



New Jersey Judiciary  
Superior Court - Appellate Division  
**Civil Case Information Statement**

Please type or clearly print all information.

Title in Full <b>MARY MCGINNIS AND THOMAS WALSH MCGINNIS V. C. R. BARD, INC., BARD MEDICAL DIVISION, A DIVISION OF C. R. BARD, INC., BARD UROLOGICAL DIVISION, A DIVISION OF BARD MEDICAL DIVISION, AND JOHN DOES 1-20.</b>	Trial Court or Agency Docket Number <b>BER-L-017543-14 (*)</b>
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• Attach additional sheets as necessary for any information below.

**Appellant's Attorney \*** Email Address: **DCOONER@MCCARTER.COM**  
**DMARTINEZ@MCCARTER.COM**

Plaintiff  Defendant  Other (Specify)

Name <b>DAVID J COONER, Esq.</b>	Client <b>C. R. BARD, INC.*</b>			
Street Address <b>FOUR GATEWAY CTR 100 MULBERRY ST</b>	City <b>NEWARK</b>	State <b>NJ</b>	Zip <b>07102-4056</b>	Telephone Number <b>973-622-4444</b>

**Respondent's Attorney \*** Email Address: **ASLATER@MAZIESLATER.COM**  
**LTREAT@MAZIESLATER.COM (\*)**

Plaintiff  Defendant  Other (Specify)

Name <b>ADAM M SLATER, Esq.</b>	Client <b>MARY MCGINNIS*</b>			
Street Address <b>103 EISENHOWER PKY</b>	City <b>ROSELAND</b>	State <b>NJ</b>	Zip <b>07068</b>	Telephone Number <b>973-228-9898</b>

Give Date and Summary of Judgment, Order, or Decision Being Appealed and Attach a Copy:

- (1) February 8, 2018: Order granting in part and denying in part both Plaintiffs' and Defendant's Motions in Limine;**
- (2) March 6, 2018: Order denying Defendant's Motion for Summary Judgment on (a) Plaintiffs' Punitive Damages Claims, and (b) on Plaintiffs' product liability claims, including as to Plaintiffs' claims for design defect and failure to warn;**
- (3) April 23, 2018: Order denying Defendant's Motion for Directed Verdict;**
- (4) April 30, 2018: Final Order of Judgment entering jury verdict, and compensatory and punitive damages awards in favor of Plaintiffs; and**
- (5) October 11, 2018: Orders denying Defendant's post-trial Motions for Judgment Notwithstanding the Verdict, or In the Alternative, New Trial, and Remittitur.**

Have all the issues as to all the parties in this action, before the trial court or agency, been disposed? (There may not be any claims against any party in the trial court or agency, either in this or a consolidated action, which have not been disposed. These claims may include counterclaims, cross-claims, third-party claims, and applications for counsel fees.)  Yes  No

If outstanding claims remain open, has the order been properly certified as final pursuant to R. 4:42-2?  Yes  No  N/A

A) If the order has been properly certified, attach copies of the order and the complaint and any other relevant pleadings to the order being appealed. Attach a brief explanation as to why the order qualified for certification pursuant to R. 4:42-2.

B) If the order has not been certified or has been improperly certified, leave to appeal must be sought. (See R. 2:2-4; 2:5-6.) Please note that an improperly certified order is not binding on the

(\*) truncated due to space limit. Please find full information in the additional pages of the form.

Appellate Division.

If claims remain open and/or the order has not been properly certified, you may want to consider filing a motion for leave to appeal or submitting an explanation as to why you believe the matter is final and appealable as of right.

Were any claims dismissed without prejudice?

Yes  No

If so, explain and indicate any agreement between the parties concerning future disposition of those claims.

Is the validity of a statute, regulation, executive order, franchise or constitutional provision of this State being questioned? (R. 2:5-1(h))  Yes  No

Give a Brief Statement of the Facts and Procedural History:

**This is a medical device product liability case that is one of more than 100 cases pending against C. R. Bard, Inc. (“Bard”) in New Jersey related to the Avaulta Solo and Align-TO pelvic mesh prescription devices. Pursuant to the federal statutes and accompanying FDA regulations governing these types of medical devices, Bard submitted applications to the Food and Drug Administration (“FDA”) to allow the company to market the Avaulta Solo and Align-TO for the treatment of stress urinary incontinence and pelvic organ prolapse. As part of this regulatory application process, commonly known as the § 510(k) process, Bard submitted and the FDA reviewed studies and data related to the design of the products, as well as the Instructions for Use and other warning materials. In March 2007, the FDA cleared the Avaulta Solo and Align-TO for marketing, consistent with federal regulations.**

**On March 12, 2009, Plaintiff Mary McGinnis had Bard’s Avaulta Solo and Align-TO mesh products implanted by her treating physician to treat her stress urinary incontinence and pelvic organ prolapse. Thereafter, on March 31, 2011, Plaintiff and her husband filed a complaint alleging product liability and other claims against Bard seeking compensatory and punitive damages.**

**Prior to trial, both parties filed numerous motions in limine. Particularly relevant to this appeal, on February 16, 2018, the trial court denied Bard’s Motion in limine to present evidence related to the FDA’s regulatory authority over and review of the Avaulta Solo and Align-TO, in turn precluding any mention of the § 510(k) clearance process to which these devices were subject and the FDA regulations, standards, and guidances that influenced Bard’s decisions during the development process, thereby gutting one of Bard’s core defenses and preventing Bard’s witnesses from fully explaining their decisions and actions. As demonstrated during the proffer at trial on April 10, 2018, this evidence was particularly important to Bard’s defense under the North Carolina Product Liability Act (the “Act”), which governed the negligent design and failure to warn claims. The Act expressly considers whether a company complied with such industry standards and governmental regulations in determining whether a company acted reasonably.**

**Bard also filed Motions for Summary Judgment seeking dismissal of Plaintiffs’ product liability claims given the absence of proof and also sought the dismissal of Plaintiffs’ punitive damage claims. As to the latter, the parties agreed that New Jersey law applied. Although the New Jersey Products Liability Act, N.J.S.A. 2A:58C-5(c), prohibits punitive damages in cases involving products that are approved or licensed by the FDA or that are generally recognized as safe and effective, on March 6, 2018, the trial court denied Bard’s motions for summary judgment on the punitive damages issue.**

**The Honorable James DeLuca, J.S.C., presided over a trial commencing on March 19, 2018. On April 12, 2018, the jury awarded \$23 million to Plaintiff on her claims for design defect and failure to warn, and \$10 million to her husband for loss of consortium. The following day, the jury awarded \$35 million in punitive damages. The trial court entered the Final Order of Judgment on April 30, 2018. On May 2, 2018, C. R. Bard, Inc. filed motions for Judgment Notwithstanding the Verdict, or In the Alternative, New Trial, and Remittitur, and heard oral argument on June 15, 2018. On October 11, 2018, the Trial Court issued an oral decision denying the motions and entered accompanying Orders the same day.**

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Revised: 04/02/2016, CN 10501 (Appellate Civil CIS)

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To the extent possible, list the proposed issues to be raised on the appeal as they will be described in appropriate point headings pursuant to R. 2:6-2(a)(5). (Appellant or cross-appellant only.):

1. The Trial Court erroneously precluded Defendant from introducing or alluding to any evidence relating to the FDA and the 510(k) clearance process, including Defendant's compliance with federal regulations and standards;
2. The Trial Court erroneously denied Defendant's Motion for Summary Judgment, including as to Plaintiffs' design defect and failure to warn claims;
3. The Trial Court erroneously denied Defendant's Motion for Summary Judgment on Plaintiffs' Punitive Damages Claims;
4. The Trial Court erred during the punitive phase of trial by precluding Defendant from introducing evidence of its appropriate conduct, including compliance with applicable Federal Regulations related to manufacturing and distributing the products at issue;
5. The Trial Court erroneously failed to enter judgment for Defendant as a matter of law because Plaintiffs failed to offer legally sufficient evidence that a defect in the Avaulta Solo or Align-TO proximately caused Plaintiffs' injuries;
6. The Trial Court erred when it denied Defendant's Motion for Judgment as a matter of law as to Plaintiffs' design defect claim;
7. The Trial Court improperly failed to enter judgment for Defendant on Plaintiffs' failure-to-warn claim because Plaintiffs did not prove that Defendant's warnings were inadequate;
8. The Trial Court's erroneous exclusion of FDA evidence requires a new trial;
9. The Trial Court improperly failed to enter judgment for Defendant on Plaintiffs' failure-to-warn claims because Plaintiffs failed to establish that any failure to warn proximately caused Plaintiffs' injuries;
10. The Trial Court improperly applied the learned intermediary doctrine;
11. The Trial Court erred by refusing to enter judgment for Defendant on punitive damages;
12. The Trial Court improperly denied Defendant's Motion for Judgment Notwithstanding the Verdict, or in the alternative, a New Trial based on the clear weight of the evidence;
13. The Trial Court made improper evidentiary rulings that resulted in certain of plaintiffs' fact witnesses being permitted to provide expert testimony without proper foundation or qualification;
14. The Trial Court made improper evidentiary rulings that resulted in precluding certain of Defendant's company representatives from testifying about matters properly within the scope of their work, knowledge and experience;
15. The Trial Court's evidentiary rulings, both individually and cumulatively, require a new trial, including but not limited to rulings with regard to the admissibility of MSDS evidence and financial information;
16. The Trial Court erroneously failed to eliminate or remit the excessive compensatory and punitive damage awards;
17. The Trial Court committed cumulative error depriving Defendant of a fair trial requiring reversal.

If you are appealing from a judgment entered by a trial judge sitting without a jury or from an order of the trial court, complete the following:

1. Did the trial judge issue oral findings or an opinion? If so, on what date? 10/11/2018  Yes  No
2. Did the trial judge issue written findings or an opinion? If so, on what date? \_\_\_\_\_  Yes  No
3. Will the trial judge be filing a statement or an opinion pursuant to R. 2:5-1(b)?  Yes  No  Unknown

**Caution:** Before you indicate that there was neither findings nor an opinion, you should inquire of the trial judge to determine whether findings or an opinion was placed on the record out of counsel's presence or whether the judge will be filing a statement or opinion pursuant to R. 2:5-1(b).

Date of Your Inquiry:

Is the validity of a statute, regulation, executive order, franchise or constitutional provision of this State being questioned? **(R.2:5-1(h))**  Yes  No  
 If yes, you will need to serve the appropriate government attorney.

1. Is there any appeal now pending or about to be brought before this court which:
  - (A) Arises from substantially the same case or controversy as this appeal?  Yes  No
  - (B) Involves an issue that is substantially the same, similar or related to an issue in this appeal?  Yes  No

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If the answer to the question above is Yes, state:

Case Title

**Hrymoc v. Ethicon, Inc., et al.**

Trial Court Docket#

**L-013696-14**

Party Name

**Ethicon, Inc.**

2. Was there any prior appeal involving this case or controversy?

Yes  No

If the answer to question above is Yes, state:

Case Name and Type (direct, 1st PCR, other, etc.)

**ELIZABETH HRYMOC AND TADEUSZ HRYMOC, V.  
ETHICON, INC., ETHICON WOMEN'S HEALTH AND  
UROLOGY, A DIVISION OF ETHICON, INC., GYNECARE,  
JOHNSON & JOHNSON, AND JOHN DOES 1-20,**

Appellate Division Docket Number

**A-005151-17**

Civil appeals are screened for submission to the Civil Appeals Settlement Program (CASP) to determine their potential for settlement or, in the alternative, a simplification of the issues and any other matters that may aid in the disposition or handling of the appeal. Please consider these when responding to the following question. A negative response will not necessarily rule out the scheduling of a preargument conference.

State whether you think this case may benefit from a CASP conference.

Yes  No

Explain your answer:

**The issues raised in this appeal are hotly contested by the parties involved and affect not only this case but also scores of product liability lawsuits currently pending in the State. As such, the possibility of settlement is remote and the matter is ripe for review by the Appellate Division. Furthermore, issues on appeal are issues of law and would not benefit from inclusion in CASP.**

Whether or not an opinion is approved for publication in the official court report books, the Judiciary posts all Appellate Division opinions on the Internet.

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

**C. R. BARD, INC.**

Name of Appellant or Respondent

**11/07/2018**

Date

**030461989**

Bar #

**DAVID J COONER, Esq.**

Name of Counsel of Record  
(or your name if not represented by counsel)

**s/ DAVID J COONER, Esq.**

Signature of Counsel of Record  
(or your signature if not represented by counsel)

**DcoonER@mccarter.com, DMartinez@mccarter.com**

Email Address



New Jersey Judiciary  
Superior Court - Appellate Division  
**CIVIL Case Information Statement**  
**ADDITIONAL TRIAL COURT INFORMATION**

<b>Trial Court Docket #</b>	<b>Disposition Date</b>	<b>Trial Court County</b>	<b>Trial Court Judge</b>
BER-L-017543-14	02/08/2018	BERGEN	JAMES J. DELUCA, JSC
BER-L-017543-14	03/06/2018	BERGEN	JAMES J. DELUCA, JSC
BER-L-017543-14	04/23/2018	BERGEN	JAMES J. DELUCA, JSC
BER-L-017543-14	10/11/2018	BERGEN	JAMES J. DELUCA, JSC



New Jersey Judiciary  
 Superior Court - Appellate Division  
 CIVIL Case Information Statement

Additional appellants continued below

**Appellant's Attorney** **DKOTT@MCCARTER.COM,DKAUFMAN@MCCARTER.COM,NMCCALL**  
 Email Address: **@MCCARTER.COM**

Plaintiff  Defendant  Other (Specify)

Name <b>DAVID R KOTT, Esq.</b>		Client <b>C. R. BARD, INC.</b>		
Street Address <b>FOUR GATEWAY CTR 100 MULBERRY ST</b>	City <b>NEWARK</b>	State <b>NJ</b>	Zip <b>07102-4056</b>	Telephone Number <b>973-622-4444</b>

**Appellant's Attorney** **MGEIST@REEDSMITH.COM,EMORALES@REEDSMITH.COM,DOCKETI**  
 Email Address: **NGECF@REEDSMITH.COM**

Plaintiff  Defendant  Other (Specify)

Name <b>MELISSA A GEIST, Esq.</b>		Client <b>C. R. BARD, INC.</b>		
Street Address <b>136 MAIN STREET SUITE 250</b>	City <b>PRINCETON</b>	State <b>NJ</b>	Zip <b>08540</b>	Telephone Number <b>609-987-0050</b>

**Appellant's Attorney** Email Address: **SDELMAURO@MCCARTER.COM,DMARTINEZ@MCCARTER.COM**

Plaintiff  Defendant  Other (Specify)

Name <b>STEVEN H DEL MAURO, Esq.</b>		Client <b>C. R. BARD, INC.</b>		
Street Address <b>FOUR GATEWAY CTR 100 MULBERRY ST</b>	City <b>NEWARK</b>	State <b>NJ</b>	Zip <b>07102-4056</b>	Telephone Number <b>973-622-4444</b>

**Appellant's Attorney** Email Address: **DCOONER@MCCARTER.COM,DMARTINEZ@MCCARTER.COM**

Plaintiff  Defendant  Other (Specify)

Name <b>DAVID J COONER, Esq.</b>		Client <b>BARD MEDICAL DIVISION, BARD UROLOGICAL DIVISION</b>		
Street Address <b>FOUR GATEWAY CTR 100 MULBERRY ST</b>	City <b>NEWARK</b>	State <b>NJ</b>	Zip <b>07102-4056</b>	Telephone Number <b>973-622-4444</b>

**Appellant's Attorney** **MGEIST@REEDSMITH.COM,EMORALES@REEDSMITH.COM,DOCKETI**  
 Email Address: **NGECF@REEDSMITH.COM**

Plaintiff  Defendant  Other (Specify)

Name <b>MELISSA A GEIST, Esq.</b>		Client <b>BARD MEDICAL DIVISION, BARD UROLOGICAL DIVISION</b>		
Street Address <b>136 MAIN STREET SUITE 250</b>	City <b>PRINCETON</b>	State <b>NJ</b>	Zip <b>08540</b>	Telephone Number <b>609-987-0050</b>

**Appellant's Attorney** Email Address: **SDELMAURO@MCCARTER.COM,DMARTINEZ@MCCARTER.COM**

Plaintiff  Defendant  Other (Specify)

Name <b>STEVEN H DEL MAURO, Esq.</b>		Client <b>BARD MEDICAL DIVISION, BARD UROLOGICAL DIVISION</b>		
Street Address <b>FOUR GATEWAY CTR 100 MULBERRY ST</b>	City <b>NEWARK</b>	State <b>NJ</b>	Zip <b>07102-4056</b>	Telephone Number <b>973-622-4444</b>

Additional respondents continued below

**Respondent's Attorney** Email Address: **DESTES@MAZIESLATER.COM,**

Plaintiff  Defendant  Other (Specify)

Name **DAVID M ESTES, Esq.** Client **MARY MCGINNIS**

Street Address **103 EISENHOWER PKY** City **ROSELAND** State **NJ** Zip **07068** Telephone Number **973-228-9898**

**Respondent's Attorney** Email Address: **ASLATER@MAZIESLATER.COM,LTREAT@MAZIESLATER.COM,KKE**  
**LSEN@MAZIESLATER.COM,**

Plaintiff  Defendant  Other (Specify)

Name **ADAM M SLATER, Esq.** Client **THOMAS WALSH MCGINNIS**

Street Address **103 EISENHOWER PKY** City **ROSELAND** State **NJ** Zip **07068** Telephone Number **973-228-9898**

**Respondent's Attorney** Email Address: **DESTES@MAZIESLATER.COM,**

Plaintiff  Defendant  Other (Specify)

Name **DAVID M ESTES, Esq.** Client **THOMAS WALSH MCGINNIS**

Street Address **103 EISENHOWER PKY** City **ROSELAND** State **NJ** Zip **07068** Telephone Number **973-228-9898**

Appellant's attorney email address continued below

**PARTY NAME: C. R. BARD, INC. ATTORNEY NAME: DAVID R KOTT, Esq.**  
**DKOTT@MCCARTER.COM**  
**DKAUFMAN@MCCARTER.COM**  
**NMCCALL@MCCARTER.COM**  
**PARTY NAME: C. R. BARD, INC. ATTORNEY NAME: MELISSA A GEIST, Esq.**  
**MGEIST@REEDSMITH.COM**  
**EMORALES@REEDSMITH.COM**  
**DOCKETINGECF@REEDSMITH.COM**  
**PARTY NAME: C. R. BARD, INC. ATTORNEY NAME: STEVEN H DEL MAURO, Esq.**  
**SDELMAURO@MCCARTER.COM**  
**DMARTINEZ@MCCARTER.COM**  
**PARTY NAME: BARD MEDICAL DIVISION, BARD UROLOGICAL DIVISION ATTORNEY NAME: DAVID J COONER, Esq.**  
**DCOONER@MCCARTER.COM**  
**DMARTINEZ@MCCARTER.COM**  
**PARTY NAME: BARD MEDICAL DIVISION, BARD UROLOGICAL DIVISION ATTORNEY NAME: MELISSA A GEIST, Esq.**  
**MGEIST@REEDSMITH.COM**  
**EMORALES@REEDSMITH.COM**  
**DOCKETINGECF@REEDSMITH.COM**  
**PARTY NAME: BARD MEDICAL DIVISION, BARD UROLOGICAL DIVISION ATTORNEY NAME: STEVEN H DEL MAURO, Esq.**  
**SDELMAURO@MCCARTER.COM**  
**DMARTINEZ@MCCARTER.COM**

Respondent's attorney email address continued below

**PARTY NAME: MARY MCGINNIS ATTORNEY NAME: ADAM M SLATER, Esq.**  
**ASLATER@MAZIESLATER.COM**  
**LTREAT@MAZIESLATER.COM**  
**KKELSEN@MAZIESLATER.COM**  
**PARTY NAME: MARY MCGINNIS ATTORNEY NAME: DAVID M ESTES, Esq.**

**DESTES@MAZIESLATER.COM**

**PARTY NAME: THOMAS WALSH MCGINNIS ATTORNEY NAME: ADAM M SLATER, Esq.**

**ASLATER@MAZIESLATER.COM**

**LTREAT@MAZIESLATER.COM**

**KKELSEN@MAZIESLATER.COM**

**PARTY NAME: THOMAS WALSH MCGINNIS ATTORNEY NAME: DAVID M ESTES, Esq.**

**DESTES@MAZIESLATER.COM**