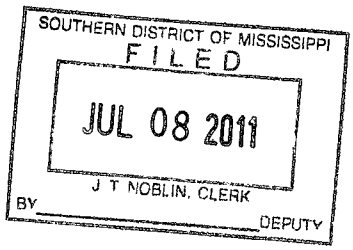
IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION



UNITED STATES OF AMERICA
EX REL. JOANNE HARTWIG,

Relator

VS.

Civil Action No. 3:11CV413 CWR-LRA

TO BE FILED IN CAMERA AND UNDER SEAL Pursuant to 31 U.S.C. § 3730

MEDTRONIC, INC.; MEDTRONIC SOFAMOR DANEK USA, INC.; THOMAS A. ZDEBLICK, M.D.; TAZ CONSULTING, INC.; CURTIS A. DICKMAN, M.D.; VANTAGE CONSULTING, INC.; ADAM LEWIS, M.D.; TAZ, LLC; LEWIS MEDICAL SERVICES, PLLC; LEWIS PROPERTIES, LLC; JACKSON NEUROSURGERY CLINIC, PLLC; and JOHN DOE DEFENDANTS 1-5000

Defendants.

RELATOR'S COMPLAINT FOR DAMAGES UNDER THE FALSE CLAIMS ACT, 31 USC § 3729 ET SEQ., THE ANIT-KICKBACK STATUTES, AND OTHER LAW

COME NOW the United States of America ex rel. Joanne Hartwig, Relator/Plaintiff, and, pursuant to 31 U.S.C. § 3729, et seq., and other applicable rules and law, files the instant Complaint against Medtronic, Inc.; Medtronic Sofamor Danek USA, Inc.; Thomas A. Zdeblick, M.D.; TAZ Consulting, Inc.; Curtis A. Dickman, M.D.;

Vantage Consulting, Inc.; Adam Lewis, M.D.; TAZ, LLC; Lewis Medical Services, PLLC; Lewis Properties, LLC; Jackson Neurosurgery Clinic, PLLC; and John Doe Defendants 1-5000, and for cause would show as follows:

NATURE OF THE CASE

1. This action is filed on behalf of the United States of America by Relator Joanne Hartwig to recover treble damages, civil penalties, disgorgement of gross receipts or profits, the imposition of a constructive trust, attorneys' fees, expenses, exemplary damages and all other applicable remedies, arising out of false claims conspired for, presented, and fraudulently concealed by false statement and/or record by the Defendants as against the Medicare, Medicaid, TRICARE, and all other programs administered by the United States of America related to health care, through the Department of Health and Human Services, the United States Military, or otherwise.

2. The Defendants in this matter have engaged in a civil and criminal enterprise utilizing fraud, material misrepresentation, civil conspiracy, deceit, and contumacious conduct constituting outrage. In furtherance of their enterprise, the Defendants have violated a number of provisions of the United States Code, and implicating other Federal authorities, including, but not limited to:

a. the False Claims Act under 31 U.S.C. § 3729, et seq.;

b. 18 U.S.C. §1035 of the Criminal Code covering the making of "False Statements Relating to Health Care Matters" involving any health care benefit program, public or private;

c. 18 U.S.C. 1347 of the Criminal Code covering "Health Care Fraud" involving any health care benefit program, public or private;

d. 18 U.S.C. §§1341, 1342, 1352, 1356, and 1357, covering Mail Fraud, Wire Fraud, Travel to Effect the Scheme, Money Laundering, and Use of Dirty Money, to effectuate the fraudulent scheme; and

e. 45 C.F.R. 46, covering the conduct of medical research on human subjects with the support of federal funds, known as the "Common Rule".

f. The violation of the terms of settlement of other cases with the United States, specifically with regard to a Corporate Integrity Agreement entered into between Medtronic and the Office of Inspector General of the Department of Health and Human Services and Medtronic Sofamor Danek USA, Inc. and the making of false and fraudulent statements and material misrepresentations with regard thereto.

3. This cause of action is brought by the Relator pursuant to the *qui tam* provisions of 31 U.S.C. § 3729, et seq. and other applicable rules and law.

PARTIES

4. Joanne Hartwig is an adult resident citizen of Hinds County, Mississippi, residing at 5029 Springridge Road, Raymond, Mississippi 39157, who brings this action by virtue of being an original source of the information on which the allegations are based, having direct and independent knowledge on which these allegations are based and having voluntarily provided her information to the Government prior to filing suit.

5. This action may be joined by the State of Mississippi, and any other state or local authorities, pursuant to 31 U.S.C. 3732(b), should it discover that the fraudulent, conspiratorial activities of the Defendants have damaged said entities due to payments obtained by false claims under Medicaid or other programs.

6. Upon information and belief, Defendant, Medtronic, Inc. is a Minnesota Corporation with its principal place of business at 710 Medtronic Parkway, Minneapolis,

Minnesota 55432, where it may be served with process. Medtronic Sofamor Danek, USA, Inc. is a Tennessee corporation, with its principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132, where it may be served with process. These Defendants may be referred to herein collectively as "Medtronic."

7. Upon information and belief, Thomas A. Zdeblick, M.D. is a physician licensed to practice medicine in the state of Wisconsin, where he may be served with process at 621 Science Drive, Madison, Wisconsin 53711. Defendant TAZ Consulting, Inc. is a Wisconsin corporation, which may be served with process on Thomas Zdeblick c/o John Suby, CPA, 2901 W. Beltline Hwy Ste 201, Madison, Wisconsin 53713. These Defendants may be referred to herein collectively as "Zdeblick."

8. Upon information and belief, Curtis A. Dickman, M.D. is a physician licensed to practice medicine in the state of Arizona, where he may be served with process at 2910 North 3rd Avenue, Phoenix, Arizona 85013. The precise entity organization of Defendant Vantage Consulting, Inc., also known as Vantage Investments (hereinafter "Vantage"), is not known; however, Defendant Vantage may be served with process in any manner allowed by the Federal Rules of Civil Procedure, including upon one of its officers, Curtis A. Dickman. These Defendants may be referred to herein collectively as "Dickman."

9. Upon information and belief, Defendant Adam Lewis, M.D. is licensed to practice medicine in the state of Mississippi where he maintains a medical practice in Hinds County, Mississippi with Defendant Jackson Neurosurgery Clinic, PLLC. Upon information and belief, Defendant Adam Lewis maintains all or a portion of his practice through Defendant

Lewis Medical Services, PLLC. Upon information and belief, Dr. Lewis also is engaged in a business which maintains interests in medical hardware and medical product development, known as TAZ, LLC. TAZ, LLC may be served through its registered agent, Zoe Lewis Musick, formerly known as Zoe Lewis Gasc, at 971 Lakeland Drive, Suite 1250, Jackson, Mississippi 39216. Defendants Adam Lewis, M.D.; Jackson Neurosurgery Clinic, PLLC; Lewis Medical Services, PLLC, and Lewis Properties, LLC, may be served through Adam Lewis at 971 Lakeland Drive, Suite 1250, Jackson, Mississippi 39216. These Defendants may herein be referred to collectively as "Lewis."

10. John Doe Defendants 1-5000 have also been included in the event discovery reveals other responsible parties which are unknown at this time.

JURISDICTION AND VENUE

11. Jurisdiction and venue are proper in this Court pursuant to 28 U.S.C. 1331 and 31 U.S.C. 3732. The causes of action alleged herein arise out of actions and/or omissions which occurred or accrued, in part, in Hinds County, Mississippi, and certain Defendants' principal places of business are in Hinds County, Mississippi, which is located within the judicial district of this Court.

FACTUAL ALLEGATIONS AND CAUSES OF ACTION

12. The factual allegations and averments of this Complaint are being pled with the level of particularity required, as limited by the yet-to-be-discovered actions and/or omissions of the Defendants and any unknown co-conspirators. See *United States ex rel. Grubbs, M.D. vs. Kanneganti, M.D.*, 565 F.3d 180 (5th Cir. 2009); see also Fed. R. Civ. P. 8, 9.

13. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products which it projected to enjoy broad application with spinal surgeons and their patients on a nationwide basis.

14. Medtronic anticipated that both products would initially be limited in application.

15. Motivated by greed and a desire to gain a competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end users. This course of conduct utilized fraud, false statements material misrepresentation, and deceit in order to broaden the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

16. On or after January 29, 2002, Medtronic was advised in response to its notification of intent to market an anterior plate fixation system under the name of PYRAMID. The marketing of the device had been approved by the FDA. However, the indications for use of such device limited its application to "the lumbosacral level below the bifurcation of the vascular structures," or in other words the L5-S1. See Appendix A.

17. On or after July 2, 2002, Medtronic received notification that its premarket approval application for its INFUSE® bone graft products had been approved by the FDA. However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the INFUSE® bone graft and to study potential side effects and complications such as the promotion of tumors by the bone morphogenic

protein component of the INFUSE® bone graft, or rhBMP-2, and other studies. See Appendix B.

18. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from these products whether or not they would eventually be allowed to remain on the market.

19. In furtherance of its fraudulent course of conduct, Medtronic utilized false statements and employed a scheme that involved jointly its INFUSE® and PYRAMID products.

20. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-CAGE®, was the only approved device to act as the delivery vehicle for the INFUSE® bone graft into the body.

21. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

22. In one of Dr. Zdeblick's first attempts to tout his LT-CAGE® and the rhBMP-2, which would become the active ingredient in INFUSE®, he encountered some drawbacks to his goal of promoting his and Medtronic's products, due to the journal's policies in following industry standards before printing peer-reviewed material. See article in the journal *Spine* published in 2000, attached as Appendix C.

23. Not only were the drawbacks related to industry standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain

provisions at 42 U.S.C. 300u, et seq., whereby the Federal Government had entered the field of medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services would require that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. 300u-1.

24. The drawbacks encountered with the 2000, peer-reviewed *Spine* article were as follows:

a) Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.". Id. at 376;

b) The study was conducted under FDA regulations, and was "..designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study." Id. at 377; and

c) It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article. Id. at 381.

25. In the article, the BMP was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, wherein it closed with the following: "..it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition." Id. at 380.

26. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that "[p]erhaps vascularization... and

fixation procedures are as important as the biochemical composition of the 'filler'." Id. at 381.

27. Vascularization is achieved merely through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other words, if the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results, ***Zdeblick and Medtronic's INFUSE® products would be useless and unnecessary.***

28. Certain efforts would follow which would alleviate the drawbacks encountered with the 2000 *Spine* article.

29. In 2002, Dr. Zdeblick was successful in having himself installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the Journal of Spinal Disorders had enjoyed a fourteen year history under the co-editorship of Dr. Dan Spengler and Dr. Tom Ducker. Once installed, Dr. Zdeblick successful supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would enable him greater control and would aid his participation in the fraudulent scheme.

30. During this same period of time, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

31. In one of Dr. Zdeblick's actions as editor-in-chief, he set about to re-purpose the journal in a way which would aid him in the furtherance of the fraudulent scheme

through the streamlining of the publication process. In his first Editorial Commentary in *Journal of Spinal Disorders and Techniques*, Dr. Zdeblick recognized that:

> The practitioner treating patients with spinal problems has an immense variety of therapeutic choices. It has become increasingly difficult for spine surgeons to keep pace with all of the specific techniques that are available. Furthermore, there is no one forum available for the spine surgeon to keep up to date on the new techniques. After discussions with the orthopedic and neurosurgery communities, as well as Dr. Ducker and the publisher, we have decided to change the focus of the journal to surgery and techniques.

See Appendix D.

32. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques*, announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice. See Appendix D.

33. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques...", and in furtherance of that goal Dr. Zdeblick announced that his *Journal* would publish Class II or better clinical articles but would "*occasionally accept cutting-edge articles with less than one year follow-up.*" See Appendix C (emphasis added). To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his Journal "to keep up with the fast pace of progress in the treatment of spinal patients." Id.

34. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of the *Journal of Spinal Disorders and*

Techniques to further the goals of the fraudulent scheme which is the subject of this Complaint.

35. In the third edition printed under his editorship, Dr. Zdeblick issued a joint Editorial Commentary with the editor-in-chief of Spine, Jim Weinstein. See Appendix E. In that editorial Commentary, Dr. Zdeblick acknowledged that the journal Spine only published "studies that have institutional review board (IRB) approval and have strictly observed a sufficient follow-up period..." Id. In contrast, however, Dr. Zdeblick's journal would employ "[s]horter clinical follow-up and technical descriptions [which] will allow publication on cutting-edge topics in a timely fashion." Id.

36. In the October, 2002 edition, the fifth under his editorship, Dr. Zdelbick's journal published an article entitled "Anterior Lumbar Interbody Fusion using RHBMP-2 with Tapered Interbody Cages." See Appendix F. This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of the PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and educational training and speaking agreements. See Pyramid product literature, Appendix G.

37. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for the INFUSE® bone graft. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP [the bone morphogenic protein

component in INFUSE®] would provide a significant advance for patient outcome and satisfaction following spinal fusion. See Appendix H, pg. 3.

38. In their October 2002, *Journal of Spinal Disorders and Techniques* article touting the benefits of INFUSE®, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. See Exhibit "F." Not only did Dr. Zdeblick fail to disclose that he profited from each and every surgery which used INFUSE® through rights in the exclusive delivery vehicle, his LT-CAGE®, but no reference whatsoever to their financial ties to Medtronic was made by either Dr. Zdeblick or Dr. Dickman.

39. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its INFUSE® product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise as set forth in this Complaint, and the support of Federal funds to do so.

40. As part and parcel to Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for INFUSE®. As the article shows, it was actually received on March 28, 2002, or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002. See Appendix F, pg. 337.

41. In this initial article, Zdeblick's LT-CAGE® device is touted as representing "a significant technological advance over first general cylindrical cages." However, no mention is made of Zdeblick's patent or other interest in the device directly or as the only

approved delivery vehicle for INFUSE®. See Appendix H, Page 346-47. The article insufficiently disclosed the potential for complications, and concluded with the statement "the 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 the adverse effects associated with that procedure." See Appendix F at 348.

42. No mention is made of any comparative study using simple plaster of Paris, as suggested by Dr. O'Brien.

43. At the same time Dr. Zdeblick's journal was publishing the initial article on INFUSE®, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout INFUSE® potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is INFUSE® Bone Graft Superior to Autograph Bone? An Integrated Analysis of Clinical Trials using the LT-CAGE® Lumbar Tapered Fusion Device". See article, Appendix I.

44. This second article was received by Dr. Zdeblick's journal on October 11, 2002, was accepted for publication two months later on December 19, 2002, and was published in Vol. 2 of 2003. See Appendix I, at pg. 113. Once again, Dr. Zdeblick and others, in furtherance of Medtronic's fraudulent scheme, failed to disclose their financial ties to Medtronic. Id.

45. This second article would serve as the second covert advertisement for the INFUSE® product and states "the purpose of our analysis was to investigate the potential statistical superiority of INFUSE® bone graft to autograft...". Id. at Page 113. This second article acknowledged that autogenous bone was 'the gold standard by which all

other procedures are measured.'" Id. at Page 118. It co-opted the dream of Marshall Ulrist, the physician who discovered BMP, to find a replacement for autograft and sensationalized the search for a replacement as a potentially "impossible task," asking the question "what material could researchers develop that would be better than a naturally occurring material?" Id. at 118.

46. This second article went on to announce the July 2002 FDA approval of rhBMP-2. Id. at 119.

47. The article closed by concluding "we think that these analyses demonstrate the superiority of using INFUSE® bone graft...with its superiority, INFUSE® bone graft may now become the *new gold standard* for replacing autograft bone inside the LT-CAGE® device when used with lumbar spinal fusions. INFUSE® bone graft is now used exclusively for this purpose in our institutions." Id. at 122 (emphasis added).

48. Following this conclusion, the article included as an "acknowledgement" an expression of gratitude to the physicians "who provided patients for this study and to "the clinic research group at Medtronic Sofamor Danek *for their help in data collection and statistical analyses.*" Id. (emphasis added). However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

49. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of the Defendants' fraudulent enterprise. However, unchecked by appropriate peer-review, the Defendants were able to systematically accomplish their goals.

50. Indeed, in its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 article as reporting that INFUSE® "..may become the 'new gold standard' in spinal fusion surgery." See excerpts of 2003 annual Report, Appendix J, at pg. 13 [pictorial].

51. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "INFUSE® Bone Graft quickly became the gold standard for certain types of lumbar fusion." See Appendix K, at pg. 10.

52. It has recently been reported that certain members of the medical community, through the publication *Spine Journal*, have or will be releasing a journal addition which serves as an expose of the failures of Dr. Zdeblick, Medtronic, and others to disclose their clear conflicts of interest and to hide the linkage of INFUSE® to serious side effects. See Appendix M, article appearing in the June 28, 2011 Milwaukee Journal Sentinel entitled "Experts Repudiate Medtronic's Research", by John Fauber. Unfortunately, the depth of the Defendants' fraud has not been brought to light prior to the filing of this Complaint.

53. Medtronic's fraudulent scheme has accomplished its goals and resulted in a revenue stream ranging from 700 million to 900 million dollars per year. Medtronic's fraud upon the medical community has proven to be overwhelmingly successful. It has been reported that "at about the same time that the Journal Sentinel starting running stories about INFUSE®, editors at the *Spine Journal* began receiving complaints from doctors around the country who were pointing out contradictions between papers

published by doctors with financial ties to Medtronic and other data involving INFUSE® complications." See Journal Sentinel article of John Fauber, Appendix L.

54. Further, the use of INFUSE® by physicians around the country expanded well beyond the initially approved L5-S1 levels to include the entire spine, eventually resulting in serious complications when used in the cervical spine.

55. Despite mounting evidence regarding the conflicts of interest and failure to report serious side effects, Medtronic's fraudulent scheme continues to date. Contemporaneous to the filing of this Complaint, Medtronic appears to be attempting to insulate the company from its fraudulent scheme at the expense of those employed by the company in the joint fraudulent enterprise.

56. In the Journal Sentinel article of June 28, 2011, authored by John Fauber, it is reported that Medtronic's new chairman and CEO Omar Ishrak has issued a statement in response to the forthcoming *Spine Journal* issue. It is reported in that article that Medtronic's response states "while the spine journal articles raise questions about *researchers' conclusions* in *their* peer-reviewed literature, the articles do not raise questions about the data Medtronic submitted to the FDA in the approval process or the information available to the physicians today through the instructions-for-use brochure attached to each product sold." See Appendix L.

57. The Journal Sentinel article further reports as follows:

> In an interview Tuesday with Journal Sentinel, Medtronic officials said they now are looking into the issue of whether published articles failed to properly report various complications linked to INFUSE®. 'We are very serious about this' said Richard Kuntz, Medtronic's Senior Vice President and Chief Scientific, Clinical and Regulatory Officer. 'We will do a full

> analysis of these papers.' Kuntz and Christopher O'Connell, an executive vice president who oversees the Medtronic Division that includes INFUSE®, also said they will provide a full accounting of royalties and other payments to doctors who authored INFUSE® papers."

Id.

58. Unfortunately, Medtronic's fraudulent scheme continues undetected to the present day, as even those reports state "none of the royalty payments were for INFUSE®." Id. Evidence brought forth by Plaintiff Hartwig shows, and discovery will further show, that Medtronic has incorporated the use of sham consulting, royalty, and educational/training agreements and (a) the furtherance of its fraudulent scheme and (b) the concealment of its fraudulent scheme.

59. In furtherance of its fraudulent course of conduct, Medtronic utilized the participation of physicians in the fraudulent scheme through the payment of sham consulting fees, royalty fees, and other educational fees and benefits.

60. In 2002, around the time of (a) Dr. Zdeblick's takeover of the *Journal of Spinal Disorders*; (b) the FDA approval of Medtronic's premarket application for INFUSE®; and (c) the FDA's approval of the PYRAMID plate as a substantial equivalent, Plaintiff Hartwig's treating physician, Adam I. Lewis, M.D., filed incorporation papers with the Mississippi Secretary of State's Office under the names Lewis Products, LLC; Lewis Medical Services, PLLC; and Adam Lewis, M.D., P.A. See Appendix M. Dr. Lewis had previously incorporated his medical practice under the name Jackson Neurosurgery Clinic, PLLC in 1999. See Appendix N.

61. Plaintiff Hartwig would eventually file a medical malpractice suit against Dr. Lewis, upon which a jury found in her favor and awarded compensatory damages. See Judgment, attached hereto as Appendix O.

62. During the course of discovery in that matter, Dr. Lewis gave material false testimony in his deposition (a) in furtherance of Medtronic's fraudulent scheme and (b) in furtherance of the fraudulent concealment of Medtronic's fraudulent scheme. In that deposition, Dr. Lewis fell materially short of his oath to tell the whole truth, and testified falsely when asked whether he had any pecuniary or financial interests with Medtronic. Specifically, that portion of the testimony went as follows:

Q. Who were the plates that you placed in Ms. Hartwig manufactured by?

A. From Medtronic.

Q. Now, you referenced a Blackstone Medical Group earlier. Do you have a financial or pecuniary interest in that particular group?

A. I do not. I have – I was – served as a consultant at one time with them and worked up until December of '05, I believe, as a consultant.

Q. What about Medtronic; any similar type of relationship with them whether it be consultant or any sort of derivative interests –

A. *I have served as a consultant on the next generation of anterior lumbar plates and I have also served as a consultant for occipital neuralgia and occipital nerve stimulators. I have never received and funds or remuneration from them period.*

Q. Are you listed within various literatures as being a consultant for them or with them?

A. I don't believe so. I have no – no contracts with them period.

See deposition excerpts of Adam Lewis, pgs. 40-41, attached as Appendix P.

63. At the medical malpractice trial, Dr. Lewis would again give materially false and/or perjurious testimony when he again testified that he was not paid by Medtronic.

64. During that trial testimony, Dr. Lewis would disclose, for the first time, that he knew Dr. Curtis Dickman and had worked with Dr. Dickman on the development of the Medtronic plate. His testimony came after being confronted with the 2002 product brochure and indications for use for the PYRAMID plate, in which Dr. Dickman is listed prominently. See PYRAMID brochure, attached as Appendix G. The false and/or perjurious nature of Dr. Lewis' testimony, both in his deposition and the May 2011 trial, was not known by the Plaintiff at the time said testimony was given, and was only discovered through her own investigation in the days leading up to the filing of the instant Complaint. Dr. Lewis' involvement with Dr. Dickman and his financial interests in Medtronic's products (a) has been known to Medtronic for some time and (b) has been utilized as part of its fraudulent scheme and fraudulent concealment.

65. On May 2, 2001, in the run-up to receiving approval to market the PYRAMID plate from the FDA on January 29, 2002, Medtronic's predecessor in interest, Sofamor Danek Holdings, Inc. and its affiliated companies purchased from Dr. Dickman and his co-inventors their rights relating to the PYRAMID plate. See Appendix Q. Dr. Dickman is listed along with three other co-inventors on a Medtronic Sofamor Danek

Disclosure Form, which he signed on May 2, 2001. Id. Aided by the information obtained through the fraudulent scheme, the Defendants were eventually able to increase the approved uses for the PYRAMID plate, as set forth below.

66. In or about October, 2004, Medtronic served Requests for Admission in an action constituting a dispute over various rights associated with the PYRAMID plate filed as *Jeffrey A. Kozack v. Medtronic, Inc.*, In the United States District Court for the Southern District of Texas, Civil Action No. H-03-44-00. Through those requests, Medtronic asked the Plaintiff therein to admit as follows:

REQUEST No. 43: Admit that on January 10, 2004, you requested information on the Pyramid plate from Curtis Dickman.

Response: Admitted.

REQUEST No. 44: Admit that on February 10, 2004, Adam Lewis responded to your January 10, 2004 email and provided you with data from his use of the Pyramid plate.

Response: Admitted.

REQUEST No. 45: Admit that on February 12, 2004, Curtis Dickman responded to your January 10, 2004 email and provided you with data from his use of the Pyramid plate.

Response: Admitted.

See discovery document excerpts, attached as Appendix R.

67. As shown by Medtronic's own requested admissions, Medtronic was aware of Dr. Lewis' involvement with, and financial interest in, the PYRAMID plate. Furthermore, the conduct Medtronic was asking to be admitted under oath *would constitute a violation of its own policy regarding federal Anti-Kickback law, that being the prohibition against use by physicians of products in which Medtronic pays them royalties.*

68. In violation of the Common Rule, and in furtherance of the Defendants' fraudulent scheme to feign avoidance of the Anti-Kickback statutes, Dr. Lewis and the Defendants experimented on their patients by using the Pyramid plate and INFUSE® products without advising the patients or gaining their informed consent. The purpose of this mechanism was two-fold.

69. One goal was to provide cover for the sham agreements, whereby 'information' gathered from use on their unknowing patients could be passed off as justification for the Defendant physicians' real contributions. For example, through these sham agreements, Medtronic paid the $23 million to Zdeblick for INFUSE®, but was able to use the information gathered by his contracting physicians, such as Dr. Lewis, to justify payments for a different product.

70. The other goal in performing unauthorized uses of Medtronic products on their unknowing human subjects was to expand their approved use by showing successful off-label uses. Through this mechanism, the Defendants were able to expand the use of the Pyramid plate from spinal level L5-S1 only in 2002 to levels above that by 2007, under the name of the Pyramid +4 plate. See FDA approvals for safety and expanded use, attached as Appendix R, pgs. 6-21.

71. Plaintiff Hartwig has testified that Dr. Lewis told her the 2005 surgery would be similar as a 2001 surgery on an adjacent level. In fact, whereas the 2001 surgery merely used a retention plate at L4-L5, Dr. Lewis inserted a Pyramid plate at L3-L4 at a time when the same was an off-label use. Lewis did not, in any way, advise or indicate that he would be using a different type of plate for an off-label, or that he was conducting

research and reporting information on the use of the plate at an 'off-label' level. Thus, Lewis was experimenting and expanding the use of the Pyramid plate without Hartwig's consent, then reporting his "successful experience" with the Pyramid at expanded levels [despite a lawsuit that would eventually result in a verdict for Hartwig]. In turn, Dickman and Zdeblick would then receive a payment from Medtronic for the sham "consulting/research".

72. Indeed, Dr. Lewis testified at Plaintiff Hartwig's May, 2011 trial that he had spoken often with Dr. Dickman to tell him of his successful usage of the Pyramid plate at levels other than the approved L5-S1, and worked with Dr. Dickman on the development of the Pyramid. Yet, his name does not appear on Medtronic's Physician Payment Registry, and as set forth below, illustrates a significant component of the fraudulent scheme.

73. Returning to the quotes attributed to Medtronic under its new management by the Milwaukee Journal Sentinel article of June 28, 2011, it is reported that "Medtronic officials said they now are looking into the issue of whether published articles failed to properly report various complications linked to INFUSE®." It is further reported that Richard Kuntz, Medtronic's Senior Vice President and Chief Scientific Clinical and Regulatory Officer said "we will do a full analysis of these papers." It is further reported in the Journal Sentinel article that "Kuntz and Christopher O'Connell, an executive vice president who oversees the Medtronic division that includes INFUSE®, also said they "will **provide a full accounting of royalties and other payments to doctors** who authored INFUSE® papers." See Appendix L [emphasis added].

74. In fact, Medtronic's own policy mandates reporting of "payment data for all U.S. physicians...and organizations *performing collaborative services* on a quarterly basis." See Medtronic's Physician Registry Policy, attached as Appendix T. By Medtronic's own definition, the medical journal articles now under scrutiny by the media, the U.S. Senate, and others, and *which Medtronic now appears to be attempting to distance itself*, qualify as "collaborative services," the payment for which is reported by Medtronic on a purported voluntary basis for now and mandated by the Patient Affordable Care Act beginning in 2013.

75. In Medtronic's own policy, said journal articles are characterized as one of four activities which "will bring a physician within our definition of reportable information, wherein Medtronic's policy states:

> No. 4. Publish (original research, reviews, or editorials) on medical (basic medical science, clinic, medical, economic or social) topics *via publication media (peer- and non-peer-reviewed medical journals,* internet websites, local, national or international media outlets (intended to inform patients or healthcare practitioners.

See Appendix U. [Emphasis added].

76. Thus, by Medtronic's own definition, medical journal articles (a) qualify as a collaborative service with Medtronic and (b) are "intended to inform patients or healthcare practitioners." Id.

77. Medtronic represents that its disclosure of its physician payment registry prior to the 2013 mandate is voluntary. While said disclosure to the public at this point in time may be voluntary, it would appear that the assembly of the information contained therein is a requirement of a Corporate Integrity Agreement entered into between

Medtronic and the United States of America pursuant to the settlement of an anti-kickback lawsuit in 2006. See excerpts from corporate integrity agreement, attached as Appendix U.

78. The evidence assembled during Plaintiff's investigation, and to be developed further during the discovery of this matter, shows or will show that Medtronic's policy on physician payments has been a sham from and after 2002 at the earliest, and/or in the alternative, Medtronic's willful, knowing, deliberate, and/or reckless indifference to truth or falsity regarding its physician payments has been part and parcel to its fraudulent scheme and fraudulent concealment of said scheme.

79. On June 22, 2011, the United States Senate Finance Committee, through its chairman, Max Baucus, and senior committee member, Charles Grassley, issued a news release and copy of a demand letter the committee issued to Medtronic regarding unreported complications and financial conflicts of interest. In statements accompanying the release, Senator Baucus stated "we need to do everything we can to ensure companies aren't concealing serious medical complications from patients just to increase profits." See letter and accompanying statements, attached as Appendix V.

80. As part of its sham physician payment policy designed to further its fraudulent enterprise, Medtronic consistently, and falsely, states that "it is Medtronic's practice to not pay royalties to physician for royalty-earning products they prescribe or products purchased by their institutions. See screenshot of Medtronic's Physician Payment Registry covering Thomas A. Zdeblick and TAZ Consulting for the year 2010, attached as Appendix W.

81. Though it is a sham, Medtronic states this policy as an attempt to avoid federal Anti-Kickback laws and regulations. In fact, Medtronic and its physician agents in the fraudulent enterprise as set forth herein have engaged for years in an elaborate scheme to launder payments through the use of sham consulting, royalty, and educational/training agreements.

82. As set forth in the June 21, 2011 letter of the United States Senate Committee on Finance, Medtronic has paid Thomas A. Zdeblick, the rights holder to the LT-CAGE® and developer Medtronic's INFUSE® bone graft product, "more than $23 million in various royalties" since 2002. See Appendix W, citing to the reporting of the Milwaukee Journal Sentinel. This period of time corresponds with Dr. Zdeblick's takeover of the *Journal of Spinal Deformities*, as well as the approval of INFUSE® by the FDA, said approval being followed by the misleading and/or fraudulent reporting of Drs. Zdeblick, Dickman, and others on the INFUSE® product. It also corresponds to the introduction of the Pyramid plate of Dr. Dickman.

83. In order to funnel payments to its physician agents in this fraudulent enterprise without implicating the Anti-Kickback statutes, the use of sham agreements was employed by the participants in the enterprise. In order to further conceal the sham agreements, Medtronic states as its policy that "when Medtronic pays an entity for either services provided or royalties earned by a service provider, Medtronic does not know the amount of payment, if any, the entity makes to the service provider. As such, the payment data presented in this registry may not reflect amounts received by individual service providers." See Appendix W; see also screenshot of Medtronic's Physician

Payments Registry regarding Dr. Curtis A. Dickman and Vantage Investments, LLC, attached as Appendix X.

84. One of the physician agents Medtronic employed as a clearinghouse to launder and funnel funds to its Key Opinion Leaders and key rights holders was/is Plaintiff's treating physician, Dr. Adam Lewis. In keeping with (a) Medtronic's sham reporting policy, and (b) his materially false or perjurious testimony that he had "never received any funds or remuneration from *them*," Dr. Lewis' name does not appear in Medtronic's Physician Payments Registry. See screenshot of Medtronic Physician Registry search for "Lewis", attached as Appendix Y; see also deposition excerpts of Adam Lewis, at Page 41 of Appendix P (emphasis added).

85. However, as has previously been set forth herein, Medtronic has been fully involved with Dr. Lewis and his work with Dr. Dickman on the PYRAMID plate from the outset. See Appendix S. A further review of the deposition excerpts shows that Dr. Lewis has spoken with Medtronic agents on a number of occasions, including "the head of Medtronic, who manufactures the implant" regarding the PYRAMID plate. See Appendix P.

86. After discovering the questions being raised in the United States Senate and by the Milwaukee Journal Sentinel and other media outlets, Plaintiff Hartwig investigated further the financial connections between Medtronic and Dr. Lewis, which he had previously denied under oath. This investigation took Plaintiff to the website of the Mississippi Secretary of State's Office, where her previous investigation had revealed the companies incorporated by Dr. Lewis, with said investigation ending based on the sworn

testimony of Dr. Lewis that he had not received any payment from Medtronic. Her investigation in the days leading up to the filing of this Complaint revealed a different set of facts than the materially false attestations previously provided by Dr. Lewis.

87. As set forth above, Medtronic has paid Dr. Thomas A. Zdeblick approximately $23 million from 2002 to the present through his company, TAZ Consulting, LLC. See Appendix W. TAZ Consulting draws its name from the initials of Dr. Thomas A. Zdeblick.

88. Appearing among the filings of the Mississippi Secretary of State is a company whose name also matches the initials of Thomas A. Zdeblick. Called TAZ, LLC, this company lists as its registered office the same office suite number as that containing the medical practice of Dr. Adam Lewis. The Mississippi corporation, TAZ, LLC, lists as its registered agent a Zoe Lewis Gasc, who serves as Dr. Lewis' office administrator. See record of Miss. Sec. of State's office, attached as Appendix Z.

89. The sworn testimony of Dr. Lewis that he had never been paid by Medtronic was false and was given (a) to avoid Anti-Kickback and self-dealing implications in Plaintiff Hartwig's medical malpractice trial; and (b) to protect the concealment of the fraudulent scheme. In the understanding of Dr. Lewis, however, he was technically adhering to the truth, as his payments had been funneled first through other entities, such as Dr. Zdeblick's TAZ Consulting.

90. Through the use of these sham consulting, royalty, and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil

conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly, or in the alternative, with deliberate, conscious, or reckless indifference, in the fraudulent enterprise and fraudulent concealment set forth herein.

91. Defendants participated in the paying, receiving, and laundering of kickbacks for their own direct gain on the part of the individual Defendants, and to induce the purchase of its products on the part of Defendant Medtronic.

92. Compliance with the Anti-Kickback Statute is a condition of receiving payment from federally-funded healthcare programs. The Anti-Kickback Statute prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. § 1320a-7b(b). Through the kickback scheme as set forth herein, the Defendants knowingly, or with deliberate indifference or reckless disregard for truth or falsity, submitted directly or caused other healthcare providers to present false or fraudulent claims for payment to federal healthcare programs.

93. In making claims for services and product reimbursement, the Defendants, and each of them, represented compliance with a material condition of payment that was not in fact met, that being that the treatment rendered did not violate the Anti-Kickback Statute. Thus, the claims for payment of the Defendants, and each of them, were materially false or fraudulent.

94. This *qui tam* action is being brought to recover all funds paid through false or fraudulent claims conspired for, and presented, by the Defendants upon the Medicare and Medicaid programs, as well as all other Government programs which have been affected.

95. This Complaint is being brought by Plaintiff Joanne Hartwig for disgorgement of gross receipts, or profits, and other damages for that very reason; because Medtronic has engaged in a thorough and lengthy fraudulent enterprise employing its physician agents simply to increase profits.

COUNT I
VIOLATIONS OF 31 USC § 3729, et seq.

96. Relator restates, repleads and incorporates by reference the information set forth above as if fully forth herein.

97. Defendants acting through their officers, employees, agents, adjusters, and independent contractors, and in concert through their fraudulent enterprise and civil conspiracy, knowingly made, used, or caused to be made or caused to be used, false records in support of false claims.

98. Those false records included, but were not limited to: (a) false records generated for reimbursement of medical services for surgeries and related care; (b) false records generated for reimbursement of Medtronic products; (c) false records generated to conceal the fraudulent scheme to maintain the appearance of compliance with Anti-Kickback laws and regulations; (d) false records generated in order to launder money in an effort to facilitate the fraudulent scheme to maintain the appearance of compliance with Anti-Kickback laws and regulations; (e) false records intended to defraud the Office of the Inspector General

into believing Medtronic was in compliance with the provisions of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Medtronic Sofamor Danek USA, Inc., entered into as part of a settlement of other claims; (f) and others.

99. Defendants submitted or caused to be submitted these false records or statements in order to get false or fraudulent claims approved or paid by the Government, and/or to avoid further payments, penalties, or obligations under the reverse false claims provisions of 31 U.S.C. § 3729(a)(7).

100. WHEREFORE, Relator demands judgment against the Defendants jointly and severally in the amount of three times the false or fraudulent charges, or overcharges, submitted for payment to the United States Government, for a civil penalty against the Defendants each jointly and severally in an amount between Five Thousand, Five Hundred Dollars ($5,500.00) and Eleven Thousand ($11,000.00) for each violation of 31 U.S.C. §3729, et seq., or such other maximum amount allowed by law; for the maximum amount allowed to the Qui Tam Plaintiff under 31 U.S.C. § 3730(d) of the False Claims Act; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorneys fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just and proper.

COUNT II
VIOLATION OF 31 USC §3729(a)(2)

101. Relator restates, repleads and incorporates by reference the information set forth above as if fully set forth herein, and allege violations of 31 U.S.C. §3729(a)(2).

102. WHEREFORE, Relator demands judgment against the Defendants jointly and severally in the amount of three times the overcharges submitted for payment to the United States Government, for a civil penalty against the Defendants each jointly and severally in an amount between Five Thousand, Five Hundred Dollars ($5,500.00) and Eleven Thousand Dollars ($11,000.00) for each violation of 31 U.S.C. § 3730(d) of the False Claims Act; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorneys fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just and proper.

COUNT III
VIOLATIONS OF 31 U.S.C. §3729(a)(3)

103. Relator restates, repleads and incorporates by reference the information set forth above as if fully set forth herein, and allege violations of 31 U.S.C. §3729(a)(3).

104. WHEREFORE, Relator demand judgment against the Defendants jointly and severally in the amount of three times the overcharges submitted for payment to the United States Government, for a civil penalty against the Defendants each jointly and severally in an amount between Five Thousand, Five Hundred Dollars ($5,500.00) and Eleven Thousand Dollars ($11,000.00) for each violation of 31 U.S.C. § 3730(d) of the False Claims Act; for treble damages or any other applicable provision of law, including any alternate remedy

provisions; for its court costs and reasonable attorneys fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just and proper.

COUNT IV
VIOLATIONS OF 42 U.S.C. § 1320a-7b(b)

105. Relator restates, repleads and incorporates by reference the information set forth above as if fully set forth herein, and allege violations of 42 U.S.C. §1320a-7b(b), and other Anti-Kickback Statutes.

106. WHEREFORE, Relator demand judgment against the Defendants jointly and severally in the amount of three times the overcharges submitted for payment to the United States Government, for a civil penalty for each violation of 42 U.S.C. §1320a-7b(b), the Anti-Kickback Statute; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorneys fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just and proper.

COUNT V
CIVIL PENALTIES OR AWARDS
ARISING FROM CRIMINAL CONDUCT

107. Relator restates, repleads and incorporates by reference the information set forth above as if fully set forth herein, and allege violations of various civil codes providing for all civil penalties or awards allowed relative to any criminal conduct of the Defendants, if any, including but not limited to those relative to 18 U.S.C. §§1341, 1342, 1352, 1356, and

1357, covering Mail Fraud, Wire Fraud, Travel to Effect the Scheme, Money Laundering, and Use of Dirty Money, to effectuate the fraudulent scheme.

108. WHEREFORE, Relator demand judgment against the Defendants jointly and severally in the fullest amount allowed by law, for a civil penalty for each violation of the federal criminal codes, enumerated above or otherwise; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorneys fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just and proper.

COUNT VI
VIOLATIONS OF 45 C.F.R. 46, et seq.

109. Relator restates, repleads and incorporates by reference the information set forth above as if fully set forth herein, and allege violations of the various federal statutes known as the "Common Rule," located at 45 C.F.R. 46, et seq., or elsewhere, covering the conduct of medical research on human subjects with the support of federal funds.

110. WHEREFORE, Relator demand judgment against the Defendants jointly and severally in the fullest amount allowed by law, for all civil penalties or awards allowed for each violation of the Common Rule; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorneys fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just and proper.

COUNT VII
VIOLATIONS OF THAT CERTAIN SETTLEMENT AGREEMENT BETWEEN MEDTRONIC AND HHS

111. Relator restates, repleads and incorporates by reference the information set forth above as if fully set forth herein, and allege violations of the terms of settlement of other cases with the United States, specifically with regard to a Corporate Integrity Agreement entered into between Medtronic and the Office of Inspector General of the Department of Health and Human Services and Medtronic Sofamor Danek USA, Inc. and the making of false and fraudulent statements and material misrepresentations with regard thereto.

112. WHEREFORE, Relator demand judgment against the Defendants jointly and severally in the fullest amount allowed by law, for all civil penalties or awards allowed for each violation of the Corporate Integrity Agreement entered into between Medtronic and the Office of Inspector General of the Department of Health and Human Services and Medtronic Sofamor Danek USA, Inc. and the making of false and fraudulent statements and material misrepresentations with regard thereto; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorneys fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just and proper.

COUNT VIII
UNJUST ENRICHMENT, EQUITABLE AND GENERAL RELIEF

113. Relator restates, repleads and incorporates by reference the information set forth above as if fully set forth herein, and allege that the Defendants' conduct, if allowed,

would constitute unjust enrichment and falls under the equitable powers of the Court to address and remedy.

114. WHEREFORE, Relator further demands judgment against the Defendants jointly and severally for a fair and reasonable amount to be determined by a jury, for treble damages, civil penalties, disgorgement of gross receipts or profits, the imposition of a constructive trust, attorneys' fees, expenses, exemplary damages and all other applicable remedies, and for such other and further relief as this Court deems meet, just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff/Relator demands judgment against the Defendants, requesting relief as follows:

A. Awarding treble damages or any other applicable provision of law, including any alternate remedy provisions for each false or fraudulent charge, or overcharge, submitted for payment to the United States government;

B. Awarding civil penalties against the defendants each jointly and severally in an amount between five thousand, five hundred dollars ($5,500.00) and eleven thousand ($11,000.00) for each violation of 31 U.S.C. §3729, et seq.; of 42 U.S.C. §1320a-7b(b), and other Anti-Kickback Statutes; of 45 C.F.R. 46, et seq.; of the Settlement Agreement with the Office of Inspector General, Department of Health and Human Services; or such other maximum amount allowed by law;

C. Awarding restitution and disgorgement of gross receipts, or profits;

D. Awarding declaratory and injunctive relief as permitted by law or equity, as necessary to protect the public health and welfare;

E. Awarding exemplary/punitive damages;

F. Awarding attorneys' fees and costs and expenses; and

G. Providing such further relief as may be just and proper.

AND if Plaintiff/Relator has prayed for incorrect or insufficient relief, she requests that the prayer for relief be amended to allow for such other or further relief, both legal and equitable, as this Court deems meet, just and proper in the premises.

Respectfully submitted,

UNITED STATES OF AMERICA EX REL.
JOANNE HARTWIG, Plaintiff/Relator

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DEMAND FOR JURY TRIAL

Relator/Plaintiff demands a jury trial on all issues for which a jury is available.

Respectfully submitted,

UNITED STATES OF AMERICA EX REL.
JOANNE HARTWIG, Plaintiff/Relator

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