



1-1-2011

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Recommended Citation

Christopher Braniff, *Chapter 521: Overexposed: Radiology Errors Lead to Harm from CT Scans*, 42 MCGEORGE L. REV. (2016).

Available at: <https://scholarlycommons.pacific.edu/mlr/vol42/iss3/18>

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Chapter 521: Overexposed: Radiology Errors Lead to Harm from CT Scans

Christopher Braniff

Code Sections Affected

Health and Safety Code §§ 115111, 115112, 115113 (new).
SB 1237 (Padilla); 2010 STAT. Ch 521.

I. INTRODUCTION

Fearing a potential stroke, Michael Heuser visited Cedars-Sinai Medical Center in Los Angeles.¹ His doctor ordered a computed tomography (CT) examination, a common tool used to diagnose potential stroke victims.² As part of the examination, doctors injected Michael with an iodine solution while a series of X-rays created a detailed image of how blood flowed to Michael's brain.³ Not long after this examination, Michael began experiencing new symptoms: reddened skin and sudden hair loss.⁴ A subsequent investigation revealed that each CT scan had mistakenly administered eight times the intended dosage of radiation,⁵ causing Michael to receive the equivalent radiation of approximately 50,000 chest X-rays.⁶

Investigators traced the problem back to an error made when the hospital reconfigured their CT examination machine to improve image quality eighteen months earlier.⁷ Because every scan performed by an examination contained its own set of computerized instructions, the error made by Cedars-Sinai staff was repeated a number of times.⁸ Thus, from February 2008 until October 2009, 206

1. See Alan Zarembo, *Senate Approves Bill on CT Scans: Measure is Aimed at Preventing Errors in Radiation Doses*, L.A. TIMES, May 29, 2010, at A4 (noting that Heuser went to the hospital for a CT brain scan, commonly used to detect strokes).

2. *Id.*

3. See Alan Zarembo, *Cedars-Sinai is Investigated in 206 Radiation Overdoses*, L.A. TIMES, Oct. 10, 2009, at A3 (explaining the CT scan procedure).

4. Press Release, Senator Alex Padilla, Senate Health Committee Supports Padilla Bill to Prevent Radiation Overdoses (Apr. 21, 2010), available at http://dist20.casen.govoffice.com/index.asp?Type=B_PR&SEC={5EACFA15-EA6B-41D8-9711-C030F9FAD5EE}&DE={7AFB8AD0-79AD-4A75-9188-FE8CA689FFE5} [hereinafter Padilla Press Release] (on file with the *McGeorge Law Review*).

5. Alan Zarembo, *Hospital Error Leads to 206 Radiation Overdoses*, L.A. TIMES, Oct. 13, 2009, at A3.

6. Padilla Press Release, *supra* note 4.

7. Zarembo, *Hospital Error Leads to 206 Radiation Overdoses*, *supra* note 5 (explaining that it is not uncommon for radiologists to override the instructions that come pre-programmed by the manufacturer); see also Walt Bogdanich, *After Stroke Scans, Patients Face Serious Health Risks*, N. Y. TIMES, July 31, 2010, at A1 (noting that officials "intentionally used high levels of radiation to get clearer images . . .").

8. Bogdanich, *supra* note 7. The CT scanners used at Cedars-Sinai had a feature that automatically adjusted the dose of radiation depending on the patient's size and the body part being scanned. Instead of using

patients received an overdose of radiation.⁹ Other hospitals around the country have also reported radiation overdoses due to their CT scanners.¹⁰

Chapter 521 addresses the problem of accidental radiation overdose by changing requirements in the Health and Safety Code relating to CT examinations.

II. LEGAL BACKGROUND

Medical imaging is a common tool in the diagnosis of many types of diseases.¹¹ Greater use of medical imaging has led to an increase in both the amount of radiation patients are exposed to and the errors associated with administering such examinations.¹²

A. Radiation from Medical Imaging is on the Rise

Between 1981 and 2006, the average annual effective dose of ionizing radiation¹³ received by Americans has nearly doubled.¹⁴ Ionizing radiation can damage DNA and cause cancer.¹⁵ This increase is due almost entirely to the increase of medical imaging procedures.¹⁶ The average amount of radiation Americans receive from medical imaging procedures is seven times greater than it was in 1980¹⁷ and accounts for forty-eight percent of all exposure to ionizing radiation.¹⁸

a predetermined radiation level for their CT examinations, technicians used this automatic feature, which inadvertently raised the dose of radiation administered by eight times. *Id.*

9. Zarembo, *Hospital Error Leads to 206 Radiation Overdoses*, *supra* note 5. By May 2010, there were more than 260 confirmed cases of over-radiation. Zarembo, *Senate Approves Bill on CT Scans*, *supra* note 1.

10. Alan Zarembo, *FDA Addresses Radiation Safety*, L.A. TIMES, Feb. 10, 2010, at A10.

11. Barry F. Wall, *Ionising Radiation Exposure of the Population of the United States: NCRP Report No. 160, 136 RADIATION PROTECTION DOSIMETRY 136 (2009)* (discussing a recent report published by the National Council on Radiation Protection and Measurement).

12. *See id.* (explaining that the use of medical imaging has increased the exposure of radiation among the U.S. population).

13. DOUGLAS C. GIANCOLI, *PHYSICS FOR SCIENTISTS AND ENGINEERS WITH MODERN PHYSICS 1100* (3d ed. 2000). The average annual effective dose of ionizing radiation is the amount of ionizing radiation an average American is exposed to over the course of a year. *Id.* Ionizing radiation is radiation that can ionize atoms or molecules and thus cause significant damage to biological tissue. *Id.*

14. Wall, *supra* note 11, at 136 (noting an increase by a factor of 1.7).

15. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMIN., *INITIATIVE TO REDUCE UNNECESSARY RADIATION EXPOSURE FROM MEDICAL IMAGING 3* (2010), available at <http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/UCM200087.pdf> [hereinafter FDA REPORT] (on file with the *McGeorge Law Review*).

16. Wall, *supra* note 11, at 136.

17. Walt Bogdanich, *Radiation Offers New Cures, and Ways to Do Harm*, N.Y. TIMES, Jan. 24, 2010, at A1.

18. Wall, *supra* note 11, at 136.

The single largest contributor of medical imaging radiation is the CT examination, accounting for half of all medical exposures.¹⁹ A single CT examination may result in a patient receiving the equivalent amount of radiation as 100 chest x-rays, depending on the type of scan administered.²⁰ In 2006, sixty-two million Americans received CT examinations, which have increased ten percent annually over the past two decades.²¹

B. Errors Leading to Overdose of Radiation

According to the U.S. Food and Drug Administration (FDA), medical imaging should only expose a patient to the minimum radiation “necessary to produce a high-quality image.”²² “[S]oftware flaws, faulty programming, poor safety procedures or inadequate staffing” can all lead to accidental overdoses.²³ Newer CT machines might display the radiation dosage administered, but most devices do not warn when a radiation dose exceeds safe levels.²⁴ Although the CT machines at Cedars-Sinai hospital displayed the dosage of radiation administered on a computer screen during each examination, operators failed to take notice.²⁵ Because the hospital failed to save record of the radiation dosage, the completed examination contained no record that patients had been overdosed.²⁶

Determining how often radiotherapy accidents occur is difficult.²⁷ Accidents often go unreported.²⁸ Years may pass after a patient is exposed to an overdose of radiation before cancer or organ damage becomes apparent.²⁹ One study estimated that as many as 29,000 future cancers could be related to CT examinations performed in the United States in 2007.³⁰

In October 2009, the FDA issued a warning against overexposure to radiation from CT scans and recommended that medical service providers carefully monitor the dosage of radiation received during an examination.³¹

19. *Id.* at 137.

20. FDA REPORT, *supra* note 15, at 3.

21. Wall, *supra* note 11, at 137.

22. FDA REPORT, *supra* note 15, at 2.

23. Bogdanich, *Radiation Offers New Cures*, *supra* note 17.

24. FDA REPORT, *supra* note 15, at 6.

25. Alan Zarembo, *Hospital Error in Plain Sight: Cedars-Sinai Workers Didn't Notice CT Scans' High Radiation Dosage*, L.A. TIMES, Oct. 14, 2009, at A1.

26. *Id.*

27. Bogdanich, *Radiation Offers New Cures*, *supra* note 17 (“Regulators and researchers can only guess how often radiotherapy accident occur. With no single agency overseeing medial radiation, there is no central clearinghouse of cases.”).

28. *Id.*

29. *Id.*

30. Amy Berrington de Gonzalez et al., *Projected Cancer Risks from Computed Tomographic Scans Performed in the United States in 2007*, 169 ARCHIVES OF INTERNAL MEDICINE 2071, 2074 (2009).

31. U.S. FDA, SAFETY INVESTIGATION OF CT BRAIN PERFUSION SCANS: INITIAL NOTIFICATION,

III. CHAPTER 521

Starting July 1, 2012, Chapter 521 requires hospitals and clinics to measure and record the dosage of radiation received by patients during CT scans.³² Hospitals and clinics must electronically archive each dosage and include it in a radiology report.³³ In addition, this legislation requires a medical physicist to annually verify that the dosage displayed by CT machines is within twenty percent of the true measured value.³⁴

Chapter 521 further requires hospitals and clinics to notify the patient, the referring physician, and the State Department of Public Health when certain errors have occurred.³⁵ Such errors include when an equipment defect or failure has caused a CT scan to be repeated, when the wrong patient or body part has been irradiated, and when the administered dose exceeds established protocols.³⁶

Beginning July 1, 2013, Chapter 521 also requires that “facilities that furnish CT X-Ray services shall be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting agency approved by the Medical Board of California, or the State Department of Public Health.”³⁷

IV. ANALYSIS

A. *Improving the Quality of Care through Accreditation Standards*

Chapter 521 will likely reduce the number of accidental overdoses of radiation by recording the amount of radiation received by patients during CT examinations. The Consumer Federation of California, a supporter of the legislation, noted that catching overdose errors from CT examinations was nearly impossible prior to Chapter 521 because such errors were difficult to detect.³⁸ The radiologists who administered Michael Heuser’s CT examination, for example,

available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm193293.htm> (last visited Jan. 16, 2010) (on file with the *McGeorge Law Review*).

32. CAL. GOV’T CODE § 115111(a) (enacted by Chapter 521). Chapter 521 provides that “dose of radiation shall be defined as one of the following: (1) The computer topography index volume . . . and dose length product . . . , as defined by the International electromechanical Commission . . . and recognized by the federal Food and Drug Administration [Or] (2) The dose unit as recommended by the American Association of Physicists in Medicine.” *Id.* § 115111(f)(1)-(2) (enacted by Chapter 521).

33. *Id.* § 115111(b) (enacted by Chapter 521).

34. *Id.* § 115111(c) (enacted by Chapter 521).

35. *Id.* § 115113(a)-(b) (enacted by Chapter 521).

36. *See id.* § 115111(a)(1)-(6) (enacted by Chapter 521) (listing circumstances when reporting is mandated).

37. *Id.* § 115112 (enacted by Chapter 521).

38. Consumer Federation of California, *CFC Supports SB 1237 (Padilla)—Monitoring of Overradiation*, <http://www.consumerfedofca.org/article.php?id=1319> (last visited Jan. 16, 2010) (on file with the *McGeorge Law Review*).

might have caught the error if he or she had recorded the dosage of radiation administered in the radiology report.³⁹

By requiring hospitals that perform CT examinations to be accredited by one of several organizations,⁴⁰ Chapter 521 will bring oversight of such imaging in line with national trends.⁴¹ Current federal law requires healthcare facilities seeking reimbursement for Medicare patients to meet established quality and accreditation standards.⁴² Physicians and scholars have noted that the accreditation and measurement required under federal law has been successful at improving the quality of patient care.⁴³ Because Chapter 521 adopts these same accreditation standards, patient health is likely to improve.⁴⁴

B. Changes to Machine Manufacture May Better Prevent Accidental Overdoses

Some opponents of Chapter 521 fear that it does not go far enough to fix the problem.⁴⁵ For example, Dr. Thomas Dehn, the chief medical officer for National Imaging Associates Incorporated, a private healthcare plan manager, suggests that the fixes required by Chapter 521 cannot correct for human error.⁴⁶ Because technicians are already trained to observe the dosage levels administered during a CT examination, requiring the dosage to be recorded and included in the radiology report will do little to prevent negligent technicians from doing harm.⁴⁷

Others, such as Dr. Jeffery Shuren, director of the Center for Devices and Radiological Health, suggests that the greatest cause of accidental overdoses of radiation is the machines themselves.⁴⁸ In a letter to CT machine manufacturers, Dr. Shuren cites software problems as the greatest cause of errors.⁴⁹ Such a software problem, according to a statement by Cedars-Sinai, contributed to the

39. See Zarembo, *Hospital Error in Plain Sight*, *supra* note 25 (“CT technicians are not the only medical personnel who might have caught the problem at Cedars-Sinai. Radiologists might have seen the numbers—but only if the hospital had elected to save the dosage data with the images.”).

40. CAL. GOV'T CODE § 115112 (enacted by Chapter 521).

41. See Walt Bogdanich, *F.D.A. to Increase Oversight of Medical Radiation*, N.Y. TIMES, Jan. 24, 2010, at A1 (noting the growing movement to make diagnostic medical radiation safer).

42. See Medicare Modernization Act, 42 U.S.C. § 1395cc-3(d) (2006).

43. Mark R. Chassin et al., *Accountability Measures—Using Measurement to Promote Quality Improvement*, NEW ENG. J. MED., June 23, 2010, at 2.

44. See CAL. GOV'T CODE § 115112 (enacted by Chapter 521) (detailing the accreditation standards); Chassin et al., *supra* note 43, at 2 (noting that standardized data organization can improve the quality of healthcare).

45. See Zarembo, *Hospital Error in Plain Sight*, *supra* note 25 (noting improvements that could still be made).

46. See *id.* (noting that Dehn suggests a “radiation threshold [on CT machines] that cannot be exceeded without a person acknowledging that the dosage is intentional”).

47. See *id.* (explaining that a failure by CT technicians to notice dosage levels during scans was under review).

48. Walt Bogdanich, *F.D.A. Toughens Process for Radiation Equipment*, N.Y. TIMES, Apr. 10, 2010, at A12.

49. *Id.*

accidental overdose of radiation received by Michael Hauser and others.⁵⁰ The software used by Cedars-Sinai had a feature that technicians believed would lower the dosage of radiation but, in fact, significantly raised it.⁵¹ Both Dr. Shuren and Dr. Dehn recommend that the best way to prevent accidental overdoses may be to design CT equipment incapable of exceeding a certain safe level of radiation.⁵²

C. Litigation Not Likely to Increase

Although overdoses from CT examinations will be documented under Chapter 521, such documentation is not likely to lead to a significant increase in lawsuits against healthcare providers.⁵³

Radiation injuries seldom result in lawsuits because such injuries are hard to detect.⁵⁴ Although overdosed patients face an increased risk of brain tumors, the risk is still small.⁵⁵ In cases where cancer does develop, tumors will not manifest until decades after the initial overdose of radiation.⁵⁶ This makes it difficult to prove causation in a lawsuit.⁵⁷ For this reason, many acknowledge that the class-action lawsuit filed on behalf of Cedars-Sinai patients is unlikely to be successful.⁵⁸

V. CONCLUSION

Prior to Chapter 521, hospitals and clinics were not required to measure and record the dosage of radiation received during a CT examination, making any accidental overdose of radiation difficult to catch.⁵⁹ By requiring healthcare facilities to measure and record this dosage of radiation, Chapter 521 will likely reduce the incidents of accidental overdose and lead to greater patient safety.⁶⁰ By requiring hospitals and clinics to immediately notify patients, their doctors, and the State Department of Public Health of errors in administering CT

50. Walt Bogdanich, *After Stroke Scans, Patients Face Serious Health Risks*, N.Y. TIMES, July 31, 2010, at A1.

51. *Id.*

52. Bogdanich, *F.D.A. Toughens Process for Radiation Equipment*, *supra* note 48; Zarembo, *Hospital Error in Plain Sight*, *supra* note 25.

53. Bogdanich, *Radiation Offers New Cures*, *supra* note 17.

54. *Id.* (noting that it is difficult to identify injuries from radiation because “[o]rgan damage and radiation-induced cancer might not surface for years or decades . . .”).

55. Alan Zarembo, *Ex-patients Sue Cedars-Sinai*, L.A. TIMES, Oct. 24, 2009, at A10.

56. *Id.*

57. *Id.*

58. *Id.*

59. Zarembo, *Hospital Error in Plain Sight*, *supra* note 25.

60. *See generally* Bogdanich, *F.D.A. to Increase Oversight*, *supra* note 41 (noting the hope that regulation of medical imaging will lead to a decrease in accidental exposure to radiation).

examinations, Chapter 521 will likely prevent the type of repetitive errors seen at Cedars-Sinai hospital that harmed Michael Heuser.⁶¹

61. *Id.*