Statutory Research
Bridge the Gap 2014
Rutgers University Center for Law & Justice

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Reference and Technology Librarian
Rutgers University Center for Law & Justice

Types of Statutory Materials

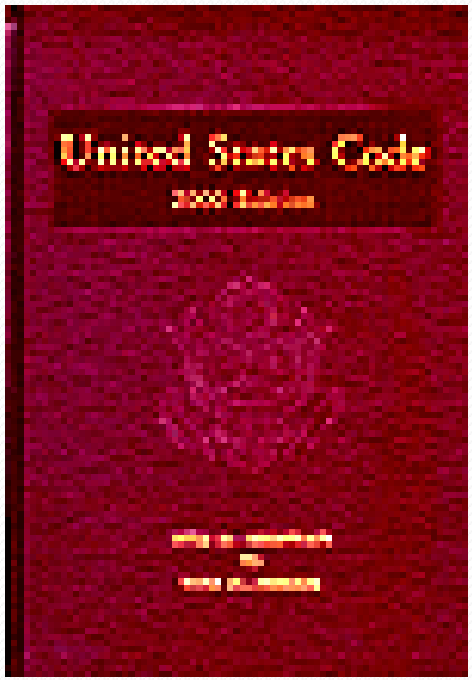
- **Constitutions**
- **Laws/Statutes/Codes**
- **Treaties**
- **Municipal Ordinances**
- **Court Rules**

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

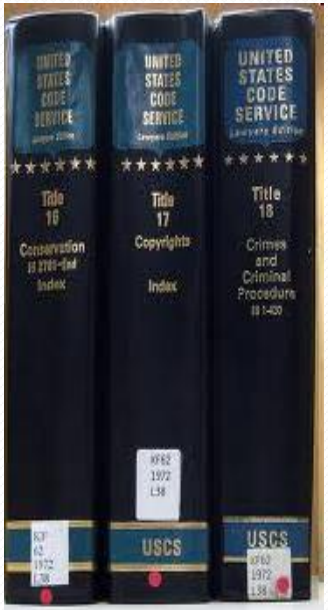
Where to Start: Print or Electronic?



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

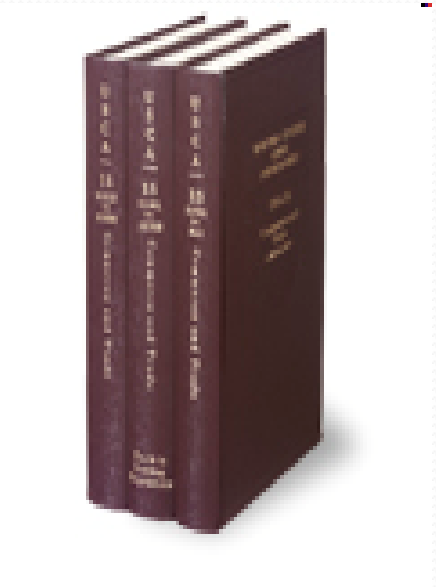
Which one?

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?

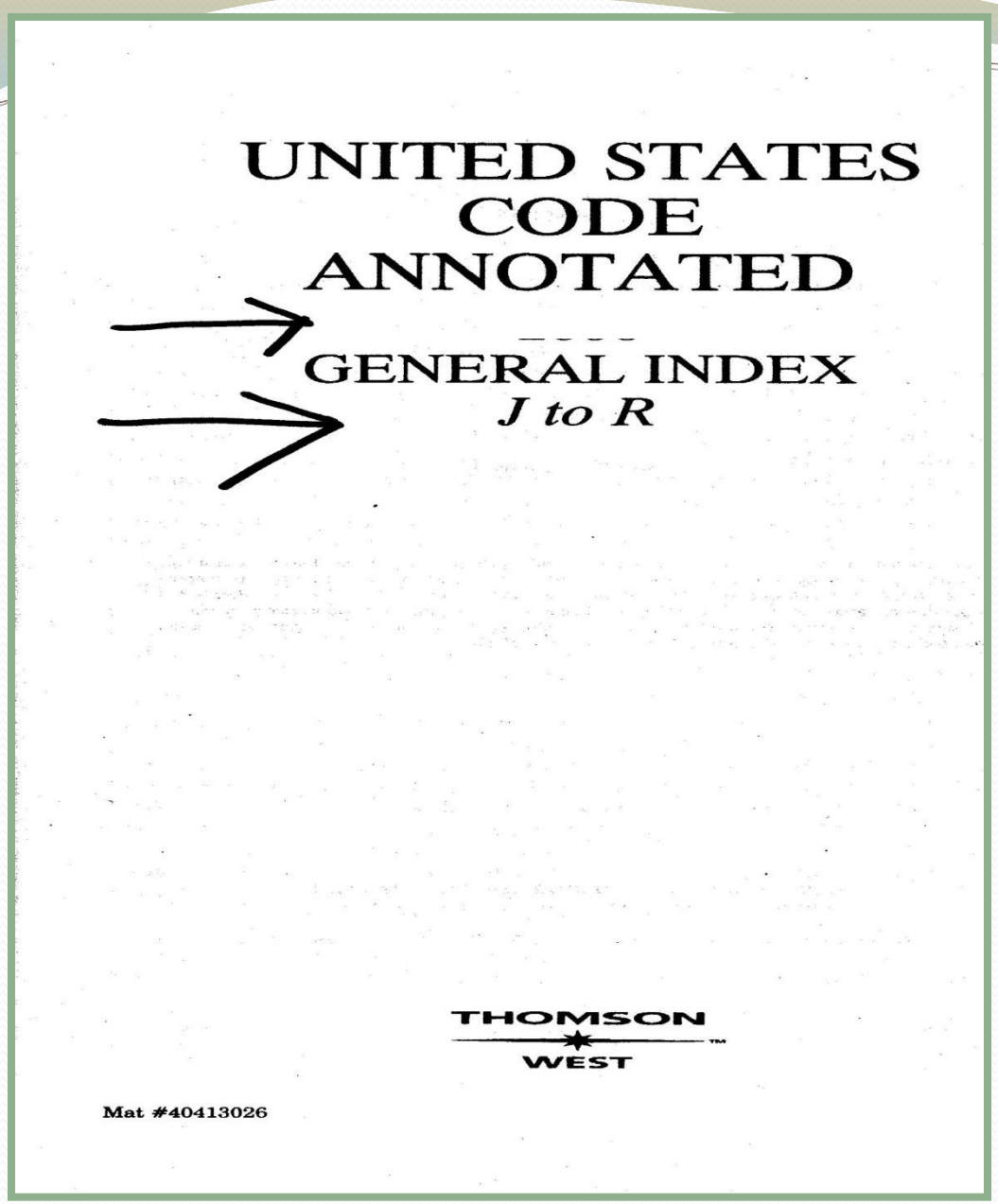
- Finding Aids

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

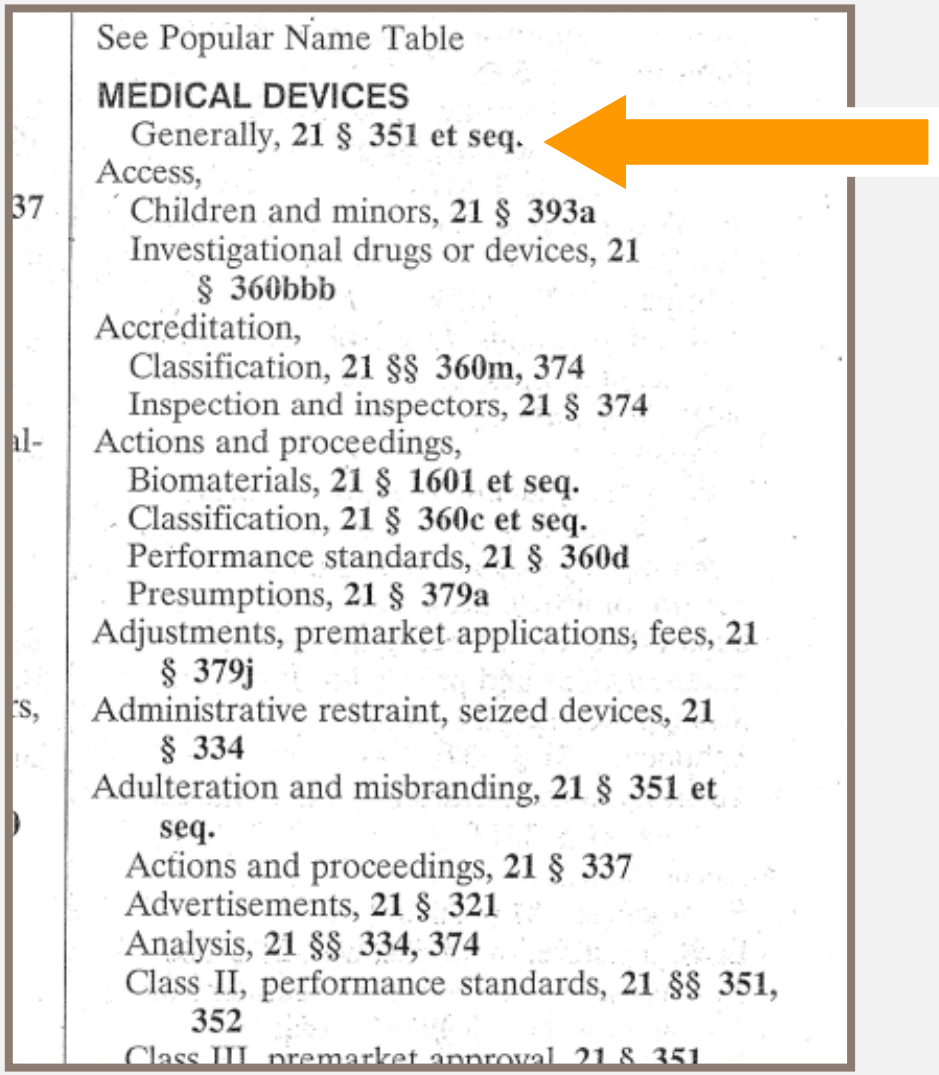
- Hard Copy
- Westlaw Next



Index volume from USCA

Index

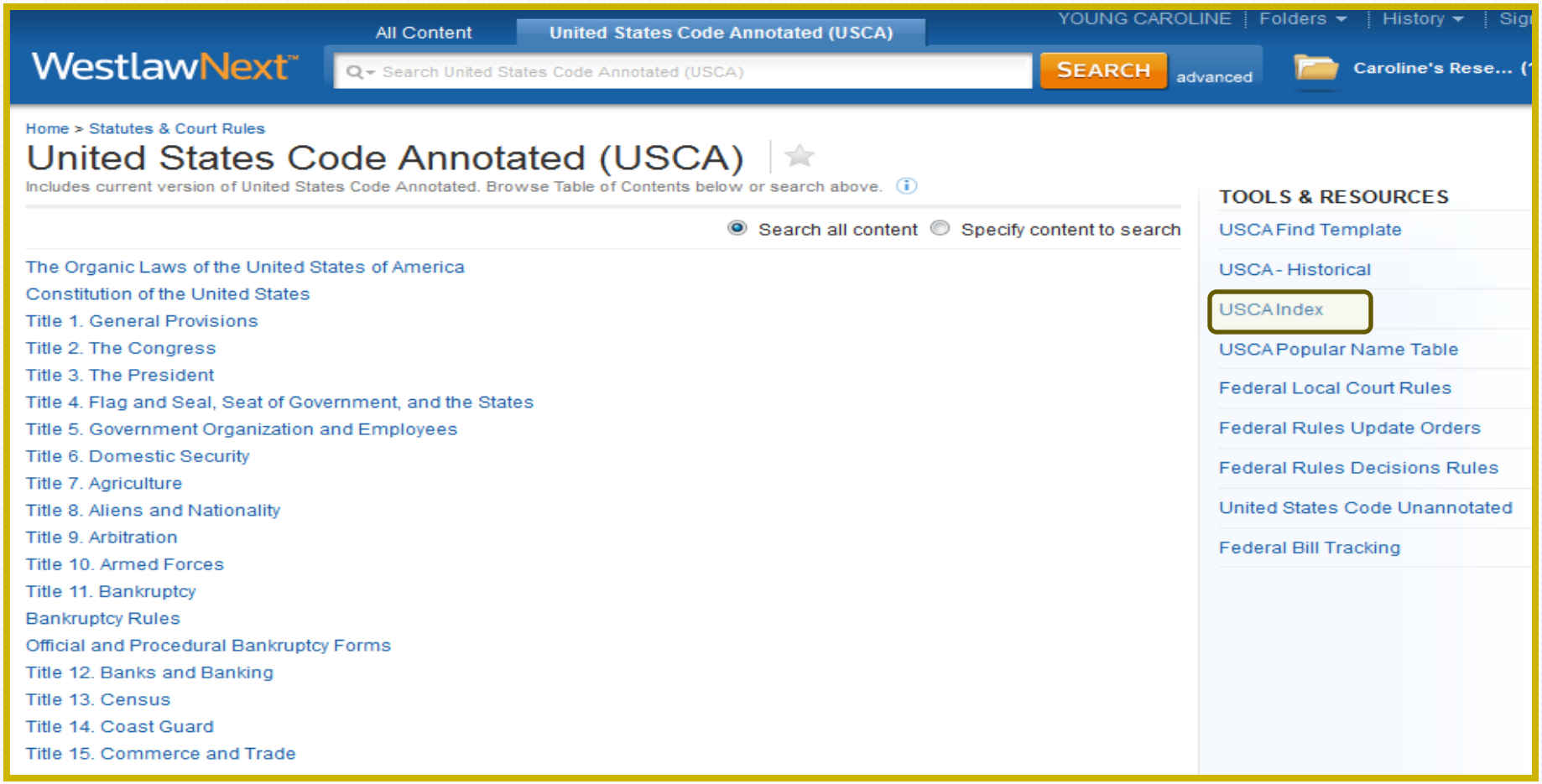
- Start by looking up the term ‘medical devices’
- Browse the ‘medical devices’ section until you find a relevant section



See Popular Name Table

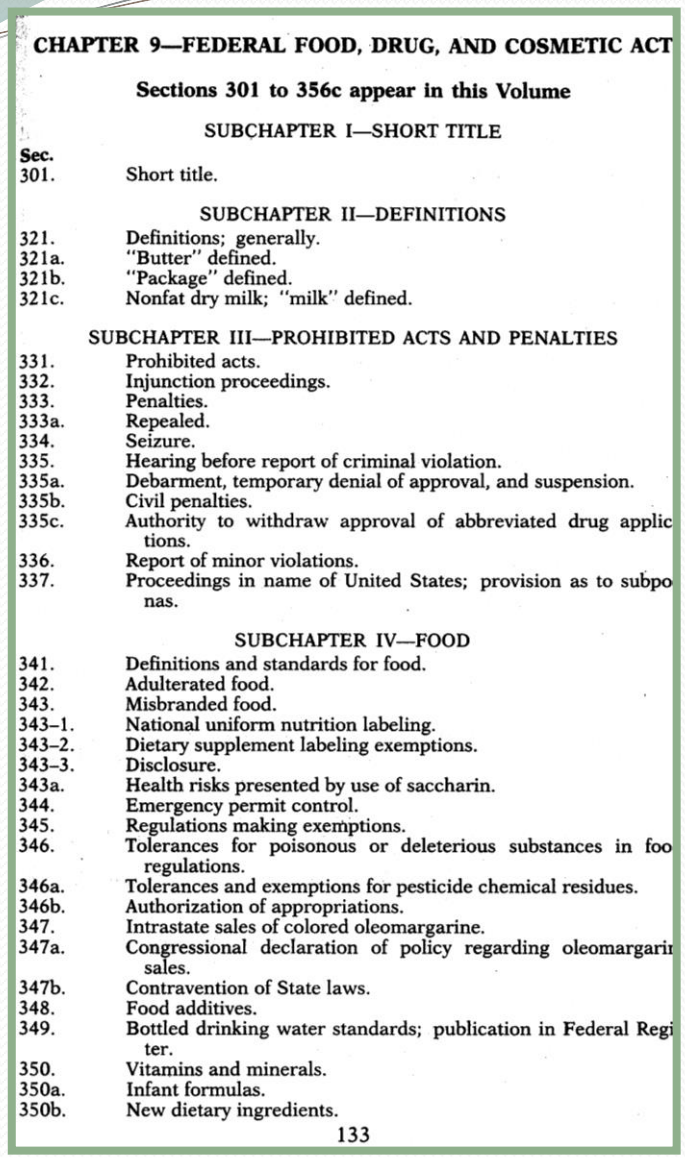
MEDICAL DEVICES
Generally, **21 § 351 et seq.**
Access,
Children and minors, **21 § 393a**
Investigational drugs or devices, **21 § 360bbb**
Accreditation,
Classification, **21 §§ 360m, 374**
Inspection and inspectors, **21 § 374**
Actions and proceedings,
Biomaterials, **21 § 1601 et seq.**
Classification, **21 § 360c et seq.**
Performance standards, **21 § 360d**
Presumptions, **21 § 379a**
Adjustments, premarket applications, fees, **21 § 379j**
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



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

SUBCHAPTER II—DEFINITIONS

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

SUBCHAPTER IV—FOOD

133

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

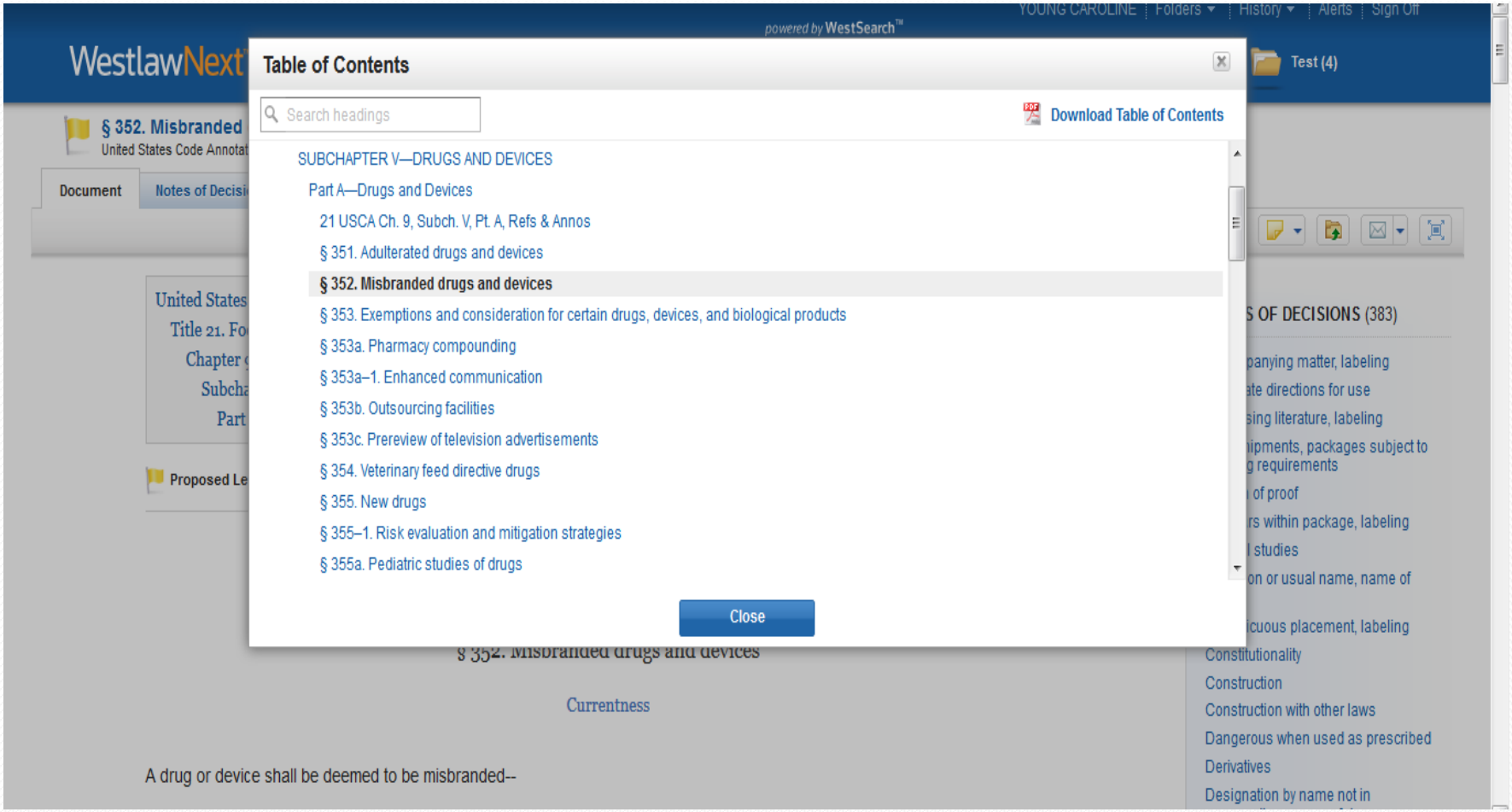
PART B—DRUGS FOR RARE DISEASES OR CONDITIONS

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

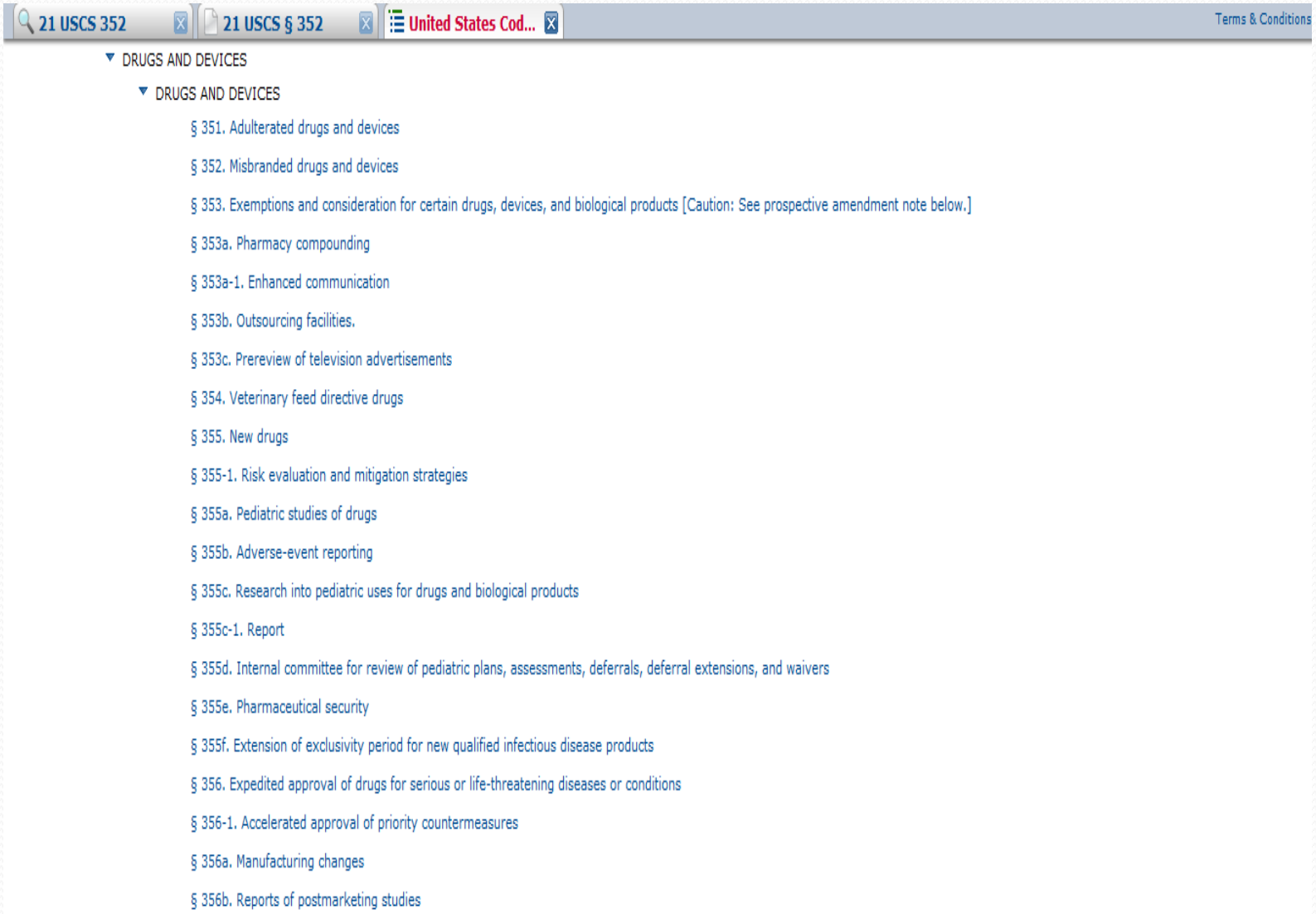
Sec. 352:

Misbranded drugs and devices

Westlaw Next - TOC

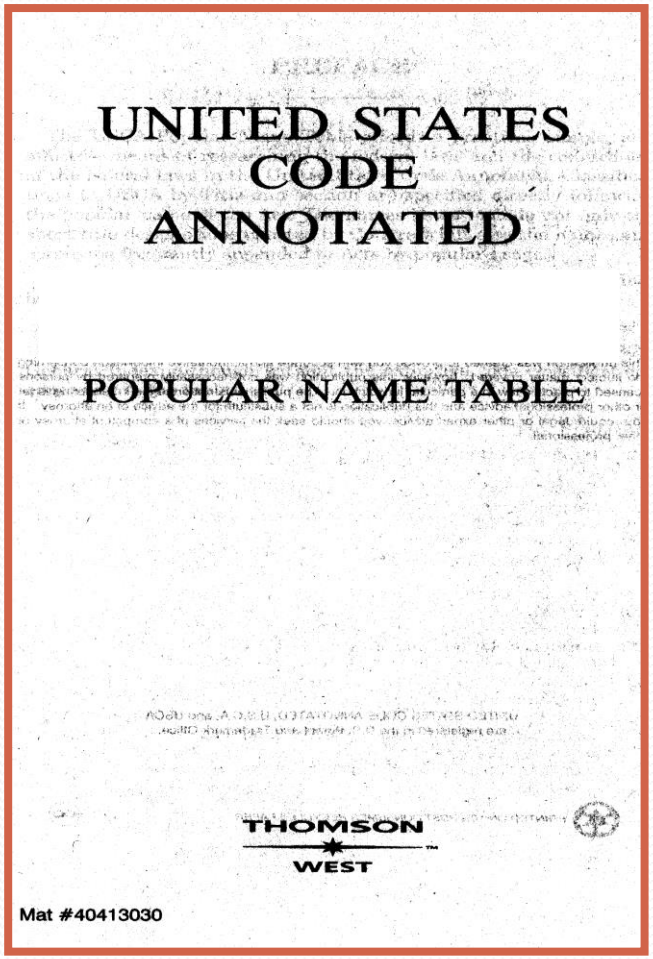


LexisAdvance - TOC



Popular Name Table

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



UCSA Popular Name Table

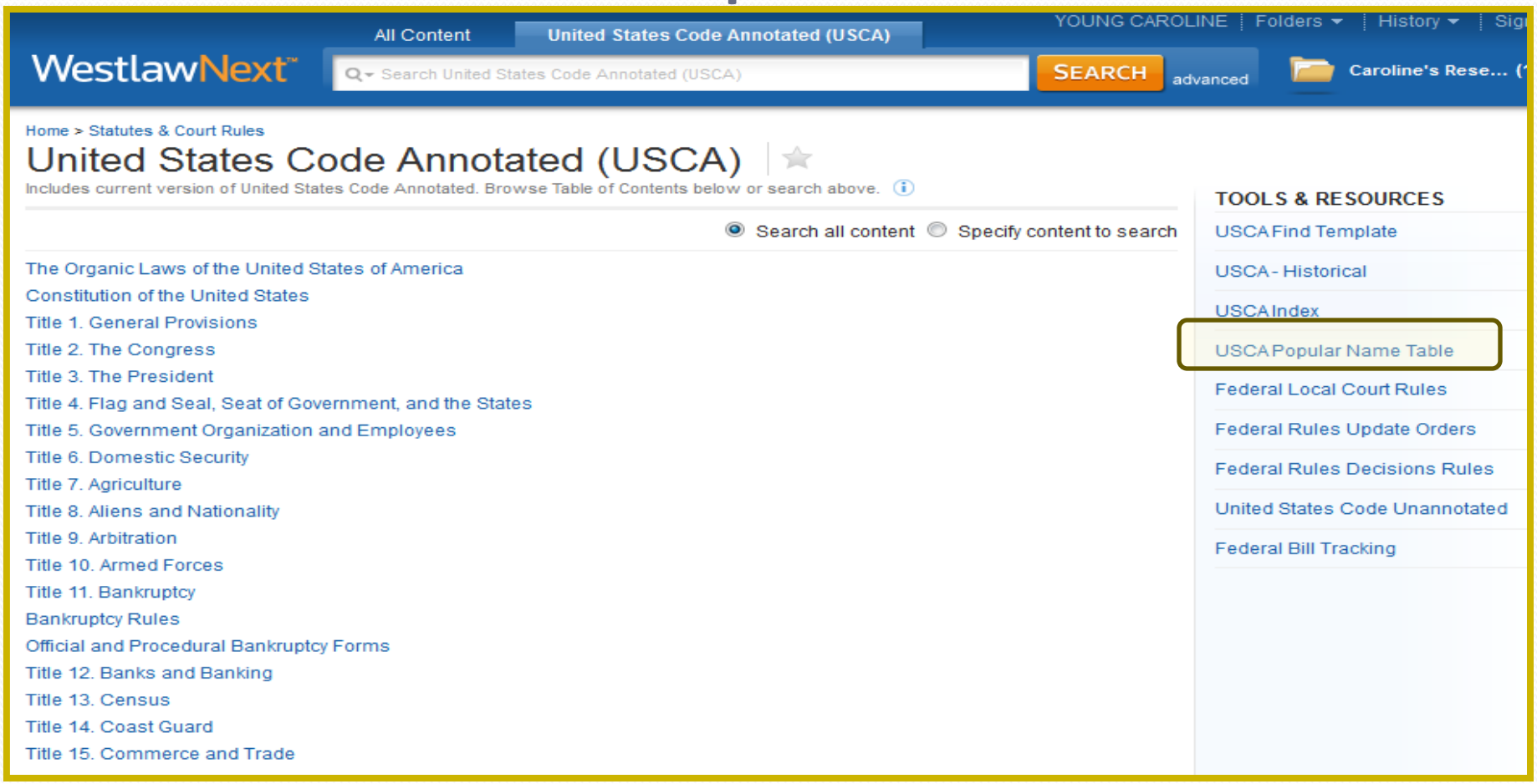
Popular Name Table

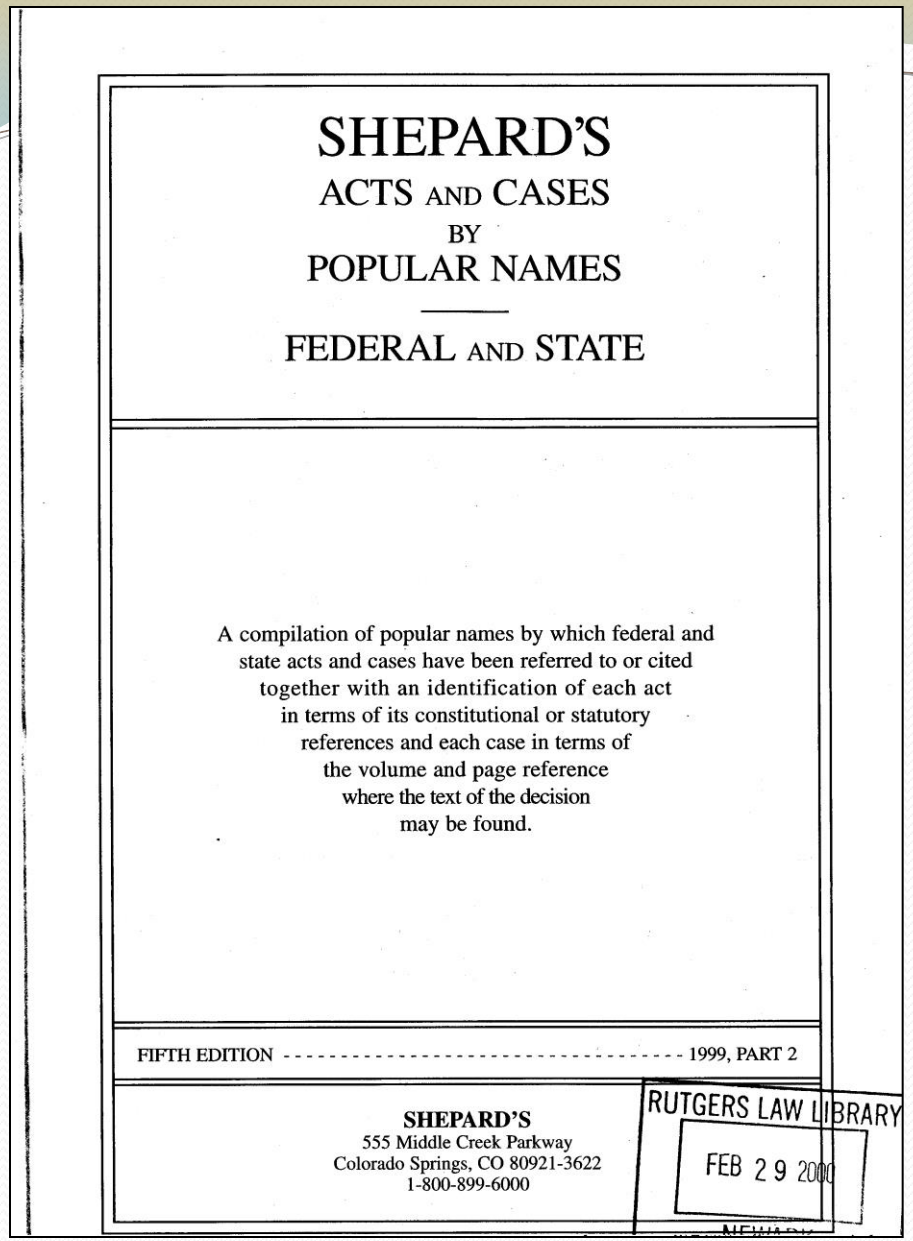
Medical Device Amendments

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





SHEPARD'S
ACTS AND CASES
BY
POPULAR NAMES

FEDERAL AND STATE

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

SHEPARD'S
555 Middle Creek Parkway
Colorado Springs, CO 80921-3622
1-800-899-6000

If you know the name of an Act --

Shepard's Acts and Cases by Popular Names is a good finding aid

dical 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.

edical Care Savings Account Act
Ga. 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.

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

edical Center Act (Chicago)
Ill. Rev. Stat. 1991, Ch. 111 1/2 § 5000 et seq.

edical Center District Act
Ill. Rev. Stat. 1991, Ch. 111 1/2, § 5000 et seq.

edical Center Quota Act
Ark. Code Ann. 1987, 6-64-505 et seq.

edical Clinic Act
Ala. Code 1975, § 11-58-1 et seq.

edical College Act
Mo. Rev. Stat., 334.160

edical Conduct Reform Act (Professional)
N.J. Stat. Ann., 45:9-19.4 et seq.

edical Consent Law
Fla. Stat. Ann., 766.103

edical 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.

edical 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.

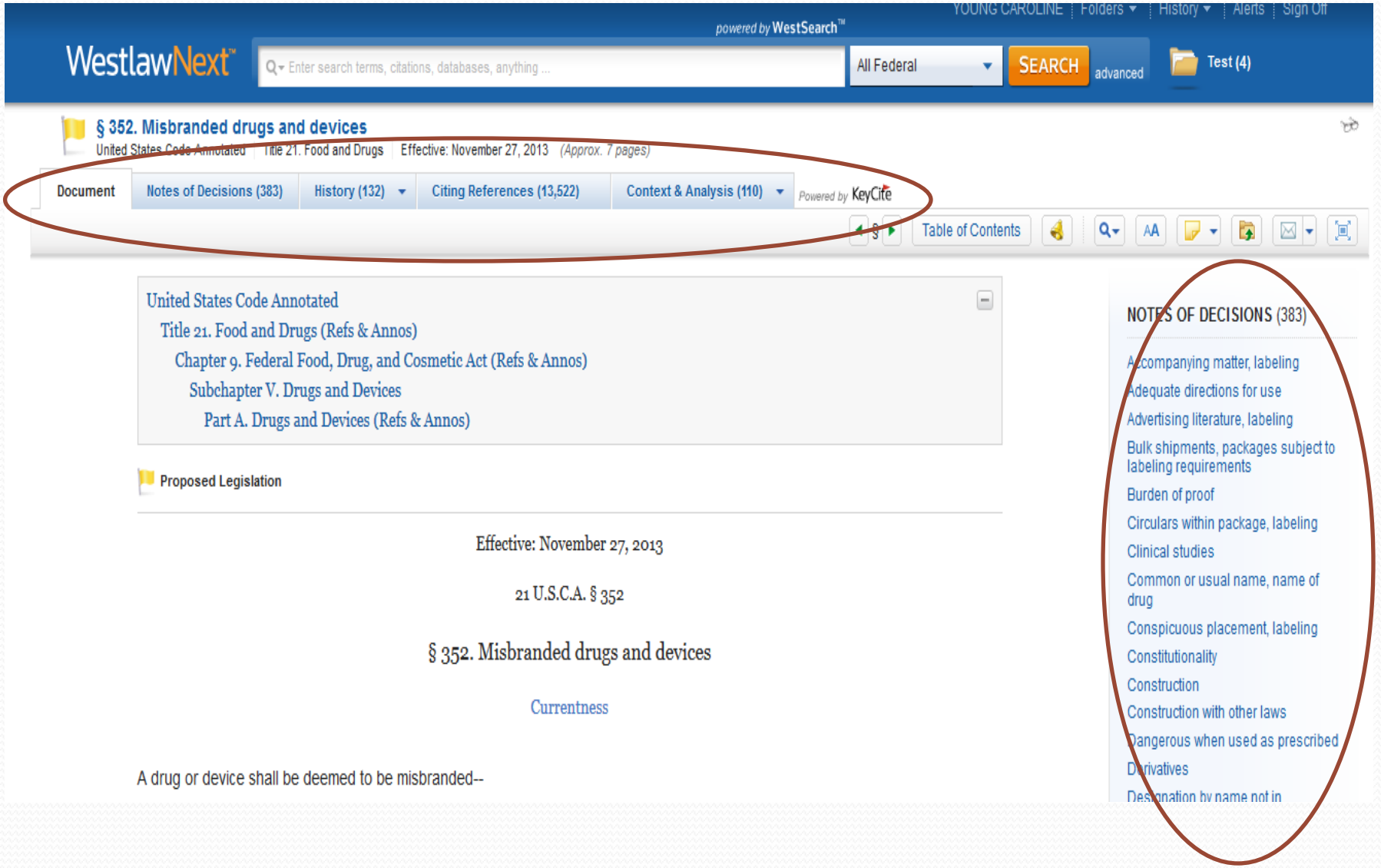
Medical Education Facilities Bond Act
N.J. Laws 1977, Ch. 235

Medical Emergencies Act (Coal Mine)
Ill. Comp. Stat. 1992, Ch. 410, § 15/1 et seq.

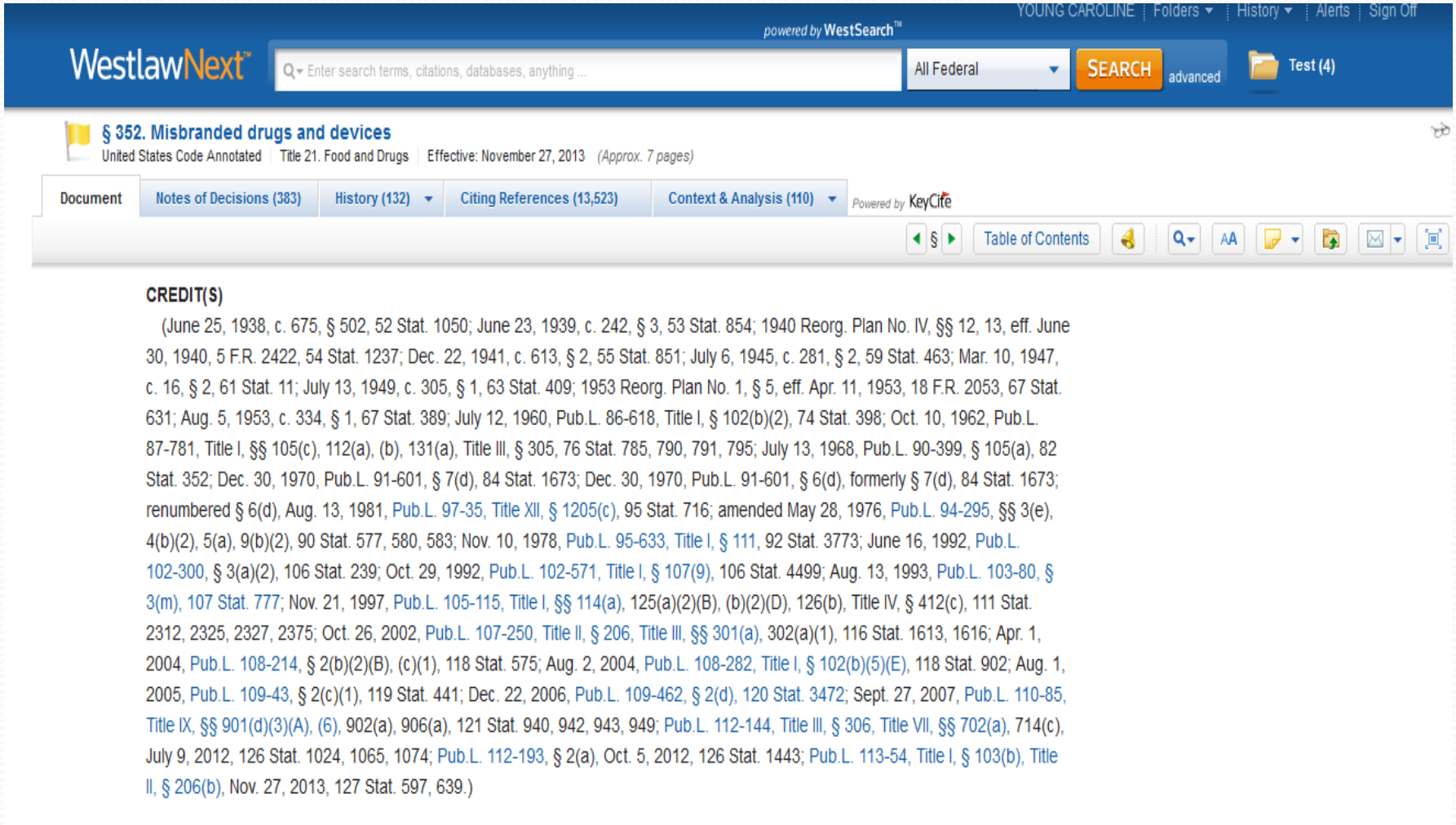
Medical Emergency Services Act
Tex. Health and Safety Code, § 773.001 et seq.

← 21 USC 301 note

Inside the Statute



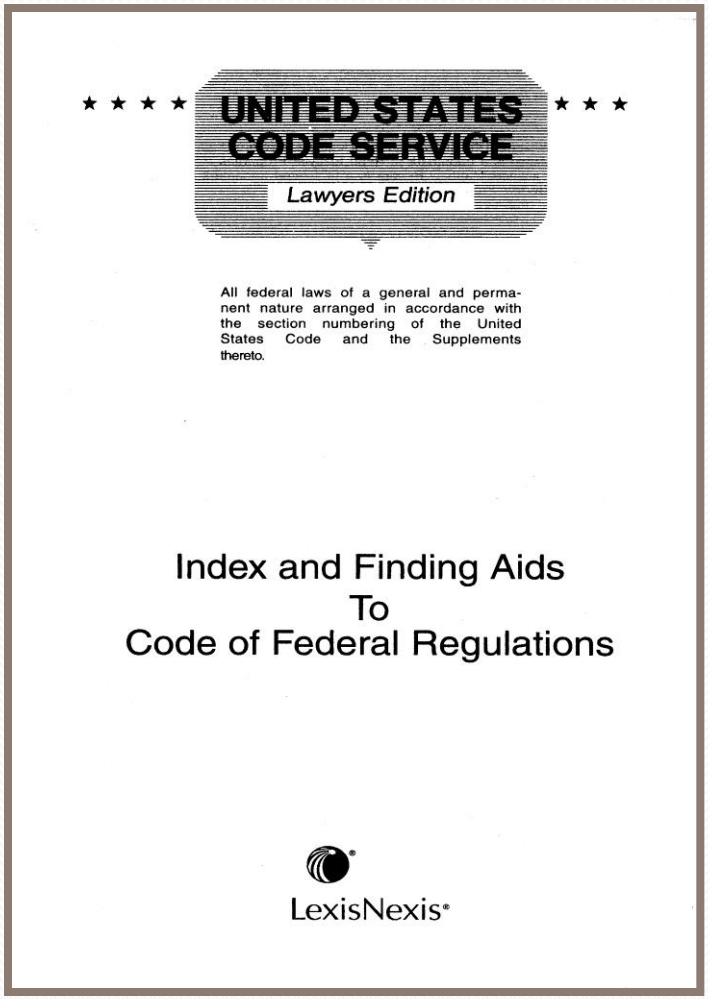
Credits – Source of law



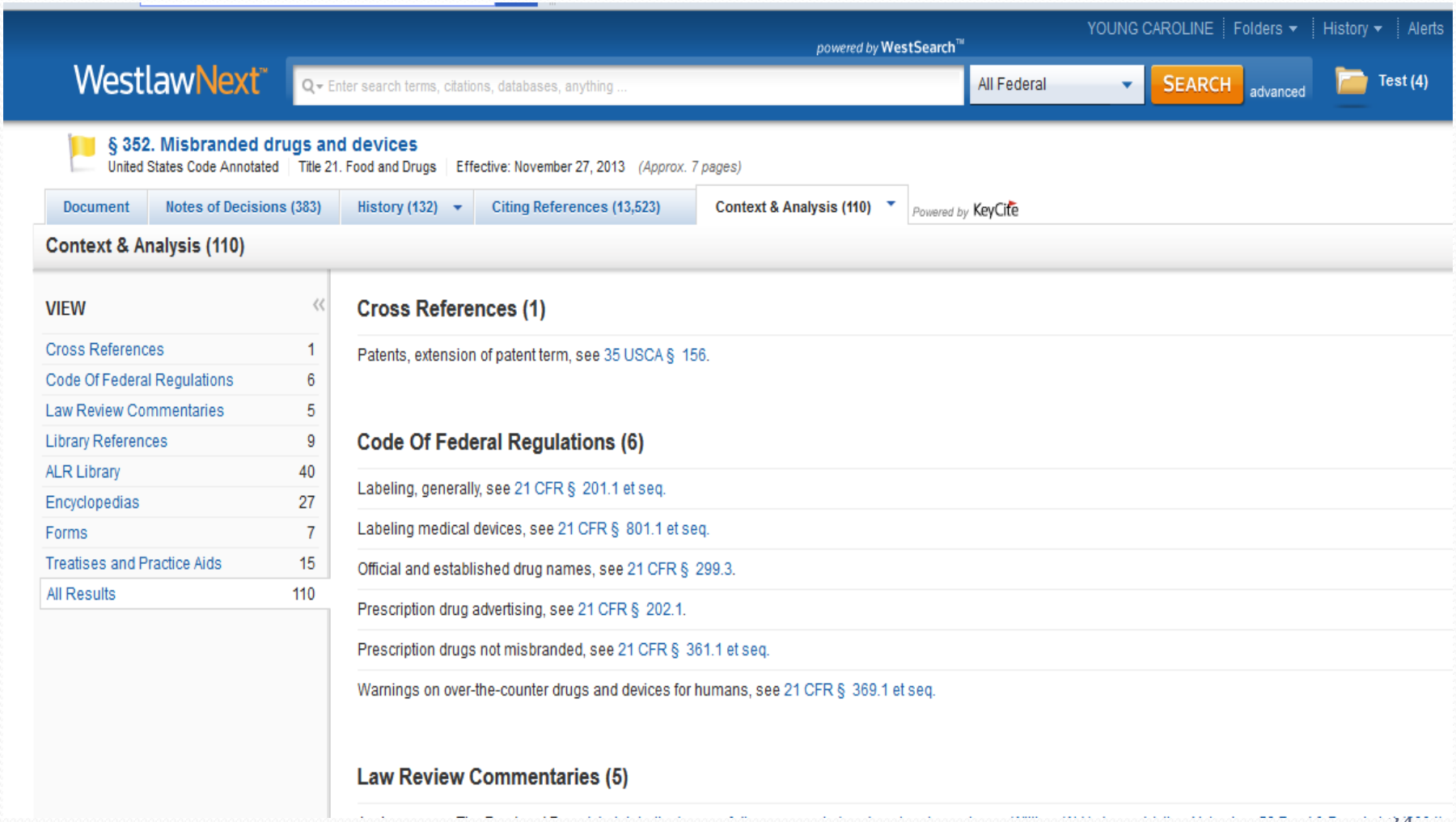
CREDIT(S)

(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



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. 1911.)

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

Drugs and Narcotics ⇐2 to 4.

CJS Drugs and Narcotics § 115, Weight and Sufficiency.

Corpus Juris Secundum

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.).

98 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 Employee 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.

25 Am. Jur. 2d Drugs and Controlled Substances § 102, Powers and Duties of Secretary of Health and Human Services; Delegation to FDA; Regulations.

25 Am. Jur. 2d Drugs and Controlled Substances § 106, Drugs Exempt from Act Provisions.

25 Am. Jur. 2d Drugs and Controlled Substances § 137, Generally.

25 Am. Jur. 2d Drugs and Controlled Substances § 138, Nonconformance With Current Good Manufacturing Practice.

Forms

Federal Procedural Forms § 31:25, Checklist-Statutes and Regulations Providing Opportunity for Hearing.

Federal Procedural Forms § 31:26, Right to Hearing.

Federal Procedural Forms § 31:76, Classification and Reclassification of Medical Device.

Federal Procedural Forms § 31:197, Scope of Division.

Federal Procedural Forms § 31:201, Seizure Actions.

4A West's Federal Forms § 5851, Complaint for Forfeiture.

4A West's Federal Forms § 5859.10, Consent Decree of Condemnation.

Treatises and Practice Aids

Federal Procedure, Lawyers Edition § 35:42, Right to Hearing.

Federal Procedure, Lawyers Edition § 35:219, Device Classes.

Federal Procedure, Lawyers Edition § 35:280, Necessity of Approved Application.

Federal Procedure, Lawyers Edition § 35:389, Grounds for Seizure.

§ 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 (t)]

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

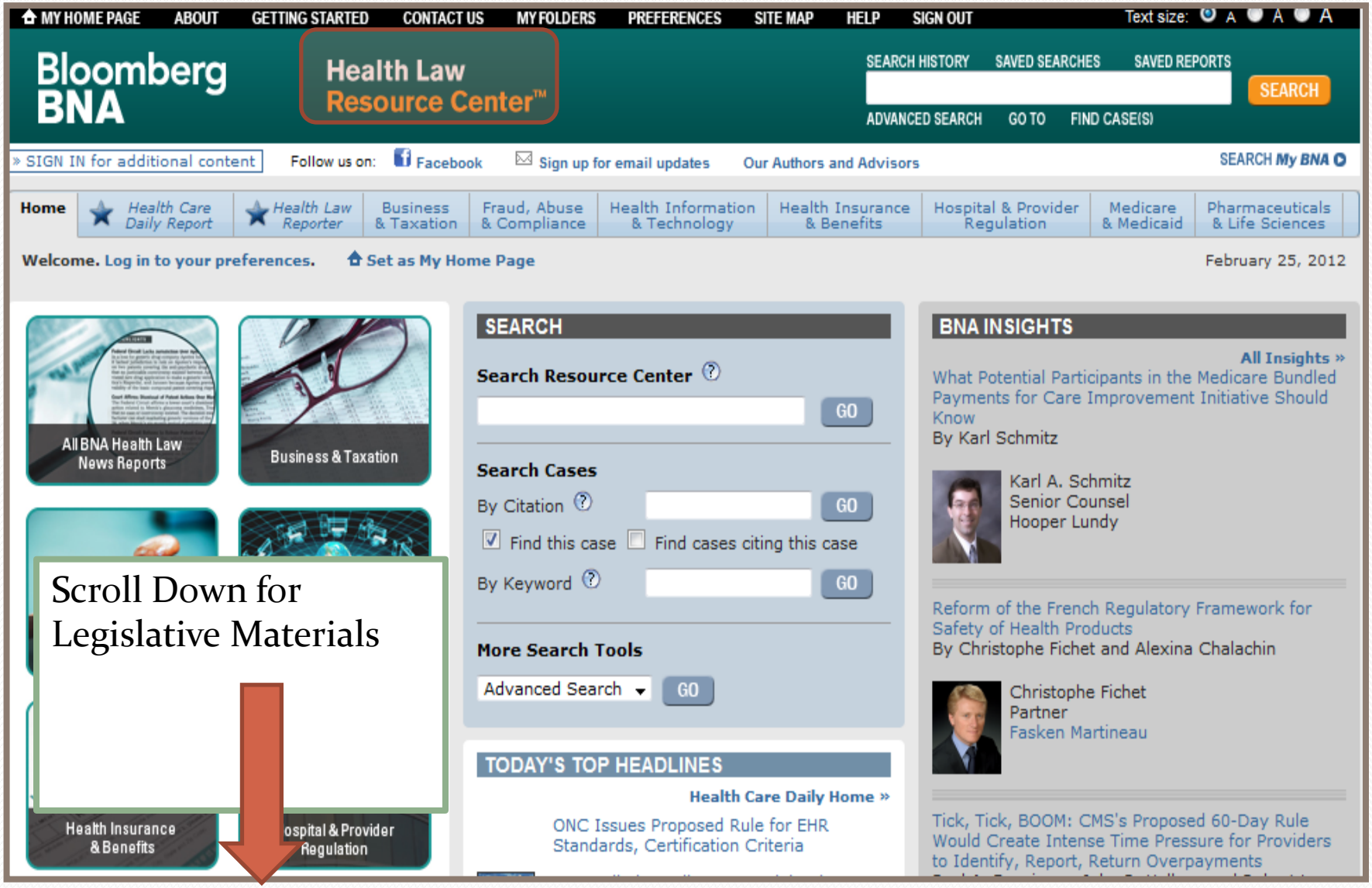
If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use.

Use electronic resources to update the statute

KeyCite/Shepardize the Statute

- Is it still good law?
- Is there pending legislation?

Great Alternative Statute Resources: Bloomberg BNA Mini Libraries



FEDERAL LAWS, REGS & AGENCY DOCUMENTS

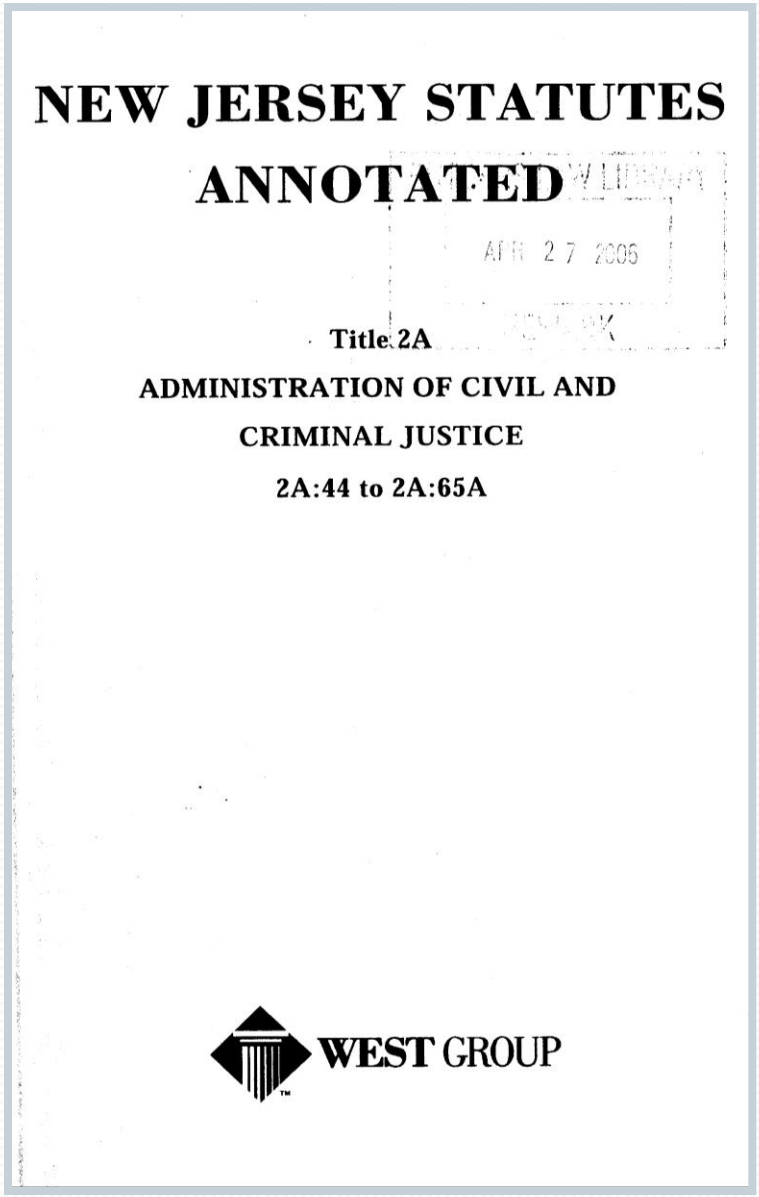
- U.S. Code
- Federal Legislation
- Code of Federal Regulations
- Federal Register
- Agency Documents

STATE INFORMATION

- State Legislation Developments
- State Regulatory Developments
  - » Create Regulatory Summary Report
- State Law Topical Surveys

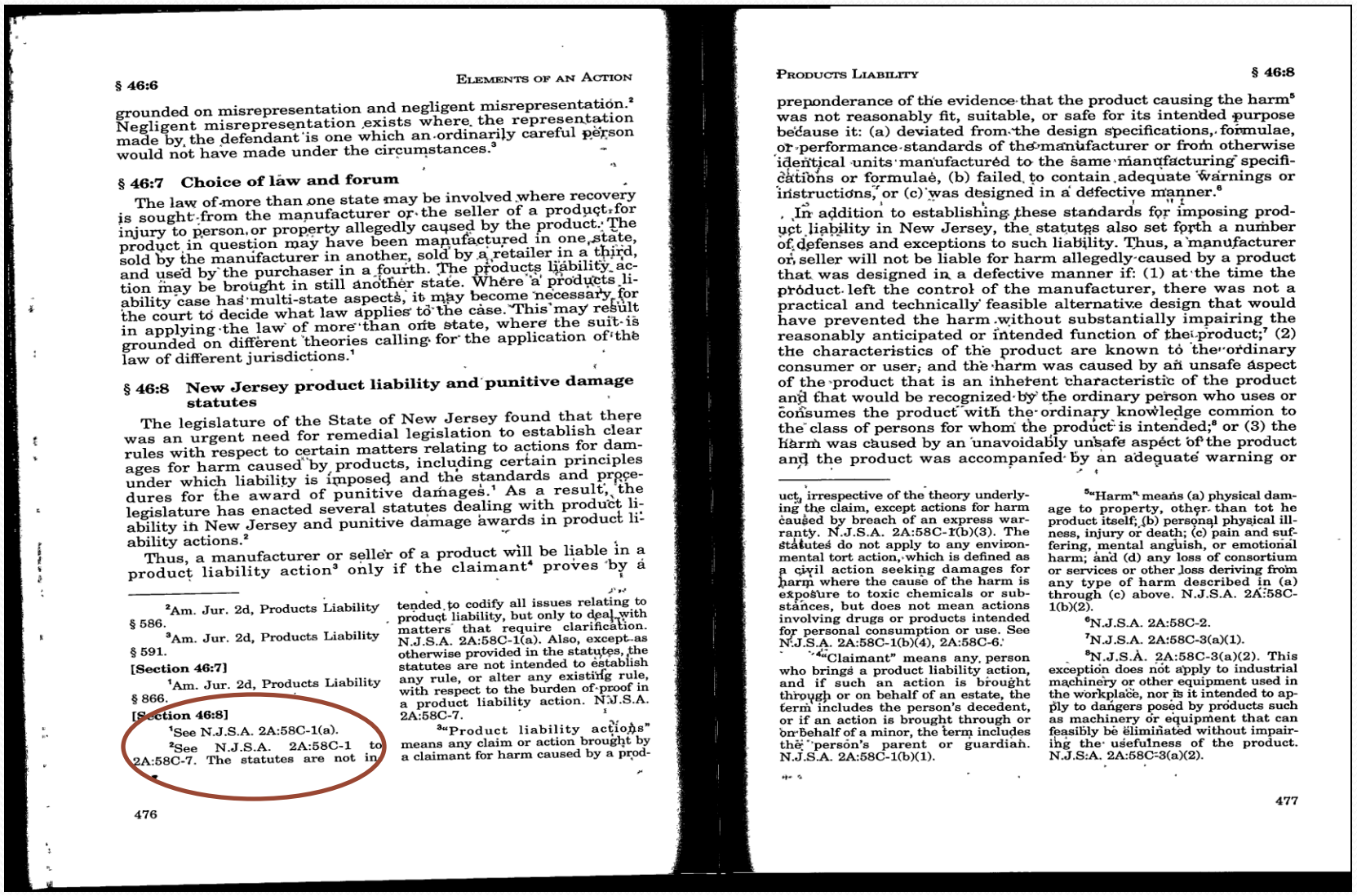
Keyword Search-Last Resort

After checking federal law, do the same thing for state law:



- Secondary Source
- Check index
- Review TOC
- Check popular name table if you know the name of an Act
- Find text of statute
- Note cross references, secondary sources and historical note
- Check for relevant regulations
- Always check the pocket part/update electronically
- Shepardize/KeyCite

New Jersey Practice, Volume 52, 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 action[3] only if the claimant[4] proves by a

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

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

[Section 46:7]

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

[Section 46:8]

[1]See N.J.S.A. 2A:58C-1(a).

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

[3]"Product liability actions" 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. 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).

preponderance of the evidence that the product causing the harm[5] 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

[5]"Harm" means (a) physical damage to property, other than tot he 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).

[6]N.J.S.A. 2A:58C-2.

[7]N.J.S.A. 2A:58C-3(a)(1).

[8]N.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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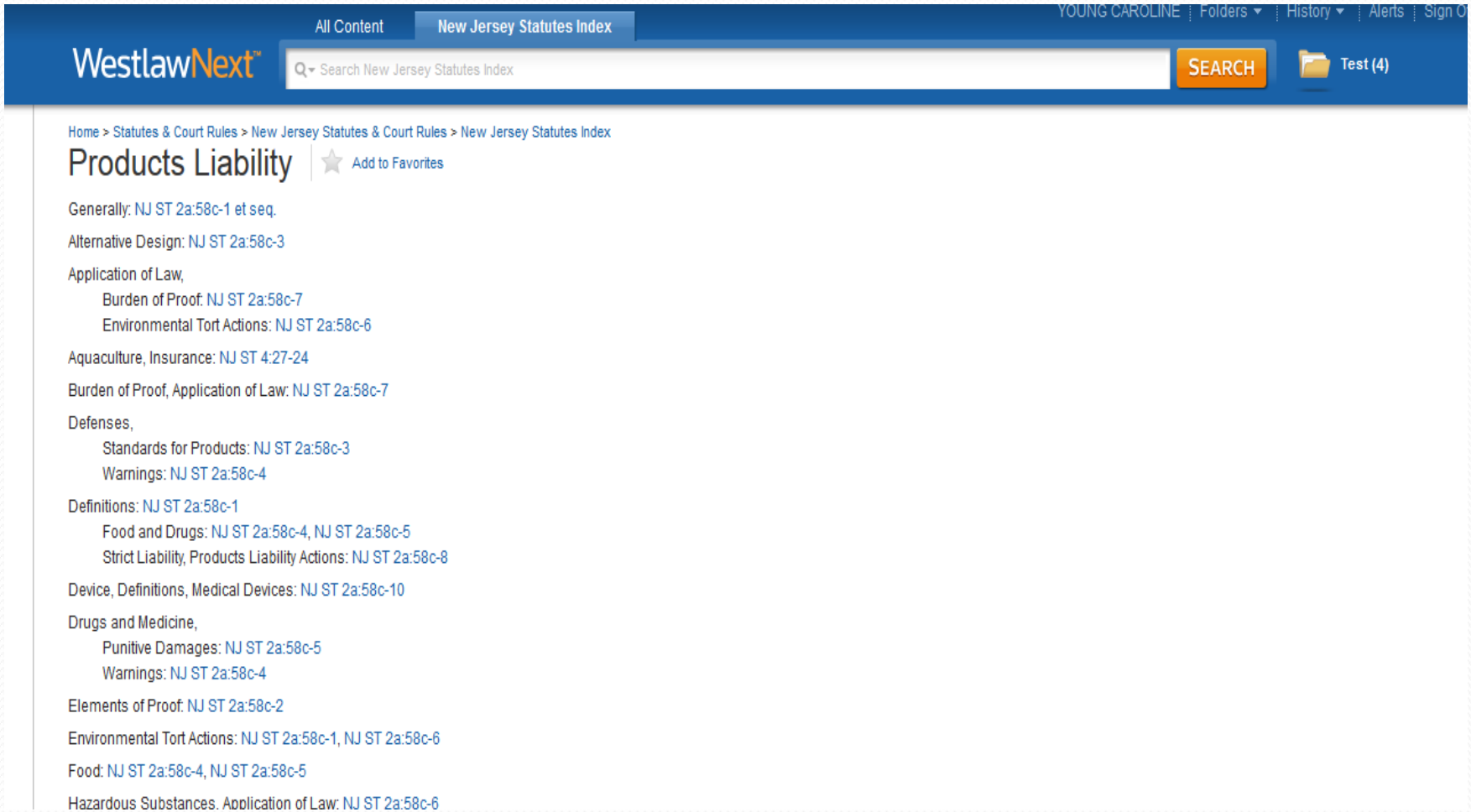
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New Jersey Products Liability Statute

NJSA 2A:58C

CHAPTER 58C

PRODUCTS LIABILITY

Section

Law Review and Journal Commentaries

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

Cipollone decision: Providing guidelines for federal preemption of product liability claims. Marc Z. Edell and Harriet Dinegar Milks, 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. 1589, 517 U.S. 559, 134 L.Ed.2d 809, on remand 701 So.2d 507, rehearing denied.

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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N.J. Stat. § 2A:58C-1 (Copy citation)

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New Jersey Statutes > TITLE 2A. ADMINISTRATION OF CIVIL AND CRIMINAL JUSTICE > SUBTITLE 6. SPECIFIC CIVIL ACTIONS > CHAPTER 58C. PRODUCT LIABILITY

§ 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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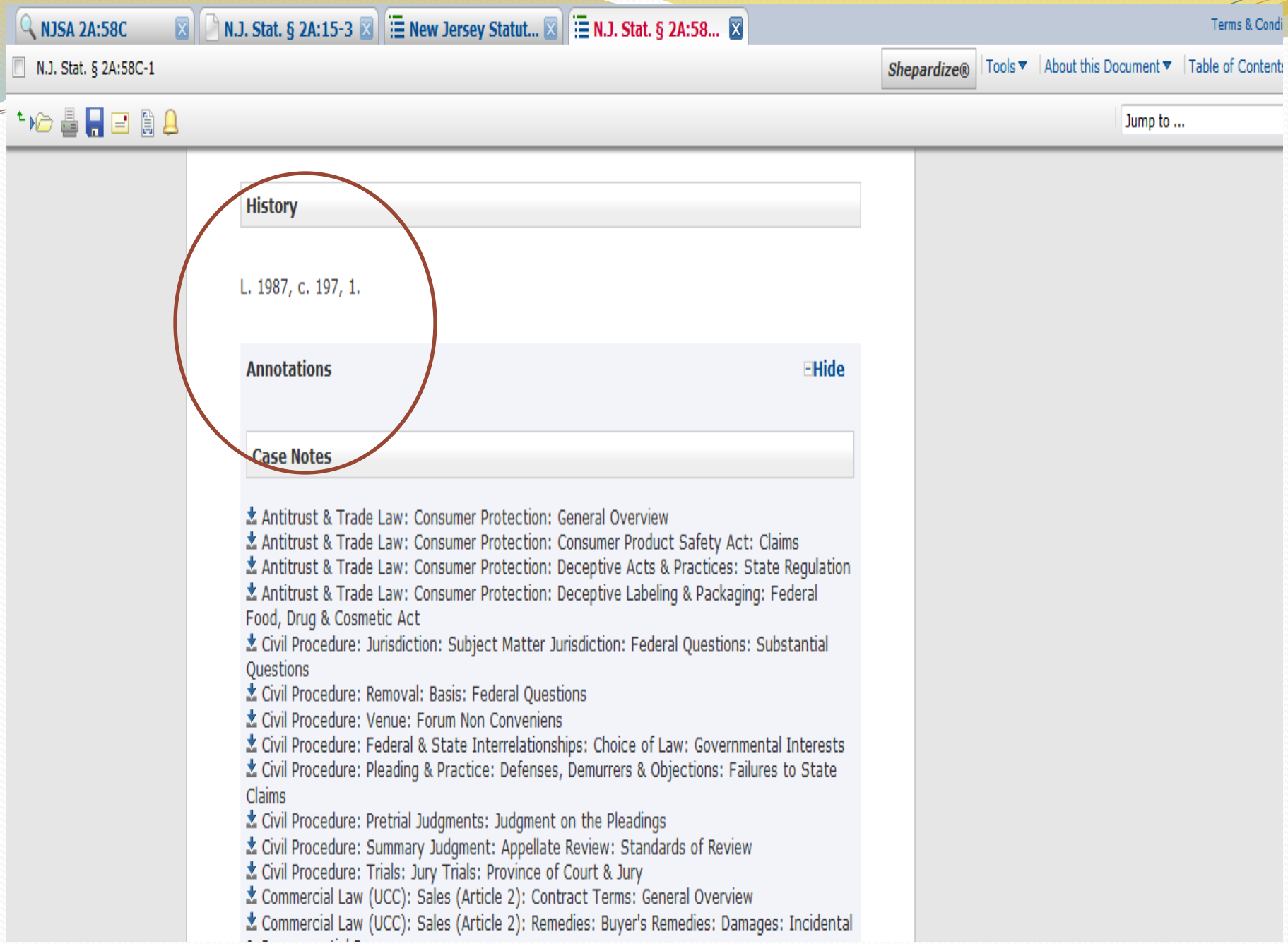
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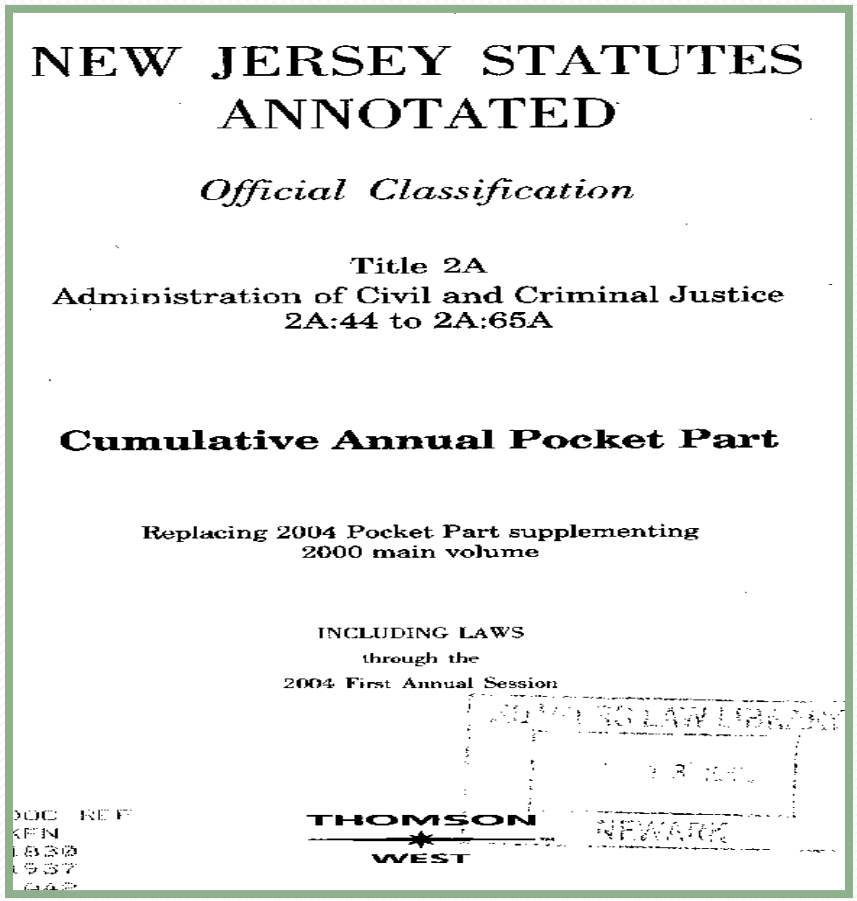

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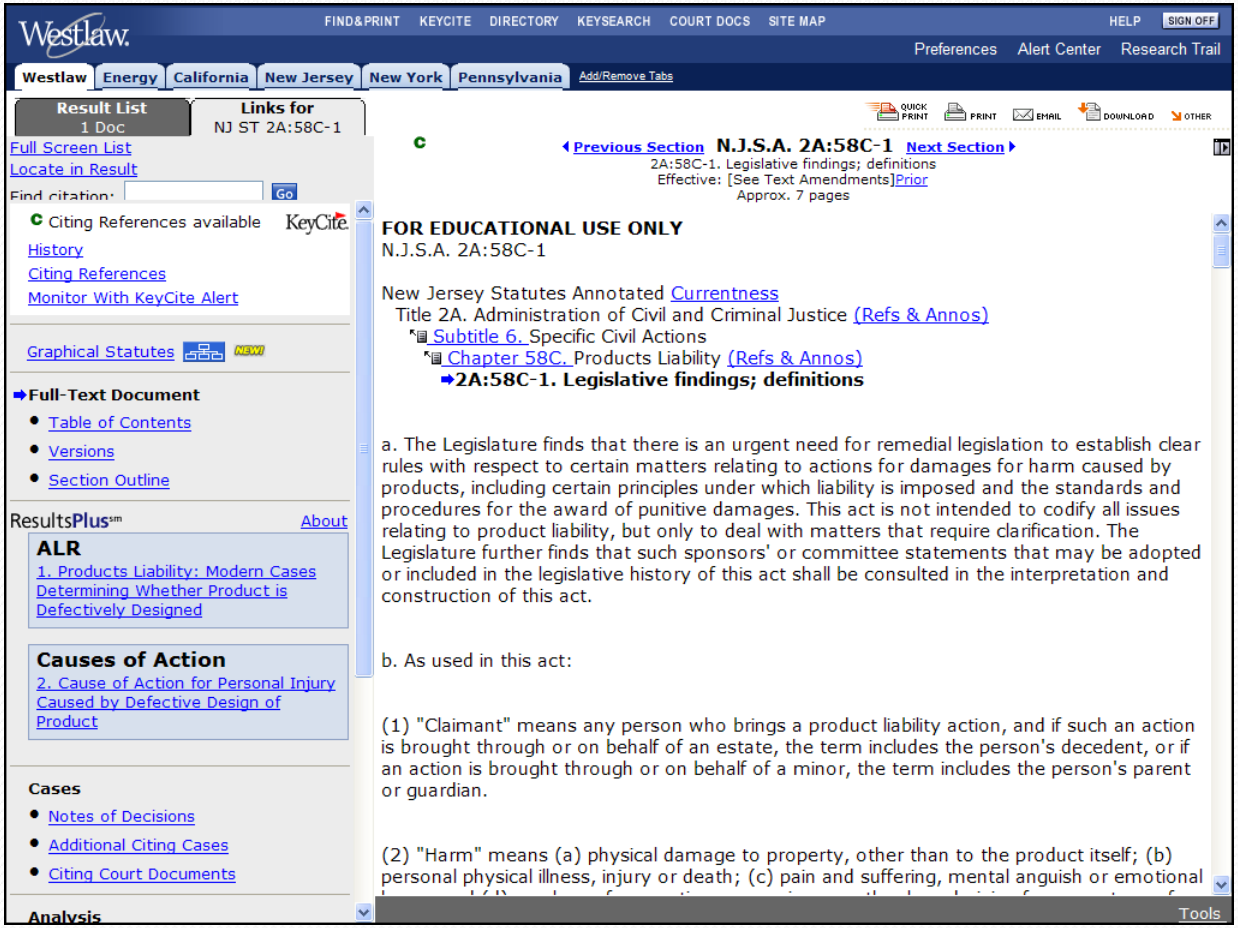

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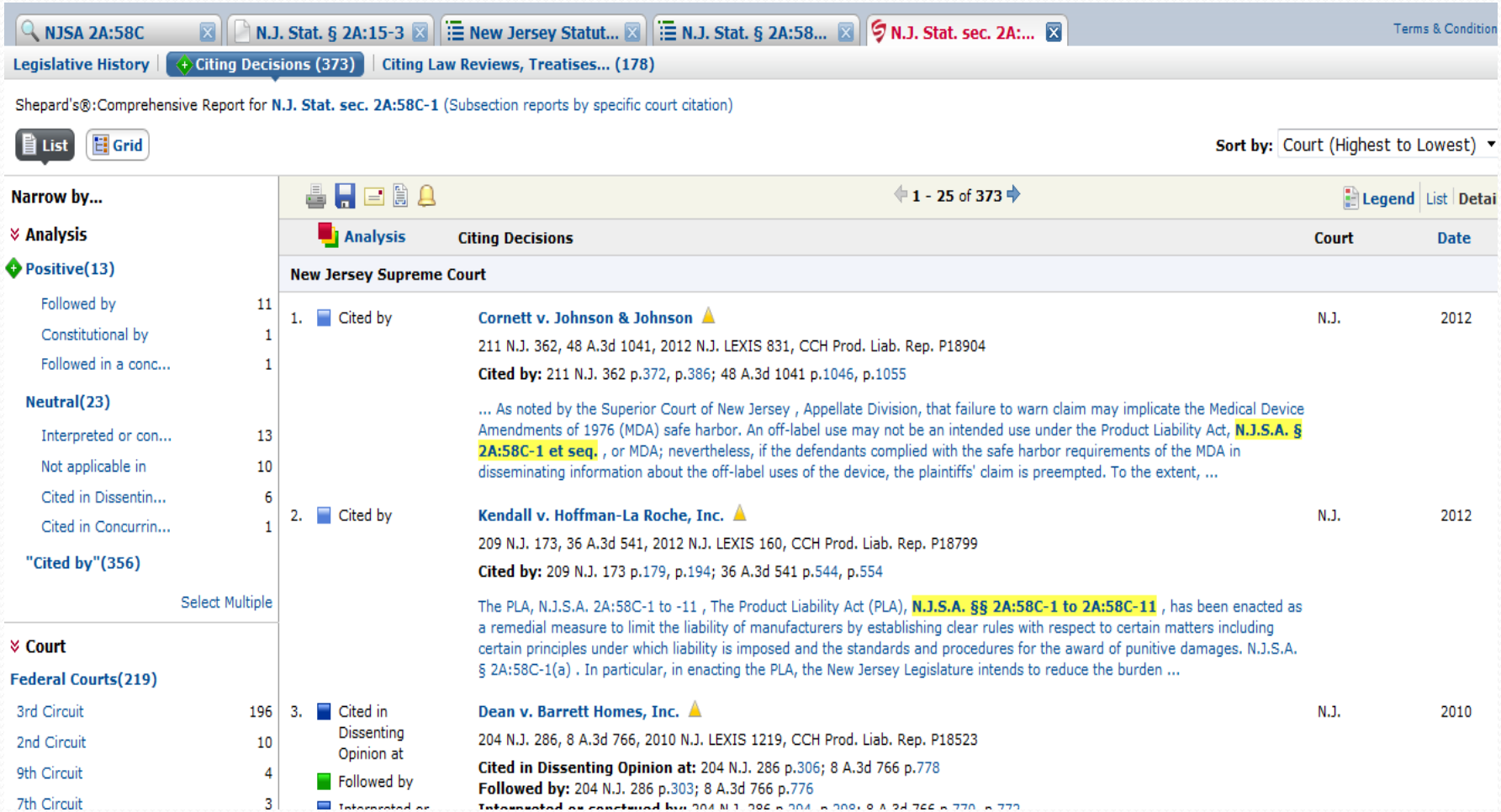

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