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Attorneys for Defendants Ethicon, Inc.  
and Johnson & Johnson

IN RE PELVIC MESH/GYNECARE  
LITIGATION

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION, ATLANTIC COUNTY

CIVIL ACTION

CASE NO. 291

Master Case No. L-6341-10

Honorable Carol E. Higbee, P.J.Cv.

**MASTER ANSWER AND JURY DEMAND  
OF DEFENDANT JOHNSON &  
JOHNSON**

Defendant Johnson & Johnson, in answer to the plaintiffs' Master Long Form Complaint, states as follows:

1. Except to admit that Johnson & Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey, Johnson & Johnson denies each and every allegation of the Master Long Form Complaint as it pertains to Johnson & Johnson and leaves plaintiffs to their proofs.

## **SEPARATE DEFENSES**

### **FIRST DEFENSE**

The plaintiffs' claims against Johnson & Johnson are barred because Johnson & Johnson does not design, develop, manufacture, market, promote or sell any product.

### **SECOND DEFENSE**

Johnson & Johnson has never had possession and control over the products at issue in this action, and therefore the Complaint as to each cause of action fails to state a claim against Johnson & Johnson.

### **THIRD DEFENSE**

The Complaint fails to state a cause of action upon which relief can be granted.

### **FOURTH DEFENSE**

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

### **FIFTH DEFENSE**

Plaintiffs' claims are barred for lack of subject matter jurisdiction.

### **SIXTH DEFENSE**

Plaintiffs' claims are barred for lack of personal jurisdiction.

### **SEVENTH DEFENSE**

The Complaint must be dismissed because the plaintiffs provided insufficient process.

### **EIGHTH DEFENSE**

The Complaint must be dismissed because the plaintiffs provided insufficient service of process.

**NINTH DEFENSE**

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because plaintiffs may lack standing and/or capacity to bring such claims.

**TENTH DEFENSE**

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

**ELEVENTH DEFENSE**

Venue in Atlantic County is improper in any individual case in which the plaintiff does not reside in Atlantic County or otherwise cannot establish an independent basis for venue in Atlantic County under New Jersey law and any such plaintiff's case should be dismissed on this basis.

**TWELFTH DEFENSE**

Venue in this Court is improper, and this matter should be dismissed on intra-state or interstate forum non conveniens grounds.

**THIRTEENTH DEFENSE**

Venue in this Court is improper because Atlantic County may not be a proper or fair venue for Johnson & Johnson given Atlantic County's over-exposure to prior mass tort pharmaceutical cases. This matter should be dismissed on this basis.

**FOURTEENTH DEFENSE**

Certain of plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

**FIFTEENTH DEFENSE**

Plaintiffs' alleged causes of action have been improperly joined under the applicable Rules of Civil Procedure and the laws of the applicable state.

### **SIXTEENTH DEFENSE**

The improper joinder of plaintiffs' alleged causes of action violate the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the applicable state.

### **SEVENTEENTH DEFENSE**

Johnson & Johnson is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in this State and any other state whose law is deemed to apply in this case.

### **EIGHTEENTH DEFENSE**

Plaintiffs have failed to plead fraud, fraudulent concealment, constructive fraud and misrepresentation with the particularity required under Rule 4:5-8(a) of the Rules Governing the Courts of the State of New Jersey and the common law of New Jersey, any rule or statute of any other state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

### **NINETEENTH DEFENSE**

Johnson & Johnson specifically pleads as to plaintiffs' fraud, fraudulent concealment, constructive fraud and misrepresentation claims, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

### **TWENTIETH DEFENSE**

Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and by state and

federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the Gynecare products at issue<sup>1</sup> are regulated by the U.S. Food and Drug Administration (“FDA”) under the Medical Device Amendments, 21 U.S.C. § 360c, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulation.

#### **TWENTY-FIRST DEFENSE**

At all relevant times, Johnson & Johnson was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360c, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations, and plaintiffs’ claims are accordingly barred.

#### **TWENTY-SECOND DEFENSE**

Plaintiffs’ claims against Johnson & Johnson are expressly and/or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. § 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).

#### **TWENTY-THIRD DEFENSE**

Plaintiffs’ claims are barred because Johnson & Johnson complied with all applicable state and federal statutes regarding the Gynecare products at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that plaintiffs’ claims are not barred, Johnson & Johnson is entitled to a presumption that the Gynecare products at issue are free from any defect or defective condition as the plans or design for the Gynecare products at issue or the methods and

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<sup>1</sup> The phrase “Gynecare products at issue” includes the products collectively referenced in Paragraph 13 of the Master Long Form Complaint as “Defendants’ Pelvic Mesh Products.”

techniques of manufacturing, inspecting, and testing the Gynecare products at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the Gynecare products at issue or the methods and techniques of manufacturing, inspecting, and testing the Gynecare products at issue were adopted.

**TWENTY-FOURTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder.

**TWENTY-FIFTH DEFENSE**

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Johnson & Johnson complied with all applicable statutes and with the requirements and regulations of the FDA.

**TWENTY-SIXTH DEFENSE**

Any claims by plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Johnson & Johnson to petition the government.

**TWENTY-SEVENTH DEFENSE**

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for medical devices.

**TWENTY-EIGHTH DEFENSE**

Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by plaintiffs is subject to the exclusive regulation of the FDA.

**TWENTY-NINTH DEFENSE**

Plaintiffs' claim for punitive damages is barred because the Gynecare products at issue were manufactured and labeled in accordance with the terms of FDA's clearance of the Gynecare products at issue.

**THIRTIETH DEFENSE**

Plaintiffs' claims are barred in whole or in part by plaintiffs' failure to assert a safer design for any of the Gynecare products at issue.

**THIRTY-FIRST DEFENSE**

Plaintiffs' claims are barred in whole or in part because the Gynecare products at issue provided a benefit to users of such products and greatly outweighed any risk created by using such products, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

**THIRTY-SECOND DEFENSE**

Johnson & Johnson made no express or implied representations or warranties of any kind to plaintiffs, nor did plaintiffs rely on any representations or warranties made by Johnson & Johnson to others. To the extent plaintiffs relied upon any representations or warranties, such reliance was unjustified.

### **THIRTY-THIRD DEFENSE**

Any express or implied warranties alleged to have been made by Johnson & Johnson were disclaimed.

### **THIRTY-FOURTH DEFENSE**

Johnson & Johnson did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between plaintiffs and Johnson & Johnson, and/or by plaintiffs' failure to give Johnson & Johnson timely notice of the alleged breach of warranty and an opportunity to cure. Johnson & Johnson further specifically pleads as to any breach of warranty claim all affirmative defenses available to Johnson & Johnson under the Uniform Commercial Code, as enacted in the State of New Jersey or any other state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

### **THIRTY-FIFTH DEFENSE**

Johnson & Johnson specifically pleads as to any claim alleging a violation of consumer protection laws, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

### **THIRTY-SIXTH DEFENSE**

The injuries resulting from the use of the Gynecare products at issue, were not foreseeable to Johnson & Johnson given the state of scientific knowledge and state of the art at the time of the alleged injuries. At all times relevant, the Gynecare products at issue conformed



to state-of-the-art specifications and state-of-scientific knowledge for such products at that time, as well as all applicable statutes and regulations, including those of the FDA.

**THIRTY-SEVENTH DEFENSE**

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the Gynecare products at issue in this case and thus the “last clear chance” and assumption of the risk doctrines bar in whole or in part the damages plaintiffs seek to recover herein.

**THIRTY-EIGHTH DEFENSE**

Plaintiffs’ claims are barred, in whole or in part, because Johnson & Johnson acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its products.

**THIRTY-NINTH DEFENSE**

At all relevant times herein, the products in question were manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

**FORTIETH DEFENSE**

Plaintiffs’ inadequate warning claims are barred because the alleged risk of which plaintiffs claim is open, obvious, and/or a matter of common knowledge.

**FORTY-FIRST DEFENSE**

Plaintiffs’ claims are barred in whole or in part because the Gynecare products at issue were consistent with and/or exceeded consumer expectations.

**FORTY-SECOND DEFENSE**

Plaintiffs' claims are barred in whole or in part because the Gynecare products at issue were at all times properly prepared, packaged, and distributed, and were not defective or unreasonably dangerous.

**FORTY-THIRD DEFENSE**

Adequate and complete warnings and instructions were provided with the Gynecare products at issue. The Gynecare products at issue were neither defective nor unreasonably dangerous when used according to their Instructions for Use.

**FORTY-FOURTH DEFENSE**

At all relevant times, the warnings and instructions accompanying the Gynecare products at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the products were presumptively adequate.

**FORTY-FIFTH DEFENSE**

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

**FORTY-SIXTH DEFENSE**

Johnson & Johnson is not liable to the plaintiffs because the end user of the Gynecare products at issue, plaintiffs' physician(s), were sophisticated users of the products.

**FORTY-SEVENTH DEFENSE**

Johnson & Johnson states that the sole proximate cause of the injuries and/or damages alleged by plaintiffs was the actions, omissions, or negligence of a person or persons, other than Johnson & Johnson, for whose actions, omissions, or negligence Johnson & Johnson is in no way liable. Plaintiffs are not, therefore, entitled to recover from Johnson & Johnson in

this action. As to plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of plaintiffs, if any, Johnson & Johnson expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of the applicable states.

#### **FORTY-EIGHTH DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by plaintiffs' own fault, which bars or proportionately reduces Johnson & Johnson's liability, if any, for plaintiffs' alleged damages.

#### **FORTY-NINTH DEFENSE**

The plaintiffs voluntarily and unreasonably chose to encounter known dangers.

#### **FIFTIETH DEFENSE**

The liability of Johnson & Johnson, if any, for plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of the applicable states.

#### **FIFTY-FIRST DEFENSE**

In the event Johnson & Johnson is held liable to plaintiffs, which liability is expressly denied, and any other co-defendants are also held liable, Johnson & Johnson is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the applicable states.

#### **FIFTY-SECOND DEFENSE**

There is no causal relationship between Johnson & Johnson's conduct and the injuries and damages alleged by plaintiffs in the Complaint.

#### **FIFTY-THIRD DEFENSE**

At all times mentioned herein, plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of plaintiffs bars in whole or in part the damages which plaintiffs seek to recover herein.

#### **FIFTY-FOURTH DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the Gynecare products at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said products.

#### **FIFTY-FIFTH DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the products at issue in this case, if any, were not legally caused by the Gynecare products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

#### **FIFTY-SIXTH DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the Gynecare products at issue in this case, if any, were caused by the acts or omissions of third parties for which Johnson & Johnson has no legal responsibility.

**FIFTY-SEVENTH DEFENSE**

Johnson & Johnson expressly denies any third party engaging in the acts alleged by plaintiffs was acting as Johnson & Johnson's agent or servant, at the instruction of Johnson & Johnson, or within its control. Therefore, plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

**FIFTY-EIGHTH DEFENSE**

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the products at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Johnson & Johnson.

**FIFTY-NINTH DEFENSE**

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

**SIXTIETH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

**SIXTY-FIRST DEFENSE**

The claims of plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to properly preserve evidence necessary to the determination of the claim.

### **SIXTY-SECOND DEFENSE**

Plaintiffs' claims against Johnson & Johnson are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than the plaintiff, or, if not disclosed by the plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

### **SIXTY-THIRD DEFENSE**

Some or all of plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of the applicable states.

### **SIXTY-FOURTH DEFENSE**

To the extent plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

### **SIXTY-FIFTH DEFENSE**

Plaintiffs' alleged damages, if any, are barred in whole or in part by plaintiffs' failure to mitigate such damages.

### **SIXTY-SIXTH DEFENSE**

The sale, labeling and marketing of the Gynecare products at issue in this litigation is not, and was not, likely to mislead or deceive the public.

**SIXTY-SEVENTH DEFENSE**

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

**SIXTY-EIGHTH DEFENSE**

Plaintiffs' claims are barred in whole or in part under Section 402A, comments j and k of the Restatement (Second) of Torts.

**SIXTY-NINTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, to the extent plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

**SEVENTIETH DEFENSE**

Any recovery by plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

**SEVENTY-FIRST DEFENSE**

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

**SEVENTY-SECOND DEFENSE**

The Complaint fails to state facts sufficient to entitle plaintiffs to an award of punitive damages.

**SEVENTY-THIRD DEFENSE**

Plaintiffs' claims for punitive damages are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), pursuant to *McDarby v. Merck & Co., Inc.*,

401 N.J. Super. 10 (App. Div.), *certif. granted in part and denied in part*, 196 N.J. 597 (2008), *appeal dism'd as improv. granted*, 200 N.J. 267 (2009) (holding that a punitive damages claim brought pursuant to PLA's exception in N.J.S.A. 2A:58C-5c was preempted under the *Buckman* decision). The *McDarby* decision is dispositive in this case, requiring that plaintiffs' punitive damages claims be dismissed on this basis.

#### **SEVENTY-FOURTH DEFENSE**

No act or omission of Johnson & Johnson was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

#### **SEVENTY-FIFTH DEFENSE**

Plaintiffs' claims for pain and suffering are barred because they violate Johnson & Johnson's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and the applicable states.

#### **SEVENTY-SIXTH DEFENSE**

The imposition of punitive or exemplary damages would violate Johnson & Johnson's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. To the extent that punitive damages awarded to any plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive



damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Johnson & Johnson's conduct within the State where each plaintiff resides, or in any other way subject Johnson & Johnson to impermissible multiple punishment for the same alleged wrong.

#### **SEVENTY-SEVENTH DEFENSE**

Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

#### **SEVENTY-EIGHTH DEFENSE**

With respect to plaintiffs' demand for punitive damages, Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*,

517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.

#### **SEVENTY-NINTH DEFENSE**

Johnson & Johnson asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of the applicable states.

#### **EIGHTIETH DEFENSE**

Johnson & Johnson denies that it is indebted in any sum whatsoever to plaintiffs and will demonstrate to this Court and the jury it is not responsible for any injuries or damages that may have occurred according to the allegations set forth in plaintiffs' Complaint.

#### **EIGHTY-FIRST DEFENSE**

Johnson & Johnson specifically pleads as to plaintiffs' claims for punitive damages, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

#### **EIGHTY-SECOND DEFENSE**

Johnson & Johnson specifically pleads as to plaintiffs' strict liability claims, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

### **EIGHTY-THIRD DEFENSE**

Johnson & Johnson specifically pleads as to as to plaintiffs' negligence claims, including plaintiffs' separate negligence claim under Connecticut law, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

### **EIGHTY-FOURTH DEFENSE**

Johnson & Johnson hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

### **EIGHTY-FIFTH DEFENSE**

Johnson & Johnson reserves all available defenses permitted by the applicable law, in accordance with the procedure set forth in Paragraph 12 of Case Management Order No. 3.

### **EIGHTY-SIXTH DEFENSE**

Johnson & Johnson reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

### **EIGHTY-SEVENTH DEFENSE**

Several of plaintiffs' claims are subsumed by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-1, *et seq.*

**EIGHTY-EIGHTH DEFENSE**

Plaintiffs' claims are barred and/or limited by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.*

**EIGHTY-NINTH DEFENSE**

Plaintiffs' claims are barred by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-3(a)(1).

**NINETIETH DEFENSE**

Plaintiffs' claims are barred by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-3(a)(2).

**NINETY-FIRST DEFENSE**

Plaintiffs' claims are barred by the New Jersey Product Liability Act, N.J.S.A. 2A:58C-3(a)(3).

**NINETY-SECOND DEFENSE**

Because the Gynecare products at issue were accompanied by an adequate warning or instruction, plaintiffs' claims are barred by New Jersey case law and the New Jersey Product Liability Act, N.J.S.A. 2A:58C-1, *et seq.*

**NINETY-THIRD DEFENSE**

Plaintiffs' claims are barred and/or limited by the New Jersey Comparative Negligence Act, N.J.S.A. 2A:15-5.5 *et seq.*

**NINETY-FOURTH DEFENSE**

Plaintiffs' claims for exemplary and/or punitive damages are barred, in whole or in part, by the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9 *et seq.*

**NINETY-FIFTH DEFENSE**

Without reference to or waiver of any conflicts of law arguments by Johnson & Johnson, plaintiffs cannot state a claim under the New Jersey Consumer Fraud Act because all claims for harm caused by a product are governed by the New Jersey Products Liability Act, pursuant to the New Jersey Supreme Court's decision in *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 948 A.2d 587, 596 (N.J. 2008).

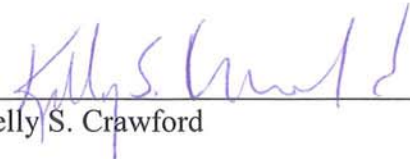
WHEREFORE, Johnson & Johnson denies that it is liable to the plaintiffs for damages or any other relief requested in the "Prayer for Relief" section of plaintiffs' Complaint, including the paragraph beginning "WHEREFORE" and subparagraphs (1)-(9) thereto, Johnson & Johnson prays that:

- (1) plaintiffs take nothing by reason of their Complaint;
- (2) the Complaint be dismissed in its entirety and that a Judgment against plaintiffs and in favor of Johnson & Johnson be entered;
- (3) Johnson & Johnson be awarded its costs and expenses; and
- (4) this Court award Johnson & Johnson any other and general or specific relief as this Court may deem just and proper.

Of Counsel:

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By:   
\_\_\_\_\_  
Kelly S. Crawford

*Attorneys for Defendants  
Ethicon, Inc. and Johnson & Johnson*

Dated: June 28, 2011

**DEMAND FOR TRIAL BY JURY**

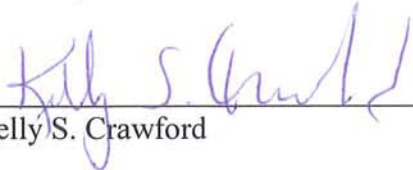
Johnson & Johnson demands a trial by jury of twelve of all claims triable as of right by jury.

Of Counsel:

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By: \_\_\_\_\_

  
Kelly S. Crawford

Dated: June 28, 2011

*Attorneys for Defendants  
Ethicon, Inc. and Johnson & Johnson*

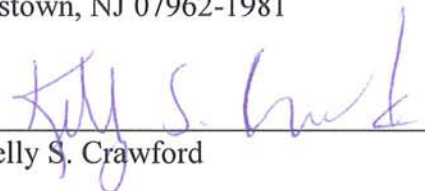
**RULE 4:5-1 CERTIFICATION**

The undersigned counsel for Defendants Ethicon, Inc. and Johnson & Johnson hereby certifies that this case is among many cases involving pelvic mesh products manufactured by Ethicon, Inc. which have been assigned for centralized case management to the Honorable Carol Higbee, Superior Court, Law Division, Atlantic County, by Order dated September 13, 2010 and captioned In re Pelvic Mesh/Gynecare Litigation, Case No. 291. The undersigned further certifies that Defendants' counsel is unaware of the identities of any other persons or entities who should be joined in the within action.

Of Counsel:

Christy D. Jones, Esq.  
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By:   
Kelly S. Crawford

Dated: June 28, 2011

*Attorneys for Defendants  
Ethicon, Inc. and Johnson & Johnson*

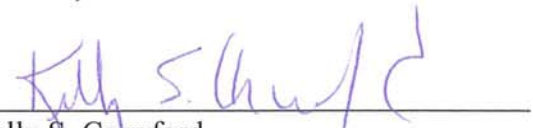
**DESIGNATION OF TRIAL COUNSEL**

Pursuant to the provisions of Rule 4:25-4, the Court is advised that Kelly Strange Crawford, Esq. is designated as trial counsel for Defendants Ethicon, Inc. and Johnson & Johnson.

Of Counsel:

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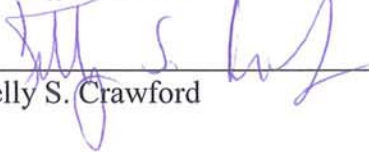


**CERTIFICATION OF SERVICE**

I certify that on this date I caused the attached Master Answer and Jury Demand of Defendant Johnson & Johnson to be served by LexisNexis File & Serve and Federal Express upon:

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