

**INFORMATION ON THE C-8 (PFOA) MEDICAL MONITORING PROGRAM SCREENING TESTS
PREPARED BY THE MEDICAL PANEL FOR THE C-8 CLASS MEMBERS**

The Medical Panel has made recommendations about medical screening tests that C-8 Class Members could have done to find out if they have any of the Probable Link Conditions identified by the Science Panel. This document is about the Medical Monitoring Program. For each of the Probable Link conditions, the document explains who is eligible to have the screening tests and the possible benefits and risks of the screening tests. The Medical Panel wants you to understand the benefits and risks of the tests, so you can decide whether you want to have the tests done. We encourage you to read about the tests and discuss this information with the doctor who can do the screening tests.

Background Information

In February 2005, the West Virginia Circuit Court approved a Settlement Agreement in a class action lawsuit entitled *Jack Leach et al. v. E.I. du Pont de Nemours and Co., Civil Action No. 01-C-608*. The suit was about release of a chemical known as C-8, also known as PFOA, from DuPont's Washington Works facility located in Wood County, West Virginia. "Class Members" are current or former residents of the communities affected by release of C-8. The Settlement had several parts.

The Settlement Agreement established a Science Panel to investigate possible links between exposure to C-8 and any diseases. The Panel's research found that C-8 exposure was probably linked to high cholesterol, thyroid disease, ulcerative colitis, testicular cancer, kidney cancer, and high blood pressure during pregnancy. This document is about these six "probable link conditions."

The Settlement Agreement also established a Medical Panel to develop medical procedures to screen for the six conditions and a Medical Monitoring Program to do the medical screening. The Program will work with doctors in the communities exposed to C-8 to provide medical screening to Class Members. The Settling Parties selected Harold Sox, MD; Melissa McDiarmid, MD, MPH, DABT; and Dean Baker, MD, MPH to be on the Medical Panel. The Medical Panel relied on medical practice guidelines and the medical literature to develop the Medical Monitoring Protocols.

Medical Monitoring Program Protocols

The Medical Monitoring Program is available to all Class Members regardless of their past C-8 exposure. The medical screening will be done by a physician or another licensed medical care provider. The Administrator of the Medical Monitoring Program will explain how to make an appointment for screening. In most cases, you will answer some questions and have a very low-risk procedure, such as a physical examination or a blood test. Based on the results, the doctor may recommend that you have additional medical tests to determine whether you have the probable link condition or disease.

Before agreeing to have screening, you should discuss with the doctor the benefits and risks of doing the screening tests. Completing the questionnaire and doing the simple screening tests have minimal risk. If the screening tests are positive, the doctor may recommend additional tests that could cause discomfort or put you at a small risk. You should understand the benefits and risks of these diagnostic tests, as well as the benefits and risks of being diagnosed with a probable link disease and possibly needing treatment. Please understand that this Medical Monitoring Program does not provide payment for treatment if you are diagnosed with a probable link condition or disease.

Who Should Have the Screening Tests? The recommended Medical Monitoring Program screening tests depend on your age, gender, and pregnancy status. For example, the screening at some ages might be based only on you completing a medical questionnaire, while the screening at other ages can include both completing the questionnaire and having a physical examination or a diagnostic test. The doctor will know which tests to do, which will depend on your age and your answers to the questionnaire.

You can see which screening protocols are recommended for you in the following table:

SCREENING BY AGE

< 15 years	<ul style="list-style-type: none"> – High cholesterol – Thyroid disease (at parents' discretion) – Testicular cancer (exam not part of Program, but done as regular care)
15-18 years	<ul style="list-style-type: none"> – High cholesterol – Thyroid disease (at parents' discretion) – Ulcerative colitis – Testicular cancer
18-19 years	<ul style="list-style-type: none"> – High cholesterol – Thyroid disease – Ulcerative colitis – Testicular cancer
20 or older years	<ul style="list-style-type: none"> – High cholesterol – Thyroid disease – Ulcerative colitis – Testicular cancer – Kidney cancer
Pregnant Females	<ul style="list-style-type: none"> – Blood pressure & urine protein should be measured at each prenatal visit – these tests are part of standard prenatal care and may not be reimbursed by the Program. Pregnant women may receive blood pressure monitoring devices provided by the Program.

Information about the Probable Link Conditions and Medical Screening Tests

This section provides information on the probable link conditions, and the possible benefits and risks of the screening tests. The Medical Panel encourages you to discuss this information with the doctor who is scheduled to do the screening tests.

High Cholesterol

Cholesterol is a lipid the human body needs to function properly. High cholesterol does not cause symptoms, but people with it have a higher risk of getting heart disease and stroke.

In the US population, 13% (13 out of 100) of adults have untreated high cholesterol. However, a national study reported that about one-half of adults have high cholesterol if the study counted adults with high blood cholesterol plus people who had been told by a doctor they had high cholesterol or were being treated for high cholesterol. The proportion of children with high cholesterol is lower than in adults (about 1 in 10), but the proportion has been increasing.

Probable Link Findings. The Science Panel found that cholesterol levels were higher in both adults and children with higher C-8 exposures. The Science Panel study showed that about 1,500 people in a town of 10,000 people would have high cholesterol if exposed to the lowest level of C-8. The Panel's research showed that about 2,100 people in a town of 10,000 exposed to the highest level of C-8 would have high cholesterol. Therefore, high exposure to C-8 would result in 600 extra adults with high cholesterol in a town of 10,000. Most C-8 Class Members were not exposed to PFOA at the highest levels, so the actual increase in the number of adults with high cholesterol would be smaller. The highest exposure to C-8 had a smaller effect on cholesterol levels in children than it did in adults.

Recommended Medical Screening. The Medical Panel recommends that all Class Members should be screened for high cholesterol unless they have already been diagnosed or are under treatment for high cholesterol. You do not need to have the screening test and, therefore, are not eligible for the test if you have already been told by a doctor that you have high cholesterol or you are already being treated for high cholesterol. The screening test is a blood test called the fasting serum lipid profile test. The best way to do this test is for you to have the blood sample drawn in the morning before you eat breakfast. The doctor can tell you more about this blood test.

Follow up Diagnostic Tests. No other tests are needed to determine whether you have high cholesterol.

Benefits and Risks. There is essentially no risk to having the screening test done. The blood test requires drawing only a very small sample of blood. The possible benefit of finding out that you have high blood cholesterol is that you could try to lower your cholesterol levels by increasing exercise, losing weight if overweight, and eating foods that are lower in fat and cholesterol. If you still have high cholesterol after trying these behavior changes, a doctor may prescribe medications to lower your cholesterol levels. Doctors are aware of the potential risks of these medications and can explain them to you. Again we remind you that treatment, such as for high cholesterol, is not part of the Medical Monitoring Program, so you would have to discuss any treatments with your personal doctor.

Thyroid Disease

Thyroid hormones help control growth and development and how the body uses energy. These hormones are produced by the thyroid gland which is located in the neck. Usually the body closely controls how much of the thyroid hormones is produced. Thyroid disease means the levels of thyroid hormones are either too high (called hyperthyroidism) or too low (called hypothyroidism). Some people have thyroid disease that can be detected using a simple blood test, although they do not have any symptoms. However, if the levels of thyroid hormones are very abnormal, people can develop symptoms and other health problems. These people are considered to have "thyroid disease". The purpose of the tests the Medical Panel recommends is to screen for subclinical (meaning no symptoms) thyroid disease.

Thyroid disease is fairly common. For example, every year about 40 people in a town of 10,000 people who were not exposed to C-8 will develop thyroid disease. Thyroid disease is more common in women and older people, and hypothyroidism (thyroid hormones being too low) is much more common than hyperthyroidism (thyroid hormones being too high). The number of people with subclinical thyroid disease is much larger than for thyroid disease that causes symptoms. A national survey found that 4.3% (about 430 in 10,000) had subclinical hypothyroidism, while only 0.3% (or 30 in 10,000) had clinical hypothyroidism. Women are 50% more likely than men to have thyroid disease.

Probable Link Findings. The Science Panel found that C-8 exposure was probably related to thyroid disease. The Panel's findings mean that a town of 10,000 people exposed to the highest level of C-8 would have 60-80 new cases of thyroid disease each year. A town exposed to the lowest level of C-8 would have 40 cases. The actual number of extra cases would be less than 20 to 40 since most Class Members were not exposed to the highest levels of C-8. The Science Panel also found evidence of an increase in risk of thyroid disease in children, but the evidence is not as strong as in adults because it is based on parents' reports of thyroid disease rather than actually measuring thyroid hormone or receiving a physician's report of thyroid disease.

Medical Panel recommendation. The Medical Panel recommends that Class Members 18 years and older should be screened for thyroid disease unless they have already been diagnosed with thyroid disease or are already being treated for thyroid disease. You do not need to have the screening test and, therefore, are not eligible for the test if you have already been told by a doctor that you have thyroid disease or you are already being treated for thyroid disease. The screening test is a blood test to measure serum thyroid stimulating hormone (TSH).

The Medical Panel does not recommend routine screening for thyroid disease in Class Members less than 18 years of age. Screening of Class Members under the age of 18 for thyroid disease may be done at the discretion of the physician and parents or legal guardian.

The Medical Panel also recommends that if you are a female who becomes pregnant or decides to try to become pregnant, you should be screened again for thyroid disease using the blood test for serum TSH even if you have already been screened in the Program. This screening should be done once at the first prenatal care visit.

Benefits and risks. The screening test involves drawing a small sample of blood, so the risk of the screening test is very small. The primary issue for you to consider is what decisions you might have to make if the test shows that you may have thyroid disease. The potential risks of having subclinical thyroid disease are 1) progression to thyroid disease with symptoms and other health problems; and 2) increased risk of developing heart disease. Doctors can monitor by periodic testing the possible development of thyroid disease, but another approach would be to start treatment, which would make further testing unnecessary. The usual treatment for people with low thyroid levels is to take a small thyroid hormone replacement pill, which is a safe treatment if taken in the prescribed dose.

Essentially all doctors recommend treatment for people with thyroid disease. However, it is not as clear whether doctors should treat people with subclinical hypothyroid disease. Treatment might not benefit the person and there could be side effects of the medicines. You should make the decision whether to be treated for subclinical thyroid disease in consultation with your doctor. As noted above, the C-8 Medical Monitoring Program does not provide treatment.

Ulcerative Colitis

Ulcerative Colitis (UC) is a disease of the large bowel (the colon). It can cause repeated episodes of crampy abdominal pain, bloody diarrhea, fever and weight loss. The symptoms of ulcerative colitis tend to come and go.

About 200 people in a city of 100,000 people have ulcerative colitis (UC) and 1 to 20 new cases develop each year. New cases peak between ages 15-40 years and after age 50. The frequency of ulcerative colitis is slightly higher in males. Rates are higher in people of Jewish descent and lower in African- Americans and Hispanics.

Science Panel findings. The Science Panel found that greater exposure to C-8 was related to higher rates of UC. The Science Panel estimated that with the largest exposure to C-8 the risk of developing UC doubled. This finding means that if an entire population were exposed at that C-8 level, the number of new UC cases each year in a city of 100,000 people might be between 2 and 40 people, an increase of between 1 and 20 cases. The actual increase would be less since most Class Members were not exposed to the highest C-8 levels.

Medical Panel recommendations. The Medical Panel determined that all Class Members age 15 years and older should be screened by a questionnaire for symptoms of this condition. Based on your answers to this questionnaire, the doctor may recommend additional tests. You should discuss these additional tests and your options with the doctor.

Benefits and risks. The additional tests of the colon in a person with symptoms may include a doctor examining the insides of the colon by endoscopy (sigmoidoscopy or colonoscopy). You should decide whether you want to have these additional tests during a conversation with the doctor. The important points to discuss include the size of the UC risk in the C-8 exposed population and whether you have any other risk factors for UC, such as family history and ethnicity. You should also consider the risk of a complication during colonoscopy, most commonly a bowel tear, estimated to be about 0.35% (or 35 per 10,000) or for sigmoidoscopy, estimated to be about half the above rate. The decision about choosing sigmoidoscopy versus colonoscopy is also made based on the symptoms and the required sedation that colonoscopy, but not sigmoidoscopy typically requires. You should discuss these issues with the doctor.

Testicular Cancer

Testicular cancer is the most common cancer in young men ages 15-35 years, but it is still quite uncommon. Testicular cancer is about 1% of all new cancers in men. In the US population, about 6 in 100,000 men develop testicular cancer per year. This means that 3 men will develop testicular cancer each year in a town of 100,000 people who were not exposed to C-8. Risk factors for this cancer are undescended testes (cryptorchidism), a family history of testicular cancer, or cancer in the opposite testicle. Early signs of testicular cancer can include a mass in the testicle or scrotum, testicular firmness, or scrotal fullness.

Science Panel Findings: The Science Panel found that greater exposure to C-8 was related to higher rates of testicular cancer. According to the Panel, the risk of developing testicular cancer was 3 to 6 times higher in males with the highest exposure to C-8. This finding means that if an entire population were exposed at that C-8 level, the number of new testicular cancer cases each year in a city of 200,000 people would be 9 to 18 cases, which is an increase of 6 to 15 cases. The actual increase would be less since most Class Members were not exposed to the highest C-8 levels.

Medical Panel recommendations. The Medical Panel recommends asking males older than 15 years about symptoms of testicular cancer. Men aged 15-50 should have a testicular exam performed by a clinician. Males older than 50 years should have a testicular exam only if they have symptoms of testicular cancer. Based on the results, the doctor may order additional tests, such as a testicular ultrasound. Under the age of 15, a testicular examination is standard preventive health care.

The Medical Panel also recommends that doctors should teach males how to do a testicular self- examination and encourage them to do it. You should talk with the doctor about this option.

Benefits and risks. You should talk to your doctor about the benefits of having a testicular examination and training to do self-examination. Risk factors for testicular cancer increase the benefit of screening. These include the increased risk of testicular cancer in the C-8 exposed population, a family history of testicular cancer, a testicle that has remained in your abdomen, a previous testicular lesion, or new onset of breast swelling.

If you have one or more risk factors or a positive examination of the testicles, you should ask the doctor about the ultrasound scan of the testicles. If a mass is present, ultrasound is very effective in showing whether the mass is in the testicle. Ultrasound is less effective in making a diagnosis of cancer. Additional tests would be needed.

The risk of harm from screening is very small. The main risk is anxiety after a positive test. The most important benefit is effective treatment of testicular cancer: 95 out of 100 males survived 5 years after treatment.

Kidney Cancer

Kidney cancer accounts for 2% of cancer cases in the US population. It occurs 1.6 times more often in men than in women, equally in whites and African-Americans, and mostly among older people. About 2 men and 1 woman in a town of 10,000 would develop kidney cancer each year. Half of kidney cancer patients are age 65 or older when diagnosed. The incidence is very low among younger people.

Kidney cancer typically does not have early warning signs. Common first symptoms in patients with kidney cancer are hematuria (blood in the urine), abdominal pain, and/or an abdominal mass. Less commonly patients may have abdominal pain or fever.

Science Panel findings. The Science Panel found that greater exposure to C-8 was related to higher rates of kidney cancer. According to the Panel, the risk of developing kidney cancer was 2 times higher with the highest exposure to C-8. This finding means that if an entire population were exposed at that C-8 level, the number of new kidney cancer cases each year in a town of 10,000 people would be 6 cases, which is an increase of 3 cases. The actual increase would be less since most Class Members were not exposed to the highest C-8 levels.

Medical Panel recommendations. The Medical Panel recommends that all adult Class Members 20 years and older should be screened for kidney cancer. Because of the low risk of developing kidney cancer in younger adults, the screening procedure is different for adults younger than 40 than for adults 40 years or older. The screening for people 20 to 39 years will include a symptom questionnaire. If any symptoms are present, the physician should do an abdominal examination and obtain a urine test to check for blood. The screening for people 40 years or older will include a symptom questionnaire, abdominal examination, and urine test to check for blood. Based on the results of the questionnaire and screening tests, the doctor may order additional tests. These additional tests could include imaging studies of the kidney using ultrasound, or abdominal CT scan or MRI. The doctor can explain more about these tests.

Benefits and risks. The benefit of screening for kidney cancer is that it may be detected early enough for surgery to cure it. The screening itself has no important harms. However, a positive screening test would lead to an imaging test. Before the recommended imaging tests, a liquid dye is injected in a vein to help detect a cancer. A bad reaction to the dye that is typically used occurs in 7 patients in 1000, with more severe reactions occurring in 1 patient in 1000. The doctor can give you more information about the tests, and their benefits and risks if the results of the screening tests indicate that you should have the additional tests.

Pregnancy-Induced Hypertension

The term “pregnancy-induced hypertension” (PIH) includes high blood pressure that starts during pregnancy (called “gestational hypertension”) and “preeclampsia” which is diagnosed when the woman has both high blood pressure and evidence of protein in the urine. Doctors can conduct other tests as well to make the diagnosis of preeclampsia. These conditions can lead to very high blood pressure and have serious effects on the mother’s body and the baby. Therefore, clinical management of all pregnancies should include regular screening for blood pressure and protein in the urine.

High blood pressure during pregnancy develops in about 6 out of 100 pregnancies. Preeclampsia is diagnosed in 2 to 5 of 100 of all pregnancies and 10 out of 100 first pregnancies. About half of women who develop high blood pressure during pregnancy develop preeclampsia later in the pregnancy. About one-quarter of women who have high blood pressure prior to becoming pregnant develop preeclampsia.

Science Panel findings. The Science Panel found that greater exposure to C-8 was related to higher rates of high blood pressure during pregnancy and preeclampsia. According to the Panel, the risk was 20% to 30% higher in women with the highest exposure to C-8. This finding means that if an entire population were exposed at that C-8 level, the number of cases of high blood pressure associated with 10,000 pregnancies would be about 750 women rather than 600 women. The number of cases of preeclampsia with 10,000 pregnancies would be about 500 women rather than 400 women. The actual increase would be less since most Class Members were not exposed to the highest C-8 levels.

Medical Panel recommendations. The Medical Panel recommends that every pregnant woman should be screened for PIH at every prenatal visit by measuring the blood pressure and taking a simple urine test. The doctor may order additional tests if indicated by the findings of the simple screening tests. You should be aware that measuring blood pressure and testing urine for protein are parts of normal prenatal care even if you had not been exposed to C-8. Because the Settlement Agreement stated that the Medical Monitoring Program should not pay for screening tests that would ordinarily be done for people who were not exposed to the C-8 contaminated water, you should have the blood pressure and urine testing done by your personal prenatal care doctor as a regular part of your prenatal care rather than by the Medical Monitoring program.

The Medical Panel also recommends that if a pregnant Class Member is concerned about developing high blood pressure, she can use a home-use digital blood pressure monitoring device to monitor her blood pressure in between prenatal care visits. The Medical Monitoring Program will provide reimbursement for this device.

Benefits and risks. Screening for gestational hypertension and preeclampsia is a standard part of prenatal care. The screening tests to measure blood pressure and test for protein in the urine are minimal risk procedures. Additional tests recommended to evaluate preeclampsia require taking small samples of blood, which is also considered to be a minimal risk procedure. The benefits of early detection and treatment are substantial. The balance of harms and benefits strongly favor the benefits. Therefore, this screening should be available to all pregnant women.