IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) IMPLANT PRODUCTS LIABILITY LITIGATION	*	Master Docket No. 1:17-md-02775
	*	JUDGE CATHERINE BLAKE
	*	
	*	**THIS DOCUMENT RELATES**
	*	**TO BHR TRACK CASES**

DEFENDANT SMITH & NEPHEW INC.'S
ANSWER TO MASTER AMENDED CONSOLIDATED COMPLAINT

Defendant, Smith and Nephew, Inc., ("S&N"), hereby files its Answer to Plaintiffs' Master Amended Consolidated Complaint ("MACC") [DE 124].[1]

INTRODUCTION

In the Memorandum and Order dated March 26, 2018 [DE 608] ("March 26, 2018 Order" or "Order"), 2018 U.S. Dist. LEXIS 49021 (D.Md. Mar. 26, 2018), this Court analyzed the MACC's allegations in light of principles of federal preemption and the pleading requirements of federal law. As relevant here, this Court explained that "[t]here is no doubt that the federal government has regulated the BHR system" and that "[a]s a Class III device it was subject to a rigorous approval process and continues to be regulated even after receiving premarket approval." Order at 13 (citing *Walker v. Medtronic, Inc.*, 670 F.3d 569, 572-74 (4th Cir. 2012)). The Court explained that "premarket approval is FDA recognition of a particular medical device's fitness for the market. Having received that approval, the BHR system cannot be labeled unreasonably dangerous by state law without imposing requirements on medical devices different from or in addition to federal regulations." Order at 15 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319

[1] The MACC was filed prior to the JPML's Order indicating that THA cases should also be included in the MDL. As such, it pertains only to BHR Track Cases.

(2008)). Although S&N has withdrawn certain BHR sizes for certain patient populations, this Court underscored the "critical" point that "only the FDA has the authority to withdraw approval from a device, and it did not do so here." Order at 5 n.5. Further, "[a] manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means." Order at 18. Likewise, the Court explained that "the FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information." Order at 15 (citing 21 U.S.C. § 360e(e)(1)(A)-(B)).

Applying these principles, the Court rejected efforts to defer a ruling on these threshold legal issues. It did so because its Order would "draw boundaries" by excluding claims that were preempted or inadequately pleaded and thus "guide future argument and discovery." Order at 10-11.[2] As a result, the Court dismissed "state tort law claims . . . that would require finding a device unreasonably dangerous [and] would undermine Congress's decision to leave such questions to the FDA." *Id*. at 15.[3] Further, the Court dismissed Plaintiffs' claims based upon manufacturing defect. *Id*. at 27. Finally, the Court ruled that aspects of Plaintiffs' surviving claims also were preempted to the extent that they imposed additional requirements on S&N or usurped FDA's role

[2] *See,* e.g., *Dorsey v. Shearin*, No. CIV.A. JKB-12-1243, 2013 WL 1975667, at *12 (D. Md. May 10, 2013) ("The claim will accordingly be dismissed without prejudice and respondent will not be required to file an answer regarding this claim."); *Roane v. Everbank*, No. 2:13-cv-1819-CWH, 2013 WL 4505415, at *2 (D.S.C. Aug. 22, 2013) (same); *Chivalry Film Prods. v. NBC Universal, Inc.*, No. 05-cv-05627(GEL), 2006 WL 89944, at *4 (S.D.N.Y. Jan. 11, 2006) ("Defendants will not need to answer allegations that are stricken; nor, of course, will they be required to answer claims that have been dismissed").

[3] Order at 2 ("The plaintiffs' two strict liability claims are preempted because they require the court to impose requirements on Smith & Nephew that differ from or add to FDA requirements."); *id.* at 14 ("The court will grant Smith & Nephew's motion to dismiss these two claims because finding a device unreasonably dangerous adds to or differs from federal requirements."); *id.* at 14 n.9 ("The reasoning in this section applies as well to any other cause of action that might require proof that the BHR device was unreasonably dangerous.").

within the statutory and regulatory scheme.[4] S&N submits this Answer to the MACC guided by the Court's Order drawing boundaries as to the scope of the claims in this MDL.

S&N'S ANSWER TO THE MACC'S ALLEGATIONS

In response to the individually-numbered paragraphs of the MACC, S&N responds as follows:

1. S&N admits that this MDL consolidates a number of products liability lawsuits in the District of Maryland, *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*, 1:17-md-2775. S&N admits that the MACC was filed "pursuant to Case Management Order 3." S&N denies that the Birmingham Hip Resurfacing ("BHR") System is "a dangerous and recalled metal-on-metal ('MOM') hip implant." S&N denies any and all remaining allegations contained in Paragraph 1.

2. S&N denies that it "designed, manufactured, and sold a dangerous and defective product, the Birmingham Hip Resurfacing System ("BHR") in the United States beginning in 2006." Indeed, the BHR System in the United States received pre-market approval ("PMA") from the United States Food and Drug Administration ("FDA") in May 2006, which established as a matter of federal law that the BHR is safe and effective. *See* March 26, 2018 Order at 15 ("[P]remarket approval is FDA recognition of a particular medical device's fitness for the market").

[4] Order at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"); *id.* at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations."); *id.* at 18 ("Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement."); *id.* at 23 n.15 ("To the extent the plaintiffs' adopt, or their underlying state failure to warn claims require, a fraud-on-the-FDA claim, that claim would be preempted under *Buckman*.").

3. S&N admits that plaintiffs seek compensation under various legal theories, but denies that S&N "is liable to Plaintiffs under state law claims" on any theory alleged. Many of the claims in the MACC are preempted by federal law, as set forth in the Court's March 26, 2018 Order. S&N denies any and all remaining allegations contained in Paragraph 3.

4. The allegations in Paragraph 4 concerning "FDA-mandated manufacturing practices and manufacturing defects in Plaintiffs' devices" relate to claims that have been dismissed by the Court's March 26, 2018 Order, such that no response regarding such allegations is required. *See* March 26, 2018 Order at 27 ("plaintiffs' manufacturing defect claim will be dismissed"). To the extent a further response is required, S&N denies the allegations of Paragraph 4. Contrary to the allegations of Paragraph 4, many of the claims in the MACC have been held to be preempted, as set forth in the Court's March 26, 2018 Order. Further, the FDA has never revoked or withdrawn BHR System's PMA-approval or its finding that the BHR System is reasonably safe and effective for its intended use. *See* March 26, 2018 Order at 5 n.5.

5. S&N denies the allegations of Paragraph 5. Contrary to Plaintiffs' allegations, the Court has ruled that federal law does preempt certain state law under these circumstances in the Court's March 26, 2018 Order.

6. S&N lacks knowledge or information sufficient to form a belief about the truth of Plaintiffs' allegations, and thus denies them. S&N further denies that any act or omission on its part is responsible for Plaintiffs' alleged injuries and damages, and denies any and all liability to Plaintiffs.

7. The allegations of Paragraph 7 are admitted.

8. S&N lacks knowledge or information sufficient to form a belief about the truth of Plaintiffs' allegations regarding complete diversity of jurisdiction, and thus denies them. S&N

admits the amount in controversy for one or more of the Plaintiffs in this MDL exceeds the jurisdictional amount for federal diversity jurisdiction. To the extent this Paragraph states a legal conclusion, no response is required.

9. S&N admits that this Court has jurisdiction over S&N, that the Judicial Panel on Multidistrict Litigation established an MDL in this court pursuant to 28 U.S.C. § 1407, and that S&N has, at certain times, sold medical devices in this forum. S&N denies that it has "d[one] business . . . with some Plaintiffs in this case" as it does not sell medical devices to consumers directly. S&N denies any and all remaining allegations contained in Paragraph 9.

10. S&N admits that it is a medical technology company, and that it is a wholly owned subsidiary of Smith & Nephew plc, a public entity incorporated under the laws of England and Wales. S&N denies any and all remaining allegations contained in Paragraph 10.

11. S&N admits that it manufactures, distributes, markets and sells certain hip implant devices in the United States, that certain of those devices are used in total hip arthroplasty or resurfacing arthroplasty, and that certain of those implant devices relate to the acetabulum or femoral head. S&N also admits that its hip implant devices include the BHR System. S&N denies the remaining allegations contained in Paragraph 11, and specifically denies that it "recalled" the BHR System "due to high failure rates."[5]

[5] To the contrary, in June 2015, S&N contraindicated the BHR System in women and voluntarily removed 46 mm and smaller-sized femoral resurfacing heads and corresponding acetabular cups from the market as a result of data suggesting that female patients, male patients age 65 and older, and patients requiring smaller femoral head components were at a greater risk of early revision than other patients. The FDA classified the withdrawal as a recall in September 2015. The BHR System remains on the market for male patients younger than 65 years old with femoral resurfacing heads larger than 46 mm and corresponding acetabular cups. In those patients, the BHR System has received the highest rating from the Orthopedic Data Evaluation Panel, indicating that the BHR System has at least 10 years of strong performance and is in full compliance with the current NICE guidelines for orthopedic implants.

12. S&N admits that it manufactures, distributes, markets and sells certain joint replacement systems, and that, in May 2006, after receiving PMA approval from the FDA, S&N began selling the BHR System in the United States. S&N denies that any Plaintiff in this litigation received a BHR System before May 2006. S&N admits that the BHR System includes a resurfacing femoral head and a resurfacing acetabular cup. S&N denies any and all remaining allegations contained in Paragraph 12.

13. S&N admits that Plaintiffs purport to describe the differences between a resurfacing arthroplasty and a total hip arthroplasty, but denies that the summary contained in Paragraph 13 is complete. Further, S&N lacks knowledge or information sufficient to form a belief about the source or accuracy of the pictures included in Paragraph 13. S&N denies any and all remaining allegations contained in Paragraph 13.

14. S&N admits that Plaintiffs purport to describe the sizes, positioning, and articulation of BHR System components, but denies that the summary contained in Paragraph 14 is complete. S&N denies any and all remaining allegations contained in Paragraph 14.

15. S&N admits that its FDA-approved labeling identified risks associated with the BHR System to implanting surgeons. S&N denies the remaining allegations contained in Paragraph 15, and specifically denies that "toxic levels of metal ions in the patient's bloodstream also cause neurological and cardiac problems and organ failure."

16. S&N states that FDA-approved labeling describes the procedure for conversion of the BHR resurfacing surgery to a total hip arthroplasty. This revision procedure is a design feature approved by the FDA, and the allegations in Paragraph 16 and any other claims challenging the design features of the BHR system have been dismissed by this Court's March 26, 2018 Order,

such that no response to allegations regarding the same is required. *See supra* at 1-3 & nn. 2-4. To the extent a further response is required, the allegations of Paragraph 16 are denied.

17. S&N states that the procedure for revision of a BHR resurfacing surgery is described in the FDA-approved labeling, this revision surgery involves design aspects of the BHR System which were FDA-approved, and the allegations in Paragraph 17 and any other claims challenging design features, including the FDA-approved labeling, of the BHR System have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 17 ("Any claim . . . that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations."); *id.* at 18 ("Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement."). To the extent a further response is required, the allegations of Paragraph 17 are denied. S&N specifically denies that patients implanted with the BHR System "would generate extreme amounts of metal debris and metal particles," and that "younger, more active patients … were certain to need future revision of their BHR implant."

18. S&N admits that certain BHR System components were recalled in 2007, but lacks knowledge or information sufficient to form a belief about what Plaintiffs intend to mean by "labeling problems and other issues," and therefore denies all allegations regarding the same. S&N further denies that any Plaintiff in this MDL received any BHR System involved in these recalls or that these recalls affected any of these Plaintiffs in any way. S&N denies any and all remaining allegations contained in Paragraph 18.

19. The allegations of Paragraph 19 are denied. S&N specifically denies that the DePuy ASR metal-on-metal hip prosthesis recalled in August 2010 "confirm[ed] … the dangers" of the BHR System. S&N further denies that Plaintiffs' description of the referenced article by Underwood, et al., *A Comparison of Explanted Articular Surface Replacement and Birmingham Hip Resurfacing Components,* J. Bone Joint Surg. 2011 Sep.; 93(9); 1169-77, is accurate or complete.[6]

20. This Court's March 26, 2018 Order dismissed any claims for alleged "failure to recall or remove" the BHR System from the U.S. market, such that no response is required. *See* March 26, 2018 Order at 15 ("[T]he FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information"); *id.* at 14 n.9 ("The reasoning in this section applies as well to any other cause of action that might require proof that the BHR device was unreasonably dangerous."). To the extent a further response is required, S&N admits that certain metal-on-metal device implants have been removed from the U.S. market, but denies the remaining allegations contained in Paragraph 20. Answering further, the performance of the metal-on-metal hip implants referenced in Paragraph 20 was not the same as the BHR System. Furthermore, the FDA was aware of the data on metal-on-metal hip implants, including those of the other manufacturers referenced in Paragraph 20, as well as the performance of the BHR System, and has never revoked Smith & Nephew's PMA-approval or its finding that the BHR System is reasonably safe and effective for its intended use.

[6] While the article speaks for itself, it notably contains findings that refute Plaintiffs' assertion that the ASR and BHR System implants have "similar dangers." These include: (1) the DePuy ASR implant had a failure rate of 12% at 5 years compared with 4.3% for the BHR System; (2) the ASR implant had a significantly increased rate of wear of the acetabular component and a significantly increased occurrence of edge loading compared to the BHR, which could be attributed to differences in design between the ASR and BHR, and (3) differences in design between the ASR and BHR Systems may provide the explanation as to why the ASR is more sensitive to suboptimal positioning than the BHR.

21. The allegation that S&N "failed to notify physicians and patients" seeks to impose a state law obligation to issue additional warnings for the BHR System, a claim that was dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement"). To the extent a further response is required, S&N admits that in June 2015, S&N voluntarily removed BHR femoral head sizes for women and for men 65 years or older or requiring femoral head sizes of 46 mm or smaller from the U.S. Market. S&N denies the remaining allegations contained in Paragraph 21, and specifically denies that "metal ion testing, imaging, and [unspecified] other conservative measures" were necessary or appropriate, and the FDA has never suggested such procedures for asymptomatic patients.

22. The allegations of Paragraph 22 relate to failure to recall and failure to warn claims that have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 5 n.5 ("[O]nly FDA has the authority to withdraw approval from a device, and it did not do so here"); *id.* at 15 ("[T]he FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information"). To the extent a further response is required, the allegations of Paragraph 22 are denied except to admit that in November 2014, S&N issued an Urgent Field Safety Notice regarding the possibility for early revision in some patient population groups. S&N specifically denies that Plaintiffs' description or characterization of the Urgent Field Safety Notice is accurate or complete. The statements in that document speak for themselves and no further response is necessary.

23. Any claims based on the allegation that S&N "should have recalled the BHR long before September 2015" have been dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 5 n.5; *id.* at 15. To the extent a further response is required, the allegations of Paragraph 23 are denied. The FDA has never revoked or withdrawn its PMA-approval of the BHR System or its finding that the BHR System is reasonably safe and effective for its intended use. *Id.*

24. This Court's March 26, 2018 Order has dismissed any challenges to the safety of the BHR System, to the warnings that accompanied the BHR System and any claims that assert that additional warnings or information should have been provided to the medical community or patients. *See* March 26, 2018 Order at 16 n.10, 17, 18. As such, no response to allegations regarding the same is required. To the extent a further response is required, the allegations of Paragraph 24 are denied.

25. This Court's March 26, 2018 Order has dismissed any challenges to the adequacy of any of the information in "the product labeling, patient information sheet, and instructions for use ('IFU') of the BHR," such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 25 are denied.

26. This Court's March 26, 2018 Order has dismissed any challenges to the safety of the BHR System, to the warnings that accompanied the BHR System and any claims that assert that additional warnings or information should have been provided to the medical community or patients. *See* March 26, 2018 Order at 16 n.10, 17, 18. As such, no response is required. To the extent a further response is required, the allegations of Paragraph 26 are denied.

27. Claims based on allegations that S&N represented that the "BHR Hip allows surgeons to resurface your joint with a safe and effective metal implant," and any similar

allegations, have been dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."). To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about what was represented to unspecified patients or Plaintiffs in an unidentified communication, and therefore denies all allegations contained in this Paragraph.

28. Any claims based on the alleged representation that the "BHR was actually safe" are supported by FDA's approval of the BHR system and have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. Order at 15 ("[P]remarket approval is FDA recognition of a particular medical device's fitness for the market. Having received that approval, the BHR system cannot be labeled unreasonably dangerous by state law without imposing requirements on medical devices different from or in addition to federal regulations"). To the extent a further response is required, the allegations of Paragraph 28 are denied.

29. S&N lacks knowledge or information sufficient to form a belief about whether the "outsert" described in Paragraph 29 "actually was viewed and did influence [any] Plaintiffs," and Plaintiffs have not identified any particular Plaintiffs who claim to have seen or been influenced by it, and S&N therefore denies all allegations regarding the same. Answering further, approximately 80% of the current Plaintiffs in this MDL were implanted with the BHR System before the April 2011 circulation date shown on the bottom right hand corner of the "outsert," and S&N therefore specifically denies that the "outsert" "actually was viewed and did influence" any of those Plaintiffs. S&N denies any and all remaining allegations contained in Paragraph 29.

30. The allegations of Paragraph 30 are denied. Further answering, S&N incorporates its answer to Paragraph 29. Moreover, the Court's March 26, 2018 Order dismisses Plaintiffs' strict liability claims, manufacturing defect claims, and limits the scope of Plaintiffs' other claims. *See supra* at 1-3 & nn.2-4.

31. The allegations of Paragraph 31 are denied.

32. The allegations of Paragraph 32 state legal conclusions which do not require a response. To the extent a further response is required, S&N states that it has been "truthful . . . about the safety of the BHR." S&N denies that Plaintiffs accurately and completely describe "dut[ies] under the laws of the various states," and denies any and all remaining allegations contained in Paragraph 32.

33. The allegations of Paragraph 33 state legal conclusions that do not require a response. Further answering, any claim based on an allegation that S&N had a duty to disclose additional information to "Plaintiffs, Plaintiffs' surgeons and the medical community" seek to impose additional state law requirements on S&N. This and any similar claims have been dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N denies any and all remaining allegations contained in Paragraph 33.

34. The allegations of Paragraph 34 state legal conclusions that do not require a response. Further answering, any claim based on allegations that S&N had a duty to provide additional information "about the safety of the BHR" has been dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 17. To the extent a further response is required, S&N denies any and all remaining allegations contained Paragraph 34.

35. The allegations of Paragraph 35 state legal conclusions which do not require a response. To the extent a further response is required, S&N states that it has been truthful in all respects to the FDA about the safety of the BHR. S&N further denies that private Plaintiffs can enforce "a duty to be truthful" allegedly owed to the FDA about the safety of the BHR. Any such claims are preempted. *See* March 26, 2018 Order at 23 n.15 ("To the extent the plaintiffs adopt, or their underlying state failure to warn claims require, a fraud-on-the-FDA claim, that claim would be preempted under *Buckman*"). S&N denies any and all remaining allegations contained in Paragraph 35.

36. The allegations of Paragraph 36 state legal conclusions which do not require a response. To the extent a further response is required, S&N denies that it failed to provide all required facts to the FDA. S&N further denies that private Plaintiffs can enforce any duties allegedly owed to the FDA. Any claims based on breach of an alleged duty to provide material facts to the FDA are preempted. *See* March 26, 2018 Order at 23 n.15 ("To the extent the plaintiffs adopt, or their underlying state failure to warn claims require, a fraud-on-the-FDA claim, that claim would be preempted under *Buckman*"). S&N denies any and all remaining allegations contained in Paragraph 36.

37. The allegations of Paragraph 37 are denied.

38. The allegations of Paragraph 38 relate to claims that have been dismissed by the Court's March 26, 2018 Order, and therefore no response is required. Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). Any and all claims based on alleged representations "that the BHR was safe" are preempted. *Id.* To the extent a further response is

required, S&N denies any misrepresentations to any Plaintiff, and denies any and all remaining allegations contained in Paragraph 38.

39. To the extent the allegations contained in this Paragraph relate to alleged design issues with the BHR System, they have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. To the extent a further response is required, the allegations of Paragraph 39 are denied.

40. Any claims based on the allegation that S&N should have withdrawn the BHR System from the market have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 5 n.5 ("[O]nly FDA has the authority to withdraw approval from a device, and it did not do so here"); *id.* at 15 ("[T]he FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information"). To the extent a further response is required, the allegations of Paragraph 40 are denied.

41. S&N denies that it made any false or misleading claims to the "general public, the medical community and to Plaintiffs in particular." S&N admits that Plaintiffs purport to describe in part certain referenced press releases, but denies that those descriptions are accurate or complete, and further denies that they were "false and misleading." Plaintiffs' claim that Smith & Nephew misrepresented that the BHR device was safe for its intended use is preempted by federal law. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). S&N denies any and all remaining allegations contained in Paragraph 41.

42. S&N lacks knowledge or information sufficient to form a belief about what was "told" at unspecified times in an unspecified manner to unspecified "patients and the medical

community," and therefore denies all allegations regarding the same. Furthermore, hip implants using ceramic materials do present a higher risk of fracture than the BHR System. S&N denies any and all remaining allegations contained in Paragraph 42.

43. S&N lacks knowledge or information sufficient to form a belief about what was "told" at unspecified times in an unspecified manner to unspecified "patients and the medical community," and therefore denies all allegations regarding the same. Further answering, hip implants using ceramic materials can generate greater wear than the BHR System. S&N denies any and all remaining allegations contained in Paragraph 43.

44. S&N lacks knowledge or information sufficient to form a belief about what was "told" at unspecified times in an unspecified manner to unspecified "patients and the medical community," and therefore denies all allegations regarding the same. Answering further, cobalt and chromium ions are measured in microns, a billionth of a liter. Human beings do have cobalt and chromium in their body; they are necessary ingredients in a human's biochemistry. Cobalt and chromium are filtered through a person's kidneys. These statements are further described and corroborated in the FDA-approved labeling for the BHR System, and statements consistent with FDA-approved labeling are not actionable under the Court's Order. S&N denies any and all remaining allegations contained in Paragraph 44.

45. S&N lacks knowledge or information sufficient to form a belief about what was "told" at unspecified times in an unspecified manner to unspecified "patients and the medical community," and therefore denies all allegations regarding the same. Answering further, cobalt and chromium ions are measured in microns, a billionth of a liter. The release rates cited in Paragraph 45 of "3-5 microns … initially" and "only a few microns per year" thereafter are supported by literature cited in the FDA-approved label, and statements consistent with FDA-

approved labeling are not actionable under the Court's Order. S&N denies any and all remaining allegations contained in Paragraph 45.

46. S&N admits that Plaintiffs purport to describe an April 2011 patient information sheet, but denies that the description of its contents is accurate or complete. S&N denies any and all remaining allegations contained in Paragraph 45.

47. S&N lacks knowledge or information sufficient to form a belief about what was represented to unspecified "patients and the medical community," and therefore denies all allegations regarding the same. Further, the risk of pseudotumors was disclosed in the FDA-approved label before the April 2011 patient information sheet was released. S&N denies any and all remaining allegations contained in Paragraph 47.

48. S&N lacks knowledge or information sufficient to form a belief about what was represented at an unspecified time in an unspecified manner to unspecified "patients and the medical community," and therefore denies all allegations regarding the same. Answering further, the patient information sheet quoted at Paragraph 29 (MACC at 10) states that the BHR System "may" last longer "than a total hip replacement made from traditional materials." The FDA-approved labeling in effect at the time of the April 2011 patient information sheet cites comparative studies showing BHR System revision rates that are comparable to or better than hip implants using ceramic or polyethylene materials, and statements consistent with FDA-approved labeling are not actionable under the Court's Order. S&N denies any and all remaining allegations contained in Paragraph 48.

49. The allegations of Paragraph 49 are denied. Answering further, the allegations as stated are contradictory. Paragraph 49 states the S&N's "own testing show[s] that the BHR

generated far higher levels of chromium ion in patients compared to its own total hip replacement device," but the study cited in Paragraph 49 is described as showing exactly the opposite.

50. Any claims based on the allegation that S&N misrepresented "that the BHR was safe" have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). Further, any claims that S&N had to "correct[] this [allegedly] false impression or update[] patients on the real world data" seek to impose state law requirements in addition to those imposed by the FDA and are expressly preempted. Any such claims have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about what was represented at unspecified times in an unspecified manner to unspecified "patients and the medical community," and therefore denies all allegations regarding the same. Additionally, S&N lacks knowledge or information sufficient to form a belief about unspecified "flaws in the study's methodology," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 50.

51. S&N denies that any of the statements or information referred to in Paragraphs 51(a)-(g) are "false, misleading, and/or omit[] material information." S&N lacks knowledge or information sufficient to form a belief about what unspecified "patients and the medical community" were "pointed" to, and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 51, including all subparts.

52. S&N denies that it made unspecified "false and misleading representations" on its website or in any patient "outsert," and denies any and all remaining allegations contained in Paragraph 52.

53. S&N lacks knowledge or information sufficient to form a belief about what unspecified Plaintiffs "viewed," "received," or "rel[ied] upon," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 53.

54. S&N lacks knowledge or information sufficient to form a belief about what unspecified Plaintiffs viewed, were aware of, or relied upon, and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 54.

55. Any allegations that S&N misrepresented "the safety of the BHR" have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). To the extent a further response is required, the allegations of Paragraph 55 are denied.

56. Many of the allegations of Paragraph 56, (e.g., Paragraph 56(a) and (b)) challenge the safety and efficacy of the BHR and have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). Some of the allegations (e.g., 56(f)) were relied upon by the FDA in approving the BHR and cannot be challenged or impugned by private litigants. Some of the statements (e.g. 56(h)) are contradicted by the FDA-approved labeling which specifically warns of the possibility of reaction to metal. Some of the allegations (e.g., 56(m)) refer to design features approved by the FDA; this and any similar design claims have

been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See supra* 1-3 & nn.2-4. To the extent a further response is required, the allegations of Paragraph 56, including all subparts, are denied.

57. Any claims based on alleged misrepresentations that "the BHR was safe" have been dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18. To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about unspecified statements that were allegedly made to the "medical community" and unspecified patients, and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 57.

58. The allegations of Paragraph 58 are denied.

59. Any claims based on alleged statements regarding the "safety of the BHR" have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 18. In addition, any claims based on allegations that S&N should have provided additional information regarding the BHR are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See id.* at 16 n.10, 17, 18. To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about what statements were made to unspecified "surgeons and the medical community," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 59.

60. Any allegations that S&N misrepresented "the safety of the BHR" have been dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26,

2018 Order at 18. To the extent a further response is required, the allegations of Paragraph 60 are denied.

61. Any claim that S&N should have disclosed to patients or physicians that Dr. McMinn allegedly believed that the resurfacing procedure had a "1,000 patient learning curve" is expressly preempted and has been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N admits that Plaintiffs purport to describe and characterize a 2011 surgical technique document, but denies that the description and characterization is accurate or complete. Answering further, the FDA-approved the language "uncomplicated procedure," and any claim that S&N should have disclosed to the FDA that Mr. McMinn allegedly believed that the procedure had a "1,000 patient learning curve" is preempted. S&N denies any and all remaining allegations contained in Paragraph 61.

62. The allegations of Paragraph 62 are denied except to admit the contents of the "Apples to Oranges" document reproduced in Paragraph 62.

63. Any claims based on the allegation that Smith & Nephew had an obligation to "update the medical community" seek to impose state law duties in addition to federal requirements, are expressly preempted, and have been dismissed by the Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about an unspecified "study," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 63.

64. S&N lacks knowledge or information sufficient to form a belief about what was sent to unspecified surgeons, and therefore denies all allegations regarding the same. S&N admits that Plaintiffs purport to describe and characterize an unspecified 2010 "letter," but denies that the description and characterization is accurate or complete. Answering further, all of the statements in Paragraph 64 (a)-(f) are contained in a 2008 document from the MHRA's Expert Advisory Group ("EAG"). In other Paragraphs of the MACC, Plaintiffs deny that S&N ever provided any information from the MHRA to Plaintiffs, so the MACC is internally inconsistent. S&N denies any and all remaining allegations contained in Paragraph 64, including subparts.

65. Any claims based on allegations that S&N misrepresented that "BHR is safe" have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). Any claims based on allegations that S&N should have issued additional warnings or information to physicians are expressly preempted and have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *Id.* at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 65 are denied.

66. The allegations of Paragraph 66 are denied.

67. To the extent Paragraph 67 contends S&N should have issued additional warnings to "surgeons, the medical community and patients," the claim is expressly preempted and has been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N admits that it notified the FDA of MHRA guidance in 2011. Answering further,

alleged failures to communicate with the FDA are impliedly preempted. Furthermore, Paragraph 67 is based on allegations that S&N should have issued additional warnings regarding metal ion testing, but FDA has never suggested that such metal ion testing be performed in asymptomatic patients. S&N denies any and all remaining allegations contained in Paragraph 67.

68. Any claims based on allegations that S&N should have provided additional information to surgeons beyond that contained in the FDA-approved labeling are expressly preempted and have been dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, neither Paragraph 68 nor the remainder of the MACC identifies "previous MHRA information" that S&N allegedly provided in "Dear Doctor letters." The MACC also alleges that S&N never sent any MHRA information to physicians, so it is internally inconsistent. S&N lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 68, and therefore denies the same.

69. Any claims based on allegations that S&N represented that "the BHR was safe" have been dismissed by this Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about what was represented to unspecified physicians and patients, and therefore denies all allegations contained in this Paragraph of the MACC.

70. Any claims that S&N should have disclosed additional information to Plaintiffs or their surgeons are expressly preempted and have been dismissed by this Court's March 26, 2018

Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 70 are denied.

71. Any claims based on the alleged representation that "the BHR was safe" have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). Further, any claims based on the allegation that S&N should have provided to surgeons and the medical community additional information beyond that in the FDA-approved labeling are also expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 71 are denied.

72. Any claims based on the "safety of the BHR" have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). To the extent a further response is required, the allegations of Paragraph 72 are denied except to admit that S&N ran an advertisement in the Journal of Bone and Joint Surgery in 2010, which speaks for itself.

73. S&N admits that Plaintiffs purport to describe and quote from a 2010 Journal or Bone and Joint Surgery ("JBJS") advertisement, but denies that it made any "representations that were false, misleading, and/or omitted material information," and therefore denies all remaining allegations contained in Paragraph 73, including subparts.

74. Any claims based on allegations that S&N represented that "the BHR was safe" have been dismissed by the Court's March 26, 2018 Order, such that no response to allegations

regarding the same is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). To the extent a further response is required, the allegations of Paragraph 74 are denied.

75. Any claims that S&N should have provided the "medical community" additional information beyond that in the FDA-approved labeling are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about unspecified "new findings" in unidentified "literature and clinical studies," or about what was communicated to unspecified members of the "medical community," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 75.

76. Any claims based on allegations that S&N "misrepresented the safety of the BHR" have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18. Any claims based on allegations that S&N should have provided additional information to surgeons beyond that contained in the FDA-approved labeling are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See id.* at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 76 are denied. Answering further, Paragraph 76 does not identify "other studies" or "the truth about these [unspecified] studies" that allegedly should have been provided to physicians.

77. Any claims based on allegations that S&N should have provided additional information to surgeons beyond that contained in the FDA-approved labeling are expressly

preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 77 are denied.

78. Any claims based on allegations that S&N represented "that the BHR was safe" have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("[A] manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."). To the extent a further response is required, the allegations of Paragraph 78 are denied.

79. Any claims based on the allegations that S&N should have provided additional information beyond that in the FDA-approved labeling are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 79 are denied. Answering further, Paragraph 79 mischaracterizes S&N's statements in the Journal of Bone and Joint Surgery cited in Paragraph 73. Paragraph 79 does not identify any of the "numerous studies" allegedly published by Dr. Langton or explain their significance.

80. The allegations of Paragraph 80 are denied.

81. Any allegation that S&N had to "warn of the high learning curve for surgeons" and S&N's alleged reliance on inventor-surgeon data are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or

differ from federal regulations."). To the extent a further response is required, the allegations of Paragraph 81 are denied.

82. Any claims based on allegations that S&N should have provided additional information beyond that in the FDA-approved label are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about unspecified "critici[sm]" by unidentified "researchers," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 82.

83. S&N admits that in 2010, the JBJS published an article by Langton, et al., called *Adverse Reaction to Metal Debris Following Hip Resurfacing*, and admits that Plaintiffs purport to characterize and quote from that article, which speaks for itself, but S&N denies that Plaintiffs' characterizations and quotations are accurate and complete.[7] S&N denies any and all remaining allegations contained in Paragraph 83.

84. Any claims based on the allegations that S&N should have provided additional information to surgeons beyond that contained in the FDA-approved labeling are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N admits that data from McMinn and Treacy shows high survival rates for the BHR at 5 years. S&N lacks knowledge or information sufficient to form a belief about what was

[7] Answering further, the article cited in Paragraph 83 finds that the ASR implant manufactured by DePuy had a 9.8% failure at 5 years; the Conserve implant manufactured by Wright had a less than 1% failure rate at 5 years; and BHR had a 1.5% revision rate at 10 years. The article further states that problems with positioning hip implants have been known since at least 1998. The article states that "when exposed to low levels of wear, most patients with a resurfaced hip do extremely well." The Langton article supports BHR use.

"disclose[d]" to unspecified individuals, and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 84.

85. Any claim based on the allegation that S&N should have disclosed the "learning curve of implanting the BHR as 1,000 surgeries" is expressly preempted and has been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about a "descri[ption]" allegedly made by McMinn, and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 85.

86. Any claims based on alleged failure to conduct post-approval studies are expressly and impliedly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response regarding such allegations is required. *See supra* at 1-3 & nn.2-4. Any claims based on allegations that S&N "misle[d] the medical community about the safety of the BHR" are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response regarding such allegations is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 86 are denied.

87. S&N admits that Plaintiffs purport to characterize and quote a 2012 article in International Orthopaedics, but denies that the characterization and quotation are accurate and complete. The article cited in Paragraph 87, which speaks for itself, states that: "the BHR arthroplasty device shows good results in terms of revision rate in register data as well as in clinical studies." While the authors note that the original surgeons had better revision rates, the rates for surgeons who were not designers were also "good." S&N denies any and all remaining allegations contained in Paragraph 87.

88. S&N admits that Plaintiffs purport to describe and characterize a study published in 2012, but denies that the description and characterization is accurate and complete. The Holland study, which speaks for itself, points to a revision rate in females and smaller femoral heads that had been in the FDA-approved label since 2010. S&N denies any and all remaining allegations contained in Paragraph 88.

89. S&N admits that Plaintiffs purport to characterize and quote from a study published in 2012, but denies that the characterization and quotation is accurate and complete. While Paragraph 89 refers to "seven out of eight revision surgeries in revision patients" six of the eight involved DePuy's ASR implant, not the BHR. S&N denies any and all remaining allegations contained in Paragraph 89.

90. Any claims based on the alleged representation that "the BHR was safe" have been dismissed by the Court's March 26, 2018 Order, such that no response is required. Further, any claims that S&N should have provided additional information to "the medical community, patients and Plaintiffs" are expressly preempted and have also been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 90 are denied. S&N provided all of the cited studies to the FDA.

91. S&N lacks knowledge or information sufficient to form a belief about an unidentified and unspecified "disparity in revision rates between these groups of patients," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 91.

92. S&N admits that Plaintiffs purport to describe and characterize the study referenced in Paragraph 92, but denies that the description and characterization is accurate and complete. S&N denies any and all remaining allegations contained in Paragraph 92.

93. S&N admits that Plaintiffs purport to describe and characterize the study referenced in Paragraph 93, but denies that the description and characterization is accurate and complete. S&N denies any and all remaining allegations contained in Paragraph 93.

94. Plaintiffs' allegation that S&N omitted that the "BHR was not safe" is preempted by federal law, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."). Allegations that S&N was required to provide additional information to the medical community likewise is preempted, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 94 are denied, including all subparts.

95. The allegations of Paragraph 95 are denied.

96. S&N lacks knowledge or information sufficient to form a belief about what unspecified "[a]dditional discovery" will "produce," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 96.

97. The allegations of Paragraph 97 are denied.

98. Any claims based on allegations that "the BHR was not safe" are preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."). Any

claims based on the allegation that S&N should have withdrawn the smaller head sizes of the BHR System earlier are expressly and impliedly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 5 n.5 ("Only the FDA has the authority to withdraw approval from a device, and it did not do so here."); *id.* at 15 ("the FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information"). To the extent a further response is required, the allegations of Paragraph 98 are denied.

99. S&N admits that Plaintiffs purport to describe and characterize data referenced in Paragraph 99, but denies that the description and characterization is accurate and complete, and S&N denies any and all remaining allegations contained in Paragraph 99. S&N specifically denies that the BHR had an "unreasonably high risk of premature failure for certain patient populations as early as 2007."

100. S&N admits that Plaintiffs purport to describe and characterize the study referenced in Paragraph 100, but denies that the description and characterization is accurate and complete. Furthermore, S&N provided the study cited in Paragraph 100 to the FDA. S&N denies any and all remaining allegations contained in Paragraph 100.

101. Any claims based on allegations regarding "the BHR's supposed safety" are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. Any claim based on the allegation that S&N should have disclosed the results of articles to "the medical community or patients" is preempted and has been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N admits that Plaintiffs purport to characterize and quote the article referenced in Paragraph

101, but denies that the characterization and quotation is accurate and complete. S&N lacks knowledge or information sufficient to form a belief about what was communicated to unspecified members of the "medical community" and unidentified "patients and Plaintiffs," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 101.

102. "Any claim . . . that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations." March 26, 2018 Order at 17. Any claim that S&N should have withdrawn smaller component sizes of the BHR System from the market earlier are expressly and impliedly preempted and have been dismissed by the Court's March 26, 2018 Order. *See* March 26, 2018 Order at 5 n.5 ("Only the FDA has the authority to withdraw approval from a device, and it did not do so here"); *id.* at 15 ("the FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information"). Accordingly, no further response is required. To the extent a further response is required, the allegations of Paragraph 102 are denied except to admit that on September 10, 2015, there was a Class II recall of smaller femoral head sizes and related acetabular cup sizes of the BHR System. S&N specifically denies that it made any incomplete or misleading disclosures to the "public and Plaintiffs."

103. S&N admits that Plaintiffs purport to describe a 2012 FDA Advisory Panel meeting, but denies that the description is accurate and complete. Further, "[a]ny claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as

an attempt to impose requirements that add to or differ from federal regulations." March 26, 2018 Order at 17. S&N denies any and all remaining allegations contained in Paragraph 103.

104. S&N admits that "survivorship" refers to the inverse of "revision," but denies any and all remaining allegations contained in Paragraph 104.

105. S&N admits that Plaintiffs purport to describe and characterize data referenced in Paragraph 105, but denies that the description and characterization is accurate and complete. Paragraph 105 refers to 397 "device problems" and states that there were 356 "reportable complaints" during a particular time period, but "a device problem" is not equivalent to a reportable complaint. S&N denies any and all remaining allegations contained in Paragraph 105, and specifically denies that "[n]umerous complaints also were not lodged with the FDA until six months or longer after [S&N] received them" and that "in some cases they were not logged until several years later."

106. S&N admits that Plaintiffs purport to describe and characterize data referenced in Paragraph 106, but denies that the description and characterization is accurate or complete. S&N expressly denies that it "failed to actively report or conduct follow-up investigations, for more than half of these safety problems to the FDA." The allegations that there was "no code available" for 64 of the incidents and that 153 incidents stated "no information" does not signify that there was an inadequate or improper investigation in violation of federal requirements. S&N denies any and all remaining allegations contained in Paragraph 106.

107. The allegations of Paragraph 107 are denied. S&N specifically denies that it "failed to report the risk of metallosis and its adverse events to the FDA," and notes that the risk of "metallosis" has been warned of in the FDA-approved BHR labeling since the BHR went on the market in May 2006. S&N also specifically denies that it "went to great lengths to blame device

failures on other sources," that Paragraph 107's subparts support any alleged "great lengths," or that S&N "avoided responsibility" for the BHR's risks. Further, neither Paragraph 107 nor any other Paragraph of the MACC states any facts indicating that any of the reports referred to in Paragraph 107(a)-(f) were incorrect or inaccurate. S&N denies any and all remaining allegations contained in Paragraph 107, including all subparts.

108. S&N denies that it "tried to hide the true cause of the BHR's failure rate." S&N admits that Plaintiffs purport to describe and characterize data compiled by the National Joint Registry of England and Wales, but denies that the description and characterization is accurate and complete. Further, the National Joint Registry of England and Wales data cited in Paragraph 108 was provided to the FDA. S&N denies any and all remaining allegations contained in Paragraph 108.

109. The allegations of Paragraph 109 are denied for lack of information sufficient to justify a belief, as the Paragraph does not identify the "separate study of the BHR device" supposedly referred to.

110. The allegations of Paragraph 110 are denied.

111. The FDA required S&N to report 5-year survivorship rates, and state law cannot add to or modify this requirement. Any claims that S&N should have provided additional information beyond that contained in the FDA-approved labeling are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ

from federal regulations."). To the extent a further response is required, the allegations of Paragraph 111 are denied.

112. Paragraph 112 does not identify any of the "many studies" that allegedly have "huge decreases in follow up after 5 years." S&N therefore lacks knowledge or information sufficient to form a belief about any such studies, and denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 112.

113. Any claims based on allegations that S&N should have "provide[d] updates from medical authorities concerning the safety of the BHR device" are preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of 113 are denied.

114. The allegations of 114 are denied.

115. The allegations of 115 are denied. *See also supra* at 1-3 nn.2-4 (explaining that Court dismissed certain claims and limited other remaining claims).

116. Any claims based on an alleged failure to withdraw the BHR System is preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 5 n.5 ("Only the FDA has the authority to withdraw approval from a device, and it did not do so here."); *id.* at 15 ("the FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information"). To the extent a further response is required, S&N admits that, pursuant to FDA approval, it continues to sell certain BHR components for use in certain patient populations, and that certain other hip implants have been recalled or removed from the U.S. market. S&N denies any and all remaining allegations contained in Paragraph 116.

117. S&N admits that Plaintiffs purport to describe and characterize the Committee on Safety of Devices and October 2006 minutes of the Expert Advisory Group, but denies that the description and characterization is accurate and complete. S&N denies any and all remaining allegations contained in Paragraph 117.

118. S&N admits that Plaintiffs purport to describe and characterize an analysis by the Australian Register of Therapeutic Goods, but denies that the description and characterization is accurate and complete. S&N denies any and all remaining allegations contained in Paragraph 118.

119. Any claims based on an allegations that S&N should have provided additional information to surgeons beyond that in the FDA-approved labeling are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, and no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17. To the extent a further response is required, S&N admits that Plaintiffs purport to describe and characterize the report referenced in Paragraph 119, but denies that the description and characterization is accurate or complete.[8] Additionally, neither Paragraph 119 nor any other Paragraph in the MACC identify the alleged "early advertising and communications to surgeons relying on the MHRA to show the BHR's safety" referred to in Paragraph 119, other portions of the MACC deny that S&N provided any MHRA information to surgeons, so the MACC is internally inconsistent, and S&N lacks knowledge or information sufficient to form a belief about what was communicated to unspecified surgeons. Accordingly, S&N lacks knowledge or information sufficient to form a belief about the

[8] Plaintiffs mischaracterize EAG's findings by failing to acknowledge that: (1) There is no evidence of any association between hip replacements and increased incidence of any malignant disease; (2) There is no evidence that the genotoxic effects in patients with metal-on-metal hip replacements are associated with increased levels of cobalt and chromium ions; and (3) There is no evidence that increased levels of cobalt and chromium are associated with any clinical effect.

truth of the allegations contained in the last sentence of Paragraph 119, and therefore denies the same. S&N denies any and all remaining allegations contained in Paragraph 119.

120. The allegations of Paragraph 120 are denied because S&N lacks sufficient knowledge or information to form a belief about the truth of the allegations concerning Zimmer.

121. The allegations of Paragraph 121 are denied except to admit that the 2008 Australian registry information speaks for itself and is the best evidence of its content.

122. The allegations of Paragraph 122 are denied because S&N lacks sufficient information to form a belief about the truth of the allegations concerning the actions of Johnson & Johnson.

123. The allegations of Paragraph 123 are denied except to admit that the EAG minutes document speaks for itself and is the best evidence of its content.

124. Any claims based on allegations that S&N should have provided the April 20, 2010 NHRA report to unspecified surgeons is expressly preempted and has been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"). To the extent a further response is required, the allegations of Paragraph 124 are denied except to admit that the MHRA issued a medical device notice on April 22, 2010, the terms of which speak for themselves.

125. Any claim based on the allegation that S&N should have provided the MHRA May 25, 2010 report to unspecified surgeons is expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16

n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 125 are denied except to admit that the MHRA issued a medical device notice on May 25, 2010, the contents of which speak for themselves. Further, implantation instructions and follow-up with patients that received other hip implants are irrelevant to the BHR System.

126. S&N admits that in August 2010 DePuy recalled the ASR XL Acetabular Metal-on-Metal Device.

127. Any claim based on allegations that S&N should have provided information to unspecified surgeons in addition to that provided in the FDA-approved label are expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 127 are denied except to admit that in October 2010 the EAG released a report, the contents of which speak for themselves.[9] Additionally, neither Paragraph 127 nor any other Paragraph in the MACC identifies "early advertising to surgeons relying on the MHRA to show the BHR's safety" referenced in Paragraph 127, and S&N therefore lacks knowledge or information sufficient to form a belief about any such advertising and denies all allegations regarding the same.

128. Any claim that S&N should have provided additional information to unspecified surgeons beyond that contained in the FDA-approved labeling are expressly preempted and have

[9] Moreover, Paragraph 127 omits the following statements from the EAG report: (1) not all components [of metal-on-metal hip implants] are the same and all claims may differ; (2) current evidence suggests that soft tissue reactions are extremely rare in the absence of pain and deteriorating function; (3) Clinical studies have shown good results for stem/modular [metal-on-metal] hip replacements including revision rates comparable to metal-on-polyethylene and better than ceramic-on-ceramic; (4) Soft tissue reactions are "rare" but can occur in both male and female patients; (5) "Early analysis of the London Implant Retrieval Center ("LIRC") data has revealed that approximately one third of failures have a cup inclination greater than 50 degrees," and (6) Clinical outcome reports from non-inventor surgeons using the BHR System showed a 95.8% five-year survival rate.

been dismissed by the Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 128 are denied except to admit that the EAG issued an October 2010 report, the contents of which speak for themselves and are the best evidence of their contents. Additionally, neither Paragraph 128 nor any other Paragraph in the MACC identifies "early advertising to surgeons relying on the MHRA to show the BHR's safety" referenced in Paragraph 128, and S&N therefore lacks knowledge or information sufficient to form a belief about any such advertising and denies all allegations regarding the same.

129. The allegations of Paragraph 129 are denied except to admit that Matthies, et al. published a study in "The Bone & Joint Journal," the contents of which speak for themselves and are the best evidence of their contents.

130. The allegations of Paragraph 130 are denied except to admit that the FDA published a metal-on-metal hip implant web page in February 2011, the terms and conditions of which speak for themselves.

131. The allegations of Paragraph 131 are denied except to admit that on May 6, 2011, the FDA issued an order asking manufacturers of metal-on-metal hip implants to provide certain information to the FDA. The contents of the FDA's order speaks for itself.

132. Any claims that S&N should have provided the February 28, 2012 MHRA notice to unspecified surgeons is expressly preempted and have been dismissed by the Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10. 17, 18. To the extent a further response is required, the allegations of Paragraph 132 are denied except to admit that on February 28, 2012, the MHRA issued a medical device notice, the terms of which speak for themselves. Additionally, neither Paragraph 132 nor

any other Paragraph in the MACC identify the "early advertising and communications to surgeons relying on the MHRA to show the BHR's safety" referenced in Paragraph 132, and S&N therefore lacks knowledge or information sufficient to form a belief about any such advertising and denies all allegations regarding the same.

133. The allegations of Paragraph 133 are denied except to admit that on May 9, 2012, Health Canada issued a public health communication, the terms of which speak for themselves.

134. Any claim that S&N should have provided the June 25, 2012 MHRA update to unspecified U.S. surgeons is expressly preempted and has been dismissed by the Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 134 are denied except to admit that on June 25, 2012, the MHRA updated its previous medical device alert, the terms of which speak for themselves. The MHRA update also contains the following statement: "The majority of patients implanted with [metal-on-metal] hip replacements have well functioning hips and are thought to be at a low risk of developing serious problems." Additionally, neither Paragraph 134 nor any other Paragraph in the MACC identifies the "early advertising and communications to surgeons relying on the MHRA to show the BHR's safety" referenced in Paragraph 134, and S&N therefore lacks knowledge or information sufficient to form a belief about any such advertising and denies all allegations regarding the same.

135. The allegations of Paragraph 135 are admitted.

136. S&N lacks knowledge or information sufficient to form a belief about the purported reasons for Stryker's decision to recall metal-on-metal hip systems and thus denies all allegations regarding the same.

137. S&N lacks knowledge or information sufficient to form a belief about the allegations of paragraph 137 and therefore denies them.

138. S&N lacks knowledge or information sufficient to form a belief about whether a Senior Vice President made the specified statement, for which no source is identified, and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 138.

139. The allegations of Paragraph 139 are denied except to admit that on January 17, 2013, the FDA issued a safety communication regarding metal-on-metal implants, the terms of which speak for themselves.[10]

140. The allegations of Paragraph 140 are denied except to admit that on January 18, 2013, the FDA published a proposed rule requiring manufacturers of metal-on-metal hip implants to provide specified information to the FDA, the terms of which speak for themselves.

141. The allegations of Paragraph 141 are denied for lack of information sufficient to justify a belief.

142. The allegations of Paragraph 142 are denied except to admit that Bisschop, et al., published a study entitled *High Prevalence of Pseudotumors in Patients with a Birmingham Hip Resurfacing Prosthesis*, (J. Bone Joint Surg. Am. 2013) 4; 95(17). The contents of the study speak for themselves.

[10] Furthermore, the FDA's safety communication contains the following statements: (1) "Presently, the FDA does not have enough scientific data to specify the concentration of metal ions in a patient's body or blood necessary to produce adverse systemic effects;" (2) "The FDA does not believe there is a clear need to routinely check metal ion levels in the blood if the orthopedic surgeon feels the hip functioning properly and the patient is asymptomatic;" and (3) "At this time, the FDA is not recommending a specific metal ion level as a trigger for revision or other medical intervention;"

143. The allegations of Paragraph 143 are denied except to admit that Langton, et al., published a study in 2013 in BMJ Open 2013; 3:e001541. The terms of that study speak for themselves.

144. Any claim based on allegations S&N should have removed smaller component sizes of the BHR System from the market earlier than 2015 is preempted and has been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 5 n.5 ("Only the FDA has the authority to withdraw approval from a device, and it did not do so here"); *id.* at 15 ("[T]he FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information"). To the extent a further response is required, the allegations of Paragraph 144 are denied.

145. The allegations of Paragraph 145 are admitted.

146. The allegations of Paragraph 146 are denied.

147. Any claims based on the allegation that S&N had a "duty to update or continue to communicate MHRA actions that implicated the safety of the BHR" is expressly preempted and has been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"). To the extent a further response is required, the allegations of Paragraph 147 are denied.

148. The allegations of Paragraph 148 are denied.

149. The allegations of Paragraph 149 are denied.

150. The allegations of Paragraph 150 are denied except to admit that Mr. McMinn was a designing surgeon of the BHR System and that he had an ownership interest in Midland Medical Technologies ("MMT").

151. The allegations of Paragraph 151 are denied except to admit that S&N purchased MMT in 2003, that McMinn served, at certain times, as a consultant orthopedic surgeon to S&N, and that Mr. McMinn trained some surgeons in BHR implantation and contributed to BHR's surgical technique guide.

152. The allegations of Paragraph 152 are denied. Further, Mr. McMinn's "Make Resurfacing Great Again" marketing campaign does not involve an S&N product.

153. The allegations of Paragraph 153 are denied.

154. Any claims that challenge the statements in the "PMA for the BHR System" granted by the FDA have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 21 ("[A] plaintiff cannot pursue a claim alleging fraud-on-the-FDA for a defendant's failure to disclose information"). To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about the statement allegedly made by Dr. William Maloney, III, and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 154.

155. The Court dismissed any claims for "defective manufacture" of the BHR on March 26, 2018, such that no response is required. Any claim based on "problems with studies submitted to the FDA" are preempted, as Plaintiffs cannot challenge the FDA's PMA approval of the BHR System or reliance upon those studies. *See* March 26, 2018 Order at 21. To the extent a further response is required, the allegations of Paragraph 155 are denied.

156. S&N denies that it or anyone on its behalf made "affirmative false representations," and the allegations of Paragraph 156 are therefore denied, including all subparts.

157. The allegations of Paragraph 157 are denied.

158. The allegations of Paragraph 158 are denied.

159. The allegations of Paragraph 159 are denied.

160. The allegations of Paragraph 160 state legal conclusions which do not require a response. To the extent a further response is required, the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act of 1976 ("FDCA") speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 160.

161. The allegations of Paragraph 161 state legal conclusions which do not require a response. To the extent a further response is required, the MDA and Code of Federal Regulations interpreting it, including but not limited to 21 C.F.R. § 814.80, speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 161.

162. This Court dismissed all claims for allegedly defective manufacture of the BHR System in its March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 27 ("[P]laintiffs' manufacturing defect claim will be dismissed"). Further, the allegations of Paragraph 162 state legal conclusions which do not require a response. To the extent a further response is required, the FDA's Quality Systems Regulations and Current Good Manufacturing Practices ("CGMP") speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 162.

163. Further, any claims challenging the design or manufacture of the BHR System have been dismissed by the Court in its March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 27 ("[P]laintiffs' manufacturing defect claim will be dismissed").

Further, the allegations of Paragraph 163 state legal conclusions which do not require a response. To the extent a further response is required, the FDA's CGMP requirements, including, but not limited to 21 C.F.R. § 820.1(a)(1), speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 163.

164. Any claims challenging the design or manufacture of the BHR System were dismissed by the Court in its March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 27 ("[P]laintiffs' manufacturing defect claim will be dismissed"). Further, the allegations of Paragraph 164 state legal conclusions which do not require a response. To the extent a further response is required, the cited federal regulations cited in Paragraph 164 speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 164.

165. The allegations of Paragraph 165 state legal conclusions which do not require a response. To the extent a further response is required, the FDA's CGMP/QSR, including but not limited to 21 C.F.R. § 822.8, speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 165.

166. The allegations of Paragraph 166 state legal conclusions which do not require a response. To the extent a further response is required, the FDA's CGMP/QSR regulations, including, but not limited to 21 C.F.R. § 820.198(b), speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 166.

167. The allegations of Paragraph 167 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. § 820.198(c) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 167.

168. The allegations of Paragraph 168 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. §§ 820.250 and § 820.1(a)(3) speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 168.

169. The allegations of Paragraph 169 state legal conclusions which do not require a response. To the extent a further response is required, "FDA requirements" speak for themselves, and S&N denies any and all remaining allegations contained in Paragraph 169.

170. The allegations of Paragraph 170 state legal conclusions which do not require a response. To the extent a further response is required, 21 U.S.C. § 360i speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 170.

171. The allegations of Paragraph 171 state legal conclusions which do not require a response. To the extent a further response is required, 21 U.S.C. § 360i speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 171.

172. The allegations of Paragraph 172 state legal conclusions and do not require a response. To the extent a further response is required, 21 C.F.R. § 803.50(a) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 172.

173. The allegations of Paragraph 173 state legal conclusions and do not require a response. To the extent a further response is required, 21 C.F.R. §§ 814.82 and 803.50(b)(1) speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 173.

174. The allegations of Paragraph 174 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. §§ 803.50(b)(3) and 803.52(f), (9), speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 174.

175. The allegations of Paragraph 175 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. § 803.53 speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 175.

176. The allegations of Paragraph 176 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. §§ 806.10(a) and (b) speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 176.

177. The allegations of Paragraph 177 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. § 806.10(c) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 177.

178. The allegations of Paragraph 178 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. § 7.3(g) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 178.

179. The allegations of Paragraph 179 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. § 7.3(h) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 179.

180. The allegations of Paragraph 180 state legal conclusions which do not require a response. To the extent a further response is required, 21 U.S.C. § 351(e) and (h) speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 180.

181. The allegations of Paragraph 181 state legal conclusions which do not require a response. To the extent a further response is required, 21 U.S.C. § 331(a) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 181.

182. The allegations of Paragraph 182 state legal conclusions which do not require a response. To the extent a further response is required, the MDA and 21 U.S.C. § 360(e) speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 182.

183. The allegations of Paragraph 183 state legal conclusions which do not require a response. Further, any claims challenging the design, manufacturer, or FDA-approved labeling of the BHR System have been dismissed by the Court's March 26, 2018 Order, such that no response is required. To the extent a further response is required, the MDA and the Code of Federal Regulations implementing it, including but not limited to 21 C.F.R. § 814.8, speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 183.

184. S&N admits that the FDA issued an Approval Order for the BHR System, the terms of which speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 184.

185. The allegations of Paragraph 185 state legal conclusions which do not require a response. To the extent a further response is required, FDA's regulations speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 185.

186. The allegations of Paragraph 186 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. § 814.39(a) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 186.

187. The allegations of Paragraph 187 state legal conclusions which do not require a response. Further, the allegation is contrary to the Court's March 26, 2018 Order recognizing the continued approval of the BHR System notwithstanding alleged failures to comply with certain conditions of PMA approval. *See* March 26, 2018 Order at 5 & n.5 ("Only the FDA has the

authority to withdraw approval from a device, and it did not do so here."). S&N denies any and all remaining allegations contained in Paragraph 187.

188. The allegations of Paragraph 188 state legal conclusions which do not require a response. To the extent a further response is required, the FDCA speaks for itself. Further, the FDA has never found that S&N's commercial distribution of the BHR System violated the FDCA or the Approval Order authorizing S&N to distribute the BHR System in the United States. S&N denies any and all remaining allegations contained in Paragraph 188.

189. The allegations of Paragraph 189 state legal conclusions which do not require a response. Further, any claim based on the allegation that S&N should have unilaterally updated its label has been dismissed by the Court's March 26, 2018 Order, such that no response is required. To the extent a further response is required, the allegations of Paragraph 189 are denied.

190. The allegations of Paragraph 190 state legal conclusions which do not require a response. Further, any claims challenging the manufacture of the BHR System or its FDA-approved labeling have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17. To the extent a further response is required, S&N denies that Plaintiffs accurately or completely describe federal labeling and manufacturing requirements, and denies any and all remaining allegations contained in Paragraph 190.

191. The allegations of Paragraph 191 state legal conclusions which do not require a response. Further, any claims that S&N should have changed the labeling for the BHR System have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17. To the extent a further response is required, 21 C.F.R. § 814.39(d)(1) and (2) speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 191.

192. The allegations of Paragraph 192 state legal conclusions which do not require a response. To the extent a further response is required, 21 C.F.R. § 814 speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 192.

193. The allegations of Paragraph 193 state legal conclusions which do not require a response. To the extent a further response is required, the allegations of Paragraph 193 are denied except to admit that the MDA contains an express preemption provision at 21 U.S.C. § 360(k), the terms of which speak for themselves.

194. The allegations of Paragraph 194 state legal conclusions which do not require a response. To the extent a further response is required, S&N denies that Plaintiffs' purported description of federal preemption is complete and accurate, and denies any and all remaining allegations contained in Paragraph 194.

195. The allegations of Paragraph 195 are denied. The Court's March 26, 2018 Order rules that preemption continues to apply notwithstanding an alleged failure to comply with the conditions set out in the PMA Approval Order and the recall of smaller head sizes of the BHR System. *See* March 26, 2018 Order at 5 & n.5

196. The allegations of Paragraph 196 are admitted.

197. The allegations of Paragraph 197 are admitted except to clarify that the FDA approved the BHR for commercial distribution in the United States with conditions.

198. The allegations of Paragraph 198 are admitted. Further answering, the FDA has never found that S&N distributed the BHR System in violation of the FDCA.

199. The allegations of Paragraph 199 state legal conclusions, which do not require a response. To the extent a further response is required, S&N denies that Plaintiffs' purported description of its duties under federal law is complete and accurate. The allegations of Paragraph

199, including all subparts, are denied, except that the terms of the Approval Order speak for themselves.

200. The allegations of Paragraph 200 state legal conclusions, which do not require a response. To the extent that a further response is required, S&N denies that Plaintiffs' purported description of its duties under federal law is complete and accurate. The allegations of Paragraph 200 are denied except to admit that the terms of the Approval Order speak for themselves.

201. The allegations of Paragraph 201, including all subparts, are denied.

202. The allegations of Paragraph 202 state legal conclusions, which do not require a response. The allegations of Paragraph 202 have been rejected by the Court's March 26, 2018 Order, such that no response is required. More specifically, the Court rejected the assertion that an alleged failure to follow requirements of the Approval Order "voids any legal protection . . . from tort claims," *see* March 26, 2018 Order at 5 n.5, or that S&N can be liable for a failure to issue additional warnings to the public, healthcare professionals, or Plaintiffs, *id.* at 17. To the extent a further response is required, the allegations of Paragraph 202 are denied.

203. The Court's March 26, 2018 Order dismissed allegations contained in Paragraph 203, including, for example, any claims relating to a manufacturing defect, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 27. To the extent a further response is required, the allegations of Paragraph 203 are denied.

204. The allegations of Paragraph 204 are denied. S&N further states that FDA has never concluded that S&N violated the PMA approval order.

205. Any claims related to any of the post-approval studies required by the FDA in the Approval Order have been dismissed by the March 26, 2018 Order, such that no response is

required. *See supra* at 1-3 & nn.2-4. To the extent a further response is required, the allegations of Paragraph 205 are denied.

206. Any claims relating to the UK post-approval study have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See supra* at 1-3 & nn.2-4. To the extent a further response is required, the allegations of Paragraph 206 are denied. Answering further, the FDA has never found S&N to be in violation of the UK post-approval study. The study has been completed, and its results have been incorporated in the BHR labeling.

207. Any claims based on allegations related to the U.S. post-approval study have been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See supra* at 1-3 & nn.2-4. To the extent a further response is required, the allegations of Paragraph 207 are denied except to admit that on certain occasions, the FDA reported the status of the U.S. BHR study as "progress inadequate" because patient enrollment milestones were not met. S&N specifically denies that "[m]andatory reports for the study were submitted late to the FDA at least three times in the last eleven years."

208. The allegations of Paragraph 208 are denied except that S&N admits that the PMA Approval Order required quarterly teleconferences only with certain surgeons, not the surgeons who implanted the BHR System in Plaintiffs. Claims relating to an alleged failure to conduct quarterly teleconferences and to provide the FDA with an analysis of adverse events and complaints are expressly and impliedly preempted.

209. S&N admits that a training program began on or about December 13, 2006, but otherwise denies the remaining allegations of Paragraph 209. S&N specifically denies that it "admitted to the FDA that surgeons were performing resurfacing operations" involving the BHR System "despite having not been trained at all by [S&N]."

210. Any claim based on an alleged failure to advise Plaintiffs or their surgeons of the "1,000 surgery learning curve" is expressly preempted and has been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"). To the extent a further response is required, the allegations of Paragraph 210 are denied.

211. The allegations of Paragraph 211 are denied. Further, federal law did not require S&N to "provide the same training opportunities that it promised to the initial group of 'core' U.S. surgeons who received training in England" as to other surgeons.

212. The allegations of Paragraph 212 are denied.

213. Paragraph 213 relates to claims that have been dismissed by the Court's March 26, 2018 Order, including sub-paragraphs (h) - (j), (l) – (o), such that no response to allegations regarding the same is required. To the extent a further response is required, the allegations of Paragraph 213, including all subparts, are denied.

214. The allegations of Paragraph 214 state legal conclusions which do not require a response. To the extent a further response is required, S&N denies that Plaintiffs are pursuing solely parallel state law claims, and the Court's March 26, 2018 Order limits the claims Plaintiffs may bring. S&N denies any and all remaining allegations contained in Paragraph 214.

215. The Court's March 26, 2018 Order has dismissed any claim that S&N had an affirmative duty to update medical professionals as new risks arose through the Changes Being Effected ("CBE") process, 21 C.F.R. § 814.39(d), or that John Goode's e-mail imposed an ongoing

obligation on S&N to update the label, such that no response is required. *See* March 26, 2018 Order at 16 n.10 (ruling that CBE regulation "is discretionary, not mandatory, and thus any state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"); *id.* at 17 ("any claim . . . that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"). To the extent a further response is required, the allegations of Paragraph 215 are denied.

216. The Court's March 26, 2018 Order specifically rejects the contention that S&N was under an affirmative duty to use the CBE process to update its labeling, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 216 are denied.

217. The Court's March 26, 2018 Order has specifically rejected the allegation that S&N "assumed a duty to continue to update its labeling as new information about the safety of the BHR developed through the same process," such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 217 are denied except to admit that S&N used the CBE process to update its labeling to include information as to pseudotumors in December 2009.

218. The Court's March 26, 2018 Order specifically rejects the allegation that Federal law imposed an obligation on S&N to update the labeling through the CBE process, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 218 are denied.

219. Further, the Court's March 26, 2018 Order specifically rejects the allegation that S&N was required to use the CBE process to update its labeling and that Plaintiffs can bring a cause of action based on the CBE process, such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 219 are denied.

220. The allegations of Paragraph 220 are denied.

221. The allegations of Paragraph 221 state legal conclusions which do not require a response. To the extent a further response is required, S&N denies that the PMA and FDA directives defined S&N's duty of reasonable care under state laws. S&N denies any and all remaining allegations contained in Paragraph 221.

222 - 229. Paragraphs 222 – 229 relate to allegations that the BHR was manufactured defectively. The Court's March 26, 2018 Order dismissed all claims for manufacturing defect. *See* March 26, 2018 Order at 26-27. Accordingly, the allegations of Paragraphs 222 -229 relate to claims which are no longer part of this MDL, such that no response is required. In any event, to the extent a further response is required, the allegations of Paragraphs 222 – 229 are denied.

230. The allegations of Paragraph 230 state legal conclusions which do not require a response. To the extent a further response is required, S&N denies any and all remaining allegations contained in Paragraph 230.

231. The allegations of Paragraph 231 state legal conclusions which do not require a response. Further, the Court's March 26, 2018 Order rejects the allegation that the PMA Approval Order incorporated all federal requirements into state law and that S&N had a duty of reasonable care "to update the medical community and Plaintiffs about the safety of its device," such that no

response is required. *See* March 26, 2018 Order at 17. To the extent a further response is required, the allegations of Paragraph 231 are denied.

232. The allegations of Paragraph 232 state legal conclusions which do not require a response. To the extent a further response is required, the allegations of Paragraph 232 are denied.

233. The allegations of Paragraph 233 state legal conclusions which do not require a response. To the extent a further response is required, the allegations of Paragraph 233 are denied.

234. The allegations of Paragraph 234 are denied.

235. The allegations of Paragraph 235 are denied.

236. The allegations of Paragraph 236 are denied.

237. The allegations of Paragraph 237 are denied.

238. The allegations of Paragraph 238 are denied.

239. The allegations of Paragraph 239 are denied except to admit that S&N began a BHR training program for surgeons on or about December 13, 2006.

240. The allegations of Paragraph 240 are denied. S&N specifically denies that it "admitted to the FDA that surgeons were performing resurfacing operations [using the BHR System] despite Smith & Nephew not training them."

241. The allegations of Paragraph 241 are denied except to admit that S&N did attempt to assist patients in finding surgeons trained to use the BHR System, and that the language on any S&N website speaks for itself.

242. The allegations of Paragraph 242 are admitted, and S&N notes that the quoted language "[t]he BHR is intended for use only by surgeons who have received appropriate training and are familiar with the implant components, instruments, surgical technique (including with [sic]

the importance of correct positioning), clinical applications, adverse events and associated risks" is contained in the FDA-approved label.

243. The allegations of Paragraph 243 are denied.

244. The allegations of Paragraph 244 state legal conclusions which do not require a response. To the extent a further response is required, the allegations of Paragraph 244 are denied.

245. Any claim based on the allegation that S&N "tout[ed] the safety" of the BHR System has been dismissed by the Court's March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). To the extent a further response is required, the allegations of Paragraph 245 are denied.

246. The Court's March 26, 2018 Order rejects the allegation that S&N "voluntarily assumed a duty to use reasonable care to update the medical community and patients, including Plaintiffs, about new information about the safety of the BHR," such that no response is required. *See* March 26, 2018 Order at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 246 are denied.

247. The allegations of Paragraph 247 are denied.

248. The Court's March 26, 2018 Order has rejected the allegation that S&N had a duty "to warn the medical community, consumers, and Plaintiff of any danger associated with the device," such that no further response to allegations regarding the same is required. *See* March 26, 2018 Order at 16 n.10, 17. Further, the allegations of Paragraph 248 state legal conclusions which do not require a response. To the extent that a response is required, the allegations of Paragraph 248 are denied except to admit that federal requirements required S&N to provide the FDA with certain adverse event reporting information.

249. The allegations of Paragraph 249 state legal conclusions which do not require a response. To the extent a further response is required, 21 U.S.C. § 352(a) and (j) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 249.

250. The allegations of Paragraph 250 state legal conclusions which do not require a response. To the extent a further response is required, the provisions of the FDCA speak for themselves, S&N denies that Plaintiffs accurately and completely describe the FDCA's labeling provisions, and S&N denies any and all remaining allegations contained in Paragraph 250.

251. The allegations of Paragraph 251 state legal conclusions which do not require a response. To the extent a further response is required, 21 U.S.C. § 331(a) speaks for itself. S&N denies any and all remaining allegations contained in Paragraph 251.

252. The allegations of Paragraph 252 are admitted.

253. The allegations of Paragraph 253 relate to claims that have been dismissed by the Court's March 26, 2018 Order, which prohibits any challenges to the labeling which accompanied the BHR System, such that no response is required. *See*, *e.g.,* March 26, 2018 Order at 17. To the extent a further response is required, the "Patient Information" document speaks for itself, and S&N denies any and all remaining allegations contained in Paragraph 253.

254. The allegations of Paragraph 254 relate to claims which have been dismissed by the Court's March 26, 2018 Order, which prohibits challenges to the labeling which accompanied the BHR System, such that no response is required. *See*, *e.g.,* March 26, 2018 Order at 17. To the extent a further response is required, the content of the "Patient Information" document speaks for itself, S&N denies that it made any "misleading omission," and S&N denies any and all remaining allegations contained in Paragraph 254.

255. The allegations of Paragraph 255 relate to claims which have been dismissed by the Court's March 26, 2018 Order, which prohibits challenges to the labeling which accompanied the BHR System, such that no response is required. *See*, *e.g.*, March 26, 2018 Order at 17. To the extent a further response is required, the content of the "Patient Information" document speaks for itself, S&N denies that it made any "mislead[ing]" representations, and S&N denies any and all remaining allegations contained in Paragraph 255.

256. The allegations of Paragraph 256 relate to claims which have been dismissed by the Court's March 26, 2018 Order, which prohibits challenges to the labeling which accompanied the BHR System, such that no response is required. *See*, *e.g.*, March 26, 2018 Order at 17. To the extent a further response is required, the allegations of Paragraph 256 are denied.

257. The allegations of Paragraph 257 are denied. Further, the allegations of Paragraph 257 relate to claims which have been dismissed by the Court's March 26, 2018 Order, which prohibits challenges to the labeling which accompanied the BHR System, such that no response is required. *See*, *e.g.*, March 26, 2018 Order at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"); *id.* at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements").

258. The allegations of Paragraph 258 relate to claims which have been dismissed by the Court's March 26, 2018 Order, which prohibits challenges to the labeling which accompanied the BHR System, and which dismissed claims for alleged "misbranding," such that no response is required. *E.g.*, *id.* at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 258 are denied.

259. The Court's March 26, 2018 Order has dismissed any claims for alleged "misbranding," such that no response is required. *E.g.*, *id.* at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 259 are denied.

260. The Court's March 26, 2018 Order has dismissed any claims for alleged "misbranding," such that no response is required. *E.g.*, *id.* at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 260 are denied.

261. The allegations of Paragraph 261 relate to claims which have been dismissed by the Court's March 26, 2018 Order, which prohibits challenges to the labeling which accompanied the BHR System, such that no response is required. *E.g.*, *id.* at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 261 are denied.

262. The Court's March 26, 2018 Order has dismissed any claims challenging the labeling which accompanied the BHR System, or for alleged "misbranding," such that no response is required. *E.g.*, *id.* at 16 n.10, 17. To the exten a response is required, the allegations of Paragraph 262 are denied.

263. The Court's March 26, 2018 Order has dismissed any claims for alleged "misbranding," such that no response is required. *E.g.*, *id.* at 16 n.10, 17. To the extent a further response is required, the allegations of Paragraph 263 are denied.

264. The Court's March 26, 2018 Order has dismissed any claims for alleged "misbranding," such that no response is required. *E.g.*, *id.* at 16 n10, 17. To the extent a further response is required, the allegations of Paragraph 264 are denied.

265. The allegations of Paragraph 265 are denied and are contradicted by the Court's March 26, 2018 Order holding that S&N is entitled to the legal protection of preemption under the PMA. *See* March 26, 2018 Order at 5 n.5.

266. The allegations of Paragraph 266 are denied and are contradicted by the Court's March 26, 2018 Order holding that S&N is entitled to the legal protection of preemption under the PMA. *See* March 26, 2018 Order at 5 n.5.

267. The allegations of Paragraph 267 are denied and are contradicted by the Court's March 26, 2018 Order holding that S&N is entitled to the legal protection of preemption under the PMA. *See* March 26, 2018 Order at 5 n.5.

268. The allegations of Paragraph 268 are denied and are contradicted by the Court's March 26, 2018 Order holding that S&N is entitled to the legal protection of preemption under the PMA. *See* March 26, 2018 Order at 5 n.5.

269. The Court's March 26, 2018 Order prohibits any claims that the BHR System was "defective, unsafe, unfit for the purposes intended, . . . [or] not of merchantable quality," such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). To the extent a further response is required, the allegations of Paragraph 269 are denied.

270. The Court's March 26, 2018 Order has dismissed any claims that S&N failed to disclose information not required by the FDA-approved labeling to "Plaintiff[s] and the medical community," such that no response is required. *See* March 26, 2018 Order at 18 (""Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement"). To the extent a further response is required, the allegations of Paragraph 270 are denied.

271. The allegations of Paragraph 271 are denied. *See* March 26, 2018 Order at 18.

272. The allegations of Paragraph 272 state legal conclusions which do not require a response. To the extent a further response is required, the Court's March 26, 2018 Order limits the scope of permissible parallel claims Plaintiffs may bring in this MDL, and S&N denies any and all remaining allegations contained in Paragraph 272.

273. The allegations of Paragraph 273 are denied.

274. The allegations of Paragraph 274 are denied. *See* March 26, 2018 Order at 18.

275. The allegations of Paragraph 275 state legal conclusions which do not require a response. To the extent a further response is required, the Court's March 26, 2018 Order limits the federal requirements which Plaintiffs may enforce through state law tort claims in this MDL, S&N denies that Plaintiffs accurately and completely characterize the FDCA or federal regulations, and S&N denies any and all remaining allegations contained in Paragraph 275.

276. The allegations of Paragraph 276 state legal conclusions which do not require a response. To the extent a further response is required, S&N denies any and all remaining allegations contained in Paragraph 276.

277. The allegations of Paragraph 277 are denied.

278. The allegations of Paragraph 276 state legal conclusions which do not require a response. To the extent a further response is required, the allegations of Paragraph 278 are denied. Further, the Court's March 26, 2018 Order rejects the allegation that state contract law principles define the scope of S&N's duties or the claims Plaintiffs may bring in this MDL. *See* March 26, 2018 Order at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations").

279. The allegations of Paragraph 279 are denied. Further, the Court's March 26, 2018 Order rejects the allegation that state contract law principles define the scope of S&N's duties or the claims Plaintiffs may bring in this MDL. *See* March 26, 2018 Order at 18.

280. S&N lacks knowledge or information sufficient to form a belief about what is meant by "important services" provided to unspecified "medical professionals," or "catastrophic consequences," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 280.

281. S&N lacks knowledge or information sufficient to form a belief about what is meant by "this information" or unspecified "medical professionals," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 281.

282. The allegations of Paragraph 282 are denied.

283. The allegations of Paragraph 283 state legal conclusions which do not require a response. Further, the Court's March 26, 2018 Order prohibits claims based on alleged representations regarding the safety of the BHR and claims that S&N should have updated the FDA-approved labeling, such that no response is required. *See* March 26, 2018 Order at 17. To the extent that a response is required, the allegations of Paragraph 283 are denied.

284. The allegations of Paragraph 284 are denied.

285. The allegations of Paragraph 285 are denied.

286. The allegations of Paragraph 286 state legal conclusions which do not require a response. Further, the Court's March 26, 2018 Order limits the federal requirements which can be enforced through state law tort claims in this MDL. To the extent a further response is required, the FDCA and federal regulations speak for themselves, and S&N denies any and all remaining allegations contained in Paragraph 286.

287. The allegations of Paragraph 287 are denied. Further, the Court's March 26, 2018 Order limits the federal requirements that can be enforced through state law tort claims in this MDL.

288. The allegations of Paragraph 288 are denied.

289. The allegations of Paragraph 289 are denied.

290. The allegations of Paragraph 290 are denied.

291. The Court's March 26, 2018 Order rejected the allegation that the July 30, 2010 email imposed a continuing obligation on S&N to update its labeling, such that no response is required. *See* March 26, 2018 Order at 16 n.10 ("The dictates of an agency official, however, cannot overturn federal regulations"). To the extent a further response is required, the allegations of Paragraph 291 are denied. Paragraph 291 also misstates the July 30, 2010 e-mail from John Goode.

292. The allegations of Paragraph 292 relate to claims which have been specifically rejected by the Court in its March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"). To the extent a further response is required, the allegations of Paragraph 292 are denied.

293. Further, the Court's March 26, 2018 Order specifically rejects the allegation that S&N had an ongoing duty to update its label after July 30, 2010, such that no response is required. *See* March 26, 2018 Order at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"). To the extent a further response is required, the allegations of Paragraph 293 are denied.

294. The first two sentences of Paragraph 294 state legal conclusions which do not require a response. Further, any claims based on alleged statements regarding the "safety of Smith & Nephew's BHR device" and a duty to inform the medical community or patients have been dismissed by this Court's March 26, 2018 Order, such that no response to allegations regarding the same is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."); *id.* at 17 ("Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement"). To the extent a further response to this Paragraph is required, S&N admits that there are federal requirements regarding reporting adverse events to the FDA. S&N lacks knowledge or information sufficient to form a belief about what unspecified statements were allegedly represented to unspecified members of the "medical community, the general public, and potential patients," and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 294.

295. The Court's March 26, 2018 Order prohibits claims based on representations "that the BHR was safe" or that S&N had a duty to "provide updated studies and survivorship," such that no response is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA pproved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."). To the extent a further response is required, the allegations of Paragraph 295 are denied.

296. The allegations in Paragraph 296(a)-(e) relate to claims that have been dismissed by the Court in its March 26, 2018 Order, such that no response to these allegations is required. *See* March 26, 2018 Order at 18 ("Any claim that Smith & Nephew had a duty to warn the general

public or the medical community is, however, expressly preempted because there is no such parallel federal requirement"). To the extent a further response is required, the allegations of Paragraph 296, including all subparts, are denied.

297. The Court's March 26, 2018 Order has dismissed any claim that S&N had a duty to issue additional warnings to Plaintiffs, such that no response is required. *See* March 26, 2018 Order at 18. To the extent a further response is required, the allegations of Paragraph 297 are denied.

298. The Court's March 26, 2018 Order has dismissed any claim that S&N had a duty to issue additional warnings to Plaintiffs, such that no response is required. *See* March 26, 2018 Order at 18. To the extent a further response is required, the allegations of Paragraph 298 are denied.

299. The Court's March 26, 2018 Order has dismissed any claim that S&N had a duty to issue additional warnings to Plaintiffs, such that no response is required. *See* March 26, 2018 Order at 18. To the extent a further response is required, the allegations of Paragraph 299 are denied.

300. The Court's March 26, 2018 Order has dismissed any claim that S&N had a duty to issue additional warnings to Plaintiffs, such that no response is required. *See* March 26, 2018 Order at 18. To the extent a further response is required, the allegations of Paragraph 300 are denied.

301. S&N incorporates and reasserts the averments of Paragraphs 1-301 set forth above as if fully set forth herein.

302. The Court's March 26, 2018 Order has dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR

System, such that no response is required. *See* March 26, 2018 Order at 2 ("The plaintiffs' two strict liability claims are preempted because they require the court to impose requirements on Smith & Nephew that differ from or add to FDA requirements"); *id*. at 14 ("The court will grant Smith & Nephew's motion to dismiss these two claims because finding a device unreasonably dangerous adds to or differs from federal requirements"); *id* at 14 n.9 ("The reasoning in this section applies as well to any other cause of action that might require proof that the BHR device was unreasonably dangerous"). To the extent a further response is required, the allegations of Paragraph 302 are denied.

303. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, and many of these sub-paragraphs of Paragraph 303 relate to design or manufacturing claims which the Court dismissed in its March 9, 2018 Order, including (a), (g) and (j), such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 303, including all subparts, are denied.

304. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, and many of the sub-parts of Paragraph 304 involve allegations that relate to claims which have been dismissed by the Court's March 26, 2018 Order, including (h) – (m), such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 304, including all subparts, are denied.

305. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 305 are denied.

306. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 306 are denied.

307. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 307 are denied.

308. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 308 are denied.

309. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 309 are denied.

310. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 310 are denied.

311. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 311 are denied.

312. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 312 are denied.

313. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 313 are denied.

314. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 314 are denied.

315. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26,

2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 315 are denied.

316. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 316 are denied.

317. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 317 are denied.

318. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 318 are denied.

319. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 319 are denied.

320. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 320 are denied.

321. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 321 are denied.

322. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 322 are denied.

323. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design and manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 323 are denied.

324. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design and manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March

26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 324 are denied.

325. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 325 are denied.

326. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 326 are denied.

327. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 327 are denied.

328. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 328 are denied.

329. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 329 are denied.

330. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 330 are denied.

331. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 331 are denied.

332. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 332 are denied.

333. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26,

2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 333 are denied.

334. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 334 are denied.

335. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 335 are denied.

336. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 336 are denied.

337. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 337 are denied.

338. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 338 are denied.

339. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 339 are denied.

340. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 340 are denied.

341. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 341 are denied.

342. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26,

2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 342 are denied.

343. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 343 are denied.

344. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 344 are denied.

345. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 345 are denied.

346. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 346 are denied.

347. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 347 are denied.

348. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 348 are denied.

349. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 349 are denied.

350. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 350 are denied.

351. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26,

2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 351 are denied.

352. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 352 are denied.

353. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action and any claims challenging the design or manufacturing of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 353 are denied.

354. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 354 are denied.

355. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 355 are denied.

356. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 356 are denied.

357. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 357 are denied.

358. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, S&N admits that the MDA contains an express preemption provision, 21 U.S.C. § 360k, which speaks for itself.

359. The Court's March 26, 2018 Order limits the claims that can be brought in this MDL. The Court has dismissed Plaintiffs' Strict Products Liability cause of action and all claims which challenge the design of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 359 are denied.

360. The Court's March 26, 2018 Order limits the claims that can be brought in this MDL. The Court has dismissed Plaintiffs' Strict Products Liability cause of action and all claims which challenge the design of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 360 are denied.

361. The Court's March 26, 2018 Order limits the claims that can be brought in this MDL. The Court has dismissed Plaintiffs' Strict Products Liability cause of action and all claims which challenge the design of the BHR System or the FDA-approved labeling which accompanied it, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 361 are denied.

362. S&N hereby incorporates and reasserts the responses set forth in Paragraphs 1-361 as if fully set forth herein.

363. The allegations of Paragraph 363 state legal conclusions which do not require a response. To the extent a further response is required, S&N admits that Plaintiffs purport to describe duties owed under state and federal law, but denies that Plaintiffs' description is accurate or complete. Further, the Court's March 26, 2018 Order limits the claims which can be brought by Plaintiffs in this MDL. *E.g.*, March 26, 2018 Order at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"); *id.* at 18 ("Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement"). S&N denies any and all remaining allegations contained in Paragraph 363.

364. The allegations of Paragraph 364 are denied.

365. The allegations of Paragraph 365 are denied.

366. The Court has dismissed all claims of manufacturing defect in its March 26, 2018 Order, such that no response is required. *See* March 26, 2018 Order at 26-27. To the extent a further response is required, the allegations of Paragraph 366 are denied.

367. The allegations of Paragraph 367 are denied.

368. The Court's March 26, 2018 Order has dismissed claims that S&N should have issued additional warnings to Plaintiffs or their implanting surgeons, such that no response is required. *See* March 26, 2018 Order at 17, 18. To the extent a further response is required, the allegations of Paragraph 368 are denied.

369. The Court's March 26, 2018 Order has dismissed claims that S&N should have issued additional warnings to Plaintiffs or their implanting surgeons, such that no response is required. *See id.* at 17, 18. To the extent a further response is required, the allegations of Paragraph 369 are denied.

370. The Court's March 26, 2018 Order has dismissed all claims challenging the design of the BHR System, such that no response to allegations regarding the same is required. *Id.* at 14 n.9 (dismissing "any other cause of action that might require proof that the BHR device was unreasonably dangerous"). To the extent a further response is required, the allegations of Paragraph 370 are denied.

371. The allegations of Paragraph 371 are denied.

372. S&N admits that Plaintiffs purport to describe duties owed under federal law, but denies that Plaintiffs' description is accurate or complete. S&N denies any and all remaining allegations contained in Paragraph 372.

373. The allegations of Paragraph 373 are denied.

374. The allegations of Paragraph 374 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"); *id.* at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"); *id*. at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval

means"); *id.* ("Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement").

375. The allegations of Paragraph 375 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

376. The allegations of Paragraph 376 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

377. The allegations of Paragraph 377 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

378. The allegations of Paragraph 378 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

379. The allegations of Paragraph 379 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

380. The allegations of Paragraph 380 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

381. The allegations of Paragraph 381 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

382. The allegations of Paragraph 382 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

383. The allegations of Paragraph 383 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

384. The allegations of Paragraph 384 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

385. The allegations of Paragraph 385 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

386. The allegations of Paragraph 386 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

387. The allegations of Paragraph 387 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

388. The allegations of Paragraph 388 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

389. The allegations of Paragraph 389 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

390. The allegations of Paragraph 390 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

391. The allegations of Paragraph 391 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

392. The allegations of Paragraph 392 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

393. The allegations of Paragraph 393 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

394. The allegations of Paragraph 394 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

395. The allegations of Paragraph 395 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

396. The allegations of Paragraph 396 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

397. The allegations of Paragraph 397 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

398. The allegations of Paragraph 398 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

399. The allegations of Paragraph 399 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

400. The allegations of Paragraph 400 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

401. The allegations of Paragraph 401 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

402. The allegations of Paragraph 402 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

403. The allegations of Paragraph 403 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

404. The allegations of Paragraph 404 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

405. The allegations of Paragraph 405 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

406. The allegations of Paragraph 406 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

407. The allegations of Paragraph 407 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

408. The allegations of Paragraph 408 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

409. The allegations of Paragraph 409 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

410. The allegations of Paragraph 410 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

411. The allegations of Paragraph 411 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

412. The allegations of Paragraph 412 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

413. The allegations of Paragraph 413 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

414. The allegations of Paragraph 414 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

415. The allegations of Paragraph 415 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

416. The allegations of Paragraph 416 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

417. The allegations of Paragraph 417 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

418. The allegations of Paragraph 418 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

419. The allegations of Paragraph 419 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

420. The allegations of Paragraph 420 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

421. The allegations of Paragraph 421 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

422. The allegations of Paragraph 422 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

423. The allegations of Paragraph 423 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

424. The allegations of Paragraph 424 are denied. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

425. The allegations of Paragraph 425 state legal conclusions for which no response is required. To the extent that a response is required, these allegations are denied.

426. The allegations of Paragraph 426 state legal conclusions for which no response is required. To the extent that a response is required, these allegations are denied.

427. The allegations of Paragraph 427 state legal conclusions which do not require a response. To the extent a further response is required, these allegations are denied.

428. The allegations of Paragraph 428 state legal conclusions for which no response is required. To the extent that a response is required, these allegations are denied.

429. Most of the sub-parts of Paragraph 429 contain allegations that relate to claims that have been dismissed by the Court's March 26, 2018 Order, including (sub-paragraph (a) – (g), (i) – (j), (l) – (n), such that no response to such allegations is required. To the extent a further response is required, the allegations of Paragraph 429, including all subparts, are denied.

430. The allegations of Paragraph 430 state legal conclusions which do not require a response. The Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 430 are denied.

431. The allegations of Paragraph 431 are denied.

432. The allegations of Paragraph 432 are denied.

433. The Court's March 26, 2018 Order prohibits claims based on alleged representations "that the BHR was safe," such that no response is required. *See* March 28, 2018

Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). To the extent a further response is required, the allegations of Paragraph 433 are denied.

434. The allegations of Paragraph 434 are denied.

435. Further, the Court's March 26, 2018 Order prohibits claims based on alleged representations "that the BHR was safe," such that no response to allegations regarding the same is required. *See* March 28, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"). To the extent a further response is required, the allegations of Paragraph 435 are denied.

436. The allegations of Paragraph 436 are denied.

437. The allegations of Paragraph 437 are denied.

438. The allegations of Paragraph 438 are denied.

439. The allegations of Paragraph 439 are denied.

440. Smith & Nephew hereby reasserts the averments set forth in Paragraphs 1-439 as if set forth fully herein.

441. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018 Order at 2 ("The plaintiffs' two strict liability claims are preempted because they require the court to impose requirements on Smith & Nephew that differ from or add to FDA requirements"); *id.* at 14 ("The court will grant Smith & Nephew's motion to dismiss these two claims because finding a device unreasonably dangerous adds to or differs from federal requirements"); *id.* at 14 n.9 ("The reasoning in this section applies as well to any other cause of action that might require proof that the BHR device was unreasonably dangerous"). To the extent a further response is required, S&N

admits that it manufactured and distributed the BHR System in interstate commerce in the United States pursuant to a PMA approval issued by the FDA. S&N denies any and all remaining allegations contained in Paragraph 441.

442. The Court's March 26, 2018 Order dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, S&N admits that it distributed the BHR System in interstate commerce in the United States pursuant to a PMA approval granted by the FDA, but denies any all remaining allegations contained in this Paragraph of the MACC.

443. The Court's March 26, 2018 Order has dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 443 are denied.

444. The Court's March 26, 2018 Order has dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 444, including all subparts are denied.

445. The Court's March 26, 2018 Order has dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 445, including all subparts, are denied.

446. The Court's March 26, 2018 Order has dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018

Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 446 are denied.

447. The Court's March 26, 2018 Order has dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 447 are denied.

448. The Court's March 26, 2018 Order has dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 448 are denied.

449. The Court's March 26, 2018 Order has dismissed Plaintiffs' Strict Products Liability – Failure to Warn cause of action, such that no response is required. *See* March 26, 2018 Order at 2, 14 & n.9. To the extent a further response is required, the allegations of Paragraph 449 are denied.

450. S&N hereby reasserts and reasserts the averments set forth in Paragraphs 1-449 as if fully set forth herein.

451. The allegations of Paragraph 451 state legal conclusions which do not require a response. Further, the Court's March 26, 2018 Order has dismissed any claims based on allegations that S&N had a duty to issue warnings beyond that contained in the FDA-approved labeling. To the extent a further response is required, S&N denies that Plaintiffs accurately and completely describe state common law, and denies any and all remaining allegations contained in Paragraph 451.

452. The allegations of Paragraph 452 are denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"); *id.* at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"); *id*. at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"); *id.* ("Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement").

453. The allegations of Paragraph 453 state legal conclusions which do not require a response. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 453 are denied.

454. The allegations of Paragraph 454 re denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

455. The allegations of Paragraph 455 state legal conclusions which do not require a response. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 455 are denied.

456. The allegations of Paragraph 456 state legal conclusions which do not require a response. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' negligence

cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of paragraph 456 are denied.

457. S&N hereby reasserts the averments of Paragraphs 1-456 as if fully set forth herein.

458. S&N admits that Plaintiffs purport to describe and characterize alleged duties under state and federal law, but denies that Plaintiffs' description and characterization is accurate or complete. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"); *id.* at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations"); *id*. at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means"); *id.* at 18 ("Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement"). S&N denies any and all remaining allegations contained in Paragraph 458.

459. The allegations of Paragraph 459 are denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

460. The allegations of Paragraph 460 are denied. Further, the Court's March 26, 2018 Order has dismissed claims based on allegations that S&N had a duty to provide warnings in addition to those contained in the FDA-approved labeling. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

461. The allegations of Paragraph 461 are denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

462. The allegations of Paragraph 462 are denied. Further, the Court's March 26, 2018 Order has dismissed all claims challenging the design of the BHR System. *E.g.*, March 26, 2018 order at 14 n.9 (dismissing "any other cause of action that might require proof that the BHR device was unreasonably dangerous").

463. The allegations of Paragraph 463 are denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

464. The allegations of Paragraph 464 are denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

465. The allegations of Paragraph 465 are denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

466. The allegations of Paragraph 466 are denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18.

467. The Court's March 26, 2018 Order has dismissed the claim in Paragraph 467(a) and (f) to the extent such claim is based on representations "that the BHR was safe," such that no response to these allegations is required. *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly

what FDA approval means"). To the extent a further response is required, S&N lacks knowledge or information sufficient to form a belief about what was represented to unspecified Plaintiffs, and therefore denies all allegations regarding the same. S&N denies any and all remaining allegations contained in Paragraph 467.

468. The allegations of Paragraph 468 are denied except to admit that S&N submitted a 2015 Annual Report to the FDA, which speaks for itself. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"); *id.* at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations").

469. The allegations of Paragraph 469 are denied.

470. The allegations of Paragraph 470 are denied.

471. The allegations of Paragraph 471 are denied.

472. S&N lacks knowledge or information sufficient to form a belief about what representations allegedly were made to unspecified Plaintiffs and unidentified health care providers and physicians, and S&N therefore denies all allegations regarding the same. S&N denies any all remaining allegations contained in this Paragraph of the MACC.

473. The allegations of Paragraph 473 are denied.

474. The allegations of Paragraph 474 are denied.

475. The allegations of Paragraph 475 are denied.

476. The allegations of Paragraph 476 are denied.

477. The allegations of Paragraph 477 are denied.

478. The allegations of Paragraph 478 are denied.

479. The allegations of Paragraph 479 state legal conclusions and do not require a response. To the extent a further response is required, S&N denies that Plaintiffs accurately and completely describe and characterize duties allegedly owed. Further, the Court's March 26, 2018 Order limits the federal requirements that can be enforced through state law tort claims in this MDL. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18. S&N denies any and all remaining allegations contained in Paragraph 479.

480. S&N lacks knowledge or information sufficient to form a belief about what was "disseminated" to unspecified "health care professionals and consumers," and therefore denies all allegations regarding the same. S&N denies any all remaining allegations contained in this Paragraph of the MACC.

481. S&N lacks knowledge or information sufficient to form a belief about what unspecified "health care professionals and consumers" relied upon, and therefore denies all allegations regarding the same. S&N denies any all remaining allegations contained in this Paragraph of the MACC.

482. The allegations of Paragraph 482 are denied.

483. The allegations of Paragraph 483 are denied.

484. The allegations of Paragraph 484 state legal conclusions which do not require a response. Further, the Court's March 26, 2018 Order has dismissed any claims based on allegations that S&N had a duty to issue warnings beyond that contained in the FDA-approved labeling. *See* March 26, 2018 Order at 14 n.9 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements."). To the extent a

further response is required, S&N denies that Plaintiffs accurately and completely describe state common law, and denies any and all remaining allegations contained in Paragraph 484.

485. The allegations of Paragraph 485 are denied.

486. The allegations of Paragraph 486 are denied. Further, the Court's March 26, 2018 Order has dismissed any claims based on representations that "the BHR was safe." *See* March 26, 2018 Order at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means").

487. The allegations of Paragraph 487 are denied.

488. The allegations of Paragraph 488 are denied. Further, the Court's March 26, 2018 Order limits the scope of Plaintiffs' Negligent Misrepresentation cause of action. *E.g.*, March 26, 2018 Order at 16 n.10 ("[A]ny state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements"); *id.* at 17 ("Any claim, however, that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations").

489. The allegations of Paragraph 489 state legal conclusions and do not require a response. Further, the Court's March 26, 2018 Order limits the federal requirements that can be enforced through state law tort claims in this MDL. *E.g.*, March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, the allegations of Paragraph 489 are denied.

490. S&N reasserts the averments set forth in Paragraph 1-489 as if fully set forth herein.

491. The allegations of Paragraph 491 state legal conclusions and do not require a response. Further, the Court's March 26, 2018 Order limits the federal requirements that can be enforced through state law tort claims in this MDL. *See* March 26, 2018 Order at 16 n.10, 17, 18.

To the extent a further response is required, S&N admits that Plaintiffs purport to describe and characterize alleged duties owed, but denies that Plaintiffs' description and characterization is accurate or complete. S&N denies any and all remaining allegations contained in Paragraph 491.

492. The allegations of Paragraph 492 are denied. Further, the Court's March 26, 2018 Order limits the federal requirements that can be enforced through state law tort claims in this MDL. *See* March 26, 2018 Order at 16 n.10, 17, 18.

493. The allegations of Paragraph 493 state legal conclusions and do not require a response. Further, the Court's March 26, 2018 Order limits the federal requirements that can be enforced through state law tort claims in this MDL. *See* March 26, 2018 Order at 16 n.10, 17, 18. To the extent a further response is required, S&N admits that Plaintiffs purport to describe and partially quote the cited federal regulations, but denies that those descriptions and quotations are accurate and complete. The cited federal regulations speak for themselves. S&N denies any and all remaining allegations contained in Paragraph 493.

494. The allegations of Paragraph 494 are denied.

495. The allegations of Paragraph 495 are denied.

496. The allegations of Paragraph 496 state legal conclusions and do not require a response. To the extent that a further response is required, the allegations of Paragraph 496 are denied.

497. The allegations of Paragraph 497 are denied.

498. The allegations of Paragraph 498 are denied.

499. The allegations of Paragraph 499 are denied.

500. S&N reasserts the averments set forth in Paragraph 1-499 as if fully set forth herein.

501. The Court's March 26, 2018 Order has dismissed claims related to the allegations set forth in Paragraph 501. *E.g.*, March 26, 2018 Order at 15 ("[P]remarket approval is FDA recognition of a particular medical device's fitness for the market. Having received that approval, the BHR system cannot be labeled unreasonably dangerous by state law without imposing requirements on medical devices different from or in addition to federal regulations"); *id.* at 18 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."). As a result, no response is required to Paragraph 501. To the extent a further response is required, S&N denies that Plaintiffs accurately describe and characterize "warranties" allegedly made by S&N, and denies any and all remaining allegations contained in Paragraph 501.

502. The Court's March 26, 2018 Order has dismissed claims related to the allegations set forth in Paragraph 502, such that no response is required. *E.g.,* March 26, 2018 Order at 15; *id.* at 18. To the extent a further response is required, S&N denies that Plaintiffs accurately describe and characterize "warranties" allegedly made by S&N, lacks knowledge or information sufficient to form a belief about any statements made to unspecified Plaintiffs and unidentified "physicians, patients, Plaintiffs, and the general public," and therefore denies all regarding the same, and denies any and all remaining allegations contained in Paragraph 502.

503. S&N lacks knowledge or information sufficient to form a belief about what unidentified "health care providers and patients" or unspecified Plaintiffs "rely upon," and therefore denies all allegations contained in this Paragraph of the MACC.

504. The Court's March 26, 2018 Order has dismissed the claims related to the allegations of Paragraph 504, such that no response is required. *E.g.,* March 26, 2018 Order at 15; *id.* at 18. To the extent a further response is required, the allegations of Paragraph 504 are denied.

505. The Court's March 26, 2018 Order has dismissed the claims related to the allegations of Paragraph 505, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 505 are denied.

506. The Court's March 26, 2018 Order has dismissed the claims based on representations that the BHR was "safe for [its] intended use," such that no response to allegations regarding the same is required. *E.g.,* March 26, 2018 Order at 15, 18 . To the extent a further response is required, S&N admits that Plaintiffs purport to characterize and quote from a press release, but denies that the characterization and quotation are accurate and complete, and S&N denies any and all remaining allegations contained in Paragraph 506.

507. The allegations of Paragraph 507 are denied.

508. The allegations of Paragraph 508 are denied. The resurfacing device that is the subject of Mr. McMinn's "Make Resurfacing Great Again" marketing campaign is not an S&N product and is not a metal-on-metal device.

509. The allegations of Paragraph 509 are denied.

510. The Court's March 26, 2018 Order has dismissed claims related to representations that the BHR was "safe for [its] intended use," such that no response to allegations regarding the same is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 510 are denied.

511. The allegations of Paragraph 511 are denied.

512. The allegations of Paragraph 512 are denied.

513. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26,

2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 513 are denied.

514. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 514 are denied.

515. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 515 are denied.

516. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 516 are denied.

517. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 517 are denied.

518. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 518 are denied.

519. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 519 are denied.

520. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 520 are denied.

521. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 521 are denied.

522. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 522 are denied.

523. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 523 are denied.

524. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26,

2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 524 are denied.

525. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 525 are denied.

526. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 526 are denied.

527. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 527 are denied.

528. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 528 are denied.

529. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. To the extent a further response is required, the allegations of Paragraph 529 are denied.

530. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26,

2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 530 are denied.

531. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 531 are denied.

532. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 532 are denied.

533. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 533 are denied.

534. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 534 are denied.

535. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 535 are denied.

536. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 536 are denied.

537. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 537 are denied.

538. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 538 are denied.

539. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 539 are denied.

540. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 540 are denied.

541. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26,

2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 541 are denied.

542. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 542 are denied.

543. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 543 are denied.

544. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 544 are denied.

545. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 545 are denied.

546. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 546 are denied.

547. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 547 are denied.

548. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 548 are denied.

549. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 549 are denied.

550. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 550 are denied.

551. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 551 are denied.

552. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.*, March 26,

2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 552 are denied.

553. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 553 are denied.

554. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 554 are denied.

555. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 555 are denied.

556. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 556 are denied.

557. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 557 are denied.

558. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 558 are denied.

559. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 559 are denied.

560. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 560 are denied.

561. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 561 are denied.

562. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26, 2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 562 are denied.

563. The Court's March 26, 2018 Order has dismissed claims based on representations that the BHR System was safe and effective, such that no response is required. *E.g.,* March 26,

2018 Order at 15, 18. To the extent a further response is required, the allegations of Paragraph 563 are denied.

564. The allegations of Paragraph 564 are denied.

565. The allegations of Paragraph 565 are denied.

566. The allegations of Paragraph 566 are denied.

567. S&N here by reasserts the averments set forth in Paragraphs 1-566 as if fully set forth herein.

568-603. Paragraphs 568-603 relate to manufacturing defect claims which were dismissed by the Court's March 26, 2018 Order, such that no response is required. March 26, 2018 Order at 27 ("Accordingly, the plaintiffs' manufacturing defect claim will be dismissed"). In an abundance of caution, to the extent a further response is required, the allegations contained in Paragraphs 567-603 are denied.

604. S&N here by reasserts the averments set forth in Paragraphs 1-603 as if fully set forth herein.

605. The allegations of Paragraph 605 are denied.

AFFIRMATIVE DEFENSES

S&N asserts the following Affirmative Defenses without admitting or conceding that it bears the burden of proof on each of its affirmative defenses. Additionally, pursuant to the Court's holding in its March 26, 2018 Order regarding the causes of action identified in Plaintiffs' short-form complaints, *see* Order at 27 ("Some of those claims [in Plaintiffs' short-form complaints] will meet that [federal pleading] standard, others will not, but without further briefing the court cannot decide where each claim falls. The parties should consider the court's analysis above, including possible preemption concerns, and attempt to reach an agreement on the future of those claims. If an agreement cannot be reached, further briefing on those claims will be ordered."), and

CMO No. 3 [DE 120] (staying responses to Plaintiffs' short-form complaints pending further Court order), the affirmative defenses set forth below pertain only to Plaintiffs' MACC. S&N reserves all rights to respond and assert additional affirmative defenses to any causes of action set forth in any of Plaintiffs' short-form complaints.

FIRST AFFIRMATIVE DEFENSE

(No Post-Sale Duty to Plaintiffs)

1. S&N had no duty to warn Plaintiffs about any possible dangers in using its products which were not known at the time of manufacture and sale of the products.

SECOND AFFIRMATIVE DEFENSE

(Assumption of the Risk)

2. Plaintiffs were fully informed of the risks and possible consequences of the use of S&N's products, if any, and expressly and/or impliedly assumed the risks associated with the use of S&N's products, and any recovery should be reduced or barred in accordance with the doctrines of express or implied assumption of the risk.

THIRD AFFIRMATIVE DEFENSE

(Comparative Fault–Plaintiffs)

3. Plaintiffs are barred from recovering some or all of the alleged damages they seek in their Complaint by virtue of Plaintiffs' own negligence and fault, which directly and proximately caused Plaintiffs' alleged damages, if any. Among other things, Plaintiffs failed to take steps necessary for their safety and well-being that reasonably prudent persons would have taken under the same circumstances.

FOURTH AFFIRMATIVE DEFENSE

(Comparative Fault–Plaintiffs and Others)

4. Plaintiffs' alleged damages, if any, were proximately caused by the negligence, carelessness and/or fault of Plaintiffs and/or firms, persons, corporations, or entities other than

S&N, and that such negligence and/or other fault comparatively reduces the percentage of any negligence and/or other fault that may be attributed to S&N.

FIFTH AFFIRMATIVE DEFENSE

(Superseding Cause)

5. Any damage sustained by Plaintiffs was the result of superseding or intervening causes arising from the acts or omissions of persons over whom S&N had no authority or control.

SIXTH AFFIRMATIVE DEFENSE

(Failure to Mitigate Damages)

6. Plaintiffs are barred from recovering some or all of the alleged damages they seek by virtue of their failure to take reasonable, necessary, appropriate and feasible steps to mitigate their alleged damages.

SEVENTH AFFIRMATIVE DEFENSE

(Proximate Cause)

7. Any and all actions and/or failures to act by S&N, if any, were not the proximate cause of any damages suffered or to be suffered by Plaintiffs. Said damages, if any, were proximately caused by actions of and/or failures to act by Plaintiffs and/or by actions and/or failures to act by other or third parties. Such actions were not reasonably foreseeable and constituted supervening, superseding, or intervening efficient causes for which S&N is not liable.

EIGHTH AFFIRMATIVE DEFENSE

(Statute of Limitations)

8. Many of the Plaintiffs bring claims which are barred by the applicable statute of limitations in their jurisdictions.

NINTH AFFIRMATIVE DEFENSE

(Laches)

9. Plaintiffs may be barred from any recovery against it by the doctrine of laches, due to Plaintiffs' unreasonable delay in filing their Complaints.

TENTH AFFIRMATIVE DEFENSE

(Federal Preemption)

10. Plaintiffs' claims are expressly and impliedly preempted by the Medical Device Amendment of 1976 to the Federal Drug and Cosmetic Act, 21 U.S.C. § 321, et seq. and the Federal Drug & Cosmetics Act.

ELEVENTH AFFIRMATIVE DEFENSE

(Contributory Negligence)

11. Plaintiffs' negligence claims are barred because the damages alleged operative Complaint were proximately caused or contributed to by the negligence of Plaintiffs.

TWELFTH AFFIRMATIVE DEFENSE

(Contracts)

12. Any alleged liability based on express warranty and misrepresentation claims, if any, is barred or limited by any applicable contracts.

THIRTEENTH AFFIRMATIVE DEFENSE

(Unintended Use)

13. If any product designed, manufactured and/or distributed by S&N is identified as having contributed in any way to Plaintiffs' damages, such damages were the result of such product having been used in a manner or for a use (1) neither intended for nor foreseen by S&N; (2) not in accordance with the instructions and labels provided by S&N; and/or (3) not in accordance with the applicable standard of care.

FOURTEENTH AFFIRMATIVE DEFENSE

(Informed Consent)

14. Plaintiffs provided informed consent to and understood or were informed about the risks and consequences about which Plaintiffs now complain. Plaintiffs are thus barred from pursuing this action.

FIFTEENTH AFFIRMATIVE DEFENSE

(Nature)

15. Plaintiffs' alleged injuries and damages, if any, are the result of the operation of nature over which Defendant has no control.

SIXTEENTH AFFIRMATIVE DEFENSE

(Lack of Privity)

16. Any actions for breach of warranty in Plaintiffs' Complaint are barred in applicable jurisdictions because of the lack of privity between Plaintiffs and Defendant.

SEVENTEENTH AFFIRMATIVE DEFENSE

(No Reliance on Warranties)

17. Any actions for breach of warranty or misrepresentation are barred in applicable jurisdictions because at no time did Plaintiffs, their agents, servants, representatives, or predecessors in interests rely on any promises, warranties, express or implied, or representations which may have been made by S&N.

EIGHTEENTH AFFIRMATIVE DEFENSE

(Express Warranties Were True)

18. If, and only if, S&N made any express warranties and those warranties induced Plaintiffs or another person to use its products, then S&N denies that such express warranties were untrue or that its product failed to conform to such express warranties.

NINETEENTH AFFIRMATIVE DEFENSE

(Known Risks)

19. To the extent Plaintiffs allege failure to warn against S&N, the doctors and other healthcare providers who were associated with the products that are the subject of this lawsuit, knew or should have been aware of any risk and/or hazard that Plaintiffs allege rendered the subject product defective and that allegedly caused Plaintiffs' injuries, damages, and/or losses, if any, and, to the extent that such doctors or other healthcare providers failed to advise, inform, and warn

Plaintiffs of such risks and hazards, such failure is imparted to Plaintiffs under agency principles, and Plaintiffs are therefore barred from any recovery against Defendant.

TWENTIETH AFFIRMATIVE DEFENSE

(Learned Intermediary)

20. Any duty to warn Plaintiffs of the risks and hazards associated with the subject product was discharged by providing adequate warnings to physicians and receiving hospitals and therefore the Learned Intermediary Doctrine bars recovery of any damages.

TWENTY-FIRST AFFIRMATIVE DEFENSE

(No Additional Warnings Required)

21. The product at issue was neither defective nor unreasonably dangerous, therefore, no additional warnings or instructions were required.

TWENTY-SECOND AFFIRMATIVE DEFENSE

(Primary Jurisdiction)

22. The Federal Government by and through its appointed agency, the Federal Food and Drug Administration (FDA), has issued rules and regulations intended to pervasively regulate and control the class of products, such as the one complained of in the underlying Complaint. For that reason, Plaintiffs' Complaint fails because this Court lacks subject matter jurisdiction based on the FDA's primary jurisdiction.

TWENTY-THIRD AFFIRMATIVE DEFENSE

(Waiver and/or Estoppel)

23. Plaintiffs have waived and/or are estopped from asserting any claim for damages or seeking any other relief against S&N based on conduct and activities by the Plaintiffs with respect to the events which are the subject matter of the Complaint.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

(Claims for Breach of an Express Warranty are Barred by Disclaimers)

24. Plaintiffs' alleged claims for breach of an express warranty are barred by disclaimers.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

(Failure to Provide Timely Notice)

25. Plaintiffs' alleged claims for breach of an express warranty are barred by Plaintiffs' failure to provide timely notice of the alleged breach of any such warranties.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

(Conditions of Warranties)

26. Plaintiffs are barred from asserting any claim against S&N in the event such alleged warranties are proven at trial. Plaintiffs failed to fulfill the conditions of warranties alleged in the Complaint as to S&N.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

(Failure to Exercise Ordinary Care)

27. The injury, damage or loss allegedly suffered by the Plaintiffs herein, if any, was legally caused by the negligent or willful failure of the Plaintiffs to follow the advice and instructions of their physicians and/or S&N, and in otherwise failing to exercise ordinary care on their own behalf.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

(Failure to Follow Warnings)

28. Any injuries or damages sustained by Plaintiffs while using the product were proximately caused by Plaintiffs' failure to follow the warnings supplied with the product, which warning adequately warned of the risks involved in the product's use.

TWENTY-NINTH AFFIRMATIVE DEFENSE

(Misuse of Product)

29. Any injuries and damages complained of were proximately caused by misuse of the product, which was not reasonably foreseeable when Defendant marketed the product.

THIRTIETH AFFIRMATIVE DEFENSE

30. Plaintiffs' claim for punitive or exemplary damages is unconstitutional to the extent that Plaintiffs seek to punish S&N without the protection of constitutional safeguards, including but not limited to the right to proof beyond a reasonable doubt and the prohibition against excessive fines, as guaranteed by the Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States and similar protections afforded by the Constitutions of the States.

THIRTY-FIRST AFFIRMATIVE DEFENSE

31. Plaintiffs' claim for punitive or exemplary damages 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 S&N for the same allegations, and as such constitute multiple punishments for the same alleged conduct resulting in deprivation of S&N's property without due process of law and will result in unjustified windfalls for Plaintiffs and/or Plaintiffs' counsel, in violation of the Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States and similar protections afforded by the Constitutions of the States.

THIRTY-SECOND AFFIRMATIVE DEFENSE

32. Plaintiffs' claim for punitive or exemplary damages is unconstitutional in that the laws establishing the standards for granting and asserting punitive or exemplary damages are vague and ambiguous, thereby violating S&N's constitutional rights to due process under the Eighth and Fourteenth Amendments to the Constitution of the United States and similar protections afforded by the Constitutions of the States.

THIRTY-THIRD AFFIRMATIVE DEFENSE

33. Plaintiffs' claim for punitive damages against S&N cannot be maintained, because an award of punitive damages under current United States and state law 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 Fourteenth Amendment to the United States Constitution, the due process provisions of the States' Constitutions, and the common law and public policies of the States.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

34. Plaintiffs are not entitled to recover for economic damages that were not actually incurred. To that end, Plaintiffs' recovery, if any, for actual damages must be reduced by the amount forgiven, adjusted, or otherwise provided by any healthcare provider, any healthcare insurance company, Medicare, or any other collateral source. This is required whether or not Plaintiffs are still responsible for such reduction, and whether the reduction was provided as a result of contract, for some other consideration or simply gratuitous.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

35. Plaintiffs are not entitled to recover for economic damages that were not actually incurred. To that end, Plaintiffs' recovery, if any, for actual damages must be reduced by the amount of lost earnings that were provided by Plaintiffs' employers that were not required to be paid, but were gratuitously paid nevertheless. This reduction is required because Plaintiffs are not responsible for reimbursement of such earnings, and would result in an improper windfall to Plaintiffs.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

(State of the Art)

36. Plaintiffs' claims fail because S&N's product was designed, manufactured, and marketed in accordance with the state of the art.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

(Failure to State a Claim)

37. The Complaint fails to state a claim upon which relief can be granted.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

(Additional Defenses)

38. S&N hereby gives notice that it intends to rely upon any additional affirmative defenses which become available or apparent during discovery and thus reserves the right to amend its answer to assert additional defenses.

PRAYER FOR RELIEF

WHEREFORE, S&N prays for judgment as follows:

1. That Plaintiffs take nothing by way of the MACC;

2. That judgment be entered in favor of S&N and against Plaintiffs and that the MACC be dismissed with prejudice;

3. That S&N be awarded its costs of suit incurred in the defense of this action;

4. That S&N be awarded, as allowed by law, its attorneys' fees incurred in the defense of this action;

5. For a trial on all issues so triable; and

6. For such other relief as this Court deems proper.

JURY DEMAND

S&N demands a trial by jury on all issues so triable.

Dated: April 27, 2018

Respectfully submitted,

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Counsel for Defendant Smith & Nephew, Inc.

CERTIFICATE OF SERVICE

I, Sara J. Gourley, hereby certify that on this 27th day of April, 2018, I electronically filed the foregoing with the Court using the CM/ECF system, and thereby delivered the foregoing by electronic means to all counsel of record.

/s/ Sara J. Gourley
Counsel for Defendant Smith & Nephew, Inc.