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	ed: August 7, 2002)	
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ELIZABETH DUTTON SWEET and FREDERICK H. GREIN,	*	FILED
JR., in their capacities as Executors under the will of	*	AUG 7 2002
William H. Sweet,	÷ ★	U.S. COURT OF FEDERAL CLAIMS
and	*	
MASSACHUSETTS	*	
INSTITUTE OF	* Price-Anderson Ac	t; Indemnification;
TECHNOLOGY,	 * Statutory Construct * Interpretation 	tion; Contract
and	* _ ★	
MASSACHUSETTS GENERAL	*	
HOSPITAL,	*	
Plaintiffs,	*	
ν.	*	
THE UNITED STATES,	*	
Defendant. * * * * * * * * * * * * * * * * *	*	

James B. Re, Boston, MA, for plaintiff Elizabeth Dutton Sweet and Fredrick H. Grein, Jr., Executors under the will of William H. Sweet, M.D.

Owen Gallagher, Boston, MA, for plaintiff Massachusetts Institute of Technology.

Joseph L. Doherty, Jr., Boston, MA, for plaintiff Massachusetts General Hospital.

Brian M. Simkin, U.S. Department of Justice, Washington, DC, with whom were Robert D. McCallum, Jr., Assistant Attorney General, and Director David M. Cohen, for defendant.

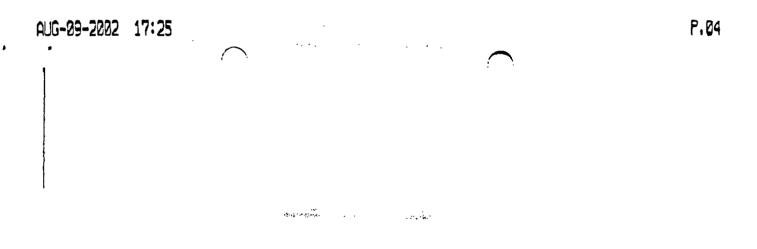
OPINION

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FIRESTONE, Judge.

This dispute comes before the court on defendant United States' ("government's") motions for summary judgment in part and to dismiss in part. The dispute centers on a series of agreements entered into pursuant to the Atomic Energy Act of 1954 and subsequent amendments in the Price-Anderson Act passed in 1957 to encourage the development of nuclear capabilities in the United States. The Atomic Energy Commission ("AEC") and its successor agency, the Nuclear Regulatory Commission ("NRC"), entered into agreements with plaintiff Massachusetts Institute of Technology ("MIT") to allow MIT to operate a nuclear reactor and to use it for nuclear medicine research. In addition, as part of its licensing agreement, the AEC entered into an interim indemnity agreement with MIT, which was later superseded by additional indemnity agreements between MIT and AEC/NRC. Pursuant to these indemnity agreements, the United States agreed to indemnify MIT for certain damages resulting from radiation exposure, for amounts in excess of \$250,000 up to an aggregate limit of \$500,000,000. The issue before this court is whether the indemnity agreements cover the damages described below.

During the late 1950's and early 1960's, plaintiff MIT allowed plaintiff Dr. William H. Sweet, M.D., who was affiliated with plaintiff Massachusetts General Hospital ("Mass General"), to conduct a series of medical trials at the MIT reactor. The



trials involved boron neutron capture therapy ("BNCT"). MIT was licensed to test BNCT as a treatment for a deadly form of brain cancer by directly radiating the brains of patients after they had received injections of a boron compound; the boron was intended to make the use of radiation more effective by concentrating the effects of the radiation on the diseased parts of the patients' brains. The trials were not successful, and a number of Dr. Sweet's patients were injured or died as a result. Many years later, when surviving Sweet's patients were injured or died as a result. Many years later, when surviving family members learned of the problems with the BNCT trials, they sued MIT, Mass General, and Dr. Sweet in the United States District Court for the District of Massachusetts for damages.¹ After trial in the district court, a jury found Dr. Sweet and Mass General liable for wrongful death and negligence, while it found for MIT on all counts. The background and verdicts in that litigation are set out in a number of opinions issued by Chief Judge William G. Young; many of his opinions are cited throughout this opinion and are referred to numerically as <u>Heinrich I</u> through <u>Heinrich V</u>. The cases to which these labels apply are reported as follows: <u>Heinrich I is Heinrich v. Sweet</u>, 44 F. Supp. 2d 408 (D.Mass. 1999); <u>Heinrich II</u> is 49 F. Supp. 2d 27 (D.Mass. 1999); <u>Heinrich III is 62 F. Supp. 2d 282 (D.Mass. 1999); Heinrich IV</u> is 83 F. Supp. 2d 214 (D.Mass. 2000); and <u>Heinrich V</u> is 118 F. Supp. 2d 73 (D.Mass. 2000). The matter before this court arises from that litigation.

¹ The United States was also sued, inter alia, for its part in approving the trials and providing the boron. The United States was ultimately dismissed from the action.

In May 2000, plaintiffs Dr. Sweet² and MIT filed the present action. Dr. Sweet is seeking indemnification from the United States for the liability and defense costs resulting from the Massachusetts district court litigation, while MIT is seeking just reimbursement of its defense costs.³ Mass General joined the action in May 2001 seeking both types of indemnification. All three plaintiffs claim that under the Atomic Energy and Price-Anderson Acts, MIT's license, and the E-39 indemnity agreement between the AEC/NRC and MIT, the federal government is contractually obligated to indemnify each of them for their liability and legal defense costs. Additionally, because of potential ongoing lawsuits filed by other BNCT patients of Dr. Sweet's, plaintiffs are additionally asking this court for a declaratory judgment establishing their right to indemnity from any future "public liability" claims and the associated legal defense costs.

On January 12, 2001, the government moved to dismiss plaintiffs' declaratory relief claims, arguing that these claims fall outside this court's jurisdiction. In addition, the government moved for summary judgment as to plaintiffs' indemnification claims, arguing that under the terms of the relevant statutory provisions and indemnification

² Dr. William H. Sweet passed away on January 22, 2001. On May 18, 2002, this court granted a motion to substitute Elizabeth Dutton Sweet and Frederick H. Grein, Jr. for Dr. Sweet, in their capacity as Dr. Sweet's executors. Throughout this opinion, however, the court will refer to Dr. Sweet as one of the named plaintiffs in this matter.

³ MIT first contacted the NRC by letter on November 8, 1995, to assert a claim for indemnification. Over the course of the next few years, the NRC consistently refused to provide MIT with indemnity. Dr. Sweet contacted the NRC by letter on August 10, 1999, and the NRC refused to provide him with indemnity as well.

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agreement, the parties are not entitled to indemnification for the liability stemming from the medical trials conducted by Dr. Sweet and Mass General at the MIT reactor facility. Briefing on these motions was completed on April 17, 2002, and the court heard oral argument on June 18, 2002.

For the reasons that follow, the court rules that under the Price-Anderson Act, plaintiffs are entitled to indemnification from the United States for both their "public liabilities" stemming from the <u>Heinrich</u> litigation which underpins this matter, and for their legal defense costs accrued in connection with that litigation.

I. BACKGROUND

Because this case requires the court to construe both the indemnity agreement and its statutory underpinnings, a brief description of the Atomic Energy and Price-Anderson Acts is required. In addition, because this complaint is based on facts and claims made in the <u>Heinrich</u> litigation, a brief review of the district court proceedings is also in order.

A. The Atomic Energy and Price-Anderson Acts

1. The Original Provisions

Congress enacted the Atomic Energy Act of 1954 ("AEA"), Pub. L. 703, 68 Stat. 919 (1954) (codified as amended at 42 U.S.C. §§ 2011-2297h (2000)), to encourage private sector development of atomic energy for peaceful purposes. <u>See H.R. REP. NO.</u> 2181, 83d Cong., 2d Sess., 1-11 (1954). In its original form, the AEA provided for licensing of private construction, ownership, and operation of commercial and nonprofit Pub. L. 94-197, §§ 4(b), 5(b), 10(b), 89 Stat. 1113-14. The NRC issued a final rule implementing the Hathaway Amendment on March 26, 1984. 49 Fed. Reg. 11,146 (March 26, 1984) (explaining that the final rule was issued "to conform certain sections of 10 C.F.R. Part 140 both to Pub. L. 94-197 and the Atomic Energy Act of 1954, as amended").

When Congress amended the Price-Anderson Act again in 1988, it reinstated the indemnification for legal costs. Section 170(k) of the AEA, which is applicable to nonprofit educational institutions such as MIT, was again amended to include "such legal costs of the licensee as are approved by the Commission" within the "aggregate indemnity for all persons indemnified in connection with each nuclear incident." Pub. L. 100-408, § 8, 102 Stat. 1066, 1074 (August 20, 1988) (42 U.S.C. § 2210(k)). This amendment also establishes federal district court jurisdiction over "public liability" causes of action. Pub. L. 100-408, § 11, 102 Stat. at 1076-77. This latter amendment, however, applies only "with respect to nuclear incidents occurring on or after" August 20, 1988, the effective date of the amendment. Pub. L. 100-408, § 20, 102 Stat. at 1084.

B. MIT's License and Indemnity Agreements

1. MIT's License

On or about June 9, 1958, the AEC licensed MIT to possess and operate a nuclear research reactor located in Cambridge, Massachusetts ("MIT reactor"). The MIT license indicated that, "Experimental facilities are provided for use in neutron diffraction work,

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horizontal beam experiments, neutron beam therapy experiments, exponential assembly experiments, and neutron irradiation studies."

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2. The Interim Indemnity Agreement

On or about May 25, 1959, the AEC issued an indemnity agreement to MIT – with an effective date of June 9, 1958 – to "indemnify and hold harmless" MIT and "other persons indemnified as their interests may appear" from "public liability in excess of S250,000 arising from nuclear incidents" Further, the "aggregate indemnity for all persons indemnified in connection with each nuclear incident" was not to exceed S500,000,000, "including the reasonable cost of investigating and settling claims and defending suits for damage."

The terms of the interim indemnity agreement also provided that they would be "superseded, in due course, by the execution and issuance of a formal indemnity agreement" between MIT and the AEC.⁵ On March 29, 1962, the AEC finalized the standard form indemnity agreement applicable to nonprofit educational institutions. 27 Fed. Reg. at 2884, 2887-88.

⁵ This statement is consistent with AEC comments, published in the Federal Register on April 22, 1961, noting that it had "entered into temporary indemnity agreements with licensees pending the adoption of the forms" and that, after the effective date of the amendments, it would "tender to each licensee subject thereto a definitive indemnity agreement" that would "supersede the temporary agreements." 26 Fed. Reg. at 3457.

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3. Indemnity Agreement No. E-39

Subsequent to issuance of the interim indemnity agreement to MIT, the AEC and MIT entered into "Indemnity Agreement No. E-39" pursuant to § 170k of the AEA. This agreement indicated that it was "effective as of 12:01 A.M., on the 9th day of June, 1958 and supersedes the interim indemnity agreement between the licensee and the Atomic Energy Commission dated May 25, 1959." The final agreement did not change MIT's coverage in any material respect.

Article III, paragraph 1, provided: "The Commission undertakes and agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interests may appear, from public liability." Similarly, Article III, paragraph 3, provided: "The Commission agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interests may appear, from the reasonable costs of investigating, settling and defending claims for public liability." The AEC agreed to indemnify and hold harmless MIT and "other persons indemnified as their interests may appear" from public liability in excess of \$250,000 arising from nuclear incidents, and capped the aggregate indemnify arising from each nuclear incident at \$500,000,000.

MIT's license application was accompanied by assurances related to the numerous safety precautions that were to be employed during operations at the reactor to prevent unplanned releases of radiation. <u>See MIT's April 9, 2001 Resp.</u> to Def.'s Mot., Ex. 2. For example, MIT planned to implement measures to "restrict the radiation so as to minimize the hazards to the doctors and experimenters," and there was to be radiation monitoring equipment on site to alert medical staff and patients "in event of too high a radiation level in the therapy room."

The following is the AEC's contemporaneous appraisal of MIT's proposed safety measures: "MIT has submitted data describing the control and safety instrumentation and the administrative procedures relating to the use of the facility for neutron beam therapy experiments and medical therapy. The instrumentation and procedures appear to provide adequate protection for the health and safety of the public and personnel participating in the use of the facility for these purposes." MIT's April 9, 2001 Resp., App. at 3. The AEC also found that "the MIT reactor can be operated with an acceptable degree of risk to the health and safety of the public." <u>Id.</u>

C. The <u>Heinrich</u> Litigation in Massachusetts District Court

1. The Complaints

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On September 21, 1995, four surviving family members of cancer patients treated at the MIT reactor and Brookhaven National Laboratory in the 1950's and 1960's filed a putative class action lawsuit against MIT, Mass General, Dr. Sweet, and the United States in the U.S. District Court for the Eastern District of New York ("<u>Heinrich litigation</u>").⁶

⁶ The <u>Heinrich</u> suit was filed originally in the Eastern District of New York by virtue of the inclusion of a number of parties who are no longer in the suit: Shields Warren and Charles Dunham, who were the federal officers at the AEC responsible for funding and overseeing the experiments; the estate of Dr. Lee Edward Farr; and Associated Universities, Inc. ("AUI"). AUI held a license similar to MIT's to conduct nuclear medicine trials at the Brookhaven National

The <u>Heinrich</u> plaintiffs alleged that the doctors and institutions authorized to practice nuclear medicine pursuant to the AEC-issued licenses had used terminally-ill patients as "guinea pigs" for dangerous, non-therapeutic medical experiments involving BNCT, which was at that time an experimental treatment for a form of incurable brain cancer called glioblastoma multiforme. Specifically, the amended <u>Heinrich</u> complaint alleged the following;

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This action is brought to seek redress from the defendants who were responsible for using the decedents of plaintiffs and the class they represent as human guinea pigs, without their consent, in a series of extremely dangerous, painful and unproven medical experiments for which there was no reasonable basis to believe that the decedents would receive any therapeutic value.

Laboratory, in Upton, New York, and Dr. Farr conducted research under this license at the Brookhaven facility. The original <u>Heinrich</u> plaintiffs and putative class members were patients treated at either of the two facilities, and the named defendants included Mr. Warren, Mr. Dunham, Dr. Farr, Dr. Sweet, MIT, Mass General, and AUI. On November 16, 1996, the New York court dismissed the claims against defendants Messrs. Warren and Dunham and substituted the United States as a defendant. The case was thereafter transferred to the United States District Court for the District of Massachusetts by order dated September 17, 1997. <u>See Heinrich I</u>, 44 F. Supp. 2d at 410 n.2. Of the four original named plaintiffs, only two proceeded to trial: Evelyn Heinrich and Henry M. Sienkewicz, Jr., both on behalf of patients who had been treated only at the MIT reactor.

Dr. Sweet, Mass General, and MIT also claim that a separate indemnity agreement between the AEC and AUI – covering operations at the Brookhaven National Laboratory – provides them with indemnification in this matter. However, the government has opted to reserve argument related to the Brookhaven agreement for a later time, presumably because the BNCT patients involved in the litigation that has prompted this suit before the Court of Federal Claims – <u>Heinrich v. Sweet</u> in U.S. District Court for the District of Massachusetts – were treated only at MIT. Because the Brookhaven indemnity agreement is not the subject of the dispositive motions currently before the court, the court only considers the MIT indemnity agreement at this time.

According to the <u>Heinrich</u> complaint, BNCT involved a two-step process: injecting a patient with a boron compound (intravenously or via the carotid artery) and thereafter exposing the patient's brain to an external source of slow neutron radiation. The complaint explained that, in theory, BNCT offered a localized and thus desirable treatment for brain cancer because it was thought at the time that the boron compound would concentrate in tumor cells rather than healthy cells and, subsequently, the slow neutron exposure would result in lethal ionizing radiation to eliminate the tumor cells that had absorbed the boron.

The medical trials covered by the <u>Heinrich</u> complaint were divided into two distinct categories: (1) the experiments in which patients underwent the full BNCT procedure, which involved the injection of boron (in some form) immediately prior to or during exposure to slow neutron radiation; and (2) the experiments where patients were injected with boron, or some other potential neutron capturing substance, but were not exposed to slow neutron radiation, solely to test the performance of the compound itself for future BNCT experiments. For both categories of experiments, the gravamen of the complaint was that:

Defendants never obtained the consent of the plaintiffs' or the class' decedents or of the class members for these radiation and injection experiments. None of these named victims nor the remainder of the class were advised of the true nature of the experiments, the lack of any reasonable medical basis for such experiments or the excruciating pain and likely death which would occur as a result of such experiments. Defendants affirmatively misled the plaintiffs' and class' decedents by exploiting the decedents' desperate health condition,

downplaying the risk of BNCT and grossly overstating the possible health benefits and, in the case of the injectees who did not receive BNCT, by failing to advise them that they were injected with toxic substances. This misconduct was made worse by the deliberate decision of defendants, acting in concert, never to advise the decedents during their lifetime or the class, even to this day, of the true facts of what occurred. P.15

The <u>Heinrich</u> complaint asserted several causes of action: a "Bivens" claim for deprivation of constitutional rights (Count I); a "fraud-deceit" claim (Count II); battery (Count III); intentional infliction of emotional distress (Count IV); strict liability for inherently dangerous activities (Count V); personal injury caused by exposure to toxic substances (Count VI); failure to obtain informed consent (Count VII); wrongful death (Count VIII); crimes against humanity (Count IX); negligence (Count X); and negligent misrepresentation (Count XI). As relief, the <u>Heinrich</u> plaintiffs sought "compensation for pain, suffering and wrongful death of their decedents, for their own pain and suffering, and for punitive damages to deter defendants from ever again using any human beings, particularly the terminally ill, as guinea pigs for scientifically untested and unproven experimental procedures and to deter defendants from ever using any person for any medical experiment without first obtaining their informed consent after full and accurate disclosure." The claims that were eventually presented to the jury were for two plaintiffs who had received both the boron injections and radiation therapy: Evelyn Heinrich on behalf of her husband George Heinrich, and Henry M. Sienkewicz, Jr., on behalf of his mother Eileen Rose Sienkewicz.

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2. The Nuclear Regulatory Commission's Refusal to Defend

By letter dated November 8, 1995, MIT's counsel forwarded a copy of the <u>Heinrich</u> complaint to the NRC's Director of Nuclear Reactor Regulation, stating that the claims raised in the <u>Heinrich</u> suit were "subject to indomnification under Indemnity Agreement E-39 between the Atomic Energy Commission and MIT" Following an extensive exchange of correspondence on the issue, Marjorie S. Nordlinger, a staff attorney in the NRC's Office of the General Counsel, notified MIT's counsel of the NRC's opinion that "NRC indemnity should not be invoked in this case" insofar as "the Price-Anderson liability system did not cast the government as insurer of personal harms from medical administrations or from medical treatments without informed consent, but as indemnifier for unexpected but possible public dangers associated with the operation of nuclear reactors or materials used to fuel them." As such, the NRC refused to fund MIT's litigation in the Massachusetts district court. Dr. Sweet received a similar response to his query in 1999.

3. The Massachusetts District Court's Ruling on "Public Liability Action"

During the course of litigation in the district court, MIT filed a motion requesting partial summary judgment on the applicability of the Price-Anderson Act to its claims. <u>See Heinrich III</u>, 62 F. Supp. 2d at 290. In <u>Heinrich II</u>, the court had ruled that New York law applied to the plaintiffs' state law claims, including applicable New York statutes of

limitations. In response, in arguing <u>Heinrich III</u>, MIT contended that because the action fell within the provisions of the Price-Anderson Act, it was the statute's choice of law rules that should apply, thereby refining the choice of law issue further. Chief Judge Young agreed with MIT, and before the case could proceed to trial, he deemed it necessary to address the applicability of the Price-Anderson Act as a threshold matter.⁷

Chief Judge Young framed the issue as follows:

The determinative issue, therefore, is whether the indemnification agreements between the Commission and the various private defendants in this action covered the activities challenged by the Plaintiffs. If they did, the claims of plaintiffs Heinrich and Sienkewicz would be subject to Massachusetts law because their decedents were treated in Massachusetts.

Heinrich III, 62 F. Supp. 2d at 297-298. For the purposes of the litigation before him,

Chief Judge Young held that:

[T]he challenged conduct in the instant litigation . . . is subject to an indomnification agreement with the United States. There are a variety of reasons for so holding. First, the available evidence suggests that a valid and binding indemnification agreement does exist that <u>may</u> eventually be interpreted to cover the challenged conduct. . . . Second, holding that an indemnification obligation is in place and that the Act therefore applies does no harm to the Plaintiffs. Indeed, as will be seen below, it significantly aids them by preserving some of the state law claims that would otherwise be time-barred, including a potential claim for punitive damages. Third, <u>it would be both impractical and inequitable to require the United States to litigate the</u>

⁷ As observed by Chief Judge Young, in accordance with the *Erie* doctrine, when a federal court considers "substantive" issues of state law – such as statutes of limitations – the federal court must follow state law. <u>Heinrich II</u>, 49 F. Supp. 2d at 33 (citing <u>Guaranty Trust Co. of N.Y.</u>, 326 U.S. 99, 110 (1945)). In this instance, because Chief Judge Young was deciding the proper statutes of limitations for the separate New York (Brookhaven) and Massachusetts (MIT) causes of action, the applicability of the Price-Anderson Act became important.

issue of indemnification at this stage in the proceedings, yet some ruling on the issue of the applicability of the Act is required before the litigation can continue.

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Heinrich III, 62 F. Supp. 2d at 298 (emphasis added). In making this ruling, Chief Judge

Young realized that there were significant limitations inherent in his ruling. For example,

although the NRC was arguing that MIT's indemnity agreement did not cover the conduct

alleged by the <u>Heinrich</u> plaintiffs, and the plaintiffs were arguing that the Brookhaven

indemnity agreement would not cover any damages awarded in this case because it

excludes "bad faith" and "willful misconduct," see id. at 298 n.3, Judge Young held:

Whether these positions turn out to be correct is irrelevant to the present question which is, simply, whether an indemnification agreement exists that <u>presumptively</u> applies to the challenged conduct. This Court will not require the United States to litigate a final determination of the scope of its indemnification duties prior to establishment, if any, of primary liability on the part of the private defendants.

Id. (emphasis added). He went on to conclude:

It must be emphasized that this ruling is based only on a preliminary record and <u>is intended in no way to bind any subsequent tribunal faced with the task</u> of determining whether the United States in fact must indemnify a judgment rendered against the private defendants. Instead, the Court is simply treating the question as one of threshold importance: does an indemnification agreement exist between the United States and the various private defendants that presumptively applies to the challenged conduct in this litigation? If so, the Act will apply in this case, regardless of whether or not the indemnification agreement is later interpreted to reach the conduct of the private defendants.

Id. at 298 (emphasis added).

4. The Massachusetts District Court Trial and Verdict

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After the court concluded that the case was properly before it under the Price-Anderson Act but before trial, the court denied class certification, severed the claims of a later-added plaintiff named Marc Oddo to proceed as an independent action, and dismissed plaintiffs Rosemary Gualtieri on behalf of her father Joseph Mayne and Walter Carl Van Dyke on behalf of his father Walter Carmen Van Dyke. <u>See Heinrich V</u>, 118 F. Supp. at 73 n.1. A jury was impaneled in the <u>Heinrich</u> case on September 7, 1999. On October 15, 1999, at the close of the trial, the jury returned verdicts for the remaining two plaintiffs, Evelyn Heinrich and Henry M. Sienkewicz, Jr., against Dr. Sweet and Mass General for wrongful death and negligence. MIT was found not liable on all claims, and the United States was dismissed as a defendant pursuant to the "government contractor exception" to the Federal Tort Claims Act, 28 U.S.C. §§ 2671-2680 (2000). In total, the jury held Dr. Sweet individually liable in the amount of \$1,750,000 for the wrongful death claims, and jointly and severally liable with Mass General in the amount of \$3,000,000 for the negligence claims.

Dr. Sweet's counsel forwarded the <u>Heinrich</u> jury verdict to the NRC by letter dated October 20, 1999, indicating, among other things, that "defense counsel are drafting posttrial motions which will be filed this week" and that "[w]e are strongly optimistic that punitive damages will be eliminated entirely and that the compensatory damages will be either eliminated or reduced." During these post-trial proceedings, Dr. Sweet filed his complaint in this court on May 11, 2000, MIT filed its complaint on May 22, 2000, and Mass General filed its complaint on July 27, 2001.

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The <u>Heinrich</u> court entered judgment in favor of Ms. Heinrich and Mr. Sienkewicz and against Dr. Sweet and Mass General on September 29, 2000. In so doing, the court granted post-trial motions made by Dr. Sweet and Mass General for reduction of the jury verdict for wrongful death, and denied Mass General's motion for judgment as a matter of law on the defense of charitable immunity. On the former issue, the court held that the plaintiffs' claims for wrongful death arose in 1961 and, applying the provisions of the applicable 1961 Massachusetts wrongful death statute, limited plaintiffs' damages to S20,000. In its decision denying the defense of charitable immunity, the court stated:

[D]uring the treatment of both Heinrich's and Sienkewicz's decedents, Sweet had actual knowledge of the imprecision of the localization of the boron injections to the cancerous brain tissue and the related imprecision of the neutron radiation, with the result that unacceptably high degrees of radiation necrosis were occurring in these and other of his patients. In short, Sweet well knew during his care of these patients that his BNCT treatments were not helping them, and, in fact, were causing severe side effects unrelated to the progressive effect of the fatal brain tumors. He pressed ahead anyway, believing in complete good faith that such experimentation on dying patients held out hope for other cancer victims. However praiseworthy his goal, his conduct with respect to the patients involved here was, as the jury found, negligent....

Heinrich V, 118 F. Supp. 2d at 90-91 (internal citations omitted).

In total, the district court found both Dr. Sweet and Mass General individually liable in the amount of \$40,000 for wrongful death (\$20,000 per plaintiff), and jointly and

severally liable in the amount of \$750,000 for negligence. On October 23, 2000, the court stayed execution of the judgments pending appeal, and Dr. Sweet and Mass General filed their appeal in the U.S. Court of Appeals for the 1st Circuit. Oral argument was held on May 7, 2002, and the appeal is still pending at this time. <u>Heinrich v. Sweet</u>, No. 00-2554 (1st Cir. filed Dec. 7, 2000).

II. DISCUSSION

A. Standard of Review

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986). See Rule 56(c) of the Rules of the Court of Federal Claims ("RCFC"). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Liberty Lobby, 477 U.S. at 247-48. In deciding whether summary judgment is appropriate, it is not the court's function "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Id. at 249.

Whether or not plaintiffs are entitled to indemnification from the federal government turns on questions of contract and statutory interpretation that are properly before this court on motion for summary judgment. <u>Olympus Corp. v. United States</u>, 98 F.3d 1314, 1316 (Fed. Cir. 1996) (holding that "summary judgment is appropriate where the sole dispute concerns the proper interpretation of a public contract"); <u>United States v.</u> <u>Montoya</u>, 827 F.2d 143, 146 (7th Cir. 1987) (holding that statutory interpretation is something a trial court undertakes as a matter of law).

B. Claims for "Public Liability" Under the Price-Anderson Act

At issue in this case of first impression is whether the damages awarded to the <u>Heinrich</u> plaintiffs by the Massachusetts district court – to compensate them for the harmful radiation exposures they sustained during the BNCT trials – constitute a "public liability" under the Price-Anderson Act and MIT's indemnity agreement, for which plaintiffs are entitled to government indemnification. Plaintiffs argue that the term "public liability" encompasses all damages arising from "licensed activities" conducted at the reactor site – such as the BNCT trials for which MIT secured its license – which result in harm or death resulting from radiation exposure.

The government counters that the Price-Anderson Act and MIT's indemnity agreement do not extend coverage to all damages arising from radiation exposure caused by licensed activities, because the Price-Anderson Act and indemnity agreement only provide coverage for those exposures caused when the reactor itself fails to properly operate in a safe manner.⁸ Both the government and plaintiffs premise their arguments on

The government has modified its argument over the course of this litigation. In the early stages of briefing, the government focused its argument on the issue of "intent" and its contention that the Price-Anderson Act only provided coverage for "accidents" and not for "intentional" acts of radiation exposure. Thus, the government argued that it could not be responsible for intentional acts of malpractice. In addition, the government argued in its January

the plain terms of the Price-Anderson Act and MIT's indemnity agreement, trade practice, and the legislative history behind the Price-Anderson Act. Each of their arguments will be examined in turn.

The Term "Public Liability" - as Used in the Price-Anderson Act and the E-39 Indemnity Agreement - Shall be Given Its Plain Meaning

The court begins its inquiry into the meaning of "public liability" by examining the

plain language of the Price-Anderson Act and MIT's E-39 Indemnity Agreement.⁹ As

noted above, the Price-Anderson Act defines "public liability" as "any legal liability

Congress, of course, did not restrict a nuclear incident or occurrence to any one single happening but, at bottom, what is required is some event, circumstance or condition in which the licensed facility [the reactor] operates in an unexpectedly unsafe manner.

Tr. at 8 (cmphasis added). The government further clarified its view, that intentional acts <u>can</u> be covered by the Price-Anderson Act: "Now a nuclear incident that is brought about by an intentional act is covered by Price-Anderson, assuming other requirements of the statute are met." Tr. at 20. This new position therefore negates the government's earlier arguments related to the ENO concept.

' Importantly, for the purposes of this motion, the government concedes that each of the plaintiffs falls within the definition of "person indemnified," even though the indemnity agreement is only with MIT. Therefore, without deciding whether in fact Dr. Sweet and Mass General are parties covered by the Price-Anderson Act and indemnity agreement, the court turns to the core issue.

^{12, 2002} motion to dismiss that the term "nuclear incident" had to be read consistently with another term added to the Act in 1966, "extraordinary nuclear occurrence" or "ENO." Because the definition of ENO referred to "unintentional" damages, the government argued that the words "incident" and "accident" should be read interchangeably.

At oral argument, however, the government abandoned its "accident" approach and stated that in order to establish a "public liability," plaintiffs must establish that the indemnity provisions only cover "unexpected" radiation exposures resulting from the reactor's failure to operate in a safe manner. The government summarized its views as follows:

arising out of or resulting from a nuclear incident or precautionary evacuation 42

U.S.C. § 2014(w). The same definition is echoed in Article I of the E-39 Indemnity

Agreement, which states:

During the period 12:01 A.M., June 9, 1958 to 12:01 A.M., September 6, 1961, inclusive: "Public liability" means any legal liability arising out of or resulting from a nuclear incident

From 12:01 A.M., September 6, 1961: "Public liability" means any legal liability arising out of or resulting from a nuclear incident

"Nuclear incident" is in turn defined in the same article of both the E-39 Agreement and

the Price-Anderson Act as:

[A]ny occurrence or series of occurrences at the location or in the course of transportation causing bodily injury, sickness, disease, or death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive or other hazardous properties of the radioactive material.

(Emphasis added.)

There is no dispute between the parties that plaintiffs seek indemnification for

damages associated with injuries that arose at the MIT reactor "location."¹⁰ In addition,

¹⁰ While the government agrees that the <u>Heinrich</u> plaintiffs' injuries took place at the "location" of the reactor, the government contends that the location of the medical trials was "irrelevant" to the <u>Heinrich</u> court, and should also be irrelevant to this court in discerning the definition of "occurrence." The court disagrees, because this court must give meaning to the language of the Price-Anderson Act, and Congress' inclusion of the phrase "at the location" cannot be discounted. <u>See United States v. Menasche</u>, 348 U.S. 528, 538-539 (1955) (holding that it is the Court's duty to give effect to every clause and word of a statute). Moreover, this limitation in the Price-Anderson Act imposes an important limitation on the scope of this court's ruling here. In particular, the government argues that if the court were to accept plaintiffs' argument, it could result in extending Price-Anderson Act coverage to any harm caused by excessive radiation exposure at any nuclear medicine facility in the United States. This is plainly

the parties agree that the injuries at issue resulted from the "hazardous properties of the radioactive material" employed in the BNCT therapy.¹¹ The dispute between the parties boils down to their differing views on the meaning of the term "occurrence" as it appears in the definition of "nuclear incident," because "occurrence" is not defined in the Price-Anderson Act or within the MIT indemnity agreement.

a. The Plain Meaning of "Occurrence"

Plaintiffs argue that the term "occurrence" is plain on its face and extends to <u>any</u> occurrence or event at the reactor which results in a radiation-related injury. This, they argue, includes the injuries suffered by the <u>Heinrich</u> plaintiffs. According to plaintiffs, rules of statutory and contract construction compel the court to apply the ordinary or general meaning of "occurrence" to this case. According to plaintiffs, "In ordinary English usage, an 'occurrence' is something that happens, irrespective of cause," a meaning that is proffered by virtually all dictionaries. In particular, plaintiff MIT cites the <u>Merriam-Webster</u> online dictionary, which first defines "occurrence" as "something that occurs," and second, as "the action or instance of occurring." MERRIAM-WEBSTER

not the case under the plain words of the Act.

¹¹ In this connection, plaintiffs concede that if the injuries to the <u>Heinrich</u> plaintiffs had been unrelated to the radiation, but were instead caused by problems with the anesthesia or with the craniotomies required by the medical protocol, they would not have an indemnification claim. <u>See</u> Tr. at 63-64. As such, this ruling does not reach any damages suffered by patients who received boron injections but were not exposed to radiation in the MIT reactor. On the record before this court, however, it appears that the <u>Heinrich</u> plaintiffs who remained in the litigation did suffer their injuries by virtue of the radiation phase of the BNCT therapy. <u>See Heinrich I</u>, 44 F. Supp. 2d at 410-11.

COLLEGIATE DICTIONARY (2002), <u>available at http://www.m-w.com/cgi-bin/dictionary</u>. <u>Merriam-Webster</u> also provides a list of synonyms for "occurrence": "event, incident, episode, and circumstance." According to plaintiffs, under this generally-accepted definition, each patient's exposure to the directed radiation at the reactor constituted an "occurrence" covered by both the Price-Anderson Act and indemnity agreement.

The government challenges plaintiffs' argument and contends that some dictionaries define "occurrence" to include an element of the "unexpected." In particular, the government relies on <u>Webster's New International Dictionary</u>, which states as its third definition: "Any incident or event, esp. one that happens without being designed or expected; as, an unusual occurrence." WEBSTER'S NEW INT'L DICTIONARY (2d Ed. 1943).¹²

In addition, the government also argues that the word "occurrence" is a "term of art" used throughout in the insurance industry to mean an "unexpected" or "unintended" consequence, and that the court should therefore construe the term to mirror this insurance "trade usage" meaning. For support, the government points to various treatises which state that the term "occurrence" has been historically used in the insurance industry to "specify an unexpected cause of loss," citing the treatise <u>Couch on Insurance</u>. The government argues that the <u>Heinrich</u> plaintiffs' injuries were not "unexpected" because

¹² The first and second definitions provided by this source are as follows: "1.a. A casual meeting; b. That which occurs, esp. adversely. 2. Appearance or happening; as, the occurrence of a fire."

Dr. Sweet and Mass General had reason to know, even early on in the BNCT trials, that the BNCT therapy was not yielding any beneficial results, but they nonetheless continued to radiate patients. Thus, because the harm to the patients was "expected," the government contends the BNCT trials were not "occurrences" and that consequently, the damages arising from those trials did not give rise to "public liability."

Whether this court should take into account evidence of trade usage or custom to interpret the language of the Price-Anderson Act is guided by well-settled rules of statutory construction. "Courts presume that Congress expressed its legislative intent through the ordinary meaning of the words it chose to use, and if the statutory language is unambiguous, the plain meaning of the words ordinarily is regarded as conclusive." In re TMI, 67 F.3d 1119, 1123 (3d Cir. 1995). In determining whether or not a particular term is ambiguous, "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." Robinson v. Shell Oil Co., 519 U.S. 337, 341 (1997). Ordinarily, absent evidence in the legislation that Congress intended that a commonly-used word should be given a special "trade usage" meaning, the court should rely on the ordinary or general meaning of the word. See NORMAN SINGER, STATUTES AND STATUTORY CONSTRUCTION § 47:29 (West Group 6th ed. 2000) ("A difficulty arises when a term has both a common and technical meaning, both equally well established. In

this event, absent contrary legislative intent, or other manifested meaning, the term is presumed to have its common meaning." (Internal citations omitted.)).

Here, application of these principles of construction dictates that the court not look to the insurance industry definition, but instead rely on the ordinary meaning of the term. First, there is nothing ambiguous about the word "occurrence." It has a well-understood plain meaning. In addition, the government has not identified – and the court has not found – anything in the Price-Anderson Act or its legislative history to suggest that Congress intended for the word "occurrence" to be given a special "trade usage" meaning.

The government does not fare any better with its contract construction argument. It is not disputed that the MIT indemnification agreement does not require the parties to interpret "occurrence" as a term of art. Therefore, the court may only look to the trade usage only if it finds that the word is ambiguous. Whether a contract term is ambiguous presents a question of law. Fortec Constructors v. United States, 760 F.2d 1288, 1291 (Fed. Cir. 1985). It is well-settled that "extrinsic evidence will not be received to change the terms of a contract that is clear on its face." <u>Beta Sys., Inc. v. United States</u>, 838 F.2d 1179, 1183 (Fed. Cir. 1988); <u>Community Heating & Plumbing Co., Inc. v. Kelso</u>, 987 F.2d 1575, 1578 (Fed. Cir. 1993). "Where a contract is not ambiguous, the wording of the contract controls its meaning and resort cannot be had to extraneous circumstances or subjective interpretations to determine such meaning." <u>Perry & Wallis, Inc. v. United</u> States, 427 F.2d 722, 725 (Ct. Cl. 1970) (citing <u>Duhame v. United States</u>, 119 F. Supp. 192, 195 (Ct. Cl. 1954)).

Guided by these tenets, the court finds that the use of the term "occurrence" in the MIT indemnification agreement is clear on its face and does not require the court to resort to extrinsic evidence. The court finds, after surveying numerous dictionaries on its own, that "occurrence" is generally defined to mean: "1. The action, fact, or instance of occurring; 2. Something that takes place." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2000). <u>Random House</u> defines "occurrence" as "the action, fact or instance of occurring" and "something that happens: event [or] incident." RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE 1340 (2d ed. 1987). Based on these definitions, the court finds that in this instance, the term "occurrence" simply means an "event," and that the term consequently encompasses the radiation exposures caused by the BNCT trials conducted at the MIT reactor.

b. "Occurrence" As a Term of Art

Even if this court were to accept the government's arguments – that the term "occurrence" is a term of art that must be harmonized with the meaning it has been given by the insurance industry – it would not alter this outcome. On March 5, 2002, this court ordered the parties to provide more detail regarding the insurance industry's use of the term "occurrence" in the 1950's and 1960's, contemporaneous to the passage of the Price-

Anderson Act. The briefs filed by the parties in response to that order demonstrate that the term "occurrence" was not at that time limited to "unexpected" events.

Citing a number of articles and treatises published around the time that the Price-Anderson Act was being debated in Congress, plaintiffs demonstrate that "occurrence insurance policies" often included "intentional" or "expected" injuries. In fact, Gilbert L. Bean, an insurance expert who was involved in drafting the standard form Comprehensive General Liability Policy ("CGL") in 1966,13 explains that it was understood that the term "occurrence" was broad and covered more than accidents, and therefore the term was virtually always accompanied by explicit restrictions to limit coverage. See Gilbert L. Bean, The Accident Versus the Occurrence Concept, INS. L.J. 550, 552 (1959) (describing how the substitution of "occurrence" for "accident" was "coupled with an exclusion of intentional injury or damage"); Robert P. Lentz, Additional Coverages, The Annals of the Soc'y of Chartered Prop. & Casualty UNDERWRITERS 66, 67 (1958) (explaining that whenever an underwriter substituted "occurrence" for "caused by accident," a restricting definition was included, which stated that the "damage must be unexpected and not intended.").

. . .

¹³ The CGL was drafted by members of the insurance industry in order to bring some uniformity to the language used in policies. <u>See</u> 7A J. APPLEMAN, INSURANCE LAW AND PRACTICE § 4491 (Berdal ed. 1979). The CGL was first introduced in the 1940's, and was revised on a large scale in 1966.

In view of the foregoing, the absence of any such qualifications in the Price-

Anderson Act is very telling. It means that in enacting the Price Anderson Act, Congress understood that using the term "occurrence" without qualification would extend coverage to <u>all</u> events at federally-licensed reactors resulting in radiation harm. Or alternatively, at the very least, Congress' lack of qualification regarding the term "occurrence" means that Congress intentionally eschewed the trade usage meaning of the word, and instead chose to employ the plain meaning.

2. "Nuclear Incidents" Are Not Limited to Radiation Exposures Caused by Problems with Operation of the Reactor

The government argues that even if this court finds that the term "occurrence" includes all types of events and includes "expected" harms, plaintiffs still cannot prevail, because the Price-Anderson Act limits coverage to liability arising from the <u>reactor</u> not performing as it should. According to the government, when the term "nuclear incident" is examined in the broader context of the Price-Anderson Act and its legislative history, it is plain that Congress intended to provide indemnification solely when the harmful radiation exposure that causes damage is caused by some failure in the operation of the <u>reactor</u> itself.¹⁴

Plaintiffs counter that there is nothing in the Price-Anderson Act or in MIT's license that limits recovery related to those harms that are caused by some problem with

¹⁴ The government recognizes that Price-Anderson Act liability coverage may extend to damages caused during the transport of nuclear materials, but such damages are not at issue here.

the reactor itself. To the contrary, plaintiffs contend that the Price-Anderson Act extends coverage for radiation injuries that arise from problems associated with any "licensed activity." In the instant case, the MIT license provides not only for the operation of the MIT reactor, but also for specific radiation experiments that the federal government approved: "Experimental facilities are provided for use in neutron diffraction work, horizontal beam experiments, neutron beam therapy experiments, exponential assembly experiments, and neutron irradiation studies." As such, the MIT license not only allows MIT to <u>operate</u> a nuclear reactor, but also to <u>use</u> the reactor for certain enumerated purposes. In such circumstances, plaintiffs argue, harmful radiation exposures caused by those experiments are covered by the Price-Anderson Act. For the reasons that follow, the court agrees with plaintiffs.

The Price-Anderson Act, 42 U.S.C. § 2210, provides indemnification for all licensees, and § 2014(p) provides that, "The term 'licensed activity' means <u>an activity</u> <u>licensed</u> pursuant to this chapter and covered by the provisions of section 2210(a) of this title." (Emphasis added.) Given the terms of MIT's license quoted above, <u>see supra</u> part I.B.1., it is clear that the BNCT trials fell within the category of "licensed activities" at the MIT reactor, and as such, they fell within the scope of the indemnification provisions. In this connection, the court is mindful of the fact that Congress debated, then included, three express exceptions to legal liability arising out of, or resulting from, nuclear

incidents, but did <u>not</u> exclude liability for on-site medical experiments.¹⁵ The absence of an exception for medical experiments conducted at reactor sites – such as the BNCT therapy – is therefore significant.

In addition, the court cannot ignore the fact that before it authorized MIT to use the reactor for medical experiments, the AEC invested a great deal of forethought into how to protect the public, including patients, from radiation injuries. The AEC required MIT to supplement its license with details regarding the safety precautions it intended to employ with respect to the BNCT trials at the reactor site, about which the AEC observed: "MIT has submitted data describing the control and safety instrumentation and the administrative procedures relating to the use of the facility for neutron beam therapy experiments and medical therapy. The instrumentation and procedures appear to provide adequate protection for the health and safety of the public and personnel participating in the use of the facility for these purposes." 23 Fed. Reg. 2232, 2234 (April 4, 1958). The public "participating in the use of the facility for these purposes," would include patients. In the face of this information, AEC still executed the form indemnification agreement, without creating any special exception for injuries to patients resulting from radiation exposure during the medical trials.

¹⁵ The Price-Anderson Act excludes coverage for claims made under state or federal workers' compensation acts, for war damages, and for damage to property located at the reactor site and used in connection with the licensed activity. <u>See</u> 42 U.S.C. § 2015(w); S. REP. NO. 296, <u>reprinted in</u> 1957 U.S.C.C.A.N. 1803, 1819.

Moreover, while it is true that in these circumstances the reactor itself performed

in accordance with the trial specifications – it apparently delivered the radiation to the sites and in the amounts desired by Dr. Sweet and Mass General during the BNCT trials – the licensed medical trials failed because the boron did not work in conjunction with the radiation as the experimenters had hoped it would. At oral argument, plaintiff Mass General compellingly explained why these injuries are "nuclear incidents" and not simple

malpractice, as asserted by the government:

The reason [the BNCT therapy] didn't work was because of a basic assumption that was made, that was hoped for, about the way that this neutron would work when it did bombard the boron.... [Because] the glioblastoma multiforme is different from normal brain tissue, it doesn't have the bloodbrain barrier that protects it. So the unique nature of this was, we can deliver boron by injecting it into the patient and we know it will collect in the tumor, and it won't collect in the rest of the brain cells. The problem that they found out, on autopsy afterwards, which is the basis of this claim, was that there was still too much of it in the blood vessels surrounding the tumor, and it was the damage to the blood vessels that prevented [BNCT therapy] from working. It was a misunderstanding of the way that the neutrons from the source material within the reactor would affect the patients, that was the problem... . [The damage came] from a miscalculation as to the effect of the use of [the nuclear material] that they thought was going to be safe because of the bloodbrain barrier and because of the unique concept of the boron and collection of the boron within the tumor tissue. That . . . lack of knowledge was what directly led to the complications and the damages here and that is as clear, I think, as can be that it is injury relating directly to use of the reactor.

Tr. at 61-64. And also at oral argument, MIT read from an expert report submitted as

evidence during the Massachusetts district court trial to describe the unexpectedly

dangerous properties of the radiation exposure involved:

"The third reason [for the failure of these experiments] was the innate characteristics of the thermal neutron beam itself." And [the report] goes on to explain, "The thermal neutron beam peaks at [the surface], whereas the epithermal beam peaks at about two centimeters." Basically, it was giving a much higher dose at the upper regions of the brain. That was part of the reason they talked about the craniotomy, which was done at MIT, to open the brain.... [Y]ou still had an inherent characteristic of the beam for this type of experiment, which was not known until you went up there, and you got a new type of beam at the reactor.

Tr. at 69.

In view of the foregoing, the court finds that the BNCT experiments fall squarely within the ambit of the license granted to MIT, and thus the harm caused by those experiments indeed resulted in "nuclear incidents." This subsequently gives rise to a right to indemnification under the plain terms of the Price-Anderson Act and the MIT E-39 Indemnity Agreement.

3. The Legislative History of the Price-Anderson Act Does Not Bar Indemnification for Plaintiffs

Finally, the government's reliance on the legislative history of the Price-Anderson Act to support its contention that Congress only intended to provide coverage when radiation exposure was caused by the reactor failing to operate as intended is misplaced. While it is no doubt true that Congress' overarching rationale was to provide indemnification for the damages arising from a large-scale reactor failure with the Price-Anderson Act, it did not <u>limit</u> the availability of indemnification to such incidents. To the contrary, the legislative history shows that Congress was fully aware of the unique nature of the medical research being conducted at various nuclear reactors such as MIT's, but it did not exclude damages arising from the failure of those experiments from coverage.

The limited legislative history on point demonstrates that Congress was concerned with <u>all</u> of the activities that could expose the American public to the dangerous properties of radiation, and not just with the operation of the reactor itself. As the Senate

Conference Report states:

The second definition is of "licensed activity" which means any activity for which a license is issued, pursuant to the provisions of the act, but for which the Commission requires financial protection under section 170a [codified at 42 U.S.C. § 2210(a)].

The definition of "nuclear incident" is designed to protect the public against any form of damages arising from the special dangerous properties of the materials used in the atomic energy program. It includes any damages which may result from any hazardous property of source, special nuclear, or byproduct material. It includes bodily injury or death, loss of or damage to property, and loss of use of property. While most incidents will be happenings which can be pinpointed in time - such as a runaway reactor or an inadvertent exposure to radiation – it was not thought that an incident would necessarily have to occur within any relatively short period of time.... The occurrence which is the subject of this definition is that event at the site of the licensed activity, or activity for which the Commission has entered into the contract, which may cause damage The indemnification agreements are intended to cover damages caused by nuclear incidents for which there may be liability no matter when the damage is discovered, i.e., even after the end of the license. That is why the definition of "nuclear incident" has the phrase "any occurrence * * * causing bodily injury, sickness, disease, or death" and why the definition of "public liability" is tied to "any legal liability arising out of, or resulting from, a nuclear incident * * *."

S. REP. NO. 296, reprinted in 1957 U.S.C.C.A.N. 1803, 1817-18 (emphasis added).

This legislative history confirms that Congress intended to extend coverage for damages caused by radiation associated with <u>any</u> licensed activity, including medical experiments. Because the BNCT trials were a licensed activity, and because the radiation used in those experiments was the cause of the <u>Heinrich</u> plaintiffs' harms, the plaintiffs in this matter are now entitled to indemnification for the "public liability" arising from the BNCT trials.

C. Claims for Indemnification of Legal Defense Costs under the Price-Anderson Act

Having concluded that Dr. Sweet's and Mass General's claims for indemnification are valid as claims for "public liability," the court now turns to the additional claim made by all the plaintiffs – Dr. Sweet, Mass General, and MIT – that they are entitled to indemnification from the legal costs of investigating and defending the <u>Heinrich</u> suit in the Massachusetts district court and the First Circuit Court of Appeals. In particular, plaintiffs rely on Article III, paragraph 3 of MIT's Indemnity Agreement No. E-39, which provides:

The Commission agrees to indemnify and hold harmless the licensee and other persons indemnified, as their interests may appear, from the reasonable costs of investigating, settling and defending claims for public liability. The government argues that this provision of the indemnity agreements is no longer a valid, enforceable contract term.¹⁶ According to the government, the 1975 Hathaway Amendment excluded legal costs from the layer of indemnity available from the federal government for any claims not made prior to passage of the amendment. The government further contends that plaintiffs are not entitled to recovery under the 1988 Price-Anderson Act amendment which reinstated indemnification for legal costs because the 1988 amendments apply only to public liabilities arising after 1988.

Plaintiffs disagree, and argue that the government has failed to demonstrate how the 1975 and 1988 amendments took away their right to indemnification for nuclear incidents that had already occurred but had not yet been discovered at the time each amendment was enacted. The court must agree.

"[1]t is well settled that statutes are presumed to operate prospectively unless express language in the statute provides otherwise." Ford v. United States, 33 Fed. Cl. 560, 565 (1995) (citing Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208-09 (1988)). See also United States v. Security Industrial Bank, 459 U.S. 70, 79-80 (1982) ("The first rule of construction is that legislation must be considered as addressed to the future, not to the past.") (quoting Union Pac. R. Co. v. Laramie Stock Yards Co., 231 U.S. 190, 199 (1913)). Unless the language of a statute or its legislative history indicate

¹⁶ This is actually the government's second argument against indemnification of legal costs; its first argument depended upon a favorable outcome in the overall public liability determination, and as such, is moot.

otherwise, a statute is to be applied prospectively. <u>People of the State of Cal. ex rel. Dept.</u> of Transp. v. United States, 27 Fed. Cl. 130, 138 (1992). This presumption against statutory retroactivity is especially strong where the newly-passed provisions might affect contractual rights, for which stability and predictability are important features. <u>See</u> <u>Security Industrial Bank</u>, 459 U.S. at 79-82 (1982). The Federal Circuit has adopted the following standard: "absent specific direction to the contrary, a new statute applies only prospectively because such a position 'has the benefit of fairness and common sense."^w <u>Wilson v. United States</u>, 917 F.2d 529, 537 (Fed. Cir. 1990).

Both parties recognize that the Hathaway Amendment modifies certain sections of the Price-Anderson Act in order to exclude indemnification from legal costs. In particular, Congress withdrew the authority for Article III, paragraph 3 of the standard form indemnity agreement upon which MIT's E-39 agreement was based. As described in the <u>Federal Register</u>:

[A] Ithough the cost of investigating and settling liability claims and defending suits for damages is retained as part of financial protection, i.e., both primary and secondary insurance, the final rule modifies certain sections of 10 C.F.R. Part 140 in conformance with Pub. L. 94-197 to exclude these costs from government indemnity.

49 Fed. Reg. 11,146, 11,148 (March 26, 1984). While the NRC's regulations were accordingly changed – requiring a change in the standard form indemnity agreements applicable to nonprofit educational licensees – there was no indication that Congress

intended to alter existing indemnity agreements such as the E-39 agreement between the AEC/NRC and MIT. Both parties agree that MIT's agreement was never amended.

The government argues that despite this failure to amend the E-39 agreement, however, it was amended "by operation of law" because in Article V.of the indemnity agreement, the parties had agreed that they would "enter into appropriate amendments of this agreement to the extent that such amendments are required pursuant to the Atomic Energy Act of 1954, as amended, or licenses, regulations, or orders of the Commission." The government supports this proposition with case law indicating that contracts in conflict with statutes must be declared void. <u>See, e.g., Urban Data Sys., Inc. v. United States</u>, 699 F.2d 1147 (Fed. Cir. 1983).

The court disagrees with the government, and finds that the 1975 Hathaway Amendment did not alter the contractual relationship between MIT and the NRC. There is nothing in the terms of the new regulation that <u>required</u> that existing agreements be modified; as quoted above, in Article V of the indemnity agreement MIT agreed that it would "enter into appropriate amendments of this agreement to the extent that such amendments are required." Yet apparently the government did not act in the wake of the Hathaway Amendment to modify the agreement, nor did it demand that MIT do so. In fact, while the E-39 agreement was indeed modified three times between 1975 and 1988, none of these amendments contained the provisions the government is now asking this court to impute into the contract as a matter of law. Furthermore, according to plaintiffs,

the latest amendment to the agreement, effective July 1, 1989, added a new provision to the E-39 agreement establishing that indemnity is to include "such legal costs of the licensee as are approved by the Commission." At the time, the NRC clearly believed that indemnity of legal costs was still a feature of the E-39 agreement. As such, this court is not inclined to conclude otherwise.¹⁷

The court also rejects the government's argument concerning the effect of the 1988 amendments. The 1988 legislation amended the Price-Anderson Act to once again include "such legal costs of the licensee as are approved by the Commission," effective through August 1, 2002. Pub. L. 100-408, § 8, 102 Stat. 1074 (42 U.S.C. § 2014(k) (1989)). However, according to the government, because those amendments apply only "with respect to nuclear incidents occurring on or after" the effective date of the amendments – August 20, 1988 – the allegations made herein by MIT, Mass General, and Dr. Sweet are not covered.

Because this court has found that the 1975 Hathaway Amendment did not remove plaintiffs' rights to indemnity for the "nuclear incidents" that occurred at the MIT reactor in the 1950's and 1960's, the court also holds that these rights to indemnity were not altered by the 1988 amendments which reinstated the right to indemnification for legal

¹⁷ This holding, like the court's holding regarding the existence of a "nuclear incident," is supported by legislative history. According to Congress, the financial protection provisions of the Price-Anderson Act were "to run for the life of the license," and were designed "to cover the incident occurring during the period of the license." See S. REP. NO. 296, <u>reprinted in</u> 1957 U.S.C.C.A.N. at 1811, 1822.

costs associated with incidents occurring after August 20, 1988. In effect, through this series of amendments, Congress only removed indemnity for "nuclear incidents" that occurred <u>between</u> 1975 and 1988, but did not affect the rights of parties concerning pre-1975 incidents, unless their express indemnity agreements specified otherwise, which MIT's did not. This reading is validated by another provision of the 1988 amendment legislation: § 3 revised § 170(k) of the AEA to provide financial protection for nonprofit educational institutions "with respect to <u>licenses issued between August 30, 1954, and August 1, 2002</u>." Pub. L. 100-408, § 3, 102 Stat. 1067 (42 U.S.C. § 2110(k)).

For all these reasons, the court finds no indication that Congress intended to create a gap in coverage for legal costs between 1975 and 1988. Accordingly, the court holds that by the plain terms of the amendments, MIT's, Mass General's, and Dr. Sweet's claims for indemnification from the defense costs arising from the <u>Heinrich</u> litigation – which focuses on claims dating back to the 1950's and 1960's – were not abrogated by operation of the statutory amendments.

For the first time in its May 25, 2001 reply brief, the government raised an alternative argument that the government's obligation to indemnify plaintiffs for defense costs was not triggered until the <u>Heinrich</u> plaintiffs' claims were in litigation and Dr. Sweet, Mass General, and MIT had individually accrued \$250,000 in legal costs. According to the government, this is the proper interpretation of Article III, paragraphs 3 and 4, of the E-39 indemnity agreement. The government argues that plaintiff MIT has

conceded this point by making the following statement in paragraph 49 of its complaint: "MIT's satisfaction of the first \$250,000 of reasonable costs triggers the government's obligation to indemnify MIT." Again, the court must disagree with the government's conclusion.

It is true that each plaintiff would never have had a claim for legal defense costs in the event its legal fees totaled less than \$250,000, but the accrual of \$250,001 in defense costs cannot be interpreted to be the trigger of the government's obligation to defend. This would lead to an absurd result, keying plaintiffs' legal right to indemnification for defense costs to, for example, the vagaries of law firm billing practices and courts' litigation schedules. While the accrual of more than \$250,000 in legal defense costs is certainly the condition precedent to a claim being made for indemnity from the federal government under the Price-Anderson Act, the date on which a party hits the \$250,000 tally cannot be the triggering event dictating whether or not that party has right to indemnification. In this case, plaintiffs had a pre-existing, contracted-for right to indemnification for their legal costs in excess of \$250,000 for "nuclear incidents" that occurred in the early 1960's.

Further, the government's final attempt to defeat liability by contending that "plaintiffs have not and cannot persuasively demonstrate that application of the Hathaway amendment to exclude their indemnity claims for defense costs disrupts 'settled expectations' in any specific regard," is also unpersuasive. MIT, in its brief, argues that

under well-settled contract principles, MIT reasonably expected that the government's indemnification obligations would always be governed by its agreement with the government and the statute in effect at the time it entered into that agreement, and the court agrees. See United States v. Winstar Corp., 518 U.S. 839, 895 (1996) ("when the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals.") MIT secured its license from the AEC in 1958, and subsequently entered into the required indemnity agreement with the government in order to conduct experiments at its reactor that would have been impossible to conduct in the absence of the government's promised contribution in the event of a nuclear incident. In the early 1960's, Dr. Sweet conducted his BNCT research, but it was not until 1995 that the Heinrich plaintiffs discovered the relationship between their injuries and the experiments, when the President's Advisory Committee on Human Radiation Experiments disclosed the true nature of the BNCT trials. The government's suggestion that MIT would have conducted these experiments in the absence of federal indemnification is unconvincing.

For all these reasons, the court rejects the government's reconstruction of the Price-Anderson Act's indemnity provisions, and holds that MIT, Mass General, and Dr. Sweet are entitled to indemnification of the investigation and defense costs generated by the <u>Heinrich</u> litigation.

D. Plaintiffs' Claims for Declaratory Relief

The government has moved to dismiss plaintiffs' claim for declaratory relief concerning their liabilities under the Price-Anderson Act. Plaintiffs are seeking a judgment declaring the rights and liabilities of the parties under the MIT indemnity agreement, and declaring that the United States is obligated to indemnify the plaintiffs named herein from any claims brought by or on behalf of other patients who received BNCT at MIT.

The government correctly states that the Court of Federal Claims generally does not "have the general equitable powers of a district court, to grant prospective relief." <u>Bowen v. Massachusetts</u>, 487 U.S. 879, 905 (1988). Nor does the Declaratory Judgment Act vest this court with jurisdiction to award the type of relief desired by plaintiffs. <u>See</u> <u>United States v. King</u>, 395 U.S. 1, 5 (1969) ("There is not a single indication in the Declaratory Judgment Act or its history that Congress, in passing that Act, intended to give the Court of Claims an expanded jurisdiction that had been denied to it for nearly a century.").

While plaintiffs have correctly argued that this court has the power to grant declaratory relief in certain narrow circumstances, those circumstances are not present here. This court has the authority to grant prospective relief only when such relief is "tied and subordinate to a money award." <u>McKeel v. Islamic Republic of Iran</u>, 722 F.2d 582, 591 (9th Cir. 1983); <u>Schweiger Constr. Co., Inc. v. United States</u>, 49 Fed. Cl. 188, 207

(2001) ("The court may also issue declaratory rulings that are 'incident of and collateral to' a money judgment.") (citing James v. Caldera, 159 F.3d 573, 580-81 (Fed. Cir. 1998)). The court's straightforward holding today – that pursuant to the E-39 indemnity agreement, the federal government is obligated to indemnify MIT, Mass General, and Dr. Sweet for their public liabilities and legal defense costs related to the <u>Heinrich</u> litigation – is binding and precedential. Any claim for indemnification arising from other experiments must be separately evaluated.¹⁸ The court therefore concludes that declaratory relief is inappropriate in this instance.

III. CONCLUSION

For the foregoing reasons, the government's motion to dismiss plaintiffs' claims for declaratory relief is GRANTED and its motion for partial summary judgment as to the indemnification claims made by all three plaintiffs is DENIED. The court will contact the parties within the next fourteen days to set a schedule for the next steps in this litigation.

> NANCY B. FIRESTONE Judge

¹⁸ Plaintiffs request declaratory relief because at the time they filed their complaints in the Court of Federal Claims, they alleged that there was a series of patients similarly treated and injured, all of whom could possibly pursue litigation identical to the <u>Heinrich</u> litigation. However at oral argument, plaintiffs conceded that the potential for the filing of similar suits has diminished considerably, in light of the Massachusetts district court's denial of the <u>Heinrich</u> plaintiffs' motion for class certification, and the expiration of the applicable three-year statute of limitations since the discovery of the nature of the BNCT trials.

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DATE: 12/06/2000

TYPE: Other Office

TO: Chairman Meserve

FROM: John F. Cordes

CONTACT: Marjorie Nordlinger

SUBJECT: STATUS OF LITIGATION IN THE COURT OF FEDERAL CLAIMS FOR SUMS ALLEGEDLY OWED UNDER THE PRICE-ANDERSON ACT (UPDATE OF SECY-00-128 & SECY-00-136)

PAGES: 012

TEXT:

NOTE: CONFIDENTIAL ATTORNEY CLIENT AND ADJUDICATORY MATERIAL: LIMITED TO NRC UNLESS COMMISSION DETERMINES OTHERWISE

The purpose of this memorandum is to update the status of <u>Massachusetts Institute of Technology v</u>. <u>United States</u> and <u>Dr William H. Sweet v. United States</u>, lawsuits seeking Price-Anderson payments under an indemnification agreement between NRC (successor to AEC) and M.I.T., licensee of a research reactor.

Summary.

M.I.T. and Dr. William Sweet are currently suing the United States for Price-Anderson indemnification in the United States Court of Federal Claims. They seek payment for any liabilities found against them in <u>Heinrich v. Sweet</u>, a federal district court lawsuit seeking damages from experimental boron neutron capture therapy (BNCT), and in any other lawsuits with similar BNCT claims already filed (we know of one) or to be filed. BNCT is a medical therapy which uses boron injections to protect healthy tissue, and thus to isolate the lethal effects of administering a direct beam of radiation from a reactor to kill only cancerous cells. BNCT underlying the <u>Heinrich</u> claims was conducted in part by Dr. Sweet on brain cancer patients using a beam at M.I.T.'s reactor in the 1950's and early 1960's. M.I.T. and Dr. Sweet seck NRC reimbursement of damages judgmen's and incurred legal costs.

A final judgment was entered by the District Court in <u>Heinrich</u> recently, and the deadline for appeals is not until January. The verdicts, as they now stand, are against only the Massachusetts General Hospital and Dr. Sweet and total \$830,000. The combined legal fees of M.I.T. for its successful defense along with those of Dr. Sweet will substantially exceed one million dollars and perhaps even two million dollars.

We are represented in court by the Department of Justice. We are working with DOJ counsel to present, with respect to at least a portion of the claims, legal arguments asserting the court's lack of jurisdiction and prudential arguments relating to plaintiff's failures to detail their claims and seek resolution before the Commission. Our overarching substantive defense is that damages for radiological medical therapy, delivered as prescribed and without incident, are not within the coverage of the Price-Anderson Act even though the radiation emanated from an indemnified licensee's reactor. This position relies in large measure on the lack of any indication that Congress intended to extend the Price-Anderson protections to what are in effect claims of medical malpractice, and on various indications that Congress intended otherwise.

If the court should disagree, we have available back-up arguments with the potential to reduce the damages substantially if not entirely. We may be able to argue, for example, that significant portions of the underlying tort claim relate to non-radiological related injuries from actions in the Massachusetts General Hospital. In addition, the precise terms of the Price-Anderson Act, read technically, may well preclude or significantly diminish claims for legal expenses.

Below, this paper gives a detailed background of the <u>Heinrich</u> litigation, the lawsuits we face in the Claims Court, and the Price-Anderson questions at stake. In addition, the paper touches on some practical considerations. For instance, *1129 while the Price-Anderson statute itself does not indicate how the NRC (or DOE) should pay indemnification claims found valid by the agency or by a court, the paper points to legislative history supporting a view that sums may be paid out of an agency's existing appropriations, but where existing funds are unavailable for the purpose, the agency is to seek an appropriation from Congress. If Congress fails to appropriate the funds, the legislative history indicates that funds should come

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from the so-called "judgment fund," which is used to pay general government liabilities unaccounted for elsewhere in law.

The paper also notes additional cases in which the United States is not a named defendant but where, if the plaintiffs prevail, Price-Anderson claims likely will be brought to the NRC. We are considering and will consult with NRR and NMSS whether in light of the increase we are experiencing in Price-Anderson litigation and the issues being presented, we should propose any additional recommendations or amplify any existing recommendations for legislative action, for example to deal with legal costs, punitive damages, or funding.

Background

The Commission has long since had notice of the initiation in 1995 of the <u>Heinrich v. Sweet</u> lawsuit against M.I.T. and Boston neurosurgeon Dr. William Sweet. Massachusetts General Hospital (Mass General), and others for damages resulting from boron neutron capture therapy (BNCT) trials 1. The BNCT trials had been performed some thirty-odd years earlier on patients suffering from late-stage brain cancer. The trials took place at the Brookhaven and M.I.T. reactors, with Mass General also delivering boron injections unaccompanied by radiation. NRC's interest and subsequent involvement result solely from use of the licensed M.I.T. reactor for irradiation of some of the patients. 2

The Commission received more recent notice of two lawsuits against the United States filed in the Court of Federal Claims seeking indemnification for legal defense costs incurred in <u>Heinrich v. Sweet</u> and declaratory relief for any public liability incurred based on the BNCT trials. <u>See</u> SECY-00-128 & SECY-00-136. In addition, OGC has on occasion discussed the status of these proceedings informally with Commissioners' staff members.

On August 25, 2000, in collaboration with our office, the Department of Justice filed answers to the two Claims Court complaints against the United States. A status conference was recently held by the Claims Court judge who consolidated the two cases. At that time she set a briefing schedule making the government's initial brief on threshold legal issues due on December 22, 2000. Thus, it seemed that this would be an appropriate time to send the Commission a review of the background, a discussion of the issues and an explanation of our approach to these cases.

Discussion:

A. <u>Status of Lawsuit Underlying MIT's and</u> <u>Sweet's Actions Seeking Indemnification from NRC</u>

By early fall 1999, all but two of the original Heinrich v. Sweet plaintiffs had fallen by the wayside due to impermissibly late filing, failures to state cognizable claims, and the like. The two remaining plaintiffs were relatives or estates of George Heinrich and Eileen Sienkewicz. An interesting quirk of the case is that those plaintiffs were able to survive a statute of limitations bar on at least some claims only because M.I.T., a defendant, had successfully asserted over the objection of the plaintiffs that the lawsuit arose under federal law, the Price-Anderson Act, and was thus triable in federal district court in Massachusetts. In agreeing with M.I.T. on Price-Anderson's applicability, the district court judge described his ruling as a necessary preliminary matter, but he expressly rendered it without prejudice to any subsequent dispute between NRC and M.I.T. regarding whether federal indemnity was owed. This decision had the practical effect of bringing plaintiffs Heinrich and Sienkewicz under Massachusetts law where the time har was less favorable to defendants (including M.I.T.1 than the New York law which applied to the others.

In commenting on M.I.T.'s paradoxical position, the judge noted that M.I.T. chose to risk exposure to potential damages in the instant case in order to protect its ability to seek U.S. indemnification for legal costs already incurred by M.I.T., as well as damages and costs in any potential lawsuits alleging radiation injury from similar uses of M.I.T.'s reactor. Our office had previously informed M.I.T. of our view that the indemnification accorded them under Price-Anderson did not cover their liability in the circumstances at issue here -- i.e., where the alleged harms were not even claimed to result from an accident or fault in the reactor or problem related to reactor operation. The radiation doses, as prescribed by the patients' physician for treatment of their condition as he had diagnosed it, caused the patients' injuries, to the extent they suffered radiation injuries at all. 3

The Massachusetts plaintiff's tried their case for wrongful death, negligence, etc. to a jury in the United States District Court in Boston. Their theory of the case

was that defendants had jointly participated in experiments on Heinrich and Seinkewicz, or in other words, had engaged in a course of treatment that the defendants knew or should *1130 have known had no realistic therapeutic value and that caused plaintiffs' decedents pain and death. The defendants had done so, allegedly, by wrongfully putting their interest in acquiring research data ahead of the well being of their patients. Moreover, the plaintiffs maintained, the defendants had not advised the subjects of their experiments of the true facts so that any consent given was uninformed and thus negated.

Late in October, 1999, the jury in <u>Heinrich v</u>. <u>Sweet</u> brought in money verdicts against Mass General and that hospital's employee Dr. Sweet jointly as follows: On Heinrich's claim: \$250,000 for negligence and \$250,000 for wrongful death, and on Sienkewicz's claim \$500,000 for negligence and \$2 million for wrongful death. The jury also awarded punitive damages separately against Dr. Sweet and Mass General. For Heinrich, the punitive damages assessed against Sweet were \$750,000 and against Mass General \$1,250,000 for a total of \$2 million. For Seinkewicz, the punitive damages totaled \$3 million --\$2 million from Mass General and \$1 million from Dr. Sweet.

The jury found against plaintiffs and in favor of Mass General and Dr. Sweet on the claims of lack of consent. As the judge later explained it, they found that the patients were informed that the treatment was risky and uncertain. (The concealment of the doctor's greater interest in the outcome of the experiment which had governed his decision to proceed in the face of the risks had played a separate legal role in tolling the statute of limitations for fraudulent concealment). The jury found in favor of M.I.T on the lack of consent claim as well as all other claims that had been brought against M.I.T.,

Motions filed shortly after the verdict by defendants Mass General and Sweet to eliminate or reduce the damages remained undecided for nearly a year. No final judgment had been rendered at the time (last summer) when Dr. Sweet and M.I.T. filed their suits against the United States seeking indemnification.

On September 29, 2000, the District Court judge in <u>Heinrich v. Sweet</u> issued judgment. With obvious regret, the judge agreed with an argument made by defendants Dr. Sweet and Mass General that the 1961 Massachusetts wrongful death statute in place at the time the BNCT claims arose governed the substantive rights of the parties and, accordingly, the jury's verdicts could not stand as to wrongful death and punitive damages. Under the applicable wrongful death statute, damages were not to exceed \$20,000 per defendant, Consistent with that decision, Heinrich's recovery for wrongful death was reduced to \$40,000, (\$20,000 each from Sweet and Mass General). Heinrich also retained the negligence award of \$250,000 as originally decided, for the total sum of \$290,000. Sienkewicz's recovery was likewise reduced to \$20,000 each from Sweet and Mass General plus the original negligence award of \$500,000, for a total sum of \$540,000. Both plaintiff's were also awarded statutory interest from the date of judgment and costs. The plaintiffs sought reconsideration of the reduction of the verdict; however, the judge reaffirmed the judgment in a one and a half line final order, now the final judgment, issued November 7, 2000.

Any appeal of the final decision or interlocutory decisions on which it was based will be due in the United States Court of Appeals for the First Circuit on January 8, 2001. 4

B. The MIT and Dr. Sweet Lawsuits for U.S. Indemnification Under Price Anderson

Notwithstanding that at the time of their filing there was no final judgment against any defendant in <u>Heinrich v. Sweet</u>, both plaintiffs sued the United States in the Court of Federal Claims based on that lawsuit. M.I.T. sued for indemnification from the legal costs that it had incurred in defending against the claims in <u>Heinrich v. Sweet</u>, which (as of June, 2000) it set as "presently in excess of one million (\$1,000,000.) M.I.T. also sought a declaratory judgment that M.I.T. has a right to be indemnified against the reasonable costs of investigating and defending against the claims already asserted and against any future public liability arising out of the BNCT clinical trials.

Dr. Sweet also brought suit for his alreadyincurred legal costs ("not less than \$336,498.96) and any future costs in defending against liability on any claim brought in consequence of the BNCT clinical trials at Brookhaven or MIT and for any amount for which be may be or may become liable in the <u>Heinrich</u> action or any potential lawsuit based on the BNCT clinical trials at either site. For example, there is already a lawsuit by an additional plaintiff, Oddo, alleging that his discovery of the basis of his claim was more recent and that therefore the statutory limitations period had not run. The federal district court refused to -

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consolidate the <u>Oddo</u> action with <u>Heinrich v. Sweet</u> because it came too late in those proceedings.

The Department of Justice (Civil Division, Commercial Branch), supported by OGC, is defending both lawsuits in the Claims Court. The government has filed answers to the Sweet and M.I.T. complaints. As an outcome of a status conference with the judge, the government soon will soon be filing a brief (due on December 22) with threshold arguments on Claims Court jurisdiction, exhaustion of administrative remedies, and the scope of coverage of the NRC's indemnification agreement with M.I.T..

*1131 C. Defenses

Our discussion here will not be exhaustive, but will present the main questions that likely will arise in the Claims Court lawsuits.

1 The Cases were Prematurely Brought to the Court of Federal Claims

JURISDICTION

As we have noted previously, at the time of filing there had been no judgment entered against M.I.T. or Dr. Sweet. Both plaintiffs sought declaratory judgments that the United States would be bound to indemnify them from any damages for which they would be held liable. However, relief in the form of declaratory judgment is generally unavailable in the Court of Federal Claims. Although specific money judgements were since entered in Heinrich, those judgments may soon become subject to appeals and cross-appeals in the United States Court of Appeals for the First Circuit, and thus are not yet final. Even aside from the actual money claims made by Dr. Sweet and M.I.T., there remain requests for declaratory judgments indemnifying Sweet and M.I.T. in future cases. It is highly doubtful that the Claims Court is empowered to render prospective relief of this kind.

EXHAUSTION

We are considering defenses based on the lack of exhaustion of administrative remedies. Because the NRC lacks a mandatory administrative process to seek indemnification and because Congress provided none, we cannot raise a failure to exhaust remedies as an absolute jurisdictional har, but it might be possible to persuade the Court that for prudential reasons it should send the plaintiffs first to the NRC with their indemnification claims. This would allow the Commission to pass on both the legal and factual sufficiency of the indemnification claims. This could prove a litigating advantage, ultimately, because reviewing courts likely would defer to reasonable Commission decisions.

Both plaintiffs seek legal fees in addition to payment of the judgments against them. However, the Commission has noted that under Section 170k of the Atomic Energy Act, as applicable at the time of the events at issue and today, legal fees are payable, if at all, only after the educational reactor licensee has paid out \$250,000 in "public liability" damages. See In the Matter of the Regents of the University of California at Los Angeles, CLI-97-6, 45 NRC 358, 363 n.3 (1997). 5 M.I.T. has given the Commission no representation that it has paid any damages at all, or that it is responsible for any such damages, let alone \$250,000 in public liability damages. By the applicable statutory terms, public liability damages do not include legal costs.

In any event, only legal fees "as are approved by the Commission" are payable, and none has been submitted for Commission approval. <u>See</u> Atomic Energy Act §170k(1), 42 U.S.C. § 2210(k)(1).

2. Merits Defenses

Our threshold and primary defense is that the Price-Anderson Act does not apply to either case at bar. This is so because the Price-Anderson Act is called into play as the result of a "nuclear incident," and injury from BNCT is not a "nuclear incident" under the Act. 6 We agree that Congress intended a broad definition of nuclear incident which would include all manner of intended and unintended accidents, malfunctions and the like resulting in radiological damage including expected or unexpected radiological harms from planned or unplanned events involved in the nuclear energy fuel cycle. Nonetheless, in our view, Congress never contemplated stretching the definition so far as to require government liability for harms directly attributable the diagnoses and prescriptions determined by physicians to be appropriate for their patients.

Unfortunately, our conclusion can be disputed under the Price-Anderson Act's wording by focusing on the word "occurrence" and assuming that its most minimal meaning, <u>i.e.</u>, anything and eventhing that takes place, is the controlling definition. Under that

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formulation, "nuclear incident" includes any radiological damage whatsoever, if it resulted from the hazardous properties of source, special nuclear or byproduct material.

On the other hand, the term "occurrence" can be understood to mean that something of an unusual or unexpected nature takes place. Under that understanding, for there to be a nuclear incident there must be something out of the routine. And the incident should be within the contemplation of the statute as a whole, which addressed the nuclear energy industry. Legislative history strongly suggests, and subsequent legal writers have stated, that the Joint Committee on Atomic Energy had in mind and the drafters of the Price-Anderson Act consistently used the word *1132 "incident" in the sense of "accident.". See, e.g., Trosten and England, "Waiving Defenses: A New Approach to Protecting the Public Against Financial Loss from Use of Atomic Energy," Fed. Bar J. 27:27:56 n.6, Winter (1967).

M.I.T. argues that it is indemnified by NRC from liability for any radiological harm where the radioactive materials come from its licensed reactor. We responded to M.I.T. from the outset that we would agree that the indemnification would be required if a patient undergoing treatment were harmed by a malfunction of the reactor, by the reactor's failing to deliver the prescribed dosage or some like incident related to the reactor's performance. On the other hand, just as the NRC has never believed that its regulatory role over radio-pharmaceuticals extends to a physician's diagnosis or prescribed therapeutic measures, we do not believe that our regulatory authority -- and with it our indemnification or liability -- should or was ever intended to cover, or insulate from responsibility, physicians within the close confines of the physician- patient relationship.

In persuading a court of the reasonableness of our position on the meaning of the statutory language we can muster support from the failure of the Congress ever to discuss medical treatment liabilities in the hundreds of pages of Price-Anderson legislative history and from the focus on accidents or unexpected harms from reactor operation, as well as from contemporaneous and later references to the Joint Committee on Atomic Energy's use of the word incident to avoid the use of the word "accident." We can also point to the overwhelming expressed conviction of the legislators that the likelihood of a qualifying incident was so small that the Act might never need to be called upon - - a position totally inconsistent with an interpretation that included the injurious results of medical mistake or malpractice. The enacting legislators' concerns over excessive exposure of the Federal treasury would have also been inconsistent with their extending coverage to any harm to patients resulting from medical use of radioactive materials. 7

Finally, there is some judicial support for our position that the Price-Anderson Act does not cover medical malpractice-type claims, but only radiation injuries arising out of the nuclear energy (fuel cycle) program. See, e.g., Acuna v. Brown & Root, Inc., 200 F.3d 335, 340 (5th Cir. 2000).

3. <u>Issues That Arise If It Is Found That There</u> <u>Was a Nuclear Incident</u>

The judge would have to grapple with many interesting and difficult questions which would arise in this case were she to accept plaintiffs' construction of "nuclear incident" as including anything that happened and resulted in radiological harm:

How many nuclear incidents are there? This matters in adhering to the statutory scheme because, for example, there is a \$250,000 threshold for liability payments (and \$500,000,000 liability limit) for each incident. We know of nothing in the Price-Anderson Act that would help elucidate how we or a court should analyze whether separate cases of medical error are for Price-Anderson purposes discrete incidents or a common incident.

As a technical matter, was the radiation that emanated from the M.I.T. reactor the cause of injury? According to Heinrich's district court complaint, unlike conventional radiation therapy, BNCT used an "allegedly benign external source of energy, slow neutrons, which become lethal only when captured by substances introduced into the tissues of the tumor." Thus, it may well be said that the injury was caused by the boron, or framed differently, that the benign external source of energy which were converted to the uses that caused the damage were not "hazardous properties" from which the Price-Anderson Act sought to protect the general public.

Are the damages for pain inflicted by boran injections away from the nuclear facility separable from the damages for the results of treatment at the

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M.I.T. reactor? If not, there will be considerable difficulty in determining to what extent they are payable under Price-Anderson.

These questions, and others, demonstrate that stretching the outer limits of the term "nuclear incident" to include the circumstances of the matters before us results in a "bad fit." This result supports our view derived from extensive review of the legislative records that Congress never contemplated this stretch and thus made no effort to address it.

D. Policy Considerations

As government lawyers, we understandably tend to defend vigorously against lawsuits demanding significant sums of money from the United States Treasury. The Commission, too, must be careful about authorizing expenditures of government money. See <u>Regents of the University of California</u>. CLI-97-6, 45 NRC at 362. This is especially true when we believe that a reasonable interpretation of the Atomic Energy Act precludes payment. Thus, the Commission did not hesitate to deny the University of California's request for legal fees under the Price-Anderson Act in CLI-97-6 *1133 based on our recommendation that the Act, reasonably read, did not permit such payments.

Here, though, as we suggested above, we cannot say that there is no ambiguity in the statutory language. While there are additional plaintiffs already seeking damages for BNCT, the total sums currently at stake would likely not exceed a few million dollars. And a concern could arise out of the NRC's seeming to back away from indemnification commitments -- <u>i.e.</u>, some might see a chilling effect on medical research. Moreover, it could be argued that because M.I.T. is the only reactor that currently holds an Atomic Energy Act 104 license for both research and operation for medical use, this type of case would be unlikely to arise again. In that light, one might consider that it would be better policy to acknowledge an obligation to indemnify and to seek the necessary appropriations from Congress.

We considered and rejected that approach. First, our review of the legislative record convinces us that Congress did not contemplate indemnification claims for medical malpractice-type claims. Second, the several million dollars potentially at stake here is not an insignificant amount. Third, M.I.T. is currently expecting to go forward with new and improved BNCT treatment, and we would be reluctant to put the agency in a position of acknowledging an obligation to indemnify if the results prove harmful not therapeutic. Finally, there are a number of Price-Anderson claims currently in litigation 8 and one of them is likely soon to cause the agency to demonstrate that Price-Anderson indemnification is real.

E. <u>Financial Considerations of how to Fund</u> Indemnification

As the Commission is aware, the Price Anderson Act does not require advance funding because the expectation was that a call on federal indemnification was highly unlikely and would happen only in the event of a catastrophic accident, often referred to as "2 runaway reactor," For large commercial reactors, government indemnity would not arise as a practical possibility unless there were such an accident, at least not so long as there remained a significant number of reactors to contribute to the retroactive premium pool. This, however, is not true for facilities for which the Commission required the purchase of low amounts of insurance or for educational reactors for which the statute waived any requirement for insurance. See Atomic Energy Act, §170k, 42 U.S.C. § 2210(k).

Legislative history of the 1988 amendments to the Act contains in floor debate an uncontradicted "clarification" by Senator Breaux oſ his "understanding...[of] the general agreement of the method of payment under [then] current law". S. Cong. Rec. 2336 (March 16, 1988). In brief, the agencies are authorized to pay out the sums before appropriations if sufficient operating funds are available. Alternatively, agencies could seek additional appropriations. "If Congress failed to make the necessary appropriation, the indemnified person could sue under the indemnity agreement, and any resulting final judgments against the United States would presumably be payable from the permanent judgment appropriation," *i.e.*, the "judgment fund. <u>ld</u>at 2337-2338.

Conclusion:

There is no action that the Commission need take at this time. We expect hearings on legislation to renew Price Anderson sometime next year. In that light, we intend to consult with NRR and NMSS whether it is advisable to recommending to the Commission that it consider possible additional recommendations or greater emphasis on its present ones.

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Footnotes:

1 BNCT is a medical therapy which uses boron injections to protect healthy tissue. The boron is expected to concentrate in cancerous tissues where it absorbs the beam of slow neutrons from the reactor. The resulting alpha-particle emissions are then expected to destroy the cancerous tissues while only minimal harm is done to healthy tissues outside the region of boron concentration.

2 The United States was involved in the case in the defense of two federal officials acting within the course of their duties. Neither NRC nor DOE was named as a defendant.

3 The claims of wrongful death and negligence were not that the radiation was <u>per se</u> wrong to deliver or delivered negligently in a physical sense, but rather that it was wrong or negligent for the radiation to have been delivered in light of the knowledge that it was highly unlikely that the painful process would improve the patients' condition or extend their lives.

An appeal, if any, ordinarily is due 30 days L after the entry of judgment except when the United States is a party when the appeal period is 60 days. Here the United States was a party, as substituted for the estates of the two AEC officials sued for their alleged negligence in supervision of the BNCT activity. The district court dismissed all claims against the United States on February 9, 2000. Heinrich v. Sweet, 83 F. Supp. 2d 214, 224 (D. Mass 2000.) The dismissal rested on the "an independent contractor defense" to Federal Tort Claims Act liability; i.e., the court found that AEC officials were not sufficiently dominant over the private defendants to be held liable. The Court stated that the BNCT "was not ... the result of detailed supervision or day-to -day control by the Commission." Id.

5 As a separate point, we have some doubt whether legal costs may be paid to "other parties indemnified" as distinguished from the licenseeoperator with whom an Indemnification Agreement is executed. We understand that DOE's position on this issue is that only its prime contractor, with whom it signs a contract of indemnification, is eligible to be paid its litigation costs in addition to indemnification for damages. We have not yet fully researched this issue, but are to date unaware of any reason to disagree with the DOE position, as we understand it. Moreover, on policy grounds, we would be reluctant to conclude that Congress intended to (or the NRC now should) undercut Price-Anderson's mechanism channeling all liability costs to the licensee. Channeling liability costs, designed to protect suppliers while assuring funds for public damages no matter how an accident was caused, was also expected to simplify *1133 litigation and control legal costs. Encouraging each separate defendant to retain separate counsel by making the retainer cost-free would impede such important goals.

6 Section 11, the definitions section of the Atomic Energy Act, defines nuclear incident, in relevant part, to mean "any occurrence, including an extraordinary nuclear occurrence, within the United States causing, within or outside the States, bodily injury, sickness, disease, or death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic explosive, or other hazardous properties of source, special nuclear, or byproduct material..." 42 U.S.C. § 2014q.

It is true that the existing categories of indemnity agreements do not include medical uses, and M.I.T. is the only reactor operator with an Atomic Energy 104a license (permitting reactor operation for use in medical therapy). Nonetheless, the Commission arguably had discretion from the outset to designate additional categories of facilities for financial protection requirements and indemnification. Only later, in the 1988 Price-Anderson amendments, did Congress actually require the Commission to consider whether to indemnify medical uses of radioactive materials. But even at that time the nature of the indemnity under NRC consideration was for the possession and fabrication of nuclear materials for medical uses and not indemnification of errors of medical practitioners in diagnostic or prescription. As the Commission is aware, it did not in the end extend cover to any medical uses.

8 There are no other cases that we know of where the United States or NRC is a named defendant, However, there are several cases pending where indemnified licensees may seek indemnification from NRC. For example, in Hall v. Babcock & Wilcox . No. 94-0951 (W.D. Pa.) a public liability action alleges damages from a nuclear hazard that was discharged from an indemnified facility. See also Neil, et al. v. Boeing North American, et al. No. 99-08264 (C. D. Cal.) (claim against among others, defendants Rockwell International and Rocketdyne, for nuclear hazards from wrongly disposed wastes from their facility licensed and indemnified by NRC, as successor to AEC.). Tokerud v. Pacific Gas and Electric, No. C-98-1409 CW (N.D. Cal.) (claims of

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injury to former employee at Vallecitos, a licensed and indemnified test reactor.) DOJ has advised that it cannot spare counsel to follow these cases or to take over the defense when the expenses would exceed the amount that triggers indemnity. Accordingly, they are all in the hands of private counsel.

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