UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Undetermined quantities of all articles of finished and in-process foods, etc.

Defendants,

and

HI-TECH PHARMACEUTICALS, INC., and JARED WHEAT,

Claimants.

HI-TECH PHARMACEUTICALS, INC.,

Plaintiff,

v.
MARGARET A. HAMBURG, M.D., et al.

Defendants.

Civil Action No. 1:13-cv-3675

Hon. Willis B. Hunt, Jr.

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF CLAIMANTS' HI-TECH PHARMACEUTICALS, INC. AND JARED WHEAT'S MOTION FOR SUMMARY JUDGMENT DISMISSING THE SEIZURE ACTION OF THE UNITED STATES AND GRANTING JUDGMENT ON CLAIMANTS' ADMINISTRATIVE PROCEDURE ACT COMPLAINT

Hi-Tech Pharmaceuticals, Inc., and Jared Wheat (collectively "Claimants") respectfully submit the following undisputed material facts in support of their Motion for Summary Judgment.

1. DMAA is an "organic substance," which is naturally found in the geranium plant. Declaration of Jack Wenik ("Wenik Decl.") Ex. 1, Declaration of Cara Welch ("Welch Decl.") at ¶ 17; Wenik Decl. Ex. 51, Declaration of Paul Simone at ¶ 73; Wenik Decl. Ex. 53, Ping, *A Study On The Chemical Constituents Of Geranium Oil*, 25 Journal of Guizhou Institute of Technology, February 1996; Li, *Identification and Quantification of Dimethylamylamine in Geranium by Liquid Chromatography Tandem Mass Spectrometry*, Analytical Chemistry Insights 2012:7 47-58.

2. Hi-Tech, is a Georgia corporation that manufactures and distributes dietary supplements that are sold in more than 100,000 retail locations including, for example, GNC, CVS, Walgreen's, Wal-Mart, K-Mart, Kroger and convenience stores nationwide. Wenik Decl. Ex. 66, Administrative Procedure Act Complaint, filed as Docket Entry No. 2 in 1:13-cv-01747-KBJ, District Court for the District of Columbia, on November 7, 2013, at ¶ 5; Answer of United States (Doc. 52) at ¶ 5.

3. Hi-Tech incorporates DMAA into many of the dietary supplements it manufactures and sells including, for example, Black Widow, Lipodrene, Yellow Scorpion, Fastin XR and Stimerex-ES. *Id.*

4. Since 2010, Hi-Tech has sold over 200 million doses of DMAA containing products with only a handful of adverse events of any sort. Wenik Decl. Ex. 2, Declaration of Michael Lumpkin, Ph.D., DABT ("Lumpkin Decl.") at ¶¶ 98-99.

5. The Government has detained large quantities of Hi-Tech's DMAA containing goods, which, to this day, remain impounded at Hi-Tech facilities in Georgia. Wenik Decl. Ex. 3, United States' Responses to Requests for Admissions, at Requests 12 and 13.

6. Sometime in 2010, Amy Eichner, an official of the United States Anti-Doping Agency ("USADA"), with virtually no training or expertise in chemistry, Wenik Decl. Ex. 4, Deposition of Amy Eichner ("Eichner Dep.") at 12:9-12:22, became convinced that DMAA presented a health risk to athletes, Wenik Decl. Exhs. 4-5, Eichner Dep. at 27:6-28:19; Fabricant Dep. at 52:2-53:21, and that it could not be found in the geranium plant, but was rather a "drug." Wenik Decl. Ex. 6, GOV-007409.

7. Serviceman Michael Lee Sparling died during military training on June 1, 2011, a death that news media suggested was caused by DMAA. *See, e.g.*, Wenik Decl. Ex. 7, GOV-008127-GOV-008138.

8. Eichner spoke to Sparling's family, which had filed a wrongful death suit as a result of the incident. Wenik Decl. Ex. 4, Eichner Dep. at 39:15-40:17.

9. Eichner expressed concerns about DMAA to the Food and Drug Administration ("FDA"). On October 13, 2010, Dr. Robert J. Moore, an FDA supervisor in the Division of Dietary Supplements, advised Eichner that DMAA "is found in many plants," that plants are dietary ingredients under DSHEA, and that DMAA "appears to be a dietary ingredient under [DSHEA] because it is a constituent of another dietary ingredient (i.e., a plant)." Wenik Decl. Ex. 8, GOV-007430-GOV-007435, at 007433.

10. Also on October 13, 2010, Dr. Moore advised Eichner that DMAA could be found in geranium oil which had "a fairly long history of food use as an essential oil" and also provided her the cite to a 1996 scientific study by Ping that had detected DMAA in geranium oil. *Id.* at 007430-007431.

11. Eichner expressed her view that the Ping study was from a "third rate university in China" and that DMAA was a drug. Wenik Decl. Ex. 9, USADA007072-USADA007077, at 007073.

12. Eichner enlisted the aid of the National Center for Natural Product Research at the University of Mississippi ("NCNPR") to conduct research regarding DMAA. Her main contact at this entity was Dr. Ikhlas Khan. Dr. Khan was a professor at the University of Mississippi and the Associate Director of the NCNPR at the University. From October 2002 until January 2015, he was the Center's Assistant Director. Wenik Decl. Ex. 10, Khan Initial Expert Report/Declaration at ¶ 7; Ex. 11, Khan Dep. at 71:5-71:12; Ex. 4, Eichner Dep. at 33:11-33:22.

13. Eichner reached out to Dr. Khan asking him for assistance in determining whether DMAA could be found in geraniums. Wenik Decl. Ex. 11, Khan Dep. at 71:5-71:12; Ex. 4, Eichner Dep. at 33:11-33:22.

14. Eichner believed that Dr. Khan would conduct the "definitive" study as to whether DMAA could be found in geraniums. Wenik Decl. Ex. 9 at USADA007073.

15. Khan admitted that it was Eichner and her colleague at the USADA, Larry Bowers, who helped form the hypothesis in his first study that DMAA could not be found in geraniums. Wenik Decl. Ex. 11, Khan Dep. at 69:14-70:5.

16. Eichner was introduced to Dr. Khan's colleague, Dr. Mahmoud A. ElSohly. Wenik Decl. Ex. 4, Eichner Dep. at 33:11-33:22.

17. Dr. ElSohly was also a professor at the University of Mississippi and affiliated with the NCNPR. He was also President of a related entity, Phytochemical Services, Inc., in Mississippi, which performed testing services for NCNPR. Beginning in December 2010, Eichner negotiated with Drs. Khan and ElSohly for them to conduct a study of DMAA and geraniums. Wenik Decl. Ex. 4, Eichner Dep. at 85:11-86:1.

18. In April of 2011, Eichner arranged for a consulting agreement to be executed between the USADA and Dr. ElSohly's company wherein his company would test geranium samples for the presence of DMAA. *See* Wenik Decl. Ex. 12, ElSohly 3480-3489.

19. On May 27, 2011, Eichner told Drs. Khan and ElSohly that she had heard a rumor that other researchers had detected DMAA in geranium oil and she was concerned how this might affect their efforts to lobby FDA regarding DMAA. Dr. ElSohly responded by informing Eichner that he and his colleagues had developed a very sensitive method to detect DMAA and that they had indeed found low levels of DMAA in the geranium samples that Eichner had supplied to them. Wenik Decl. Ex. 13, ElSohly 4318-4322 at 44319.

20. Eichner and her colleague at the USADA, Larry Bowers, agreed with Drs. ElSohly and Khan to avoid positive DMAA test results by raising the

detection limit in their published article so that a finding that no DMAA was detected could be reported. *See* Wenik Decl. Ex. 14, ElSohly 4330-4335.

21. The published article of Drs. Khan and ElSohly, *Pelargonium Oil and Methyl Hexaneamine (MHA): Analytical Approaches Supporting the Absence of MHA in Authenticated Pelargonium graveolens Plant Material and Oil*, Journal of Analytical Toxicology (2012), Wenik Decl. Ex. 15, GOV-027840-GOV-027854, reported that DMAA had not been detected in the geranium samples studied.

22. Eichner helped supress other test results that showed DMAA to be contained in geraniums suppressed from public view. Eichner gained access to an unpublished version of research results regarding DMAA by Zhang and Armstrong and she forwarded it to Drs. Khan and ElSohly. Wenik Decl. Ex. 16, ElSohly 2181-2190.

23. Eichner admitted the "possibility" that either she or a colleague at the USADA had communicated with Zhang and Armstrong about their "embargoed" draft article to "try and understand" it. Wenik Decl. Ex. 4, Eichner Dep. at 147:13-149:14.

24. The version of the Zhang/Armstrong article of 2012 that Eichner reviewed reported the detection of DMAA in significant amounts in two of eight geranium samples. Wenik Decl. Ex. 17, ElSohly 1738-1743.

25. After being in the hands of Drs. Khan and ElSohly, the published version of the Zhang and Armstrong Study reported no detection of DMAA. *See* Wenik Decl. Ex. 18, ElSohly 2600-2604.

26. In April 2012, the FDA sent Warning Letters to several companies that marketed DMAA containing products, advising them that DMAA was dangerous and not a dietary ingredient under DSHEA. Wenik Decl. Ex. 19, April 27, 2012 Press Release.

27. FDA trumpeted its "success" by noting that all but one of the companies that had received a warning letter had removed DMAA from their products and the marketplace. Wenik Decl. Ex. 20, FDA Consumer Alert, Fabricant Ex. 28 at 2.

28. The one holdout, USP Labs, LLC, ultimately caved into FDA pressure and removed DMAA from its products in April 2013, a result that FDA official Dr. Daniel Fabricant shared with Dr. Khan. Wenik Decl. Ex. 21, Ole Miss. 008982-008983.

29. In August of 2012 an article was published in *Analytical Chemistry Insights* by Charlie Li, which found that DMAA was in geraniums. Wenik Decl. Ex. 22, GOV-012486-GOV-012497.

30. This prompted Dr. Khan to reach out to NCNPR's federal program officer, Dr. Daniel Fabricant of the FDA. Dr. Khan proposed to Dr. Fabricant a

strategy for a new, multi-center DMAA study to refute the findings of Li's work. Wenik Decl. Ex. 23, August 9, 2012 email to Fabricant, Fabricant Ex. 23.

31. Dr. Fabricant approved the strategy. Wenik Decl. Ex. 24, Fabricant Ex. 24.

32. Thereafter, Drs. Khan and ElSohly began what would become their 2014 Multi-Center Study regarding DMAA and geraniums. Wenik Decl. Ex. 25, *Methylhexanamine is not detectable in Pelargonium or geranium species and their essential oils: A multi-center investigation*," Drug Testing and Analysis (2014), 7(7), 645-54 (the "Multi-Center Study").

33. One of the four laboratories working on the Multi-Center Study reported to Drs. Khan and ElSohly in April 2013 that it had indeed detected DMAA in several geranium samples from China. Wenik Decl. Ex. 26, ElSohly 2267-2272.

34. In April 2013, Dr. ElSohly gave a power point presentation at the University of Mississippi wherein he suppressed any mention of the positive DMAA test results. Wenik Decl. Ex. 27, 2013 ElSohly Power Point Slides.

35. The Power Point slides were shared with Dr. Fabricant who had attended the presentation. Wenik Decl. Ex. 5, Fabricant Dep., at 175:7-175:24; 176:8-177:3; 177:25-178:6.

36. The positive DMAA test results did not make their way into the article published by Drs. Khan and ElSohly. *See* Wenik Decl. Ex. 25, Multi-Center Study.

37. At no time did the FDA revise its website or Q&A's regarding DMAA to advise the public of test results showing DMAA was in fact found in geraniums. *See* DMAA in Dietary Supplements – Questions & Answers, available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm346576.htm.

38. In early November 2013, the *Atlanta Journal Constitution* published a lengthy article that discussed Claimants' sale of products containing DMAA. Wenik Decl. Ex. 28, November 2, 2013 *Atlanta Journal Constitution* article.

39. In the article, reporter Danny Robbins related comments by FDA's Dr. Fabricant that the FDA was not aware that Claimants were marketing DMAA-containing products until being informed about this by the *Atlanta Journal Constitution*. *Id*.

40. Under DSHEA, there is no premarket approval requirement for dietary supplements. Wenik Decl. Exhs. 34, Keefe. Dep. 74:8-74:12; and 35, Welch Dep. 72:10-72:15.

41. Under DSHEA, the burden is on the FDA to prove that a dietary supplement/ingredient is unsafe. *Id.* Keefe Dep. at 74:13-74:17; Welch Dep. at 72:16-72:24; 73:5-73:15. *See, also,* Wenik Dec. Ex. 5, Fabricant Dep. (former

head of FDA Dietary Supplements Division), at 81:24-81:25; 154:17-155:16 (no premarket approval requirement, burden on FDA to show a dietary supplement/ingredient is unsafe).

42. Not a single serious illness or death has been shown to have been caused by DMAA. Wenik Decl. Ex. 36, Order, Sparling v. Doyle, et al., Dkt. No. EP-13-CV-323-DCG (W.D. Tex. July 27, 2015); Wenik Decl. Exhs. 2, Lumpkin Declaration at ¶¶ 94-96; 37, Elkind Declaration at ¶¶ 75, 85.

43. The FDA has publicly admitted that adverse events temporally associated with DMAA were not necessarily caused by DMAA. Wenik Decl. Ex. 19, April 27, 2012 Press Release.

44. When the FDA issued warning letters and press releases regarding DMAA it was aware of 42 adverse events that had occurred regarding DMAA in the several years it had been in the marketplace as a dietary supplement ingredient. Wenik Decl. Ex. 19, April 27, 2012 FDA Press Release.

45. Less than a year after this publicity, the number of adverse events had more than doubled to 86. Wenik Decl. Ex. 39, GOV-007908-GOV-007910 (April 30, 2013 DMAA Q&A).

46. A Department of Defense study, completed in June 2013, found: 1) it was unlikely that DMAA played a significant role in the deaths of four service personnel who had consumed DMAA, 2) there was no statistically significant

association between DMAA use and adverse medical events or outcomes, and 3) soldiers consuming DMAA had 40% **lower** odds of having an adverse medical outcome. Wenik Decl. Ex. 41, DOD Study (GOV-002688-GOV-002796) at GOV-002714-15, GOV-002736.

47. Several peer reviewed studies examined the physiological effects of DMAA and found, at worst, transient increases in blood pressure that did not have clinical significance. Wenik Decl. Exhs. 37, Elkind Declaration at ¶¶ 52-68; 2, Lumpkin Declaration at ¶¶ 43-54; 68-75.

48. The Government sent one of Hi-Tech's competitors, USP Labs, LLC, a warning letter about DMAA in April 2012. Wenik Decl. Ex. 3, (United States' Responses to Requests for Admission) at Request 2.

49. USP Labs sent letters in response and it was not until more than a year later, in April 2013, that the FDA finally sent a formal response to USP Labs. *Id.* at Request 4.

50. The FDA made no effort to physically remove DMAA containing products from Hi-Tech's facilities. *Id.* at Requests 12, 13.

51. Synthetic ingredients can be dietary ingredients under DSHEA. Wenik Decl. Ex. 35, Welch Dep. at 27:7-27:23; Answer (Doc. 52) at ¶ 14.

52. Hi-Tech has stipulated that the DMAA used in its dietary supplements was synthetically produced. Doc. 58.

53. Geraniums have been in the food supply since before October 15, 1994. Both geraniums and DMAA, as a constituent or extract of geraniums, are dietary ingredients pursuant to DSHEA. Wenik Decl. Ex. 38, Heuer Declaration at ¶¶ 51-53; 90-93; Wenik Decl. Exh. 43, Kababick Rebuttal Report, at ¶ 13; Wenik Decl. Ex. 35, Welch Dep. at 77:25-78:15.

54. No new dietary ingredient notifications ("NDI") were ever filed with the FDA for DMAA. Wenik Decl. Ex. 3, United States' Responses to Requests for Admissions, at Request 20.

55. An extract or constituent of a botanical is a dietary ingredient that is expressly excluded from the definition of "food additive" (and thus not subject to regulation as a food additive). Wenik Decl. Exhs. 34, Keefe Dep. at 93:18-96:11; *see also,* Wenik Decl. Ex. 3, United States' Responses to Requests for Admission, at Request 25 ("food additives" do not include dietary ingredients/supplements by statute).

56. Geraniums are complex and contain scores of compounds/components. Wenik Decl. Ex. 54, Kababick Dep. at 86:13-86:87:14 (well over 100 components); Ex. 11, Khan Dep. at 74:20-75:2 (there are hundreds of substances in geraniums, only about 90 of which have been identified).

57. It is only in recent years that scientists have developed standards for DMAA and accurate methods to detect it. *See* Wenik Decl. Ex. 55, Brown Initial

Decl. at page 5 (new methods developed to detect DMAA in geranium raw materials since its introduction into dietary supplements); Wenik Decl. Ex. 54, Kababick Dep. at 110:7-11:6 (Kababick recently developed method to detect and quantify DMAA); Wenik Decl. Ex. 11, Khan Dep. at 94:24-95:9 (Khan developed new method to detect DMAA); Ex. 14, ElSohly 4330-4335 (ElSohly developed new sensitive detection method).

58. There is no evidence of tampering with or contamination of the samples used by researchers who detected DMAA in geraniums. *See* Wenik Decl. Ex. 54, Kababick Dep. at 150:24-151:5; 160:3-160:22 (no evidence of tampering or contamination); Ex. 56, Brown Dep. at 147:6-1478:18 (no evidence of contamination); Wenik Decl. Ex. 11, Khan Dep. at 223:15-223:23 (no evidence of contamination).

59. Dr. Khan and his colleague, Dr. Mahmoud ElSohly, developed a very sensitive method for detecting DMAA and did detect low levels of DMAA in geraniums samples. *See* Wenik Decl. Ex. 13, ElSohly 4318-4322.

60. Drs. Khan and ElSohly, conspired with the USADA to change the reporting detection limit in their published article so as to show no DMAA detected. *See* Wenik Decl. Ex. 14, ElSohly 4330-4335.

61. The Zhang/Armstrong article of 2012 reported no detection of DMAA in its published version. *See* Wenik Decl. Ex. 18, ElSohly 2600-2604.

62. The published version of the Zhang/Armstrong Study was completely re-written from its original form which, among other things, noted the detection of DMAA in significant amounts in two of eight geranium samples. *Compare* Wenik Decl. Ex. 17, ElSohly 1738-1743.

63. Amy Eichner had access to the original unpublished version of the Zhang/Armstrong Study, and she forwarded it to Drs. Khan and ElSohly. Wenik Decl. Ex. 16, ElSohly 2181-2190.

64. Eichner admitted the "possibility" that either she or a colleague at the USADA had communicated with Zhang or Armstrong about their "embargoed" draft to "try and understand" it. Wenik Decl. Ex.4, Eichner Dep. at 147:13-149:14.

65. The 2014 Multi-Center Study, Wenik Decl. Ex. 25, "*Methylhexanamine is not detectable in Pelargonium or geranium species and their essential oils: A multi-center investigation*," Drug Testing and Analysis (2014), 7(7), 645-54 (the "Multi-Center Study"), intentionally omitted data from one of its four laboratories that detected DMAA in multiple geranium samples. *See* Wenik Decl. Ex. 26, ElSohly 2267-2272; Ex. 11, Khan Dep. at 135:3-151:20.

66. James Kababick omitted from his expert report that he personally detected DMAA in geranium oil samples. Wenik Decl. Ex. 54, Kababick Dep. at 58:17-59:17.

67. In an official report, the Government of New Zealand concluded that it was likely that DMAA was a naturally occurring constituent of geraniums. Wenik Decl. Ex. 58, July 2015 Classification of 1,3-dimethylamylamine, at 3.

68. In emails to Drs. Khan and ElSohly, Amy Eichner noted that, one of the labs used by the USADA, Banned Substance Control Group, had detected DMAA in geranium oil samples provided by the USADA and she sought advice from Drs. Khan/ElSohly about this. Wenik Decl. Ex. 4, Eichner Dep. at 130:2-132:2.

69. Scientists have not identified all of the biosynthetic pathways for plants. *See* Wenik Decl. Exhs. 55 (Kababick Dep.) at 84:18-84:22; 57 (Brown Dep.) at 60:5-60:11.

70. Substances which are GRAS are not food additives and thus not covered by the statutes and regulations regarding same. Wenik Decl. Ex. 34, Keefe Dep. at 79:9-79:14.

71. A substance can qualify as GRAS without any FDA opinion on the issue and without a company providing to the FDA any information to support a GRAS determination. *Id*. at 81:17-81:24.

72. A dietary supplement manufacturer or distributor can self-affirm that a substance/ingredient is GRAS and there is no obligation on the company to report that self-affirmation to the FDA. *Id.* at 75:7-75:17.

73. While information to support a GRAS determination must be publicly accessible, it need not be peer-reviewed, published articles. *Id.* at 155:7-155:11.

74. FDA official Dr. Daniel Fabricant felt that DMAA posed a danger as a "drug" that had been introduced into the food supply. Wenik Decl. Ex. 5, Fabricant Dep. at 67:22-68:4.

75. Banning a lawful dietary ingredient is a lengthy process that requires rulemaking, notice and comment. Wenik Decl. Exhs. 39 (GOV-007908-GOV-007910); 61(HT00563-HT00566 (FDA Q&A's)); 5 (Fabricant Dep.) at ¶¶162:6-162:20.

76. There was no rulemaking regarding DMAA. *See* Answer (Doc. 52) at ¶16.

77. The FDA provided millions of dollars in funding to the National Center for Natural Product Research at the University of Mississippi ("NCNPR"). *See* Wenik Decl. Exhs. 35 (Welch Dep.) at 49:4-49:21; 51:20-52:6; 5 (Fabricant Dep.) at 61:12-62:25.

78. The NCNPR research activities were directed and approved by government officials who served as its project officers, first Dr. Daniel Fabricant, Wenik Decl. Ex. 11, Khan Dep. at 38:2-38:7; 35, Welch Dep. at 53:14-53:20; 5, Fabricant Dep. at 53:22-54:13; and later Dr. Cara Welch. Wenik Decl. Exhs. 11, Khan Dep. at 36:23-37:11; 35, Welch Dep. at 50:12-50:20.

79. NCNPR officials, notably the Government's expert, Dr. Khan, regularly communicated with FDA officials about the status and progress of their research and sent draft manuscripts to the FDA for review. Wenik Decl. Exhs. 35, Welch Dep. at 51:3-51:14; 52:7-53:2; 11, Khan Dep. at 36:23-37:25.

80. Dr. Khan referred to Dr. Daniel Fabricant of the FDA as his "boss." Wenik Decl. Ex. 61, 6/21/12 email string.

81. The FDA/Government was directly involved with Dr. Khan to craft research to refute other scientists' work that found DMAA in geraniums. Dr. Khan provided a "strategy" to Dr. Daniel Fabricant of the FDA for what ultimately became the 2014 Multi-Center Study. Wenik Decl. Ex. 23, August 9, 2012 email to Dan Fabricant.

82. Dr. Fabricant approved Khan's strategy for the new study. Wenik Decl. Ex. 24, August 9, 2012 email to Ikhlas Khan.

83. Dr. Fabricant of the FDA testified that Eichner emailed him her opinions regarding DMAA. Dr. Fabricant also spoke with Eicnher via telephone of her concerns that DMAA was a health risk and he was also aware of her giving speeches in 2011 and 2012 about the purported dangers of DMAA. Wenik Decl. Ex. 5, Fabricant Dep. at 52:2-53:21.

84. Dr. Fabricant regularly sought out the advice of both Drs. Khan and ElSohly, scientists whose judgment he trusted. *Id.* at 65:65-66:6; 66:11-67:8.

85. Both Drs. Khan and ElSohly thought DMAA was dangerous, and both thought, even before they conducted what became their 2012 Study, that DMAA was not in geraniums. *Id.* at 126:23-127:6; 128:3-130:16.

86. Dr. Fabricant had conversations with Dr. Khan to be kept updated about Dr. Khan's new DMAA research. Wenik Decl. Ex. 5, Fabricant Dep. at 163:18-164:12.

87. In April of 2013, Drs. Khan and ElSohly were desperately seeking clarification of positive DMAA test results received from one of their laboratories in China because they were preparing to present their results at a conference. Wenik Decl. Ex. 26, ElSohly 2267-2272.

88. Dr. ElSohly gave a power point presentation in April 2013 at a conference held at the University of Mississippi where he falsely stated that DMAA was not detected in samples from China. *Compare* Wenik Decl. Ex. 26, at ElSohly 2270 (DMAA detected in samples 13040, 13041, 13047, 13048 and 13049) with Ex. 27, (2013 ElSohly Power Point Slides) Fabricant Ex. 38 at page 31 (DMAA "not detected" in these samples).

89. Dr. Fabricant was a chair of the conference, attended Dr. ElSholy's presentation and obtained a copy of the power point slide deck for the FDA. Wenik Decl. Ex. 5, Fabricant Dep. at 175:7-175:24; 176:8-177:3; 177:25-178:6.

90. Government expert James Kababick, who had been lobbying for action against DMAA as early as January 2012, Wenik Decl. Ex. 62, GOV-007705-GOV-007706, was part of this dialogue. *See* Wenik Decl. Ex. 63, GOV-007710-GOV-007712.

91. Dr. Fabricant of the FDA admitted talking generally to Kababick about DMAA. Wenik Decl. Ex. 5, Fabricant Dep. at 102:13-102:24.

Respectfully submitted,

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1(D)

Pursuant to Local Rules 5.1(C) and 7.1(D), I hereby certify that the above document was prepared in Microsoft Word using 14-point Times New Roman font.

CERTIFICATE OF SERVICE

I hereby certify that the above document was electronically filed using the CM/ECF system and was served upon counsel of record via electronic mail on this 30th day of December, 2016.

/s/ Jack Wenik

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