

Statutory Research

Bridge the Gap 2014

**Rutgers University Center for
Law & Justice**

Prof. Caroline Young, J.D., M.L.I.S.
Head of Circulation
Reference and Technology Librarian
Rutgers University Center for Law & Justice

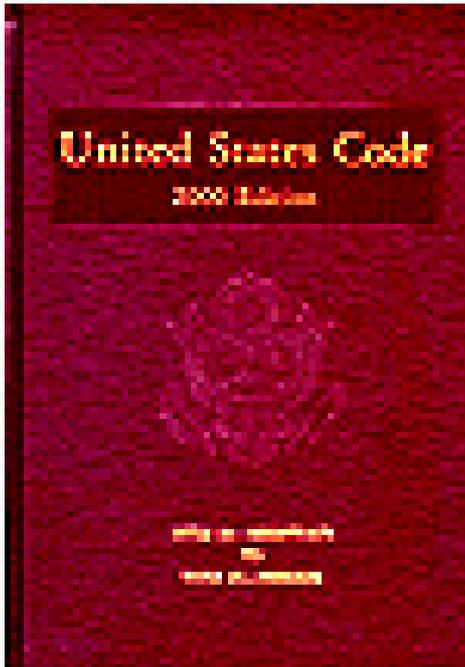
Types of Statutory Materials

- **Constitutions**
- **Laws/Statutes/Codes**
- **Treaties**
- **Municipal Ordinances**
- **Court Rules**

The Importance of Statutory Research

- Always check to see if there is a controlling statute(s) on point when you begin your research
- The trend: More legislatures are enacting statutes in areas that were traditionally controlled by common law

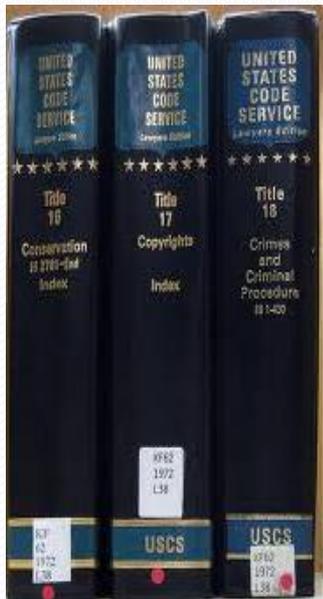
Where to Start: Print or Electronic?



U.S.C. vs. U.S.C.A. vs. U.S.C.S

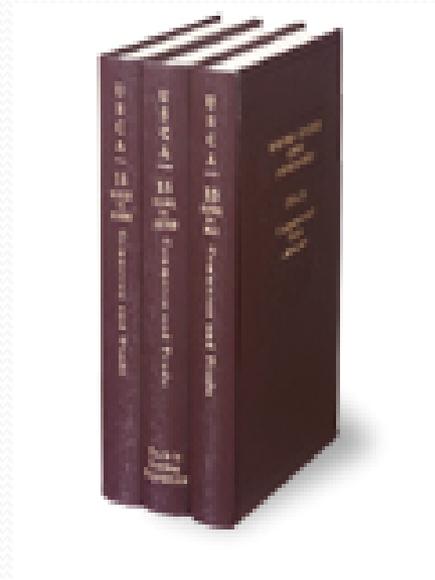
Which one?

USE AN ANNOTATED VERSION!



USCS

OR



USCA

West USCA vs. Lexis USCS

Which one?

Overriding Process

- **Find the Statute(s)**
- Use the tools provided to you with the annotations (print or electronic)

Find the Statute

- **Check a secondary source if you are unfamiliar with key words/topic**
- **Use the index**
- **Review TOC**
- **Check popular name table if you know the name of an Act**
-

Use the Annotations and Tools

- Review the text of statute
- Note cross references, secondary sources and historical note
- Check for relevant regulations
- Always check the pocket part/update electronically
- Shepardize/KeyCite

The Statutory Research Process

Your problem involves issues relating to mislabeling of medical devices, products liability, and negligence. What do you do first?

Identify Key Words

- Bone screw?
- Medical Devices?
- Product Liability?

How Do You Identify Key Words?

- Consult a secondary source

How do You Find the Right Statute?

- Finding Aids

Finding Aids

- Index
- Table of Contents
- Popular Name Table (in all codes)
- Shepard's Acts and Cases by Popular Name
- Secondary Source
- Keyword Search-last resort!

Indexes

- Hard Copy
- Westlaw Next

UNITED STATES
CODE
ANNOTATED



GENERAL INDEX

J to R



THOMSON
WEST

Mat #40413026

Index
volume
from
USCA

Index

- Start by looking up the term 'medical devices'
- Browse the 'medical devices' section until you find a relevant section

	See Popular Name Table
	MEDICAL DEVICES
	Generally, 21 § 351 et seq.
	Access,
37	Children and minors, 21 § 393a
	Investigational drugs or devices, 21 § 360bbb
	Accreditation,
	Classification, 21 §§ 360m, 374
	Inspection and inspectors, 21 § 374
al-	Actions and proceedings,
	Biomaterials, 21 § 1601 et seq.
	Classification, 21 § 360c et seq.
	Performance standards, 21 § 360d
	Presumptions, 21 § 379a
	Adjustments, premarket applications, fees, 21 § 379j
ts,	Administrative restraint, seized devices, 21 § 334
	Adulteration and misbranding, 21 § 351 et seq.
	Actions and proceedings, 21 § 337
	Advertisements, 21 § 321
	Analysis, 21 §§ 334, 374
	Class II, performance standards, 21 §§ 351, 352
	Class III, premarket approval, 21 § 351



WestlawNext Index

The screenshot shows the WestlawNext interface for the United States Code Annotated (USCA). At the top, there are navigation tabs for "All Content" and "United States Code Annotated (USCA)". A search bar is present with the text "Search United States Code Annotated (USCA)" and a "SEARCH" button. Below the search bar, there are radio buttons for "Search all content" (selected) and "Specify content to search". The main content area lists the titles of the USCA, from Title 1 to Title 15, along with "Bankruptcy Rules" and "Official and Procedural Bankruptcy Forms". On the right side, there is a "TOOLS & RESOURCES" sidebar with a list of links, including "USCA Find Template", "USCA - Historical", "USCA Index" (highlighted with a red box), "USCA Popular Name Table", "Federal Local Court Rules", "Federal Rules Update Orders", "Federal Rules Decisions Rules", "United States Code Unannotated", and "Federal Bill Tracking".

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All Content United States Code Annotated (USCA)

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Q Search United States Code Annotated (USCA) SEARCH advanced Caroline's Rese... (1

Home > Statutes & Court Rules

United States Code Annotated (USCA) | ★

Includes current version of United States Code Annotated. Browse Table of Contents below or search above. ⓘ

Search all content Specify content to search

The Organic Laws of the United States of America

- Constitution of the United States
- Title 1. General Provisions
- Title 2. The Congress
- Title 3. The President
- Title 4. Flag and Seal, Seat of Government, and the States
- Title 5. Government Organization and Employees
- Title 6. Domestic Security
- Title 7. Agriculture
- Title 8. Aliens and Nationality
- Title 9. Arbitration
- Title 10. Armed Forces
- Title 11. Bankruptcy
- Bankruptcy Rules
- Official and Procedural Bankruptcy Forms
- Title 12. Banks and Banking
- Title 13. Census
- Title 14. Coast Guard
- Title 15. Commerce and Trade

TOOLS & RESOURCES

- USCA Find Template
- USCA - Historical
- USCA Index**
- USCA Popular Name Table
- Federal Local Court Rules
- Federal Rules Update Orders
- Federal Rules Decisions Rules
- United States Code Unannotated
- Federal Bill Tracking

TOC

- Hard Copy
- Westlaw Next
- Lexis Advance

CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

Sections 301 to 356c appear in this Volume

SUBCHAPTER I—SHORT TITLE

Sec.
301. Short title.

SUBCHAPTER II—DEFINITIONS

321. Definitions; generally.
321a. "Butter" defined.
321b. "Package" defined.
321c. Nonfat dry milk; "milk" defined.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

331. Prohibited acts.
332. Injunction proceedings.
333. Penalties.
333a. Repealed.
334. Seizure.
335. Hearing before report of criminal violation.
335a. Debarment, temporary denial of approval, and suspension.
335b. Civil penalties.
335c. Authority to withdraw approval of abbreviated drug applications.
336. Report of minor violations.
337. Proceedings in name of United States; provision as to subpoenas.

SUBCHAPTER IV—FOOD

341. Definitions and standards for food.
342. Adulterated food.
343. Misbranded food.
343-1. National uniform nutrition labeling.
343-2. Dietary supplement labeling exemptions.
343-3. Disclosure.
343a. Health risks presented by use of saccharin.
344. Emergency permit control.
345. Regulations making exemptions.
346. Tolerances for poisonous or deleterious substances in food regulations.
346a. Tolerances and exemptions for pesticide chemical residues.
346b. Authorization of appropriations.
347. Intrastate sales of colored oleomargarine.
347a. Congressional declaration of policy regarding oleomargarine sales.
347b. Contravention of State laws.
348. Food additives.
349. Bottled drinking water standards; publication in Federal Register.
350. Vitamins and minerals.
350a. Infant formulas.
350b. New dietary ingredients.

Using the Table of Contents

Look at the beginning of a section in the code to get a sense of how the law is organized.

Sec.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

- 351. Adulterated drugs and devices.
- 352. Misbranded drugs and devices. ←
- 353. Exemptions and consideration for certain drugs, devices, and biological products.
- 353a. Pharmacy compounding.
- 354. Veterinary feed directive drugs.
- 355. New drugs.
- 355a. Pediatric studies of drugs.
- 356. Fast track products.
- 356a. Manufacturing changes.
- 356b. Reports of postmarketing studies.
- 356c. Discontinuance of a life saving product.
- 357. Repealed.
- 358. Authority to designate official names.
- 359. Nonapplicability of subchapter to cosmetics.
- 360. Registration of producers of drugs or devices.
- 360a. Repealed.
- 360b. New animal drugs.
- 360c. Classification of devices intended for human use.
- 360d. Performance standards.
- 360e. Premarket approval.
- 360f. Banned devices.
- 360g. Judicial review.
- 360h. Notification and other remedies.
- 360i. Records and reports on devices.
- 360j. General provisions respecting control of devices intended for human use.
- 360k. State and local requirements respecting devices.
- 360l. Postmarket surveillance.
- 360m. Accredited persons.

PART B—DRUGS FOR RARE DISEASES OR CONDITIONS

- 360aa. Recommendations for investigations of drugs for rare diseases or conditions.
- 360bb. Designation of drugs for rare diseases or conditions.
- 360cc. Protection for drugs for rare diseases or conditions.
- 360dd. Open protocols for investigations of drugs for rare diseases or conditions.
- 360ee. Grants and contracts for development of drugs for rare diseases and conditions.

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

- 360gg. Omitted.
- 360hh. Definitions.
- 360ii. Program of control.
- 360jj. Studies by Secretary.
- 360kk. Performance standards for electronic products.
- 360ll. Notification of defects in and repair or replacement of electronic products.
- 360mm. Imports.

Sec. 352:

Misbranded drugs and devices

Westlaw Next - TOC

The screenshot displays the WestlawNext interface with a 'Table of Contents' pop-up window. The pop-up window has a search bar labeled 'Search headings' and a 'Download Table of Contents' button. The table of contents lists the following items:

- SUBCHAPTER V—DRUGS AND DEVICES
 - Part A—Drugs and Devices
 - 21 USCA Ch. 9, Subch. V, Pt. A, Refs & Annos
 - § 351. Adulterated drugs and devices
 - § 352. Misbranded drugs and devices**
 - § 353. Exemptions and consideration for certain drugs, devices, and biological products
 - § 353a. Pharmacy compounding
 - § 353a-1. Enhanced communication
 - § 353b. Outsourcing facilities
 - § 353c. Prereview of television advertisements
 - § 354. Veterinary feed directive drugs
 - § 355. New drugs
 - § 355-1. Risk evaluation and mitigation strategies
 - § 355a. Pediatric studies of drugs

The background interface shows the 'WestlawNext' logo, a user profile for 'YOUNG CAROLINE', and a document titled '§ 352. Misbranded' under 'United States Code Annotations'. A sidebar on the right lists 'NOTES OF DECISIONS (383)' with various topics like 'Constitutionality', 'Construction', and 'Designation by name not in'.

LexisAdvance - TOC

21 USCS 352 x 21 USCS § 352 x United States Cod... x

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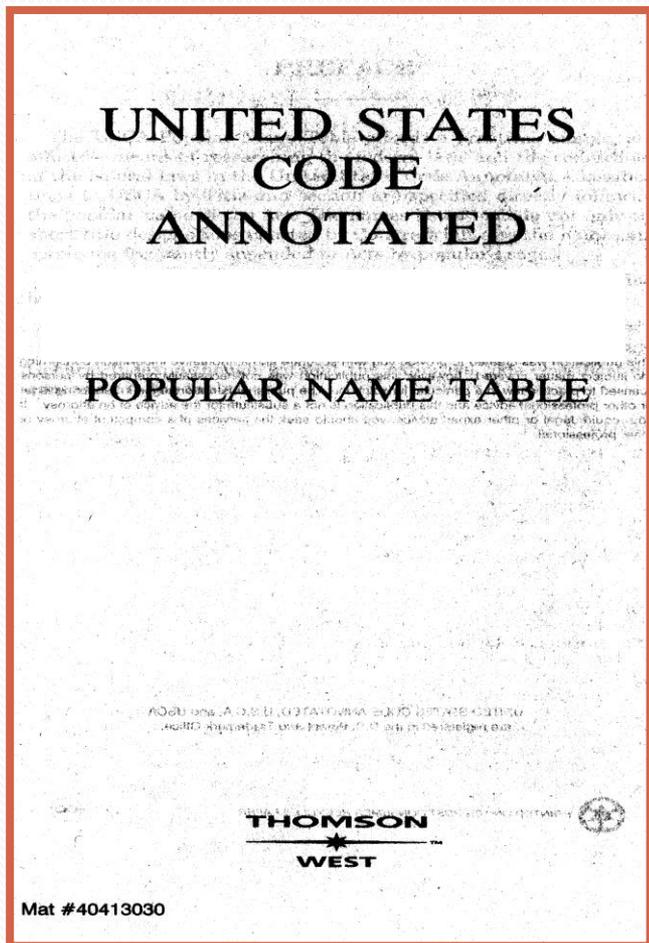
▼ DRUGS AND DEVICES

▼ DRUGS AND DEVICES

- § 351. Adulterated drugs and devices
- § 352. Misbranded drugs and devices
- § 353. Exemptions and consideration for certain drugs, devices, and biological products [Caution: See prospective amendment note below.]
- § 353a. Pharmacy compounding
- § 353a-1. Enhanced communication
- § 353b. Outsourcing facilities.
- § 353c. Prereview of television advertisements
- § 354. Veterinary feed directive drugs
- § 355. New drugs
- § 355-1. Risk evaluation and mitigation strategies
- § 355a. Pediatric studies of drugs
- § 355b. Adverse-event reporting
- § 355c. Research into pediatric uses for drugs and biological products
- § 355c-1. Report
- § 355d. Internal committee for review of pediatric plans, assessments, deferrals, deferral extensions, and waivers
- § 355e. Pharmaceutical security
- § 355f. Extension of exclusivity period for new qualified infectious disease products
- § 356. Expedited approval of drugs for serious or life-threatening diseases or conditions
- § 356-1. Accelerated approval of priority countermeasures
- § 356a. Manufacturing changes
- § 356b. Reports of postmarketing studies

Popular Name Table

- Hard Copy
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- Lexis Advance (sort of)
- Shepard's Acts and Cases by Popular Name



UCSA Popular Name Table

Popular Name Table

Medical Device Amendments

Medical Device Amendments of 1976

Short title, see 21 USCA § 301 note

Pub.L. 94-295, May 28, 1976, 90 Stat. 539 (15 § 55; 21 §§ 321, 331, 334, 351, 352, 358, 360, 360c to 360k, 374, 379, 379a, 381; 42 § 3512)

Medical Device Amendments of 1992

Short title, see 21 USCA § 301 note

Pub.L. 102-300, June 16, 1992, 106 Stat. 238 (21 §§ 301 note, 321, 331, 334, 346a, 352, 353, 356, 357, 360c, 360d, 360g, 360h, 360i, 360i notes, 360l, 360mm, 371, 372, 372a, 376, 381; 42 § 262)

Pub.L. 103-80, § 4(b), Aug. 13, 1993, 107 Stat. 779 (21 § 321)

WestlawNext Popular Name Table

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A compilation of popular names by which federal and state acts and cases have been referred to or cited together with an identification of each act in terms of its constitutional or statutory references and each case in terms of the volume and page reference where the text of the decision may be found.

FIFTH EDITION ----- 1999, PART 2

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FEDERAL AND STATE ACTS CITED BY POPULAR NAME

Med

Medical Care Recovery Act

Sept. 25, 1962, P.L. 87-693, 76 Stat. 593, 42 U.S. Code §§ 2651 to 2653
D.C. Code Ann., § 4-501 et seq.

Medical Care Savings Account Act

Del. Code Ann., 33-20B-1 et seq.
Ida. Code 1947, 41-5301 et seq.
Ill. Comp. Stat. 1992, Ch. 820, § 152/1
Mich. Comp. Laws Ann., 550.981 et seq.
Mont. Laws 1995, Ch. 295
N.M. Stat. Ann., 59A-23D-1 et seq.
Pa. Purdon's Stat., Title 72, § 3402a.2 et seq.

Medical Center Act

P.R. Laws Ann. 1954, Title 24, § 49a et seq.

Medical Center Act (Chicago)

Ill. Rev. Stat. 1991, Ch. 111 1/2 § 5000 et seq.

Medical Center District Act

Ill. Rev. Stat. 1991, Ch. 111 1/2, § 5000 et seq.

Medical Center Quota Act

Ark. Code Ann. 1987, 6-64-505 et seq.

Medical Clinic Act

Ala. Code 1975, § 11-58-1 et seq.

Medical College Act

Mo. Rev. Stat., 334.160

Medical Conduct Reform Act (Professional)

N.J. Stat. Ann., 45:9-19.4 et seq.

Medical Consent Law

Fla. Stat. Ann., 766.103

Medical Contribution Act (Employee)

Ga. Code Ann., 31-9-1 et seq.
Ill. Rev. Stat. 1991, Ch. 48, § 35a et seq.
La. Rev. Stat. Ann., 40:1299.50 et seq.

Medical Corporation Act

Ark. Code Ann. 1987, 4-29-301 et seq.
Cal. Business and Professions Code § 2500 et seq.
Ill. Rev. Stat. 1991, Ch. 32, § 631 et seq.
La. Rev. Stat. Ann., 12:901 et seq.

Minn. Stat. Ann., 319A.01 et seq.

N.Y. Public Health Law 1953 (Consol. Laws Ch. 45), § 4400 et seq.
S.D. Codified Laws 1967, 47-11-1 et seq.

Medical Corporation Act (Non-Profit Health Maintenance Organization)

N.Y. Public Health Law 1953 (Consol. Laws Ch. 45), § 4400 et seq.

Medical Cost Advisory Committee Act

Ill. Rev. Stat. 1991, Ch. 23, § 5090 et seq.

Medical Database Commission Act

N.C. Gen. Stat. 1943, § 131E-210 et seq.

Medical, Dental and Hospital Service Corporation Readable Insurance Certificate Act

N.C. Gen. Stat. 1943, § 58-66-1 et seq.

Medical, Dental, Optometric and Hospital Service Corporation Act

Ariz. Rev. Stat. 1956, § 20-821 et seq.

Medical Device Amendments of 1992

June 16, 1992, P.L. 102-300, 21 U.S. Code § 301 nt.

Medical Disaster Insurance Fund Act

Colo. Rev. Stat., 8-46-301 et seq., 8-65-101 et seq.

Medical Disciplinary Act

S.C. Code Ann. 1976, § 40-47-200 et seq.

Medical Disciplinary Board Act

Wash. Rev. Code Ann., 18.72.010 et seq.

Medical Education and Tertiary Care Act

Fla. Stat. Ann., 395.60 et seq., 395.801 et seq.

Medical Education Facilities Bond Act

N.J. Laws 1977, Ch. 235

Medical Emergencies Act (Coal Mine)

Ill. Comp. Stat. 1992, Ch. 410, § 15/1 et seq.

Medical Emergency Services Act

Tex. Health and Safety Code, § 773.001 et seq.

← 21 USC 301 note

Inside the Statute

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§ 352. Misbranded drugs and devices
United States Code Annotated Title 21. Food and Drugs Effective: November 27, 2013 (Approx. 7 pages)

Document Notes of Decisions (383) History (132) Citing References (13,522) Context & Analysis (110) Powered by KeyCite

Table of Contents

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter V. Drugs and Devices
Part A. Drugs and Devices (Refs & Annos)

Proposed Legislation

Effective: November 27, 2013

21 U.S.C.A. § 352

§ 352. Misbranded drugs and devices

Currentness

A drug or device shall be deemed to be misbranded--

NOTES OF DECISIONS (383)

- Accompanying matter, labeling
- Adequate directions for use
- Advertising literature, labeling
- Bulk shipments, packages subject to labeling requirements
- Burden of proof
- Circulars within package, labeling
- Clinical studies
- Common or usual name, name of drug
- Conspicuous placement, labeling
- Constitutionality
- Construction
- Construction with other laws
- Dangerous when used as prescribed
- Derivatives
- Designation by name not in

Credits – Source of law

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§ 352. Misbranded drugs and devices
United States Code Annotated | Title 21. Food and Drugs | Effective: November 27, 2013 (Approx. 7 pages)

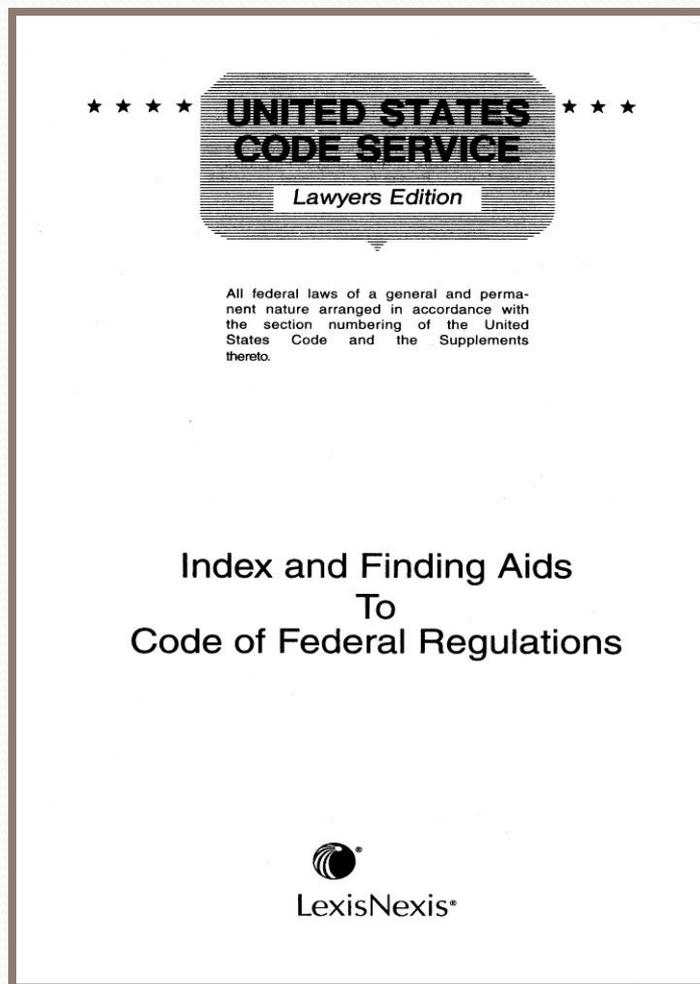
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CREDIT(S)

(June 25, 1938, c. 675, § 502, 52 Stat. 1050; June 23, 1939, c. 242, § 3, 53 Stat. 854; 1940 Reorg. Plan No. IV, §§ 12, 13, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Dec. 22, 1941, c. 613, § 2, 55 Stat. 851; July 6, 1945, c. 281, § 2, 59 Stat. 463; Mar. 10, 1947, c. 16, § 2, 61 Stat. 11; July 13, 1949, c. 305, § 1, 63 Stat. 409; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 5, 1953, c. 334, § 1, 67 Stat. 389; July 12, 1960, Pub.L. 86-618, Title I, § 102(b)(2), 74 Stat. 398; Oct. 10, 1962, Pub.L. 87-781, Title I, §§ 105(c), 112(a), (b), 131(a), Title III, § 305, 76 Stat. 785, 790, 791, 795; July 13, 1968, Pub.L. 90-399, § 105(a), 82 Stat. 352; Dec. 30, 1970, Pub.L. 91-601, § 7(d), 84 Stat. 1673; Dec. 30, 1970, Pub.L. 91-601, § 6(d), formerly § 7(d), 84 Stat. 1673; renumbered § 6(d), Aug. 13, 1981, Pub.L. 97-35, Title XII, § 1205(c), 95 Stat. 716; amended May 28, 1976, Pub.L. 94-295, §§ 3(e), 4(b)(2), 5(a), 9(b)(2), 90 Stat. 577, 580, 583; Nov. 10, 1978, Pub.L. 95-633, Title I, § 111, 92 Stat. 3773; June 16, 1992, Pub.L. 102-300, § 3(a)(2), 106 Stat. 239; Oct. 29, 1992, Pub.L. 102-571, Title I, § 107(9), 106 Stat. 4499; Aug. 13, 1993, Pub.L. 103-80, § 3(m), 107 Stat. 777; Nov. 21, 1997, Pub.L. 105-115, Title I, §§ 114(a), 125(a)(2)(B), (b)(2)(D), 126(b), Title IV, § 412(c), 111 Stat. 2312, 2325, 2327, 2375; Oct. 26, 2002, Pub.L. 107-250, Title II, § 206, Title III, §§ 301(a), 302(a)(1), 116 Stat. 1613, 1616; Apr. 1, 2004, Pub.L. 108-214, § 2(b)(2)(B), (c)(1), 118 Stat. 575; Aug. 2, 2004, Pub.L. 108-282, Title I, § 102(b)(5)(E), 118 Stat. 902; Aug. 1, 2005, Pub.L. 109-43, § 2(c)(1), 119 Stat. 441; Dec. 22, 2006, Pub.L. 109-462, § 2(d), 120 Stat. 3472; Sept. 27, 2007, Pub.L. 110-85, Title IX, §§ 901(d)(3)(A), (6), 902(a), 906(a), 121 Stat. 940, 942, 943, 949; Pub.L. 112-144, Title III, § 306, Title VII, §§ 702(a), 714(c), July 9, 2012, 126 Stat. 1024, 1065, 1074; Pub.L. 112-193, § 2(a), Oct. 5, 2012, 126 Stat. 1443; Pub.L. 113-54, Title I, § 103(b), Title II, § 206(b), Nov. 27, 2013, 127 Stat. 597, 639.)

If you know the statute you can often find the regulations



Always Check for Regulations

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§ 352. Misbranded drugs and devices
United States Code Annotated Title 21. Food and Drugs Effective: November 27, 2013 (Approx. 7 pages)

Document Notes of Decisions (383) History (132) Citing References (13,523) Context & Analysis (110) Powered by KeyCite

Context & Analysis (110)

VIEW	«
Cross References	1
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Law Review Commentaries	5
Library References	9
ALR Library	40
Encyclopedias	27
Forms	7
Treatises and Practice Aids	15
All Results	110

Cross References (1)

Patents, extension of patent term, see 35 USCA § 156.

Code Of Federal Regulations (6)

Labeling, generally, see 21 CFR § 201.1 et seq.

Labeling medical devices, see 21 CFR § 801.1 et seq.

Official and established drug names, see 21 CFR § 299.3.

Prescription drug advertising, see 21 CFR § 202.1.

Prescription drugs not misbranded, see 21 CFR § 361.1 et seq.

Warnings on over-the-counter drugs and devices for humans, see 21 CFR § 369.1 et seq.

Law Review Commentaries (5)

Update the Statute-Check the pocket part!

appropriate, shall provide assistance on request, to the extent resources are available, to the Secretary for the purposes of carrying out this section.

(June 25, 1938, c. 675, § 416, as added Aug. 10, 2005, Pub.L. 109-59, Title VII, § 7202(b), 119 Stat. 2191.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

2005 Acts. House Conference Report No. 109-203, see 2005 U.S. Code Cong. and Adm. News, p. 452.

Statement by President, see 2005 U.S. Code Cong. and Adm. News, p. S24.

Effective and Applicability Provisions

2005 Acts. Amendments by Pub.L. 109-59, §§ 7201 to 7204, effective Oct. 1, 2005, see Pub.L. 109-59, § 7204, set out as a note under 21 U.S.C.A. § 331.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

[See main volume for text of (a) to (e)]

(f) Certain class III devices

[See main volume for text of (1)]

(2)(A) In the case of a device classified under section 360c(f) of this title into class III and intended solely for investigational use, paragraph 1 (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 360j(g)(2) of this title.

(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 360e of this title, paragraph 1 (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 360c of this title, or

(ii) on the ninetieth day after the date of the promulgation of such regulation,

whichever occurs later.

[See main volume for text of (g) to (i)]

¹ So in original. Probably should be "subparagraph".

LAW REVIEW AND JOURNAL COMMENTARIES

A modest proposal to rename the FDA: Apologists for carcinogens, teratogens, and adulterated drugs. Mark Klock, 36 *Ariz. St. L.J.* 1161 (2004).

LIBRARY REFERENCES

American Digest System
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CJS Drugs and Narcotics § 14, Adulteration; Manufacturing Practices.

Research References

ALR Library
133 ALR, Fed. 229, What is "New Drug" Within Meaning of § 201(P) of Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 321(P)).
43 ALR, Fed. 320, Necessity of Formal Hearing Prior to Issuance of Regulations Under

§ 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 371(E)).

12 ALR, Fed. 475, Validity, Construction, and Application of Color Additive Provisions of Federal Food, Drug, and Cosmetic Act, as Amended (21 U.S.C.A. §§ 321(T, U), 362(A, E), 376), and of Implementing Regulations.

13 ALR, Fed. 747, Regulation of Health Devices Under Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301 et seq.) as Affected by Religious Guaranties of First Amendment.

129 ALR, Fed. 1, Construction and Application of National Childhood Vaccine Injury Act (42 U.S.C.A. §§ 300aa et seq.).

88 ALR, Fed. 124, Federal Pre-emption of State Common-Law Products Liability Claims Pertaining to Drugs, Medical Devices, and Other Health-Related Items.

93 ALR 5th 103, Products Liability: Statements in Advertisements as Affecting Liability of Manufacturers or Sellers for Injury Caused by Product Other Than Tobacco.

75 ALR 4th 13, Liability for Retaliation Against At-Will Employees for Public Complaints or Efforts Relating to Health or Safety.

1 ALR 4th 921, Products Liability in Connection With Prosthesis or Other Products Designed to be Surgically Implanted in Patient's Body.

94 ALR 3rd 748, Liability of Manufacturer or Seller for Injury or Death Allegedly Caused by Failure to Warn Regarding Danger in Use of Vaccine or Prescription Drug.

94 ALR 3rd 1080, Promotional Efforts Directed Toward Prescribing Physician as Affecting Prescription Drug Manufacturer's Liability for Product-Caused Injury.

Encyclopedias

42 Am. Jur. Proof of Facts 2d 97, Cosmetics Injuries.

49 Am. Jur. Proof of Facts 2d 125, Teratogenic Drugs.

7 Am. Jur. Proof of Facts 3d 1, Injuries from Drugs.

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

[See main volume for text of (a) to (e)]

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

[See main volume for text of (g) to (l)]

(v)¹ Single-use medical devices; required statements on labeling

If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use.

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 ▾ [Subchapter V](#). Drugs and Devices
 ▾ [Part A](#). Drugs and Devices ([Refs & Annos](#))
 ▸ **§ 352. Misbranded drugs and devices**

A drug or device shall be deemed to be misbranded--

(a) False or misleading label

If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under [section 355](#) or under [section 262\(a\) of Title 42](#) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in [section 355\(a\)](#) of this title or in [section 262\(a\) of Title 42](#) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term "health care economic information" means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.

(b) Package form; contents of label

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... the Health Care Financing Administration (HCFA) to plaintiffs who received settlement in products liability class action against manufacturers of orthopedic **bone screws**, which letters asserted right to recover settlement proceeds as repayment for Medicare costs under the Medicare Secondary Payer (MSP) statute, ...

... Payer (MSP) statute, constituted "final agency action" subject to judicial review under the Administrative Procedures Act (APA). In re Orthopedic **Bone Screw** Products Liability Litigation, E.D.Pa.2001, 202 F.R.D. 154, reversed 346 F.3d 386, certiorari denied 124 S.Ct. 2872, 542 U.S. 919, 159 ...

2. 21 U.S.C.A. § 337
UNITED STATES CODE ANNOTATED TITLE 21. FOOD AND DRUGS CHAPTER 9--FEDERAL FOOD, DRUG, AND COSMETIC ACT SUBCHAPTER III--PROHIBITED ACTS AND PENALTIES § 337. Proceedings in name of United States; provision as to subpoenas

... Food, Drug, and Cosmetic Act (FDCA), which imposes criminal penalties, but creates no private right of action. In re Orthopedic **Bone Screw** Products Liability Litigation, C.A.3 (Pa.) 1999, 193 F.3d 781. Conspiracy ⇐ 1.1 There is no private right of action for ...

3. 21 U.S.C.A. § 360e
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New Jersey Practice, Volume 52, Elements of an Action

§ 46:6

ELEMENTS OF AN ACTION

grounded on misrepresentation and negligent misrepresentation.² Negligent misrepresentation exists where the representation made by the defendant is one which an ordinarily careful person would not have made under the circumstances.³

§ 46:7 Choice of law and forum

The law of more than one state may be involved where recovery is sought from the manufacturer or the seller of a product for injury to person or property allegedly caused by the product. The product in question may have been manufactured in one state, sold by the manufacturer in another, sold by a retailer in a third, and used by the purchaser in a fourth. The products liability action may be brought in still another state. Where a products liability case has multi-state aspects, it may become necessary for the court to decide what law applies to the case. This may result in applying the law of more than one state, where the suit is grounded on different theories calling for the application of the law of different jurisdictions.¹

§ 46:8 New Jersey product liability and punitive damage statutes

The legislature of the State of New Jersey found that there was an urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products, including certain principles under which liability is imposed and the standards and procedures for the award of punitive damages.¹ As a result, the legislature has enacted several statutes dealing with product liability in New Jersey and punitive damage awards in product liability actions.²

Thus, a manufacturer or seller of a product will be liable in a product liability action³ only if the claimant⁴ proves by a

²Am. Jur. 2d, Products Liability § 586.

³Am. Jur. 2d, Products Liability § 591.

[Section 46:7]

¹Am. Jur. 2d, Products Liability § 866.

[Section 46:8]

¹See N.J.S.A. 2A:58C-1(a).

²See N.J.S.A. 2A:58C-1 to 2A:58C-7. The statutes are not in

tended to codify all issues relating to product liability, but only to deal with matters that require clarification. N.J.S.A. 2A:58C-1(a). Also, except as otherwise provided in the statutes, the statutes are not intended to establish any rule, or alter any existing rule, with respect to the burden of proof in a product liability action. N.J.S.A. 2A:58C-7.

³Product liability actions⁴ means any claim or action brought by a claimant for harm caused by a prod-

PRODUCTS LIABILITY

§ 46:8

preponderance of the evidence that the product causing the harm⁵ was not reasonably fit, suitable, or safe for its intended purpose because it: (a) deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, (b) failed to contain adequate warnings or instructions, or (c) was designed in a defective manner.⁶

In addition to establishing these standards for imposing product liability in New Jersey, the statutes also set forth a number of defenses and exceptions to such liability. Thus, a manufacturer or seller will not be liable for harm allegedly caused by a product that was designed in a defective manner if: (1) at the time the product left the control of the manufacturer, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product;⁷ (2) the characteristics of the product are known to the ordinary consumer or user, and the harm was caused by an unsafe aspect of the product that is an inherent characteristic of the product and that would be recognized by the ordinary person who uses or consumes the product with the ordinary knowledge common to the class of persons for whom the product is intended;⁸ or (3) the harm was caused by an unavoidably unsafe aspect of the product and the product was accompanied by an adequate warning or

uct, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty. N.J.S.A. 2A:58C-1(b)(3). The statutes do not apply to any environmental tort action, which is defined as a civil action seeking damages for harm where the cause of the harm is exposure to toxic chemicals or substances, but does not mean actions involving drugs or products intended for personal consumption or use. See N.J.S.A. 2A:58C-1(b)(4), 2A:58C-6.

⁴"Claimant" means any person who brings a product liability action, and if such an action is brought through or on behalf of an estate, the term includes the person's decedent, or if an action is brought through or on behalf of a minor, the term includes the person's parent or guardian. N.J.S.A. 2A:58C-1(b)(1).

⁵"Harm" means (a) physical damage to property, other than the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish, or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in (a) through (c) above. N.J.S.A. 2A:58C-1(b)(2).

⁶N.J.S.A. 2A:58C-2.

⁷N.J.S.A. 2A:58C-3(a)(1).

⁸N.J.S.A. 2A:58C-3(a)(2). This exception does not apply to industrial machinery or other equipment used in the workplace, nor is it intended to apply to dangers posed by products such as machinery or equipment that can feasibly be eliminated without impairing the usefulness of the product. N.J.S.A. 2A:58C-3(a)(2).

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New Jersey Products Liability Statute

NJSA 2A:58C

CHAPTER 58C PRODUCTS LIABILITY

Section

- 2A:58C-1. Legislative findings; definitions.
2A:58C-2. Liability of manufacturer or seller; proof by preponderance of evidence product not reasonably lit, suitable or safe for its intended purpose.
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2A:58C-11. Medical devices; liability of provider.

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Beyond preemption: The role of federal and state regulatory standards in product liability litigation. William C. Slatery, 150 N.J.Law. 41 (1993).

Cipollone decision: Providing guidelines for federal preemption of product liability claims. Marc Z. Edell and Harriet Dinegar Mills, 150 N.J.Law. 37 (1993).

Comparative fault in design defect cases: Is the pendulum swinging out of control? Roy Alan Cohen and Frank Fazio, 150 N.J.Law. 19 (1993).

Learned intermediary doctrine in drug and medical device litigation. Arthur Ian Miltz, 150 N.J.Law. 32 (1993).

Nationalizing tort law: the republican attack on women, blue collar workers and consumers. Michael L. Rustad, 48 Rutgers L.Rev. 673 (1996).

Rules and relationships: the varieties of wrongdoing in tort law. Timothy D. Lytton, 28 Seton Hall L.Rev. 359 (1997).

The dark side of tort reform: searching for racial justice. Frank M. McClellan, 48 Rutgers L.Rev. 761 (1996).

Tort reform New Jersey style: Analysis of the new laws and how they became law. 20 Seton Hall Legis.J. 563 (1996).

Yes, New Jersey, there is a Product Liability Act. Marc S. Klein, 150 N.J.Law. 12 (1993).

United States Supreme Court

Due process, punitive damages, grossly excessive awards, lawful conduct of defendant outside state, see BMW of North

America, Inc. v. Gore, 1996, 116 S.Ct. 1539, 517 U.S. 559, 134 L.Ed.2d 809, on remand 701 So.2d 507, rehearing denied.

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2A:58C-1

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2A:58C-1. Legislative findings; definitions

a. The Legislature finds that there is an urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products, including certain principles under which liability is imposed and the standards and procedures for the award of punitive damages. This act is not intended to codify all issues relating to product liability, but only to deal with matters that require clarification. The Legislature further finds that such sponsors' or committee statements that may be adopted or included in the legislative history of this act shall be consulted in the interpretation and construction of this act.

b. As used in this act:

(1) "Claimant" means any person who brings a product liability action, and if such an action is brought through or on behalf of an estate, the term includes the person's decedent, or if an action is brought through or on behalf of a minor, the term includes the person's parent or guardian.

(2) "Harm" means (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

(3) "Product liability action" means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.

(4) "Environmental tort action" means a civil action seeking damages for harm where the cause of the harm is exposure to toxic chemicals or substances, but does not mean actions involving drugs or products intended for personal consumption or use.

L.1987, c. 197, § 1, eff. July 22, 1987.

Senate Judiciary Committee Statement
Senate, No. 2805—L.1987, c. 197

Subsection a. of section 1 sets forth a declaration of legislative purpose. The act is intended as a remedial measure to clarify certain matters pertaining to the rules governing actions for harm caused by products and to establish statutory standards and procedures for the imposition of punitive damages.

Subsection b. of section 1 contains definitions of the terms "claimant," "harm," and "product liability action" and "environmental tort action." These definitions establish the scope of the act, which is intended to apply to all actions for harm caused by products, except actions for harm caused by breach of an express warranty.

Sections 2 through 4 contain provisions dealing with actions for damages for harm caused by products. These sections are intended to establish clear rules with respect to specific matters as to which the decisions of the courts in New Jersey have created uncertainty, while reserving the concept that manufacturers may be held strictly liable for harm caused by products that are defective. The provisions of sections 2 through 4 are not intended to codify all issues relating to product liability, but only to deal with matters that require clarification. These sections do not, for example, affect existing statutory and common law rules concerning contributory negligence and comparative fault or other matters not expressly addressed by this legislation. In particular, sections 2 through 4 are not intended to affect the holding in *Suter v. San Angelo Foundry & Machine Company*, 81 N.J. 150 (1979), with respect to the application of the principle of comparative fault in cases involving workplace injuries.

Section 2 identifies the theories under which a manufacturer or seller may be held liable for harm caused by a product. These comprise manufacturing defects, warning defects, and design defects. Except as modified by the provisions of sections 3 and 4, the elements of these causes of action are to be determined according to the existing common law of the State.

Section 3 clarifies certain matters relating to liability for harm caused by an alleged design defect. Paragraph (1) of subsection a. of section 3 provides that a manufacturer or seller is not liable if at the time the product left the manufacturer's control there was not available a practical and feasible alternative design that would have prevented the harm without substantially impairing the usefulness or intended function of the product. Under recent decisions of the New Jersey courts, it is clear that evidence concerning the availability of alternative designs (sometimes referred to as the "state of the art") is relevant in determining whether a product is defective in design, but it is unclear what effect is to be given to a determination that no safer alternative design was feasible when a product was manufactured. This provision makes clear that such a determination precludes liability in a design-defect case not falling within the exception provided for in subsection b. of section 3.

Paragraph (2) of subsection a. of section 3 applies to products whose characteristics are known to the ordinary consumer. It provides

that such a product is not defective in design if harm results from an inherent characteristic of the product that is known to the ordinary person who uses or consumes it with the knowledge common to the class of persons for whom the product is intended. This provision, which adopts the rule established by comment i to section 402A of the American Law Institute's Restatement (Second) of Torts, recognizes that there are many common products, such as foods and other consumer products, whose use necessarily involves some risk of harm. For example, use of butter may conceivably affect cholesterol levels in the arteries and be linked to heart disease, but the product is not for this reason "defective." This "consumer expectations" test has been recognized by the New Jersey courts. See *O'Brien v. Muskin Corp.*, 94 N.J. 169 (1983); *Suter v. San Angelo Foundry & Machine Company*, 81 N.J. 150 (1979); *Whitehead v. St. Joe Lead Co., Inc.*, 729 F.2d 238 (3d Cir.1984). This rule is intended to apply to familiar consumer products of the kind identified in comment i to section 402A of the Restatement (Second) of Torts. It is not intended to apply to other products, such as machinery or other equipment encountered in the workplace. Similarly, it is not intended to apply to dangers posed by products such as machinery or equipment that can feasibly be eliminated without impairing the usefulness of the products, because such dangers are not "inherent."

Paragraph (3) of subsection a. of section 3 provides that a manufacturer or seller is not liable for a design defect if harm results from an unavoidably unsafe aspect of a product and the product was accompanied by an adequate warning or instruction, as provided in section 4 of the act. This provision is based on comment k to section 402A of the Restatement (Second) of Torts and is intended to be applied principally in cases involving prescription pharmaceuticals and vaccines. The use of such products ordinarily entails some risk of side effects, and it is intended that such products shall not be found "defective" if they are properly manufactured and are accompanied by proper warnings or instructions.

Subsection b. of section 3 establishes a limited exception to the provisions of paragraph (1) of subsection a. concerning compliance with the state of the art. In an extraordinary case, a court may conclude that the state-of-the-art provision does not apply if the court makes all of the following determinations: (1) that a product is egregiously unsafe or ultrahazardous; (2) that the ordinary user or consumer of the product cannot reasonably be expected to have knowledge of the product's risks, or the product poses a risk of serious injury to persons other than the user or consumer; and (3) that the product has little or no usefulness. It is intended that such a finding would be made only in genuinely extraordinary cases—for example, in the case of a deadly toy marketed for use by young children, or of a product marketed for use in dangerous criminal activities.

Section 4 provides that a manufacturer or seller is not liable in a warning-defect case if an adequate warning is given when the product has left the control of the manufacturer or seller or, in the case of dangers discovered after the product has left control, if an adequate warning is then given by the manufacturer or seller. The

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§ 2A:58C-1. Findings; definitions

- a.** The Legislature finds that there is an urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products, including certain principles under which liability is imposed and the standards and procedures for the award of punitive damages. This act is not intended to codify all issues relating to product liability, but only to deal with matters that require clarification. The Legislature further finds that such sponsors' or committee statements that may be adopted or included in the legislative history of this act shall be consulted in the interpretation and construction of this act.
- b.** As used in this act:
- (1) "Claimant" means any person who brings a product liability action, and if such an action is brought through or on behalf of an estate, the term includes the person's decedent, or if an action is brought through or on behalf of a minor, the term includes the person's parent or guardian.
 - (2) "Harm" means (a) physical damage to property, other than to the product itself; (b)

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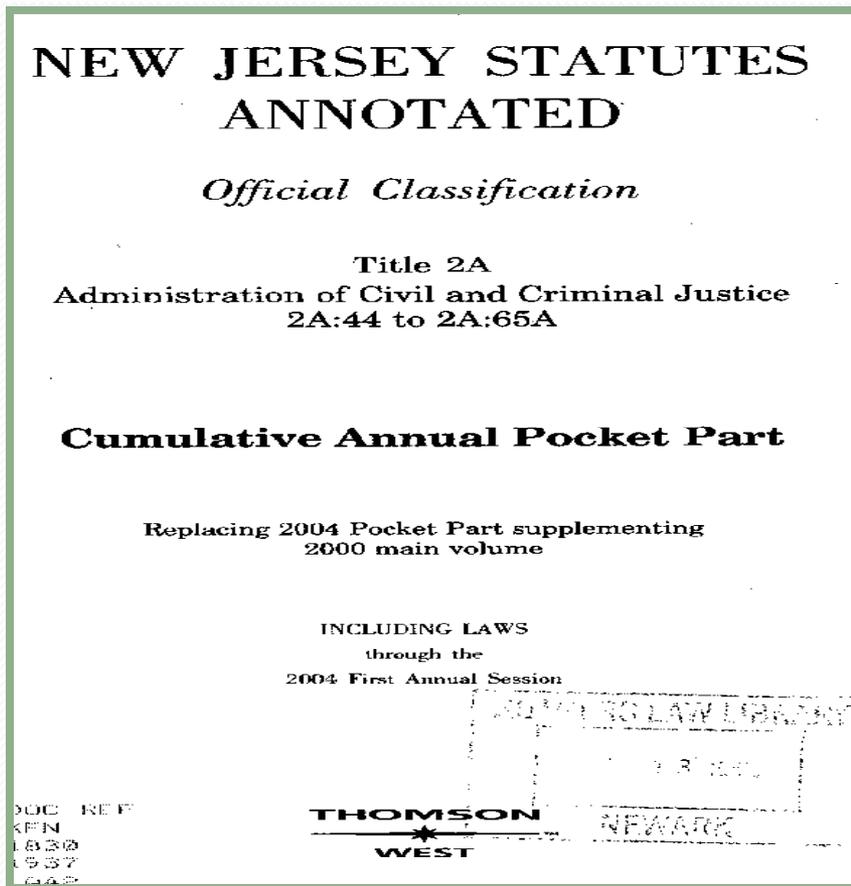
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 ➔ **2A:58C-1. Legislative findings; definitions**

a. The Legislature finds that there is an urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products, including certain principles under which liability is imposed and the standards and procedures for the award of punitive damages. This act is not intended to codify all issues relating to product liability, but only to deal with matters that require clarification. The Legislature further finds that such sponsors' or committee statements that may be adopted or included in the legislative history of this act shall be consulted in the interpretation and construction of this act.

b. As used in this act:

(1) "Claimant" means any person who brings a product liability action, and if such an action is brought through or on behalf of an estate, the term includes the person's decedent, or if an action is brought through or on behalf of a minor, the term includes the person's parent or guardian.

(2) "Harm" means (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional

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	2.	<input type="checkbox"/> Cited by	Kendall v. Hoffman-La Roche, Inc. ▲ 209 N.J. 173, 36 A.3d 541, 2012 N.J. LEXIS 160, CCH Prod. Liab. Rep. P18799 Cited by: 209 N.J. 173 p.179, p.194; 36 A.3d 541 p.544, p.554 The PLA, N.J.S.A. 2A:58C-1 to -11 , The Product Liability Act (PLA), N.J.S.A. §§ 2A:58C-1 to 2A:58C-11 , has been enacted as a remedial measure to limit the liability of manufacturers by establishing clear rules with respect to certain matters including certain principles under which liability is imposed and the standards and procedures for the award of punitive damages. N.J.S.A. § 2A:58C-1(a) . In particular, in enacting the PLA, the New Jersey Legislature intends to reduce the burden ...	N.J.	2012	
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