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April 11, 2005

**BY E-MAIL**

Administrator For DuPont/Leach Settlement  
c/o Maryanne K. Aiello, Esq.  
Assistant General Counsel  
The Garden City Group, Inc.  
105 Maxess Road  
Melville, NY 11747

Re: Jack W. Leach, et al. v. E.I. duPont de Nemours and Company  
(Circuit Court of Wood Cty, WV, Civil Action No. 01-C-608): Preliminary Data  
For Review By Science Panel

Dear Administrator:

This letter supplements the letter we sent on April 5, 2005, in connection with Plaintiffs' initial submission of information to the Science Panel. After reviewing the initial feedback from the Panel, we prepared a revised, more detailed index of the materials (which materials we understand you received on April 8, 2005) to provide more detail on the nature of the documents submitted, their length, and "confidentiality" status. The revised index is attached as Exhibit A. Also in response to initial feedback from the Panel, we are providing additional clarification as to why Plaintiffs have submitted such a large volume of materials, other than published journal articles, for review by the Panel. We hope this clarification will explain why Plaintiffs believe it is important for the Panel to consider more than just the selected published journal articles and reports submitted by DuPont in order to adequately assess the nature and extent of any "association(s)" and "probable link" between C-8 and any human disease(s) under the Settlement among the parties.

During the lengthy lawsuit against DuPont that eventually led to the creation of the Science Panel under the Settlement, DuPont produced to Plaintiffs over one million pages of

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documents that revealed many years of internal, industry studies of health effects among workers exposed to C-8 (including data from extensive medical monitoring of C-8 workers dating back to the 1970s), much of which is not mentioned or documented in the published literature or in EPA's hazard and risk assessments. These internal studies include, among other things, internal studies of C-8 workers' liver enzymes, heart attack rates, cancer claims, birth defects, fertility problems, worker exposure histories, and C-8 blood levels. These internal documents reveal significant data with respect to adverse health effects among humans exposed to C-8. Thus, although the published data also reveal adverse human health effects attributable to C-8 exposure, a complete understanding of the full extent of all adverse health effects attributable to C-8 exposure among humans cannot be achieved without carefully considering the extensive internal evidence of adverse health effects that DuPont and industry found among C-8 exposed workers but decided either not to publish or not to "confirm" through appropriate follow up studies. Although the published worker health data are considerably more succinct, it reveals only the data that the authors chose to submit for publication. Thus, many of the important health effects actually observed among workers are revealed only in the scattered internal company memos and other documents we are submitting, which have not previously been made available to the scientific community for consideration (except to Plaintiffs' experts in the lawsuit).

We also are submitting the deposition transcripts of several of DuPont's key medical/epidemiological researchers who were involved in the vast majority of the internal studies at issue. These include transcripts from DuPont's corporate medical director and each of DuPont's lead corporate epidemiologists, who were involved in these studies between the late 1970s and the present. These depositions provide important insight into the context in which the available health data was developed and why it was or was not published or pursued. Plaintiffs also provided copies of the deposition transcripts of the two female Washington Works employees studied by DuPont in 1981 whose children were born with birth defects following the mothers' exposure to C-8 in the workplace. These transcripts provide valuable information regarding the nature and extent of each woman's exposures to C-8 at the plant and the health effects experienced by the women and their children, which data is not otherwise available. Also included among the exhibits to those transcripts are photographs depicting some of the birth defects at issue. Although the exhibits to all of the submitted transcripts are lengthy and generally duplicate much of what is being provided in the chronologically-organized internal industry health studies data, we provided all of the exhibits so that it is clear to the Panel members which documents are being discussed.

As mentioned above and as discussed with the Panelists during the initial interview process, the charge to the Panel in this case to determine whether there is any "association" or "probable link" between C-8 and any human disease(s) is extremely unique from a scientific perspective. Unlike the typical scenario in which epidemiologists might be asked to opine on whether they believe there is sufficient evidence that a particular chemical "causes" a particular disease (which some epidemiologists may view as requiring some very large percentage of the evidence (say 90-95%) to convincingly support such "causation," here the parties have agreed that the Panel is to determine only whether it is "more likely than not" (whether 51% of the

evidence supports the view) that there is an "association" or "probable link"" between C-8 exposure and human disease. As explained during the initial interviews with the Panelists, the Panel was created in the context of a settlement of medical monitoring claims brought under West Virginia law where the parties agree that the standard to be applied is simply whether there is a "probable link" between exposure and human disease, within the special meaning given that term by the West Virginia Supreme Court in the case of Bower v. Westinghouse Elec. Corp., 206 W. Va. 133, 522 S.E.2d 424 (1999). This "probable link" standard is more liberal than the traditional "causation" standard:

Bower states that the plaintiff need only demonstrate a "probable link" between the substance in question and human disease. This language appears to be a relaxation of the traditional requirement that a toxic-tort plaintiff prove general causation, that is, that the substance in question causes the disease afflicting the plaintiff. The evidence on that issue may, of course, be disputed, but it is still required that general causation be established by a preponderance of the evidence. Bower, without explanation, reduces the necessary proof to a "probable link" and thereby suggests that testimony from a toxicologist or other expert that Substance A probably causes Disease B in humans is sufficient. This formulation of the "proven hazardous substance" element [of traditional medical monitoring claims] is unique and greatly expands the number of substances that are potential bases for medical monitoring claims.

Imbriglia, S., Bower v. Westinghouse: Liberalizing the Prerequisites For Medical Monitoring (published at [www.heckerbrown.com](http://www.heckerbrown.com)). In evaluating the available data to determine whether it is more likely than not that such an association or probable link exists, the Panel should be free to consider and weigh all of the available data, not just published materials:

Depending upon a scientist's judgment of the internal validity or inherent quality of a particular study, an individual "piece" may be clear and well defined, or fuzzy and indefinite. Depending upon a scientist's judgment of external validity of a particular study, he or she may decide that an individual piece forms a large and central part of the picture, is just a small piece on the periphery of the picture, or not part of the picture at all. [citation omitted] In addition, a scientist's experience, expertise and basic judgment are involved. The objective for the scientist, then, is to take the available puzzle pieces, judge their internal and external validity, and assemble a theory or working diagnosis. That is, to bring together the clear and definite and the most relevant pieces into a coherent, sensible, comprehensive, and "elegant" picture of "reality," a picture that represents the scientist's decision about "what is happening."

Clapp, R. W. & Ozonoff, D., Environment and Health: Vital Intersection or Contested Territory?, 30 Am. J. Law & Med. 189, 212 (2004).

Because it is important under the Settlement and applicable West Virginia legal standards that the Panel have access to all available data to independently evaluate "what is happening" with C-8 and whether there is any "association" or "probable link" with human disease, Plaintiffs insisted that the Science Panel not be restricted to considering only published data and insisted

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that there be no restriction on the type of data that the Science Panel could receive in order to discharge its duties under the Settlement. Thus, as provided in Section 10.2.2(a)(6)(ii) of the final November 2004 Settlement Agreement, language is included that confirms there is no restriction on the content or volume of materials submitted by the parties to the Panel, and additional language is provided in Section 12.2.3(a)(1) of the Settlement confirming the Panel's authority to consider, not just published materials, but "any other relevant studies and/or data" in assessing human health effects attributable to C-8. For example, the Settlement provides that, in connection with its duties under "Phase I," of its work, the Panel "shall be free to consider all scientifically relevant data including, but not limited to, data relating to C-8 exposure among workers, among people in other communities, and any other human exposure data, along with animal and toxicity data relating to C-8." (Settlement, at Section 12.2.3(a)(1))

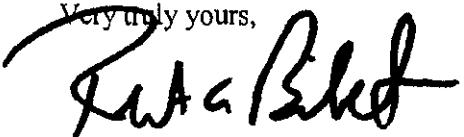
Thus, distinguished from what might normally be the procedure in a project designed for external peer review or journal publication, the Panel is not required to restrict its "association" and "probable link" conclusions or recommendations to only that which is documented in the published/peer reviewed literature, but is free to base those conclusions and recommendations on "any" studies or data it finds relevant, whether published, peer reviewed, or not. The Panel is completely free to consider and weigh (or totally reject and discount) all such data in whatever manner it finds useful for its purposes under the Settlement for the benefit of the class being studied, regardless of whether such data would normally be used to support a project designed for typical outside peer review or publication. In this admittedly very unusual process, the parties have agreed to accept the conclusions of the Panel for the purposes set forth in the Settlement (including medical monitoring obligations) without the need for any peer review or acceptance for publication of the Panel's work. Quite simply, the Panel is free to consider and rely on (or totally reject or discount) any data it wants to in evaluating the available data under the unique, West Virginia Bower standards, regardless of normal peer review and publication restraints, and regardless of whether that evidence would normally satisfy traditional "causation" standards in any other context.

In addition to submitting otherwise unavailable human health effects data, Plaintiffs also are submitting data to assist the Panel in reviewing the nature and extent of actual C-8 exposure among the class of people exposed to C-8 from DuPont's Washington Works Plant in West Virginia. The class consists of tens of thousand of individuals for which the Panel will be designing the Community Study under the Settlement and for which Plaintiffs are undertaking their \$70 million Health Project. Unfortunately, data on the level of C-8 in the air, water, soils, dust, and other environmental media to which the class is exposed is not readily available in published materials. We have, therefore, attempted to provide as much relevant data as is readily available regarding exposures among the class, including information relating to the potential cumulative impact and synergistic effects of related perfluorinated chemicals in the environment.

We hope these clarifications are useful and request that you forward this letter to each of the Panel members. Plaintiffs remain available to discuss these issues in further detail with the Panel and to address any additional questions they may have regarding any of the submitted data,

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pursuant to the procedures set forth in the Settlement. Thank you for your prompt attention to this request.

Very truly yours,  
  
Robert A. Bilott

RAB:mdm

Attachment

cc: R. Edison Hill, Esq. (w/ attachment)  
Larry A. Winter, Esq. (w/ attachment)  
Gerald J. Rapien, Esq. (w/ attachment)  
Laurence F. Janssen, Esq. (w/ attachment)