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ALEXANDRIA, VIRGINIA

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

UNITED STATES OF AMERICA	)	
	)	CRIM. NO. 1:13-CR-130-1
v.	)	
	)	Hon. Claude M. Hilton
GALLANT PHARMA INTERNATIONAL INC.,	)	
	)	
Defendant.	)	

STATEMENT OF FACTS

Were the United States to proceed to trial in this case, it would provide testimonial and documentary evidence to prove beyond a reasonable doubt that Defendant GALLANT PHARMA INTERNATIONAL INC. ("GALLANT PHARMA") did:

(1) Fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, and facilitate the transportation, concealment, and sale of, such merchandise after importation, knowing such merchandise to have been imported and brought into the United States contrary to law, in violation of Title 18, United States Code, Section 545;

(2) With the intent to mislead and defraud, introduce into interstate commerce misbranded drugs in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2);

(3) Knowingly engage in the wholesale distribution in interstate commerce of prescription drugs in the Commonwealth of Virginia without being licensed to do so, in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), and 353(e)(2)(A).

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The testimonial and documentary evidence would establish, at a minimum, the following facts:

1. Between approximately August 2009 and August 2013, GALLANT PHARMA INTERNATIONAL INC. ("GALLANT PHARMA") was a company dedicated to the illegal importation and sale of misbranded and non-FDA-approved chemotherapy drugs and injectable cosmetic drugs and devices in the United States.

2. GALLANT PHARMA was incorporated in Canada, but was not licensed to sell drugs by the Canadian government. Co-defendant SYED HUDA (a/k/a "Farhan Huda") served as GALLANT PHARMA's president and as one of two directors of GALLANT PHARMA (along with an unindicted co-conspirator). GALLANT PHARMA was owned by co-defendants SYED HUDA and TALIB KHAN.

3. In the United States, GALLANT PHARMA first established its headquarters at the apartment of HUDA and his wife, DEEBA MALLICK, in the Crystal City neighborhood of Arlington, Virginia, in the Eastern District of Virginia. GALLANT PHARMA later leased office space in McLean, Virginia, in the Eastern District of Virginia, and eventually moved to a larger office space in Springfield, Virginia, in the Eastern District of Virginia, which was vacated in June 2013. Rent on the Springfield, Virginia, office space, was paid in full for a one-year period, using a check drawn on a Bank of Nova Scotia account held in the name of GALLANT PHARMA.

4. Co-founder and co-owner HUDA was primarily responsible for the United States-based portion of the conspiracy, including: identifying a drop shipper willing to accept illegal importations on behalf of GALLANT PHARMA; locating space for GALLANT PHARMA to store misbranded and non-FDA-approved drugs and devices; establishing relationships with

customers in the Washington, D.C. metropolitan area; interviewing and hiring sales representatives in other parts of the United States; and establishing merchant accounts with credit card processors, for receipt of illegal proceeds via wire transfer into Canadian bank accounts.

5. Co-owner and co-founder KHAN was primarily responsible for the international portion of the conspiracy, including: determining which drugs and devices to sell in the United States; establishing relationships with international suppliers; directing those suppliers to send drugs and devices to trans-shippers in Canada and the United Kingdom; arranging for trans-shipment from Canada and the United Kingdom to the United States; interviewing and hiring sales representatives in the United States; and paying suppliers, sales representatives, and office employees out of the Canadian and Barbadian accounts.

6. MALLICK was the United States citizen wife of HUDA. In 2009, HUDA moved from Canada to the United States to live with MALLICK, and established GALLANT PHARMA's United States headquarters in the Eastern District of Virginia. Between approximately fall 2009 and February 2012, MALLICK served as the office manager for GALLANT PHARMA. In that position, MALLICK prepared sales invoices, tracked sales representative commissions, packaged and shipped misbranded and non-FDA-approved drugs and devices from the Eastern District of Virginia to customers across the United States, and processed customer credit card payments through Elavon. MALLICK had a personal checking account at Capital One, which was used for GALLANT PHARMA finances through at least 2011. At times, MALLICK, at the direction of HUDA, personally endorsed and deposited illegal proceeds in the form of check payments, initiated wire transfers to international suppliers, and wrote commission checks to sales representatives. Generally, however, HUDA indorsed check

payments from GALLANT PHARMA customers. HUDA was added as a co-owner of the Capital One checking account in February 2011.

7. Co-defendant ROBERT WACHNA was recruited by HUDA and KHAN as GALLANT PHARMA's first sales representative. WACHNA had previously worked in the pharmaceuticals industry in Canada, and served as a GALLANT PHARMA sales representative in the upstate New York area.

8. Co-defendant MERRIAM was recruited by HUDA and KHAN as GALLANT PHARMA's second sales representative. HUDA and KHAN engaged MERRIAM in or around August 2009, to assist HUDA with acquiring initial customers for GALLANT PHARMA in the Washington, DC metropolitan area.

9. On or about October 1, 2009, HUDA sent an e-mail to two recipients stating: "Just wanted to give you a quick update. We are working under a new company called Gallant Pharma. The majority of our business now is in Cosmetic products like Botox and in Oncology, i.e. Gemzar, Taxotere, etc."

10. HUDA and KHAN recruited co-defendant MUNAJJ ROCHELLE, a longtime friend of KHAN, as GALLANT PHARMA's third sales representative. ROCHELLE initially worked as a California-based sales representative, and later became a sales representative manager. Among other things, ROCHELLE was responsible for final approval of sales representative hiring, training the sales representatives, and holding weekly conference calls between the sales representatives. For a time in 2012, ROCHELLE managed GALLANT PHARMA's telephone call center in Barbados, which had been set up by KHAN after KHAN relocated from Canada to Barbados.

11. GALLANT PHARMA employed many other sales representatives across the United States, including co-defendants HARVEY WHITEHEAD, PATRICIA DURR, and LISA CORONITI.

12. Co-defendant ANOUSHIRVAN R. SARRAF was a cosmetic surgeon and the owner of Aphrodite Skin Care Clinic in McLean, Virginia, in the Eastern District of Virginia. In or around fall 2009, HUDA entered an agreement with SARRAF on behalf of GALLANT PHARMA, wherein SARRAF would accept illegal importations intended for GALLANT PHARMA in exchange for a discounted price on misbranded and non-FDA-approved injectable cosmetic drugs and devices. When shipments of drugs and devices intended for GALLANT PHARMA were sent to the United States by KHAN or trans-shippers, KHAN would forward the tracking numbers initially to MALLICK and HUDA, then later to co-defendants ROBERT SPARKS and TANYA SMITH (a/k/a "Toni"), and would direct those individuals to collect the packages from SARRAF's office a few days later.

13. Prior to the establishment of the drop-shipping arrangement with SARRAF in 2009, drugs intended for GALLANT PHARMA were illegally imported to, and stored by, an unindicted co-conspirator in Chicago, Illinois.

14. Co-defendant MIRWAISS AMINZADA was one of GALLANT PHARMA's suppliers. AMINZADA obtained and sold misbranded and non-FDA-approved drugs through companies he operated in Canada and the United Arab Emirates. Initially, AMINZADA provided the misbranded and non-FDA-approved drugs to KHAN in Canada, and KHAN personally shipped the drugs to SARRAF's medical practice. Later, AMINZADA shipped drugs intended for GALLANT PHARMA to GALLANT PHARMA's trans-shipper in the United Kingdom.

15. KHAN arranged for drugs intended for GALLANT PHARMA to first pass through Canada or the United Kingdom via Canada Post or Royal Mail, respectively, both of which feed into the United States Postal Service ("USPS") for delivery in the United States. KHAN also ensured that large shipments intended for GALLANT PHARMA were broken into several smaller packages, to further reduce the likelihood of CBP seizure and reduce the loss to GALLANT PHARMA in the event of a seizure. KHAN further ensured that Customs declarations included misleading information about the shipment, including an understated dollar value and a misleading description of contents.

16. On many occasions, KHAN and HUDA personally completed false customs declarations and thereby illegally imported misbranded drugs and devices from Canada to the Eastern District of Virginia. For example, on or about October 13, 2010, HUDA addressed two Canada Post packages to himself at his apartment on Crystal Drive in Arlington, Virginia, in the Eastern District of Virginia, and falsely stated that the packages contained "medical supplies" worth $100 Canadian dollars. Similarly, on or about September 23, 2011, KHAN mailed ninety-eight (98) vials of misbranded Alimta 100mg obtained from AMINZADA from Canada to SARRAF in the Eastern District of Virginia, which were received by HUDA on or about September 25, 2011.

17. On or about December 10, 2009, HUDA sent an e-mail from the Eastern District of Virginia to an employee at Elavon, a Visa and Mastercard processor in the United States, falsely stating that GALLANT PHARMA sold "commodity type items", including the following "sample list of items":

Compression garments - $100 - $200
Plastic Surgery healing kits - $120-$150
Breast wrap healing kids - $120-$150

Elevation pillows - $50-$100
Cellulite Reduction creams and treatments - $50-$1500
Home beauty devices - $300-$1000
Scar Reduction creams $50-$80
Consultation gowns and robes $80-$150

18. On or about April 15, 2010, HUDA and the other director of GALLANT PHARMA (an unindicted co-conspirator) falsely stated in the Elavon merchant application form that GALLANT PHARMA sold "medical supplies, creams, [and] patches." Elavon approved the merchant application, processed more than $1.9 million in credit card sales for GALLANT PHARMA, and transferred those illegal proceeds first to a Toronto Dominion Bank account ending in 5209 held by GALLANT PHARMA, and, later, to a Bank of Nova Scotia account ending in 1416 held by GALLANT PHARMA. These bank accounts, which were both located in Canada, were controlled by HUDA. The Toronto Dominion Bank account had the other director of GALLANT PHARMA as a co-signor. The Bank of Nova Scotia account was also controlled by KHAN.

19. Between August 2009 and August 2013, GALLANT PHARMA imported and sold at least the following drugs and devices in the United States:

Product	*Use*
Alimta	Intravenous chemotherapy for lung cancer
Anzemet	Anti-nausea treatment for surgery and chemotherapy patients
Avastin	Intravenous chemotherapy for colon, lung, kidney, and brain cancer, subject to FDA "black box" warning. Cold-chain product.
Botox	Injectable treatment for forehead wrinkles and eye muscle disorders, subject to FDA "black box" warning. Cold-chain product.
Dysport	Injectable treatment for forehead wrinkles and abnormal head position/neck pain, subject to FDA "black box" warning. Cold-chain product.
Eloxatin	Intravenous chemotherapy for colon cancer, subject to FDA "black box" warning
Faslodex	Injectable treatment for breast cancer
Gemzar	Intravenous chemotherapy for breast, lung, pancreatic, and ovarian cancer

Product	*Use*
Herceptin	Intravenous chemotherapy for breast cancer, subject to FDA "black box" warning. Cold-chain product.
Juvederm 2, 3, and 4	Non-FDA-approved injectable cosmetic filler for wrinkles. Cold-chain product.
MabThera	Non-FDA-approved intravenous chemotherapy for non-Hodgkin's lymphoma. Cold-chain product.
Neulasta	Injectable treatment to reduce infections associated with reduced blood cells and platelets (a side effect of chemotherapy). Cold-chain product.
Neupogen	Injectable treatment to reduce infections associated with reduced blood cells and platelets (a side effect of chemotherapy). Cold-chain product.
Ristova	Non-FDA-approved intravenous chemotherapy for non-Hodgkin's lymphoma
Rituxan	Injectable chemotherapy for non-Hodgkin's lymphoma, subject to FDA "black box" warning. Cold-chain product.
Taxotere	Intravenous chemotherapy for lung and breast cancer, subject to FDA "black box" warning
Velcade	Intravenous chemotherapy for multiple myeloma patients who have already had several unsuccessful courses of treatment
Xeomin	Injectable treatment for cervical dystonia and blepharospasm, subject to FDA "black box" warning
Zometa	Injectable treatment for bone tumors and hypercalcemia

20. GALLANT PHARMA was not licensed as a prescription drug wholesaler by the Commonwealth of Virginia.

21. Some of the drugs and devices sold by GALLANT PHARMA in the United States were not approved by the FDA for use on patients in the United States.

22. The FDA-approved drugs sold by GALLANT PHARMA were subject to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et. seq.* The drugs sold by GALLANT PHARMA were prescription only, and were misbranded in that, *inter alia*, they: did not bear adequate directions for use and were not subject to an exemption from that requirement; were accompanied by non-FDA-approved packaging and inserts; and lacked the FDA-required National Drug Code ("NDC") number. Sometimes, the drug packaging and inserts were written in languages other than English. The drugs sold by GALLANT PHARMA also lacked the FDA-required pedigree, which protects patient health by tracking each sale, purchase, or trade of a

drug from the time of manufacturing to delivery to the patient. GALLANT PHARMA sold these misbranded and non-FDA-approved drugs and devices to physicians licensed to practice medicine in the United States, and never directly to individual patients.

23. Immediately after establishing GALLANT PHARMA's presence in the Eastern District of Virginia, on or about September 25, 2009, GALLANT PHARMA received a cease and desist letter from the law firm of Hunton & Williams LLP on behalf of Medicis, "the exclusive authorized marketer of Restylane and Perlane in the United States and Canada." The letter informed GALLANT PHARMA that GALLANT PHARMA's marketing of Restylane and Perlane violates the FDCA and may subject GALLANT PHARMA "to substantial criminal and civil penalties." Attached to the letter were GALLANT PHARMA marketing materials, created and sent by MERRIAM to potential clients, which falsely claimed that GALLANT PHARMA had been "strictly working within the current FDA rules and regulations for almost 10 years."

24. GALLANT PHARMA sold misbranded and non-FDA-approved drugs and devices obtained from suppliers in, among other places, India, Turkey, Switzerland, the United Kingdom, and the United Arab Emirates. At least one supplier in the United Kingdom required a copy of a medical license before selling to GALLANT PHARMA, to hide that GALLANT PHARMA was an unlicensed prescription drug wholesaler. Initially, SARRAF provided his medical license to HUDA for this purpose. In or around March 2011, after that license expired and SARRAF did not provide a copy of his new license to HUDA, KHAN altered the expiration date on SARRAF's medical license to make it appear that the license was still valid.

25. On one occasion, a supplier in the United Kingdom informed KHAN that they would not be able to sell GALLANT PHARMA a particular injectable drug without a valid

prescription. HUDA and KHAN discussed this issue and decided to obtain the injectable drug from a different supplier.

26. Many of the drugs sold by GALLANT PHARMA were cold-chain drugs subject to strict temperature controls. International trans-shippers included standard ice packs, not dry ice (as licensed distributors in the United States utilize) with shipments of cold-chain drugs. on many occasions, the ice packs were melted by the time the shipments were retrieved from SARRAF's medical practice. Likewise, when GALLANT PHARMA packaged and shipped cold-chain drugs via Federal Express ("FedEx") to customers across the United States, the shipments included standard ice packs, not dry ice. HUDA had seen a document purporting to be from Allergan, the manufacturer of Botox, stating that Botox could remain stable at higher temperatures for a period of time. At times, GALLANT PHARMA customers complained that the ice packs had melted by the time of delivery. On one occasion, a trans-shipper was reluctant to send cold-chain drugs to GALLANT PHARMA during the summer, but HUDA directed the trans-shipper to send the drugs and simply to include an additional ice pack.

27. At times, GALLANT PHARMA sold intravenous chemotherapy drugs that contained stickers falsely indicating that the drugs were intended for clinical trial.

28. On several occasions, GALLANT PHARMA customers complained after received drugs with packaging and inserts written in a language other than English. Upon receiving such complaints, HUDA or KHAN would authorize a price reduction.

29. In or around August 2012, federal agents confronted SARRAF about his role in GALLANT PHARMA. HUDA discussed this confrontation with SARRAF, and stopped using SARRAF as a drop-shipper shortly after this incident.

30. In or around August 2012, tampered Botox entered GALLANT PHARMA's supply chain. Among other things, several Botox vials were broken, contained an improperly-colored liquid, and/or were missing protective caps. Some packages containing the Botox vials were discolored, and some lot numbers and expiration dates were mismatched between the vials and the packages.

31. GALLANT PHARMA determined that AMINZADA was the supplier of this tampered Botox. In an email exchange with AMINZADA, HUDA characterized the introduction of tampered Botox as "criminal," and noted that he did "not use that term lightly." Nonetheless, GALLANT PHARMA did not report these issues to FDA, Allergan (the authorized manufacturer and distributor of Botox), or the authorities.

32. In late summer 2012, following the tampered Botox and the FDA's confrontation of SARRAF, HUDA and KHAN decided to try to sell GALLANT PHARMA. Ultimately, HUDA and KHAN entered a profit-sharing arrangement with RxPad, through which RxPad would fulfill orders placed by GALLANT PHARMA sales representatives.

33. Between August 2009 and August 2013, GALLANT PHARMA received illegal proceeds of at least $12,400,000 from the sale of misbranded and non-FDA-approved drugs and devices in the United States.

34. Between August 2009 and August 2013, GALLANT PHARMA enjoyed net profits of approximately $3,400,000 from the sale of misbranded and non-FDA-approved drugs and devices in the United States.

35. GALLANT PHARMA operated primarily for a criminal purpose or primarily by criminal means, pursuant to U.S.S.G. § 8A1.2(b)(1).

Respectfully submitted,

Dana J. Boente
Acting United States Attorney

By: Lindsay A. Kelly
Lindsay A. Kelly
Assistant United States Attorney

OFFICER'S CERTIFICATE

I have read this Statement of Facts and carefully reviewed every part of it with counsel for GALLANT PHARMA INTERNATIONAL INC. ("GALLANT PHARMA"). I voluntarily agree, on behalf of GALLANT PHARMA, that the above Statement of Facts is true and accurate, and that had the matter proceeded to trial, the United States would have proved the same beyond a reasonable doubt.

I am also satisfied with counsel's representation in this matter. In addition, despite any potential or actual conflict of interest which may exist now or in the future, GALLANT PHARMA hereby consents to the simultaneous representation by Womble Carlyle Sandridge and Rice LLP (including but not limited to its attorneys Mark Schamel and Lela Ames) of GALLANT PHARMA and Syed Huda (a/k/a "Farhan Huda"), with respect to the matters covered in this Statement of Facts and Plea Agreement.

I certify that I am President and a Director of GALLANT PHARMA and am duly authorized to execute this Agreement on behalf of GALLANT PHARMA.

Date: 12/6/13

Syed Huda,
GALLANT PHARMA INTERNATIONAL INC.
President and Director

CERTIFICATE OF COUNSEL

I am GALLANT PHARMA INTERNATIONAL INC.'s ("GALLANT PHARMA") attorney. I have carefully reviewed the above Statement of Facts with my client. In connection with such representation, moreover, I have examined the relevant documents and have discussed the terms of this Agreement with GALLANT PHARMA's authorized representative. Based on our review of the foregoing materials and discussion, I am of the opinion that this Statement of Facts has been duly and validity authorized, executed, and delivered on behalf of GALLANT PHARMA and is a valid and binding obligation of GALLANT PHARMA. To my knowledge, the decision of GALLANT PHARMA to stipulate to these facts is an informed and voluntary one.

Date: 12/02/13

Mark Schamel, Esquire
Counsel for GALLANT PHARMA INTERNATIONAL INC.