

## **Medical Panel Response to the Parties Regarding Request for Clarification of Medical Panel Guidance of September 20, 2014 and Request to Meet with the Science Panel**

The Medical Panel will address two items about which the Parties have requested further clarification. These regard 1) the interim guidance of the Medical Panel's anticipated Medical Monitoring periodicity dated September 20, 2014 and 2) the Medical Panel's request to meet with the Science Panel.

1) In response to questions put forth by the Parties regarding the Medical Panel's interim guidance document on periodicity and duration of medical screening dated September 20, 2014, the Medical Panel has prepared a clarifying memo presented here.

The following request for clarification was made in email messages to the Medical Panel on October 1 and 23, 2014:

“Plaintiffs’ Class Counsel seek clarification from the Medical Panel as to whether the “guidance” document the Panel provided to the Parties dated September 20, 2014, does, in fact, reflect any final decision by the Medical Panel on any aspect of its Medical Monitoring Protocol “screening frequency” (even if only as to the timing of a second round of screening) or “screening duration.”

The Medical Panel wishes to clarify that the September 20, 2014 Guidance document was its interim assessment of the reasonably anticipated timing of the next screening that would be recommended for the eligible population undergoing initial screening. It was not meant as the final guidance regarding either frequency or duration of screening. Rather, it was an interim communication to the parties that subsequent screening was a forth coming recommendation from the Medical Panel. We felt that this information of recommended subsequent screening was needed somewhat urgently in order to answer questions anticipated from screening participants during upcoming public meetings and during the initial screening which was imminently underway.

We see that the September 20<sup>th</sup> document requires clarification in some areas which we provide here.

First, the document does not discuss the **ultimate duration** of the medical screening program, nor do we, a short three months after our September memo, have more data upon which to make such a recommendation now. The Medical Panel desires to give an evidence-based recommendation on this point and thus is proceeding carefully here regarding ultimate duration of screening. Secondly, we do see a need to enlarge upon and refine our previous preliminary guidance regarding **periodicity of screening**. As noted above and stated in

the September 20<sup>th</sup> document, the Medical Panel recommended that the next re-screening among eligible class members would be three years after the initial screening. .

The September 20<sup>th</sup> document also attempted to address periodicity of screening for scenarios in which eligible class members who did not have symptoms at the time of initial screening did subsequently develop symptoms during the interval prior to the next general screening in three years. The September 20<sup>th</sup> document indicated that procedures should be established to allow additional screening of symptoms as needed and according to professional judgment up to a frequency of every six months if class members report developing new symptoms. The Medical Panel now wishes to provide clarification regarding the scenarios that might trigger the need for follow up testing outlined in the September 20<sup>th</sup> document (bottom of p. 2, top of p. 3) regarding additional testing following new onset of relevant symptoms. Specifically, even if a class member had received prior additional screening or diagnostic testing, but was not then diagnosed to have the probable link condition the threshold which triggers the end of screening eligibility of the participant—(that of having been diagnosed with one of the six linked conditions)--is not met. Therefore, this participant would be eligible for further periodic follow-up more frequently than the three year period suggested as the interim period. Eligibility for additional screening or diagnostic testing should be determined by the screening physician based on responses to the screening questionnaire, which may be administered if and when a class member reports developing new symptoms different than existed at the time of the prior screening.

Other matters which may influence our Medical Panel decision about frequency of screening in the future are advances in scientific knowledge. For example, recently, the efficacy of screening low-dose Computerized Tomography (CT) scanning for early lung cancer detection has been proven. While this example is not specific to one of the six linked conditions, it illustrates the point that the Medical Panel's judgment will be open to on-going advances in scientific knowledge and practice guideline changes. Because the horizon for follow up screening is already projected to be years long, (i.e., at least three years) the possibility of such a medical advance for one of the six conditions could alter the original Medical Panel protocol.

Therefore, the Medical Panel protocols should be received as 'interim' and based on knowledge at the time the documents were authored.

2) The second item requiring response relates to the Medical Panel's request to meet with the Science Panel. As per the email of September, 25, 2014:

"DuPont requests some additional information as to what the Medical Panel seeks from the members of the Science Panel and why it would be done now,

as opposed to waiting to have the benefit of a better understanding of the scope and nature of the initial screening data.”

The Medical Panel is completely aware of the scope of each of the two panels’ work and does not see this request as implying any effort to alter the Science Panel’s decisions regarding the six probable link conditions. Rather, because the Science Panel members and their publications are a major resource for the Medical Panel decision-making regarding the issues of screening periodicity and termination and indeed, the Science Panel’s findings are not yet exhaustively available in the peer reviewed scientific literature, the Medical Panel would find it useful to discuss the findings and the context of their scientific investigations.

Because the decision-making about screening periodicity and termination are a function of the exposure burden of PFOA, its kinetics in the body and the epidemiology of the six probable link conditions in the cohort, sources of data on each of these elements are important to the Medical Panel.

With the initial estimates of low participation in the current screening campaign, the Medical Panel does not believe the results of the first round of screening will be sufficiently informative or more importantly, representative of the health experience of the C8 cohort to provide a sufficient foundation upon which to base its subsequent screening recommendations. Therefore, we do not believe we need to wait for these data to have a meeting with the Science Panel.

While the scientific literature is a resource the Medical Panel can use for decision-making, we note that the majority of those publications are the work of the Science Panel. While each individual Medical Panel member could perform a separate literature review, it is the Medical Panel’s view that a two-day meeting with the Science Panel would be the most efficient way to review and discuss the pertinent data.