

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESAL PRICE)	MDL NO. 1456
LITIGATION)	Civil Action No. 01-12257-PBS
_____)	
THIS DOCUMENT RELATES TO)	Hon. Patti B. Saris
ALL CLASS ACTIONS)	Chief Mag. Judge Marianne B. Bowler
_____)	

JOHNSON & JOHNSON, CENTOCOR, INC., JANSSEN PHARMACEUTICA PRODUCTS, L.P., MCNEIL-PPC, INC., AND ORTHO BIOTECH PRODUCTS, L.P.’S ANSWER TO PLAINTIFFS’ THIRD AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT

Defendants Johnson & Johnson (“J&J”), Centocor, Inc. (“Centocor”), Janssen Pharmaceutica Products, L.P. (“Janssen”), McNeil-PPC, Inc. (“McNeil-PPC”), Ortho Biotech Products, L.P., incorrectly sued as “Ortho Biotech” (“Ortho Biotech”) (collectively the “J&J Defendants”), for their Answer to Plaintiffs’ Third Amended Master Consolidated Class Action Complaint (the “TAMCC”), state:

I. INTRODUCTION

1. The J&J Defendants admit that Plaintiffs seek to bring this action as alleged in Paragraph 1 of the TAMCC. The J&J Defendants deny that Plaintiffs are entitled to maintain this action in the manner alleged.

2. The J&J Defendants deny the allegations in Paragraph 2 of the TAMCC that pertain to them. To the extent the allegations in Paragraph 2 of the TAMCC allege conspiracies between the J&J Defendants and others in the pharmaceutical distribution chain pursuant to

claims and counts that have been dismissed by the Court, no response is required. To the extent the allegations in Paragraph 2 of the TAMCC refer to the knowledge, conduct or actions of persons or entities other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

3. To the extent the allegations in Paragraph 3 of the TAMCC are directed to persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, deny those allegations. The J&J Defendants admit that certain of them manufacture medicines that are covered under Medicare Part B, and that Congress previously mandated that Medicare Part B reimbursements be based, in part, upon AWP. The J&J Defendants admit that certain of them have reported certain pricing information for their medicines to pharmaceutical industry pricing publications. The J&J Defendants admit that the AWPs published in trade publications are typically higher than the prices ultimately paid by providers purchasing medicines from wholesalers and distributors. The J&J Defendants deny the remaining allegations in Paragraph 3 of the TAMCC that pertain to them.

4. To the extent the allegations in Paragraph 4 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants admit that Congress previously mandated that Medicare Part B reimbursements be based, in part, upon AWP, and further admit that Medicare Part B medicines are generally, but not always,

administered in a healthcare provider's office. The J&J Defendants deny the remaining allegations in Paragraph 4 of the TAMCC that pertain to them.

5. The J&J Defendants deny the allegations in Paragraph 5 of the TAMCC that pertain to them. To the extent the allegations in Paragraph 5 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

6. To the extent the allegations in Paragraph 6 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants admit that Plaintiffs purport to bring this action as alleged in Paragraph 6 of the TAMCC, but the J&J Defendants deny that Plaintiffs are entitled to maintain this action in the manner alleged. The J&J Defendants deny the remaining allegations in Paragraph 6 of the TAMCC that pertain to them.

7. The J&J Defendants deny the allegations in Paragraph 7 of the TAMCC that pertain to them. To the extent the allegations in Paragraph 7 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

8. Answering Paragraph 8 of the TAMCC, the J&J Defendants admit that Plaintiffs have filed attachments to the TAMCC titled Appendix A and Appendix B. The J&J Defendants deny that any of the medicines attributed to them and listed in Appendix A and Appendix B other than Procrit® and Remicade® are subject of any of Plaintiffs' claims against the J&J Defendants. Plaintiffs' allegations pertaining to those other medicines related solely to Plaintiffs' Together Rx claims, which claims have been dismissed by the filing of the TAMCC. To the extent the allegations in Paragraph 8 of the TAMCC are deemed to include allegations against the J&J Defendants, they are denied.

II. JURISDICTION AND VENUE

9. The J&J Defendants admit that this Court has federal question subject matter jurisdiction. The J&J Defendants admit that, upon information and belief, diversity jurisdiction exists.

10. The J&J Defendants admit the allegations in Paragraphs 10 of the TAMCC.

11. The J&J Defendants admit the first two sentences in Paragraph 11 of the TAMCC. The J&J Defendants deny the remaining allegations in Paragraph 11 of the TAMCC.

12. The J&J Defendants admit the allegations in Paragraphs 12 of the TAMCC.

III. PARTIES

13-59. The J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 13 through 59 of the TAMCC and, therefore, deny those allegations.

60-61. The J&J Defendants deny the allegations in Paragraphs 60 through 61 of the TAMCC that pertain to them. To the extent the allegations in Paragraphs 60 through 61 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than

the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

62-119. The allegations in Paragraphs 62 through 119 of the TAMCC are directed other defendants and require no response from the J&J Defendants. To the extent the allegations in Paragraphs 92 through 119 of the TAMCC are deemed to include allegations against the J&J Defendants, they are denied.

120. J&J admits it is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J denies the remaining allegations in Paragraph 120 of the TAMCC.

121. Centocor admits it is a Pennsylvania corporation and has been a wholly-owned subsidiary of J&J since its acquisition by J&J in October 1999. Centocor admits its principal place of business is located at 200 Great Valley Parkway, Malvern, Pennsylvania. Centocor admits that it manufactures, markets and distributes prescription pharmaceuticals. Centocor denies the remaining allegations in Paragraph 121 of the TAMCC.

122. Janssen admits it is a New Jersey limited partnership and that its principal place of business is located at 1125 Trenton-Harbouton Road, Titusville, New Jersey 08560. Janssen admits that it is a subsidiary of J&J. Janssen admits that Plaintiffs sued Janssen for its role in the supposed Together Rx conspiracy. Janssen avers that Plaintiffs' Together Rx claims have been dismissed by the filing of this TAMCC, and, accordingly, the TAMCC no longer purports to state a claim against Janssen. Janssen denies the remaining allegations in Paragraph 122 of the TAMCC.

123. McNeil-PPC admits it is a New Jersey corporation. McNeil-PPC admits it is an indirect (not direct) subsidiary of J&J. McNeil-PPC admits that Plaintiffs sued McNeil-PPC for

its role in the supposed Together Rx conspiracy. McNeil-PPC avers that Plaintiffs' Together Rx claims have been dismissed by the filing of this TAMCC, and, accordingly, the TAMCC no longer purports to state a claim against McNeil-PPC. McNeil-PPC denies the remaining allegations in Paragraph 123 of the TAMCC.

124. Ortho Biotech admits it has been a wholly-owned subsidiary of J&J since its formation by J&J in 1990. Ortho Biotech admits it manufactures and distributes prescription pharmaceuticals. Ortho Biotech denies the remaining allegations in Paragraph 124 of the TAMCC.

125. Centocor admits it sells ReoPro (abciximab), an anti-blood clotting medication, Retavase (reteplase), an anti blood clotting agent, and Remicade (infliximab), an anti-inflammatory medicine that is covered by Medicare Part B. Ortho Biotech admits it sells Procrit (epoetin alfa), a medicine indicated for the treatment of anemia that is covered by Medicare Part B, Leustatin (cladribine), a medicine indicated for the treatment of leukemia, Orthoclone (muromonab-CD3), a medicine indicated to prevent organ transplant rejection, and an IV formulation of Sporanox (itraconazole), a medicine indicated for the treatment of fungal infections. The J&J Defendants deny the remaining allegations in Paragraph 125 of the TAMCC.

126-147. The allegations in Paragraphs 107 through 131 of the TAMCC are directed to other defendants and require no response from the J&J Defendants. To the extent the allegations in Paragraphs 126 through 147 of the TAMCC are deemed to include allegations against the J&J Defendants, they are denied.

IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

148. To the extent the allegations in Paragraph 148 of the TAMCC are directed to other defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants deny the allegations in Paragraph 148 of the TAMCC that pertain to them.

149. Upon information and belief, the J&J Defendants admit the allegations in Paragraph 149 of the TAMCC.

150-157. To the extent the allegations in Paragraphs 150 through 157 of the TAMCC refer to the knowledge, conduct, opinions or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. Further answering Paragraph 150 of the TAMCC, the J&J Defendants admit that Congress previously mandated that Medicare Part B reimbursements be based, in part, upon AWP. Further answering Paragraphs 151 and 152 of the TAMCC, the J&J Defendants admit that independently produced pricing publications periodically report AWP's for prescription medicines sold in the United States. The J&J Defendants state that the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 152 of the TAMCC are the best evidence of their contents. The J&J Defendants deny the remaining allegations in Paragraphs 150 through 157 of the TAMCC that pertain to them.

158-160. The J&J Defendants admit the allegations in Paragraphs 158 through 160 of the TAMCC, except to the extent the Medicare Modernization Act has now altered the coverage provided by the Medicare Program of self administered drugs.

161. The J&J Defendants admit that the reimbursement methodology for medicines covered by Medicare Part B was set forth at 42 C.F.R. § 405.517, which is the best evidence of its contents.

162. The J&J Defendants deny the allegations in the first sentence of Paragraph 162 insofar as it contains material in quotation marks the source of which is not identified. The J&J Defendants deny the second sentence of Paragraph 146 insofar as 42 C.F.R. § 405.517 contains no reference to a “ceiling” on reimbursement amounts.

163. The J&J Defendants admit the allegations in Paragraph 163 of the TAMCC.

164. Answering Paragraph 164 of the TAMCC, the J&J Defendants admit that the Medicare Program has publicly announced that it would use the AWP published in independently produced pricing publications as the basis for reimbursement. The J&J Defendants state that the Program Memo AB-99-63 cited in Paragraph 164 of the TAMCC is the best evidence of its contents.

165. The J&J Defendants state that the Program Memo AB-99-63 cited in Paragraph 165 of the TAMCC is the best evidence of its contents.

166-167. The J&J Defendants admit the allegations in Paragraphs 166 through 167 of the TAMCC, except to the extent reimbursement has been altered by the Medicare Modernization Act.

168. To the extent the allegations in Paragraph 168 of the TAMCC refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants admit that there are no government regulations describing how AWPs are calculated,

nor any other statutory or regulatory definitions or descriptions of AWP's. The J&J Defendants admit that certain of them have reported certain pricing information for their medicines to independently produced pricing publications. The J&J Defendants deny the remaining allegations in Paragraph 168 of the TAMCC that pertain to them.

169-170. The J&J Defendants state that the April 2003 OIG report cited in Paragraphs 169 through 170 of the TAMCC is the best evidence of its contents. The J&J Defendants deny that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to the J&J Defendants.

171. To the extent the allegations in Paragraph 171 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 171 of the TAMCC that pertain to them.

172-173. The J&J Defendants state that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 172 through 173 of the TAMCC is the best evidence of its contents. The J&J Defendants deny that Plaintiffs have accurately characterized the findings, opinions, statements or conclusions of Congressman Stark, or that such are applicable to the J&J Defendants. The J&J Defendants deny the remaining allegations in Paragraphs 172 through 173 of the TAMCC that pertain to them.

174-175. To the extent the allegations in Paragraphs 174 through 175 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief

as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants deny knowledge or information sufficient to form a belief as to the identity of the DOJ and criminal investigations referred to in Paragraph 174, and therefore deny said allegation. The J&J Defendants deny the allegations in Paragraph 175 of the TAMCC that pertain to them.

176. To the extent the allegations in Paragraph 176 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants admit that certain of them have submitted suggested AWP's for their medicines to independently produced pricing publications.

177-200. To the extent the allegations in Paragraphs 177 through 200 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants deny the remaining allegations in Paragraphs 171 through 200 of the TAMCC that pertain to them.

201. The J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 201 of the TAMCC and, therefore, deny those allegations.

202-207. To the extent the allegations in Paragraphs 201 through 207 of the TAMCC and its subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those

allegations. The J&J Defendants state that the *Red Book* and the unidentified DOJ report cited in Paragraph 203 of the TAMCC and the pleadings cited in Paragraphs 205 through 206 of the TAMCC and subparts are the best evidence of their contents. To the extent the allegations in Paragraphs 202 through 207 of the TAMCC are deemed to include allegations against the J&J Defendants, they are denied.

208. To the extent the allegations in Paragraph 208 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants state the 2003 CMS document cited in Paragraph 208 of the TAMCC is the best evidence of its contents. The J&J Defendants deny that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement or conclusion. The J&J Defendants admit that certain of them sell medicines, that said medicines are sold in a competitive market and that, as such, steps are taken to keep certain information relating to said medicines confidential. The J&J Defendants deny the remaining allegations in Paragraph 208 of the TAMCC that pertain to them.

209-212. The J&J Defendants deny the allegations in Paragraphs 209 through 212 of the TAMCC that pertain to them. To the extent the allegations in Paragraphs 209 through 212 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

213. The J&J Defendants deny the allegations of Paragraph 213 of the TAMCC.

214-215. The allegations in Paragraphs 214 through 215 of the TAMCC state legal conclusions to which no response is required. To the extent a response is required, the J&J

Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraphs 214 through 215 of the TAMCC that refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, and, therefore, the J&J Defendants deny those allegations. The J&J Defendants deny the remaining allegations in Paragraphs 214 through 215 of the TAMCC that pertain to them.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

216. The J&J Defendants deny the allegations in Paragraph 216 of the TAMCC that pertain to them. To the extent the allegations in Paragraph 216 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

217-446. The allegations in Paragraphs 217 through 446 of the TAMCC are directed to other defendants and require no response from the J&J Defendants. To the extent allegations in Paragraphs 217 through 446 of the TAMCC are deemed to include allegations against the J&J Defendants, they are denied.

447. Except for Procrit® and Remicade®, the J&J Defendants deny that any of the medicines manufactured or sold by them listed at Appendix A or in paragraph 447 are subject to the claims set forth in the TAMCC. All of the other medicines listed therein, including the medicines manufactured or sold by Ortho McNeil Pharmaceutical Inc. and Ortho Neutrogena, neither of which is a party to the TAMCC, were subject only to Plaintiffs' claims relating to the supposed Together Rx conspiracy, which claims have been dismissed by the filing of the TAMCC. The J&J Defendants deny the remaining allegations in Paragraph 447 of the TAMCC that pertain to them.

448. The J&J Defendants admit that the governmental agencies listed in Paragraph 448 of the TAMCC have conducted investigations concerning pricing in the pharmaceutical industry and that certain of the J&J Defendants have participated in such investigations. The J&J Defendants deny the remaining allegations in Paragraph 448 of the TAMCC that pertain to them.

449. The J&J Defendants state that the rebate agreement cited in Paragraph 449 of the TAMCC is the best evidence of its contents. The J&J Defendants deny the remaining allegations in Paragraph 449 of the TAMCC that pertain to them.

450. The J&J Defendants deny the allegations in Paragraph 450 of the TAMCC except Ortho Biotech admits that it sells Procrit® (epoetin alfa) and that it promotes Procrit® for non-dialysis uses.

451. To the extent the allegations in Paragraph 451 of the TAMCC refer to or rely on third party publications, the J&J Defendants are without sufficient knowledge to form a belief as to the truth of those allegations and, therefore, deny those allegations. To the extent the allegations in Paragraph 451 of the TAMCC are directed to another defendant, the J&J Defendants are without sufficient knowledge and information to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 451 of the TAMCC that pertain to them.

452. The J&J Defendants deny the allegations in Paragraph 452 of the TAMCC, except that Centocor admits that the published AWP for a 100mg vial of Remicade was \$611.33 in November 1999, and was \$665.65 in 2001.

453. The J&J Defendants state that the document entitled "Office-Based Infusion Guide" is the best evidence of its contents. The J&J Defendants deny the conclusions drawn by

Plaintiffs from this document are accurate, and deny the remaining allegations in Paragraph 453 of the TAMCC that pertain to them.

454. The J&J Defendants deny the allegations in Paragraph 454 of the TAMCC that pertain to them.

455. The J&J Defendants state that the document J&J000121-123 and the *Red Book* cited in Paragraph 455 of the TAMCC are the best evidence of their contents. The J&J Defendants deny the conclusions drawn by Plaintiffs from these documents are accurate, and deny the remaining allegations in Paragraph 455 of the TAMCC that pertain to them.

456. The J&J Defendants admit that certain of them sell medicines, that said medicines are sold in a competitive market and that, as such, steps are taken to keep certain information relating to said medicines confidential. The J&J Defendants deny the remaining allegations in Paragraph 456 of the TAMCC that pertain to them.

457-551. The allegations in Paragraphs 457 through 551 of the TAMCC are directed to another defendant and require no response from the J&J Defendants. To the extent allegations in Paragraphs 457 through 551 of the TAMCC are deemed to include allegations against the J&J Defendants, they are denied.

VI. PLAINTIFFS' CLAIM FOR DAMAGES

552. The J&J Defendants deny that Plaintiffs have suffered damages or injuries as alleged in Paragraph 552 of the TAMCC. The J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 552 of the TAMCC and, therefore, deny those allegations.

VII. CLASS ALLEGATIONS FOR THE PURPORTED “AWP PAYOR CLASS”

553-556. The J&J Defendants admit that Plaintiffs purport to bring this action as alleged in Paragraphs 553 through 556 of the TAMCC, but the J&J Defendants deny that Plaintiffs are entitled to maintain this action in the manner alleged. The J&J Defendants deny the remaining allegations in Paragraphs 553 through 556 of the TAMCC.

557-562. The allegations in Paragraphs 557 through 562 of the TAMCC state legal conclusions to which no answer is required. The J&J Defendants deny the allegations in Paragraphs 557 through 562 of the TAMCC.

COUNT I (RICO)

563-591. The Court dismissed Count I in its Order dated February 25, 2004. Accordingly, the J&J Defendants do not respond to Paragraphs 563 through 591 of the TAMCC. To the extent a response is required, the J&J Defendants deny all allegations contained within Count I of the TAMCC that pertain to them.

COUNT II (RICO)

592. Answering Paragraph 592 of the TAMCC, the J&J Defendants reallege and incorporate their responses to the allegations in Paragraphs 1 through 591 of the TAMCC.

593. To the extent the allegations in Paragraph 593 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants admit that Plaintiffs purport to bring this action and to seek relief under Count II of the TAMCC as alleged in Paragraph 593, but the J&J Defendants deny that Plaintiffs are entitled to maintain this action

as alleged or to any relief against the J&J Defendants under Count II. The J&J Defendants deny the remaining allegations in Paragraph 593 of the TAMCC.

594. The allegations in Paragraph 594 of the TAMCC state a legal conclusion to which no answer is required, except that the J&J Defendants deny that Plaintiffs are entitled to maintain this action as a class action.

595. To the extent the allegations in Paragraph 595 of the TAMCC and subparts state legal conclusions, the J&J Defendants aver that no answer is required. The J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 595 and subparts and, therefore, deny those allegations.

596-600. The J&J Defendants deny the allegations in Paragraphs 596 through 600 that pertain to them. To the extent the allegations in Paragraphs 596 through 600 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants state that the unidentified "industry report" cited in Paragraph 600 of the TAMCC is the best evidence of its contents.

601-623. To the extent the allegations in Paragraph 601 through 623 of the TAMCC include allegations against the J&J Defendants, they are denied. To the extent the allegations in Paragraphs 601 through 623 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

624. The allegations in Paragraph 624 of the TAMCC state legal conclusions to which no response is required. To the extent a response is required, the J&J Defendants deny the allegations in Paragraph 624 of the TAMCC.

COUNT III (DECLARATORY RELIEF)

625. Answering Paragraph 625 of the TAMCC, the J&J Defendants reallege and incorporate their responses to the allegations in Paragraphs 1 through 624 of the TAMCC.

626. The J&J Defendants deny the allegations in Paragraph 626 of the TAMCC that pertain to them. The allegations in Paragraph 626 of the TAMCC state legal conclusions to which no response is required. To the extent a response is required, the J&J Defendants deny that Plaintiffs have standing to bring this action, and denies that an actual case and controversy exists. To the extent the allegations in Paragraph 626 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

627-628. To the extent the allegations in Paragraphs 627 through 628 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants deny the remaining allegations in Paragraphs 627 through 628 of the TAMCC that pertain to them.

COUNT IV (CONSUMER PROTECTION STATUTES)

629. Answering Paragraph 629 of the TAMCC, the J&J Defendants reallege and incorporate their responses to the allegations in Paragraphs 1 through 628 of the TAMCC.

630. The J&J Defendants admit that Plaintiffs purport to bring this action and to seek relief under Count IV of the TAMCC as alleged in Paragraph 630, but the J&J Defendants deny that Plaintiffs are entitled maintain this action as alleged or to any relief against the J&J Defendants under Count IV. The J&J Defendants deny the remaining allegations in Paragraph 630 of the TAMCC.

631. To the extent the allegations in Paragraph 631 of the TAMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. J&J, Janssen, McNeil-PPC and Ortho Biotech admit that their principal places of business are located in New Jersey. Centocor admits that its principal places of business is located in Pennsylvania. The J&J Defendants admit that certain states have enacted consumer protection laws, but the J&J Defendants deny that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. The J&J Defendants deny the remaining allegations in Paragraph 631 of the TAMCC and subparts that pertain to them.

632-636. The J&J Defendants deny the allegations in Paragraphs 632 through 636 of the TAMCC and subparts that pertain to them. To the extent the allegations in Paragraphs 632 through 636 of the TAMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

**COUNT V
(CONSUMER PROTECTION LAWS – PURPORTED MEDICARE PART B CO-PAY
SUBCLASS)**

637. Answering Paragraph 637 of the TAMCC, the J&J Defendants reallege and incorporate their responses to the allegations in Paragraphs 1 through 636 of the TAMCC. The J&J Defendants admit that Plaintiffs purport to bring this action and to seek relief under Count V of the TAMCC as alleged in Paragraph 637, but the J&J Defendants deny that Plaintiffs are entitled maintain this action as alleged or to any relief against the J&J Defendants under Count V. The J&J Defendants deny the remaining allegations in Paragraph 637 of the TAMCC.

638. The J&J Defendants admit that Plaintiffs purport to bring this action and to seek relief under Count V of the TAMCC as alleged in Paragraph 638, but the J&J Defendants deny that Plaintiffs are entitled maintain this action as alleged or to any relief against the J&J Defendants under Count V. The J&J Defendants deny the remaining allegations in Paragraph 638 of the TAMCC.

639. The J&J Defendants admit that that Plaintiffs purports to bring this action naming the individuals or funds specified in paragraph 639 as class representatives, but the J&J Defendants deny that Plaintiffs are entitled to maintain this action in the manner alleged or that the named individuals or funds are proper class representative. The J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 639 of the TAMCC and, therefore, deny those allegations.

640. The J&J Defendants admit that that Plaintiffs purports to bring this action in the manner specified at paragraph 640, but the J&J Defendants deny that Plaintiffs are entitled to maintain this action in the manner alleged.

641-644. The J&J Defendants deny the allegations in Paragraphs 641 through 644 TAMCC and subparts that pertain to them. To the extent the allegations in Paragraphs 641 through 644 of the TAMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

**COUNT VI
(CONSUMER PROTECTION LAWS – PURPORTED THIRD-PARTY PAYORS
PART B MEDIGAP CLASS)**

645. Answering Paragraph 645 of the TAMCC, the J&J Defendants reallege and incorporate their responses to the allegations in Paragraphs 1 through 644 of the TAMCC. The J&J Defendants admit that Plaintiffs purport to bring this action and to seek relief under Count VI of the TAMCC as alleged in Paragraph 645, but the J&J Defendants deny that Plaintiffs are entitled maintain this action as alleged or to any relief against the J&J Defendants under Count VI. The J&J Defendants deny the remaining allegations in Paragraph 645 of the TAMCC.

646. The J&J Defendants admit that Plaintiffs purport to bring this action and to seek relief under Count VI of the TAMCC as alleged in Paragraph 646, but the J&J Defendants deny that Plaintiffs are entitled maintain this action as alleged or to any relief against the J&J Defendants under Count VI. The J&J Defendants aver that any assertion of this claim on behalf of a nationwide class is barred by Judge Saris' August 16, 2005 Order regarding class certification. To the extent the allegations in Paragraph 646 of the TAMCC state legal conclusions, the J&J Defendants aver that no answer is required. The J&J Defendants deny the remaining allegations in Paragraph 646 of the TAMCC.

647. The J&J Defendants admit that that Plaintiffs purports to bring this action naming in the manner specified in paragraph 647, but the J&J Defendants deny that Plaintiffs are entitled maintain this action as alleged or to any relief against the J&J Defendants under Count VI.

648-651. The J&J Defendants deny the allegations in Paragraphs 648 through 651 TAMCC and subparts that pertain to them. To the extent the allegations in Paragraphs 648 through 651 of the TAMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

**COUNT VII
(CONSUMER PROTECTION LAWS – PURPORTED PHYSICIAN ADMINISTERED
CLASS FOR CONSUMERS AND TPPS)**

652. Answering Paragraph 652 of the TAMCC, the J&J Defendants reallege and incorporate their responses to the allegations in Paragraphs 1 through 651 of the TAMCC. The J&J Defendants admit that Plaintiffs purport to bring this action and to seek relief under Count VII of the TAMCC as alleged in Paragraph 652, but the J&J Defendants deny that Plaintiffs are entitled maintain this action as alleged or to any relief against the J&J Defendants under Count VII. The J&J Defendants deny the remaining allegations in Paragraph 652 of the TAMCC.

653. The J&J Defendants admit that Plaintiffs purport to bring this action and to seek relief under Count VII of the TAMCC as alleged in Paragraph 653, but the J&J Defendants deny that Plaintiffs are entitled maintain this action as alleged or to any relief against the J&J Defendants under Count VII.

654-656. The J&J Defendants admit that that Plaintiffs purports to bring this action naming the individuals or funds and in the manner specified in paragraphs 654 through 656, but

the J&J Defendants deny that Plaintiffs are entitled to maintain this action in the manner alleged or that the named individuals or funds are proper class representative.

657-659. The J&J Defendants deny the allegations in Paragraphs 657 through 659 TAMCC and subparts that pertain to them. The J&J Defendants aver that any assertion of this claim on behalf of a nationwide class is barred by Judge Saris' August 16, 2005 Order regarding class certification. To the extent the allegations in Paragraphs 657 through 659 of the TAMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

COUNT VIII (NOT PLED)

COUNT IX (CIVIL CONSPIRACY – PBMs)

660. Answering Paragraph 660 of the TAMCC, the J&J Defendants reallege and incorporate their responses to the allegations in Paragraphs 1 through 659 of the TAMCC.

661. The J&J Defendants admit that Plaintiff CMHV purports to bring this action as alleged in Paragraph 661 of the TAMCC, but the J&J Defendants deny that Plaintiff CMHV is entitled to maintain this action in the manner alleged or that CMHV is a proper class representative. The J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 661 of the TAMCC and, therefore, deny those allegations.

662-665. The J&J Defendants deny the allegations in Paragraphs 662 through 665 of the TAMCC and subparts that pertain to them. To the extent the allegations in Paragraphs 662 through 665 of the TAMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants are without knowledge

or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations.

666-667. The J&J Defendants deny the allegations in Paragraphs 666 through 667 of the TAMCC that pertain to them.

UNNUMBERED “WHEREFORE” PARAGRAPH AND REQUEST FOR JURY TRIAL

The J&J Defendants deny Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief and “WHEREFORE” paragraph following Paragraph 667 of the TAMCC.

DEFENSES

First Defense

Plaintiffs and the putative class fail to state a claim against the J&J Defendants upon which relief may be granted.

Second Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Third Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the filed rate doctrine.

Fourth Defense

Plaintiffs and the putative class have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of the J&J Defendants as alleged in the TAMCC.

Fifth Defense

To the extent Plaintiffs and/or any member of the putative class obtain recovery in any other case predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against the J&J Defendants based on the TAMCC pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

Sixth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitutions of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and any other States whose laws are or become relevant in the course of this multidistrict litigation.

Seventh Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by the J&J Defendants in judicial, legislative or administrative proceedings of any kind or at any level of government.

Eighth Defense

Plaintiffs and the putative class' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction or otherwise compromised their claims.

Ninth Defense

Any and all actions taken by the J&J Defendants with respect to any of the matters alleged in the TAMCC were taken in good faith and in accordance with established industry practice.

Tenth Defense

Plaintiffs and the putative class' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Eleventh Defense

Plaintiffs' and the putative class' claims are preempted by the dormant Commerce Clause of the United States Constitution.

Twelfth Defense

Plaintiffs' and the putative class' claims against the J&J Defendants are barred because the J&J Defendants have complied with all applicable regulations of the federal and state governments.

Thirteenth Defense

Plaintiffs' and the putative class' claims against the J&J Defendants are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

Fourteenth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because they violate the J&J Defendants' rights under the Due Process and *Ex Post Facto* clauses of the

United States Constitution, as well as all applicable state constitutions, insofar as Plaintiffs and the putative class members seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

Fifteenth Defense

The J&J Defendants' statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs or the putative class.

Sixteenth Defense

Plaintiffs and the putative class fail to state with particularity facts to support the fraud allegations, and fail to plead with particularity the fraudulent concealment and multi-source medicine allegations against the J&J Defendants contained in the TAMCC.

Seventeenth Defense

Plaintiffs and the putative class fail to allege with particularity their civil conspiracy claims against the J&J Defendants as required by Fed. R. Civ. P. 9(b).

Eighteenth Defense

Plaintiffs' and the putative class' claims against the J&J Defendants are barred, in whole or in part, because the J&J Defendants did not make any false statements to Plaintiffs or to any members of the putative class members. As to any statement asserted against the J&J Defendants that Plaintiffs and the putative class allege to be false or misleading, the J&J Defendants had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Nineteenth Defense

Plaintiffs' and the putative class' claims against the J&J Defendants are barred because the J&J Defendants did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

Twentieth Defense

Plaintiffs' and the putative class' RICO claims against the J&J Defendants are barred, in whole or in part, due to Plaintiffs' failure to properly allege a RICO enterprise as required by 18 U.S.C. § 1962(c).

Twenty-First Defense

Plaintiffs' and the putative class' RICO claims against the J&J Defendants are barred, in whole or in part, due to their failure to plead facts showing that the J&J Defendants and the PBMs are ongoing organizations whose members function as a continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981).

Twenty-Second Defense

Plaintiffs' and the putative class' RICO claims against the J&J Defendants are barred, in whole or in part, due to their failure to allege that the J&J Defendants conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).

Twenty-Third Defense

Plaintiffs and the putative class lack standing to bring their RICO claims against the J&J Defendants because they cannot show the J&J Defendants directly caused their alleged injuries as required by 18 U.S.C. § 1964(c) and *Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992).

Twenty-Fourth Defense

Plaintiffs' and the putative class' civil conspiracy claims against the J&J Defendants are barred, in whole or in part, by their failure to allege a concerted action as required by *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1564 (1st Cir. 1994) and *Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp. 2d 344, 359 (D. Mass. 2002), and/or by their failure to allege a coercive conspiracy as required by *Fleming v. Dance*, 22 N.E.2d 609, 611 (Mass. 1939).

Twenty-Fifth Defense

Plaintiffs' and the putative class' civil conspiracy claims against the J&J Defendants are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. *See Grant*, 183 F. Supp. 2d at 364.

Twenty-Sixth Defense

The J&J Defendants deny that Plaintiffs and the putative class have valid consumer protection claims against the J&J Defendants under California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington or any other State whose law is or becomes relevant in the course of this multidistrict litigation. However, if such claims are found to exist, the J&J Defendants pleads all available defenses under the Acts.

Twenty-Seventh Defense

Any allegedly fraudulent statements or conduct of the J&J Defendants did not directly or proximately cause the alleged injuries of Plaintiffs and/or any members of the putative class as required under state consumer protection laws, including without limitation those of Florida, Illinois, Louisiana, New Jersey, New York, Pennsylvania, Texas and Washington.

Twenty-Eighth Defense

The J&J Defendants' conduct was neither "deceptive," "misleading," "unlawful" nor "illegal" as required under certain state consumer protection laws, including without limitation those of Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Texas and/or Washington.

Twenty-Ninth Defense

To the extent that Plaintiffs and the putative class members attempt to seek equitable relief against the J&J Defendants, they are not entitled to such relief because they have an adequate remedy at law.

Thirtieth Defense

Plaintiffs and the putative class lack standing to bring their asserted consumer protection claims against the J&J Defendants under certain state consumer protection laws, including without limitation those of Delaware, Florida, Louisiana, New Jersey, Pennsylvania and Washington.

Thirty-First Defense

Plaintiffs and the putative class did not rely on the allegedly fraudulent statements or conduct of the J&J Defendants as required under certain state consumer protection laws, including without limitation those of New York and Pennsylvania.

Thirty-Second Defense

Any allegedly fraudulent statement or conduct of the J&J Defendants was not consumer-oriented as required under certain consumer protection law, including without limitation that of New York.

Thirty-Third Defense

Plaintiffs' and the putative class' claims against the J&J Defendants for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

Thirty-Fourth Defense

Plaintiffs' and the putative class' claims for injunctive relief against the J&J Defendants are barred by the doctrines of *in pari delicto* and/or unclean hands.

Thirty-Fifth Defense

This action cannot be maintained as a class action because (1) the certification and maintenance of this action as a class would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch; (2) the claims of Plaintiffs and the putative class cannot be properly joined with one another because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences; (3) the named Plaintiffs and the putative class cannot satisfy the procedural requirements of Fed. R. Civ. P. 23; (4) the questions of fact at issue are not common to the alleged class, but rather, are highly specific and will vary dramatically from person to person and entity to entity; and/or (5) class certification would violate the J&J Defendants' rights provided by the Fifth, Seventh and Fourteenth Amendments to the United States Constitution as well as by the Constitutions of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and any other States whose laws are or become relevant in the course of this multidistrict litigation, including but not limited to the J&J Defendants' right to procedural and substantive safeguards, which include traditional defenses to liability.

Thirty-Sixth Defense

Plaintiffs' and the putative class' antitrust claims against the J&J Defendants (1) are barred because they have not suffered any antitrust injury; (2) are barred in whole or in part for lack of standing; and/or (3) should be dismissed because the alleged conspiracy does not make economic sense and is economically implausible.

Thirty-Seventh Defense

Any alleged restraints complained of in the TAMCC are ancillary to legitimate, competitive activity.

Thirty-Eighth Defense

The J&J Defendants' conduct was not intended to have, did not have and was not likely to have had any adverse effects on competition in any relevant market.

Thirty-Ninth Defense

Plaintiffs' and the putative class' claims against the J&J Defendants under Section 1 of the Sherman Act, 15 U.S.C. § 1, are barred to the extent recovery is based on indirect purchases of medicines.

Fortieth Defense

Plaintiffs' and the putative class' antitrust claims against the J&J Defendants under the various state antitrust statutes are barred in whole or in part to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly interstate in nature.

Forty-First Defense

Plaintiffs' and the putative class' antitrust claims against the J&J Defendants under the various state unfair trade and competition statutes are barred in whole or in part to the extent

those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly intrastate in nature.

Forty-Second Defense

Plaintiffs' and the putative class' antitrust claims against the J&J Defendants under the various state consumer protection and consumer fraud statutes are barred in whole or in part to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly intrastate in nature.

Forty-Third Defense

Plaintiffs' and the putative class' antitrust claims against the J&J Defendants under the various state unfair trade, unfair competition, consumer protection and consumer fraud statutes are barred to the extent (1) those claims represent an impermissible circumvention of the states' antitrust statutes; and (2) those statutes apply only to deceptive or misleading conduct and/or govern only consumer transactions.

Forty-Fourth Defense

Third party payor Plaintiffs' and third party payor putative class members' claims against the J&J Defendants are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price on the ground that third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums, co-pays or other charges.

Forty-Fifth Defense

Plaintiffs' and the putative class' claims against the J&J Defendants are barred, in whole or in part, with respect to any alleged overcharge or supracompetitive price because such supracompetitive price, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members.

Forty-Sixth Defense

Plaintiffs' and the putative class' claims against the J&J Defendants are barred, in whole or in part, due to their failure to join indispensable parties.

Forty-Seventh Defense

Plaintiffs' and the putative class' claims against the J&J Defendants are barred, in whole or in part, because they have suffered no damages as a result of the matters alleged in the TAMCC.

Forty-Eighth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties.

Forty-Ninth Defense

Plaintiffs' and the putative class' claims against the J&J Defendants for damages are barred, in whole or in part, (1) because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to the J&J Defendants; (2) because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the TAMCC; (3) by the

doctrine of consent and/or ratification to the extent that Plaintiffs and/or putative class members have received and paid for medicines manufactured, marketed and sold by the J&J Defendants after the filing of Plaintiffs' original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

Fiftieth Defense

The J&J Defendants are entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs and/or the putative class, with respect to the same alleged injuries.

Fifty-First Defense

Any damages recovered by the Plaintiffs and the putative class from the J&J Defendants must be limited by the applicable statutory ceilings on recoverable damages.

Fifty-Second Defense

Plaintiffs and the putative class fail to allege facts or a cause of action against the J&J Defendants sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

Fifty-Third Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' punitive damages claims against the J&J Defendants: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the TAMCC are legally insufficient to support a claim for punitive damages against the J&J Defendants; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give the J&J Defendants prior notice of the conduct for which punitive damages may be imposed, and the severity of the penalty that may be imposed, and are void for vagueness in violation of the J&J Defendants' due process rights guaranteed by the Fifth and Fourteenth Amendments to the

United States Constitutions and the constitutions of any applicable states' laws; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate the J&J Defendants' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and applicable states' laws; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against the J&J Defendants for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of the J&J Defendants' medicines would constitute impermissible multiple punishments for the same wrong, in violation of the J&J Defendants' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law and statutory law of any applicable states' laws; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate the J&J Defendants' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' law; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according the J&J Defendants the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate the J&J Defendants' rights

guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' laws.

Fifty-Fourth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against the J&J Defendants cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of the J&J Defendants, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is not properly instructed regarding Plaintiff's and the putative class' burden of proof with respect to each and every element of a claim for punitive damages, and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate the J&J Defendants' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law and public policies of any applicable states' laws.

Fifty-Fifth Defense

To the extent punitive damages are sought, Plaintiff's and the putative class' claim for punitive damages against the J&J Defendants cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate the J&J Defendants' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate the J&J Defendants' right not to be subjected to an excessive award; and (3) be improper under the constitutions, common law and public policies of any applicable states' laws.

Fifty-Sixth Defense

The J&J Defendants adopt by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Fifty-Seventh Defense

The J&J Defendants hereby give notice that they intend to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. The J&J Defendants also reserve the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and/or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

WHEREFORE, the J&J Defendants demand that: (1) The Third Amended Master Consolidated Complaint be in all respects dismissed as to them; (2) That they be awarded their costs of defending this action, including their reasonable attorneys' fees; and (3) That they be awarded such other and further relief as the Court may deem just and proper.

Dated: New York, New York
November 3, 2005

Respectfully Submitted,

/s/ Andrew D. Schau

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Inc., and Ortho Biotech Products, L.P.

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of November, 2005, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to Verilaw Technologies successor entity LexisNexis File & Serve for posting and notification.

/s/ Andrew D. Schau

Andrew D. Schau