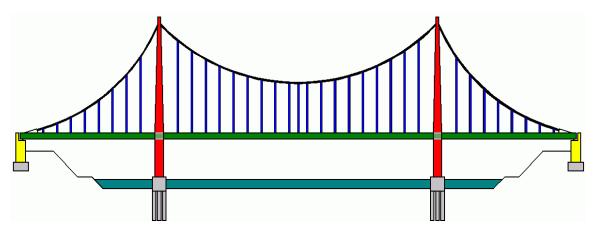


#### The 22<sup>nd</sup> Annual

#### **BRIDGE THE GAP**



#### **Legal Research Program**

Presented by the New Jersey Law Librarians Association

http://njlla.org

Saturday, March 29, 2014

**Rutgers Center for Law and Justice - Newark** 

**Outreach Education Committee** 

Andrea Battel, Chairperson

Kathleen Agno Karen Brunner Marjorie Crawford Jay Greenstone Gayle Lynn-Nelson Dianne Oster Anne Shulman Kathy Taggart Caroline Young

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#### PROGRAM SCHEDULE AND FACULTY - 2014

REGISTRATION		9:00 AM - 9:30 AM		
INTRODUCTION/ROLE PLAY		9:30 AM - 9:45 AM		
Gayle Lynne-Nelson Senior Librarian Relations Consultant LexisNexis	Kathy Taggart Senior Research Services Librarian Lowenstein Sandler LLP	Jay Greenstone. Senior Research Librarian McCarter & English, LLP		
FEDERAL & STATE CASE LAW		9:45 AM - 10:15 AM		
Kathleen Agno Senior Research Libr Greenberg Traurig, I				
FEDERAL & STATE STATUTES		10:15 AM - 10:45 AM		
Caroline Young Head of User Service Rutgers Law Library	~			
BREAK		10:45 AM - 11:00 AM		
ADMINISTRATIVE RESOURCES		11:00 AM - 11:30 AM		
Dianne Oster Associate Professor/S Seton Hall Law Libra	Serials/Government Documentary	ts Librarian/Rodino Archivist		
SECONDARY SOURCES		11:30 AM - 12:10 PM		
Andrea Battel Branch Librarian U.S. Court of Appeal	Kathy Taggart Senior Research Services Librarian Lowenstein Sandler LLP			
USING GOOGLE FOR LEGAL RE	ESEARCH	12:10 PM - 12:30 PM		
Kathy Taggart Senior Research Serv Lowenstein Sandler				
SURVIVAL TIPS		12:30 PM - 1:00 PM		
Robert J. Menendez, Associate Lowenstein Sandler	-			

#### **BIOGRAPHIES**

**Kathleen Agno** is a Senior Research Librarian at Greenberg Traurig, LLP in Florham Park, NJ. Kathy has a J.D. from Seton Hall University School of Law and an M.L.I.S. from Rutgers University School of Communication, Information and Library Studies.

Andrea Battel has served as the Branch Librarian at the U.S. Court of Appeals Branch Library in Newark for over 20 years. She is an active member of the American Association of Law Libraries (AALL) and NJLLA. She has been a member of NJLLA's Outreach Education committee for over 15 years, participating in its Basic Legal Reference program and its Bridge the Gap workshops. Andrea has an M.L.S. degree from Rutgers University School of Communication, Information, and Library Studies and an M.A. degree from Fordham University.

**Karen B. Brunner** is Director of Library Services for Riker Danzig Scherer Hyland Perretti LLP in Morristown. In addition to administrative and reference duties, much of her time is devoted to teaching legal research, organizing CLE seminars and participating on firm committees including managers, technology and library. Karen is an active member of AALL, and chaired the Annual Meeting Program Committee for the 2005 conference in San Antonio. She was the first president of NJLLA and participates on many committees. Karen teaches the course, Information Resources in Law, for Rutgers University School of Communication and Information, where she received her M.L.S. degree.

**Marjorie E. Crawford** is Head of the Technical and Automated Services Department of Rutgers Law Library – Newark. Marjorie received her M.L.I.S. from Rutgers University School of Communication and Information.

**Jay Greenstone** is a reference librarian with the law firm of McCarter & English in Newark, NJ. Jay received his M.L.S. from Rutgers University. He received a B.A. degree from Drew University while majoring in history. Jay has over 20 years of experience as a private law firm reference librarian.

**Gayle Lynn-Nelson** is a Senior Librarian Relations Consultant for the LexisNexis Librarian Relations Group where she serves librarians in New York, New Jersey and Philadelphia. Gayle received her J.D. from Western State University College of Law and her M.L.S. from Rutgers University School of Library and Information Studies. Gayle has over 20 years of professional experience in law firm and court libraries.

**Robert J. Menendez, Esq.** is an associate in the Corporate Department of Lowenstein Sandler in Roseland. He focuses on a variety of corporate transactions including investment fund formation and public and private merger and acquisition transactions, as well as securities law matters. While in law school, he served as a judicial intern to The Honorable William J. Martini of the U.S. District Court for the District of New Jersey.

**Dianne Oster** is an Associate Professor and Serials/Government Documents Librarian and the Archivist of the Peter J. Rodino collection at Seton Hall University School of Law. She earned her M.L.S. from Rutgers, The State University, her M.A. from Seton Hal University and a B.A. from Montclair State University.

Anne Shulman is the research librarian at the Morristown law firm, Riker Danzig Scherer Hyland Perretti LLP. Anne obtained her undergraduate degree from Brandeis University, her law degree from Boston College, and her M.L.S. from Rutgers University School of Communication, Information and Library Studies. She has worked as a librarian since 1998 and is an active member of NJLLA.

Kathy Taggart is the Senior Research Services Librarian at Lowenstein Sandler in Roseland. She is actively involved in the New Jersey Law Librarians Association, currently serving as Past President. She has participated in NJLLA's Bridge the Gap and Basic Legal Reference programs, and has spoken on the topics of legal web sites and legal research at NJLA, NJ ICLE, NBI and the Garden State Paralegal Convention. Kathy has a B.A. from Franklin & Marshall College and has taken a number of courses towards an M.L.S. from Rutgers University.

Caroline Young is the Head of User Services at Rutgers Law Library – Newark. She received her J.D. from the Benjamin N. Cardozo School of Law and her M.L.I.S. from Pratt Institute. Caroline teaches Advanced Legal Research and New York Legal Research at Rutgers Law School – Newark. She provides reference services and research instruction, as well as overseeing the library's catalog software and related technologies. Before coming to Rutgers, Caroline worked at a legal research company and was a reference librarian at the New York University School of Medicine.

#### **FACT PATTERN**

Mrs. Jane Doe, a 43-year-old New Jersey resident, sustained a fracture in the C5-C6 region of her spinal column. Accordingly, she underwent spinal fusion surgery. During the course of the surgery, the orthopedic surgeon utilized orthopedic bone screws in the pedicles of the spine to secure the fusion.

Orthopedic bone screws, while approved by the FDA for certain uses, are not approved for use in the pedicles of the spine. Following the surgery, the bone screw broke, leaving Mrs. Doe paralyzed.

Mrs. Doe filed suit against our client, Bone Screw, Inc., in New Jersey state court. The case was moved to federal court. Among other things, Mrs. Doe is claiming:

- 1. Negligence in the use of the screw in the spine
- 2. Mislabeling of the medical device
- 3. Fraud on the FDA

Research the claims set forth above. Search both state and federal sources to determine if Mrs. Doe's state claims are preempted by the relevant federal law.

#### HOW TO FLESH OUT AN ASSIGNMENT:

#### **JUST ASK**

#### J JURISDICTION

What Materials Should You Look At:
Federal or State?
Court or Administrative Decisions?
Legislative or Regulatory Sources?
Or a combination?

#### U USEFUL TIPS

Are You Reinventing the Wheel? Ask If There Are: Internal Briefs or Memos Written Already? An Expert in the Firm? Any Recent Articles Seen?

#### S SCOPE OF RESEARCH

How Deep Should You Delve? Scour the Universe? Scratch the Surface?

#### T TERMS OF ART

What Are The Buzz Words? The Catch Phrases? What Do They Mean?

#### A ACRONYMS

M.D.A.?? F.D.A.?? P.L.A.?? W.H.A.T. D.O. T.H.E.Y. M.E.A.N.??

#### S SOURCES

What Is The "Bible" For Your Topic? What Is The "Definitive Work?"

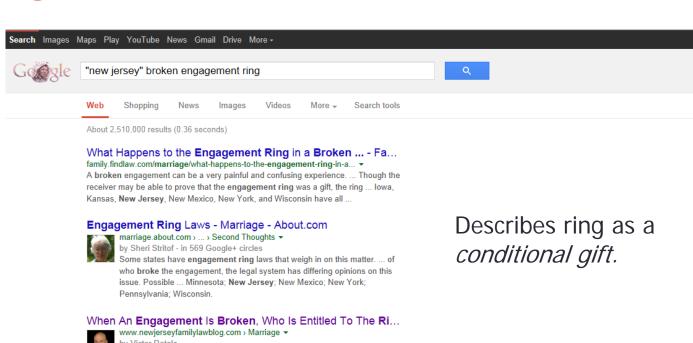
#### K KEY COST CONSTRAINTS

How Much Can You Bill the Client?
Your Time - Hours Add Up \$\$\$
Lexis/Westlaw Costs \$\$\$
Document Retrieval Services \$\$\$
FedEx \$\$\$ Faxes \$\$\$ Messengers \$\$\$

### CASE LAW RESEARCH

### Sample research issue

 What happens to an engagement ring when a couple decides to call off their engagement?





by Victor Rotolo

Apr 30, 2013 - But what happens to that ring if the engagement is broken? most states, including New Jersey, classify engagement rings as conditional gifts ..

South Jersey Divorce Attorney - Who Keeps the Engagemen... www.sjfamilylawyers.com/2012/02/who-keeps-engagement-ring-in-nj/ > by Robert Adinolfi

Feb 13, 2012 - Valentine Marriage Proposals in New Jersey - That Diamond May Not ... If the engagement is broken, the condition will not be met and the ring .

#### The Wedding is Off! Who Gets the Engagement Ring? | The...



www.lombardolawoffices.com/.../the-wedding-is-off-who-gets-t... • by Joseph Lombardo

Mar 26, 2013 - Our New Jersey divorce lawyers explain who gets the engagement ring ... leads to a broken engagement, the wronged party may be quick to ..

Cites to a case: Aronow v. Silver, 223 N.J. Super. 344 (Ch. Div. 1987)

### Digest System

### Reporters:

- Outline of the law
- Divides the law into over 400 topics
- Arranged by jurisdiction
  - Federal
  - State
  - Regional

 Headnotes: cases are read by editors and they write brief paragraphs which summarize the legal issues and points of law in the case.

### Key numbers:

- Broad topic
- Subtopic

#### Parts of a case

 Synopsis: summary of the case (searchable)

 Headnotes (searchable) Aronow v. Silver, 223 N.J.Super. 344 (1987)

538 A.2d 851

KeyCite Yellow Flag - Negative Treatment

Declined to Follow by Cooper v. Smith, Ohio App. 4 Dist., November 7, 2003.

223 N.J.Super. 344 Superior Court of New Jersey, Chancery Division, Burlington County.

Philip ARONOW, Plaintiff,

V.

Elizabeth SILVER, Defendant.

Robert SILVER and Cybil Silver, his wife,
Third-Party Plaintiffs and Intervenors,

V.

Philip ARONOW, Defendant.

Decided Nov. 17, 1987.

#### SYNOPSIS

After breakup of engagement, former fiancé brought suit to recover engagement ring, proceeds from stock, and title in condominium. The Superior Court, Burlington County, Chancery Division, Haines, A.J.S.C., held that: (1) engagement ring must be returned to former fiancé, regardless of fault; (2) former fiancé was entitled to sole title in condominium upon discharge of former fiancée's liability on mortgage; (3) stocks and proceeds from stocks held jointly in anticipation of marriage were to be returned to original donors; and (4) former fiancée was not liable to parents of former fiancée for monies expended in preparation of marriage.

So ordered

West Headnotes (6)

II Gift

- Qualified or Conditional Gifts

191 Gifts

1911 Inter Vivos

191k34 Qualified or Conditional Gifts

Upon termination of engagement to many, donor was entitled to return of engagement ring, regardless of who caused the breakup; gift of ring was conditioned upon marriage and upon nonfulfillment of condition, ring must be returned to donor.

15 Cases that cite this headnote

#### Breach of Marriage Promise

> Nature, Form, and Right of Action

61 Breach of Marriage Promise 61k14 Nature, Form, and Right of Action

Former fiance's suit for return of engagement ring and other gifts in anticipation of marriage was not barred by statute abolishing right of action for breach of contract to marry; suit was to recover conditional gifts, not damages. N.J.S.A. 2A:23-1 et seq.

13 Cases that cite this headnote

#### 3] Gifts

Oualified or Conditional Gifts

191 Gifts

1911 Inter Vivos

191k34 Qualified or Conditional Gifts

Former fiancé was entitled to sole title in condominium, in which couple had planned to live following marriage, after engagement had been broken, where credible evidence demonstrated all payments toward condominium were made by him, provided former fiancée was removed from liability on condominium's mortgage; fiancée's ownership as tenant in common was a conditional gift.

8 Cases that cite this headnote

#### [4] Gifts

Qualified or Conditional Gifts

191 Gifts

1911 Inter Vivos

191k34 Qualified or Conditional Gifts

Former fiancé was entitled to proceeds of stock purchased by him in anticipation of marriage, which was mistakenly put in fiancée's name only, instead of joint ownership, and sold by her after engagement was broken.

3 Cases that cite this headnote

### Finding Cases: The Digest Approach

- Method 1: Descriptive Word Search
  - What are your terms?
  - Are there related terms?
- Method 2: Table of Contents
- Method 3: Known Key Number Search
  - Gifts K34

### Method 1: Descriptive Word Index

#### WEST'S **NEW JERSEY** DIGEST 2d

#### **Nothing under**

- Engagement ring
- Marriage
- Ring

Volume 25

DESCRIPTIVE - WORD INDEX DR — G





Mat # 40035034

#### 25 N J D 2d-543

#### References are to Digest Topics and Key Numbers

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GIFTS ≈34

For references to other topics, see Descriptive-Word Index

\$\infty 30(3)\$. Delivery of certificate or bank book.

N.J.Super.A.D. 1954. Delivery of a chose in action without assignment is regarded as valid, as respects gift, where there is, for instance, in the case of a bank account, the delivery of a pass book.

Foster v. Reiss, 107 A.2d 24, 31 N.J.Super. 496, certification granted 108 A.2d 211, 16 N.J. 221, reversed 112 A.2d 553, 18 N.J. 41, 48 A.L.R.2d 1391.

©30(4). Deposit in names of donor and donee.

N.J.Super.A.D. 2002. The creation of a joint account, with a right of survivorship, in a bank or other financial institution does not, by itself, constitute an inter vivos gift by the party depositing assets into the account to the other named party.

Lebitz-Freeman v. Lebitz, 803 A.2d 156, 353 N.J.Super. 432, certifica-tion granted 812 A.2d 1110, 175 N.J. 78, appeal dismissed 845 A.2d 105, 179 N.J. 262.

\$\infty\$30(5)-32. For other cases see earlier editions of this digest, the Decential Digests, and WESTLAW.

Library references

C.J.S. Gifts

\$32. Gifts of donor's note or check. ≈32(1). In general.

N.J.Super.A.D. 1976. A check or promissory note drawn or executed by a purported donor may not be subject of a

Scherer v. Hyland, 380 A.2d 704, 153 N.J.Super. 521, affirmed 380 A.2d 698, 75 N.J. 127.

⇒32(2)-33(1). For other cases see earlier editions of this digest, the Decennial Digests, and WESTLAW.

Library references C.I.S. Gifts

\$33. Forgiveness of debt of dones.

≈33(2). Gift as affected by delivery of obligation to donee

N.J.Super.Ch. 1955. Even if instrument, which defendant asserted to be evidence of renunciation by deceased of any claim against defendant for money given defendant, represented an attempted gift, it would fail as an inter vivos gift or a gift causa mortis, in view of fact that the instrument evidencing the obligation remained in deceased's custody in her safe deposit box.

Guerin v. Cassidy, 119 A.2d 780, 38 N.J.Super. 454.

≈34. Qualified or conditional gifts.

references C.J.S. Gifts §§ 37-40, 64

N.J.Super.A.D. 1990. Engagement ring is "conditional gift"; condition is marriage and ring is returnable only if engagement is broken.

Winer v. Winer, 575 A.2d 518, 241 N.J.Super. 510.

Engagement ring was not marital property subject to equitable distribution; ring had been conditional gift before marriage and, upon marriage, ring unconditionally became former wife's property and it retained its character as separate property not subject to equitable distribution. N.J.S.A. 2A:34-23.1.

Winer v. Winer, 575 A.2d 518, 241 N.J.Super. 510.

N.J.Super.L. 1989. Woman was entitled to receive 12.5 percent of appraised value of her former fiance's property, less 12.5 percent of principal reductions on mortgage and less cost of capital improvements, where woman contributed 12.5 percent of purchase price of property while she was engaged to her fiance, the engagement was broken off sometime after closing and it was intention of parties to take title to property as tenants in common and share ownership in proportion to financial contributions; intention that woman would have equal ownership upon marriage represented a gift by fiance conditioned upon marriage. N.J.S.A. 46:3-

Asante v. Abban, 568 A.2d 146, 237

N.J.Super.Ch. 1987. Upon termination of engagement to marry, donor was entitled to return of engagement ring, regardless of who caused the breakup; gift of ring was conditioned upon marriage

† This Case was not selected for publication in the National Reporter System For legislative history of cited statutes, see New Jersey Statutes Annotated

\$\isigma 34 \text{ GIFTS}

10D NJD 2d-238

#### For later cases, see same Topic and Key Number in Pocket Part

and upon nonfulfillment of condition, ring must be returned to donor.

Aronow v. Silver, 538 A.2d 851, 223 N.J.Super. 344.

Former fiancé was entitled to sole title in condominium, in which couple had planned to live following marriage, after engagement had been broken, where credible evidence demonstrated all payments toward condominium were made by him, provided former fiancée was removed from liability on condominium's mortgage; fiancée's ownership as tenant in common was a conditional gift.

Aronow v. Silver, 538 A.2d 851, 223 N.J.Super. 344.

Former fiancé was entitled to proceeds of stock purchased by him in anticipation of marriage, which was mistakenly put in fiancée's name only, instead of joint ownership, and sold by her after engagement was broken.

Aronow v. Silver, 538 A.2d 851, 223 N.J.Super. 344.

Former fiancée was entitled to sole ownership of stock which was initially owned by her, but transferred to joint ownership with her fiancé, in anticipation of marriage, after engagement was broken Aronow v. Silver, 538 A.2d 851, 223

N.I.Super, 344. N.J.Super.Ch. 1964. Ring given as gift inter vivos to defendant need not be returned by her after annulment of mar-

Gerard v. Distefano, 202 A.2d 220, 84

\$35. Validity.

Library references

C.J.S. Gifts §§ 13, 31

≈36. — In general.

N.J.Super.A.D. 1996. Validity of mortgage given as gift should be determined based on existence of three elements required to prove valid inter vivos gift, without reference to contractual consideration for the conveyance

Jennings v. Cutler, 672 A.2d 1215, 288 N.J.Super. 553.

Fact that girlfriend who was given gift of mortgage might never have received sums secured by mortgage because prop-

erty might not have been sold or, if sold, might not have generated sufficient proceeds to pay off mortgage did not invali-date gift of mortgage, although it might have disappointed girlfriend's expecta-

> Jennings v. Cutler, 672 A.2d 1215, 288 N.J.Super, 553.

N.J.Super.A.D. 1985. Mother's gift of her residence to her son could be invalidated as improvident gift in light of relationship of trust which mother justifiably reposed in her son, inadequate explanation of consequences of her act, and lack of independent legal advice.

Petruccio v. Petruccio, 501 A.2d 593, 205 N.J.Super. 577.

It is not necessary that undue influence must actually be shown to have been exerted before improvident gift can be

Petruccio v. Petruccio, 501 A.2d 593, 205 N.J.Super. 577.

#### — Mistake and misrepresenta-

For other cases see earlier editions of this digest, the Decennial Digests, and WEST-

#### - Fraud, duress, and undue influence.

N.J. 2008. "Undue influence" is a mental, moral, or physical exertion of a kind and quality that destroys the free will of the testator by preventing that person from following the dictates of his or her own mind as it relates to the disposition of assets, generally by means of a will or inter vivos transfer in lieu thereof. In re Estate of Stockdale, 953 A.2d

454, 196 N.J. 275.

N.J. 1967. Whenever it appears that the relations between the parties to an inter vivos gift are of such character that in reasonable probability they do not deal with each other on terms of equality be cause one has given friendship and justifiably reposes confidence in the other, that on the donee's side superior knowledge exists as to the nature of the transaction proposed by him, as well as the detriment to be suffered by the donor if he engages in it, and the donee fails to see to it that the donor thoroughly understands its na

† This Case was not selected for publication in the National Reporter Systen For legislative history of cited statutes, see New Jersey Statutes Annotated

### Method 2: Table of Contents

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#### **GIFTS**

#### SUBJECTS INCLUDED

Voluntary transfers of property without consideration, whether executed or to take effect on the death of the giver

Acceptance and revocation thereof

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Rights and liabilities of parties thereto as between themselves and as to others in general

#### SUBJECTS EXCLUDED AND COVERED BY OTHER TOPICS

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For detailed references to other topics, see Descriptive-Word Index

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L INTER VIVOS, \$\sim 1-52.

II. CAUSA MORTIS, \$53-85.

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- ⇒1. Nature of gift in general.
- 2. What law governs.
- 3. Statutory provisions.
- 4. Requisites in general.
- 5. Gifts distinguished from other transactions.
  - (1). In general.
  - (2). Gift or sale.
  - (3). Gift or transfer in trust.
- 6. Power to make gift.
- 7. Property which may be subject of gift.
- 7.1. In general.
- 8. Real property and interests therein.
- 9. Personal property in general.

10D NJD 2d-229

GIFTS

#### I. INTER VIVOS.—Continued.

- Forgiveness of debt of donee.
  - (1). In general.
- (2). Gift as affected by delivery of obligation to donee.
- 34. Qualified or conditional gifts.
- Validity.
- 36. In general.
- Mistake and misrepresentation.
- 38. Fraud, duress, and undue influence.
- 39. Illegality.
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- 41. Revocation and rescission.
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- (6). Gift of notes or securities in general.
- 50. Questions for jury.
- Instructions.
- 52. Verdict and findings.

#### II. CAUSA MORTIS.

- ≈53. Requisites in general.
- 53.5. What law governs.
- 54. Gifts causa mortis distinguished from other transactions.
- 54.1. In general.
- Gifts inter vivos.
- 56. Property which may be subject of gift.
- 57. Time of taking effect.
- 58. Parties.
- Expectation of death.
- 60. Intent.
- 61. Necessity for execution.

10D NJD 2d-237

GIFTS ≈34

For references to other topics, see Descriptive-Word Index

\$\infty 30(3)\$. Delivery of certificate or bank book.

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Foster v. Reiss, 107 A.2d 24, 31 N.J.Super. 496, certification granted 108 A.2d 211, 16 N.J. 221, reversed 112 A.2d 553, 18 N.J. 41, 48 A.J.R.2d 1391.

©30(4). Deposit in names of donor and donee.

N.J.Super.A.D. 2002. The creation of a joint account, with a right of survivorship, in a bank or other financial institution does not, by itself, constitute an inter vivos gift by the party depositing assets into the account to the other named party.

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Scherer v. Hyland, 380 A.2d 704, 153 N.J.Super. 521, affirmed 380 A.2d 698, 75 N.J. 127.

⇒32(2)-33(1). For other cases see earlier editions of this digest, the Decennial Digests, and WESTLAW.

Library references

\$33. Forgiveness of debt of donee.

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Guerin v. Cassidy, 119 A.2d 780, 38 N.J.Super. 454.

34. Qualified or conditional gifts.

C.J.S. Gifts §§ 37–40, 64

N.J.Super.A.D. 1990. Engagement ring is "conditional gift"; condition is marriage and ring is returnable only if engagement is broken.

Winer v. Winer, 575 A.2d 518, 241 N.J.Super. 510.

Engagement ring was not marital property subject to equitable distribution; ring had been conditional gift before marriage and, upon marriage, ring unconditionally became former wife's property and it retained its character as separate property not subject to equitable distribution. N.J.S.A. 2A:34-23.1.

Winer v. Winer, 575 A.2d 518, 241 N.J.Super, 510.

N.J.Super.L. 1989. Woman was entitled to receive 12.5 percent of appraised value of her former fiance's property, less 12.5 percent of principal reductions on mortgage and less cost of capital improvements, where woman contributed 12.5 percent of purchase price of property while she was engaged to her fiance, the engagement was broken off sometime after closing and it was intention of parties to take title to property as tenants in common and share ownership in proportion to financial contributions; intention that woman would have equal ownership upon marriage represented a gift by fiance conditioned upon marriage. N.J.S.A. 46:3–17.

Asante v. Abban, 568 A.2d 146, 237

N.J.Super.Ch. 1987. Upon termination of engagement to marry, donor was entitled to return of engagement ring, regardless of who caused the breakup; gift fring was conditioned upon marriage

† This Case was not selected for publication in the National Reporter System For legislative history of cited statute, see New Jersey Statutes Annotated \$\ist\$34 GIFTS

10D NJD 2d-238

#### For later cases, see same Topic and Key Number in Pocket Part

and upon nonfulfillment of condition, ring must be returned to donor.

Aronow v. Silver, 538 A.2d 851, 223 N.J.Super. 344.

Former fiancé was entitled to sole title in condominium, in which couple had planned to live following marriage, after engagement had been broken, where credible evidence demonstrated all payments toward condominium were made by him, provided former fiancée was removed from liability on condominium's mortgage; fiancée's ownership as tenant in common was a conditional gift.

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Former fiancée was entitled to sole ownership of stock which was initially owned by her, but transferred to joint ownership with her fiancé, in anticipation of marriage, after engagement was broken. Aronow v. Silver, 538 A.2d 851, 223

N.J.Super.Ch. 1964. Ring given as gift inter vivos to defendant need not be returned by her after annulment of mar-

> Gerard v. Distefano, 202 A.2d 220, 84 N.I.Super, 396.

\$35. Validity.

Library references

C.J.S. Gifts §§ 13, 31.

⇔36. — In general.

N.J.Super.A.D. 1996. Validity of mortgage given as gift should be determined based on existence of three elements required to prove valid inter vivos gift, without reference to contractual consideration for the conveyance.

Jennings v. Cutler, 672 A.2d 1215, 288 N.J.Super. 553.

Fact that girlfriend who was given gift of mortgage might never have received sums secured by mortgage because prop-

erty might not have been sold or, if sold, might not have generated sufficient proceeds to pay off mortgage did not invalidate gift of mortgage, although it might have disappointed girlfriend's expecta-

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N.J.Super.A.D. 1985. Mother's gift of her residence to her son could be invalidated as improvident gift in light of relationship of trust which mother justifiably reposed in her son, inadequate explanation of consequences of her act, and lack of independent legal advice.

Petruccio v. Petruccio, 501 A.2d 593, 205 N.J.Super. 577.

It is not necessary that undue influence must actually be shown to have been exerted before improvident gift can be

Petruccio v. Petruccio, 501 A.2d 593, 205 N.J.Super. 577.

#### €=37. — Mistake and misrepresenta-

For other cases see earlier editions of this digest, the Decennial Digests, and WEST-TAW

#### €=38. — Fraud, duress, and undue influence.

N.J. 2008. "Undue influence" is a mental, moral, or physical exertion of a kind and quality that destroys the free will of the testator by preventing that person from following the dictates of his or her own mind as it relates to the disposition of assets, generally by means of a will or inter view transfer in lieu thereof.

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N.J. 1967. Whenever it appears that the relations between the parties to an inter vivos gift are of such character that in reasonable probability they do not deal with each other on terms of equality because one has given friendship and justifiably reposes confidence in the other, that on the donee's side superior knowledgexists as to the nature of the transaction proposed by him, as well as the detriment to be suffered by the donor if he engages in it, and the donee fails to see to it that the donor thoroughly understands its na

† This Case was not selected for publication in the National Reporter Systen For legislative history of cited statutes, see New Jersey Statutes Annotated

### Method 3: Known Key Number

10D NJD 2d-237

GIFTS ≈34

For references to other topics, see Descriptive-Word Index

\$\infty 30(3)\$. Delivery of certificate or bank book.

N.J.Super.A.D. 1954. Delivery of a chose in action without assignment is regarded as valid, as respects gift, where there is, for instance, in the case of a bank account, the delivery of a pass book.

Foster v. Reiss, 107 A.2d 24, 31 N.J.Super. 496, certification granted 108 A.2d 211, 16 N.J. 221, reversed 112 A.2d 553, 18 N.J. 41, 48 A.L.R.2d 1391.

\$\infty\$ 30(4). Deposit in names of donor and donee.

N.J.Super.A.D. 2002. The creation of a joint account, with a right of survivorship, in a bank or other financial institution does not, by itself, constitute an inter vivos gift by the party depositing assets into the account to the other named party.

Lebitz-Freeman v. Lebitz, 803 A.2d 156, 353 N.J.Super. 432, certifica-tion granted 812 A.2d 1110, 175 N.J. 78, appeal dismissed 845 A.2d 105, 179 N.J. 262.

\$\infty\$30(5)-32. For other cases see earlier editions of this digest, the Decential Digests, and WESTLAW.

Library references

C.J.S. Gifts

\$32. Gifts of donor's note or check. ≈32(1). In general.

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Asante v. Abban, 568 A.2d 146, 237

N.J.Super.Ch. 1987. Upon termination of engagement to marry, donor was entitled to return of engagement ring, regardless of who caused the breakup; gift of ring was conditioned upon marriage

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\$\isigma 34 \text{ GIFTS}

10D NJD 2d-238

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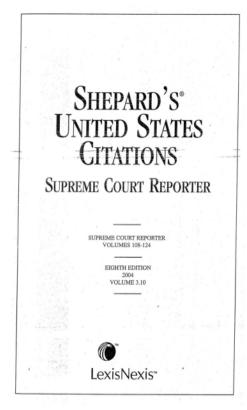
### Finding Other Cases: The Citator Approach

- What it does: Citators helps you confirm that your case law citation references are strong, accurate and on-point.
  - It can also identify cited cases that discuss specific issues of interest.
- Also known as Shepardizing
  - Westlaw: KeyCite
- Best to do this online because your information would be current.

- How to Shepardize (using the print volumes):
  - Collect the bound volumes and supplements listed in the "What Your Library Should Contain" box on the front cover of the most recent supplement.
  - A complete citator set usually, but not always, contains:
    - one or more bound volumes;
    - a red paperback cumulative supplement; and
    - a gold annual or semi-annual supplement.

## Searching by Citator

Case Name



Third Circuit References

SUPREME COURT REPORTER Vol. 116 76TxL1639 63FS2d165 103F3d2445 97FS2d12854 943FS51033 78TxL439 f) 67FS2d28 245F3d5224 103F3d8445 97FS2d14854 943FS61034 86VaL1249 67FS2d1131 f) 245F3d228 107F3d319 97FS2d15854 943FS11035 110YLJ947 f) 74FS2d5153 264F3d360 228F3d607 97FS2d7855 f) 966FS840 113YLJ27 f) 74FS2d6153 282F3d1211 228F3d6609 d) 97FS2d857 966FS1841 129LE944n f) 74FS2d154 2004USDist 228F3d6609 f) 97FS2d860 966FS7841 135LE1151n 74FS2d10156 LX6687 d) 254F3d575 966FS2842 f) 171FS2d14 48A5159n 106FS2d5228 f) 2004USDist 254F3d2576 966FS4842 158FS2d6176 254F3d14578 50.45.38n [LX669] f) 171FS2d15 966FS10842 51Æ493n 193FS2d5389 2004USDist e) 254F3d579 966FS9843 52.4826n 218FS2d117 [LX11552 966FS11843 254F3d15580 301FS2d43 965FS568 f) 254F3d582 16FS2d1114 f) 210FS2d<sup>14</sup> -2240-321FS2d197 965FS9570 e) 16FS2d1118 254F3d9583 240BRW5162 Medtronic, Inc. e) 965FS571 d) 227FS2d858 254F3d 10583 19FS2d1065 Cir. 2 965FS3571 314F3d197 f) 19FS2d1069 172FRD9294 y Lohr 171F3d5771 965FS4571 32FS2d1102 f) 986FS368 Cir. 7 195F3d5105 34FS2d934 986FS 13370 d) 32FS2d1104 109F3d51246 (518US470) 195F3d6105 90FS2d633 37FS2d1140 986FS14370 109F3d61246 (135LE700) 274F3d700 f) 96FS2d<sup>6</sup>413 986FS4371 38FS2d1099 109F3d101249 116SC806 937FS13182 78FS2d51032 110FS2d3390 986FS9371 121F3d71075 56F3d1335 937FS15184 143FS2d2412 986FS 10371 102FS2d1123 f) 126F3d902 98F3d618 937FS10185 145FS2d15573 140FS2d1016 986FS15371 126F3d5907 119SC677 e) 937FS186 f) 146FS2d680 161FS2d1014 120SC11148 4FS2d657 126F3d8909 f) 146FS2d5683 161FS2d<sup>6</sup>1015 938FS1168 19FS2d626 126F3d15909 120SC1918 988FS2755 174FS2d5945 161FS2d405 120SC111926 f) 19FS2d627 131F3d662 988FS3755 179FS2d1064 229FS2d388 D 120SC1932 f) 96FS2d570 f) 189F3d636 d) 988FS756 189FS2d951 229FS2d13389 98FS2d766 219F3d607 120SC12485 e) 988FS757 259FS2d414 233FS2d13 115FS2d736 121SC1015 j) 340F3d445 988FS12757 295FS2d441 246FS2d643 [1197 950FS247 d) 121SC1020 240FS2d1019 988FS14757 f) 295FS2d449 al 121SC101020 Cir. 6 f) 950FS6249 988FS 15757 Cir. 9 302FS2d425 105F3d1092 f) 950FS9249 121SC2415 2003USApp f) 988FS758 f) 302FS2d432 105F3d41093 j 121SC2441 960FS1383 21FS2d419 ILX27248 313FS2d477 122SC1023 105F3d111093 d) 960FS1384 92F3d1811 43FS2d260 h) 313FS2d478 105F3d71094 122SC52235 960FS131384 f) 313FS2d478 89FS2d1259 92F3d4811 124SC1765 105F3d101094 24FS2d953 92F3d6811 136FS2d1201 Cir. 4 105F3d131094 48FS2d874 f) 92F3d812 136FS2d5201 f) 103F3d326 105F3d141094 96F3d554 48FS2d10875 d) 136FS2d205 92F3d11812 e) 96F3d559 103F3d2327 105F3d151094 57FS2d5624 94F3d1264 175FS2d8612 103F3d3328 96F3d562 105F3d81096 117FS2d10872 177FS2d5192 d) 94F3d1265 103F3d7329 105F3d121098 102F3d622 153FS2d6940 94F3d131265 103F3d8329 122F3d167 d) 105F3d1099 q) 153FS2d<sup>5</sup>942 291FS2d208 j) 94F3d1268 0 194F3d179 103F3d10330 173F3d394 d) 153FS2d943 100F3d666 194F3d6179 211FRD142 f) 114F3d39 180F3d1747 172FS2d1031 107F3d739 0 194F3d182 Cir. 3 116F3d7103 209F3d5891 178FS2d957 d) 107F3d740 218F3d638 d) 2004USApp f) 116F3d7104 e) 231F3d223 297FS2d1144 f) 107F3d741 [LX14942 218F3d638 179F3d5 231F3d6223 e) 175FRD11 110F3d131408 2004USApp 218F3d139 183F3d310 231F3d14229 110F3d51413 129F3d15 [LX714942 271F3d603 231F3d10234 Cir. 8 2004USApp 110F3d61413 134F3d65 288F3d5590 ~) 231F3d237 2004USApp d) 110F3d1414 250F3d55 ILX1114942 69Fed Appx 231F3d<sup>10</sup>238 ILX15366 110F3d131414 348F3d280 2004USApp 246F3d5554 152F3d1055 935FS75 f) 110F3d13 LX14942 968FS5300 248F3d5522 184F3d7808 94F3d111 938FS776 84FS2d777 248F3d6522 236F3d958 110F3d141414 945558 132F3d9155 84FS2d6780 346F3d1593 e) 236F3d960 f) 110F3d14 945FS 13 1 159F3d8819 84FS2d782 22Fed Appx 236F3d11961 945FS1012 f) 159F3d823 108FS2d521 236F3d15961 110F3d151414 956FS93 f) 159F3d7823 108FS2d13522 947FS1140 f) 236F3d962 f) 110F3d<sup>18</sup> 956FS 196 f) 159F3d10823 108FS2d524 984FS5591 236F3d10964 956FS296 159F3d5824 130FS2d732 f) 984FS5595 956FS696 273F3d787 j) 110F3d1417 184F3d247 218FS2d805 d) 47FS2d893 967FS576 e) 273F3d792 121F3d6475 184F3d5248 218FS2d806 47FS2d5894 273F3d12793 IFS2da86 125F3d1311 e) 184F3d250 248FS2d6460 64FS2d655 d) 273F3d795 IFS2d1086 146F3d1055 f) 184F3d254 266FS2d478 92FS2d648 f) 273F3d15795 14FS2d210 154F3d51031 j) 184F3d256 320FS2d446 97FS2d1821 j) 273F3d799 2JFS2d144 160F3d61264 d) 193F3d791 51FS2d53 Cir. 5 97FS2d853 284F3d899 160F3d51265 193F3d5791 97FS2d10854 95F3d4 f) 2004USDist 54FS2d74 172F3d687 193F3d7791 103F3d445 97FS2d11854 [LX148 Continued

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### Do the math:

#### Sample Pricing (from 2008)

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   search all content and the price
   includes all documents clicked
   on unless the document is
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- Map out your search strategy before you login;
- Watch your spelling;
- Use the smallest database possible;
- Use Segment or Field searching
- Printing Do you really need it?
- Mix it up

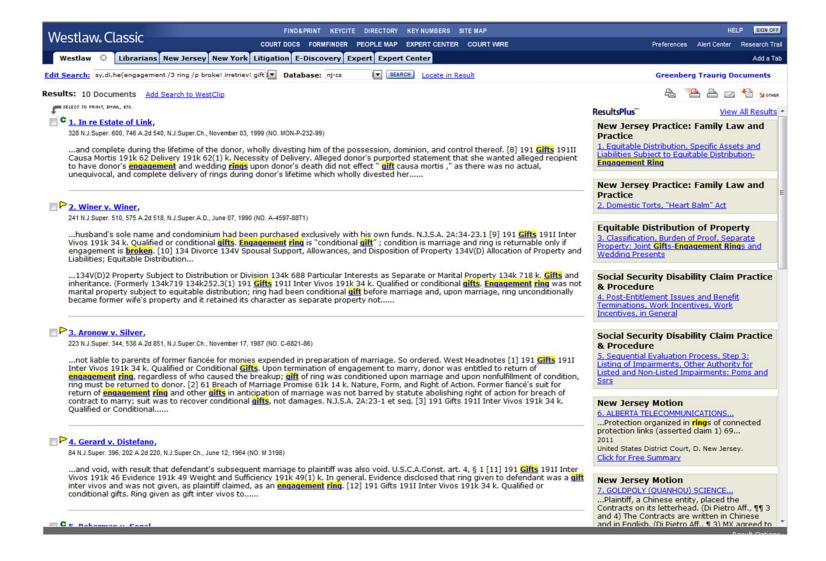
### Search Strategies

- Consider what is being asked jot down the key terms or concepts.
  - Are they terms of art?
  - What are synonyms or related terms?
- Link key terms together
  - Consider the connectors (Within X terms? Within the same sentence? Paragraph?)
  - Start broad, but not too broad!
- Think about what database to search
  - Use smaller databases where it makes sense to do so
  - By jurisdiction or specialization (e.g. Experts, Markman, Real Estate)
- Use a Reference Attorney to get assistance with search construction if you aren't sure or want additional insight.

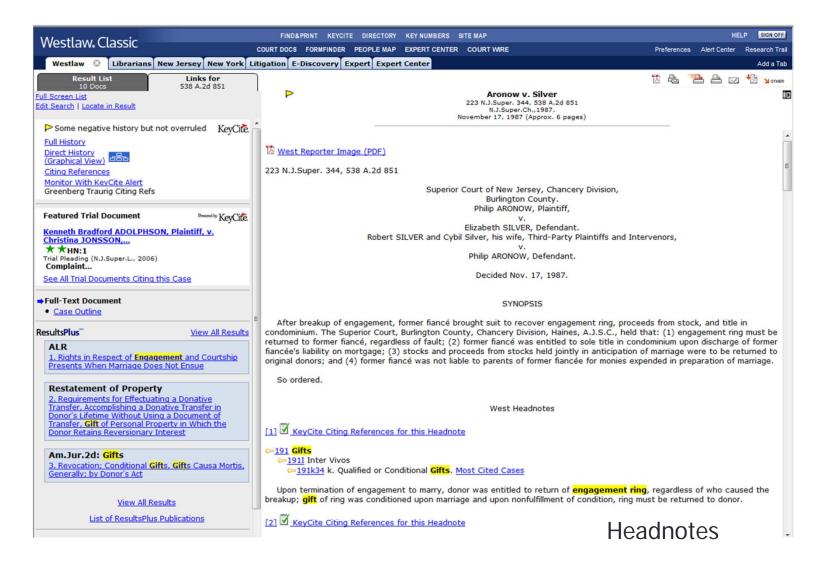
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- "At least": search term must appear at least N times in your document
  - Lexis: atlN(search term)
  - Westlaw: Atleast5(contract)
- Lexis:
  - Core-Terms/Overview/Headnote
- Westlaw:
  - SY,DI,HE = Synopsis/Digest/Headnote
  - WP = words and phrases:
    - Use this segment when looking for the definition of something or how courts have interpreted a phrase.
    - Example: wp(reasonable)

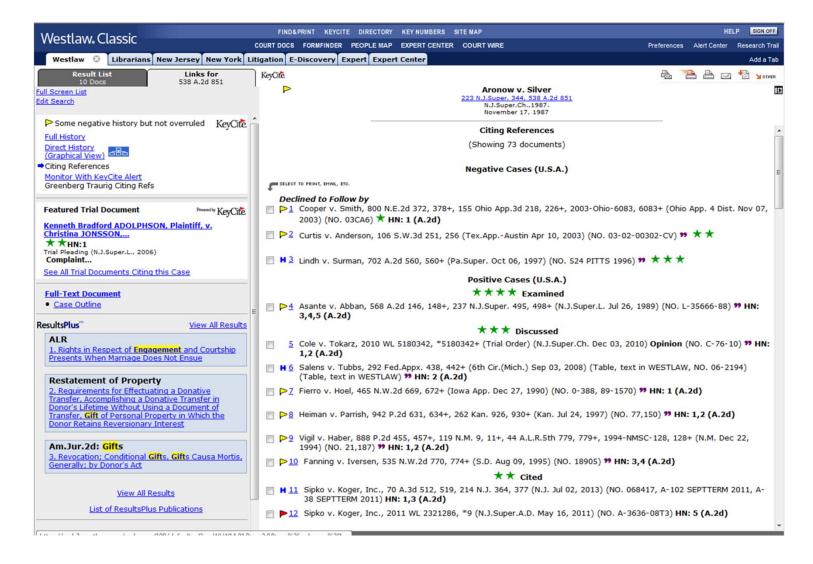
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### Westlaw: Synopsis/Headnotes



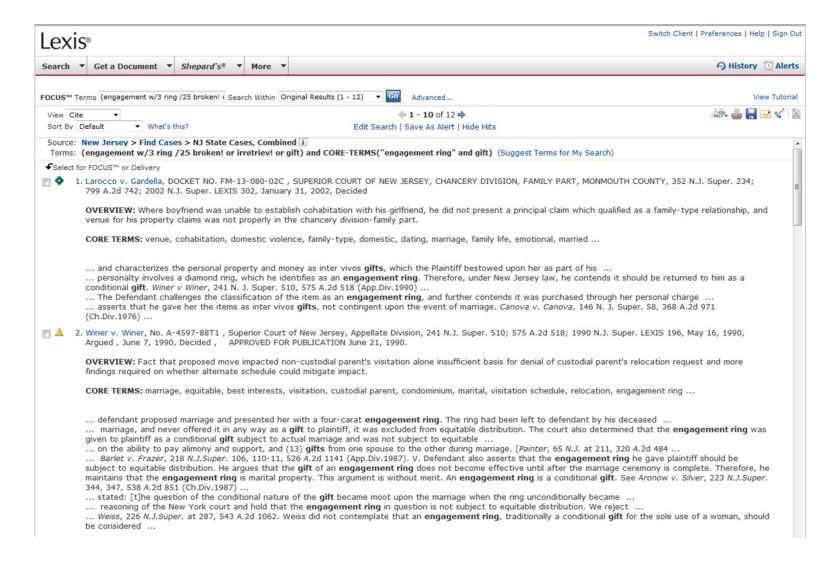
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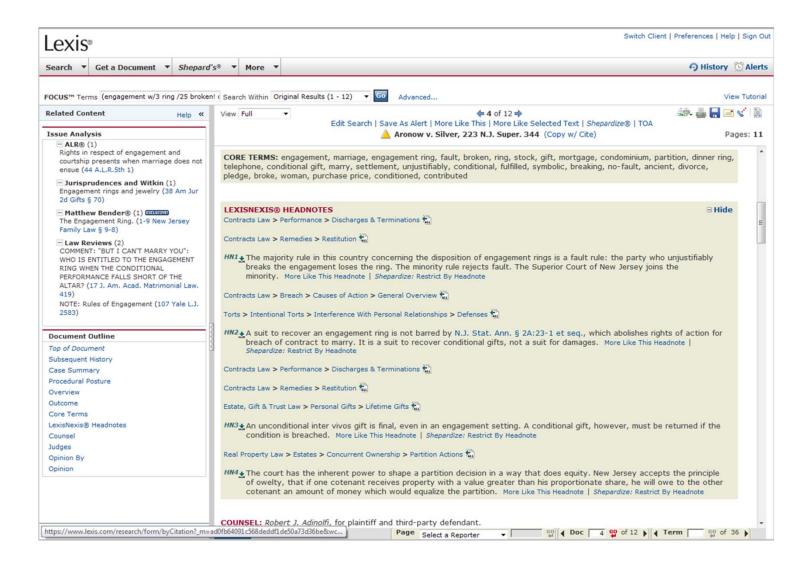
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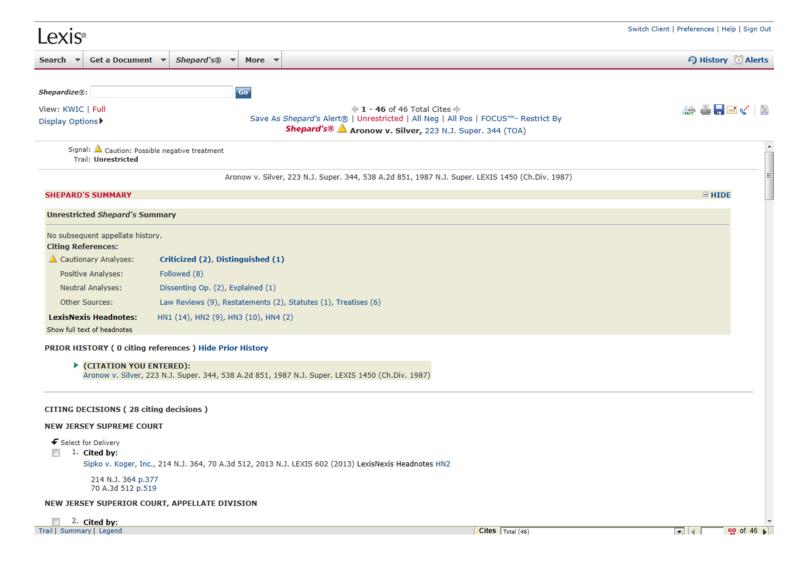
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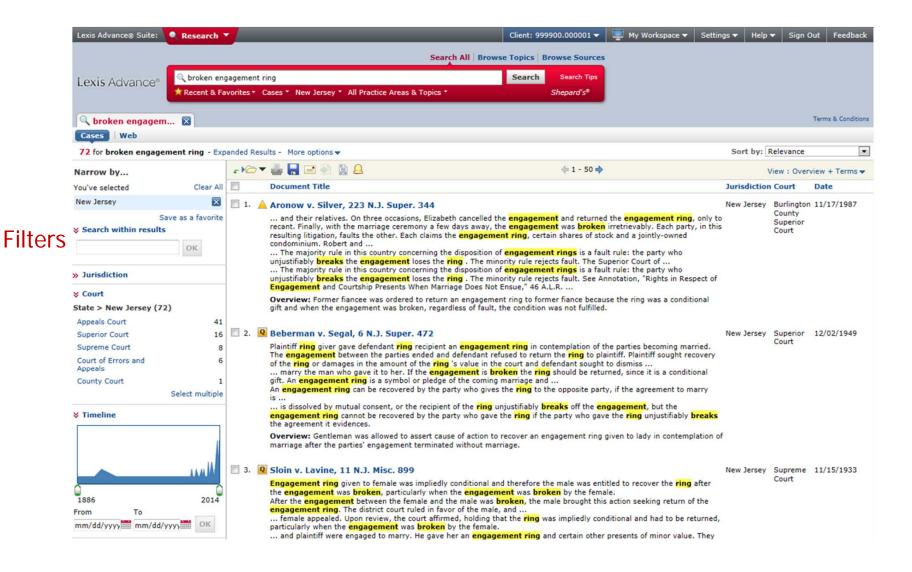
### Lexis: Core Terms/Headnotes



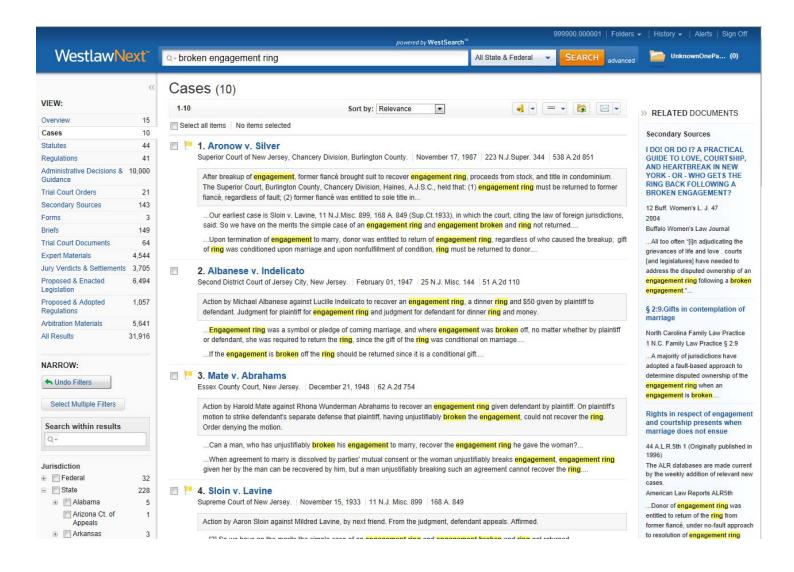
### Lexis: Shepard's



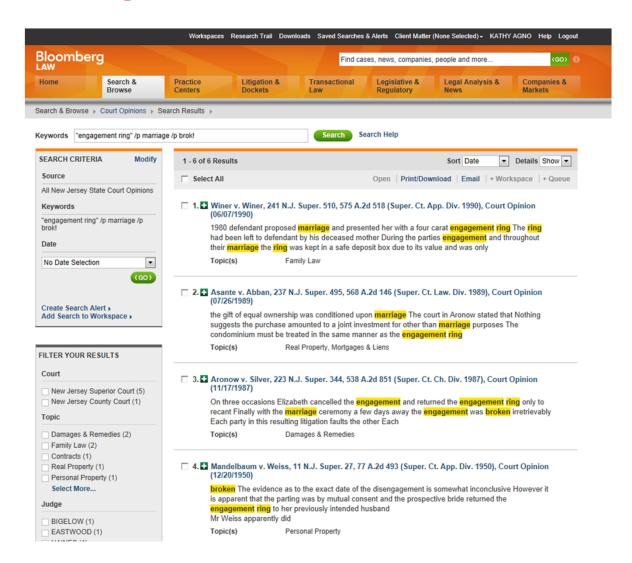
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# Statutory Research Bridge the Gap 2014 Rutgers University Center for Law & Justice

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

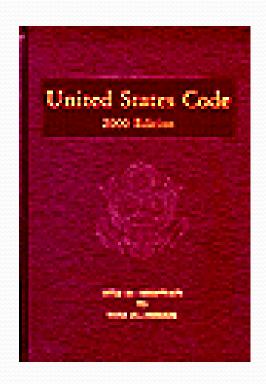
# Types of Statutory Materials

- 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?

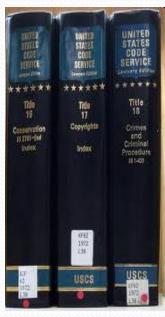




# U.S.C. vs. U.S.C.A. vs. U.S.C.S

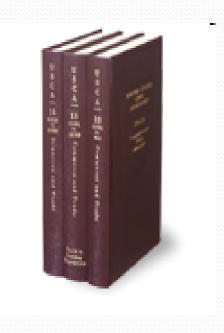
Which one?

# **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

ä

# 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

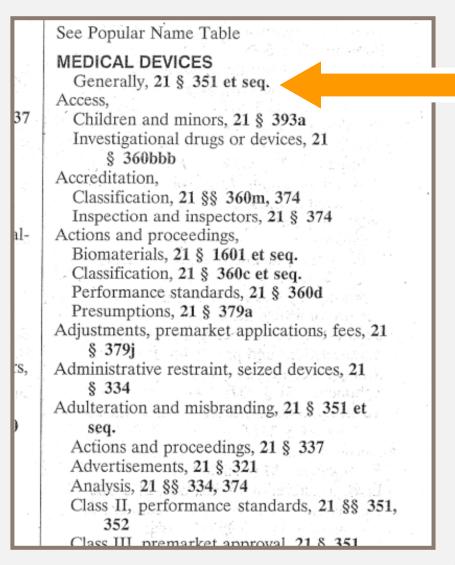
Index volume from USCA

THOMSON WEST

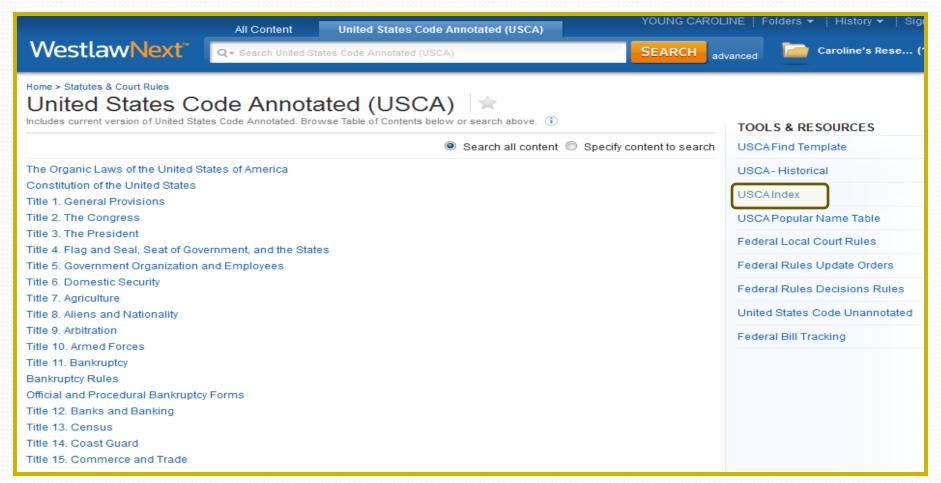
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# Index

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



# 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 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. Authority to withdraw approval of abbreviated drug applic 335c. tions. 336. Report of minor violations. 337. Proceedings in name of United States; provision as to subpo 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 foo 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 oleomargaria sales. Contravention of State laws. 347b. 348. Food additives. 349. Bottled drinking water standards; publication in Federal Regi

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350.

350a.

350b.

Vitamins and minerals.

New dietary ingredients.

Infant formulas.

# 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.

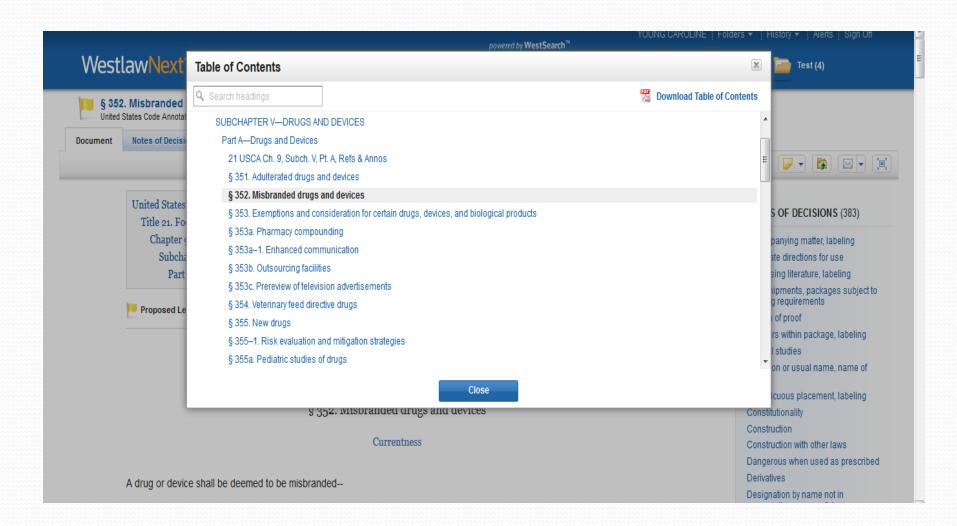
### FOOD AND DRUGS Ch. 9

	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.
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	360b.	New animal drugs.  Classification of devices intended for human use.
	360c. 360d.	Performance standards.
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	360i.	Records and reports on devices.
	360j.	General provisions respecting control of devices intended for human use.
	360k.	State and local requirements respecting devices.
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	360m.	Accredited persons.
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	12/02/	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.
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	360gg.	Omitted.
	360hh.	Definitions.
	360ii.	Program of control.
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	360kk.	Performance standards for electronic products.
	360ll.	Notification of defects in and repair or replacement of electronic products.
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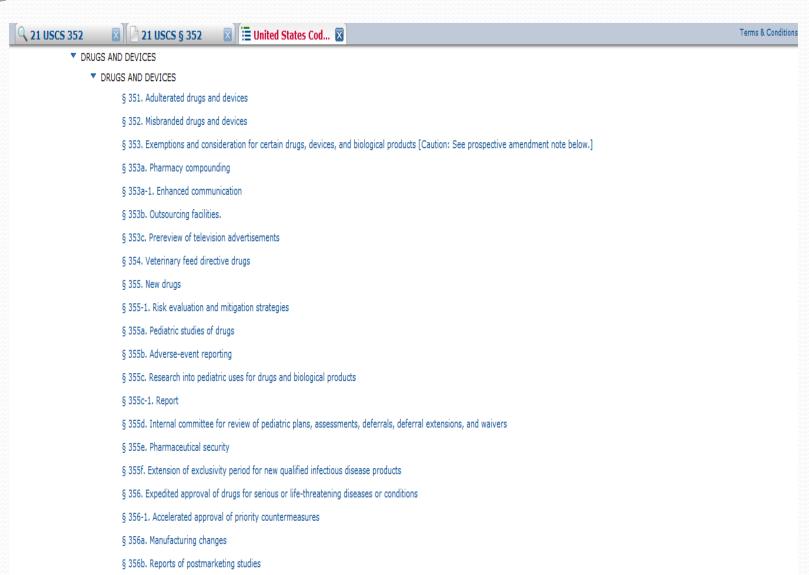
### Sec. 352:

## Misbranded drugs and devices

# Westlaw Next - TOC

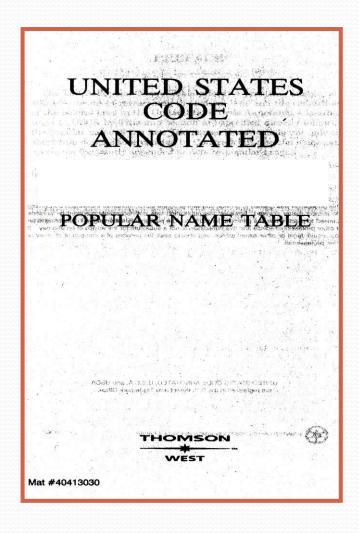


# **LexisAdvance - TOC**



# 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)

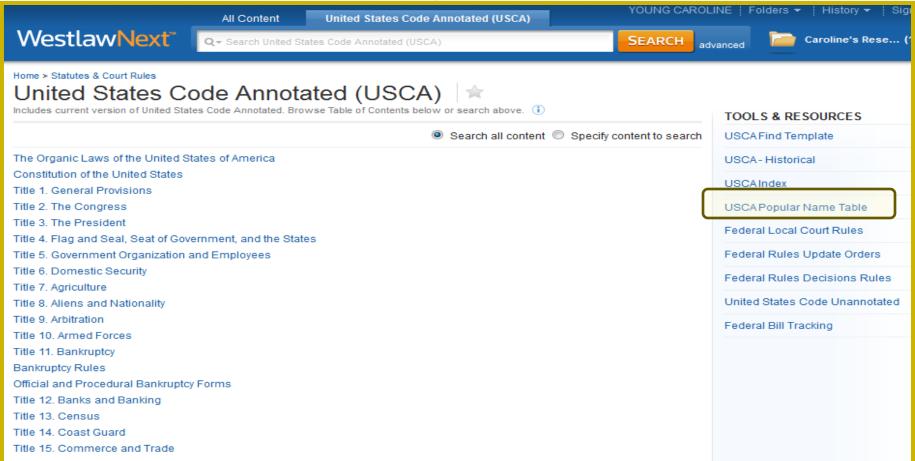
### Medical Device Amendments of 1992

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, PARI

### SHEPARD'S

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FEB 2 9 2000

MELLIA

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 .C. Code Ann., § 4-501 et seq.

### dical Care Savings Account Act

a. Code Ann., 33-20B-1 et seq. da. Code 1947, 41-5301 et seq. 1. Comp. Stat. 1992, Ch. 820, § 152/1 Aich. 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

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

### edical Center Act (Chicago)

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

### edical Center District Act

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

### edical Center Ouota 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.

### ledical Corporation Act

Ark. Code Ann. 1987, 4-29-301 et seq. Cal. Business and Professions Code § 2500 et seq.

III. Rev. Stat. 1991, Ch. 32, § 631 et seq. La. Rev. Stat. Ann., 12:901 et seq.

### Minn. Stat. Ann., 319A 01 ct 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)**

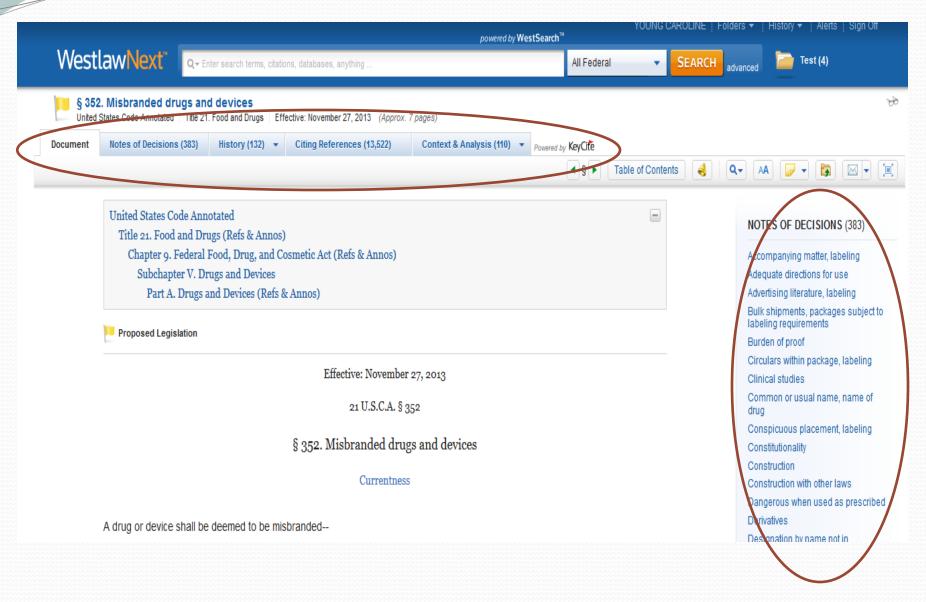
III. Comp. Stat. 1992, Ch. 410, § 15/1 et seq.

### **Medical Emergency Services Act**

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

# 21 USC 301 note

# Inside the Statute



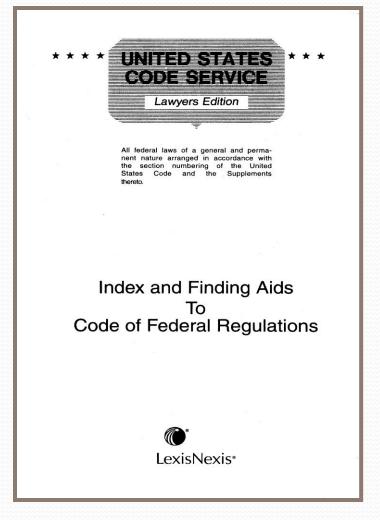
# Credits - Source of law



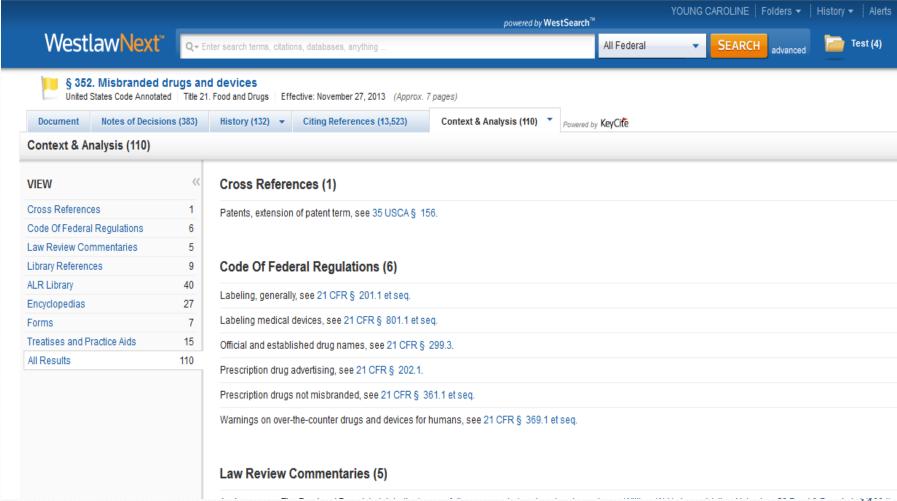
### CREDIT(S)

(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, 16, 2005,

#### 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 <sup>1</sup> (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  $^{\rm I}$  (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 (a) 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 adulter- (2004).

#### LIBRARY REFERENCES

#### American Digest System

Drugs and Narcotics \$2 to 4.

CJS Drugs and Narcotics § 115, Weight and

#### Corpus Juris Secundus

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 Roby

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, Teratogenc 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

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

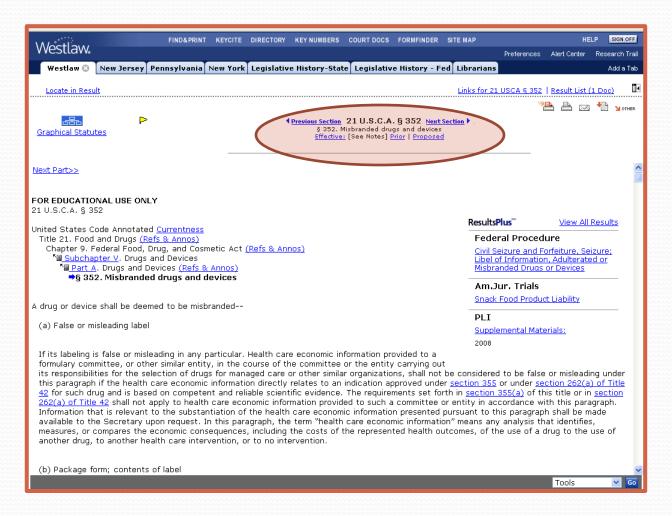
Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as 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.

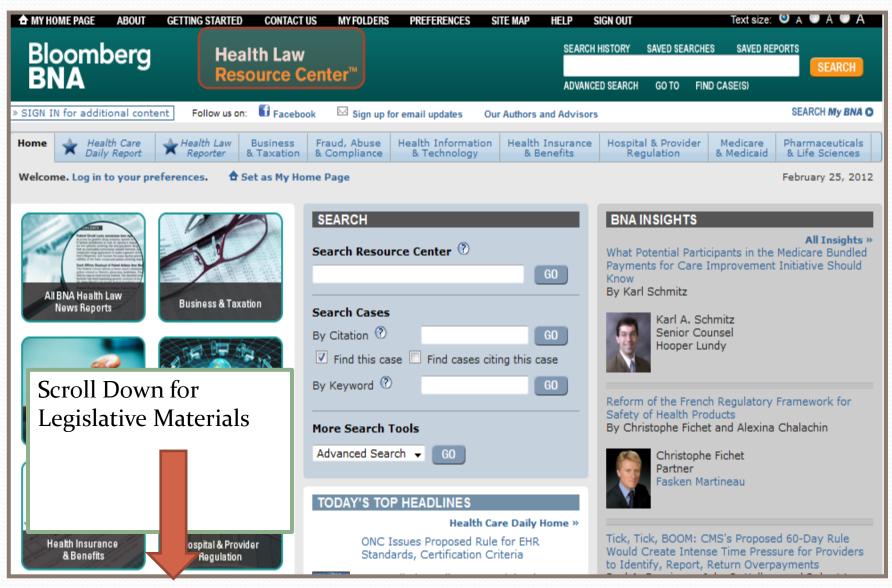
## Use electronic resources to update the statute



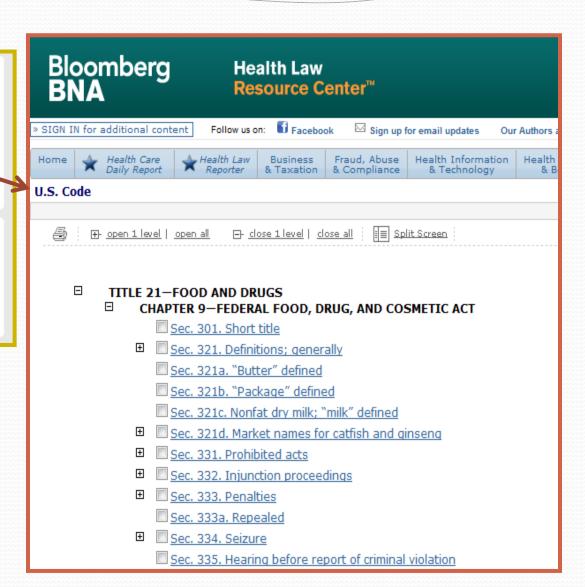
# KeyCite/Shepardize the Statute

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

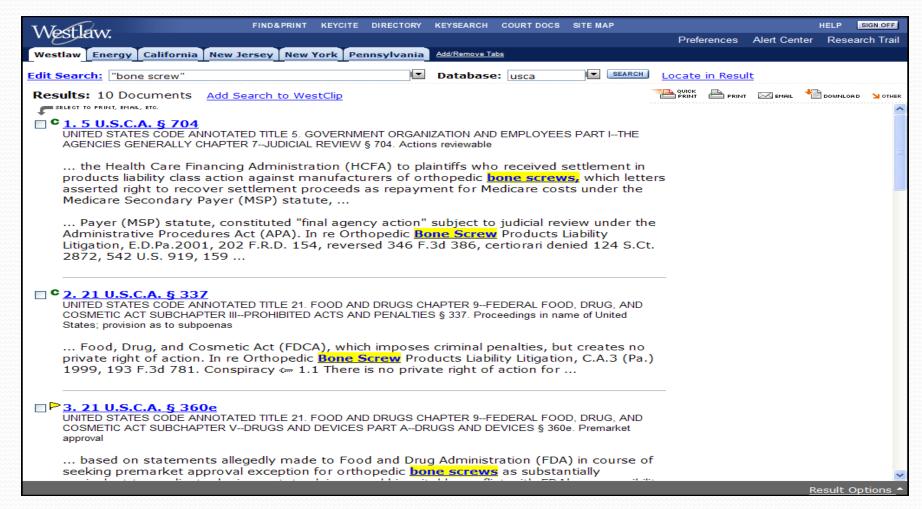
#### Great Alternative Statute Resources: Bloomberg BNA Mini Libraries



# 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 Terest Regulatory Summary Report State Law Topical Surveys



# **Keyword Search-Last Resort**



# NEW JERSEY STATUTES ANNOTATED

APR 2 7 2006

ADMINISTRATION OF CIVIL AND
CRIMINAL JUSTICE
2A:44 to 2A:65A



# 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

§ 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

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. 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

#### [Section 46:7]

<sup>1</sup>Am. Jur. 2d, Products Liability § 866.

#### [Section 46:8]

<sup>1</sup>See N.J.S.A. 2A:58C-1(a). <sup>2</sup>See N.J.S.A. 2A:58C-1 A:58C-7. The statutes are not in

<sup>2</sup>Am. Jur. 2d, Products Liability 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.

3"Product liability actions" means any claim or action brought by a claimant for harm caused by a prodPRODUCTS LIABILITY

§ 46:8

preponderance of the evidence that the product causing the harm<sup>5</sup> 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).

<sup>5</sup>"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-

<sup>6</sup>N.J.S.A. 2A:58C-2.

<sup>7</sup>N.J.S.A. 2A:58C-3(a)(1).

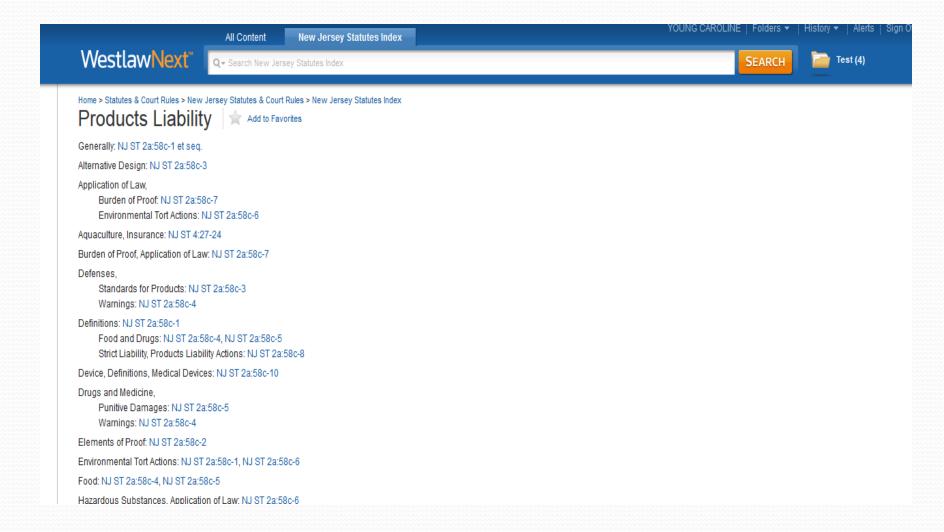
<sup>8</sup>N.J.S.À. 2A:58C-3(a)(2). This exception does not apply to industrial machinery or other equipment used in the workplace, nor is it intended to apply to dangers posed by products such as machinery or equipment that can feasibly be eliminated without impairing the usefulness of the product.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

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<sup>§ 586.</sup> 

<sup>&</sup>lt;sup>3</sup>Am. Jur. 2d, Products Liability § 591.

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### **New Jersey Products Liability Statute**

#### NJSA 2A:58C

#### CHAPTER 58C

#### PRODUCTS LIABILITY

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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).

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#### PRODUCTS LIABILITY

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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, cff. 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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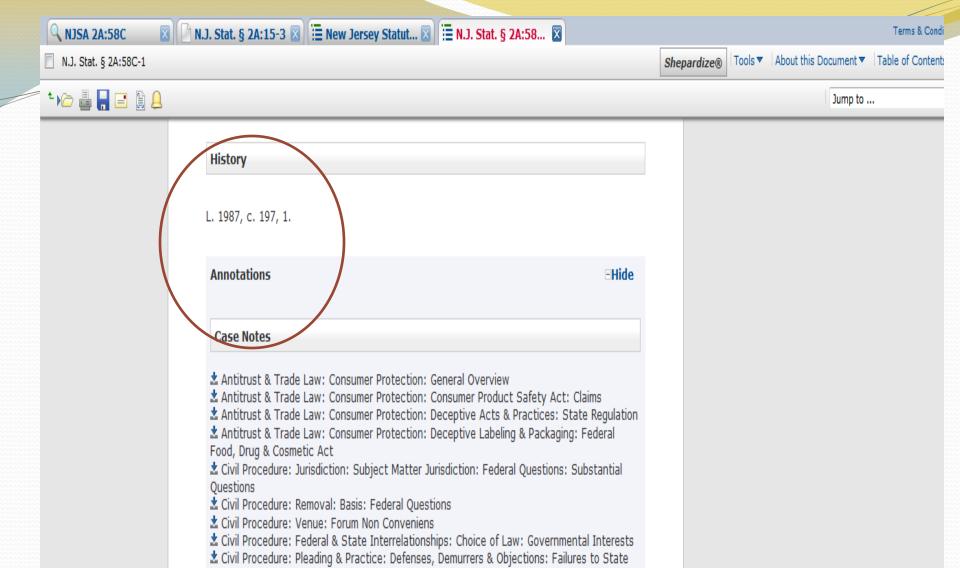
#### N.J. Stat. § 2A:58C-1 (Copy citation)

This section is current through New Jersey 215th Legislature Second Annual Session, P.L. 2013 c. 268 and JR 14State Constitution current through Nov. 2013 Election

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 quardian.
  - (2) "Harm" means (a) physical damage to property, other than to the product itself; (b)



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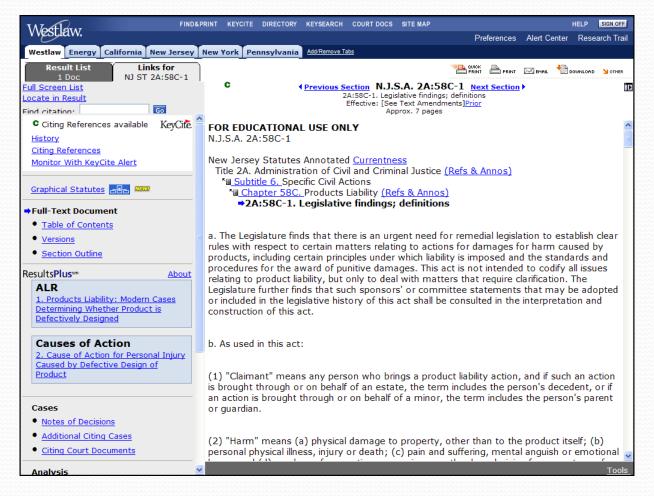
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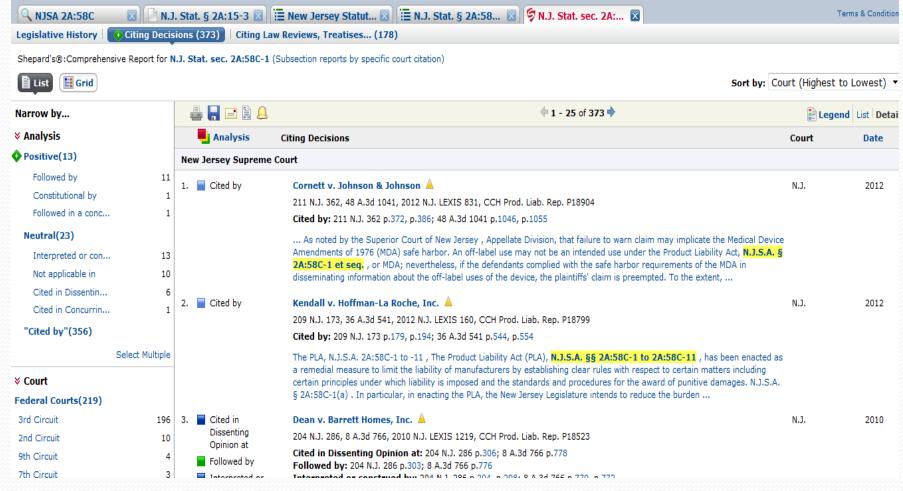
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New Jersey Register (N.J.R.)	New Jersey Administrative Code(N.J.A.C.)

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**EPA** 

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travel industry, as well as the FAA and Pipeline and Hazardous Materials Safety Administration. The ARC now seeks input from the general public and is particularly interested in feebback from entities subject to passenger notification regulations persornibed by U.S. Hazardous Materials (49 CFR 175.25). We note that operators transporting passengers in commence under 14 CFR parts 135 and 91 are subject to the noted 49 CFR regulation, and it is important that a final AC provide a clear, acceptable, and effective means for these operators to communicate hazardous materials regulations to their passengers.
The ARC will review all comments

received and consider them in its final recommendation to the FAA Issued in Washington, DC, on February 26,

Christopher Glasow Director, Office of Hazardous Materials Safety FR Doc. 2019-04;09 Filed 3-3-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 OFR Part 15 [Docket No. FDA-2013-N-0745]

Action Plan for the Collection Action Man for the Collection, Analysis, and Availability of Demographic Subgroup Data in Applications for Approval of Food and Drug Administration-Regulated ical Products: Notice of Public

AGENCY: Food and Drug Administration,

ACTION: Notification of public hearing; SUMMARY: The Food and Drug

public hearing to obtain input on the issues and challenges associated with the collection, analysis, and availability of demographic subgroup data in applications for approval of FDA-regulated human medical products DATES: The public hearing will be held on April 1, 2014, from 9 am. to 3 p.m. on April 1, 2014, from 9 a.m. to 3 p.m. Submit electronic or written requests to make oral presentations at the hearing by March 21, 2014. Electronic or written corrurents will be accepted after the hearing until May 16, 2014. ADDRESS ES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Eldg. 31,

Conference Center, the Creat Room (Rm. 1508A), Silver Spring, Mill 20989.
Entrance for the public hearing participants (non-FDA employees) is participants (non-FDA employees) is security check procedures will be performed. For parking and security information, please refer to http://www.fd.com/pack-glores/conference-for-firetravel industry, as well as the FAA and Conference Center, the Great Room (Rm. in product labeling or on FDA's Web

comments should be identified with the comments should be identified with the corresponding docket number for the public meeting as follows: "Docket No. TDA-2013-4-0745, Action Plan for the Collection, Analysis, and Availability of Demographic Subproup Data in Applications for Approval of FDA-Regulate d Human Medical Products, Public Hearing."

PROBLEM RESIDENT OF THE REPORT OF THE PROBLEM OF TH Rm. 2303, Silver Spring, MD 20993 240-402-4201, email: FDA SIA907@ fdn.hhs.gov. SUPPLEMENTARY INFORMATION:

#### I. Background

In section 907 of the Food and Drug A dministration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), the Act IFDA SIA (Pub. L. 112-144), the U.S. Congress directed FDA to produce a report that addressed the extent to which chinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups, including sex. age, rase, and ethnicity. is included in applications submitted to FDA. Specifically, Congress asked FDA to consider four key topic areas: (1) A to consider four key topic areas: (1) A description of existing tools to ensure submission of demographic information along with how information about differences in safety and effectiveness of Administration (FDA) is announcing a medical products according to demographic subgroup is made available to health care providers, researchers, and patients; (2) an analysis of the extent to which demographic data of the extent to which demographic data subset analyses are presented in applications; (3) an analysis of demographic subgroup representation in clinical trials submitted to FDA in support of product applications; and (4) an analysis of the extent to which a summary of troo dust safety and summary of product safety and effectiveness data by demographic subgroup is made available to the public

site.
To comply with that request, in
August 2013, FIJA published a report
'Collection, Analysis, and Availability
of Demographic Subgroup Data for FIJAApproved Medical Products." <sup>1</sup> The

Against a proper of the service of t

review templates and FDM, standard operating policies and procedure) guide regulatory review staff in the assessment of marketing applications to ensure that demographic data and subset analyses are included in the information FDM, uses in its review and approval processment to which. However, the procedure of the procedure of

sex, race, and age—that is, the
applications mentioned demographic
subsets in some way. The report noted
that ITA is now down application subsets in some way. The sport note of that FDA's new day application regulations (21 CFR part 314; specifically 53 145) call for demographic analysis in all applications of the specifically 53 the specifically 53 the demographic analysis in all applications and effectiveness. Cuidance and standard operating procedures for drugs and biologies also emphasize the importance of such analyses. These war no regulations sequenting demographic no regulations sequenting demographic nor explaints of the specifical specifical polications contained a rubbet analysis for age and sex, with a lower percentage of applications containing a rubbet analysis for race and ethnicity. detect relevant subgroup effects.
The report stated that all biologics, drugs, and the majority of the medical

\*FDA, \*Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Madical Products,\* Aspect FOOL, available at high New Madical Products,\* Aspect FOOL, available at high logishis of Johann Stood

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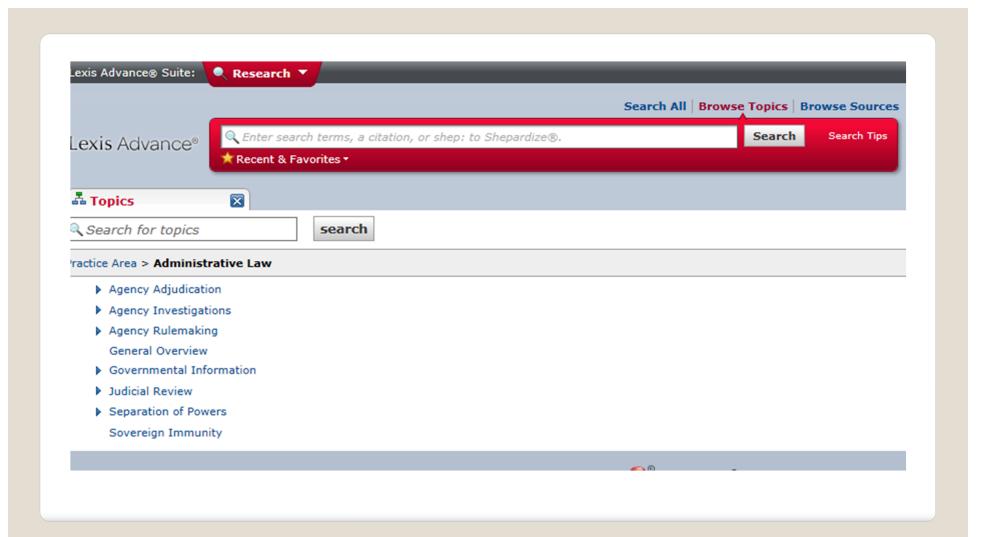
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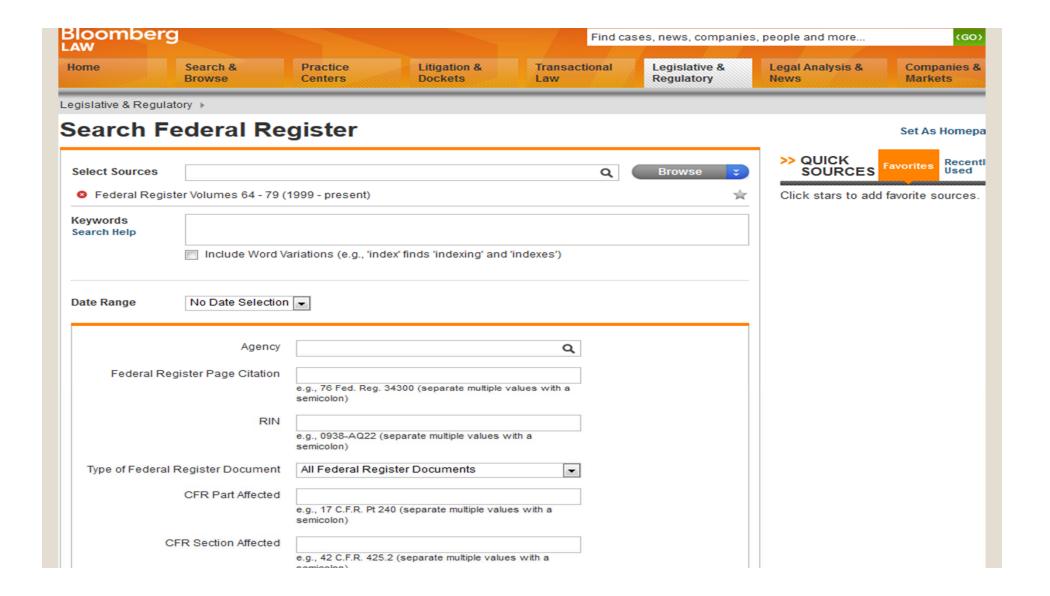
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The two publications dealing with administrative law in the state of New Jersey. They closely follow the format of the federal administrative publications except that the NJR is published once every 2 weeks and the code in print is a looseleaf service update monthly incorporating all changes adopted in NJR. LexisNexis is the official publisher and obligated to provide a free online version to the public.

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http://www.lexisnexis.com/hottopics/njcode/

**New Jersey Register** (from July 1995 on) at <a href="http://www.lexisnexis.com/njoal">http://www.lexisnexis.com/njoal</a>.

The **New Jersey Register** from the first issue (September 25, 1969) through June 1995 can be accessed through the New Jersey State Library at <a href="http://www.njstatelib.org/slic home/law library/new jersey legal">http://www.njstatelib.org/slic home/law library/new jersey legal</a> <a href="mailto:resources/new jersey register">resources/new jersey register</a>

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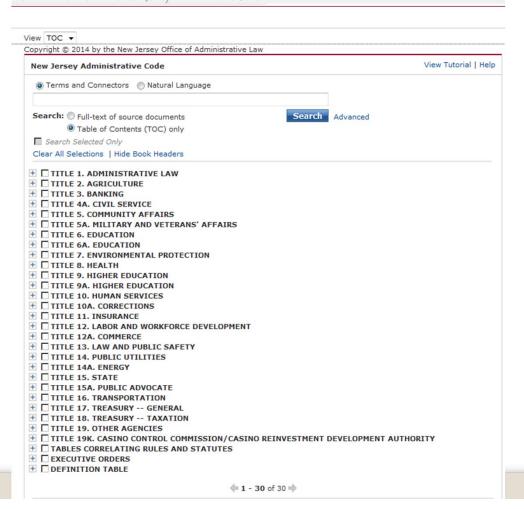
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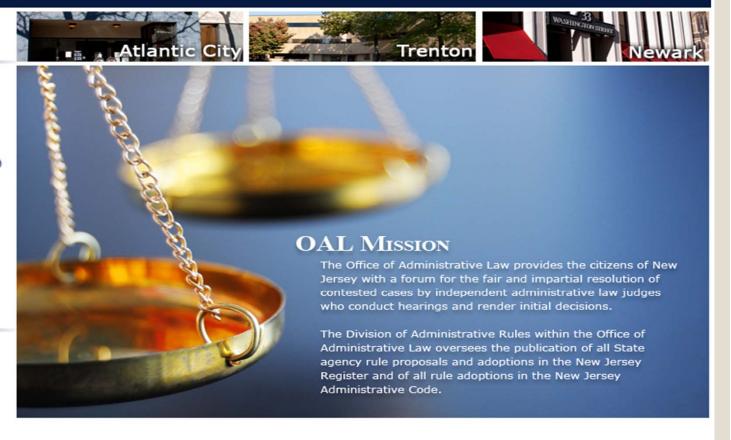
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--Each state has a similar system of publishing rules/regulations of its executive agencies, departments or commissions of government.

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	3.	Cross reference table from NJSA to NJAC for regulations issued under statute		
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Update:	1.	New Jersey Register for new regulations. Use Index to Rule Proposals and Adoptions for regulations affecting NJAC cite		
	2.	Lexis or Westlaw		
	3.	Internet - free access to NJ Register - http://www.lexisnexis.com/njoal/		
	4.	Contact the agency or check the web site for additional information on recent or proposed regulatory changes		
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### The End

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"property" whose damage gives rise to a claim under the Act. Rispens, 621 N.E.2d at 1089. That result, apparently accepted by the legislature, dictates disallowance of the claim for damage to the defective product, whether or not accompanied by other damage. Thus, for the same reasons given in Progressive, we hold that damage caused to other property by a defective product does not create a claim for damage to the product itself. We also think there are other persuasive reasons to reject the Dutsch rule. If recovery hinges on the presence of other damage, many cases will be launched into quests for some collateral damage. An oil stain on a garage floor from a failed engine or a burnt blade of grass from a fire should not create a claim where none existed.

We conclude that it was error for the trial court to refuse to instruct the jury that damage to the product itself, i.e., the motor home, was not recoverable under the Products Liability Act. In reviewing a trial court's decision to give or refuse tendered instructions, the Court considers: (1) whether the instruction correctly states the law; (2) whether there was evidence in the record to support the giving of the instruction; and (3) whether the substance of the tendered instruction is covered by other instructions which are given. Wooley v. State, 716 N.E.2d 919, 926 (Ind. 1999). An erroneous instruction merits reversal if it could have formed the basis for the jury's verdict. Canfield v. Sandock, 563 N.E.2d 1279, 1282 (Ind. 1990).

Here, it is clear that Indiana Pattern Instruction No. 11.40 left the jury with the mistaken impression that it should award full damages for the motor home to Progressive if it determined that Fleetwood was liable to Progressive in Progressive's products liability claim, and that the trial court erred in refusing to give Fleetwood's instruction. Ordinarily, a new trial would be

required. However, where, as here, liability was determined by the jury and the basis of the jury's damages award is apparent, it is appropriate to vacate the portion of the damages award not recoverable as a matter of Indiana law. See Ind. Appellate Rule 15(N)(5) (now App. R. 66(C)(4)) ("The court, with respect to all or some of the parties or upon all or some of the issues, may order: ... (ô) In the case of excessive or inadequate damages, entry of final judgment on the evidence for the amount of the proper damages...").

No challenge is raised to the award of prejudgment interest beyond a challenge to the underlying judgment. Accordingly, prejudgment interest should be awarded in proportion to the amount of the judgment that is affirmed.

#### CONCLUSION

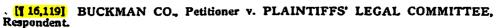
We affirm the jury's award of damages in the amount of \$6,587.89, reverse the damages award in the amount of \$162,500, and remand with direction that judgment be entered for the plaintiff in the amount of \$6,587.89 plus prejudgment interest of \$1,826.56.

SHEPARD, Chief Justice, and SULLIVAN, Justice, concur. RUCKER, Justice, concurs in result with separate opinion in which DICKSON, Justice, concurs.

#### [Concurrence]

RUCKER, Justice, concurring in result: Because of the doctrine of stare decisis, I concur in the result reached by the majority. Both Martin Rispens & Son v. Hall Farms, Inc., 621 N.E.2d 1078 (Ind. 1993), and Reed v. Central Soya Co., Inc., 621 N.E.2d 1069 (Ind. 1993), compel the outcome in this case.

DICKSON, Justice, concurs.



U.S. Supreme Court; 98-1768; February 21, 2001. S31 US 341, 121 SCt 1012, 148 LEd2d 854. Appeal from the U.S. Court of Appeals, 3d Circuit; 97-1783; Stapleton, Circuit Judge. Reversed.

The opinion of the U.S. Court of Appeals, 3d Circuit, appears at CCH PRODUCTS LIABILITY REPRITS ¶ 15,408.

Preemption Doctrine: Pedicle Screws: Medical Device Amendments: Implied Preemption: Fraud on FDA.—State-law fraud-on-the-FDA claims regarding off-label use of bone screws in the surgery of spinal pedicles conflicted with the powers granted to the FDA to deter fraud and balance varied statutory objectives; therefore the claims were impliedly preempted by the Federal Food, Drug, and Cosmetic Act and the Act's Medical Device Amendments. The screws were approved by the FDA as being substantially equivalent to devices that were already on the market prior to the Amendments' enactment in 1976. The federal statutory scheme empowered the FDA to punish and deter fraud against the agency, which had at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud. Compliance with state tort law in addition to the FDA's detailed regulatory regime would increased the burdens facing medical device manufacturers. Furthermore, the fraud-on-the-FDA claims, if successful, could have judged

¶ 16,119

#### **CURRENT**

## Rules Governing The Courts OF THE State of New Jersey

AMENDMENTS TO SEPTEMBER 1, 2013

Comments and Annotations include cases reported through 213 N.J. 570 and 431 N.J. Super. 92



#### WITH COMMENTS AND ANNOTATIONS

by

SYLVIA B. PRESSLER (1969-2010) &
PETER G. VERNIERO

Cite this Volume

PRESSLER & VERNIERO, Current N.J. COURT RULES, (GANN) followed by a reference to authors' comment on specific rule, e.g., PRESSLER & VERNIERO, Current N.J. (DORF RULES, Comment R. 4:4-4, (GANN)

#### 4:50-2. Time of Motion

The motion shall be made within a reasonable time, and for reasons (a), (b) and (c) of R. 4:50-1 not more than one year after the judgment, order or proceeding was entered or taken.

Note: Source-R.R. 4:62-2 (second sentence).

#### COMMENT

- 1. Generally.
- 2. Void Judgments.
- 3. Reasonable Time.
- 1. Generally. The basic scheme of the rule is to require that a R. 4:50-1 motion be made within a reasonable time under the circumstances, and to impose an outer limit of one year on motions made pursuant to subsection (a) mistake, inadvertence, surprise, or excusable neglect; subsection (b) newly discovered evidence; and subsection (c) fraud, misrepresentation, or misconduct. See Orner v. Liu, 419 N.J. Super. 431, 437 n.7 (App. Div. 2011); Bascom Corp. v. Chase Manhattan, 363 N.J. Super. 334, 340 (App. Div. 2003), certif. den. 178 N.J. 453 (2004) certif. den. 178 N.J. 453 (2004).

Where the order or judgment from which relief is sought is not served or otherwise transmitted to the party complaining of it, the timeliness of the application is measured by when the party had actual notice. Farrell v. TCI of Northern N.J., 378 N.J. Super. 341, 353-354 (App. Div. 2005).

- 2. Void Judgments. The ordinary rule is that a motion pursuant to subsection (d) must be made within a reasonable time despite the voidness of the judgment or order. See United Pacific Ins. Co. v. Lamanna's Estate, 181 N.J. Super. 149 (Law Div. 1981); Last v. Audubon Park Associates, 227 N.J. Super. 602 (App. Div. 1988), certif. den. 114 N.J. 491 (1989); Citibank, N.A. v. Russo, 334 N.J. Super. 346, 353 (App. Div. 2000). But see contra, Berger v. Paterson Veterans Taxi, 244 N.J. Super. 200 (App. Div. 1990), holding that a void judgment not entitled to enforcement or execution may be moved against under this rule at any time. Nevertheless, where defendant failed to seek relief under this rule and intervening rights of an innocent third person arose in the meantime, relief will be denied. City of Newark v. (497) Block 1854, 244 N.J. Super. 402 (App. Div. 1990); Friedman v. Monaco and Brown Corp., 258 N.J. Super. 539, 545 (App. Div. 1992); Reaves v. Egg Harbor Tp., 277 N.J. Super. 360 (Ch. Div. 1994).
- 3. Reasonable Time. What constitutes a reasonable time is, of course, dependent on the totality of the circumstances. See Moore v. Hafeeza, 212 N.J. Super. 399 (Ch. Div. 1986)(an application by the mother of a child born out of wedlock seeking reconsideration of a paternity decision 16 years after the birth based on developments in HLA testing failed to meet the reasonable time standard); Mt. Olive Com. v. Tp. of Mt. Olive, 340 N.J. Super. 511, 531 (App. Div. 2001), reaff'd after remand 356 N.J. Super. 500 (App. Div.), certif. den. 176 N.J. 73 (2003) (laches is a relevant consideration in the decision to modify or refuse to enforce a consent decree in public interest litigation). Note that the one-year limitation for reasons (a), (b) and (c) of the Rule does not mean that filing within one year automatically qualifies as within a reasonable time. Orner v. Liu, 419 N.J. Super. 431, 436-437 (App. Div. 2011).

#### 4:50-3. Effect of Motion

A motion under R. 4:50 does not suspend the operation of any judgment, order or proceeding or affect the finality of a final judgment, nor does this rule limit the power of a court to set aside a judgment, order or proceeding

### N.J. Court Rules - Annotated - Pressler & Verniero Table of Contents Search Updates Page # Gol

4:50-2 Page #1811

<u>4:50-3</u>

#### 4:50-2. Time of Motion

The motion shall be made within a reasonable time, and for reasons (a), (b) and (c) of R.  $\underline{4:50-1}$  not more than one year after the judgment, order or proceeding was entered or taken.

Note: Source\_\_R.R. 4:62-2 (second sentence).

#### COMMENT

What's New?

**1. Generally.** The basic scheme of the rule is to require that a R. <u>4:50-1</u> motion be made within a reasonable time under the circumstances, and to impose an outer limit of one year on motions made pursuant to subsection (a) mistake, inadvertence, surprise, or excusable neglect; subsection (b) newly discovered evidence; and subsection (c) fraud, misrepresentation, or misconduct. See Orner v. Liu, <u>419 N.J. Super. 431</u>, <u>437 n.7 (App. Div. 2011)</u>; Bascom Corp. v. Chase Manhattan, <u>363 N.J. Super. 334</u>, <u>340 (App. Div. 2003)</u>, certif. den. 178 N.J. 453 (2004) certif. den. 178 N.J. 453 (2004).

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What's New?

**3. Reasonable Time.** What constitutes a reasonable time is, of course, dependent on the totality of the circumstances. See Moore v. Hafeeza, <u>212 N.J. Super.</u> 399 (Ch. Div. 1986)(an application by the mother of a child born out of wedlock seeking reconsideration of a paternity decision 16 years after the birth based on developments in HLA testing failed to meet the reasonable time <a href="http://www.gannlaw.com/OnlineApp/ResearchTools/Main/get\_file.cfm?book\_code=1&gr...">http://www.gannlaw.com/OnlineApp/ResearchTools/Main/get\_file.cfm?book\_code=1&gr...</a>

Court Rules Page 2 of 2

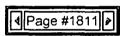
standard); Mt. Olive Com. v. Tp. of Mt. Olive, <u>340 N.J. Super. 511</u>, <u>531</u> (App. Div. 2001), reaff'd after remand <u>356 N.J. Super. 500</u> (App. Div.), certif. den. 176 N.J. 73 (2003) (laches is a relevant consideration in the decision to modify or refuse to enforce a consent decree in public interest litigation). Note that the one-year limitation for reasons (a), (b) and (c) of the Rule does not mean that filing within one year automatically qualifies as within a reasonable time. Orner v. Liu, <u>419 N.J. Super. 431</u>, <u>436</u>-437 (App. Div. 2011).

#### 4:50-3. Effect of Motion

A motion under R.  $\underline{4:50}$  does not suspend the operation of any judgment, order or proceeding or affect the finality of a final judgment, nor does this rule limit the power of a court to set aside a judgment, order or proceeding for fraud upon the court or to entertain an independent action to relieve a party from a judgment, order or proceeding.

Note: Source\_\_R.R. 4:62-2 (third and fourth sentences).

4:50-2



4:50-3

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### ELEMENTS OF AN ACTION

2013-2014 Edition

Issued in September 2013

By

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#### Chapter 46

#### **Products Liability**

§ 46:1	Summary of law
§ 46:2	Bases of liability
§ 46:3	Negligence
§ 46:4	Breach of warranty
§ 46:5	Strict liability in tort
§ 46:6	Fraud, deceit, and misrepresentation
§ 46:7	Choice of law and forum
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§ 46:11	Inability to repair or correct nonconformity
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#### § 46:1 Summary of law

The term "products liability" refers to the liability of a manufacturer, processor, or non-manufacturing seller for injury to the person or property of a buyer or third party caused by a product, which has been sold.

There are several federal acts that may have great importance in any products liability case. These include the Consumer Product Safety Act,<sup>2</sup> the Flammable Fabrics Act,<sup>3</sup> the Hazardous Substances Act,<sup>4</sup> and the Special Packaging of Household Substances

#### [Section 46:1]

<sup>&</sup>lt;sup>1</sup>Am. Jur. 2d, Products Liability § 1.

<sup>&</sup>lt;sup>2</sup>15 U.S.C.A. §§ 2051 et seq.

<sup>&</sup>lt;sup>3</sup>15 U.S.C.A. §§ 1191 et seq.

<sup>&</sup>lt;sup>4</sup>15 U.S.C.A. §§ 1261 et seq.

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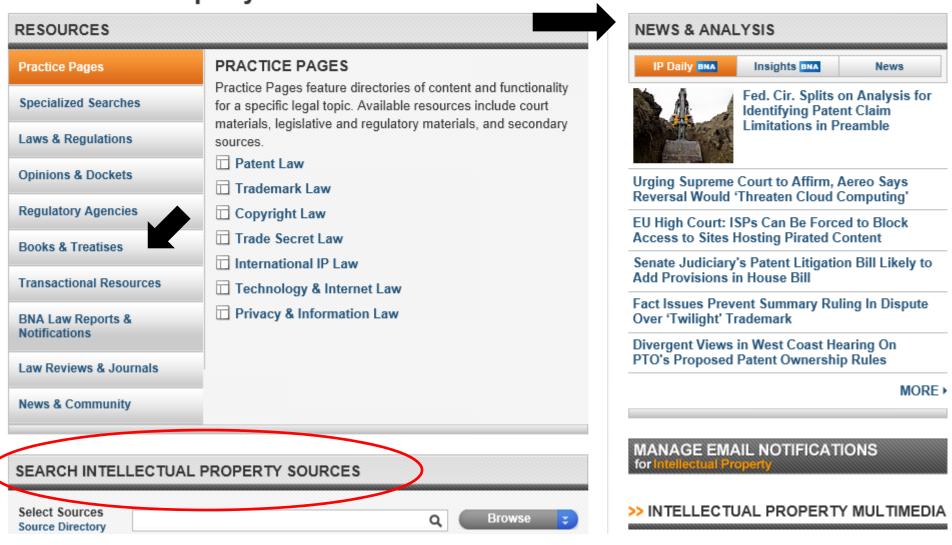
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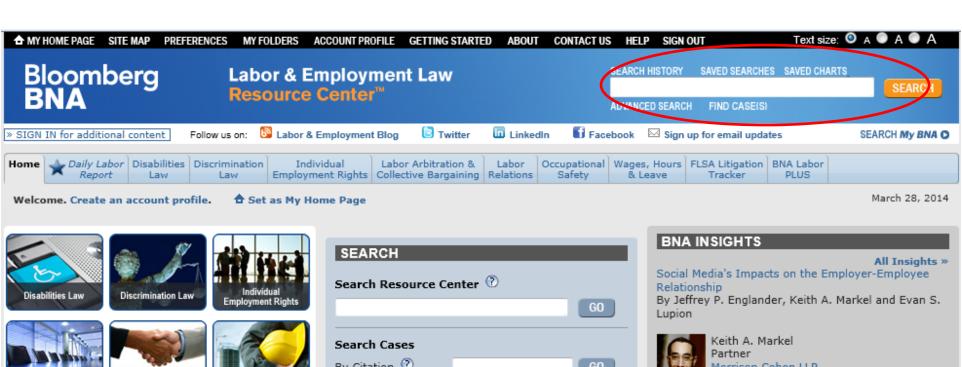
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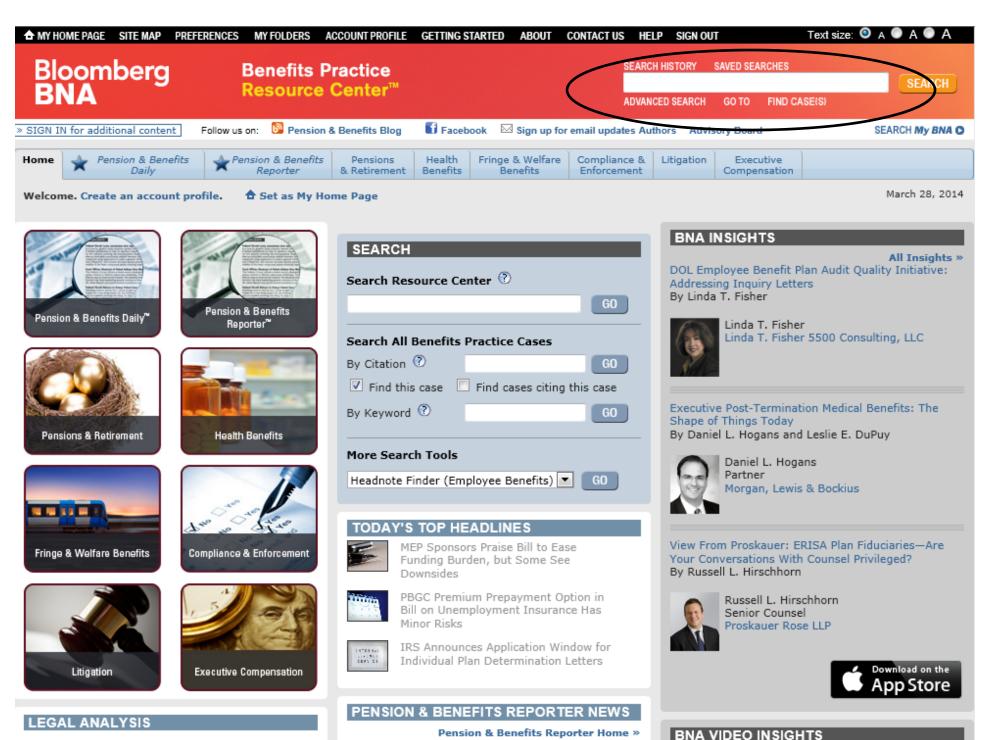
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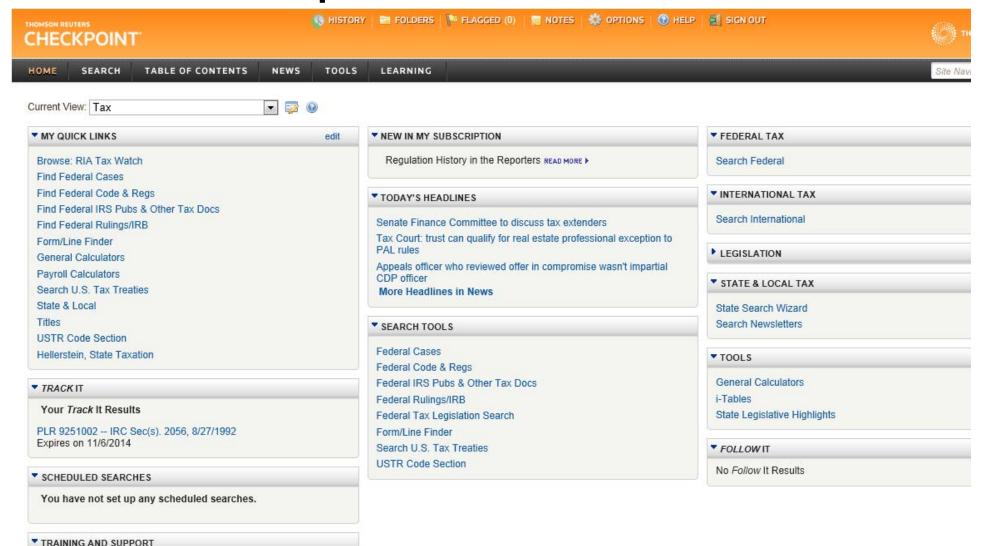
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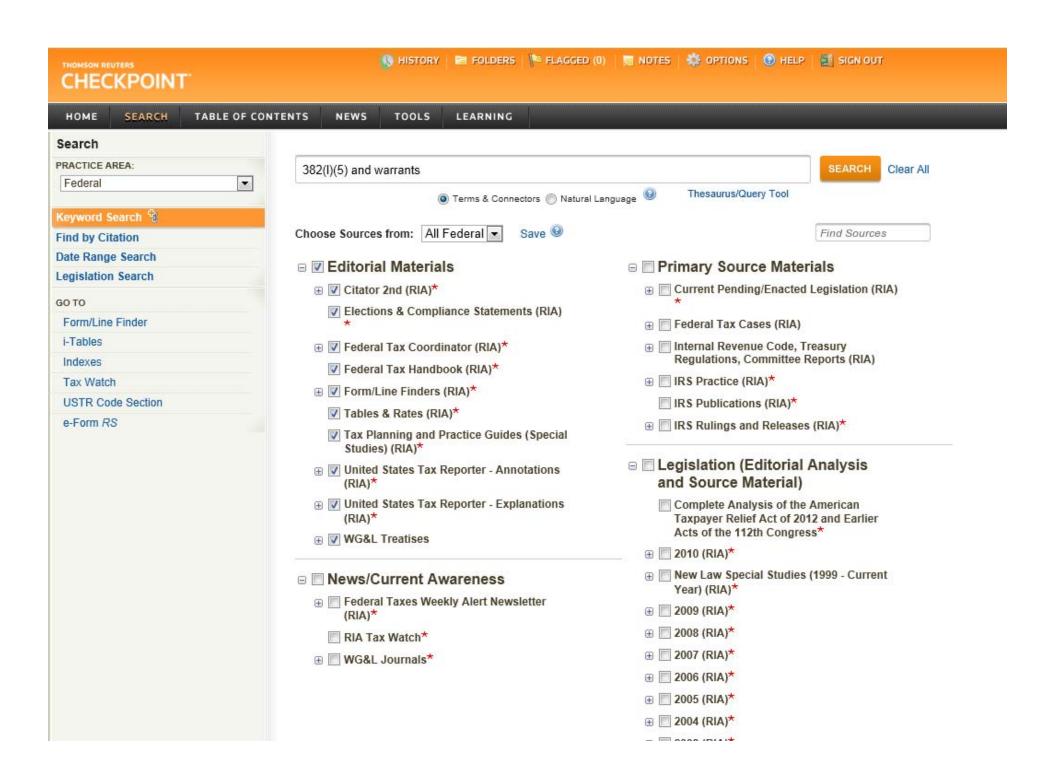
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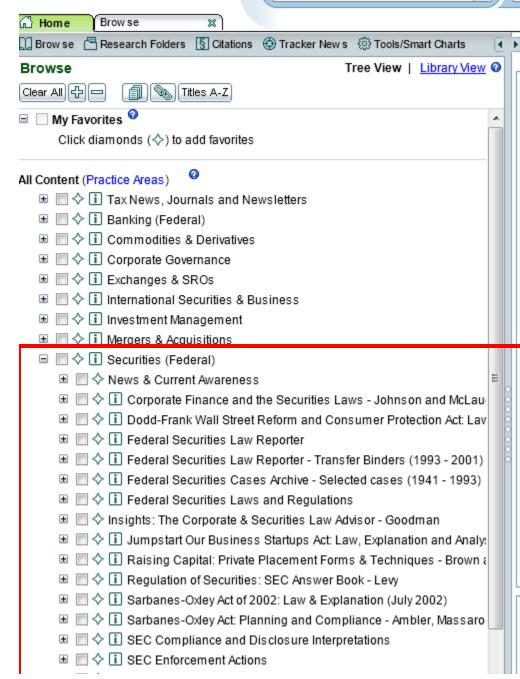
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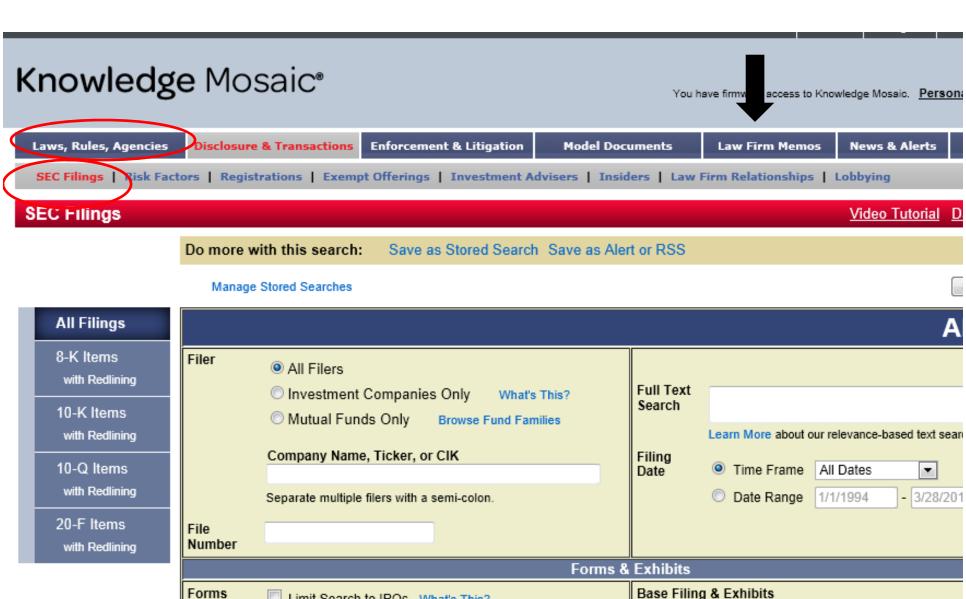
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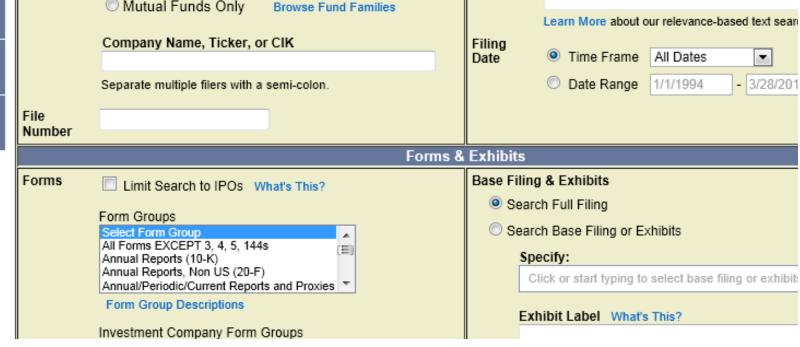
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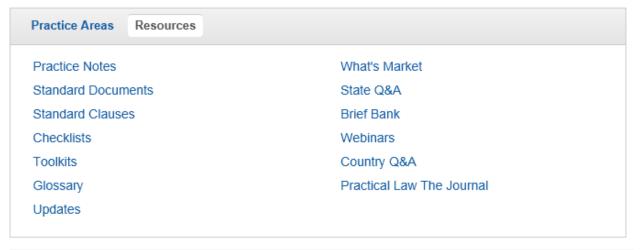






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#### Closing Private M&A Transactions Checklist

Resource type: Checklist

Status: Maintained

Jurisdiction: USA

This Checklist summarizes the key steps that need to be taken and the issues that need to be considered when preparing a private M&A transaction for closing. This Checklist is not intended to be exhaustive. It covers those steps and issues that are common to most private M&A transactions. There may be additional steps or issues depending on the complexity of a particular deal.

PLC Corporate & Securities

This Checklist assumes that the signing of the principal transaction document precedes the closing of the transaction. Although some transactions do have a simultaneous signing and closing, most M&A transactions have the closing follow a period of time after the signing. There are usually various regulatory, corporate and third-party consents that need to be obtained before completing a transaction. The parties, particularly the seller, may not want to begin the process of obtaining these consents until they have a signed agreement. In some cases, they may not be able to start the process without a signed agreement. For more information on M&A transactions, see *Practice Note*, *Signing and Closing M&A Transactions: Signing and Closing: Simultaneous or Gap?*.

#### The Closing Checklist

The first step towards a successful closing of a private M&A transaction is the preparation of a comprehensive *closing checklist*. This is a list assigning responsibility for actions to be taken and documents to be delivered at on or before the closing. It is important to an organized closing and should be













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connection with violations of the Foreig Corrupt Practices Act. This is one of multiple FCPA-based resolutions announced by a Japanese company in the last three years alone, and continue several recent trends in FCPA enforcement, say attorneys with Davis Polk & Wardwell LLP.

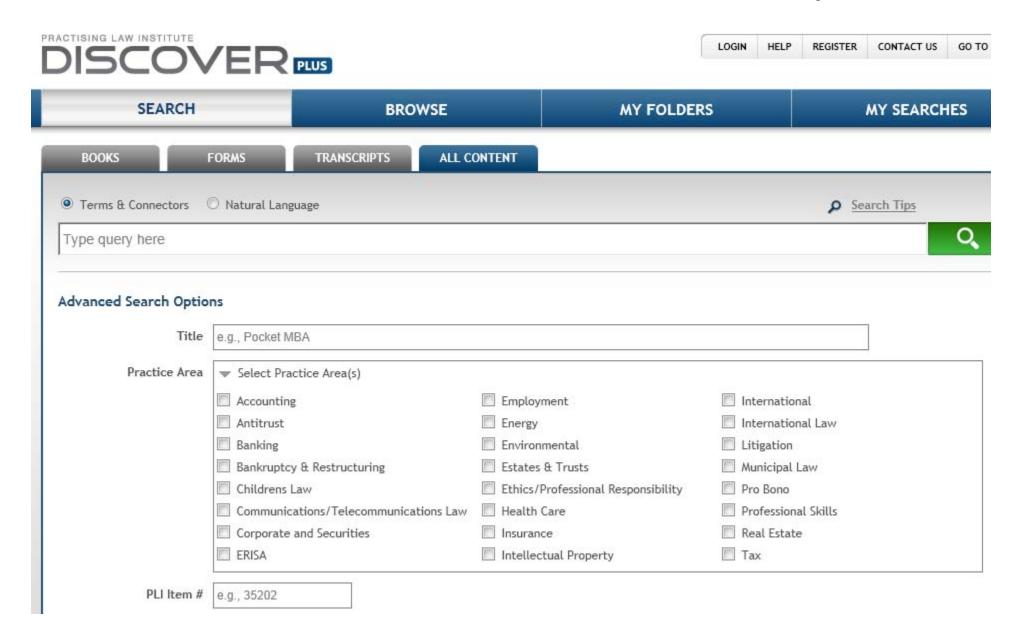
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- o To pinpoint relevant sections within the treatise/loose-leaf service, consult its finding aids, i.e., table of cases, table of statutes, subject index, table of contents, etc.
- O Don't forget to update by checking the pocket part/supplement.

#### RESTATEMENTS OF THE LAW

- Consult the Restatements for background information, research into common-law subjects, and sources of persuasive authority.
- o Check the library's catalog for print versions of Restatements.
- o Check Lexis and Westlaw for selected series and topics coverage.
- O Begin your research in the print version of Restatements by consulting the subject index or table of contents for material on specific topics. Next, check the noncumulative appendix volume(s) for case notes. Finally, consult the pocket part or softcover supplement for the most recent updates.

#### INTERNET SOURCES

- o Always check the site for information regarding its timeliness. When was it last updated? Not all web sites are as diligent as Lexis and Westlaw at keeping current.
- When formulating your search, be mindful of correct spelling and possible variations among web sites. If your search is unsuccessful, check for the web page for "tips" which might improve response.
- o Confirm authorities found online using traditional legal research tools.

#### SOURCES FOR USEFUL INFORMATION ON THE INTERNET

#### **ATTORNEY INFORMATION**

Martindale Hubbell www.martindale.com

West Legal Directory/Findlaw <a href="http://lawyers.findlaw.com">http://lawyers.findlaw.com</a>

#### BASIC LEGAL RESEARCH SEARCH ENGINES

Findlaw www.findlaw.com

Hieros Gamos <u>www.hg.org</u>

#### **NEW JERSEY WEBSITES**

State New Jersey Home Page <a href="www.state.nj.us">www.state.nj.us</a>

NJ District Court <a href="http://www.njd.uscourts.gov/">http://www.njd.uscourts.gov/</a>

NJ PACER Access <a href="https://ecf.njd.uscourts.gov/cgi-bin/ShowIndex.pl">https://ecf.njd.uscourts.gov/cgi-bin/ShowIndex.pl</a>

NJ Bankruptcy Court www.njb.uscourts.gov

NJ Judiciary www.judiciary.state.nj.us

NJ Legislature www.njleg.state.nj.us

Rutgers Law School <a href="http://law.newark.rutgers.edu">http://law.newark.rutgers.edu</a>

NJ Online (news) www.nj.com

#### FEDERAL GOVERNMENT INFORMATION

USA www.usa.gov

FedStats www.fedstats.gov

(federal government statistics from over 100 agencies)

Bureau of Labor Statistics <a href="http://stats.bls.gov">http://stats.bls.gov</a>

(CPI and other economic data)

U.S. Congress <a href="http://congress.gov">http://congress.gov</a>

(federal legislation, Congressional

Record, etc.)

FDsys <a href="http://www.gpo.gov/fdsys/">http://www.gpo.gov/fdsys/</a>

(Federal Register, Congressional

Record, other government publications)

#### FEDERAL COURT WEBSITES

US Supreme Court <u>www.supremecourtus.gov</u>

US Court of Appeals – Third Circuit <a href="www.ca3.uscourts.gov">www.ca3.uscourts.gov</a>

Federal Judicial Center www.fjc.gov

(court data, rules, publications, etc.)

U.S. Courts Locator http://www.uscourts.gov/Home.aspx

#### **STATE WEBSTITES**

National Commissioners on Uniform www.nccusl.org

State Laws

National Conference of State Legislatures <u>www.ncsl.org</u>

National Center for State Courts http://www.ncsc.org/

State Government Websites http://www.statelocalgov.net/

#### **FAVORITE LAW SCHOOL WEBSITES**

Cornell Law School Legal <a href="http://www.law.cornell.edu/">http://www.law.cornell.edu/</a>

**Information Institute** 

Washburn Law School <a href="http://washlaw.edu/">http://washlaw.edu/</a>

NYU Law School http://www.law.nyu.edu/library/research/foreign\_intl/

#### **BUSINESS INFORMATION SOURCES**

Hoovers www.hoovers.com

Securities and Exchange Commission <u>www.sec.gov</u>

NASDAQ www.nasdaq.com

Go directly to the company website

#### **EXPERTS**

ExpertWitness.com <u>www.expertwitness.com</u>

ExpertPages www.expertpages.com

Internet Legal Research Guide <a href="www.ilrg.com/experts\_ref.html">www.ilrg.com/experts\_ref.html</a>

#### **MEDICAL INFORMATION**

PUBMED/Medline (medical articles) <u>www.ncbi.nlm.nih.gov/PubMed</u>

American Medical Association <u>www.ama-assn.org</u>

#### **SEARCH ENGINES**

Bing http://www.bing.com/

Google www.google.com

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Yahoo www.yahoo.com

#### WEBSITE WITH USEFUL LINKS

New Jersey Law Librarians Association <a href="www.njlla.org">www.njlla.org</a>

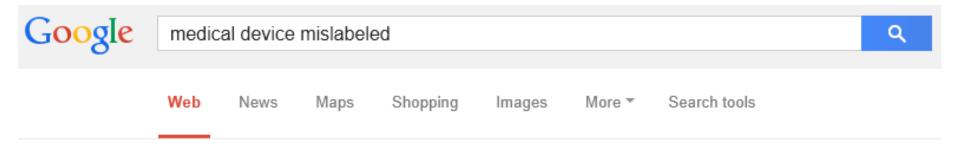
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By Kathy Taggart
Senior Research Services Librarian
Lowenstein Sandler LLP

# SEARCH OPERATORS

# A space is an assumed "and"



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#### Bryan Medical Tracoe Mini 3.0mm Tracheostomy Tube - Misl...

www.fda.gov/MedicalDevices/.../ucm361... ▼ Food and Drug Administration ▼ Jul 22, 2013 - The Tracoe Mini 3.0mm Tracheostomy Tubes were mislabeled on the device packaging. The outside of the device packaging stated a 3.0mm ...

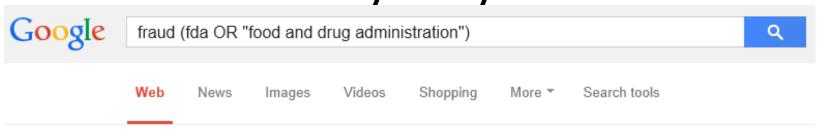
#### Device Labeling - Food and Drug Administration

www.fda.gov/MedicalDevices/DeviceReg... ▼ Food and Drug Administration ▼ Mar 12, 2014 - Device Advice - Introduction to labeling requirements for medical devices, including advertising, over the counter, exemptions, in vitro ... Part 801 - General Device Labeling ... - Quality System Regulation ...

#### [PDF] Medical Device Labeling Facts

www.loftware.com/.../Medical%20Devices\_Labeling%20Fact%20Sheet.p... ▼
in inefficiency and mislabeling which can significantly impact the bottom line. Local
Labeling Barriers. In today's global supply chains, Medical. Device ...

# Put a phrase in quotes; you can use OR for synonyms



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#### Health Fraud Scams - Food and Drug Administration

www.fda.gov/.../healthfraud/default.htm ▼ Food and Drug Administration ▼ Feb 14, 2014 - Health fraud scams refer to products that claim to prevent, treat, or cure diseases or other health conditions, but are not proven safe and ...

#### Medication Health Fraud - Food and Drug Administration

www.fda.gov/.../MedicationHealthFraud/ ▼ Food and Drug Administration ▼ Feb 14, 2014 - In general, health fraud drug products are articles of unproven effectiveness that claim to treat disease or improve health. In addition to wasting ...

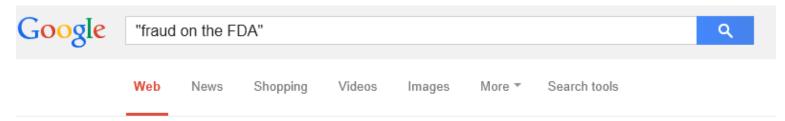
#### Health Fraud > For Consumers - Food and Drug Administr...

www.fda.gov/.../HealthFraud/ucm267375... ▼ Food and Drug Administration ▼ Jan 15, 2014 - At this very minute, someone is falling for a health fraud scam. It's happening all around us. They target all of us with promises of quick fixes and ...

#### Beware of Online Cancer Fraud - Food and Drug Administr...

www.fda.gov/.../ucm048383.htm ▼ Food and Drug Administration ▼ Jan 30, 2014 - FDA and the Federal Trade Commission have launched a program targeting online health fraud that takes advantage of people with cancer.

# Try lots of different searches



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#### "Fraud-on-the-FDA" Failure to Warn Claims Are ... - Sedgwic...

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Mar 28, 2012 - "Fraud-on-the-FDA" Failure to Warn Claims Are Preempted by
Federal Law. Pharmaceutical Law Update. March 2012. The extent to which ...

#### [PDF] Fraud on the FDA - article.DOC

www.lrrlaw.com/files/.../Fraud%20on%20the%20FDA%20-%20article.p... ▼
Fraud on the FDA: U.S. Supreme Court Rejects New Application of a Familiar Theory by Joice B. Nidy, Esq., Duckor, Spradling and Metzger, A Law Corporation.

#### Buckman Co. v. Plaintiffs' Legal Comm. - Wikipedia, the free ...

en.wikipedia.org/.../Buckman\_Co.\_v.\_Plaintiffs'\_Legal\_Com... ▼ Wikipedia ▼ The case concerned whether the FDCA (Food, Drug and Cosmetic Act), a federal statute, pre-empted a state-law fraud-on-the-FDA claim. Although finding it on ...

#### FDA Law Blog: Recent "Fraud on the FDA" Court Decision S...

www.fdalawblog.net/fda\_law\_blog\_hyman.../recent-fraud-on.html ▼
Nov 26, 2007 - In the preemption world, "fraud on the FDA" cases are fairly common.
As one court recently used the term, fraud on the FDA means a drug or a ...

#### PRODUCTS LIABILITY: Federal Law Preempts Texas Fraud...

www.nlrg.com/.../PRODUCTS-LIABILITY-Federal-Law-Preempts-Texa... ▼
Apr 27, 2012 - Legal research on products liability. "Federal Law Preempts Texas
Fraud-on-the-FDA Rebuttal Statute," by Jeremy Taylor, National Legal ...

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"Fraud-on-the-FDA" Failure to Warn Claims Are Preempted by Federal Law

#### Pharmaceutical Law Update

March 2012

The extent to which federal law preempts state law claims is an issue that has been in the forefront of drug and medical device litigation throughout the past few years. In the context of medical device litigation, the U.S. Supreme Court rendered its seminal Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), decision determining that federal law preempts state law causes of action based on a medical device manufacturer's alleged fraudulent representations to the Food and Drug Administration (FDA). Since that decision, federal courts have been considering whether the Buckman analysis applies more broadly to all claims asserting allegations of "fraud-on-the-FDA," or simply just to causes of action titled "fraud-on-the-FDA." Compare Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961 (6th Cir. 2004), with Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006), affd by an equally divided court sub nom. Warner-Lambert Co., LLC v. Kent, 552 U.S. 440, 128 S. Ct. 1168 (2008). The Fifth Circuit Court of Appeals is the most recent court to weigh in on this issue in Lofton v. McNeil Consumer & Specialty Pharm., et al, 2012 WL 579772 (5th Cir. Feb. 22, 2012).

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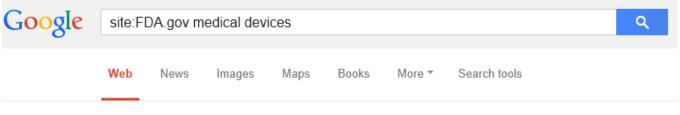
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www.fda.gov/MedicalDevices/ ▼ Food and Drug Administration ▼ Mar 20, 2014 - Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff ... Medical Device Databases - 510(k) Clearances - Device Registration and Listing

#### Consumers (Medical Devices) - Food and Drug Administration

www.fda.gov/medicaldevices/.../default.ht... ▼ Food and Drug Administration ▼ Mar 18, 2014 - Information about Medical Devices that may be of interest to Consumers.

#### Consumer Updates > Medical Devices - Food and Drug Adm...

www.fda.gov/.../ucm149209.htm ▼ Food and Drug Administration ▼ Fighting Diabetes' Deadly Impact on Minorities. FDA's Office of Minority Health advances prevention, better treatment. Fighting Diabetes' Deadly Impact on ...

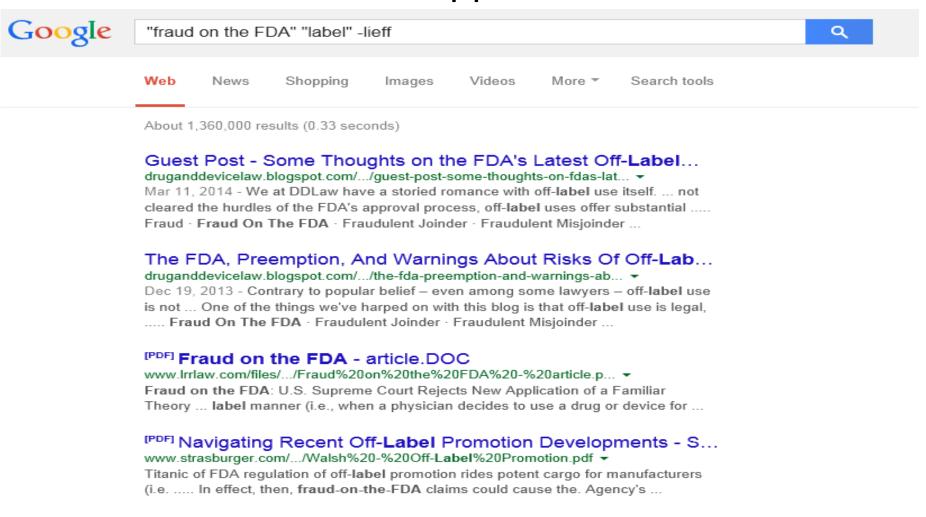
#### List of Device Recalls - Food and Drug Administration

www.fda.gov/medicaldevices/.../default.ht... ▼ Food and Drug Administration ▼ Feb 6, 2014 - FDA posts consumer information about the most serious medical device recalls. These products are on the list because there is a reasonable ...

#### News & Events (Medical Devices) - Food and Drug Administ...

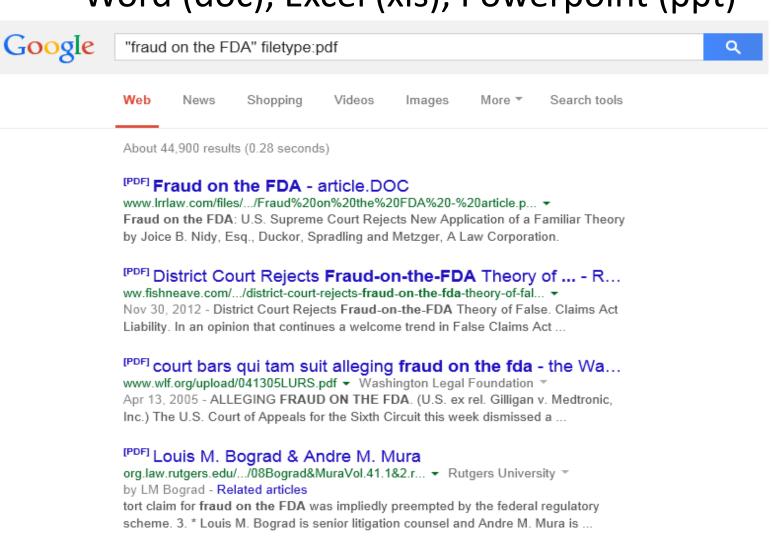
www.fda.gov/MedicalDevices/NewsEvents/ ▼ Food and Drug Administration ▼ Mar 20, 2014 - Medical device news-making events, videos, and meetings and conferences

# Use quotes to ensure words appear (even one word); use minus sign next to a word to have it not appear



The Preemption War: When Federal Bureaucracies Trump Lo... books.google.com/books?isbn=0300152205
Thomas O. McGarity - 2008 - LAW

# Narrow your search to one filetype – Adobe (pdf), Word (doc), Excel (xls), Powerpoint (ppt)

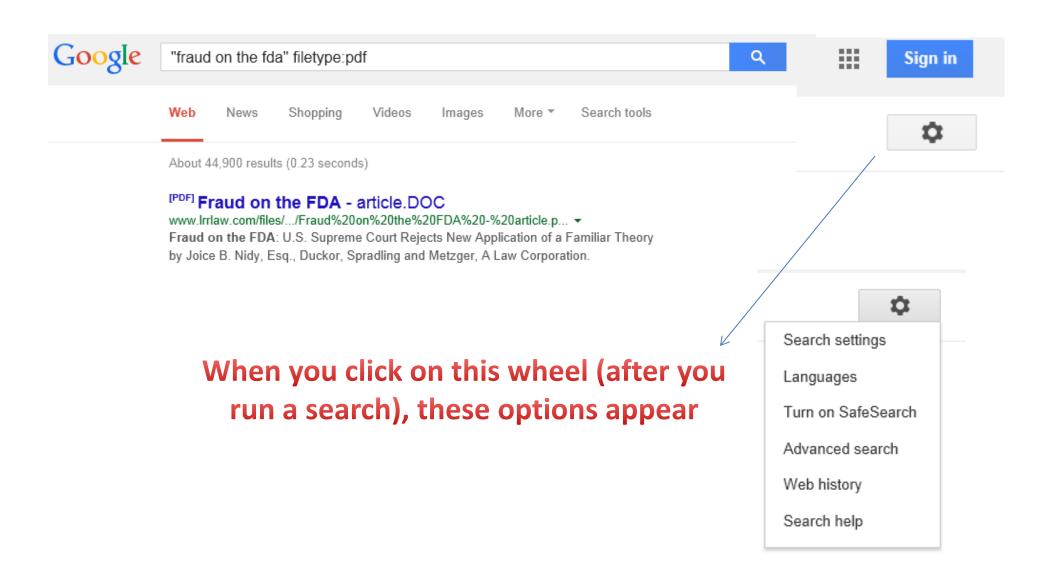


#### [PDF] Buckman—Its Impact Over a Decade Later - Paine, Tarw...

www.painetarwater.com/news/elderwilliams.pdf -

District of Pennsylvania dismissed the plaintiffs' fraud-on-the-FDA claims on the grounds that, among other things, a pri- vate right of action did not exist for Fed-.

# Finding Search Features



# Search Settings

 Change things like search predictions and number of results per page

#### Google Instant predictions

When should we show you results as you type?

- Only when my computer is fast enough.
   Instant is currently on for web search. Manually change it below.
- Always show Instant results.
- Never show Instant results.

#### Results per page



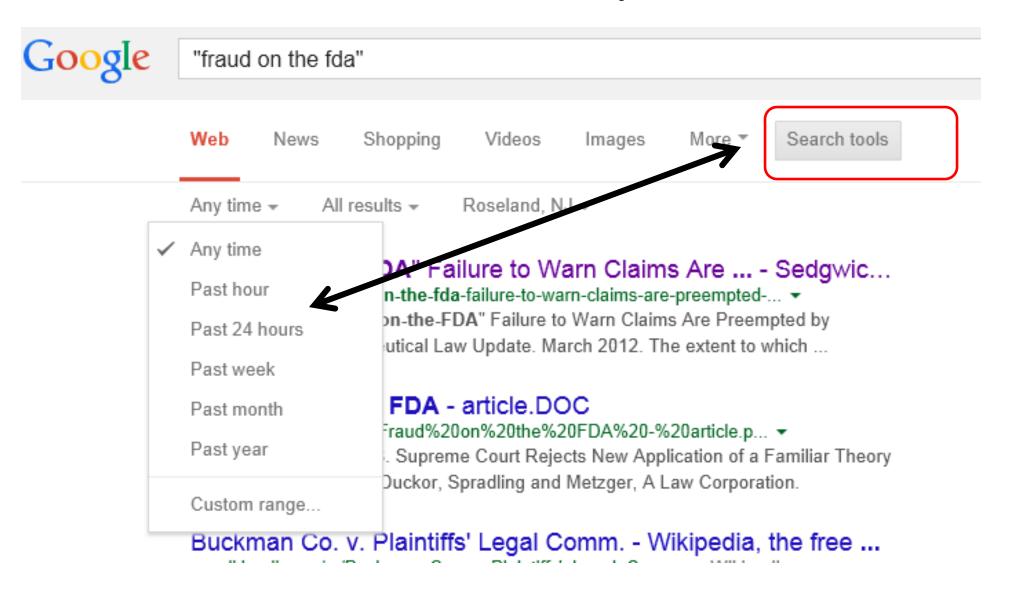
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 From this page, use all the search operators we discussed, plus more (language, where terms appear (in title only, in text only), etc.

Then narrow your results by	
language:	any language
region:	any region
last update:	anytime
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#### "fraud on the fda"

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#### Drug and Device Law: Breaking News - Fosamax Preemptio...

druganddevicelaw.blogspot.com/.../breaking-news-fosamax-preemption-... ▼ 2 days ago - Instead, Plaintiffs' contention appears to be a fraud-on-the-FDA theory which was rejected by the Supreme Court in [Buckman], or alternatively, is based largely ...

#### Drug and Device Law: Preemption Applies Even Though the...

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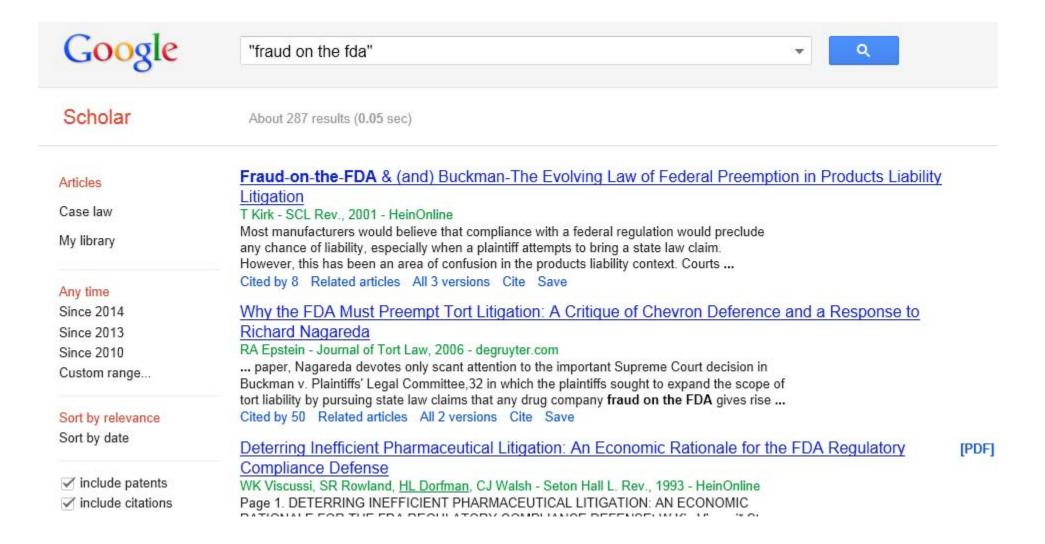
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www.reedsmith.com/files/uploads/.../Fosamax\_MDL-wide.pd... ▼ Reed Smith ▼ 2 days ago - state law causes of action merely required some proof of fraud on the FDA but such ... fraud on the FDA claims are preempted did not apply to automatically ...

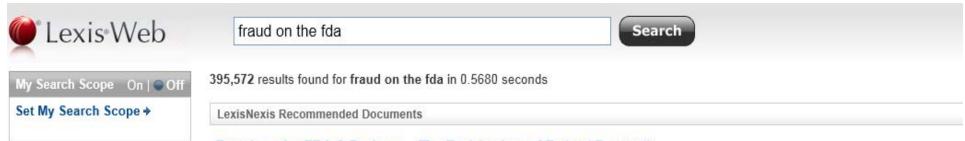
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http://scholar.google.com



### Use Lexis Web

http://lexisweb.com



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#### Fraud-on-the-FDA & Buckman - The Evolving Law of Federal Preempti.....

I. Introduction Most manufacturers would believe that compliance with a federal regulation would preclude any chance of liability, especially when a plaintiff attempts to bring a state law claim. However, this has been an area of confusion in the ...... LENGTH: 16627 words Fraud-on-the-FDA & Buckman - The Evolving Law...stated that the plaintiffs fraud-on-the-FDA claims were impliedly preempted...much direction outside of fraud-on-the-FDA claims. The states appear...

Author: Trent Kirk\*

Publication: University of South Carolina South Carolina Law Review - Read Excerpt

### BUCKMAN STOPS HERE! LIMITS **ON** PREEMPTION OF STATE TORT CLAIMS INVOLVING ALLEGATIONS OF **FRA....**

Introduction In Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp., 1 the Supreme Court of the United States ruled that a plaintiff could state a claim against a patent holder for monopolization, even though patents normally confer .....state-law tort claim for fraud on the FDA was impliedly preempted by...viability of a stand-alone state fraud-on-the-FDA claim. The Court held that...139 Buckman argued that any fraud-on-the-FDA claims were preempted, either...

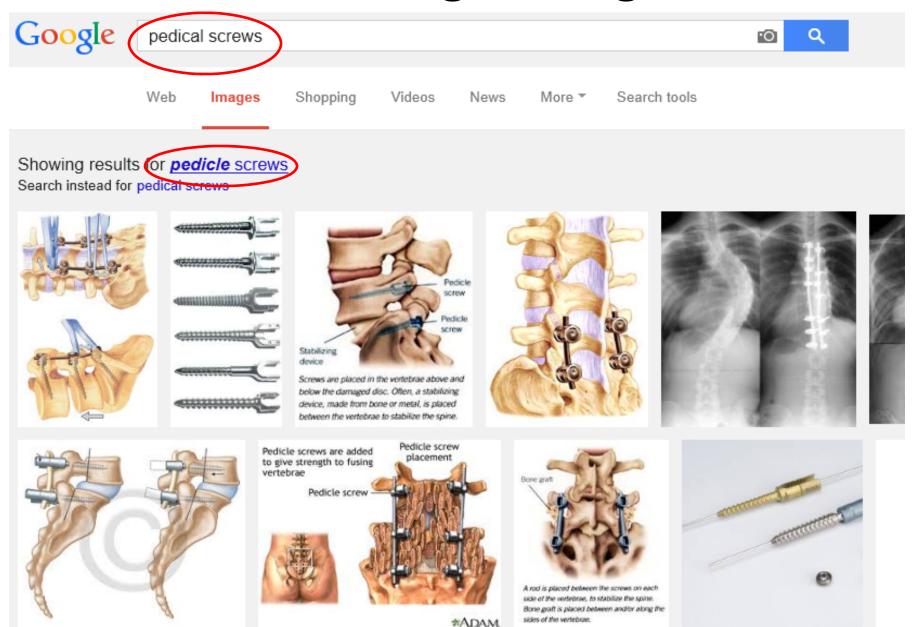
Author: Louis M. Bograd and Andre M. Mura \*

Publication: Rutgers School of Law-Camden Rutgers Law JournalRutgers Law Journal · Read Excerpt

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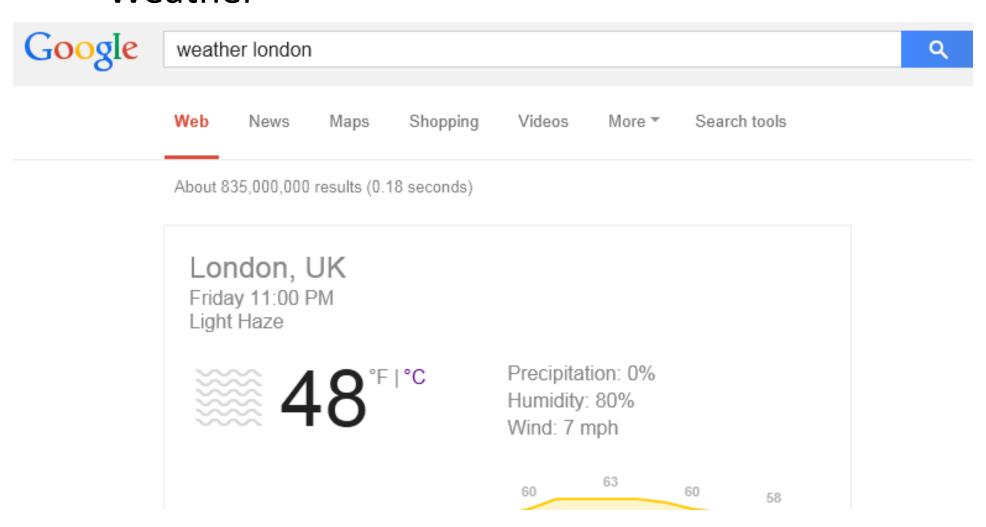
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- Useful in researching parties in litigation
- Does company exist? What does the location look like? Use Satellite View
- Street View if available, can see details of buildings, car ownership, etc.



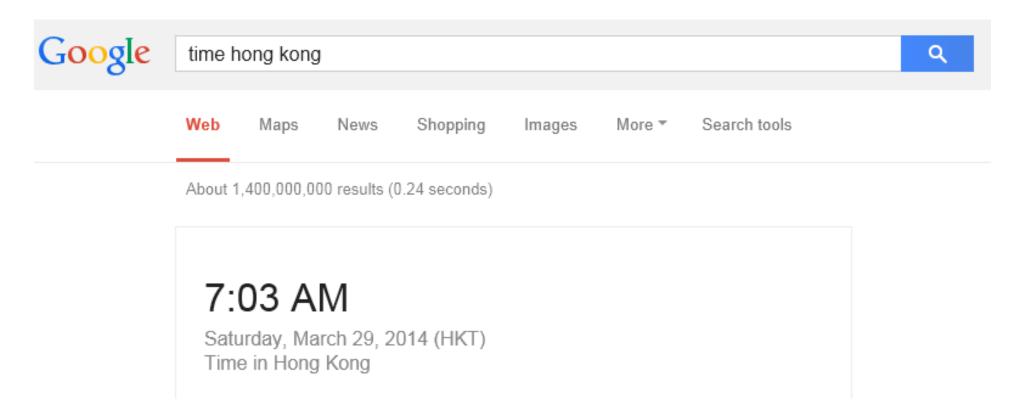
## Other Specialized Functions

Weather



# Other Specialized Functions

• Time



# Wikipedia?

 Use only as a starting point – go to original sources and do your own analysis

### Riegel v. Medtronic, Inc.

From Wikipedia, the free encyclopedia

Riegel v. Medtronic, Inc., 552 U.S. 312 № (2008), is a United States Supreme Court case in which the Court held that the pre-emption clause of the Medical Device Amendment bars state common-law claims that challenges the effectiveness or safety of a medical device marketed in a form that received premarket approval from the Food and Drug Administration.

It modified the rule in Medtronic, Inc. v. Lohr, 518 U.S. 470 & (1996).

#### See also [edit]

- Eli Lilly & Co. v. Medtronic, Inc.
- FDA Preemption
- List of United States Supreme Court cases, volume 552

#### Further reading [edit]

- Syllabus and opinion in printable format from Justia.com
- Korobkin, Russell (2007). "Who Should Protect the Public? The Supreme Court and Medical Device Regulation". New England Journal of Medicine 357 (17): 1680–1681. doi:10.1056/NEJMp078142 ₺. PMID 17960010 ₺.

### Tales of Woe

- Be careful what you use! You are responsible for your work product and its accurancy, currency and reliability
- Let me tell you about......
  - Jersey corporation law
  - Wikipedia vs. US Code

## **Getting Creative**

- Use other search engines such as Yahoo, Bing, Exalead, SearchLion (video, twitter), and more (see <a href="http://www.philb.com/whichengine.htm">http://www.philb.com/whichengine.htm</a>)
- Search Twitter using Topsy or Snapbird
- For long shots, use search engine Millionshort to remove top million (or100k or 10k) most popular sites from its index

## Good luck!

Kathy Taggart ktaggart@lowenstein.com