UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

HUMANA INC.	:	CASE NO. 2:14-cv-02405-JTF-cgc
Plaintiff,	:	
v.	:	
MEDTRONIC SOFAMOR DANEK USA, INC. and MEDTRONIC, INC.	:	
Defendants.		

COMPLAINT AND
DEMAND FOR JURY TRIAL

PARTIES

1. Plaintiff, Humana Inc., is a Delaware corporation with its principal place of business at 500 West Main Street, Louisville, Kentucky. The following subsidiaries of Humana Inc. provide medical coverage in various states and regions throughout all 50 States and Puerto Rico. Arcadian Health Plan, Inc., CarePlus Health Plans, Inc., Cariten Health Plan, Inc., Cariten Insurance Company, CHA HMO, Inc., Emphesys Insurance Company, Humana AdvantageCare Plan, Inc., Humana Benefit Plan of Illinois, Inc., Humana Employers Health Plan of Georgia, Inc., Humana Health Benefit Plan of Louisiana, Inc., Humana Health Company of New York, Inc., Humana Health Insurance Company of Florida, Inc., Humana Health Plan of California, Inc., Humana Health Plan of Ohio, Inc., Humana Health Plan of Texas, Inc., Humana Health Plan, Inc., Humana Health Plans of Puerto Rico, Inc., Humana Insurance Company, Humana Insurance Company of Kentucky, Humana Insurance Company of New York, Humana Insurance of Puerto Rico, Inc., Humana Medical Plan of Pennsylvania, Inc., Humana Medical Plan of Utah,

Inc., Humana Medical Plan, Inc., Humana Regional Health Plan, Inc., Humana Wisconsin Health Organization Insurance Corporation, and M.D. Care, Inc. (collectively, "Operating Subsidiaries"). Operating Subsidiaries have assigned the claims pleaded herein to Plaintiff. Humana Inc. and its operating subsidiaries are referred to collectively as "Humana."

2. Defendant Medtronic, Inc. ("Medtronic") is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

3. Defendant Medtronic Sofamor Danek USA, Inc. ("MSD") is a Tennessee corporation, with its principal place of business at 2600 Sofamor Danek Drive, Memphis, Tennessee 38132. Defendant MSD is a wholly owned subsidiary of Defendant Medtronic. Medtronic and MSD are referred to collectively as "Defendants."

JURISDICTION AND VENUE

4. This Court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities and/or resided in the State of Tennessee.

5. This Court has personal jurisdiction over Defendants under Tenn. Code Ann. §20-2-201 and §20-2-14 et seq. (the Long Arm Statutes) because they have systematically and continuously transacted business in this state, either on their own or through the control of their subsidiaries, and supplied their products in this state.

6. Subject matter jurisdiction exists under 28 U.S.C. §1331. Because Humana Inc. asserts claims under 18 U.S.C. §1962, subject matter jurisdiction also exists under 18 U.S.C. §1964(c). Supplemental jurisdiction over Humana Inc.'s pendent state law claims exists under 28 U.S.C. §1367.

7. Venue over Defendants is proper in this District and Division because Shelby County is where Defendants reside, do business, and/or are headquartered, and specifically

because Defendants have had substantial, systematic, and continuous contacts with the State of Tennessee in Shelby County.

SUMMARY

8. This action arises from payments made by Humana for medical procedures employing Defendants' Infuse device and a component of the device known as recombinant bone morphogenetic protein-2 ("rhBMP-2" or "BMP"). Defendants paid for and sponsored publication of academic and peer-reviewed literature that falsely represented Infuse and BMP as safe and effective for uses not approved by the Food and Drug Administration ("FDA"). Defendants knew or should have known that Humana would rely on the fraudulent literature to pay for Infuse and/or BMP.

9. Defendants also aided and facilitated hospitals and physicians in obtaining payments from Humana through false statements and fraudulent omissions and concealment to obtain insurance payouts where Infuse and/or BMP was used. Humana would not have paid for such claims had it known the true facts regarding the uses of Infuse and/or BMP or the risks and efficacy of such uses.

10. Humana suffered damages and is entitled to subrogation as a result of payments Humana made for ineffective and unsafe use of Infuse or BMP, including revision surgeries, when far more medically sound and less expensive alternative procedures were available and would have been performed but for Defendants' tortious conduct. Defendants' wrongful acts include their intentional and/or negligent misrepresentations, fraudulent concealment and omissions, violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), violations of the consumer protection statutes of the fifty States, the District of Columbia and the

Commonwealth of Puerto Rico, breach of express and implied warranties, unjust enrichment, and conversion.

11. Humana is entitled not only to compensatory damages but also to punitive damages because of Defendants' malicious, intentional, grossly negligent, and reckless conduct in not disclosing the true risks of off-label uses of Infuse and BMP and in aiding and facilitating the submission of claims to Humana for payment of procedures involving such off-label uses, which were not disclosed to Humana as part of such claims. Defendants' tortious acts caused Humana to pay millions of dollars for Infuse and/or BMP for the ultimate benefit of Defendants.

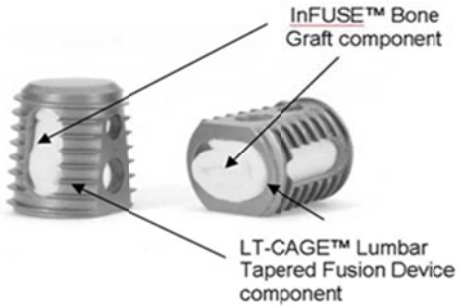
FACTS

The Infuse Bone Graft Device

12. Defendants manufactured, designed, marketed, promoted, and sold Infuse for use in lumbar spine fusion surgeries.

13. Infuse contains a bioengineered bone-protein, BMP, and it is used as an alternative to bone grafting, which involves the transplantation of a piece of bone from the patient's own hip (or bone from a cadaver) to the spine to promote bone growth. The purported goal of Infuse is to achieve the ultimate outcome of bone transplantation by stimulating bone growth with the use of BMP without producing the possible adverse side effects of a bone grafting procedure, which can be painful at the donor site.

14. The Infuse device is a "system" that combines two components: (1) BMP soaked into an absorbable collagen sponge (ACS); and (2) a metallic spinal fusion cage, called an "LT-Cage."



15. The LT-Cage allegedly maintains the spacing between vertebrae and temporarily stabilizes the diseased region of the spine, while the Infuse bone graft component is used to form bone, with the goal of permanent stabilization (fusion) of the spine.

16. During surgery, BMP is soaked onto and binds with the absorbable collagen sponge that is designed to resorb, or disappear, over time. As the sponge dissolves, the BMP is designed to stimulate the cells to produce new bone.

The Pre-Market Approval For Infuse

17. The FDA reviewed the safety and effectiveness of the Infuse device only for the uses Defendants specified in their Pre-Market Approval ("PMA") application, and the regulations are premised on that specific review.[1]

18. As presented in Defendants' original PMA application, Infuse consists of two components: (1) the tapered LT-CAGE Lumbar Tapered Fusion Device Component, a thimble-sized hollow metal cylinder that keeps the vertebrae in place and provides a frame that contains and directs the development of new bone growth; and (2) The Infuse Bone Graft Component, which includes an Absorbable Collagen Sponge ("ACS") that acts as a carrier and scaffold for the BMP, the actual active ingredient that is reconstituted in sterile water and applied to the ACS.

[1] *See* 21 U.S.C.§ 360c(a)(2) (stating that the FDA measures the "safety and effectiveness of a device… with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use"); *id.*§ 360e(c)(1) (2012).

19. Although Defendants sold these two components separately, the initial approved labeling for the product indicates Infuse requires both components.

20. The PMA was accompanied by an attachment setting forth the general "Conditions of Approval."

21. These general conditions (applicable to all Class III approved devices during 2002) require Defendants to submit a PMA supplement "when unanticipated adverse effects, increase in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."

22. The general "Conditions of Approval" section of the PMA also sets forth, in part, that "[c]ontinued approval of this PMA is contingent upon submission of post-approval reports required under 21 C.F.R. 814.84 (2012) at intervals of 1 year from the date of approval of the original PMA." These reports must include any adverse results or reactions from the use of Infuse.

23. The general "Conditions of Approval" section of the PMA provided, in part, that Defendants must comply with The Medical Devices Reporting Regulation and "report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer: 1. May have caused or contributed to a death or serious injury; or 2. Has malfunctioned and such device or similar device marked by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

24. Such post-approval reports must include "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices

('related' devices includes devices which are the same or substantially similar to the applicant's device); and reports in the scientific literature concerning the device."

25. The FDA Advisory Committee hearing involving the initial PMA of Infuse took place on January 10, 2002.

26. Defendants' agents, Thomas A. Zdeblick, M.D., Hallett Matthews, M.D., and Scott Boden, M.D., three of Defendants' most highly paid consultants and royalty recipients, were present and testified on behalf of Defendants at the hearing.

27. Agents Zdeblick, Matthews, and Boden assured the Committee (particularly through Defendant's agent Boden) that the only approval sought, *i.e.,* use of Infuse for the single level lumbar anterior approach, would prevent leakage of the BMP into the neural elements of the spine.

28. At the time of this hearing, Defendants' agent Thomas A. Zdeblick, M.D. was a consultant for Defendants, making $400,000 per year for eight days of consulting (not including "royalties" he received from Defendants).

29. At the time of this hearing, Defendants' agent Scott Boden, M.D. was receiving at least $100,000 per year in consulting fees from Defendants (not including "royalties" he received from Defendants).

30. At the time of this hearing, Defendants' agent Hallett Mathews, M.D. was making an average of at least $250,000 per year in consulting fees from Defendants.

31. At the time of this hearing, Defendants' agents Dr. David Polly, J. Kenneth Burkus, M.D., and Charles Branch, M.D. were all listed by Defendants as resources for this hearing, and were presumably present, but did not speak (all received significant consulting and/or royalty payments from Defendants) as discussed below.

32. Six months following the initial hearing, the Committee on July 2, 2002, voted to approve Infuse for use with the tapered LT-Cage in a single level Anterior Lumbar Interbody Fusion ("ALIF") procedure.

After Approval, Defendants Focused on Promoting Off-Label Use of BMP Because Off-Label Use was the Most Profitable Use

33. The FDA-approved use had an extremely small share of the spinal fusion market because the vast majority of spinal fusion surgeries are "posterior" as opposed to the "anterior" approach approved by the FDA for Infuse.

34. Because the approved use was limited to an ALIF procedure using the LT-CAGE, Defendants endeavored to expand BMP's market to surgeries involving a posterior or lateral approach.

35. In order to expand the market for BMP and dramatically improve profits from its use, Defendants engaged in a sophisticated and deeply deceptive marketing strategy that continues to the present.

36. Defendants have spent hundreds of millions of dollars funding, assisting, and encouraging physicians to use and insurers to pay for off-label use of BMP by overstating the benefits and effectiveness of BMP while minimizing the serious risks and adverse outcomes of off-label BMP use. The reliable scientific evidence demonstrates that Defendants' claims regarding BMP are false and BMP is not safe or effective.

37. Defendants' efforts were wildly successful. Defendants listed sales of Infuse at approximately $900 million for 2011 alone. The vast majority of these sales, 85% to 90%, were not of the Infuse device approved by the FDA, but were sales of BMP, only one of the components.

38. Sean Hirschkorn was a sales representative and Medtronic employee who promoted Infuse sales in Southwestern United States from 2004 through 2008. According to Hirschkorn, the Posterior Lumbar Interbody Fusion ("PLIF") and Transforaminal Lumbar Interbody Fusion ("TLIF") off-label procedures were far more common surgeries than the ALIF procedure.

39. Chris Eddy, a regional sales manager in Northwestern United States from 2002 to 2004, also reported that the vast majority of Infuse sales were for "off-label" uses, citing the high volume of sales coupled with very low numbers of ALIF procedures (the only FDA-approved spinal procedure) actually being performed.

40. Victor Harmon, a sales associate, corroborated these reports by disclosing that the vast majority of Infuse procedures were in fact off-label and that the product was "tremendous" with regard to Defendants' overall growth.

41. Defendants tied their sales representatives' compensation almost solely to their sales quotas for the first component, the BMP/Sponge, but had no incentives or bonuses related to the sales of the second component, the LT-CAGE.

42. This compensation plan was purposeful and intended to increase sales of BMP for off-label use.

43. Defendants' reimbursement strategy with insurance carriers was also designed to, and did, promote the sale of BMP for off-label use.

Defendants Used Key Opinion Leaders to Promote the Profitable, Off-Label Use of BMP

44. Defendants expanded BMP sales by paying large amounts of money to "Key Opinion Leader" ("KOL") spine surgeons around the country, many of whom then published articles, or appeared at special "dinners" or continuing education seminars advocating BMP use

in posterior approach surgeries, without the LT-CAGE, while misrepresenting the benefits and efficacy of BMP and, at the same time, minimizing the risks or dangers of using BMP.

45. Defendants paid at least $210 million to these KOLs, who, in turn, improperly influenced and promoted the sale of BMP.

46. Defendants cultivated financial relationships with KOLs, paying them handsomely for consulting fees, disguised royalties, travel expenses, seminars, and other perks, in order to encourage and reward these physicians for promoting the off-label use of BMP. Both Defendants and KOLs knew BMP was not more effective than autograft bone, but was in fact, far more dangerous.

47. Defendants promoted BMP use through KOLs because if these influential physicians were willing to promote off-label use of BMP, other surgeons would follow suit, which is what in fact happened.

48. Defendants and their KOLs, working as co-conspirators in furtherance of this off-label enterprise, understood that physicians, health care providers, and health insurers and third party payors, such as Humana, learned about new spinal procedures and products through various sources of information including: (a) medical literature; (b) medical conferences and seminars; (c) sales representatives from drug and device companies, like Defendants; and (d) consulting with peers in the spine surgery community.

49. Defendants, with their KOLs, sales representatives, and other agents, infiltrated each of the sources of information listed above.

50. Defendants and their KOLs systematically corrupted and tainted the sources of information regarding Infuse and BMP either through explicit misrepresentations of fact or

through the withholding of information when Defendants, their KOLs, and other agents had a duty to speak.

51. Defendants and their KOLs knew and conspired to keep secret that the KOLs were simply highly paid salesmen of Defendants' products, and were not, as they appeared, objective scientists and investigators giving opinions regarding the safety and efficacy of BMP.

52. Defendants and their KOLs withheld the fact that Defendants paid the KOLs huge sums of money based on the sales of Defendants' products. Defendants paid this money at the same time the KOLs made supposedly "unbiased," objective scientific statements regarding the risks and benefits of Infuse.

53. Humana did not and could not have known of the conspiracy amongst Defendants, the KOLs, sales representatives, and other agents of Defendants.

54. Because of Defendants' conduct, Humana relied on opinions and scientific research published by Defendants and their KOLs in paying claims for off-label use of Infuse and/or BMP. Humana would not have paid such claims if it had known that Defendants, while engaged in this deceptive enterprise, had tainted every credible and independent source of investigation available to Humana to conduct outside research about the benefits and efficacy of Infuse and/or BMP when compared to more traditional fusion approaches.

Agent Scott Boden

55. Between 1996 and 2010, Defendants' agent Scott Boden, M.D. received compensation from Defendants of $28,796,034.00.

56. During such period of time, Defendants' agent Scott Boden, M.D. wrote extensively on the use of Infuse and BMP in an off-label manner.

57. By way of example and not limitation, Defendants' agent Scott Boden, M.D. wrote that use of BMP is likely to be effective even for uses and in a manner contrary to the Infuse PMA. His article in *Orthopedic Nursing* also praises the benefits of the product, noting that while BMP "is quite expensive, [its] potential to lessen morbidity, accelerate healing and provide more consistent results undoubtedly justify these costs in appropriately selected patients."

58. By way of example and not limitation, Defendants' agent Scott Boden, M.D., along with Drs. Paul A. Anderson, Keith H. Bridwell, and Jeffrey C. Wang, authored a July 2007 article in the *Journal of Bone and Joint Surgery*, titled "What's New in Spine Surgery." The article discussed, among other things, a study that examined the use of BMP in a Posterolateral Fusion procedure, contrary to the ALIF approved by the Infuse PMA. According to the authors, the study reported that BMP improved fusion rates when used in combination with iliac crest bone graft ("ICBG") in an unapproved procedure in which BMP was wrapped around local bone as a bulking agent.

Agent Thomas Zdeblick

59. Defendants paid their agent Thomas A. Zdeblick, M.D. an annual salary of $400,000 under a contract that only required him to work eight days per year.

60. Defendants' agent Thomas A. Zdeblick, M.D. received $34,168,739.81 from Defendants between 1996 and 2010.

61. Defendants' agent Thomas A. Zdeblick, M.D. also has been a significant contributor to Defendants' promotion of BMP, authoring seven peer-reviewed articles on BMP and appearing as a presenter at medical conferences and symposia in which the topics included discussion of uses of BMP.

62. Only a few months after Infuse was approved, Defendants' agent Thomas Zdeblick, M.D. authored a 2003 paper in which he declared that BMP could become "the new gold standard" in spine surgery and added that it was being used "exclusively" at his institution. The paper was published in the *Journal of Spinal Disorders & Techniques*, where Zdeblick is the editor-in-chief, but failed to mention that he received significant royalties on the Medtronic LT-Cage, which is the second component of Infuse.

63. On the website, www.Back.com, which is owned and operated by Defendants, Defendants' agent Thomas A. Zdeblick, M.D. describes the advantages of BMP and appears in an online video discussing the benefits of the product which he claims includes no adverse events. Conspicuously, the video only discusses spinal surgery from the posterior approach of the spine, a procedure contrary to the restrictions in the Infuse PMA, and fails to discuss or provide any merit to the approved approach. In this video, Defendants' agent Thomas A. Zdeblick states "we looked at the safety concerns with Infuse very carefully and did not find any adverse events, it's a naturally occurring protein and well accepted by patients." (Emphasis added).

Agent Kenneth Burkus

64. Defendants' agent J. Kenneth Burkus, M.D., is an orthopedic surgeon and a self-described "consultant" for Defendants.

65. Defendants' agent J. Kenneth Burkus, M.D. received $6,380,336.83 from Defendants between 1996 and 2010.

66. During such period of time, Defendants' agent J. Kenneth Burkus, M.D. was the lead author of four of the original thirteen studies of Infuse sponsored by Defendants.

67. All of the studies by Defendants' agent, J. Kenneth Burkus, M.D., failed to report

any of the observed adverse events recently revealed by an independent review of his data.

Agents Lawrence Lenke and Keith Bridwell

68. Defendants' agents, Lawrence "Larry" G. Lenke, M.D. and Keith H. Bridwell, M.D., two surgeons from Washington University in St. Louis, acted as KOLs or "guest surgeons" during "corporate visits" in which Defendants would invite unsuspecting targeted surgeons to attend training sessions in Memphis, Tennessee.

69. While in Memphis, the visiting surgeons met with Defendants' corporate officers, product managers, and guest surgeons, such as Lawrence "Larry" G. Lenke, M.D. and Keith H. Bridwell, M.D. The visiting surgeons also received "hands-on training" on Infuse, including instruction in cadaver labs. The guest surgeon would show the visiting surgeons how to use Infuse. Defendants chose which surgeons to invite to these corporate visits based, in part, on the volume of Infuse procedures they performed.

Agent Regis Haid

70. Defendants' agent Regis Haid, M.D. received $25,549,813 from Defendants between 1996 and 2010.

71. Agent Regis Haid, M.D. led a study sponsored by Defendants that was peremptorily halted.

72. Defendants' agent Regis Haid, M.D. reported, "no unanticipated device-related adverse events occurred."

73. Defendants' agent Regis Haid, M.D. asserted that no patient required reoperation because of an adverse event related to the use of BMP.

74. Defendants' agent Regis Haid, M.D. concluded that the study "confirmed the safety" of BMP and suggested that the findings might "eliminate the need" for autograft in "successful PLIF."

75. The study noted, "[a]lthough not desirable, bone formation in the spinal canal does not appear to have a discernible effect on the patient outcomes," and "the de novo rhBMP-formed bone occurred predictably, not compressing the neural structures." The authors surprisingly did not find the incidents of bony overgrowth to be a clinically significant concern.

76. Defendants' agent Regis Haid, M.D. failed to include **any** data pertaining to patients requiring an additional surgery to remove ectopic bone growth. Another physician who was part of the study reported that two of his patients involved in the study "had significant posterior bony over-growth impinging on their nerve roots requiring additional surgery." One of these patients required two surgeries "to clear excessive bone formation from his spinal canal." Rather than disclose this critical safety information, Defendants' agent Regis Haid, M.D. chose to contrive the findings of his study and "confirmed the safety" of BMP.

Defendants Published a False "Fact Sheet"

77. Following FDA approval of Infuse, Defendants published a "Fact Sheet." The Fact Sheet falsely represented, in part, the following:

> **Fact Sheet**
>
> Spinal fusion surgery with INFUSE® Bone Graft and the LT-CAGE® Device is essentially the same as traditional autograft procedures, without the need for the additional surgery to harvest bone from the patient's hip. Scientists determined that rhBMP-2, with an absorbable collagen sponge as the carrier, (INFUSE® Bone Graft) is an effective replacement for autograft bone in spinal fusion surgery. This conclusion is based on data resulting from a large-scale, multi-center, prospective, randomized, two-year study involving 279 degenerative disc disease patients implanted with INFUSE® Bone Graft and the LT-CAGE® Lumbar Tapered Fusion Device. The study assessed the safety, efficacy and therapeutic benefits of the new procedure as compared to traditional autograft procedures… The data showed that the study met all of its primary endpoints… Long-term cost offsets

(within two years of surgery): Significantly fewer complications that would require follow-up visits.

78. Defendants did not reveal that its employees significantly altered the printed/reported results of the "studies" referred to in the Fact Sheet to reflect better outcomes for BMP and worse outcomes for the alternative procedures, than what was actually observed.

79. Nor did Defendants disclose that these "scientists" were extremely highly compensated by Defendants or that their employees actively edited, participated in the creation of, and/or ghostwrote the text used in the published study.

Defendants Made False Statements and Misrepresentations Regarding BMP on Their Websites

80. Defendants misrepresented the efficacy of BMP through their corporate-sponsored websites and cited to the false and misleading studies created by Defendants.

81. On www.medtronic.com, Defendants falsely claim "[b]one formation remote from the site of the implantation was not seen in the clinical trials."

82. Defendants mislead viewers through the bolded section "**I have heard people talk about hip pain after harvesting lasting up to 2 years or longer. Is that true?**"

83. Defendants warrant a 94.5% fusion rate with Infuse compared to autograft's 88.7% on the company-sponsored website www.infusebonegraft.com.

84. The purported success rates are derived from two studies provided on the website. Defendants paid five of the seven authoring physicians of these articles collectively $76,603,827 in various forms of compensation. Defendants did not adequately disclose their financial relationship with these physicians, and Defendants failed to provide accurate and unbiased information to physicians and patients on the corporate-sponsored website.

www.back.com

85. Defendants published a website providing back pain resources, including surgical and non-surgical treatment options.

86. Surgical options described on the website include Spinal Fusion, ALIF, DLIF, PLIF, and TLIF.

87. Defendants posted a section on June 27, 2002, entitled "Surgery from the Front or Back: Is There a Difference?"

88. The author, Dr. Thomas Schuler, discussed the benefits and complications related to ALIF (approved use of Infuse) and PLIF (an FDA unapproved procedure when used with the BMP in Infuse).

89. Dr. Schuler first discussed the complications related to a PLIF surgery conducted without the advantages afforded by the BMP in Infuse. He shared that PLIFs frequently require an autograft, which is bone generally removed from the pelvis or iliac crest of the patient using either chisels or different awls. Dr. Schuler further explained:

> The reason for taking the autograft is that it is very effective and is the gold standard for use in the fusion surgery that we have had to date. The problem with the removal of this bone is that it can be very painful. In fact, around 25% of patients who have had this bone graft procedure have some sort of chronic pain associated with the graft site after surgery.

Dr. Schuler then described the benefits of the BMP in Infuse, asserting:

> The beauty of this substance is that it will allow us to obtain a solid fusion without any of the complications of harvesting bone graft. In essence, surgeons get the same or better results without the problems. For patients who are petrified of pain and bone grafts, this is wonderful news.

www.necksurgery.com

90. Defendants published www.necksurgery.com, touting the website as "[t]he online resource for questions about neck pain, spinal health and treatment options."

91. Necksurgery.com lists several surgical options for the neck, which include Anterior Cervical Discectomy with Fusion ("ACDF"), an "off-label" surgery when performed with Infuse.

92. Navigating the site brings a list of links to "Articles."

93. One of these articles is entitled "INFUSE Bone Graft/PEEK Interbody Spacer/Anterior Cervical Plate Clinical Trial Underway." This page was published February 13, 2008 and updated September 07, 2011. For nearly two pages, the article heralds the benefits of Infuse, stating that "[o]ver 500,000 patients have been successfully treated since FDA approval in 2002," and that "[o]ver 15 FDA-approved clinical trials have been performed using INFUSE Bone Graft, making it the most studied biologic agent available to surgeons today."

94. However, thirteen of the fifteen studies referenced in this "article" have been repudiated for gross bias and inaccurate disclosures of adverse effects.

Defendants' False and Misleading Studies Caused Humana to Pay for Infuse

95. Humana provides health insurance coverage through health insurance policies ("Policies"). The Policies provide coverage for medical treatment provided to Members ("Members"). Humana's Polices cover Members in all 50 states.

96. Humana requires pre-approval for non-emergent procedures such as spinal fusion surgery. As part of the pre-approval process, the medical treatment provider must give information to Humana regarding the procedure.

97. Defendants published a Reimbursement Guide ("Guide") for medical service providers. The Guide provided step-by-step instructions as to how a medical service provider could obtain payment from an insurance company, like Humana, for the off-label use of Infuse and/or BMP. The instructions included obtaining "peer reviewed studies" from a "Medtronic sales representative." The studies referenced were the fraudulent studies sponsored by Defendants and their KOLs.

98. Defendants, on their own and through the use of their agents, engaged in a systematic campaign to publish studies that contained false and misleading information regarding Infuse and/or BMP.

99. These studies were designed to create a library of academic literature Humana and other insurers and health care providers would rely on to approve and pay for the use of Infuse and/or BMP.

100. Defendants intended for Humana and others, to rely on the false and misleading studies to pay for Infuse and/or BMP.

101. Defendants and their KOLs systematically corrupted and tainted the sources of information Humana relied on for coverage determinations.

102. In approving spinal fusion surgeries, Humana relied on the false and misleading studies published by Defendants regarding Infuse and/or BMP.

103. The false information published by Defendants was material to Humana's payment decisions, and Defendants intended for Humana to rely on such information to pay for Infuse and/or BMP.

104. Absent such false representations and/or omissions, Humana would not have provided insurance coverage for Infuse and/or BMP.

105. Defendants also sponsored and/or conducted regular seminars for physicians and other providers to assist with reimbursement of Infuse and/or BMP from health insurers.

106. Defendants provided false and misleading information, including the false and misleading studies sponsored by Defendants, that Defendants intended the providers and physicians to rely on in selecting Infuse and/or BMP and then seeking reimbursement from Humana and others for the use of Infuse and/or BMP.

107. Defendants also aided and facilitiated the submission of claims by health care providers and physicians for Humana to pay for procedures in which the off-label use of Infuse and/or BMP was not adequately disclosed.

Leading Spine Experts Repudiate Medtronic Studies

108. On June 1, 2011, *The Spine Journal* published a special edition entirely dedicated to addressing serious patient safety and ethical concerns stemming from the use of BMP in spinal surgeries.

109. *The Spine Journal's* articles discussed Defendants' failure to report accurately the serious side effects from its clinical trials.

110. *The Spine Journal's* articles discussed Defendants' failure to report that many of the authors of the sponsored studies failed to disclose that they received substantial compensation and had significant financial ties to Defendants.

111. This special edition analyzed thirteen peer-reviewed articles about BMP by industry-sponsored authors, including many sponsored by Defendants, finding that these articles had inaccurately reported the safety and risks associated with BMP.

112. Defendants' sponsored studies authored by KOLs universally touted the benefits of BMP and simultaneously failed to disclose the adverse events associated with its use.

113. In an editorial summarizing the findings of the special issue, five prominent

physicians wrote that the earlier trials and reports sponsored by Defendants were "remarkable for the complete absence of reported rhBMP-2-related clinical adverse events." In fact, the initial studies did not report "a single adverse event associated with rhBMP-2 use in 780 protocol patients."

114. Defendants' sponsored studies "underestimated the risks of rhBMP-2 use despite indication from the earliest trials." For example, Defendants' sponsored articles omitted mention of adverse events which were evident from the earliest trials, including "inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement."

115. Defendants' sponsored studies also omitted mention of sterility and cancer risks associated with BMP.

116. One of the most damaging aspects of this article was the disclosure that the risk of adverse events associated with BMP is actually ***10 to 50 times the original estimates*** reported in Defendants' sponsored studies.

117. According to *The Spine Journal* editorial, the thirteen articles sponsored by Defendants reported only successful fusions and low rates of complications with Infuse. The reviewing physicians opined that the articles "may have promoted widespread and poorly-considered on-label and off-label use, eventual life-threatening complications and deaths."

118. In the original thirteen studies performed by Defendants' influenced physicians, zero adverse events were reported out of 780 clinical patients. According to these studies, not a single adverse event was attributed to BMP. In other words, the product was falsely marketed as perfect.

Senate Committee Investigation Reveals
False Information Published by Defendants

119. The United States Senate Committee on Finance ("Senate Committee") investigated whether Defendants continued to misrepresent the adverse events caused by Infuse and BMP, as well as the possibility that Defendants improperly influenced the reporting of results collected from clinical trials and reporting regarding BMP.

120. Following this investigation, the Senate Committee published a report of its findings on October 25, 2012 ("Senate Report").

121. The 16-month inquiry led the Senate Committee to conclude:

i. Defendants were heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Defendants. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles. Medical journals should ensure industry role contributions be fully disclosed.

ii. Defendants paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty, and other miscellaneous arrangements.

iii. An e-mail exchange shows that Defendants' employee recommended against publishing a complete list of adverse events possibly associated with Infuse in a 2005 Journal of Bone and Joint Surgery article.

iv. Defendants' employees inserted language into studies that promoted Infuse as a better technique than taking a bone graft from the pelvic bone (autograft technique) by emphasizing the pain of the autograft technique.

v. Documents indicate that Defendants prepared Dr. Hal Mathew's remarks to the U.S. Food and Drug Administration (FDA) advisory panel meeting prior to Infuse being approved. At the time, Dr. Mathews was a private physician but was hired as a vice president at Medtronic in 2007.

vi. Defendants' documents show the company unsuccessfully attempted to adopt weaker safety rules for a clinical trial studying Infuse in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

122. As Doctors Michael Heggeness and Charles Mick observed, there is no way that a surgeon making the decision on what procedure and/or medical device to use for their patients, would use a procedure and/or medical device where the manufacturer of the device had paid the lead authors of the studies amounts ranging from $1.7 million to $64 million, and where the manufacturers own marketing employees were "secret" co-authors and co-editors of those very studies, resulting in the material distortion of the actual findings and results of those "studies."

123. The federal judiciary has recognized a genuine risk that financial conflicts of interest induce bias in scientific research. The Federal Judicial Center's key reference guide for judges considering scientific issues in their cases explains, "[j]udges and juries . . . must consider financial conflicts of interest when assessing scientific testimony. The threshold for pursing the possibility of bias must be low."

124. Research published in the *New England Journal of Medicine*, as well as other surveys, show that information brought by industry representatives to physicians impacts medical decision-making. The false and misleading information created by Defendants was intended to induce Humana and other insurance companies to pay for Infuse and/or BMP.

The Spine Journal Article Reveals False and Misleading Studies Paid For by Defendants

125. The published articles listed below were repudiated by *The Spine Journal,* and the authors' financial relationships with Defendants were only discovered through their investigation and disclosed by the Senate Report. All of the articles contain false and misleading information regarding Infuse and/or BMP.

126. Defendants paid their KOL Scott Boden, M.D. $28,796,034.00 from 1996-2010.

a. **Scott Boden** and Thomas A. Zdeblick et al., *The use of rhBMP-2 in interbody fusion cages. Definitive evidence of osteoinduction in humans*, 25 J. Spinal Disord. 376 (2000).
b. **Scott Boden** and John G. Heller et al., *Use of recombinant human bone morphogenetic protein-2 to achieve posterolateral lumbar spine fusion in humans: a prospective, randomized clinical pilot trial: 2002 Volvo Award in clinical studies*; 27 Spine 2662 (2002).
c. **Scott Boden**, Steven Glassman, John Dimar, Kenneth Burkus et al., *The efficacy of rhBMP-2 for posterolateral lumbar fusion in smokers*, 32 Spine 1693 (2007).

127. Defendants paid their KOL Charles Branch, M.D. $3,155,625.61 from 1996-2010.

a. **Charles Branch**, Regis Haid, Kenneth Burkus and J.T. Alexander., *Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages*, 4 Spine J. 527 (2004).

128. Defendants paid their KOL J. Kenneth Burkus, M.D. $6,380,336.83 from 1996-2010.

a. **J. Kenneth Burkus**, Michael F. Gornet, Curtis A. Dickman and Thomas A. Zdeblick, *Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages*, 15 J. Spinal Disord. Tech. 337 (2002).
b. **J. Kenneth Burkus**, Ensor E. Transfeldt et al., *Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenic protein-2*, 27 Spine 2396 (2002).
c. **J. Kenneth Burkus**, S.E. Heim, Michael F. Gornet and Thomas A. Zdeblick, *Is INFUSE bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT-Cage lumbar tapered fusion device*, 16 J. Spinal Disord. Tech. 113 (2003).
d. **J. Kenneth Burkus**, Charles Branch, J.T. Alexander and Regis Haid, *Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages*, 4 Spine J. 527 (2004).
e. **J. Kenneth Burkus** and Matthew Gornet et al., *Use of rhBMP–2 in combination with structural cortical allografts surgery: clinical and radiographic outcomes in anterior lumbar spinal fusion*, 87 J. Bone Joint Surg. Am. 1205 (2005).
f. John R. Dimar, Steven D. Glassman, **J. Kenneth Burkus** and Leah Y. Carreon, *Clinical outcomes and fusion success at 2 years of single-level instrumented posterolateral fusions with recombinant human bone morphogenic protein-2/compression resistant matrix versus iliac crest bone graft*, 31 Spine 2534 (2006).

g. **J. Kenneth Burkus**, Steven Glassman and John Dimar et al. *The efficacy of rhBMP–2 for posterolateral lumbar fusion in smokers*, 32 Spine 1693 (2007).
h. John Dimar, Steven Glassman, **J. Kenneth Burkus**, et al. *Clinical and radiographic analysis of an optimized rhBMP–2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis*, 91 J. Bone Joint Surg. Am. 1377 (2009).
i. **J. Kenneth Burkus** and Steven Glassman et al., *Recombinant human bone morphogenetic protein–2 on an absorbable collagen sponge with an osteoconductive bulking agent in posterolateral arthrodesis with instrumentation. A prospective randomized trial*, 9 J. Bone Joint Surg. Am. 1604 (2009).

129. Defendants paid their KOL Curtis Dickman, M.D. $3,272,941.85 from 1996-2010.

a. J. Kenneth Burkus, Michael F. Gornet, **Curtis A. Dickman** and Thomas A. Zdeblick, *Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages*, 15 J. Spinal Disord. Tech. 337 (2002).

130. Defendants paid their KOL John Dimar, M.D. $1,766,366.21 from 1996-2010. Defendants also paid Concept Properties, LLC, a limited liability corporation owned in part by Defendants' KOL John Dimar, M.D., $64,831,268.00 from 1996-2010.

a. **John R. Dimar**, Steven D. Glassman, J. Kenneth Burkus and Leah Y. Carreon, *Clinical outcomes and fusion success at 2 years of single-level instrumented posterolateral fusions with recombinant human bone morphogenic protein-2/compression resistant matrix versus iliac crest bone graft*, 31 Spine 2534 (2006).
b. Steven D. Glassman, J. Kenneth Burkus and **John R Dimar** et al. *The efficacy of rhBMP–2 for posterolateral lumbar fusion in smokers*. 32 Spine 1693 (2007).
c. **John R Dimar**, Steven D Glassman, J Kenneth Burkus, Philip W Pryor, James W Hardacker and Leah Y. Carreon, *Clinical and radiographic analysis of an optimized rhBMP-2 formulation as an autograft replacement in posterolateral spine arthrodesis*, 91 J. Bone Joint Surg. Am. 1377 (2009).

131. Defendants paid their KOL Steven Glassman, M.D. $1,748,263.36 from 1996-2010. Defendants also paid Concept Properties, LLC, a limited liability corporation owned in part by Defendants' KOL Steven Glassman, M.D., $64,831,268.00 from 1996-2010.

a. John R. Dimar, **Steven D. Glassman**, Kenneth J. Burkus and Leah Y. Carreon, *Clinical outcomes and fusion success at 2 years of single-level*

instrumented posterolateral fusions with recombinant human bone morphogenic protein-2/compression resistant matrix versus iliac crest bone graft, 31 Spine 2534 (2006).

b. **Steven D. Glassman**, J. Kenneth Burkus and John Dimar et al. *The efficacy of rhBMP–2 for posterolateral lumbar fusion in smokers*. 32 Spine 1693 (2007).

c. John R Dimar, **Steven D Glassman**, J Kenneth Burkus, Philip W. Pryor, James W Hardacker and Leah Y. Carreon, *Clinical and radiographic analysis of an optimized rhBMP-2 formulation as an autograft replacement in posterolateral spine arthrodesis*, 91 J. Bone Joint Surg. Am. 1377 (2009).

d. J. Kenneth Burkus and **Steven Glassman** et al., *Recombinant human bone morphogenetic protein–2 on an absorbable collagen sponge with an osteoconductive bulking agent in posterolateral arthrodesis with instrumentation. A prospective randomized trial*, 9 J. Bone Joint Surg. Am. 1604 (2009).

132. Defendants paid their KOL Matthew Gornet, M.D. $3,985,776.22 from 1996-2010. Gornet Enterprises, LLC is a limited liability corporation owned in part by Defendants' Agent Matthew Gornet, M.D.

a. J. Kenneth Burkus, **Matthew F. Gornet**, Curtis A. Dickman and Thomas A. Zdeblick, *Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages*, 15 J. Spinal Disord. Tech. 337 (2002).

b. J. Kenneth Burkus, S.E. Heim, **Michael F. Gornet** and Thomas A. Zdeblick, *Is INFUSE bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT-Cage lumbar tapered fusion device*, 16 J. Spinal Disord. Tech. 113 (2003).

c. J. Kenneth Burkus and **Matthew Gornet** et al., *Use of rhBMP–2 in combination with structural cortical allografts surgery: clinical and radiographic outcomes in anterior lumbar spinal fusion*, 87 J. Bone Joint Surg. Am. 1205 (2005).

133. Defendants paid their KOL Regis Haid, M. D. $25,549,813.96 from 1996-2010.

a. Charles Branch, **Regis Haid**, Kenneth Burkus and J.T. Alexander., *Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages*, 4 Spine J. 527 (2004).

b. Gerald E. Rodts, **Regis Haid** et al., *Anterior cervical discectomy and fusion involving a polyetheretherketone spacer and bone morphogenetic protein*, 2 J. Neurosurg. Spine 521 (2005).

134. Defendants paid their KOL John G. Heller, M.D. $1,774,436.29 from 1996-2010.

a. Scott Boden and **John G. Heller** et al., *Use of recombinant human bone morphogenetic protein-2 to achieve posterolateral lumbar spine fusion in*

humans: a prospective, randomized clinical pilot trial: 2002 Volvo Award in clinical studies; 27 Spine 2662 (2002).

135. Defendants paid their KOL Gerald E. Rodts, Jr., M.D. $3,181,962.56 from 1996-2010.

a. **Gerald E. Rodts,** Regis Haid et al., *Anterior cervical discectomy and fusion involving a polyetheretherketone spacer and bone morphogenetic protein*, 2 J. Neurosurg. Spine 521 (2005).

136. Defendants paid their KOL Volker Sonntag, M.D. $22,852,083.93 from 1996-2010.

a. **Volker Sonntag**, et al., *A prospective, randomized, controlled cervical fusion study using recombinant human bone morphogenetic protein–2 with the CORNERSTONE–SR allograft ring and the ATLANTIS anterior cervical plate*, 28 Spine 1219 (2003).

137. Defendants paid their KOL Ensor Transfeldt, M.D. $3,562,320.44 from 1996-2010. Additionally, Defendants paid Inspire, LLC, a limited liability corporation owned in part by Defendants' KOL Ensor Transfeldt, M.D., $2,909,005.00.

a. J. Kenneth Burkus, **Ensor E. Transfeldt** et al., *Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenic protein-2*, 27 Spine 2396 (2002).

138. Defendants paid their KOL Thomas A. Zdeblick, M.D. $34,168,739.81 from 1996-2010.

a. Scott Boden and **Thomas A. Zdeblick** et al., *The use of rhBMP-2 in interbody fusion cages. Definitive evidence of osteoinduction in humans*, 25 J. Spinal Disord. 376 (2000).
b. J. Kenneth Burkus, Michael F. Gornet, Curtis A. Dickman and **Thomas A. Zdeblick**, *Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages*, 15 J. Spinal Disord. Tech. 337 (2002).
c. J. Kenneth Burkus, S.E. Heim, Michael F. Gornet and **Thomas A. Zdeblick**, *Is INFUSE bone graft superior to autograft bone? An intergrated analysis of clinical trials using the LT-Cage lumbar tapered fusion device*, 16 J. Spinal Disord. Tech. 113 (2003).

139. Defendants' officials recommended against publishing "a complete list of adverse events possibly associated with Infuse." In 2004, Dr. Julie Bearcroft, the Director of Technology Management in Medtronic's Biologics Marketing Department, wrote an email to other high-level Medtronic employees stating:

> *I have made some significant changes to this document (some at the request of Dr. Burkus) both in format and content. . . . How much information should we provide relative to adverse events?. . .You will see my [note] in the attached document but I don't think significant detail on this section is warranted.*

140. The prior draft of the paper included material adverse events. However, Defendants' KOL J. Kenneth Burkus, M.D., deliberately and intentionally deleted these adverse events from the final published report.

141. This was confirmed by the findings of the Senate Committee. According to the Senate Report, "Medtronic recommended against including information in the study that was ultimately revealed to have an association between Infuse and weakening that could lead to collapse of the bone and implant and required patients undergo additional surgery."

Defendants Over-Emphasized Pain for Alternative Spinal Treatments

142. The Senate Report uncovered documents that show "Medtronic edited draft publications to stress the pain patients experienced from undergoing a bone graft procedure instead of receiving InFuse."

143. Neil Beals, Medtronic's Vice President of Biologic Marketing, sent emails to authoring physicians in two separate studies suggesting that more emphasis be placed on the elimination of "donor site" pain when the surgeon elected to use Infuse and/or BMP instead of a bone graft.

144. Defendants' website promoted the benefits of Infuse over traditional iliac crest bone grafts, stating that "[a]ccording to numerous studies, the harvesting procedure is actually more painful than the fusion itself, and nearly a third of patients experience hip pain two years following surgery." However, these studies only included such information after persistent insistence by Medtronic's Vice President.

145. Vice President Beals worked directly with Defendants' KOL J. Kenneth Burkus, M.D. and encouraged him to include information emphasizing the pain related to the "donor site."

146. After reviewing a draft of Defendants' KOL J. Kenneth Burkus, M.D.'s study, Vice President Beals emailed Dr. Burkus, stating "a bigger deal should be made of elimination of donor site pain with Infuse."

147. Nearing publication, Vice President Beals again sent an email suggesting, "would it be appropriate to make a bigger deal out of donor site pain?"

148. At the apparent direct request of Vice President Beals, a sentence was incorporated into the final published study stating, "[t]he use of rhBMP-2 is associated with high fusion rates without the need for harvesting bone graft from the iliac crest and exposing the patient to adverse effects associated with that procedure."

149. Again, Vice President Beals inserted comments encouraging discussion of donor site pain on a draft article co-authored by another KOL Volker Sonntag, M.D.

150. According to the Senate Report, Defendants paid their KOL Volker Sonntag, M.D. nearly $23 million dollars. The article co-written by Dr. Sonntag stated, "[b]y 12 months after surgery, the patients [*sic*] graft-site pain resolved…and no patient complained about the graft-site appearance."

151. Despite this finding, Vice President Beals inserted comments on the draft stating, *"ALTHOUGH THE PATIENTS DID NOT COMPLAIN ABOUT APPEARANCE DIDN'T SOME STILL EXPERIENCE PAIN AT THE DONOR SITE? SEEMS LIKE RESIDUAL EFFECT OF DONOR SITE SHOULD BE NOTED."*

152. In a subsequent email, Medtronic's Vice President wrote, "I would also add in more discussion on donor site pain and need for osteogenetic graft material (plant seed of doubt for just using allograft by itself)."

153. These suggestions were incorporated into the final published version of the scientific article without mention of the nearly $23 million dollars Defendants paid their KOL Volker Sonntag or of Defendants' significant participation in the ghostwriting of the study.

Defendants Arranged to Delete Adverse Events From Their Funded Studies

154. The Senate Report found that "Medtronic employees not only edited the draft manuscript to include comments supportive of Infuse, they also covertly participated in the peer-review process … on behalf of the physician authors named on the paper."

155. Defendants' KOL J. Kenneth Burkus, M.D. "sent a draft manuscript of the study to Medtronic officials asking for assistance with 'further data analysis.'"

156. Bill Martin, Vice President for Spinal Marketing Global Communications and Medical Education at Medtronic, made it clear to other employees that Defendants "would play a 'supporting cast' in assisting Dr. Burkus."

157. Defendants' KOL, J. Kenneth Burkus, M.D. informed Bill Martin that he "wanted his name last (and all the neuro's first) so that it would be well accepted by the Neurosurgical community."

158. Vice-President Richard Treharne also instructed Defendants' KOL Steven Glassman, M.D. to dramatically downplay references to what he referred to as complications related to Infuse by stating in an email, "[a]gain it is probably too late, but page 14 line 13 says 'The high complication rate is alarming and warrants intense scrutiny.' I think what you are trying to say is that the occurrence adverse events (not effects as in the title) in these patients was higher than expected and warrants further investigation."

159. Vice President Richard Treharne (recipient of the original FDA approval letter for Infuse in 2002) wrote an email to Defendants' KOL J. Kenneth Burkus, M.D. stating, "in looking over the data, I was impressed with how well the BMP patients actually did. So much so that I added a few paragraphs at the end that you may not agree with."

160. The additions to Defendants' KOL J. Kenneth Burkus, M.D.'s study by Vice President Richard Treharne read in part: "in conclusion, this detailed, independent review of the results which represent the first of use osteoinductive proteins in a PLIF procedure are encouraging."

161. All of the above were unknown to *The Spine Journal*'s peer-review committee. However, following submission of the initial draft to *The Spine Journal,* the peer-reviewing physicians were critical of the article's "presentation of the study results." The bias added by Defendants was so apparent that critiques by the peer-reviewers included: "[u]nless the authors can discuss the results of this study in an unbiased manner, which they have not been able to do in its present form, this data should not be published." Another reviewing physician stated, "The manuscript is full of biased statements that are a reflection of the data evaluators-the company that markets the product…As it stands it is an advertisement for a specific product without significant scientific merit."

162. In response to the concerns expressed by the peer-reviewing physicians, Defendants' response "**seemingly misled *The Spine Journal*"** (emphasis added), according to the Senate Report. In response to a letter from one of *The Spine Journal's* peer-reviewers, Defendants assisted in a draft response, noting, "[t]o help eliminate any potential bias, only one of the co-authors was a clinical investigator – the other three were independent reviewers of all the data. Since these data are taken from a clinical IDE study sponsored by a company, only the company would have all the data in its database—data that is reviewed by FDA auditors. We don't believe any discussion of bias is needed for the text."

163. The Senate Report found that these "independent reviewers"—Defendants' KOLs Regis Haid, M.D. and J. Kenneth Burkus, M.D.—received $7,793,000 and $722,000, respectively, by the end of 2003 and a total of $31,930,150.79 by 2010.

164. According to the Senate Report, the "draft letter, written at least in part by Medtronic on behalf of Dr. Burkus, did not disclose the company's role in directly editing the paper, nor did it disclose the magnitude of financial payments made to the supposed 'independent reviewers.'"

165. The Senate Report also uncovered an email, between Medtronic's Senior Vice President and President for Europe, Canada, Latin America and Emerging Markets, Michael Demane, to Medtronic's Vice President Bill Martin. Realizing that Defendants' significant involvement in editing and ghostwriting had been uncovered, Demane stated, "this is going to hurt more than help because of the reviewers [*sic*] comments. Too late to turn back tho [*sic*]," in response to an upcoming editorial criticizing the study.

YODA Confirmed Infuse And BMP Did Not Perform As Represented By Defendants

166. Following *The Spine Journal* article, Medtronic provided a $2.5 million grant to Harlan Krumholz, M.D. to fund the Yale University Open Data Access Project ("YODA").

167. YODA's stated goal was to "increase transparency and enhance the public trust in industry-funded clinical trials by facilitating the independent assessment and dissemination of data relevant to the benefits and harms of drugs and devices."

168. Through YODA, two academic teams, Oregon Health and Science University ("Oregon") and University of York ("York"), conducted independent reviews with full access to all of Defendants' clinical trials, post-marketing, and safety data regarding BMP.

Oregon Review

169. Oregon stated that "[t]he primary aims of this report are 1) to estimate the effectiveness and harms of rhBMP-2 in spinal fusion in a systematic review using the individual patent data ("IPD") when available, and 2) to assess reporting biases in published articles of industry-sponsored studies."

170. Oregon released its findings in June 2013 and found that: "there was serious selective reporting and underreporting of adverse events in the published articles for both rhBMP-2 and ICBG groups, especially in the Medtronic trials published early. The actual rates of adverse events were much higher than reported."

171. More specifically, Oregon reported that the IPD contained "315 adverse events in the rhBMP-2 group and 274 adverse events in the autograft group two years after surgery."

172. These findings are in direct contrast with the published version of Defendants' sponsored studies, which simply reported either "no unanticipated device-related adverse events" or "no adverse events directly or attributable to rhBMP-2."

173. The Oregon study defined reporting bias as "…[the] incomplete or inaccurate reporting of study outcomes and encompasses publication bias, outcome reporting bias, multiple publication bias, location bias, language bias, time lag bias, citation bias, and others (e.g. ghostwriting, misrepresentation of facts, reframing)."

174. After comparing results reported in the published literature to individual patient data, the authors concluded that "[e]vidence of reporting bias in the published articles of industry-sponsored trials is substantial."

175. The misrepresentations and bias were not limited only to the benefits of BMP. Some publications overemphasized "donor site hip pain," which was only assessed in the control group patients and only on the side of their iliac crest bone graft ("ICBG").

176. The authors recognized the consequences of this widespread reporting bias by stating "[s]uch underreporting and practice could affect the spine surgeons' ability to evaluate the balance between the benefits and harms of using rhBMP-2 and prevent informed consent."

177. Following an independent review of Defendants' data, Oregon found that BMP had more adverse events and an increased risk associated with its use, when compared to the gold standard traditional ICBG.

178. Specifically, the YODA reviewers from Oregon found that BMP resulted in:

a. an overall risk of cancer almost triple that of ICBG;

b. contrary to a previously published Medtronic-sponsored study, BMP does not have a higher rate of success in posterolateral fusions;

c. subsidence occurred in four times as many patients using BMP in comparison to ICBG;

d. a cohort study reported more aggressive resorption of the graft and endplates in the rhBMP-2 group compared with ICBG;

e. 315 adverse events were found within studies in direct contrast to published results stating "no unanticipated device-related adverse events."

179. Furthermore, "a meta-analysis of the IPD showed that there was moderate strength [of] evidence of no consistent differences between rh-BMP-2 and ICBG in overall success and fusion."

180. This finding directly contradicts the false and misleading information provided by Defendants that touted greater fusion rates with BMP when compared to ICBG.

181. Oregon concluded "[there was] substantial evidence of reporting bias, no evidence that rhBMP2 is more effective than ICGB in spinal fusion, and some evidence of an association with important harms."

York Review

182. Similarly, York stated that the three objectives of their independent review of Defendants' data were to "1) examine the potential benefits of rhBMP-2; 2) examine the potential harms of rhBMP-2; and 3) assess the reliability of the published evidence base."

183. In June of 2013, York published results that were similar to those of Oregon. The review found:

"a. The use of BMP in spinal surgery had modest benefits when compared with ICBG surgery 24 months after surgery;

b. a near doubling in number of cancers with BMP;

c. heterotopic bone growth was 5.57 times more likely to occur in PLIF and TLIF spinal fusions using BMP as opposed to ICBG;

d. osteolysis or bone destruction was 4.26 times more likely to occur in a TLIF and 3.17 times more likely in PLIF using Infuse than in a spinal fusion using ICBG;

e. retrograde ejaculation was 4.76 times more likely with BMP than with ICBG;

f. hardware failure was as high as 8.37 times more likely to occur using BMP than with ICBG with a comparator like the Maverick disc system;

g. analyses of adverse event IPD from the Medtronic-sponsored trials showed some adverse events to be more common among BMP patients…Arthritis, implant-related events, retrograde ejaculation, adverse wound events and neurological, urogenital and vascular events were also more common among BMP patients; and finally,

h. studies published in the wider literature and post marketing data raise concerns about other adverse events not captured or easily apparent in the IPD provided, including heterotopic bone formation, osteolysis, retrograde ejaculation, urinary retention, and dysphagia. Owing to the non-randomised nature of the studies and difference between them, the strength of this body of evidence is weak and findings should be interpreted cautiously."

184. York commented specifically on the reliability of Defendants' published evidence, stating, "we found adverse events to be incompletely and inadequately described in the trial publications."

185. Additionally, "comparing the CSR categories against the adverse events described in published journal articles suggests that adverse event reporting across the Medtronic publications is relatively sparse and inconsistent."

186. The main conclusion York arrived at was that "[BMP] seems to increase the chance of successful fusion, according to Medtronic definitions, but this does not translate to clinically meaningful benefits in pain reduction, function or quality of life."

187. Defendants manipulated the studies by creating a threshold definition of what constituted a **fusion** that is not accepted by the spine community, but permitted Infuse to have positive results in the "studies." Defendants' definition allowed for "translation of less than or equal to 3 mm and angulation of less than 5 degrees." The Mayo Clinic defines spinal fusion as "…surgery to permanently connect two or more vertebrae in your spine, eliminating motion between them." Defendants defined spinal fusion as a success or failure according to their own made-up definition.

BMP Leads To A Five-Fold Increase In Cancer

188. Doctors Eugene J. Carragee, Bradley K. Weiner, and other esteemed authors in the most recent study published in the September 4, 2013 edition of *The Journal Of Bone And Joint Surgery,* looking into the connection of BMP and cancer, determined that the patients exposed to a 40 milligram dose of BMP experienced a 7.77% increase in risk of developing cancer in comparison to ICBG spinal fusions. When multiple cancers in a single patient were not considered, five-fold more patients developed one or more cancers when compared to ICBG. Therefore, for every 17.4 patients, one patient developed cancer within two years of their spinal fusion using BMP. More specifically, BMP may play a role in the tumor progression of pancreatic and breast cancer cells and the epithelial-to-mesenchymal, enabling the tumor to penetrate more deeply in lung cancer.

189. Notably, the population for this cancer study was selected based on its low risk or likelihood for developing cancer from other external factors. The physician authors warn, "the cancer risk associated with rhBMP-2 may be greater in populations with a higher prevalence of indolent or in situ cancer (e.g., older individuals, those with a history of cancer or known concurrent cancer, and those with genetic or exposure-related predisposition)."

Agency, Alter-Ego, Joint Venture, and Conspiracy

190. At all times, Defendants and the KOLs were the agents, servants, partners, aiders and abettors, and/or co-conspirators of each other and/or engaged in a joint venture with each other.

191. At all times herein mentioned, each Defendant and KOL was operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other

Defendants and KOLs while knowing their collective and individual conduct constituted a breach of duty owed to Humana.

192. At all times herein mentioned, Defendants were fully informed of the actions of their agents, representatives, contractors, and/or employees, and thereafter, no officer, director or managing agent of Defendants repudiated those actions. The failure to repudiate constituted adoption and approval of said actions, and all Defendants and each of them thereby ratified those actions.

193. At all times mentioned herein, there existed (and still exists) a unity of interest between certain Defendants and KOLs such that any individuality and separateness between them has ceased, and they are the alter-egos of each other.

194. Each Defendant herein expressly or impliedly agreed to work with and assist each other Defendant and unnamed parties, including but not limited to KOLs, toward the common purpose of the off-label promotion and use of BMP toward the common interest of pecuniary gain.

Tolling Of Applicable Statutes of Limitations

195. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Humana has been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on Humana's part. Humana could not have reasonably discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendants are estopped from relying on any statute of limitations.

Use of the Mails and Wires

196. During the relevant period, Defendants used thousands of mail and interstate wire communications to create and manage their fraudulent scheme. Defendants' scheme involved national marketing and sales plans and programs, and encompassed sales representatives, KOLs, physicians, providers, and patients across the country. Defendants' use of the mails and wires to perpetrate their fraud involved thousands of communications during the relevant period, including:

a. Communications, including financial payments, with the KOLs discussing and relating to the publication of articles touting off-label uses of Infuse and/or BMP for which it was not safe and medically efficacious, as detailed above;

b. Communications, including financial payments, with doctors, hospitals, vendors, distributors, sales representatives, health insurers, and patients that fraudulently misrepresented that Infuse and/or BMP was scientifically proven to be safe and medically efficacious for off-label uses;

c. Communications with health care providers, patients and health insurers, including Humana, inducing payment for Infuse and/or BMP to be made based on misrepresentations and omissions concerning the safety and efficacy of Infuse and/or BMP; and

d. Receiving the proceeds of Defendants' improper scheme.

FIRST CAUSE OF ACTION

Fraudulent Misrepresentation, Concealment, Omission and Fraud in the Inducement

197. Humana incorporates all of the above paragraphs as if fully rewritten herein.

198. Defendants repeatedly made knowing misrepresentations and concealed facts concerning the safety, efficacy, and necessity of Infuse and/or BMP.

199. Defendants misrepresented the safety, efficacy, and necessity of Infuse and/or BMP through fraudulent studies and peer-reviewed publications. Defendants and their KOLs knew of or acted with reckless disregard for the truth of the efficacy and risks of using Infuse and/or BMP.

200. Defendants knew or acted with reckless disregard for the truth that the advertisements, promotional statements, and other communications made to Humana regarding Infuse and/or BMP were materially false and misleading.

201. Defendants knowingly or acting with reckless disregard for the truth misrepresented, omitted, and/or concealed material information from Humana.

202. Defendants intended for Humana to rely on these representations or omissions, and Defendants knew Humana was not aware such representations were false.

203. Defendants had a duty to correct these false and misleading representations but failed to do so.

204. Humana justifiably relied on the misrepresentations and omissions by Defendants and paid for Infuse and/or BMP to treat conditions for which it was not sufficiently proven to be safe and effective.

205. Humana would not have paid for Infuse and/or BMP and the health costs associated with its use but for Defendants' fraudulent and intentional misrepresentations and omissions.

206. Examples of Defendants' fraudulent misrepresentations, concealments, omissions, and/or fraud in the inducement include, but are not limited to:

a. Defendants fraudulently concealed, omitted, and/or misrepresented the health and safety hazards, symptoms, diseases, and/or health problems associated with Infuse and/or BMP for the uses promoted by Defendants;

b. Defendants fraudulently concealed, omitted, and/or misrepresented their illegal, improper, and unethical schemes to promote and market the off-label use of Infuse and/or BMP as detailed in the factual allegations of this Complaint;

c. Defendants fraudulently concealed, omitted, and/or misrepresented their illegal, improper, and unethical participation in drafting many of the clinical studies published by their KOLs. Unsuspecting health care providers relied on such studies regarding the risk and benefit of Infuse and/or BMP in treating patients for the uses and in the manner intended by Defendants to which Humana was forced to pay claims for the use of Infuse;

d. Defendants, as described above, fraudulently concealed, omitted and/or misrepresented information about the known comparative risks and benefits of the use of Infuse and/or BMP and the relative benefits and availability of alternate products, treatments, and/or therapies;

e. Defendants failed to disclose the conflicts of interest and biases created by these Defendants' large payments to their KOLs, who advocated off-label use through Continuing Medical Education ("CME") efforts, lectures, dinner meeting and published articles and studies purporting to be "objective" scientific information;

f. Defendants engaged in the systematic off-label promotion and misrepresentations as described in greater detail above; and

g. Defendants aided and facilitated hospitals and physicians in obtaining payments from Humana through false statements and fraudulent omissions and concealment related to claims for use of Infuse and/or BMP in procedures, which procedures Humana would not have paid for had it known the true facts regarding Infuse and/or BMP or that Infuse and/or BMP was used in such procedures.

207. As the direct, proximate, and legal cause and result of Defendants' fraudulent concealment, omissions, misrepresentations relating to the effectiveness of Infuse and/or BMP, Humana suffered damages in an amount to be proven at trial, together with interest and costs.

SECOND CAUSE OF ACTION

Violation of 18 U.S.C. § 1962(c)

208. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

209. Defendants violated 18 U.S.C. § 1962(c) in connection with their activities in the Off-Label Marketing Enterprise ("OLME").

210. Defendants are the "persons" within the meaning of 18 U.S.C. § 1961(3) who, as set forth above, conducted or participated in conducting the affairs of the OLME through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

211. OLME is an "enterprise" which was created and/or used as a tool to effectuate Defendants' pattern of racketeering activity. The OLME is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including their employees and agents and the sales representatives and KOLs employed by Defendants to promote Infuse and/or BMP for off-label uses. The OLME is ongoing organization that functions as a continuing unit. The Defendant "persons" are distinct from the OLME.

212. Defendants and other members of the OLME created and maintained systematic links for a common purpose—to aid in marketing Infuse and/or BMP for off-label uses. Each of the participants in the OLME received substantial revenue from the scheme to promote Infuse and/or BMP for off-label uses. Such revenue was exponentially greater than it would have been if Infuse and/or BMP was marketed appropriately. All participants were aware of Defendants' control over the activities of the OLME promoting Infuse and/or BMP for off-label uses. Furthermore, each portion of the enterprise benefited from the existence of other parts.

213. The OLME engaged in and affected interstate commerce because it marketed, sold, purchased, or provided Infuse and/or BMP to thousands of individuals throughout the United States.

214. Defendants have exerted control over the OLME, and Defendants have participated in the operation or management of the affairs of the OLME.

215. Defendants have conducted and participated in the affairs of the OLME through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), § 1952 (use of interstate facilities to conduct unlawful activity).

216. Defendants used thousands of mail and interstate wire communications to create and manage its fraudulent scheme. Defendants' scheme involved marketing sales plans and programs that encompassed agents, sales representatives, vendors, distributors, KOLs, physicians, hospitals, and victims nationwide.

217. Defendants' use of the mails and wires to perpetrate its fraud involved thousands of communications, including, but not limited to:

a. Communications, including financial payments, with the KOLs discussing and relating to the publication of articles touting off-label uses of Infuse for which it was not safe and medically efficacious, as detailed above;

b. Communications, including financial payments, with doctors, hospitals, vendors, distributors, sales representatives, health insurers, and patients that fraudulently misrepresented that Infuse was scientifically proven to be safe and medically efficacious for off-label uses;

c. Communications with health insurers and patients, including Humana, inducing payment for Infuse and/or BMP to be made based on misrepresentations and omissions concerning the safety and efficacy of Infuse and/or BMP and the manner in which Infuse and/or BMP was used; and

d. Receiving the proceeds of Defendants' improper scheme.

218. Defendants' pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341, wire fraud under 18 U.S.C. § 1343, and use of interstate facilities to conduct unlawful activity under 18 U.S.C. § 1952. Defendants' fraudulent scheme consisted of deliberately misrepresenting the uses for which Infuse and/or BMP was safe and medically efficacious so that Humana paid for Infuse and/or BMP to treat symptoms for which it was not scientifically proven to be safe and medically efficacious, and actively concealing and causing others to conceal, information about the true safety and efficacy of Infuse and/or BMP to treat those conditions and the manner in which Infuse and/or BMP was used.

219. In implementing the fraudulent scheme, Defendants were acutely aware that Humana depended on the honesty and integrity of Defendants in representing the medical efficacy of Infuse and/or BMP.

220. Each of Defendants' fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

221. Defendants' fraudulent marketing scheme depended on concealing their involvement in the off-label promotion of Infuse and/or BMP. Indeed, the OLME was created

precisely to make it appear to the public that Defendants did not have a hand in any discussions or promotion of off-label use.

222. Additionally, as described above, Defendants had the OLME perform off-label promotion in the semblance of legitimate consultants' meetings, continuing education seminars, journal articles, and medical education events. Defendants' involvement was hidden because Defendants hid their financial connections with the KOLs. These activities and others described above concealed Defendants' fraudulent promotional activities, and Humana could not have discovered the fraudulent scheme alleged herein earlier with the exercise of reasonable diligence. Indeed, much of the fraudulent scheme, to this day, remains concealed by Defendants.

223. The above-described racketeering activities amounted to a common course of conduct intended to deceive and harm Humana. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Humana. Defendants' racketeering activities are part of their ongoing business and constitute a continuing threat to the property of Humana.

224. Humana was injured in its business and property by reason of these violations in that it made millions of dollars in payments for Infuse and/or BMP that it would not have made had Defendants not engaged in its pattern of racketeering activity. By reason of the unlawful acts engaged in by Defendants, Humana has suffered ascertainable loss and damages.

225. As a direct and proximate result, Humana was injured in its business or property by the predicate acts constituting the pattern of racketeering activity. Specifically, Humana has been injured in its business or property by paying for the use of Infuse and/or BMP for off-label purposes that would not have been paid absent Defendants' and the other OLME participants' unlawful conduct.

226. Accordingly, Defendants are liable to Plaintiff for three times the actual damages, in an amount to be proven at trial, together with interest thereon and costs.

THIRD CAUSE OF ACTION

Violation of U.S.C. § 1962(d) by Conspiring to Violate 18 U.S.C. § 1962(c)

227. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

228. 18 U.S.C. § 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section."

229. Defendants have violated Section 1962(d) by conspiring to violate Section 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the OLME described previously through a pattern of racketeering activity.

230. Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Humana of money.

231. The nature of the above-described co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy give rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

232. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962 (c), Humana has been and is continuing to be injured in its business or property as set forth fully

above. By reason of the unlawful acts engaged in by Defendants, Humana has suffered ascertainable loss and damages.

233. Accordingly, Defendants are liable to Plaintiff for three times the actual damages, in an amount to be proven at trial, together with interest thereon and costs.

FOURTH CAUSE OF ACTION

Negligent Misrepresentation

234. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

235. Defendants made false representations and/or omissions of material facts to Humana regarding Infuse and/or BMP.

236. Defendants aided and facilitated hospitals and physicians in obtaining payments from Humana through false statements and fraudulent omissions and concealment related to claims for Infuse procedures, which procedures Humana would not have paid for had it known the true facts regarding how Infuse was used in such procedures

237. Defendants were negligent in making these false representations and/or omissions of material fact because Defendants knew or should have known such facts were false.

238. Humana justifiably and reasonably relied on such misrepresentations and/or omissions and was induced to pay for the use of Infuse and/or BMP.

239. Humana would not have paid for the use of Infuse and/or BMP had it known of the true ineffectiveness and, in some cases, safety risks related to such use.

240. As the direct, producing, proximate and legal result of the Defendants' misrepresentations, Plaintiff has sustained damages in an amount to be proven at trial, together with interest thereon and costs.

FIFTH CAUSE OF ACTION

Subrogation Liability

241. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

242. Throughout the relevant period, Humana provided health insurance products, including, but not limited to, managed care products, third party administration services, and indemnity products, to groups and individuals on both an insured and an employer-funded basis. Humana provided these products to members in whom Infuse and/or BMP was used in a treatment of a condition or illness.

243. The damages sustained by Humana include, but are not limited to, the benefits paid for or provided to plan members or insureds incurred as a result of the plan member or insured being injured by or seeking treatment as a proximate result of the use of Infuse and/or BMP.

244. Humana provided these and other benefits to their insureds and plan members not as volunteers but under the contractual agreements specifying the respective rights and obligations of Humana and its members and insureds. These agreements specifically grant Humana broad subrogation and reimbursement rights.

245. Humana has contractual and equitable rights of subrogation and reimbursement against Defendants to recover damages to the extent of health benefits paid or provided on behalf of members and insureds implanted with Infuse and/or BMP.

SIXTH CAUSE OF ACTION

Violations of the Consumer Protection Statutes of the Fifty States, The District of Columbia, and the Commonwealth of Puerto Rico

246. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

247. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in knowing violation of any and all state consumer protection statutes when Defendants knowingly and intentionally misrepresented and/or omitted information regarding the safety, efficacy and necessity of Infuse and/or BMP and caused physicians and consumers to submit claims to Humana for which they were reimbursed.

248. The above described course of fraudulent conduct and concealment, constitute acts, uses, or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed below.

249. Defendants have violated the consumer protection statutes in the fifty States, the District of Columbia, and the Commonwealth of Puerto Rico, as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code §8-19-1, *et seq.;*

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. §45.50.471, *et seq.;*

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. §44-1522, et seq.;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code §4-88-101, et seq.;

e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §17200, et seq.;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. §6-1-105, et seq.;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. §42-110b, et seq.;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code §2511, et seq.;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code §28-3901, et seq.;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §501.201, et seq.;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §10-1-392, et seq.;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §480, et seq.;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code §48-601, et seq.;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS §50511, et seq.;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. §24-5-0.5.1, et seq.;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code §714.1 b, et seq.;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. §50-623, et seq.;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. §367.110, et seq.;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. §51:1401, et seq.;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. §207, et seq.;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code §13-101, et seq.;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. §445.901, et seq.;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §325F.67, et seq.;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. §75-24-1, et seq.;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. §407.0 10, et seq.;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code §30-14-101, et seq.;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §59-1601, et seq.;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. §598.0903, et seq.;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. §358-A: 1, et seq.;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. §56:8-1, et seq.;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. §57-12-1, et seq.;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §349, et seq.;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §75-1.1, et seq.;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §51-15-01, et seq.;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. §1345.0 1, et seq.;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 §751, et seq.;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. §646.605, et seq.;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. §201-1, et seq.;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. §6-13.1-1, et seq.;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws §39-5-10, et seq.;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws §37-24-1, et seq.;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code §47-18-101, et seq.;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code §17.4 1, et seq.;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. §13-11-1, et seq.;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit 9, §2451, et seq.;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code §59.1-196, et seq.;

vv. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code §19.86.010, et seq.;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code §46A-6-101, et seq.;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, et seq.;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. §40-12-100, et seq.; and

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, et seq., the applicable statute for the Commonwealth of Puerto Rico.

250. As a direct and proximate result of Defendants' unfair methods of competition and unfair and deceptive acts or practices, Humana has suffered damages in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION

Breach of Express Warranty

251. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

252. Defendants used journal articles, advertising media, sales representatives, agents, and KOLs to cause the use of Infuse and/or BMP by representing the quality to Infuse and/or BMP to Humana and other third party payors, health care professionals, and the public in such a way as to induce its purchase or use.

253. Through these representations, Defendants made an express warranty that Infuse and/or BMP would conform to the representations. More specifically, Defendants represented that Infuse and/or BMP was safe and effective to treat conditions of Humana's Members. In allowing the implantation of Infuse and/or BMP, Humana's Members relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that Infuse and/or BMP was not safe and effective.

254. Defendants manipulated studies as promotional materials that created express written representations of the safety and efficacy of Infuse and/or BMP, including that adverse events related to the use of Infuse and/or BMP did not exist or were significantly reduced. These specific misrepresentations went beyond mere puffery as they were published in reputable peer-reviewed scientific journals.

255. The representations, as set forth above, contained or constituted affirmations of fact or promises made by Defendants (sellers) to Humana, which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises. The representations were false, as Infuse and/or BMP did not conform to the representations made by Defendants, because Infuse and/or BMP was not safe and effective.

256. Defendants were merchants pursuant to §2-104 of the Uniform Commercial Code ("UCC"). *See* KCC §355.2-104.

257. As a direct and proximate result of Defendants' breaches of warranties, Humana has incurred health care costs related to Infuse and/or BMP that have been paid by Humana, but are the responsibility of Defendants, in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION

Breach of Implied Warranty

258. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

259. Prior to the time Humana's beneficiaries were implanted with Infuse and/or BMP, Defendants impliedly warranted to them that Infuse and/or BMP was of merchantable quality and safe and fit for the use of which it was intended.

260. Humana is unskilled in the research, design, and manufacture of Infuse and/or BMP, and reasonably relied entirely on the skill, judgment, and implied warranty of Defendants in paying for procedures involving the implantation of Infuse and/or BMP.

261. Defendants breached the implied warranty for Infuse and/or BMP because said devices were defective, unmerchantable, not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor were these products minimally safe for their expected purpose.

262. As a direct and proximate result of Defendants' breaches of warranties, Humana has incurred health care costs related to Infuse and/or BMP that have been paid by Humana, but are the responsibility of Defendants, in an amount to be proven at trial.

NINTH CAUSE OF ACTION

Unjust Enrichment

263. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

264. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants profited from payments that Humana made for Infuse and/or BMP.

265. In exchange for the payments they made for Infuse and/or BMP, and at the time they made these payments, Humana expected that Infuse and/or BMP was a safe and medically effective treatment for the condition or illness for which it was prescribed.

266. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Humana paid for Infuse and/or BMP when it otherwise would not have done so.

267. As a result of Defendants' acts, Defendants have been unjustly enriched by Humana's payments for Infuse and/or BMP.

268. Humana is entitled in equity to restitution from Defendants in an amount to be proven at trial and such other relief as the Court deems just and proper.

TENTH CAUSE OF ACTION

Conversion

269. Plaintiff incorporates all of the above paragraphs as if fully rewritten herein.

270. Defendants, by the actions alleged above, have exerted unauthorized control over the property of Humana.

271. Humana owned, and has a right to possession of, the money which is in the possession of Defendants.

272. Defendants have exerted unauthorized ownership of money belonging to Humana to the exclusion of Humana's rights.

273. Defendants have unlawfully converted property of Humana.

274. Defendants have made profits as a result of the unlawful conversion.

275. As a direct and proximate result of Defendants' unauthorized control over the property of Humana, Humana has suffered damages in an amount to be proven at trial.

JURY DEMAND

276. Humana demands a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each claim for relief, jointly and severally, as follows:

A. For general damages, in an amount exceeding the jurisdictional threshold of this Court to be proven at trial;

B. On the RICO claims, three times the damages Humana has sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiff's costs in this suit, including reasonable attorneys' fees;

C. On Plaintiff's claims for fraud, damages in the amount of Humana's payment for Infuse and/or BMP, such amounts to be determined at trial, plus Plaintiff's costs in this suit, including reasonable attorneys' fees;

D. On Plaintiff's claims under the Consumer Protection Statutes of all fifty States, all measures of damages allowable under such statutes, such amount to be determined at trial, plus Plaintiff's costs in this suit, including reasonable attorneys' fees;

E. On Plaintiff's claims for negligence, breach of warranty, unjust enrichment, and conversion, recovery in the amount of Humana's payment for Infuse and/or BMP, such amounts to be determined at trial;

F. For an award of pre-judgment and post-judgment interest as provided by law;

G. For consequential damages, in an amount to be proven at the time of trial;

H. For exemplary or punitive damages against Defendants;

I. For an award providing for payment of costs of suit, including reasonable attorneys' fees and expert fees;

J. For injunctive relief as appropriate; and

K. For such other and further relief as this Court may deem just and proper.

Dated: May 30, 2014.

Respectfully submitted,

/s/ V. Brandon McGrath _____

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