UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: TYLENOL (ACETAMINOPHEN) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	§	**MDL NO. 2436**
	§	**2:13-md-02436**
	§	**HON. LAWRENCE F. STENGEL**
THIS DOCUMENT RELATES TO ALL CASES	§	

MASTER SHORT FORM ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS JOHNSON & JOHNSON AND McNEIL-PPC, INC. TO COMPLAINTS FILED IN OR TRANSFERRED TO MDL 2436

Defendants Johnson and Johnson ("J&J") and McNeil-PPC, Inc. ("MCNEIL")[1] (collectively, "Defendants", by and through their undersigned counsel, hereby file this Master Short-Form Answer and Affirmative Defenses ("Master Short-Form Answer"), pursuant to Case Management Order No. 7. The Master Short-Form Answer is not intended to, and shall not, waive any applicable defenses available to Defendants. Defendants may respond to any particular complaint by way of motion(s) permissible under the Federal Rules of Civil Procedure and Case Management Orders in MDL 2436 or otherwise. Defendants may also file counterclaims, cross-claims and/or third-party complaints, pursuant to Rules 13 and 14 of the Federal Rules of Civil Procedure, in connection with any particular individual action.

[1] McNEIL-PPC, Inc. submits this on its own behalf and on behalf of McNeil Consumer Healthcare Division of McNEIL-PPC, Inc., an unincorporated division of McNEIL-PPC that is not separately amenable to suit.

To avoid unnecessary motion practice and to streamline the pretrial proceedings in *In Re: Tylenol (Acetaminophen) Marketing, Sales Practices & Products Liability Litigation* ("MDL 2436"), MDL No. 2436, Defendants have agreed not to challenge the proper location of venue for MDL pretrial proceedings only. Defendants further state that they will not contest, via motion practice, service of process in pretrial proceedings so long as service is properly effected as set forth in the Federal Rules of Civil Procedure and as specifically set forth in CMO No. 7.

GENERAL DENIALS AND LIMITED ADMISSIONS

General Denials. Defendants deny each and every allegation contained in Plaintiff's Complaints that relate to or are directed to Defendants or any of their purported agents or employees. Defendants deny that Plaintiff has been damaged to any extent or amount, and Defendants deny that any Plaintiff is entitled to any relief in any form whatsoever from Defendants.[2] Defendants deny that there is any theory in law or fact or any legal relationship under which any Plaintiff is entitled to damages in any amount or form from Defendants.

Limited Admissions. Defendants admit that Johnson & Johnson is a corporation organized under the laws of the State of New Jersey with its headquarters and principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Defendants also admit that McNEIL-PPC, Inc. is a New Jersey corporation with its principal place of business in Skillman, New Jersey. McNEIL admits that it has engaged in developing, designing, licensing, manufacturing, labeling, distributing, selling and marketing Tylenol products for uses consistent with the packaging and labeling. Defendants deny that J&J has developed, designed, licensed, manufactured, labeled, distributed, sold or marketed any product. Defendants further admit that Tylenol products are safe and effective for uses consistent with the packaging and labeling.

[2] The Master Short-Form Answer heretofore uses the singular term "Plaintiff" in referring to both single-Plaintiff and multi-Plaintiff actions, and/or

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Defendants in this matter. Defendants, therefore, assert the following defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts so warrant, Defendants may withdraw any of these defenses as they deem appropriate. Further, Defendants reserve the right to amend their Answer and Defenses to assert additional defenses, cross-claims, counterclaims and other claims and defenses as discovery proceeds or to the extent any case is set as a bellwether trial and/or remanded to a transferor or other appropriate court. Without assuming any burden of pleading or proof that would otherwise rest on Plaintiff, Defendants state as follows:

FIRST DEFENSE

The Complaint fails to state, in whole or in part, a claim upon which relief can be granted.

SECOND DEFENSE

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

THIRD DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by McNEIL or other manufacturer. Pursuant to the doctrines of assumption of the risk and/or informed consent, this conduct bars, in whole or in part, the damages that Plaintiff seeks to recover herein.

FOURTH DEFENSE

The injuries and damages, if any, sustained by Plaintiff resulted in whole or in part from their own culpable conduct, intentional acts, contributory or comparative negligence, assumption of risk, and want of care. Accordingly, any damages recovered should be reduced and/or barred in accordance with the applicable law.

FIFTH DEFENSE

Each and every claim asserted or raised in the Complaint may be time barred, in whole or in part, by the applicable statute of limitations and/or statute of repose and/or may be otherwise untimely.

SIXTH DEFENSE

The Complaint fails to plead a claim or claims with requisite specificity.

SEVENTH DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrine of waiver.

EIGHTH DEFENSE

Plaintiff failed to give proper notice of any alleged breach of warranty, whether express or implied. Thus, Plaintiff' claims for breach of warranty are barred.

NINTH DEFENSE

Defendants neither made nor breached any express warranties, implied warranties, and/or 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, by the lack of privity between Plaintiff and Defendants, and/or by Plaintiff's failure to give Defendants timely notice of the alleged breach of

warranty. Defendants further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code.

TENTH DEFENSE

If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other independent, unforeseeable, superseding or intervening cause or causes.

ELEVENTH DEFENSE

Tylenol® has been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and regulations promulgated thereunder. Therefore, Plaintiff's claims predicated on state tort law are barred, in whole or in part, by the doctrine of federal preemption, the Supremacy Clause of the United States Constitution, Article IV, clause 2, and any applicable federal law or regulations.

TWELFTH DEFENSE

To the extent that Plaintiff asserts claims based on McNEIL's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law including, but not limited to, the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, Docket No. 2000N-1269 (January 24, 2006) and/or under the Final Rule, Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Anti-rheumatic Drug Products for Over-the-Counter Human Use; Final Monograph, Federal Register Vol. 74, No. 81 (April 29, 2009), 21 CFR Part 201, Docket No. FDA-1977-N-0013.

THIRTEENTH DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating drugs, including Tylenol®, and is specifically charged with determining the content of warnings and labeling for drugs.

FOURTEENTH DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Defendants to warn Plaintiff directly of alleged dangers associated with the use of Tylenol®, such claims are barred under the learned intermediary doctrine because McNEIL discharged its duties to warn in the warnings to prescribing physicians.

FIFTEENTH DEFENSE

Plaintiff's claims are barred because the injuries allegedly sustained by Plaintiff were not proximately caused by any act or omission of McNEIL. The negligence of other persons or entities who are not parties to this suit was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Defendants anticipate that more specific information regarding the identity and potential liability of these non-parties will be developed during discovery.

SITEENTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the acts and omissions (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of one or more persons or entities over whom Defendants exercise no control and for whom Defendants are not legally responsible, including, without limitation, the Plaintiff, and for whom

Defendants may not be held accountable. Defendants anticipate that more specific information regarding the identity and potential liability of these non-parties will be developed during discovery.

SEVENTEENTH DEFENSE

If Plaintiff was injured by any product manufactured, sold, and/or distributed by McNEIL, to the extent those injuries occurred because the product was used for a purpose other than that for which it was intended, in a manner other than that in which it was intended to be used, and/or in disregard of instructions and direction regarding its use, such misuse was not reasonably foreseeable to McNEIL and Plaintiff damages should be reduced in whole or in part.

EIGHTEENTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from conditions, illnesses, and/or reactions unrelated to the use of the subject product or products, including, but not limited to, a pre-existing and/or unrelated medical, genetic, and/or environmental conditions; diseases; illnesses; allergic, idiosyncratic, or idiopathic reactions; subsequent medical conditions; and/or natural courses of conditions. Defendants are not responsible for any injuries or losses resulting from such pre-existing and/or unrelated conditions, illnesses, and/or reactions, and Plaintiff damages should be reduced in whole or in part.

NINETEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the product at issue was made in accordance with the state of the art at the time it was manufactured.

TWENTIETH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the methods, standards, and techniques utilized by McNEIL in manufacturing, distributing, marketing, or labeling the subject product and in issuing warnings and instructions with respect to its use were proper and conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured and distributed, barring Plaintiff's recovery. Further, Tylenol® was safe for its respective normal and foreseeable use at all times, not unreasonably dangerous or defective, and its benefits exceeded any associated risks.

TWENTY-FIRST DEFENSE

Plaintiff's claims are barred in whole or in part under comment *k* to Section 402A of the Restatement (Second) of Torts.

TWENTY-SECOND DEFENSE

Plaintiff's claims are barred in whole or in part because McNEIL provided legally adequate "directions or warnings" as to the use of Tylenol® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment *j* to Section 402A of the Restatement (Second) of Torts.

TWENTY-THIRD DEFENSE

Plaintiff's claims are barred under Sections 2, 4, 6(c), 6(d) and comment *f* to Section 6, of the Restatement (Third) of Torts: Products Liability.

TWENTY-FOURTH DEFENSE

With respect to each and every cause of action, Plaintiff cannot state claims founded in strict liability because, among other things, comments *j* and *k* to Section 402A of the Restatement (Second) of Torts limit Plaintiff's claims, if any, to a negligence cause of action.

TWENTY-FIFTH DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended respective functions of Tylenol®.

TWENTY-SIXTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to prevent or mitigate damages.

TWENTY-SEVENTH DEFENSE

Plaintiff's claims are barred in whole or in part because McNEIL's conduct conforms with medical knowledge.

TWENTY-EIGHTH DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Defendants deny, then the product was unavoidably unsafe as defined in the Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH DEFENSE

McNEIL's advertisements and labeling with respect to the product which is the subject of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution and this State.

THIRTIETH DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability, if any, resulting from any activities undertaken by Defendants, which were unavoidable given the state of human knowledge at the time those

activities were undertaken. With respect to Plaintiff's claims, if it is determined there exists a risk inherent in the subject product, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST DEFENSE

At all times relevant herein, any product which is the subject of this action manufactured and distributed by McNEIL in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was manufactured and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND DEFENSE

With respect to each and every purported cause of action, the acts of Defendants were at all times done in good faith and without malice.

THIRTY-THIRD DEFENSE

To the extent there were any risks associated with the use of the product which is the subject of this action which Defendants knew or should have known and which gave rise to a duty to warn, McNEIL at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state law.

THIRTY-FOURTH DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money for which Defendants are liable.

THIRTY-FIFTH DEFENSE

Plaintiff has not suffered any actual injury or damages for which Defendants are liable.

THIRTY-SIXTH DEFENSE

Defendants are entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

THIRTY-SEVENTH DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, and/or to the extent Plaintiff seeks to privately enforce any provision of the FDCA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) and 21 U.S.C. § 337.

THIRTY-EIGHTH DEFENSE

There is no causal relationship between Defendants or their activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiff.

THIRTY-NINTH DEFENSE

To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Defendants' liability, if any, should be precluded or reduced accordingly.

FORTIETH DEFENSE

Defendants are not liable for negligence and violated no duty that may have been owed to Plaintiff.

FORTY-FIRST DEFENSE

The extent of any risk associated with the use of Tylenol®, the existence of which is not admitted, was, at the time of the distribution of said product by McNEIL, unknown and could not have been known by the use of ordinary care by McNEIL.

FORTY-SECOND DEFENSE

Plaintiff's damages, if any, are barred or reduced by the doctrine of avoidable consequences.

FORTY-THIRD DEFENSE

Defendants deny any liability, but if either J&J or McNEIL is ultimately found liable to Plaintiff, then it shall only be liable for its equitable share of Plaintiff's recovery since any liability which would be found against Defendants will be insufficient to impose joint liability.

FORTY-FOURTH DEFENSE

This case may be subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTY-FIFTH DEFENSE

The claims of the Plaintiff may be barred, in whole or in part, from recovery because Plaintiff has made statements or taken actions that preclude Plaintiff from asserting claims or constitute waiver of Plaintiff's claims.

FORTY-SIXTH DEFENSE

Plaintiff' claims are barred because McNEIL complied with all applicable state and federal statutes regarding the product in question, including the requirements and regulations promulgated by the U.S. Food and Drug Administration and contained in Chapter 21 of the Code of Federal Regulations as well as the industry standards based upon the state of knowledge existing at the relevant time alleged by the Complaint. Tylenol® was reasonably fit, suitable, and safe for its respective intended uses, thereby barring Plaintiff's recovery. In the event that Plaintiff's claims are not barred, Defendants are entitled to a presumption that the product in question is free from any defect or defective condition as the plans or design for the product or the methods and techniques of manufacturing, inspecting, and testing the product were in

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

FORTY-SEVENTH DEFENSE

Defendants are entitled to protection under the *Noerr-Pennington* doctrine, which provides that parties who exercise their First Amendment right to communicate and/or petition the government are immune from liability premised on any such efforts.

FORTY-EIGHTH DEFENSE

Plaintiff received all or substantially all of the benefit from the subject product that Plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from Defendants must be correspondingly barred or reduced.

FORTY-NINTH DEFENSE

To the extent Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution and any applicable State Constitution.

FIFTIETH DEFENSE

Plaintiff's claims may be barred, in whole or in part, from recovery due to spoliation of evidence.

FIFTY-FIRST DEFENSE

No act or omission of Defendants was oppressive, fraudulent, or malicious and, therefore, any award of punitive damages is barred. Plaintiff's claim for punitive damages is subject to the

limitations and requirements of the law of this State and/or any other state whose law is deemed to apply in this case.

FIFTY-SECOND DEFENSE

The imposition of punitive or exemplary damages would violate Defendants' constitutional rights, including but not limited: (1) 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, (2) the excessive fines clause in the Eighth Amendment to the Constitution of the United States, and (3) the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. Punitive damages may not be recovered to the extent such damages are (1) imposed by a jury that is (a) not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award, (b) not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment, (c) 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 (d) 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. Punitive damages may also not be recovered to the extent such damages are (2) 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 Defendants' conduct within the State where Plaintiff resides, or in any other way subjecting Defendants to impermissible multiple punishment for the same alleged wrong.

FIFTY-THIRD DEFENSE

An award of treble damages violates the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution.

FIFTY-FOURTH DEFENSE

Defendants incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts under the Due Process Clause of the Fourteenth Amendment to the United States Constitution, including but not limited to standards set forth in *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.

FIFTY-FIFTH DEFENSE

Defendants assert the provisions of all applicable statutory caps on damages of any sort, including compensatory, punitive, non-economic or exemplary damages, under applicable regulations and/or laws.

FIFTY-SEVENTH DEFENSE

To the extent Plaintiff alleges that death occurred, any damages for a wrongful death claim may only be based on the destruction to the decedent's power to labor and earn money.

Absent any factual allegations indicating that Plaintiff's power to labor and earn money at the time of death had been destroyed, such request for damages is barred.

FIFTY-SIXTH DEFENSE

Pending a determination of applicable law, Defendants plead all pertinent affirmative defenses under applicable state law(s), and reserve the right to assert further or additional affirmative defenses if it is determined that such defenses exist under applicable state law(s).

WHEREFORE, Defendants request that Plaintiff's Complaint be dismissed with prejudice with all costs and fees assessed against Plaintiff along with such other relief that the Court may deem just and proper.

Dated: June 10 , 2013

/s/ Christy D. Jones
Christy D. Jones (MS No. 3192)
BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC
1020 Highland Colony Parkway, Suite 1400
Ridgeland, MS 39157
Telephone: (601) 948-5711
Facsimile: (601) 985-4500
E-Mail: christy.jones@butlersnow.com

Attorneys for Defendants McNeil PPC-Inc. and Johnson & Johnson

ButlerSnow 16270252v1