C-8 Medical Monitoring Program – Program Status and Protocol Revision

Jack Leach et al. v. E.I. du Pont de Nemours and Co.

Medical Panel – September 22, 2025

Summary: Heretofore, the C-8 Medical Monitoring Program has relied on *periodic medical monitoring* to detect Probable Linked Conditions (PLCs), the medical conditions the Science Panel identified as more likely to occur in Class Members exposed to PFOA. Periodic medical monitoring consists of asking Program participants about symptoms during scheduled visits and doing blood and urine tests followed by doctors ordering diagnostic testing as indicated. These evaluations could be scheduled every three years. The Medical Panel has intermittently reviewed the C-8 Program databases to assess the clinical outcomes of periodical medical monitoring. The last of these reviews, which was completed in 2021, was described in a report to the Settling Parties. The Medical Panel did not identify any Program participants who had been diagnosed with the most serious PLCs – kidney cancer, testicular cancer, or ulcerative colitis – through their participation in the periodic medical monitoring visits. During the past two years, the Panel has completed an additional review of hospital medical records of key diagnostic procedures performed on Program participants to detect kidney cancer, testicular cancer, or ulcerative colitis. We found no Medical Monitoring Program-identified cases of these three PLCs from our review of the medical records of the procedures. Based on these findings, we believe periodic medical monitoring should end. Instead, we recommend that the Program provide medical monitoring to Class Members using a protocol that would allow Class Members to request a diagnostic evaluation based on concerns about the three serious PLCs or if they have developed new or worrisome symptoms. In addition, other exposed persons who have not previously registered for the medical monitoring program, but who have new or worrisome symptoms may also be reimbursed for diagnostic evaluations by registering for the program.

Terminology: The Medical Panel has not consistently used terms, such as monitoring and screening, during our communications to the Settling Parties. Therefore, we will explain the terms used in this report to be consistent with definitions in the Settlement Agreement. Medical monitoring is defined in the Settlement Agreement to mean "diagnostic medical examinations, tests or procedures utilized to detect Human Disease." The Medical Panel developed protocols for medical monitoring that included two components. The first component has been "periodic medical monitoring" visits which could be scheduled by Program participants every three years following an "initial medical monitoring" visit.

These visits included screening for symptoms or signs of the PLCs using questionnaires and blood and urine tests. Based on the findings, the doctors could order additional diagnostic tests and procedures as indicated. The second component was a provision for "symptom-related medical monitoring" in which Program participants who believed they were experiencing new or worrisome symptoms could request a medical monitoring visit. As with the periodic medical monitoring visits, the protocols consisted of screening by a doctor to evaluate the symptoms followed by diagnostic testing as indicated. The Medical Panel sometimes has called these two components periodic screening and symptom-related screening visits because the first step of each visit was for a doctor to ask screening questions before ordering diagnostic testing. However, to be consistent with the Settlement Agreement, we will call these visits "medical monitoring" because the purpose has been to provide diagnostic evaluation for the PLCs.

Science Panel context: The Science Panel identified probable links for six conditions which the Medical Panel has generally divided into two groups. The first group includes kidney cancer, testicular cancer, and ulcerative colitis. These conditions are serious medical conditions with long or unknown durations of increased risk associated with PFOA exposure, and their diagnosis requires use of key procedures such as a computed tomography (CT) scan, magnetic resonance imaging (MRI) scan, or colonoscopy. Medical screening – which is routine clinical testing among persons with no symptoms – is not recommend for these conditions in standard medical practice. The second group of conditions – pregnancy-related hypertension and preeclampsia, increased serum cholesterol, and thyroid dysfunction – can be less serious or asymptomatic for long periods and can typically be identified through medical laboratory testing. Screening for these latter conditions is recommended in standard medical practice for some members of the general population, such as pregnant women or older adults.

The Science Panel identified probable links for testicular cancer and kidney cancer based primarily on modest increases in risk when comparing the highest to the lowest quartiles of PFOA exposure within the Mid-Ohio Valley population. Because cancer can take a long time to become clinically evident, the duration of increased risk for these cancers can be decades following exposure. The Panel also identified increased risk for ulcerative colitis. Research has not identified a possible mechanism for this observation, so the duration of potential increased risk is not known. The implications for the Program are that medical monitoring for kidney cancer, testicular cancer, and ulcerative colitis should continue for the foreseeable future.

The implications for medical monitoring of the other three PLCs are different. The Science Panel identified a probable link between PFOA exposure and risk of pregnancy-related hypertension and preeclampsia. However, screening is done routinely during prenatal care, so it was not included in the Medical Monitoring Program. The Science Panel found an probable link between PFOA exposure and an increase in serum cholesterol. The initial protocol recommended periodic medical monitoring, since cholesterol screening was not uniformly recommended for younger people in the general population at that time. However, cholesterol screening in younger people has become common, so screening is now part of standard medical practice and may not be warranted in the Medical Monitoring Program. The Science Panel did several studies of thyroid dysfunction and concluded there was a probable link; however, the findings were modest and "inconsistent" in the observed effects across the studies conducted by the Science Panel and by sex within studies (e.g., increased thyroid stimulating hormone in some studies and decreased in others). Mild thyroid dysfunction does not cause symptoms in most people. Routine periodic monitoring for asymptomatic mild thyroid dysfunction may not be warranted among the Class Members.

Medical monitoring protocols: The Medical Panel submitted protocols for initial medical monitoring in May 2013, with an update in November 2013 to recommend symptom-related medical monitoring for participants who request evaluations because they had developed new or substantially changed symptoms. The Panel submitted recommendations on the periodicity of medical monitoring (every three years after the initial evaluation) in 2014. The Panel has recommended minor revisions since that time, with a more substantial revision in 2021 based on an updated review of the medical literature on diagnostic protocols and procedures for the PLCs.

Program database and medical records review: The Medical Panel has intermittently reviewed the Program databases to assess clinical findings based on the protocols. The last review was done in 2021, resulting in a report to the Settling Parties. The databases indicated that between 2014 and 2021, a total of 3,327 Class Members participated in the initial medical monitoring, of whom 326 were evaluated a second time. It did not appear that any Class Members had requested an evaluation or been evaluated based on the symptom-related medical monitoring component of the protocol.

During the 2021 database review, we observed that some participants had been recorded in the "final diagnosis" database as having been diagnosed with one of the three serious PLCs. Upon further analysis, we determined that all of the reported diagnoses had been diagnosed prior to participation in the Medical Monitoring Program. We did not find any

participants with a serious PLC who had been first diagnosed by testing performed in the Program.

For the database review, we relied on the Final Diagnosis form in the Program and found no one with a serious PLC. As a check on the accuracy of the Program's procedures to record the clinical outcomes, we identified participants who had undergone key diagnostic procedures for a serious PLC and whose doctor or medical center had asked the Program to pay for the procedure. The Program was not able to obtain all of the records, but the yield was substantial. At least two of us reviewed each report. We did not identify any records showing that a participant had been diagnosed with one of the three serious PLCs through the Program-supported diagnostic procedures.

The result of the 2021 database review and diagnostic procedures medical records review is that we have not identified any Program participants who have been diagnosed with kidney cancer, testicular cancer, or ulcerative colitis because of findings arising from their participation in the periodic medical monitoring protocols. Considering incidence rates in the general population, let alone possible increased rates associated with PFOA exposure, we expect that some Class Members have developed one of the serious PLCs during the past decade. Therefore, we believe people are being diagnosed but not through their participation in the Program. There could be many reasons, but the primary reasons are low Program participation, low annual incidence of these conditions even with possible increased risk due to PFOA exposure, and inherent weaknesses of periodic medical monitoring to identify rare but serious conditions, such as, a participant developing one of the rare conditions before or after the time of the periodic medical monitoring visit, having one of these conditions but not have suggestive symptoms at the time of the visit, or having suggestive symptoms which were much more likely to be caused by common medical conditions than by the rare condition.

Recommendation: The Medical Panel recommends that the Program terminate periodic medical monitoring while still providing medical monitoring for kidney cancer, testicular cancer, and ulcerative colitis for Class Members who request diagnostic evaluationsBecause the duration of excess risk associated with PFOA exposure could still be decades for kidney or testicular cancer and is unknown for ulcerative colitis, the Program should provide diagnostic evaluations for these conditions to Class Members who request testing because of concerns that they may have a serious PLC or because they have new or worrisome symptoms. In addition, other exposed persons who have not previously registered for the medical monitoring program, but who have new or worrisome

symptoms may also be reimbursed for diagnostic evaluations by registering for the program.
This recommendation could be considered a modification of the symptom-related medical monitoring component of the original protocol. The current protocols specify the diagnostic tests and procedures doctors could order and do not need to be updated. The Program will need to determine mechanisms for implementing this recommendation. We are willing to discuss possible approaches with the Program director, but Program design and implementation are beyond the scope of the Medical Panel charge.

The Panel recommends against periodic medical monitoring for preeclampsia, increased serum cholesterol, and thyroid dysfunction Screening for preeclampsia and increased cholesterol are now standard medical practice and do not need to be monitored by the Program. The Panel does not believe it is warranted to monitor periodically for thyroid dysfunction due to the low Program participation and yield.

The Program should also develop a mechanism to reimburse Class Members and other exposed persons for expenses related to diagnostic evaluations of the serious PLCs by their personal physicians. This recommendation is consistent with section 12.3.2 (d) of the Settlement Agreement. We did not previously address this section of the Settlement Agreement but believe it could be an important option going forward.