

Memorandum

To: Michael Kaplan
CC: Bobby Rickard, Donna Zimmerman, Susan Stalnecker, Robin Leonard
Date: 2/24/2006
Re: Epidemiology Review Board and PFOA

We, the members of the Epidemiology Review Board (ERB) for DuPont, are writing to provide comments on and raise questions about DuPont's research program on potential health risks of perfluorooctanoic acid (PFOA). The ERB has heard presentations on multiple occasions over the last several years with regard to PFOA, addressing on-going studies of workers, population exposures and exposure biomarkers, and toxicology. Recently, the February 18 meeting of the ERB focused exclusively on DuPont's program of research on PFOA. This presentation was informative and gave the ERB some handle on the scope of the program, its directions, and its management. We would, however, like to reach a still better level of understanding.

These presentations of the research activities and discussions of potential health effects of PFOA also raise concern for members of the ERB about the role of this group in DuPont's overall approach to PFOA. The February 18 meeting left questions only partially answered as to the long-range and strategic management of the research program, which now involves multiple lines of investigation and several institutions. **Given the many gaps in understanding of population exposures to PFOA and of possible health consequences, we strongly advise against any public statements asserting that PFOA does not pose any risk to health. It appears to us that no party can claim sufficient knowledge that PFOA does or does not pose any risk to health. We also question the evidential basis of DuPont's public expression asserting, with what appears to be great confidence, that PFOA does not pose a risk to health. In this circumstance, as we understand it, the burden of proof is now placed on DuPont's shoulders to assemble the best scientific evidence that can be assembled.**

While we interpret our general charge as providing guidance on epidemiologic research and attendant ethical issues, the discussions around PFOA necessarily involve interdisciplinary research. Epidemiologic findings must be interpreted in a broad context set by the full set of scientific evidence. Consequently, we find it difficult to limit the scope of our questions and advice solely to the epidemiologic studies. The February 18 meeting was intended to provide this context and it did so successfully, but left the general concerns set out in this letter.

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We write, then, to ask that you bring greater clarity to the ERB's role in the context of the PFOA investigations. The description by Bobby Rickard needs augmentation, and the mentioned advisory committee architectures that do not appear to be firmly in place. From the ERB's perspective, DuPont does not have an adequately integrated research plan, particularly for the longer-term. We have yet to see a written document that sets out all of the elements of the research plan, with timelines. Consequently, our ability to assist with the epidemiologic research program is constrained and may be of less value to you than we could make it. Given the level of worker exposures relative to community levels, it is clear that well designed epidemiologic studies of exposed employees are needed. It is not clear, however, that DuPont has yet put in place the appropriate level of commitment to launching scientifically adequate health studies of potentially exposed employees.

We have joined the ERB because of our shared view that DuPont has a strong commitment to use epidemiologic approaches to assure the health of its workers and to make certain that its manufacturing activities and products do not threaten public health. Such ideals are vital, but often difficult to implement in practice. The current concern about PFOA is a formidable challenge for DuPont's researchers, including its epidemiologists. We want to be as helpful as possible, but find ourselves at sea about, and therefore somewhat frustrated by, the lack of an integrated DuPont approach.

We recommend careful consideration of the issues that we have raised in this letter as well as further discussion with the ERB. Specifically we urge that a plan be established for epidemiologic studies of PFOA risk in the DuPont workforce and that this plan be located in the context of DuPont's integrated research plan concerning PFOA biological effects. We are, as always, willing to assist in this effort, but we believe that there is need that this plan be developed as a high priority—the highest, from our point of view.

Epidemiology Review Board

Thomas Beuchamp
Mark Cullen
Ellen Eisen
Jonathan Samet
Noah Seixas
David Wegman

Final sent

Memorandum

To: Michael Kaplan
CC: Bobby Rickard, Donna Zimmerman, Susan Stalneckner, Sol Sax, Robin Leonard
Date: 2/27/2006
Re: Epidemiology Review Board and PFOA

We, the members of the Epidemiology Review Board (ERB) for DuPont, are writing to provide comments on and pursue questions about DuPont's research program on potential health risks of perfluorooctanoic acid (PFOA). The ERB has heard presentations on multiple occasions with regard to PFOA, addressing on-going studies of workers, population exposures and exposure biomarkers, and toxicology. The February 17 ERB meeting focused on DuPont's program of research on PFOA. This presentation provided information on the scope of the program, its directions, and its management. It also raised issues about research planning in general on PFOA and specifically about the role of the ERB in DuPont's approach to questions on PFOA.

The February 17 presentation only partially answered our questions about the long-range and strategic management of the research program, which now involves multiple lines of investigation and several institutions. The presentation called attention to the gaps in our understanding of the routes of population exposures to PFOA and possible health consequences. We believe that no party can claim sufficient knowledge that PFOA does or does not pose any risk to health. Thus, we question the evidential basis of DuPont's public expression asserting that PFOA does not pose a risk to health. **In this circumstance, as we understand it, the burden of proof to establish the safety of PFOA is now placed on DuPont's shoulders.** You need to assemble the best scientific evidence that can be assembled. All of us on the ERB are interested in working effectively to assist DuPont in conducting the epidemiologic research needed to resolve the current uncertainties.

In order that we be able to work effectively, on our end, we ask that you bring as much clarity to the ERB's role, in the context of the PFOA investigations, as possible. We find ourselves confused about which plans and strategies are actually in place—or can be put in place. For example, Bobby's description of the advisory committee architectures included elements that do not appear to be firmly in place. Will they be in place soon? Are we expected to fill in any gaps? From our perspective, DuPont needs to place priority on the development of a document that describes all elements of its integrated research plan, with associated timelines. Without such a document, our ability to assist with the epidemiologic

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research program is diminished. We will be of far less value to you than we could be with such a document. Also, given the level of worker exposures relative to community levels, your integrated research document should include well-designed epidemiologic studies of exposed employees. In the absence of such a document, DuPont's program for launching scientifically adequate health studies of potentially exposed employees will be less clear, pertinent, and well-developed than we think it should be.

We became members of the ERB because we were convinced that DuPont has historically had an emulable record of commitment to the use epidemiologic approaches to assure the health of its workers and to make certain that its manufacturing activities and products do not threaten public health. Such ideals are profoundly important, but also sometimes difficult to implement in practice. The current concern about PFOA is a formidable challenge for DuPont's researchers, including its epidemiologists. We seek to be as helpful as possible in meeting this challenge, but we find ourselves frustrated, sometimes left a bit directionless, by the lack of an integrated DuPont approach. We are trying to express in this letter, with some emphasis, how important this is to us—and we think how important it is to you as well.

We hope that every responsible party at DuPont will give careful consideration to the concerns we have raised in this letter. We hope that you will respond as quickly as possible, and then engage in further discussion with the ERB. It is very important to us that a plan be established for epidemiologic studies of PFOA risk in the DuPont workforce and that this plan be integrated within the context of DuPont's research plan concerning PFOA biological effects. We are, as always, eager to assist in this effort. We believe that there is a pressing need that this research plan—and its requisite, associated documents—be developed as a high priority—the highest, from our point of view.

Epidemiology Review Board

Tom L. Beauchamp
Mark R. Cullen
Ellen A. Eisen
Jonathan M. Samet
Noah Seixas
David H. Wegman