phone indicated that the pilot was being conducted as a demonstration of how personally identifying information could be protected. Members asked when the pilot project would be complete. EPA staff responded that results of this work may be available in about six months.

A member of the SAB noted that in public comments on the Science and Transparency Rule, concern had been expressed about whether information from important studies, such as the “six cities study” data set, would be available for use under the requirements of the proposed rule. Dr. Doa responded that the EPA was in the process of looking at all of the public comments on the proposed rule and that the Agency was considering approaches to address issues raised in the comments.

A member noted that the proposed rule required that data be made publicly available to allow replication of the studies supporting EPA regulations. The member asked whether it would be necessary to withhold so much data under a tiered approach to protect PII that studies could not be replicated. Dr. Doa responded that this would depend upon the data set and tiering system being used. Another member commented that the CDC pilot did not apply to third party data. EPA staff responded that the pilot focused on the use of EPA data and that the final rule would build upon the information obtained from the pilot.

A member asked Dr. Doa to explain the difference between study replication and validation as discussed in the proposed rule. She responded that replication could be more narrowly defined as reproducing results. Another member noted that under a tiered approach, there would be more restricted access provided when more data were available. The member asked Dr. Doa to explain what was meant by “more data available.” The member asked whether this referred to the number of records in a dataset. He noted that the amount of data available should not change the access requirements. Dr. Doa responded that in this context, “more data available” meant more “sensitive data available.” She noted that if more sensitive data were available, fewer people should have access to the data. Several other SAB members commented on processes used by other federal agencies to protect PII and noted that the EPA should build on the work of those other agencies.

Public Comments

Dr. Honeycutt thanked Dr. Doa for her presentation and called for public comments from individuals who had registered in advance to provide oral statements. He stated that he would ask each person on the list of public speakers⁶ to present comments. He asked that speakers limit their comments to three minutes. He indicated that he would allow time for one or two follow-up SAB questions per speaker.

Ted Steichen of the American Petroleum Institute provided oral comments and a written statement.⁷ Mr. Steichen commented that the SAB should focus on responding to the charge questions that had been submitted by the EPA and refrain from discussing issues that were not specific to the two charge questions. He commented that privacy concerns were important and noted that advances in encryption technology and blinding of data had made it possible to enhance transparency while protecting privacy. He commented that protection of confidential business information should not be weakened and expressed the opinion that the results of EPA analyses of CBI could potentially be made available to the public while protecting the privacy of this information.

Mary Rice of the Harvard Medical School provided oral comments and a written statement⁸ on behalf of the American Thoracic Society. Dr. Rice expressed concerns about the EPA's planned rule, *Strengthening Transparency in Regulatory Science*. She commented that the proposed rule would allow EPA to ignore large portions of the scientific literature when making decisions about protection of human health. She commented that some studies could not be deidentified to protect patient privacy and therefore they could not be used under the proposed rule. She commented that the proposed rule would function as a roadblock against the use of epidemiologic research in EPA rulemaking. She commented that the proposed rule would give the EPA Administrator discretion to choose which studies were acceptable for use by the Agency in regulatory decision making, with no accountability to the public. She commented that the SAB should advise EPA to abandon the rule.

A member of the SAB asked Dr. Rice whether her comments reflected the opinions of the American Thoracic Society. She responded that they did and indicated that the American Thoracic Society supported looking at the full body of evidence available to support rulemaking.

George Thurston of the New York University School of Medicine provided oral and written comments on behalf of the North American Chapter of the International Society for Environmental Epidemiology.⁹ Dr. Thurston commented that: (1) in a world of big data it was no longer possible to publicly release CBI or PII datasets in a way that the privacy of those data could be guaranteed, and (2) if the data were made available to vested interests, past experience had shown that those data would likely be misused by consultants in a way that served the vested interests, and sought to undermine the original study conclusions if the vested interests did not like study results.

A member asked Dr. Thurston whether it was possible to use National Health and Nutrition Examination Survey (NHANES) data without breaching privacy. Dr. Thurston responded that some of the data could not be made public without breaching privacy. Another SAB member noted that all NHANES data were not truly accessible. Members asked Dr. Thurston to comment further on his concern about the use of data by special interests. Dr. Thurston indicated that he was concerned about the misuse of data by vested interests.

Ms. Genna Reed of the Union of Concerned Scientists provided oral comments. She expressed concern about the process of the SAB consultation. Ms. Reed commented that the SAB consultation on the Science and Transparency Rule was too limited and would not provide timely advice for the rule-

making process. She commented that the EPA had not made the full proposed rule available to the SAB for review and had not answered the questions about implementation of the proposed rule that had previously been submitted by the SAB. She commented that the EPA was continuing to work toward completion of the rulemaking without receiving advice from the SAB. She commented that the EPA should ask the SAB to review the full proposed rule and receive SAB advice before proceeding.

Bernard Goldstein of the Environmental Protection Network provided oral and written comments.^{10,11} Dr. Goldstein commented that was inappropriate to advance a major new plan on how to utilize the scientific literature for regulatory purposes without asking advice from the SAB about the whole plan. Dr. Goldstein commented on practical problems that should be addressed in implementing the proposed rule. In particular, he discussed a specific study that had identified formaldehyde as cause of human leukemia. Dr. Goldstein commented on a number of issues that would prevent public access to data from this study.

Christopher Frey of the North Carolina State University provided oral and written comments.¹² Dr. Frey commented on EPA's process of appointing SAB members. He commented that the current appointment process did not take scientific expertise into consideration but emphasized increased member turnover, geographic diversity, and representation of government agencies, and barred EPA grant recipients from academia but not government agencies. He commented that the process had led to fewer researchers serving on the SAB and had increased representation of biases related to regulated industries. Dr. Frey also commented that the current EPA Administration had proposed science-based regulations without paying proper attention to the science. He also commented that the proposed Science and Transparency Rule had been developed without input from the SAB. Dr. Frey commented on the scope of the consultation on the Science and Transparency Rule, expressing concern that EPA was not engaging a properly constituted SAB in a broad scale interactive and deliberative review of the scientific basis and implications of the entire proposed rule. Dr. Frey also commented that the SAB should have been engaged in providing scientific review and advice on other EPA rules.

Christina Franz of the American Chemistry Council provided oral and written comments.¹³ She commented that EPA should incorporate stronger data and model access requirements into cooperative agreements and grants while complying with privacy and confidentiality requirements and laws. She also commented that EPA should confer with the data owners of CBI to determine how to make data available to the greatest extent possible without disclosing the CBI within data, studies, or models. She noted that the type of regulatory decision and the specific requirements of the statute involved would likely affect how data could be made available. She commented that making a final study report publicly available without the underlying CBI could be an effective way to provide the relevant information to the public. She commented that National Institutes of Health guidelines should be consulted for information on protecting data while promoting data access. She also commented that when data may not be available for independent evaluation because of privacy concerns, EPA should attempt to work with data owners to reach an agreement to make the information available without jeopardizing the privacy, confidentiality, or the proprietary interests that deserve protection.

Roy Gamse provided oral and written comments.^{14,15,16} Mr. Gamse commented that the proposed Science and Transparency Rule should be withdrawn because it would have the effect of removing from consideration important scientific studies on human health effects of pollution and toxic chemicals. Mr. Gamse referred SAB members to the written comments that had been submitted by the International Society for Environmental Epidemiology (ISEE). The ISEE comments were attached to Mr. Gamse's written comments. He indicated that the ISEE comments provided examples that showed why masking of personal identity would not work. Mr. Gamse also questioned why the Science and Transparency

Rule was being proposed as a requirement for only the EPA, rather than as legislation or regulations applying to all health-regulating agencies. He commented that if the requirements of the rule applied to the Food and Drug Administration, development of new drugs would likely be halted.

Albert Rizzo of the American Lung Association provided oral and written comments.¹⁷ Dr. Rizzo commented that the proposed rule was developed to address a problem that did not seem to exist. He commented that EPA's existing approach to the use of science, with detailed review and deliberation, was already transparent and had worked well for decades. Dr. Rizzo indicated that EPA's review of National Ambient Air Quality Standards was an example of a process that explored peer reviewed studies to understand what could be concluded from the findings. Dr. Rizzo commented that many studies, including old studies, were based on data that could not legally be made public. He commented that the requirement to keep this information confidential to protect research participants did not make the data any less valid. Dr. Rizzo commented that the SAB consultation did not provide enough time to review the proposed Science and Transparency Rule and that more in-depth discussion by the SAB was needed.

A member of the SAB commented that inaccurate data and poor statistical analysis had been used to support some regulations and he thought the proposed rule would address these problems.

Discussion of Mechanisms for Secure Access to Personally Identifying Information and Confidential Business Information under the Proposed Science and Transparency Rule

Dr. Honeycutt thanked the speakers for providing public comments and indicated that the SAB had been given two charge questions for the consultation. He noted that the first question asked the SAB to comment on the use of a tiered approach for access to PII data, and the second question asked the SAB to comment on whether the EPA should use of studies involving CBI and PII to make regulatory decisions. Dr. Honeycutt called for SAB comments in response to the questions.

SAB members discussed the scope of the charge questions and the information that had been provided by EPA for the consultation. A member commented that that the charge questions were quite narrow. He suggested that the SAB conduct a broader review of the proposed rule. Other members agreed with the comment. A member expressed concern that the SAB had not been given sufficient information to answer the charge questions. The member commented that implications of the requirements of the proposed rule were not clear. He indicated that the proposed rule could result in perverse outcomes, but it was difficult to comment on this issue without more specific information about how the rule would be implemented.

Members commented that it would be helpful to receive additional information from EPA indicating how the tiered approach for providing access to CBI and PII would work. A member noted that the examples provided in the comments from the International Society for Environmental Epidemiology were helpful. Another member agreed that it would be helpful to receive more specific information about tiered approaches. Members indicated that it was not clear how a tiered approach and public access could work together. A member commented that it would have been helpful to know more about the kind of tiered approach that EPA was considering.

Members discussed specific suggestions in response to the charge questions. A member noted that EPA could benefit from SAB comments on whether it was necessary to provide access to original data from a study in order to meet the requirements of the proposed rule and how privacy information could be protected. A member commented that microaggregation was a useful method for protecting the privacy

of data. Members further discussed microaggregation and how it was used to protect privacy of data. Members commented that a tiered approach involved different levels of access to data and noted that measures to ensure data security should be considered as part of the tiered approach.

A member expressed the opinion that tiered data access would be a productive approach to protecting privacy. He noted that there appeared to be some confusion about what it meant to test or validate a study. He commented that study validation showed a level of confidence in the conclusions of a study. He noted that it might be possible to reproduce a study but this did not necessarily indicate confidence in the conclusions. Another member commented that he thought a tiered approach to protect privacy could work, but additional information was needed to understand how study data could be accessed in tiered approaches. He noted that reanalysis of data had been proposed as a mechanism to validate studies. He indicated that it was important to determine who would conduct these reanalyses and how access to data would be provided. Members discussed how the Internal Revenue Service (IRS) had used a tiered approach to protect the privacy of data. A member noted that the IRS had created “dummy data sets” for reanalyses in order to maintain the confidentiality of real data. He recommended that the EPA adopt this kind of approach.

Members discussed the need to receive additional clarifying information. A member again commented that it was difficult to understand how a tiered approach to implementing the proposed rule would work. He suggested that the EPA provide information about studies used in the past that would be subject to concerns about protection of PII and CBI under the requirements of the proposed rule. He noted that, without this kind of information, the scope of the problem was not clear, and it was difficult to evaluate potential solutions and understand what would be required to implement them. Another member commented on the need for better definition of the requirements of the proposed rule. The member noted that the proposed rule required that data and models underlying the science be made publicly available in a manner sufficient for validation and analysis. The member commented that, in this context, the definition of “publicly available” was not clear. The member questioned whether the rule would require that data and models be made available to any member of the public who requested it. The member indicated that the SAB needed a better understanding of this requirement to comment on tiered approaches to protecting PII. Another member commented that, because of privacy concerns, it would be difficult for the EPA to obtain underlying data from many studies. The member noted that the question of how much data could be made available to the public was complex.

Members discussed whether “old” studies would be available for use under the requirements of the proposed rule. Members noted that EPA had previously relied on peer reviewed papers and underlying data to develop regulations and therefore old studies were available for use. A member commented that norms were different in the past, data storage technology had changed, and all of the data from old studies might not be available. Another member commented that in the past, EPA relied on published papers but the Agency did not hold all of the data. He commented that under the requirements of the proposed rule some old studies could probably not be used because data would not be available. Another member commented that the requirement to make data publicly available was useful because science was best when more than one group looked at it.

SAB members discussed NIH experience with tiered approaches to data availability. A member commented that using NIH experience as a model for the tiered approach may not be very useful because much of the data EPA needed to support regulations had a spatial/temporal component not present in NIH data. He also noted that it was not clear that the owners of non-federal data would want to provide the data to EPA and in fact may not be able to provide data without permission from study

participants. The member commented that it would be helpful for the SAB to see an example of the kind of tiered approach that EPA intended to use.

A member reiterated the comment that the requirement to make data publicly available involved complex issues. The member commented that the SAB was already engaged in a separate review of the entire proposed rule beyond the relatively narrow questions provided for the consultation. She suggested that the SAB be given more time to consider additional information and develop a review of the whole rule. Another member commented that in answering the narrow charge questions for the consultation, the SAB would not be addressing other important issues.

Dr. Honeycutt responded to concerns expressed by SAB members about the consultation. He noted that the EPA had asked SAB members to provide individual comments in response to the specific charge questions that had been given to the Board. He noted that the SAB was also conducting a review of the entire rule and would develop a consensus report of the Board's findings and recommendations. Several members reiterated concerns about providing limited comments for the consultation. A member asked whether the time frame for developing a consensus report on the proposed rule was the end of the calendar year. Dr. Honeycutt indicated that he would like to have the report completed by the end of the calendar year.

A member noted that a workgroup had been formed to develop a draft SAB review of the science and transparency rule. He asked for a status update on work that had been completed by the workgroup. Dr. Honeycutt indicated that members of the workgroup were continuing to develop a draft report that would be reviewed by the entire SAB in a public meeting. He indicated that other SAB workgroups were also developing draft reports on the proposed rules that the Board had agreed to review. He noted that these reports would all be discussed by the full Board.

Members continued to discuss the kind of advice provided by the SAB in a consultation. A member observed that the consultation letter and report to the Agency would contain specific comments from SAB members but not consensus advice. He noted that this was not the most common kind of SAB report provided to EPA and suggested that it might not be as useful as a consensus report. Another member commented that a consultation would be useful because it provided a range of diverse opinions. Dr. Honeycutt responded to SAB members, indicating that consultations were conducted less frequently than consensus reviews, but he noted that the EPA had specifically requested a consultation on mechanisms for secure access to PII and CBI, and that individual comments from the consultation would be available to all SAB members for consideration when they discussed the Board's consensus report on the Science and Transparency Rule. Several members indicated that they would mention their concerns about the need for a consensus advice rather than a consultation in their individual comments.

Members discussed the potential effects of the proposed Science and Transparency Rule on rulemaking. Members commented that it would be helpful for the EPA to develop a list of key rulemakings that would rely on the use of CBI and PII. They noted that EPA could use this information to focus on developing approaches to make the most relevant data sets publicly available. A member commented that it was not clear which proposed rules would be subject to the requirements of the Science and Transparency Rule. Members commented that most chemical rules would probably be affected. A member commented that existing rules would be affected if the EPA changed them. Members discussed the applicability of the Science and Transparency Rule to National Ambient Air Quality Standards that were reviewed every five years and to Superfund sites with five year reviews. Several members commented that the potential implications of the proposed rule could be quite large and that more clarity was needed in defining the requirements of the proposed rule. A member commented that increased

transparency had been emphasized in current research and therefore the proposed rule might not have a great impact. Other members disagreed, noting that if historical studies were not available for use in rulemaking, the Science and Transparency Rule would have a large impact. Members also noted that the Science and Transparency Rule pertained to significant regulatory actions and therefore it would affect a large number of rules.

Dr. Honeycutt asked members whether there were additional issues to discuss. A member commented that it might not be necessary to make raw data publicly available to meet the requirements of the Science and Transparency Rule because exposure-response analyses could be conducted without obtaining all of the raw data from studies. He noted that dose-response analyses were often conducted using an analysis data set. He noted that the analysis data set was the most important piece of information used in major regulations, and making this information available might not necessitate the release of CBI and PII. Another member commented that the proposed rule required making all of the data from pivotal studies publicly available. A member responded that data used for these kinds of analysis were usually aggregate data sets not the raw study data. He commented that the raw data could be protected. Another member questioned who would develop the aggregate data sets that would be made publicly available. In response, a member commented that these data sets would be developed by those who produce exposure-response curves. A member commented that it would be necessary to view the raw study data in order to determine whether it had been used in developing the regulation, and if the raw data were confidential business information this would pose a problem.

Before concluding the discussion, members further discussed the definition of a tiered approach and the need to receive examples of tiered approaches for protecting CBI and PII. A member noted that without having specific models to evaluate it was difficult to advise EPA.

Brief Clarifying Public Comments

Dr. Honeycutt thanked SAB members for their comments and stated that the SAB would hear brief clarifying public comments. The DFO indicated that two individuals had requested time to present clarifying public comments. Dr. Honeycutt called Christopher Frey and Bernard Goldstein to offer brief clarifying comments.

Dr. Christopher Frey commented on additional analyses of the proposed rule that would be useful. He commented that implementation of the proposed rule would entail significant costs and noted that a staff background document addressing alternatives would be useful. He also mentioned that it might be useful to involve the SAB in reviews to determine whether it was necessary to make specific study data available to the public.

Dr. Bernard Goldstein commented that if data from an existing study were to be shared, it might be necessary to consult and receive approval from an Institutional Review Board.

Closing Remarks and Next Steps

Dr. Honeycutt thanked members of the SAB for participating in the teleconference and reviewed the follow-up action items and next steps. He stated that the next step would be to develop a compilation of individual written comments from SAB members for the consultation. He asked that SAB members to send written responses to the charge questions to the DFO by Friday, September 13th. He indicated that he would work with the DFO to incorporate the individual comments into a report. He again noted that the report would contain individual comments of SAB members and would not be a consensus report.

Materials Cited

The following meeting materials are available on the EPA Science Advisory Board website, www.epa.gov/SAB, on the August 27, 2019 meeting page.

<https://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/d2abf27dbbcb6cf6852584420063e436!OpenDocument&Date=2019-08-27>

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- ¹ Roster
 - ² Federal Register Notice
 - ³ Agenda
 - ⁴ Preliminary Comments from SAB Members (as of 8/21/19)
 - ⁵ Charge for Mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) under the proposed rule Strengthening Transparency in Regulatory Science
 - ⁶ Registered Public Speakers
 - ⁷ Oral Statement from Ted Steichen, American Petroleum Institute
 - ⁸ Oral Statement from Mary B. Rice, American Thoracic Society
 - ⁹ Comments Submitted by George D. Thurston, North American Chapter of the International Society for Environmental Epidemiology
 - ¹⁰ Comments Submitted by Bernard D. Goldstein, Environmental Protection Network
 - ¹¹ Additional Comments Submitted by Bernard D. Goldstein, 9/13/2019
 - ¹² Comments Submitted by H. Christopher Frey
 - ¹³ Comments submitted by Christina Franz, American Chemistry Council
 - ¹⁴ Oral Statement from Roy N. Gamse
 - ¹⁵ Comments Submitted by Roy Gamse - Question About the SAB working Group Process
 - ¹⁶ Written Statement from Roy N. Gamse
 - ¹⁷ Statement from Albert Rizzo, American Lung Association

ATTACHMENT A – Other Attendees
U.S. Environmental Protection Agency Science Advisory Board
August 27, 2019

Name	Affiliation
Allen, George	NESCAUM
Apfel, Carrie	Earthjustice
Bankoff, Barbara	Bankoff Associates
Beitsch, Rebecca	The Hill
Bloomer, Bryan	EPA
Botelho, Ligia Duarte	Bergeson and Campbell, PC
Broder, Michael	EPA
Carpenter, Tom	
Cone, Shane	
D’Amico, Louis	EPA
D’Arcy, Daniel	Bipartisan Policy Center
Delaney, Mike	Massachusetts Water Resources Authority
Dockins, Chris	EPA
Dooley, William	Association of State Wetland Managers
Evans, Caren Kagan	Environmental Protection Network
Fletcher, M.K.	AFLCIO
Flowers, Lynn	EPA
Franz, Christina	American Chemistry Council
French, Timothy	Truck and Engine Manufacturers Association
Frey, H. Christopher	North Carolina State University
Gamse, Roy	
Goldstein, Bernard	Environmental Protection Network
Hakkinen, Pertti	NIH, NLM
Hale, Zack	S&P Global Market Intelligence
Harrilchak, Marisa	Hutton Andrew Kurth
Hashimoto, Hayden	Clean Air Task Force
Hegstad, Maria	Inside EPA
Hetes, Bob	EPA
Hill-Hammond, Shaunta	EPA
Hockstad, Leif	EPA
Irby, Sebastian	Environmental Protection Network
Iwicki, Matt	Boeing Company
Kenyatta, Miles	Shell
Krock, Richard	The Vinyl Institute
Lamson, Amy	EPA
Lange, Sabine	Texas Commission on Environmental Quality
Lee, Stephen	Bloomberg Environment
Lefohn, Allen	A.S.L. and Associates
Limaye, Vijay	NRDC
McMillan, Brian	American Association for Justice

Name	Affiliation
Mikyungee, Jennifer	
Miller, Jason	Federal News Network
Moran, Kelly	TDC Environmental, LLC
Mudasiru, Omobola	API
Olsen, Jay	Utah Department of Agriculture
Pant, Pallavi	Health Effects Institute
Pavich, Dave	Phillips 66 Company
Reed, Genna	Union of Concerned Scientists
Rees, Sarah	South Coast Air Quality Management District
Reilly, Sean	E&E News
Rice, Mary	Harvard Medical School, American Thoracic Society
Rives, Glenn	International Paper
Rizzo, Albert	American Lung Association
Rohr, Annette	EPRI
Sarang, Surbhi	Earthjustice
Schreiber, Danielle	Verdant Law, PLLC
Schwarber, Adria	American Institute of Physics
Shannon, Danielle	EPA
Sianey, Joanna	Environmental Defense Fund
Smith, Sindy	State of Utah
Snider, Annie	Politico
Steichen, Ted	American Petroleum Institute
Stevenson, Jayne	Environmental Defense Fund
Thompson, Janie	House Committee on Science Space and Technology
Thurston, George	NYU School of Medicine
Warshaw, Jean	Warshaw Legal
Wilson, Linda	New York State Government