UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 91-12912-RGS

CYNTHIA D. SMITH, INDIVIDUALLY, AS GUARDIAN AND NEXT FRIEND OF SARAH SMITH AND BENJAMIN SMITH, AND AS EXECUTRIX OF THE STATE OF THOMAS B. SMITH

v.

GENERAL ELECTRIC COMPANY AND
BOSTON EDISON COMPANY

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTION TO EXCLUDE EXPERT TESTIMONY

April 23, 2004

STEARNS, D.J.

This case raises a difficult and important issue. Does the "gatekeeping" rule of Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), preclude a jury from considering a novel and controversial scientific theory of causation that, while plausible, is nonetheless on the outer rim of supportable science? The issue before the court, as it has been refined after prolonged litigation, is whether a scientifically reliable hypothesis supports plaintiff's claim that chronic low-level exposure to inhaled or ingested plutonium and americium alpha emitters can cause the onset of chronic myelogenous leukemia (CML) in human beings.[1] A hearing was held under Daubert auspices at which plaintiff's and

[1]CML is a rare form of leukemia, largely affecting adult males in the later stages of life. In the general population the yearly occurrence of CML rarely exceeds one per 100,000. An association between ionizing radiation and CML has been established, principally through studies conducted of the survivors of the World War II atomic bomb attacks on Japan. The studies, which involved exposures to massive and instantaneous bursts of gamma radiation, provide no definitive answers about the carcinogenic effects of long-term exposure to low-

defendants' experts testified.

The controversy can be summarized as follows. The decedent, Thomas Smith, was exposed to chronic doses of external and internal ionizing radiation while employed intermittently at Boston Edison's Pilgrim nuclear power station between June of 1972 and February of 1988.[2] He was diagnosed with CML in 1989 and died from complications of the disease in June of 1992. CML is caused by a chromosomal mutation in stem cells that reside in the bone marrow.[3] Studies of CML patients suggest that the mutation permits the translocation of genetic material between chromosomes 9 and 22 and a fusion of the bcr and abl genes, which leads to the unregulated multiplication of myeloid blood cells. Positing radiation as the mutating agent, the immediate issues are whether pathways exist that permit the migration of inhaled alpha emitters from the lungs to the endosteal cells on the surface of the bone, and if so, whether the resulting emissions are capable of penetrating the

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level radiation. According to defendants' expert, Dr. Ann Kennedy, viruses and chemical exposures can also induce CML, although in most cases there is no means of identifying the likely cause with any assurance of certainty.

[3]The fact that Smith was exposed to ionizing radiation is not disputed. Contemporary records at the Pilgrim plant indicate that Smith was exposed to a cumulative external radiation dose of 5.1 rem. For Daubert purposes, the court (after some refinements) accepted the calculation of plaintiff's expert Dr. Linkov that Smith also received an internal exposure to 9 rem of plutonium or 15.8 rem of a combination of plutonium and americium. Defendants accept these figures for present purposes, but do not agree that the actual dosage was even this high. In fairness to the plaintiff, much of the blame for the difficulty in calculating Smith's actual exposure is attributable to Boston Edison's historically deficient record keeping. Moreover, while I agree with defendants that plaintiff is precluded from basing any theory of legal liability on Smith's external exposure, I do not agree that her experts are thereby precluded from testifying to the possible effects of his total exposure to ionizing radiation.

[3]The exact identity of the cell type that gives rise to CML is unknown. Dr. Hill, if I understood his testimony, postulates that there may be more than one type. Dr. Kennedy, if I understood her testimony, believes that the target cells are precursor cells of CFUc cells.

exterior of the bone to pluripotent stem cells in the marrow. Plaintiff's experts identify three possible pathways. First, that the emitters may be transmitted through the bloodstream by alveolar macrophages, white blood cells whose protective function is to absorb invasive particulates in the lung.[4] Second, that a similar transmission may occur through the lymph nodes. And finally, that some particulates may pass directly through the alveolar membrane into the bloodstream and ultimately to the bone surface. Defendants' experts, while skeptical of the pathways postulated by plaintiff's experts,[5] agree that some emitters do migrate to the surface of the bone. However, they maintain that the resulting emissions are too weak to reach the stem cells in the center of the marrow. According to defendants, alpha emissions associated with plutonium and americium atoms have an emission range of no more than 40 microns,[6] thus rendering the likelihood of an alpha dose penetrating the endosteal layer and the fat cells lining the cortical and trabecular bones and striking a pluripotent cell "infinitesimally small" and "a very, very rare event."[7] Plaintiff's experts

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[4]According to defendants' expert, Dr. Cline, a respected hematologist, macrophages do not circulate in the peripheral blood, but reside solely in organ tissue.

[5]Dr. Cline postulates that plutonium and americium dissolve over time directly into in the blood and emulate calcium in seeking out the cortical and trabecular bone surfaces.

[6]Plaintiff's experts dispute the 40 micron figure, contending that the range can extend to 200 microns.

[7]This point is made in response to Dr. Hill's theory that a single alpha particle passing through the bone marrow is capable of causing CML. Dr. Cline estimates the chances of CML being caused by a single alpha particle emission to be on the order of $1 \times 10^{16}$, thus putting a staggering numerical ceiling on Dr. Hill's "single shot" theory. In Dr. Cline's opinion, the numerical improbability of a "single shot" occurrence is why any epidemiological association between CML and the inhalation of alpha emitters is so weak. Dr. Hill also testified to a "bystander" effect, whereby non-irradiated cells in proximity to irradiated cells show similar transformations. Dr. Kennedy agreed that a bystander effect has been observed *in vitro* in animal studies, but has never been isolated *in vivo*.

respond that americium and plutonium, being soluble, are capable of penetrating the endosteum (the inner surface of the bone). Moreover, they dispute the theory that the target cells reside exclusively in the center of the marrow, while at the same time pointing to mouse studies that indicate that plutonium 239 and americium 241 over time do reach the center of the bone marrow.[8]

Defendants' main argument relies on epidemiological evidence that strongly suggests the absence of any elevated risk of CML from the exposure to alpha emitters at an instantaneous dose of less than 21 rem or a chronic dose of less than 42 rem. Defendants rely in particular on studies of persons whose occupations expose them to inhaled alpha emitters, such as uranium miners and plutonium workers. See, *e.g.*, Shilnikova, *et al.*, "Cancer Mortality Risk Among Workers at the Mayak Nuclear Complex," Radiation Research, June 2003. While these studies show elevated incidences of lung, liver, and bone cancers in the exposed population, they do not appear show an elevated risk of leukemias, or where they do, the level of risk seldom if ever approaches the epidemiologist's RR 2.0 (doubling) "gold standard" (at least without a significant widening of the confidence interval).[9]

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[8]There is some irony in plaintiff's resort to a mouse study, given their resounding criticism of Dr. Kennedy for relying on animal studies in formulating her opinions.

[9]Defendants are particularly critical of Dr. Oliver for her alleged overreliance on epidemiological studies that focused on external rather than internal exposure to ionizing radiation, or on studies involving injected (as opposed to inhaled) substances such as thorium and radium. The universe of available epidemiological studies is fairly small, and the court has prior familiarity with most of them. See Whiting v. Boston Edison, 891 F. Supp 12 (D. Mass. 1995). I found Dr. Oliver's interpretation of the studies on which she relied to be reasonably accurate, given the latitude for disagreement created by inevitable imperfections in the design of the studies, their often ambiguous findings, and the difficulty of extracting useful parallels from studies of exposures to radionuclides other than plutonium and

As conceived by the Supreme Court, Daubert was intended to supplant the inflexible and ultra-orthodox "general acceptance" test of Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), with a more liberal relevancy test derived from the Federal Rules of Evidence. "That the Frye test was displaced by the Rules of Evidence does not mean, however, that the Rules themselves place no limits on the admissibility of purportedly scientific evidence." Daubert, 509 U.S. at 589. Two considerations guide the exercise of a judge's discretion to admit or exclude expert testimony under the federal rules. First, a proffered expert must be shown to be qualified by "knowledge, skill, experience, training, or education" in his or her proposed area of expertise. Fed. R. Evid. 702. Second, "under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." Daubert, 509 U.S. at 589. Stated more colorfully, a trial judge has the obligation to screen out of the trial process "expertise that is *fausse* and science that is junky." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 159 (1999) (Scalia, J., concurring).

"Reliability," which is the touchstone of Daubert, is a difficult term to define in a judicial context. The reason that this is so is because of an inevitable tension between science and the law in their conflicting approaches to problem solving. "Burdens of proof, while they work well in resolving most legal disputes, do not easily lend themselves to the resolution of scientific controversies. Science, by and large, rejects binary decision making

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americium. While defendants' criticism of Dr. Oliver's views contains much by way of substance, I do not find her testimony so implausible as to impugn her credentials as a witness. Nor do I rule out her opinion that the Cardis study, if read in conjunction with Wing, gives support to a finding of a doubling of the relative risk of contracting CML in circumstances similar to those postulated for Smith.

in favor of a more nuanced quest for understanding. While a scientist might testify that a supposed fact has been proven to be false, the same scientist, when asked about conflicting data, will say only that an asserted fact has not been disproved or 'falsified,' and could therefore 'possibly' be true." United States v. Massachusetts Water Resources Authority, 97 F. Supp. 2d 155, 157 (D. Mass. 2000). In other words, the same evidence that might not meet the standards that the law uses to establish admissibility, might nonetheless warrant a scientist's serious consideration. This is true because the history of science is one of confounded dogma. See Natalie Angier, Study of Mice Reproduction Discovers Egg Regeneration: Data Challenges a Central Idea of Biology, N.Y. TIMES, March 11, 2004, at A18.

In Daubert, the Supreme Court attempted to address this implicit tension by recommending to judges some of the same tools that science itself uses in determining reliability. "Ordinarily, 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. 'Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.'" Daubert, 509 U.S. at 593. "Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication. . . . [S]ubmission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected." Id. "Additionally in the case of a particular scientific technique, the court should ordinarily consider the known or potential rate of error . . . and

the existence and maintenance of standards controlling the technique's operation . . . ." Id. at 594. "Finally, 'general acceptance' can yet have a bearing on the inquiry." Id. The Court then added a pertinent qualification. "The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." Id. at 595.[10]

Under Rule 402, all relevant evidence is admissible. According to Rule 401, "'[r]elevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." But the Daubert Court, in reminding judges of their obligation under Rule 702 to scrutinize the qualifications of proffered experts, also "imposed a special relevancy requirement. . . . To be admissible, expert testimony must be relevant not only in the sense that all evidence must be relevant, see Fed. R. Evid. 402, but also in the incremental sense that the expert's proposed opinion, if admitted, likely would assist the trier of fact to understand or determine a fact in issue." Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 81 (1st Cir. 1998). The most authoritative guidance as to the

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[10]Daubert is not a mechanical or exhaustive test. In some cases, the Daubert factors may have no bearing at all. See United States v. Hankey, 203 F.3d 1160, 1169 (9th Cir. 2000); United States v. Frazier, 322 F.3d 1262, 1266-1267 (11th Cir. 2003). It is also open to a court to fashion new criteria relevant to the facts and circumstances of a particular case. For example, the Ninth Circuit on reconsideration of Daubert after remand by the Supreme Court, noted that "[o]ne very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. . . . [I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317 (9th Cir. 1995). Also, expert evidence that passes Daubert's reliability test may still be excludable under Rule 403, if its probative value is outweighed by the danger of unfair prejudice.

meaning of this "special relevancy requirement" is provided by General Electric Co. v. Joiner, 522 U.S. 136 (1997), where the Court "placed a gloss on Daubert's insistence that trial courts focus on an expert's methodology, rather than his conclusions, in order to determine the reliability of his testimony." Ruiz-Troche, 161 F.3d at 81.

> [C]onclusions 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 that 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.

Joiner, 522 U.S. at 146.

In the case at hand, the easiest issue is that of the qualifications of the witnesses.[11] Dr. Christine Oliver is a Massachusetts General Hospital physician, board certified in occupational, preventive, and internal medicine, and with an impressive background in epidemiological research; Dr. Colin Hill is a radiobiologist from the University of Southern California, a member of the board of editors of the International Journal of Radiation Biology, and a referee for the journal Radiation Research; while Dr. William Thilly is a professor of toxicology at the Massachusetts Institute of Technology (MIT) and the former Director of MIT's Center for Environmental Health Sciences. Defendants, for their part, offered Dr. David Hoel, an internationally recognized specialist in radiation epidemiology and a

[11]While defendants make the brief aside that Dr. Oliver is a "professional" witness, it is not a point that they pursue, most probably because their highly respected Dr. Hoel is himself no stranger to the courtroom. A stronger criticism lies in the fact that Dr. Oliver has little or no experience in the field of radiation-induced cancers. Her expertise is rather in asbestos-related respiratory diseases. Nonetheless, I differentiate this case from Whiting, supra, where I found that the plaintiff's proposed expert witnesses did not pass the preliminary qualifications test of Rule 702.

researcher for the National Academy of Sciences; Dr. Martin Cline, the Emeritus Professor of Oncology at the University of California at Los Angeles and a widely published authority in the field of hematology; Dr. Ann Kennedy, a radiation biologist affiliated with the Harvard School of Public Health, a BEIR V panelist, and an experienced clinical investigator; and Dr. Thomas Sowdon, the former Chief Radiological Scientist at the Pilgrim station.

The science, as presented, teaches that the problem is not that too much is known about the association between ionizing radiation and a disease like CML, but too little. The question to which the court sought an answer was whether any reliable scientific hypothesis supported plaintiff's theory that exposure to inhaled alpha emitters at the postulated dosage could cause the onset of CML. While I have no doubt that scientific opinion, as well as the weight of the epidemiological evidence, strongly supports the views of defendants' experts, I also strongly doubt that I have the authority to conclude a case simply because I am convinced that one side's science is superior to the other's.

> Daubert does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. As long as an expert's scientific testimony rests upon "good grounds, based on what is known," Daubert, 509 U.S. at 590 (internal quotation marks omitted), it should be tested by the adversary process – competing expert testimony and active cross-examination – rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies, see id. at 596. In short, Daubert neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance. It demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.

Ruiz-Troche, 161 F.3d at 85. While I can see a benefit to a rule empowering judges to act as the ultimate arbiters of scientific disputes, at least insofar as they may impact on the

conduct of litigation, it would be a difficult rule to reconcile with the constitutional delegation of the fact-finding duty to juries. I cannot dismiss plaintiff's experts as poseurs or witnesses for hire. They are serious scientists with controversial views that are in many respects on the periphery of the mainstream, but views that are not so divorced from a scientific method of investigation that they can be dismissed as quackery or armchair conjecture.[12] Hence, as I understand Daubert, my role is over, and the role of the jury begins.

In the context of a full trial on the merits, plaintiff's general causation hypothesis may prove too tenuous to withstand brevis judgment. In this regard, it is worth noting that a ruling admitting expert testimony "is not final on the reliability of [expert] opinion evidence, and the opponent of that evidence may challenge its validity before the trier of fact." Commonwealth v. Lanigan (II), 419 Mass. 15, 26 (1994). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596.

ORDER

For the foregoing reasons, I conclude that plaintiff has presented a sufficiently plausible theory of general causation to withstand defendants' motion to exclude her expert witnesses on the subject. The motion is therefore DENIED. The Clerk will convene a scheduling conference with the view of bringing this long-litigated case to an

[12]Whether a jury would find plaintiff's general causation theory sufficient to satisfy the Massachusetts "substantial factor" test is not an issue that I address. See Superior Court Civil Practice Jury Instructions § 11.2.9(a) ("The defendant's conduct was the legal cause of the plaintiff's injury if it was a substantial factor in bringing it about and without which the harm would not have occurred."). I do, however, agree with defendants that plaintiff misinterprets O'Connor v. Raymark Industries, Inc., 401 Mass. 586 (1988), on this point.

appropriate conclusion.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE