11-2-1999

In Re: TMI Litigation

Filed November 2, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 96-7623/7624/7625

IN RE: TMI LITIGATION

LORI DOLAN; JOSEPH GAUGHAN; RONALD WARD; ESTATE OF PEARL HICKERNELL; KENNETH PUTT; ESTATE OF ETHELDA HILT; PAULA OBERCASH; JOLENE PETERSON; ESTATE OF GARY VILLELLA; ESTATE OF LEO BEAM,

Appellants No. 96-7623

IN RE: TMI LITIGATION

ALL PLAINTIFFS EXCEPT LORI DOLAN, JOSEPH GAUGHAN, RONALD WARD, ESTATE OF PEARL HICKERNELL, KENNETH PUTT, ESTATE OF ETHELDA HILT, PAULA OBERCASH, JOLENE PETERSON, ESTATE OF GARY VILLELLA AND ESTATE OF LEO BEAM,

Appellants No. 96-7624

IN RE: TMI LITIGATION

ALL PLAINTIFFS; ARNOLD LEVIN; LAURENCE BERMAN; LEE SWARTZ

Appellants No. 96-7625

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
(Civil No. 88-cv-01452)
(District Judge: Honorable Sylvia H. Rambo)

ARGUED: June 27, 1997

Before: GREENBERG and McKEE, Circuit Judges, and
GREENAWAY, District Judge*

(Opinion filed: November 2, 1999)

ARNOLD LEVIN, ESQ.
LAURENCE S. BERMAN, ESQ.
(Argued)
CRAIG D. GINSBURG, ESQ.
Levin, Fishbein, Sedran & Berman
510 Walnut Street, Suite 500
Philadelphia, PA 19106

LEE C. SWARTZ, ESQ.
Hepford, Swartz & Morgan
111 North Front Street
P.O. Box 889
Harrisburg, PA 17108

Attorneys for Appellants in
No. 96-7623/7624/7625

LOU TARASI, ESQ.
Tarasi & Johnson, P.C.
510 Third Avenue
Pittsburgh, PA 15129

Of Counsel for Certain Appellants
Identified in the Entry of Appearance
in Appeal No. 96-7624/7625

---

* The Honorable Joseph A. Greenaway, Jr., United States District Court Judge for the District of New Jersey, sitting by designation.

STEPHEN A. SALTZBURG, ESQ.
(Argued)
Howrey Professor of Trial Advocacy,
Litigation and Professional
Responsibility
George Washington Law School
720 20th Street, N.W.
Washington, D.C. 20052

Of Counsel for Appellants in
No. 96-7623/7624/7625

DANIEL J. CAPRA, ESQ.
Reed Professor of Law
Fordham University School of Law
Lincoln Center
140 West 62nd Street
New York, NY 10023

Of Counsel for Certain Appellants
Identified in the Entry of Appearance
in Appeal No. 96-7625

A.H. WILCOX, ESQ. (Argued)
ELLEN K. SCOTT, ESQ. (Argued)
ERIC J. ROTHSCHILD, ESQ.
(Argued)
Pepper, Hamilton & Scheetz, LLP
3000 Two Logan Square
18th and Arch Streets
Philadelphia, PA 19103

LEWIS S. KUNKEL, JR., ESQ.
THOMAS B. SCHMIDT, III, ESQ.
Pepper, Hamilton & Scheetz LLP
200 One Keystone Plaza
North Front & Market Streets
P.O. Box 1181
Harrisburg, PA 17108

Attorneys for Appellees in
Nos. 96-7623/7624/7625

REUBEN A. GUTTMAN, ESQ.
Provost & Umphrey
1350 New York Avenue, N.W.
Suite 1040
Washington, D.C. 20005

NED MILTENBERG, ESQ.
Associate General Counsel
Association of Trial Lawyers of
America ("ATLA")
1050 31st Street, N.W.
Washington, D.C. 20007

Amicus Curiae, Association of Trial
Lawyers of America ("ATLA"), in
Support of Appellants

TABLE OF CONTENTS

I. INTRODUCTION 6

II. PROCEDURAL HISTORY 8

III. SCIENTIFIC BACKGROUND 18

A. Overview of Relevant Principles of Nuclear Physics 18
1. Atomic and Nuclear Structure 18
2. Radioactivity 24
3. Ionizing Radiation 28
4. Radiation Quantities and Units 31
5. Health Effects of Ionizing Radiation 35
i. Deterministic Effects 38
ii. Stochastic Effects 41
6. Radiation in the Environment 44
i. Natural Radiation 44
ii. Man-made Radiation 49

IV. NUCLEAR ENGINEERING 54
A. Nuclear Reaction 54
B. The Operation of Nuclear Power Plant 59
C. Barriers to Release of Radioactive Materials into the Environment 65

V. THE ACCIDENT AND ITS AFTERMATH 66
A. The Accident at TMI-2 66
B. Radioactive Materials Released to the Environment 70
C. Pathways of Exposure to Radioactive Materia ls 71

VI. LEGAL DISCUSSION 72
A. The Trial Plaintiffs' Appeal 72
1. Background 72
2. Standards Governing the Admissibility of Scientific Evidence 79
3. Trial Plaintiffs' Dose Exposure Expert Witnesses 85
i. Ignaz Vergeiner 85
a. Qualifications 85
b. Vergeiner's Opinion. 86
c. Discussion and Conclusions 87
ii. Charles Armentrout and Victor Neuwirth 95
a. Qualifications 95
b. Armentrout's Observations and Experiences 96
c. Discussion and Conclusion 98
d. Neuwirth's Soil Sample Analyses and Armentrout's Dose Estimates. 99
e. Discussion and Conclusion 101
iii. James Gunckel 105
a. Qualifications 105
b. Gunckel's Opinion 108
c. Discussion and Conclusions 112
iv. Vladimir Shevchenko 118
a. Qualifications 118
b. Shevchenko's Tree Study 120
c. Discussion and Conclusions 123
d. The Cytogenetic Analysis 126
e. Discussion and Conclusions 130
v. Gennady Kozubov 135
a. Qualifications 135
b. Kozubov's Opinion 135
c. Discussion and Conclusions 137
vi. Olga Tarasenko 139
a. Qualifications 139
b. Tarasenko's Opinion 140

c. Discussion and Conclusions 142
vii. Bruce Molholt 145
a. Qualifications 145
b. Molholt's Opinions 146
c. Discussion and Conclusions 149
viii. Sigmund Zakrzewski 155
a. Qualifications 155
b. Zakrzewski's Opinion 158
c. Discussion and Conclusions 159
ix. Theodor Sterling 161
a. Qualifications 161
b. Sterling's Opinion 161
c. Discussion and Conclusions 163
x. Steven Wing 166
a. Qualifications 166
b. Wing's Mortality Study 166
c. Discussion and Conclusions 168
d. Wing's Cancer Incidence Study 170
e. Discussion and Conclusions 173
xi. Douglas Crawford-Brown 173
a. Qualifications 175
b. Crawford-Brown's Opinion 175
c. Discussion and Conclusions 176
4. Effect of the Exclusion of Wing's Lung Cancer Testimony 179
5. Exclusion of Experts' Submissions as Untimely 181
6. Conclusion 190
B. The Non-Trial Plaintiffs' Appeal 191
C. The Monetary Sanctions Appeal 200
D. Reassignment Upon Remand 201

VII. CONCLUSION 203

OPINION OF THE COURT

McKEE, Circuit Judge

I. INTRODUCTION

These three appeals arise out of the nuclear reactor accident which occurred on March 28, 1979, at Three Mile Island in Dauphin County, Pennsylvania.1 Two of the appeals concern the personal injury claims of more than 2,000 Three Mile Island area residents who allege that they have developed neoplasms2 as a result of the radiation released into the environment as a result of the reactor accident. The first appeal is that of a group of ten trial plaintiffs who were selected by the parties after the District Court adopted the plaintiffs' case management order, which called for a "mini-trial" of the claims of a group of "typical" plaintiffs (the "Trial Plaintiffs"). The critical issue there is the trial plaintiffs' ability to demonstrate that they were exposed to doses of radiation sufficient to cause their neoplasms. Proof of that causation depended on the admissibility of the testimony of several experts that the Trial Plaintiffs retained. These experts attempted to testify about the amount of radiation released into the environment by the nuclear reactor accident, and thereby correlate the plaintiffs' neoplasms to that accident.

Defendants challenged the admissibility of the experts' testimony and the District Court was therefore required to hold extensive in limine hearings pursuant to its "gatekeeping" role under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Following those hearings, the court excluded the overwhelming majority of the Trial Plaintiffs' proposed expert testimony as to dose exposure. Following the exclusion of the dose exposure

---

1. Sometime prior to argument, the appellees moved to consolidate these appeals. We denied that request by order dated December 24, 1996. We did, however, instruct the Clerk to list these three appeals before a single
merits panel. We now believe that the most expeditious way to dispose of these appeals is to consolidate them and dispose of them in one opinion. Therefore, we have entered an order consolidating these three appeals.

2. A neoplasm is "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 mass of tissue which may be either benign or malignant." STEDMAN'S MEDICAL DICTIONARY 931 (26th ed. 1995).

testimony, the defendants moved for summary judgment alleging that Trial Plaintiffs could not establish causation absent the excluded expert testimony regarding dose.

The District Court agreed and held that, as a result of its rulings under Daubert, Trial Plaintiffs were unable to connect their neoplasms to the TMI accident. Accordingly, the court granted summary judgment in favor of defendants and against the Trial Plaintiffs. In re TMI Litigation Consolidated Proceedings, 927 F. Supp. 834 (M.D. Pa. 1996). The District Court then reasoned that its Daubert rulings would be binding on all of the other plaintiffs, i.e., the Non-Trial Plaintiffs, if there were evidentiary issues common to all plaintiffs, Id. at 837. Therefore, the court therefore extended its Trial Plaintiff summary judgment decision to the Non-Trial Plaintiffs, and granted summary judgment to the defendants on all of the claims of the approximately 2,000 remaining TMI personal injury plaintiffs. The propriety of that extension is the subject of the second appeal.

The third and last appeal concerns the propriety of the District Court's imposition of monetary sanctions against certain of the plaintiffs' counsel for violations of pre-trial discovery requirements and orders. The sanctioned counsel have requested that the TMI personal injury litigation be reassigned to another trial judge upon remand, if we reverse the District Court in either or both of thefirst two appeals.

For the reasons that follow, we will affirm the grant of summary judgment to the defendants on the claims of the Trial Plaintiffs (No. 96-7623). We will, however, reverse the grant of summary judgment to the defendants on the claims of the Non-Trial Plaintiffs (No. 96-7624), but we will affirm the imposition of monetary sanctions and deny the request for reassignment (No. 96-7625).

II. PROCEDURAL HISTORY3

---

3. The procedural history of this litigation is almost as complicated as the scientific principles implicated by the Daubert challenges that we discuss below. However, an understanding of the procedural history is necessary to our discussion of the District Court's decision to grant summary judgment against the Non-Trial Plaintiffs as well as the Trial Plaintiffs.

On March 28, 1979, radioactive materials were released into the environment as the result of an accident which occurred at Unit 2 of the Three Mile Island nuclear power generating station in Dauphin County ("TMI-2"). Three Mile Island is a small island in the Susquehanna River, approximately fifteen miles downstream from Harrisburg, Pennsylvania. Following the accident, thousands of personal injury and other non-personal injury claims 4 were filed against the owners and operators of the nuclear facility.5

As noted, more than 2,000 plaintiffs filed claims for personal injuries6 purportedly caused by exposure to the radioactive materials released during the accident. Some of these personal injury claims were originally filed in the early 1980's in state and federal district courts in Pennsylvania, New Jersey and Mississippi. The defendants removed the state court actions to federal district courts in Pennsylvania and New Jersey, under the authority of the Price-Anderson Act, Pub.L. No. 85-256, 71 Stat. 576 (1957).7

---

4. The defendants have settled non-personal injury claims brought by individuals, businesses and non-profit organizations within a twenty-five mile radius of the TMI facility. See Stibitz v. General Public Utility Corp., 746 F.2d 993, 995 n.1 (3d Cir. 1984).

5. The defendants are General Public Utilities, Inc., Metropolitan Edison Co., Jersey Central Power & Light Co., Pennsylvania Electric Co., Babcock & Wilcox, Co., McDermott Inc., Raytheon Constructors, Inc., and Burns & Roe Enterprises, Inc. They were, at the time of the accident, either the owners and operators of the facility or companies which had provided design, engineering and/or maintenance services to the owners and operators or vendors of equipment or systems installed in the facility. In re TMI Litigation Cases Consol. II, 940 F.2d 832, 836 (3d Cir. 1991).

6. The personal injury plaintiffs allege that they have developed radiation induced neoplasms because of their exposure to ionizing radiation resulting from the TMI accident.

7. As we noted in In re TMI Litigation Cases Consolidated II, 940 F.2d 832, 837 n.2 (3d Cir. 1991), the Price-Anderson Act was enacted in 1957 as an amendment to the Atomic Energy Act of 1946, Pub.L. No. 79-585, 60 Stat. 755. The Atomic Energy Act was designed to establish an industry to generate inexpensive electrical power and it envisioned turning "atomic power into a source of energy" by turning "swords into plowshares." Pacific Gas & Electric Co. v. State Energy Resources

After removal, the District Court for the Middle District of Pennsylvania ordered, inter alia, that all pending TMI personal injury cases in the Middle District be "consolidated for pretrial proceedings only." App. 13097. The District Court also ordered that the caption of every subsequent personal injury pleading should be identified as a personal injury claim. Id.

After we held that the Price-Anderson Act did not create a cause of action as a federal tort and was not intended to confer jurisdiction on federal district courts, see Stibitz v. General Public Utilities Corp., 746 F.2d 993, 997 (3d Cir. 1984) and Kiick v. Metropolitan Edison Co., 784 F.2d 490,

---

Conservation & Development Commission, 461 U.S. 190, 193 (1983). The Atomic Energy Act envisioned the nuclear energy industry as a government monopoly; however, Congress ultimately decided to permit the private sector to become involved. See Atomic Energy Act of 1954, Pub.L. No. 830-703, 68 Stat. 919. The 1954 Act "grew out of Congress' determination that the national interest would best be served if the Government encouraged the private sector to become involved in the development of atomic energy for peaceful purposes under a program of federal regulation and licensing." Pacific Gas & Electric Co., 461 U.S. at 206-07. Nonetheless, the private sector was wary of the potential exposure it faced in the event of a nuclear accident because of the nature of nuclear energy. Thus, while assuring Congress that the risk of a major nuclear accident was low, "spokesmen for the private sector informed Congress that they would be forced to withdraw from the field if their liability were not limited by appropriate legislation." Duke Power
Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59, 64 (1978). In response, Congress enacted the Price-Anderson Act to protect the public and encourage the development of the atomic energy industry. In re TMI, 67 F.3d 1103, 1107 (3d Cir. 1995)(citations and internal quotations omitted), cert. denied, #6D6D 6D# U.S. ___, 116 S. Ct. 1034 (1996).
The Price-Anderson Act limited the "potential civil liability of nuclear power plant operators and provided federal funds to help pay damages caused by nuclear accidents." Id. The Act requires nuclear facilities operators to purchase a specified amount of insurance from private carriers and further provides for government indemnification above the insurance amounts to an established aggregate limit on liability. In re TMI Litigation Cases Consolidated II, 940 F.2d at 837 n.2. The Price-Anderson Act has been amended three times, most recently in 1988; yet the goal continues to be "to encourage private sector participation in the beneficial uses of nuclear materials." Id. at 853.

493 (3d Cir. 1986), the state court actions were remanded, and the federal court actions were transferred to the appropriate state courts. The cases originally removed to the Middle District of Pennsylvania, and those originally filed in the Middle District, were either remanded or transferred to the Court of Common Pleas of Dauphin County. Thereafter, in 1985 and 1986, the bulk of the personal injury claims which are the subject of this appeal were filed in the state courts.8

On October 15, 1985, the Dauphin County Common Pleas Court entered a case management order. In that order, the Court of Common Pleas ordered that all cases be consolidated for pretrial purposes, and also required that all pleadings be captioned to identify which plaintiffs' group they applied to. That is, all personal injury cases received from the federal court were consolidated under the caption "Cases Consolidated I" and the cases filed in state court after our decision in Stibitz, were consolidated under the caption "Cases Consolidated II."

In 1988, Congress enacted the Price-Anderson Amendments Act of 1988, Pub.L. No. 100-408, 102 Stat. 1066. Those amendments to the Price-Anderson Act created a federal cause of action for "public liability actions"9 and provided that all such suits arise under the Price-Anderson Act, 42 U.S.C. S 2014(h). The Act also provided for consolidation of such actions, including those already filed,

---

8. However, personal injury cases continued to befiled after 1986. The last case filed that is included in these appeals was Kline, et al. v. General Public Utilities Corp. et al., No. 1:CV 96-451 (M.D. Pa.), and it was filed on March 15, 1996. However, the latest personal injury case filed is Tyler et al v. General Public Utilities Corp. et al., No. 1:CV 96-1028
(M.D. Pa.), and it was filed on June 7, 1996. Brief of Appellants in No. 96-7624, at 6 n.8. Apparently, Tyler is not included in this appeal.

9. The Price-Anderson Amendments Act defined a"public liability action" as "any suit asserting public liability." 42 U.S.C. S 2014(h). "Public liability" was defined as "any legal liability arising out of or resulting from a nuclear incident or precautionary evacuation," except for certain claims covered by workers' compensation, incurred in wartime or that involve the licensed property where the nuclear incident occurs. 42 U.S.C. S 2104(w).

in one federal district court. 42 U.S.C. S 2210(n).10 Following enactment of that Act, the defendants removed all the pending state actions to the United States District Court for the Middle District of Pennsylvania.

Thereafter, the District Court for the Middle District of Pennsylvania conducted a case management conference. The personal injury cases known as "Cases Consolidated I" and "Cases Consolidated II" which had been removed from the Court of Common Pleas of Dauphin County were then pending in the Middle District along with the companion actions to the "Cases Consolidated II" which had been filed by forty-two plaintiffs in Mississippi federal and state court to take advantage of the more lenient Mississippi statute of limitations.11 As a result of discussions during the conference, the District Court entered an order which required counsel to

> meet to streamline the record with an eye toward reducing the number of duplicative plaintiffs and suits, assigning fewer case numbers for the various actions, and deciding which cases needed new complaints to be filed and which actions do not need answers filed.

Supp. App. at 78. In response to the order, counsel for plaintiffs and defendants submitted a Stipulation which provided, inter alia, that the pending TMI personal injury cases referred to as "Cases Consolidated I" and "Cases Consolidated II," together with the companion Mississippi cases, would be consolidated under a single civil action number "for administrative purposes" (emphasis added). App. Vol. I, at 440. The Stipulation required that pleadings dealing with issues common to all plaintiffs, or a legal issue potentially applicable to all plaintiffs, bear the caption "In re TMI Consolidated Proceedings" as well as the additional

---

10. We subsequently upheld the constitutionality of the retroactive application of the federal jurisdiction provisions of the Price Anderson Amendments Act. In re TMI Litigation Cases Consolidated II, 940 F.2d 832 (3d Cir. 1991), cert. denied, 503 U.S. 906 (1992).

11. Counsel for the forty-two plaintiffs concede that they filed suit in Mississippi to take advantage of Mississippi's six-year statute of limitations. Pennsylvania had a two-year statute. In re TMI, 67 F.3d 1103, 1105 n.3 (3d Cir. 1995), cert. denied, 516 U.S. 1154 (1996).

legend: "This document Relates to: All Plaintiffs." Id. The Stipulation further required that pleadings dealing with issues relating to one or more identified plaintiffs be captioned "In Re TMI Consolidated Proceedings" and identify lead counsel, the number of plaintiffs represented by lead counsel and the number of plaintiffs to whom the pleadings refer. Id. The Stipulation also expressly provided that

> 3. Nothing in . . . this Stipulation . . . shal l be deemed to constitute or affect any waiver of claim, defense or issue, including but not limited to the statute of limitations, choice of law and bifurcation or consolidation for trial of claims, defenses, issues, parties or proceedings.

Id. The Stipulation was subsequently approved by the District Court.

Thereafter, in July of 1992, the defendants filed a motion for summary judgment directed to the forty-two plaintiffs who had sued in Mississippi state and federal courts. Defendants alleged that those claims were untimely under Section 11(b) of the Price-Anderson Amendments Act of 1988, codified at 42 U.S.C. S 2014(hh) (the choice of law provisions), which provides that "the substantive rules of decision in [any public liability action] shall be derived from the law of the State in which the nuclear incident involved occurs," and under Section 20(b) of that Act, (the effective date provision), which provides that "the amendments made by Section 11" of the Act "shall apply to nuclear incidents occurring before, on, or after the date of the enactment of this Act." 42 U.S.C. S 2014 note. The District Court ruled that the Mississippi actions were time-barred, dismissed the respective claims, and granted summary judgment in favor of the defendants because it reasoned thatS 20(b), read in conjunction with S 11, compelled the retroactive application of Pennsylvania's two-year statute of limitation to the plaintiffs' claims. In re TMI Cases Consolidated II, No. 88-14532, slip op. at 2-6 (M.D. Pa. Aug. 16, 1993).

On appeal, the Mississippi plaintiffs argued, inter alia, that retroactive application of the choice of law provision violated constitutional guarantees of due process. We disagreed, and held that the retroactive application of the choice of law provision was a rational exercise of Congress' legislative power. Accordingly, we affirmed the District Court's grant of summary judgment, and its dismissal of the claims of the forty-two plaintiffs. In re TMI, 89 F.3d 1106 (3d Cir. 1996), cert. denied, ___ U.S. ___, 117 S. Ct. 739 (1997).

The defendants then moved for summary judgment against all the TMI plaintiffs, claiming that they had not breached the duty of care owed to the plaintiffs. The District Court denied the motion. The court held that state law on that issue was preempted, and that federal law determines the standard of care. In re TMI Litigation Cases Consolidated II, No. 88-1452, slip op. at 36 (M.D. Pa. Feb. 18, 1994). The court also held that federal regulations12 set the standard of care, and that each plaintiff must prove his or her individual exposure to radiation in order to establish causation, but not to establish a breach of the duty of care. Id. at 30-31. Upon defendants' motion, the District Court certified the duty of care and causation questions for interlocutory appeal.13 On that appeal, we held that plaintiffs must establish that (1) the defendants released radiation into the environment in excess of the levels permitted by the federal regulations in effect in 1979; (2) the plaintiffs were exposed to this radiation, although not necessarily at the levels prohibited by those regulations; (3) they have injuries; and (4) radiation was the cause of those injuries. In re TMI, 67 F.3d 1103, 1119 (3d Cir. 1995), cert. denied, 516 U.S. 1154 (1996).

After remand, the District Court conducted lengthy in limine hearings in November of 1995 and in February and

---

12. See 10 C.F.R. SS 20.105, 20.106 (1979). These regulations were in effect at the time of the TMI accident. In re TMI, 67 F.3d 1103, 1108 n.10 (3d Cir. 1996), cert. denied, 516 U.S. 1154 (1996). However, the regulations have been significantly modified since then. Id. at 1111 n.19.

13. The District Court also certified a question concerning punitive damages. We held in a separate opinion that punitive damages are recoverable under the Price-Anderson Amendments Act of 1988 so long as the money to pay such award does not come from the United States Treasury. In re TMI, 67 F.3d 1119 (3d Cir. 1995), cert. denied, 517 U.S. 1163 (1996).

March of 1996, pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Those hearings all relate to plaintiffs' radiation dose and medical causation expert witnesses. In January and April of 1996, the District Court issued several opinions granting the majority of the defendants' motions in limine. See In re TMI Cases Consolidated II, 166 F.R.D. 8 (M.D. Pa. 1996) (granting in part defendants' motions to exclude plaintiffs' medical causation experts); Id., 922 F. Supp. 1038 (M.D. Pa. 1996)(same); Id., 922 F. Supp. 997 (M.D. Pa. 1996) (granting in part defendants' motions to exclude plaintiffs' radiation dose and medical causation experts); Id., 911 F. Supp. 775 (M.D. Pa. 1996) (granting in part defendants' motions to exclude plaintiffs' radiation dose experts); Id., 910 F. Supp. 200 (M.D. Pa. 1996)(same). Although the District Court was convinced that the majority of the plaintiffs' expert witnesses were well-qualified, the court nonetheless "found many of their opinions to be based on methodologies that were scientifically unreliable and upon data that a reasonable expert in the field would not rely upon." In re TMI Litigation Consolidated Proceedings, 927 F. Supp. 834, 839 (M.D. Pa. 1996). Accordingly, it ruled that the much of the expert testimony was inadmissible under Daubert, and its progeny. In April of 1996, the defendants filed a motion for summary judgment. They based the motion upon their contention that the District Court's Daubert rulings left the plaintiff 's with no admissible evidence as to the radiation dose levels resulting from the TMI accident.

A subsidiary issue arose during the summary judgment proceedings as to whom the summary judgment rulings would apply. That dispute had its beginnings in June of 1993, when the District Court adopted the plaintiffs' proposed case management plan which called for an"initial mini-trial of the claims of twelve `typical' plaintiffs," half chosen by plaintiffs and half chosen by defendants. App. at 168. Under the plaintiffs' plan (which was adopted by the District Court), discovery would proceed immediately as to all issues, including punitive damages and, upon completion of discovery, "the twelve illustrative Plaintiffs would then proceed to trial on all their claims." Id.

Ultimately, ten test plaintiffs,14 who have been diagnosed with the listed illnesses, were chosen.15

When the defendants filed their motion for summary judgment, they captioned it as pertaining to "All Plaintiffs" and argued that the District Court's summary judgment motion should be binding on all plaintiffs, not just the ten trial or test case plaintiffs. The District Court agreed, stating:

> 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 on all Plaintiffs. Likewise, Plaintiffs are correct that insofar as a ruling is based on a more narrow, Plaintiff-specific inquiry, the ruling will 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

---

14. As things developed, one of the defendants' test case selections withdrew from the test group. Consequently, the District Court permitted defendants to chose one of the parties originally selected by plaintiffs to
be dismissed from the test case group. In re TMI Litigation Consolidated Proceedings, 927 F. Supp. 834, 837 n.5 (M.D. Pa. 1996). Thus, the test case group consisted of ten plaintiffs.

15. Those plaintiffs are: 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; Richard Ward, osteogenic carcinoma of the right leg; Pearl Hickernell, breast cancer; Ethelda Hilt, adenocarcinoma of the ovaries; and Kenneth Putt, bladder cancer, acoustic neuroma.

> Plaintiffs' evidentiary burden at this state of the litigation, it will fail to meet the same burden as to every Plaintiff. It would be an exercise in futility and a waste of 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 will be applicable to all Plaintiffs.

927 F. Supp. at 838.

The District Court ruled on the merits of the summary judgment motion that the Trial Plaintiffs had failed to present either direct or indirect evidence of the doses of cancer inducing levels of radiation that they were exposed to. Id. at 870. Accordingly, the court extended its grant of summary judgment to all of the plaintiffs' cases.

> Because the court finds the quantum of 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 on all Plaintiffs.

Id. at 838. Accordingly, the court granted summary judgment against all of the plaintiffs, both trial and nontrial.

These appeals followed.

Appeal Number 96-7623 is the appeal of the ten Trial Plaintiffs. They argue that the District Court improperly excluded their proffered expert witnesses' testimony on dose exposure, thereby erroneously subjecting them to summary judgment. They do not argue that summary judgment was improper given the District Court's Daubert rulings. Thus, if we determine that the District Court's exclusion of their dose exposure testimony was proper, we must affirm the summary judgment for the defendants against the trial plaintiffs. Consequently, the primary issue for our determination in case number 96-7623 is the propriety of the District Court's exclusion of testimony of the dose exposure experts. If, however, we decide that the court improperly excluded some or all of that evidence, we must then decide whether the evidence that was admissible is sufficient to create a genuine issue of material fact.

Appeal Number 96-7624 is the appeal of all of the TMI personal injury plaintiffs except the ten Trial Plaintiffs. Appellants there argue that the District Court improperly extended its Trial Plaintiffs' summary judgment decision to them. Appeal Number 96-7625 is the appeal of sanctioned counsel for the majority of the plaintiffs. Counsel argue that the District Court's imposition of monetary sanctions against them for discovery violations was improper. Each appeal is considered separately.

It is both impractical and unwise to begin our analysis of the Daubert challenge to the scientific testimony without first providing a brief discussion of the fundamental principles of nuclear physics, nuclear engineering, the TMI-2 accident, ionizing radiation, and the health effects of ionizing radiation on the human body. These scientific principles are at the center of the damage that plaintiffs claim they suffered as a result of the TMI accident and the District Court's Daubert rulings. Total immersion in the complexities of these disciplines is neither required, nor possible. Accordingly, we offer the following overview of the controlling principles with an awareness that doing so stretches the boundaries of our institutional competence, and with a recognition of our need to borrow heavily from others in academic disciplines far from the familiar confines of the law.

III. SCIENTIFIC BACKGROUND

A. Overview of Relevant Principles of Nuclear Physics.

1. Atomic and Nuclear Structure.

Plaintiffs alleged that the accident at TMI resulted in a release of radiation into the atmosphere that caused changes to the atomic structure of their chromosomes and resulted in the formation of neoplasms. Their allegations thus implicate the structure of the atom -- the basic building block of matter -- and the physics of orbiting electrons.16

The atom consists of a small but massive central nucleus surrounded by one or more orbital electrons. JOHN R. LAMARSH, INTRODUCTION TO NUCLEAR ENGINEERING 8 (2d ed. 1983). Orbiting electrons are negatively charged, much smaller in mass than the neutron, and their distances from the nucleus are much larger than the radius of the nucleus. DAVID BODANSKY, NUCLEAR ENERGY: PRINCIPLES, PRACTICES AND PROSPECTS 346 (1996). The average distance from the nucleus to the place where the outermost electron is found provides an approximate measure of atomic size. This distance is approximately the same for all atoms, except a few of the lightest atoms, and is about 2 #46# 10 -8 centimeters.17 LAMARSH, at 11.

The nucleus has two constituent parts of approximately equal mass -- the neutron and the proton.18 BODANSKY, at 346. Each is much more massive than the electron. LAMARSH, at 6-7. Together, they are called nucleons. BODANSKY, at 346. The neutron and proton differ in that the neutron is neutral while the proton has a positive charge equal in magnitude to the negative charge of the electron. Id. An atom is neutral or "un-ionized" when the number of positively charged protons equals the number of negatively charged electrons. D. J. BENNET, ELEMENTS OF NUCLEAR POWER 1 (2d ed. 1981).19 "Nuclides" are very important to our

---

16. As we discuss below, radiation has the potential to fatally interfere with one of more orbiting electrons.

17. It is difficult to define the exact size of an atom because the orbiting
electrons may at times move very far from the nucleus but at other times pass close to it. LAMARSH, at 7.

18. At one time, it was believed that neutrons and protons were the fundamental particles of nature. However, it is now understood that they are not the fundamental particles of nature, but themselves are composed of more elementary particles called quarks. BODANSKY, at 346. While knowledge of the existence of quarks and other elementary particles is crucial to an understanding of the origins of the universe and
of the ultimate structure of matter, their existence can be ignored in a discussion of nuclear reactors, radioactivity and nuclear fission. Id.

19. Forces exist in an atom that are critical to atomic structure. "Coulomb repulsion" is an electrostatic force, governed by Coulomb's

discussion. They are differing "species" of atoms whose nuclei contain particular numbers of protons and neutrons. LAMARSH, at 8. A nuclide is given the shorthand notation AZ X, where X is the symbol for the chemical element, Z is the atomic number and A is the atomic mass number. KNIEF, at 29. In general practice, however, the subscript Z is omitted

---

law, which exists between objects that carry the same electrical charge. BODANSKY, at 349 n.3. The repulsion exists not only on a macroscopic scale, but also on an atomic scale, BENNET, at 8, and, therefore, it exists
between the protons in the nucleus because they are positively charged. Consequently, Coulomb repulsion tends to disrupt (or burst) the nucleus. Id. The fact that the nucleus of a stable atom is not disrupted indicates that there is another force which overrides Coulomb repulsion, and holds the nucleus together. Id. This force, known as the "strong" or "nuclear force", exists between particles that are incredibly close to each
other, within about 3 #46# 10-15 meters. The strong force acts with approximately equal strength between two protons, two neutrons or a proton and a neutron and binds the nucleus together, so long as the separation between the particles is less than 3#46# 10-15 meter space in which the strong force operates to cancel Coulomb repulsive. Id.

Coulomb repulsion is not the only electrostatic force defining atomic structure. "Coulomb attraction" exists between oppositely charged particles and this attractive force, operating between the electrically positive protons and the electrically negative electrons, causes the electron to orbit around the nucleus of the atom. RONALD ALLEN KNIEF, NUCLEAR ENGINEERING: THEORY AND TECHNOLOGY OF COMMERCIAL NUCLEAR POWER

29 (2d ed. 1992).

The chemical properties of an element are determined by the number of electrons surrounding the nucleus in an un-ionized atom, and the number of electrons orbiting the atom is equal to the number of protons in the nucleus. BODANSKY, at 346. That is, a neutral atom has the same number of protons and electrons, and the number of protons in the nucleus, (given the symbol "Z"), is the atomic number of a particular element and identifies it. KNIEF, at 29. Electrons are responsible for the chemical behavior of the atoms and they identify the chemical elements. LAMARSH. at 8. Consequently, each element is identified in terms of its atomic number, Z. BODANSKY, at 346.

The number of neutrons in the nucleus is known as the "neutron number" and is denoted by the letter "N". L AMARSH, at 8. The sum of the number of neutrons and protons, i.e., nucleons, in the nucleus is called the atomic mass number or "mass number", A. Thus, the formula: A = Z + N. Id.

because once the element, X, is given, so is the atomic number, Z. BODANSKY, at 346. Nuclides whose nuclei contain the same number of protons, i.e., the same Z, but different numbers of neutrons, i.e., different N and therefore a different mass number, A, are called isotopes of the element. BENNET, at 2. All elements have a number of isotopes, Id., and they are virtually identical in their chemical properties to the elements they are isotopes of. BODANSKY, at 346. However, the masses and other characteristics of their nuclei are different. BENNET, at 2. An isotope of an element is given the same shorthand notation as the nuclide. For example, naturally occurring oxygen, whose chemical symbol is "O", consists of three isotopes, 16 O, 17O, and 18O. Id. Each has 8 protons and electrons, i.e., the same atomic number, Z, but they have 8, 9 and 10 neutrons respectively, i.e., different N (N = A - Z). The nuclei of a given element can have the same mass number, A, but have a different atomic number, Z, in which case it is called an isobar. BODANSKY, at 346.

Though counterintuitive in the extreme, it is nevertheless a fact of atomic structure that the mass of an atom is less than the sum of the masses of its constituent parts. BENNET, at 4; BODANSKY, at 350; KNIEF, at 29; LAMARSH, at 28. The difference between the mass of the assembled atom and the sum of the mass of the component atomic parts is known as the "mass defect". KNIEF, at 29. However, mass is not really lost in the assembly of an atom from its component parts. Rather, the mass defect is converted into energy when the nucleus is formed. Id. The conversion is explained by the "principle of the equivalence of mass and energy in which Einstein stated that mass and energy are different forms of the same fundamental quantity."[20] BENNET, at 4. Therefore, in any reaction where there is a reduction in mass, the decrease is accompanied by a release of energy. Id. The energy associated with the mass defect is called "binding energy" and it represents the total energy that would be required to disassemble a nucleus into its constituent neutrons and protons. BODANSKY, at 350.

---

20. The equivalence between mass and energy is expressed in Einstein's famous equation, E = mc2, where E is energy, m is mass and c is the speed of light. KNIEF, at 28.

Binding energy increases in a nucleus as the number of particles in the nucleus increase. In other words, binding energy increases with a corresponding increase in atomic mass number. LAMARSH, at 28. However, the rate of increase is not uniform. KNIEF, at 30.

The amount of binding energy in a nucleon is important when determining possible sources of nuclear energy. LAMARSH, at 28. A nuclei is stable or tightly bound when the binding energy per nucleon is high. Accordingly, a relatively large amount of energy must be supplied to break the stable nuclei apart. Id. When a tightly bound nucleus is broken apart and two nuclei of intermediate mass are formed, a relatively large amount of energy is released. BENNET, at 7. In contrast, nuclei with low binding energy per nucleon are easily broken apart, and less energy is released. LAMARSH, at 29.

The now familiar term, "nuclear fission" refers to the process of causing a tightly bound nucleus to split into two nuclei of intermediate mass. Id. The process proceeds in the direction of increased binding energy per nucleon. B ENNET, at 7. That is, the nuclei of intermediate mass created by the fission process have greater binding energy than the original nucleus. LAMARSH, at 30. When the nuclei of intermediate mass have greater binding energy than the original nucleus, energy is released during the formation of the final nuclei. BODANSKY, at 351. This energy that is released as a result of the fission process is the source of energy in a nuclear reactor. LAMARSH, at 30. It is what we commonly refer to as "nuclear energy".

Atoms can exist only in certain states or configurations, with each state having its own specific energy. B ODANSKY, at 351. The different energy states correspond to different electron orbits of different radii, LAMARSH, at 15, each with an energy level equal to the sum of the kinetic and potential energies of the electron in its orbit. B ODANSKY, at 351. The lowest state of energy is called the "ground state" and it is the state in which the atom is normally found. LAMARSH, at 15. However, an electron can, as a result of a nuclear reaction, jump from its normal orbit to an orbit that is farther from the nucleus. An increase in energy corresponds to this "jump", and when an atom has more energy than its ground state it is said to be in an"excited state". BENNET, at 8. An atom can have a number of excited states which correspond to the number of jumps the electron has made. Id. The highest energy state occurs when the electron is completely removed from the atom. LAMARSH, at 15. The complete removal of an electron from an atom is called "ionization" and the resulting atom is said to be "ionized". Id.

The nucleons in the nuclei also move in orbits; however, the orbits of nucleons are not as well defined, and are not as well understood, as the orbits of electrons. L AMARSH, at 16. Like atoms, nuclei normally exist in the ground state. BENNET, at 8; BODANSKY, at 352. However, nuclei can reach excited states just as atoms can. BENNET, at 8; BODANSKY, at 352. The process is more complicated in nuclei than in atoms because excitation of nuclei can result in several nucleons being raised to excited levels simultaneously. BENNET, at 8. Although it is not yet possible to account theoretically for the exact energy levels of nuclei, as it is possible to do so for atoms. BODANSKY, at 352. It is generally true that the energies of the excited states and the energies between states are much greater for nuclei than for atoms. LAMARSH, at 16. The greater energy results from the greater forces acting between nucleons. These forces are much stronger that the forces acting between electrons and the nucleus. Id.

With a few exceptions, excited states in either atoms or nuclei exist for only a very short time, about 10^{-14} seconds. BENNET, at 9. Excess energy is quickly emitted and the system, either atomic or nuclear, decays to states of lower energy until it ultimately returns to its ground state. LAMARSH, at 15. The process of going from one state to another is called a "transition". Id. The energy lost in a transition is usually carried off by electromagnetic radiation,[21] BENNET, at 9; BODANSKY, at 352, with the lost

---

21. Sometimes, however, the energy can be transferred to an electron through a process known as "internal conversion" which leaves the nuclide unchanged. At other times, an excited state can decay be emitting a particle, such as a beta (b) particle or a neutron, thus changing the atomic number of the nuclide. BODANSKY, at 352 n.8.

energy equal to the difference in the energies of the two states.[22] LAMARSH, at 15.

2. Radioactivity.

As suggested by our discussion thus far, nuclei are either stable or unstable. For all practical purposes, stable nuclei remain unchanged forever. Unstable nuclei decay spontaneously into lighter nuclei pursuant to a time scale that is unique for every element (the "half-life").[23] The half-life for a given element is defined as the time required for one-half of a given sample of the element to "decay." If the half-life is greater than some undefined fraction of a second, the process of decay is called "radioactivity." Half-lives vary from less than a second to many billions of years. BODANSKY, at 353. Radioactivity is then, the process by which unstable nuclei seek stability. KNIEF, at 31. Frequently, the original unstable nucleus, called the "parent nucleus", decays to another radioactive nucleus, called the "daughter nucleus." LAMARSH, at 19. There may be more than one radioactive daughter nuclei produced until stability is reached. BENNET, at 11. This process of the creation and subsequent decay of several daughter nuclei is referred to as a "decay chain". LAMARSH , at 19.[24]

---

22. The electromagnetic radiation corresponding to an atomic or nuclear transition is contained in a single discrete packet called a "photon". BODANSKY, at 352. At one time, light and other forms of electromagnetic radiation were described as waves. However, it is now known that electromagnetic radiation behaves at times like a particle. Id. Thus, a photon is both wave-like and particle-like in character. LAMARSH, at 7. Visible light is associated with transitions involving the outer electrons of atoms. X rays correspond to transitions involving the inner electrons of atoms. Gamma (g) rays correspond to transitions from nuclei. However, all are photons and there is no difference among them other than their energy, with visible light having the lowest energy and gamma (g) rays having the highest energy. In fact, there is really no need to distinguish between photons from atomic transitions, i.e., x rays, and photons from nuclear transitions, i.e., g rays. The names date from the time of their discovery and are probably kept only as a reminder of their origin. BODANSKY, at 352.

23. Sometimes designated as: "T1/2 ".

24. For example, there are three natural radioactive decay chains whose parent isotopes have very long-half lives. The three are uranium 238 (T1/2 = 4.51 x 109 years), uranium 235 (T1/2 = 7.1 46 x 108 years), and thorium 232 (T1/2 = 1.41 x 1010 years), and their decay chains contain many radioactive daughter isotopes leading eventually in each case to a stable isotope of lead. BENNET, at 18-19.

The exact time at which any single nucleus will decay cannot be determined. KNIEF, at 34. However, the average behavior of a very large sample of radioactive material can be described statistically. BENNET, at 15. For a given nuclide, there is an average time, called the "decay constant", which characterizes its rate of decay. Id. The decay constant is defined as the probability per unit of time that a decay will occur. KNIEF, at 34. The amount of radioactivity present during a decay is referred to as "activity". F RED A. METTLER, JR., M.D., AND ARTHUR C. UPTON, M.D., MEDICAL EFFECTS OF IONIZING RADIATION 7 (2d ed. 1995) (hereinafter "MEDICAL EFFECTS"). The activity of a given sample is the average number of disintegrations per unit of time. For a large sample, the activity is the product of the decay constant and the number of atoms present. Id. The traditional unit for measuring radioactivity is the curie (Ci), which is defined as 3.7 #46# 1010 disintegrations per second.[25]

A radioactive nuclide is called a "radionuclide." KNIEF, at 32. During the process of radioactive decay, the nucleus spontaneously emits an alpha (a) particle or a beta (b) particle. BODANSKY, at 354. The emission of these particles is often accompanied by the emission of one or more gamma (g) rays. Id. An alpha (a) particle is a highly stable nucleus of the isotope helium 4 (4He), consisting of two protons and two neutrons. LAMARSH, at 20.[26] Alpha (a) particles have a double positive charge and are emitted in a discrete energy spectrum. Id. They have a low level of energy and, therefore, are only capable of penetrating matter a small distance.[27]

Decay by alpha particle emission is rather rare for nuclides lighter than lead (Pb) which has an atomic number (Z) of 82. BODANSKY, at 355. However, many of the naturally

---

25. The curie, is however, being superseded by a new measuring unit called the "Becquerel" (Bq), which is defined as one disintegration per second. BENNET, at 16.

26. Thus, the emission of an alpha (a) particle reduces the atomic number (Z) of the unstable nuclei by two and the mass number (A) by four. LAMARSH, at 20.

27. The most energetic of the alpha (a) particles are stopped after passing through less than 10 centimeters of air or about 0.1 millimeters of a material such as water. BODANSKY, at 355.

occurring radioactive elements with atomic numbers between 84 (polonium) and 92 (uranium), i.e., the heavier elements, decay by alpha particle emission. BENNET, at 13. When these elements decay, the daughter product is closer to the stability region than the parent. Id. In addition, the daughter nucleus of these heavier elements is frequently formed at an excited state of energy so that the excited nucleus immediately decays further to its ground state by the emission of gamma (g) radiation. Id. Thus, the decay of a heavy radioactive isotope by alpha particle emission also produces gamma (g) radiation. Id.

A beta (b) particle is an electron of nuclear, not orbital, origin, KNIEF, at 33, but it is identical to the electrons that orbit the nucleus. BODANSKY, at 355. Because it is an electron, it has much less mass than an alpha particle. Id. A neutron that is bound into the nucleus is not stable. LAMARSH, at 7. During decay, a neutron in the nucleus is transformed into a proton and an electron and it is this electron which is emitted as a beta (b) particle. Id.; BENNET, at 13.

Because beta (b) particle decay has the effect of transforming one of the neutrons into a proton, the resulting daughter nucleus has the same mass number (A) as the parent, but its atomic number (Z) is greater by one. Id. Moreover, the daughter nucleus may be formed in an excited state, and decay to its ground state by the emission of gamma (g) radiation. Id.

In most cases, beta particles are negatively charged and are more properly designated as b- particles. Positive electrons, called "positrons" or b+ particles, are emitted from artificial radionuclides that are produced when positive particles, such as protons or alpha (a) particles, combine with a nucleus to form an unstable proton-rich nucleus. BODANSKY, at 355. These beta particles are very rare in naturally existing material. Id.

Beta (b) particles do not all have the same energy. BENNET, at 13. The spectrum of the energy of these particles, ranges from zero to a fixed maximum or "endpoint energy." BODANSKY, at 357.[28] However, the average energy of beta

---

28. The endpoint energy corresponds to the mass difference between the parent atom and the residual product, as the principle of conservation of mass plus energy demands. BODANSKY, at 357.

particles is about one-third, BENNET, at 13, to one-half, BODANSKY, at 357, the endpoint energy. The remaining two-thirds to one-half of maximum possible beta (b) particle energy is shared with another particle called the neutrino.29 BENNET, at 13; BODANSKY, at 357. A neutrino is one of nature's more curious phenomena. It has no charge, and virtually no mass. KNIEF, at 33. It was once thought to have no mass; however, it is now believed that the neutrino may have mass, albeit very small mass. BODANSKY, at 357; Malcolm W. Browne, Los Alamos Experiment Shows Neutrino Probably Has Mass, N.Y. Times, May 7, 1996.

Beta (b) particle decay usually occurs when a nuclide has an excess of neutrons. BENNET, at 13; B ODANSKY, at 358. A beta particle has greater penetrating ability than an alpha particle, BENNET, at 21, with average penetration distances ranging from 0.1 to 1 g/cm2, increasing with increasing energy. BODANSKY, at 355. A neutrino, however, has great penetrating power and can pass through very large amounts of material without stopping. Id. at 358.

As discussed earlier, gamma (g) radiation is electromagnetic radiation emitted in the form of photons by nuclei in excited states of energy. Except as noted below, gamma (g) emission is not a primary process of radioactive decay. Instead, it follows alpha (a) particle or beta (b) particle emission. Gamma (g) rays do not have mass or charge, and they are therefore capable of much greater penetration of matter than alpha (a) or beta (b) particles.30 BODANSKY, at 355.

Earlier, we noted that excited states in nuclei exist for a very short time (about 10-14 seconds). Consequently, half-lives for gamma (g) ray emission are typically very short. BODANSKY, at 359. However, some nuclei have long-lived

---

29. Strictly speaking, the neutrino emitted in b#48# decay is an anti-neutrino, while the neutrino itself is emitted in b+ decay. When the distinction between them is not important, they are both referred to as neutrinos. Again, strictly speaking, the b#48# and neutrino are called particles, while the b+ and anti-neutrino are called anti-particles. BODANSKY, at 357.

30. Gamma rays can penetrate to distances ranging from 5 to 20 g/cm2. BODANSKY, at 355.

excited states, called "isomeric states", with half-lives ranging from a fraction of a second to many years. Id. In fact, in some cases, the excited state is so long that the nuclei appear semi-stable. LAMARSH, at 21. The decay to a lower state of energy by gamma (g) ray emission in a nuclei in an isomeric state is called an "isomeric transition". Id. In such a case, gamma (g) ray emission appears to be the primary radioactive process of, rather than incident to, alpha (a) or beta (b) particle emission. Gamma ray emission can, however, ultimately be traced back to either initiating process.31 BODANSKY, at 359.

3. Ionizing Radiation.

The legal dispute before us is rooted in the damage that purportedly resulted from defendants' release of ionizing radiation into the atmosphere. There are a number of ways in which an ion, or charged particle, can interact with an atom. First, because it is charged, the particle exerts an electrostatic or "Coulomb force" on the atom's electrons. The exertion of Coulomb force has various effects upon an atom. One or more of the electrons may move to an outer orbit, leaving the atom in an excited state of energy or an electron may be entirely ejected from the atom. The latter event results in the formation of an ionized atom. L AMARSH, at 88. When an atom is ionized, it is split into an ion pair. The negatively charged electron of this pair is the negative ion, and the atom minus its negatively charged electron is the positive ion. BENNET, at 20. This process of ionization produces ionizing radiation.32 MEDICAL EFFECTS, at 1.

The second possible result is that the charged particle may penetrate the cloud of orbiting electrons and collide with the nucleus. After collision, the charged particle is scattered from the nucleus, and, since momentum and

---

31. There is an alternative to gamma (g) ray emission called "internal conversion", in which the excitation energy is transferred to one of the inner electrons of the atom. Typically, gamma (g) ray radiation and internal conversion are competing processes by which excited nuclei reach the ground state. BODANSKY, at 359.

32. Ionizing radiation is only a small part of the electromagnetic spectrum, which includes radio waves, radar, microwaves, ultraviolet radiation and electric power. MEDICAL EFFECTS, at 1-2.

energy are conserved in the collision, the nucleus recoils. If the charged particle has sufficient mass and energy, the recoiling nucleus may be ejected from its own electron cloud and itself become a charged particle. LAMARSH, at 88. In addition, under certain circumstances, the charged particle, particularly if it is an alpha (a) particle, may undergo a nuclear reaction when it collides with the nucleus. The charged particle may also be accelerated by the electrostatic or Coulomb field of the electrons or the nucleus and a photon may be emitted.33 Id.

Whichever of these alternative results occurs, a charged particle is created. When a charged particle passes through matter, it excites and ionizes atoms in its path. Id. However, these charged particles lose energy by virtue of the electrostatic forces created by their interaction with the atoms that comprise the matter through which the charged particles pass. KNIEF, at 70. The electrostatic forces acting upon the charged particles are proportional to the product of the charges and inversely proportional to the square of the distance between them. Thus, the force decreases rapidly with distance, but becomes negligible only at very large distances. Id. At any given interval, a charged particle experiences forces from a very large number of electrons. The resulting energy losses are well defined for each charged particle and each material medium. Id. The net macroscopic effect of charged-particle interactions is characterized by range and linear energy transfer ("LET"). Id. Range is the average distance traveled by a charged particle before it completely stops. The LET is the amount of energy deposited per unit of particle track, which gives rise to the excitation and ionization. LAMARSH , at 89. The range and the LET of a specific radiation contribute to the effect they have on a material, with the range determining the distance of penetration and the LET determining the distribution of energy deposited along the path. K NIEF, at 70.

The LET is of particular significance to an inquiry into the biological effects of radiation. Those effects depend

---

33. This latter kind of radiation that is emitted when a charged particle becomes accelerated, is called "bremsstrahlung". Id. LAMARSH, at 88.

upon the extent to which energy is deposited by radiation as excitation and ionization within a given biological system. LAMARSH, at 89. The LET increases with the mass and charge of a moving particle. Id. Consequently, heavy charged particles, such as alpha (a) particles, are referred to as high LET radiation. Id.

Charged particles, are referred to as "directly ionizing radiation" because they are directly responsible for producing ionization. LAMARSH, at 88; B ENNET, at 20; BODANSKY, at 354. Uncharged particles, such as gamma (g) rays, lead to excitation and ionization only after interacting with matter and producing a charged particle. Accordingly, uncharged particles are referred to as "indirectly ionizing radiation." LAMARSH, at 88.

While gamma (g) rays can interact with matter in a variety of ways, there are, for purposes of our analysis, three important types of interaction between gamma (g) radiation and matter -- the "photoelectric effect", "pair production" and "Compton scattering." BENNET, at 21. Because very short-range forces govern electromagnetic mechanisms, a gamma (g) ray must essentially"hit" an electron for an interaction to occur. KNIEF, at 71. In the photoelectric effect, which is the most important process at low gamma (g) ray energies, BENNET, at 199, the gamma (g) ray interacts with the entire atom, the gamma (g) ray disappears and one of the atomic electrons is ejected from the atom. LAMARSH, at 79. As a result, the energy of the gamma (g) ray or photon is converted completely to kinetic energy of an orbital electron. KNIEF, at 71. If the gamma (g) ray ejects an inner electron, the resulting hole in the electron cloud is filled by one of the outer electrons. LAMARSH, at 16, 79. This transition is accompanied either by the emission of an X ray or by the ejection of another electron.

Pair production occurs only for high-energy gamma (g) rays and only in the vicinity of a heavy nucleus. Id. at 80; BENNET, at 21. The gamma (g) ray is annihilated; and an electron pair -- a positron and a negatron -- is created. LAMARSH, at 80. When this occurs the energy of the gamma (g) ray converted to mass, and kinetic energy of the electron pair. KNIEF, at 71. Once they are formed, the positron and negatron move around and ultimately lose energy as a result of collisions with atoms in the surrounding matter. LAMARSH, at 80. After the positron has slowed to very low energies, it combines with a negatron, the two disappear and two photons are produced. LAMARSH, at 80-81. The photons that are produced are called "annihilation radiation." Id. at 7.

Compton scattering occurs when the gamma (g) ray strikes an electron and is scattered. The electron that is struck in this process recoils and acquires some of the kinetic energy of the gamma (g) ray, Id. at 81, thus reducing the energy level of the reaction. KNIEF, at 71. Since the gamma (g) ray does not disappear as it does during the photoelectric effect, and is not annihilated as it is in pair production, the Compton-scattered gamma (g) ray is free to interact again. LAMARSH, at 82.

Although uncharged particles cause indirect ionizing radiation, it is nonetheless possible to refer to the LET of uncharged particles. However, because they have a relatively low rate of energy loss when compared to the rate of energy loss of charged particles, gamma rays (g) are referred to as "low LET radiation." LAMARSH, at 89. The distinction between high LET radiation and low LET radiation has important biological consequences. Id. Given the same dose of radiation, biological damage from high LET radiation is much greater than damage from low LET radiation. Id. at 402.

4. Radiation Quantities and Units.

Radiation can be measured by counting the number of ionized particles it produces as it passes through air. INTERNATIONAL ADVISORY COMMITTEE, THE INTERNATIONAL CHERNOBYL PROJECT, TECHNICAL REPORT 20 (1991) (hereinafter "CHERNOBYL "). Originally, the amount of radiation exposure for X- and gamma (g) radiations was measured in units of the roentgen (R), KNIEF, at 72, which is defined as the number of electrical charges produced in a unit mass of air. CHERNOBYL, at 20.[34] Alternatively, a roentgen can be defined

---

34. One roentgen is that quantity of X or gamma (g) radiation which produces a total charge of one electrostatic unit of either sign in one cubic centimeter of air at 1 atmosphere at 0o Celsius. LAMARSH, at 400.

in terms of the amount of energy released in the production of ions with a total charge of one electrostatic unit of either sign. BENNET, at 197.[35] Thus, the roentgen is a unit of exposure in air and not a unit of radiation dose to body tissue. Moreover, it is not applicable to higher energy X-rays or to particulate radiations. MEDICAL EFFECTS, at 8. Consequently, the roentgen is not very useful for comparing the effects of various radiations on biological systems, particularly the human body. KNIEF, at 73.

When radiation penetrates material, its energy is absorbed and released by the constituent atoms of the material that is penetrated. CHERNOBYL, at 20. The absorbed energy per unit mass of material is termed the "absorbed dose." Id.[36] Two units are used to measure absorbed dose of any type of radiation. The original unit of absorbed dose is the "rad" (radiation absorbed dose) and is defined as 100 ergs of energy per gram of material. LAMARSH, at 401. The new unit of absorbed dose under the Systeme International d'Unites ("SI")[37] is the gray ("Gy"), which is defined as one joule of energy absorbed per kilogram of matter. CHERNOBYL, at 20. Because a rad and a gray are defined in terms of energy, it is possible to equate rads with grays, with one gray being equivalent to 100 rads (1Gy = 100 rads), or one

---

35. Under this definition, a roentgen is equivalent to depositing about 88 "ergs" in 1 gram of air. KNIEF, at 73. An "erg" is a unit of energy and one roentgen under the alternative energy description is energy sufficient to move the point of a sharpened pencil about 1.5 millimeters across a piece of paper. Id.

36. Heavy, highly charged particles, such as alpha (a) particles, lose energy rapidly over distance and, therefore, do not penetrate matter deeply. For example, alpha (a) particles do not penetrate the layer of dead cells on the surface of the skin. CHERNOBYL, at 19. Beta (b) particles, because of their smaller charge and much smaller mass, are much more penetrating, BENNET, at 20, and may penetrate up to several centimeters into the body. CHERNOBYL, at 19. X- and gamma (g) rays have much greater penetrating power than either alpha (a) or beta (b) particles, BENNET, at 20, and they are therefore used for medical diagnostic purposes. CHERNOBYL, at 19.

37. The SI is a modernized metric system which is becoming the standard for expressing scientific and technical data. However, much scientific and technical literature still contains the older, more customary units. KNIEF, at 671

rad equivalent to 10 milligrays (1 rad = 10 mGy). 38 MEDICAL EFFECTS, at 8.

However, the absorbed dose is not the only factor to be considered in estimating radiation effects on the human body. The effects also depend on the LET of the radiation. KNIEF, at 73; LAMARSH, at 402. Even when the amounts of energy absorbed are the same, alpha (a) particles are more damaging to human tissue than gamma (g) radiation because of the higher LET of alpha (a) radiation. BENNET, at 198. The fact that different types of radiation have different biological effects for the same absorbed dose is described in terms of the relative biological effectiveness ("RBE") of the radiation. LAMARSH, at 402. The RBE depends on the dose, the dose rate, the physiological condition of the subject, and various other factors. The RBE is determined through experimentation. KNIEF, at 73; LAMARSH, at 403. Accordingly, there is no one RBE for a given type of radiation, and the unit is used almost exclusively in radiobiology. L AMARSH, at 403.

RBE is, however, used to approximate the quality factor ("Q") of radiation, which is usually the upper limit of RBE for a specific type of radiation. Id.; K NIEF, at 73. For example, X-rays and gamma (g) rays have a Q of 1, beta (b) particles have a Q of 1 to 1.7, depending on their energy, and alpha (a) particles have a Q of 20. C HERNOBYL, at 20; KNIEF, at 74. To estimate the effect of a given type of radiation on body tissue, it is necessary to determine the dose equivalent. The dose equivalent is arrived at by multiplying the absorbed dose by the quality factor of the radiation. The original unit of dose equivalence is the "rem" (roentgen equivalent man) and is the product of the absorbed dose in rad and the Q of the particular radiation. LAMARSH, at 404. Thus, if the radiation is gamma (g)

---

38. There is another type of unit which is sometimes used for very high energy radiation and for particulate radiation. That unit is the "kerma" (kinetic energy released inmatter) and it is used because it includes not only the energy deposited in the local area but also the additional energy deposited as a result of bremsstrahlung. For most purposes, the rad and the kerma are interchangeable. A major exception is the calculation of doses for atomic bomb survivors. There, the kerma was higher than the rad. MEDICAL EFFECTS, at 8.

radiation, then an absorbed dose of 1 rad produces a dose equivalent of 1 rem, and if the radiation is alpha (a) particle radiation, then an absorbed dose of 1 rad produces a dose equivalent of 20 rem. The new SI unit of dose equivalence is the sievert (Sv) and is the product of the absorbed dose in gray (Gy) and the Q of the radiation. BENNET , at 198. Since one gray equals 100 rads (1 Gy = 100 rads), then one sievert equals 100 rem (1 Sv = 100 rem), LAMARSH , at 404, or one rem equals 10 millisieverts (1 rem = 10 mSv). MEDICAL EFFECTS, at 8.

The effect of a given dose equivalent varies depending on the tissue or organ exposed to the radiation. CHERNOBYL, at 20. For example, a given dose of radiation to the hand may have a different and far less serious effect than the same dose delivered to a blood-forming organ. Similarly, the biological effect of a given dose of radiation to a blood-forming organ will be different from a like exposure to reproductive tissue. LAMARSH, at 404. However, equal dose equivalents from different sources of radiation, if delivered to the same point in the body, should have approximately the same biological effect. Id. at 403.

The "effective dose" (E), is a unit that is derived from the equivalent dose in an attempt to indicate the combined effect of different doses of radiation upon several different tissues or body parts. CHERNOBYL, at 20. The effective dose is the product of the equivalent dose in a tissue or organ (T) multiplied by a factor called the "tissue weighing factor" (WT), which represents the contribution of that tissue or organ to the total harm resulting from uniform radiation exposure to the whole body. Id.[39]

Each of the preceding units, (i.e., absorbed dose, equivalent dose and effective dose) relate to the radiation exposure of an individual. There are, however, units of exposure for groups of people. They are arrived at by

---

39. By way of illustration, the tissue weighing factor for the gonads is 0.20, the tissue weighing factor for red bone marrow is 0.12, and the tissue weighing factor for the skin and bone surface is 0.01. CHERNOBYL, at 20. The effective dose is the weighted sum of the equivalent doses in all the tissues and organs of the body and is a measure of the total risk from any combination of radiations affecting any organs of the body. Id.

multiplying the average dose to the exposed group by the number of people in the group. CHERNOBYL, at 20-21. The units are the "collective equivalent dose," which relates to a specified tissue or organ, and the "collective effective dose," which relates to all the people exposed to the radiation. Id. Both units are expressed in terms of man-rems or man-sieverts. LAMARSH, at 405, and they represent the total consequences of the exposure of a population or group. CHERNOBYL, at 21.

5. Health Effects of Ionizing Radiation.

Soon after the discovery of x-rays and natural radioactivity, clinical evidence suggested that ionizing radiation is harmful to human tissue. ANNALS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, ICRP PUBLICATION 60, 1990 RECOMMENDATIONS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL P ROTECTION 94 (1990)(hereinafter "ICRP 60"). The initial evidence was mainly noted from the effect of ionizing radiation on human skin.40 Id. at 92. Later, scientists realized that exposing germinal tissue in plants and animals to ionizing radiation produced effects not only in the plants and animals that were actually exposed, but also in subsequent generations of the exposed plants and animals. Id. Scientific studies and investigations over the last century, have now given us a wealth of information about the effects of radiation on humans.41 These studies include extensive in vitro and in vivo animal experiments, Id., the comprehensive epidemiological studies of the survivors of the atomic bombings of Hiroshima and Nagasaki, studies of x-rayed tuberculosis patients; and studies of people exposed to ionizing radiation during treatment for ankylosing spondylitis, cervical cancer and tinea capitis. NATIONAL RESEARCH COUNCIL, COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, HEALTH EFFECTS OF EXPOSURE TO LOW LEVELSOF IONIZING RADIATION 2(1990)

---

40. Ionizing radiation causes nonmalignant skin damage called erythema or reddening of the skin. LAMARSH, at 409.

41. One commentator has noted that "more than 80,000 studies have been reported in the scientific literature, indicating that radiation effects
have been studied far more thoroughly than other environmental impacts." KNIEF, at 77.

(hereinafter "BEIR V"). These studies have allowed science to "narrow the range of uncertainties in human radiobiology." CHERNOBYL, at 37.

As noted earlier, an atom is ionized when an electron is ejected from its orbit and expelled from the atom. As ionizing radiation passes through human tissue, it can transfer its energy along the tracks of the charged particles to the atoms and molecules of the tissue and ionize the atoms and molecules of that tissue. CHERNOBYL , at 37.

There are two mechanisms by which ionizing radiation can alter human cells. LAMARSH, at 409. First, the ionization can directly alter biological structures by the disruption or breakage of molecules. Id.; ICRP 60, at 96. Second, biological structures can be altered indirectly by chemical changes set in motion by the transfers of energy to the medium as the ions pass through the molecular structure of human tissue. ICRP 60, at 96. Most of this energy transfer takes place in the water of our cells simply because water is the major component of the human body. 42 MEDICAL EFFECTS, at 13; BEIR V, at 12. When an ionizing particle passes through a water molecule, it may ionize it and produce an ionized water molecule, H2O+, and an electron. The electron can be trapped and produce a hydrated electron, eaq. BEIR V, at 12. However, the ionized water molecule, H2O+, reacts with another water molecule to produce a free radical called the "hydroxyl radical, OH." Id.43 This particular free-radical is very reactive because it has an unpaired electron and seeks to pair its electron in order to stabilize itself. BEIR V, at 13. At high initial concentrations, back reactions occur which produce hydrogen molecules, hydrogen peroxide and water. Id. However, the water molecule is not always ionized in this process. It can also simply become excited and break up into the hydrogen radical, H., and the hydroxyl radical, OH.. Id.

The result of this chemical process is the formation of the

---

42. Human cells are made up of 70% water. MEDICAL EFFECTS, at 13.

43. A free radical is an atom or molecule that has a single unpaired electron. MEDICAL EFFECTS, at 13.

three highly reactive species: the hydrated or aqueous electron, eaq, the hydroxyl radical, OH., and the hydrogen radical, H.. Id. All three are highly reactive and can damage the molecular structure of human cells. Id. Free radicals are produced almost immediately after an energy transfer.44 They move rapidly in the medium, can travel some distance from the site of the original event that creates them, and they can cause chemical changes in the medium. Id. However, even though free radicals are highly reactive and potentially very dangerous to the structure of cells in human tissue most recombine to form oxygen and water in about 10-5 seconds without causing any injury. MEDICAL EFFECTS, at 13.

Ionization radiation can damage cells whether the radiation results directly from the electrons set in motion or indirectly by the chemical production of free radicals. CHERNOBYL, at 37. A great deal of evidence suggests that DNA is the principal target in an irradiated cell, and is the most critical site for lethal damage. ICRP 60, at 96; BEIR V, at 13. DNA is believed to be the "critical cellular component injured," as low doses of radiation. MEDICAL EFFECTS, at 16. The random character of energy absorption events caused by ionizing radiation can damage vital parts of DNA in several ways including single-strand or double-strand breaks in the DNA molecule. ICRP, at 96. However, it has been postulated that the majority of DNA strand breaks are not due to the direct effects of ionizing radiation, but rather are caused by the hydroxyl radical. MEDICAL EFFECTS, at 14; see also BEIR V, at 14. Irradiation can also cause a number of recombinational changes to cells. ICRP 60, at 96.

Not all irradiation-caused damage to DNA is harmful. Cells have evolved complex repair systems and when a single-strand break occurs, it is quite possible that the site of the damage can be identified and the break very quickly repaired. Id.; CHERNOBYL, at 38. In such a case, the DNA structure is returned to its original form, and there is no long term cellular consequence. ICRP 60, at 96. For example, if ionizing radiation affects a single protein within

---

44. A They are created in about 10-12 seconds. BEIR V, at 13.

a cell, the cell can simply produce a new protein and there is no functional change. CHERNOBYL at 37. Alternatively, the repair may not return to DNA to its original form, but DNA integrity may be retained. Id.

While it is possible for double strand breaks in DNA to be repaired, the consequences of a double strand break are very serious. ICRP 60, at 96. Chromosomal aberrations are a result of DNA that is damaged by irradiation. These aberrations can be measured quantitatively as a function of absorbed dose. Id. at 97. The outcome could be cell reproductive death, misrepair reflected in a mutation or extensive gene deletion. Id. at 96.

If cellular damage is not repaired, it may prevent the cell from surviving or reproducing, or it may result in a viable but modified cell. CHERNOBYL, at 38. The two outcomes have severe, and different, implications for the human body, leading to either "deterministic" or "stochastic" effects. Id. Deterministic effects are entirely predictable and their severity is an inevitable consequence of a given dose. LAMARSH, at 409. Stochastic effects are those that occur at random, i.e., they are of an aleatory or statistical nature. CHERNOBYL, at 38. Thus, stochastic effects are those whose probability of occurrence, as opposed to severity, is determined by dose. LAMARSH, at 409.

i. Deterministic Effects.

Deterministic effects result when an organism can no longer compensate for the extent of dead cells by proliferating viable cells. ICRP 60, at 99. Cell death or cell killing is the main process involved in deterministic effects. Id. Unless the dose is very high, most types of cells are not immediately killed, but continue to function until they attempt to divide. Id. The attempt to divide will fail, probably because of severe chromosome damage, and the cell will die.[45] Id. Cell death usually becomes apparent within a few hours or days after irradiation. Id. at 97.

---

45. Although individual cell death in a tissue is stochastic, the total effect of the death of a high number of cells in a tissue is deterministic.
ICRP 60, at 99; CHERNOBYL, at 38.

Cell death is not always life threatening because most body organs and tissues are unaffected by the loss of even a substantial number of cells. CHERNOBYL, at 38. It is only when a tissue or organ absorbs a certain threshold dose high enough to kill or impair the reproduction of a significant fraction of vital cells within the tissue or organ that there is a clinically detectable impairment of function. ICRP 60, at 99. If enough cells are killed, the function of the tissue or organ is impaired. Id. at 97. In extreme cases the organism dies. Id. The severity of the effect is dependent on the dose. Id. Thus, the likelihood of a deterministic effect is zero at a dose lower than some threshold, but the likelihood increases to certainty above such a threshold dose, with the severity of the harm increasing with dose. CHERNOBYL, at 38-39.

Cells that divide rapidly are very sensitive to radiation and it is in these cells that the damage from radiation appears to be the greatest. KNIEF, at 75. Such cells include lymphocytes, immature bone marrow cells and intestinal epithelium. Slightly less sensitive cells include those of the lens of the eye and the linings of the stomach, esophagus, mouth and skin. Cells of intermediate sensitivity include those of the liver, kidneys, lungs, thyroid andfibrous tissue. Cells that divide slowly or not at all are the least sensitive to radiation. CHERNOBYL, at 39. These include mature red blood cells, muscle connective tissue as well as bone, cartilage and nervous tissue. Id. Thus, if a person receives a whole body absorbed dose of 1 Gy or 100 rad, generally only those cells with very high sensitivity would be killed. However, as the whole body absorbed dose is increased, additional cells and organs could die and thereby alter the person's clinical presentation. Id. Obviously, if exposure to ionizing radiation results in damage to vital organs or tissues, it may well be fatal. Id.

The likelihood of a deterministic effect is practically zero for absorbed doses below 1 Gy or 100 rad. Above that absorbed dose level, deterministic effects occur. Some examples of deterministic effects are erythema, bone marrow depression, radiation cataracts, sterility, and acute radiation syndrome. Id.; MEDICAL EFFECTS, at 280.46

Clinically significant bone marrow depression has a threshold for acute absorbed doses of about 0.5 Gy or 50 rad and for protracted exposure over many years of about 0.4 Gy or 40 rad per year. CHERNOBYL, at 39. Absent appropriate medical care, bone marrow depression will result in half of the people in a heterogeneous population who are acutely exposed to a dose of about 3 to 5 Gy or 300 to 500 rad.47 Id. The threshold for opacities significant enough to cause vision impairment (which occurs after some delay) appears to be in the range of 2 to 10 Gy or 200 to 1000 rad for an acute exposure to x-rays or gamma (g) rays. The threshold for chronic exposure over many years is thought to be about 0.15 Gy or 15 rad per year. Id.

Death is almost certainly the deterministic effect for an individual exposed to a whole body dose of about 6 Gy or 600 rad or higher over a short period. Id. A 3 Gy or 300 rad dose would be lethal for half of an irradiated population who receive little or no medical care, the so called"median lethal dose". Id. However, it has been postulated that for people in good health who receive very intensive medical treatment, the median lethal dose may be from 5 Gy or 500 rad to as high as 9 Gy or 900 rad. Id.

---

46. The threshold for temporary sterility in men for a single absorbed dose to the testis is about 0.15 Gy or 15 rad and the threshold under conditions of prolonged exposure is about 0.4 Gy or 40 rad. CHERNOBYL, at 39. The threshold for permanent sterility is 3.5 to 6 Gy or 350 to 600 rad for acute exposure and 2 Gy or 200 rad for prolonged exposure. Id. The threshold for permanent sterility in women is an acute absorbed dose between 2.5 to 6 Gy or 250 to 600 rad or a protracted dose over many years of about 0.22 Gy or 22 rad. Id.

47. The estimate of the number of people who would die within a certain number of days without medical attention following a significant whole body absorbed dose is called the "lethal dose estimate" and, in this example, would be expressed as "LD50/60", meaning "Lethal Dose for 50% of the population within 60 days without medical attention." KNIEF, at 76.

ii. Stochastic Effects.

Stochastic effects are those which result when an irradiated cell is modified rather than killed. C HERNOBYL, at 39. Even at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to modify it. ICRP 60, at 98. Thus, there is a finite possibility for the occurrence of a stochastic event even at very small doses. Id. Consequently, it is assumed that there is no threshold for the initiation of a stochastic event. Id. , at 98; MEDICAL EFFECTS, at 73. Put another way, it is believed that stochastic effects can occur even at the lowest doses and, therefore, the possibility of a stochastic effect has to be taken into account at all doses. ICRP 60, at 67. The probability that cancer will result from radiation increases proportionally with dose. ICRP 60, at 69. CHERNOBYL, at 40. However, it is currently believed that there is no threshold dose below which the probability of cancer induction is zero. ICRP 60, at 69; CHERNOBYL, at 40. It is presumed that any transformed cell can become cancerous and become a malignant tumor. CHERNOBYL, at 40.

There are two generally recognized types of stochastic events. The first can occur in somatic cells and may result in the induction of cancer in the exposed person. The second can occur in cells of the germinal tissue and may result in hereditary disorders in the descendants of the irradiated.48 CHERNOBYL, at 39-40; ICRP 60, at 69, 106-07. However, even though hereditary stochastic effects have been demonstrated on highly irradiated mice, CHERNOBYL, at 42, hereditary stochastic effects have not yet been clearly demonstrated in humans. BEIR V, at 4. Thus, any such effects are based on extrapolation from mice to humans.49

---

48. "There are approximately 4 #46# 1013 cells in the average adult person.
. . . [and they] are divided into two broad classes: somatic cells and germ
cells. Almost all of the cells in the body are somatic cells. These are the
cells that make up the organs, tissues, and other body structures. The germ cells, which are also called "gametes", function only in reproduction." LAMARSH, at 406.

49. Such extrapolation has led to the estimate that at least 1 Gy or 100 rad of low-dose, low LET radiation is necessary to have any hereditary stochastic effect on humans. BEIR V, at 4.

Genetic studies of the almost 15,000 children of the survivors of the atomic bombing in Japan have not yielded evidence of a statistically significant increase in severe hereditary effects. CHERNOBYL, at 42; BEIR V, at 4. Of course, the difficulties encountered in studying the probability of hereditary effects are formidable and include the need to monitor very large numbers of people in irradiated and controlled populations. The difficulty is increased because hereditary effects caused by radiation may be indistinguishable from hereditary disease due to other causes. CHERNOBYL, at 42.

It is cancer induction -- the first stochastic event -- that it as issue here. The cell modification caused by ionizing radiation is presumably the result of specific molecular DNA changes by a process known as "neoplastic transformation." It is assumed that there is no threshold for the induction of the molecular changes at the DNA site. ICRP 60, at 97, 107. The potential for unlimited cellular proliferation characteristically results from molecular changes. Id., at 107. Nevertheless, this change alone does not result in a malignant transformation because other changes occur in a malignant transformation. Id. Carcinogenesis is currently believed to be a multistep process requiring two or more intracellular events to transform a normal cell into a cancer cell. BEIR V, at 135. The changes that occur are believed to proceed sequentially. ICRP 60, at 97. The initial events in the production of a cell or cells with the potential to develop into a cancer are known as "initiation". Id. The initiated cell or cells must undergo further changes, usually after a long time and possibly after stimulation by a promoting substance or catalyst, before becoming a cell with malignant potential. Id. Thereafter, the division and multiplication of such cells gives rise to an occult tumor in the "progression" stage. Id. at 97-98. "Progression" refers to the proliferation of a subpopulation of cells within a tumor. BEIR V, at 137. This subpopulation expands and overgrows the less aggressive cells. Id. The carcinogenic process, includes the growth of a primary cancer to a detectable size (e. g., about 1 cm in diameter and containing billions of cells). In humans it can take many years for such a tumor to spread to other tissues. ICRP 60, at 98.

The period between exposure to radiation and possible detection of a resulting cancer is called the "latency period". Id. at 107. By way of example, the median latency period for induced leukemia may be about 8 years. The latency period for many induced solid tumors, such as tumors of the breast or lung. Id. The "minimum latency period" is the shortest time in which a specified radiation-induced tumor is believed to occur after exposure. Id. It is about two years for acute myeloid leukemia, and between 5 and 10 years for other types of cancers. Id.

Significantly, the severity of a cancer does not depend on the level of the dose that triggered it. ICRP 60, at 60; CHERNOBYL, at 40. The mathematical model used to describe radiation induced cancer is the "linear risk model". BEIR V, at 4; CHERNOBYL, at 40. It is expressed as $y = ax$, where y is the incidence of excess cancer, a is a constant, and x is the dose. MEDICAL EFFECTS, at 81. The linear risk model posits that each time energy is deposited in a cell or tissue, there is a probability of the induction of cancer. Id. Thus, the effect of each small dose is additive, and therefore spreading a given dose out over time does not reduce the ultimate risk. Id.

Although there is scientific consensus that ionizing radiation can cause cancer, ionizing radiation, is not currently known to leave a tell-tale marker in those cells which subsequently become malignant. NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, NCRP STATEMENT NO. 7, THE PROBABILITY THAT A PARTICULAR MALIGNANCY MAY HAVE BEEN CAUSED BY A SPECIFIED IRRADIATION 1 (1992) (hereinafter "NCRP 7"). Medical examinations and laboratory tests can determine the type and extent of a cancer, suggest an optimal treatment, and provide a likely prognosis, but they rarely (if ever) provide definite information as to its cause. Id. Consequently, medical evaluation, by itself, can neither prove nor disprove that a specific malignancy was caused by a specific radiation exposure. Id. Therefore, the primary basis to link specific cancers with specific radiation exposures is data that has been collected regarding the increased frequency of malignancies following exposure to ionizing radiation. Id. In other words, causation can only be established (if at all) from epidemiological studies of populations exposed to ionizing radiation. Id.; LAMARSH, at 413.

However, the task of establishing causation is greatly complicated by the reality that a given percentage of a defined population will contract cancer even absent any exposure to ionizing radiation. In industrialized countries where the life expectancy averages about 70 years, about 30% of the population will develop cancer and about 20% of the population will die of cancer. CHERNOBYL , at 42. It is estimated that if 100,000 persons with an age and sex distribution typical of the United States are exposed to a whole body dose of 0.1 Sv and are followed over their lifetimes, between 770-810 people would develop fatal cancers in excess of the normal incidence. BEIR V, at 6.

6. Radiation in the Environment.

The inquiry into cause is further complicated by the fact that radiation is a "constituent element" of our environment, and mankind has been exposed to it since our first appearance on this planet. CHERNOBYL , at 23. Obviously, natural environmental radiation has been, and continues to be, augmented by man-made radiation. Consequently, "the radiation environment of today differs from that of yesterday, and it will continue to be transformed in the future." Id. The total average annual dose, from both natural radiation and man-made radiation, is 3.6 mSv or 360 mrem. BEIR V, at 18.

i. Natural Radiation.

There are two major sources of natural radiation. These are cosmic radiation and terrestrial radiation. L AMARSH, at 427. Cosmic radiation is highly energetic radiation that bombards the earth from outer space. Terrestrial radiation originates in radionuclides found in the earth and in our own bodies. Id. Together, cosmic and terrestrial radiation deliver the highest radiation dose that people normally receive.50 CHERNOBYL, at 23.

---

50. The average annual dose of natural radiation is 2.4 millisieverts (mSv) or 240 millirems (mrems). Natural background radiation levels vary widely throughout the world. The dose of 2.4 mSv or 240 mrems is

Cosmic radiation consists primarily of a highly-energetic mixture of protons (about 87%), alpha (a) particles (about 11 percent), and a trace of heavier nuclei (about 1%) and electrons (about 1%). LAMARSH, at 427. However, the atmosphere acts as a shield, greatly weakening cosmic rays before they reach earth. MEDICAL EFFECTS, at 32. About 26 cosmogenic radionuclides have been identified. They are produced by the action of cosmic radiation. LAMARSH, at 429. However, of the 26, only tritium (3H)51, beryllium-7 (7Be), sodium-22 (22Na) and carbon-14 (14C), contribute appreciably to irradiation, MEDICAL EFFECTS, at 32, and only carbon-14 (14C), is responsible for significant radiation doses. LAMARSH, at 429. Fortunately, carbon-14 is a relatively short-lived radionuclide.52 It primarily results from the atmospheric interaction of thermalized cosmic ray neutrons and nitrogen. Id. The concentration of 14C is about the same in all living species, i.e., 7.5 picocuries per gram of carbon. Id. Because approximately 18% by weight of the human body is carbon, 14C contributes an estimated annual dose of 0.007 mSv or 0.7 mrems. Id.

The average dose of cosmic radiation at or near sea level is 0.37 mSv per year or 37 mrems per year. Id.; CHERNOBYL, at 23. However, the dose rate increases with altitude, doubling about every 1500 meters. CHERNOBYL, at 23. Consequently, people living at high altitudes53 may have an average annual dose level reaching 1 mSV or 100 mrems. Id.

Terrestrial radiation accounts for as much as 85% of the

---

a world-wide average. However, it has been estimated that the average annual dose in the United States from natural background radiation is higher, around 3 mSv or 300 mrems, because of a reevaluation of the quantities and effects of radon gas. KNIEF, at 88. For a brief discussion of radon gas, see below.

51. Tritium is a radioactive isotope of hydrogen. There is another isotope of hydrogen call deuterium (2H) or heavy hydrogen. Deuterium is not radioactive. LAMARSH, at 8; MEDICAL EFFECTS, at 391, 396.

52. T1/2 = 5730 years.

53. For example, Denver, Colorado or Bogota, Colombia. CHERNOBYL, at 23.

total average annual dose of natural radiation, i.e., a little over 2.0 mSv or 200 mrems annually Id. There are approximately 340 naturally-occurring nuclides on earth, and of these, about 70 are radioactive. LAMARSH , at 429. They are called primordial radionuclides because they have existed in the earth's crust since the earth was formed. Id. Those now present on earth have half-lives comparable to the age of the universe. MEDICAL EFFECTS, at 33. Accordingly, primordial radionuclides with half-lives of less than about 108 years can no longer be detected. Id. Primordial radionuclides with half-lives of more than 1010 years have decayed very little up to now. Id.

Primordial radionuclides produce secondary radionuclides through the process of radioactive decay. There are three distinct chains of primordial radionuclides: (1) the uranium series, which originates with 238U; (2) the thorium series which originates with 232 Th; and (3) the actinium series, which originates with 235 U. Together, the parent of each chain and its respective daughter products contribute significantly to terrestrial irradiation. Id.

Uranium is found in various quantities in most rocks and soils, and it is the main source of radiation exposure to people out-of-doors. CHERNOBYL, at 23. The uranium isotopes are alpha (a) particle emitters and, therefore, they do not contribute to gamma (g) ray exposure.54 MEDICAL EFFECTS, at 33. Since uranium isotopes are generally present in low concentrations, they do not contribute significantly to the internal alpha (a) ray dose delivered to humans. Id. However, since these isotopes are found in soil and fertilizers, they migrate into our food chain, and therefore, into our tissue. Id. at 35.

Another significant source of terrestrial radiation exposure is radium-226 (226Ra)-- an isotope which originates in the uranium series -- and its daughter

---

54. Naturally occurring uranium consists of threeisotopes, 234U, 235U and 238U. Uranium-238, the parent of the uranium series is the most abundant isotope, present in the amount of 99.28%, and it is in equilibrium with 234U, which is present in the amount of 0.0058%. Uranium-235, present in the amount of 0.71%, is the parent of the actinium series. MEDICAL EFFECTS , at 33.

products. Radium-226, with a half-life of 1622 years, is an alpha (a) emitter and is present in all rocks, soils and water. Id. Radium is chemically similar to calcium and it passes through the food chain into humans because plants absorb it from the soil.55 The annual dose attributable to the intake of 226Ra is 7 microsieverts (Sv) or 0.7 mrem. Id. at 36.

Approximately 95% of the world's people live in areas where the annual average dose from outdoor external radiation sources is about 0.4 mSv or 40 mrems. CHERNOBYL, at 24. However, there are areas in the world where people are exposed to very high levels of terrestrial radiation. For example, thorium-rich monozite sands in certain areas of Brazil and India also have exceptionally high levels of irradiation. LAMARSH, at 429.56

Radium-226 is also an important source of terrestrial radiation exposure because it decays to radon-222 (222Rn), a noble gas radionuclide with a half-life of 3.8 days that emits alpha (a) particles and contributes to gamma (g) radiation through its gamma-emitting descendants. Id. Radon is an odorless, colorless, nonreactive gas that poses no significant biological threat. Id. Alpha (a) particles emitted by radon outside the body do not penetrate skin. Id. However, the daughter elements formed as radon decays can be a significant source of natural irradiation and potential biological damage. CHERNOBYL, at 24. Once inhaled, the radon daughters may be deposited in the tracheo-bronchial tree. Id. Some of the radon daughters -- the polonium isotopes, 218 (radon A) and 214 (radon C 1) -- emit alpha (a) particles. 218Po (radon A) provides the major alpha (a) particle dose to the tracheo-bronchial tree, and it therefore poses an increased risk of lung cancer. C HERNOBYL, at 24.

---

55. In the human body, 70% to 90% of radium is found in bone. MEDICAL EFFECTS, at 35.

56. Similarly, in Guarapari, Meaipe and Pocos de Caldas in Brazil, exposure dose rates can be 100 times the norm, and in the coastal areas of Kerala and Tamil Nadu in India, exposure rates can be 1000 times higher than the norm. CHERNOBYL, at 24.

Because it is a noble gas, radon diffuses from its point of origin. LAMARSH, at 430. Moreover, because it is the immediate daughter product of the decay of radium-226 (226 Ra), it can be present in radium-bearing rocks, soils and home construction materials. Id at 429-30. Radon enters buildings primarily through the underlying and surrounding soils and, secondarily from building materials, outdoor air, tap water and natural gas. CHERNOBYL, at 24. Since concentration increases in enclosed spaces, radon concentration is much higher indoors than outdoors. MEDICAL EFFECTS, at 37-38. Radon is the largest contributor to terrestrial radiation because people spend most of their time indoors.[57] Levels of radon in the air vary from place to place, season to season, day to day and hour to hour. Id.

Both lead-210 (210Pb) and polonium-210 (210Po), which, as noted above, are decay products of radon-222 (222Rn), are introduced into the human body through inhalation as well as through the food chain. LAMARSH, at 429-30. 222Rn is a noble gas and therefore, tends to diffuse into the atmosphere where it can travel large distances before decaying into 210Pb. Id. at 430. 210Pb is not inert and attaches to dust and moisture particles in the atmosphere soon after it is formed. Consequently, it can be inhaled directly into the body or fall onto leafy vegetables or pasture grasses from where it can enter the food chain. Id. at 430, 433. Lead-210 does not lead to significant internal radiation doses because it is a rather weak beta (b) particle emitter. However, its daughter product, 210Po, is a powerful, highly-energetic alpha (a) particle emitter and it provides very significant doses of radiation. Id. at 431.

Because both radionuclides can enter the body through ingestion, internal radiation exposure is influenced by dietary patterns. CHERNOBYL, at 24. For example, both radionuclides are present in seafood thus, in countries such as Japan, where seafood is a dietary staple, annual intakes of both radionuclides are significantly higher than in countries where seafood is not a staple. Id. Both

---

57. It is responsible for more than half of the natural radiation we are exposed to, i.e., 1.3 mSv per year or 130 mrems per year. CHERNOBYL, at 24.

radionuclides concentrate in lichens. Accordingly, people in the extreme northern hemisphere who eat the meat of animals that graze on lichens (caribou and reindeer) have levels about ten times higher than the norm. Id. Both 210Pb and 210Po are found on broadleaf tobacco plants, Id. at 433. Both of these radionuclides have also been detected in commercial tobacco products and in cigarette smoke. CHERNOBYL, at 24.

There is a dispute within the scientific community as to whether background radiation produces stochastic effects. The International Commission on Radiological Protection assumes that stochastic effects may be induced by natural radiation and man-made radiation. ICRP 60, at 93. It has been inferred that about 3% of cancer deaths each year in the United States are attributable to background radiation, with 1.5 to 2% due to natural radiation, 0.5% to medical uses and 1% or less to occupational sources. See Luis Felipe Fajardo, Ionizing Radiation and Neoplasia, in NEW CONCEPTS IN NEOPLASIA AS APPLIED TO DIAGNOSTIC PATHOLOGY 99 (Cecilia M. Fenoglio-Preiser, Ronald S. Weinstein and Nathan Kaufman, eds., 1986). However, it has also been reported that natural background has not yet been proven to be cancer inducing, and, some scientists claim that natural background radiation does not cause cancer. Id.

ii. Man made Radiation.

Here, of course, we are most directly concerned with radiation from the nuclear power plant at TMI. It is undisputed that the production of electricity by nuclear power can add to the radioactivity in our environment. Irradiation occurs in the production of electricity, and in all stages of the fuel cycle, i.e., mining, fuel fabrication, transportation, reactor operation and reprocessing CHERNOBYL, at 26-27. However, under normal circumstances, and without considering the effect of nuclear power plant accidents, the overall impact of nuclear power generation on the total population is reported to be very small. MEDICAL EFFECTS, at 45.

There are three major sources of man-made radiation other than nuclear power plants. These are: industrial processes other than nuclear power generation that also use radionuclides, medical irradiation, and nuclear weapons testing. CHERNOBYL, at 24.

Medical irradiation is generally divided into three categories: (1) diagnostic x-ray examinations; (2) the use of radiopharmaceuticals in nuclear medicine; (3) therapeutic applications of radiation. MEDICAL E FFECTS, at 47.58

Nuclear weapons testing occurs either above ground ("atmospheric testing"), or underground.59 Radionuclides released in atmospheric testing can enter the body directly or be deposited on the earth's surface from whence they may later be absorbed via the food chain, or be absorbed through by way of external radiation. MEDICAL EFFECTS, at 44.

Generally, estimates of human exposure to fallout are more concerned with atmospheric (and more particularly stratospheric), fallout than with local or tropospheric fallout because radionuclides in the stratosphere result in fallout worldwide. Id. In fact, stratospheric particulate fallout accounts for most of mankind's worldwide exposure to fission products. Id. Fallout consists of numerous radioactive byproducts of atomic reactions. However, only four of these have half-lives of sufficient length to be of significant concern to present and future populations: 14C, with a half-life of 5730 years; 137Cs and 90Sr, both with a half-life of 30 years; and 3H, with a half-life of 12 years. CHERNOBYL, at 25. 14C provides almost two-thirds of the dose exposure because of the relatively short half-lives of the other three radionuclides. Id. The average annual dose to individuals from atmospheric testing is 0.01 mSv or 1

---

58. The average annual dose due to medical irradiation is between 0.4 and 1 mSv or 40 to 100 mrems. CHERNOBYL, at 47. Of the three categories of medical irradiation, diagnostic x-ray examinations account for almost 95% of the total dose received. Id.

59. Atmospheric testing began in 1945. From then until 1980 there were more than 400 nuclear weapons tested in the atmosphere. CHERNOBYL, at 25. In 1963, the United States, the United Kingdom, and the former USSR entered into the Partial Test Ban Treaty, and undertook to cease atmospheric testing. However, France and China continued atmospheric testing. Id. All of the atmospheric tests released significant amounts of radioactive material into the environment. CHERNOBYL, at 47.

mrems. Id. There have been approximately 1300 underground nuclear weapons tests. MEDICAL EFFECTS, at 44. However, a well-contained underground explosion delivers little, if any, radionuclides to the environment, except for occasional venting. Id.

Industrial processes, such as electricity production, mining, and the use of certain building materials and fertilizers produce above average concentrations of natural radionuclides. CHERNOBYL, at 25. Coal contains more radionuclides than other fossil fuels and burning coal produces a large amount of particulate emissions. M EDICAL EFFECTS, at 39. Other sources of industrial irradiation include certain consumer products, such as luminous timepieces, electronic and electrical devices, video display terminals, antistatic devices, and smoke detectors. MEDICAL EFFECTS, at 42. However, tobacco products probably contribute the greatest radiation dose of all consumer products. Id. at 43. It has been postulated that the radionuclides 210Pb and 210Po are responsible for the high incidence of lung cancer in smokers. BEIR V, at 19; LAMARSH, at 433.

It is generally conceded that atmospheric weapons testing has contributed more to man-made radiation than nuclear power plants. Id. at 45. On average, the annual dose from all facets of the nuclear fuel cycle is less than 0.1% of that from natural radiation, CHERNOBYL, at 26, or less than 10 mSv or 1 mrem a year. KNIEF, at 88. In fact, it has been postulated that atmospheric releases of radionuclides from fossil fuel plants, especially coal plants without scrubber systems, may be greater than the releases of radionuclides from nuclear power plants. MEDICAL E FFECTS, at 45.

Nevertheless, it is beyond dispute that nuclear power plants in general, and nuclear accidents in particular, can release harmful radioactivity into the environment. Irradiation occurs not only in the production of electricity but in all stages of the fuel cycle, i.e., mining, fuel fabrication, transportation, reactor operation and reprocessing CHERNOBYL, at 26-27.60

---

60. Under normal circumstances, and without considering the effect of nuclear power plant accidents, the overall impact of nuclear power generation on the total population is reported to be very small. MEDICAL EFFECTS, at 45.

61. Charged particles and gamma (g) rays can also induce fission, but they are not significant for our purposes because neutron induced fission is the basis of commercial nuclear power, KNIEF, at 41, and it is that fission that occurred at TMI.

Accordingly, before proceeding with our discussion of the District Court's application of Daubert to the expert testimony that was offered to prove that TMI-2 released radiation that caused the Trial Plaintiffs' neoplasms we will briefly discuss the operation of a nuclear power plant in an effort to better determine if Trial Plaintiffs proffered sufficient evidence to connect their injuries to the nuclear reactions that took place inside the nuclear generator at TMI-2. For purposes of assessing the Daubert challenges to the experts in this case, we will limit our discussion of nuclear fission to reactions initiated by neutrons.61

Filed November 2, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 96-7623/7624/7625

IN RE: TMI LITIGATION

LORI DOLAN; JOSEPH GAUGHAN; RONALD WARD; ESTATE OF PEARL HICKERNELL; KENNETH PUTT; ESTATE OF ETHELDA HILT; PAULA OBERCASH; JOLENE PETERSON; ESTATE OF GARY VILLELLA; ESTATE OF LEO BEAM,

Appellants No. 96-7623

IN RE: TMI LITIGATION

ALL PLAINTIFFS EXCEPT LORI DOLAN, JOSEPH GAUGHAN, RONALD WARD, ESTATE OF PEARL HICKERNELL, KENNETH PUTT, ESTATE OF ETHELDA HILT, PAULA OBERCASH, JOLENE PETERSON, ESTATE OF GARY VILLELLA AND ESTATE OF LEO BEAM,

Appellants No. 96-7624

IN RE: TMI LITIGATION

ALL PLAINTIFFS; ARNOLD LEVIN; LAURENCE BERMAN; LEE SWARTZ

Appellants No. 96-7625

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
(Civil No. 88-cv-01452)
(District Judge: Honorable Sylvia H. Rambo)

ARGUED: June 27, 1997

Before: GREENBERG and McKEE, Circuit Judges, and GREENAWAY, District Judge*

(Opinion filed: November 2, 1999)

IV. NUCLEAR ENGINEERING

A. Nuclear Reaction.62

The bulk of electricity generated in the United States is the result of thermal energy (i.e., heat) produced in either fossil-fueled boilers or nuclear power plants. ANTHONY V. NERO, JR., A GUIDEBOOKTO NUCLEAR REACTORS 3 (1979). Nuclear power plants generate energy through nuclear fission. Id. Nuclear fission provides nearly one hundred million times as much energy as the burning of one carbon atom of fossil fuel. KNIEF, at 4. Fission therefore has obvious advantages over fossil-fuel based energy production. It has been estimated that the complete fission of just one pound of uranium would release approximately the same amount of energy as the combustion of 6,000 barrels of oil or 1,000 tons of high-quality coal. NERO, at 4. However, the major disadvantage of the fission process is now painfully obvious. It requires mankind to harness and control one of the most awesome physical powers in the universe. In addition, potentially deadly radioactive materials are produced in the process. KNIEF, at 4

Neutron interactions with nuclei are possible because the absence of a charge allows a neutron to approach a nucleus without repulsion from an opposing force. BENNETT, at 23. The important reactions occur at relatively low energies and include "elastic scattering", "inelastic scattering", "neutron capture" and fission. BODANSKY at 46. Chance determines

* The Honorable Joseph A. Greenaway, Jr., United States District Court Judge for the District of New Jersey, sitting by designation.

62. The general term "nuclear reaction" describes any of a wide number of interactions involving nuclei. BODANSKY, at 46.

which of these reactions occur for a given neutron. Id. at 48.

In elastic scattering, a neutron and nucleus collide without any change in the structure of the target nucleus. Id. It is, therefore, like "the collision of two billiard balls of unequal mass." BENNET, at 23. Although the structure of the nucleus is unchanged in elastic scattering, the laws of motion cause the neutron to change direction and speed and the nucleus recoils. BODANSKY, at 47. The total kinetic energy of the system is unchanged, but some of the neutron's energy is transferred to the target nucleus. Id. Elastic scattering can occur with any target nucleus, but in nuclear reactors it is most significant when the target nucleus is relatively light, and the loss of kinetic energy is, therefore, relatively large. Id. In that scenario, elastic scattering effectively reduces the energy of the neutrons without depleting their number.

Inelastic scattering differs from elastic scattering because the target nucleus is left in an excited state. Id. The target nucleus decays, usually quickly, to the ground state with the emission of gamma (g) rays. The total kinetic energy of the neutron and the target nucleus after the scattering is less than that of the neutron before the scattering, with the difference equaling the energy of the gamma (g) rays. Id. An important characteristic of inelastic scattering is that neutrons lose on average much more energy per collision than they do in elastic scattering. BENNET, at 28.

In neutron capture, which occurs in the first stage of many reactions, the neutron combines with the target nucleus to form an excited compound nucleus. BODANSKY, at 47. The term "neutron capture" is usually restricted to cases where the excited compound nucleus decays by the emission of gamma rays.63 Id. The number of gamma rays emitted in the de-excitation varies. Id.

Neutron capture can occur for almost any target nucleus and it plays two general roles in nuclear reactors. First, it

---

63. An example is: formation: n + 238U fi 239U*
de-excitation: 239U* fi 239U + g's

BODANSKY, at 47.

consumes neutrons that might otherwise initiatefission. Second, it transforms nuclei produced in fission into other nuclei. Id. Further, as will be discussed below, the reaction is significant because it is the first step in the production of plutonium-239 in reactors. Id.

As noted earlier, a nuclear reactor produces energy from fission. However, fission is possible for only a very few target nuclei, the most important being isotopes of uranium and plutonium. Id. at 48. If an appreciablefission yield is produced by neutron incidents upon a target nucleus, that nuclear species is termed fissile. Id. at 61. In a typical fission reaction, the excited compound nucleus divides into two fragments plus several neutrons.64 Id. at 48. The energy released in fission comes from the large kinetic energy of the fission fragments. Id. An averagefission event produces nearly 200 million electron volts of energy (200 MeV). KNIEF, at 45. In contrast, approximately 2-3 electron volts (eV) of energy is released for each carbon atom burned with oxygen. Id. Neutrons produced by the fission event have an average energy of 2 million electron volts (2 MeV). BENNET, at 55. The fission fragments come to rest within about 10-3 centimeters of the fission site so that all of their energy is converted into heat. LAMARSH, at 76. It is important to remember that he fission products are all radioactive. BENNET, at 30. The formation of eachfission product is followed by a series of beta decays that continues with successive emission of b- particles until a stable isobar is reached. BODANSKY, at 48. In addition, gamma rays are emitted in the de-excitation of the fission fragments, assuming they are formed in excited states, as well as in the de-excitation of the products of the successive b-decays. Id..

---

64. A typical fission reaction illustrated for a 235U target is of the general form:

n + 235U fi236U* fi144Ba + 89Kr + 3n.

The products in this example are barium 144 (atomic number Z = 56), krypton 89 (Z=36), and 3 neutrons. BODANSKY, at 48. Many other outcomes are also possible, always subject to the condition that the sums of the atomic numbers of the products are the same as those of the initial system. Id. Both the 144Ba and 89Kr nuclei areradioactive. Id.

The release of significant amounts of energy fromfission requires a chain reaction. Id. at 69. Fission forms the backbone of the required chain reaction. NERO , at 5. Earlier, it was noted that neutrons produced by fission in the uranium fuel have an average energy of 2 MeV. However, fission in uranium will not result in a chain reaction if the neutrons interact at energies close to those in which they were emitted. BODANSKY, at 73. Consequently, it is necessary to reduce the energy of the neutrons from this average energy region to a more favorable region below 1 electron volt (eV) by elastic collisions with the nuclei of a moderator. Id. Commonly used moderators are hydrogen in water, deuterium in heavy water or carbon in graphite. Id. at 74. After a sufficient number of elastic collisions with the moderator, the neutrons have reached a low or "thermal energy" and a chain reaction can occur. NERO , at 7.

A chain reaction is sustained by the emission of low energy neutrons from fissioning nuclei. BODANSKY, at 50. A nuclear reactor such as TMI-2 is "merely" the system in which a controlled chain reaction takes place. LAMARSH, at 103. In order for a self-sustaining chain reaction to occur, at least one of the neutrons produced in one fission event must cause a second fission event from which one neutron causes a third fission event, and so on. Id. at 102. Each such generation must have more fission events than the preceding one if a continuing and useful chain reaction is to occur. BODANSKY, at 69.65 The condition for establishing a chain reaction is commonly expressed as the "achievement of criticality". Id. "Criticality" is described quantitatively in terms of the multiplication factor, denoted by the symbol k, LAMARSH, at 102, or the criticality factor, BODANSKY, at 69, which is defined as the ratio of the number offissions (or fission neutrons) in one generation divided by the number of fissions (or fission neutrons) in the preceding generation.

---

65. The average number of neutrons emitted infission is crucial for establishing the practicality of a chain reaction. Id. at 64. The number of neutrons varies from event to event, ranging from 0 to about 6. Id. Generally 2 or 3 neutrons are emitted per event. Id. The excess is necessary because some neutrons will be lost to capture reactions and other neutrons will leave the region where the chain reaction is to be established. Id.

LAMARSH, at 102. A system is critical if k equals 1. Id. If k is greater than 1, the system is "supercritical," "and a divergent chain reaction exists in which the neutron density and fission rate increase, possibly at an explosive rate as in an atomic bomb." BENNET, at 54. If k is less than 1, the system is "subcritical" and the chain reaction decreases and eventually stops. Id

In a nuclear reactor, the operator can vary the value of k by varying the rate at which neutrons are produced within the reactor with the rate at which they are absorbed or disappear.66 LAMARSH, at 103. To increase the power being produced by the reactor, the operator increases k to a value greater than 1 so that the reactor becomes supercritical. Id. When the desired level has been reached, the operator adjusts k to one so that the reactor is critical and maintains the desired level. Id. To reduce power or shut the reactor down, the operator reduces k to less than 1, making the reactor subcritical. Id.

Earlier, we noted that neutron capture wastes neutrons if we consider only fission. However, neutron capture plays an important role in reactors because through it nonfissionable nuclei become fissile. BODANSKY, at 61, 78. Neutron capture in thorium-232 (232Th) and uranium-238 (238U) leads, with interveningb- decays, to the production of the fissile nuclei uranium-233 (233U) and plutonium-239 (239Pu). Id. at 61. Therefore, 232 Th and 238U are termed fertile. Id. Where uranium is used as the fuel, plutonium-239 (239Pu) is ultimately produced by the capture of neutrons in fertile uranium-238 (238U). The 239Pu can be used for the production of atomic weapons or in other reactors. BODANSKY, at 78. It also contributes fissile material which is consumed in the reactor before the fuel is removed, supplementing the original fissile 235U in the fresh fuel. Id. Essentially, through neutron capture, the fertile nuclei become fissile nuclei enabling the nuclear reaction to continue in the reactor.

---

66. Nuclear bombs and explosives cannot be controlled in this way and therefore are not called reactors. LAMARSH, at 103.

B. The Operation of Nuclear Power Plant.67

At its most elementary level, a nuclear reactor is a deceptively simple apparatus. Simply put, a nuclear power plant produces heat energy that is converted to steam in a boiler. Affidavit of John A. Daniel at P 17. The steam is used to turn a turbine, which is connected to, and turns an electrical generator that produces electrical power. Id. The apparent simplicity of this basic operation is made even more deceptive when one considers the awesome power of the forces at work within nuclear reactors such as TMI-2. However, beyond this elementary level, a nuclear power plant is an extraordinarily complex system. The heat energy is produced in a vessel called a "reactor," because it contains the nuclear reactions. Id. The reactor vessel is a steel pressure vessel with walls that are 8-1/2 inches thick, surrounded by a concrete and steel shield over 8 feet thick. Id. at 23.

The TMI-2 nuclear reactor at issue here was a standard Babcock & Wilcox pressurized water reactor ("PWR").68 It

---

67. The following description is taken, for the most part, from two sources -- the affidavit of a defense expert witness and a report commissioned by the Nuclear Regulatory Commission. We rely on these sources because appellants have not provided us with any evidence of the workings of a nuclear power plant, and because the basic operation of a nuclear power plant is not in dispute. See 927 F. Supp. at 846. The affidavit is of John A. Daniel, a nuclear engineer who is currently a consultant to the nuclear power industry, and can be found in the Consolidated Appendix at 14759-14889. The government report is MITCHELL ROGOVIN, NUCLEAR REGULATORY COMMISSION INQUIRY GROUP, NUREG/CR-1250, TMI REPORT TO THE COMMISSIONERS AND TO THE PUBLIC AT 10-13 (1980).

68. The physical plant of a PWR nuclear power plant consists of a reactor building, a turbine building, an auxiliary building, a fuel handling building and a control and service building. Daniel Aff. at P 23. The reactor vessel, pressurizer, associated piping, reactor coolant pumps and steam generators are collectively referred to as the "reactor coolant system" and are located in the reactor building. Id. The reactor building is actually a large pressure vessel designed to withstand the pressure increase which would result if there was a rupture in reactor coolant piping. Id. at P 24. During the plant's operation, the reactor building is kept air tight and access to the building is through personnel air locks, similar to those used on spacecraft. Id.

used uranium dioxide (U02) as a fuel. Id. at PP 17, 18; J. A. Daniel, Noble Gas Transport During the TMI-2 Accident (1993) 87. The UO2 is formed into ceramic pellets, each of which is about one-half inch in diameter. Daniel Aff. at P 17. Fuel pellets are stacked into metal rods called "fuel pins", which are arranged into square "fuel assemblies." Id. The fuel assemblies are approximately twelve feet high, contained in the reactor, and are collectively referred to as the "reactor core". Id. The fuel assemblies contain several control rods with instruments, some of which monitor the reactor, and others which speed up or slow down the reaction. Id. These control rods, contain materials with large thermal neutron absorption capacities. BODANSKY, at 80. The rods are either inserted or withdrawn to maintain the appropriate level of criticality, (where k equals 1), and enable the reactor to operate at steady power for long periods of time. BENNET, at 107-08. The reactor contains water some of which serves to cool the reactor during the nuclear reaction, and some of which is heated to steam by the chain reaction. The fuel rods containing the uranium fuel are sheathed in rods that prevent the fuel pellets from coming into direct contact with the water in the reactor core and are called the fuel cladding. MITCHELL ROGOVIN, NUCLEAR REGULATORY COMMISSION INQUIRY GROUP, NUREG/CR-1250, TMI REPORT TO THE COMMISSIONERS AND TO THE PUBLIC 10 (1980)(hereinafter "NUREG/CR-1250"). Daniel Aff. at P 17.

The nuclear reaction in the core is generated by a neutron source which emits neutrons in a manner designed

---

The turbine, condenser and electrical generator are housed in a concrete and steel building called the "turbine building". Id. at P 23. The
auxiliary building contains the auxiliary systems used to process and maintain the chemical and radiological purity of the reactor coolant. Id. The fuel handling building houses the storage facilities for new and used fuel. Id. After it is removed from the reactor core, the used fuel is stored
underwater in the "spent fuel pool." Id. The auxiliary and fuel handling buildings have redundant air filtration units which are designed to remove filterable radioactive particles before being discharged to the environment. Id. The plant operations personnel monitor and maintain control of the various plant systems from a central control room located in the control and service building. Id.

to initiate a chain reaction. Most fission products are solid at fuel temperature, but some are gases. Id. at P 18. Some of the fission products, especially the noble gases krypton and xenon, migrate to the edge of the fuel pellet and collect in the space between the fuel and the cladding. Since some of the fission products may escape from the cladding into the water in the reactor, the reactors are designed to contain cooling water within its own closed loop. Id.

In a PWR of the TMI-2 type, there are three cooling systems. Daniel Aff. at P 19. A PWR coolant system[69] is a circuit or closed loop of distilled water with a small amount of boric acid. NUREG/CR-1250 at 10. The primary circuit, called the "primary coolant" or "reactor coolant", circulates water through the reactor core. Daniel Aff. at P 19. During normal reactor operation, the water in the primary coolant is kept at an average temperature of 575o F and pressures high enough, (around 2200 pounds per square inch), to keep the water from boiling to steam. NUREG/CR-1250 at 10. The water in the primary coolant circulates and recirculates through this loop. Id. While it is circulating and recirculating, the primary coolant water picks up heat from the fission reaction in the reactor core and carries the heat from the core through two "hot leg" pipes to two steam generators. Daniel Aff. at P 19; NUREG/CR-1250 at 10. The steam generators are tanks, approximately 35 feet tall, in which the primary coolant water passes through a large number of narrow tubes that transfer heat to water contained in another, separate circuit, called the "secondary circuit" or "feedwater loop." Daniel Aff. at P 19; NUREG/CR-1250 at 10. The water in the secondary circuit, called "feedwater," is maintained at a lower pressure than the water in the primary coolant circuit, Daniel Aff. at P 19, allowing the feedwater to boil to steam. Id.; NUREG/CR-1250 at 10. The steam in the secondary circuit is called the "main steam system". Daniel Aff. at P 19.

The primary coolant water, having lost some of its heat in the secondary circuit, is then returned to the reactor core through four pipes, known as "cold legs." NUREG/CR-1250

---

69. There are two virtually identical coolant loops in the TMI-2 reactor, called the "A" and "B" loops. NUREG/CR-1250 at 11.

at 11. Once the primary coolant water is returned to the reactor core, it is heated once again by the nuclear reaction, and the cycle repeats. Id. The primary coolant water is kept moving at high speed in the primary circuit by four reactor coolant pumps -- enormous devices each of which requires enough electricity for its own operation to light a small town. Id.

At a point between the reactor and the steam generator, there is a pipe leading to the bottom of a large vessel or tank called a "pressurizer". NUREG/CR-1250 at 11. During normal operation, coolant water does not circulate back and forth through this pipe. Id. The pressurizer is normally kept a bit more than half full of coolant water. Above the water is a cushion, or "bubble," of steam. Id.; Daniel Aff. at P 20. The pressurizer is a means of keeping the pressure in the reactor coolant system relatively constant, to prevent the reactor coolant water from boiling. NUREG/CR-1250 at 11. The steam cushion at the top of the pressurizer can be made larger or smaller by slight heating or cooling of the pressurizer water just beneath it. Id. When the bubble temperature and pressure are increased, the bubble tends to push water from the pressurizer out into the primary reactor coolant loop, thereby increasing pressure in the loop. Id. When the temperature and pressure in the pressurizer are lowered, steam condenses and the bubble shrinks. Id. Consequently, water tends to come from the reactor coolant loop into the pressurizer, and the overall system pressure is lowered. Id.

A relief valve, referred to as a "power-operated relief valve" ("PORV"), is located in a pipe leading out of the top of the pressurizer, at the top of the space normally occupied by the steam bubble. Daniel Aff. at P 21, NUREG/CR-1250 at 11. The PORV is designed to open automatically when the system begins to overpressurize. NUREG/CR-1250 at 11. Theoretically, if the pressure in the coolant system rises very abruptly, the PORV will open, some of the steam will rush out to a drain tank, thus shrinking the bubble, more water will move up into the pressurizer from the primary coolant loop, and system pressure will decrease. Id.; Daniel Aff. at P 21. A rupture disk is provided on the drain tank to relieve pressure if the drain tank becomes too full. Daniel Aff. at P 21. When the system pressure is back to normal, the PORV is supposed to close automatically. NUREG/CR-1250 at 11. If the PORV fails to close, there is a backup, called a "block valve". Daniel Aff. at P 21. There are two other safety valves in addition to the PORV. NUREG/CR-1250 at 11; Daniel Aff. at P 21.

The heart of the secondary circuit or feedwater loop is the steam generator. NUREG/CR-1250 at 11. After the water in the secondary circuit is heated to steam by the hot water from the primary coolant system, the steam moves through the secondary circuit or feedwater loop to a steam turbine which turns the power generator that produces the electricity. NUREG/CR-1250 at 11. The steam then passes through a condenser, where it is cooled and condensed into water once again and recycled through the steam generators. Id. at 11-12. The pipe line returning the water from the condenser to the steam generator also contains the condensate polishers or "demineralizers". Id. at 12. The demineralizers are basically water softeners, that use ion exchange resins to purify the feedwater. Id.

The condenser itself is cooled by water from the third circuit, i.e., the cooling towers, Id. at 12; Daniel Aff. at P 19, which are the familiar landmarks of nuclear plants. The water in the condenser circuit, having been warmed in the process of condensing steam back into water, is pumped up to the cooling towers. NUREG/CR-1250 at 12. The condenser water is thus cooled by exposure to the atmosphere as it tumbles down a steep run of steps and then is pumped back into the condensers. Id. The escaping water vapor is the plume or cloud which can often be seen coming out of the cooling tower. Id.70

---

70. During this process, chemicals may be added to the reactor coolant to fine tune the nuclear reaction in the reactor core, and to remove any impurities that may have collected in the coolant. Daniel Aff. at P 22. During power operations, a small flow of reactor coolant is bled off from the reactor coolant system and passed through a series of filters and demineralizers. Id. If additional water is needed in the reactor coolant system, it is added from water stored in tanks located in an auxiliary building. Id. The system that collects water from the reactor coolant system and adds water to the reactor coolant system is called the "makeup and purification system". Id. Any gases collected from the reactor coolant system are collected in waste gas decay tanks. Id.

In addition to the systems peculiar to a PWR, the TMI-2 reactor had a general safety system common to all reactors called the "emergency core cooling system" ("ECCS"), which is designed to supply cooling water to the hot reactor core if there is a loss of water due to a break in the reactor coolant system. NUREG/CR-1250 at 12. If the break is small, the leakage flowing from the break may not be significant and the system's internal pressure will stay high, making it difficult for the ECCS to pump water in. Id. Consequently, the plant has high pressure injection ("HPI") pumps to deliver water from a large borated water storage tank ("BWST"). Id. However, the HPI pumps are not able to deliver enough water if the break is large. Id. Therefore, the system has a set of low pressure injection ("LPI") pumps that can deliver water to the core rapidly when a large pipe break has caused the system's internal pressure to drop. Id. The LPI pumps also draw water from the BWST. Id.

The LPI pumps also have another purpose. When a reactor is shut down, the radioactive waste in the fuel continues to produce a considerable, but diminishing, amount of decay heat for days following shutdown. This heat must be removed if the core is to be kept from melting. Id. Even after the reactor is shut down, the accumulated fission products continue to decay and release energy within the reactor. LAMARSH, at 350. This fission product decay is called "decay heat". Id. A method for handling the decay heat and for cooling the reactor core after shutdown must be provided or the temperature of the fuel may rise to a point where the fuel's integrity is compromised and fission products are released. Id.

After shutdown, the reactor is first cooled by the continued normal operation of the steam generators until the reactor coolant system is cooled to a temperature of about 300$F and an internal system pressure below 400 psi. NUREG/CR-1250, at 12. Then, valves are opened to let one of the LPI pumps circulate coolant through the reactor core and out to a special heat exchanger to bring the system temperature down to about 120#DE#-140#DE#F. Id.71

---

71. The LPI system is called the "decay heat removal system" when it performs this function. NUREG/CR-1250 at 12.

Finally, there is an ECCS system called the "coreflood tanks." These are two tanks almost completelyfilled with water under a medium-pressure of about 600 psi. Id. They stand above the reactor and a check valve prevents the higher reactor core system pressure from driving more water into them. Id. If a large pipe break occurs, it takes a few minutes for the HPI and LPI pumps to deliver cooling water to the core. Id. Therefore, the coreflood tanks are designed to drop their thousands of gallons of water to cool the core until the HPI and LPI pumps deliver cooling water. Id.

C. Barriers to Release of Radioactive Materials into the Environment.

A nuclear reactor must obviously have barriers designed to prevent the fission products from entering the working areas of the reactor or escaping into the environment. NUREG/CR-1250 at 342. The first such barrier is the ceramic fuel matrix in which the fission products are produced. Id. The uranium dioxide (UO2) used in the TMI-2 reactor is a ceramic fuel which has microscopic boundaries ("grain boundaries") between the molecules. Daniel, Noble Gas Transport at 87. These boundaries serve as microscopic roadways for certain fission products to travel out of the fuel. Id. Thus, some of the elements that are volatile or gaseous at the operating temperature of the fuel are able to migrate through the ceramic fuel. NUREG/CR-1250 at 342. However, the majority of the fission products that are produced are either trapped or chemically bound. Id.

The second barrier to the release of fission products is the fuel cladding. The UO2 ceramic pellets are sealed in the fuel rods to prevent the fuel pellets from directly contacting the water in the reactor core. There is a small gap between the fuel and the fuel cladding. Noble gases such as krypton and xenon, and other volatile nuclides are contained in that gas. However, if a defect or rupture develops in the fuel cladding, volatile fission products can be released into the coolant. Id. at 343. At the time of the TMI-2 accident, the Nuclear Regulatory Commission generally allowed operation of a reactor with up to 1% of the fuel having a defect in its cladding.[72] Id.

The third barrier is the reactor coolant. Many of the volatile fission products, the radioiodines and radiohalogens, are soluble in the coolant in "ionic" (electrically charged) form. Id. at 343. These materials can be removed by demineralizers, such as those in the makeup and purification system of the reactor, or they may remain dissolved in the coolant. Id. The majority of these radionuclides are contained in the primary coolant system, Id., and are soluble in the coolant. Id. Their solubility decreases and they tend to precipitate or "plate out" as the pH of the primary coolant is increased. Id. The noble gas radionuclides, kryptons and xenons, have very low solubility in the coolant, particularly in the presence of other gases such as hydrogen, and they evolve into a gas or vapor phase above the coolant or wherever the coolant is depressurized. Id.

The fourth barrier is the reactor pressure vessel and the piping of the primary coolant system, which are made of heavy walled steel. Id. The fifth barrier is the containment building itself. It is designed to withstand overpressurization and external impacts and contain or delay fission product releases during an accident. Id.

V. THE ACCIDENT AND ITS AFTERMATH

A. The Accident at TMI-2.[73]

---

72. Even in the absence of defective fuel elements, a small background concentration of fission products exists in the primary coolant system, because of the fissioning of trace quantities of uranium ("tramp uranium") in or on the fuel cladding material. NUREG/CR-1250 at 342.

73. Although the defendants have previously conceded that radioactivity was released into the environment as a result of the TMI-2 accident, see 67 F.3d at 1119, there is apparently some dispute about the "specific operation of the TMI-2 PWR during the accident. . . ." 927 F. SUPP. at 846. Our description of the accident is taken from defense exhibits. Plaintiffs have not offered an explanation of how the accident occurred, and have focused instead on the biological damage they allege it caused.

What has been described as the "[n]ation's worst nuclear accident"74 began at about 4:00 a.m. on Wednesday, March 28, 1979, The Comptroller General Report to the Congress, Three Mile Island: The Most Studied Nuclear Accident in History 1 (1980). Ironically, the "nation's worst nuclear accident" grew out of a minor malfunction, or transient that occurred in the nonnuclear part of the system. NUREG/CR-1250 at 3. For some reason, several feedwater pumps, 75 that normally drew heat from the PWR's cooling water, shut-off automatically.76 Id. at 310. The system was designed so that when the feedwater pumps tripped, the main turbine and electrical generator also tripped. Id. Thus, by design, the turbine and generator tripped approximately one second later. Id. Three seconds after the turbine tripped, the pressure in the reactor coolant system increased to a level that caused the PORV to open in order

---

Nevertheless, a basic understanding of the defendant's theory of how the accident occurred provides helpful background to a Daubert analysis of the disputed expert testimony plaintiffs attempted to offer. It is in this context only that we set forth a description of the accident. We caution, however, that the description we set forth is intended only for the limited
purpose of framing our Daubert discussion. It is not intended to suggest the appropriate resolution of any factual dispute that may linger as to the precise manner in which the numerous controls all failed at TMI.

74. Prior to the TMI-2 accident, there were "major" reactor accidents at the National Reactor Testing Laboratory in Idaho in 1955 and 1961, at the Fermi Reactor in Detroit, Michigan in 1966 and at Browns Ferry 1 in Alabama in 1975. BODANSKY, at 212-13. Major accidents outside of the United States occurred at Chalk River, Canada in 1952, Windscale, England in 1957, Lucens, Switzerland in 1969 and, perhaps the most famous of all reactor accidents, at Chernobyl, in Ukraine about 30 miles south of the border with Belarus, (both of which were then part of the former USSR) in 1986. Id.

75. Neither the condensate nor the feedwater systems are unique to nuclear power plants. Both systems are similar to those used in fossil-fuel plants. NUREG/CR-1250 at 310.

76. The exact reason why the water pumps tripped has not been determined. NUREG/CR-1250 at 311. However, it has been postulated that the operations of a condensate polisher in the auxiliary building was implicated in the tripping of a condensate pump which in turn caused the tripping of the main feedwater pumps. NUREG/CR-1250 at 310-311.

to release the pressure. Id. When the PORV opened, the fission process in the reactor core automatically shut down. Id. Consequently, the heat generation in the reactor core dropped to decay heat levels. J. A. Daniel, Noble Gas Transport at 5.

However, the PORV did not close as it should have when the system pressure was reduced to acceptable levels. Instead, it remained open for approximately 2 hours. Comptroller General Report ("CGR") at 2. Unfortunately, the personnel operating Unit 2 did not realize that the PORV had not closed. They believed that it had automatically closed when the system was depressurized. Id. ; NUREG/CR-1250 at 324. Because the PORV remained open, reactor coolant water flowed from the reactor coolant system into the reactor coolant drain tank, which is designed to collect reactor coolant that is released from the reactor coolant system through the PORV during power operation. Daniel, Noble Gas Transport at 6. The continued flow of reactor coolant water into the reactor coolant drain tank caused a safety valve to lift on the drain tank and a drain tank rupture disk to burst. Id. This rupture disk burst allowed the reactor coolant water to be discharged directly into the reactor building, which overfilled along with its sump pumps. Id. The reactor building sump pumps were on automatic and aligned with the auxiliary building sump tank. Id. at 31. When the reactor building sump pumps overfilled, some coolant water was transferred to the aligned auxiliary building sump tank. Id. For some reason, there was no rupture disk on the sump tank and reactor coolant water was discharged directly into the auxiliary building. Id. at 31; CGR at 2. The contaminated coolant water continued to flow from the reactor building into the auxiliary building for several days. CGR at 2. Estimates of the amount of radioactive water discharged into the reactor and auxiliary buildings range from 700,000 gallons, Nuclear Energy Institute, The TMI 2 Accident: Its Impact, Its Lessons, http://www.nei.org/pressrm/facts/TMI-2.htm>, to 5,000,000 gallons. NUREG/CR-1250 at 339.

Approximately 2 minutes into the accident, the emergency core cooling system ("ECCS") began pumping water into the reactor core. CGR at 2. However, operations personnel, still believing that the PORV had closed, and therefore unaware that reactor coolant water was escaping from the reactor coolant system, turned off most of the water flowing to the core through the ECCS. Id. They did so believing that they were preventing the reactor system from becoming filled with water -- a condition they were required to prevent. Id.

However, there was not enough coolant water being circulated through the reactor coolant system to cool the reactor core because reactor coolant water was being discharged into the reactor building. Consequently, the core reaction was producing more heat than the coolant system was removing, and the core began to heat up. Daniel, Noble Gas Transport at 6. The loss of reactor coolant water allowed the reactor core to become uncovered. Id. Within three hours of the beginning of the accident, as much as two-thirds of the twelve-foot high core was uncovered. Temperatures reached as high as 3500 to 4000 degrees Fahrenheit or more in parts of the core during its maximum exposure. THE REPORT OF THE PRESIDENT'S COMMISSION ON THE ACCIDENT AT THREE MILE ISLAND, THE NEED FOR CHANGE: THE LEGACY OF TMI 100 (1979) (THE KEMMENY REPORT).

About 2-1/2 hours into the accident, some of the fuel rods in the reactor cracked, releasing xenon and other fission product gases, which had accumulated in the fuel rod gap between the fuel and the cladding, into the coolant water. Daniel Aff. at P 28. Over the next few hours, more fuel rods cracked, releasing radioactive iodine and cesium into the primary coolant water as well as additional noble gases. Id.

A series of events then unfolded involving various reactions, valves and controls. The end result was that, nearly 10 hours into the accident, there was a sudden spike of pressure and temperature in the reactor building. Id. at 329. Initially, the spike was dismissed as some type of instrument malfunction. Id. at 330. However, operations personnel learned on March 29th that the spike was caused by the explosion of hydrogen gas in the reactor building. Id. at 329; CGR at 2. Fears of another hydrogen explosion developed when a hydrogen gas bubble was later found in the reactor system. CGR at 2; NUREG/CR-1250 at

336, 338. Presumably, there was a concern that another hydrogen explosion would damage the reactor vessel, leading to further releases of radioactive material. NUREG/CR-1250 at 338. However, the fears about another hydrogen explosion were later learned to be unfounded. Id.; CGR at 2.

During the last days of March and the first week of April, operations personnel began to regain control and contain the radioactive releases caused by the accident. See NUREG/CR-1250 at 334-39. However, it was not until the afternoon of April 27, 1979 that stable conditions were finally established in TMI-2. Id. at 339.

B. Radioactive Materials Released to the Environment.

The parties generally agree that the radioactivefission products released to the environment as a result of the accident escaped from the damaged fuel and were transported in the coolant through the letdown line into the auxiliary building. NUREG/CR-1250 at 343; Daniel, Noble Gas Transport at 33 ("The major pathway forfission product transport to the auxiliary building was through the letdown piping of the makeup and purification system."); Daniel Aff. at P 22. Once in the auxiliary building, the radioactive fission products were released into the environment through the building's ventilation system.77 NUREG/CR-1250 at 343; Daniel, Noble Gas Transport at 60. Because of the volatility of noble gases and

---

77. TMI-2 also contained a treatment system, called the "liquid radwaste treatment system", which was designed to collect, process, monitor and recycle or dispose of radioactive liquid wastes prior to discharge to the environment. After the system processed the liquid radwaste, it was discharged into the Susquehanna River. However, because the primary coolant water flowed into the auxiliary building during the accident, the liquid radwaste treatment system was overwhelmed and radioactive materials were released to the Susquehanna River. The Nuclear Regulatory Commission's Special Inquiry Group concluded that the quantity of radioactive materials contained in the liquid released into the Susquehanna River was not significant. NUREG/CR-1250, at 347-51. None of the plaintiffs here claim harm as a result of the releases of liquid radwaste into the river.

radioiodines, those elements were the primary radionuclides available for release from the auxiliary building. NUREG/CR-1250 at 343. Two krypton isotopes, 87 and 85, were not released in significant quantities because of the short half-life of 87Kr and because of the small amount of 85Kr in the reactor core. Id. Nonetheless, despite the various filters, radioiodines were released.[78] After the first day, the quantities of 88Kr and 135Xe were reduced by radioactive decay. Id. All of the 133I contained in the coolant which was released to the auxiliary building eventually decayed to 133Xe and 133mXe. Id. These radionuclides were the predominate ones released from the plant to the environment. Id. at 344; Daniel Aff. at P 35.

C. Pathways of Exposure to Radioactive Materials.

The various mechanisms of human exposure to radioactive materials after such materials have been released into the environment are called "pathways". NATIONAL RESEARCH COUNCIL, RADIATION DOSE RECONSTRUCTION FOR EPIDEMIOLOGIC USES 28 (1995) (hereinafter "RADIATION DOSE RECONSTRUCTION"). The pathways are"qualitatively well-known and their relative importance is understood." CHERNOBYL, at 31. Generally, when radioactive materials from nuclear power plants are released into the atmosphere, they are released into a region called the "planetary boundary layer." This is an area between the surface of the ground and an elevation of 100 meters. RADIATION DOSE RECONSTRUCTION, at 28. Once the radioactive material is released, turbulence in the atmosphere mixes the effluent particles and gases within the resulting contaminated cloud or "plume" and the plume is transported downwind. Id. The mixing of the radioactive particles and the transport of the resulting plume are called "dispersion". Id.

Obviously, the extent and direction of a dispersion depends on many factors including wind direction, wind speed and weather, as well as the heat content of the plume, and the characteristics of a given terrain over which

---

78. They included, 131I,133I and 135I,because of their abundance in the coolant and the length of their half-life. Id.

the plume may be carried. CHERNOBYL, at 32. As the radioactive cloud is dispersed and transported by prevailing winds, exposure to the radionuclides first occurs through external and internal irradiation. Id., at 31; RADIATION DOSE RECONSTRUCTION, at 29. The contents of the plume are depleted over time as the radionuclides settle to the ground in response to gravitational forces ("dry deposition") of through precipitation or combination with airborne moisture such as fog (wet deposition). CHERNOBYL , at 31-32. However, as suggested by some of our discussion above, exposure can continue by external irradiation from deposits of radioactive material, inhalation of any materials suspended in the atmosphere, or transfer of the radioactive material through the terrestrial and aquatic environment to food and water, and then to internal irradiation. Id.

VI. LEGAL DISCUSSION

With the foregoing discussion in mind, we are ready to begin our discussion of the District Court's evidentiary rulings. The Daubert challenge to the plaintiffs' experts implicates the reliability of the expert testimony that plaintiffs sought to admit into evidence. We now begin our analysis of that testimony, the issues of causation and the scientific principles implicated by the plaintiffs' attempt to establish the requisite nexus between the accident at TMI-2 and their injuries.

A. The Trial Plaintiffs' Appeal.

1. Background.

The 10 Trial Plaintiffs claim that their diseases, or the fatal diseases of the decedents whose claim their personal representatives assert, were caused by the radioactive materials released into the environment as result of the TMI-2 accident. More specifically, they allege their conditions were caused by gamma (g) ray exposure from radioactive iodine, xenon and krypton. In re TMI Litigation Consolidated Proceedings, 927 F. Supp. 834, 840 (M.D. Pa. 1996)(the "Summary Judgment Opinion").

We have previously held that plaintiffs seeking to recover for injuries allegedly caused by TMI-2 must show that: (1)

the defendants released radiation into the environment in excess of the levels permitted by federal regulations in effect in 1979, i.e., 0.5 rems (500 mrems) or 5 mSv; (2) the plaintiffs were exposed to this radiation (although not necessarily at levels prohibited by those regulations); (3) the plaintiffs have injuries; and (4) radiation was the cause of those injuries. See In re TMI, 67 F.3d 1103, 1119 (3d Cir. 1995), cert. denied, 516 U.S. 1154 (1996). We have also held that the "exposure element requires that plaintiffs demonstrate they have been exposed to a greater extent than anyone else, i.e., that their exposure levels exceeded the normal background level." Id. (citation and internal quotations omitted).

Throughout this litigation, the defendants have conceded that radioactive materials were released into the environment, and that the releases at the plant boundaries exceeded 0.5 rem (500 mrem). However, they claim that no plaintiff was in an area where he or she could have been exposed to dose in excess of 0.5 rem. In re TMI, 67 F.3d at 1109. Appellees point to a number of studies undertaken by governmental entities in the years immediately following the TMI-2 accident. The Nuclear Regulatory Commission ("NRC"), the Department of Energy ("DOE"), the Environmental Protection Agency ("EPA"), the Department of Health, Education and Welfare ("HEW"), a special President's Commission (the "Kemmeny Commission"), a special NRC investigation (the "Rogovin Report"), and the Pennsylvania Department of Health, all studied various aspects of the accident. Appellees' Br. at 3-4. The government entities studied the timeline of events recorded by in-plant computers and strip charts during the accident to determine what was happening minute by minute. Id. at 4. The inquiry examined the records from monitors located in several locations inside the plant including the ventilation stack through which the radioactive releases occurred. Offsite monitors at multiple locations where either the utility operating the plant or the Commonwealth of Pennsylvania had instruments collecting and recording data on doses in the communities surrounding Three Mile Island were also studied.79 Id. The governmental entities

---

79. Instruments used to measure airborne radiation, known as thermoluminescent dosimeters ("TLDs"), were used by the utility,

also collected and assessed thousands of environmental samples of milk, water, soil, vegetation, and food. Id. They made whole body counters available at no charge to the public, and over seven hundred people were scanned to see if they had any radionuclides in their bodies from the accident. Id. Local hospitals provided free thyroid scans to anyone interested, and hundreds of people took advantage of these scans to discover any radioactive iodine that might have accumulated in their thyroids. Id. The DOE also conducted an extensive examination of the damaged reactor core in an attempt to quantify the amount of fission products remaining so as to better calculate the quantity that was released into the environment. Id.

Defendants insist that all of these studies consistently concluded that the accident released something less than nine million curies of the noble gases, xenon and krypton, and radioactive iodine resulting in exposures of no more that 100 mrem in the immediate vicinity of the plant, and dropping quickly to tens or just a few millirems within a few miles of the plant. Id. at 5. For example, the NRC Special Inquiry Group Report concluded that the radioactive releases resulted in an average equivalent dose of 1.4 mrem to the approximately two million people living in the area. NUREG/CR-1250 at 153. Defendants contend that these studies conclusively demonstrate that the accident did not cause in releases of radionuclides in sufficient amount to pose a significant threat to the health of the people living around Three Mile Island. Appellees' Br. at 5. For example, the Ad Hoc Population Dose Assessment

---

Metropolitan Edison, and by the Commonwealth to monitor radiation in the surrounding communities in a program known as the TMI Radiation Environmental Monitoring Program ("REMP"). Summary Judgment Opinion, 927 F. Supp. at 848. According to the NRC's Special Inquiry Group, "TLDs provide the best estimate of the integrated radiation dose at a specific location. . . ." NUREG/CR-1250, at 358. A TLD consists of "[a] material, generally a salt such as lithium-fluoride, which can store energy absorbed from nuclear radiation. This stored energy is later released from the [material] by heating and evaluated electronically to give information about the total radiation dose." President's Commission, Report of the Task Group on Health Physics and Dosimetry 39 (1979).

Group80 concluded that the predominant exposure to people outside the plant boundaries occurred in the north-northwest sectors, the east-northeast sectors and the south-southeast sectors, with the east-north east sector registering the highest cumulative dose of 83 mrem. AD HOC POPULATION DOSE ASSESSMENT GROUP, POPULATION DOSE AND HEALTH IMPACT OF THE ACCIDENT AT THE THREE MILE ISLAND NUCLEAR STATION 44 (1979). The Ad Hoc Group also concluded the following regarding the potential health effects on the population living around Three Mile Island:

> The projected total number of fatal cancers is less than 1 (0.7). The additional number of non-fatal cancers in 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 either the existing annual incidence of similar effects or the potential effects estimated to result from the 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 discernible. The uncertainties in the risk from low-level ionizing radiation would not alter this conclusion.

Id. at 60.

As the years passed and health concerns about the accident persisted, the Commonwealth of Pennsylvania's Department of Health conducted several epidemiological81 studies of the community surrounding Three Mile Island.82

---

80. The Ad Hoc Group was composed of representatives of the Nuclear Regulatory Commission, the Environmental Protection Agency, and the Department of Health, Education and Welfare (now the Department of Health and Human Services).

81. Epidemiology is the "study of the distribution and determinants of health-related states and events in populations and the application of this study to control of health problems." FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 174 (1994)."Epidemiology is concerned with the incidence of disease in populations and does not address the question of the cause of an individual's disease." Id. at 167.

82. The studies are: Bratz, J.R., et al., Three Mile Island (TMI) Pregnancy
Outcome Study-Final Report (1988); Tokuhata, George K., et al., Cancer

The Department of Health examined pregnancy outcomes, cancer incidence and cancer mortality in the Three Mile Island area and compared them with state and national norms. The Department's studies concluded there were no significant differences between the studied groups and the state and national norms. Appellees' Br. at 5. The defendants believe that these epidemiological studies further support their claim that the radionuclides released by the accident did not pose any significant health risks.

However, the Trial Plaintiffs rely, in part, on a report of the TMI Public Health Fund,83 which opined, inter alia, that the aforementioned studies were seriously flawed insofar as they attempted to calculate dose exposures to the individuals in the communities surrounding Three Mile Island. See THREE MILE ISLAND PUBLIC HEALTH FUND, A REVIEW OF DOSE ASSESSMENTS AT THREE MILE ISLAND AND RECOMMENDATIONS FOR FUTURE RESEARCH, APPENDIX A 1 (1984). Plaintiffs gathered their own experts to conduct many of the tests recommended by the TMI Public Health Fund in its report. Appellants' Br. at 11. The scientific team that the Trial Plaintiffs assembled focused on "biological indicators of radiation dose." Trial Plaintiffs contend that those biological indicators constitute a "body of evidence . . . greatly overlooked or ignored in early studies. . . ." Id. at 12. According to the Trial Plaintiffs, the biological indicators of

---

Mortality and Morbidity Incidence Around TMI, Division of Epidemiological Research, PA Department of Health, (1985); Digon, E., et al., Infant, Fetal Neonatal and Perinatal Mortalities in the Three Mile Island Area, (1988); Ramasway, K., et al., Three Mile Island (TMI) Population Registry-Based Cohort Mortality: 1979-1985 Period, (1988).

83. The Three Mile Island Public Health Fund was established as part of the settlement of a class action for economic losses attributable to the TMI-2 accident. The plaintiffs there consisted of three separate classes --
one class consisted of businesses which suffered economic loss, one class consisted of individuals who suffered economic loss and one class consisted of individuals who sought medical detection services allegedly needed because of the accident. Under the settlement, a $25 million fund was established, with $20 million available to pay the claims of the businesses and individuals in the first two classes and $5 million set aside for the Public Health Fund, the purpose of which was to, inter alia, "finance studies of the long term health effects of the TMI incident." In re Three Mile Island Litigation, 557 F. Supp. 96, 97 (M.D. Pa. 1982).

radiation dose conclusively demonstrate that area residents were exposed to an equivalent dose of over 100 rem or 1 Sv. Summary Judgment Opinion, 927 F. Supp. at 848. Perhaps because of their faith in the reliability of these biological indicators, Trial Plaintiffs proceeded to try their respective claims on the theory that each of the Trial Plaintiffs had been exposed to an equivalent dose of at least 10 rem or 100 mSv each.84 See Brief of Non-Trial Plaintiffs (No. 96-7624), at 18, 38.

To support their contention that they were each exposed to significantly higher doses of ionizing radiation than the governmental studies calculated, and the defendants admit to, the Trial Plaintiffs developed a "blowout" theory. Under that theory, one or more unfiltered hydrogen blowouts occurred on the afternoon of the first day of the accident, whereby large quantities of radioactive noble gases and other radioactive nuclides, such as iodine and cesium, were expelled into the environment. Summary Judgment Opinion, 927 F. Supp. at 857. They assert that, after the blowout, an extremely dense, yet narrow, plume of radioactive effluents traveled through the atmosphere evading all of the radiation monitors in place in the areas surrounding the plant and the communities. Id.

The "blowout" theory was first developed by Trial Plaintiffs' expert, Richard Webb, who opined in a report that a total of 106 million curies of noble gases were released during the accident, more than half of which escaped during a two and one-half hour "blowout" on the afternoon of the first day of the accident. Webb did not testify at the in limine Daubert hearing. After the first round of hearings ended, Webb left a voice-mail message for defendants' counsel recanting his proposed testimony. The

---

84. In contrast, the appellees' expert calculated that only one of the Trial
Plaintiffs was exposed to a dose greater than 25 mrem. She is Jolene Peterson, who appellants claim was exposed to an maximum dose of 75 mrem. Appellees' expert further calculated that plaintiffs Pearl Hickernell, Ethelda Hilt, Leo Beam and Ronald Ward, were exposed to maximum doses under 10 mrem and that plaintiffs Garry Villella, Lori Dolan, Joseph Gaughan and Paula Obercash were exposed to maximum doses between 15 and 25 mrem. Summary Judgment Opinion, 927 F. Supp. at 852.

District Court concluded that Webb's recantation only confirmed its intention to exclude Webb's proffered testimony as unreliable.85 In re TMI Litigation Cases Consolidated II, 911 F. SUPP. 775, 791 (M.D. Pa. 1996).

However, because of the significance of the "blowout" theory to plaintiffs' case, the District Court did permit the Trial Plaintiffs to use another witness -- a nuclear engineer named David Lochbaum -- to replace Webb's testimony about a blowout. Lochbaum testified at an in limine hearing that significantly more than 10 million curies of noble gases reached the environment as a result of the accident. He opined that these gases were released from steam generator B in the early hours of the accident. However, somewhat contradictorily, he also testified that he "did not believe that there was evidence of a blowout." In re TMI Litigation Cases Consolidated II, 922 F. Supp. 997, 1052 (M.D. Pa. 1996). He testified, however, that if a blowout did occur, it was of limited length -- on the order of minutes and not over the two or three hours Webb believed. Id. Nonetheless, he testified that the blowout did release significant amounts of noble gases even though it lasted only a short time. Id.

The District Court concluded that Lochbaum's testimony was dependent upon other of the Trial Plaintiffs' experts being able to demonstrate that significant amounts of radionuclides were emitted. The court reasoned that if other experts were able to competently testify about significant amounts of noble gases being emitted, then Lochbaum's testimony was admissible on the issue of the source of the emissions. Thus, the court concluded that if no other expert could competently testify about significant releases of radionuclides, Lochbaum's proffered testimony about a blowout must be excluded. Id. Consequently, the trial plaintiffs proffered several witnesses whose testimony was relevant to the existence of a blowout. It is those witnesses for the most part, whose testimony was challenged under Daubert, and whose reliability is now at issue.

With this background established, the stage is properly set to begin our analysis of the District Court's Daubert

---

85. The Trial Plaintiffs do not argue that Webb's report and testimony should have been admitted.

decisions regarding the Trial Plaintiffs' dose exposure experts.

2. Standards Governing the Admissibility of Scientific Evidence.

Federal Rule of Evidence 702 provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

In Daubert v. Merrell Dow Pharmaceuticals, Inc ., 509 U.S. 579 (1993), the Court set forth parameters for determining when proffered expert testimony can be admitted into evidence.86 The Court held

> an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation -- i.e., "good grounds," based on what is known. In short, the requirement that an expert's testimony pertaining to "scientific knowledge" establishes a standard of evidentiary reliability.

Id. at 590.87 Rule 702 also requires that the evidence or testimony "assist the trier of fact to understand the

---

86. In Daubert, the Court also held that Fed. R. Evid. 702 does not incorporate the common law rule, known as the " Frye rule". See Frye v. United States, 54 App. D.C. 46, 293 F. 1013, 1014 (1923). In Frye, the court held that expert testimony is admissible only insofar as it is based on a technique that is "generally accepted" in the scientific community.

87. Daubert concerned the admissibility of scientific evidence proffered by
plaintiffs that demonstrated that the prescription anti-nausea drug, Bendectin, marketed by defendant and ingested by pregnant women, caused birth defects. Because the issue in Daubert was scientific knowledge, the Court did not discuss "technical or other specialized knowledge" to which Rule 702 also applies. Daubert, 509 U.S. at 590 n.8. Recently, however, the Supreme Court has decided that Daubert applies not just to testimony based on "scientific" knowledge, but also to "technical or other specialized knowledge." Kumho Tire Co., Ltd. v. Carmichael, ___ U.S. ___, 119 S. Ct. 1167 (1999).

evidence or to determine a fact in issue." "This condition goes primarily to relevance." Id. at 591. This "consideration has been aptly described . . . as one of `fit' ". Id. Rule 702's " `helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. Id. at 591-92.

The Court in Daubert concluded that Rule 702"clearly contemplates some degree of regulation of the subjects about which an expert may testify." Id. at 589. Thus, the Court established a "gatekeeping role for the judge." Id. at 597. The Court wrote:

> Faced with a proffer of expert scientific testimony, . . . the trial judge must determine at the outset, pursuant to Rule 104(a),88 whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Id. at 592-93. The Court held that these matters should be established "by a preponderance of proof," Id. at 593 n.10, and identified some "general observations," relevant to the proponent's burden, while acknowledging that the factors it identified were not all-inclusive. Id. ("[m]any factors will bear on the inquiry.").

First, "a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested." Id. "Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication." Id. Publication, which is an element of peer review, "is not a sine qua non of admissibility: it does not equate with reliability." Id.

---

88. Fed. R. Evid. 104(a) provides: "Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or
the admissibility of evidence shall be determined by the court, subject to the provisions of subsection (b)[pertaining to conditional admissions].

However, submission to the scrutiny of the scientific community is a component of "good science." Id. Accordingly, "[t]he fact of publication (or lack thereof) in a peer reviewed journal. . .will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology upon which an opinion is premised." Id. at 594. Third,"in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation." Id. Fourth, andfinally, "general acceptance" can have bearing on the inquiry. Id. "Widespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique which has been able to attract only minimal support with the community may properly be viewed with skepticism." Id. However, "general acceptance" is "not a necessary precondition to the admissibility of scientific evidence." Id. at 597. Indeed, the Court specifically declined to require general acceptance when it rejected the Frye rule. See n.86 supra. Rather, general acceptance is but one factor that is considered along with all other factors relevant to the 702 inquiry.

The Court concluded by emphasizing that the "inquiry envisioned by Rule 702 is . . . a flexible one," and by reminding the trial courts that the "focus . . . must be solely on principles and methodology, not on the conclusions they generate." Id. at 595. The Court also noted that the District Court should be mindful of other applicable rules in assessing a proffer of expert scientific testimony under Rule 702. Specifically, Rule 703 which provides that expert opinions based on otherwise inadmissible hearsay are to be admitted only if the facts or data relied upon are of a type reasonably relied upon by experts in the particular field in forming opinions; Rule 706 which allows the court in its discretion to procure the assistance of an expert of its own choosing; and Rule 403 which permits the exclusion of relevant evidence if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. Id.

We applied the teachings of Daubert in deciding In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717 (3d Cir. 1994), cert. denied, 115 S. Ct. 1253 (1995)(hereinafter "Paoli II"). There, we held that Rule 702 has two major requirements. First of all, the proffered "expert" must be qualified to express an expert opinion. This "qualifications" requirement is liberally interpreted and includes"a broad range of knowledge, skills, and training," Paoli II, at 741.89 However, "the level of expertise may affect the reliability of the expert's opinion." Id.

Secondly, the proffered expert opinion must be reliable. Thus, "an expert's testimony is admissible so long as the process or technique [as opposed to the conclusion] the expert used in formulating the opinion is reliable." Id. at 742 (emphasis added). We listed various factors enunciated in Daubert that assist in evaluating whether a given scientific methodology is reliable, and we also relied upon several factors we had previously identified in United States v. Downing, 753 F.2d 1224 (3d Cir. 1985). Paoli II, at 742. We held that the District Court's inquiry under Rule 702 should be guided by the criteria set forth in Daubert and Downing as well as other factors that may be relevant to a given inquiry. The factors we specifically identified include:

> "(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put."

Paoli II, at 742 n. 8. We also noted that the proffered expert testimony must assist the trier of fact. In other words, admissibility depends in part on "the proffered connection between the scientific research or test result to be

---

89. The liberal policy of admissibility under Rule 702 extends to the substantive as well as the formal qualification of experts.

presented and particular disputed factual issues in the case." Id. at 743.

Furthermore, we cautioned that the standard for determining reliability "is not that high," Id. at 745, even given the evidentiary gauntlet facing the proponent of expert testimony under Rule 702. Thus, plaintiffs do not "have to prove their case twice -- they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable."[90] Id. at 744. In other words, "the evidentiary requirement of reliability is lower than the merits standard of correctness." Id.

> "The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The judge might think that there are good grounds for an expert's conclusion even if the judge thinks that there are better grounds for some alternative conclusion, and even if the judge thinks that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result."

Id. Thus, in Paoli II we explained

> the primary limitation on the judge's admissibility determinations is that the judge should not exclude evidence simply because he or she thinks that there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect. The judge should only exclude the evidence if the flaw is large enough that the expert lacks the `good grounds' for his or her conclusions.

Id. at 746.[91]

The test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether

---

90. The distinction is indeed significant as it preserves the fact finding role of the jury.

91. Such a flaw undermines the fact finding role of the jury by allowing it to reach factual conclusions which may be based on "unreliable" evidence and, therefore, are more likely to be erroneous.

the opinion is supported by the best methodology or unassailable research. Rather, the test is whether the "particular opinion is based on valid reasoning and reliable methodology." Kannankeril v. Terminix International Inc., 128 F.3d 802, 806 (3d Cir. 1997) (emphasis added). The admissibility inquiry thus focuses on principles and methodology, not on the conclusions generated by the principles and methodology. Id. (citing Paoli II at 744). The goal is reliability, not certainty. Once admissibility has been determined, then it is for the trier of fact to determine the credibility of the expert witness. Id. (citing Paoli II at 743-746). "The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination." Id. Therefore, if the methodology and reasoning are sufficiently reliable to allow the fact finder to consider the expert's opinion, it is that trier of fact that must assess the expert's conclusions. The inquiry is a factual one, not a legal one.

Nonetheless, "conclusions and methodology are not entirely distinct from one another." General Electric Co. v. Joiner, ___ U.S. ___, 117 S. Ct. 512, 519 (1997). The court "must examine the expert's conclusions in order to determine whether they could reliably flow from the facts known to the expert and the methodology used." Heller v. Shaw Industries, Inc., 167 F.3d 146, 153 (3d Cir. 1999). "A court may conclude that there is simply too great a gap between the data and the opinion proffered." Joiner, at 519. However, such an opinion will be excluded not because it is necessarily incorrect, but because it is not sufficiently reliable and therefore too likely to lead the factfinder to an erroneous conclusion.

Here, the District Court assessed the disputed expert testimony under Rule 702 and held that it did not meet the conditions precedent to admissibility under Daubert. We subject the District Court's interpretation of Rule 702 to plenary review. Paoli II at 749. However, we review the District Court's decision to admit or exclude scientific evidence for an abuse of discretion. Joiner, at 519.92 An

---

92. In Joiner, the Court rejected the view that a district court's decision
on the admissibility of scientific evidence should be reviewed under a heightened or stringent abuse of discretion standard. That view is the one we adopted in Paoli II at 749-50.

abuse of discretion arises when the District Court's decision "rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact." Hanover Potato Products, Inc. v. Shalala, 989 F.2d 123, 127 (3d Cir. 1993). An abuse of discretion can also occur "when no reasonable person would adopt the district court's view." Id. However, we do not interfere with the District Court's exercise of discretion "unless there is a definite and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors." Id.

With the parameters of our inquiry in mind of our review in mind, the teachings of Daubert and the aforementioned scientific principles as our guideposts, we can now proceed to apply yardstick of Daubert to the expert opinions at issue here and determine if they were properly excluded under the Rules of Evidence.

3. Trial Plaintiffs' Dose Exposure Expert Witnesses.

i. Ignaz Vergeiner.

a. Qualifications.

Ignaz Vergeiner is a meteorologist with undergraduate degrees in mathematics and physics, and a Ph.D. in meteorology; all of which were earned at the University of Innsbruck in Austria. He is an Associate Professor in the Department of Meteorology and Geophysics at the University of Innsbruck and has taught graduate and undergraduate courses at that University for twenty years. App. Vol. V., at 3578. He was proffered as an expert in boundary level meteorology in alpine regions.93 His

---

93. During his testimony, Vergeiner offered the following definition of "boundary layer meteorology": "Meteorology would be the scientific description of processes occurring in the layer of air between the earth's surface, land or ocean, an up to 10 miles, 20 miles, 50 miles, depending on your discipline; even further, if you wish. But mainly it's the lower 10
miles, 15 miles. And boundary layer meteorology would be the same, but restricted to the layer of air adjacent to the surface, which may be a few hundred meters up to a couple of miles. And boundary layer meteorology, the characteristic is that you work near the earth's surface, which means you have friction and you have the influence of heat input

testimony was offered to explain how the hypothesized plume containing the highly radioactive release that is part of "blow out," traveled and dispersed throughout the area surrounding Three Mile Island.

b. Vergeiner's Opinion.

Vergeiner's proffered testimony covered three areas. First, as an expert in boundary level meteorology, he sought to testify about the weather conditions at Three Mile Island and the surrounding areas during, and immediately following, the accident. He was to testify about his plume dispersion hypothesis based upon his studies of the weather conditions. Secondly, he sought to estimate radiation doses in certain areas surrounding Three Mile Island. Finally, he sought to testify about his distrust and skepticism of the original plant data from TMI-2 concerning plume dispersion and radiation releases in an effort to counter the defendants' evidence regarding exposure.

Essentially, Vergeiner opined that a weather inversion, in combination with the alpine terrain that surrounds Three Mile Island, prevented the radioactive plume from rising high into the atmosphere, spreading out and dispersing in the expected "Gaussian" manner.94 App. Vol. V., at 4005-09. Instead, he believed that the radioactive plume remained narrow, concentrated and intense and moved

---

at the earth's surface. Now, for example, this means that the winds change with height in the boundary layer much more than they do in the upper part of the atmosphere. Then you would have the daily range of temperature, warming and cooling, which would be mainly restricted to the boundary layer. And you would have one characteristic, you might have turbulence. You don't always have turbulence, but the boundary layer is a place where you typically may find turbulence." App. Vol. V., at 3999-4000. Vergeiner also testified that the land surrounding Three Mile Island consisted of alpine or mountain terrain. For meteorological purposes, a mountain is a structure that is elevated 50 meters or more above the flat terrain. Id. at 4006-07, 4081-82.

94. Under the "Gaussian plume model", dispersion is three-dimensional, i.e., dispersion will be downwind, cross-wind and vertical. See Environmental Software and Services, AirWare: Urban Air Quality Assessment and Management (visited January 4, 1999) http://www.ess.co.at/AIRWARE/gauss.html>.

erratically in a north, northwest direction from Three Mile Island. He believed that it frequently came in contact with hilly terrain which caused it to reconcentrate, and that after it reconcentrated, it touched down on the ground and exposed the population to high levels of radiation. Id. at 3583-85; 3761-68; 4017-29. To illustrate his plume dispersion theory, Vergeiner produced a water model and a "plume movie". The latter is not a "movie" at all, but is rather a series of sketches he drew by which he illustrated the plume movement he hypothesized. Id. at 3769-775; 4076-78. The water model is a video of a large scale model he built in which colored water was injected into a tank filed with clear water that contained a model of alpine terrain. Id. at 3756-60.

Vergeiner's qualifications as an expert in meteorology were not in dispute. Nonetheless, the defendants moved to exclude all of his proffered testimony under Rule 702. After a hearing, the District Court subjected his proffered testimony to an exhaustive and rigorous Daubert/Paoli II analysis and excluded the majority of it, including the plume movie and the water model. In re TMI Litigation Cases Consolidated II, 911 F. Supp. 775, 791-799 (M.D. Pa. 1996). However, the court held that, as an expert in meteorology, Vergeiner could testify about the weather conditions during and immediately following the accident if the Trial Plaintiffs could demonstrate how that testimony would assist the jury in determining a pertinent fact. Id. at 799.

c. Discussion and Conclusions.

The Trial Plaintiffs argue that by excluding the overwhelming majority of Vergeiner's proposed testimony, the District Court "elevate[d] its opinion of science over that of Dr. Vergeiner's, even though the court had no training in the complex meteorological issues that he discussed. . . ." Trial Plaintiffs' Br. at 24. We disagree. Preliminarily, we note that a proponent of rejected expert testimony could always level such a challenge against an unfavorable Daubert ruling. However, an adverse ruling under Daubert does not, in and of itself, suggest that a court substituted its opinion for that of a trained scientist. Here, we conclude that the trial court did not substitute its scientific opinion for Vergeiner's. Rather, the court correctly applied the Daubert/Paoli II guidelines and properly found the bulk of Vergeiner's testimony "unreliable and therefore inadmissible under Rule 702." 911 F. Supp. at 799. Although wefind it unnecessary to review the District Court's application of each Daubert/Paoli II criteria, we believe a few examples demonstrate that the District Court's decision to exclude the bulk of Vergeiner's proposed testimony was not an abuse of discretion.

First, in formulating his plume dispersion hypothesis, Vergeiner discarded standard and generally accepted computer models, especially the Gaussian plume model.95 App. Vol. V, at 4003-07. At the hearing, Vergeiner testified that the Gaussian plume model was not an adequate model to hypothesize plume dispersion given the weather conditions on the day of the accident, and considering the terrain surrounding Three Mile Island. Id. at 4007; 4051-54. In rejecting the standard computer models, Vergeiner wrote in one of his two reports:

Clearly, available synoptic meteorological96 observations

---

95. The Gaussian plume model was the model used by appellants' expert, Keith Woodward, to formulate his opinion as to the atmospheric dispersion of the radioactive materials released as a result of the accident. See Affidavit of Keith Woodard, at P 14. However, by referring to the Gaussian plume model, we do not mean to suggest that it is the model Vergeiner should have used. Rather, it is mentioned only as an example of a generally accepted computer model.

96. At the hearing, Vergeiner offered the following definition of "synoptic meteorology."

> Synoptic meteorology is essentially the--comes out of the realization that when you plot weather observations taken at the same time, you know, which could be nighttime in Europe and late afternoon in this country, then you can draw maps. And you start to interpret them and you find out that, you willfind certain prominent features, like weather fronts, and they would move in a coordinated way, right? You would get the rainsfirst in, God knows where, in Chicago, and later on you would get them further east. And this is what's called synoptic meteorology.
>
> And to do that, of course, you don't want to look only at surface observations, but you do want to look at upper air observations,

> cannot determine the flow field and dispersion characteristics down to a scale of hundreds of meters or a few kilometers, as needed to estimate local transport and diffusion from TMI releases. . . .
>
> So why not straightway model the flow numerically using the power of modern computers? Let me remind the reader of the enormous complexity of such a task. Transport and dispersion models exist to the hundreds, many of them in the nuclear industry or in the scientific "grey zone" around it. . . .
>
> Quite a few of these models are global in scale, and some apparently have succeeded in simulating the path and contaminating action of the Chernobyl clouds reasonably well, after years of tuning and verification on the many observations available. . . .
>
> Documentation is a problem, as well as the need for special graphics and internal routines, or compatibility of various computer languages. Not all applications have been successes. . . .
>
> It was my judgement, therefore, not only that it did not seem feasible to obtain access and results within a

---

> because the air moves faster at upper levels. And in order to interpret your features, you do want both surface and upper air observations.
>
> And for upper air, there is a network of balloons soundings, these big balloons with an instrument package, and they are launched every 12 hours at stations like Pittsburgh, New York--Albany, New York, Washington, D.C., stations at about that distance. And from those radio soundings, you get temperature and winds and pressure at upper levels. They are the backbone of synoptic meteorology.

App., Vol. V, at 4033-34. As part of his synoptic meteorological analysis, Vergeiner presumably analyzed "a wide range of meteorological data, including national data regarding the movement of weather fronts throughout the country, regional data from the eastern part of the United States, and local data from the TMI area." App. Vol. V, at 3549. The District Court found that synoptic analysis is a standard meteorological technique that has been subjected to significant peer review. 911 F. Supp. at 794-95.

> limited time span and financial frame, but that relatively simpler, well-tested, more robust and accessible models might be just as good, even preferable. This may appear to do injustice to the more than 50 man-years' expert work condensed in this enormous structure. There is no doubt that each of these models is capable of computing flow structures very suggestive of real nature, but I couldn't convince myself that the enormously increased expense would bear a sound relation to similarly improved results.

Ignaz Vergeiner, Treatise on the TMI-2 Accident of March 28, 1979, Particularly its Meteorological Aspects Including Transport and Dispersion of the Radionuclides Released 49-50 (July 1994)(unpublished)(hereinafter "Vergeiner I"); App. Vol. V, at 3634-35.

Rather than using the standard computer models, Vergeiner chose to use a "numerical model" which he initially referred to by the acronym "AMBIMET," Vergeiner I, at 51; App. Vol. V, at 3636, but which he later called, in his second report, the "FITNAH model operated by AMBIMET." Ignaz Vergeiner, Treatise on the Meteorological Aspects of the TMI-2 Accident 49 (February 1995) (unpublished) (hereinafter "Vergeiner II"); App. Vol. V, at 3752. In any event, he described the model he used, whether AMBIMET or FITNAH, as "a regional one, not designed to simulate local flows on the scale of hundreds of meters" that "requires proper synoptic input." Vergeiner I, at 51-52; App. Vol. V, at 3636-37.

However, Vergeiner never provided any testimony, documentation or any other evidence that the numerical models he did use are generally accepted within the meteorological or the broader scientific community. Although the "general acceptance" test of Frye v. United States, 54 App. D. C. 46, 293 F. 1013 (1923), was displaced by the Federal Rules of Evidence, Daubert, 509 U.S. at 589, "general acceptance" in the scientific community can "yet have a bearing on the inquiry," and be an "important factor in ruling particular evidence admissible." Daubert, at 594. "[A] known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism." Id. (quoting United States v.

Downing, 753 F.2d 1224, 1239 (3d Cir. 1985)). Thus, while general acceptance is not the focus of the inquiry, it is a relevant factor which may be considered. Accordingly, a court may well cast a jaundiced eye upon a technique which is not supported by any evidence of general acceptance absent other indicia of reliable methodology. Here, it is impossible to know whether the disputed model's methodology can or has been tested or whether the model has been subjected to peer review or publication. Neither can we determine its known or potential rate of error. Consequently, we can hardly conclude that the plume dispersion model Vergeiner hypothesized meets the Daubert requirement of evidentiary reliability.

Second, Vergeiner's "plume movie" (which, as noted earlier, is but rather a series of sketches[97] he drew to illustrate his hypothesized plume movements) is based on pure speculation. In his second report, Vergeiner presented his opinion as to behavior of the plume. He wrote:

> For conclusion, I present my own tentative TMI plume "movie" for the first few hours. . . Its chief purpose is visualization of possible plume shifts and exposures, and realization of the kind of information we would need to be reasonably sure about transport and dispersion of TMI-2 effluents. [The plume movie] is the beginning of an investigation, not the end.

App. Vol. V, at 3769 (emphasis added). The speculative nature of the plume movie was made even more apparent during Vergeiner's deposition when he described the plume movie.

> I make it clear that the [plume movie] and following are not meant to be -- I think the way I write it is that they are the beginning of a discussion and not the end of a discussion. . . . And I realize it's absolutely clear, and I state it, that this, this is an assumption, I think it's not an unreasonable one, it has some foundation, but at this stage it is just a, well, it's more than a provocation, but this --

---

97. The plume movie is located in Vergeiner II and is referred to therein as Figure 9.1. Vergeiner II, at 67-71; App. Vol. V, at 3769-74.

Q: It's the articulation of a hypothesis yet to be explored?

A: Of a hypothesis, and it is an illustration, cer tainly an illustration of winds turning rapidly, which they did, that one is for sure, and the consequences of a plume, I wanted to illustrate how distorted a plume can become. I wanted to illustrate the effects. I just don't have enough of a database to prove details of this. This is absolutely clear and conceded. Absolutely clear .

Id. at 3941.

Rule 702 not only requires that the scientific opinion proffered by the expert be supported by "good grounds," Daubert, at 590, it also mandates that the challenged testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." This requirement is one of relevance and expert evidence which does not relate to an issue in the case is not helpful. Id. at 591. The expert's testimony must "fit," and admissibility depends, in part, on a connection between the expert opinion offered and the particular disputed factual issues in the case. Paoli II, at 743. "Fit is not always obvious, and scientific validity for one purpose is not necessarily validity for other unrelated purposes." Id. Here, Vergeiner's report and testimony make clear that his plume movie was merely an assumption visualizing possible plume movements. Given its speculative character, the plume movie was properly excluded under Daubert.

We note that in order for expert testimony to be reliable, and therefore admissible, it must be based on the methods and procedures of science rather than subjective belief or speculation. Kannankeril, 128 F.3d at 806 (citing Paoli II, 35 F.3d at 744). Consequently, Vergeiner's plume movie, and, (as will be discussed), his water model, are also lacking in scientific reliability and are inadmissible because of their speculative character. Nevertheless, we believe that the plume movie and the water model are more appropriately inadmissible because they lack fit.

The water model does not "fit." The water model is a video of a large scale model tank, the bottom of which is a topographical map of alpine terrain. The tank isfilled with water, a dye is injected into the water and a current is run through the water to simulate air flow. Its intended purpose is to demonstrate how a material will disperse in the atmosphere in relation to terrain and air patterns. See 911 F. Supp. at 792 n.10. However, the water model is just as speculative as the plume movie. In his deposition, Vergeiner testified that the water model was a demonstration and a "tool for visualization," but was not intended"to exactly simulate flows at the time of the TMI accident." App. Vol. V, at 3930-31. In fact, Vergeiner testified that"[t]here's no way to [simulate the complete atmospheric structure] in a simple shallow water model." Id., at 3930. Simply put, the water model does not assist the finder of fact and is, therefore, not admissible under Rule 702.

Most importantly, we note that Vergeiner's proffered testimony about the amount of radioactive materials delivered to the areas where the plume traveled was totally unreliable. That testimony was intended to explain how the hypothesized plume containing the high concentrations of radionuclides (believed to be part of the "blowout") dispersed throughout the Three Mile Island Area exposing the population to high levels of radiation.

In the field of radiation dose reconstruction, 98 "the amount of radionuclides released from a site over a specific period" is called the "source term". RADIATION DOSE RECONSTRUCTION, at 16. A proper dose reconstruction study should determine the amount of radionuclides released over a specified period as well as the rate of release as a function of time. Id. Consequently, a complete description of the source term "includes what was released and in what form and where and when the release occurred." Id. The National Research Council's Committee on an Assessment of [Center for Disease Control and Prevention] Radiation Studies, has noted that if dose reconstruction studies are credible, they "must rely on solid science, state-of-the-art

---

98. "[D]ose reconstruction is defined as the process of estimating doses to the public from past releases to the environment of radionuclides . . . .
These doses form the basis for estimating health risks and for determining whether epidemiologic studies are warranted." RADIATION DOSE RECONSTRUCTION, at 7.

methods, and careful peer review." Id. at 14. The Committee further noted that "[u]ltimately, a dose reconstruction study will be judged by the scientific community on the basis of the technical quality of the study and its contribution to science." Id.

Vergeiner is a meteorologist and not an expert in radiation dose reconstruction.99 He admitted that he received the source term he used to calculate the radiation exposure from Trial Plaintiffs' counsel. App. Vol. V, at 4103-04. He also testified that the gross magnitude of his releases were the same as those postulated by Webb (before Webb recanted his proposed expert testimony)100 but he admitted that his release times were different than Webb's. Id. However, Vergeiner was not able to explain the difference. Id.

Moreover, Vergeiner violated an elementary principle of credible dose reconstruction in estimating dose exposure. The National Research Council's Committee on an Assessment of CDC Radiation Studies has stated,"[t]he credibility of a comprehensive source term study depends upon confirming that all pertinent documents have been seen and evaluated. Complete records are essential in identifying the source term." RADIATION DOSE RECONSTRUCTION, at 18. However, there is nothing in the record before us that indicates that Vergeiner attempted to verify the source terms he took from Trial Plaintiffs' counsel. Consequently, his dose estimates can not be ruled credible or reliable. Accordingly, they cannot assist a fact finder.

The problem inherent in the source terms that counsel supplied was apparent when Vergeiner's plume concentration hypothesis was tested. In his first report, Vergeiner compared his estimated dose measurement to that recorded by the thermoluminescent dosimeters ("TLD's") in the TMI Radiation Environmental Monitoring Program101 for the TMI-area community of Middletown,

---

99. The District Court specifically found that Vergeiner was not an expert in dose reconstruction or dose estimation. 911 F. Supp. at 797-98. The Trial Plaintiffs do not challenge that finding.

100. See p. 77, supra.

101. See p.76 n.79, supra.

Pennsylvania. Vergeiner accepts that the TLD measured dose from March 28, 1979, the date of the accident, to April 28, 1979, was 9.1 mrems (.91 mSv). Vergeiner I, at 10; App. Vol. V, at 3595. But, his estimated dose measurement for Middletown was 200 mrems (2mSv) in only three hours on March 28, 1979. Id. Aside from expressing his basic and fundamental mistrust of TLD's, see, e.g., App. Vol. V, at 4106, Vergeiner was unable to explain the discrepancy between the TLD measured dose at Middletown and his estimate. His best explanation was rather cryptic and enigmatic:

> So the reader has a chance to draw conclusions for himself, even if I may suggest a conclusion, but the reader can check this, these assumptions, and he has a chance to see for himself. He can choose which he believes. He can reduce Webb's estimate, he can do other things.

App. Vol. V, at 3968. However, Vergeiner's testimony must assist the fact finder in understanding the evidence or determining a disputed issue of fact. His cryptic explanation for the difference in dose measurement does neither.

We conclude, therefore, that the District Court did not abuse its discretion in excluding Vergeiner's testimony about issues other than the relevant weather conditions.

ii. Charles Armentrout and Victor Neuwirth.

a. Qualifications.

Charles Armentrout has an undergraduate degree in physics from the University of Maine, a master's degree in physics from Wesleyan University and a master's degree in radiological physics from Columbia University College of Physicians and Surgeons. He is an Associate Professor at the University of Southern Maine. Victor Neuwirth has an undergraduate degree in chemistry from the State University of New York at Stony Brook and a master's degree in Chemistry from the State University of New York at New Paltz. He is a laboratory associate and Professor of Chemistry at the University of Southern Maine. Armentrout and Neuwirth authored a joint report for the Trial Plaintiffs

(Affidavit of C. E. Armentrout and Victor J. Neuwirth, App. Vol. VIII, at 7339-65);102 however, the District Court discussed their proffered testimony separately.

Armentrout's proffered testimony based on his own observations and experiences covered two separate areas: (1) a discussion of what he called "anomalously high" radiation readings registered shortly after the TMI-2 accident; and (2) a discussion of radiation survey meter readings allegedly recorded by a local resident during the TMI-2 accident.103 Neuwirth's proffered testimony concerned the results of his analyses of soil samples taken from Three Mile Island and the surrounding area. He performed his analysis at Armentrout's request. Then, based on Neuwirth's analyses, Armentrout made radiation dose exposure estimates.

b. Armentrout's Observations and Experiences.

In his written report, Armentrout wrote that on March 31, 1979, he and a former student assembled radiation detection equipment on the roof of the science building at the University of Southern Maine. The equipment consisted of a gamma-beta Geiger-Muller detector, pre-amplifier and

---

102. Armentrout and Neuwirth prepared an original report and a revision. The original report is dated February 20, 1995, and the revision is dated May 11, 1995. The revision makes no substantive changes to the original report, it merely corrected some mathematical errors. App. Vol. VIII, at 7827.

103. Armentrout's proposed testimony also covered two other areas. He was to testify about the results of analyses of soil samples taken from Three Mile Island and surrounding areas that Neuwirth performed at his request. He was also to give an explanation of the rate-dependent behavior of Geiger-Muller radiation detectors. However, in an unpublished order and opinion, the District Court precluded Armentrout from testifying as to the substance of Neuwirth's soil sampling analyses. In re TMI, No. 88-1452 (M.D. Pa. Nov. 9, 1995). The Trial Plaintiffs do not
challenge that ruling. Armentrout's proposed testimony about Geiger-Muller radiation detectors was not discussed by either party in the District Court. 911 F. Supp. at 799 n.22, and the Trial Plaintiffs do not discuss it in the brief they filed in this appeal. Consequently, we assume that this portion of Armentrout's proposed testimony has been abandoned by the Trial Plaintiffs. In any event, the issue is clearly waived.

count divider. Affidavit of C. E. Armentrout and Victor Neuwirth, at 2-3; App. Vol. VIII, at 7340-41. In his report he wrote, and at the in limine hearing he testified, that the detection equipment recorded two "anomalous bursts" of radiation activity. Affidavit, at 3; App. Vol. VIII, at 7341; Tr. at 1249; App. Vol. VIII, at 7769. He described the bursts as "significant radioactive sample[s]. . . detectable and identifiable only then as being mixed beta-gamma radiation." Affidavit, at 3; App. Vol. VIII, at 7341. He memorialized his observations in a letter to the President of the University of Southern Maine. Exhibit A to Affidavit; App. Vol. VIII, at 7367-72. In addition to his own observation of anomalous bursts of radiation, Armentrout's report claims that "one or more governmental installations near Portland," Maine, recorded radiation readings similar to those he recorded. Affidavit, at 4; App. Vol. VIII, at 7342. Armentrout also notes that an article in the February 8, 1980 issue of SCIENCE magazine reported that elevated levels of Xenon-133 (133Xe) were recorded in Albany, New York, on March 29 and 30, 1979. In the opinion of the authors of that article, the increased levels of 133 Xe "could be attributed to releases from the Three Mile Island reactor accident." App. Vol. VIII, at 7375. Armentrout believes that the SCIENCE magazine article confirms his conclusion based on his recorded bursts of radiation activity, that the TMI plume passed over the area. Affidavit, at 4; App. Vol. VIII, at 7342. However, Armentrout candidly admitted that his observed readings did not tell him what radionuclides were released as a result of the accident or how large the releases were. Tr. at 1290; App. Vol. VIII, at 7810.

The defendants did not challenge Armentrout's qualifications as an expert. Rather, they argued that this portion of his proffered testimony would not be helpful to the trier of fact. The court declined to "trudge through the Daubert/Paoli II" analysis and simply found that this portion of Armentrout's proffered testimony does not" `fit' within any material fact in issue." 911 F. Supp. at 800. Consequently, the court precluded Armentrout from testifying about his observation of anomalous bursts of radiation. Id.

Armentrout was also proffered to testify about efforts he made to verify radiation readings taken by residents living near Three Mile Island during the accident. In his report, he wrote that in 1992 he had several telephone conversations with a man who lived on the west shore of the Susquehanna River opposite Three Mile Island in Etters, Pennsylvania. According to Armentrout, that man claimed that he was trained in the use of radiation detection instruments and said that he had recorded and preserved "significant gamma emissions from TMI made in the time-frame of the accident." Affidavit, at 24; App. Vol. VIII, at 7362. Armentrout located similar instruments and traveled to the Three Mile Island area to visit the man and verify the readings. However, Armentrout could notfind him. Nonetheless, Armentrout met a neighbor of the man who remembered that he (the neighbor) and the man Armentrout was seeking had purchased identical detection instruments. The neighbor told Armentrout that he took a reading during the accident that sent his detection instrument off scale. Armentrout opined that this conversation verified the missing man's reports of high readings taken during the accident.

Not unexpectedly, the defendants challenged this portion of Armentrout's proffered testimony as being totally unreliable, rank hearsay. The District Court agreed and precluded this portion of Armentrout's proffered testimony. 911 F. Supp. at 800-801.

c. Discussion and Conclusion.

We conclude that the District Court properly precluded both portions of Armentrout's proffered testimony. His testimony about his attempts to verify the high radiation readings made by the unidentified man in Etters is purely anecdotal and any reliance on the unconfirmed Etters readings is totally lacking in scientific reliability. Moreover, his proffered testimony about the readings of bursts of radiation activity fails to satisfy the helpfulness prong of Rule 702. Armentrout's equipment on the roof of the university's science building recorded two bursts of radiation activity. Those two observations, his claim that government installations around Portland, Maine, recorded similar activity, and the article in SCIENCE magazine, form the basis of his conclusion that the TMI plume passed over the northeastern part of the United States.

Rule 702's "helpfulness" or "fit" prong"requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." Daubert, at 592. Armentrout merely assumed that his observations of two bursts of radiation activity were the result of the TMI plume passing over his area of southern Maine. That assumption is supported by nothing other than conjecture, and we do not believe that the District Court erred in ruling the evidence inadmissible under Rule 702.

Moreover, assuming arguendo that Armentrout's opinion that the TMI plume passed over the northeast United States has scientific reliability, his opinion still would not be helpful to the trier of fact. The Trial Plaintiffs proffered Armentrout's testimony in an effort to demonstrate that they were exposed to levels of radiation sufficient to cause their injuries. They based their trial strategy on the theory that as a result of the accident, they were exposed to an equivalent dose of at least 10 rems or 100 mSv each. 104 However, Armentrout admitted that he could not tell with any degree of scientific certainty how large the radioactive releases from the accident were. The connection between his testimony and a crucial fact in issue, i.e., whether the Trial Plaintiffs were exposed to equivalent doses of 10 rems or 100 mSv each was tenuous at best because he could not testify as to the magnitude of the releases of radionuclides.

d. Neuwirth's Soil Sample Analyses and Armentrout's Dose Estimates.

As noted above, Neuwirth performed analyses of soil samples obtained from the Three Mile Island area at Armentrout's request. Neuwirth concentrated the soil samples by chemical extraction and used a sodium iodine detector to take integrated counts of radionuclides. Affidavit, at 7-9; App. Vol. VIII, at 7345-7347. Although Neuwirth found that certain Three Mile Island area soil samples contained radioactive materials, he was unable to identify specific radionuclides. Affidavit, at 21; App. Vol. VIII, at 7359. Because he was unable to identify any specific radionuclide, Armentrout directed him to calculate the half-life of each sample as a whole. Neuwirth calculated

---

104. See p. 77, supra.

the gross activity of the samples in 1994 and then recounted the gross activity of the same samples one year later in 1995. Based on these two points, Neuwirth calculated a generalized half-life calculation for each of the samples. Affidavit, at 14-15; App. Vol. VIII, at 7352-53. From the analyses of the soil samples and the calculation of the gross activity of the samples, Neuwirth and Armentrout concluded that the gross radioactivity in the Three Mile Island soil samples was attributable tofission products from the reactor accident. Affidavit, at 20; App. Vol. VIII, at 7358 ("Thus, these decay data and at least some of the test results lead us to infer that significant quantities of nongaseous primarily beta-emittingfission product nuclides were released in the TMI event.").

Armentrout then used the half-life calculations to make dose estimates. He attributed the difference between the two counts to the decay of fission products having a half-life of about one-year,[105] such as cesium-134 (134Ce) or cerium-144 (144Cr). Affidavit, at 16, 23; App. Vol. VIII, at 7354, 7361; see also Affidavit, at 21; App. Vol. VIII, at 7359 Extrapolating back to 1979, the year of the accident, Armentrout opined that there must have been thousands of times the amount of fission products in the soil then. Affidavit, at 16; App. Vol. VIII, at 7354. For example, the gross activity of soil sample no. 19887 was measured to have 1.2 picocuries per gram in 1995, Affidavit, at 15; App. Vol. VIII, at 7353, which Armentrout extrapolated back to a 1979 activity of 320,000 picocuries per gram.[106] Affidavit, at 16; App. Vol. VIII, at 7354.

---

105. Armentrout attributed the difference in gross activity between the two counts to radionuclides having a half-life of about one year because radionuclides having extremely short half-lives would have disappeared from the samples and no activity would be detected in the year interval between 1994 and 1995, while radionuclides having long half-lives are regarded as stable and no activity would be detectable in just one year. App. Vol. VIII, at 7822. Further, Armentrout regarded radionuclides having half-lives of about one year to be not naturally occurring and, therefore, fission products. Id. at 7794.

106. A pico is one-trillionth (10-12) of a given unit. MEDICAL EFFECTS, APPENDIX III, CONVERSION T ABLES.

Although Neuwirth's expert qualifications were accepted, his proffered testimony was challenged as lacking"fit." Defendants argued that no valid connection could be made between the results of his soil samples and the TMI accident. Armentrout's extrapolation back was also challenged as lacking scientific reliability. After a Daubert/Paoli II analysis, the District Court found that neither opinion was derived from scientific method and neither represented good science. Therefore, the court precluded Neuwirth and Armentrout from testifying. 911 F. Supp. at 804.

e. Discussion and Conclusion.

We find no error in the Court's ruling. Neuwirth and Armentrout hypothesized that the radioactive decay that Neuwirth's analyses found in the TMI soil samples was directly attributable to fission products released to the environment by the reactor accident. That hypothesis is testable, and it was in fact tested. However, the results of that testing undermined Neuwirth's conclusions.

Because Neuwirth was unable to discover any specific radionuclides causing the activity he found in his analyses, Armentrout sent portions of the samples to Data Chem laboratory. That lab was to perform a spectrographic analysis capable of identifying specific radionuclides and activity levels for each identified radionuclide. App. Vol. VIII, at 7812-13. Data Chem's analyses found that the overwhelming portion of the activity in the samples was the result of naturally occurring background radionuclides. App. Vol. VIII, at 7887-89; see also App. Vol. VIII, at 7636 and App. Vol. XIV, at 11679-87. The only fission product found by Data Chem was cesium-137 (137 Ce). Armentrout testified in his deposition that 137 Ce was "ubiquitous" because of fallout from nuclear weapons testing 107 and because it is a fallout product from the Chernobyl accident. App. Vol. VIII, at 7468. Consequently, Armentrout conceded that it was impossible to determine the source of 137Ce. Id.

However, Armentrout did not modify his hypothesis as a result of the Data Chem findings:

---

107. See p. 65, supra.

Q: Did you factor into your revised report any of the information communicated to you in the Data Chem report?

A: No, I never have.

App. Vol. VIII, at 7819. Daubert recognized that science is "an empirical endeavor in which testing plays a crucial role." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE,at 71. Indeed, a "key question to be answered in determining whether a theory . . . is scientific knowledge that will assist the trier of fact [is] whether it can (and has been) tested." Daubert, at 593.

Here, the hypothesis was undermined by Data Chem's testing, yet the hypothesis was not further modified or explained in view of Data Chem's "analysis." Armentrout and Neuwirth's failure to properly revise their attribution of the gross radioactivity in the soil samples to fission products from the reactor accident is the antithesis of good science and dramatically undermines their proffered opinions.

Moreover, the half-life back calculation methodology Armentrout used to estimate the levels of fission products released during the accident was based on an assumption that the gross activity in the samples was due tofission products. Armentrout's own testimony established theflaws in that approach. Since he was unable to identify any specific radionuclides in the soil samples, Neuwirth calculated the gross activity in the samples at two points in time and determined the decay rate in the samples. Then, Armentrout made an assumption that the gross activity in the samples was due to fission products released in the accident and that the decay rate Neuwirth calculated established the half-life of the fission product radionuclides. He then extrapolated the levels found in 1994 back to 1979 and concluded that the samples had been contaminated with high levels of fission product nuclides as a result of the reactor accident. However, the flaw in Armentrout's half-life calculation methodology lies in the fact that, as Armentrout's report conceded, "all soil samples contain some natural radioactive materials." Affidavit, at 16; App. Vol. VIII, at 7354. Consequently, it is impossible to determine the half-life of any particular radionuclide in a sample which has an admittedly unknown mix of radionuclides, because any observed decline in activity may be due to a mix of radionuclides with short half-lives and radionuclides with long half-lives. Armentrout admitted as much in his deposition:

> Q: Are you actually counting the half-life of any particular radionuclide or are you actually counting the decrease in counts of the mixture?
>
> A: What we're doing is taking the two, a pair of v alues for any of the sources, any of the numbers, sample numbers.
>
> Q: And these are all integrated counts, aren't the y?
>
> A: Those are all integral counts, yes, and we're t aking the value of the later time and the earlier time and a known time in between and calculating from, for the exponential decay law what the effective half-life of that material is, based upon these data.
>
> Q: The effective half-life of the material is not referring to any particular radionuclide, but a mix of whatever is in there, correct?
>
> A: That's very true.
>
> Q: So it may be a large decay of something with a short half-life or a small decay of something with a very long-half life, correct?
>
> A: That's correct.
>
> Q: Is it appropriate, given that range, to arrive at any conclusion concerning the half-life of any particular radionuclide?
>
> A: Depending upon what's in the mix, it could or couldn't be.
>
> Q: And you don't know what's in the mix, correct?
>
> A: Well, if we examine each of the spectra we coul d see, for example, there is or is not any cesium which is 30 years. Over a year's span of time the long half-life material like cesium would be level. In other words,

> wouldn't raise or lower the base. Anything else in there that I can think of, the natural stuff like the uranium decays would be all along. Anything that's short, weeks or months or whatever, would have been gone, so they would be zero. So if you don't have many items in there, then I think your data are all right, at least temporarily.
>
> Q: On a tentative basis?
>
> A: Tentative basis, yes, for a one-year span for t wo readings. Nobody is saying it's probative, but we want to keep watching these to see how the decay, because then you can plot the picture of the curve and begin to get its shape. . . .

App. Vol. VIII, at 7503 (emphasis added). Trial Plaintiffs now complain because the District Court refused to admit testimony of a witness who conceded that his opinion was not probative of the very issue the Trial Plaintiffs sought to establish through that testimony. Moreover, Armentrout conceded that using only two points in time, one year apart, to count the activity in the samples, does not tell anything about the sample other than the average half-life for the entire mix of radionuclides. He testified that:

> If you have a mixture of materials and you do this kind of work, you are going to get I suppose an average half-life for the mix. But I am not sure what it means.

App. Vol. VIII, at 7793.

Armentrout's assumption that the gross activity in the soil samples was due to fission products was not supported by his own methodology. He essentially admitted that the methodology of counting gross activity in the samples at only two points in time to establish a half-life of the radionuclides in the sample would not enable him to identify any specific radionuclide, let alone afission product radionuclide, but would only produce an average half-life for the entire mix of unknown radionuclides. His assumption that the activity was due to fission products remains just that, an assumption. Although Daubert/Paoli analysis does not preclude testimony merely because it may be based upon an assumption, the supporting assumption must be sufficiently grounded in sound methodology, and reasoning to allow the conclusion it supports to clear the reliability hurdle. Assumption-based conclusions that do not meet that test can hardly be relied upon as"good science." Here, Neuwirth made an intermediate count of one of the soil samples and discovered that 75% of the activity disappeared in one month. This, in turn, suggested that the radionuclide in the sample was not a fission product radionuclide but rather naturally occurring radon. App. Vol. VIII, at 7495-96.

Consequently, because Armentrout's attribution of the difference between the two counts to the decay offission products was an assumption based on a flawed methodology, Armentrout's use of data derived from that assumption to extrapolate back to 1979 to arrive at the conclusion that the soil samples were contaminated with high levels of accident released radionuclides was completely lacking in scientific validity and reliability. Because the methodology used to produce the data upon which Armentrout extrapolated back to arrive at dose estimates lacked scientific validity and reliability, we need not determine whether "extrapolation back in time, using known levels of compounds and a scientifically valid mathematical formula for the extrapolation, would meet the standards of Rule 702 and Daubert." Heller v. Shaw, 167 F.3d at 162. The data which Armentrout developed from his flawed methodology was unreliable and it can to be morphed into "good science" by scientifically valid mathematical back-extrapolation.

Accordingly, the District Court did not abuse its discretion in excluding Neuwirth and Armentrout's soil sample analyses, the half-life calculations and extrapolated dose estimates.

iii. James Gunckel

a. Qualifications.

James Gunckel is a biologist who earned an undergraduate degree from Miami University (Ohio) and a master's degree and Ph.D. from Harvard University. He is a Distinguished Professor emeritus at Rutgers University in New Brunswick, New Jersey. Before his retirement he was, at various times, Chairman of the Botany Department, Chairman of the Radiation Science Center, Chairman of the Department of Radiation and Environmental Health and Safety, and Chairman and Organizer of the Health Safety Council. In addition to his academic and administrative appointments at Rutgers, Gunckel collaborated, over a twenty year period, with the late Arnold A. Sparrow, Ph.D., at the Brookhaven National Laboratory, studying the effects of radiation on plants. He is, as the District Court acknowledged, "a pioneer in the area of studying radiation effects on plants." 911 F. Supp. at 809. His report consisted of an evaluation of trees in the Three Mile Island area which he opined were damaged by radiation and an investigation he made of TMI area residents who claimed to have experienced radiation induced symptoms. His involvement as an expert witness began in 1987, eight years after the reactor accident. Based on his evaluation and investigation, Gunckel opined as to the radiation dose to which the trees and the residents were exposed.

Filed November 2, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 96-7623/7624/7625

IN RE: TMI LITIGATION

LORI DOLAN; JOSEPH GAUGHAN; RONALD WARD; ESTATE OF PEARL HICKERNELL; KENNETH PUTT; ESTATE OF ETHELDA HILT; PAULA OBERCASH; JOLENE PETERSON; ESTATE OF GARY VILLELLA; ESTATE OF LEO BEAM,

Appellants No. 96-7623

IN RE: TMI LITIGATION

ALL PLAINTIFFS EXCEPT LORI DOLAN, JOSEPH GAUGHAN, RONALD WARD, ESTATE OF PEARL HICKERNELL, KENNETH PUTT, ESTATE OF ETHELDA HILT, PAULA OBERCASH, JOLENE PETERSON, ESTATE OF GARY VILLELLA AND ESTATE OF LEO BEAM,

Appellants No. 96-7624

IN RE: TMI LITIGATION

ALL PLAINTIFFS; ARNOLD LEVIN; LAURENCE BERMAN; LEE SWARTZ

Appellants No. 96-7625

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
(Civil No. 88-cv-01452)
(District Judge: Honorable Sylvia H. Rambo)

ARGUED: June 27, 1997

Before: GREENBERG and McKEE, Circuit Judges, and GREENAWAY, District Judge*

(Opinion filed: November 2, 1999)

b. Gunckel's Opinion.

Gunckel believed that prior estimates of the amount of radiation released as a result of the accident were unreliable. Gunckel Affidavit of May 13, 1993, at 1-5 (hereinafter "1993 Affidavit"). Thus, he devised a method of estimating dose exposure based on his work with Dr. Sparrow at the Brookhaven National Laboratory where they created a gamma field to irradiate plants in order to study the effects of the radiation on the plants. The gamma field was operated as follows:

> [t]here was a cobalt-60 source, for gamma radiation, in the center of the field. The plants, mostly seedlings and cuttings, were planted in concentric rows around the source and planted so that successive rows reflected a "doubling dose" concept, for one could expect that to double the dose could double the effect. The source was lowered below the ground to permit entry for two hours of watering, cultivation and data taking. The observations centered on slight and severe growth inhibition or a lethal dose to growth processes from both chronic and acute exposure.

1993 Affidavit, at 5-6; App. Vol. V, at 3320-21. Gunckel testified at the in limine hearing that, except for the two hours a day that the gamma source was lowered into the ground, the plants were constantly irradiated through the growing season, i.e., April through November, for a period of 20 years. App. Vol. V, at 3485. The plants, randomly designated, but consisting of hardwoods as well as conifers, were exposed to a controlled amount of radiation, ranging from an absorbed dose of 2,000 rads (20 Gy) for the plants

---

* The Honorable Joseph A. Greenaway, Jr., United States District Court Judge for the District of New Jersey, sitting by designation.

closest to the gamma source to 2 rads (20 mGy) for the plants farthest from the gamma source. Id. at 3484.

Gunckel explained that irradiation has direct and indirect effects on plants. The two most import direct effects are mitotic delay and cell death, both of which are due to damage to the nucleus of the plant. 1993 Affidavit, at 7; App. Vol. V, at 3322. The most significant indirect effect is growth inhibition. 1993 Affidavit, at 6; App. Vol. V, at 3321.

From their observations of the effects of the irradiation on the plants in the gamma field, Gunckel and Sparrow determined the dose needed to cause a certain effect in a plant. App. Vol. V, at 3484 ("That was our basic objective, and the basic objective was simply to create a data bank of correlating dose with effects on a variety of plants."). Applying his work at Brookhaven to the TMI reactor accident, Gunckel hypothesized that:

> Radiation induced growth effects in trees would occur in areas where residents experienced symptoms indicating exposures to radioactivity at the time of the TMI accident and that those tree effects would occur in several species showing relative sensitivities (slight and severe growth effects, and lethality) corresponding to those determined in Brookhaven.

Gunckel Affidavit of October 23, 1995, at 12 (hereinafter "1995 Affidavit"); App. Vol. V, at 12. Using the Brookhaven gamma field data, Gunckel found three species of trees which are present in the Three Mile Island area for which there was radiosensitive data from the Brookhaven experiments. 1993 Affidavit, at 9; App. Vol. V, at 3324. Those trees were spruce, pine and Norway maple. Id.

Pursuing his hypothesis, Gunckel interviewed 15 residents of the TMI area regarding the health effects they experienced as a result of the reactor accident. 108 App. Vol. V, at 3490-92. He interviewed the residents not to

---

108. Gunckel described the radiation induced health effects as "malaise, metallic taste, cessation of menses, epilation, sore throat, petechiae, diarrhea, conjunctivitis and rhinitis, which indicate the radiation sickness syndrome of 100-300 rems [1-3 Sv]. 1993 Affidavit, at 11; App. Vol. V, at 3326.

determine whether "what they complained of was true or false." Id. at 3490. Rather, he was "trying to associate people with possible episodic evidence [of radiation induced symptoms] with a plant indicator." Id. Based on his interviews, Gunckel concluded that 5 of the 15 people were exposed to erythemic doses, i.e., an equivalent dose sufficient to cause erythema.109 Id. at 3492. He testified that an erythemic dose is between 300 rems (3 Sv) and 360 rems (3.6 Sv). Id. at 3496. Consequently, he concluded that an equivalent dose of 300-360 rems was "the top dose at TMI that we could recognize by our yardsticks." Id.

After identifying the areas where residents described health effects purportedly related to the reactor accident, Gunckel searched for damaged trees in those areas. As a result of his search, he observed "lethal effects. . . in more than 80 spruce, pine and maple trees up to 15 miles from the TMI facility." 1993 Affidavit, at 10; App. Vol. V, at 3325. He reported:

> Slight to severe growth inhibition and lethal (or sub-lethal) damage was observed in all three species. In the spruce, lethal effects were more easily identified since, when the terminal bud is killed, there are no axillary buds to replace it, so the top of the spruce appears as a dead skeleton of branches. In the pine, when the terminal bud is killed, the six to eight axillary buds develop into major branches, giving the tree an apparently flat top. This effect is comparable to the effect found in the pine trees at Chernobyl.
>
> Sub-lethal radiation speeds up maturation so that in the maples, the leaves abscise. They form a corky layer at the leaf base, cutting off the water supply, causing the leaves to fall. The inner bark contains conducting tubes (phloem) which transport sugars. The phloem tissue is made up of anucleate sieve cells with adjacent companion cells. These companion cells with very large nuclei are targeted by the radiation, die and lesions form in the bark. Death results over a period of time when the sugar supply to the older part of the tree is exhausted. The acute lethal dose to spruce . . . is 1,020

---

109. See p. 35 n.40 and p. 39-40, supra.

> rem [10.02 Sv]. The acute lethal dose to the apical meristems of white pine branches . . . is 1,000 rem[10 Sv]. The sub-acute lethal dose for maples . . . is 3,000 rem [30 Sv]. The maple received the same 1000 rem dose as the spruce or pine. . . . To have observed the lethal and sublethal effects near TMI, doses of this magnitude had to have occurred. The dose which killed the chromosomes in the spruce by a direct effect on the target . . . is the same dose as is responsible for the indirect effect which caused the range of slight to severe growth inhibition, a morphological lethal dose, which is the indirect effect.

1993 Affidavit, at 9-10; App. Vol. V, at 3324-25. He then explained that "[t]he doses which caused injury to the nucleus of cells in plants will also injure the nucleus of cells in animals and humans." 1993 Affidavit, at 12; App. Vol. V, at 3327. Accordingly, he concluded that because the damage to the trees was caused by exposure to very high levels of radiation, the health effects suffered by the TMI residents he interviewed "cannot be dismissed as unrelated to the TMI accident on the a priori belief that doses were too low." Id. Consequently, as a result of his investigation, Gunckel offered his opinion that "during the early days of the TMI accident, individuals received erythemic doses in the range of 300 to 1000 rems [3 Sv to 10 Sv]." 1993 Affidavit, at 12; App. Vol. V, at 3327.

The District Court excluded all of Gunckel's proffered testimony. It found that Gunckel's methodologies of investigation of human health and as to his tree studies "lack scientific validity and reliability pursuant to Rule 702." 911 F. Supp. at 810. It also found that because Gunckel is not a medical doctor he is not qualified "to opine as a medical expert with respect to his human . . . health study." Id. The court also held that Gunckel's testimony lacked "fit" because he was unable to verify that the tree damage occurred at the time of the TMI accident, rather than at some earlier or later date. Id. Finally, the court found that Gunckel's dose estimates are logically inconsistent "with the lack of human casualties in the areas where the tree damage was noted." Id.

c. Discussion and Conclusions.

At the outset, the Trial Plaintiffs contend that the District Court misunderstood the purpose of Gunckel's interviews of TMI area residents who claimed to have suffered radiation induced medical symptoms. They submit that Gunckel sought medical information from those people, not to render diagnoses, but rather to help him identify geographical areas surrounding TMI where he could pursue his hypothesis and begin to search for radiation-damaged trees. Trial Plaintiffs' Br. at 21 n.31. They assert that the court's Daubert/Paoli II admissibility analysis was flawed from the start because of a fundamental misunderstanding of Gunckel's study. We disagree.

While Gunckel's stated purpose in interviewing the residents about their allegedly radiation-induced medical conditions may have been as the Trial Plaintiffs claim, it is clear that he strayed far afield from that stated purpose and diagnosed 5 residents as having radiation-induced erythema. App. Vol. V, at 3535-36; see also 1993 Affidavit, at 11; App. Vol. V, at 3309 ("The fact that erythemic responses also occurred in many cases at TMI clearly established that there was a higher level of exposure. A resident, in the WNW sector living about 10 miles west of TMI at 900 feet elevation . . . experienced a classical case of erythema from only a few minutes exposure on March 30, 1979."). Although Gunckel is a respected scientist, he is neither a medical doctor nor a health physicist. 110 So far as the record is concerned, his only knowledge of the health effects of radiation was obtained from literature he reviewed in connection with his retention as an expert in this litigation. App. Vol. V, at 3388. He plainly does not meet Rule 702's "Qualifications" requirement and cannot, therefore, offer an expert opinion as to radiation-induced medical conditions. See Paoli II, at 741.

Gunckel's opinion as to the radiation damaged trees is less problematic, especially considering his acknowledged expertise in the area of radiation effects on plants. Essentially, Gunckel found trees which he claimed were

---

110. "Health physics is the name given to the study of problems related to the protection of man from exposure to radiation." LAMARSH, at 397.

damaged by radiation, and, using the results of his work at Brookhaven, he extrapolated back to determine the dose which caused the damage. At the in limine hearing, he explained his methodology as follows:

> Q: We need to establish the relationship of your technique to methods which have been established to be reliable. Now, your technique, let's talk about your technique at TMI. Does that relate to reliable standards and methods which you used at Brookhaven? Is there a relationship between the two?
>
> A: Oh, there's a relationship. But we can't take m uch credit for what we did at TMI. All we did was observe the results. And you go backward. We did the original going from dose to results. All we did was observe the results at TMI and go to Brookhaven for the dose.
>
> Q: And you used, as I understand it, the informati on and data that you accumulated at Brookhaven to reach the conclusions you reached here, correct?
>
> A: Correct.
>
> Q: And I think you've already indicated that the Brookhaven data is very reliable, correct?
>
> A: Correct.

App. Vol. V, at 3516-17.

However, the District Court was critical of Gunckel's methodology. The court stated that the "TMI tree studies bear no functional relevance to the Brookhaven studies." 911 F. Supp. at 807. The court believed that the Gunckel's TMI tree study bore little methodological relationship to the Brookhaven studies because the Brookhaven studies involved cellular and subcellular evaluations to determine the extent of radiation damage while Gunckel's TMI tree study involved simply observing morphological damage to trees. Id. at 807 n.36. However, we believe that the District Court's criticism of Gunckel's TMI tree study methodology was inappropriate. Although the focus of the Brookhaven radiation studies was cellular and subcellular, see App. Vol. V., at 3485 ("our ultimate objective was to predict doses based upon chromosome volume, or nuclear volume."), Gunckel testified that his work at Brookhaven also involved observing morphological damage to trees:

> Q: [D]id you have the opportunity to visibly observe the trees and the effects that the irradiation was having on them?
>
> A: Yeah, absolutely. This was done on a daily basi s. . . .
>
> *********************
>
> Q: As a result of that experience for those 20 yea rs that you've just discussed, are (sic) you able to visibly observe the radiation effects on conifers?
>
> A: Yes. Within the limits of those that we studied, yes. We didn't study them all.

App. Vol. V, at 3485-86. Consequently, so long as Gunckel could demonstrate that his work at Brookhaven involved mature trees, and not tree seedlings, and that he performed differential diagnoses on the trees he studied at TMI to rule out other causes for the damage he observed (both of which he did)111 Gunckel's TMI tree study methodology is not as flawed as the District Court believed.

Gunckel's methodology lies in its novelty. It has, apparently, only been used in this litigation. Gunckel candidly admitted that during his years at Brookhaven he never worked in reverse to determine dose from observed damage. He testified:

> Q: I appreciate that you have spent your professio nal career studying the effects of a known amount of radiation on the development of trees. Have you ever, in your professional career, tried to do the reverse and test it? In other words, try to infer a dose from what

---

111. There was a factual dispute in the District Court as to whether the Brookhaven study involved mature trees, as opposed to seedlings, and whether Gunckel performed differential diagnoses on the trees he claimed were damaged by radiation to rule out other causes for the damage, most notably insects and certain fungi. However, the district court resolved that factual dispute in Gunckel's favor. 911 F. Supp. at 808; 809.

> you see in a tree and then test it to see if your inferred dose was reasonably accurate?
>
> A: No. We didn't get that far. It took us 20 years to get this other data together. This is not an easy thing to do. We simply hadn't gotten that far. And then Arnold Sparrow up and died in the midst of all this, so that ended the whole project.

App. Vol. V, at 3392. However, the quality of a given study does not necessarily correlate to the novelty of its methodology. Gunckel's TMI tree study is rooted in the kind of methodology that gives his study validity and reliability, notwithstanding the novelty of what he did, or the fact that his study was undertaken for this litigation. If the Brookhaven studies demonstrate that irradiation in the amount of dose a will result in z amount of radiation damage to a tree, we believe that a scientist of Dr. Gunckel's renown (20 years of his professional life studying the effects of known amounts of irradiation on trees at Brookhaven) can certainly observe damaged trees and determine the dose of radiation necessary to cause the observed damage, so long as adequate and competent differential diagnoses are performed.

Defendants argue that Gunckel's methodology is unreliable because it is impossible to determine dose from observed damage. In support of that argument, they cite Gunckel's collaborator at Brookhaven, Dr. Sparrow, who was of the opinion that while "stunted or dwarfed plants, misshapen organs, or mottled flowers or leaves are often the results of radiation . . . . external examination of such abnormal plants will provide very little information as to the basic cause of these effects." Arnold H. Sparrow, Brookhaven Lecture Series, The Role of the Cell Nucleus in Determining Radiosensitivity, May, 16, 1962, at 1. However, this apparent dispute between the two collaborators does not render Gunckel's methodology unreliable. The dispute goes to the weight to be afforded Gunckel's expert opinion, not the reliability of his methodology. In a Daubert/Paoli II analysis, the focus is not on determining "which of several competing scientific theories has the best provenance." Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998). Rather, we focus on determining whether the "opinion is based on valid reasoning and reliable methodology." Kannankeril, 128 F.3d at 806.

No one can seriously suggest that Gunckel's work at Brookhaven was not good science. We believe that the methodology Gunckel used in his TMI tree study meets the Daubert/Paoli II admissibility requirements in so far as methodology is concerned. See Paoli II, at 745 n.14 (suggesting that if expert uses a methodology only slightly different from a clearly reliable methodology, the court should be more likely to accept the altered methodology than if it was evaluating the altered methodology as an original matter).

That is not to say, however, that the District Court abused its discretion in excluding Gunckel's proffered testimony. Although Daubert insisted that the focus of the admissibility inquiry "must be solely on principles and methodology, not on the conclusions that they generate," Daubert, at 595, the Court subsequently amplified that principle in Joiner. There, the Court wrote:

> conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

118 S. Ct. at 519. Consequently, although principles and methodology remain the focus of a Daubert inquiry, "this focus need not completely pretermit judicial consideration of an expert's conclusions." Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d at 81; see also Heller, at 153; 161 (holding that district court was correct when it questioned an expert's conclusions).

When Gunckel's ultimate conclusions are examined, it is clear that they must be rejected, not simply because they could not "reliably flow from the facts known to the expert and the methodology used," Heller, at 153, but rather because they fly in the face of reality. Gunckel's written opinion concludes that during the early days of the reactor accident, "individuals received erythemic doses in the range of 300 to 1000 rems, depending upon the isotopes to which they were exposed." 1993 Affidavit, at 12. At the in limine hearing, Gunckel testified that although a dose of 1,000 rems was the dose to the trees in the TMI area, a dose of 300-360 rems was a "credible" dose range for humans. App. Vol. V, at 3501. But, he admitted that a dose of 360 rems is the "official lethal dose" for humans. Id. at 3498. He testified: "That's an LD50/60. In other words, 50 percent of the population would die from that dose in 60 days." Id.

Thus, equivalent doses between 300 to 1000 rems are extremely high. They are so high that such doses would have caused deterministic effects in the population living around Three Mile Island.112 Yet, except for Gunckel's claim that he discovered 5 people who suffered from radiation-induced erythema, the record does not demonstrate, and the Trial Plaintiffs do not contend, that anyone living in the area surrounding Three Mile Island ever reported a deterministic effect caused by the fission product radionuclides released from the TMI accident to any health care provider or health care facility.113 Similarly, even though Gunckel admitted that a dose of 360 rems is a lethal dose, the record does not reflect an epidemic of human casualties near the allegedly found radiation

---

112. See p. 38-40, supra.

113. The record does contain a study commissioned by the defendants which concluded that from June 30, 1978 to June 30, 1993, there were no increases in hospital utilization that can be attributed to the reactor accident. See Larry R. Fosselman, A Look at Hospital Utilization Relative to Three Mile Island 3 (July 14, 1995)(unpublished) (App. Vol. XII, 10234-38). Fosselman's report recites that he was asked "whether any data exists which might tend to prove or disprove the hypothesis that the TMI accident in March, 1979, produced any changes in health evidenced by demand on the services of acute health care providers." Id. at 1. His conclusion, based on a review of hospital utilization data and his personal observations, is "that the March 28, 1979, Three Mile Island accident caused no detectable adverse health effects in the relevant seven-county area as demonstrated by hospital utilization and health care provider reports." Id. at 5.

damaged trees.114 In fact, if these disputed dose estimates are correct, we would expect that half of the population around Three Mile Island would have died within 60 days of the nuclear accident there. Obviously, that did not happen.

Consequently, given the complete lack of any reports of deterministic effects following the reactor accident, and the undeniable reality that statistically significant human casualties did not occur following the accident, Gunckel's conclusions are not trustworthy. Thus, the District Court did not abuse its discretion in excluding Gunckel's testimony in its entirety.

iv. Vladimir Shevchenko.

a. Qualifications.

Shevchenko is a scientist from the former Soviet Union who has a Ph.D. in Biological Sciences. His area of expertise is radiation genetics, with particular emphasis on the cellular and subcellular effects of radiation on plants. App. Vol. VI, at 4519. He also has experience in cytogenetic studies on chromosomal aberrations in human lymphocytes. Id. at 4199. From 1962 to the present, he has studied the effects of ionizing radiation on plants and animals in the Eastern Ural Radiation Belt, the site of a nuclear accident which occurred in 1957 at the Mayak military plant where atomic weaponry was produced. Id. In addition, he has studied radiation effects on plants and animals in the Chernobyl region since shortly after the nuclear accident there in 1986. Id. Since 1993, he has

---

114. Gunckel attempted to explain that while the lethal dose for humans is 360 rems, the "lethal" dose is not really lethal. He testified: "The official lethal dose for humans is 360. . . . But that isn't people. That's
the other thing you have to watch. That's laboratory animals. And you can't do experiments on people and get data like that. So that's the reason why you can't dwell on these so-called lethal doses or even think for a moment that they are lethal. They aren't." App. Vol. V, at 3498. However, even assuming arguendo that the reported lethal dose of 360 rems is imprecise, the absence of any reported deterministic effects would still undermine Gunckel's conslusion to the extent that we doubt it could survive a Daubert inquiry even then. 360 rems is undeniably an extremely high dose even assuming that it is not lethal.

participated in a study of the people and the environment at the Semipalatinsk Nuclear Testing Grounds where people were exposed to ionizing radiation as a result of nuclear weapons testing. Id. He has been Scientific Advisor to the Russian Parliament on the effects of the Chernobyl accident, Chairman of the Radiation Genetics Section of the Scientific Council on Radiobiology of the Russian Academy of Sciences, and Advisor on Radiation Genetics to the United Nations. Appellants' Br. at 27. Shevchenko received the Red Banner Award for his work on the Chernobyl accident that is an honor received by only four other members of the Russian Academy of Sciences. Id. at 28. The District Court acknowledged that "[l]ikely more than other expert before the court, Professor Shevchenko has had extensive first-hand experience examining the effects of radiation exposure." 911 F. Supp. at 816.

Shevchenko's expert opinion testimony covered two distinct areas. The first area dealt with his morphological study of trees in the Three Mile Island area which he claims were damaged by radiation from the reactor accident, together with his radiation dose estimates based on the observed damage. The second area was his testimony about the substance of a cytogenetic analysis performed by a colleague, Dr. Galina Snigiryova, the head of the Cytogenetic Laboratory of the Moscow Institute of Diagnostic Surgery, on blood samples of a group of Three Mile Island area residents.115 Based on Snigiryova's cytogenetic analysis, Shevchenko used a regression curve

---

115. According to the Trial Plaintiffs' plan, Shevchenko was to testify not only about Snigiryova's cytogenetic analysis, but also about the tests and reports prepared by, inter alia, Gennady Kozubov and Olga Tarasenko, both of whom are scientists from the former Soviet Union and were apparently recruited by Shevchenko to provide expert reports. Trial Plaintiffs' Br. at 26-27. The District Court found that the substance of Snigiryova's report was within the area of Shevchenko's expertise and he was, therefore, permitted to testify about it. 911 F. Supp. at 811. However, the court found that the substance of Kozubov's and Tarasenko's tests and reports was outside the area of Shevchenko's expertise. Thus, he was not permitted to testify about their tests. Id. As it turned out, both Kozubov and Tarasenko were called as witnesses at the in limine hearings. Their testimony is discussed infra.

to arrive at radiation dose estimates. Each area of his proffered testimony is discussed separately.

b. Shevchenko's Tree Study.

Shevchenko's tree study is contained in an affidavit he prepared on July 6, 1994.116 App. Vol. VI, at 4198-4211. In it, he states that he visited the Three Mile Island area for a three week stay beginning on June 18, 1994.117 Id. at 4198. During that time, he conducted a morphological study of radiation-damaged trees in various areas around Three Mile Island. Id. In addition, Shevchenko met with James Gunckel and he and Gunckel conducted a joint study of radiation-damaged trees in the area. Id. Shevchenko and Gunckel "discussed in depth the possible causes" of the damage to the trees. Id.

The starting point of Shevchenko's tree study is his belief that there are several woody plants which can be used as long-term "indicators" of "relatively high exposures from radionuclide emissions." Id. at 4202. His belief is based on his own studies of plants and trees in those areas of the former Soviet Union where there have been known radiation releases, and "definitive dose data from the Brookhaven Gama Field." Those woody plants are pine, spruce and maple trees. Id. at 4206.

---

116. Shevchenko's Affidavit is captioned "Affidavit of Vladimir R. Shevchenko, Ph.D., Dr. Sc., Concerning the Dose to Any Individual from the TMI Unit Accident." In addition to discussing radiation-damaged trees, the affidavit contains a discussion of radiation sickness and disease allegedly suffered by TMI area residents, together with a discussion of radiation-induced illnesses and death suffered by animals in the TMI region. Further, the affidavit concludes with Shevchenko's dose estimates, not simply as to the trees he studied, but also as to the humans and animals in the TMI area. The district court did not mention the human and animal references in its analysis of this area of Shevchenko's expert testimony. Thus, we assume that the Trial Plaintiffs did not proffer Shevchenko as an expert competent to give testimony about dose estimates to humans. In addition, the Trial Plaintiffs' brief does not mention those aspects of Shevchenko's affidavit. Consequently, we assume that the focus of our inquiry is only on Shevchenko's tree study.

117. Shevchenko had a follow-up visit to the area in January of 1995. App. Vol. VI, at 4214.

According to Shevchenko, the most significant morphological change in the pine tree in response to a lethal exposure to ionizing radiation "is related to the death of the terminal bud in the main leader shoot." Id. at 4202.

> This change removes the apical dominance of the leader over the most apical 6 or 7 axillary buds when then formed short, multi-budded lateral branches and resulted in a tree with an easily identifiable,flat, bushy tree top.

Id. Shevchenko claims that spruce trees are more sensitive to radiation than pine and that exposure to high levels of ionizing radiation "causes death of all terminal buds," which "causes the tree top to look like a skeleton made of branches." Id. at 4203. At the dead top of the spruce tree, "lateral buds able to renew growth likely do not exist, so that it is easy to identify such trees visually." Id. In the maple tree,

> [t]he phloem companion cells on the inner bark are the most sensitive to ionizing radiation, their death being the cause of dead spots on the bark of the tree. This causes visible effects like lesions in the bark, large wounds on the tree trunks and the loss of bark. Maple trees die by indirect effect. Ionization of water by beta-rays will, depending on the dose, shatter the xylem, water-conducting vessels. When a maple tree dies following irradiation, it does so very gradually. First, the leaves in the center of the crown shrivel and die after one week. Next, the rest of the leaves develop anthocyanins, develop fall coloring within a few weeks, and then the leaves dehisce more or less normally but only after about 4-6 weeks. In the spring, shoots in the middle or lower part of the crown are slow to develop sparse leaves and lesions appear in the bark. Thus, the main indicators of radiation damage which can still be observed 15 years after the accident are wounds on the surface of the bark. Such wounds have a typical appearance and are easily identified. . . . Often such trees have dry branches and dry tops.

Id. at 4204-05.

In the course of his morphological tree study, Shevchenko "observed damaged spruce, pines and maples" and concluded that irradiation "is the cause of the full spectrum of the observed morphological anomalies." Id. at 4206. He opined:

> It is important that in some places which were affected by the radioactive cloud after the accident, simultaneous damage to spruce, pines and maples as well as to other trees was observed, which is evidence of ionizing radiation effects. The radiation damage to each tree is morphologically different -- damage to top buds, dead tree tops, flat tree tops, bark wounds. The presence of a whole spectrum of tree damages in the same area and all with a very high frequency cannot be explained by anything but the effects of ionizing radiation exposure.

Id. Finally, he gave a dose estimate based on his observations of the tree damage. In his "professional opinion . . . the cases of tree damage. . . in the TMI region, based on results of my personal observations . . ., are related to the effects of ionizing radiation in doses of about 200 to 1,000 rem [2 Sv to 20 Sv]." Id. at 4211.

Initially, the District Court held that the tree study and the dose estimates were admissible. 911 F. Supp. at 816-817. Although the court conceded that the defendant's objection was well-founded, the court concluded that Shevchenko's experiences in studying first-hand the effects of ionizing radiation trumped any technical deficiencies in his methodology. The court wrote: "[W]hat his testimony may lack in rigid conforming to technical standards is amply counterbalanced by his extensive experience." Id. at 817.

Shevchenko's methodology was further attacked in a motion for reconsideration. Once again, the court conceded that the challenge to the methodology was "accurate and insightful." In re TMI Litigation Cases Consolidated II, 922 F. Supp. 997, 1014 (M.D. Pa. 1996). Nonetheless, the District Court found that Shevchenko's expertise and experience were sufficient to overcome methodological deficiencies, primarily because the proffered testimony satisfied Rule 702's helpfulness or fit requirement. Id. The court found:

> Because of his first-hand experience, Professor Shevchenko's observations will be helpful to the trier of fact. Even if Professor Shevchenko were to do nothing more than to verify that he observed radiation damaged trees in the former Soviet Union, and note that the damage he saw in the TMI area was consistent with his observations of tree damage in the former Soviet Union, his testimony would assist the jury in determining whether it is more likely than not that the TMI area was contaminated during the TMI accident.

Id.

Shevchenko's dose estimates did not fare so well on reconsideration. In a nutshell, the court found that it was unable to determine Shevchenko's dose estimate methodology. The court wrote:

> The most certain thing that the court can say regarding the dose calculations derived from the tree study methodology is that after reading all of Professor Shevchenko's reports, deposition testimony, and the hearing transcripts, the court is unable to define the precise steps of his methodology. Each time Professor Shevchenko states his methodology Defendants challenge a component of that methodology and Professor Shevchenko alters the methodology to rebut the challenge. It is axiomatic that such methodological fluctuations are not scientific. . . . A purportedly scientific opinion that constantly changes merely to avoid critique can hardly be said to be based upon "good grounds."

Id. at 1015. Consequently, the court granted the motion for reconsideration insofar as it challenged dose estimates and excluded Shevchenko's proffered dose estimate testimony.

c. Discussion and Conclusions.

We are troubled by the District Court's exclusion of Shevchenko's dose estimate testimony based on its inability to determine Shevchenko's dose estimate methodology. The court found that Shevchenko could testify "as to the observations he made of damaged trees in the TMI area and to his comparison of the damage observed here with tree damage at radiation exposed sites in the former Soviet Union," Id. at 1015, but that he could not offer dose estimates based on his tree study. In other words, the court found that Shevchenko could testify that he found radiation damaged trees near TMI, but that he could not draw any conclusions as to the radiation dose which caused that damage.

As noted above, the court's reason for excluding Shevchenko's dose estimates was its stated inability to divine Shevchenko's dose estimate methodology. However, we do not believe that it is as difficult to determine that methodology as the District Court concluded. Shevchenko found three species of trees in the vicinity of TMI which he claims were damaged by ionizing radiation, and he then compared them with trees of the same species which he believes to have been damaged by ionizing radiation in the former Soviet Union. As noted above, those species are pine, spruce and maple. At least with regard to pine and spruce, Shevchenko referred to studies of radiation damaged trees around Chernobyl where, presumably, dose exposures had been calculated. Shevchenko's affidavit noted that, as a result of the studies in the former Soviet Union, the "frequency of morphological anomalies of pines in the Chernobyl accident area was observed in 1986-1987 where exposures were from 200 -400 R (2.0 to 4.0 Gy)." App. Vol. VI at 4202. Additional studies in the Chernobyl area demonstrate that "the lethal dose" for spruce is about 1000 R (10 Gy)," and "[e]xposure of 3.5 to 4.0 Gy causes death of all terminal buds of spruce trees." Id. at 4203.

Given that data, we can identify Shevchenko's dose estimate methodology. He simply compared the degree of damage to certain trees in the TMI area with the degree of damage to the same species of trees in the former Soviet Union. If the degree of morphological damage was similar, Shevchenko used the dose exposure estimates from the Soviet Union trees to deduct the dose exposure necessary to cause the similar morphological damage to the TMI area trees. Admittedly, Shevchenko's dose estimate methodology relies in part on his own ipse dixit, rather than on something more readily verifiable, and, in that regard, it is open to attack. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1315-16 (9th Cir.), cert. denied, 516 U.S. 869 (1995) ("[S]omething doesn't become`scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were `derived by the scientific method' be deemed conclusive. . . ."). However, Shevchenko's methodology also relies heavily on his "first-hand experience examining the effects of radiation exposure." 911 F. Supp. at 817. It is this first-hand experience which the District Court weighed heavily in favor of admitting Shevchenko's tree study. In our view, the dose estimate methodology is simply the next sequential step up from the tree study methodology. Inasmuch as the dose estimate methodology flows logically from the tree study methodology, we believe that the District Court's conclusion that the dose estimate methodology was based on inadequate methodology was inappropriate.

Similarly, to the extent that the District Court's exclusion of the dose estimates was based on the court's belief that Shevchenko's methodology changed in response to challenges, see 911 F. Supp. at 1014, the exclusion was also inappropriate. If Shevchenko's methodology did change to meet Daubert challenges, those changes strike at the heart of Shevchenko's credibility as a witness and the weight to be afforded his testimony. See Ambrosini v. Labarraque, 101 F.3d 129, 141 (D.C. Cir. 1996) (District Court improperly conflated the questions of admissibility of expert testimony and the weight appropriately to be accorded such testimony by a fact finder).

Nonetheless, we do not believe that the court abused its discretion in excluding Shevchenko's dose estimates. Shevchenko's dose estimates suffer from the same infirmity as Gunckel's. Shevchenko's dose estimates are also extraordinarily high. They range from a low of 200 rem to a high of 1000 rem. As noted earlier, deterministic effects begin to occur at doses above 100 rem (1 Sv). See CHERNOBYL, at 39.118 The higher the dose estimates climb

---

118. The Chernobyl PROJECT noted that deterministic effects begin above 100 rad (1 Gy). However, it also reported that "[f]or most practical

from the low of 200 rem to the high of 1000 rem, the closer Shevchenko's dose estimates approach a point where significant human casualties should have occurred from acute radiation syndrome.119 That didn't happen. In short, even though Shevchenko's dose estimate methodology may be reliable, his conclusions based on that methodology are not. A reliable methodology "cannot sanitize an otherwise untrustworthy conclusion." Heller, at 155.

d. The Cytogenetic Analysis.

As noted earlier, Galina Snigiryova120 performed a cytogenetic121 analysis on blood samples of a group of 29

---

applications, the radiation weighing factor is unity; that is, the numerical
values for absorbed dose [rad] and equivalent dose [rem] will be equal." Chernobyl, at 21. That is especially true where gamma (g) radiation is alleged to be the source of the harm. The quality factor, Q, of gamma (g) radiation is 1. Thus, the absorbed dose and the equivalent dose of gamma (g) radiation will be equal. See p. 33-34 supra.

119. For example,

> [i]n the absorbed skin dose range of 2 to 7 GY (200 to 700 rad), the hematopoietic syndrome [a subgroup of acute radiation sickness] 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.

MEDICAL EFFECTS, at 280.

120. Snigiryova's qualifications as an expert were not disputed. She has Ph.D. in Radiation Biology and, in addition to being the head of the Cytogenetic Laboratory of the Moscow Institute for Diagnostic and Surgery, she has carried out, inter alia, cytogenetic investigations on people exposed to ionizing radiation following the Chernobyl accident and on people irradiated as a result of nuclear weapons testing in the Semipalatinsk Nuclear Testing Grounds. Curriculum Vitae of Galina Snigiryova, App. Vol. VI, at 5102.

121. Cytogenetics is "[t]he branch of genetics concerned with the structure and function of the cell, especially the chromosomes." STEDMAN'S MEDICAL DICTIONARY 436 (26th ed. 1995).

Three Mile Island area residents.122 According to Snigiryova, it is possible to evaluate absorbed radiation doses and to predict resulting biological effects of radiation exposure based on an analysis of the cytogenetic effects of ionizing radiation on human peripheral lymphocytes.123 App. Vol. VI, at 5103. The cytogenetic method is based on an analysis of the frequency of chromosome aberrations in peripheral lymphocytes. Id. Snigiryova's cytogenetic study focused upon a chromosome aberration known as a dicentric. 124 Id.

---

122. Snigiryova's report, captioned Cytogenetic Analysis of the People Living in the Neighborhood of TMI Nuclear Power Plant, is contained in Vol. VI of the Appendix at 5103-5117.

123. A lymphocyte is "[a] white blood cell formed in lymphatic tissue throughout the body. . . ." STEDMAN'S MEDICAL DICTIONARY 1008 (26th ed. 1995).

124. The Trial Plaintiffs have not provided us with an explanation of what a dicentric is. Consequently, we refer to the report of defendants' expert, Michael A. Bender, Ph.D., a Senior Scientist in the Medical Department of the Brookhaven National Laboratory, who has studied chromosome aberrations for 38 years and has "participated in the development, verification, and application of biological radiation dosimetry using aberrations in lymphocytes form human peripheral blood samples since 1961." App. Vol. XII, at 9961. Dr. Bender's report states:

> Chromosomal aberrations are generally studied in cell divisions, during which the chromosomes are visible in the ordinary optical microscope. When such divisions of peripheral lymphocytes, called mitoses, are examined it is possible to enumerate aberrations of various kinds. In mitosis each chromosome, of which there are normally 46 in human cells, appears as a double linear structure with parallel "chromatids," which will become daughter chromosomes after cell division is completed, still attached at a point along their length called the centromere. Generally speaking, prior to its replication before cell division each chromosome behaves as a single linear structure. If the chromosome is broken and/or rearranged prior to replication, what are termed"chromosome type" aberrations result. These affect both chromatids of the chromosome (as a result of replication of the aberrant linear structure to form daughter chromosomes). If breaks and/or rearrangements occur after chromosome replication, however, the individual chromatids behave independently, with (one trivial exception) breaks and/or rearrangements affecting only one of the two parallel chromatids. These are called "chromatid type" aberrations.

at 5109. A high frequency of dicentrics is indicative of radiation exposure. Id. at 5109.

The residents whose blood samples were drawn for the cytogenetic analysis were selected by counsel for the plaintiffs; presumably based on criteria proposed by Shevchenko. App. Vol. VI, at 4978. The blood was drawn on two separate occasions in 1994 and 1995, and shipped to Snigiryova in Russia. Snigiryova made short-term peripheral blood cultures, fixed and stained them according to standard procedures and examined the resulting slides for chromosomal aberrations. Id. at 5103-5104.

She then counted the dicentrics in the blood samples. Of the 29 people whose blood was subjected to the cytogenetic analysis, she found that 22 had "[q]uantitative and structural changes in a cell chromosome system." Id. at 5112. She also found dicentrics in 19 people and found one cell with a threecentric in one person. Id. Snigiryova concluded that the average frequency of dicentrics was .2

> Because human peripheral lymphocytes are all in a pre-replication stage of the cell cycle while in the circulation, their irradiation when in the body results only in aberrations of the chromosome type when they are later caused it divide in vitro for cytogenetic examination; no chromatid type aberrations are induced. Thus only chromosome aberrations are useful as indicators of human radiation exposure.
>
> Aberrations of either the chromatid or the chromosome type may be simple chromosome breaks, resulting in a shortened chromosome or chromatid and a fragment lacking a centromere (an acentric fragment), or be the result of intrachanges or interchanges between two or more breaks in the same or different chromosomes. If of the chromosome type, two break exchanges may either be what cytogeneticists call "symmetrical," including translocations and inversions, or "asymmetrical," including dicentric and ring chromosomes. The latter are what are generally used for cytogenetic dosimetry, mainly because their topology is radically different from that of normal chromosomes, so that they are easily and efficiently detected. A dicentric, as the name implies, has two centromeres instead of the normal one, while a ring lacks any ends.

App. Vol. XII, at 20-22.

per 100 cells, which was ten times higher that the control value she used of 2 dicentrics per 10,000 cells examined, obtained from a study of individuals who lived in Moscow. Id. at 5110. Based on her cytogenetic analysis, Snigiryova opined that the group of TMI residents whose blood she analyzed were exposed to ionizing radiation from the TMI reactor accident. Id. at 5112.

Snigiryova's cytogenetic analysis was contained in her written report. She did not testify at an in limine hearing after the admissibility of her report was challenged. Instead, over objection, the District Court permitted Shevchenko to offer an opinion as to Snigiryova's analysis because it found that cytogenetic analysis was within Shevchenko's area of expertise. 911 F. Supp. at 811.

Snigiryova's written report does not contain a dose estimate based on her dicentric enumeration. However, Shevchenko did make a dose estimate based on Snigiryova's dicentric counts. Using a "calibration curve," Shevchenko calculated that the dose exposures among the TMI group which was the subject of the cytogenetic analysis ranged from 60 to 80 rems [0.6 to 0.8 Sv] for someone with 2 dicentrics per 500 cells, to 90 to 120 rems [0.9 to 1.2 Sv] for someone with 3 dicentrics per 500 cells, and 120 to 200 rems [1.2 to 2 Sv] for someone with 5 dicentrics per 500 cells. App. Vol. VI, at 4220.

Initially, the District Court rejected the attempt to preclude the cytogenetic study and Shevchenko's dose estimates, holding, as it did with Shevchenko's tree study, that Shevchenko's extensive experience "counterbalanced" whatever his testimony lacked "in rigid conformity to technical standards." 911 F. Supp. at 817. However, on a motion for reconsideration, the court found that Shevchenko's methodology of arriving at dose estimates based on Snigiryova's cytogenetic analysis was unreliable because too long a period of time expired between the alleged exposure and the analysis. Id. at 1013. Consequently, the District Court granted the motion to reconsider with respect to Shevchenko's dose estimates and prohibited him from estimating dose based upon Snigiryova's cytogenetic study. Id. However, the court denied the motion with respect to the cytogenetic analysis.

It held that Shevchenko could testify as to the substance of the cytogenetic analysis and to the findings regarding the presence or absence of chromosome aberrations. Id.

e. Discussion and Conclusions.

The District Court's exclusion of Shevchenko's dose estimates based on Snigiryova's cytogenetic study presents us with a difficult question. It is undisputed that "[a] chromosome aberration occurs when cells are irradiated and the chromosomes are broken and can rejoin with time after exposure." RADIATION DOSE RECONSTRUCTION, at 52. In fact, the enumeration of unstable chromosome aberrations is "among the most sensitive markers for radiation exposure." Id. at 59. Moreover, counting the number of dicentrics is an accepted method, not simply for determining if the subject of the analysis was irradiated, but also for estimating radiation dose to the individual.

> Chromosome aberrations induced in . . . human lymphocytes have been the system of choice for a biologic dosimeter used to quantify the dose to which an individual has been exposed or to verify or corroborate a suspected dose exposure for which no physical dose measurements have been available. These studies used mainly a dicentric aberration. . . .

Id. (emphasis added); see also MEDICAL EFFECTS, at 55 ("Dicentrics are an important biologic dosimeter."). The enumeration of chromosome aberrations can be used to estimate doses as low as 0.10 Gy [10 rad]. 125 Id. at 53.

However, dicentrics are unstable chromosome aberrations whose frequency deceases with time after exposure. RADIATION DOSE R ECONSTRUCTION, at 52. Consequently, if unstable chromosome aberrations are "measured within a year after acute exposure there will be little decay and the sensitivity will allow it to serve as a good dosimeter." Id. at 59. However, the reliability of this indicator decreases over time. Thus, the farther away in time from the alleged exposure, the less useful the dicentric

---

125. At lower doses and lower dose rates, the enumeration of chromosome aberrations is unlikely to help with dose reconstruction. RADIATION DOSE RECONSTRUCTION, at 60.

enumeration will be as an indicator of radiation exposure and the foundation for a dose estimate. See Id. at 53 ("It must be kept in mind that the decay found in this end point makes it useful only for an individual recently exposed to radiation. Authors have reported values for the average disappearance half-time of lymphocytes containing dicentric and centric rings ranging from 130 days. .. to 3 years. . . ."). To circumvent the problem inherent in using a dicentric enumeration as a method for estimating dose exposure, stable chromosome aberrations, and more precisely, translocations,126 are now being used as markers for radiation exposure. Id. at 59 ("The disadvantages associated with unstable markers are avoided when stable markers, such as reciprocal translocations, . . . are used."). Translocations are measured by a process called the"FISH" (Fluorescent In Situ H ybridization)127 method and "[v]alidation measurements made by [the FISH method] have shown that the frequency of reciprocal translocations in whole-body-exposed individuals is constant with time after exposure." Id. at 60.

Here, Snigiryova's dicentric count was done 15 years after the alleged exposure. Since dicentrics disappear over time, the usefulness of her dicentric enumerations as a basis to make dose estimates is open to question. She estimated in her report that dicentrics eliminate at the rate of approximately fifty percent per year and that cells with

---

126. See p. 127-128 n.124, supra.

127. The FISH method is also known as "chromosome painting" and is described as follows:

> In this technique, the DNA is thermally denatured to provide single strands of DNA. These targeted strands are incubated with nontarget DNA probes that bind to the DNA sequences that are homologous. The target DNA is stained, and the nontarget DNA is counterstained. Under a fluorescence microscope the target DNA appears yellow, and the nontarget DNA appears red. In the case of a translocation, the affected DNA strand will appear to be partially red and partially yellow. This method detects only a fraction of the translocations, so that it is necessary to apply a multiplication factor to estimate total translocation frequency.

MEDICAL EFFECTS, at 65.

chromosome aberrations eliminate at a rate of approximately fifty percent in three years. App. Vol. VI, at 5110-11. She conceded, not only that the use of her dicentric enumeration for dose estimation was problematic, but also that the enumeration of stable chromosome aberrations using the FISH method was the preferable methodology. Her report states:

> The problem of the estimation of dose radiation using the cytogenetic data is very problematically (sic) in this situation. Firstly, this is connected with the long period after TMI accident. In such situation it seems necessary to estimate stable chromosome aberrations in lymphocytes of peripheral blood, using FISH method. . . . Analysis of stable chromosome aberrations is more important in such situations because translocations owing to their special structure may go through mitosis without complication. It is to allow to find stable chromosome aberrations a long period after irradiation and their frequency will not change.

Id. at 5111. Shevchenko admitted in his deposition that the FISH method was the preferable methodology upon which to base a dose estimate for the TMI residents who were the subject of Snigiryova's dicentric enumeration due to the length of time between the alleged exposure and the enumeration. Id. at 4585.

Nonetheless, the Trial Plaintiffs claim that Shevchenko can make a reliable dose estimate using a dicentric enumeration on the basis of a regression analysis. His regression analysis is nothing more than a multiplication of the total number of dicentrics enumerated by Snigiryova to arrive at the higher number of dicentrics presumably existing after exposure as a result of the reactor accident. Id. at 4220. Of course, in the regression analysis, the multiplier is the crucial variable. Snigiryova and Shevchenko both opined that the frequency of dicentrics to translocations observed soon after irradiation is equal. See Id. at 5111 (Snigiryova: "According to some data the frequencies of unstable (dicentrics, centric rings and acentric fragments) and stable (translocations) aberrations observing after irradiation are about equal.") and Id. at

4794 (Shevchenko: "The original frequency under the effect of radiation is the same, one to one ratio has been shown."). Consequently, because of the equality of frequency of dicentrics to translocations at the time of initial irradiation, a correlation between unstable dicentrics and stable translocations can be developed and from that correlation a ratio can be determined. That ratio can be used to develop the multiplier in the regression analysis.

The ratio of dicentrics to translocations at the time of the analysis is crucial to developing the correct multiplier. Nevertheless, Snigiryova's cytogenetic analysis focused solely on dicentrics and not on translocations. The number of translocations in the chromosomes of the TMI residents who were the subject of the analysis is an unknown. Therefore, neither a ratio nor a multiplier can be developed, and without that ratio, there can be no reliable dose estimate. Shevchenko admitted as much in a report, dated February 4, 1996. That report states a "ratio of translocation frequency to dicentric frequency. . . must be used in order to reconstruct the TMI doses using dicentrics." Id. at 4342. Shevchenko admitted at the time he made his dose estimate that there was no established ratio between dicentrics and translocations for the group studied by Snigiryova. In his February 21, 1995, report, he wrote: "Unfortunately so far we don't know a ratio between stable and unstable chromosome aberrations for persons suffered from the TMI accident." Id. at 4220.

Nonetheless, despite his admission that the ratio of translocations to dicentrics was unknown when he made his dose estimate, Shevchenko estimated a dose range between 60 to 200 rem based on a multiplier of 6-8. Id. at 4220. His admission that he did not know a translocation/dicentric ratio at the time he made his dose estimate, effectively negated the reliability of the dose estimate. Furthermore, Shevchenko changed his multiplier over time from 6-8 in his February 21, 1995, written report, Id. at 422, to 5 at the in limine hearing on November 22, 1995, Id. at 4811, to 2-3 in a March 4, 1996, written report, Id. at 4357. However, he never explained why he changed the multiplier; and he never made a corresponding change in his dose estimate despite the changing multiplier. Consequently, determining what, if any role, his regression analysis occupied in his dicentric dose estimate methodology is problematic.

Earlier, we wrote that the District Court's exclusion of Shevchenko's dose estimate presented us with a difficult question. Radiation dose estimation based on dicentric enumeration is a valid and reliable scientific methodology, but the validity and reliability decrease as the time gap between the alleged irradiation and the dicentric count increases Accordingly, the fifteen year delay between the alleged irradiation and the dicentric count here is a factor that must be considered in determining the continued validity of Shevchenko's dose estimate based on Snigiryova's dicentric count. As noted earlier, Daubert does not require that the proffered expert is correct. Paoli II, at 744. Rather, the proponent of the challenged testimony need only demonstrate that their opinions are reliable. So long as the expert's testimony rests upon

> `good grounds', it should be tested by the adversary process -- competing expert testimony and active cross-examination -- rather than excluded from juror's scrutiny for fear that they will not grasp its complexities or satisfactory weigh its inadequacies.

Ruiz-Troche, at 85 (citing Daubert, at 596). Thus, if the only evidentiary hurdle was the fifteen year gap between the alleged irradiation and the dicentric enumeration, Shevchenko's dose estimate could, arguably, survive Daubert/Paoli II scrutiny.

Here, however, both Snigiryova and Shevchenko conceded the FISH method is the reliable methodology for dose estimation where there is a long span between exposure and the cytogenetic study. In her report, Snigiryova wrote:

> The problem of the estimation of dose estimation using the cytogenetic data is very problematically in this situation. Firstly, this is connected with a long period after the TMI accident. In such situation it seems necessary to estimate stable chromosome aberrations in lymphocytes of peripheral blood, using FISH method (fluorescence in situ hybridization).

App. Vol. VI, at 5111 (emphasis added). And, at his deposition, Shevchenko was asked about this statement at his deposition. The following exchange occurred:

> Q: Do you agree with that statement?
>
> A: Yes. I was just trying to show that that's how the situation is and I was trying to show what the problem is.

Id. at 4585. Furthermore, Shevchenko admitted that a known dicentric/translocation ratio for the TMI group must be used to estimate dose using a dicentric enumeration. As noted above, the delay here was 15 years. Given that delay and Shevchenko's concessions, we can not say the District Court abused its discretion in excluding Shevchenko's dose estimates under the court's Daubert/Paoli II analysis.

v. Gennady Kozubov.

a. Qualifications.

Gennady Kozubov is a forestry engineer with a Doctor of Biological Sciences degree. App. Vol. VI, at 5156-57. He is the Chief Scientific Worker-Advisor at the Institute of Biology, Komi Science Center -- Ural Division, Russian Academy of Science. Id. at 5124. His area of expertise is dendrology, which he defined as the "science of trees including the systematics and morphology of woody plants." Id. at 5158. Since 1986, he has studied the effects of the Chernobyl accident on woody plants. Kozubov believes that a dendrometric analysis of the growth rings of trees can determine if the trees were damaged by irradiation and a dose estimate can be inferred from that damage. Kozubov performed a dendrometric analysis on wood core borings obtained from the area around Three Mile Island. 128

b. Kozubov's Opinion.

In his written report, Kozubov relied upon his study of irradiated trees in the Chernobyl area to conclude that radiation at high levels can suppress the annual growth of tree rings and that radiation at low levels can stimulate

---

128. He testified that he received a patent from the former Soviet Union to develop this dendrometric analysis technique. Id. at 5181.

that growth. Id. at 5126-28. Although he indicated that tree ring growth is dependent upon a number of other factors, including precipitation, temperature, sunlight and mineral nutrition, Kozubov opined that if a large enough sample of trees of the same species, growing under identical conditions except for exposure to radiation, is examined, then the differences in their annual growth rings can be used to infer the doses the trees were exposed to. Id. at 5126-28.

Kozubov received wood boring samples that Shevchenko collected from the area surrounding Three Mile Island in 1995. Id. at 5128. The samples were "mostly 2 samples" from each of 35 spruce trees and 14 pine trees, which Shevchenko collected at a height of 1.2 to 1.5 meters. Id. He also received 9 pine and 13 spruce samples from Shevchenko to use as a control group. Id. at 5131.

When Kozubov received the samples he polished them so that the annual growth rings were clearly visible. Id. at 5168. Where polishing did not clearly reveal the annual rings, special equipment was used to enhance the visibility of the rings. Id. The samples were observed under a measuring microscope, starting "at the bark and going deep into the center," and the thickness of the annual rings from 1974 to 1985 was measured. Id. All of the indicators of ring growth were entered into a computer, average statistical data were calculated, and a graph was constructed. Id. at 5169. Absorbed doses were then calculated on the basis of the formula which Kozubov developed in connection with a patent he received for his dendrometric analysis technique.

Applying this dendrometric analysis, Kozubov concluded that (1) the spruce samples showed a "distinct inhibition of annual wood increment" in 1979, and a "stimulation" in 1980, and thus were irradiated;129 (2) radiation doses ranged from 0.5/0.6 to 1.9/2.0 Gy [50/60 to 190/200 rad]; (3) the irradiated trees were located mainly west and northwest of the TMI reactor; and (4) his conclusions are "trustworthy" because the samples subjected to the

---

129. Kozubov's report recites that he was unable to perform the dendrometric analysis on the pine samples. The reason he could not do so is unclear. App. Vol. VI, at 5132.

dendrometric analysis were compared to the control group. Id. at 5137.

The defendants challenged Kozubov's opinion claiming that he did not follow the requirements of his own methodology. After an in limine hearing, the District Court found that his dendrometric analysis methodology was reliable. In re TMI Litigation Cases Consolidated II, 910 F. Supp. 200, 203 (M.D. Pa. 1996). However, the court excluded Kozubov's proffered testimony and his dendrometric analysis because it did not " `fit' within the litigation." Id. At the in limine hearing, Kozubov testified that his dendrometric analysis, standing alone, would not prove that the samples were irradiated. It had to be correlated with a study of seeds, needle growth and wilting processes of the leading shoots of the trees to confirm the conclusions of the analysis. However, no such correlation was undertaken. Consequently, based in large part upon Kozubov's own concession as to the absence of critical correlation the court held that Kozubov's testimony and his dendrometric analysis would not assist the jury"in determining whether or not persons (and trees) in the TMI area at the time of the accident were exposed to radiation." Id.

c. Discussion and Conclusions.

Kozubov's admission that the dendrometric analysis would not by itself permit him to conclude that growth ring variations were caused by irradiation seriously undermines his opinion that the TMI tree samples were irradiated as well as the reliability of his dose estimates. As a result of his work after Chernobyl, he testified that he discovered that tree growth becomes chaotic after irradiation, id. at 5203, presumably because irradiation changes the metabolism of the trees. Id. The deviations caused by irradiation can be observed in seeds, needle growth, and wilting processes. Id. at 5204. Consequently, and presumably to exclude other causes of observed variations in tree ring growth, Kozubov's dendrometric analysis methodology requires correlation. He testified:

> [W]e always say that [the dendrometric] method is only used with other methods. One cannot use just one method to give this estimate.

> That's why in Chernobyl, we also studied the needle growth, also we studied growth patterns, seeds and also the wilting process of the leading shoots. That's why our estimations had a compound picture. If we use only this one [dendrometric] method, of course we will not say that this was caused by exposure.

Id. at 5204. But, no studies of seeds, etc. were done by Kozubov or anyone else130 to confirm the accuracy of the dendrometric analysis and the dose estimates for the accident at Three Mile Island.

The District Court found that the missing correlation went to the helpfulness or fit requirement of Rule 702. However, we believe that the missing correlation affected the essential reliability of the methodology itself rather than its "fit," because correlation is an essential element of the dendrometric analysis. The failure to correlate renders the methodology unreliable and the District Court therefore correctly concluded that the expert's testimony was inadmissible. Paoli II, at 745 ("[A]ny step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.").

Moreover, the failure to correlate was not the only misapplication of the methodology. In Kozubov's formula for estimating doses, the coefficient of accordance,"C", is a critical variable which is derived by measuring tree ring increments following a known dose exposure. App. Vol. VI, at 5128. In his report, Kozubov recited coefficients of accordance for trees irradiated as a result of the Chernobyl accident. Id. Those coefficients were determined at Chernobyl by using radiation doses which were known and measured by TLD readings. Id. at 4614. However, in a follow up report written after his initial report, Kozubov

---

130. The Trial Plaintiffs suggest that Kozubov did not need to perform the studies to confirm his dendrometric analysis because he could rely on Shevchenko's and Gunckel's morphological tree studies to supply the missing correlation. Trial Plaintiffs' Br. at 38. However, they do not provide any record citations which show that either Shevchenko or Gunckel made a study of seeds, needles or wilting processes.

wrote that the dose estimation formula "had a number of restrictions, as applied to the TMI accident." Id. at 5139. Significantly, he admitted that he did not have a coefficient of accordance for the trees he examined from TMI.

> First of all, is the lack of reliable evidence on the reaction of the native species of trees to the radiation exposure, the impossibility of experimental estimation of the coefficient of accordance "C".

Id.

But, the lack of the coefficient of accordance makes the entire dose estimation formula unworkable. Without a coefficient of accordance, the methodology cannot produce any dose estimate, let alone a reliable dose estimate. Thus, Kozubov's admitted inability to arrive at a coefficient of accordance constitutes a failure of the methodology.

We agree that Kozubov's proffered testimony should be excluded, but our reasoning differs from that of the District Court. Inasmuch as our differing viewpoints is rooted in different interpretations of Rule 702, we exercise plenary review over the District Court's interpretation of Rule 702. See Paoli II, at 749. However, here, we end up in the same place as the District Court. We merely take a different route. However, both routes result in the exclusion of Kozubov's testimony, and we will therefore affirm the District Court's result as to Kozubov.

vi. Olga Tarasenko.

a. Qualifications.

Olga Tarasenko is a medical doctor who has a Ph.D. in immunology,131 and is the head of the Immuno-Diagnostic Laboratory at the Russian Center of Molecular Diagnostic and Medical Treatment. She participated in the study of people exposed to ionizing radiation from nuclear weapons testing at the Semipalatinsk Nuclear Testing Grounds, and Trial Plaintiffs wanted her to testify about the results of an

---

131. Immunology is "[t]he science concerned with the various phenomena of immunity, induced sensitivity and allergy." STEDMAN'S MEDICAL DICTIONARY 856 (26th ed. 1995).

immunological study that she performed on blood samples of 19 residents of the Three Mile Island area.

b. Tarasenko's Opinion.

Tarasenko performed a comparative immunological study on blood samples from 5 groups of individuals. App. Vol. VI at 5209. The five groups were: (1) 19 people allegedly subjected to ionizing radiation as a result of the TMI reactor accident;132 (2) a group of irradiated people who participated in the clean-up following the Chernobyl nuclear power plant accident;133 (3) a control group from Moscow; (4) a group of inhabitants of Muslumovo village in the South Ural region of Russia exposed to ionizing radiation as a result of the Kyshtym accident;134 and (5) a group of inhabitants of a "clean" village in the Altai region of the former Soviet Union. Id. Her study was an attempt to determine whether the TMI area residents exhibited immune system depression, and if they did, to compare their immune system parameters with the immune parameters of people in the former Soviet Union who were exposed to known levels of ionizing radiation. Herfindings, contained in her written report, were as follows:

> In [the TMI group] even average characters substantially differ not only from generally accepted levels on immunocompetent cells but from the levels

---

132. Tarasenko performed her study at the request of Shevchenko and Snigiryova. The blood samples Tarasenko analyzed were taken from the same TMI area residents whose blood Snigiryova subjected to her cytogenetic analysis. App. Vol. VI, at 5305.

133. The Russian word for the people who were involved in the clean-up in the aftermath of the Chernobyl accident translates into English as "Liquidators." App. Vol. VI, at 4220. Tarasenko testified that, with one exception, the Liquidators whose blood she analyzed were exposed to approximately 25 rems [0.25 Sv] of ionizing radiation. Id. at 5299.

134. Muslumovo village is located in the area where a nuclear accident occurred in 1957 at the Mayak military plant which produced atomic weapons. The Mayak military plant was located near the city of Kyshtym. That area is referred to as the Eastern Ural Radiation Belt. App. Vol. VI, at 4199-20; 5209. According to Tarasenko, the Muslumovo residents were exposed to levels of ionizing radiation reaching 100 rems [1 Sv]. Id. at 510.

> obtained in control groups (Moscow and Altai inhabitants). . . .
>
> A sharp disbalance of immunoregulating cells was revealed. This disbalance in combination with the disturbances mention above evidences the presence of mixed immunodeficite (sic) status in the [TMI group].
>
> Such disturbances are observed in the patients who use immunodepressants (widely used antibiotics, aspirin and other medicines can be referred to this group of chemicals) and suffer from cancer, autoimmune diseases, syndrom (sic) of chronic weariness and others. It is undoubtedly necessary to carry out a dynamic examination of all persons in[the TMI group], regular observation of their immune status, medical and prophylactic measures.

Id. at 5209-10. Her written report does not discuss the possibility or probability that the mixed immunodeficit status of the TMI area residents was caused by exposure to ionizing radiation. She testified that when she did the comparative study, her purpose was not "to interpret these results." Id. at 5375. Rather, "it was[her] purpose to obtain this data, to record these results." Id.

However, after her opinion was challenged,135 Tarasenko testified at the in limine hearing that the TMI area residents' immune system deficits that her written report associated with the use of immunodepressents, etc., are possibly the result of radiation exposure. Id. at 5308. She explained as follows:

> The conclusion is this, characteristics that we have determined for inhabitants in the area of Three Mile Island, they are hardly different, show almost no differences or -- well, there is not quite an equivalent sign, but almost, almost the same as characteristics found for the inhabitants of Muslumovo village. . . .
>
> In other words, our conclusion is this, changes that we see in inhabitants of the Three Mile Island region are even deeper than in those who lived in that village and

---

135. Tarasenko's qualifications as an expert were not disputed.

> were eradiated (sic) as a consequence of the Kyshtym accident.
>
> *************************
>
> Our conclusion is that the immunodepression was found in both these groups under comparison. TMI group and Muslumovo group, immunodepression was present. The extent of immunodepression, however, was more prominent in the Three Mile Island accident.

Id. at 512-13; 520.

Tarasenko testified that she was able to offer an opinion that the immunodepression that she found in the TMI area residents could have been radiation induced because after she provided her written report to Shevchenko, she received "information [from Shevchenko that] allowed me to rule out those other causes that are listed in the last paragraph of the report." Id. at 5309. The information she received was the summaries of the health histories of the 19 Three Mile Island area residents whose blood she examined. Those summaries were contained in Snigiryova's report of her cytogenetic analysis. Id. at 5377.

The District Court excluded Tarasenko's proffered comparative immunological study in its entirety not under Daubert/Paoli II, but under Rule 703. The court concluded that she "lacked the foundation to make the judgments she did." In re TMI Litigation Cases Consolidated II, 922 F. Supp. 997, 1024 (M.D. Pa. 1996). Consequently, the court held that Tarasenko's "conclusions are not based upon `good grounds' and are not scientifically reliable." Id.

c. Discussion and Conclusions.

Although the "primary locus" of the District Court's gatekeeping role is Rule 702, a court "should also be mindful of other applicable rules," Daubert , at 590; 595, when conducting a Daubert analysis. Rule 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or

> inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703.

Rule 703 thus focuses on the data underlying the expert's opinion. Paoli II, at 747. It permits experts to rely on hearsay so long as that hearsay is of the kind normally employed by experts in the field. Id. (quoting In re "Agent Orange" Product Liability Litigation, 611 F. Supp. 1223, 1245 (E.D. N.Y. 1985)). Therefore,

> when a trial judge analyzes whether an expert's data is of a type reasonably relied on by experts in thefield, he or she should assess whether there are good grounds to rely on this data to draw the conclusion reached by the expert.

Id. at 749. If the data underlying the expert's opinion are so unreliable that no reasonable expert could base an opinion on them, the opinion resting on that data must be excluded. Id. at 748. The key inquiry is reasonable reliance and that inquiry dictates that the "trial judge must conduct an independent evaluation into reasonableness." Id. Rule 703's reliability standard is similar to Rule 702's reliability requirement, i.e., "there must be good grounds on which to find the data reliable." Id.

The Trial Plaintiffs claim that the information Tarasenko received from Shevchenko was the medical history summaries of the 19 people whose blood was the subject of her immunological study. While admitting that the information consisted of incomplete summaries, not complete hospital or medical records, the Trial Plaintiffs claim that the summaries contained a considerable amount of reliable information that Tarasenko could reasonably use to rule out the other causes of immunodepression noted in her written report, and thus allow her to conclude that the immunodepression was caused by ionizing radiation. They point to Tarasenko's testimony that the summaries included information regarding

> presence or absence of autoimmune diseases . . .[the] presence or absence of oncological cancer diseases, whether [the person] was a smoker or nonsmoker, and

> if he was a smoker what was the extent of smoking, then [the person's age], then a list of major diseases, as well as complaints.

App. Vol. VI, at 5375-77.

These summaries were the only information that Tarasenko had about the health histories of the people whose blood she examined. Id. at 5377; 5383. Although Tarasenko received these summaries from Shevchenko, they were not made by Shevchenko, nor were they based on medical or hospital records. Instead, the summaries were made by employees of Trial Plaintiffs' counsel, and they were based on interviews those employees had with the people whose blood samples were taken for Snigiryova's cytogenetic analysis. Id. at 4576. Apparently, the interviews were based upon questions formulated by Shevchenko. Id.136 Nonetheless, the summaries were made for litigation, not for the purpose of obtaining medical treatment. There is nothing improper about a medical report prepared solely for litigation. Paoli II, at 762. However,

> a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and hence should either examine the patient or review the patient's medical records simply to determine that a patient is ill and what illness that patient has contracted.

Id. In Paoli II we concluded that where the physician who had been retained strictly for litigation purposes based pathological causation on nothing more than a plaintiff 's self-report of an illness, the District Court's exclusion of the resulting evidence did not constitute an abuse of discretion. Common sense alone suggests that such evidence is"based on an unreliable source of information." Id.

That rationale applies here. The medical history summaries generated by the interviews for submission to Trial Plaintiffs' expert witnesses were unreliable and Tarasenko did not have good grounds to rely on them to

---

136. At his deposition, Shevchenko testified that "[a]t the moment when the blood was taken, the information was taken from the participants according to my scheme."

arrive at her conclusion that the immunodepression her comparative study revealed was caused by ionizing radiation. Tarasenko should have done more. She should have either reviewed her study subjects' medical and hospital records or examined the subjects herself. See Id. ("[G]enerally, a doctor needs one reliable source of information showing that the plaintiff is ill and either a physical examination or medical records will suffice -- but the doctor does need at least one of these sources."). She cannot rely on medical summaries prepared from interviews conducted by nonprofessionals as Tarasenko did here. This is especially true when the nonprofessionals are aligned with counsel for one of the litigants. In fact, in Tarasenko's initial report, she said that in order to arrive at an opinion as to the cause of the immunodepression, it is "undoubtedly necessary to carry out a dynamic examination of all persons [in the TMI group], regular observation of their immune status, medical and prophylactic measures." App. Vol. VI, at 5210. We agree. Tarasenko's own report thus demonstrates that the data supporting her challenged opinion were not reliable, and the District Court did not abuse its discretion in excluding her testimony.

vii. Bruce Molholt.

a. Qualifications.

Bruce Molholt earned a B.A. in mathematics from Hendrix College, a M.S. in microbiology from the University of Arkansas School of Medicine and a Ph.D. in microbiology from Indiana University. He did post-doctoral work in molecular biology and genetics at the University of Stockholm in Sweden, the University of Ghent in Belgium, and the University of Heidelberg in Germany. He taught immunology at the University of Kansas from 1960 to 1972 and at the Medical College of Wisconsin from 1976 to 1978. He was a Superfund toxicologist with the Environmental Protection Agency from 1984 to 1988. He has been a Visiting Professor in the Environmental Studies Program at the University of Pennsylvania since 1988. In addition, he is a principal in, and the Program Director of, Risk Assessment and Toxicology at Environment Research Management, Inc. App. Vol. VII, at 5412-5413.

The Trial Plaintiffs characterized Molholt as an expert in two separate areas -- toxicology137 and risk assessment.138 He was proffered to render opinions as to dose exposure and medical causation.139 Id . at 42.

b. Molholt's Opinions.

Molholt's first report (which the Trial Plaintiffs' characterize as his "Dose Exposure Report") was dated April 8, 1993. It is in the form of an affidavit and is untitled. Id. at 5424-5433. In it, Molholt opined that "[l]ymphocyte depression is the major sequela of radiation exposure," and therefore, "the pattern of depressed lymphocyte production

---

137. Molholt defined a "toxicologist" as"a scientist who evaluates the relationship between exposure to potentially hazardous substances and the onset of certain diseases." App. Vol. VII, at 6336.

138. Molholt defined "risk assessment" as follows:

> Whereas toxicology is qualitative, that is, does a certain substance have an inherent property which can cause disease, risk assessment takes it one step further. It attempts to quantify that relationship. That is, how much exposure to a toxic substance will cause disease; or if a disease is present, could this have been due to a given exposure to toxic substances knowing the amount of exposure.

App. Vol. VII, at 6336. To illustrate the difference between toxicology and risk assessment, Molholt offered the following:

> [T]oxicology is saying that if you are exposed to arsenic, you may develop mental insufficiency. If you are exposed to trichloroethylene, you may suffer liver damage. That is the discipline of toxicology.
>
> Risk assessment takes arsenic and says you must be exposed to ten milligrams per kilogram of soil for ten days, then you are at risk for these central nervous system difficulties. . .. [Risk assessment] tends to quantify not only what the level of exposure that is required for the onset of a certain disease, but then you are at risk for that disease with a hundred percent assurance, fifty percent assurance.
>
> Or in the carcinogenic realm, a whole different paradigm. And that is, if you are at risk from a certain exposure, what is your individual

probability of risk put in a probabilistic formula.

Id. at 6344-45.

139. Molholt's expertise as a toxicologist and a risk assessor were not disputed.

. . . may be used as a long-lived form of human dosimetry[140] to back-calculate the intensity of population exposures during radiation exposures such as occurred during the TMI accident." Id. at 5424-25. He noted reports by other authors that "[d]irect measurements of circulating lymphocyte levels in blood samples withdrawn from TMI area residents confirm that they suffered statistically significant lymphocyte depression following the accident." Id. at 5428. He also noted additional reports that "TMI area residents were found to have profound lymphocyte depression five years following the 1979 reactor accident." Id. at 5429. Using his back-calculation technique, Molholt concluded that "the immunological evidence supports the conclusion that human radiation exposures exceeded 100 rems [1 Sv] as a result of the TMI accident." Id.

Molholt's April 8, 1993, report was challenged under Daubert, but Trial Plaintiffs submitted another Molholt report, dated March 13,1995, before the court could rule on that motion. Id. at 5435-5520. They characterized that report as a "Medical Causation Report." It is entitled "Risk Assessments for TMI Test Cases." The stated purpose of the March 13 report was

> to examine the medical histories of each of the[Trial Plaintiffs'] cases and determine, with reasonable scientific certainty, whether or not the cancers they each developed following the 28 March 1979 TMI-2 accident are more likely than not due to radiation exposures received as a result of the accident.

Id. at 5437. A general discussion of lymphocyte depression occupies a significant portion of Molholt's Medical Causation Report. Id. at 5442-48. His report also contains a "lymphocyte profile" for each test plaintiff. He used the profiles to determine whether the test plaintiffs' cancers were caused by ionizing radiation. Id. at 5452-99. In his Risk Assessment Report, Molholt identified six"parameters" on which he "scored" each test plaintiff on a scale of one to

---

140. Dosimetry is "the science of determining radiation fields and dose to individuals, or materials, by using any and all known types of detectors and calculational techniques." President's Commission, Report of the Task Force Group on Health Physics and Dosimetry 36 (1979).

three; the maximum score being 18. Using these parameters and his scoring system, Molholt determined that a score of 9 or above demonstrated that causation was established with reasonable scientific certainty. Id. at 5451; 6490-94; 6572-73. Applying that methodology, Molholt concluded that the Trial Plaintiffs "received their carcinogenic insults as a result of radionuclides released by the March-April 1979 accident in the Unit 2 nuclear reactor at Three Mile Island." Id. at 5509.

When the Trial Plaintiffs filed their supplemental brief regarding Molholt's lymphocyte back-calculation dosimetry, they attached a third Molholt report, dated May 1, 1995, entitled "Utilization of Scientific Methodology in the Reconstruction of Radiation Doses to Human Receptors During the 1979 Nuclear Reactor Accident at Three Mile Island." Id. 5523-63. This report elaborates upon the April 8, 1993, Dose Exposure Report by providing supplemental lymphocyte data. In it, Molholt again concluded that"the TMI accident released radionuclides in amounts sufficient to irradiate persons in the nearby area with <!DDAG> 100 rems." Id. at 5523. The report also contained "an additional ten phenomena," which Molholt referred to as "corollary hypotheses." He opined that the presence of those phenomena in the TMI area confirmed his dose exposure opinion that the accident released <!DDAG> 100 rems [1 Sv] of ionizing radiation. Id. at 5536-27.

However, despite his three reports, the Trial Plaintiffs agreed to withdraw a portion of Molholt's proffered testimony. During the in limine hearings Trial Plaintiffs' counsel reported to the court:

> The subject of the defendants' briefing and attack on Dr. Molholt was his use of lymphocyte counts to attempt to back-calculate dose. . . . We were willing to have the [defendants' Daubert] motion granted in the limited aspect of the attack, which is the lymphocyte count, and not proffer Dr. Molholt to opine on that methodology.

App. Vol. V, at 4123. But, counsel indicated that Molholt "would still be tendered consistent with other aspects of his reports." Id. at 4124.

Not unexpectedly, a dispute arose as to what remained of Molholt's proffered testimony once the lymphocyte back-calculation methodology was withdrawn. Trial Plaintiffs claimed that they only withdrew Molholt's testimony regarding his lymphocyte methodology and its conclusions. They insisted that they had not withdrawn Molholt's proffered testimony on his "corollary hypotheses," in his May 1, 1995, report.141 App. Vol. VII, at 6383-84. Consequently, they argued that Molholt was still able to testify about those hypotheses. The defendants disagreed and argued that Molholt characterized his corollary hypotheses "as evidence for clinical lymphocyte depression and immunosuppression," and that this was exactly the line of testimony that Trial Plaintiffs withdrew as part of the lymphocyte back-calculation methodology. Id. at 6381.

The District Court found that the May 1, 1995 report containing the corollary hypotheses was filed in response to its February 14, 1995 order for additional briefing on the back-calculation methodology. The court reasoned that since the back-calculation methodology was withdrawn, the May 1, 1995 report "is no longer relevant to this case." Consequently, Molholt's May 1, 1995 report was also excluded, leaving only his March 13, 1995 report. 922 F. Supp. at 1026.

As noted above, Molholt's March 13, 1995 report was entitled "Risk Assessments for TMI Test Cases." In it Molholt concluded that each of the Trial Plaintiffs' cancers was caused by exposure to ionizing radiation released by the reactor accident. The District Court found Molholt's methodology scientifically unreliable and excluded Molholt's risk assessment and/or causation testimony in its entirety. Id. at 1031. The District Court also found that Molholt did not meet the reliability requirement of Rule 703. Id.

c. Discussion and Conclusions.

At the outset, the Trial Plaintiffs argue that the District Court's exclusion of Molholt's May 1, 1995, report was error

---

141. Although not explicitly stated by the Trial Plaintiffs, their withdrawal of Molholt's lymphocyte back-calculation methodology also acted as a withdrawal of Molholt's April 8, 1993 expert report.

because the May 1st report did not relate only to the withdrawn lymphocyte back-calculation methodology. They claim that Molholt's "corollary hypotheses" referred to in the May 1st report constitutes a methodology, separate and apart from the lymphocyte back-calculation methodology, from which Molholt can derive a dose exposure estimate. Trial Plaintiffs' Br. at 45. We disagree.

We note, as did the District Court, see 922 F. Supp. at 1025, that the cover letter to Trial Plaintiffs' counsel accompanying Molholt's May 1st report clearly indicates that the May 1st report is in response to the District Court's February 14, 1995, order requesting supplemental information supporting the use of the lymphocyte back-calculation methodology. App. Vol. VII, at 5521. The cover letter is compelling evidence that Molholt was responding to the court's inquiries about the back-calculation methodology when he submitted the subsequent report. 142 Molholt's proffered testimony about that methodology was withdrawn by counsel. The District Court could reasonably conclude that once the methodology was withdrawn, any report submitted in support of that methodology was also withdrawn. Moreover, the text of the report clearly indicates that the corollary hypotheses do not stand as an independent methodology for determining dose estimates. Molholt's May 1st report states

> [my] first hypothesis, as stated in my affidavit of April 1993, was that if persons who were near TMI at the time of the accident can be shown to have chronic lymphocyte depression and immunosuppression 5, 10 and 15 years later, then they must have been exposed to 100 rems during the accident.

Id. at 5524. Molholt postulated that if hisfirst hypothesis is correct, then decreased lymphocyte levels in peripheral blood and increased cytogenetic damage in peripheral blood lymphocytes should be observed in the TMI population exposed to ionizing radiation. Id. at 5525. He opined,

---

142. The cover letter stated: "Enclosed you will please find my response to the Court's memorandum of 14 February 1995 relating to Defendant's (sic) motion to exclude my testimony in limine in the ongoing TMI litigation."

therefore, that the presence of both phenomena would be a confirmation of his first hypothesis. Id. Molholt then reported that others have reported both decreased lymphocyte levels and increased cytogenetic damage in TMI area residents. Id. at 5525-26. Consequently, Molholt concluded that the presence of both phenomena confirm the validity of his first hypothesis. Id.

After concluding that his first hypothesis had been confirmed, Molholt then discussed his corollary hypotheses. Id. at 5526-5531. It consisted of "ten phenomena" which he claimed should be expected following an exposure to <!DDAG> 100 rem.[143] He claimed, again based on the reports of others, that the ten phenomena were present and, therefore,"these additional ten hypotheses comprise a very convincing biodosimetry data set that radiation exposures exceeded doses of 100 rem during the TMI accident." Id. at 5527.

The corollary hypotheses do not stand as an independent methodology from which to arrive at a dose estimate. They were a secondary method which Molholt used as confirmation of his first hypothesis. The foundation for the first hypothesis was the lymphocyte back-calculation methodology that was withdrawn. The District Court logically concluded that if the lymphocyte back-calculation methodology was withdrawn, any evidence in support of that methodology ought to be excluded. We agree, and therefore conclude that the District Court did not abuse its discretion in excluding the May 1, 1995 report.

Consequently, only Molholt's March 13, 1995, "Risk Assessment for TMI Test Cases" report remained. That report purported to be a causation report that inquired into whether the Trial Plaintiffs' cancers were caused by ionizing

---

143. The ten phenomena the presence of which comprise Molholt's corollary hypotheses are: (1) erythema, eye irritation, nausea, vomiting and hair loss; (2) metallic and iodine tastes and smells; (3) radioiodines in excess in local fauna; (4) increased neonatal hypothyroidism from radioiodine emissions; (5) increased incidence of adult thyroid diseases; (6) increased infectious diseases in exposed persons; (7) increased infectious diseases in exposed animals; (8) increased incidence of autoimmune diseases; (9) increased incidence of cancer; and (10) radiation damage to trees. App. Vol. VII, at 5526-27.

radiation from the reactor accident. However, Molholt wrote that the report focused "on three aspects of the histories of each test plaintiff" rather than the "mechanisms of radiation carcinogenesis." Id. at 5437. The three "aspects" were:

> 1. Were test plaintiffs exposed to sufficient io nizing radiation in 1979 to experience lymphocyte depression and/or immunosuppression? Blood analyses and decline in health status are indicators.
>
> 2. Were there other indications by Plaintiffs of a cute radiation exposure at the time of the TMI-2 accident, such as erythema, nausea, iodine taste, etc.?
>
> 3. Were the test plaintiffs in areas of known radi ation exposure at the time of the TMI-2 accident, i.e., downwind or in areas which have borne subsequent evidence of radiation exposure such as arboreal apical ablation?

Id. Presumably in an effort to focus on these three aspects, Molholt developed six "parameters" on which he scored each plaintiff. He described the parameters as "relevant causal criteria," and stated that he "attempted to apply four weighted scores to" each of the six parameters," to arrive at a "determination of cancer causality as resulting from TMI-2 accident emissions with reasonable scientific certainty." A score of <!DDAG> 50 percent established "reasonable scientific certainty for causality." Id. at 5451. The six parameters are:

> Proximity to TMI -- taking into account not only the actual distance from Three Mile Island but whether or not the test plaintiff was located downwind from the TMI-2 reactor during the accident and for what period of time.
>
> Acute Symptomatology -- acute signs of radiation exposure during the accident, including erythema, nausea, eye or mucous membrane irritation and metallic taste or smell (these require relatively high doses).
>
> Radiation-Damaged Trees -- evidence of radiation damage in trees in the immediate area frequented by the test plaintiffs during the accident.

> Lymphocyte Depression and Immunosuppression -- the continuing degree of lymphocyte depression following March 1979 as well as immunosuppression as indicated by increased susceptibility to infections diseases. For two test plaintiffs, cytogenetic analyses are available.
>
> Age of Test Plaintiff at Cancer Diagnosis -- weighted high for youngest cases, median for 20s and 30s, low for 40s and 50s and negatively for <!DDAG> 60.
>
> Lag Time -- weighted high for <!DDAG> 5 years for solid tumors, 2 years for leukemias and less as time of diagnosis approaches 1979.

Id. at 5451. Based on the score Molholt assigned to each trial plaintiff after weighing each parameter, he concluded that the Trial Plaintiffs' cancers were caused by the radionuclides released as a result of the accident. Id. at 5541; 5509.

We are at a loss to determine how Molholt scored each parameter to arrive at his causation conclusion. In his report, Molholt wrote that "[t]hese six contributors to causal certainty [i.e., the parameters] are not equally weighted." Id. But, at the in limine hearing, he testified that "in general, and I don't mean specifically, but in general, I attempted to weigh these six criteria equally." Id. at 6571. On cross-examination, he attempted to explain the contradiction as follows:

> A: [A]lthough my objective was to weigh each of these equally, that is, to give them one-sixth of the total -- actually 16.6 percent of the total score, in fact, when there was an outstanding criterion like dicentric chromosome formation, that tended to overwhelm the other five criteria, such that if I have been in a position of making the 50 percent reasonable scientific certainty standard employed or not, in other words, if I was at that boundary, I would have weighed the chromosomal criteria more than damaged trees or more than lymphocyte depression or more than lag time.
>
> Q: So if you got a positive answer on chromosome abnormalities, that carried the day?

A: If I were at that boundary between certainty an d uncertainty, which is the 50 percent standard that has been employed, at least up until Daubert and Paoli[II], what I was attempting to do was to quantify these criteria in such a way that I could, on an individual basis of each one of these, make a 50 percent determination, but then collectively to say, on that system of three, two, one, you have six criteria, the highest score is 18 if all six criteria are satisfied in terms of what we know about exposure requirements and carcinogenesis, radiation carcinogenesis.

So if those six criteria were all satisfied to the fullest, you would have a score of 18. That's the highest you could get. The lowest you could get is, if none of them were satisfied at all, and that's zero. So I took nine as being the boundary.

Q: And if they hit nine, then you said that's enou gh?

A: No, I didn't. That's when I would reach into my basket of tricks and pull out dicentric chromosomes or some other characteristic that I thought deserved more credence than trying to equally weigh them. Now, as it turned out . . . I didn't have any that were nine . . . . They were all ten or more.

Id. at 6572-73. From this exchange, we can only conclude that the methodology Molholt used to score and weigh his parameters to determine causation is purely subjective.144 In order for expert testimony to meet Daubert's reliability standard, it must be based on the methods and procedures of science, not on subjective belief and unsupported speculation. Kannankeril, at 805. Molholt's subjective methodology is suspect. As quoted above, he testified that when he was at the boundary between certainty and

---

144. Because Molholt's parameter scoring methodology is entirely subjective it is obvious that it does not satisfy a number of the Daubert factors. It was never peer reviewed, there is no known or potential rate of error, there are no discernable standards governing its operation, and it is not generally accepted. Daubert, at 593-594. Further, and significantly, it is impossible to test a hypothesis generated by a subjective methodology because the only person capable of testing or falsifying the hypothesis is the creator of the methodology.

uncertainty, i.e., when according to his own scoring system a trial plaintiff 's score reached nine, he "would reach into [his] basket of tricks" to pull out something which he thought deserved more weight. Not unexpectedly, he always found something in his magical basket which caused the score to exceed nine and pass from uncertainty to certainty. However, we are as unimpressed with his "Felixian"145 basket of tricks as the District Court was, and we conclude that the exclusion of Molholt's March 13, 1995 report was not an abuse of discretion.

viii. Sigmund Zakrzewski.

a. Qualifications.

Sigmund Zakrzewski earned a Ph.D. in biochemistry from the University of Hamburg in Germany and has spent his entire career in cancer research. For most of his professional life, he was the Principal Cancer Research Scientist at the Roswell Park Cancer Institute in Buffalo, New York. He is presently a Professor Emeritus at the State University of New York -- Buffalo, an appointment he had held since 1987. App. Vol. IX, at 7912-7914. He was offered as an expert to give his opinion as to the cause of the cancers of the Trial Plaintiffs.146

---

145. See Felix The Cat: "Whenever he gets in a fix, he reaches into his bag of tricks." Chris Milburn, Felix, Felix, Felix (visited Sept. 13, 1999)
http://www.primenet.com/#A1#cmilburn/#A1#felix/felix.htm>.

146. Zakrzewski is not a medical doctor, toxicologist or risk assessor. Consequently, his qualifications to give an opinion on causation were attacked by the defendants. The defendants also attacked his qualifications on the grounds that none of his cancer research involved the health effects of ionizing radiation. However, the District Court found
that he met "the threshold requirement for qualification as an expert." 922 F. Supp. 1038, 1049 (M.D. Pa. 1996). That finding is not attacked on appeal.

Filed November 2, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 96-7623/7624/7625

IN RE: TMI LITIGATION

LORI DOLAN; JOSEPH GAUGHAN; RONALD
WARD; ESTATE OF PEARL HICKERNELL;
KENNETH PUTT; ESTATE OF ETHELDA HILT;
PAULA OBERCASH; JOLENE PETERSON; ESTATE OF
GARY VILLELLA; ESTATE OF LEO BEAM,

Appellants No. 96-7623

IN RE: TMI LITIGATION

ALL PLAINTIFFS EXCEPT LORI DOLAN, JOSEPH
GAUGHAN, RONALD WARD, ESTATE OF PEARL
HICKERNELL, KENNETH PUTT, ESTATE OF ETHELDA
HILT, PAULA OBERCASH, JOLENE PETERSON, ESTATE
OF GARY VILLELLA AND ESTATE OF LEO BEAM,

Appellants No. 96-7624

IN RE: TMI LITIGATION

ALL PLAINTIFFS; ARNOLD LEVIN; LAURENCE
BERMAN; LEE SWARTZ

Appellants No. 96-7625

ON APPEAL FROM THE UNITED STATES DISTRICT
COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
(Civil No. 88-cv-01452)
(District Judge: Honorable Sylvia H. Rambo)

ARGUED: June 27, 1997

Before: GREENBERG and McKEE, Circuit Judges, and
GREENAWAY, District Judge*

(Opinion filed: November 2, 1999)

b. Zakrzewski's Opinion.

Zakrzewski's report, dated September 15, 1994, Id. at 7920-31, states that in 1993 he was contacted by Trial Plaintiffs' counsel and asked "to review cases of different types of cancer . . . allegedly due to the release of radioactivity resulting from the nuclear accident . . ." at TMI-2. Id. at 7920. As a result, he reviewed"ten cases involving two cases of chronic leukemia, two cases of acute leukemia, two cases of thyroid cancer, one case of thyroid adenoma (benign tumor), one case of osteogenic sarcoma, one case of breast cancer and one case of adenosarcoma of ovaries." Id. at 7921.147 His report details nine factors he considered in evaluating the cases, viz., (1) the type of cancer; (2) age of victims at the time of the accident; (3) occupation at the time of the accident; (4) whereabouts of the victims at the time of the accident; (5) latency period between alleged exposure and diagnosis; (6) other cancer cases in the neighborhood of the plaintiff 's residence or the place of business; (7) possible exposure to carcinogens other than radiation; (8) prior exposure to medical radiation; and (9) any evidence, other than the victim's disease indicating the possibility of exposure to ionizing radiation. Id. He explained that because he is not a physician he did not attempt to review any medical records. Rather, he relied on the diagnosis of the physician of each trial plaintiff 's case he evaluated. Id. He concluded that "the four cases of leukemia . . . were most likely caused by exposure to radiation released during the TMI accident, " Id. at 7923, that "the three cases of thyroid cancer were most likely caused by radioactive fallout resulting from the

* The Honorable Joseph A. Greenaway, Jr., United States District Court Judge for the District of New Jersey, sitting by designation.

147. In other words, Zakrzewski reviewed the Trial Plaintiffs' cases.

TMI accident," Id. at 7924, that "the most likely cause of [the] osteosarcoma is exposure to radioactive fallout originating from the nuclear accident at TMI," and that "whole body exposure to radiation" is the most likely cause of the breast cancer and the ovarian cancer." Id. at 7926.

The District Court sustained defendants' Daubert challenge to Zakrzewski's testimony. See In re TMI Litigation Cases Consolidated II, 922 F. Supp. 1038, 1051 (M.D. Pa. 1996).

c. Discussion and Conclusions.

At the in limine hearing, Zakrzewski testified that the only data he relied upon in arriving at his causation opinion were a summary sheet for each trial plaintiff. App. Vol. IX, at 8158. Each summary sheet contained a family history of other diseases, as well as

> personal information about the person, age at the time of accident, age at the time of diagnosis, location of the residence and location of place of work, and of course, occupation, or school, and any possible other factors which could have caused the malignancy. And also, some information about personal observation, were you aware of the accident, did you observe any vegetation damage, and similar information.

Id. at 8136. The summary sheets were prepared by Trial Plaintiffs' counsel and transmitted to him by a woman identified as a consultant to the plaintiffs. 148 Id. at 8157-58. Zakrzewski testified that he did not develop a methodology for assessing causation and then request appropriate data. App. Vol. IX, at 8158. Rather, it appears that he was provided with the data and then constructed a methodology. Id. at 8158-8159.

Earlier, we noted the interaction between Rule 702 and Rule 703. The latter requires that the trial judge determine

---

148. That woman was Marjorie Aamodt, who, along with her husband Norman, "have been identified as `consultants' to Plaintiffs in the context of this litigation." 922 F. Supp. at 1047. The District Court noted that the Aamodt's are "not listed as expert witnesses and have not supplied any expert reports for this case." Id.

whether the proffered expert "is basing his or her opinion on a type of data reasonably relied upon by experts." Paoli II, at 748. Here, we cannot fault Zakrzewski for relying on the diagnoses of the Trial Plaintiffs' physicians. He did so because of his realization of the limitations endemic to his lack of medical training and expertise. However, we share the District Court's concern over reliance on the summary sheets prepared by Trial Plaintiffs' counsel, and given to him by plaintiffs' consultant. As the District Court noted: "No evidence has been placed on the record as to how these summary sheets were created." 922 F. Supp. at 1050. They have no demonstrated indicia of reliability, and it is the burden of the party offering the expert scientific testimony to demonstrate reliability by a preponderance of the evidence. Paoli II, at 744. Absent some evidence as to how the sheets were prepared and the sources of the information contained in them, it is impossible to assess their reliability.

The Trial Plaintiffs do not waste any ink trying to convince us that the summary sheets furnish adequate support for an expert opinion. Consequently, our analysis of this issue could end here, and we could merely affirm the exclusion of Zakrzewski's testimony with no further discussion. However, Trial Plaintiffs claim that Zakrzewski did not rely solely on the summary sheets. They assert that he also relied on the "scientific evidence" of plaintiffs other experts in arriving at his causation opinion. Trial Plaintiffs Br. at 56. For example, Zakrzewski assumed that the Trial Plaintiffs were exposed to radiation and the basis for that assumption was the dose evidence developed by others, i.e., damaged trees (Shevchenko and Gunckel), impaired immunity (Tarasenko and Molholt); and anecdotal accounts of radiation-induced illnesses (Gunckel). App. Vol. IX, at 7927-7929. Essentially, the Trial Plaintiffs attempt to show reasonable reliance by postulating that their other experts' opinions were sufficiently reliable to support Zakrzewski's expert opinion. However, the reliability of those other opinions is the focus of our entire inquiry. Trial Plaintiffs' argument in this regard is the intellectual equivalent of having the left hand put the rabbit into the hat so it can be pulled out by the right hand. We have already upheld the District Court's exclusion of the evidence Trial Plaintiffs now seek to morph into a reliable foundation for Zakrzewski's opinion. We conclude that the District Court did not abuse its discretion by excluding Zakrzewski's testimony.

ix. Theodor Sterling.

a. Qualifications.

Theodor Sterling earned a Ph.D. from the Tulane University. He is an epidemiologist and a Professor on the Faculty of Applied Science and School of Computing Science at Simon Fraser University in Burnaby, British Columbia. Sterling notes that, generally, his research is "directed toward the understanding of the effects of environment on human health." App. Vol. IX, at 8190. More particularly, he reports that his "major areas of research have been the effects of air pollutants including tobacco; the effects of herbicides especially of mixtures of herbicides known as Agent Orange; the effects of radiation both for treatment of, and source of, cancer, the effects of occupational exposures especially to asbestos, dioxins in various forms and formaldehyde." Id.

Sterling submitted a report, dated April 25, 1995, entitled "Analysis of the Elevated Cancer Risks Associated with the 1979 Three Mile Accident."149Id. at 8222-8243. In it, he wrote that the "scientific hypothesis investigated is whether the health of individuals living near Three Mile Island was adversely affected by the accidental release of radioactivity." Id. at 8237.

b. Sterling's Opinion.

At the in limine hearing, Sterling testified that he was retained to perform an epidemiological analysis on certain data from certain groups of people who lived in the Three

---

149. Sterling submitted a second report in the form of a "Supplemental Affidavit" dated February 2, 1996. Id. at 8244-51. However, the District Court found that Sterling's February 2, 1996 Supplemental Affidavit was untimely filed and excluded it. In re TMI Litigation Cases Consolidated II,
922 F. Supp. 1038, 1046 (M.D. Pa. 1996).

Mile Island area. App. Vol. IX, at 8282. His report identified those groups150 and reported the results of his analysis:

> The Haystack Garment Workers: A cohort151 of 69 women employed by Hesteco Manufacturing Co. and present at the factory premises at the time of the accident. Ten women have developed cancer since then. This number of cancers is greater than would be expected had the cohort developed cancer at the same incidence rate as a comparable group of women selected from the general population.
>
> The Harrisburg Schoolchildren: A cohort consisting of

---

150. In addition to the groups listed, Sterling's report contained an analysis of a group of 15 female high-school aged softball players. App. Vol. IX, at 8225. However, this group was withdrawn from Sterling's proffered testimony. 922 F. Supp. at 1047.

151. In epidemiology, a cohort is "[a]ny designated group of persons followed or traced over a period of time to examine health or mortality experience." FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 172 (1994). In a cohort study, the epidemiologist

> identifies two groups of individuals: (1) individuals who have been exposed to a substance that is thought might cause a disease and (2) individuals who have not been exposed. Both groups are followed for a specified length of time, and the proportion of each group that develops the disease is compared. If the exposure is associated with or causes the disease, the [epidemiologist] would expect a greater proportion of the exposed individuals to develop the disease.

Id. at 134. Cohort studies are also known as concurrent studies, follow-up studies, incidence studies, longitudinal studies and prospective studies and these alternative names "describe an essential feature of the method, which is observation of the population for a sufficient number of person-years to generate reliable incidence or mortality rates in the population subsets. This generally implies study of a large population, study for a prolonged period (years), or both. Id. at 173. Cohort studies can also be retrospective. In a retrospective cohort study, the epidemiologist gathers historical data about exposure and disease outcome of the exposed cohort. Id. at 134 n.35. The health effects are identified and the date analyzed in a manner similar to that used in a prospective study. "The observed health effects are then compared with health effects expected based on an appropriate control population or related to variations in estimated doses." RADIATION DOSE RECONSTRUCTION, at 69.

> 1991 students attending four Harrisburg elementary schools at the time of the accident. At least six of these students have developed cancer. This number of cancers is greater than would be expected had the cohort developed cancer at the same incidence rate as a comparable group of children selected from the general population.
>
> The Ten Mile Cohort: A cohort consisting of all persons under the age of 25 years at the time of the accident, living within a ten mile radius of Three Mile Island. This cohort showed a dramatic increase in leukemia incidence rates following the accident.
>
> First Trimester Infants: The cohort of infants born to mothers who were in the first trimester of pregnancy at the time of the accident, and who lived within a 10 mile radius of Three Mile Island. This cohort showed a greater incidence of congenital malformations than a cohort of infants to mothers from the same region who became pregnant after the accident, and than a cohort of infants born in Atlanta from 1968 to 1979.

Id. at 8225-26. Sterling answered his hypothesis in the affirmative. The District Court excluded Sterling's testimony as scientifically unreliable under Rule 702. 922 F. Supp. at 1048. The court also excluded it under Rule 703, because the court concluded that Sterling relied upon data that experts in the field would find unreliable. Id.

c. Discussion and Conclusions.

Sterling admits that "[s]tatistical analysis of epidemiological data is much abused." App. Vol. IX, at 8237. Nonetheless, there are methods by which the epidemiologist can design a study to minimize, if not entirely eliminate, bias and error.152 The REFERENCE MANUAL

---

152. Epidemiologists define "bias" in a way that differs from its ordinary meaning. They define it as:

> [a]ny effect at any stage of investigation or inference tending to produce results that depart systematically from the true values. The term "bias" does not necessarily carry an imputation of prejudice or other subjective factor, such as the experimenter's desire for a

ON SCIENTIFIC EVIDENCE notes that, although epidemiological findings always involve a degree of uncertainty,

> systematic methods for assessing the characteristics of persons included in the study and their risk of disease can be used to help rule out known sources of bias and error. . . . The epidemiologist uses sample size calculations and inclusion and exclusion criteria for identifying exposed and unexposed groups . . . to reduce potential bias and error.

REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 127. In determining who will comprise the study group, the epidemiologist must articulate "[a] list of criteria for inclusion in and exclusion from the study." Id. at 138. These criteria should be documented clearly before the subjects are recruited for the study to ensure that no overt or covert biases enter into the selection process." Id. The danger inherent in not clearly articulating criteria for inclusion and exclusion is that any biases that enter into the selection process "could lead to erroneous inferences regarding causation." Id.

Here, Sterling had absolutely no part in the selection of the participants he studied. During cross-examination at the in limine hearing, he testified that the participants in the study groups and the data given to him was selected by the Aamodts:

> particular outcome. This differs from conventional usage in which bias refers to a partisan point of view.
>
> ****************************
>
> The two main types of bias are selection bias, in which there is a systematic difference between those individuals included in the study and those who are not, and information bias, which involves error in measuring disease or exposure among those included in the study.

REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 172.

Error, also called random error or sampling error,"is that due to chance when the result obtained in the sample differs from the result that would be obtained if the entire population (universe) were studied." Id. at 174.

> Q: How did you go about looking for the groups tha t you analyzed here?
>
> A: We were contacted by Mrs. Aamodt and Mr. Aamodt who had done some additional -- had some done work (sic), and we were asked to calculate risks for these groups.
>
> Q: So they selected the groups and provided you wi th the data, and then you did the statistical calculations regarding the data they provided?
>
> A: That is correct.

App. Vol. IX, at 8284. As noted above, the Aamodts also provided data to Zakrzewksi for his report. Apparently, they are the eminences grises of this litigation. However, despite the central role the Aamodts seem to have played in the research conducted by various experts proffered by Trial Plaintiffs, the Trial Plaintiffs failed to demonstrate that the Aamodts were qualified to select the participants for Sterling's study. See 922 F. Supp. at 1948 ("[T]here is no evidence on the record from which the court can make any judgment regarding the qualifications of the Aamodts to create and execute the selection portion of an epidemiological study design."). The Trial Plaintiffs have not referred us to anything in the record from which we could determine that the Aamodts are qualified to select the participants and the data for a cohort study. Consequently, the data upon which Sterling relied are woefully lacking in Rule 703 reliability.

The absence of evidence that the Aamodts selected the participants in the groups in a manner consistent with that suggested by the Reference Manual on Scientific Evidence creates a profound flaw in Sterling's methodology. There is no way to insure that participants were not selected or excluded in a manner that would bias the study. Moreover, it appears that there are no articulated selection criteria here because the Aamodts selected participants whom they knew had cancer. The Aamodts included certain of the Trial Plaintiffs in the selected groups. App. Vol. IX, at 8248-50. The groups Sterling studied therefore had a built-in bias so that a finding of increased cancer incidence was inevitable. An epidemiological opinion based on such a study is not reliable, and the District Court did not abuse its discretion when it excluded Sterling's testimony.

x. Steven Wing.

a. Qualifications.

Steven Wing earned a Ph.D. in epidemiology from the University of North Carolina in 1983 and is currently an Assistant Professor in the Department of Epidemiology at the University of North Carolina at Chapel Hill. 153 He submitted two reports. The first, dated January of 1994, is entitled, "Mortality Trends in Relation to the Accident at Three Mile Island." App. Vol. VIII, at 6828-6840. Trial Plaintiffs refer to this report as the "Mortality Study." The second report, dated February 25, 1995, is entitled"Re-Analysis of Cancer Incidence Near Three Mile Island Nuclear Plant." Id. at 6869-82. Wing's second report is a re-analysis of the data collected in connection with a cancer incidence study in the TMI area conducted by Maureen C. Hatch, an epidemiologist from Columbia University, and others. See Maureen C. Hatch, Jan Beyea, Jeri W. Nieves and Mervyn Susser, Cancer Near the Three Mile Island Nuclear Plant: Radiation Emissions, 132 Am. J. of Epidemiology 397 (1990)(hereinafter "Hatch/Susser study"). The Trial Plaintiffs refer to Wing's February 25th report as the "Cancer Incidence Study."

Each report is discussed separately.

b. Wing's Mortality Study.

In his Mortality Study, Wing wrote that Norman Aamodt, the plaintiffs' consultant, contacted him and asked him to review the results of a study of mortality trends which Aamodt had conducted. App. Vol. VIII, at 6831. According to Aamodt's study,154 mortality trends in the five counties

---

153. Wing's qualifications as an expert were not challenged.

154. There is nothing in the record that indicates that Aamodt is qualified to perform an epidemiological study. Aamodt's study was, however, very elementary. Wing described it as follows:

> Aamodt conducted his epidemiological analysis using paper and pencil and the vital statistics data published by the Pennsylvania

surrounding Three Mile Island were higher in 1980"than would have been expected based on the trends for earlier and later years." Id. Aamodt suggested to Wing that "high doses of radiation to small populations residing on the elevated terrain in the path of the noble gas plumes from the TMI accident lead to the deaths of some older people who were already in poor health. . . ." Id. Wing confirmed the results of Aamodt's mortality study and agreed to conduct a more sophisticated study of mortality rates in the Three Mile Island Area. Id. at 6832.

In that follow up analysis, Wing had access to computerized records of death and population counts by age in the five-county area. He calculated age-adjusted death rates and isolated for specific causes of death. Id. at 6833. His analysis also included a study of mortality trends in all Pennsylvania counties and in the continental United States. Id. at 6834; 6836. Wing concluded that the following major findings suggested an effect of the TMI accident:

> 1. an elevation of 1980 mortality in the five co unties around TMI amounting to about 490 more deaths than would have been expected from 1979 rates;
>
> 2. an increase in cancer mortality among young children in the five counties in 1980-82;
>
> 3. an increase of infectious disease death rates i n the five counties after the accident; and
>
> 4. a geographic clustering of areas with higher-th an-expected 1980 mortality in parts of Pennsylvania and the Middle Atlantic and New England States.

> Department of Health. He added the annual numbers of death for the five counties around TMI (Cumberland, Dauphin, Lebanon, Lancaster and York) and divided each number by the total estimated population, provided by the State or computed by extrapolation, to form annual crude death rates. When he plotted the rates over time, he noted an abrupt rise in the death rate in 1980, the year after the accident.

App. Vol. VIII, at 6832.

> These results, considered in the context of other studies and uncertainties about exposure estimates, may reflect mortality impacts of high-level radiation exposures from the 1979 accident at Three Mile Island.

Id. at 6839.

The District Court sustained the defendants' Rule 702 challenge to Wings' mortality study testimony and excluded it following an in limine hearing. The court held that the study doesn't "fit" as required by Rule 702. 155 In re TMI Litigation Cases Consolidated II, 911 F. Supp. 775, 820 (M.D. Pa. 1996).

c. Discussion and Conclusions.

We agree that Wing's mortality testimony lacks the requisite fit under Rule 702.156 Wing wrote that the "ability of an epidemiological analysis to detect health effects of an environmental agent depends on having good information on exposures of individuals and the relevant biological responses." App. Vol. VIII, at 6838. However, he conceded that he had no information on dose exposure, and cautioned that the results of his study "should be interpreted in that context." Id. He seconded his own caveat at the in limine hearing when he conceded that few specific conclusions could be drawn between the increased mortality his study found and the releases from the reactor accident because he did not have any estimates of radiation doses. On direct examination, he testified:

> Well, it's important to note that this study does not have any estimates of radiation doses, and it's a study

---

155. The District Court did find, however, that Wing's mortality study met the reliability test of Daubert/Paoli II, 922 F. Supp. at 819.

156. The District Court also found that Wing's testimony would "unnecessarily confuse the jury," and was therefore inadmissible under Fed. R. Evid. 403. Rule 403 provides: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." However, because we find that Wing's mortality testimony does not "fit," we need not review the District Court's Rule 403 analysis.

> simply of death rates, and as such, there are not very specific conclusions that can be drawn. . . . So it's not an analysis of the association between dose and mortality. It's an investigation of an observation that was originally made in Vital Statistics data to understand who experienced this in terms of the age groups, what causes of death in the local area showed this, and which did not.

Id. at 7214-15. On cross-examination, he admitted that even though his study demonstrated an elevated mortality in 1980, he could not attribute that elevation to radiation.157 In fact, Wing conceded that the mortality elevation was probably influenced by other factors. On cross-examination, the following exchange occurred:

> Q: Am I correct to understand, then, that the mort ality data you present may also reflect other factors?
>
> A: I'm quite sure other factors are reflected, y es. And I mean to say by that, other factors, other additional factors.158

Id. at 7250.

Wing's admission that his study was a mortality study only, and not an analysis of an association159 between dose

---

157. He testified: "I can't conclude that the elevation, the observed elevation, is due to radiation, from this study." Id. at 7250.
158. In his report, Wing wrote that one factor explaining, or tending to explain, the increased mortality he observed in 1980 may be the epidemics of pneumonia and influenza that occurred in the winters of 1979-80 and 1980-81. App. Vol. VIII, at 6839. However, at the in limine hearing, Wing testified that he investigated the pattern of flu epidemics, but "did not see any clear evidence that this was the year with the big flu epidemic, and therefore, that's why mortality was elevated in that year." Id. at 7251. Nonetheless, Wing held to his opinion that the increased mortality may also reflect other factors.

159. Association is a term of art in epidemiology. It is defined as "[t]he degree of statistical dependence between two or more events or variables. Events are said to be associated when they occur more or less frequently together than one would expect by chance. Association does not necessarily imply a causal relationship. Events are said not to have an association when the agent (or independent variable) has no apparent effect on the incidence of a disease (the dependent variable). REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 171.

and mortality, combined with his admission that he was unable to conclude that the elevated mortality was due to radiation exposure clearly demonstrates a lack of"fit." He does not even make a tenuous connection between the radionuclides released during the reactor accident and the elevated cancer mortality his study revealed. Consequently, the District Court did not abuse its discretion in excluding Wing's mortality testimony.160

d. Wing's Cancer Incidence Study.

As noted above, Wing's cancer incidence study is a re-analysis of the data in the Hatch/Susser study. The Hatch/Susser study was undertaken at the request of the Three Mile Island Public Health Fund161 and tested "a priori hypotheses that risks of specified cancers may have been raised by exposure to radiation emanating" from TMI-2 as a result of the reactor accident. Hatch/Susser study, at 398. There were 5,493 incident cases of cancer diagnosed in study area residents from January 1, 1975, to December 31, 1985. Id. at 399-400. Hatch, Susser et al., divided the TMI area into geographical study tracts and analyzed pre- and post-accident cancer incidence relative to dose, both from accident emissions and from routine plant emissions, within those tracts.162 Id. at 400-02. The dose exposure level used for accident emissions was very low -- an average of approximately 0.1 Sv, with 1 mSv the projected maximal dose. Id. at 400. Routine plant emissions were estimated to be 0.006 mSv per year. Id.

The primary cancers Hatch/Susser, et al., considered were leukemia163 and childhood cancers.164 However, the

---

160. The District Court viewed Wing's mortality study as a "preliminary analysis, meant to be supplemented by further study and testing." 911 F. Supp. at 820. We agree with that view. Wing's mortality study strikes us as more of a work-in-progress than a final epidemiological study.

161. See p. 76 n.83, supra.

162. The Hatch/Susser study dose estimates were derived from original plant data, meteorological data from a weather station maintained at the TMI plant, and a Gaussian plume dispersion model. Hatch/Susser study, at 400-01.

163. Hatch/Susser excluded chronic lymphocytic leukemia, which is considered to be nonradiogenic. Hatch/Susser study, at 400.

164. Leukemia and childhood malignancies were selected because of "either short latency periods or sensitivity to low-dose radiation, or both."

Hatch/Susser study, at 400.

grouping of " `all cancers' was selected for the sake of completeness." Id. at 400. The Hatch/Susser study concluded:

> For accident emissions, the authors failed to find definite effects of exposure on the cancer types and population subgroups thought to be most susceptible to radiation. No associations were seen for leukemia in adults or for childhood cancers as a group. For leukemia in children, the odds ratio was raised, but cases were few (n = 4), and the estimate was highly variable. Moreover, rates of childhood leukemia in the Three Mile Island area are low compared with national and regional rates. For exposure to routine emissions, the odds ratios were raised for childhood cancers as a whole and for childhood leukemia, but confidence intervals165 were wide and included 1.0. For leukemia in adults, there was a negative trend. Trends for two types of cancer ran counter to expectation. Non-Hodgkin's lymphoma showed raised risks relative to both accident and routine emissions; lung cancer (adjusted only indirectly for smoking) showed raised risks relative to accident emissions, routine emissions and background gamma radiation. Overall, the pattern of results does not provide convincing evidence that radiation releases from the Three Mile Island nuclear facility influenced cancer risk during the limited period of follow-up.

Id. at 397.

Wing's reanalysis of the Hatch/Susser data began with the a priori hypothesis that the levels of radiation exposures were higher than the levels used in the Hatch/Susser

---

165. A confidence interval is "[a] range of values within which the results of a study sample would be likely to fall if the study were repeated numerous times. . . . The width of the confidence interval provides an indication of the precision of the point estimate or relative risk found in the study; the narrower the confidence interval, the greater the confidence in the relative risk estimate found in the study. Where the confidence interval contains a relative risk of 1.0, the results of the study are not statistically significant." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 173.

study. App. Vol. VIII, at 6871. That hypothesis was based on the "ongoing collection of evidence suggestive of high-level radiation exposures in the pathways of radioactive gas plumes." Id. Using that hypothesis, Wing reanalysed the Hatch/Susser data based on the relationship between cancer incidence and accident exposures characterized by a single dose response line derived from the cancer incidence in all of the study tracts. He focused on "incidence of all cancers and lung cancer" and the category of"all leukemias." Id. at 6875. The dose response line has a rising slope when increased dose corresponds to an increase of cancer, a zero slope when there is no change in cancer incidence with increased dose, or a negative slope when there is a decline in cancer incidence corresponding to an increase in dose. Id. at 6874; 7232-32. Wing determined the difference between the dose response lines in the pre-accident period (1976-79) and the post-accident period (1981-1985). Id. at 7231. Statistical analysis was then used to derive the slope of the dose response line which best fits the cancer incidence data across all study tracts.

Wing's re-analysis showed "that cancer rates, and specifically lung cancer and leukemia, increased more following the accident in areas estimated to have been in the pathway of radioactive plumes than in other areas." Id. at 6879. Consequently, he concluded that the increases in cancer incidence "are consistent with allegations that the magnitude of radiation exposures from the accident were much higher than has been assumed in past studies." Id.

The District Court found that Wing's re-analysis was "only marginally scientifically reliable." In re TMI Litigation Cases Consolidated II, 922 F. Supp. 997, 1019 (M.D. Pa. 1996). However, because "marginally scientifically reliable is not unreliable," the court found that the re-analysis met the Daubert/Paoli II reliability standards. Id. Consequently, the cancer incidence study was ruled admissible, except for that portion of the study which analyzed lung cancer. 911 F. Supp. at 823. The District Court believed that the lung cancer portion of the cancer incidence study did not meet Rule 702's fit requirement because of the latency period for lung cancer which Wing used in his study. Id. at 822-23.

e. Discussion and Conclusions

The District Court's exclusion of the lung cancer portion of Wing's cancer incidence study is troublesome. Wing's re-analysis demonstrated that cancer rates, and specifically lung cancer and leukemia rates, increased following the accident in those areas estimated to have been in the path of the alleged radioactive plume. He used a minimum latency period for lung cancer of four to eight years, and he based that period upon a study of lung cancer in uranium miners.166 However, the defendants' expert167 testified that the general latency period for solid tumors, other than thyroid cancer, but including lung cancer, is between ten and fifteen years. App. Vol. XIV, at 11959. In addition, the defendants claim that Wing misread the study from which he derived his lung cancer latency period. In their view, a correct reading of that study would demonstrate that the latency period for lung cancer is up to sixteen years. Appellees' Br. at 52.

The issue of the latency period for lung cancer is important because of the time frame of Wing's cancer incidence study. The Hatch/Susser study used incident cancers from 1975 to 1985, and Wing used the same incident cancers. The reactor accident occurred in 1979 and the last year covered by his study was 1985. Therefore, the period between the accident and the last year of the study was six years. Consequently, the ability to make a plausible association between the accident and a diagnosis of post-accident lung cancer depends upon the length of the latency period. If the latency period is four to eight years, as Wing claimed, then a sufficient latency period elapsed between exposure and diagnosis to make a

---

166. The study is JAY H. LUBIN, ET AL., RADON AND LUNG CANCER RISK: A JOINT
ANALYSIS OF 11 UNDERGROUNDMINERS STUDIES (U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, NIH Publication No. 94-3644, 1994), and is found at App. Vol. VIII, at 7294-7310.

167. The defendants' expert who testified as to the latency period for lung cancer was David G. Hoel. Hoel is the Professor and Chair of the Department of Biometry and Epidemiology of the Medical University of South Carolina in Charleston, South Carolina. App. Vol. XII, at 10352.

plausible association between the exposure and the lung cancer. If, however, the latency period is ten tofifteen years, as the defendants claim, then an insufficient latency period elapsed between the date of the accident and the last year of the study to draw a plausible association between radiation released by the reactor accident and a diagnosis of lung cancer.

The District Court decided to exclude the lung cancer portion of Wing's cancer incidence study because it lacked "fit." 911 F. Supp. at 823. It found that Wing's findings regarding all cancers and leukemia suggest increased levels of radiation exposure, and therefore, "fit," because they are relevant to a fact in issue, viz., the radiation dose received by the plaintiffs. Id. at 823. However, the court held that "failure to explain the discrepancy between expected latency periods and his lung cancer findings" negates his study's fitness. Id.

We assume that the District Court believed that Wing used an insufficient latency period between the date of the accident and diagnoses of post-accident lung cancer and therefore could not make an association between exposure and onset of lung cancer. However, that finding assumes that the latency period was ten to fifteen years as claimed by defendants. Thus, it appears that the District Court credited the defendants' expert over Wing. We believe that was error.

Earlier in its analysis of Wing's cancer incidence study, the District Court wrote that the lung cancer latency question "decreases the credibility of Dr. Wing'sfindings." Id. at 822. However, such credibility issues arise only after admissibility has been determined, Kannankeril , at 806, and they are decided by the jury. See Breidor v. Sears, Roebuck & Co., 722 F.2d 1134, 1138-39 (3d Cir. 1983) ("Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge."). Here, by crediting the opinion of the defendants' expert, the District Court conflated its gatekeeping function with the fact-finders' function as the assessor of credibility. See Kannankeril, at 809 ("The trial judge must be careful not to mistake credibility questions for admissibility questions.").

Consequently, we believe that it was error for the District Court to exclude Wing's lung cancer testimony.

xi. Douglas Crawford-Brown.

a. Qualifications.

Douglas Crawford-Brown earned a Ph.D. in nuclear science and health physics from the Georgia Institute of Technology. He is currently a Professor at the University of North Carolina at Chapel Hill, North Carolina, and the Director of the Institute for Environmental Studies at the University. He is also a member of the faculty of the Ecology Program, and the faculty of the Public Policy Analysis Program.168 App. Vol. V, at 3198. He was offered as an expert in exposure assessment, which he said is a "distinct stage[ ] of risk assessment. Id. at 3200. He defined "risk assessment" as a

> process by which you first determine whether a substance or a risk agent is able to produce effects, and then you determine the amount of exposure or the amount of the substance that's in the environment, and then you determine the relationship between exposure and severity of effects. And then you summarize that as an estimate of the probability and severity of effects and uncertainty distribution in a distribution of variability in the population.

Id. at 3199.

b. Crawford-Brown's Opinion.

The Trial Plaintiffs characterized Crawford-Brown"as a kind of chairperson" for their "team of experts," Trial Plaintiffs' Br. at 16. He reviewed the reports of the Trial Plaintiffs' other dose exposure experts and, on the basis of that review, offered an opinion as to the radiation dose to which Three Mile Island area residents were exposed as a result of the reactor accident. In his February 27, 1995, Affidavit, he opined as follows:

> Based on the . . . considerations of evidence, and conditional on establishing that the effects noted were

---

168. Crawford-Brown's qualifications were not in dispute.

> in most likelihood caused by radiation exposures, it is my professional opinion that the findings above are consistent with the claim that individuals located in the vicinity of the points of biological dosimetry received dose equivalents at levels in excess of 100 rem. This opinion in based on a full consideration of the coherence of the evidence, with similar conclusions being reached across the various inference options.

App. Vol. V, at 3081. Thus, in order to give his exposure assessment, Crawford-Brown assumed that the effects that the other dose experts claimed (chromosome dicentrics, tree damage, anecdotal reports of erythema, metallic taste, etc., increased rates of cancer post-accident) were actually caused by radiation, and he assumed that those experts' estimates of the dose required to produce those effects were correct.

The District Court excluded his proffered testimony in its entirety because it did not meet Rule 702's reliability requirement.169 In re TMI Litigation Cases Consolidated II, 911 F. Supp. 775, 826 (M.D. Pa. 1996). The court found that Crawford-Brown's testimony was unreliable because "he chose to rely blindly upon the conclusions generated by Plaintiffs other experts," rather than evaluating the "relative strength or weakness of each of the strands of evidence (e.g., biological dosimetry data) available to him." Id. at 825.

c. Discussion and Conclusions.

We share the District Court's concern with the reliability of Crawford-Brown's "process or technique." He testified that in arriving at his conclusions he relied on the opinions of plaintiffs' other dose experts and assumed the correctness of each expert's proposition. App. Vol. V, at 3257. For example, he did not testify that the tree damage observed by Shevchenko and Gunckel was an effect of

---

169. The district court also found that it was inadmissible because it was irrelevant under Rule 402. 911 F. Supp. at 826. Federal Rule of Evidence 402 provides: "All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible."

radiation. Rather, he testified that he had "to leave that to someone else who is an expert in that area to decide." Id. at 3237. Similarly, he testified that he accepted Snigiryova's dicentric enumeration for the population she studied in arriving at his dose estimate. Id. at 3212. He did not testify that increased cancer and leukemia rates observed by Wing in his cancer incidence study were caused by radiation. Rather, Crawford-Brown testified "Well, again, my opinion is conditional on another expert establishing that the leukemia rates are due to radiation exposures." Id. at 3215. Thus, his opinion is somewhat analogous to the last domino in the line that begins to fall when thefirst domino is toppled.

Crawford-Brown admitted that (unlike Kozubov) he did not use trees for dosimetry. He testified: "If you mean has it actually been used in dosimetry studies by people like myself who do dosimetry, then no." Id. at 3235. He also testified that he had never heard of a study where cancer or leukemia rates were used to estimate dose. "I know of no cases where that's been done. I can't imagine why somebody would have done it. . . ." Id. at 3251. Moreover, he testified in his deposition that he never made any attempt to assess the validity of any of the assumptions the other experts used to formulate their opinions.

> Q: With respect to any of the stated assumptions, do you make any effort to assess their validity?
>
> A: No. They are hypothetical in each case.
>
> Q: This is maybe asking the same question or a clo sely related question. But have you made any effort to assess the probability that these assumptions are true or not?
>
> A: No.

Id. at 3157.

However, by not assessing the validity of the other experts' assumptions, Crawford-Brown ignored his own stated principles of risk assessment. He testified that the "risk assessment community recognizes" that"all relevant lines of inference170 should be examined, and then there

---

170. In epidemiology, inference is "[t]he intellectual process of making generalizations from observations. In statistics, the development of

should be a study done of the coherence across those lines of reasoning." Id. at 3200. He further testified that a "complete exposure assessment would look at all lines of reasoning." Id. at 3182. In addition, he testified that in making an exposure assessment, he would make an assessment of the strengths and weaknesses of the available evidence. He testified as follows at his deposition:

> Science can't distinguish between the estimates. What it can say is something about the relative strength of each of the estimates -- which ones you believe and which ones you disbelieve, to what degree do you believe them or disbelieve them.
>
> And then, in my work, anyway, that is then called a cumulative confidence distribution. You ask, now considering all the lines of reasoning, how confident are you that it's less than one rem, ten rems, a hundred rems, a thousand rems, and so forth. And that assignment of confidence at any given dose [estimate] depends on how much you're weighing the various lines of evidence.

Id. at 3108-09. However, he did not assign any confidence to any of the assumptions he relied upon. Rather, he explained that his testimony "really is . . . not a statement about the complete coherence of all bodies of data, which I think ultimately need to go into an assessment of the exposure. And I've left that to others in this process to integrate together. I don't see that as my role here." Id. at 3182.

Crawford-Brown's failure to assess the validity of the opinions of the experts he relied upon together with his unblinking reliance on those experts' opinions, demonstrates that the methodology he used to formulate his opinion was flawed under Daubert as it was not calculated to produce reliable results. Thus, the District Court did not abuse its discretion in excluding Crawford-Brown's testimony.

---

generalization from sample data, usually with calculated degrees of uncertainty." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 174.

4. Effect of the Exclusion of Wing's Lung Canc er Testimony.

A trial court is not precluded from granting summary judgment merely because expert testimony is admitted. If, even given the proffered expert testimony, the proponent "still has failed to present sufficient evidence to get to the jury," summary judgment is appropriate. Heller, at 152 (citing Daubert, at 596); see also Paoli II, at 750 n.21. Earlier, we concluded that the District Court abused its discretion by excluding the lung cancer portion of Steven Wing's cancer incidence study. Consequently, we must determine whether the improperly excluded expert testimony is sufficient to create a material issue of fact. Heller, at 152. See In re TMI Litigation Consolidated Proceedings, 927 F. Supp. 834 (M.D. Pa. 1996). 171

The District Court's grant of summary judgment in favor of the defendants was the inevitable result of its exclusion of the testimony of the Trial Plaintiffs' dose exposure witnesses. At the conclusion of the Daubert challenges to the dose experts, the Trial Plaintiffs' dose exposure testimony rested upon the admissible testimony of four witnesses. The District Court identified them and summarized their admissible testimony as follows:

> [T]he 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.

927 F. Supp. at 863.

The court held that Trial Plaintiffs had to produce evidence demonstrating that "it is more likely than not that each of the Trial Plaintiffs' neoplasms were the result of their exposure to ionizing radiation during the TMI accident, in order to create a genuine issue of material

---

171. The District Court's summary judgment opinion.

fact." Id. at 866-87. Because the Trial Plaintiffs elected to try their cases on the theory that they were exposed to equivalent doses of at least 10 rems each, they had to produce evidence of that degree of exposure. The District Court reasoned that the crucial causation issue was the Trial Plaintiffs' ability to produce admissible source term[172] evidence. Id. at 867. However, at the time of the summary judgment motions, the Trial Plaintiffs had no admissible source term evidence. Id.

The only possible source term evidence was Lochbaum's equivocal "blowout" testimony, which the District Court had earlier determined would be admissible only if the Trial Plaintiffs' other experts could demonstrate that significant amounts of radionuclides were released as a result of the accident. 922 F. Supp. at 1052. However, because of earlier exclusionary rulings there was no other admissible source term evidence, and, consequently, the District Court found that "there is insufficient dose evidence . . . to make Lochbaum's testimony helpful to the trier of fact." 927 F. Supp. at 867. The District Court also found that Lochbaum's blowout testimony was so equivocal that it "lacked the certainty of a professional judgment" and was, therefore, insufficient to defeat a motion for summary judgment."[173] Id. at 868. Consequently, the District Court found that the Trial Plaintiffs did not demonstrate that the reactor accident released high concentrations of radioactive materials to the environment. Id. In brief, the Trial Plaintiffs had no evidence that they were exposed to 10 rems of ionizing radiation and, therefore, there was no material factual dispute in regard to causation.

The admission of Wing's lung cancer testimony would not change that result. It is important to remember not only that the District Court found that the "all cancer" and "leukemia" portions of Wing's cancer incidence study were admissible and that the court considered that testimony in

---

172. See p. 94 supra.

173. The Trial Plaintiffs' do not challenge the District Court's exclusion of Lochbaum's testimony or its finding that his testimony would not be sufficient to defeat the defendants' summary judgment motion. In fact, his name is only mentioned in passing. Trial Plaintiffs Br. at 14 n.24.

its summary judgment analysis. The problem with Wing's cancer incidence study is that Wing assumed high levels of radiation exposure, see App. Vol. VIII, at 6871, and he therefore attributed the elevated cancer rates to that assumed exposure. But, as a result of the exclusionary rulings, there was no evidence of record to support Wing's assumption of high levels of radiation releases. Furthermore, Wing admitted at the in limine hearing that if the radiation levels were as postulated in the Hatch/Susser study, then he would not be able to make a causal connection between the accident releases and the elevated cancer rates. Id. at 7276-77. Consequently, the District Court ruled because the Trial Plaintiffs could not support Wing's assumption of high levels of radiation releases, "the Wing cancer study does nothing to assist Plaintiffs in creating a material factual dispute or meeting their burden of proof." 927 F. Supp. at 869. Even though we disagree with the exclusion of Wing's lung cancer testimony, we agree with that conclusion.

Consideration of Wing's improperly excluded lung cancer testimony would not create a genuine issue of material fact. If all of his cancer and leukemia testimony could not defeat a summary judgment motion, we are at a loss to see how a consideration of his lung cancer testimony would defeat that motion. Wing's lung cancer testimony is based on an assumption of high levels of radiation exposure which the Trial Plaintiffs were not able to prove. Consequently, Wing's lung cancer testimony would not create an issue of fact. Although exclusion of the lung cancer testimony was an abuse of discretion, its admission would not change the ultimate outcome.

5. Exclusion of Experts' Submissions as Untimely.

The Trial Plaintiffs argue that the District Court committed reversible error by refusing to consider "vast amounts of plaintiffs' expert evidence, on the basis of untimeliness." Trial Plaintiffs' Br. at 59. However, with the exception of a brief discussion of the District Court's decision not to allow Shevchenko to testify about the results of a FISH study,174 Id. at 66, the Trial Plaintiffs have

---

174. For a discussion of the FISH methodology, see p. 131 n.127, supra. In regard to the exclusion of Shevchenko's testimony of the FISH study,

not specifically identified what "vast amounts" of evidence they claim the District Court refused to consider. Nor have they attempted to explain how the court's alleged refusal affected either the admissibility determinations or the court's summary judgment decision.

It is clear that the District Court excluded a number of Trial Plaintiffs' experts' filings as a sanction for counsels' discovery violations. Apparently, the Trial Plaintiffs' counsel's filing of untimely expert reports was a recurring problem in this litigation.

On November 9, 1995, the District Court excluded the testimony of a number of experts because their reports were untimely filed. No memorandum of law explaining that order was issued concurrently with the order. However, on January 5,1996, the District Court filed an opinion which, inter alia, explained the reasons for the November 9, 1995, order. See In re TMI Litigation Cases Consolidated II, 911 F. Supp. 775, 828 (M.D. Pa. 1996). There, the District Court noted that its order of November 13, 1994, directed the disclosure of Trial Plaintiffs' expert reports on dose to be

---

the district court noted:

> Neither Professor Shevchenko nor Dr. Snigiryova analyzed the TMI blood samples using the FISH method prior to the November 1995 in limine hearings. Their reports indicate that they are presently re-analyzing the blood samples using the FISH method, and that these results will validate their findings from the general cytogenetic analysis. This argument distorts the letter and spirit of the Federal Rules of Civil Procedure beyond recognition. Final reports of Plaintiffs' dose experts, containing a complete statement of the methodologies employed and the basis for the opinions, were due March 1, 1995. Had Plaintiffs produced the actualfindings of a study using the FISH method on the TMI blood samples at the November in limine hearings, the court would likely have admitted those findings and allowed Defendants wide latitude to cross-examine. That Plaintiffs only recognized the importance of conducting the FISH analysis after the filing deadlines passed is not sufficient justification for admitting such evidence one year after the filing deadline and four months after the in limine hearings on dose concluded.

922 F. Supp. at 1013.

filed by March 1, 1995. Id. According to the court, "some eight months later and without an explanation, Plaintiffs attempted to introduce new reports for a total of ten experts. Moreover, the bulk of these reports were to be delivered by previously unidentified experts." Id. Noting that "[f]or litigation purposes, the facts of this case must at some point become complete," the District Court felt compelled to "draw . . . a line in the sand." Id. at 828-29. Accordingly, it concluded that by March 1, 1995,"the discrete body of factual evidence with respect to the issue of dose became fixed. . . ." Id. at 829. Therefore, it held that any attempts "to build on this body of facts" after March 1, 1995, were misplaced and, consequently, it excluded the untimely reports. Id.

Despite the court's clear warning, and the equally distinct line that had been drawn, Trial Plaintiffs' counsel persisted in filing reports after deadlines had passed. We are normally reluctant to rely on lengthy excerpts from a District Court's opinion to facilitate our own, independent resolution of an appeal from that court's rulings. However, the chronology of the various case management orders and discovery orders is crucial to a complete understanding of the District Court's reasons for imposing the sanction of exclusion of evidence. Accordingly, we set forth at length the following excerpt from the District Court's opinion dated April 2, 1996. It details the chronology and places Trial Plaintiffs' claims in perspective.

> Defendants have objected, both in their filings and during the in limine hearings, to the admission of supplemental expert reports filed by Plaintiffs subsequent to the court ordered filing deadlines. For the most part, the court has avoided piecemeal rulings on this issue opting instead to make one uniform ruling. The issue is now ripe for disposition. A brief background discussion will place matters in context.
>
> A. Case Management History
>
> The timeliness issue has recurred in many settings within this litigation and has been particularly troubling to the court. Historically, the court has encountered significant difficulty in keeping the parties

adhered to any case management order. As a result, there have been close to a dozen "case management orders." 7/10/92 Proposed Schedules of Plaintiffs and Defendants for Taking Cases to Trial; 6/15/93 Case Management Order (setting jury selection for 7/6/94); 11/12/93 Revised Case Management Order (moving jury selection to 10/3/94 at the request of parties); 5/13/94 Order Amending Case Management Schedule (moving jury selection to 4/13/95); 7/28/94 Order (granting Plaintiffs' request for further amendment of pre-trial schedule); 10/14/94 Order (further amending pre-trial schedule at Plaintiffs' request, and noting that absent extreme and compelling circumstances no further amendments will be entertained); 10/19/94 Order (directing parties to submit final joint case management schedule in response to correspondence from counsel); 11/3/94 Order (adopting parties'final joint case management schedule, noting that said order is binding and that it will not be amended absent extreme and compelling circumstances); 5/8/95 Order (moving jury selection to 6/3/96). Much to its own detriment, the court has been flexible and accommodating with respect to the pre-trial schedule.

In November 1994, having grown weary of the parties' inability to comply with set deadlines and fearing that the instant action would languish, the court ordered the parties to draft a final joint case management schedule. On November 3 the court adopted the schedule proposed by the parties and again indicated that the schedule would not be altered absent extreme and compelling circumstances. On May 8, 1995, the court issued an order supplementing the November 1994 case management order to place the case on the June 1996 trial list. Since the entry of the May 8 order, the court, although permitting minor alterations to the schedule, has denied any motion to amend that would effectively remove the case from the June 1996 trial list.

The captioned action, involving approximately 2,000 Plaintiffs, was consolidated under one case number in 1988. To an extent, circumstances beyond the court's control, such as the filing of interlocutory appeals and Congress's amendment of the Price Anderson Act, have stymied the prompt resolution of this action. Nevertheless, a review of the docket reveals that the test cases's torpid progression toward trial is due in part to the parties' willingness to stipulate to extensions of time and alterations of the case management schedule and the court's historical willingness to accommodate such requests.

B. Plaintiffs' Expert Reports

Defendants object to the admission of all of Plaintiffs' expert reports and supplemental affidavits filed subsequent to the court ordered filing deadlines. Although tedious, the following review of Plaintiffs practice in filing expert reports is warranted.

Pursuant to an order dated May 13, 1994, Plaintiffs were to file the expert reports of James Gunckel, Richard Webb and Ignaz Vergeiner not later than August 1, 1994. This order also directed that expert reports on medical causation were to be filed not later than September 1, 1994 and that expert reports on punitive damages were to be filed not later than October 1, 1994. On August 1, 1994, Plaintiffs filed the 6/94 report of Ignaz Vergeiner ("TMI Treatise 1"), and the 5/26/94 and 8/1/94 affidavits of Douglas Crawford-Brown. On August 4, 1994, Plaintiffs filed the 8/1/94 preliminary report of Richard Webb entitled"A Preview Short Synopsis." Thus, the report of James Gunckel was not timely filed on August 1, and the August 4 filing of the Webb "Preview" was both untimely and in contravention of Rule 26(a)(2) of the Federal Rules of Civil Procedure ("The report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor ..."). The court was remiss in not striking these filings immediately and, in temporarily overlooking these rule violations, the court may have unwittingly encouraged Plaintiffs' improper conduct. The record reflects that these 1994 filings were only the first in a long stream of improper and untimely filings.

On September 15, 1994, one and one-half months after the filing deadline, Plaintiffs filed the 7/6/94 Affidavit of Vladimir Shevchenko. On November 3, 1994, the court entered the final joint case management schedule. This schedule extended the deadline for Plaintiffs' filing of dose and medical causation expert reports to March 1, 1995. On March 1, Plaintiffs filed the expert "reports" of the following experts: Armentrout, Crawford-Brown, Gunckel, Hinrichesen, Lochbaum, Shevchenko, Vergeiner, Webb, Wing, Fajardo, Winters, Zakrzewski. On March 14, without leave of court, Plaintiffs supplemented their March 1 filing with the reports of Shevchenko, Tascaev, Kozubov, Popov, Portman, Tarasenko, and Snigiryova. On March 15, again without leave of court, Plaintiffs supplemented their March 1 filing with the report of Bruce Molholt. Finally, on March 29, without leave of court, Plaintiffs filed a third supplement to the March 1 filing adding to the reports of Shevchenko and Zakrzewski. Thus, as of April 1995, Plaintiffs had late-filed a significant portion of their expert reports on dose and medical causation.

In February 1995, the court issued a preliminary memorandum of law related to Defendants' motion in limine to exclude Dr. Molholt's 4/8/93 report, and ordered limited additional briefing with respect to certain of the Paoli II factors. In re TMI, Mem. Op. at 22 (M.D. Pa. February 14, 1995) ("[T]he court has invited the parties to respond concisely to the issues raised ... this is not an invitation to deluge the court with paper. Clear, concise, relevant information will assist the court in reaching a just resolution; likewise, the submission of frivolous or irrelevant information will be frowned upon.") As exhibits to their court-ordered filing, Plaintiffs submitted several new expert reports (5/1/95 Molholt; 4/24/95 Kerman; 5/2/95 Kerman; 2/27/95 Crawford-Brown). In September 1995, Plaintiffs, again without leave of court, untimely filed the reports of Theodore Sterling and Ronald Kerman.

The next battery of Plaintiffs' expert reports were filed as exhibits to their opposition to Defendants' motion in limine to exclude Plaintiffs' dose experts. On October 25, Plaintiffs filed as exhibits the updated reports of the following experts: Vergeiner (two separate affidavits dated 10/18/95), Armentrout (10/10/95 Aff.; 10/22/95 Aff.), Gunckel (8/23/95 Aff.), Shevchenko (10/6/95 Aff.), Wing (10/19/95 Aff.), Crawford-Brown (10/20/95 Aff.), Molholt (9/8/95 Aff.; 9/14/95 Aff.). On October 31, with leave of the court,175 Plaintiffs' supplemented the record with the following affidavits/new reports: Armentrout (9/20/95 Aff.; 5/11/95 Aff.), Blanch (10/31/95 Aff.), Kerman (10/30/95 Aff.), King (10/30/95 Aff.), Reyblatt (10/31/95 Aff.), Shevchenko (10/6/95 Aff.), Kozubov (9/12/95 Aff.), Smirennyi (10/30/95 Aff.), Wing (10/27/95 Aff.). On January 16, 1996, as exhibits to a brief in opposition to Defendants' motion to compel, Plaintiffs filed the following supplemental affidavits: Crawford-Brown, Ornstein, Purcell, Reyblatt. Finally,

---

175. The district court explained that it re-opened discovery for the following reason:

> Through a Memorandum and Order dated October 19, 1995, the court re-opened discovery from October 20 to October 30 for the purpose of granting Plaintiffs access to original plant data stored at the Emaus Street repository. The court granted Plaintiffs motion to compel despite the fact that "[a]fter sitting on their right to access these materials for nearly one decade, Plaintiffs now, one week before their brief on the in limine issues is due and after the formal close of discovery, request that Defendants be compelled to produce the aforementioned documents merely because it would not be inordinately difficult for Defendants to do so." 10/19/95 Order at 3. Plaintiffs offered the court no explanation as to why they had failed to view this material during the formal discovery period. Id.
>
> Pursuant to its granting the motion to compel, the court allowed Plaintiffs "to supplement their brief in opposition to Defendants' motion in limine." The court allowed Plaintiffs to supplement the record to the extent that something in the original strip chart data proved helpful to their case. Plaintiffs were not granted permission to supplement the record with anything beyond the scope of the "new" original plant data.

922 F. Supp. at 1003 n.7.

> during February 1996, Plaintiffs filed the following supplemental affidavits without leave of court: Wing (10/19/95 Aff.; 1/26/96 Aff.; 1/31/96 Aff.; 2/7/96 Aff.), Kozubov (1/30/96 Aff.), Armentrout (2/1/96 Aff.), Milhollin (5/5/96 Aff.), Griffin (1/30/96 Aff.), King (2/16/96 Aff.).

In re TMI Litigation Cases Consolidated II, 922 F. Supp. 997, 1000-03 (M.D. Pa. 1996), (original footnotes omitted).

The District Court concluded that Trial Plaintiffs' repeated untimely filings of experts' reports provided adequate grounds to exclude reports filed without leave of court subsequent to court ordered filing deadlines. Id. at 1007. Realizing, however, that the exclusion of all untimely filed reports "would result in the effective dismissal of much of the Plaintiffs' case" and, was, therefore,"unduly harsh" to the Trial Plaintiffs who had nothing to do with their counsel's disregard of court orders, the District Court sought to seek the via media between a blanket exclusion and its concern that Trial Plaintiffs not pay too dear a price for the conduct of their attorneys. Id. It referred back to its aforementioned January 5, 1996, order and opinion, and reasoned that after publication of that order and opinion, "there could be no question" that continuedfiling of expert submissions without leave of court was prohibited. Id. at 1008. Accordingly, it decided to exclude all supplemental affidavits filed after January 5, 1996. However, it allowed all supplemental affidavits and reports filed after to March 1, 1995, but prior to January 5, 1996, whose admissibility had not yet been ruled upon.176Id.

Federal Rule of Civil Procedure 37(b)(2)(B) authorizes the District Court to sanction a party's failure to comply with a discovery order by "prohibiting that party from introducing designated matters into evidence." Although the exclusion of evidence for violation of a discovery order is an "extreme sanction," Dudley v. South Jersey Metal, Inc., 555 F.2d 96,

---

176. The District Court also issued an order to show cause why monetary sanctions should not be imposed against certain of Trial Plaintiffs' counsel. On August 7, 1996, the district court entered an order imposing monetary sanctions against counsel. That order is the subject of Appeal No. 96-7625, discussed infra.

99 (3d Cir. 1917), the "trial court's exclusion of testimony for failure of counsel to adhere to a pretrial order will not be disturbed on appeal absent a clear abuse of discretion." Semper v. Santos, 845 F.2d 1233, 1237 (3d Cir. 1988). In Paoli II, at 791, we recognized the continuing applicability of Meyers v. Pennypack Woods Home Owners Ass'n, 559 F.2d 894 (3d Cir. 1997) to a Rule 37 exclusion analysis. In Pennypack, we listed certain factors which must be considered in evaluating whether the District Court properly exercised its discretion. They are:

> (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the district court's order.

559 F.2d at 904-05. The District Court applied the Pennypack factors here and concluded that

> (1) Defendants would be prejudiced by the admission of certain of the untimely reports insofar as the rigorous pre-trial schedule precludes them from having sufficient time to prepare to cross-examine on the late-filed reports; (2) Defendants are unable to cure the prejudice insofar as the court is unwilling to further alter the pre-trial schedule because such alteration would necessitate postponing the trial date; (3) waiver of the Rule 37 sanctions would disrupt the orderly trial of this case as well as a multitude of other cases on the court's docket; and (4) Plaintiffs repeated violation of numerous orders of this court, failure to seek leave of court before filing untimely reports, and "covert" filing of additional reports as exhibits to a variety of unrelated motions rather than "overtly" making supplemental filings, rises to the level of bad faith.

922 F. Supp. at 1004.

We agree with the court's analysis. Accordingly, we do not believe that the District Court abused its discretion in imposing the sanction of exclusion under Rule 37. All of the reports which defendants sought to exclude werefiled after the formal close of discovery. Discovery in this litigation was open for nearly one decade. Trial Plaintiffs' counsel can hardly complain that they had inadequate time to provide the desired reports, nor can they claim that the exclusion of the late reports in response to their practice of continually ignoring District Court deadlines caught them by surprise. Counsel's failure to comply with the deadlines imposed by the District Court is inexcusable. The District Court recognized it as such, and responded appropriately.

Although it appears from the record that the defendants knew the identity of the expert witnesses in a timely fashion, the record also shows that the substance of the experts' reports was not known to the defendants. Many of the timely reports have little, if any, resemblance to the supplemental initial reports which the Trial Plaintiffs subsequently filed. For example, Molholt's March 13, 1995 and May 1, 1995 reports differ in a number of significant ways from his initial April 8, 1993 report. Furthermore, experts' submissions continued to be made up to, during, and even after, the in limine hearings.

In Paoli II, the District Court precluded a physician from testifying about a medical monitoring program that he thought the plaintiffs should undergo because counsel did not timely submit a Fed. R. Civ. P. 26(b)(4) statement detailing the substance of the physician's testimony about the monitoring program. We found that to be an abuse of discretion because the failure to timely file was only a "slight deviation from pre-trial notice requirements, and admitting the witness was likely to cause only slight prejudice to the defendants, who were already aware of the basic substance of the witness' testimony." Paoli II, at 792. However, the considerations which led us to find an abuse of discretion in Paoli II are not present here. Here, the District Court was faced with a pattern of filings that constituted a flagrant violation of pre-trial orders. The pattern was as persistent as it was unjustified. The District Court's exclusion under Rule 37 was well within its discretion.

6. Conclusion.

Earlier in our discussion we noted that although the Trial Plaintiffs appeal from the District Court's grant of summary judgment to the defendants, they do not argue that the grant of summary judgment was improper in view of the court's admissibility decisions on their dose experts. In other words, they do not argue that the District Court erred when it found that the admissible expert testimony of Vergeiner, Shevchenko and Wing was insufficient to create a genuine issue of material fact. Consequently, our inquiry has focused on the propriety of the District Court's gatekeeping role under Daubert and not on the standards governing the grant of summary judgment. As we explained earlier, we need to decide whether the improperly excluded testimony created a genuine issue of material fact only if we determined that the District Court erred in its Daubert analyses of the proffered experts.

However, with the exception of Wing's lung cancer testimony, we have found that the District Court's admissibility determinations were well within its discretion as a gatekeeper. We have also determined that the improper exclusion of Wing's lung cancer testimony does not create a genuine issue of material fact. Finally, we have found that the District Court did not abuse its discretion by excluding evidence under Fed. R. Civ. P. 37(b)(2)(B). Therefore, we will affirm the District Court's grant of summary judgment in favor the defendants and against the Trial Plaintiffs.

B. The Non-Trial Plaintiffs' Appeal.

As we noted in the Procedural History portion of this opinion, the District Court held that its decision on the defendants' summary judgment motion directed to the Trial Plaintiffs would be binding on all plaintiffs to the extent that the Trial Plaintiffs' ruling turns on broad evidentiary issues common to all plaintiffs. See In re TMI Litigation Consolidated Proceedings, 927 F. Supp. 834, 838 (M.D. Pa. 1996). Consequently, when the District Court held that the Trial Plaintiffs could not present dose evidence sufficient to resist summary judgment, it extended that holding to all plaintiffs. The court held:

> Because the court finds the quantum of 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 on all Plaintiffs.

Id. at 838.

Not unexpectedly, the Non-Trial Plaintiffs contend that the extension of the Trial Plaintiffs' summary judgment decision to them was improper. In support of that contention, they make a number of arguments, viz., (1) that their cases were consolidated for administrative purposes only; (2) that P 3 of the Stipulation is a clear reservation of rights that there would not be a consolidated trial that binds all plaintiffs; (3) that the Non-Trial Plaintiffs have the right to present different proofs, experts and theories of recovery than those presented by the Trial Plaintiffs; (4) that this is not a class action and they were never given the opportunity to "opt-out" of a consolidated trial; (5) that it is unfair to extend the discovery sanctions imposed against the Trial Plaintiffs against them; (6) that they never agreed that they had to demonstrate that they were exposed to 10 rems or more of radiation in order establish causation; and (7) personal injury causation is a highly individualized question which needs to be determined in a case-by-case basis.

The defendants contend that the District Court's extension of the summary judgment to the Non-Trial Plaintiffs was correct. They argue that because of consolidation, the case management orders governing discovery and all pre-trial proceedings applied to all plaintiffs, both trial and non-trial.177 They reason that

---

177. Defendants also argue that it is clear "that summary judgment can be entered in cases consolidated for pretrial purposes, and result in the termination of all of the consolidated cases." Appellees' Br. at 14. In support of that proposition, they rely on our opinion in In re Donald J. Trump Casino Sec. Litig. -- Taj Mahal Litigation , 7 F.3d 357, 367 (3d Cir.
1993), cert. denied, 510 U.S. 1178(1994), where we held that transferred cases consolidated for pretrial purposes under the 28 U.S.C. S 1407 can be terminated by a transferee court under Rule 12(b)(6). However, Trump does not apply here because S 1407 concerns multidistrict litigation and, more importantly, the parties in all of the cases transferred under S 1407, were before the District Court that granted the pre-trial dispositive motions.

inasmuch as summary judgment is a pre-trial proceeding, it therefore applied to all of the plaintiffs, and the extension of the summary judgment decision was therefore a natural result of the consolidation order.

However, we believe that both sides to this appeal have failed to see some essential issues which mitigate against the extension of the summary judgment motion to the Non-Trial Plaintiffs. The primary inquiry should be determining the effect of consolidation on the substantive rights of the parties in the consolidated cases. The TMI plaintiffs' cases were consolidated under Rule 42(a), which provides:

> When actions involving a common question of law or fact are pending before the court, it may order a joint hearing or trial of any or all the matters in issue in the actions; it may order all the actions consolidated; and it may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay.

Fed. R. Civ. P. 42(a). The purpose of consolidation 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." In re Prudential Securities Inc. Ltd. Partnerships Litigation, 158 F.R.D. 562, 571 (S.D.N.Y. 1994). Consolidation, however, is only a matter of "convenience and economy in administration." Johnson v. Manhattan Ry. Co., 289 U.S. 479, 497 (1933).178 Consolidation "does not merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another." Id.

We have not had many occasions to cite Johnson v. Manhattan Ry. Co. in our prior opinions. In Bradgate Associates v. Fellows, Read & Associates, Inc., 999 F.2d 745, 750 (3d Cir. 1993), we noted that although consolidated cases are heard together, "they are not necessarily merged forever and for all purposes." There, commenting on Johnson, we wrote:

---

178. Consolidation in Johnson was made pursuant to 28 U.S.C. S 734, a precursor to Fed. R. Civ. P. 42.

> Johnson cautions that while consolidated cases may be treated as one lawsuit in order to conserve judicial resources, the procedure should not impose the heavy toll of a diminution of any party's rights.

Id. (emphasis added). The facts in Bradgate, while admittedly not at all like the facts here, nonetheless demonstrate that consolidation is not intended to affect the substantive rights of the parties to the consolidated cases.

The parties in Bradgate were Bradgate Delaware and Bradgate New Jersey, both of which were real estate development firms. The former was a Delaware corporation, and the latter was a New Jersey corporation. Presumably, both were part of Bradgate Associates. Fellows, Read was a New Jersey engineering firm that had contracted with either Bradgate Delaware or Bradgate New Jersey to provide engineering services. A controversy arose and Fellows, Read sued Bradgate Delaware in New Jersey state court to recover payment for services rendered. Bradgate Delaware responded by filing a federal lawsuit in New Jersey alleging fraud, negligence and breach of contract and removing Fellows, Read's state suit to federal court where the state and federal cases were consolidated.

Bradgate Delaware alleged in its federal complaint and its removal petition that diversity existed because Bradgate Delaware was the successor in interest to Bradgate New Jersey. The latter was the entity which Fellows, Read claimed was the real party in interest in the engineering services contract. Fellows, Read challenged Bradgate Delaware's diversity allegations claiming that Bradgate New Jersey was still a viable corporate entity and that Bradgate Delaware had not succeeded to Bradgate New Jersey's interests. Thus, according to Fellows, Read, diversity did not exist, and the district court had no subject matter jurisdiction. For reasons not relevant here, the district court agreed that it had no diversity jurisdiction and remanded both the original federal action and the removed state action back to New Jersey state court. Fellows, Read appealed the district court's decision to remand that portion of the case which was originally filed in federal court.

We found that a remand of both cases was error that prejudiced Fellows, Read. We reasoned that finding an absence of diversity terminates a case originallyfiled in federal court. But, a finding of lack of subject matter jurisdiction does not extinguish a removed state court case. The state court case is simply remanded to state court. However, the district court, "diminished Fellows, Read's rights by prolonging litigation over claims which should have been dismissed," by remanding both cases to state court, instead of dismissing the federal court case and remanding only the state court case. Id. at 751. The proper procedure the district court should have followed was to "apply the rules pertaining to dismissal and remand as if the cases had retained their separate identities and had never been consolidated." Id.

Admittedly, Bradgate and the Non-Trial Plaintiffs' appeal here are not remotely similar. In fact, the result in Bradgate is the exact opposite of the result here. That is, while the court was forcing Fellows, Read to litigate a case it should not have had to litigate, the District Court here was denying the Non-Trial Plaintiffs the opportunity to litigate the cases they wanted to litigate. Nevertheless the principle underlying Bradgate, i.e., that consolidation cannot affect the substantive rights of the parties to the consolidated cases, is applicable to the Non-Trial Plaintiffs' consolidated cases, and is consistent with our application of Johnson.

It is beyond dispute that the District Court's extension of the Trial Plaintiffs' summary judgment decision to the Non-Trial Plaintiffs' claims adversely affected the substantive rights of the Non-Trial Plaintiffs. However, under Johnson and Bradgate, the District Court could not properly extinguish the substantive rights of the 1,990 Non-Trial Plaintiffs merely because all of the cases had been consolidated.

Upon close examination, the TMI Non-Trial Plaintiffs and Trial Plaintiffs are even more separated than the plaintiffs in Bradgate because the Non-Trial Plaintiffs were not even litigating their claims and not presenting arguments to the District Court. The TMI personal injury litigation here involves a "test plaintiff " approach to trying a mass tort case. However, there is nothing here to indicate that the

Non-Trial Plaintiffs were given an opportunity to object the defendants' motion for summary judgment or otherwise protect their substantive claims.

Moreover, Rule 42(b) states:

> The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues, always preserving inviolate the right of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States.

Fed. R. Civ. P. 42(b)(emphasis added). The extension of the summary judgment decision to the Non-Trial Plaintiffs implicates their Seventh Amendment jury trial rights. Summary judgment does not violate a party's Seventh Amendment jury trial rights so long as the person having the right to the jury trial is an actual participant in the summary judgment proceeding. See City of Chanute, Kansas v. Williams Natural Gas Co., 995 F.2d 641, 657 (10th Cir. 1992) ("[S]ummary judgment, applied properly, does not violate the Seventh Amendment.") (citing Fidelity & Deposit Co. v. United States ex rel. Smoot, 187 U.S. 315, 319-21 (1902)). However, absent a positive manifestation of agreement by Non-Trial Plaintiffs, we cannot conclude that their Seventh Amendment right is not compromised by extending a summary judgment against the Trial Plaintiffs to the non-participating, non-trial plaintiff. In fact, a Seventh Amendment argument was made in the District Court, but the argument was summarily dismissed. 927 F. Supp. at 838 n.7.

The District Court's extension of the Trial Plaintiffs' summary judgment decision to the Non-Trial Plaintiffs would also improperly extend the doctrine of collateral estoppel/issue preclusion. See DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3d Cir. 1990). In DeLuca, we commented on a defense theory that a group of consolidated Bendectin cases should be dismissed because of positive outcomes for Bendectin defendants in other cases. We said:

> [W]e do not have the authority to create special rules to address the problems posed by continued Bendectin litigation. Principles of issue preclusion have not developed to the point where we may bind plaintiffs by the finding of previous proceedings in which they were not parties, even by a proceeding as thorough as the multidistrict common issues trial.

Id. at 952. Although DeLuca is distinguishable from the same as the Non-Trial Plaintiffs' case, the District Court's extension of the Trial Plaintiffs' summary judgment decision to the nonTrial Plaintiffs' claims implicates the issue preclusion concerns we found troublesome in DeLuca.

Finally, we believe that the District Court erred by holding that all plaintiffs had to present evidence that they were exposed to 10 rem or more of ionizing radiation in order "to establish causation on the basis of a specific radiation exposure level." 927 F. Supp. at 865. Based on its review of the scientific literature, Id. at 834; 844-45, the District Court found that there is a consensus in the scientific community that, at levels of exposure below 10 rem, the causal link between exposure and cancer induction is purely speculative. Id. at 865. Consequently, the court held that, faced with evidence of an equivalent exposure below 10 rem, "no rational jury . . . could find it more likely than not that radiation induced a given neoplasm." Id.

At exposure levels below 10 rem (100 mSv) or 10 rad (100 mGy), cancer risks are based on extrapolations from risks seen at higher exposure levels. See RADIATION DOSE RECONSTRUCTION, at 8 ("It is important to note that serious health effects of exposure to ionizing radiation, such as an increase in cancer, have not been observed directly at doses below 0.2 Gy (20 rad) among the survivors of the atomic bombing of Hiroshima and Nagasaki. The risks assumed to occur at doses below 0.2 Gy (20 rad) are, therefore, extrapolations from the risks seen at intermediate[0.2-2.0 Gy (20-200 rad)] and high [>2 Gy (>200 rad)] doses to doses above natural background radiation."); see also MEDICAL

EFFECTS, at 69 ("Virtually all of the data used to derive risk estimates for low-dose levels are obtained from situations in which the exposure level actually occurred at dose levels above 0.1 Gy (10 rad)."). However, the fact that risks of cancer from exposure at low doses are based on extrapolations from higher doses does not mean that the scientific community believes that there is no causal connection between a low-level exposure and cancer induction. We do not believe that the scientific community views that connection to be speculative. Rather, as noted above, at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to adversely modify it. ICRP, at 98. Indeed, scientists assume that there is no threshold for the induction of cancer. MEDICAL EFFECTS, at 69. In other words, ionizing radiation can cause cancer even at the lowest doses, and therefore it has to be taken into account at all dose levels. ICRP, at 67.

The Non-Trial Plaintiffs ought to be able to attempt to establish that doses below the threshold selected by Trial Plaintiffs has induced their neoplasms, or caused their pathologies. Accordingly, we conclude that it was error for the District Court to hold that all the plaintiffs had to demonstrate an exposure of at least 10 rem to satisfy their burden of establishing causation. By doing so, the District Court was, in effect, deciding, contrary to the opinions of the scientific community, that 10 rem was the threshold for cancer induction, and that exposure to lesser doses of ionizing radiation could not reasonably be believed to cause cancer.179

The District Court's finding that all plaintiffs had to demonstrate an equivalent dose exposure of 10 rem or more did not affect the outcome of the Trial Plaintiffs' cases because, as noted earlier, they proceeded on the theory that they were exposed to at least that equivalent dose of

---

179. Although, as noted in our discussion of the physics involved here, many observations of atomic behavior lead to counter-intuitive conclusions, we nevertheless think that common sense alone mitigates against establishing a bright line threshold for safe irradiation. We do not believe, for example, that a person who has been exposed to 10 rem of radiation is at risk for developing a neoplasm, but someone exposed to 9.99 rem is not.

ionizing radiation. The Trial Plaintiffs' medical causation experts premised their opinions that radiation was the cause of the test plaintiffs' neoplasms on their expectation that the dose exposure experts would demonstrate that the test plaintiffs were exposed to 10 rem or more of ionizing radiation. 927 F. Supp. at 862-863. Although discovery is closed as to all plaintiffs, we do not know anything about the trial theories of the Non-Trial Plaintiffs. We do not know whether they would also agree to proceed on the basis of an equivalent exposure of at least 10 rem. Moreover, we do not know the level of exposure the Non-Trial Plaintiffs' medical causation experts based their opinions on.

We also note that not only is there a statistical association between radiation and health effects, but also that a method for determining the likelihood of radiation-caused malignancy has been established by the National Council on Radiation Protection and Measurements. See NCRP 7. The Council has established a "probability of causation (PC) approach" for determining the probability (as opposed to absolute proof) that a particular malignancy may have been caused by exposure to ionizing radiation. Although the radiation dose to the individual is a variable in the PC equation, there is no specific dose required to make the equation workable.180

Accordingly, we hold that the District Court's extension of the summary judgment to the Non-Trial Plaintiffs was error, and we will reverse the grant of summary judgment to the defendants on the Non-Trial Plaintiffs' claims and remand for further proceedings.181

---

180. We take no position as to whether an expert opinion as to tumor causation that is based upon the PC approach could withstand a Daubert challenge or a challenge under Rule 703. We note the PC approach here, however, as it demonstrates, at least one of the problems in the District Court's decision to hold Non-Trial Plaintiffs to the 10 rem threshold.

181. With regard to the claims of the Non-Trial Plaintiffs, we note that over 1,600 of them are represented by the law firms of Levin, Fishbein, Sedran & Berman, Esqs., and Hepford, Swartz & Morgan, Esqs. However, approximately 300 of the Non-Trial Plaintiffs are represented by The Tarasi Law Firm, P. C., and the remaining Non-Trial Plaintiffs are

C. The Monetary Sanctions Appeal.

Trial Plaintiffs' counsel, Arnold Levin, Laurence Berman and Lee Swartz, appeal from the District Court's imposition of monetary sanctions against them in the amount of $500 each for violations of the mandatory disclosure requirements of Fed. R. Civ. P. 26(a) and for disregard of court orders issued pursuant to Fed. R. Civ. P. 26(f). This appeal closely overlaps the Trial Plaintiffs' assertion that the District Court's exclusion of evidence under Fed. R. Civ.

---

represented either by Shawn A. Bozarth, Esq., or Peter J. Neeson, Esq. On August 5, 1996, a Notice of Appeal was filed in the district court on behalf of all the plaintiffs, including the Non-Trial Plaintiffs. On October 31, 1996, Entries of Appearance were filed with the Clerk of Court by Levin, Fishbein, Sedran & Berman and Hepford, Swartz & Morgan on behalf of the appellants they represent, all of whom were specifically identified in the Entry of Appearance. On November 22, 1996, Lou Tarasi, Esq., of The Tarasi Law Firm, P. C., filed his Entry of Appearance on behalf of the appellants he represents, but no specific appellant was identified. No Entry of Appearance was filed by Shawn A. Bozarth, Esq., on behalf of his clients, or by Peter J. Neeson, Esq., on behalf of his clients.

A brief on behalf of the appellants represented by Levin, et al., and by Hepford, et al., was timely filed. However, no brief was filed on behalf of the appellants represented by The Tarasi Law Firm. Mr. Tarasi appears only on the Brief of the Levin and Hepford appellants as "Of Counsel for the Appellants Identified in the Entry of Appearance." No briefs were ever filed by Messrs. Bozarth and Neeson and their names do not appear on the brief filed by Levin, et al., and Hepford, et al.

The appellees filed a motion, under Fed. R. App. P. 31(c) and Third Circuit LAR 107.2(b), to dismiss the appeals of the appellants represented by Tarasi, Bozarth and Neeson based on their failure to file briefs. Mr. Tarasi responded by filing a motion to join in the brief filed by Levin and Hepford. Messrs. Bozarth and Neeson did not respond to appellees' motion to dismiss. On April 15, 1997, order was entered granting Tarasi's motion to join in the Levin and Hepford brief. However, the appellees' motion to dismiss was referred to the merits panel for disposition.

The April 15, 1997 order moots the motion to dismiss the appeal as to the Tarasi appellants. However, because Messrs. Bozarth and Neeson did not file briefs or in any way respond to the appellees' motion to dismiss, we will dismiss the appeals as to the appellants represented by them.

P. 37 was an abuse of discretion. As noted above, the District Court filed a well-reasoned and comprehensive Memorandum Opinion, dated August 7, 1996, explaining its rationale for the imposition of monetary sanctions against counsel. We can add nothing to that analysis. For the reasons we have already cited in our affirmance of the District Court's exclusion of evidence, we also hold that the District Court did not abuse its discretion by imposing monetary sanctions against counsel and we will affirm substantially for the reasons set forth in the District Court's August 7, 1996 Memorandum Opinion.182

D. Reassignment Upon Remand.

One matter remains. Plaintiffs' counsel seek reassignment of this case from Judge Rambo to another judge upon remand. They argue that the history of this case reflects "sharp exchanges between counsel and court" and "hostile rebukes of counsel by the court." Sanction's Br. at 44. However, as grounds for the requested reassignment, they assert:

> But, plaintiffs are not relying on such conduct in seeking reassignment. Rather, plaintiffs' contention is that the TMI district court's rulings show such a strong and unjustified displeasure with plaintiffs' counsel and disbelief in plaintiffs' experts and the case that a reasonable person, knowing all of the facts regarding the district court's ruling, may well conclude that the judge is not impartial and cannot make objective rulings with respect to plaintiffs' case.

Id. This is counsel's second attempt to do an end run around Judge Rambo. In a petition for a writ of mandamus seeking reassignment which trial-plaintiffs' counselfiled after the District Court's in limine rulings, counsel alleged, inter alia, that Judge Rambo conducted "herself so as to create `an appearance of a lack of impartiality that jeopardizes the credibility of her evidentiary and procedural rulings.' " See Dolan v. General Public Utilities, No. 96-7264,

---

182. We review the imposition of discovery sanctions for an abuse of discretion. Paoli II, at 750.

slip. op. at 3 (3d Cir. May 10, 1996). In our decision denying the writ we stated:

> The Supreme Court has made clear that "judicial rulings alone almost never constitute valid basis for a bias or impartiality motion. Liteky v. United States, 114 S. Ct. 1147, 1157 (1994). Thus, we have held "disagreement with a judge's determinations and rulings cannot be equated with the showing required to so reflect on impartiality as to require recusal. Jones v. Pittsburgh Nat'l Corp., 899 F.2d 1350, 1356 (3d Cir. 1990). Petitioners' allegations amount to little more that disagreement with her legal rulings. Disqualification is not an appropriate remedy for disagreement over a legal ruling. In the event the court's evidentiary rulings may be in error, they are subject to review on appeal.
>
> Petitioners also assert Judge Rambo should be disqualified because she allegedly made remarks to counsel that demonstrate personal bias. But "opinions formed by the judge on the basis of facts introduced or events occurring in the proceedings, do not constitute a basis for a bias or partiality motion unless they display a deep-seated favoritism or antagonism that would make fair judgment impossible." Liteky , 114 S. CT. at 1157. After an extensive review of the record we find no evidence of "deep-seated favoritism" in the remarks made by Judge Rambo.

Id. at 7.

In spite of this explanation of our reasons for denying counsel's initial attempt to get their case before a different judge, counsel reiterate the same arguments that we previously rejected in support of the instant appeal. A meritless legal position does not become meritorious merely by repeating it in a subsequent appeal. Plaintiffs' counsel have ignored our opinion in Dolan. In Dolan, we specifically stated that disqualification is not a "remedy" to an adverse judicial ruling. Trial counsel's arguments regarding assignment of a new judge have not changed since Dolan, but neither has the law. Counsel are really complaining about the substance of Judge Rambo's rulings against them. However, as we informed them in Dolan, adverse rulings do not warrant disqualification.183

For the above reasons, we will affirm the district court's imposition of monetary sanctions and deny the request for reassignment.

VII. CONCLUSION

To restate our decision in each appeal, we will affirm the District Court's grant of summary judgment in favor of the defendants on the Trial Plaintiffs' claims and will affirm the District Court's imposition of monetary sanctions against certain of Trial Plaintiffs' counsel. We will reverse the grant of summary judgment in favor of the defendants on the Non-Trial Plaintiffs' claims and remand for further proceedings, excepting the grant of summary judgment to defendants on the claims of the Non-Trial Plaintiffs represented by Shawn A. Bozarth, Esq., and Peter J. Neeson, Esq. See n.181, supra. We will dismiss the appeals of those particular appellants for failure to file briefs. See Matute v. Procoast Nav. Ltd., 928 F.2d 627, 630-31 & n.1 (3d Cir.), cert. denied, 502 U. S. 919 (1991), overruled on other grounds, Neely v. Club Med Management Services, Inc., 63 F.3d 166, 177-78 (3d Cir. 1995). Finally, we will deny the request for reassignment.

---

183. Moreover, we can not help but comment on the commendable manner in which Judge Rambo has handled this exceedingly difficult, intricate and complex litigation. She has done so in a manner that reflects patience, fairness, and a desire to let both sides be heard. For example, as noted earlier, she allowed plaintiffs to present a portion of Wing's testimony even though she believed it to be marginally admissible. She allowed reports to be submitted after her January 5, 1996 order even though that order warned counsel about ignoring deadlines.

This is not to say that this litigation has proceeded without shortened tempers, strained patience, heated exchanges, or legal error. Such is often encountered in litigation of this magnitude, importance and complexity. However, it appears to us that Judge Rambo has continued to preside over this litigation as fairly as is humanly possible, and in a manner that is remarkably free of legal error.

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit