IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

IN RE: TMI LITIGATION CONSOLIDATED PROCEEDINGS

CIVIL ACTION NO. 1:CV-88-1452

This Document Relates to: All Plaintiffs

## <u>ORDER</u> & JUDGMENT

In accordance with the accompanying memorandum of law, IT **IS HEREBY** ORDERED THAT Defendants' motion for summary judgment is GRANTED and judgment is entered in favor of Defendants as to all Plaintiffs.

SYLVIA H. RAMBO, Chief Judge Middle District of Pennsylvania

Dated: June 7, 1996.

FILED HARRISBURG, PA JUN 7 1996 MARY E. D'ANDREA. CLERK

Contrast from A Deputy Clerk

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Memorandum of Law

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#### MEMORANDUM

On March 28, 1979, a nuclear incident occurred at the Unit 2 reactor of the Three Mile Island nuclear power facility in Dauphin County, Pennsylvania. Among other things, the incident spawned the instant litigation<sup>=</sup> which has been pending on the court's docket for one decade longer than all but one case on the court's docket.' Due in significant part to the tremendous amount of time and effort expended by the parties and the court over the past year, ten test cases were finally scheduled for trial beginning in June.<sup>3</sup> In January and April of this year, the court issued a series of <u>Daubert</u> rulings excluding the bulk of Plaintiffs' expert scientific testimony as scientifically unreliable. <u>In re TMI Cases Consol. II,</u> 166 F.R.D. 8 (M.D. Pa.

<sup>1.</sup> The court notes that a plethora of government *investigations*, privately funded studies, and the ignition of a *national* dialogue as to the safety and utility of nuclear power are among the other important acts spawned by the TMI incident.

<sup>2. &</sup>lt;u>Holloway v. Cohen</u>, Civil No. 1:CV-85-1338, has been stayed for ten years awaiting the conclusion of state court proceedings.

<sup>3.</sup> On May 30, 1996, the court issued an order removing the cases from the June trial list.

1996) (granting in part Defendants' motions in limine to exclude Plaintiffs' medical causation experts); id. 922 F. Supp. 1038, 1996 WL 166713 (M.D. Pa. April 5, 1996) (same); id. 922 F. Supp. 997, 1996 WL 166707 (M.D. Pa. April 2, 1996) (granting in part Defendants' motions in limine, to exclude Plaintiffs' dose and medical causation experts); id 910 F. Supp. 200 (M.D. Pa. January 10, 1996) (granting in part Defendants' motion in <u>limine</u> to exclude Plaintiffs' dose experts); id. 911 F. Supp. 775 (M.D. Pa. 1996) (same). Defendants now move for summary judgment.' The parties have briefed the issues and Defendants' motion is ripe for disposition. Before reaching the merits of Defendants' motion, however, the court must first address the subsidiary yet important issue of to whom the court's summary judgment ruling will apply. Defendants argue that based upon the way in which they have framed their motion, any ruling by the court should be binding upon all Plaintiffs. Conversely, Plaintiffs argue that the ruling should bind only the test Plaintiffs.

To resolve this issue, the court refers back to its memorandum and accompanying order dated June 15, 1993. Through that order the court adopted Plaintiffs' proposed case management

<sup>4.</sup> This is the second time that Defendants have moved for summary judgment. The first motion, related to the issue of duty, was denied by this court on February 18, 1994. The United States Court of Appeals for the Third Circuit, affirming in part this court's ruling, found that Defendants violated the duty of care owed. In <u>re TMI Cases Consol. II</u>, 67 F.3d 1103, 1118 (3d Cir. 1995). Accordingly, the only remaining legal and factual issues in the case relate to causation and damages. See id at 1119.

plan and "test plaintiff" approach, and rejected Defendants' case management plan and "track litigation" approach. In its discussion of Plaintiffs' proposed plan, the court noted the following:

Plaintiffs claim that this initial trial would provide a basis for the parties realistically to evaluate their respective cases and promote settlement of this action. Defendants contend that "the 'test-case' approach does not portend to resolve anything except the test cases selected." Therefore, Defendants assert that the initial twelve-Plaintiff<sup>s</sup> trial would not promote settlement or be otherwise useful.

In re TMI Cases Consolidated II, No. 1:CV-88-1452, mem. op. at 26 [M.D. Pa. June 15, 1993] [footnote added]. Defendants now argue that "(tlhe fact that'the court has scheduled <u>trial</u> for ten `test case' plaintiffs does not mean that all the <u>pretrial</u> consolidated proceedings, designated with the caption 'All Plaintiffs," should

Hereafter, pleadings dealing with issues common to all plaintiffs, or a legal issue potentially. applicable to all plaintiffs shall be captioned "In Re TMI Consolidated Proceedings" and shall bear the additional legend, "This Document Relates To: All Plaintiffs. . . . "

(continued...)

<sup>5.</sup> Initially, twelve test cases were scheduled for trial, **six** test parties selected by Plaintiffs and six selected by Defendants. One of Defendants' selections subsequently withdrew from the test group. Accordingly, the court permitted Defendants to chose one of the parties originally selected by Plaintiffs to be dismissed from the "test Plaintiff action."

<sup>6.</sup> On July 9, 1992, the court approved a stipulation which provided for the use of different captions on documents applying to all plaintiffs as opposed to those applying merely to certain individual plaintiffs. Specifically, the stipulation noted as follows:

be regarded retrospectively as applicable only to those 'test case' plaintiffs." (Defs.' Reply Mem. at 26.) Indeed, the purpose of consolidating an action pursuant to Federal Rule of Civil Procedure 42(a) is to streamline and economize pretrial proceedings so as to avoid duplication of effort, and to prevent conflicting outcomes in cases involving similar legal and factual issues. <u>See In re Prudential Securities Ltd. Partnerships</u> <u>Litigation</u>, 158 F.R.D. 562, **571 (S.D.N.Y. 1994)**; <u>Bank of Montreal</u> **V.Eagle Associates**, 117 F.R.D. 530, 533 (S.D.N.Y. 1987).

The court finds that resolution of the issue before it turns on the grounds upon which the court ultimately grants or denies summary judgment. Defendants are correct that to the extent the ruling turns on broad evidentiary issues common to all Plaintiffs, the ruling will be binding upon all Plaintiffs. Likewise, Plaintiffs are correct that insofar as a ruling is based upon a more narrow, Plaintiff-specific inquiry, the ruling will

6. (...continued)

A pleading dealing with issues applicable to one or more identified plaintiffs shall be captioned "In Re TMI Consolidated Proceedings" and shall bear the additional legend, "This Document Relates To:" and shall include lead counsel's name, number of plaintiffs represented by lead counsel and number of plaintiffs for whom the pleading refers. An additional page bearing the legend, "This Document Relates to the Following Plaintiffs:" shall be attached and each such individual plaintiff shall be named.

7/8/92 Amended Stipulation at 3 (approved in 7/9/92 order).

apply only to certain Plaintiffs. The court's reading of documents related to the June 15, 1993 order, in conjunction with subsequent case management orders and evidentiary rulings, indicates that discovery and evidentiary matters were to proceed on an "All Plaintiffs" basis. A contrary intention or result would obviate all benefits of having consolidated the many separate actions. Each Plaintiff's case depends upon expert testimony to prove both exposure and medical causation. Expert discovery is complete, and all expert reports have been filed. Thus, to the extent that the expert testimony of record fails to meet the test Plaintiffs' evidentiary burden at this stage of the litigation, it will fail to meet the same burden as to every It would be an exercise in futility and a waste of Plaintiff. valuable resources to allow the many separate actions consolidated under this caption to proceed if it were clear that the cases could not withstand a motion for summary judgment. Under such circumstances, the court's summary judgment ruling would be applicable to all Plaintiffs.'

<sup>7.</sup> Plaintiffs argue that their Seventh Amendment right to a jury trial would be abrogated should the court make the instant ruling binding upon all Plaintiffs. The court cannot agree. Insofar as the evidence before the court is insufficient to either create a material factual dispute or carry Plaintiffs' burden at trial, Plaintiffs do not, as a matter of law, have any right to a jury trial. <u>City of Chanute v. Williams Natural Gas Co.</u>, 955 F.2d 641, 656 (10th Cir. 1992) ("[S)ummary judgment, applied properly, does not violate the Seventh Amendment.") (citing <u>Fidelity & Deposit Co.</u> **V.**United States ex rel. Smoot, 187 U.S. 315, 319-21 (1902)).

In accordance with the discussion that follows, the court will grant Defendants' motion for summary judgment on the ground that Plaintiffs have failed to present evidence sufficient to create a material factual dispute on the issue of dose, and therefore, have failed to state their prima facie case. Because the court finds the quantum of Plaintiffs' expert evidence on the issue of dose to be insufficient, and because, no Plaintiff will be able to state a prima facie case without adequate dose evidence, the instant ruling is binding upon all Plaintiffs.

### I. <u>Background</u>

## A. <u>Procedural History</u>

The consolidated claims in this case were initially filed shortly after the TMI incident in the state and federal courts of Pennsylvania, New Jersey and Mississippi. Since the initial filings, these cases have traveled to and from the Supreme Court, the Third Circuit Court of Appeals, and several district courts on numerous occasions. Moreover, jurisdictional questions related to these actions prompted Congress to amend the Price Anderson Act to ensure federal court jurisdiction, <u>see</u> S. Rep. **100-218**, 100th Cong. 2d Sess., **1988 U.S.C.C.A.N. 1476, 1488** Inoting that the TMI litigation provided the impetus for amending the federal jurisdiction section of the Act). A brief review of the consolidated claims' meandering journey to this court is warranted.

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In the mid and late 1980s, based upon the assertion that Plaintiffs' claims arose under the Price Anderson Act, Pub. L. No. 85-256,71 Stat. 576 (codified as amended in various sections of title 42 of the United States Code), Defendants removed Plaintiffs' state court actions to federal courts in Pennsylvania and Mississippi. On appeal, the Third Circuit found that because the Nuclear Regulatory Commission ("NRC") had determined that the TMI incident did not constitute an "extraordinary nuclear occurrence, "<sup>a</sup> the TMI claims did not arise under the provisions of

8. Pursuant to 10 C.F.R. §§ 140.84 and 140.85, the NRC may determine that there has been an Extraordinary Nuclear Occurrence ["ENO") where two sets of criteria are met. "Criterion I relates to whether there has been a substantial discharge or dispersal of radioactive material off the site of the reactor, or that there has been a substantial level of radiation offsite." NUREG-0637, Report to the Nuclear Regulatory Commission from the Staff Panel on the Commission's Determination of an Extraordinary Nuclear Occurrence [ENO] at  $8 \ (NRC \ 1980)$ . If Criterion I is met, the Criterion II factors are evaluated. Criterion II is met if any of the following findings are made:

- (1) The event has resulted in the death or hospitalization, within 30 days of the event, of five or more people located offsite showing objective clinical evidence of physical injury from exposure to the radioactive, toxic, explosive or other hazardous properties of the reactor's source, special nuclear, or byproduct material; or
- (2) \$2,500,000 or more damage offsite has been or will probably be sustained by any one person, or \$5 million or more of such damage in total has been or will probably be sustained, as the result of such event; or

continued...)

the Price-Anderson Act. Stibbitz V.General Pub. Utils. Corp., 746 F.2d 993 (3d Cir. 1984), cert. denied, 469 U.S. 1214 (1985); Kiick v. Metropolitan Edison Co., 784 F.2d 490 (3d Cir. 1986). As such, the Third Circuit ruled that this court lacked jurisdiction to hear the actions. Stibbitz, 746 F.2d at 997; Kiick, 784 F.2d at 494-95. Pursuant to that rulings, this court remanded those actions originally filed in state court, and transferred those actions originally filed in federal court, to the appropriate state courts.

Following this court's remand and transfer of cases to state courts, Congress amended the Price-Anderson Act. 42 U.S.C. § 2001 (Price-Anderson Amendments Act of 1988). The amendment retroactively provided a federal forum for all claims arising out of <u>any</u> nuclear incident, whether or not that incident was declared to be an "extraordinary nuclear occurrence." 42 U.S.C. § 2210(n)(2). Original jurisdiction was conferred upon district courts located where the incident occurred, and provision was made for the removal of any action previously. filed or currently pending in state court. § 2210(n)(2). Subsequently, the constitutionality of the Act's federal forum provision was upheld

<u>Id.</u> at 11.

8.

(... continued)

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<sup>(3)</sup> The Commission finds that \$5,000 or more of damage offsite has been or will probably be sustained by each of 50 or more persons, provided that \$1 million or more of such damage in total has been or will probably be sustained, as the result of such event.

in <u>In re TMI Liticration Cases Consol.II</u>, 940 F.2d 832 (3d Cir. 1991), <u>cert. denied</u>, 503 U.S. 906 (1992). Pursuant to \$ 2210(n)(2), all remaining claims were then consolidated in this court.

On January 26, 1993, Defendants moved for summary judgment on all pending personal injury claims on the element of duty of care. Defendants argued that to prove liability, Plaintiffs would need to demonstrate that Defendants violated their duty of care by exposing each Plaintiff to radiation in excess of .5 rem. See <u>infra</u>, at 11-12 [defining "rem"). On February 18, 1994, this court issued a memorandum and order denying Defendants' motion. The Third Circuit affirmed this court's ruling in part, holding that "the duty of care is measured by whether defendants released radiation in excess of the levels permitted by [10 C.F.R.) §§ 20.105 or 20.106, as measured at the boundary of the facility, not whether each plaintiff was exposed to those excessive radiation levels." In re TMI Litig. Cases Consol. II, 67 F.3d 1103, 1117-18 (3d Cir. 1995), cert. denied, 116 S. Ct. 1034 (1996).

In November of 1995, and in February and March of 1996, this court conducted extensive <u>Daubert</u> hearings related to Plaintiffs' dose and medical causation experts. In January and April of 1996, this court issued several memoranda of law and accompanying orders granting the majority of Defendants' motions in <u>limine</u>. As these opinions, hundreds of pages in aggregate

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length, detail the court's reasoning, the court will not restate that reasoning here. In brief, however, the court notes that despite **finding** the vast majority of Plaintiffs' experts to be well qualified, the court found many of their opinions to be based upon methodologies that were scientifically unreliable and upon data that a reasonable expert in the field would not rely upon. Accordingly, in the exercise of its "gatekeeping" function, the court found it necessary to exclude much of Plaintiffs' proffered expert testimony. On April 19, 1996, Defendants filed the instant motion for summary judgment on the issues of dose and medical causation.

# B. <u>Scientific Background'</u>

To understand the framework through which the court must view the scientific evidence in this case, it is necessary to have a basic understanding of the concepts and principles used by scientists to evaluate the impact of radiation exposure in human beings. The court will first provide a brief overview of basic concepts of radiation.

Next the court will review relevant dose-related terms and concepts including the concept of background radiation, and the processes of dose reconstruction and risk assessment. Finally, the court will explain the basic operation

<sup>9.</sup> In this section the court will present an overview of relevant scientific principles. The court will elaborate upon principles introduced here, to the extent that it is necessary, when reaching the merits of Defendants' motion for summary judgment.

of a Babcox.& Wilcox pressurized water nuclear reactor, and will discuss general meteorological concepts relevant to the movement and dispersion of radioactive plumes.

### 1. Basic Concepts of Radiation

Atoms are the smallest unit of an element, and are composed of three types of particles: protons, neutrons and electrons. They may be stable or unstable. Unstable atoms emit surplus energy from the nucleus in a process known as radioactive decay. The energy emitted through radioactive decay is radiation. See generally, Allen v. United States, 588 F. Supp. 247, 260-87 (D. Utah 1984) (providing exhaustive discussion of basic principles of radiation and nuclear physics).

> For the purposes of this lawsuit, there are three basic types of ionizing radiation. An <u>alpha particle</u> is composed of two neutrons and two protons . . . A <u>beta ray</u> is a single electron. A <u>gamma ray</u> is a photon, or bundle of energy which contains some of the properties of both matter and light.

Johnston v. United States, 597 F. Supp. at 384 (emphasis added). Gamma radiation is short wave length electromagnetic radiation spontaneously emitted by a nucleus during certain radioactive decays. (7/12/95 Aff. of John Fraizer at 14.) It has a high penetrating ability and can pass through the human body. In the instant action, Plaintiffs allege gamma ray exposure from xenon, radioactive iodine, and to a lesser extent, krypton.

Scientists quantify radiation in the following manner:

(a) s radiation passes through air, it can be measured by counting the number of ionized particles it produces. The quantity exposure' has been historically defined as the number of electrical charges produced in a unit mass of air and measured in units of roentgens (R). . . As radiation penetrates any material; its energy is absorbed and released by the constituent atoms. The absorbed energy per unit mass of material is termed the absorbed dose. The old unit of absorbed dose was the rad, defined as 100 ergs of energy per gram of material. . . . The effects of radiation on any material, including biological materials such as tissue, depend on the magnitude of the absorbed dose.

International Advisory Committee, "The International Chernobyl Project, Technical Report," at 20 (IAEA 1991) (hereinafter "Chernobyl Report"). The rad has been replaced by the international unit, the "gray" (Gy). One gray is equal to 100 rads. Another relevant dosimetric quantity is the "rem" (roentgen equivalent man). One rem is equal to one hundred milirems (mrems). The rem has been replaced by the international unit the "sievert" (Sv). One sievert equals 100 rems (0.01 mrem). Because much of the TMI literature predates the conversion to international units, the court will use rad and rem quantities to insure consistency with materials being cited.

## 2. Radiation **Exposure and Dose**

### a. <u>Background Radiation</u>

All persons are exposed to radiation in their day to day existence. This radiation, known as "background radiation," comes

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from both natural and man-made sources. National Research Council, Committee on the Biological Effects of Ionizing Radiation, "Health Effects of Exposure to Low Levels of Ionizing Radiation" at 17 (1990) ("BIER V")<sup>10</sup>; <u>see</u> also Chernobyl Report at 23-28. The BEIR V report states the following regarding annual exposure to background radiation in the United States:

> three of the **six** radiation sources, namely radiation from occupational activities, nuclear power production (the fuel cycle), and miscellaneous environmental sources (including nuclear weapons testing fallout), contributed negligibly to the average effective dose equivalent, i.e., less than 0.01 millisievert [mSv)/year (1 mrem/year).

A total average annual effective dose equivalent of 3.6 mSv (360 mrem)/year to

10. In <u>O'Conner v. Commonwealth Edison Co.</u>, 807 F. Supp. 1376, 1382-83 n.6 (C.D. Iii. 1992), the court provided the following history of the BEIR reports:

The National Academy of Sciences was established by President Abraham Lincoln in 1863 to provide the federal government with the advice of the best scientific minds in the country. It has a committee specifically dedicated to the health effects of ionizing radiation that issues periodic reports containing the most recent knowledge in this field. The most recent report is "Health Effects of Exposure to Low Levels of Ionizing Radiation: 1990 ("BEIR V"). . . . The BEIR Reports are reliable authorities containing the distilled advice of scientists who have reviewed all of the eminent scientific literature in this field. It provides a yardstick by which a court can measure the validity of the various expert opinions offered by litigants.

<u>id.</u>

members of the U.S. population is contributed by the other three sources: naturally occurring radiation, medical uses of radiation, and radiation from consumer products. By far the largest contribution (82%) is made by natural sources, two thirds of which is caused by radon and its decay products. Approximately equal contributions to the other one-third come from cosmic radiation, terrestrial radiation, and internally deposited radionuclides. The importance of environmental radon as the largest source of human exposure has only recently been recognized.

The remaining 18% of the average annual effective dose equivalent consists of radiation from medical procedures (x-ray diagnosis, 11% and nuclear medicine, 4%) and from consumer products (3%).' The contribution by medical procedures is smaller than previously estimated. For consumer products, the chief contributor is, again, radon in domestic water supplies, although building materials, mining, and agricultural products as well as coal burning also contribute. Smokers are additionally exposed to the natural radionuclide polonium-210 in tobacco, resulting in the irradiation of a small region of the bronchial epithelium to a relatively high does . . . that may cause an increased risk of lung cancer.

BIER V at 18-19. The <u>Johnston</u> court also made the following interesting observations regarding natural background radiation:

In order to make these units of measurement more meaningful, it is of interest to note what doses some common experiences yield. The earth in Florida gives a person living there a dose of approximately 23 mrem per year. If a person lives there for 64 years, he will receive a dose of  $64 \ge 23$  mrem = 1472 mrem'from Florida dirt in a lifetime. This is equal to 1.472 rem. If another person lives in Colorado for 64 years, he will receive a dose of  $64 \ge 90$  mrem = 5760 mrem from Colorado dirt in a lifetime. This is equal to 5.76 rem. In 1970, approximately 129,000,000 Americans were exposed to x-rays for medical or dental purposes . . . The average American by age 64 will receive about 6.5 rem of radiation from x-rays. Consequently, total [(lifetime)] doses of approximately 12 rem would be common for a [64 year old] Colorado resident who had normal exposure to dirt and x-rays.

Johnston, 597 F. Supp. at 389-90 (internal citations omitted) (citing BEIR III)." The effect of radiation exposure upon a human being is controlled by a number of variables. For example, the effects depend "not only on the absorbed dose, but also on the type and energy of the radiation causing the dose." Chernobyl Report at 20. In addition, the likelihood of observing effects will depend upon the tissue or organ irradiated and the degree of sensitivity of that tissue or organ to radiation. <u>Id.</u>

## b. <u>OuantifyinO Dose/Dose Reconstruction</u>

When considering the potential biological effects of exposure to ionizing radiation, it is necessary to consider the pathway through which the radiation entered the body.

> Following any release of radionuclides to atmosphere, people can be exposed via a number of different routes. As the radioactive cloud is dispersed and transported by the prevailing

<sup>11.</sup> Based upon the findings of the BEIR V report, the <u>Johnston</u>, court's characterization of the effects of medical exposure may be overstated. HEIR V at 19 ("The contribution [to background exposure] by medical procedures is smaller than previously estimated."). Nevertheless, the <u>Johnston</u> court's illustrations of "typical" background exposure assist in placing the issue of exposure in the instant case in the appropriate context.

winds, people are initially exposed to radiation by two principal routes: external irradiation from material in the cloud and internal irradiation following inhalation of radioactive material in the air. Subsequently, the *contents* of the cloud are gradually depleted during its dispersion as radioactive materials are transferred to the ground and water bodies under dry weather conditions, with precipitation or in fog. People may then be exposed and may continue to be exposed by other routes, the three main ones being: external irradiation from the deposited material itself, the inhalation of any material resuspended into the atmosphere, and the transfer of material through the terrestrial and aquatic environment to food and water, which can give rise to internal irradiation.

Chernobyl Report at 31. Among other reasons, the pathway of exposure is important because it provides key information regarding potential exposure. For example, where exposure is internal, from ingestion of a radionuclide, exposure will continue for the life of the radionuclide and will be highest in those organs most susceptible to exposure from the radionuclide ingested. See National Resource Council, <u>Radiation Dose</u> <u>Reconstruction for Epidemiologic Uses</u> 41-3 (1995); <u>see infra</u> at 20-21 (discussing authoritative materials upon which this handbook is based).

Two categories of effects may be observed following exposure to ionizing radiation: deterministic effects and stochastic effects. Deterministic effects of exposure to radiation arise from cell death. When a threshold number of cells within a given tissue or organ are killed, "there will be clinically observable pathological conditions such as a loss of tissue *function* or a consequential reaction as the body attempts to repair the damage. If the tissue is vital and is damaged sufficiently, the end result will be death." Annals of the ICRP, ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection" at- 14 (1991) (hereinafter "ICRP 60").<sup>12</sup> Acute radiation syndrome, <sup>13</sup> for example, is a

12. According to the <u>O'Conner</u> court,

The International Commission on Radiological Protection was founded in 1928, and since 1950 has been providing general guidance on the widespread use of radiation sources. The ICRP is comprised of eminent international scientists who review the world's literature on issues related to the health effects of radiation and periodically publish reports containing reliable consensus science statements in this field. These reports can be used by a court to evaluate expert's claims.

Id. at 1382 n.4 (citation omitted).

13. The textbook <u>Medical Effects of Ionizing Radiation</u> provides the following discussion of acute radiation syndrome:

The acute radiation syndrome is generally divided into 4 subgroups: (1) CNS syndrome, (2) cardiovascular syndrome, (3) gastrointestinal syndrome, and (4) hematopoietic syndrome. The acute <u>CNS</u> <u>syndrome</u> (group V) is generally reached only when the whole-body irradiation dose exceeds 50 Gy (5000 rad). The survival time is less than 48 hrs. . . . In general, symptoms are identified almost immediately and consist of disorientation, apathy, ataxia, prostration, and often tremor and convulsions. These seizures may result from minimal external stimuli. The cause of death is believed to be a *function* of several causes, including

(continued...)

deterministic effect of radiation exposure. Stochastic effects occur when the irradiated cell is modified rather than killed.

13. (...continued)

vascular damage, meningitis, myelitis, and encephalitis. Fluid infiltrates into the meninges, brain, and choroid plexus, causing marked edema. The resulting pressure may cause pressure on critical structures. . .

When acute absorbed skin doses in the range of 7 to 50 GY (700 to 5000 rad) are received, the <u>gastrointestinal</u> <u>syndrome</u> (group IV) may occur. In most circumstances, after the prodromal period, a latent period of approximately 1 to 4 days during which the patient is asymptomatic occurs. The clinical progress of the syndrome is a manifestation of the radiosensitivity and failure of both the gastrointestinal syndrome and the bone marrow. The symptoms include lethargy, diarrhea, dehydration, and sepsis. The earliest pathologic changes can be identified as degenerative abnormalities in the small bowel epithelium. . .

In the absorbed skin dose range of 2 to 7 GY (200 to 700 rad), the <u>hematopoietic</u> <u>syndrome</u> (groups II and III) may be encountered. After the prodromal period, the duration of the asymptomatic latent period is 1 to 3 wks. The signs and symptoms result from radiation damage to the bone marrow, lymphatic organs, and immune response. In this syndrome, rapid reduction in the lymphocytes and a somewhat more delayed reduction of leukocytes, platelets, and red cells occur. The granulocytopenia leads to infection, and the thrombocytopenia leads to hemorrhage. Mean survival is usually 2 to 6 wks, with the nadir of the various blood elements occurring approximately 30 days after exposure. Death usually results from hemorrhage and infection.

Fred A. Mettler, Jr., M.D. and Arthur C. Upton, M.D., <u>Medical</u> <u>Effects of Ionizing Radiation</u> **279-80 (W.B.** Saunders Co. 1995) (D-X-155) (hereinafter <u>"Medical Effects").</u> Chernobyl Report at 39-40. The modified cell replicates itself, and over time, may develop into cancer. The risk of contracting cancer as a result of radiation exposure increases in relation to the dose of radiation to which a person is exposed. See <u>generally</u>, Chernobyl Report at 40-41 ("[F]atal cancer risk factor following exposure to relatively low doses delivered at low dose rates is smaller than the values assessed for high doses at high dose rates."); BEIR V at 20-24 (discussing radiobiological concepts impacting on biological consequences of a given dose of radiation). Accordingly, to determine the effect that radiation exposure will have on a person, it is necessary to quantify the dose of the exposure. The following dosimetric quantities are used within the field of health physics to express exposure:

Absorbed dose: The amount of radiation energy that is absorbed per kilogram of tissue. It is expressed in grays (Gy).

Equivalent dose: The absorbed dose weighted for the harmfulness of different radiations (by radiation weighting factors) to take into account the different types of radiation and their energies. It is expressed in sieverts (Sv), with submultiples of millisieverts (mSv) . For most practical applications, the radiation weighting-factor is unity; that is, the numerical values for absorbed dose and equivalent dose will be equal.

**Effective dose:** The equivalent dose weighted for the susceptibility of harm of different human tissues. It is a (modified) equivalent dose and is also expressed in sieverts.

Chernobyl Report at 21.

Although uncertainties remain, the last decade has seen tremendous advances-in what is known about radiation induced cancers. See BEIR V at 1 ("Since the completion of the 1980 BEIR III report, there' have been *significant* developments in our knowledge of the extent of radiation exposures from natural sources and medical uses as well as new data on the late health effects of radiation in humans . . . . Furthermore, advanced computational techniques and models for analysis have become available for radiation risk assessment."). Long term studies on the survivors of Hiroshima and Nagasaki, British akylosing spondylitis patients treated with radiation therapy, and other persons exposed to radiation via nuclear weapons testing or occupational exposures, have increased the body of knowledge regarding the health effects of radiation exposure. <u>See</u> United Nations Committee on the Effects of Atomic Radiation ("UNSCEAR"), "Sources and Effects of *lonizing* Radiation" at Appendix F, p. 620 (1993) (hereinafter "UNSCEAR 1993").<sup>14</sup> Based upon these advances,

14. The <u>O'Conner,court</u> provided the following statement about UNSCEAR:

The United Nations Committee on the Effects of Atomic Radiation (UNSCEAR) was established by the United Nations General Assembly in 1955. The committee is made of eminent experts in the field of radiation from the international scientific community. It periodically issues **Reports (sic)** that summarize the main conclusion of all of the world's published scientific literature **in** the field. These reports of consensus science can be used to

continued...)

and relying upon the findings of these authoritative compilations, the National Research Council in 1995 published a comprehensive handbook on the mechanics of dose reconstruction. <u>Radiation Dose</u> <u>Reconstruction for Epidemiologic Uses</u> (1995) (hereinafter <u>"Radiation Dose Reconstruction")."</u>

Radiation Dose Reconstruction focuses on the process of reconstructing a dose from a past exposure to radiation to provide a basis for estimating health risks arising from the exposure. <u>Id.</u> at 7. As such, it is well suited to serve as a framework for evaluating the evidence in the captioned matter. The following

14. (...continued)
 measure the validity of the claims of
 litigants.

Id. at 1382 n.3 (citation omitted).

15. The preface describes the goals of the publication as follows

As public concern mounts over past and current exposure to ionizing radiation stemming from environmental releases of radioactive materials, there is a growing need to define the criteria to be met by studies that reconstruct exposures and doses and to provide guidance in the studies' epidemiologic use. Absent this, dose reconstruction studies are not likely to stand serious scientific scrutiny or to meet public concerns. . . This report should set the objectives to be attained by such studies and provide guidelines for their conduct. It is aimed at providing generic information to scientists entering the field and to interested members of the public.

Radiation Dose Reconstruction, at vii (emphasis added).

"steps" are identified in Radiation Dose Reconstruction as

integral to any dose reconstruction analysis:

\*Source term<sup>®</sup> **analysis** consists of estimating the magnitude of releases to the *environment* of radionuclides and the periods over which they were released, *including* episodic releases from nonroutine events.

\*Pathway analysis examines the transport of released radionuclides through *environmental* pathways to determine their *concentrations* in environmental media to which people were exposed. These media include air, surface and groundwater, and soil, among others.

\*Assessment of radiation doses and risks brings together all of the data on releases, transport, lifestyle and dietary habits, analysis of agricultural and food-distribution practices, and biologic factors, including the use of biologic dosimetry, to determine doses or to corroborate evidence of doses and to estimate the likelihood of disease in the exposed persons.

#### \*Examination of epidemiologic

considerations takes into account the size and demographic structure of the potentially affected population, the availability and quality of *information* needed to estimate the dose, the medical information needed, and the feasibility of conducting an investigation that is sufficiently informative and free of **bias**.

\*Uncertainty and sensitivity analysis identifies the importance of changes in the parameters and values used to estimate

<sup>16. &</sup>quot;The source term is the amount of radionuclides released from a site to the environment over a specific period. The rate of release as a function of time should also be determined. Releases can be to the atmosphere, to surface waters, to groundwater, or to soil." <u>Radiation Dose Reconstruction</u> at 16.

confidence intervals"' in the overall analysis of the dose reconstruction. . .

<u>Radiation Dose Reconstruction</u> at 9 (footnote added; emphasis in original). It is also noted that "[h]istoric records are commonly the *foundation* of a dose reconstruction project, and [that] it is always preferable to use measured data (historic data) rather than models in reconstruction of doses." <u>Id.</u> at 10. Finally, the report stresses that "[d]ose reconstruction studies must *rely* on solid science, state-of-the-art methods, and careful peer review if they are to be viewed as credible. Ultimately, a dose reconstruction study will be judged by the scientific community primarily on the basis of the technical quality of the study and its contribution to science." <u>Id.</u> at 14.

### c. <u>Risk Assessment</u>

Once a dose reconstruction analysis is performed, it is possible to make a risk assessment based upon the calculated exposure level. Risk assessments of this nature are made by reference to, among other things, "dose-response curves" which delineate the connection between radiation exposure at various doses and cancer induction. Stated in the most general terms,

<sup>17.</sup> A "confidence interval" is "[a]n estimate, expressed as a range, for a quantity in a population. If an estimate from a large sample is unbiased, a 95% confidence interval is the range from two standard errors below to two standard errors above the estimate. Intervals obtained this way cover the true value about 95% of the time. . . . " <u>Reference Manual on Scientific Evidence</u> at 396 (Fed. Judicial Ctr. 1994) (hereinafter "Reference Manual").

UNSCEAR and the ICRP recognize the "curve" for solid cancers to be linear<sup>18</sup>, while the "curve" for leukemias is recognized to be linear-quadratic." See BEIR V at 140-44 ("The dose-response

18. "The linear model suggests that each time energy is deposited in the susceptible target there is a probability of [tumor] initiation." <u>Medical-Effects</u>, at 81. The <u>Johnston</u>, court explained the linear curve as follows:

If one assumes that the risk per rem is the same at low doses as it is at high doses, one is assuming that if a million people exposed to 100 rem will have 10 excess cancers, then a million people exposed to 10 rem will have one excess cancer. When such an assumption is drawn on a standard dose response graph, the result is a straight line. This assumption is *known* as the linear hypothesis.

<u>Johnston v. United States</u>, 579 F. Supp. 374, 393 (D. Kan. 1984) | citing BEIR III at 520).

19. The linear quadratic curve presumes that all reactions are dose-dependent. <u>See Medical Effects</u> at 8l ("Because each of these factors may change differently with dose, the risk and shape of the curve in a certain dose region *cannot* be extrapolated with certainty either up or down . . . ."). In <u>Johnston</u>, the court provided the following *explanation* of both quadratic and linear quadratic curves:

In the field of radiation science, the linear hypothesis and the threshold hypothesis are not the only theories used by respected scientists to predict the *carcinogenic* effect of radiation. There is also the quadratic hypothesis which suggests that a low dose of radiation is less carcinogenic per rad than a high dose of radiation. When the quadratic hypothesis is drawn on a standard dose response graph, the result is a downward dipping curve. Another theory is the <u>linear-quadratic</u> hypothesis. This one blends aspects of the linear hypothesis with aspects of the quadratic hypothesis. It yields a curved line on a standard dose response graph which falls

continued...)

relationship for the *induction* of radiogenic transformation reflects a balance between an increase with dose in the proportion of cells that are transformed and a decrease in cell survival."); <u>Medical Effects</u> at 82 (*explaining* linear, quadratic and linearquadratic dose-response curves). The scientific literature is in agreement that no study has shown a dose-response relationship at doses under 10 rems. <u>See BEIR V at 4-5; Medical Effects</u> at 86 ["there is, in fact, no proven body of data that established an increase in human cancer levels below about 0.1 Gy (10 rad)); see <u>also</u> UNSCEAR 1994 at 50-60 (Annex A) summarizing the findings of epidemiological studies attempting to establish a dose-response relationship following exposure to low-LET radiation); UNSCEAR 1993 at 676, 679-80 (Annex F); Chernobyl Report at 41 ("statistically significant direct observations in man in homogenous populations . . . are available for doses down to about 200 mSv."). Moreover, at doses below 10 rads, biological markers of dose<sup>20</sup> and exposure become less helpful as indicators.

19. (...continued)
 between the linear line and the quadratic
 curve.

Johnston, 597 F. Supp. at 393 (citing BIER III at iii).

20. "(E]xposure can be estimated from dose, which in turn can be reconstructed through internal indicators (biomarkers . . .) after the exposure has taken place." Environmental Protection Agency Guidelines on Exposure Assessment, 57 Fed. Reg. 22,888, 22,898 (May 29, 1992) (hereinafter "EPA Guidelines"). These markers include chromosome "aberrations, micronuclei, DNA adducts, or mutations." <u>Radiation Dose Reconstruction</u> at 51. It is further noted that: (continued...)

<u>Radiation</u> <u>Dose</u> <u>Reconstruction</u> at 58 ("For retrospective dose reconstruction, it is generally agreed that markers of exposure are not useful below an acute dose of 0.1 Gy (10 rad)."); see <u>generally</u> id, at 51-59. Accordingly, the most that scientists can do is extrapolate and speculate regarding the dose-response relationship at such low levels of exposure. In addition to the dose-response curves, risk assessments must consider a number of factors that could increase or decrease a person's propensity to develop cancer following radiation exposure. These factors include, but are not limited to: age at the time of exposure, sex, genetic predisposition, whether the individual smokes, and the possibility of exposure to other toxic agents. See Radiation Dose, Reconstruction at 48; ICRP 60 at 120-22; EPA Guidelines at 22,900. Finally, a comprehensive dose assessment depends upon the calculation of an organ dose. Id. at 47 ["The organ dose is especially important when developing doses to compare to site-

# 20. (...continued)

There are three kinds of biologic markers: markers of exposure or dose, markers of effect, and markers of susceptibility. Biologic markers of effect record biologic responses in individuals who have been exposed to a genotoxic agent, but markers of exposure (or dose) do not necessarily indicate effects. Superimposed on this are markers of susceptibility; those that could be. used to identify persons who **are** at increased risk of developing a disease that could be triggered by a given exposure.

<u>Id.</u> at 51-52.

specific health effects.") Knowledge of the type of radionuclide to which an individual was exposed is relevant when calculating organ dose. <u>See Allen</u>, 588 F. Supp. at 308 ("Once ingested or inhaled, the degree of exposure actually experienced depends upon the highly variable physical and chemical qualities of each individual radionuclide.").

3. Principles Relevant to a Nuclear Reactor Accident

### a. <u>Pressurized Water Reactors</u>

The basic principles associated with the operation of pressurized water reactors ("PWR") are not at issue in this case (although the specific operation of the TMI-2 PWR during the accident **is**). An understanding of these basic principles is necessary to understand the release and source term evidence in this case. Plaintiffs, however, have not introduced evidence providing a description of these basic principles. The court's searching review of the record has revealed one governmental report and one affidavit that explain these principles in layperson's terms. Since the basic operation of a pressurized water reactor is not at issue in the litigation, the court finds it proper to rely on the following excerpt from the Daniel affidavit for its educational value:

> A nuclear power plant produces heat energy that is converted to steam in a boiler. The steam is used to turn a turbine, which is connected to an electrical generator. The

> > 27

heat is produced in a steel vessel called a <u>reactor</u>, since nuclear reactions are contained within the vessel. In a reactor design such as TMI-2, uranium fuel is used to provide the The fuel is formed into a heat energy. ceramic pellet approximately 1/2 inch in diameter, and about a half-inch long. These pellets are stacked into metal rods called fuel pins, and the fuel pins are arranged into square arrays called <u>fuel</u> assemblies. The fuel assemblies are approximately 12 feet in height, and are collectively referred to as the reactor <u>core</u> contained in the reactor vessel. Within the fuel assemblies are several tubes which have *instruments* to monitor the reactor and other tubes that contain control rods which "'speed up" or "slow The fuel pellets are down" the reaction. protected from direct contact with water in the core by the rods made of zirconium, which is sometimes called the fuel <u>cladding.</u>

In a pressurized water reactor, such as TMI-2, there are three cooling circuits. The primary circuit is a closed loop circuit and circulates water through the reactor core. This circuit is called the primary coolant, or The reactor coolant is <u>reactor</u> <u>coolant.</u> maintained at a pressure that is high enough to prevent it from boiling. The reactor coolant picks up the heat from the fission reaction and carries it out of the core to two steam generators (or boilers). These are tanks approximately 35 feet tall in which the primary water passes through a large number of small diameter tubes, transferring heat to water flowing in the secondary circuit, which is outside these tubes. Water in the secondary circuit is maintained at a lower pressure and boils to **make** steam which occupies much more volume than water. That steam therefore "pushes" itself out at high velocity to the turbine-generator unit. The steam in the secondary circuit is called the <u>main steam system.</u> The steam passes from the turbine to a condenser which is cooled in turn by the third circuit, water from the cooling towers. Water collected in the condenser is pumped back to the steam generators. The

water in this portion of the secondary circuit 1S called <u>feedwater.</u>

The water in the primary loop is kept from boiling by keeping it under high pressure -- normally about 2200 pounds per square inch. A large vessel connected to the primary loop called the <u>pressurizer</u> is used to *maintain* this pressure. The pressurizer is normally about half full of water, with a steam cushion in the top half. As the water in the primary loop heats up or cools down, it expands or contracts by many hundreds of cubic feet. The steam cushion in the pressurizer takes up the slack, while maintaining pressure on the reactor coolant water.

The control system adjusts the pressure exerted by the pressurizer by controlling the temperature of the water in the pressurizer with electric heaters, and with a cooling water spray. A relief valve is provided on the pressurizer to prevent overpressurizing the system. This valve is a power-operated relief valve, or PORV. If this valve is opened to relieve the excess pressure, the steam or water flows to a drain tank. If the drain tank becomes over filled, a rupture disk is provided on the tank to relieve pressure. The relief valve has a backup, which is called a block valve. Additionally, two large safety valves provide protection against larger transients.

The reactor coolant may have chemicals added to it for fine adjustment of the nuclear reaction taking place in the reactor core, and to remove any impurities that may have collected in the coolant. During power operation, a small flow of reactor coolant is bled off from the reactor coolant system and passed through a series of filters and demineralizers. If any additional water is needed in the reactor coolant system, it is added from water stored in tanks located in the auxiliary building. The system that collects water from the reactor coolant system and adds water to the reactor coolant system is called the <u>makeup</u> <u>purification</u> <u>system</u>.

Gases collected from the reactor coolant system are collected in tanks called <u>waste cTas</u> <u>decay</u> <u>tanks.</u>

The reactor vessel, pressurizer, associated piping, reactor coolant pumps, and steam generators are called the <u>reactor</u> <u>coolant</u> <u>system.</u> The reactor vessel is a steel pressure vessel with walls that are 8 1/2inches thick, surrounded by a concrete and steel shield over 8 feet thick. The reactor coolant system is housed in a cylindrical building, which is actually a large pressure vessel called the <u>reactor</u> <u>building</u>. The turbine, condenser, and electrical generator are housed in a concrete and steel building called the <u>turbine</u> <u>building</u>. Auxiliary systems used to process and *maintain* the chemical and radiological purity of the reactor coolant are housed in what is called The <u>fuel</u> <u>handling</u> the <u>auxiliary</u> <u>building</u>. building, as its name implies, contains storage facilities for new and used fuel. The used fuel, after removal from the reactor core, is stored underwater in the spent fuel pool. The plant operators monitor and maintain control of the various plant systems from a central control room located in the control service building.

4/28/93 Aff. of John Daniel at 117, **11** 19-25 (emphasis in original); <u>see also</u> Mitchell Rogovin, Nuclear Reg. Comm'n Inquiry Group, NUREG/CR-1250, TMI Report to the Commissioners and to the Public 10-13 (1980) (section titled "Primer on the Pressurized Water Reactor: From A-Loop to Zircaloy") (hereinafter "Rogovin Report").

### b. <u>Plume Dispersion</u>

Once fission product noble gases are released into the atmosphere, the path that they travel and the degree of

concentration that they maintain over a given distance can be determined through the use of dispersion modeling and the science of meteorology. "Atmospheric dispersion modeling is really the development of mathematical relationships that describe how something that's from material that's released into the atmosphere is dispersed as it travels downwind." (11/13/95 Tr. at 149 (testimony of Keith Woodard).) The following explanation of basic dispersion modeling (with specific attention paid to a model used in evaluating the TMI plume) is illustrative:

> The basic function of the model is to calculate dispersion (dilution) of the released material as it travels downwind and to estimate the resulting concentrations of this material at ground level. The material is considered to form a "plume" as it is transported downwind. This plume trajectory (or travel direction) changes, depending on meteorological measurements of wind speed and direction updated every 15 minutes. The plume size depends on turbulence. As turbulence increases, the plume becomes larger and more Turbulence is based on vertical dilute. temperature difference measurements from the meteorological tower. Generally, turbulence increases in the daytime and decreases at night.

> The model assumes an initial elevation and plume spread depending on the effects nearby buildings have on the wind streamlines in relation to the release location (the plant vent in this case). Depending on the flow rate from the plant vent and the wind speed, the plume is divided into small segments called spatial intervals according to the travel distance for the 15-minute period. Plume dispersion is estimated at the center of each segment based on the weather measurements. The time it takes for the cloud to arrive at, and to traverse, each spatial

interval is calculated using the average wind speed for that interval. Whenever there is a change in stability, the new spatial interval rate of growth is based on the new stability.

1/15/93 Aff. of Keith Woodard at 19 14-15)

### C. Factual Background

The accident at TMI-2 began . . . at 4 a. m. on March 28(, 19791. A minor malfunction, or *transient*, in the nonnuclear part of the system would evolve a series of automated responses in the reactor's coolant system, and during all of this, the relief valve on top of a piece of equipment called "the pressurizer" would become stuck open. Owing to continued misreading of the symptoms by the operators over a 2 1/4-hour period before the relief valve was closed and the turning off of an automatic emergency cooling system, the reactor core would become partially uncovered and severely damaged. It would be another 12 hours before the plant crew and the engineers from GPU Service Company would concur in effective corrective action.

Rogovin Report at 3-4. During the incident, radiation was emitted from the Unit-2 reactor. The actual amount emitted, and whether Plaintiffs were exposed to the emissions, are central issues in this case. According to the Rogovin Report, "approximately 2.5 million curies of radioactive noble gases and 15 curies of radioiodines were released . These releases resulted in an average dose of 1.4 mrem to the approximately two million people in the site area." Rogovin Report at 153.<sup>21</sup> Plaintiffs, to the

<sup>21.</sup> Other state and federal government reports, discussed <u>infra</u>, corroborate the findings of the Rogovin Report.

contrary, contend that area residents were exposed to in excess of 100 rems of radiation. Defendants have conceded that releases at the plant boundaries exceeded normal levels of background radiation, <u>In re TMI Cases Consolidated II</u>, 67 F.3d 1103, 1118 (3d Cir. 1995). However, Defendants deny that appreciable or dangerous levels of radiation reached populated areas.

Plaintiffs' theory of the case is that a narrow yet highly concentrated plume of radioactive noble gases (primarily iodine and xenon-133) was carried away from the TMI plant during one or all of three hypothesized "blowout" periods." Plaintiffs' argue that prevailing weather conditions permitted the plume to drift through the atmosphere, moving between the thermoluminescent dosimeters ("TLDs") <sup>33</sup> which composed the TMI Radiation

23. TLDs are instruments used to measure airborne radiation. The Ad Hoc Group Report gave the following technical description of the TLDs that comprise the TMI Radiation Environmental Monitoring Program:

All 20 of the Metropolitan Edison locations had environmental TLD's manufactured and read by Teledyne Isotopes. These Teledyne Isotopes environmental dosimeters are rectangular Teflon wafers impregnated with 25% CaSO4:Dy phosphor contained in black polyethylene pouches in rectangular holders with copper filters to make the energy response more uniform ("flatten" the energy response). After exposure in the environment, measurements

<sup>22.</sup> Plaintiffs' expert David Lochbaum has indicated three potential "blowout" periods, but is unable to say with certainty that any blowout did in fact occur. <u>|Compare 1/22/96 Lochbaum</u> Report at 14 with 3/5/96 Tr. at 1455-56 (testimony of David Lochbaum).)

Environmental Monitoring Program ("REMP"), and caused the plume to remain highly concentrated for a significant distance. Plaintiffs contend that the plume made contact with higher land elevations within the TMI area, and that persons residing in areas of plume touchdown were exposed to harmful levels of ionizing radiation.<sup>24</sup>

Plaintiffs claim that they have developed radiation induced neoplasms<sup>25</sup> as a result of their exposure to ionizing

23. (...continued)

of the exposure are made on each of four separate areas of the dosimeter. The average of these four readings is used in the calculations. In the product bulletins, these dosimeters are said to have a "minimum sensitivity" of 0.5 mR and to have a "maximum error (1 standard deviation)" of "[plus or minus] .2 mR or [plus or minus] 3%, whichever is greater" for measurement of exposure from cobalt-60 gamma radiation.

Ad Hoc Population Dose Assessment Group, Population Dose and Health Impact of the Accident at the Three Mile Island Nuclear Station 13 (1979). The Rogovin Report indicates that the "TLDs provide the best estimate of the integrated radiation dose at a specific location, and can yield a source term when an isotopic spectrum and meteorological conditions are considered." Rogovin Report at 358.

24. A typographical error in the court's January 5, 1996 <u>Daubert</u>, ruling characterizes Plaintiffs' theory as stating that a majority of releases traveled in a northeasterly, rather than in a northnorthwesterly direction. <u>In re TMI</u>, 911 F. Supp. at 786.

25. A "neoplasm" is defined as:

an abnormal tissue that grows by cellular proliferation more rapidly than normal and continues to grow after the stimuli that initiated the new growth cease. N[eoplasm]s show partial or complete lack of structural organization and functional coordination with the normal tissue, and usually form a distinct

(continued...)

radiation during the TMI incident. The parties agree that the following test Plaintiffs have been diagnosed with the illnesses listed:

Paula Obercash:	acute lymphocytic leukemia
Gary Villella:	chronic myelogenous leukemia
Leo Beam:	chronic myelogenous leukemia
Joseph Gaughan:	thyroid cancer
Lori Dolan:	Hurthle cell carcinoma
Jolene Peterson:	thyroid adenoma
Ronald Ward:	osteogenic sarcoma (right leg)
Pearl Hickernell:	breast cancer
Ethelda Hilt:	adenocarcinoma of the ovaries
Kenneth Putt:	bladder cancer, acoustic neuroma.

Defendants contend that Plaintiffs have failed to establish that any of the test Plaintiffs' neoplasms are causally related to radiation exposure during the TMI incident.

## II. Legal Standards

The *instant* motion for summary judgment will be considered pursuant to Rule 56 of the Federal Rules of Civil Procedure. Summary judgment is appropriate where there are no

25. (...continued) mass of tissue which may be either benign (benign <u>tumor)</u> or malignant (carcinoma).

Stedman's Medical Dictionary 931 (5th unabridged lawyer's ed. 1982).

remaining issues of material fact to be decided, and one party is entitled to judgment as a matter of law. <u>Hankins v. Temple</u> <u>University</u>, 829 F.2d 437, 440 (3d Cir. 1987). In examining Rule 56 motions, the court must consider "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." <u>Anderson v. Liberty Lobby</u>, <u>Inc.</u>, 477 U.S. 242, 251-52 (1986).

The parties' burdens at summary judgment may be described in the following manner: once the moving party has shown an absence of evidence to support the claims of the nonmoving party, the nonmoving party must do more than simply sit back and rest on the allegations of her complaint. She must "go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on the file, ' designate `specific facts showing that there is a genuine issue for trial'" Celotex Corp. v. Catrett, 477 U.S. 317 (1986). If the nonmovant bears the burden of persuasion at trial, the moving party may meet its burden by showing that the evidentiary materials of record, if reduced to admissible form, would be insufficient to carry the non-movant's burden at trial. Chipollini v. Spencer Gifts, Inc., 814 F.2d 893, 896 (3d Cir.), cert. dismissed, 483 U.S. 1052 (1987). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be

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evidence on which the jury could reasonably find for the plaintiff." <u>Anderson</u>, 477 U.S. at 252.

In a case dependent upon expert scientific testimony, the court must determine whether the admissible scientific testimony is sufficient to carry the nonmovant's burden at trial. The Supreme Court, in <u>Daubert v. Merrell Dow Pharmaceuticals</u>, <u>Inc.</u>, 509 U.S. , , 113 S. Ct. at 2798 (1993), noted as follows:

> in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable jury to conclude that the position more likely than not is true, the court remains free to direct a judgment . . ., and likewise to grant summary judgment. . . . These conventional devices, rather than wholesale exclusion under an uncompromising "general acceptance" test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.

Id.: see also DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 958 (3d Cir. 1990)("(the) court . . . must ultimately determine whether the admissible evidence tendered by the party having the burden of proof on an issue is sufficient to permit a rational factfinder to find for that party on that issue under the appropriate burden of proof"); <u>Wade-Greaux v. Whitehall</u> <u>Laboratories.</u>, 874 F. Supp. 1441, 1485 (D.V.I.) ("Even when a court determines that expert opinion evidence is admissible, it must still determine whether it would be sufficient to sustain a jury verdict in plaintiff's favor."), <u>aff'd</u>, 46 F.3d 1120 (3d Cir. 1994); <u>cf.</u> <u>Ambrosini v. Upjohn Co.,</u> 1995 WL 637650 at \*1 n.1 [D.D.C. October 18, 1995) ("The [District of Columbia] Court of Appeals has stressed that the admissibility of an expert's opinion is `separate and distinct from the issue whether the testimony is sufficient to withstand a motion for summary judgment.' " [citation omitted]).

### III. <u>Discussion</u>

In this section, the court will first discuss its examination of the record evidence supporting both Defendants' and Plaintiffs' cases. Next, the court will explain the elements of Plaintiffs' prima facie case, and discuss the degree to which Plaintiffs have presented evidence in support of that case. Finally, the court will discuss its finding that Plaintiffs have failed to present evidence sufficient to create a material factual dispute on the issue of dose. At the outset, it is important to note that the scientific evidence must be viewed through the framework set forth by the court in the scientific background section of this memorandum of law. Thus, the court must first examine whether source term evidence has been presented to support the theory that there was a release from the plant during the accident. Next, the court must determine whether there is evidence demonstrating whether Plaintiffs were exposed to the release, and if so, whether there is evidence illustrating the pathways through which Plaintiffs were exposed. Finally, the

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court will evaluate whether the record evidence is sufficient to support the inference that radiation exposure induced the test Plaintiffs' subsequent health effects (neoplasms).

## A. <u>The Defendants'</u> <u>Case</u>

Defendants attack Plaintiffs' evidence of exposure and dose arguing that, reduced to admissible form, the evidence is insufficient for Plaintiffs to meet their burden of proof on the issue of causation at trial. (Defs.' Mem. in Supp. of Motn. for Summ. J. at 126-32 (hereinafter "Defs.' Mem. in Supp.").)

#### 1. Exposure/Dose Evidence

Defendants have offered John Daniel, a nuclear engineer, as their source term expert. Daniel "was engaged by counsel for defendants to study the sequence of events, possible pathways of releases, and magnitude of releases during the TMI accident." (Defs.' Mem. in Supp. at 42 (footnote omitted).) Daniel will testify regarding the in-depth analysis he performed on all relevant plant data and the "time line" of key events that he derived from that analysis. According to Defendants, the time line will chronicle the "events that occasioned the transport of radioactivity to the Auxiliary] Building and the release of that

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radioactivity into the Aux[iliary] Building atmosphere." (Defs.'

Mem. in Supp. at 48.) <sup>26</sup> According to Daniel's calculations:

approximately 17 million curies' of noble gas were transported to the auxiliary building by all pathways during the accident, of which approximately 14 million curies were transported during the first 48 hours. Of the 17 million curies transported to the auxiliary building, 8.6 million curies were released to the environment by all pathways during the period 4:00 A.M. on March 28th, 1979 to 6:00 A.M. April 7th, 1979. This quantity represents more than 99% of the total activity released from TMI-2 as a result of the

26. At the outset of his report, Daniel states the following purposes of the report:

It is our purpose to identify how radioactive gases were transported and were eventually released from the plant. In short, this report is intended to reconstruct what happened inside the plant during the accident, and to determine, from that information base, the maximum credible source term for release to the environment as it occurred. This report describes the events and releases that occurred from initiation of the accident at 4:00 a.m. on March 28th, 1979 until 6:00 a.m. on April 7th, 1979, and accounts for more than 99% of the releases from the plant.

(4/28/93 Aff. of John Daniel at **Ex.** A, p.1 (filed on 5/4/93 as "Revised Exhibit B" to Defendants' motion for summary judgment as to all Plaintiffs based on compliance with federal safety regulations and the supporting memorandum of law) (hereinafter 4/28/93 Daniel Report").)

27. "The curie is a special unit of activity. One curie |abbreviated Ci) is equal to 37 billion disintegrations per second." (7/12/95 Aff. of John Fraizer at <sub>9</sub> 37.) The total quantity of radioactive material released into the environment in the operation of a nuclear power plant is measured in curies. <u>Akins v. Sacramento Municipal Utility District,</u> 8 Cal. Rptr.2d 785, 785-90 (Cal. Ct. App. 1992), <u>rev. dismissed</u>, 868 P.2d 905 (Cal. 1994). accident. The predominant radionuclide release to the environment was Xe-133. The remaining 8.4 million curies of noble gas were either transferred back into the reactor building by the plant operators, or were contained in tanks in the auxiliary building.

 $(4/28/93 \text{ Aff. of John Daniel at}_{1} 35 \text{ (footnote added).) After}$ examining all potential pathways for release, Daniel reached the conclusion that the pathway for fission products from the coolant to the reactor building was through the power-operated relief valve ("PORV").<sup>28</sup> (4/28/93 Daniel Report at 99.) " (TJ he major pathway for fission product transport (from the reactor building) to the auxiliary building was through the letdown piping of the makeup and purification system." (4/28/93 Daniel Report at 33.) It is through this pathway that approximately 17 million curies were transferred to the auxiliary building; and, of that 17 million, approximately 8.6 million were released to the environment.<sup>29</sup> (Id. at 34.) Daniel concludes that the primary

<sup>28.</sup> The PORV "is provided on the pressurizer to prevent overpressurizing the system. If this value is opened to release the excess pressure, then steam or water 'flows to a drain tank (in the reactor building]." (4/28/93 Daniel Report at 99.)

<sup>29.</sup> Daniel also notes that approximately 150,000 curies of fission product noble gases were transported to the auxiliary building through the action of venting the reactor coolant drain tank to the reactor building vent header. Because the reactor building vent header is connected to the auxiliary building waste gas vent header through isolation valves, venting into the auxiliary building can occur through the isolation valves when certain conditions are met. According to Daniel, the isolation valves connecting the auxiliary building were open between 7:14 a.m. and 7:18 a.m., and between 7:44 a.m. and 7:56 a.m., on March 28, 1979. (4/28/93 Daniel Report at 31-32.)

release pathway from the auxiliary building to the environment was through plant ventilation systems. <u>IId.</u> at 60.)

In addition to determining how radioactive noble gases were released into the atmosphere, Daniel computed the core *inventory* of fission products to determine the quantities of specific radionuclides that were released into the environment. Daniel utilized the LOR2 computer code to calculate the core inventory. <u>[Id.</u> at 81.) According to his report, Daniel found this code to be the most accurate because it accounted for the concentration of boron<sup>30</sup> in the reactor coolant during periods of irradiation, "factored in the actual operating history of the TMI-2 core, (and) accounted for the different power levels that the actual core experienced." [Id.] Table 3.2 of the 4/28/93 Daniel report provides a breakdown of the core inventory of selected fission products at the time of reactor shutdown. <u>IId.</u> at 83.) By calculating the core *inventory*, Daniel was able to determine which noble gases were transported into the auxiliary building and then to the environment.

Defendants rely upon the proffered testimony of Keith Woodard to explain how the approximately 9-million curies of radioactive noble gases released from the plant were dispersed into the environment. In addition, based upon his dispersion

<sup>30. &</sup>quot;The concentration of boron is directly related to the neutron population in the core, and is therefore an important factor in determining fission product inventory." .(4/28/93 Daniel Report at 81.)

analysis, Woodard has made individual whole body dose calculations for each of the ten test Plaintiffs. Woodard is the vice president of Pickard, Lowe & Garrick, Inc. ("PLG"), a consulting/engineering firm specializing in the field of meteorological dispersion studies. (1/15/93 Aff. of Keith Woodard at **, i.)**<sup>31</sup> During the TMI accident, Woodard worked with emergency response teams to perform dose assessments to support the on-site response organization. <u>IId.</u> at q 4.) Additionally, following the accident, Woodard studied offsite exposures and reported his findings in a document titled, "Assessment of Offsite Radiation Doses from the Three Mile Island Unit 2 Accident," TDR-TMI-116, Revision 0 (July 31, 1979) (hereinafter "TDR-TMI-116"). <u>IId.</u> at 9 5.)

At the request of counsel for Defendants, Woodard performed two separate studies. The first study utilizes the Daniel source term and the Meteorological Information and Dose Assessment System dispersion model ("MIDAS") <sup>32</sup> to calculate the

<sup>31.</sup> Woodard has bachelors and masters degrees in Nuclear Engineering. [1/15/93 Aff. of Keith Woodard at 1 2.) Prior to his present employment, Woodard was employed as a project leader in the Atomic Energy Commission's Division of Reactor Licensing. In that capacity he was responsible for safety analysis and evaluation of nuclear power and research reactors. [Id.] Since 1967 he has been employed by PLG working on conducting safety evaluations related to the environmental impact of radiation releases. [Id.] Woodard has extensive experience with the use and development of computerized atmospheric dispersion models.

<sup>32.</sup> According to Woodard, MIDAS is PLG's most advanced computer dispersion model. 1/15/93 Affidavit of Keith Woodard at 1 6.)

percentage of the NRC's Maximum Permissible Concentration ("MPC") <sup>33</sup> in the TMI area. Woodard also calculates whole body dose levels using the Daniel source term. The second study also uses MIDAS, but uses the source term methodology employed in TDR-TMI-116 rather than the Daniel source term. <u>IId.</u> at q 8.) Woodard's studies both indicate that dangerous levels of radiation |e.g. greater than the NRC MPC's for one year) did not reach populated areas beyond the plant boundaries. Rather, Woodard contends, the highest concentrations of radiation were found on the Island itself, in a portion of the Susquehanna River, and on uninhabited islands in the river. <u>IId.</u> at <u>¶9</u> 22-23.) Woodard states that the outcomes of his studies are confirmed by comparing them with offsite TLD<sup>34</sup> measurements and with the inventory of

33. Woodard describes MPC as follows:

Title 10 of the Code of Federal Regulations, part 20.106 (10 CFR 20) provides permissible concentrations of radionuclides in areas normally occupied by the general public. These concentrations are based on calculations of radiation exposure (dose) that a person would receive if immersed in air containing the permissible concentration averaged over a period of 1 year. These regulations were established to limit the annual dose to the public to acceptable levels.

<u>Id.</u> at 99.)

34. A "TLD," or thermoluminescent dosimeter, is used to measure airborne radiation. For a more detailed description of the TLDs used in the TMI REMP, <u>see sera</u> note 23.

noble gases found in the containment and fuel following the accident. <u>IId.</u> at **99** 30-31.)

Finally, based upon his dispersion calculations, Woodard calculated whole body doses for each of the test Plaintiffs. Viewing the facts in a light most favorable to Plaintiffs, the court will presume Woodard's "high" dose estimates to be true. According to those estimates, only one of the ten test Plaintiffs was exposed to a dose greater than 25 mrem. That Plaintiff, Jolene Peterson, was exposed to an estimated maximum dose of 75 Four of the test Plaintiffs, Pearl Hickernell, Ethelda mrem. Hilt, Leo Beam and Ronald Ward, were exposed to estimated maximum doses under 10 mrem. The remaining test Plaintiffs, Gary Villella, Lori Dolan, Joseph Gaughan and Paula Obercash, were exposed to estimated maximum doses of between 15 and 25 mrem. These dose calculations are based upon the Daniel source term, do not make any attempt to adjust for possible shielding, <sup>75</sup> and account for changes in each Plaintiff's physical location over time. (7/12/95 Woodard Report at 39.)

Defendants also rely on a number of governmental reports in support of their position on the issue of dose. The first of these is the report of the Ad Hoc Population Dose Assessment

<sup>35.</sup> Shielding occurs, for example, when one is inside a building when a radioactive cloud passes overhead. The person inside of the building would be shielded, thus receiving a lower dose of radiation than someone standing outdoors at the same location during the same time period.

Group,<sup>36</sup> This report "is an assessment of the health impact on the approximately 2 million offsite residents within 50 miles of the Three Mile Island Nuclear Station from the dose received by the entire population (collective dose).". Ad Hoc Population Dose Assessment Group, "Population Dose and Health Impact of the Accident at the Three Mile Island Nuclear Station" at preface (May 10, 1979) (D-X-33) (hereinafter "Ad Hoc Group Report"). The Ad Hoc Group relied upon TLD data and onsite meteorological data to compile conservative dose estimates. Id. at 1-2. Noting that "any approach to assessing the collective dose depends strongly on a relatively small number of measurements," <u>id.</u> at 41, the Ad Hoc Group nevertheless found that "the data do allow reasonable estimates of the collective dose 37 to be made." Id. [footnote It is presumed that the greatest degree of exposure came added). Id. at 11 ("The principal radioactive materials from xenon. released to the *environment* appear to be xenon-133 (half-life 5.3

The Collective dose is a measure of the total radiation dose which was received by the entire population within a 50-mile radius of the Three Mile Island site. It is obtained by multiplying the number of people in a given area by the dose estimated for that area and adding all these contributions.

<u>Id.</u> at 5.

<sup>36.</sup> The group was comprised of representatives from the Environmental Protection Agency ("EPA"), the Department of Health Education and Welfare ("HEW") (now the Department of Health and Human Services), and the NRC. (Defs.' Mem. in Supp. at 53-4.)

<sup>37.</sup> According to the Ad Hoc Group Report,

days) and xenon-135 (half-life 9.2 hours) and traces of radioactive iodine, primarily iodine-131 (half-life 8.0 days)"). Milk and food samples taken during the period of March 31, 1979 through April 4, 1979, one week after the accident, confirm this hypothesis:

> The maximum concentration [of iodine] measured in milk (41pCi/liter in goat's milk, 36 pCi/liter in cow's milk) was 300 times lower than the level at which the Food and Drug Administration (FDA) would recommend that cows be removed from contaminated pasture. Cesium-137 was also detected in milk, but at concentrations expected from residual fallout from previous atmospheric weapons testing. No reactor-produced radioactivity \*has been found in any of the377food samples collected between March 29 and April30by the FDA.

<u>Id.</u> at 7 (emphasis added). The report concludes that the "predominant exposures to offsite individuals . . [are] in the NNW (north-northwest), ENE (east-northeast], and SSE [southsoutheast] sectors." <u>Id.</u> at 44. The east-northeast sector registered the highest cumulative dose -- 83 mrem.<sup>38</sup> <u>Id.</u> Further, the report predicted the following with respect to potential health effects of the TMI accident:

The projected total number of fatal cancers is less than 1 (0.7). The additional number of non-fatal cancers is also less than  $1 \ (0.7)$ . The additional number of genetic effects for all generations is also less than 1 (0.7). All of these values are small compared to

<sup>38.</sup> According to the report, the south-southeast sector had a maximum cumulative dose of 41 mrem, and the north-northwest sector had a maximum cumulative dose of 37 mrem. Ad Hoc Group Report at 44-48.

either the existing annual incidence of similar effects or the potential effects estimated to result from natural background radiation. . . Comparing the total potential health impact of the accident with the estimated lifetime natural risk indicates that these effects, if they were to occur, would not be discernable. The uncertainties in the risk from low-level ionizing radiation would not alter this conclusion.

<u>Id.</u> at 60.

Next, Defendants point to the Report of the Task Group on Health Physics and Dosimetry of the President's Commission on the Three Mile Island Accident. The Commission's Task Group used available TLD data to estimate exposure levels for the areas surrounding TMI. The Commission concluded as follows:

> Persons within a 2-mile radius of the plant probably received the highest doses. The dose to the one person known to have been on one of the nearby islands, for about 9-1/2 hours during the first few days of the accident, is estimated to be about 50 millirems (mrem). In addition, about 260 people living mostly on the east bank of the river may each have received between 20 an 70 mrem. All other people probably received less than 20 mrem.

President's Commission, "Report of the Task Group on Health Physics and Dosimetry" at 16 (1979) (D-X-48) (hereinafter "Task Group Report"). In addition to calculating these short-range dose projections, the Task Group also used available plant data" to

continued...)

<sup>39.</sup> The Task Group described the plant data relied upon as follows:

estimate a source term and determine maximum doses for a fifty mile radius surrounding TMI. <u>Id.</u> at 139-47. In terms of individual doses, the highest possible doses were assigned to those persons residing within a one-mile radius of the plant. <u>Id.</u> at 117. These persons were estimated to have been exposed to a maximum dose of 58.6 mrem. <u>Id.</u> Persons within a 5 to 10 mile radius of the plant had an estimated maximum dose of 5.2 mrem.

39. (...continued)

The radiation monitor that was situated within the auxiliary building stack at TMI (which would have given the best estimate of the real-time releases) went off-scale at 8:00 a.m. on March 28, 1979. There was another gamma monitor located about 40 'feet from the stack and less than 15 feet from the vent duct that "fed" the stack, which did not go off-Careful graphical analysis of both the scale. stack monitor (HPR-219) and the external gamma monitor (HPR-3236) strip charts showed that the count rate from both detectors rose from 7:00 a.m. to 7:45 a.m. on March 28, 1979, at approximately the same rate. The stack monitor was then used to calibrate the external gamma monitor, along with the known flow-rate in the stack; the integrated source term subsequently was calculated from the external gamma monitor readout. Due to several uncertainties, some of which cannot yet be quantified, the calibration value may be in error by as much as a factor of A check on this value was performed by two. looking at an air sample (grab sample) that was obtained on March 31, 1979, between 12:00 noon and 2:00 p.m. from the stack itself, and comparing it to the external gamma monitor readout during this same time period. These two values were within 10 percent of each other, and thus sufficed as a means of confirming the calibration value of the external gamma monitor.

Task Group Report at 140.

Id. Finally, persons living within a 40 to 50 mile radius were estimated to have been exposed to a maximum dose of 0.28 mrem. Id.

The NRC also commissioned its own study of the TMI accident. <u>See generally</u>, Rogovin Report, <u>supra</u>. Following their extensive review of radiological and health-related *conditions* before, during and after the accident, <u>see</u> Rogovin Report, Vol. II, Part 2 at 341 (summarizing inquiry conducted and data relied upon), the NRC's Special Inquiry Group reached the following *conclusion* regarding releases during the TMI accident:

There were numerous deficiencies related to radiation protection and radiological health; however, few, if any, of the deficiencies were causal factors in the TMI-2 accident. . .

The radiological consequences of the releases of radioactive material from *TMI-2* into the environment are minimal at worst and may be nonexistent. Therefore, public concern regarding the effects of releases of radioactive materials from *TMI-2* is not warranted.

Id. at 342. Noting that "[t]he buildings and equipment at the Three Mile Island Station provided substantial mitigation of the release of radioactive material to the environment," id. at 360, the NRC found that:

> the quantity of radioactive material . . . released in liquid effluents as a result of the accident is not significant . . [and] the quantity of radioactive material released in gaseous effluents due to the accident consisted of 15 Ci of I[odine-131] and 2.4 million Ci of noble gases.

Id. at 362. In addition, the report found that although not perfect, the TLDs in place at the time of the accident were "adequate to characterize the radiation levels in the environment attributable to the accident." Id. at 395; see id. at 399, 407. With respect to its analysis of potential health effects related to the accident, the NRC reviewed existing governmental reports. Id. at 399. Indicating that "[t]he studies were independently performed with different methodologies, yet arrived at similar population dose estimates," <u>id.</u>, the NRC "deemed it unnecessary to perform additional independent analysis of the raw data." Id. The NRC found the findings of both the Ad Hoc Group and the President's Commission Task Group to be accurate and verifiable. Id. at 400. Based upon these findings, the NRC concluded that "the maximum offsite individual dose was less than 100 mrem." $^{\circ 0}$ Finally, the report indicates that it is "extremely unlikely" Id. that any individual will suffer future adverse health effects as a result of the accident. Id. at 408.

Next, Defendants direct the court's attention to a study commissioned by the Pennsylvania Department of Health (PADOH) in the wake of the TMI accident. Proceedings of the Pennsylvania Academy of Sciences, 57:99-102 (1983) (reporting the PADOH

<sup>40.</sup> Additionally, Defendants note that in determining that the TMI accident was not an extraordinary nuclear occurrence ("ENO"), the NRC determined that "the best estimate of actual maximum exposure was `less than 70 or 80 mrem.' " (Defs.' Mem. in Supp. at 60 [quoting ENO Report App. E at 19).)

study) (D-X-1) (hereinafter "Proceedings"). In this study, PADOH performed dose assessments on each of the 34,000 members of the 13,000 households located within a five mile radius of TMI. <u>Id.</u> at 99. In June of 1979, a special census was conducted to identify the households included in the study.. <u>Id.</u> at 100. "The TMI Population Registry resulting from the census effort has been estimated to be 95.% complete." <u>Id.</u> Using a methodology similar to that used in TDR-TMI-116, <u>id.</u>, the PADOH study estimated both maximum and likely dose estimates for a five mile radius around TMI. According to the study, the highest possible maximum dose was 165 mrem, and the highest likely dose was 80 mrem.<sup>41</sup> <u>Id.</u> at 101.

The final study upon which Defendants rely in support of their case is a dose assessment study performed on behalf of the TMI Public Health Fund.<sup>42</sup> According to the authors, "[i]n the study reported in this paper, we tested a priori hypotheses that risks of specified cancers may have been raised by exposure to radiation emanating from the Three Mile Island nuclear power plant in Pennsylvania" during the TMI accident. Maureen C. Hatch, et al., "Cancer Near the Three Mile Island Nuclear Plant: Radiation

<sup>41.</sup> The study notes that due to the conservative methodology employed, the results were expected to <u>overestimate</u> actual doses by approximately forty percent. Proceedings at 101.

<sup>42.</sup> The TMI Public Health Fund was created through a settlement agreement which disposed of an earlier TMI-related class action suit. In accordance with the settlement agreement, the court has overseen the administration of the fund.

Emissions,".132 Am. J. of Epidemiology 397, 397 (1990) (D-X-98) (hereinafter "Hatch"). The study used census data to divide a ten mile radius surrounding TMI into "study tracts." Id. at 399. For each of the study tracts, the authors analyzed yearly cancer rates for the years 1975 to 1985. <u>Id.</u> Incidence of cancer among the study subjects was determined through reference to the subjects' medical records obtained from local and referring hospitals." Id. at 399-400. The authors assigned various cancers to respective study tracts based upon the place of residence of the patient at the time of diagnosis. Id, at 400. The study monitored cancer incidence with respect to Leukemia, cancer in children under 15 years of age, and "all cancers." Id. TMI plant data was used in *conjunction* with available meteorologic data to estimate releases and exposure during the accident. Id. at 401. Upon calculating their own release and exposure estimates, the Hatch study found the following:

> The fact that exposure patterns projected by the model and data from the thermoluminescent dosimeters [(TLDs)] compare so well indicates that available monitors were probably adequate to characterize accident releases. Thus, the comparison provides a justification for using official exposure estimates as "best estimates" of the level of radiation corresponding to points along our relative scale.

<sup>43.</sup> The study indicates that 99\$ of all records sought were obtained. Id. at 400.

Id. at 402. The overall findings of the study were summarized by

the authors as follows:

In summary, the possibility that emissions from the Three Mile Island nuclear power plant could have contributed to the observed trends, in lung cancer particularly, must be weighed against 1) the lack of effects on the cancers believed to be most radiosensitive and the indeterminate effects on children; 2) the threat of confounding by factors unmeasured or inadequately controlled; 3) inconsistency within our own data between the findings for plant emissions and background gamma radiation; and 4) the low estimates of radiation exposure and the brief interval since exposure occurred. Pending a demonstration that very low-dose gamma radiation can act as a tumor promoter or the identification of another late-stage carcinogen in the effluent stream, an effect of plant emissions in producing the unusual patterns of lung cancer and non-Hodgkin's lymphoma appears unlikely, and alternative explanations need to be considered. The increased risk that we observed for childhood cancers in relation to routine emissions is compatible with increases reported near some other nuclear installations, but confidence intervals are wide and, for leukemia, the numbers are small and the rates found in the Three Mile Island area low compared with national and regional data.

Hatch at 410-11 (emphasis added). Accordingly, Defendants contend that this study supports their theory that dangerous levels of radiation did not reach populated areas; and, as such, no adverse future health effects can reasonably be expected to have occurred.

In addition to the plethora of studies conducted in the wake of the accident, Defendants contend that there exists a significant body of biodosimetric data, collected through environmental monitoring, which tends to corroborate the ultimate conclusions of the many studies. This data includes measurements of on and off-site TLDs, and samples of air, water, milk, food, soil, vegetation and animals. (Defs.' Mem. in Supp. at 69.) The data was collected by a variety of different sources. For example, Defendants note that Metropolitan Edison's REMP, which surpassed NRC guidelines as to its extensiveness prior to the accident, was augmented during the accident to increase the breadth of the sampling program. Additionally, Defendants highlight that the Commonwealth of Pennsylvania, the NRC, the HEW, the EPA, and the DOE each also engaged in their own sampling programs in response to the accident in an attempt to gauge accident effects.

The most extensive human accident data is that collected through the NRC's whole body count program, and through thyroid scans performed at area hospitals. <u>See NUREG-0636</u>, <u>The Public</u> <u>Whole Body Counting Program Following the Three Mile Island</u> <u>Accident (1989) (D-X-35)</u>. The NRC took whole body counts of TMI area residents between April 10 and April 18, 1979. Based upon the whole body count results, the NRC determined that "no radioactivity was detected which could have originated from Unit-2 releases." <u>Id.</u> at 11. Although no such doses were detected through their study, the NRC determined that "the maximum |undetectable) dose to a typical thyroid could have been about 12 millirem." <u>Id.</u> Such a dose would have been approximately 12%

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greater than the average background dose received annually by Pennsylvania residents. <u>Id.</u> Hershey Medical Center and York Hospital both provided thyroid scans for a limited number of local residents." The thyroid scans revealed no evidence of exposure to iodine or other fission products. The 148 urinalyses performed by HEW were similarly unremarkable.

In sum, Defendants argue that all of the reports and data related to the TMI accident confirm that area residents, if exposed at all, were exposed to less than 100 mrem of radiation during the accident. (Defs.' Mem. in Supp. at 79.)

# 2. Health Effects

Defendants contend that "no significant health effects from the accident were predicted to occur and . . . none have been observed." (Defs.' Mem. in Supp. at 80.) In support of their argument, Defendants point to the same federal and state government reports referred to by the court in the preceding discussion. Specifically, Defendants note that the Ad Hoc Group predicted that less than one additional fatal cancer would occur in the population within 50 miles of the plant over the course of its lifetime, Ad Hoc Group Report at 61; that the President's Commission Task Group on Radiation Health Effects found that

<sup>44.</sup> Hershey Medical Center scanned 117 individuals, and York Hospital scanned 41 individuals. (1/21/93 Porter Affidavit at  $\P$  17-18.)

The projected number of fatal cancers or nonfatal cancers potentially induced or temporally advanced over the remaining lifetime off-site population within 50 miles of the TMI plant site from whole-body gamma radiation exposure is less than one, and the total number less than 1.5, with zero or nearzero not excluded(,]

President's Commission Report at 202; and, that the NRC Special Inquiry Group found the increased risk of developing fatal cancer as a result of the TMI incident to be approximately 1 in 100,000, while the risk of developing fatal cancer from all other sources during a lifetime was approximately one in seven, Rogovin Report at 153.

According to Defendants, the epidemiologic evidence confirms that the early estimates regarding probable health effects are correct. The PADOH has conducted epidemiological studies concerning pregnancy outcomes and\_ cancer mortality, neither of which have produced remarkable findings. See generally, J.R. Bratz, et al., <u>Three Mile Island (TMI) Pregnancy</u> <u>Outcome Study - Final Report at 4. (1988) (D-X-2) (finding that the</u> "impact of the TMI nuclear accident upon pregnancy outcome was negligible, if any"); E. Digon, et al., <u>Infant, Fetal Neonatal and</u> <u>Perinatal Mortalities in the Three Mile Island Area (1988) (D-X-</u> 3) (study of pregnancy outcomes finding that "the levels of post-TMI fetal, neonatal, perinatal or infant mortalities in the vicinity of the TMI nuclear facility were neither significantly higher than expected nor significantly different from the pre-TMI

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There is no clear evidence that the 1979 nuclear accident years. impacted significantly on the risk of late in-utero mortality or mortality during infancy . . "); PADOH, <u>Cancer Mortality and</u> Morbidity (Incidence) Around TMI at 23, 24 (1985) (D-X-13) (finding no "evidence of increased cancer risks to residents near the TMI nuclear facility); K. Ramaswamy, et al., <u>Three Mile Island</u> (TMI) Population Registry-Based Cohort Mortality: 1979-1985 Period at 17-18 (1988) (D-X-6) (finding that "[n]ormal mortality experiences and life expectancy of the TMI cohort, as observed at this time, seem to be consistent with the very low level of ionizing radiation released during the TMI accident[,]" and noting that observed limitations on study design should not significantly impact the findings); G.K. Tokuhata, <u>TMI Population Registry Based</u> Cohort Cancer Incidence July 1982-June 1989 at 6 (1991) (D-X-15) (concluding that "[t]he analyses provided no evidence that the 1979 nuclear accident has had a significant impact upon the overall incidence of cancer observed during the 7- year follow-up period beginning in 1982").

Finally, Defendants have presented evidence that there were no increases in hospital utilization between June of 1978 and June of 1993 that can be attributed to the TMI accident. See <u>generally</u> Larry Fosselman, <u>A Look at Hospital Utilization Relative</u> to Three Mile Island at 3 (July 14, 1995) (D-X-7) ("There are no deviations in the hospital utilization data that can be attributed to the March 28, 1979, Three Mile Island Accident.") Fosselman's study was based on the hypothesis that if populated areas were exposed to significant levels of radiation, there would have been a notable increase in the local demand for health services.

In sum, Defendants have presented extensive evidence documenting their position that dangerous, levels of radiation did not reach populated areas during the TMI accident. The evidence includes a source term; analyses of release pathways; plume dispersion analyses; general and epidemiological studies examining potential health effects of the accident and finding no significant effects; and, a multitude of governmental reports examining the causes and effects of the TMI accident.

#### B. <u>The Plaintiffs'</u> <u>Case</u>

#### 1. Exposure/Dose Evidence

Plaintiffs' case is premised upon the theory that one or more hydrogen "blowouts" occurred during the TMI accident, whereby large quantities of radioactive noble. gases were expelled into the environment. Following this blowout, Plaintiffs contend that a dense yet narrow plume of radioactive noble gases (from the blowout) traveled through the atmosphere, evading the TLDs in the TMI REMP, and exposing Plaintiffs to high levels of radiation. The blowout is important to Plaintiffs' theory of the case because it purports to explain how quantities of radiation higher than those estimated by Defendants were expelled into the atmosphere. The report of David Lochbaum<sup>°s</sup> is offered as Plaintiffs' source term expert to support their blowout theory.

Through his report, Lochbaum sought "to evaluate the role of the letdown line"' as a release pathway for noble gases." [3/5/96 Tr. at 1427 (footnote added).) Lochbaum examined plant data, published reports regarding the accident, and the reports of Defense experts Akers and Daniels in reaching his conclusions. His methodology entailed defining "the conditions that had to be satisfied in order for a letdown line blowout to have occurred, and then determin[ing) when, if ever, during the accident, those four conditions were met." (Id.) Lochbaum characterizes the blowout conditions as follows:

(1) the letdown line must be in operation, (2) both reactor coolant pumps in the RCS loop A must not have been in operation, (3) natural circulation through RCS loop A must not have been occurring, and (4) the connection of the letdown line to the 1A cold leg must not have been covered with water.

<sup>45.</sup> Lochbaum has a bachelor's degree in nuclear engineering and seventeen years of experience in the nuclear power industry. He is not Plaintiffs' original source term expert. The court permitted Lochbaum to submit an expert report, to be reviewed at the court's second round of <u>Daubert, hearings</u>, when Plaintiffs' expert Richard Webb suddenly recanted his proffered source term testimony at the conclusion of the first round of <u>Daubert</u> hearings. <u>In reTMI</u>, 911 F. Supp. 775, 788-91 (M.D. Pa. 1996).

<sup>46. &</sup>quot;Following a reactor shutdown, as the reactor coolant pressure drops and the reactor coolant expands, some reactor coolant must be removed from the system in order to allow depressurization to continue. The letdown line serves this purpose in a reactor trip situation." (4/28/93) Daniel Report at 33.)

(1/22/96 Lochbaum Rpt. at 3; <u>see</u> also 3/5/96 Tr. at 1427.) In his report, Lochbaum concludes that "[t]he four prerequisites for a potential `blowout' through the letdown line may have been satisfied on three occasions during the first day of the TMI-2 accident, but <u>the indications do not conclusively point to any 'blowout.</u>

added).) When summarizing plant monitor responses that indicated a possible blowout, Lochbaum noted that the "evaluation does not claim that both of these discussions apply to the TMI-2 accident. But it is <u>credible</u> that one of these radiation monitor responses could have been caused by a blowout." [Id. at 10.) At the Daubert hearings, Lochbaum stated his findings with further equivocality. "I looked at a number of system parameters to try to determine whether a blowout may have occurred . . . or evidence that would have shown that a blowout could not have occurred [a]nd for each of the periods . . . there were radiation indications that would have supported a blowout . . . and there were other indications that showed that it was unlikely a blowout occurred." (3/5/96 Tr. at 1446.) Lochbaum further testified that he did <u>"not believe there was evidence of a blowout.</u> but if a blowout occurred, its duration was of limited length. . . Α short duration blowout would still have been significant because of the high gas, concentrated gas transport that would have occurred. . . . But I did not see conclusive evidence of a blowout." Id. at 1455-56 (emphasis added).)

Despite finding no evidence of.a blowout through the letdown line, Lochbaum concludes that there "was clearly a blowout' of noble gases through steam generator B in the early hours of the accident." (1/22/96 Lochbaum Rpt. at 18.) Additionally, Lochbaum finds that there were several "unfiltered release[s] of noble gases" into the atmosphere during the [Id. at 18.) The court notes that Defendants' expert accident. Daniel also points to these pathways of release in explaining his release estimates. Based upon this, Lochbaum opines that "it is concluded with reasonable scientific certainty that significantly more than 10 million curies of noble gases were released into the Id. at 20.) Lochbaum does not explain what atmosphere." radionuclides were released or the quantities of each that were released. His opinion of the overall quantity of release appears to be based upon his assumption that "[d]ue to limited sampling and monitoring on the day of the accident, a sizeable quantity of short-lived noble gases <u>could have been</u> released to the atmosphere during a `blowout' or via the other release mechanisms instead of simply decaying away." <u>Id.</u> at 19.)

Next, Plaintiffs rely upon the testimony of Ignaz Vergeiner to support their contention that following the alleged blowout, a narrow yet highly concentrated plume of radiation was carried to locations where Plaintiffs resided. Dr. Vergeiner was offered to testify regarding plume dispersion and to give quantified dose estimates based upon the path taken by the plume.

A significant portion of Dr. Vergeiner's proffered testimony was found to be inadmissible during the <u>Daubert</u> hearings based upon the unscientific and unreliable methodology supporting his See <u>In reTMI</u>, 911 F. Supp. at 791-99 (M.D. Pa. testimony. 1996) [finding dose estimates, "plume movie"" and water model to be inadmissible). The court did, however, find Dr. Vergeiner's testimony regarding "weather conditions during and immediately Id. at 799. The following the accident" to be admissible. Daubert ruling also directed Plaintiffs to provide an offer of proof explaining "how this narrow area of testimony 'fits' absent Dr. Vergeiner's other proposed testimony." Id. While not expressly providing an offer of proof, Plaintiffs have framed Dr. Vergeiner's testimony as follows:

> Dr. Vergeiner will opine that the meteorological conditions existing at the time of the accident, combined with the alpine terrain (<u>i.e.</u>, hilly or mountainous) which exists near the TMI facility, combined to keep the radioactive plume released during the TMI accident from rising and dispersing high into the atmosphere. According to Dr. Vergeiner, radioactive plumes remained narrow, intense and intact, and moved in an erratic fashion towards the areas located north/northwest of the TMI facility, coming frequently into

<sup>47.</sup> The "plume movie" consisted of a series of hand-drawn sketches which Dr. Vergeiner "eyeballed," and which purported to be a visual representation of the plume dispersion analysis made by Dr. Vergeiner. See, e.g., Pomella V-ReOencv Coach Lines, Ltd., 899 F. Supp. 335, 343 (E.D. Mich. 1995) (finding methodology of "eyeballing" the coefficient of friction related to highway pavement under varying weather conditions to be scientifically unreliable).

contact with the hilly and semi-mountainous terrain of that area.

(Pls.' Ans. and Mem. in Response to Defs.' Motn. for Summary Judgment at 44 (hereinafter "Pls.' Op. Brief").) In their reply brief, Defendants argue that this characterization of Dr. Vergeiner's testimony flies directly in the face of the court's in To an extent, Defendants are correct. Implicit in limine ruling. the court's ruling that Dr. Vergeiner's "plume movie" was scientifically unreliable, was the finding that the methodology employed in deriving the plume movie was unreliable. Thus, it defies logic to presume that Dr. Vergeiner could verbally testify, based upon the same methodology, to the very opinions that the court refused to allow Dr. Vergeiner to present through his plume movie. Defendants are, however, mistaken to suggest that this court's ruling precludes Dr. Vergeiner from testifying as to basic meteorological concepts and prevailing weather conditions during the accident. Dr. Vergeiner is permitted to testify to the prevailing weather conditions during the accident, and to how these conditions impacted plume dispersion. He is not permitted to give quantified dose estimates, discuss his "plume movie" or demonstrate his water model.

To provide evidence of exposure and dose, Plaintiffs rely on the testimony of Steven Wing and Vladimir Shevchenko. Dr. Steven Wing, who holds a Ph.D in epidemiology and is currently a Professor of epidemiology at the University of North Carolina at

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Chapel Hill, has performed a reanalysis of the Hatch cancer incidence study.<sup>48</sup> (2/25/95 Report of Steven Wing (hereinafter "2/25/95 Wing Report").) The Hatch study found no evidence of an increase in cancer incidence following the TMI accident that could be attributed to the accident. According to Plaintiffs, Dr. Wing undertook his reanalysis based upon his belief that "the Susser/Hatch study contained an a <u>priori</u> hypothesis that doses from the TMI accident were too low to affect cancer rates." |Pls.' Op. Brief at 54.) Dr. Wing explains the possible effect of this hypothesis as follows:

> The fact that positive associations were not interpreted as giving support to the a priori hypotheses suggests strongly that the authors were unwilling to consider rejection of the null hypothesis based on evidence from their analyses, a position *consistent* with the view that exposures were too low to have produced any measurable changes in cancer incidence.

An unwillingness to consider positive findings as evidence in support of a priori hypotheses may have influenced not only interpretations of planned analyses but also the extent of exploration of other analyses that might have been sensitive under alternative assumptions. First, if the authors had considered the possibility that exposures had been grossly underestimated, positive results could have been considered not only as an indication of possible confounding, but also as an indication of a

<sup>48.</sup> Hatch et al. performed a cancer incidence study on the TMI area to determine whether the accident caused an increase in cancer incidence. Maureen Hatch, et al., "Cancer Near the Three Mile Island Nuclear Plant: Radiation Emissions," 132 Am. J.-of Epidemiology 397 (1990). The study was undertaken on a grant from the TMI Public Health Fund.

possible accident effect. The failure to consider this possibility may be due, in part, to the conditions under which the dose reconstruction for this study was performed, which stipulated that, "The principal investigator shall not attempt to make upper limit or worst case estimates of releases of radioactivity or population doses." Second, the authors'might have considered (but did not discuss) the potential for misclassification of relative doses, incomplete case ascertainment, use of residence at time of diagnosis rather than at time of accident, and lack of control for confounding factors, as problems that could lead to <u>underestimation</u> of measures of effect.

2/25/95 Wing Report at 3 (internal citation omitted).) Dr. Wing believes that an "ongoing collection of evidence [is] suggestive of high level radiation exposure in the pathways of radioactive gas plumes." [Id.] His report reveals that this body of evidence

consists of: statements from "[n]onitoring stations in Albany, WT and Portland, WE [that they] detected radioactive gas plumes at times and during weather conditions which indicated that their source was the TMT accident"; evidence of morphological damage in

trees in the TMI area that is consistent with radiation exposure, see <u>infra</u> at 69-70 (explaining the Shevchenko tree study); and interviews with area residents conducted by Plaintiffs' consultants, the Aamodts, in which' the residents provide anecdotal accounts of "reddening of the skin, hair loss, vomiting, metallic taste, and pet deaths" at the time of the accident. (2/25/96 Wing Report at 4.)

Using the same data as Hatch, but employing a slightly different methodology," Dr. Wing performed a reanalysis of the The Wing study compared pre-accident associations between data. radiation exposure and cancer to post-accident associations between the same factors. [Id. at 10.) Significantly, the study presumed high levels of radiation exposure. (2/25/95 Wing Report at 9 ("Unlike the original reports based on these data, our reanalyses assumed that absolute accident doses could have been large enough to produce measurable impacts on cancer incidence through some combination of promotion, immune system and initiation mechanisms:") The study resulted in a finding that "[a]nalyses of the post-accident change in association of the accident dose and cancer incidence showed no instances of diminution of association[,]" and showed the greatest association for leukemia.'\* [Id. at 9.) Based upon this finding, Wing

49. In his 10/19/95 affidavit, Dr. Wing explains the methodological alteration as follows:

[the] primary method used by Hatch et al. (1990) was to use socioeconomic variables to control for base line incidence in the analysis of potential accident impact. In our alternative approach, we adjust for the base line (pre-accident) association between cancer incidence and accident dose analyses of the accident effects.

(10/19/95 Aff. of Steven Wing at 4.)

50. Dr. Wing notes that the strong association with leukemia "might be expected based on previous studies showing a higher radiosensitivity of leukemia than solid tumors. . . [and] may (continued...) concludes that "[t]he increases in cancer incidence related to estimated radiation doses from the TMI accident are consistent with allegations that the magnitude of radiation exposures from the accident were much higher than has been assumed in past studies." <u>[Id.</u> at 11.) Plaintiffs argue that the Wing reanalysis, standing alone, creates a material factual dispute as to the issue of dose.

Plaintiffs' final "dose" expert <sup>s</sup>' is Vladimir Shevchenko. Professor Shevchenko has vast experience in studying the effects of ionizing radiation in the former Soviet Union. A <sub>s</sub> the court noted in its first <u>Daubert</u>, ruling:

> Professor Shevchenko holds a Ph.D in Biological sciences, and has particular

50. (...continued) also reflect, in part, a shorter latency for this cancer." Id. at 9)

Plaintiffs have also placed on the record a sealed exhibit (P-51. X-92) and sealed testimony from the <u>Daubert</u> hearings (2/16/96 Tr. at 724-29 (testimony of Bruce Molholt)), purporting to show high levels of iodine in milk samples taken on March 30, 1979. According to the testimony, several of the sixty-eight samples taken on that date contained high levels of iodine. (2/16/96 T. at)725-26.) One sample contained very high levels of iodine. The exhibit, however, does not explain where any of the milk samples were taken from. The samples are coded, and Plaintiffs have not produced the key to the code. Dr. Molholt testified that the sample with the highest level of iodine came from a farm near Mechanicsburg. [Id. at 726.) When asked how he knew this without Mechanicsburg. knowing the codes used in conjunction with the samples, he explained that he was told by reliable source. <u>[Id.</u> at 728.) That source was revealed to be Plaintiffs' consultant, Norman Aamodt. Plaintiffs have placed no admissible evidence on the record which explains where each of the samples were taken from. As such, this evidence fails to create a material factual dispute as to the issue of dose.

expertise 11 the area of radiation genetics; specifically with respect to the cellular and subcellular effects of radiation on plants. Much of this expertise has been developed through his practical experience studying radiation effects in the Eastern Ural Radiation Belt region, at the site of the Kyshtym atomic weapons plant accident, at the site of the Chernobyl nuclear power plant accident, at the Semipalatinsk Polygon, and at the sites of nuclear experiments in the Alti Region.

In reTML, 911 F. Supp. at 810 (internal citations omitted). Plaintiffs offered Professor Shevchenko to testify as to the results of a tree study he performed in the TMI area, and as to the results of cytogenetic analyses performed upon blood samples of TMI area residents.

The Shevchenko tree study concluded that trees in the TMI area exhibited morphological changes that could only be caused by radiation exposure. To conduct his study Professor Shevchenko traveled to the United States and viewed certain trees in the TMI area. <u>In reTMI</u>, 911 F. Supp. at 811. In his deposition, Professor Shevchenko indicated that he was directed to the locations of some of the damaged trees by Plaintiffs' expert James Gunckel and by Plaintiffs' *consultant* Norman Aamodt; and, that he selected some of the study trees on his own. (Shevchenko Dep. at 62-67.) It is alleged that the trees selected were in the path of the TMI plume. The methodology utilized by Professor Shevchenko in conducting his tree study has been described as follows:

The methodology consisted of visual observation of trees in the TMI area,

comparing the types and kinds of damages of the trees in the TMI area to trees observed in Chernobyl and damages in the gamma fields and making a professional judgment as to whether the damages and effects manifested by the trees in the TMI area reflected radiation exposure and dose within a specific range.

<u>In re TMI</u>, 911 F. Supp. at 811. Based merely upon his observations, Professor Shevchenko was prepared to make quantified dose estimates as to the levels of exposure necessary to cause the damage exhibited. <u>Id.</u> Ultimately, the court found Professor Shevchenko's general observations and comments regarding tree damage to be admissible, and found his quantified dose estimates to be inadmissible. <u>In re TMI</u>, 1996 WL 166707 at \*16-17. Accordingly, Professor Shevchenko will testify to the similarities he observed between the study trees in the TMI area and radiation exposed trees he has observed in the former Soviet Union.

Professor Shevchenko was also offered to testify as to a cytogenetic analysis performed on the blood samples of 29 TMI area residents. In conducting this analysis, blood samples are viewed under a microscope to. determine whether dicentric chromosomes are present. Dicentric chromosomes are chromosomes that have two centromeres rather than one, and they are a biomarker of radiation exposure. That is, the presence of elevated numbers of dicentric chromosomes provides biological evidence of a past radiation exposure. Because dicentric chromosomes disappear rapidly over time, cytogenetic analysis is most useful when conducted immediately following exposure. A method, known as the "FISH [fluorescence in situ hybridization) technique," has recently been developed to accurately detect chromosome aberrations (i.e. dicentrics) when longer periods of time have elapsed since exposure. See <u>In re TMI</u>, 1996 WL 166707 at \*13-14, for a more detailed discussion of the FISH technique.

In the summer of 1994 and winter of 1995, blood samples of TMI area residents were collected for the Shevchenko study. The samples were transported to the former Soviet Union, and a cytogenetic analysis was performed for Professor Shevchenko by Dr. Snigiryova. The analysis revealed that four of the blood samples contained elevated levels of dicentric chromosomes.<sup>52</sup> Based upon this observation, Professor Shevchenko was prepared to give a quantitative dose estimate **as** to the level of radiation that these persons must have been exposed to in order to exhibit the demonstrated levels of dicentric chromosomes. As with the tree study, the court found the general cytogenetic testimony and study findings to be admissible, and the quantified dose estimates to be inadmissible. Consequently, Professor Shevchenko will offer general testimony regarding the use of dicentric chromosomes as a

<sup>52.</sup> Professor Shevchenko bases his conclusion that there are elevated levels of dicentric chromosomes on his comparison of the TMI blood samples with a Russian control group. Defendants argue that this is an inaccurate comparison because natural levels of background radiation differ significantly worldwide. Accordingly, what may be a "normal" level of chromosome aberrations for a resident of the TMI level may be an "abnormally high" level of aberrations for a resident of the former Soviet Union, or vice versa. Viewing the facts in a light most favorable to Plaintiffs, the court will presume that the Russian controls were adequate.

biomarker of radiation exposure, and more specific testimony regarding the results of the cytogenetic analysis performed on the TMI area blood samples. Professor Shevchenko will not be permitted to give quantified dose estimates. <u>In re TMI</u>, 1996 WL 166707 at \*15-16.

Plaintiffs contend that their admissible evidence supports their theory that dangerous levels of radiation reached populated areas during the TMI accident, and that summary judgment is therefore, inappropriate.

# 2. Medical Causation Evidence

Plaintiffs rely upon four principal witnesses for their medical causation case: Dr. Louis Fajardo, Dr. Thomas Winters, Dr. Jose Galindo and Dr. Joseph Cardinale. The court has found the testimony of these experts to be admissible provided that Plaintiffs offer dose evidence sufficient to support the levels of exposure that each of these experts presumed in offering their opinions. <u>In reTML</u>, 166 F.R.D. 8, 10 (M.D. Pa. April 9, 1996) [discussing Galindo and Cardinale); <u>id.</u>, 1996 WL 166713 at \*4-5 & nn. 6-7, 12-14 [discussing Winters, Fajardo and Galindo); <u>id.</u>, 1996 WL 166707 at \*36-42 [discussing Fajardo]. The court will assume <u>arguendo</u> for the purposes of this discussion that Plaintiffs have proffered sufficient dose evidence.

Based upon a review of test Plaintiffs' medical records and use of the differential diagnosis methodology, Dr. Louis

Fajardo will testify that eight of the test Plaintiffs' neoplasms are causally related to exposure to ionizing radiation during the TMI accident. <sup>53</sup> Dr. Fajardo's opinion is premised upon an understanding that other testimony will support the contentions that Plaintiffs were exposed to at least 10 rems of radiation, and that there was an observable increase in cancer incidence in the TMI area following the accident. See In re TMI, 1996 WL 166707 at Dr. Winters will offer similar testimony based upon his \*35. review of medical records, his examination of the still-living test Plaintiffs and his use of a differential diagnosis methodology. As with Plaintiffs' other medical causation experts, Dr. Winters presumed a significant exposure when reaching his In re TMI, 1996 WL 166713 at \*2 ("(1) knew the dose conclusions. was above a hundred rems, and figured that even if it dropped' down to the 50- or 10- rem area, [my]. . . opinion would still be the However, Dr. Winters will offer his opinion that all ten same.") of the test Plaintiffs developed their respective neoplasms as a result of exposure to radiation during the TMI accident.

Finally, Drs. Galindo and Cardinale, treating physicians of test Plaintiff Lori Dolan, will testify as to the suspected etiology of her neoplasm. Both physicians will offer their opinion that it is more likely than not that Plaintiff Dolan's

<sup>53.</sup> The eight test Plaintiffs are Paula Obercash, Gary Villella, Leo Beam, Joseph Gaughan, Lori Dolan, Jolene Peterson, Pearl Hickernell, Ethelda Hilt and Ronald Ward.

thyroid cancer resulted from exposure to radiation during the TMI accident. Both doctors base their opinions upon Plaintiff Dolan's and counsel's representations that Plaintiff Dolan was exposed to high levels of radiation during the TMI accident. <u>In reTML</u> 1996 WL 166713 at \*14 (Cardinale); 166 F.R.D. at 10 (Galindo). Moreover, both doctors expressly note that they depend upon other experts to quantify the exact level of exposure received by Plaintiff Dolan. <u>Id.</u> 1996 WL 166713 at \*13 (Cardinale); 166 F.R.D. at 9 (Galindo). The treating physicians of other of the test Plaintiffs have not been identified as expert witnesses. Plaintiffs contend that their dose and causation evidence is sufficient to create material factual disputes regarding the amount and effect of radiation released during the accident.

One final point regarding Plaintiffs' expert testimony bears noting. It appears that virtually all of Plaintiffs' dose experts were directed to presume a dose in excess of 100 rems when formulating their opinions. Further, it seems that each of the experts was assured that some other expert (or experts) would establish that this high dose level was plausible. The court surmises that Plaintiffs' strategy was to layer and intertwine all of their expert testimony to effectively produce one super-expert opinion. Had each of Plaintiffs' experts produced the results they were expected to produce, this strategy may have proven to be highly effective. However, the expert providing the crucial opinion -- that demonstrating radionuclide releases high enough to

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support the presumed 100 rem dose -- recanted the bulk his opinions in an unsolicited voicemail message left with counsel for Defendants. <u>In re TMI</u>, 911 F. Supp. at 790 ("I don't get the high releases that I got before . . . There's no blowout."). Plaintiffs necessarily withdrew this expert's report, and subsequently failed to produce other testimony supporting the 100 rem assumption. As such, the record evidence no longer supports any expert opinion that is expressly premised upon the belief that Plaintiffs were exposed to high levels of ionizing radiation.

In sum, Plaintiffs' case rests upon the following evidence: the Lochbaum testimony that a blowout may or may not have occurred, and that if one did occur, more than 10 million curies of noble gases were released from the plant during the accident; Dr. Vergeiner's testimony regarding how prevailing weather conditions may have effected plume dispersion and travel during the accident; Dr. Wing's cancer incidence study; and Professor Shevchenko's cytogenetic analysis and tree study.

## C. <u>Plaintiffs' Burden of Proof</u>

Although this court has original federal question jurisdiction over the captioned action, Pennsylvania tort law controls with respect to Plaintiffs' burden of proof. 42 U.S.C. § 2014(hh)(1988). The Third Circuit has held that to succeed on their claims, Plaintiffs must show that:

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 defendants released radiation into the environment in excess of the §§ 20.105 or 20.106 levels; 2) plaintiffs were exposed to this radiation (although not necessarily at the levels prohibited by §§ 20.105 and 20.106); 3) plaintiffs have injuries; and
 4) radiation was the cause of those injuries.

<u>In re TMI</u>, 67 F.3d at 1119 (hereinafter "TMI analysis"). The Third Circuit also has held that the Pennsylvania rule that medical experts must testify to their conclusions with a "reasonable degree of medical certainty" Is an element of the plaintiff's burden of proof in toxic tort cases. <u>In re Paoli</u> <u>Railroad Yard PCB Litigation</u>, 35 F.3d 717, 751-52 (3d Cir. 1994) (citing <u>Cohen v. Albert Einstein Medical Ctr.</u>, 592 A.2d 720, 724 (1991), <u>appeal denied</u>, 602 A.2d 855 (1992)) ("the <u>Cohen</u> court strongly implied that, even if admissible, testimony with less than a reasonable degree of medical certainty was insufficient to prove causation") (hereinafter <u>"Paoli II").</u>

Defendants have conceded factor 1, and factor 3 is not disputed-by the parties. It is factors 2 and 4 that present the greatest challenges in this litigation. Another district court faced with similar issues noted as follows:

> Because cancers are synergistic the evaluation of different risk factors is an inherently complicated endeavor. The examination of a malignancy, for example, will not reveal the cause of the cancer in question. Thus, determining whether exposure to ionizing radiation contributed to causation of cancer is extremely complex. The record reflects that making such a determination requires consideration of numerous factors, including the circumstances of exposure; the amount and rate of radiation exposure; the type of radiation received (gamma, beta,

alpha, neutron, low LET and high LET); the pathways of radiation exposure; the duration of exposure; the age at manifestation of the disease; the nature of the . . . disease; the effects of other risk factors and of exposure to other carcinogenic agents; the medical history of the [Plaintiff] ; the latency period between exposure and disease manifestation; the (Plaintiff's) . . . health at the time of exposure; the (Plaintiff's) gender; and whether the [Plaintiff] manifested acute symptoms of radiation exposure just after exposure.

National Ass'n of Radiation Survivors V. Derwinski, 782 F. Supp. 1392, 1398 (N.D. Cal. 1992); see O'Conner v. Commonwealth Edison <u>Co.</u>, 807 F. Supp. 1376, 1382 (C.D. 111. 1992) ("Radiation exposure and its effects upon humans is a very complex subject.").

In explaining the "exposure" element of Plaintiffs' burden, the Third Circuit stated that Plaintiffs must show that they "were exposed to this radiation (although not necessarily at the levels prohibited by (10 C.F.R.] §§ 20.105 and 20.106)." In <u>re TMI</u>, 67 F.3d at 1119. The lowest level prohibited by sections 20.105 and 20.106 is 0.5 rems (50 mrem). <sup>54</sup> Standing alone, the court interprets this element to mean that Plaintiffs must show exposure to any amount of radiation from TMI -- even if that

<sup>54.</sup> Section 20.105 mandates, among other things, that an NRC licensee's application be approved where that licensee demonstrates that operation of the facility is not likely to cause anyone offsite to be exposed to in excess of 0.5 rems (50 mrems) of radiation annually. 10 C.F.R. § 20.105. Section 20.106 states that a licensee "shall not possess, use, or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix 'B', Table II of this part, except as authorized." 10 C.F.R. § 20.106.

amount is less than .5 rems. However, the Third Circuit also noted that "[t]his `exposure' element requires that plaintiffs demonstrate they have been exposed to a greater extent than anyone else,' i.e. that their `exposure level exceeds the normal background level.' " In re TMI, 67 F.3d at 1119.

According to the BEIR V report, the "average annual effective dose equivalent of ionizing radiations to a member of the U.S. population" (i.e. dose from background radiation) is 3.6 mSv (3.6 rems/360 mrems (1 Sv = 100 rems; 1 mSv = 1 rem)). BEIR V at 18. This presents a quandary for the court. If the Plaintiffs must demonstrate an exposure that "exceeds the normal background level," they must prove in excess of 360 mrems -- significantly more than the 50 mrem threshold set forth in 10 C.F.R. § 20.105. Moreover, from a practical standpoint, it would be virtually impossible to establish both what the normal background levels were for each of the test Plaintiffs, and that it was the TMI exposure that pushed them beyond their normal background count. It seems that to know whether TMI radiation took Plaintiffs above background, each Plaintiff would need to have been whole body counted several times prior to the accident, and immediately following the accident. By comparing the "historical" counts with the post-accident count, one might be able to determine whether TMI radiation took a particular Plaintiff beyond normal background levels. It would be unreasonable to require Plaintiffs to produce such evidence. Accordingly, the court will apply factor 2 of the

Third Circuit analysis without reference to "normal background levels." Thus, to satisfy factor 2, Plaintiffs must simply demonstrate that they were exposed to some amount of radiation, however minuscule, emitted during the TMI accident.

Presuming that Plaintiffs can show that they were exposed to radiation emitted during the TMI accident, the issue becomes whether they can also demonstrate that the exposure was more likely than not the cause of their respective neoplasms. It is with consideration of this factor that the court's analysis collides with gray areas of science and produces a complicating morass of legal rules and scientific theory. There appear to be two types of evidence with which Plaintiffs may show causation: direct evidence of the actual quantity of their radiation exposure, and indirect evidence which suggests that the exposure, even if it cannot be quantified, caused their neoplasms.

With respect to the quantity of radiation exposure, there is a consensus within the relevant international scientific community that exposure to high levels of ionizing radiation (in excess of 100 rems) will induce cancer. <u>See supra</u> at 19, 23-26. That being said, the same scientific community will also agree that: 1) it is impossible to determine the precise etiology of a given cancerous tumor; and 2) at doses below 10 rems, the causal link between radiation exposure and cancer **induction** is entirely speculative. <u>Id.</u> This raises the problem of precisely how many rems of radiation exposure suffice to meet the "more likely than not" standard? Is it possible for something that is "speculative" for scientific purposes to be "more likely than not" for legal purposes? That is, can Plaintiffs meet their burden of proof if the evidence supports the inference that they were exposed to not more than 9 rems of ionizing radiation (e.g. where scientist would say the causal link was speculative)?

After careful review of the extensive scientific record in this case, the court finds that to the extent Plaintiffs seek to establish causation on the basis of a specific radiation exposure level, they must present evidence based upon which a fact finder could reasonably infer that each Plaintiff was exposed to 10 rems or more of ionizing radiation during the TMI accident.<sup>55</sup>

The radiation protection community scientists who have gathered this data for more than half a century have concluded that scientifically observable excess numbers of cancer have appeared in populations exposed to high doses of radiation. These high doses are generally above approximately 100 rem. Since the highest dose that any of these four plaintiffs received is only 3.2 rem, we have no reliable data that gives us excess cancers for such a low level of exposure. The way radiation scientists estimate the risks at low doses is to use various hypotheses such as the linear hypothesis or the quadratic hypothesis or the linear-quadratic hypothesis. This court finds that when radiation scientists speak about a mathematical risk from a 3.2 rem dose of radiation, they are speaking about

(continued...)

<sup>55.</sup> In <u>Johnston</u>, the court alluded to the difficulty presented when the relevant scientific community can only hypothesize about the causal relationship between a toxic exposure and subsequent health effects:

If the most-eminent scientists in the world are unwilling to do more than speculate as to the causal link between radiation exposure and cancer induction at doses below 10 rems, no rational jury, confronted with identical evidence, could find it more likely than not that radiation induced a -given neoplasm. Johnston, 597 F. Supp. at 425 ("Cause in tort law needs to be founded on more than a theory or hypothesis."); id. at 426 ("when the doses are so low that the existence of any effect at all is only hypothetical theory, such calculations are mere speculation. (and) these calculations should not, nor will they, be accepted here as valid evidence on causation"); accord Paoli II, 35 F.3d at 766 (noting that even if doctor's testimony had not been excluded as scientifically unreliable, it "did not have sufficient scientific certainty to survive summary judgment"); Turoin V.Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349, 1360-61 (6th Cir. 1992) ("The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue . . . is too wide. Under such circumstances, a jury should not be

asked to speculate on the issue of causation."). Although not binding authority, the court also finds <u>Merrell Dow</u>

Johnston, 597 F. Supp. at 423 (internal citations omitted).

<sup>55. (...</sup>continued)
 "theoretical, hypothetical numbers." These
 types of numbers are not real numbers because
 if that risk exists at all it is "not something
 you can determine in a quantitative fashion in
 real life."

Pharmaceuticals, Inc. V. Havner, 907 S.W.2d 535, 541 (Tex. Ct.

App. 1994), to provide persuasive authority:

To establish proof, the expert testimony must establish the "reasonable probability" of a causal connection [T] his probability must, in equity and justice, be more than coincidence before there can be deemed sufficient proof for the Plaintiff to go to the jury. . . . In the absence of reasonable probability, the inference of causation amounts to no more than conjecture or speculation. . . [A] possible cause only becomes "probable" when in the absence of other reasonable causal explanations it becomes more likely than not that the injury was a result of its action. This is the outer limit of inference upon which an issue can be submitted to the jury.

<u>Id.</u> According to the <u>Havner</u> court, expert scientific testimony "will amount to some evidence only when it represents the overall substance of the expert's opinion and is based on more than purely speculative conclusions or personal opinion ungrounded in scientific reality." <u>Id.</u> at 542.

Even if the circumstances are such that the specific quantity of radiation exposure may not be ascertained, Plaintiffs can attempt to meet their burden with indirect evidence. The following factors, though not exhaustive, represent the type of indirect evidence which would be relevant to the issue of individual causation:

a. whether the neoplasm is radiogenic;

b. whether the diagnosis of the neoplasm occurred within a time frame consistent with scientifically established latency periods;

c. scientific literature indicating that the particular neoplasm is only susceptible to radiation induction at exposure levels far in excess of 10 rems;

d. whether Plaintiffs have ruled out other
potential causes of the test Plaintiff's
neoplasm such as potential exposure to another
toxic agent, genetic predisposition and
smoking, among others;

e. scientifically reliable studies demonstrating a statistically significant increase inn cancer incidence following the exposure to radiation;

f. indicia of radiation effects on plants and animals in the exposed area.

The court will neither apply these additional factors in a "checklist" fashion, nor base a ruling on causation on the presence or absence of any one of these factors.

It is important to note that by distinguishing conceptually between direct and indirect evidence, the court does not suggest that Plaintiffs must prove their case with only one type of evidence or the other. Rather, the court will use the above factors together with the 10 rem threshold to determine whether the quantum of Plaintiffs' evidence supports the inference of a causal link between the TMI accident and Plaintiffs' illnesses.

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### D. Application of the Law to the Facts of this Case

1. Were Plaintiffs Exposed to Radiation Released From TMI during the TMI Accident?

As the court interprets the Third Circuit's guidance, this element relates to any exposure, not to an exposure sufficient to induce a subsequent health effect. To determine whether each Plaintiff was exposed to radiation, one must know what radionuclides were released from TMI during the accident, and the quantities of each radionuclide released, i.e. the source Plaintiffs' expert David Lochbaum does not, however, offer term. specific source term testimony. Rather, Plaintiffs offer Lochbaum to testify regarding a potential blowout, and to express his opinion regarding the quantity of radioactive noble gases released during the accident. As the court will discuss infra. because Lochbaum's opinions are too speculative to stand alone, and because Plaintiffs' other admissible evidence does not bolster his opinion, the court finds that Lochbaum's testimony regarding releases from the plant does not create a material factual dispute as to the TMI source term.

Nevertheless, the court finds that the record evidence submitted by Defendants supports the inference that Plaintiffs were exposed to radiation during the TMI accident. As part of their case, Defendants have presented a plethora of state and federal government reports. These reports are in agreement that, during the accident, populated areas within a 20 mile radius of

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TMI were likely exposed to minimal levels of ionizing radiation under 100 mrems). Indeed, Defendants have conceded that readings at the plant boundaries exceeded the 0.5 rem regulatory threshold In reTMI, 67 F.3d at 1119. The court during the accident. liberally construes factor 2 of the  $\,TMI\,$  analysis to mean exposure to any amount of radiation released during the TMI accident. As a result, the court finds that there is no material factual dispute as to factor 2 of the TMI analysis. Plaintiffs were legally "exposed" to radiation. The court must, however, stress that its liberal interpretation of this factor would permit a legal finding of "exposure" even at levels which are hundreds of times lower than natural background levels of radiation. As the court's discussion below will illustrate, a legal finding of "exposure," standing alone in the instant case, would be of little significance in establishing a genuine issue of fact as to the causation prong (factor 4) of the TMI analysis.

2. Was Radiation the Cause of Plaintiffs Injuries?

To create a material factual dispute as to this element of their case, Plaintiffs must produce evidence demonstrating that it is more likely than not that each of the test Plaintiffs' neoplasms were the result of their exposure to ionizing radiation during the TMI accident. Plaintiffs may carry this burden through the production of direct or indirect evidence of an exposure to a dose of radiation capable of inducing their neoplasms (i.e. in excess of 10 rems). To establish that each Plaintiff received a cancer inducing dose of radiation, Plaintiffs must first establish that quantities of radionuclides sufficient to deliver that dose were released from TMI during the accident. In essence, Plaintiffs need source term evidence demonstrating that releases were higher than those calculated by Defendants. See <u>In re TMI</u>, 911 F. Supp. at 829 n.55 ("[d]espite its strong reservations, the court permitted [Lochbaum to make] this additional filing base upon the importance of this theory to plaintiffs' case")."

As alluded to in the preceding discussion, Plaintiffs have no admissible source term evidence. Lochbaum's expert opinions, while methodologically sound, amount to little more than speculation regarding what might have happened in the plant during the accident. Because of the equivocal and arguably contradictory nature of Lochbaum's testimony, the court in its <u>Daubert</u> ruling questioned whether the testimony "fit" within the action. See In <u>re TMI,</u> 1996 WL 166713 at \*12. That is, if Lochbaum's review of the relevant TMI data revealed no conclusive evidence of a

<sup>56.</sup> As the court indicated when discussing Plaintiffs' case, it is Plaintiffs' litigation strategy that has elevated the importance of this evidence. Because virtually all of Plaintiffs' experts (including those that have been excluded by the court's <u>Daubert</u> rulings), presumably at the direction of Plaintiffs' counsel, assumed high levels of exposure when stating their opinions, Plaintiffs needed at least one expert to provide the evidentiary foundation which supported these assumptions. Plaintiffs have ultimately failed to produce such an expert. As such, to the extent that Plaintiffs' expert opinions depend upon evidence of high releases from the plant, their opinions have been rendered invalid.

blowout, how could his theories regarding how a blowout might have occurred assist a jury? In fact, during the <u>Daubert</u>, hearings, Lochbaum went further than stating their was no "conclusive" evidence of a blowout -- he testified that ""I did not see any supporting indications that would lead me to believe that there was a blowout . . . I do not believe that there was evidence of a blowout." (3/5/96 Tr. at 1455.) Plaintiffs are not required to conclusively prove that a blowout occurred. Rather, they must demonstrate-that it is more likely than not that such an event occurred. Thus, insofar as other evidence, taken with the Lochbaum testimony, would make the probability of a blowout more likely than not, the court found that the proffered Lochbaum testimony would be helpful.

Viewing all record evidence in a light most favorable to Plaintiffs, and making all reasonable inferences in favor of Plaintiffs, the court finds that there is *insufficient* dose evidence, discussed <u>infra</u>, to make Lochbaum's testimony helpful to the trier of fact."' While the law does not require Lochbaum to

<sup>57.</sup> A substantial portion of Plaintiffs'. brief in opposition to Defendants' motion for summary judgment is devoted to a restatement of Lochbaum's report and hearing testimony. <u>See</u> Pls.' Brief in Op. at 17-43.) Additionally, Plaintiffs call into question the scientific reliability of the Daniel Report, and argue that because Daniel's wife authored much of the report, Daniel should not be permitted to testify to the section that she authored. Plaintiffs filed no motions in <u>limine</u> to exclude any of Defendants' proffered expert testimony. Moreover, Plaintiffs' have misconstrued this court's November 9, 1995 order (and the rationale supporting the order discussed within the body of the court's 1/5/96 <u>in limine</u> [continued...]

state his expert opinion with unwavering certainty, it does require him to state his expert opinion with a reasonable degree of professional certainty. The Third Circuit articulated this standard in <u>Paoli II:</u>

> When a party must prove causation through expert testimony the expert must testify with reasonable certainty that in his professional opinion, the result in question did come from the cause alleged . . . [I]f the plaintiff's . . expert cannot form an opinion with sufficient certainty so as to make a [professional] judgment, there is nothing on the record with which a [factfinder] can make a decision with sufficient certainty so as to make a legal judgment.

Id. at 751 (quoting <u>Cohen v. Albert Einstein Medical Ctr.</u>, 592 A.2d 720 (Pa. Super. 1991), <u>appeal denied</u>, 602 A.2d 855 (Pa. 1992)); <u>cf. Ambrosini</u>, 1995 WL 637650 at \*3 (acknowledging that as "gatekeeper" a "judge is attempting to evaluate an expert's opinion to determine whether it is the `hunch' of a knowledgeable scientist or if it is-scientific knowledge based upon valid

<sup>(...</sup>continued) 57. ruling) regarding non-testifying experts. The court ruled that no expert could testify regarding the report of another where the testifying expert did not have the scientific expertise to intelligently discuss the methodology and scientific underpinnings In reTML, 911 F. Supp. at 829. Accordingly, of the report. insofar as Daniel can speak intelligently to the work his wife performed on the report, and thereby afford Plaintiffs the opportunity to vigorously cross-examine, his testimony would be entirely proper. At the <u>Daubert</u>, hearings, Daniel spoke intelligently on cross-examination, exhibited a firm understanding of the methodology employed in his report, and elicited no objection from Plaintiffs as to his qualifications to testify as an The situation is analogous to the court's allowing expert. Professor Shevchenko to testify to the substance of the cytogenetic analysis performed by Dr. Snigiryova.

scientific principles and methodologies," and finding former insufficient to carry plaintiff's burden of proof at summary judgment). The court finds Lochbaum's opinions regarding the hypothesized hydrogen blowout to lack the certainty of a professional judgment. Id. Accordingly, despite being admissible and scientifically reliable for <u>Daubert</u>, purposes, the evidence is insufficient to defeat a motion for summary judgment. See <u>Daubert</u>, 113 S. Ct. at 2798 (noting that granting summary judgment is an "appropriate safegaurd[]" where evidence is admissible under <u>Daubert</u> but where the "scintilla of evidence presented . . . is insufficient to allow'a reasonable juror to conclude thatt the position more likely than not is true"); see also Ambrosini, 1995 WL 637650 at \*5 (finding that, although expert testimony was not per se inadmissible under <u>Daubert</u>, testimony did not "fit" plaintiff's burden of proof in the absence of other evidence of causation"); see also Ruiz v. Whirlpool, Inc., 12 F.3d 510, 513 [5th Cir. 1994] [noting that testimony based upon conjecture or speculation is insufficient to defeat summary judgment). Without a blowout, Plaintiffs are unable to demonstrate that release levels were significantly higher than originally presumed based upon the findings of the official studies of the TMI accident.

The balance of Plaintiffs' admissible evidence includes Dr. Wing's cancer incidence study, Professor Shevchenko's tree study and cytogenetic analysis, and Dr. Vergeiner's testimony regarding how prevailing weather conditions effected plume dispersion and travel. Taken together, this evidence does not bolster Lochbaum's testimony, create a material factual dispute, or carry Plaintiffs' burden of proof on the issue of causation.

Dr. Wing performed a reanalysis\_ of the Hatch cancer incidence study. In conducting his reanalysis, Dr. Wing presumed that TMI area residents were exposed to levels (doses) of radiation significantly higher than those reported in the government reports discussed previously in this memorandum and the doses assumed by the Hatch study. <u>See supra</u> at 45-54 (discussing the reports and study). Based upon the assumption that residents were exposed to high levels of radiation, Dr. Wing appears to have attributed the increases in cancer association found in his study to exposure to high levels of radiation. The following colloquy from the <u>Daubert</u>, hearings is illustrative:

- Q. Turning to the cancer incidence study, your reanalysis of the Susser/Hatch data, if you assume that the real level of exposures, not the relative units, but the real level of exposures was small or was low as postulated in the Susser/Hatch report, that would affect your interpretation of the data; correct?
- A. Let me put it this way: If I assumed that it was not possible that the doses were higher, than assumed by the authors of the Columbia [Susser/Hatch] paper, then it would prohibit making a causal interpretation of the observed association.

(11/21/95 Tr. at 981-82 [testimony of Dr. Wing).) In this same vein, Dr. Wing states in his report "[u]nlike the original reports

based on these data, our re-analyses (sic) assumed that absolute accident doses could have been large enough to produce measurable impacts on cancer incidence. [2/25/95 Wing Report at 9.] The record presently before the court does not support the fundamental assumption made by Dr. Wing -- that doses were significantly higher than originally estimated. In the absence of this assumption, Dr. Wing himself admits that he would be unable to make a causal interpretation based upon his findings. Because Plaintiffs have presented no evidence in support of this assumption, the court finds the Wing cancer incidence study does nothing to assist Plaintiffs in creating a material factual dispute or meeting their burden of proof. Cf. Kearnev v. Philip Morris. Inc., 916 F. Supp. 61 (D. Ma. 1996) (finding that premise upon which experts founded their opinions "involves an inferential leap for which no reasoned basis is proffered, and thus does not survive reasoned scrutiny" at summary judgment).

Because the Wing study offers no support to Plaintiffs' case, Plaintiffs are left with the Shevchenko cytogenetic analysis and tree study as their sole evidence that high doses of radiation reached populated areas and caused Plaintiffs' neoplasms. The cytogenetic analysis demonstrates that some of the 29 blood samples, taken more than fifteen years after the accident, show elevated levels of dicentric chromosomes. However, the number of dicentric chromosomes will decrease substantially in the first year following exposure; and thus, cytogenetic analyses become less accurate over time. Plaintiffs have presented no scientific evidence that would support a finding that the Shevchenko cytogenetic analysis, performed more than fifteen years after the TMI accident, is more than a minimally accurate means of proving prior exposure to radiation." Were there other, stronger evidence of exposure to greater than 10 rems of radiation on the record, the cytogenetic analysis would bolster that evidence. Absent such evidence, the cytogenetic analysis results alone do not create a material factual dispute on the issue of dose.

Finally, Plaintiffs offer the Shevchenko tree study in support of their assertion that high levels of radiation reached populated areas during the accident. Professor Shevchenko likely has more personal experience making first hand observations of radiation exposed areas than any other expert involved in this litigation. His credentials are impressive. Plaintiffs offer

There is scientific evidence on the record which indicates 58. that a cytogenetic analysis performed using the FISH method would accurately measure chromosome aberrations long after the initial However, at the commencement of the <u>Daubert</u> exposure to radiation. hearings, more than one year after the formal close of discovery, Plaintiffs' experts had failed to complete a FISH method analysis of the 29 TMI blood samples. The court notes that on the day that the <u>Daubert</u> hearings began, more than seventeen years had elapsed since the date of the TMI accident, and more than seven years had elapsed since the many separate personal injury actions had been consolidated under the instant case number. Plaintiffs had ample time to complete a FISH method analysis prior to the hearings, yet they failed do so. Cf. Coolev v. Pennsylvania Housing Finance Agency, 830 F.2d 469, 474 (3d Cir. 1987) ("If complete and adequate discovery has been afforded to the parties, then the case of the party bearing the ultimate burden of proof can be put to task by the opposition through a Rule 56 motion.").

Professor Shevchenko to testify that the trees he observed in the TMI area similar in appearance to the radiation exposed trees that he has observed in the former Soviet Union at sights such as Semipalatinsk, Chernobyl and Kyshtym. His testimony is extremely powerful insofar as it appears to place the TMI accident in the same realm with the Chernobyl accident.

Plaintiffs argue that based upon the many studies he has conducted in the former Soviet Union over his career, Professor Shevchenko can visually identify trees' that have been damaged by radiation exposure. Moreover, Plaintiffs claim that he can distinguish by observation alone damage to trees caused by pathogens, insects or lightening and damage caused by radiation. The record reveals that Professor Shevchenko's experience in identifying radiation damage in trees in the former Soviet Union derives from his studies of the cellular and subcellular effects of the exposure. Indeed, his observations of tree damage in the former Soviet Union were made in conjunction with subcellular analyses of tree tissue. (See 11/22/95 Tr. at 1195.) However, Professor Shevchenko has not performed similar studies on the trees he observed in the TMI area. (Id. | "No. I have not conducted such investigation (sic). It would demand a lot of time. I did not have such an opportunity.").) When asked whether he had an opinion as to what caused the flat top on a TMI pine tree, Professor Shevchenko indicated "Yes. I believe this is the effect of radiation, because we have observed these things in

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Semipalatinsk, Kyshtym and Chernobyl." (11/21/95 Tr. at 1088.) In qualifying his answer, Professor Shevchenko explained that one of the reasons he chose to include pine trees in his study was because "[i]n our lab as well as in other labs, investigation has been conducted on radiation genetics on pine trees." <u>[Id.</u> at 1089.)

Both the damaged in tree tops observed by Professor Shevchenko and the chromosome dicentrics are nonspecific effects of radiation exposure. They are classified as nonspecific because the same effects can be caused by things other than radiation. Professor Shevchenko will testify that based solely upon his observation of TMI trees, it is his professional opinion that the trees were damaged as a result of radiation exposure during the TMI accident. Effectively, Professor Shevchenko is asserting that his expertise is so great that he simply knows radiation damage when he sees it. To the extent that Professor Shevchenko's confidence in his abilities is warranted, the record nevertheless reflects that his observations were cursory. Professor Shevchenko testified that he did. not examine the tops of trees from a bucket truck, or by having sections cut out and brought down to him for investigation, and that he does not have sufficient expertise to (11/22/95 Tr. evaluate non-radiation induced diseases in trees. at 1184-85.) Without disputing his acumen in this area, the court finds that Professor Shevchenko's testimony that selected trees in the TMI area look like trees exposed to radiation at

Semipalatinsk, Kyshtym and Chernobyl is simply **insufficient** to carry the weight of Plaintiffs' entire case. Combining the cytogenetic evidence and the tree evidence likewise fails to carry Plaintiffs' burden. Two nonspecific effects of radiation exposure cannot meld to equal proof of specific exposure to radiation.

Finally, Dr. Vergeiner's testimony was admitted by the court subject to the condition that Plaintiffs could explain how the testimony was still relevant in light of the court's exclusion of the bulk of Dr. Vergeiner's proffered expert testimony. Had Plaintiffs presented admissible evidence demonstrating that significant quantities of noble gases were released from TMI during the accident, Dr. Vergeiner's testimony would assist the jury in understanding how prevailing weather conditions effected the plume's path and the rate at which it dispersed." However, on the current state of the record, Plaintiffs have no high release evidence. Without high releases, there is no dense yet narrow plume, and there is no need for Dr. Vergeiner to explain how such a plume might have evaded the TLDs set up to monitor airborne radiation.

<sup>59.</sup> At the time the Vergeiner testimony was conditionally admitted, Plaintiffs had no record source term evidence. Dr. Webb had been withdrawn, and the court had yet to receive the Lochbaum report. Based upon counsels' characterization of the expected findings of the Lochbaum report (e.g. that a blowout occurred), the court found that Dr. Vergeiner's meteorological testimony might prove helpful to a jury.

Viewing all evidence before the court in a light most favorable to Plaintiffs, the court finds the evidence insufficient to create any material factual dispute and insufficient to carry Plaintiffs burden of proof at trial. Plaintiffs have neither presented direct evidence that they were exposed to doses of radiation greater than 10 rems, nor have they presented indirect evidence capable of supporting the inference that they were exposed to cancer inducing levels of radiation. Accordingly, the court will grant Defendants' motion for summary judgment in its entirety.

## IV. <u>Conclusion</u>

The parties to the instant action have had nearly two decades to muster evidence in support of their respective cases. As is clear from the preceding discussion, the discrepancies between Defendants' proffer of evidence and that put forth by Plaintiffs in both volume and complexity are vast. The paucity of proof alleged in support of Plaintiffs' case is manifest. The court has searched the record for any and all evidence which construed in a light most favorable to Plaintiffs creates a genuine issue of material fact warranting submission of their claims to a jury. This effort has been in vain. The grave consequence of the court's decision to grant summary judgment in favor of Defendants is obvious -- thousands of individuals who believe that they have suffered adverse medical effects as a

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result of the TMI accident will not have an opportunity to have their claims heard by a jury of their peers. In addressing the merits of Defendants' motion for summary judgment, however, this case is like all others that come before he court in that the well articulate standards governing the award of summary judgment guide the court's evaluation of the evidence before it. Those standards combined with the scarcity of evidence of record to support Plaintiffs' claims mandate the result reached by the court today.

Middle District of Pennsylvania

Dated: June 7 , 1996.

2) Pursuant to this court's April 29, 1996 order, within fifteen days, Plaintiffs' counsel Laurence Berman, Arnold Levin and Lee Swartz shall show cause why sanctions in the amount of \$500 per attorney should not be imposed by the court.

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(SYLVIA H. RAMBO, Chief Judge Middle District of Pennsylvania

Dated: June 7, 1996.

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#### IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

# IN RE: TMI LITIGATION CONSOLIDATED PROCEEDINGS

CIVIL ACTION NO. 1:CV-88-1452

This Document Relates to: All Plaintiffs

#### <u>ORDER</u>

As summary judgment has been granted in favor of Defendants as to all Plaintiffs, IT IS HEREBY ORDERED THAT:

1) The following motions are deemed to be moot:

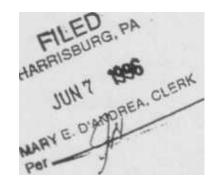
a) Judith Johnsrud's motion to quash the subpoena

filed January 3, 1995;

 b) Defendants' motion for reconsideration of the court's April 2, 1996 order regarding Vladimir Shevchenko and Steven wing filed April 12, 1996;

c) Plaintiffs' motion for leave to pursue claim of punitive damages against all Defendants filed April 15, 1996;

 d) Plaintiffs' motion for interlocutory appeal of the court's <u>in limine</u> rulings filed May 15, 1996;



Courte ad trong the record