

C8 (PFOA) Medical Panel – Guidance on Medical Monitoring Periodicity and Duration
September 20, 2014

Class Counsel requested in a message dated 9/4/2014 that the Medical Panel provide guidance on how to answer questions from Class Members about how frequently the medical monitoring will be offered and for how long. Most of this document will focus on this request.

The message also asked the Medical Panel to provide an update as to the anticipated timing and status of any additional protocol(s) that would address such issues. This paragraph provides the update. The Panel members have had periodic discussions about these long-term issues. These issues are challenging to address because the scientific and medical literature do not adequately resolve relevant issues, such as the biological mechanisms of action for C8 (PFOA) and likely latency (which is the time between the putative exposure and onset of the health condition) for each Probable Link Condition. Also in accordance with earlier decisions by the Settling Parties, the Medical Panel will not have access to long-term clinical or epidemiological data that could be used to make decisions based on rates of Probable Link Conditions in the Class Member population. At this time, the Medical Panel is not able to state an anticipated timeline when additional protocol(s) will be completed. It will be at least many months and possibly longer. Consequently, the Panel decided to focus on providing a response to the first request about how to answer questions from Class Member that are likely to be asked soon.

Screening Frequency

The Medical Panel has reviewed the medical literature and guidelines on the periodicity or frequency of repeating screening tests for the Probable Link Conditions. The Panel concludes that there are no firm standards on how frequently the screening tests should be done. Some guidelines, such as those of the United States Preventive Services Taskforce (USPST), discuss these issues and the Medical Panel has taken them into consideration in developing these recommendations. The Panel will continue this review process to address the screening frequency in the long-term.

At this time, the Medical Panel recommends that the period until the next general screening be three years from the time of the first or baseline medical monitoring. Individual Class Members who are eligible for the baseline medical monitoring program screening tests should be screened again in three years for each Probable Link Condition for which they are still eligible to be screened.

It is important to understand from the original medical monitoring protocols that any individual who has been diagnosed as having a Probable Link Condition is not eligible and should not be screened again for that condition. For example, if an individual is diagnosed as having high cholesterol, that person would not be eligible to be re-screened for cholesterol.

Similarly, if an individual was screened by the medical monitoring program symptom questionnaire for the following Probable Link Conditions: ulcerative colitis, testicular cancer, or renal cancer – and the screening doctor determined that the person's symptoms warranted having invasive diagnostic tests (e.g., colonoscopy, testicular biopsy, or abdominal CAT scan, respectively), then that individual should no longer be considered eligible to participate in future medical monitoring program screenings for that condition. These individuals who have already developed symptoms leading to use of the diagnostic tests should be followed by their personal medical care providers. The objective of the medical monitoring program is to identify conditions before they cause symptoms or when they are previously

unrecognized. Individuals who were screened, but did not have symptoms sufficient to have the invasive diagnostic tests for the conditions, would still be eligible for future medical screening.

Each of the Probable Link Conditions is unique, so this general recommendation for the screening frequency has to be modified for the specific conditions. The modifications fall into three groups of the conditions: (a) High Cholesterol and Thyroid Dysfunction; (b) Ulcerative Colitis, Testicular Cancer, and Renal Cancer; and (c) Pregnancy-Induced Hypertension.

High Cholesterol and Thyroid Dysfunction

These conditions may not cause symptoms, but they can be detected using blood tests. Individuals who have normal levels in these blood tests should be screened again in three years. Individual who have borderline normal levels on their blood tests should have shorter-term follow-up testing as specified in the Medical Monitoring protocols of May 2013. That document should be reviewed for details.

High Cholesterol. In brief, adults with borderline cholesterol (total cholesterol 190-224) and children <20 years with borderline cholesterol (170-199) should be re-tested within three months. If the average of the two tests is in the normal range, then the individual can be re-screened in three years. If the average of the tests remains in the borderline range, then the cholesterol screening test should be repeated within another 6 months.

Thyroid Dysfunction. In brief, the primary screening test is blood test to measure thyroid stimulating hormone (TSH). If the level is abnormal, then the screening should include measurement of the thyroxin hormone (T4) and free thyroxin hormone (free T4). If the T4 is normal, a follow-up TSH test should be obtained in 2-4 weeks. If the repeated TSH is normal, then the initial result is generally considered to be a false-positive and the person should be re-screened routinely after three years.

If the repeated TSH level is still abnormal, then the person is considered to have sub-clinical thyroid dysfunction and should consult with the personal medical care provider for follow-up care. If the free T4 level is abnormal (according to the testing laboratory standards), the person has overt thyroid dysfunction and should be followed by the personal medical care provider for treatment. Individuals who are diagnosed with either sub-clinical or overt thyroid dysfunction would not be eligible for future medical monitoring program re-screening for thyroid dysfunction.

Ulcerative Colitis, Testicular Cancer, Renal Cancer

As noted in the original Medical Monitoring protocols (May 2013), there are no established guidelines for screening of these conditions. The Medical Panel recommended use of symptom questionnaires to screen for these conditions. Individuals who are screened by the symptom questionnaire and the screening doctors determines that they do not have symptoms that warrant additional diagnostic tests, should be re-screened in three years when they are screened for the other Probable Link Conditions.

The Medical Monitoring program informational materials and screening questionnaire should be used to inform Class Members about the warning symptoms. Because individual Class Members could develop the relevant symptoms at any time, the Medical Monitoring program should establish a mechanism, so Class Members who are concerned that they have develop the warning symptoms could consult via telephone or in-person with a screening doctor or nurse. The screening doctor can determine whether

the person has had a new onset of the relevant symptoms that warrants ordering additional diagnostic tests for any of these three Probable Link Conditions.

The Medical Panel recommends that the repeated symptom screening can occur whenever new warning symptoms develop during the period until the general re-screening. However, reasonable judgment should be used by the Class Members and screening doctors about often it should occur (e.g., no more frequently than every 6 to 12 months). However, as stated above, once the screening doctor determines that the symptoms warrant conducting additional diagnostic tests that are invasive or higher risk (e.g., colonoscopy, testicular biopsy, abdominal CAT scan or renal biopsy, respectively), then the individual should no longer be eligible for future screening for the condition. These people should consult with their personal medical care providers for future monitoring of their health status.

Pregnancy-Induced Hypertension

Female Class Members who become pregnant at any time during the three year screening interval should be eligible for screening. Specifically, the screening should include measurement of a serum PFOA level if the woman has not previously had this test as part of the Medical Monitoring program. The serum PFOA test does not need to be repeated with subsequent pregnancies.

As noted in the original Medical Monitoring protocol (May 2013), screening for blood pressure and protein in the urine as indicators of pregnancy-related high blood pressure and preeclampsia are routine components of prenatal care regardless of prior putative exposure to C8 (PFOA). Therefore, eligibility for screening of this condition should follow the same protocol and eligibility criteria as already implemented by the Medical Monitoring program.

Screening Duration (when to stop)

The decision about when Medical Monitoring can be stopped will vary by the Probable Link Condition. It could possibly be different for individual Class Members based on the findings of the serum PFOA levels during screening. The Medical Panel will prepare protocol(s) in the future to address these issues.

At this time, the Medical Panel recommends that the screening duration for each Probable Link Condition and for all eligible Class Members continue at least three years to allow for a second screening.

As an initial guidance to answer questions by Class Members, the Medical Panel indicates it is possible that the future protocols on duration of screening for conditions such as high cholesterol and thyroid dysfunction will be guided by the findings of the initial screening for serum PFOA and the blood test results. It may be reasonable to stop screening for these conditions if the measured serum PFOA levels are within the normal range for the general US population and the screening blood tests have remained within the normal range.

Conditions such as ulcerative colitis, testicular cancer, and renal cancer have unknown, but long latency (perhaps 15 years or more), so the conditions could develop long after exposure has stopped and after serum PFOA levels have returned to normal. Therefore, the Medical Panel may recommend a longer duration of screening for these conditions using the symptom screening questionnaire. Symptom screening would stop on an individual basis for each probable link condition once a person develops the warning symptoms and has an invasive diagnostic tests or is diagnosed with the condition.