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Attorneys for Defendant, Albert Poet

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

:
Anne E. Thompson, U.S.D.J.

Plaintiff,

Criminal Number 06-
18 U.S.C. § § 1341 and 2;
21 U.S.C. § § 331(k); 333(a)(2); and
352(i)(3)

vs.

ALBERT POET,

Defendant.

**CERTIFICATION OF
WILLIAM J. HUGHES, JR. ESQ.**

William J. Hughes, of due age and sound mind, certifies as follows pursuant to 28
U.S.C. § 1746:

1. I am "Of Counsel" to the law firm of Cooper Levenson April Neidelman
Wagenheim & Levenson, P.A., which represents defendant Dr. Albert Poet in this matter.
In this capacity, I have personal knowledge of the matters set forth in this certification.

2. Attached as Exhibit 1 is a true and correct copy of an FDA investigative
report of an interview with Dr. Patrick Bitter, Jr. received from the Government as part of
discovery pursuant to Fed. R. Crim. P. 16.

3. Attached as Exhibit 2 is a true and correct copy of an FDA investigative
report of an interview with Dr. Gilbert Lee received from the Government as part of
discovery pursuant to Fed. R. Crim. P. 16.

4. Attached as Exhibit 3 is a true and correct copy of an FDA investigative report of an interview with Dr. F. Don Parsa and Touri Parsa received from the Government as part of discovery pursuant to Fed. R. Crim. P. 16.

5. Attached as Exhibit 4 is a true and correct copy of an FDA investigative report of an interview with Dr. William R. Work received from the Government as part of discovery pursuant to Fed. R. Crim. P. 16.

6. Attached as Exhibit 5 is a true and correct copy of an FDA investigative report of an interview with Dr. Panagotacos received from the Government as part of discovery pursuant to Fed. R. Crim. P. 16.

7. Attached is Exhibit 6, is a true and correct copy of the certification of Nurse Anita D'Entremont submitted by the Government in United States v. Livdahl, et al., Docket No. 04-61717-CIV-COHN (S.D. FL. Jan. 4. 2005) and *not* provided by the Government in this case.

8. Attached as Exhibit 7 is a true and correct copy of an FDA chemical analysis of the Botulinum Neurotoxin Type A in TRI's BoNT/A and produced by the Government as part of discovery pursuant to Fed. R. Crim. P. 16.

9. Attached as Exhibit 8 is a true and correct copy of the Complaint filed by the United States Department of Justice in United States v. Livdahl, et al., Docket No. 04-61717-CIV-COHN (S.D. FL. Dec. 23, 2004) and *not* provided by the Government in this case.

10. Attached as Exhibit 9 is a true and correct copy of Botulism in the United States, 1899 – 1996: Handbook for Epidemiologists, Clinicians, and Laboratory Workers,

Center for Disease Controls, U.S. Department of Health and Human Services (1998), and obtained through the internet website for the Center for Disease Controls, www.cdc.gov.

11. Attached as Exhibit 10 is a true and correct copy of Luba Vangeloba, "Botulinum Toxin: A Poison that can Heal," FDA Consumer Magazine (December 1995), and obtained from the FDA's website at www.fda.gov.

12. Attached as Exhibit 11 is a true and correct copy of pages 1 through 25 of the FDA's Medical Officer's Review of Allergan, Inc.'s application to amend its license to manufacture Botulinum Toxin Type A (March 22, 2002), and obtained from the FDA's website at www.fda.gov.

13. Attached as Exhibit 12 is a true and correct copy of the Certificate of Trademark for "Oculinum" issued to Alan B. Scott on October 12, 1982 and obtained from the U.S. Patent and Trademark Office's website at www.uspto.gov.

14. Attached as Exhibit 13 is a true and correct copy of "Botulinum toxin (BOTOX) for the treatment of "spastic dysphonia" as part of a trial of toxin injections for the treatment of other cranial dystonias.", A. Blitzer, M.F. Brin, S. Fahn, D. Lange, R.E. Lovelace, Laryngoscope, 96(11):1300-1 (November 1986).

15. Attached as Exhibit 14 is a true and correct copy of "Distant Effects of Local Injection of Botulinum Toxin," D. Lange, M. Brin, C. Warner, S. Fahn, R. Lovelace, Muscle & Nerve, 10:552-555 (July 1987).

16. Attached as Exhibit 15 is a true and correct copy of "Localized Injections of Botulinum Toxin for the Treatment of Focal Dystonia and Hemifacial Spasm," M. Brin, S. Fahn, C. Moskowitz, A. Friedman, H. Shale, P. Greene, A. Blitzer, T. List, D.

Lange, R. Lovelace, and D. McMahon, Movement Disorders, Vol. 2., No. 4, pp 237-254 (1987).

17. Attached as Exhibit 16 is a true and correct copy of "Localized Injections of Botulinum Toxin for the Treatment of Focal Laryngeal Dystonia (Spastic Dysphonia)," A. Blitzer, M. Brin, S. Fahn, and R. Lovelace, Laryngoscope, 98:193-97 (February 1987) (Presented at a medical conference on April 27, 2987).

18. Attached as Exhibit 17 is a true and correct copy of "Localized Injections of Botulinum Toxin for the Treatment of Focal Dystonia and Hemifacial Spasm," M. Brin, S. Fahn, C. Moskowitz, A. Friedman, H. Shale, P. Greene, A. Blitzer, T. List, D. Lange, R. Lovelace, and D. McMahon, Advances in Neurology, 50:599-608 (1988).

19. Attached as Exhibit 18 is a true and correct copy of "Distant Effects of Locally Injected Botulinum Toxin: Incident and Course," A. Blitzer, M. Brin, S. Fahn, and R. Lovelace, Advances in Neurology, 50:609-13 (1988).

20. Attached as Exhibit 19 is a true and correct copy of "Botulin's Therapeutic Use Expands: the neurotoxin produces significant symptomatic improvement in patients with spastic dysphonia and torticollis as well as in those with blepharospasm." J. McCann, Medical World News, Vol. 29, No. 16, p. 27 (August 22, 2988).

21. Attached as Exhibit 20 is a true and correct copy of "Adductor Laryngeal Dystonia (Spastic Dysphonia): Treatment with Local Injections of Botulinum Toxin (Botox)," M. Brin, A. Blitzer, S. Fahn, W. Gould, and R. Lovelace, Movement Disorders, Vol. 4, No. 4., pp. 287-96 (1989).

22. Attached as Exhibit 21 is a true and correct copy of "Double blind, placebo-controlled trial of botulinum toxin injections for the treatment of spasmodic

torticollis,” P. Greene, U. Kang, S. Fahn, M. Brin, C. Moscowitz, and E. Flaster, Neurology, 40:1213-1218 (August 1990) (Submitted May 24, 1989).

23. Attached as Exhibit 22 is a true and correct copy of “Effect of botulinum Toxin on extraocular muscle proprioception,” E. Manni, B. Bagolini, V. Pettorossi, and P. Errico, Documenta Ophthalmologica, 72:189-198 (1989) (Accepted May 31, 1989).

24. Attached as Exhibit 23 is a true and correct copy of “Academy Policy Statement: Botox for Spasmodic Dysphonia,” Board of Directors of the American Academy of Otolaryngology-Head and Neck Surgery, Inc., AAO-HNS Bulletin, December 1990, p. 8 (Statement adopted September 12, 1990 and policy adopted on July 20, 1990).

25. Attached as Exhibit 24 is a true and correct copy of “Double Blind Study of botulinum toxin in adductor spasmodic dysphonia,” D. Truong, M. Rontal, M. Rolnick, A. Aronson, K. Mistura, Laryngoscope, 101:630-634 (June 1991) (Accepted for Publication on August 17, 1990).

26. Attached as Exhibit 25 is a true and correct copy of “Laryngeal Dystonia: A Series with Botulinum Toxin Therapy,” A. Blitzer and M. Brin, Ann. Otol. Rhinol Laryngol, 100:85-89 (1991) (Presented to a medical conference on April 28-29, 1990).

27. Attached as Exhibit 26 is a true and correct copy of “Tratamiento del Blefaroespasma con Toxina Botulinica,” R. Pikielny, F. Micheli, M. Paradal, I. Parera, R. Giannaula, M. Gatto, MEDICINA (Buenos Aires), 50:129-134 (1990) (Accepted for Publication on January 13, 1990).

28. Attached as Exhibit 27 is a true and correct copy of "Acoustic Changes in Spasmodic Dysphonia After Botulinum Toxin Injection," P. Zwiner, T. Murry, M. Swenson, and G. Woodson, Journal of Voice, Vol 5, No. 1, pp. 78-84 (1991).

29. Attached as Exhibit 28 is a true and correct copy of "Relax and Enjoy It," Economist, Vol. 317, Issue 7685, p. 82 (December 15, 1990).

30. Attached as Exhibit 29 is a true and correct copy of "Botulinum Toxin Treatment for Spastic Torticollis," T. Anderson, J. Rivest, R. Steli, M. Steiger, H. Cohen, P. Thompson, C. Marsden, Journal of the Royal Society of Medicine, Vol. 85, pp. 524-529 (September 1992) (Accepted for Publication on November 5, 1991).

31. Attached as Exhibit 30 is a true and correct copy of an article abstract of "Comparison of the Action of Types A and F Botulinum Toxin at the Rat Neuromuscular Junction," J. Kauffman, J. Way, L. Siegel, L. Sellin, Toxicol. Appl. Pharmacol., 79(2):211-217 (June 30, 1985) (refers to botulinum toxin as BoTX).

32. Attached as Exhibit 31 is a true and correct copy of an FDA Warning Letter issued to Allergan, Inc. on June 23, 2003 and obtained from the FDA's website at www.fda.gov.

33. Attached as Exhibit 32 is a true and correct copy of the trademark assignment details of the assignment of the trademark "Oculinum" from Oculinum, Inc. to Allergan, Inc. effective June 28, 1991. This document was obtained from the U.S. Patent and Trademark Office's website at www.uspto.gov.

34. Attached as Exhibit 33 is a true and correct copy of the Certificate of Trademark for "BOTOX" issued to Allergan, Inc. on August 18, 1992 and obtained at the U.S. Patent and Trademark Office's website at www.uspto.gov.

35. Attached as Exhibit 34 is a true and correct copy of the Certificate of Trademark for "BOTOX" issued to Allergan, Inc. on June 9, 1992 and obtained at the U.S. Patent and Trademark Office's website at www.uspto.gov.

36. Attached as Exhibit 35 is a true and correct copy of the U.S. Patent and Trademark Office's official summary of the status of the trademark Oculinum, obtained from the U.S. Patent and Trademark Office's website at www.uspto.gov.

37. Attached as Exhibit 36 is a true and correct copy of an FDA investigative report of an interview with Karen Crawford received from the Government as part of discovery pursuant to Fed. R. Crim. P. 16.

38. Attached as Exhibit 37 is a true and correct copy of an FDA investigative report of an interview with Debra Dye received from the Government as part of discovery pursuant to Fed. R. Crim. P. 16.

39. Attached as Exhibit 38 is a true and correct copy of the grand jury transcript of the testimony of Maryan Mikhael, dated January 25, 2005, and *not* provided by the Government as part of discovery.

40. Attached as Exhibit 39 is a true and correct copy of the certification of FDA Special Agent Luis Perez submitted by the Government in United States v. Livdahl, et al., Docket No. 04-61717-CIV-COHN (S.D. FL. Jan. 7. 2005) and *not* provided by the Government in this case.

41. Attached as Exhibit 40 is a true and correct copy of a summary of the sales and customers of Toxin Research International prepared by the Government and *not* provided by the Government as part of discovery.

42. Attached as Exhibit 41 is a true and correct copy of the Government's Brief in Support of the Issuance of Injunctive Relief in United States v. Livdahl, et al., Docket No. 04-61717-CIV-COHN (S.D. FL. December 23, 2004) and *not* provided by the Government in this case.

43. Attached as Exhibit 42 is a true and correct copy of the detention hearing transcript in United States v. Livdahl and Karim, Docket No. 05-60021-CR-COHN (February 23, 2005) and *not* provided by the Government in this case.

44. Attached as Exhibit 43 is a true and correct copy of Chad Livdahls' Judgment of Conviction entered in United States v. Livdahl and Karim, Docket No. 05-60021-CR-COHN (January 30, 2006).

45. Attached as Exhibit 44, is a true and correct copy of a March 3, 2005 letter from Patrick T. Collins, Esq. to AUSA Mary A. Fatcher, Esquire.

46. Attached as Exhibit 45 is a true and correct copy of a May 12, 2005 letter from Patrick T. Collins, Esquire to AUSA Hope Olds, Esquire.

47. Attached as Exhibit 46 is a true and correct copy of a June 6, 2005 proffer letter from ASUA Hope Olds, Esquire to Patrick Collins, Esquire provided to the defendant by the Government under Fed R. Crim. P. 16.

48. Attached as Exhibit 47 is a true and correct copy of a July 13, 2006 letter from AUSA Eugenia Cowles, Esq. to William J. Hughes, Esq.

49. Attached as Exhibit 48 is a true and correct copy of an August 4, 2006 letter from the FDA to Cindy Ross and *not* provided to the Defense during discovery.

50. Attached as Exhibit 49 is a true and correct copy of a September 26, 2006 letter from the U.S. Attorney's Office to Heather Gifford and *not* provided to the Defense by the Government during discovery.

51. Attached as Exhibit 50 is a true and correct copy of an August 25, 2006 Memorandum of Interview of Debra O'Brien and *not* provided to the Defense by the Government during discovery.

52. Attached as Exhibit 51 is a true and correct copy of an August 15, 2006 Memorandum of Interview with Theresa Buterick and *not* provided to the Defense by the Government during discovery.

53. Attached as Exhibit 52 is a true and correct copy of a July 12, 2005 Memorandum of Interview of Shirley Spagnola and *not* provided to the Defense by the Government during discovery.

54. Attached as Exhibit 53 is a true and correct copy of the contemporaneous notes that Dr. Poet made of his July 31, 2006 conversation with Joan Hall.

55. Attached as Exhibit 54 is a true and correct copy of an August 23, 2006 Memorandum of Interview of Joan Hall and *not* provided to the Defense by the Government during discovery.

56. Attached as Exhibit 55 is a true and correct copy of a July 12, 2005 Memorandum of Interview of Joan Hall and *not* provided to the Defense by the Government during discovery.

57. Attached as Exhibit 56 is a true and correct copy of an August 10, 2005 Memorandum of Interview of Theresa McCormick and *not* provided to the Defense by the Government during discovery.

58. Attached as Exhibit 57 is a true and correct copy of a September 3, 2006 cover letter from AUSA Eugenia Cowels, Esq. to William J. Hughes, Jr., Esq.

59. Attached as Exhibit 58 is a true and correct copy of an index of discovery materials sent to the Defense by the Government on or about September 3, 2006.

60. Attached as Exhibit 59 is a true and correct copy of a September 15, 2006 letter from AUSA Eugenia Cowels, Esq. to William J. Hughes, Jr., Esq.

61. Attached as Exhibit 60 is a true and correct copy of a September 28, 2006 letter from William J. Hughes, Jr. to AUSA Eugenia Cowels, Esq.

62. Attached as Exhibit 61 is a true and correct copy of a September 30, 2006 letter from AUSA Eugenia Cowels, Esq. to William J. Hughes, Jr., Esq.

63. Attached as Exhibit 62 is a true and correct copy of a September 28, 2006 letter from William J. Hughes, Jr. to AUSA Eugenia Cowels, Esq.

64. Attached as Exhibit 63 is a true and correct copy of a October 17, 2006 letter from AUSA Eugenia Cowels, Esq. to William J. Hughes, Jr., Esq.

65. Attached as Exhibit 64 is a true and correct copy of an index of discovery materials sent to the Defense by the Government on or about October 17, 2006.

66. Attached as Exhibit 65 is a true and correct copy of a October 27, 2006 letter from AUSA Eugenia Cowels, Esq. to William J. Hughes, Jr., Esq.

67. Attached as Exhibit 66 is a true and correct copy of an index of discovery materials sent to the Defense by the Government on or about October 27, 2006.

68. Attached as Exhibit 67 is a true and correct copy of a transcript of taped telephone/personal conversations from Maryan Mikhael, received by the FDA on January 25, 2005 and *not* provided to the Defense during discovery.

69. Attached as Exhibit 68 is a true and correct copy of an August 28, 2006 Memorandum of Interview of Donna Rice and *not* provided to the Defense by the Government during discovery.

70. Attached as Exhibit 69 is a true and correct copy of an August 10, 2006 Memorandum of Interview of Lois Dyer and *not* provided to the Defense by the Government during discovery.

71. Attached as Exhibit 70 is a true and correct copy of a July 12, 2006 Memorandum of Interview of Susan Erickson and *not* provided to the Defense by the Government during discovery.

72. Attached as Exhibit 71 is a true and correct copy of an August 9, 2006 Memorandum of Interview of Heather Gifford and *not* provided to the Defense by the Government during discovery.

73. Attached as Exhibit 72 is a true and correct copy of an July 18, 2006 Memorandum of Interview of Laurie Toth and *not* provided to the Defense by the Government during discovery.

74. Attached as Exhibit 73 is a true and correct copy of the Pure Food and Drug Act of June 30, 2006, Ch. 3915, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

I certify under penalty of perjury that the foregoing is true and correct.

Executed on: 1/16/07

s/William J. Hughes, Jr. (WH1924)
WILLIAM J. HUGHES, JR.