

2A:58C-1

EX-10A

LEGISLATIVE HISTORY CHECKLIST
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(Liability of health care providers
for harm by medical devices)

NJSA: 2A:58C-1

LAWS OF: 1995 **CHAPTER:** 143

BILL NO: S1497

SPONSOR(S): Cardinale and Kyrillos

DATE INTRODUCED: October 3, 1994

COMMITTEE: **ASSEMBLY:** Insurance
SENATE: Commerce

AMENDED DURING PASSAGE: Yes Amendments during passage
First reprint enacted denoted by superscript numbers

DATE OF PASSAGE: **ASSEMBLY:** June 12, 1995
SENATE: December 15, 1994

DATE OF APPROVAL: June 29, 1995

FOLLOWING STATEMENTS ARE ATTACHED IF AVAILABLE:

SPONSOR STATEMENT: Yes

COMMITTEE STATEMENT: **ASSEMBLY:** Yes
SENATE: Yes

FISCAL NOTE: No

VETO MESSAGE: No

MESSAGE ON SIGNING: Yes

FOLLOWING WERE PRINTED:

REPORTS: Yes
HEARINGS: No

974.90 Verniero, Peter
L514 Report to the governor on the subject of tort reform.
1994a Office of the Governor, 1994.

KBG:pp

P.L.1995, CHAPTER 143, approved June 29, 1995

1994 Senate No. 1497 (First Reprint)

1 AN ACT concerning tort reform and the liability of certain
2 health care providers under certain circumstances and
3 supplementing P.L.1987, c.197 (C.2A:58C-1 et seq.).
4

5 BE IT ENACTED by the Senate and General Assembly of the
6 State of New Jersey:

7 1. As used in this act:

8 "Health care provider" or "provider" means a provider of
9 health care services and includes, but is not limited to, health
10 care professionals, hospitals, nursing homes and other health care
11 facilities.

12 "Health care service" means a service or product sold by a
13 health care provider and includes, but is not limited to, hospital,
14 medical, surgical, dental, hearing and vision services or products.

15 "Medical device" or "device" means a "device" as defined in
16 subsection (h) of section 201 of the "Federal Food, Drug and
17 Cosmetic Act," 52 Stat. 1040, (21 U.S.C. §321).

18 2. In any product liability action against a health care provider
19 for harm allegedly caused by a medical device that was
20 manufactured or designed in a defective manner, or for harm
21 caused by a failure to warn of a danger related to the use of a
22 medical device, the provider shall not be liable unless: (1) the
23 provider has exercised some significant control over the design,
24 manufacture, packaging or labeling of the medical device relative
25 to the alleged defect in the device which caused the injury, death
26 or damage; or (2) the provider ¹[had actual knowledge] knew or
27 should have known¹ of the defect in the medical device which
28 caused the injury, death or damage, or the plaintiff can
29 affirmatively demonstrate that the provider was in possession of
30 facts from which a reasonable person would conclude that the
31 provider had or should have had knowledge of the alleged defect
32 in the medical device which caused the injury, death or damage;
33 or (3) the provider created the defect in the medical device
34 which caused the injury, death or damage.

35 3. This act shall take effect immediately and shall apply to
36 causes of action which occur on or after the effective date of
37 this act.
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42 Concerns the liability of certain health care providers for harm
43 caused by certain medical devices.

EXPLANATION—Matter enclosed in bold-faced brackets (thus) in the
above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:
Senate SCM committee amendments adopted October 13, 1994.

SENATE, No. 1497

STATE OF NEW JERSEY

INTRODUCED OCTOBER 3, 1994

By Senators CARDINALE and KYRILLOS

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23 provider has exercised some significant control over the design,
24 manufacture, packaging or labeling of the medical device relative
25 to the alleged defect in the device which caused the injury, death
26 or damage; or (2) the provider had actual knowledge of the
27 defect in the medical device which caused the injury, death or
28 damage, or the plaintiff can affirmatively demonstrate that the
29 provider was in possession of facts from which a reasonable
30 person would conclude that the provider had or should have had
31 knowledge of the alleged defect in the medical device which
32 caused the injury, death or damage; or (3) the provider created
33 the defect in the medical device which caused the injury, death
34 or damage.

35 3. This act shall take effect immediately and shall apply to
36 causes of action which occur on or after the effective date of
37 this act.
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STATEMENT

42 This bill provides that health care providers shall not be liable
43 in product liability actions for damages caused by medical
44 devices which they provide, unless: (1) the provider exercised
45 some significant control over the design, manufacture, packaging

1 or labeling of the medical device relative to the defect in the
2 device which caused the injury, death or damage; or (2) the
3 provider had actual knowledge of the defect in the medical
4 device which caused the injury, death or damage, or the plaintiff
5 can affirmatively demonstrate that the provider was in possession
6 of facts from which a reasonable person would conclude that the
7 provider knew or should have known of the defect in the medical
8 device which caused the injury, death or damage; or (3) the
9 provider created the defect in the medical device which caused
10 the injury, death or damage.

11 The bill defines health care provider as any health care
12 professionals, hospitals, health care facilities or nursing homes
13 which provide health care services. The bill defines health care
14 service as a service or product sold by a health care provider
15 which includes, but is not limited to, hospital, medical, surgical,
16 dental, hearing and vision services or products. The bill defines
17 medical device as that term is used in subsection (h) of section
18 321 of the "Federal Food, Drug and Cosmetic Act," 21 U.S.C.
19 §301 et seq.

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24 Concerns the liability of certain health care providers for harm
25 caused by certain medical devices.

ASSEMBLY INSURANCE COMMITTEE

STATEMENT TO

[FIRST REPRINT]

SENATE, No. 1497

STATE OF NEW JERSEY

DATED: JUNE 1, 1995

The Assembly Insurance Committee reports favorably Senate, No. 1497(1R).

This bill provides that health care providers shall not be liable in product liability actions for damages caused by medical devices which they provide unless: (1) the provider exercised some significant control over the design, manufacture, packaging or labeling of the medical device relative to the alleged defect in the device which caused the injury, death or damage; or (2) the provider knew or should have known of the defect in the medical device which caused the injury, death or damage or the plaintiff can affirmatively demonstrate that the provider was in possession of facts from which a reasonable person would conclude that the provider knew or should have known of the defect in the medical device which caused the injury, death or damage; or (3) the provider created the defect in the medical device which caused the injury, death or damage.

The bill defines: "health care provider" as any health care professionals, hospitals, health care facilities or nursing homes which provide health care services; "health care service" as a service or product sold by a health care provider which includes, but is not limited to, hospital, medical, surgical, dental, hearing and vision services or products; and "medical device" as that term is used in the "Federal Food, Drug and Cosmetic Act."

The provisions of the bill take effect immediately and apply to causes of action which occur on or after that effective date.

This bill is identical to Assembly, No. 716(1R).

SENATE COMMERCE COMMITTEE

STATEMENT TO

SENATE, No. 1497

with committee amendments

STATE OF NEW JERSEY

DATED: OCTOBER 13, 1994

The Senate Commerce Committee reports favorably and with committee amendments Senate, No. 1497.

This bill, as amended by the committee, provides that health care providers shall not be liable in product liability actions for damages caused by medical devices which they provide, unless: (1) the provider exercised some significant control over the design, manufacture, packaging or labeling of the medical device relative to the defect in the device which caused the injury, death or damage; or (2) the provider knew or should have known of the defect in the medical device which caused the injury, death or damage or the plaintiff can affirmatively demonstrate that the provider was in possession of facts from which a reasonable person would conclude that the provider knew or should have known of the defect in the medical device which caused the injury, death or damage; or (3) the provider created the defect in the medical device which caused the injury, death or damage.

The bill defines: "health care provider" as any health care professionals, hospitals, health care facilities or nursing homes which provide health care services; "health care service" as a service or product sold by a health care provider which includes, but is not limited to, hospital, medical, surgical, dental, hearing and vision services or products; and "medical device" as that term is used in subsection (h) of section 321 of the "Federal Food, Drug and Cosmetic Act," 21 U.S.C. §301 et seq.

The provisions of the bill take effect immediately and apply to causes of action which occur on or after that effective date.



OFFICE OF THE GOVERNOR NEWS RELEASE

CN-001 CARL GOLDEN
Contact: BECKY TAYLOR
609-777-2600

TRENTON, N.J. 08625
Release: THURSDAY
JUNE 29, 1995

Governor Christie Whitman signed a package of five tort reform bills today that bring common sense and equity to the state's civil litigation system. The laws fulfill the Governor's 1994 promise to revamp the system and provide more access to the courts.

"The legislation enacted today strikes a fair balance between preserving a person's right to sue and controlling nuisance suits that drive up the cost of doing business in New Jersey" said Governor Whitman. "Both consumers and businesses will benefit from these reforms."

Sponsors of the following tort reform bills are Senators Joseph Kyrillos, Jr. (R-Monmouth) and Gerald Cardinale (R-Bergen):

1. Certificate of Merit - Senate Bill No. 1493

This bill establishes new procedures with regard to the filing of malpractice or other professional-negligence actions against certain certified professionals in which damages are sought for personal injuries, wrongful death, or property damage. That list includes accountants, architects, attorneys, dentists, engineers, physicians, chiropractors, podiatrists, and nurses and health care facilities.

The bill requires that within 60 days after a complaint has been filed, the plaintiff must provide the defendant with an affidavit from another professional supporting the claim that the care, knowledge or treatment provided by the defendant was not up to professional standards.

2. Joint-And-Several Liability - Senate Bill No. 1494

The bill provides that a defendant who is less than 60% responsible for the plaintiff's injury is liable only for that percent of the total award that corresponds to his or her percent of fault. A party that is 60% or more responsible is jointly and severally liable for the entire award.

The bill also modifies the "environmental exception." The bill provides that pure joint-and-several liability shall apply in environmental-tort cases, but only if the negligence or fault of the parties in the case cannot be apportioned.

3. Retail-Sellers' Liability - Senate Bill No. 1495

This bill immunizes product sellers from liability for injuries caused by manufacturer's defects in products that they have sold.

Carl Golden/Becky Taylor
Thursday - 6/29/95

Page Two.

4. The Punitive Damages Act - Senate Bill No. 1496

The bill provides for a cap on punitive damages. A punitive-damage award may not exceed \$350,000 or five times compensatory damages, whichever is greater. In addition, there is an exclusion from the cap for the following causes of action: bias crimes, the Law Against Discrimination, AIDS testing disclosure, sexual abuse, and civil actions against defendants who were convicted of drunk-driving violations.

5. Health-Care Providers' Liability -- Medical Devices - Senate Bill No. 1497

This bill holds health-care providers responsible for defective medical devices that they provide, based only on their own negligence.

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