



U.S. Department of Justice

United States Attorney  
District of New Jersey

402 East State Street, Room 430  
Trenton, New Jersey 08540

609/939-2154

September 15, 2006

Mr. William J. Hughes, Jr.  
Cooper Levenson Law Offices  
1125 Atlantic Avenue, 3rd Floor  
Atlantic City, NJ 08401

SEP 2006  
RECEIVED

Re: United States v. Albert Poet  
Crim. No. 06-643 (AET)

Dear Mr. Hughes:

Further to my letter of September 3, 2006, the United States hereby supplements its discovery as required by Rule 16(c) of the Federal Rules of Criminal Procedure and the Court's Order For Discovery And Inspection. The United States makes the following disclosures of experts as required by Rule 16 (a) (1) (G).

1. Dr. Marc Kenneth Walton, M.D., Ph.D.

The United States intends to call Dr. Marc Kenneth Walton as an expert on the FDA approval process for biological products and new drugs. Dr. Walton is currently employed as the Deputy Director of the Division of Neurological Products in the Office of Drug Evaluation with the Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER).<sup>1</sup> Dr. Walton previously served as the Director of the Division of Therapeutic Biologic Internal Medicine Products in the same office. Dr. Walton is familiar with the FDA's approval processes for drugs and biological products, including the approval procedures for new drug applications and biological license applications. His duties include supervision of the licensing applications for products within CDER's area of speciality as well as work on agency policy. Dr. Walton's testimony will discuss relevant topics including, but not limited to, the

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<sup>1</sup>Please note that my letter of September 3, 2006, incorrectly attributed Dr. Walton's employment to the FDA's Center for Biologic Evaluation and Research (CBER).

following:

- a. The United States Food and Drug Administration ("FDA") is the federal agency within the United States Department of Health and Human Services charged with the responsibility for protecting the health and safety of the American public by ensuring that drugs are safe and effective for their intended uses before they may be legally introduced into interstate commerce.
- b. Drugs within the FDA's purview include articles intended for use in the diagnosis, cure, mitigation, treatment, and prevention of disease in humans and articles intended for use as components of any such articles. Biological products within the FDA's purview include toxins applicable to the prevention, treatment, or cure of a disease or condition of human beings. When used to treat or mitigate the impact of a disease in humans, a biological product may be considered a "drug."
- c. A "new drug" within the FDA's purview is a "drug" that is not generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs for use under the conditions prescribed, recommended, or suggested in their labeling. A new drug which is also a biologic product cannot lawfully enter interstate commerce unless there is a biological license, new drug application, abbreviated new drug application, or notice of claimed exemption for an investigational new drug in effect with the FDA.
- d. A misbranded drug may include a drug that is offered for sale under the name of another drug.
- e. In approving any form of marketing application for a new drug or biological product, the FDA conducts inspections of manufacturing facilities to determine if the manufacturing processes adhere to "current good manufacturing processes" ("CGMP"). CGMP are designed to assure that each time a drug is produced it meets safety requirements and is characterized by the same purity, potency, stability, and sterility. Production of a drug

without FDA approval or in violation of CGMP may, if the resulting drug is used on humans, cause danger to the patient or even death.

- f. FDA approval of a product also includes a detailed review of the labeling, including the packaging, container labels, and accompanying inserts describing the product.
- g. Botulinium Toxin Type A is a toxin produced by the Clostridium Botulinium. It is considered by many to be the most potent toxin known. When present in sufficient degree in humans, Botulinium Toxin Type A causes Botulism, a disease characterized by an interruption in the communication between the nerves and the muscles which can cause paralysis and even death.
- h. Allergan holds the only FDA approval for the marketing of products containing Botulinium Toxin Type A for human use in the United States. Allergan has received approval for its BOTOX® and BOTOX® Cosmetic products. BOTOX® Cosmetic is used to improve the appearance of glabellar lines, commonly referred to as forehead wrinkles. Approval of BOTOX® and BOTOX® Cosmetic included approval of the labeling accompanying the products. This labeling provides important information about the preparation, use, storage and injection of the Allergan products.
- i. Toxin Research International, Inc. (TRI) has not applied for or received approval to market a Botulinium Toxin Type A product. There are many risks inherent in an unapproved product of this type.
- j. The terms "off-label" and "generic" apply to certain uses of and types of FDA-approved drugs.

The bases for any opinions expressed by Dr. Walton will include his experience, education, training, and review of relevant documentation. A copy of Dr. Walton's curriculum vitae is attached.

2. Additionally, the United States encloses the following documents recently obtained by the government:
  - a. Allergan file records for Dr. Albert Poet;
  - b. Allergan invoices for shipments to Dr. Albert Poet, dated 2002-2005.

Disclosure by the Defendant

The Government hereby again requests reciprocal discovery under Fed. R. Crim. P. 16(b). Specifically, we request that you allow inspection and copying of: (1) any books, papers, documents, data, photographs, tangible objects, buildings or places, or copies or portions of any of these items that are in the defendant's possession, custody, or control and which the defendant intends to use in the defendant's case-in-chief at trial; and (2) any results or reports of any physical or mental examination and of any scientific test or experiment that is in the defendant's possession or control and which the defendant intends to use in the defendant's case-in-chief at trial or which was prepared by a witness whom the defendant intends to call at trial. We further request that you disclose a written summary of testimony you intend to use under Fed. R. Evid. 702, 703 and 705 as evidence at trial. This summary should describe the opinions of the witness, the bases and reasons therefore, and the witness's qualifications.

Pursuant to Fed. R. Crim. P. 26.2, the Government also requests that the defendant disclose prior statements of witnesses the defendant will call to testify. We request that such material be provided on the same basis upon which we agree to supply the defendant with Section 3500 material relating to Government witnesses.

We wish to remind you that Fed. R. Crim. P. 12.2(a) & (b) requires you to provide the Government with written notice if the defendant intends to rely on the defense of insanity at the time of the alleged crime or intends to introduce expert testimony relating to a mental disease, defect, or other condition bearing upon the issue of whether he had the mental state required for the offenses charged.

Sentence Reduction for Acceptance of Responsibility

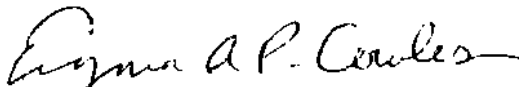
This Office will not move for the additional one-point reduction under the Sentencing Guidelines available for defendants who plead prior to the Government's initiation of

trial preparations, U.S.S.G. § 3E1.1(b), in the event your client has not entered a plea of guilty before the filing of pre-trial motions.

Please contact me at your earliest convenience concerning the possible disposition of this matter or any further discovery which you may request.

Very truly yours,

CHRISTOPHER J. CHRISTIE  
United States Attorney



By: EUGENIA A. P. COWLES  
Assistant U.S. Attorney