

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION**

**BECKY COUDERT, on behalf of herself)
and all others similarly situated,)
)
Plaintiff,)
)
v.)
)
GE HEALTHCARE, INC., a Delaware)
corporation; GE HEALTHCARE)
TECHNOLOGIES, INC., a Wisconsin)
corporation, GE HEALTHCARE IITS)
LLC, a Delaware corporation and GE)
HEALTHCARE IITS USA CORP, a)
Vermont corporation,)
)
Defendants.)**

CASE NO.: _____

CLASS ACTION COMPLAINT

COMES NOW, Becky Coudert, Plaintiff in the above-styled action, on behalf of herself and all others similarly situated, files her Complaint against GE Healthcare, Inc., a Delaware corporation, GE Healthcare Technologies, Inc., a Wisconsin Corporation, GE Healthcare IITS LLC, a Delaware corporation, and GE Healthcare IITS USA Corp., a Vermont corporation, and, in support thereof, states as follows:

INTRODUCTION

Becky Coudert brings this action on behalf of herself and a class of similarly-situated persons who have received doses of excessive radiation as a result of brain scans performed using equipment manufactured by the Defendants. The scans caused immediate physical injuries and latent injuries and have resulted in a need for medical monitoring to check for brain cancer or other serious conditions which may develop as a result. Ms. Coudert and the Putative Class seek compensatory damages necessary to establish a fund from which payments for continuing

medical monitoring and compensatory awards may be granted, under Court supervision, together with damages, restitution, declaratory and injunctive relief, attorneys' fees, costs and expenses.

PARTIES

1. Becky Coudert is an individual, residing at all relevant times in Huntsville, Madison County, Alabama.

2. At all times material hereto, Defendant, GE Healthcare Technologies, Inc., a business unit of General Electric Company, was and is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its global headquarters located in Chalfont St. Giles, Buckinghamshire, United Kingdom. At all times material to this action, Defendant GE Healthcare Technologies, Inc., was and is a primary business unit of GE Healthcare, Inc., with its business headquarters located in Waukesha, Wisconsin. At all times material to this action, Defendant GE Healthcare IITS, LLC, was and is a primary business unit of GE Healthcare, Inc., with its business headquarters located in Barrington, Illinois. At all times material to this action, Defendant GE Healthcare IITS USA Corp. was and is a primary business unit of GE Healthcare, Inc., with its business headquarters located in Burlington, Vermont. Plaintiff is informed and believes and based thereon alleges that GE Healthcare Technologies, Inc., is a wholly owned subsidiary and operating division of Defendant GE Healthcare, Inc., and was and is authorized to do business and was engaged in business in the County of Madison, State of Alabama. All Defendants are collectively referred to as "Defendants" for purposes of the allegations laid out below.

3. Defendants includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors,

successors, and assigns, and their present officers, directors, employees, agents, representatives, and other persons acting on their behalf.

JURISDICTION AND VENUE

4. Plaintiffs repeat and re-allege paragraphs 1 through 3.

5. This class action is filed on behalf of citizens of all states in which Defendants conduct business pursuant to FED.R.CIV.P. 23. There is diversity between the citizenship of many in the putative class and Defendants. The amount in controversy, as pled *infra*, exceeds \$5,000,000.00, exclusive of interest and costs. Hence, this Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d).

6. This Court has supplemental jurisdiction over Plaintiff's state claims pursuant to 28 U.S.C. § 1367(a).

7. Plaintiff seeks declaratory relief pursuant to 28 U.S.C. § 2202 and FED.R.CIV.P. 57 and injunctive relief pursuant to 28 U.S.C. § 2202 and FED.R.CIV.P. 65.

8. Venue lies with this Court pursuant to 28 U.S.C. § 1391(b)(2) as this is the judicial district which the events occurred that gave rise to the causes of action pled below.

FACTS COMMON TO ALL COUNTS

9. Plaintiffs repeat and re-allege paragraphs 1 through 8.

10. Under normal circumstances, a head CT scan is generally painless, non-invasive, and accurate. However, there is a risk of developing cancer from excessive exposure to radiation. The effective radiation from a CT scan is usually about 1 to 2 millisievert (mSv), equivalent to the background radiation dose the average person receives over four to six months. The risk of developing a brain tumor or other cancer from this radiation exposure is generally not a major health concern.

11. The CT machines manufactured and sold by Defendants comprise a medical imaging technology employing tomography, or imaging by sections or sectioning. Computed tomography (CT or CAT scan) is a diagnostic imaging procedure that uses a combination of x-rays and computer technology to produce cross-sectional scans or "slices," both horizontally and vertically, of the human body.

12. CT scans are more detailed than a standard x-ray. In computed tomography, the x-ray beam moves in a circle around the body. This allows many different views of the same organ or structure, and provides much greater detail. The x-ray information is sent electronically to a computer, which interprets the x-ray data and displays it in a two-dimensional form on a monitor. CT has become an important tool in medical imaging to supplement x-rays and medical ultrasonography. CT scanning of the head is typically used to detect, among other things, bleeding, brain injury and skull fractures, aneurysm, strokes, a blood clot or bleeding within the brain after a patient exhibits symptoms of a stroke, and brain tumors.

13. The medical devices at issue in this litigation are CT imaging machines that were researched, developed, designed, formulated, fabricated, tested, manufactured, produced, processed, assembled, inspected, marketed, labeled, promoted, packaged, advertised for sale, sold or otherwise placed into the stream of commerce by Defendants.

14. Defendants, and each of them, knew and/or intended that the CT imaging equipment manufactured by Defendants would be used to assist a physician in the treatment of a patient's condition, and specifically for the diagnosis of human illness, including the diagnosis of stroke or other brain-related disease, and that patients would be exposed to radiation in the course of the radiological procedures.

15. On or about October 9, 2008, the U.S. Food and Drug Administration ("FDA") released a notification to healthcare professionals indicating that it had become aware of radiation overexposures during perfusion CT imaging performed to aid in the diagnosis of stroke. The FDA notice stated that, for an 18 month period, beginning in February, 2008, 206 patients had received radiation doses that were approximately eight times the expected level. Instead of receiving the expected dose of 0.5 Gy (maximum) to the head, these patients received 3-4 Gy. The FDA further indicated that "the magnitude of these overdoses and their impact on affected patients were significant."

16. The FDA further indicated that it had commenced a safety investigation, suggesting that the situation may reflect more widespread problems with CT quality assurance programs. A nationwide alert was issued by the FDA warning hospitals to check CT brain scan procedures.

17. Due to either the lack of appropriate safety functions, confusing methodology, or some other cause, the machines in question have emitted a much higher level of radiation than was either intended or is reasonably safe.

18. The radiation exposure which results is a proven hazardous substance inasmuch as same is a known carcinogen.

19. The exposure to a greater level of radiation than was intended results in a significantly-increased risk of contracting a serious, latent disease, namely brain cancer.

20. Further, a monitoring procedure exists that makes early detection of brain cancer possible. This monitoring procedure is different from the regime normally recommended in the absence of significant radiation exposure to the head.

21. The brain cancer monitoring regime is reasonably necessary in light of significant radiation exposure according to contemporary scientific principles.

NAMED PLAINTIFF ALLEGATIONS

22. Plaintiffs repeat and re-allege paragraphs 1 through 21.

23. On September 8, 2009, Ms. Coudert received a CT brain perfusion scan at Huntsville Hospital to determine if she had suffered a stroke. The scan was performed by employees of Huntsville Hospital using equipment manufactured by the Defendants.

24. As a result of the scan, Ms. Coudert's hair immediately began to fall out, and, according to experts' present understanding, the genetic material of her brain cells was immediately damaged.

25. Either due to the lack of appropriate safety functions, confusing methodology, or some other cause Ms. Coudert was subject to a scan which emitted a much higher level of radiation than was either intended or is reasonably safe.

26. The radiation to which Ms. Coudert was exposed is a proven hazardous substance inasmuch as same is a known carcinogen.

27. As a proximate result of the exposure to a greater level of radiation than was intended due to Defendants negligence and/or other behavior, Ms. Coudert has a significantly-increased risk of contracting a serious, latent disease, namely brain cancer.

28. A monitoring procedure exists that makes early detection of brain cancer and/or related diseases possible. Further, the monitoring procedure is different from the regime normally recommended in the absence of significant radiation exposure to the head.

29. The monitoring regime is reasonably necessary in light of significant radiation exposure according to contemporary scientific principles.

CLASS ACTION ALLEGATIONS

30. Plaintiffs repeat and re-allege paragraphs 1 through 29.

31. Pursuant to FED.R.CIV.P. 23, Ms. Coudert brings this action on behalf of herself and a class of persons (hereinafter the "Plaintiff Class") defined as:

All individuals who received CT brain perfusion scans utilizing imaging machines manufactured by Defendants during the two year period preceding this action.

32. Ms. Coudert and the Plaintiff Class are hereinafter referred to jointly as "Plaintiffs."

33. Plaintiffs are unable to state the precise number of potential members of the Plaintiff Class because that information is exclusively in the possession of Defendants. The exact size of the Plaintiff Class, and the identity of the members thereof, would be readily ascertainable from the records of Defendants. It is believed to be in the thousands.

34. Questions of law and fact common to the Plaintiff Class exist that predominate over questions affecting only individual members, including, *inter alia*, the following:

- Whether the CT imaging machines which delivered a greater-than-normal level of radiation to Plaintiffs were negligently designed or manufactured.
- Whether the CT imaging machines which delivered a greater-than-normal level of radiation to Plaintiffs were accompanied by inadequate warnings.
- Whether the CT imaging machines which delivered a greater-than-normal level of radiation to Plaintiffs were accompanied by inadequate instruction.
- Whether the CT imaging machines which delivered a greater-than-normal level of radiation to Plaintiffs were equipped with inadequate safety features.

- Whether the level of radiation exposure experienced by the Plaintiffs was greater than the level of radiation typically administered when performing the test in question.
- Whether, and to what extent, Plaintiffs have a significantly-increased risk of contracting brain cancer or other serious latent disease as a result of exposure of high levels of radiation.
- Whether, and to what extent, a monitoring procedure exists which would make brain cancer or other serious, latent disease detectable.
- Whether, and to what extent, the equipment manufactured by Defendants breached both express and implied warranties covering same.
- Whether Defendants knew or should have known of the problems associated with the equipment at issue.

35. The claims asserted by Ms. Coudert in the action are typical of the claims of the members of the Plaintiff Class as described above, the claims arise from the same course of conduct by Defendants and the relief sought is common.

36. Ms. Coudert will fairly and adequately represent and protect the interests of the members of the Plaintiff Class. Ms. Coudert has retained counsel competent and experienced in both consumer protection and class action litigation.

37. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable. Furthermore, because the economic damages suffered by the individual class members may be relatively modest, albeit significant, compared to the expense and burden of individual litigation, it would be impracticable for most Plaintiff Class members to seek redress individually for the wrongful

conduct alleged herein. There will be no real difficulty in the management of this litigation as a class action.

**FIRST CAUSE OF ACTION
(Product Liability)**

38. Plaintiffs repeat and re-allege paragraphs 1 through 37.

39. At all times relevant to this action, Defendants were engaged in the business of researching, developing, designing, formulating, fabricating, testing, manufacturing, producing, processing, assembling, inspecting, marketing, labeling, promoting, packaging, advertising for sale, selling or otherwise placing into the stream of commerce computed tomography ("CT") machines, and/or their component parts, within the State of California and throughout the United States and Canada.

40. At all times mentioned herein, the officers and/or directors of Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of CT imaging machines, and thereby actively participated in the tortuous conduct which resulted in the injuries described herein.

41. The aforementioned Defendants' CT imaging machines and their component parts were defective and unreasonably dangerous in design and manufacture, in that, among other things, said devices, utilize x-rays and risk patient exposure to radiation, and that such devices can, if improperly calibrated, maintained or monitored, expose patients to excessive levels of radiation, potentially causing serious injury and illness.

42. The aforementioned Defendants' CT imaging machines and their component parts failed to contain adequate or proper warning concerning the defective condition, characteristics, and health risks associated with said products, including, but not limited to, the severity,

incidence and duration of such adverse health effects as set forth in the preliminary paragraphs of this Complaint.

43. Defendants, and each of them, knew that CT imaging machines would be used and that CT imaging services would be purchased by patients without inspection for defects in the CT imaging machine, or in any of its components, as to design, manufacture, and warnings.

44. CT imaging machines designed, manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warnings or instructions, because the Defendants knew or should have known of the risks of injury or serious bodily harm from CT imaging machines, but failed to provide adequate warnings to healthcare professionals or patients and continued to promote the use of such devices.

45. The Defendants, and each of them, knew or should have known of the defective condition, characteristics, and risks associated with CT imaging machines, as set forth in the preliminary paragraphs of this Complaint.

46. Plaintiffs did not know, or have reason to know, prior to the use of the aforementioned CT imaging machines, of the defective condition of the products.

47. As a further direct, proximate and legal result of the negligence of Defendants and each of them as alleged herein, Plaintiffs have incurred and will continue to incur medical, hospital and related expenses, including the costs of medical monitoring, all to her special damage according to proof at trial.

48. As a further direct and proximate result of the acts and omissions of the Defendants, and each of them, Plaintiffs have sustained and will in the future sustain loss of earnings, loss of earning capacity, and other economic damages according to proof at the time of trial.

49. As a further direct and proximate result of the acts and omissions of the Defendants, and each of them, Plaintiffs have suffered and will continue to suffer severe and serious physical and emotional damage in an amount to be ascertained according to proof at the time of trial and in excess of the jurisdictional limit of this Court.

50. Accordingly, Plaintiffs seek and are entitled to damages in an amount to be determined at trial.

**SECOND CAUSE OF ACTION
(Negligence)**

51. Plaintiffs repeat and re-allege paragraphs 1 through 37.

52. At all times mentioned herein, Defendant, and each of them, had a duty to properly research, design, formulate, test, manufacture, produce, process, assemble, inspect, market, label, distribute, prepare for use, sell, and adequately warn of the risks and dangers of CT medical imaging machines, including a duty to assure that such devices did not cause patients receiving CT scans, including CT brain perfusion scans, to suffer from unreasonable and dangerous health risks and exposure to possible harm, loss or injury.

53. At all times mentioned herein, Defendants, and each of them, failed to exercise ordinary care and negligently and carelessly researched, designed, formulated, tested, manufactured, produced, processed, assembled, inspected, marketed, labeled, distributed, prepared for use, sold, rented, leased, maintained, and repaired and failed to adequately test, research, and warn of the risks and dangers of CT imaging machines.

54. At all times mentioned herein, Defendants, and each of them, breached their duty to Plaintiffs, and were negligent in researching, designing, formulating, testing, manufacturing, producing, processing, assembling, inspecting, marketing, labeling, distributing, preparing for

use, selling, renting, leasing, maintaining, and repairing, and failing to adequately warn of the risks and dangers of CT imaging machines in that the Defendants:

- a. Failed to use ordinary care in designing and manufacturing CT imaging machines so as to avoid the aforementioned health risks to Plaintiffs;
- b. Failed to accompany CT imaging machines with proper warnings regarding the possible adverse health effects associated with the use of such machines and of the severity and duration of such possible adverse effects;
- c. Failed to conduct adequate pre-clinical testing and post-marking surveillance to determine the safety and side effects of CT scans, including, among other things, CT brain perfusion scans;
- d. Failed to provide adequate training to physicians, medical technicians, and other health care providers as to the possible adverse health effects associated with the use of CT scans, including, among other things, CT brain perfusion scans, and the severity and duration of such adverse effects;
- e. Failed to warn Plaintiffs, either directly or indirectly, orally or in writing, about the need for regular monitoring and maintenance of CT scanners to ensure early detection of potentially serious health effects, such as excessive radiation exposure;
- f. Failed to adequately test and/or warn about the possible serious health effects of CT scans, including excessive patient exposure to radiation;
- g. Failed to include or provide adequate warnings about CT scans that would alert Plaintiffs, class members, physicians, medical technicians, hospitals, and clinics,

to the potential risks, and the nature, scope, severity, and duration of any serious health effects of CT scans, including CT brain perfusion scans;

- h. Continued to promote the desirability and safety of CT scans, including CT brain perfusion scans, while providing little or no warnings about the serious injuries and health risks associated with CT scans, including CT brain perfusion scans, which may have dissuaded physicians and other medical providers from monitoring patient exposure to excessive radiation levels.
- i. Delayed warnings of and then failed to provide adequate warnings about the serious injuries and health risks associated with CT scans, including CT brain perfusion scans, which may have dissuaded physicians and other medical providers from monitoring patient exposure to excessive radiation levels.

55. As a further direct, proximate and legal result of the negligence of Defendants and each of them as alleged herein, Plaintiffs have incurred and will continue to incur medical, hospital and related expenses, including the costs of medical monitoring.

56. As a further direct and proximate result of the acts and omissions of the Defendants, and each of them, Plaintiffs have sustained and will in the future sustain loss of earnings, loss of earning capacity, and other economic damages according to proof at the time of trial.

57. As a further direct and proximate result of the acts and omissions of the Defendants, and each of them, Plaintiffs have suffered and will continue to suffer severe and serious physical and emotional damage in amount to be ascertained according to proof at the time of trial and in excess of the jurisdictional limit of this court.

THIRD CAUSE OF ACTION
(Breach of Express Warranty)

58. Plaintiffs repeat and re-allege paragraphs 1 through 37.

59. At all times mentioned herein, Defendants, and each of them, expressly warranted to Plaintiffs, and to their agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and/or in publications, package inserts, or other written materials intended for use by physicians, medical technicians, patients and the general public, that the aforementioned CT imaging machines were safe, effective, and proper for their intended use, throughout the course of that use by physicians, medical technicians, and patients.

60. In utilizing the aforementioned products, Plaintiffs relied on the skill, judgment, representations and foregoing express warranties of the Defendants, and each of them. Said warranties and representations were false in that the aforementioned CT imaging machines were not safe and were unfit for the use for which they were intended.

61. As a direct, proximate and legal result of the foregoing breach of express warranties by the Defendants, and each of them, Plaintiffs have incurred and will continue to incur medical, hospital and related expenses, including the costs of medical monitoring, all to their special damage according to proof at trial.

62. As a further direct and proximate result of the acts and omissions of the Defendants, and each of them, Plaintiffs have sustained and will in the future sustain loss of earnings, loss of earning capacity, and other economic damages according to proof at the time of trial.

63. As a further direct and proximate result of the acts and omissions of the Defendants, and each of them, Plaintiffs have suffered and will continue to suffer severe and

serious physical and emotional damage in amount to be ascertained according to proof at the time of trial.

FOURTH CAUSE OF ACTION
(Breach of Implied Warranty)

64. Plaintiffs repeat and re-allege paragraphs 1 through 37.

65. Prior to the time that the aforementioned CT imaging machines were utilized on Plaintiffs, Defendants, and each of them, impliedly warranted to Plaintiffs and to their agents and physicians that said products were of merchantable quality and safe and fit for the use for which it was intended.

66. Plaintiffs were and are unskilled in the research, design, and manufacture of CT imaging machines, and reasonably relied entirely on the skill, judgment, and implied warranty of the Defendants in researching, designing, manufacturing, and marketing the aforementioned products.

67. The CT imaging machines manufactured and sold by Defendants were neither safe for their intended use nor of merchantable quality as warranted by Defendants, in that they had dangerous propensities when put to their intended use and would cause serious injuries to the patient undergoing CT scans.

68. As a direct, proximate and legal result of the foregoing breach of implied warranties by the Defendants, and each of them, Plaintiffs have incurred and will continue to incur medical, hospital and related expenses, including the costs of medical monitoring, all to his special damage according to proof at trial.

69. As a further direct and proximate result of the acts and omissions of the Defendants, and each of them, Plaintiffs have sustained and will in the future sustain loss of

earnings, loss of earning capacity, and other economic damages according to proof at the time of trial.

70. As a further direct and proximate result of the acts and omissions of the Defendants, and each of them, Plaintiffs have suffered and will continue to suffer severe and serious physical and emotional damage in amount to be ascertained according to proof at the time of trial.

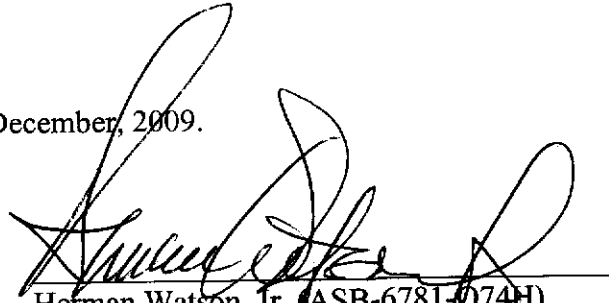
RELIEF REQUESTED

WHEREFORE, Plaintiffs pray that the Court:

1. Determine that this action is properly maintained as a Class Action pursuant to FED.R.CIV.P. 23(a) and (b)(2) and/or (b)(3);
2. Declare that Defendants acted negligently and that the equipment it manufactured at issue breached both express and implied warranties and/or the equipment was negligently designed and/or manufactured, was accompanied by inadequate safety warning, was accompanied by inadequate safety features or was accompanied by inadequate and overly-complicated instructions.
3. Award damages to Plaintiffs against Defendants for the creation of a fund which would pay for future medical monitoring of the members of the Putative Class and for the payment of damages in the event a member of the Putative Class should develop a compensable injury;
4. Enter an injunction directing Defendants to maintain the fund referenced above in a constructive trust with the Court to retain ultimate jurisdiction over same to oversee the payment of medical bills associated with continued medical monitoring and payment of compensable claims.

5. Award such other, further and different relief, including equitable, that the Court deems just and proper.

Submitted this the 15 day of December, 2009.



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