

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

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

ORTHO-MCNEIL PHARMACEUTICAL, INC.'S MASTER ANSWER

Defendant Ortho-McNeil Pharmaceutical, Inc. (“Ortho-McNeil”), 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, Ortho-McNeil hereby generally denies all allegations set forth in each such complaint.

SEPARATE DEFENSES

Ortho-McNeil also asserts the following separate defenses. Pursuant to Paragraph III(1) of Case Management Order No. 5, Ortho-McNeil reserves the right to assert additional defenses to a particular case, consistent with future scheduling orders. By alleging the separate defenses set forth below, Ortho-McNeil 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 Ortho-McNeil 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 Ortho-McNeil

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 Ortho-McNeil 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

Ortho-McNeil 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 Ortho-McNeil and/or failure of plaintiff, or plaintiff's representatives, to give timely

notice to Ortho-McNeil of any alleged breach of warranty. Ortho-McNeil 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

Ortho-McNeil 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 Ortho-McNeil 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 Ortho-McNeil is unconstitutional in that recovery of punitive or exemplary damages in this case would violate Ortho-McNeil'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 Ortho-McNeil 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 Ortho-McNeil 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 Ortho-McNeil'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 Ortho-McNeil 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 Ortho-McNeil 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 Ortho-McNeil 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

Ortho-McNeil 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 Ortho-McNeil, and accordingly it should be dismissed from the lawsuit.

THIRTY-SECOND SEPARATE DEFENSE

Ortho-McNeil 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 Ortho-McNeil respectfully prays as follows:

1. That plaintiff takes nothing by reason of the Complaint;
2. That the Complaint against Ortho-McNeil be dismissed in its entirety;
3. That Ortho-McNeil 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

Ortho-McNeil demands a trial by jury on all issues so triable.

Dated: July 20, 2012

Respectfully submitted,

s/ Michael V. Powell

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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