Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL; or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ ODL, 2401 Jefferson-Davis Highway, Alexandria, Virginia 22301; and must be filed no later than April 13, 2007.

Dated: February 5, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–2320 Filed 2–9–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated October 12, 2006 and published in the **Federal Register** on October 19, 2006, (71 FR 61800–61801), Tocris Cookson, Inc., 16144 Westwoods Business Park, Ellisville, Missouri 63021–7683, made application by letter to the Drug Enforcement Administration (DEA) to be registered as an importer of Marihuana (7360), a basic class of controlled substance listed in schedule I.

The company plans to import this product for non-clinical laboratory based research only.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. § 823(a) and 952(a) and determined that the registration of Tocris Cookson, Inc. to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Tocris Cookson, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: February 5, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–2330 Filed 2–9–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 02–09, 02–43]

Edmund Chein, M.D.; Revocation of Practitioner's Registration, Denial of Application for Exporter's Registration

Introduction and Procedural History

This is a consolidated proceeding. On November 7, 2001, the then Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Notice of Immediate Suspension of the practitioner's Certificate of Registration, AC1643661, issued to Edmund Chein, M.D. (Respondent) of Palm Springs, California. The Notice of Immediate Suspension was based on the Administrator's preliminary conclusion that Respondent's continued registration constituted ''an imminent danger to the public health and safety because of the substantial likelihood that [Respondent would] continue exporting and diverting controlled substances.'' Order to Show Cause and Notice of Immediate Suspension at 6 (2001 OSC). The Order further proposed to revoke Respondent's practitioner's registration and deny any pending applications for renewal of the registration on the ground that Respondent's continued registration would be inconsistent with the public interest. *See id.* at 1; *see also* 21 U.S.C. 823(f) & 824(a)(4).

Subsequently, on May 24, 2002, the Deputy Assistant Administrator, Office of Diversion Control, issued an additional Order to Show Cause (hereinafter 2002 OSC) to Respondent. This Show Cause Order proposed to deny Respondent's pending application for a registration as an exporter on the ground that issuance of a registration would be inconsistent with the public interest. 2002 OSC at 1; *see also* 21 U.S.C. 958(c) &(d); *id.* 823(d).

The 2001 OSC alleged that Respondent had purchased ''large amounts of anabolic steroids'' from a Mexican pharmacy and ''other illegitimate sources'' and had distributed these substances to individuals who did not have a legitimate medical need for them. 2001 OSC at 2. The OSC further alleged that on May 28, 1996, Federal agents executed a search warrant at Respondent's medical office and seized several vials of steroids for which there were no records. *Id.* The OSC further alleged that in June 1996, DEA obtained from Henry Schein, Inc., copies of invoices which documented that Respondent had purchased controlled substances on nine different occasions between January 1995 and May 1996. *Id.* at 3. The OSC alleged that Respondent had failed to keep accurate records of the purchase, inventory, and dispensation of controlled substances. *Id.*

The 2001 OSC next alleged that on January 31, 2001, DEA Diversion Investigators (DIs) went to Respondent's Palm Springs medical office, the Palm Springs Life Extension Institute (hereinafter PSLEI), to conduct an administrative inspection. *Id.* The OSC alleged that the invoices documenting the purchases of controlled substances were at an accounting firm and not at the office. *Id.* The 2001 OSC further alleged that ''none of [the] required controlled substance records were accessible,'' because the records were stored in a computer and none of the office personnel then present were capable of retrieving them. *Id.* The OSC thus alleged that Respondent had violated the Controlled Substance Act by failing ''to maintain in a readily available condition'' initial and biennial inventory records, purchase invoices, and dispensing records. *Id.*

The 2001 OSC further alleged that on February 5, 2001, DEA personnel returned to Respondent's office and obtained an inventory of controlled substances that was dated February 5, 2001, dispensing records for the period July 1, 2000, through February 1, 2001, and invoices for purchases of controlled substances from Barnes Wholesale, Inc., for the period January 1, 1999, through February 4, 2001. *Id.* The OSC also alleged that the dispensing records showed that between July 1, 2000, and February 5, 2001, Respondent dispensed anabolic steroids, a Schedule III controlled substance, and phentermine, a Schedule IV controlled substance, to persons in Korea, Belgium, Indonesia, Canada, Japan, Spain, Germany, Switzerland, Mexico, England, and Hong Kong. *Id.* at 3–4.

More specifically, the OSC alleged that Respondent had made 328 illegal exports comprised of 20 exports of phentermine 30 mg., 58 exports of phentermine 15 mg., 73 exports of testosterone gel 8 mg., 12 exports of testosterone gel 100 mg., 50 exports of testosterone estradiol gel 4 mg, 113 exports of Depo testosterone 200 mg., and two exports of testosterone 50 mg.

Id. at 4. The OSC alleged that these exports were illegal because Respondent was not registered as an exporter, *see* 21 U.S.C. 957(a), and had failed to file the necessary declarations. *See id.* section 953(e); *see also* 2001 OSC at 4. The OSC also alleged that Respondent had failed to maintain proper records of the exports. *See* 2001 OSC at 4.

The 2001 OSC alleged that upon discovering the exports, a DI contacted Dr. Darryl Garber, an associate of Respondent, who informed the DI that Respondent's clinic had patient records for each recipient of the shipments, that some of the recipients were seen at the clinic and others were seen by video conferencing, and that the controlled substances were shipped by Federal Express. *See id.* The OSC alleged that the DI instructed Dr. Garber that the shipments ''violated the Controlled Substances Act and must be stopped immediately,'' and that the DI subsequently faxed Dr. Garber the applicable provisions of the United States Code. *Id.*

The 2001 OSC next alleged that on August 23, 2001, DEA personnel visited the PSLEI and conducted a management conference with Respondent. *Id.* The OSC alleged that during this meeting, the DI told Respondent that the required records ''were not readily retrievable on the date of the inspection[ ] as required'' by Federal law and that Respondent acknowledged that he had discussed his non-compliance with Dr. Garber. *Id.* at 5. The OSC alleged that during the conference, Respondent admitted that based on the records provided to DEA in February 2001, he ''had at least 150 exporting violations already on record.'' *Id.* The OSC further alleged that Respondent admitted that he had ''continued to export controlled substances'' notwithstanding the March 2001 warning that the shipments were illegal, and that he would continue to do so until he ''received written instructions from DEA.'' *Id.* The OSC also alleged that when DEA personnel requested that Respondent produce his controlled substance shipping records, Respondent refused to do so and invoked the Fifth Amendment. *Id.*

The 2001 OSC alleged that on various dates following the August 23rd, 2001 meeting, DEA personnel faxed Respondent the applicable provisions of the United States Code and instructed him that he was not authorized to either export or import controlled substances and ''must immediately cease'' all such activity. *Id.* Based on the above allegations, the Administrator made the preliminary finding that Respondent was ''responsible for the diversion of large quantities of controlled substances in violation of 21 U.S.C. 953, 957 and 958.'' *Id.* at 6. Concluding that there was a ''substantial likelihood that [Respondent would] continue exporting and diverting controlled substances,'' the Administrator ordered the immediate suspension of Respondent's practitioner's registration. *Id.*

The 2002 OSC, which proposed the denial of Respondent's application for an exporter's registration, repeated many of the above allegations. In addition, the 2002 OSC alleged that on April 27, 2001, Respondent had applied for a registration as an exporter of Schedule III (non-narcotic) and Schedule IV controlled substances and that DEA had received the application on May 7, 2001. 2002 OSC at 2. The OSC alleged that the ''application was not accepted for filing'' and that Respondent's filing fee had been refunded. *Id.* The OSC also alleged that on December 17, 2001, DEA received from Respondent an undated application for a registration to export controlled substances in Schedule III (non-narcotic) and Schedule IV. *See id.* at 3.

The 2002 OSC further alleged that on March 13, 2002, DEA DIs executed an administrative inspection warrant at the PSLEI. *See id.* at 3. The OSC alleged that during the inspection, the DIs seized samples of controlled substances for analysis and obtained copies of invoices, inventories, dispensing logs and patient records. *Id.* The OSC alleged that these records showed that notwithstanding the previous DEA warnings that his exports were illegal, Respondent had ''continued to dispense controlled substances * * * to overseas patients until November 14, 2001,'' the date he was served with the Notice of Immediate Suspension. *Id.* Finally, the OSC alleged that ''DEA reviewed the patient records of selected overseas patients and determined that [Respondent had] deviated from the appropriate standard of care for the dispensation of controlled substances.'' *Id.* The OSC thus concluded that Respondent had ''committed acts that would render the approval of [his] pending DEA export application to be inconsistent with the public interest.'' *Id.* at 3.

Respondent timely requested a hearing on the allegations of each Show Cause Order; the cases were assigned to Administrative Law Judge (ALJ) Gail Randall. The hearing on the issues raised by the 2001 Show Cause Order was initially scheduled to begin on July 9, 2002, in Riverside, California. However, on June 6, 2002, the parties filed a joint motion to consolidate the cases and to continue the hearing. On June 13, 2002, the ALJ granted the motions. ALJ Decision at 2 (ALJ).

The first stage of the hearing was held in Riverside, California, on January 28–31, and February 3–6, 2003. During this portion of the hearing, Respondent objected to DEA's proposed eliciting of testimony of an expert witness, Dr. Robert Zipser, on the issue of whether Respondent's dispensing practices were within the standard of care. Among other things, Respondent asserted that the proposed testimony related to an issue that was outside the subject matter jurisdiction of this Agency. While the ALJ overruled Respondent's objection, she granted Respondent leave to file an interlocutory appeal on the issue. The ALJ further barred Dr. Zipser from testifying about Respondent's dispensing practices until the interlocutory appeal was resolved.

On June 23, 2003, the Acting Administrator denied Respondent's appeal. Thereafter, the second stage of the hearing was held in Arlington, Virginia, on September 9–10, 2003, and the final stage was held in Riverside on December 9 through 11, 2003.

During the hearing, both parties called witnesses and introduced documentary evidence. Following the hearing, both parties submitted proposed findings, conclusion of law, and argument.

On July 28, 2005, the ALJ issued her recommended decision. In that decision, the ALJ recommended that I revoke Respondent's practitioner's registration. ALJ at 82. The ALJ further recommended that I deny Respondent's application for an export registration. *See id.* Neither party filed exceptions.

Thereafter, the ALJ forwarded the record to me for final agency action. On December 29, 2005, Respondent's counsel submitted a letter to me setting forth various ''issues for review, exception, appeal and judicial review,'' Resp. Ltr. at 1, and including as attachments copies of various filings and motions that were previously submitted during the course of this all too lengthy proceeding. To the extent Respondent's letter raises ''exceptions'' as that term is used in the Administrative Procedure Act, *see* 5 U.S.C. 557(c), it is out of time.[1] *See* 21 CFR 1316.66(a) (requiring filing of exceptions ''[w]ithin twenty days after the date upon which a party is served a copy of the report of the'' ALJ).

Having carefully considered the record as a whole, I hereby issue this

[1] Respondent's letter does not specify which of the ALJ's findings of fact and conclusions of law he is excepting to. Nor does it provide ''a statement of supporting reasons for such exceptions, together with evidence of record * * * and citations of authorities relied upon.'' 21 CFR 1316.66(a).

final order. For the reasons set forth below, I concur with the ALJ's conclusion that Respondent's continued registration as a practitioner would be inconsistent with the public interest and therefore adopt the ALJ's recommendation that Respondent's registration should be revoked. I further concur with the ALJ's conclusion that granting Respondent's application for registration as an exporter would be inconsistent with the public interest and therefore adopt the ALJ's recommendation that the application be denied. I make the following findings.

Findings of Fact

Respondent is a medical doctor and holds a license with the Medical Board of California. Gov. Exh. 3, at 1. Respondent graduated in 1980 from the American University of the Caribbean School of Medicine and also holds a law degree. *Id.; see also* ALJ at 5. Respondent practices anti-aging medicine and is the owner of the Palm Springs Life Extension Institute (PSLEI). ALJ at 5–6.

Respondent has developed a treatment protocol called Total Hormone Replacement Therapy and obtained various patents for it.[2] *See generally* Resp. Exh. 1017. Respondent's practice involves using blood tests to determine the levels of various hormones in a person and prescribing various substances including hormones such as Human Growth Hormone and Estrogen to a patient based on the level of these hormones found in a healthy young adult. *See generally id.* Most significantly, as part of his treatment protocol, Respondent frequently prescribed and dispensed several controlled substances including testosterone in various formulations, a Schedule III anabolic steroid (*see* 21 CFR 1308.13(f)), and phentermine, a Schedule IV stimulant. *See* 21 CFR 1308.14(e). Respondent used the term ''adrenal extract'' for phentermine. *See* Gov. Exh. 117; Gov. Exh. 135.

Respondent holds a DEA Certificate of Registration as a practitioner, No. AC1643661, which authorizes him to dispense controlled substances in Schedules II, II–N, III, III–N, IV and V. Gov. Exh. 2. Respondent's registered location is 2825 Tahquitz Canyon Building A, Palm Springs, CA, 92262. *Id.*

The First Investigation

Respondent first came to the attention of DEA in 1994, when a U.S. Food and Drug Administration (FDA) Special Agent (SA) contacted Robert Brasich, a Diversion Investigator assigned to the San Diego Field Division, seeking a person to assist in an undercover investigation of Respondent. Tr. 112. The FDA SA asked the DI whether he knew of any DEA SA who could pose as body builder and perform an undercover visit with Respondent. *Id.* at 118. The FDA SA told the DI that he had personally conducted an undercover meeting during which he told Respondent that he played rugby and wanted to increase his strength and endurance. *Id.* at 120. At the end of the visit, Respondent's staff gave the FDA SA human growth hormone (HGH) and the FDA SA subsequently received shipments of HGH on several occasions.[3] *Id.; see also* Gov. Exh. 35, at 23.

On October 17, 1994, another FDA SA also performed an undercover visit with Respondent. *Id.* at 24. This SA told Respondent that he had an injured disc, that he lifted weights, and that he wanted to increase his muscle mass, and that he had taken steroids previously ''but wanted a safer alternative.'' *Id.* at 25; *see also* Tr. at 121. According to an affidavit filed to obtain a search warrant, Respondent told the SA that ''the problem with anabolic steroids in the past was their use without medical supervision, but they weren't bad if administered by a doctor.'' Gov. Ex. 35, at 25. At the end of the consultation, Respondent gave the SA prescriptions for various items including testosterone gel, a Schedule III controlled substance. *Id.* at 26. While Respondent obtained a blood sample, he issued the prescription for testosterone without obtaining the results. *Id.* at 26; *see also* Tr. at 149.

On March 17, 1995, a Customs SA performed an undercover visit with Respondent. The Customs SA told Respondent that he was a competitive powerlifter and used anadrol, an anabolic steroid, but that he wanted HGH because he had lost competitions ''to guys who [were] 'on the juice.' '' Gov. Exh. 35, at 32. During the visit, Respondent told the SA that ''[a]fter 1990, the whole body-building industry had switched to natural testosterone, and the 'new power lifting people use testosterone and HGH.' '' *Id.* Respondent also told the SA that the ''most effective treatment for [his] goal would involve both [HGH] and natural testosterone administered through the skin by means of a patch or gel.'' *Id.* Respondent further told the SA that the ''testosterone would not show up in drug testing at competitions if [he] followed [Respondent's] instructions.'' *Id.* at 33. While Respondent drew blood from the SA during this visit to determine his testosterone and HGH levels, the results were not available by the end of the consultation. *Id.* at 33–34; *see also* Tr. at 149. Respondent nonetheless gave the SA prescriptions for various items including testosterone. *Id.* at 34.

Moreover, Respondent gave the SA a letter entitled ''testosterone Replacement Therapy,'' which stated that the SA ''had been diagnosed with hypogonadism for which testosterone replacement therapy was required.'' *Id.* The letter further stated that all the testosterone prescriptions and refills would be filled by a pharmacy in Fairfax, Virginia, and that Respondent would send the SA's prescription directly to the pharmacy. *Id.* at 34–35.

Finally, on July 20, 1995, a DEA SA conducted an undercover visit with Respondent. *Id.* The SA told Respondent that he was a powerlifter and was training to make the Olympic team. *Id.* Respondent told the SA that because he ''had not done a lot of steroids in the past,'' his ''testosterone would be low which would provide a justification for prescribing testosterone.'' *Id.* at 36. Respondent drew blood from the SA, *id.* at 37, and told him that ''if the results came back low'' he would also ship him HGH. *Id.* at 36. Respondent also gave the SA ''a letter entitled 'testosterone Replacement Therapy.' '' *Id.* at 37. The letter ''was identical in substance to the letter given to'' the Customs SA during the third undercover visit. *Id.* Thereafter, the same Fairfax, Virginia pharmacy mentioned in the letter Respondent gave the Customs SA sent 50 mg. of testosterone gel to the DEA SA. *Id.* at 38.

Subsequently, on May 23, 1996, the FDA SA obtained a search warrant for the PSLEI. *Id.* at 2. Two DEA DIs participated in the execution of the search. Tr. at 130. During the search, controlled substances, which included testosterone gel, testosterone cypionate and nandrolone decanoate, were found on the premises. *Id.* at 132; Gov. Exh. 35, at 71. Moreover, while the CSA requires a registrant to maintain at his registered location purchase records, an inventory, and a dispensing log, *see* 21 CFR 1304.03 & 1304.04, no such records were found on the premises during the search. Tr. at 134. The investigation also determined that on numerous occasions between January 1, 1995, and June 3, 1996, Respondent had purchased controlled substances including diazepam (Schedule IV) and various

[2] To obtain a U.S. patent, Respondent was not required to demonstrate the safety or effectiveness of his protocol. *See* Gov. Exh. 138, at 4 (*Manual of Patent Examining Procedure* § 2107.03).

[3] HGH is not a controlled substance. The facts surrounding this visit are related solely to provide context.

anabolic steroids including deca-durabolin, nandrolone decanoate, and testosterone cypionate from Henry Schein, Inc. *See* Tr. 135, Gov. Exh. 36.

The Second Investigation

On June 29, 1998, the Medical Board of California initiated proceedings against Respondent which resulted in an administrative hearing before a state ALJ. Govt. Exh. 3, at 1; Gov. Exh. 125. In a decision dated December 27, 1999, the state ALJ issued a decision which proposed the revocation of Respondent's state medical license. Gov. Exh. 4, at 67. On January 19, 2000, the Medical Board's Division of Medical Quality entered an order adopting the ALJ's decision with an effective date of February 18, 2000.[4] *See id.* at 32

On July 20, 2000, Respondent submitted an application to renew his practitioner's registration (DEA From 224a). Gov. Exh. 1, at 1. His California license having been revoked, Respondent gave the address of his proposed registered location as 201 South Main, Suite 900, Salt Lake City, UT 84111. *Id.* at 2; Gov. Exh. 18, at 1. Moreover, in response to a question on the application, Respondent indicated that his California license had been revoked but that his Utah license was ''not affected.'' *See* Gov. Exh. 1, at 2.[5] Because Respondent had indicated that California had revoked his license, the application was not automatically renewed but forwarded to the DEA Salt Lake City office and then to the DEA Riverside, California field office, for further investigation, where it was assigned to Diversion Investigator Doris DeSantis. Tr. at 216–17.

No longer holding a valid California medical license, on or about February 16, 2000, Respondent sold the PSLEI to his sister Connie Chein, a board certified physician who practices obstetrics and gynecology in Beverly Hills, California. ALJ at 6–7. Dr. Connie Chein testified that she purchased PSLEI because under California law, ''you have to be a licensed physician to own a medical facility.'' Tr. 1087. The ALJ found that during this period, PSLEI was operated by Dr. Darryl Garber, an associate of Respondent. *See* ALJ at 13 (citing Tr. 1050). On or about December 20, 2000 (and following the Superior Court's granting of judgment setting aside the State Board's revocation order), Dr. Connie Chein sold the PSLEI back to Respondent. *Id.* at 7.[6]

Dr. Connie Chein holds a DEA Certificate of Registration as a practitioner, No. AC7093292, with a registered location in Beverly Hills, California. Gov. Exh. 43, at 8. On various occasions, PSLEI ordered controlled substances using Dr. Connie Chein's DEA registration. *See* Gov. Exh. 43, at 2–6; Gov. Exh. 17 (invoices ordering phentermine from Barnes Wholesale); Gov. Exh. 44(d), 44(g), 44(l), & 45(a) (invoices for testosterone ordered from Amend Drug & Chemical Co., Inc.); Gov. Exh. 31 (Letter dated Dec. 17, 2001, from Marshall Gilbert, Administrator, PSLEI, to Spectrum Chemicals) (''Dr. Connie Chein is no longer with [PSLEI]. Dr. Darryl Garber is now in charge of ordering all controlled substance[s].'').

During a December 13, 2001, interview with DEA Diversion Investigators (DIs) at which she was represented by counsel, Dr. Connie Chein stated that she never gave Respondent permission to use her DEA registration to order controlled substances for PSLEI. Gov. Exh. 28, at 15. Moreover, Dr, Connie Chein stated that she never received controlled substances at her Beverly Hills registered location which were intended for PSLEI and was unaware of the fact that someone at PSLEI was using her DEA registration to order controlled substances for the clinic. *Id.* at 15–17, 19.

At the hearing, Dr. Connie Chein testified that she never treated patients at PSLEI. Tr. 1092. When asked, however, as to whether she had ever prescribed or dispensed controlled substances for patients of the PSLEI, Dr. Connie Chein asserted the Fifth Amendment privilege against self-incrimination. *Id.* at 1093. Moreover, when asked whether she had ever ordered controlled substances for PSLEI, Dr. Connie Chein again invoked her Fifth Amendment privilege. *Id.* at 1094. Dr. Connie Chein also asserted her Fifth Amendment privilege when the Government attempted to question her regarding various invoices and purchase orders which used her DEA number and related documents. Tr. 1111–12; 1116–19; 1121–36.

The Government contends that notwithstanding Connie Chein's ownership, Respondent remained in charge of the Palm Springs Clinic during the period in which his state license was revoked. There is substantial evidence in the record that supports this contention.

For example, on February 27, 2000, Respondent wrote an ''Interoffice Memo'' directing the Oral/Growth Hormone Department to not ''ship any bottle to Japan, if the bottles do not appear clean to you, because the Japanese custom is extremely clean.'' Gov. Exh. 136, at 14. The memo further instructed that ''testosterone tubes frequently have adhesive that appears black to them'' and that ''it must be removed * * * before it can be shipped out.'' *Id.* The memo directed clinic employees to ''sign that you have read this letter/memo, and return it to my desk. From, Dr. Edmund Chein.'' *Id.* The memo also stated that if there were ''any questions about the quality or the product, you must let Charlie or Vanessa or me know, before'' shipping the products. *Id.* Respondent's secretary, who worked at PSLEI's Palm Springs, Cal. clinic, was Vanessa Koloen. Tr. 1331–36

Thereafter, in an Interoffice Memo dated February 29, 2000, Respondent directed the Growth Hormone Department to ship phentermine to a patient in Japan. *See* Gov. 105, at 36.

[4] Respondent, however, sought judicial review in the California state courts. On September 26, 2000, the Superior Court granted Respondent's petition in part and ordered the Medical Board to set aside its decision revoking Respondent's license and remanded the case for further proceedings; on November 9, 2000, a judgment to this effect was entered. *See* Gov. Exh. 4, at 25–26. On January 4, 2001, the Medical Board subsequently vacated and set aside its decision. *Id.* at 1.

Subsequently, on August 15, 2002, the Medical Board filed an additional accusation against Respondent which alleged thirteen grounds for discipline including incompetence, prescribing without medical indication, ''obtaining controlled substances by deceit, misrepresentation and subterfuge,'' ''dispensing controlled substances without proper privileges,'' and failing to maintain adequate controlled substance records. Govt. Exh. 124, at 18; *see also id.* at 10–11. This matter was still pending at the time the record closed. *See* ALJ at 15.

Pursuant to 5 U.S.C. 556(e), I take official notice of the fact that on September 22, 2005, Respondent entered into a Stipulation Settlement and Disciplinary Order with the State of California, which became effective on March 16, 2006. *See In the Matter of the Accusation Against: Edmund Chein, M.D.,* File No. 19–2000–107723, Decision at 1, Stipulated Settlement and Disciplinary Order at 14. I further note language in the stipulation asserting that it ''is intended to resolve'' not only California's disciplinary action but also ''any disciplinary action taken by another state or the federal government based on the conduct alleged in * * * In the Matter of Edmund Chein, M.D., Docket No. 02–9 and 02–43 pending before the United States Drug Enforcement Administration.'' Stipulated Settlement at 2–3. In accordance with the Administrative Procedure Act, publication of this order will be withheld for a fifteen day period in order to provide Respondent with ''an opportunity to show the contrary.'' 5 U.S.C. 556(e).

The ALJ also found that on June 30, 1995, the Medical Board placed Respondent on probation for a three year period for false advertising and failing to obtain a fictitious name permit. *See* ALJ at 12–13.

[5] On March 5, 2001, DEA received from Respondent a letter which requested a modification of his registration back to 2825 Tahquitz Canyon Way, Building A, Palm Springs, CA, 92262, because he had ''since * * * regained [his] California Medical License.'' Gov. Exh. 18.

[6] Given the circumstances surrounding Respondent's sale of the clinic to his sister and her sale back to him, the transaction may well have been a sham. But the Government did not attempt to prove that it was.

Specifically, the Memo reads: ''Mandy, please ship one (1) bottle of phentermine to Ms. [K. H.] immediately.[7] However, ship the oral hormone, phentermine to Yamamoto Medical Clinic, instead of to her home address.'' *Id.* Other documents in the record establish that Ms. Mandy Boriski was involved in the filling of orders for Respondent's patients and worked out of the Palm Springs, Cal. clinic. *See* Gov. Ex. 96, at 32, 33, 34, 36, 38.

One of these documents is a July 14, 2000 memo from Ms. Boriski to Dr. S.K., a German patient. The memo, which used the clinic's Palm Springs, California address states: ''I have received your fax re: the order with the pharmacy. *I am awaiting approval from Dr. Chein* for me to send the prescriptions you requested. I apologize for the delay but I am unable to send anything *without his approval.*'' Gov. Exh. 96, at 32 (emphasis added).

The record also contains a December 13, 2000 e-mail from Bob Jones, a consultant and spokeperson for PSLEI to various employees of the Palms Springs location, which discussed missing testosterone shipments to a German citizen, R.D. The e-mail, which was copied to Respondent and his Secretary Vanessa Koloen, states: ''Per Dr. Chein please send duplicates of their last shipments of these items today.'' Gx. 107, at 23. As these various documents indicate, Respondent was still the boss during the period in which his sister putatively owned the clinic and continued to direct the clinic's employees in the handling of controlled substances.

It is acknowledged that during this period, Respondent sometimes used letterhead that referred to PSLEI's ''International Division'' and gave an address in Salt Lake City, Utah, and typically used a prescription form that included his Utah medical license number. But even if Respondent actually maintained a medical practice in Utah, his doing so does not exclude a finding that during this period, Respondent continued to direct his employees regarding the distribution of drugs from the clinic's Palm Springs, California location.[8]

Indeed, in the case of patient N.K., a Japanese citizen, Respondent wrote a letter (dated October 11, 2000) to the patient on Palm Springs, California letterhead discussing the results of a ''hormonal screening panel test''; the letter also recommended that the patient take testosterone gel and Adrenal Extract (phentermine). Gov. Exh. 93, at 6. Respondent also prepared a form on ''Palm Spring Life Extension Institute, Utah'' letterhead, which prescribed numerous products including testosterone gel and phentermine (Adrenal Extract). *Id.* at 13. Both documents were faxed on October 19, 2000, and bear initials showing that the same person faxed both documents. *Compare id.* at 6, *with id.* at 13. Subsequently, on November 22, 2000, the Palm Springs, California location dispensed testosterone gel to this patient. *See* Gov. Exh. 15, at 20.

I further note that notwithstanding her putative ownership of the clinic, Respondent's sister could not provide DEA investigators with copies of the documents that transferred ownership. *See* ALJ at 20 (¶ 74). Furthermore, Respondent's sister told DEA investigators that she had been out to the clinic's Palm Springs location once in five years. *See id.* The ALJ also found that Dr. Garber operated the clinic during this period. *Id.* at 13 (¶ 52). But during this period, Dr. Garber's registered location was at his residence and not at the clinic. *Id.* at 21 (¶ 76). In any event, the ALJ's finding that Dr. Garber operated the clinic does not preclude the additional finding that Respondent continued to exercise control over the Palm Spring location's handling of controlled substances during the period in which his sister owned the clinic.

The ALJ found that Respondent dispensed controlled substance from PSLEI while his California medical license was revoked. *See* ALJ at 13–14, ¶ 52 (citing Tr. 827–29; Gov. Exh. 105, at 36, 45–46). I adopt this finding. As found above, a February 29, 2000 memo from Respondent directed an employee in the ''Growth Hormone Department'' to ''ship one (1) bottle of phentermine to [Ms. K. H., a Japanese patient] immediately.'' Gov. Exh. 105, at 36. *See also id.* at 45–46 (Feb. 29, 2000 letter from Respondent to Ms. K. H.; ''due to your twenty pound weight gain, I will add phentermine adrenal hormone immediately.''). Moreover, as explained above, the evidence shows that Respondent dispensed testosterone Gel to patient N.K. from the Palm Springs location while his California medical license was revoked.

The ALJ also found that ''on August 11, 2000, the Respondent, without a DEA registration entitling him to so act, sent controlled substances from PSLEI, International Division, in Salt Lake City, Utah, to Japan.'' *See* ALJ at 14, ¶ 53 (citing Gov. Exh. 105, at 39–42). I do not adopt this finding. While the documents which the ALJ relied on establish that HGH and ''oral hormones'' were to be shipped, they do not establish that the ''oral hormones'' included a controlled substance.

The ALJ also made a finding that ''[s]ome of the shipments sent from PSLEI were mislabled to avoid disclosing that the package contained controlled substances.'' ALJ 57, ¶ 192. Relatedly, the Government argues that various documents ''reflect[ ] PSLEI's willingness to fraudulently misidentify shipments of drugs to mislead customs officials.'' Govt. Br. at 50, ¶ 98.

The document cited by the ALJ does suggest that testosterone gel was labeled as '' 'a Skin Cream' and as a 'gift' for Customs purpose.'' Gov. Ex. 107, at 21. A subsequent e-mail, dated December 13, 2000, which was copied to Respondent, indicated that the substances had not been received and directed the Palm Springs staff to send a new shipment that day. *Id.* at 23. The e-mail further included ''guidelines for shipping to Germany'' from the patient's secretary, which stated that the goods should be declared as a ''sample'' with a value of ''$ 5.00.'' *Id.* But while the invoice that accompanied the shipment declared its value at $5.00, it also clearly described the goods as ''testosterone.'' *Id.* at 20. This document thus does not support the ALJ's finding.

The Government also points to a September 8, 2000 fax from Ms. Boriski to a Belgian citizen informing him that his order for melatonin had been shipped and ''labeled as [a] Dietary supplement * * * per your request. I

[7] To protect patient privacy, patients will be referred to by their initials.

[8] Other documents support the conclusion that Respondent remained active in practicing medicine out of the Palm Springs, California location. On May 22, 2000, Respondent sent a letter by fax to Dr. S.K. Gov. Exh. 96, at 41. In this letter, Respondent advised Dr. S.K. that her mother was ''not too old for the program'' and that ''[s]he may want to be on the silver program, which is the basic hormone-balancing program without the growth hormone.'' *Id.* Significantly, while this document was not written on PSLEI's letterhead, Respondent used the clinic's Palm Springs fax number.

The record also contains correspondence written by Respondent during this period on letterhead using the clinic's Palm Springs, Ca. address. *See* Gov. Exh. 94, at 8. In an October 6, 2000 letter, Respondent rendered medical advice to a Japanese clinic regarding patient M.I. *See id.* Subsequently, on October 13, 2000, Dr. Chein wrote this patient on PSLEI's Palm Springs, CA letterhead advising that there was a dispute between himself and the doctors at the Aoyama Medical Clinic. *Id.* at 6.

Thereafter, on December 5, 2000, Respondent wrote a letter on the clinic's Palm Springs, Ca. letterhead notifying the patient that ''starting from 9th November 2000 the relation between Aoyama Clinic and *my Institute* (Palm Springs Life Extension Institute, CA, U.S.A.) has come to an end.'' *Id.* at 5 (emphasis added). Respondent thus represented to others that he was the owner of the clinic during the period in which his sister putatively owned it. Moreover, the statement shows Respondent's continued involvement in the business affairs of the Palm Springs clinic.

hope this does eliminate any delay with customs.'' Gov. Ex. 91, at 22. However, melatonin is not a controlled substance and it is arguably accurate to describe it as a ''dietary supplement.'' Moreover, even if it was improper to declare it as a dietary supplement, this document does not establish that Respondent was aware of this practice, and a single document does not prove that it was the clinic's policy or practice to falsify customs declarations.

Finally, the record contains a letter from Dr. S.K. ordering estradiol/testosterone creme and suggesting that ''it might be [declared as] a cosmetic product.'' Gov. Exh. 96, at 45a. The Government, however, produced no evidence showing that the clinic did, in fact, mislabel the shipment. Accordingly, the ALJ's finding is not supported by substantial evidence. *See NLRB* v. *Columbian Enameling & Stamping Co.*, 306 U.S. 292, 300 (1939) (''Substantial evidence is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established.'').

The DEA On-Site Inspections and Their Aftermath

As stated above, because Respondent's state license had been revoked, DI DeSantis was assigned to conduct an investigation regarding his renewal application. On January 31, 2001, the DI went to the PSLEI in Palm Springs to interview Respondent and inspect his recordkeeping. Tr. 263; Gov. Exh. 5. Respondent was not present. Tr. 264. The DI met with Dr. Darryl Garber and presented him with a Notice of Inspection. Gov. Exh. 5.

The DI asked to see various records including invoices for the purchase of controlled substances, inventories, and dispensing logs. Tr. 268–69. Dr. Garber told the DI that he could not provide the records because PSLEI had a new computer system and no one was present who could access the records. *Id.* at 269. One of PSLEI's employees told the DI that the invoices were not on-site but rather were at the office of its accountant. *Id.* at 273. The only records the DI received were two purchase orders but these had been generated by the PSLEI and were not the invoices provided by the distributor. *See* Gov. Exh.6; Tr. 274–75. The purchase orders did, however, establish that the PSLEI had recently bought phentermine. *See* Gov. Exh.6.

The DI told Dr. Garber that the clinic was in violation of the CSA's implementing regulations because the invoices were required to be kept on-site. Tr. 274–76. The DI also informed Dr. Garber that the clinic was in violation because the records were not readily retrievable for inspection and copying. *Id.* at 274.

On February 5, 2001, the DI returned to the PSLEI to obtain the records that the clinic was required to maintain. Once again, Respondent was not present. *Id.* at 279. The DI again met with Dr. Garber and asked for the records. *Id.* Dr. Garber asked the DI to sit in the office while he retrieved the records. *Id.* The DI waited two to three hours while Dr. Garber printed out the records. *Id.* at 280.

Dr. Garber provided the DI with a one page inventory report which was dated February 5, 2001. *See* Gov. Exh. 8. Dr. Garber also provided the DI with four invoices for phentermine. Tr. 331–33; Gov. Exh. 17(a)–17(d). Although the DI had requested the invoices for all controlled substances purchased by the clinic, no invoices for the purchase of testosterone were provided. Tr. 334.

Dr. Garber also provided the DI with a dispensing log for various controlled substances including testosterone gel, testosterone estradiol gel, Subligual testosterone, testosterone, and depo testosterone. *See* Gov. Exhs. 9–16; Tr. 284. Most of the dispensing logs, however, only covered the period from July 1, 2000, through February 5, 2001.[9] *See* Gov. Exhs. 9–16. Moreover, none of the logs indicated the name of the physician who had authorized each dispensing. *See id.* The logs also included the names of numerous patients who resided in foreign countries including Belgium, France, Germany, Great Britain, Spain, Switzerland, China (Hong Kong), Indonesia, Japan, South Korea, and Canada. *See* Gov. Exhs.10, 11, 12, 15, & 16. The Government subsequently compiled from these records a separate document which listed each dispensing. *See* Gov. Exh. 46. According to this document, the dispensing logs showed that Respondent's clinic exported controlled substances 317 times during the period from July 1, 2000, through February 5, 2001.[9] *See id.*; *see also* ALJ at 57, ¶ 191. Neither Respondent nor Dr. Garber had an export registration as required under 21 U.S.C. 957 & 958.[10]

[9] The dispensing log for phentermine 15 mg. covered the period from July 26, 1999, through February 1, 2001. *See* Gov. Exh. 10. This log, however, had no entries before August 22, 2000. *See id.* The dispensing log for Depo testosterone covered the period July 1, 2000, through February 1, 2001. *See* Gov. Exh. 16.

[10] While Dr. Garber held a DEA practitioner's registration, at the time of the January 31 and February 5, 2001 visits, his registered location was his residence in Rancho Mirage, California. *See* ALJ at 21, ¶ 76. Dr. Garber did not change his registered location to the PSLEI until February 12, 2001, after the two visits. *See id.*

On March 9, 2001, DI DeSantis contacted Dr. Garber by telephone and told him that PSLEI must stop exporting controlled substances. Tr. 1245. The DI also faxed to Dr. Garber various provisions of Federal law pertaining to the exporting of controlled substances including 21 U.S.C. 953 & 960. *Id.*; *see also* Gov. Exh. 19. On the same day, Vanessa Koloen, a PSLEI employee, faxed to the DI copies of various documents including purchase orders and invoices related to the clinic's purchase of testosterone. *See* Gov. Exh. 20. The earliest documents were, however, dated November 20 & 21, 2000, *see* Gov. Exhs. 20(J) & 20(K), and the dispensing records indicated that testosterone had been dispensed before these dates. *See*, *e.g.*, Gov. Exh. 15, at 21–26. Two other documents provided by PSLEI used Dr. Garber's residence as the billing and shipping address. *See* Gov. Exhs. 20(F) & 20(G). The remaining documents were for purchases that occurred in mid to late February 2001, following the DI's second visit. *See* Gov. Exhs. 20(a), 20(b), 20(c), 20(d), 20(e).

Subsequently, on April 27, 2001, Respondent applied for a registration to export Schedule III Non-Narcotic and Schedule IV controlled substances. *See* Gov. Exh. 48, at 3–4. According to a date stamp, the application was received at DEA in May 7, 2001, and Respondent's credit card was charged on May 15, 2001. *See id.* at 3. The application, however, was never processed and the application fee was refunded through a credit to Respondent's credit card. Tr. 2092–94 The application bears the notation ''Already Have DEA#.'' Gov. Exh. 48, at 3. The application was not returned to Respondent, and no one at DEA ever notified him that the application had been rejected. *See* Gov. Exh. 34 & 39; *see also* Resp. Proposed Findings at 12 (¶ 94). In December 2001, Respondent submitted a second application for registration as an Exporter. *See* Gov. Exh. 48 at 7–8.

On August 23, 2001, DI DeSantis (accompanied by another DI) returned to PSLEI to conduct a conference with Respondent regarding the violations that had been found during the inspection. Tr. 545–47. The DI told Respondent that the violations included the clinic's lack of readily retrievable records, its lack of a biennial inventory, and its exporting of controlled substances to persons residing in foreign countries without an export registration. *Id.* at 547–48, 559.

During the meeting, Respondent produced the statutes that the DI had faxed to Dr. Garber and acknowledged that he had discussed the violations with Dr. Garber. *Id.* at 548. Respondent admitted that he did not have an

exporter's registration and claimed that under either 21 U.S.C. 953(a)(3) or (a)(4) he could export without a registration because he was sending the controlled substances to another doctor, who was legally authorized to handle controlled substances. Tr. 551–55. The DI informed Respondent that he would still need an export permit under 21 U.S.C. 953(a)(5). *Id.* at 554. These provisions, however, address the exportation of narcotic drugs and not the non-narcotic controlled substances (testosterone and phentermine) that Respondent was exporting. Rather, the export of these controlled substances is governed by 21 U.S.C. 953(e), which requires the filing of a declaration and documentary proof that the importation into the destination country is not illegal.[11] Moreover, a registration is required to export both narcotic and non-narcotic controlled substances. *See* 21 U.S.C. 957 & 958.

During the meeting Respondent did not mention that he had applied for an exporter's registration. Moreover, Respondent told the DI that he had continued to export controlled substances notwithstanding her earlier admonition to Dr. Garber to stop. Tr. 557. Respondent further admitted that there had probably been many more violations in the interim but that he would not stop until ''he received something in writing from'' the DEA. *Id.* at 558.

The other DI asked Respondent how he was shipping the controlled substances overseas. *Id.* Respondent refused to answer and invoked his Fifth Amendment privilege against self-incrimination. *Id.* He also told the investigators that ''it was up to [DEA] to find out how he was shipping [the controlled substances] overseas.'' *Id.* at 559.

During the meeting, Respondent provided the DI with several invoices for controlled substances. One of the invoices documented that on March 14, 2001, PSLEI had purchased five kilograms of micronized testosterone from Pharmacia and Upjohn and that the product was shipped to Dr. Garber's residence. *See* Gov. Exh. 21.5, at 2. At the time, Respondent owned PSLEI and Dr. Garber was no longer registered at his residence. *Id.*

Respondent also provided the DI with an invoice from Farmacias Castaneda, a pharmacy located in Tijuana, Mexico. *See* Gov. Exh. 22, Tr. 576. The invoice, which is dated June 26, 2001, indicated that the PSLEI had purchased 120 units of Depo testosterone and 40 units of Decadurabolin, two anabolic steroids and Schedule III controlled substances, from the Tijuana pharmacy. *See* Gov. Exh. 22. The pharmacy did not hold a DEA registration because DEA does not register foreign pharmacies or distributors. Tr. 573–74. Neither Respondent, nor Mr. Romero, the pharmacy's owner, was registered as an importer. *See* ALJ at 60, ¶ 205 (citing Tr. 167 & 970); Gov. Exh. 2.

On August 31, 2001, DI DeSantis sent an additional fax to Respondent which included copies of 21 U.S.C. 823, 952, 953, 954 and 958. The ''Comments'' portion of the Cover Sheet included the following statement:

> I have attached all the registration requirements . * * * concerning applicants to import or export controlled substances. You are not currently registered with DEA as an exporter/importer (nor do you possess any permits to export issued by the Attorney General), thus you are not authorized to perform either activity. You must immediately cease all [activity] in these areas as previously instructed on 02/13/01 and 8/23/01 by D/I DeSantis.

Gov. Exh. 23, at 1. On September 5, 2001, DeSantis sent an additional fax that included a copy of 21 U.S.C. 957 (Persons required to register), which had been omitted from the previous fax. *See* Gov. Exh. 24.

On November 12, 2001, DI DeSantis along with other DEA personnel, served the first Order to Show Cause and Notice of Immediate Suspension. Tr. 591. Upon her arrival at the PSLEI, the DI was informed that Respondent was out of the country and was not expected to return for possibly two weeks. *Id.* at 592. The DI then met with Dr. Garber and asked for Respondent's DEA Certificate of Registration. *Id.* at 592. Neither Dr. Garber, nor Respondent's secretary, Vanessa Koloen, knew where the certificate was. *Id.* at 593.

The DI also sought to seize the controlled substances on the premises. *Id.* Dr. Garber told the DI that Respondent ''had not purchased any controlled substances'' and that controlled substances at the clinic were purchased by him. *Id.* at 593–94. Dr. Garber refused to turn over the controlled substances. *Id.*

The DI then requested to see the invoices for controlled substance purchases to verify Dr. Garber's statement. *Id.* at 594. Clinic personnel gave the DI various invoices. *Id; see also* Gov. Exh. 45. The first of these invoices documented that on March 26, 2001, PSLEI had purchased two kilograms of testosterone (which was received on March 30, 2001) using Connie Chein's DEA number. *See* Gov. Exh. 45a. The next three invoices documented that on three dates in February and March 2001 (Feb. 16 & 21, Mar. 13, 2001), PSLEI purchased various quantities of testosterone which was shipped to Dr. Garber's residence. *See* Gov. Exh. 45(b), (c), & (d). The first two of these invoices (the Mar. 14 Pharmacia & Upjohn and the Feb. 16 Gallipot) did not have a DEA number. The third invoice (the Feb. 21 Gallipot) used Respondent's DEA number even though the controlled substances were shipped to Dr. Garber's residence. *See* Gov. Exh. 45(d), Gov. Exh. 2.

Finally, the seventh invoice documents a March 2, 2001, purchase by Dr. Garber of testosterone from Paddock Laboratories, which was shipped to Dr. Garber's residence. *See* Gov. Exh. 45(g). Of note, the invoice gives the name ''Vanessa'' in the box which includes purchase order information; in the ''Ship To Party Address'' box, the invoice gives Dr. Garber's name followed on the next line with the notation ''c/o Angela Santana.'' *Id.* The invoice also includes the handwritten notation: ''Received by Angie 3/5/01.'' *Id.* Both these individuals were PSLEI employees. Tr. 598. There is no dispute that Respondent was the owner of the PSLEI when these four purchases were made.

Thereafter, on three occasions between January and March 2002, the DI (accompanied by another DI) went to PSLEI to search through its trash. Tr. 686. During the February trash run, the DIs found 50 empty boxes for a testosterone product that had been

[11] The record contains letters from the governments of Japan and Taiwan to Respondent's associate (Dr. Garber) establishing the illegality of PSLEI's exportation of phentermine to persons residing in these countries. In a December 11, 2001 letter, the Government of Japan notified Dr. Garber that ''[w]ith regard to the medicine containing phentermine, you must not send the medicine to your patient in Japan.'' Gov. Exh. 38(C) (Tab D) (Letter from Kaoru Misawa, Deputy Director, Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labor, and Welfare of Japan, to Darryl J. Garber). According to this letter, a ''patient can import the medicine into Japan if he carries the medicine containing less than 1.125 grams of phentermine by himself when entering into Japan.'' *Id.* This letter further states that while the Government of Japan did not object to the exportation of testosterone gel to a patient in Japan, the medicine must be ''for his personal use and of the amount within one-month['s] consumption.'' *Id.*

In a January 4, 2002 letter, the Government of Taiwan informed Dr. Garber that ''phentermine * * * has been prohibited for use by the Department of Health since December 8, 1980, and is not allowed for importation.'' Gov. Exh. 38(C) (Tab E) (Letter, Kai-Yuan Tan, M.D., Director-General, Bureau of Medical Affairs, Department of Health, Taiwan, to Darryl J. Garber, M.D.).

The record also contains a letter dated July 26, 2001 from Dr. Garber to Raymond A. Conner, Diversion Group Supervisor in DEA's Riverside, California, office. In this letter, Dr. Garber acknowledged that ''[i]n Japan and Korea it is against the law to prescribe Anabolic Steroids * * * and phentermine * * * for the purpose of Anti-Aging Medicine.'' Gov. Exh. 38(C) (Tab C).

manufactured by Brovel, S.A., a Mexican firm. Tr. 709, Gov. Exh. 58. The DI subsequently had someone translate the boxes' label, which was written in Spanish. Tr. at 711. The label indicated that the testosterone was not for human consumption but rather for animal use. *See* Gov. Exh. 58, at 4; Tr. 711; *see also* Gov. Exh. 116, at 4 (declaration of FDA Associate Chief Counsel James Smith).

I do not, however, adopt the ALJ's finding that because ''Respondent does not treat animals[,] * * * the records supports an inference that this non-human use testosterone was compounded into a testosterone gel which was dispensed to the Respondent's human patients.'' ALJ at 62. I acknowledge that the existence of the boxes does create a suspicion that the substances were dispensed to human patients. But the Government produced no additional evidence that PSLEI used this testosterone to create products that were dispensed to humans. Moreover, Respondent produced credible evidence that he performed research into the development of a more effective delivery system for testosterone. The Government did not foreclose the possibility that the testosterone was used for that purpose by producing evidence that the quantity represented by the boxes was in excess of what would be needed for research purposes. While this is a close call, it is the Government that bears the burden of proof on the issue, and I therefore conclude that the ALJ's finding is not supported by a preponderance of the evidence.

During this trash run, the DIs also found a fax for an invoice documenting PSLEI's sale of various products to a resident of Japan. *See* Gov. Exh. 70. The invoice was dated October 17, 2001, and lists ''Testosterone/estradiol Gel 20 ml.'' and ''Adrenal Extract 15 mg. # 30'' as among the products sold. *Id.* As found above, PSLEI used the term ''Adrenal Extract'' for phentermine. Of further significance, the invoice establishes that PSLEI continued to export controlled substances following the August 23, 2001 conference and the August 31 and September 5, 2001 faxes which told Respondent to cease the exports.

Another document found during this trash run bears the caption ''HORMONE DEPARTMENT PRESCRIPTION SHEET.'' Gov. Exh. 73. The document, which is dated October 29, 2001, makes reference to a Japanese patient and instructs a PSLEI employee to ''Please ship Ms. [S.] a tube of female strength testosterone to Ginza at no charge, immediately.'' *Id.* The document is signed ''E. Chein, M.D.'' *Id.*

Following a third trash run, see Gov. Exh. 121, DI DeSantis obtained an Administrative Inspection warrant which was executed at PSLEI on March 13, 2002. Tr. 721. During the inspection, DEA personnel asked for the biennial inventories that are required by DEA regulations. *Id.* at 759–60. The clinic did not have them, id. at 760, and instead provided the investigators with a document entitled ''Instant Inventory Report.'' Gov. Exh. 82, at 7; Tr. at 760. DEA personnel also obtained dispensing logs and approximately 100 patient files for patients who lived outside the United States. *Id.* at 764 & 811.

The dispensing logs document hundreds of instances in which Respondent dispensed/exported controlled substances to residents of foreign countries. *See, e.g,* Gov. Exh. 84 (dispensing log for testosterone-estrogen (4mg.–50 mg. 20 ml.) covering period May 1, 2001, through December 31, 2001).[12] Many of the dispensings/ exports occurred following the August 23rd conference and the subsequent faxes. *See id.* at pp.1–15. Moreover, the log indicates that on November 13 and 14, 2001, the day after service of the Notice of Immediate Suspension, Respondent dispensed/exported this controlled substance thirteen times. *See id.* at 3–4.

The dispensing log for testosterone gel (0.8% 20 ml.) also documents that Respondent dispensed and/or exported following the service of the Notice of Immediate Suspension. *See* Gov. Exh. 87. Of note, Respondent dispensed to a Japanese patient on November 13, 2001, after service of the Notice of Immediate Suspension. *See id.* at 6.

The dispensing log for phentermine 15 mg. likewise documents that Respondent made numerous dispensings and/or exports of this controlled substance to foreign patients. *See generally* Gov. Exh. 88. Moreover, it also documents that Respondent made several dispensing/ exports after service of the Notice of Immediate Suspension. *See id.* For example, on November 13, 2001, Respondent made eight dispensings to foreign patients, and on November 14, 2001, Respondent made five dispensings to foreign patients. *See id.* at 6–7. Furthermore, on November 27, 2001, Respondent dispensed to a New Jersey patient. *See id.* at 6.[13] This dispensing occurred more than two weeks after service of the Notice of Immediate Suspension.

On October 3, 2002, an additional search warrant was executed at the PSLEI. Tr. 836. During the search, DEA investigators seized approximately 83 pill containers labeled as ''Adrenal Extract 15 mg,'' which held approximately 4300 pills, and 63 pill containers labeled as ''Adrenal Extract 30mg,'' which held approximately 3150 pills. Gov. Exh. 135. The pills were sent to the DEA Southwest Regional Laboratory for analysis. *See id.* The lab determined that the pills contained phentermine HCL. *See id.*

During the search, DEA also seized a variety of documents. Among them is the previously described ''Interoffice Memo'' from Respondent, which is dated February 27, 2000, and which directed PSLEI's oral/growth hormone departments to ensure the cleanliness of the testosterone products that were shipped to Japan. Gov. Exh. 136, at 14.

The investigators also obtained several other memos on PSLEI's letterhead that were written from ''Dr. Chein'' on March 6, April 14, and July 3, 2000, that discuss shipments to Japan and Taiwan. *See id.* at 11–13. The memos, however, are not signed and do not indicate whether the memo was created by Respondent or his sister.

DEA also seized another memo, which is dated January 14, 2002, and which is signed ''Edmund Chein MD.'' *Id.* at 10. The memo stated that ''[e]ffective January 15th, all medicines being shipped to Tokyo goes [sic] directly to the patient address, except for patients with the chart number LEI–Y.'' *Id.* The memo then directed that ''[a]ll medicines for the patients with the chart number LEI–Y will be shipped directly to the Osaka clinic address[.]'' *Id.* Finally, the memo directed that shipments for two patients should not be addressed ''as Ever young Technologies'' because the patients ''have to pay taxes on the shipments that are addressed to Ever young Technologies.'' *Id.* Respondent prepared this memo, which is signed as having been received by an employee, following the service of the Notice of Immediate Suspension.[14]

[12] The cover sheet of this document indicates that the period it covered was from ''11/30/01–5/1/01.'' Gov. Exh. 84. The document, however, also includes dispensings that occurred in December 2001. *See id.* at .5 & 1.

[13] Like the dispensing logs that were obtained in February 2001, some of the logs also failed to contain the name of the dispensing physician. *See* Gov. Exh. 86, at pp. 1–29 (testosterone gel 8mg./ml., 20 ml.); Gov. Exh. 89, at 2–8 (phentermine 15 mg.).

[14] Both the Government and Respondent elicited extensive expert testimony on whether Respondent's dispensing of testosterone and phentermine to six patients who resided in foreign countries was for a legitimate medical purpose and within the usual course of professional practice. In light of Respondent's flagrant and repeated

Continued

Discussion

Respondent's Challenges to the Proceeding

In the course of this matter, Respondent filed numerous motions challenging various aspects of this proceeding. In light of my conclusion that there is no need to consider the expert testimony regarding Respondent's practices with respect to foreign patients, many of the issues raised in these motions are now moot. Respondent also filed motions seeking to dismiss various allegations or to bar the Government from introducing evidence on various issues. Upon reviewing the record, I am satisfied that the ALJ's rulings on these motions were correct and that further discussion is not warranted.

One of the motions, however, challenges the integrity of this proceeding and therefore requires further discussion before proceeding to the merits. More specifically, Respondent alleges that the Office of Chief Counsel ''engaged in a pattern of unlawful and unethical misconduct in the instant proceeding mandating the disqualification of that office.'' Resp. Memorandum of Points and Authorities in Support of Respondent's Motion To Disqualify Office of Chief Counsel and Dismiss Administrative Proceeding at 1. The alleged ''pattern'' involves two statements in an affidavit prepared by an attorney in the Office of Chief Counsel and signed by a DEA employee which discussed the circumstances surrounding DEA's failure to process Respondent's application for an Exporter's Registration. Specifically, the employee stated that she was the acting unit chief of the registration unit when she signed the declaration (and was not), and that ''the reason why Dr. Chein obtained a refund of his registration fee was 'unexplained,' '' Resp. Memo. at 1, when there was an explanation.

Respondent argues that this amounts to the subornation of perjury and that it ''mandate[s] the disqualification of [the Office of Chief Counsel] and its replacement with * * * private counsel.'' *Id.* Respondent contends that this is so because ''[t]he Office of Chief Counsel shall defend, cover up and represent its own interests in relation to the felony perjury charge and it will also be called to testify regarding the Respondent's Complaint that is to be filed in the District Court.'' *Id.* at 3.[15] Therefore, Respondent maintains that ''private counsel * * * should be required to continue with any prosecution of this matter.'' *Id.* Respondent further asserts that it is not enough to simply ''disregard'' the ''offending evidence'' because this would not be an ''effective discouragement of the wrong.'' *Id.* at 5. Respondent thus argues that I should take the extraordinary step of dismissing the entire proceeding which took thirteen days of hearings and produced a record that includes a nearly three thousand page transcript and hundreds of exhibits.

As a component of the Department of Justice, this agency takes most seriously allegations of employee misconduct. Respondent's offer of proof, however, falls far short of establishing that an employee of the Chief Counsel's office suborned perjury. Moreover, even if Respondent could make out a prima facie case of subornation of perjury, he offers no authority that supports his proposed remedy.

[P]roof of actual perjury is a necessary element of subornation'' of perjury, *United States* v. *Hairston,* 46 F.3d 361, 376 (4th Cir. 1995), and proof of perjury requires a showing that ''[a] witness testifying under oath or affirmation * * * [gave] false testimony concerning a material matter with the willful intent to provide false testimony, rather than as a result of confusion, mistake, or faulty memory.'' *United States* v. *Dunnigan,* 507 U.S. 87, 94 (1993). Respondent, however, cannot show either willfulness on the part of the employee or that her statements were material.

The most common formulation'' of the concept of materiality is that ''a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed.'' *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956)) (other citation omitted); see also *United States* v. *Wells,* 519 U.S. 482, 489 (1997) (quoting *Kungys,* 485 U.S. at 770). The evidence must be ''clear, unequivocal, and convincing.'' *Kungys,* 485 U.S. at 772; *see also Herring* v. *United States,* 424 F.3d 384, 386–87 (3d Cir. 2005) (''[A] determination of fraud on the court may be justified only by the most egregious misconduct directed to the court itself, and * * * it must be supported by clear, unequivocal and convincing evidence.'') (int. quotations and citation omitted); *In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions,* 538 F.2d 180, 195 (8th Cir. 1976).

Moreover, ''although the materiality of a statement rests upon a factual evidentiary showing, the ultimate finding of materiality turns on an interpretation of substantive law.'' *Kungys,* 485 U.S. at 772 (int. quotations and citation omitted). As the ALJ pointed out, the issues in this case are whether Respondent's continued registration as a practitioner ''is inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f),'' and whether issuing Respondent a registration as an exporter ''would be inconsistent with the public interest as that term is defined in 21 U.S.C. 958(c) and 823(d).'' ALJ Notice and Order Denying Respondent's Motion to Disqualify Office of Chief Counsel and to Dismiss Administrative Proceedings, at 7. Applying these principles, I conclude that the two statements at issue here are not material to the resolution of the issues in this case.

The first allegedly perjurious statement is the employee's assertion that ''I am the Acting Unit Chief of the Registration Unit,'' Gov. Exh. 48, when, in fact, the employee served in this capacity on the day she was approached by the attorney about Respondent's exporter application, but served in this capacity for only a few days and was not the Acting Unit Chief on the day she signed the declaration. Tr. 2198–99. The employee did, however, investigate the facts surrounding the non-acceptance of Respondent's application. Ultimately, whether the employee was still serving as Acting Unit Chief on the day she signed the declaration is of no consequence in deciding any issue in this case. In short, the assertion is not the type of statement that ''has a natural tendency to influence'' the decision in this case because what matters is not her specific title on the date she signed the declaration but the fact that she investigated the incident. *See Kungys,* 485 U.S. at 770 (int. quotations and other citations omitted). Moreover, Respondent has produced no evidence, let alone that which is ''clear, unequivocal, and convincing'' that shows that when the employee signed the declaration, she did so with the intent to deceive. *Id.* at 772.

The second allegedly perjurious statement is the employee's assertion that ''[f]or an unexplained reason, DEA did not accept the application for filing'' and the employee's further statement speculating that ''it is likely that [Respondent] or someone from his office contacted DEA to request the refund.'' Gov. Exh. 48; Resp. Memo at 1. According to Respondent, the statement

violations of federal law, I conclude that it is not necessary to make any findings on this issue.

[15] Respondent did not submit a copy of the purported ''felony perjury charge'' for the record. He did, however, submit a copy of a proposed complaint for a *Bivens* action.

was perjurious because another employee had told the declarant ''that a Registration Unit supervisor had instructed her to refund [Respondent's] money because he already had a DEA number'' and the employee knew ''that neither [Respondent] nor anyone from his office had contacted the DEA to request a refund.'' *Id.*

Respondent's argument as to why this statement is material to any issue in the case is somewhat opaque. Apparently, Respondent believes that there was a ''mandatory'' statutory duty to register him as an exporter ''unless there was a finding that to do so would not be in the public interest'' and that ''there was no such finding'' here. Reply to Govt. Resp. to Motion to Disqualify Office of Chief Counsel at 3. Respondent further asserts that ''[i]f the DEA had acted properly, and had corrected its mistake, the Respondent would have been registered.'' *Id.*

Under longstanding DEA policy, the approval of an application for an Exporter's registration is not a ministerial act. Rather, the application is subject to an extensive pre-registration investigation which includes a review of the six statutory factors set forth in 21 U.S.C. 823(d). *See* 21 U.S.C. 958(c). Although Respondent's application should have been processed, the violations uncovered during the January and February 2001 visits, as well as the information Respondent provided on his application regarding prior disciplinary actions of the state authorities, would have supported a finding that granting his registration would be inconsistent with the public interest. Indeed, that is why the second Show Cause Order (which proposed to deny his second application for an Exporter's registration) was issued. Respondent's assertion that his application would have been granted had DEA not mistakenly failed to process his application is thus wishful thinking.

More importantly, Federal law makes clear that ''[n]o person may * * * export from the United States any controlled substance * * * unless *there is in effect* with respect to such person a registration issued by the Attorney General under section 958 of this title, or unless such person is exempt from registration under subsection(b) of this section.'' *Id.* section 957(a). DEA's regulations further state that ''[n]o person required to be registered shall engage in any activity for which registration is required *until the application for registration is granted* and a Certificate of Registration *is issued* by the Administrator to such person.'' 21 CFR 1301.13(a) (emphasis added).

Furthermore, Federal law does not provide an exemption from registration because one has submitted an application which was subsequently mishandled. *See Dennis Robert Howard, M.D.*, 62 FR 32658, 32661 (1997) (''there is no 'good faith' exemption from liability in administrative proceedings'' under the CSA). And while DEA has recognized that acting with a ''good faith belief that [one is] properly registered with DEA * * * is a mitigating factor in determining the public interest,'' *id.*, DEA has recognized this defense in only two situations. The first is where a person had previously held a registration for the activity and believed it to be still valid pending an appeal of a final order of revocation. *See Stanley Alan Azen, M.D.*, 61 FR 57893, 57895–96 (1996). The second is where an applicant applied for a registration and received from DEA controlled substance order forms that were imprinted with a new DEA number. *See Howard,* 62 FR at 32660.[16] *Howard* is thus properly understood as a case involving reliance on an affirmative act of the government.

The good faith defense recognized in *Azen* is not applicable to Respondent's situation because Respondent never held an Exporter's Registration. Nor can Respondent claim that the allegedly perjurious statement is material under the defense recognized in *Howard.* While Respondent's application fee was refunded based on an employee's mistaken belief that Respondent already had a DEA number, *see* Resp. Memo at 1, Respondent does not claim that DEA personnel told him that he did not need a separate Exporter's registration and Respondent has produced no evidence that the application form was returned to him. Indeed, in his brief, Respondent concedes that DEA ''never informed him'' that his application had been rejected. Resp. Br. 24.

Furthermore, Respondent has offered no testimony to the effect that he relied on DEA's refunding of his application fee in concluding that he did not need an Exporter's registration. In fact, during the August 2001 management conference, Respondent asserted that he was not required to obtain an Exporter's registration because he qualified for a statutory exemption under 21 U.S.C. 957(b); he did not claim that he did not need the registration because his application fee had been refunded or that the application had been returned to him and that he had relied on the handwritten statement on the application. Accordingly, because Respondent makes no claim of reliance on any act of DEA, he cannot establish the materiality of the statements regarding DEA's failure to process his application.

Finally, even if Respondent had made out a prima facie case with respect to the declarant and could show that the government counsel who prepared the affidavit also intended to deceive—a point on which Respondent offers nothing more than conclusory assertions—Respondent provides no authority to support his proposed remedy of dismissing the entire proceeding. Doing so would be an especially untoward result in light of the statutory purpose to protect the public interest. Furthermore, the Government made available the declarant and Respondent was able to thoroughly examine her and demonstrate the inaccuracies in her declaration. Under these circumstances, no further relief is warranted.

The Statutory Factors

Respondent's Practitioner's Registration

Section 304(a) of the Controlled Substances Act provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In making the public interest determination, the Act requires the consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. section 823(f).

''[T]hese factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in

[16] I decline to extend the good faith defense beyond these situations. Indeed, to do so in a case like this would create an incentive for applicants to engage in activities before they had obtained the required registration and demonstrated their fitness to perform the activity. Such a rule would clearly threaten public safety.

determining whether a registration should be revoked or an application for registration [should be] denied.'' *Id.* Moreover, case law establishes that I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

Factor One—The Recommendation of the State Licensing Board

As explained above, on three occasions the Medical Board of California has imposed sanctions against Respondent. At the time the ALJ rendered her decision, the the most recent accusation had not been resolved. The ALJ nonetheless concluded that ''[t]hroughout the Medical Board's proceedings, the Respondent has exhibited an unwillingness to practice medicine in a manner consistent with the California Medical Board's rules and regulations,'' and that Respondent's ''attitude'' and ''conduct[ ] demonstrate that [his] continued dispensing of controlled substances is not in the public interest.'' ALJ at 66–67.

There is some merit to the notion that if one is not willing to comply with State law they are not likely to comply with Federal law either. I conclude, however, that it is unnecessary to decide whether a registrant's unwillingness to comply with State rules that are unrelated to controlled substances can be considered under the Act when the registrant maintains a valid State license.

In any event, the ALJ did not have the benefit of knowing the outcome of the most recent State proceeding which placed Respondent on probation for a variety of acts that included several related to his handling of controlled substances. *See* n.4. The Stipulated Settlement and Disciplinary Order further states that it ''is intended to resolve * * * any disciplinary action taken by another State or the Federal government based on conduct alleged in * * * In the Matter of Edmund Chein, M.D., Docket No. 02–9 and 02–43 pending before the United States Drug Enforcement Administration.'' Stipulated Settlement at 2–3.

I acknowledge that the Medical Board acted within its sovereign prerogatives when it resolved matters arising under State law and decided to continue to license Respondent as a medical doctor. Moreover, a State can also adopt Federal standards as part of its State law. The Controlled Substance Act does not, however, delegate to State officials the authority to decide whether the continuation of a DEA registration is consistent with the public interest. *See* 21 U.S.C. 824. Rather, Congress entrusted that authority with the Attorney General of the United States, and that authority has been delegated solely to the officials of this Agency. *See id.*; *see also* 28 CFR 0.100(b). State officials therefore lack authority to resolve a matter pending before the Drug Enforcement Administration and the Stipulated Settlement cannot bind this agency. See, *e.g.*, *Fourth Street Pharmacy* v. *DEA,* 836 F.2d 1137, 1139 (8th Cir. 1988).

Moreover, even viewing the stipulated settlement as, in effect, nothing more than a recommendation to continue Respondent's registration, I decline to give it deference. As will be explained below, the record is replete with evidence of Respondent's repeated and flagrant violations of Federal law. Therefore, I conclude that it would be inconsistent with the public interest to defer to the Medical Board's recommendation and give it no weight in the public interest analysis.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and His Record of Compliance With Laws Relating To Controlled Substances

The Dispensing and Export Violations

As the ALJ found, on March 17, 1995, and July 20, 1995, Respondent dispensed testosterone, an anabolic steroid and Schedule III controlled substance, to two undercover agents. As the record establishes, Respondent wrote each special agent a prescription for the steroids in response to each of the agent's representations that they were competitive powerlifters and were seeking the steroids to improve their performance in athletic competitions. Respondent also issued each agent a letter stating that they had been diagnosed with hypogonadism notwithstanding that he did not have the test results. Based on this evidence, I conclude that the prescriptions violated Federal law because Respondent issued them without a legitimate medical purpose. *See* 21 CFR 1306.04(a).[17]

The record further establishes that on February 29, 2000, Respondent directed his California employees to dispense phentermine, a Schedule IV controlled substance, to a patient in Japan. On that date, Respondent's state license had been revoked and Respondent was therefore without authority under the CSA to dispense. *See* 21 U.S.C. 802(21) (''The term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * *.''); *id.* section 802(10) (''The term 'dispense' means to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner * * *.'').

Finally, the record establishes that Respondent repeatedly dispensed controlled substances to persons residing in foreign countries. As explained more fully below, Respondent violated Federal law because he was not registered as an exporter and did not file the required declarations. Moreover, the record shows that Respondent did so even after having been notified that his conduct was illegal. Finally, Respondent did so even after he was served with the Notice of Immediate Suspension.

Respondent contends that his practitioner's registration ''authorize[d] him as a registered doctor to dispense to his patient, wherever that patient is located.'' Resp. Exh. 75, at 4 (Resp. Memo. Pts. & Auth. in Support of Motion to Dismiss Export Charges); *see also* Resp. Br. at 22. According to Respondent, ''[e]xporting and dispensing to an individual simply are two completely different matters,'' Resp. Exh. 75, at 3, and ''[t]hese terms simply contemplate different conduct.'' *Id.* at 4.

Respondent further argues that under 21 U.S.C. 822(b), a registered physician is authorized to dispense to the extent authorized by his registration and in conformity with the other provisions of subchapter I. *See* Resp. Br. at 23. In Respondent's view, under the statute he was only required to comply with subchapter I, which ''expressly authorizes physicians to dispense to their patients,'' and because the export statutes are located in subchapter II, he was not required to obtain an export registration and comply with the other requirements of that subchapter. *Id.* Perhaps recognizing how unpersuasive this argument is, Respondent further claims that the statute is ambiguous and that his interpretation of section 822(b) is reasonable. *Id.*

The starting point in statutory construction is the language of the statute. *Ardestani* v. *INS,* 502 U.S. 129, 135 (1991) (other citations omitted). Section 302(b) of the CSA provides that:

[17] While these incidents occurred some time ago, there is no statute of limitations applicable to these proceedings, which are remedial in nature and are instituted to protect the public interest. *See Pettigrew Rexall Drugs,* 64 FR 8855, 8859 (1999). While the passage of time since the wrongdoing is a factor to be considered, the statute expressly directs that a registrant's ''experience in dispensing'' be considered, an inquiry which necessarily requires some review of a registrant's history. If Respondent's misconduct was limited to these two instances, this would be a different case.

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances * * * are authorized to possess, manufacture, distribute or dispense such substances * * * to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

21 U.S.C. 822(b).

As the Supreme Court has recognized, ''[t]his is a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons.'' *United States* v. *Moore,* 423 U.S. 122, 131 (1975). The statute grants a registrant authority only to perform those acts ''authorized by their registration.'' 21 U.S.C. 822(b).

Contrary to Respondent's understanding, the ''in conformity with the provisions of this subchapter'' clause is a further ''limitation'' on a registrant's authority. *Moore,* 423 U.S. at 131. It compels a registrant to obey the requirements contained in Subchapter I. What it does not do is excuse a registrant from complying with other requirements of federal law such as those imposed by Subchapter II, the Controlled Substances Import and Export Act (CSIEA). Indeed, under Respondent's interpretation, any entity which possessed a distributor's registration would also be exempt from the requirement of obtaining an exporter's registration (as well as obtaining the permits or filing the necessary declarations) because the term ''distribute'' is broadly defined as ''mean[ing] to deliver * * * a controlled substance,'' 21 U.S.C. 802(11), which is what an exporter does when it ships a product to a foreign entity.

DEA has never interpreted the Act in this manner for obvious reason—it would render the CSIEA a nullity. And contrary to Respondent's second contention that Federal law is ambiguous, both the statutes and our regulations make clear that Respondent was required to obtain an Exporter's registration to ship controlled substances to foreign countries.

Indeed, Respondent completely ignores the clear text of the Export Registration provision, 21 U.S.C. 957(a). This section expressly provides that ''[n]o person may * * * export from the United States *any controlled substance* * * * unless there is in effect with respect to such person a registration issued by the Attorney General *under section 958 of this title,* or unless such person is exempt from registration under subsection(b) of this section.'' 21 U.S.C. 957(a) (emphasis added).

While the statute does not define the term ''export,'' the regulations do. *See* 21 CFR 1300.01(b)(12). ''The term * * * means, with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).'' *Id.* Relatedly, the regulations define ''[t]he term *exporter* [to] include[ ] every person who exports * * * controlled substances listed in any schedule.'' *Id.* 1301(b)(13). Shipping a controlled substance to a person residing in a foreign country is to take out or remove the ''article from the jurisdiction of the United States,'' *id.* 1301(b)(12), even if the person the drug is being shipped to is an ultimate user.

Beyond that, Congress clearly stated that a person may not export a controlled substance, ''unless there is in effect with respect to such person a registration issued * * * under section 958 of this title.'' 21 U.S.C. 957(a). A practitioner's registration is not issued under section 958, but rather under section 823(f). It thus does not provide its holder with authority to export.

Nor is there any merit to Respondent's contention that because he shipped out only small amounts of controlled substances, he was not engaged in exporting. Section 957(a) clearly provides that exporting ''any controlled substance'' triggers the registration requirement unless a person falls within one of the three statutory exemptions. As the plain language demonstrates, there is no threshold amount which triggers the registration requirement. Rather, to export any amount, no matter how small, a person must first obtain an exporter's registration.[18]

The exemptions to the export registration requirement also foreclose Respondent's interpretation. While the statute exempts from registration ''[a]n ultimate user who possesses'' a controlled substance for lawful use by themselves or a family member, this provision does not apply to Respondent. 21 U.S.C. 957(b)(1)(C). Under this exemption, an ultimate user must have the controlled substance ''in his possession'' at the time of export from the United States. *Id.* section 956(a)(1). Shipping controlled substances to persons in foreign countries is thus not within this exemption; the other exemptions are not remotely applicable to Respondent's conduct. *See id.* Section 957(b)(1).

DEA's Regulations also provided clear notice to Respondent that he was required to register as an Exporter. Under 21 CFR 1301.13(e), ''[a]ny person who is required to be registered and who is not so registered, shall make application for registration for one of the following groups of controlled substance activities, which are *deemed to be independent of each other.*'' (emphasis added). The regulation then provides a table that lists each activity and the coincident activities that are permissible under a registration for a particular activity. As the table makes clear, dispensing and exporting are independent activities. *See id.* Moreover, exporting is not included in the Regulation's discussion of the ''[c]oincident activities allowed'' for a registration which authorizes dispensing. *See id.*

As the foregoing demonstrates, the law and regulations provided clear notice to Respondent that he could not ship controlled substances to persons residing in foreign countries without obtaining an export registration. And while it is true that Respondent was not required to obtain an Export Permit for either the testosterone or phentermine he exported,[19] he was still required to file an Export Declaration (DEA—Form 236) and submit ''documentary proof that [the] importation is not contrary to the laws or regulations of the country of destination'' for each shipment. 21 U.S.C. 953(e).[20]

As the record demonstrates, phentermine is a controlled substance in Belgium, Canada, Germany, Indonesia, Japan, the Republic of Korea, and Taiwan. Gov. Exh. 38(c), at 5. The record also establishes that both Japan and Taiwan prohibit the importation of this drug. *Id.* at Tabs D & E. Furthermore, testosterone is controlled in both Canada and the United Kingdom. *See id.* at 5.

Respondent's failure to declare these shipments to DEA prevents the United

[18] Indeed, each exportation was a felony under Federal law. *See* 21 U.S.C. § 960.

[19] While the DI may have misinformed Respondent that he was required to obtain a permit, she did not tell him that he had no obligation to comply with Federal law.

[20] Respondent also contends that he was not required to file the declarations (DEA Form 236) because the form ''requires the listing of the name and address of the 'foreign consignee/consignor,'" and that ''[i]n this case, there is no 'foreign consignee/consignor,' since the recipients are end user patients.'' Resp. Br. 26. Respondent further contends that these ''terms are used in trade to describe the persons from whom and to whom goods are shipped for sale to third parties.'' *Id.*

The short answer to this contention is that in common usage, the term ''consignee'' means ''one to whom something is consigned or shipped.'' *Merriam-Webster's Collegiate Dictionary* 246 (10th ed. 1998). Beyond that, the record contains a copy of the ''Commercial Invoice'' form that Respondent used to ship products (including testosterone) to his foreign patients. Gov. Exh. 107, at 20. Under this form, which used the term ''consignee,'' Respondent's clinic inserted the patient's name. *See id.*

States from fulfilling its treaty obligations and denies the country of destination the opportunity to determine whether a shipment of a controlled substance is permissible before it occurs. *See id.* at 3. It thus undermines the system of international cooperation to prevent the illegal flow of controlled substances. *See, e.g.,* Convention on Psychotropic Substances, 1971, Art. 21 (''[T]he Parties shall * * * [a]ssist each other in the campaign against the illicit traffic in psychotropic substances * * * [and] [c]o-operate closely with each other * * * with a view to maintaining a co-ordinated campaign against the illicit traffic.'').

Respondent further contends that he acted in good faith to obtain an Export registration. But as explained above, Federal law makes clear that ''[n]o person may* * * export from the United States any controlled substance * * * unless [a registration] is in effect,'' 21 U.S.C. 957(b), and the regulations further provide that a person cannot ''engage in any activity for which registration is required until the application * * * is granted and a Certificate of Registration is issued.'' 21 CFR 1301.13(a). Determining whether the granting of an application for an export registration is consistent with the public interest requires an extensive and time consuming investigation into the same criteria that apply to manufacturers. 21 U.S.C. 958(c) & 823(d). Granting such a registration is not a ministerial act, and in this case, the conduct uncovered before Respondent even applied for the registration was enough to deny his application.

Furthermore, the record establishes that Respondent subsequently acted with deliberate disregard for the requirements of federal law. Both during the August 2001 management conference, and in several faxes thereafter, Respondent was warned by the DI to stop the foreign shipments. He nonetheless continued to send controlled substances to persons in foreign countries. Furthermore, notwithstanding the service of the Notice of Immediate Suspension of his registration, Respondent made further dispensings of controlled substances to persons who resided both within the U.S. and abroad. Respondent's conduct demonstrates that he acted with a deliberate disregard for the law.

The Import Allegations

The record also contains evidence suggesting that Respondent obtained testosterone products from Mexico. This evidence includes the invoice which Respondent gave the DI during the August 2001 management conference. Specifically, the invoice, which was dated June 26, 2001, indicated that PSLEI had purchased 120 units of Depo testosterone and 40 units of Decadurabolin from Farmacias Castaneda, which listed its address as Tijuana, Mexico. Gov. Exh. 22. Moreover, during the February 2002 trash run, the DIs found 50 empty boxes of a testosterone product that had been manufactured by Brovel, S.A., a Mexican firm. Tr. 709, Gov. Exh. 58.

The ALJ concluded that the Government had failed to prove that Respondent ''received imported controlled substances from Mexico,'' apparently because the record ''contains evidence that the owner of the Mexican pharmacy, Dr. Romero, may have shipped the controlled substances from a location in San Diego.'' ALJ 75. The ALJ further explained that ''[t]here are no shipping documents in the record to refute this evidence.'' *Id.*

Romero was not, however, a registered importer. And even accepting the ALJ's finding that the drugs may have been shipped to Respondent from a location in San Diego, I do not find persuasive the ALJ's reasoning that Respondent therefore did not engage in importation. Indeed, I conclude that the ALJ's reasoning is contrary to well settled authority and that adopting it would gut Federal drug laws.

''Importation is a continuing crime that is not complete until the controlled substance reaches its final destination.'' *United States* v. *Camargo-Vergara*, 57 F.3d 993, 1001 (11th Cir. 1995); *see also United States* v. *Martinez,* 763 F.2d 1297, 1304 (11th Cir. 1985). The fact that someone else brought the drugs across the border, or that the drugs were shipped from a way station within the United States, does not make the final intended recipient any less an importer. As the Fifth Circuit has explained, one ''need not have participated directly in the physical movement of the [controlled substance] across the border to be convicted under 21 U.S.C. 952(a).'' *United States* v. *Lopez-Escobar,* 920 F.2d 1241, 1245 (1991). Indeed, drug dealers frequently use third parties to smuggle controlled substances into this country. That does not make them any less an importer.

Rather, the Government need only show that ''the defendant knowingly played a role in bringing the substance from a foreign country into the United States,'' *United States* v. *Jackson,* 55 F.3d 1219, 1225 (6th Cir. 1995); or that ''the defendant either imported the substance or caused it to be imported.'' *United States* v. *Nusraty,* 867 F.2d 759, 766 (2d Cir. 1989); *Accord United States* v. *Samad,* 754 F.2d 1091, 1096 (4th Cir. 1984). *See also United States* v. *Diaz-Carreon* 915 F.2d 951, 953 (5th Cir. 1990). The Government's proof satisfies either standard.

The Farmacia Castaneda invoice clearly establishes that: (1) Two controlled substances were shipped to Respondent, and (2) that the source of the controlled substances was a Mexican based pharmacy notwithstanding that the substances may have been shipped from Mr. Romero's San Diego address. The invoice further establishes that (3) Respondent caused the controlled substances to be imported by ordering them from the pharmacy. Finally, Respondent does not dispute that he received these two controlled substances but rather only whether the substances ''came from San Diego, [and] not Mexico.'' Resp. Proposed Findings at 14. The record thus contains substantial evidence that Respondent imported controlled substances.

Under Federal law, ''[n]o person may * * * import into the United States from any place outside thereof, any controlled substance * * * unless there is in effect with respect to such person a registration issued * * * under section 958 of this title'' or the person ''is exempt from registration under subsection(b).'' 21 U.S.C. 957(a). Respondent was not registered as an importer, Gov. Exh. 2, and does fall within any of the three exemptions. *See* 21 U.S.C. 957(b). I thus conclude that Respondent violated federal law when he imported depo testosterone and decadurabolin from Mexico without being registered to do so.[21]

The Record Keeping Violations

The record further establishes that Respondent committed numerous recordkeeping violations. Beginning

[21] I have reviewed Respondent's contention that these allegations should be dismissed because they were not alleged in the Order to Show Cause. While it is true that our regulations and the Administrative Procedure Act require that an Order to Show Cause contain ''a summary of the matters of fact and law asserted,'' 21 CFR 1301.37(c), an agency is not required ''to give every [Respondent] a complete bill of particulars as to every allegation that [it] will confront.'' *Boston Carrier, Inc.* v. *ICC,* 746 F.2d 1555, 1560 (D.C. Cir. 1984).

Having reviewed the pre-hearing statements, I conclude that the Government gave Respondent fair notice that the import allegations would be raised and litigated. I further conclude that Respondent had ''a meaningful opportunity to litigate the * * * issue in the hearing itself.'' *NLRB* v. *Blake Construction Co., Inc.*, 663 F.2d 272, 279 (D.C. Cir. 1981). The Government's refusal to turn over FedEx documents that would have shown that the two controlled substances had been shipped from Romero's San Diego location did not deny Respondent a meaningful opportunity to litigate the issue; indeed, I accept that the steroids may have been shipped to Respondent from a San Diego address.

with the 1994–95 investigation, during the execution of the search warrant, none of the required records were found even though Respondent had purchased a variety of controlled substances included various anabolic steroids and diazepam.

Moreover, on January 31, 2001, DEA visited Respondent's clinic and requested to see its controlled substance records. The invoices for the purchase of controlled substance were not on-site, but rather were at the office of the clinic's accountant. This violated 21 CFR 1304.04(a). Moreover, the inventory records and dispensing logs were stored in a computer system and no one was present at the clinic who could access them. Tr. 269.

DEA regulations require that ''each registered individual practitioner required to keep records'' shall maintain the records ''either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.'' 21 CFR 1304.04(g) & (f)(2). As relevant here, DEA regulations define the term ''readily retrievable'' to mean ''that certain records are kept by automatic data processing systems or other electronic or mechanized record-keeping systems in such a manner that they can be separated out from all other records *in a reasonable time*.'' *Id.* § 1300.01(b)(38) (emphasis added).

Respondent is correct that this regulation does not require that records be ''instantaneously produced.'' Resp. Br. 9. Moreover, the record does not indicate how long DEA personnel were at the clinic during the January 31, 2001 visit. Accordingly, there is no basis to conclude that the inventory and dispensing records were not readily retrievable on that date.

I nonetheless note Respondent's argument that he ''was not required to produce his records on the same day as the DEA's demand.'' *Id.* at 17. This is so, Respondent contends, because ''[n]either the statute nor the regulation prescribes a time limit within which a practitioner must produce his controlled substance records upon the DEA's request to examine them.'' *Id.*

The regulation does, however, require that records be retrievable in ''a reasonable time.'' While what constitutes ''a reasonable time'' necessarily depends on the circumstances, under normal circumstances if a practice is open for business, it should be capable of producing a complete set of records within several hours of the request. In this case, I conclude that on the second visit, the clinic's provision of the records within two to three hours complied with the regulation but barely so. To allow a registrant an even greater period of time to produce the records would create an incentive for those who are engaged in illegal activity to obstruct investigations by stalling for time in the hopes that DEA personnel would eventually give up and leave.

Most significantly, the records that were provided did not comply with DEA's regulations. The ''inventory report'' was dated February 5, 2001. It did not include a DEA number for either Respondent or his associate and did not indicate that it had been done at the opening or closing of business. 21 CFR 1304.03(a) & 1304.11(a). Furthermore, the dispensing logs did not reflect the name of the dispensing registrant. *Id.* § 1304.03(b). Moreover, the logs covered only a period of approximately seven months and not the required two years. *Id.* § 1304.04(a). Finally, no invoices for testosterone were provided even though the other records clearly showed that the PSLEI had testosterone products on hand and was actively dispensing them. *Id.* § 1304.21(a).

Nor were Respondent's recordkeeping violations limited to this time period. During the March 2002 Administrative Inspection, DEA personnel again requested to inspect Respondent's records including the required inventories. While Respondent was not available, the clinic could not provide the required inventories for the various controlled substances that were being dispensed. *See* ALJ 23.

Other Violations

The record contains evidence of further violations of DEA regulations during the period of Respondent's ownership. In March 2001, Respondent's clinic used Connie Chein's DEA number to order controlled substances even though Ms. Chein did not practice at the clinic and the clinic was not her registered location. *See* Gov. Exh. 45(a). This was a violation of 21 U.S.C. 843(a)(2) (prohibiting use of a registration number ''issued to another person'' for purpose of obtaining controlled substances). Moreover, Respondent's employees ordered controlled substances for the clinic using Dr. Garber's registration and had them shipped to Dr. Garber's residence, which was no longer a registered location. *See* Gov. Exh 45(b), (c), (d) & (g). This conduct undermines the CSA's closed system of distribution which requires that a registrant maintain a registration at each place of business from where a registrant distributes controlled substances. 21 U.S.C. 822(e); 21 CFR 1301.12. Under DEA precedents, a registrant is responsible for violations of the CSA committed by his employees and his practice's failure to comply with the Act. *See Leonard Merkow*, 60 FR 22075, 22076 (1995).

In conclusion, the evidence of Respondent's non-compliance with applicable laws related to controlled substances is extensive and shocking. Taken as a whole, Respondent's record reflects a flagrant disregard for the requirements of Federal law. Accordingly, I conclude that Respondent's continued registration as a practitioner would be inconsistent with the public interest.[22]

Respondent's Export Application

Section 1008 of the Controlled Substances Act provides that ''[t]he Attorney General may deny an application for registration [to export controlled substances in schedule III or IV] * * * if he determines that such registration is inconsistent with the public interest * * * or with the United States obligation under international treaties, conventions, or protocols in effect on May 1, 1971.'' 21 U.S.C. 958(d)(2). In making the public interest determination for an application to export Schedule III and IV controlled substances, Congress further directed that the Attorney General consider the factors applicable to manufacturers of Schedule III through V controlled substances. *Id.* section 958(c)(1). The factors are:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) Such other factors as may be relevant to and consistent with the public health and safety.

[22] I acknowledge that Respondent has not been convicted under either Federal or State law of a controlled substances offense. Given Respondent's extensive record of non-compliance with applicable laws, this factor is entitled to no weight. Moreover, because Respondent's record of violations is extensive enough to support the revocation of his registration, it is not necessary to discuss whether he engaged in other conduct which threatens public health and safety.

21 U.S.C. 823(d). As with the public interest determinations applicable to other categories of registrants, ''these factors are * * * considered in the disjunctive.'' *ALRA Laboratories, Inc.,* 59 FR 50620, 50621 (1994). I ''may * * * rely on any one or a combination of factors, and give each factor the weight [I] deem appropriate'' in considering whether to grant Respondent's application. *Id.* Moreover, case law establishes that I am ''not required to make findings as to all of the factors.'' *Hoxie*, 419 F.3d at 482.

Here, while Congress has directed a slightly different analysis than that applicable to Respondent's practitioner's registration, I conclude that the same reasons that support the revocation of that registration also require the conclusion that granting Respondent's application for an export registration would be inconsistent with the public interest. There is no need to engage in a lengthy rehashing of those factors (such as Respondent's past experience and lack of compliance with Federal law) which have already been discussed; that discussion is therefore incorporated by reference.

Both factors one and five inquire into whether an applicant has effective controls against diversion. Respondent clearly does not as demonstrated by his clinic's repeated failure to provide DEA with either initial or biennial inventories that complied with the regulations. Accurate inventories are essential to conduct accountability audits and to determine whether diversion has occurred.

Respondent asserts that ''[t]here was no diversion of controlled substances from the legitimate chain of distribution.'' Resp. Br. 6. That is not so. The record contains abundant evidence that phentermine was sent to patients in Japan, Korea, and Taiwan. *See* Gov. Exh. 128. As demonstrated by a letter from a Japanese Ministry of Health official, it was illegal to export phentermine to Japan (although a person is allowed to bring in a small amount of the drug on his person). *See* Gov. Exh. 38(C). Furthermore, Taiwan had prohibited the use of phentermine and its importation. Finally, the record indicates that it is illegal to prescribe phentermine for anti-aging purposes in Korea and Japan.

Both Japan and the United States have ratified the 1971 Convention on Psychotropic Substances, which regulates phentermine; the Republic of Korea has also become a party to the Convention by accession.[23] As explained above, under the Convention, the United States agreed to undertake certain measures including assisting other parties ''in the campaign against the illicit traffic in psychotropic substances.'' Convention on Psychotropic Substances Art. 21(b).

In light of the authority that an export registration grants, as well as our treaty obligations, it is appropriate to consider the potential impact of Respondent's conduct not only on this country, but also on other parties to the Convention.[24] The statements of various government officials regarding the prohibition on the exportation of phentermine to their countries, as well as other evidence that it is illegal to prescribe phentermine for anti-aging purposes in several of these countries, establish that Respondent's exports of phentermine to foreign patients were not within the legitimate chain of distribution and were not for a legitimate medical purpose. The shipments thus establish that Respondent has engaged in diversion. I therefore conclude that Respondent's past experience in distributing and dispensing controlled substances demonstrates that his practice lacks effective controls against diversion—indeed, he is the cause of the diversion—and that this factor further supports a finding that granting Respondent's application would be inconsistent with the public interest. For the same reason, factor one supports a finding that granting Respondent's application would be inconsistent with the public interest.

The ALJ found that Respondent has promoted technical advances in the development of new substances (Factor 3) as demonstrated by his obtaining of several patents including one for his total hormone replacement therapy. *See* ALJ at 80. The ALJ further concluded that granting Respondent an export registration ''would enhance his ability to continue to develop [the] therapy for his patients.'' *Id.*

I acknowledge that Respondent has obtained various patents for his treatment regimen and had applied for a patent for a particular testosterone composition. *See* Resp. Ex. 1016. Even so, Respondent's contributions in this area are greatly outweighed by his record of misconduct and his flagrant disregard for the requirements of federal law. This factor is thus entitled to no weight. I further note, however, that denying Respondent's application for an export registration (and revoking his practitioner's registration) does not preclude him from developing new treatment protocols. Respondent can continue to do so as long as he limits his research to non-controlled substances.

Finally, in discussing other relevant factors (Factor 6), the ALJ found ''that the public has an interest in the continued access to Respondent's total hormone replacement therapy,'' and suggested that I could consider this in deciding whether to deny Respondent's application for an export registration (as well as to revoke his practitioner's registration). ALJ at 81. I need not decide whether this is an appropriate consideration under the statute because even if it is, Respondent's extensive history of misconduct clearly outweighs any benefit to the public that would accrue from allowing Respondent to handle controlled substances as either an exporter or practitioner. And in any event, Respondent can always license his patents to other physicians or offer to teach them his medical discoveries.

Considering all of the factors, I conclude that Respondent's past experience in distributing and dispensing controlled substances is entitled to dispositive weight in the public interest determination applicable to his application for registration as an Exporter. Because that experience manifests a sustained and flagrant disregard for the requirements of Federal law, I conclude that granting Respondent's application would be inconsistent with the public interest.[25]

[23] Taiwan was also a signatory to the Convention on Psychotropic Substances. It is acknowledged that Republic of China has declared Taiwan's ratification of the Convention to be null and void.

[24] *Noramco* v. *DEA,* 375 F.3d 1148, 1156 (D.C. Cir. 2004), is not to the contrary. That case involved an assertion by a competitor of a domestic manufacturer that granting the latter an importer's registration would lead to increased diversion of narcotic raw materials in India, the country of origin. *See Penick Corp., Inc.,* 68 FR 6947, 6951 (2003). While this assertion was entirely speculative, my predecessor further ruled that DEA was not required to consider the impact on diversion in the country of origin. *See id.* In affirming that interpretation as a reasonable construction of the statute, the court of appeals reasoned that ''Congress was concerned with preventing diversion in this country rather than abroad.'' 375 F.3d at 1156.

Here, however, Federal law expressly requires that an exporter, before exporting any nonnarcotic controlled substance in schedules III or IV, ''furnish'' to DEA ''documentary proof that importation is not contrary to the laws or regulations of the country of destination for consumption for medical, scientific, or other legitimate purposes.'' 21 U.S.C. 953(e)(1). Thus, in contrast to the situation at issue in *Penick,* here, other provisions of the CSIEA suggest that in assessing Respondent's application, it is appropriate to consider the potential for diversion of the controlled substance in the destination country.

[25] Even if the Court of Appeals was to disagree with my finding that Respondent was still in charge of the Palm Springs clinic's dispensation of controlled substances during the period of his

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, AC1643661, issued to Edmund Chein, M.D., be, and it hereby is, revoked. I also order that any pending applications for renewal or modification of such registration be, and they hereby are, denied.

Pursuant to the authority vested in me by 21 U.S.C. 958(d), as well as 28 CFR 0.100(b) & 0.104, I further order that the application of Edmund Chein, M.D., for a DEA Certificate of Registration as an Exporter of controlled substances be, and it hereby is, denied.

Dated: January 19, 2007.

Michele M. Leonhart,

Deputy Administrator.

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sister's putative ownership, the scope of his misconduct during the periods in which he owned the clinic is so extensive and egregious that I would still revoke his practitioner's registration and deny his exporter's application.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Prohibited Transaction Exemption 2007–03; Exemption Application No. D–11381]

Grant of Individual Exemption Involving The Bear Stearns Companies, Inc. (BS), Bear Stearns Asset Management Inc. (BSAM), and Bear, Stearns & Co. Inc. (BSC) (Collectively, the Applicants) Located in New York, NY

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor.

ACTION: Grant of individual exemption.

SUMMARY: This document contains a final exemption issued by the Department of Labor (the Department) that provides relief from certain prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and the Internal Revenue Code of 1986 (the Code). The exemption permits the purchase of certain securities (the Securities), by an asset management affiliate of BS from any person other than such asset management affiliate of BS or any affiliate thereof, during the existence of an underwriting or selling syndicate with respect to such Securities, where a broker-dealer affiliated with BS (the Affiliated Broker-Dealer) is a manager or member of such syndicate and the asset management affiliate of BS purchases such Securities, as a fiduciary: (a) On behalf of an employee benefit plan or employee benefit plans (Client Plan(s)); or (b) on behalf of Client Plans, and/or in-house plans (In-House Plans) which are invested in a pooled fund or in pooled funds (Pooled Fund(s)); provided certain conditions as set forth, below are satisfied (An affiliated underwriter transaction (AUT)).[1] The exemption affects Client Plans and In-House Plans and their participants and beneficiaries.

EFFECTIVE DATE: This exemption is effective as of the date it is published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Angelena C. Le Blanc, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor, telephone (202) 693–8540. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On November 24, 2006, the Department published a Notice of Proposed Exemption (the Notice) in the **Federal Register** at 71 FR 67904. The document contained a proposed individual exemption from the restrictions of section 406 of the Act and section 4975(c)(1)(A) through (F) of the Code. The proposed exemption had been requested in an application filed by the Applicants, pursuant to section 408(a) of the Act, and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Accordingly, this exemption is being issued solely by the Department.

The proposed exemption gave interested persons an opportunity to comment and to request a hearing. In this regard, all interested persons were invited to submit written comments or requests for a hearing on the pending exemption on or before January 8, 2007.

The Applicants informed the Department in a letter dated January 5, 2007, that the Notice along with the supplemental statement (the Supplemental Statement), described at 29 CFR 2570.43(b)(2) of the Department's regulations, was sent by December 9, 2006, via first class mail to all Interested Persons with the exception of two (2) such Interested Persons. The Applicant further informed the Department that the Notice and the Supplemental Statement was sent by December 13, 2006, via first class mail to these two (2) remaining Interested Persons. In light of the fact that notification to these Interested Persons was delayed and in order to allow such Interested Persons the benefit of the full thirty (30) day comment period, the Department required, and the Applicants agreed to, an extension of the deadline within which these two (2) Interested Persons could comment or request a hearing on the proposed exemption. In this regard, in accordance with the Department's instructions, the Applicants sent a letter on December 19, 2006, to these Interested Persons notifying them that the comment period was extended until January 15, 2007. All comments were made part of the record.

During the comment period, the Department received no requests for a hearing. The Department did receive a comment letter from the Applicants. The written comments and the responses are discussed below.

Written Comments

In a letter dated, January 5, 2007, the Applicants' suggested revisions of the language in paragraph 19 of the Summary of Facts and Representations, as published in the Notice at 71 FR 67907, column 1, lines 58–69, and column 2, lines 1–22, in order to reflect changes in the law regarding ''hot issues.''

The Department concurs with the Applicants' suggested revisions. In this regard, paragraph 19 of the Summary of Facts and Representations, as set forth in the Notice, should have read as follows:

19. Assuming that the marketing efforts have produced sufficient indications of interest, the Applicants represent that the issuer of the securities and the selling syndicate managers together will set the price of the securities and ask the SEC to declare the registration effective. After the registration statement becomes effective and the underwriting agreement is executed, the underwriters contact those investors that have indicated an interest in purchasing securities in the offering to execute the sales. The Applicants represent that offerings are often oversubscribed, and many have an over-allotment option that the underwriters can exercise to acquire additional shares from the issuer. Where an offering is oversubscribed, the underwriters decide how to allocate the securities among the potential purchasers. However, pursuant to the National Association of Securities Dealers Rule 2790, new issue securities (as defined under such rule) may not be sold directly to:

[1] For purposes of this exemption an In-House Plan may engage in AUT's only through investment in a Pooled Fund.