

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION**

IN RE: DEPUY ORTHOPAEDICS, INC., )  
PINNACLE HIP IMPLANT PRODUCTS ) MDL DOCKET NO.  
LIABILITY LITIGATION )  
 ) 3:11-MD-2244-K  
 )  
 )  
 )

**JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND  
DEVELOPMENT LLC'S MASTER ANSWER**

Defendant Johnson & Johnson Pharmaceutical Research and Development LLC ("J&J Pharmaceutical"), pursuant to Paragraph III(1) of Case Management Order No. 5 in this matter, submits this Master Answer to all complaints previously filed directly in or transferred to this MDL proceeding for which no answers have yet been filed. This Master Answer is also submitted in response to any complaints that may in the future be filed directly in or transferred to this MDL proceeding. Pursuant to Paragraph III(1) of Case Management Order No. 5, J&J Pharmaceutical hereby generally denies all allegations set forth in each such complaint.

**SEPARATE DEFENSES**

J&J Pharmaceutical also asserts the following separate defenses. Pursuant to Paragraph III(1) of Case Management Order No. 5, J&J Pharmaceutical reserves the right to assert additional defenses to a particular case, consistent with future scheduling orders. By alleging the separate defenses set forth below, J&J Pharmaceutical is not in any way agreeing or conceding that it has the burden of proof or the burden of persuasion on any of these issues.

**FIRST SEPARATE DEFENSE**

Plaintiff's Complaint fails, in whole or in part, to state a claim upon which relief may be granted.

**SECOND SEPARATE DEFENSE**

The injuries and damages claimed by plaintiff, if any, were caused in whole or in part by the acts or omissions of persons over whom J&J Pharmaceutical has no control or right of control.

**THIRD SEPARATE DEFENSE**

At all times mentioned herein, plaintiff was negligent, careless, and at fault, and conducted himself / herself so as to contribute substantially to his / her alleged injuries and damages. Said negligence, carelessness, and fault of plaintiff bars in whole or in part the damages which plaintiff seeks to recover herein.

**FOURTH SEPARATE DEFENSE**

Plaintiff knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case, and such assumption of the risks bars in whole or in part the damages plaintiff seeks to recover herein.

**FIFTH SEPARATE DEFENSE**

Plaintiff's alleged damages, if any, are barred in whole or in part by plaintiff's failure to mitigate such damages.

**SIXTH SEPARATE DEFENSE**

Plaintiff's claims are barred, in whole or in part, because the product at issue was at all relevant times manufactured and sold consistent with available technology, scientific knowledge, and the state of the art, and in compliance with all federal, state, and local laws and regulations, and was accompanied by product information and warnings that were reasonable, full and adequate and in accordance with FDA regulating requirements and the state of medical and scientific knowledge then in existence.

**SEVENTH SEPARATE DEFENSE**

If DePuy Orthopaedics, Inc.'s products are unsafe in any way, they are unavoidably unsafe. Plaintiff's purported action is, therefore, barred by Comment k of § 402A of the Restatement (Second) of Torts and/or other applicable law.

**EIGHTH SEPARATE DEFENSE**

Even if there was negligence and/or breach of warranty on its part, which J&J Pharmaceutical expressly denies, such negligence and/or breach of warranty was not the proximate or producing cause of plaintiff's alleged injuries or damages.

**NINTH SEPARATE DEFENSE**

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

**TENTH SEPARATE DEFENSE**

If plaintiff incurred any injuries or damages as a result of the use of the products at issue, which J&J Pharmaceutical denies, such injuries or damages were due to an idiosyncratic or idiopathic reaction, or by an unforeseeable or pre-existing condition.

**ELEVENTH SEPARATE DEFENSE**

Plaintiff's claims and causes of action are preempted by Medical Device Amendments to the Federal Food, Drug & Cosmetic Act and the FDA regulations promulgated pursuant thereto.

**TWELFTH SEPARATE DEFENSE**

Plaintiff's causes of action are barred by the applicable statutes of limitation, statutes of repose, and/or doctrine of laches.

**THIRTEENTH SEPARATE DEFENSE**

Plaintiff's causes of action are barred by the doctrines of informed consent, release, and waiver.

**FOURTEENTH SEPARATE DEFENSE**

Plaintiff's causes of action are barred by the learned intermediary doctrine and/or the sophisticated user doctrine.

**FIFTEENTH SEPARATE DEFENSE**

J&J Pharmaceutical did not make to plaintiff nor did it breach any express or implied warranties and/or breach of any warranties created by law. To the extent that plaintiff relies on any theory of breach of warranty, such claims are barred by applicable law, and for lack of

privity with J&J Pharmaceutical and/or failure of plaintiff, or plaintiff's representatives, to give timely notice to J&J Pharmaceutical of any alleged breach of warranty. J&J Pharmaceutical further specifically pleads as to any breach of warranty claim all defenses under the Uniform Commercial Code existing and which may arise in the future.

**SIXTEENTH SEPARATE DEFENSE**

Plaintiff's claims of product defects are barred by Sections 2, 4, and 6(c) and (d) of the Restatement (Third) of Torts: Products Liability.

**SEVENTEENTH SEPARATE DEFENSE**

Plaintiff's claims should be diminished in whole or in part in the amount paid to plaintiff by any party or non-party with whom plaintiff has settled or may settle.

**EIGHTEENTH SEPARATE DEFENSE**

Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

**NINETEENTH SEPARATE DEFENSE**

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

**TWENTIETH SEPARATE DEFENSE**

Plaintiff's claims are barred by the equitable doctrine of estoppel.

**TWENTY-FIRST SEPARATE DEFENSE**

Plaintiff's alleged injuries are a result of pre-existing and/or unrelated medical conditions for which J&J Pharmaceutical is not responsible.

**TWENTY-SECOND SEPARATE DEFENSE**

To the extent plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

**TWENTY-THIRD SEPARATE DEFENSE**

Plaintiff has failed to plead allegations of fraud, mistake, or deception with the specificity or detail required.

**TWENTY-FOURTH SEPARATE DEFENSE**

To the extent that the products at issue in this lawsuit were changed, altered, or modified after they left the control of the manufacturer, such change, alteration, or modification was the legal cause of plaintiff's injuries, if any.

**TWENTY-FIFTH SEPARATE DEFENSE**

Plaintiff's product liability claims are barred because the benefits of the relevant products outweighed the risk.

**TWENTY-SIXTH SEPARATE DEFENSE**

Any claim for punitive or exemplary damages against J&J Pharmaceutical is unconstitutional in that recovery of punitive or exemplary damages in this case would violate J&J Pharmaceutical's constitutional rights to due process and equal protection under the Fourteenth Amendment to the Constitution of the United States and similar protections afforded by the New Jersey state constitution, and any other state whose law is deemed to apply in this case, and that any law of the state of New Jersey, whether enacted by the state's legislature or founded upon a decision or decisions of the courts, or that of any other state whose law is deemed to apply in this case, that would permit recovery of punitive or exemplary damages, is unconstitutional under these provisions.

**TWENTY-SEVENTH SEPARATE DEFENSE**

Any claim for punitive or exemplary damages against J&J Pharmaceutical is unconstitutional in that the standards for granting and asserting punitive or exemplary damages do not prohibit other plaintiffs from seeking and recovering such damages against J&J Pharmaceutical for the same allegations of defect in the same products, and as such constitute multiple punishments for the same alleged conduct resulting in deprivation of J&J Pharmaceutical's property without due process of law and will result in unjustified windfalls for plaintiff and plaintiff's counsel, in violation of the Sixth, Eighth, and Fourteenth Amendments to

the Constitution of the United States and similar protections afforded by the New Jersey state constitution, and that of any other state whose law is deemed to apply in this case.

**TWENTY-EIGHTH SEPARATE DEFENSE**

Any claim for punitive damages against J&J Pharmaceutical cannot be maintained because an award of punitive damages under current New Jersey law, and any other state's law deemed to apply to this action, would be void for vagueness, both facially and as applied. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fifth and Fourteenth Amendments to the United States Constitution, the due process provisions of the New Jersey state constitution, and the common law and public policies of New Jersey and similar protections afforded by any other state whose law is deemed to apply in this case.

**TWENTY-NINTH SEPARATE DEFENSE**

To the extent that the laws of New Jersey, and any other state whose law is deemed to apply in this case, permit punishment to be measured by the net worth or financial status of J&J Pharmaceutical and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious, and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, allows punishment to be imposed based on lawful profits and conduct of J&J Pharmaceutical in other states, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, the state laws and constitutional provisions of New Jersey, and similar protections afforded by any other state

whose law is deemed to apply in this case.

**THIRTIETH SEPARATE DEFENSE**

J&J Pharmaceutical is entitled to the protections and limitations afforded under the New Jersey Punitive Damages Act, N.J.S.A. §§ 2A:15-5.9, *et seq.*

**THIRTY-FIRST SEPARATE DEFENSE**

The Court lacks personal jurisdiction over J&J Pharmaceutical, and accordingly it should be dismissed from the lawsuit.

**THIRTY-SECOND SEPARATE DEFENSE**

J&J Pharmaceutical reserves the right, pursuant to Paragraph III(1) of Case Management Order No. 5, to raise such further and additional defenses as may be available upon the facts to be developed in discovery in each particular case and under other applicable substantive law in each particular case.

**PRAYER**

WHEREFORE, Defendant J&J Pharmaceutical respectfully prays as follows:

1. That plaintiff takes nothing by reason of the Complaint;
2. That the Complaint against J&J Pharmaceutical be dismissed in its entirety;
3. That J&J Pharmaceutical recover its reasonable costs of suit incurred in defense of this action; and
4. For such other relief as the Court deems just and proper.

**JURY DEMAND**

J&J Pharmaceutical demands a trial by jury on all issues so triable.

Dated: July 20, 2012

Respectfully submitted,

s/ Michael V. Powell

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AND DEVELOPMENT LLC

**CERTIFICATE OF SERVICE**

I certify that I filed the foregoing Master Answer on this date on the Court's ECF System and thereby, pursuant to Local Rule 5.1(d), served all counsel who are registered to receive service from the ECF System.

Dated: July 20, 2012.

s/ Seth M. Roberts  
Seth M. Roberts