IN THE CIRCUIT COURT OF
HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE and other individuals residing in West Virginia,
on behalf of herself and all others similarly situated,

Plaintiffs,

vs.

Case No. 04-C-296-2
(Honorable Thomas A. Bedell)

E.I. DU PONT DE NEMOURS AND COMPANY,
a Delaware corporation doing business in West Virginia,

Defendant.

Plaintiffs' Response to Proposed CT Scan Rule

On behalf of the Plaintiffs, class counsel is providing this Court with a response to the Claims Administrator's proposed CT Rule.[1] Plaintiffs are concerned that engrafting a requirement that participants be symptomatic before a CT scan is allowed would not only be medically unhelpful but would also take the testing outside the parameters of a medical monitoring program A CT scan can be diagnostically and medically necessary without symptoms as a prerequisite. Indeed, the Settlement MOU had no requirement that symptoms be present.

The only requirements expressed in the Settlement MOU were that a competent physician must make the determination that the CT scans were diagnostically and medically necessary related to the participant's exposure to heavy metals in the class area. Plaintiffs respectfully

[1] The Claims Administrator's proposed CT rules rely upon literature that is inapplicable and which is directed to whole body CT scans. Whole body CT scans have never been proposed at any stage of this litigation. Further, the research that is discussed in the Claims Administrator's proposed rules fails to take into account the studies which have been recently undertaken and which are continuing regarding the efficacy of CT scans to screen for lung cancer. Drs. Werntz and McGuire both have taken into account the literature pertaining to low dose radiation chest CT scans.

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request that the need for CT scans be determined by a competent physician, as exemplified by Drs. Charles Werntz and Andrea H. McGuire, based upon a participant's exposure, as specified in the Settlement MOU.[2]

Summary of Drs. Werntz and McGuires' Proposed CT Rule

1. Upon entering the medical monitoring program, an eligible participant[3] will be given the opportunity to have a baseline CT scan and will be provided with standard CT Scan release, which will outline the risks associated with CT scans.

2. The need for additional CT scans will be made available to the participant if the physician finds that the CT scan is diagnostically medically necessary based upon the participant's degree of exposure and medical history.

3. Diagnostically medically necessary does not require the presence of symptoms.

Argument

I. Under the unambiguous terms of the settlement, the physician—rather than the claims administrator—determines when a CT scan is diagnostically medically necessary.

At issue is the implementation of paragraph 3.c. from the Memorandum of Understanding.

> c. The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT scans be performed as part of the medical monitoring program. The Defendant does agree to provide CT scans that are diagnostically medically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation.

In a departure from the express language of paragraph 3.c., the Claims Administrator has identified the following factors that would satisfy medical necessity.

> (1) Signs and Symptoms, including but not limit to, paraneoplastic syndromes (production of hormone like symptoms from the tumor cells), unexplained weight loss, fever, fatigue, pain, persistent coughing or hoarseness, hemoptysis, unusual

[2] See Exhibit 1, December 9, 2010 letter from Dr. Charles Werntz, and Exhibit 2, Report from Dr. Andrea H. McGuire, August 19, 2011.
[3] To be eligible for a CT scan, the participant must be over 35 and not pregnant.

bleeding or discharge, dysphagia, persistent shortness of breath, thickening or lumps in the body, hyper pigmentation, jaundice, shoulder pain (Pancoast's Syndrome), pneumonia, persistent headaches, and or other medical signs and symptoms which are widely accepted in the medical community as potential indicators of cancer.

AND/OR

(2) **Medical history** (including known diagnoses).

The expressed and unambiguous intent of paragraph 3.c. is that the need for CT scans be driven by exposure and that any decision regarding the need for a CT scan be made by a competent physician.[4] The Claims Administrator, while attempting to provide some concrete guidance for the use of CT scans, has actually proposed a CT rule that is contrary to the express intent of paragraph 3.c. of the Settlement MOU.

First, the proposed CT rule attempts to dictate to the physician what is diagnostically medically necessary. The Settlement MOU clearly gives the physician the authority to decide what is diagnostically medically necessary.

Second, the proposed rule requires the presence of symptoms to satisfy the definition of diagnostically medically necessary. Unlike the Claims Administrator's CT rule, which ties diagnostically medically necessary to symptoms, the Settlement MOU expressly ties diagnostically medically necessary to exposure.

While Plaintiffs disagree with DuPont's position that CT scans cannot be used for screening purposes, Plaintiffs do agree with DuPont's counsel to the extent that any attempt by the attorneys to dictate to competent physicians when CT scans are diagnostically medically necessary "is improper and ill-advised and will potentially impact upon the medical decisions made by such physicians." Lees' Memorandum, RE: Proposed Letter to Judge Bedell regarding CT Scans, September 1, 2011. Plaintiffs also agree with Mr. Lees on the requirement of signs

[4] "[W]here the terms of a written instrument are unambiguous, clear and explicit, extrinsic evidence of statements of any of the parties to it made contemporaneously with or prior to its execution is inadmissible to contradict, add to, detract from, vary or explain its terms, in the absence of fraud, accident or mistake in its procurement." *Kanawha Banking & Trust Co. v. Gilbert*, 131 W.Va. 88, 101, 46 S.E.2d 225, 232-33 (1947).

and symptoms, "I believe is it [sic] a mistake to set out 'signs and symptoms' that attempt to give competent physicians instructions on how to practice medicine. This is not our role in this matter, and the language of the settlement was drafted specifically to keep the lawyers and administrators out of the business of practicing medicine." Lees' Memorandum, RE: Draft CT Scan Utilization Guidelines, August 29, 2011. Ironically, in the very same Memorandum, DuPont perpetuates the very problem it seeks to address by asking for a provision in the CT rule that would require that a participant "most likely has a disease" before a competent physician could order a CT scan.

II. Two competent physicians have given opinions on what is meant by diagnostically medically necessary.

Under the Settlement MOU, the interpretation of diagnostically medically necessary, as all parties agree, is a determination for a competent physician. Two competent physicians have provided written opinions regarding the meaning of diagnostically medically necessary in this context. Dr. Charles Werntz, Associate Professor, West Virginia University School of Medicine, who has testified before this Court on numerous occasions, has stated that "diagnostically medically necessary CT scans for the participants can be estimated purely on the basis of the exposure, without the need for the participant to be symptomatic." Dr. Werntz recommended that an initial CT scan be done for all CT eligible participants. An initial CT scan will "both allow for identification of current occult disease, and will provide baseline information, to support future testing of that participant." See Exhibit 1, Wertnz letter dated Dec. 9, 2010.

The Claims Administrator hired Dr. Andrea H. McGuire, M.D., M.B.A. Dr. McGuire has a B.S. in chemistry, a Medical Doctorate, an M.B.A., and is board certified in Nuclear Medicine, to review the CT guidelines for this case. After reviewing the Settlement MOU and numerous medical articles describing the effectiveness and risks of CT scans, Dr. McGuire concluded that, ". . . all participants should have a CT scan as part of their surveillance because it is medically

necessary in a high risk population with possible exposure to heavy metal contaminants." See Exhibit 2, McGuire Report, August 19, 2011.

III. The Claims Administrator's proposed CT Rule undermines the goal of medical monitoring, which is to detect subclinical diseases.

While CT scans under the Settlement MOU will not be routinely given, as was originally contemplated in the medical monitoring initially approved by this Court, this does not mean that CT scans have been removed as a screening tool to detect diseases before they become symptomatic. The purpose of a medical monitoring program is to detect diseases that are subclinical. Paragraph 3.c. does not change this purpose. If symptoms were required to be eligible for a CT scan, then participants would be eligible for screening under a private or governmental sponsored health insurance plan.

Conclusion

The language of the Settlement MOU clearly places the decision making regarding CT scans in the hands of the physician. The only two physicians who have commented on the implementation of the CT scans as contemplated in paragraph 3.c. are Drs. Werntz and McGuire. Both of these physicians have rejected the approach being put forth by the Claims Administrator. On behalf of the Plaintiffs, we respectfully request that this Court adopt Dr. Werntz's CT rule: (1) that all eligible participants be offered a CT scan upon entry into the medical monitoring and (2) that diagnostically medically necessary CT scans for the participants be based purely on exposure, without the need for the participant to be symptomatic.

Respectfully submitted this 21st day of September 2011.

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Defendant.

/

CERTIFICATE OF SERVICE

I, Perry Jones, counsel for Plaintiffs, hereby certify that service of **Plaintiffs' Response to Proposed CT Scan Rule** has been made upon counsel of record via U.S. Mail, postage prepaid, on this 21st day of September, 2011, addressed as follows:

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Exhibits to Plaintiffs' Response to Proposed CT Scan Rule

Exhibit 1: Letter of Dr. Charles Werntz, December 9, 2010

Exhibit 2: Report of Dr. Andrea H. McGuire, August 19, 2011

Respectfully submitted this 21st day of September 2011.

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Re: Perrine v. Dupont

Date: December 9, 2010

In response to a proposed settlement agreement in this matter, you have advised me that CT scans would be allowed only if they are "diagnostically medically necessary, as determined by a competent physician, as relevant to possible exposure to heavy metal contamination at issue in this litigation". This is significant difference from the proposed every-other-year CT scans of the chest recommended in the initial program proposal. You have requested that I review the CT scan portion of the program and that a revised recommended schedule for CT scans be developed concordant with this wording.

At the present time, the best available test to screen for lung cancer remains the low-dose screening CT scan. Recent preliminary data released by the National Lung Cancer Screening Team supports the efficacy of low-dose screening CT scan in detecting lung cancers earlier than is possible via other means and demonstrating improved survival. The dose of radiation in a low-dose screening CT scan used in this study is estimated at 20-25% that of a diagnostic CT scan, and will likely continue to decrease as the technology improves. There is not yet any data on the optimum frequency of CT scanning to screen high-risk persons for lung cancer.

The purpose of a medical monitoring program is to detect diseases which are sub-clinical, to provide knowledge or additional chance of cure for the participant. By definition, this means it would not be necessary to have symptoms to be screened. Testing which is based solely upon symptoms would occur without any medical monitoring program and should be outside of the construct of a program aimed at detecting subclinical disease. I believe that diagnostically medically necessary CT scans for the participants can be estimated purely on the basis of the exposure, without the need for the participant to be symptomatic.

Within the affected area in this community, three geographic areas with different levels of contamination have been identified. These different areas are reflected in different residency time requirements for plan entry. Those living in zone 1 have a much greater exposure and risk of disease per unit time compared to those living in zones 2 or 3. It could be reasonable to develop this program such that there is a different frequency of CT scans recommended for each zone, based upon the relative levels of contamination in each zone. It is understood that there will be a science committee that will develop the final plan, and various permutations of this option have been considered.

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My estimate is that participants in Zone 1 will need a diagnostic CT scan every 2-4 years, participants in zone 2 will need a CT scan every 4-8 years, and participants in zone 3 will need a scan approximately every 10 years.

Dr. Jackson provides the following estimates relative to the percentage of the participants in each zone based upon 2005 data:

	Zone1	Zone 2	Zone 3
Percentages	12.3%	30.2%	57.5%

Doing the math over a 30 year period:

Zone 1 (using every 3 years) = 11 CT Scans x 12.3% = 1.353 Scans

Zone 2 (using every 6 years) = 6 CT Scans x 30.2% = 1.812 Scans

Zone 3 (using every 10 years) = 4 CT Scans x 57.5% = 2.3 Scans

Summing these would yield 5.465 scans over the 30 year period of the program to "the average participant", or one scan every 5.489 years. For the purposes of estimating costs, this should be rounded to one scan every 6 years (on average).

I am not recommending any change in the entry criteria for the program. It is my recommendation that the initial CT scan (to occur with the first cycle of testing if the participant is currently over age 35, or with the first cycle of testing after a participant turns 35) be done for all participants. This will both allow for identification of current occult disease, and will provide baseline information, to support future testing of that participant.

In the original documents, I provided estimates for "leakage" of participants from the program, including both voluntary withdrawls and that which was due to diagnosis of diseases of interest. I believe that it would be simplest, and medically reasonable, to assume that the "leakage rates" due to voluntary and diagnosis-related withdrawls would remain unchanged from the prior estimates. Over time, lung cancers will present themselves clinically (although at a less curable stage), and this would still result in the participant leaving this aspect of the program at about the same rate as previously estimated.

Please contact me if you have any questions about these opinions/recommendations.

Charles L. Wermtz III, D.O., MPH, FACOEM
Associate Professor, Clinical Emphasis
Program Director - Osteopathic Occupational Medicine Residency

August 19, 2011

Edgar C. Gentle, III, Esq.

Special Master

Perrine Medical Monitoring Plan, Product of the Perrine DuPont Settlement

Dear Mr. Gentle,

I am a medical consultant with experience in academics, private practice and Medical Management. My education includes a BS in Chemistry, a Medical Doctorate and an MBA. I have additional training in Nuclear Medicine with Board Certification. I have research experience with over 30 publications and a book chapter and over 10 years of experience in reviewing medical claims for medical appropriateness based on medical literature.

I have been asked to review the CT Scan Utilization Guidelines dated November 1, 2011. There are also several Exhibits that are referenced that I have reviewed including:

- Exhibit 1-CT Scan Utilization Protocols
- Exhibit 2-Class Area Map
- Exhibit 3-Paragraph C, page 2, of Memorandum of Understanding
- Exhibit A-Publication of USFDA
- Exhibit B-ACR Practice Guidelines
- Exhibit C-American College of Radiology September 2002 Statement on CT Screening Exams

In my review, I note many inconsistencies related to the information provided and the question at hand.

The first referenced publication under background in the Utilization guidelines is the Publication of the USFDA. First, this publication relates to Whole Body CT scanning in a normal population. It is my understanding that we are addressing Chest CT Scanning in high risk populations and not whole body scanning in normal populations; therefore this article is not applicable. It also is dated March 2003-

more than 8 years ago and is not up to date with the medical literature especially the recent New England Journal article published August 4, 2011 titled, "Reducing Lung-Cancer Mortality with Low-Dose Computed Tomography Screening". Additionally, the article does reference, "that CT screening of high-risk individuals for specific diseases such as lung cancer or colon cancer is currently being studied, but results are not yet available". The study they are referencing is the National Lung Screening Trial (NLST). The data from this study is what the New England Journal article is based on. Therefore, it is my opinion that this reference has no standing because it is addressing a different modality (whole body CT scanning versus specific areas), is outdated and even references that studies are coming in the future that are now available.

The next reference is to Exhibit B-the ACR Practice guideline. The practice guidelines included are for the performance of pediatric and adult chest radiography which is a Chest x-ray. I understood the matter we were discussing is CT scanning in high risk individuals and therefore

an article on Chest x-rays would be a completely different modality and certainly not applicable to this question. The practice guideline is out of date with the most recent medical literature cited in 2005 and the guideline revised in 2006. The other practice guideline in the exhibit was ACR practice guideline for performing FDG-PET/CT in Oncology. An FDG PET/CT utilizes positron emission tomography to assess metabolic activity in different tumors using flourodeoxyglucose, a radioactive sugar. The CT in PET/CT refers to the anatomic registration portion of the metabolic study and again is a completely different modality than CT scanning in high-risk lung cancers. These guidelines are dated 2007 and are therefore dated in this continually evolving field.

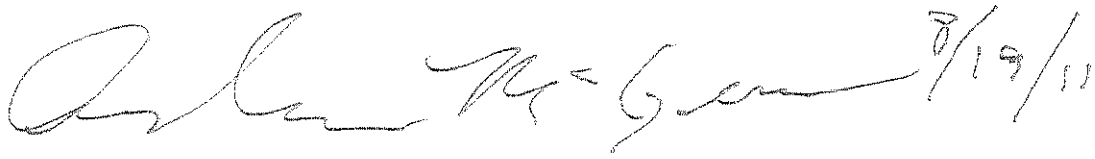
The CT scan guidelines that are quoted I believe are taken from the chest radiography practice guidelines and therefore are not applicable to another modality and neither is the reference to the American College of Radiology Board of Chancellors issued statement since it is referencing total body computed (CT) screening for patients with no

symptoms or a family history suggesting disease and we are addressing a different modality CT Scanning of the chest in patients with a high risk of cancer related to their exposure to the heavy metal contamination at issue in this litigation.

The guidelines that are listed (II. Guidelines, Page 2) are said to be based on these references that I have discussed above and therefore to base the guidelines on references about different tests than the one we are interested in and with medical references that are very out dated is not appropriate.

It is by opinion that according to the paragraph c, page 2 of the Memorandum of Understanding that was included as exhibit 3, CT scans should be provided as diagnostically medically necessary because of the high risk of the possible exposure to the heavy metal contamination at issue in this litigation. I base this on the August 4th 2011 article from the New England Journal "Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening" based on

the National Lung Screening Trial (NLST). This article relates directly to this issue because it addresses a large population (53,454) that is at similar high risk of lung cancer (30 pack year history of smoking) to your patients with heavy metal exposure as noted in Exhibit 2-Class Area Maps. The mortality in these similar at risk individuals was 20% less if they had CT scans than if just chest x-ray surveillance. This article is up to date and particularly on point to this situation. It is my opinion that because of this study all participants should have a CT Scan as part of their surveillance because it is medically necessary in a high risk population with possible exposure to heavy metal contaminants.



Andrea H McGuire, MD, MBA