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August 2, 2005

Drs. Fletcher, Steenland and Savitz
c/o Maryann K. Aiello, Esq.
Assistant General Counsel
The Garden City Group, Inc.
105 Maxess Road
Melville, New York 11747

Re: Jack W. Leach, et al. v. E.I. duPont de Nemours and Company
Circuit Court of Wood County, West Virginia, Civil Action No. 01-C-608
Science Panel

Dear Drs. Fletcher, Steenland and Savitz,

As you know, Plaintiffs' counsel recently participated in discussions and exchanged correspondence with the Science Panel and Brookmar, Inc. ("Brookmar") in an effort to seek a mutually satisfactory resolution of the "consent" issue that arose in connection with formulation of the consent document that Brookmar intends to use in the C8 Health Project. We expressed the Plaintiffs' position on this issue in our June 28, 2005 letter to the Science Panel, a copy of which was sent to Brookmar, in which we recognized that Brookmar is an independent agency approved by the Court to administer the C8 Health Project and is not subject to control by Plaintiffs' counsel. The C8 Health Project administered by Brookmar is entirely separate from the Science Panel's analysis, but data generated from this Project may be considered by the Science Panel and it reasonably should be considered. It will provide facts and data concerning the affected population and written summaries, including statistical correlations of all known variables (i.e. disease or defect incidence rates versus C8 exposures measured in duration and/or concentration of exposure, C8 Blood levels of the participants, including populations presently exposed, exposed in the past, and not exposed). In that regard, Brookmar has arranged for the Science Panel to provide input for consideration by Brookmar in formulating the Health Project. Also, the data will be provided to you on as close to a real time basis as is reasonably possible.

We remain very interested in performing any role that we can legitimately perform to assist the Science Panel and Brookmar in resolving the "consent" issue, but we must at this point express our concerns about, and request clarification of, statements contained in recent communications from the Science Panel. Plaintiffs' counsel have reviewed the exchange of correspondence between Brookmar and the Science Panel dated July 13, 2005 and July 15, 2005, respectively. As a result of our review of that correspondence we have identified very serious issues which we feel compelled to bring to your attention through this letter. Our concerns arise from the Science Panel's discussion

of the consent it seeks to have regarding utilization of the questionnaire and blood test results data to be generated during the Brookmar administered C8 Heath Project. In its communication to Brookmar, the Science Panel has stated several times that it thinks such consent is essential to a determination of whether C8 exposure **"causes"** any human disease. Specifically, the Science Panel's July 15, 2005 memorandum to Brookmar includes the following statements:

1. "As noted above, we believe that consent for Science Panel re-contact and future linkage is essential for conducting future epidemiologic studies **to determine whether C8 or PFOA causes certain health effects.**" (Emphasis supplied.)

2. "The crux of the matter is that a good scientific answer to the question '**does C8 cause health effects?**' cannot be answered by the Health Project survey alone but will require working further with the same population ...." (Emphasis supplied.)

3. "In phase 1 we can look at whether the blood levels of C8 are related to other results from the blood tests, such as cholesterol level, or liver function. However, while the relationship of C8 to cholesterol is important because high cholesterol is associated with heart disease, it will not by itself answer the question **whether C8 causes heart disease**; this will require a follow-up study." (Emphasis supplied.)

4. "In phase 3 we envision a study focusing on chronic disease, specifically cancer and heart disease, which have been implicated (but not proven) to date.

Further, in Appendix 1 to the Science Panel's July 15 memorandum, which contains text suggested by the Science Panel for the consent form, the Panel states: "The court settlement between DuPont and the community also established a Science Panel of three epidemiologists who are carrying out research to help **determine whether C8 causes any health problems**. (Emphasis supplied.)

These statements, when considered in conjunction with the extensive future epidemiologic studies on the C8 Health Project population proposed by the Science Panel in its July 15 memorandum, suggest that the current focus of the Science Panel is inconsistent with its specific mission as set forth in the Settlement Agreement executed by the Settling Parties and the Science Panel Contract executed by each member of the Science Panel. Both the Settlement Agreement and the Science Panel Contract require that, in Phase I of its work, the Science Panel must develop a protocol for and conduct a study of Human Disease for Class members exposed to C8 ("Community Study"), agree upon the criteria to be used in evaluating the Community Study and any other relevant studies or data (such as the C8 Health Project), and determine whether there is an "**Association**" between C8 exposure and any Human Disease. *See* Settlement Agreement §12.2 and Science Panel Contract § 3.2. If the Science Panel finds one or more Association(s) between C8 exposure and Human Disease, then it is required to immediately commence Phase II of its work. In Phase II the

Science Panel is required to establish, execute and analyze one or more Hypothesis Testing Studies, evaluate available scientific evidence, including all of the existing data sent to you several months ago, and determine whether such evidence establishes a "**Probable Link**" between C8 exposure and any Human Disease. *See* Settlement Agreement §12.2.3(b) and Science Panel Contract § 3.2.2.

"Association" is defined in the Settlement Agreement to mean "... that the Science Panel, after taking into consideration the available scientific evidence and whatever scientifically relevant factors the Science Panel deems appropriate, determines that a particular observed correlation between C-8 and a particular Human Disease merits further Hypothesis Testing Studies." *Settlement Agreement* § 1.4. "Probable Link" is defined by the Settlement Agreement to mean "... that based upon the weight of the available scientific evidence, it is more likely than not that there is a link between exposure to C-8 and a particular Human Disease among Class Members." *Settlement Agreement* § 1.49. These definitions are specifically incorporated into the Science Panel Contract at §1.2 and §1.16 respectively. Neither the Settlement Agreement nor the Science Panel Contract permit causation to be the standard in determining either an Association Finding or Probable Link Finding. Association merely requires that a correlation be found between C8 exposure and any Human Disease and Probable Link requires only that it be determined that it is more likely than not that there is a link between C8 exposure and any Human Disease.

Plaintiffs' counsel recognize that the process for resolving this class action litigation established in the Settlement Agreement is unlike the procedures the Science Panel members are accustomed to following in projects designed for external peer review or journal publication. Here the Panel is not required to formulate its "Association" or "Probable Link" findings through methodologies that produce "cause and effect" conclusions. The uniqueness of this project in this respect was emphasized during the initial interview of each Science Panel member by counsel for the Plaintiffs and DuPont. In particular we discussed that, unlike the typical scenario in which epidemiologists are asked to opine on whether sufficient scientific evidence exists that a particular chemical "causes" a particular disease, here the Settling Parties have agreed, and the Court has now directed, that the Science Panel is to follow the unique legal standard applicable in West Virginia legal proceedings in order to determine only whether it is "more likely than not" that there is a Probable Link between C8 exposure and any Human Disease for which an Association was found. Rather than requiring a P value of 90-95%, as is the case in many epidemiology studies, the "more likely than not" standard that governs and controls the Science Panel's work only requires a preponderance of the evidence or 51%. We recognize that the imposition of a legal standard on scientific analysis presents various problems and we appreciate that the Science Panel is accustomed to employing proof requirements that are no doubt more stringent than those that govern and control your work here. However, because this project arises from the resolution of significant legal rights and interests for both the Plaintiffs and DuPont, it is imperative that the Science Panel complete its work within the confines of the legal framework that this Settlement Agreement requires and which has been agreed to in each of your contracts.

It was not a mere matter of form that the Settlement Agreement and the Science Panel Contract included as attachments a copy the West Virginia Supreme Court's decision in *Bower v. Westinghouse Electric Corporation* coupled with a requirement that the Science Panel members carefully review it and follow its ruling relating to Probable Link. As Mr. Janssen and I discussed with each of you during our initial meeting to determine your interest in this project, the *Bower* decision establishes the legal framework for Class members to receive medical monitoring as a form of legal relief, if a Probable Link is established between C8 exposure and any Human Disease. The *Bower* decision does not require proof of causation between C8 exposure and any Human Disease before medical monitoring relief is available to Class members - it only requires that a Probable Link be established. *Bower* speaks in terms of demonstrating only that there is an "increased risk" for contracting a serious latent disease as a result of exposure to a proven hazardous substance, not in terms of demonstrating that a serious latent disease has actually been **caused** by such exposure. In the legal community it is generally recognized that the language used by the West Virginia Supreme Court in *Bower* is an exception to the traditional requirement that general causation be proved. Indeed, if the standard here were causation, the legal relief available to Class members would be far in excess of the medical monitoring relief specified in the Settlement Agreement. If causation evidence is eventually developed, through studies outside the scope of the Science Panel's Work as defined in the Science Panel Contract, between C8 exposure and Human Disease, all Class members will have the right to pursue recovery of other forms of legal damages through separate legal actions, while retaining the medical monitoring benefits they may have received under the Settlement Agreement.

We perceive that the difficult circumstances facing the Science Panel in applying the Probable Link legal standard here are analogous to the problems recently experienced by members of the U.S. EPA Science Advisory Board PFOA Review Panel. The PFOA Review Panel members were asked to express their opinions on the relationship between PFOA exposure and cancer in humans and to state their opinions in language dictated by EPA guidelines, which required the panelists to classify the existing evidence according to categories specifically and specially defined by USEPA. The majority of scientists on the Review Panel concluded that PFOA is a "likely" human carcinogen using the specific cancer descriptors dictated by USEPA, but they are now drafting extensive explanations to be included in their report so that their opinion can be understood in the appropriate scientific context.

During the interview process for this work, you each confirmed that you could follow the unique "Probable Link" standard required in this matter, as established in *Bower*, regardless of how inconsistent that standard may be with traditional causation analysis. As you know, this is a matter of great importance and urgency to our clients and must be resolved immediately so that there is no delay in resolving this critical public health issue.

If we have misunderstood the statements quoted above from the Science Panel's July 15 memorandum to Brookmar, we request that the Science Panel clarify for us what is meant when the Panel incorrectly describes its task as determining "causation" between C8 exposure and Human Disease. We also request that the Science Panel clarify why it is necessary to conduct the extensive follow-up studies on individuals who participate in the C8 Health Project, if the Panel is not attempting inappropriately to determine a "cause and effect" relationship between C8 exposure and Human Disease, and how such extensive follow-up studies are related to its Community Study and other work required in Phases I and II, as specified in the Settlement Agreement and the Science Panel Contract. We would welcome the opportunity to discuss any questions or issues the Science Panel may have after considering the concerns expressed in this letter in a joint telephone conference with the Science Panel, DuPont's counsel and the Garden City Group at a mutually convenient time.

Very truly yours,

Larry A. Winter

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