ORAL ARGUMENT REQUESTED

IN THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Case No. 07-1051

EDMUND CHEIN, M.D.,

Petitioner,

v.

MICHELE M. LEONHART, IN HER OFFICIAL CAPACITY AS DEPUTY ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION; THE U.S. DRUG ENFORCEMENT ADMINISTRATION; THE U.S DEPARTMENT OF JUSTICE; and the UNITED STATES OF AMERICA,

Respondents.

On Review from an Order of the Deputy Administrator of the U.S. Drug Enforcement Administration

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BRIEF FOR PETITIONER

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with Circuit Rule 28(a)(1), Petitioner Edmund Chein, M.D. ("Dr. Chein") states the following:

PARTIES AND AMICI

In the Drug Enforcement Administration's (DEA's) administrative hearing below, there were no intervenors or amici.

RULINGS UNDER REVIEW

Dr. Chein has petitioned this Court for review of Edmund Chein, M.D.; Revocation of Practitioner's Registration, Denial of Application for Exporter's Registration, 72 Fed. Reg. 6580 (Feb. 12, 2007) ("Decision"). A copy of the Decision appears in the appendix at _____.

The Decision followed the July 28, 2005 ruling of Gail A. Randall, Administrative Law Judge: In the matter of Edmund Chein, M.D., Recommended Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, Docket Nos. 02-9 and 02-43, U.S. Department of Justice, DEA ("FOF"). A copy of that ruling appears in the appendix at _____. There is no published citation for the ruling.

RELATED CASES

There are no cases related to this one.

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Statutory and Regulatory Addendum attached

TABLE OF AUTHORITIES

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Cases

Statutes and Regulations

This Court should reverse the Decision of Deputy Administrator Michele M. Leonhart ("Leonhart") permanently revoking Dr. Chein's DEA Certificate of Registration, AC1643661 ("Registration"), and denying Dr. Chein's application for registration as an exporter of controlled substances. 72 Fed. Reg. at 6585. The Decision is based on unproven supposition; unexplained deviation from established DEA policies, procedures, and precedent; violations of Due Process; improper withholding of material evidence; violations of statutory provisions concerning registration; and an extension of law beyond statutory limits, all in violation of the Administrative Procedure Act's (APA's)substantial evidence requirement, prohibition on agency actions that are arbitrary, capricious, and contrary to law, and prohibition on abuse of discretion.

JURISDICTION

Under Federal Rule of Appellate Procedure 28(a)(4)(A-D):

(A) DEA had jurisdiction over Dr. Chein's prescribing and dispensing of controlled substances as a physician registered under the Controlled Substances Act ("CSA"), 21 U.S.C. § 822(a)(2). Dr. Chein was registered (No. AC1643661) to prescribe and dispense Schedules II, II-N, III, III-N, IV, and V controlled substances. 72 Fed. Reg. at 6582. The DEA also had jurisdiction over Dr. Chein in light of his April 27, 2001 application for a registration to export non-narcotic Schedule III and Schedule IV controlled substances pursuant to 21 U.S.C. § 957.

(B) This is a petition for review of an order of a federal administrative agency. This court has subject matter jurisdiction in accordance with 21 U.S.C. §877. That section grants review of the Decision to this Court.

(C) The Decision of Deputy Administrator Leonhart was published in the Federal Register on February 12, 2007. According to the Federal Register, the Decision was issued on January 19, 2007. Dr. Chein received his mailed copy of the Decision after it was published in the Federal Register. The copy sent to him was dated February 21, 2007, reciting "for the purposes of 21 U.S.C. §877, notice of this final order is rendered on the date of publication [in the Federal Register]." Dr. Chein timely filed his petition for review of the order on February 20, 2007, eight days after the date of publication in the Federal Register and within the 30 day statutory time period for filing.

(D) This petition for review is from a final order that disposes of all DEA claims against Dr. Chein pursuant to 21 U.S.C. §877.

ISSUES PRESENTED

Issue 1: Whether the DEA Deputy Administrator abused her discretion and acted arbitrarily and capriciously when she deviated without explanation from DEA's practice of aiding physicians possessing registrations who have dispensed and intend to continue dispensing controlled substances to foreign patients to meet DEA requirements (a) by guiding them to file DEA Form 236 and (b) by guiding them in verifying that the recipient country accepts import of the controlled substance, all without taking any adverse action against them or requiring them to file an application for export registration.

Issue 2: Whether the DEA Deputy Administrator abused her discretion and acted arbitrarily and capriciously in violation of the APA when she revoked Dr. Chein's Registration without recognizing, let alone explaining, apposite DEA cases in which Registrations were not revoked.

Issue 3: Whether the DEA Deputy Administrator exceeded CSA statutory limits, violated controlling precedent, abused her discretion and lacked substantial evidence when she held Dr. Chein to have engaged in illegal import of controlled substances from Tijuana, Mexico when the evidence of record establishes that Dr. Chein received a shipment of controlled substances not from Tijuana, Mexico but from a pharmacy in Chula Vista, California, and there is no evidence whatsoever that he participated in or otherwise caused controlled substances to be brought into the United States from Mexico.

Issue 4: Whether the DEA Deputy Administrator violated the plain and intended meaning of the Controlled Substances Act (CSA), 21 U.S.C. §823, when she held Dr. Chein liable for alleged CSA violations committed by other physicians, who made 317 shipments to which she objected, but who possessed and acted under their own Registrations, such that her Decision failed to comply with the "public interest" test, deviated from DEA practice, and was arbitrary, capricious, contrary to law, and an abuse of discretion in violation of the APA, 5 U.S.C. §706(2)(A).

Issue 5: Whether the DEA Deputy Administrator lacked substantial evidence and applied the wrong legal standard (the one for narcotics in 21 U.S.C. §827(b)(2)(A) rather than for non-narcotics in 21 U.S.C. §827(b)(2)(B)) to evaluate the sufficiency of Dr. Chein's production of documents demanded by the agency such that her determination concerning his recordkeeping practices violates the APA, 5 U.S.C. §706(2)(A),(E); 21 U.S.C. §877.

Issue 6: Whether DEA's contemporaneous representations to Dr. Chein that DEA had received all records sought by the agency and that none additional need be supplied renders the DEA Deputy Administrator's post hoc rationalizations to the contrary arbitrary and capricious agency action, an abuse of discretion, and reasoning not supported by substantial evidence in violation of the APA, 5 U.S.C. §706(2)(A and E); 21 U.S.C. §877.

Issue 7: Whether the DEA Deputy Administrator violated Dr. Chein's Fifth Amendment right to Due Process, lacked substantial evidence required by 21 U.S.C. §877, abused her discretion and acted arbitrarily and capriciously in violation of the APA when she: (a) evaluated evidence in contravention of a pre-hearing *in limine* agreement of the parties; (b) condoned the absenting of a material government witness (against an ALJ order to appear); (c) condemned Dr. Chein for allegedly failing to produce certain records to the DEA when DEA by warrant seized and possessed those documents, yet refused to produce them at hearing; and (d) condemned Dr. Chein for illegal importation yet refused to produce records seized from him at hearing that reveal no basis for the illegal importation charge.

Issue 8: Whether absent any evidence of record that Dr. Chein's prescriptions had been diverted to the illicit drug trade, Dr. Chein's medical dispensing of personal use amounts of testosterone in forms such as gels and in low doses to patients is drug "diversion" within the meaning of the CSA or whether that conclusion by the DEA Deputy Administrator is an abuse of discretion, lacks substantial evidence, is arbitrary and capricious, and is contrary to law in violation of the APA, 5 U.S.C. §706(2)(A),(E).

STATUTES AND REGULATIONS

Under Circuit Rule 28(a)(5), pertinent statutes and regulations are in an addendum preceded by a table of contents.

FACTS

Dr. Chein is one of the world's leading authorities in the field of anti-aging medicine. See Trial Transcript ("Tr.") 2720. In 1990, he began studying the effects of age related hormone depletion effects on human physiology. See Government's Exhibit ("GX") 4 at 7. His research led to a series of seminal publications in which he postulated that hormones, including testosterone and estrogen, if replenished to youthful levels in aging adults, could retard aging and enhance overall health. See e.g., Respondent's exhibits ("RX") 1050. Those publications were the subject of critical acclaim. See RX 1052. Dr. Chein explained that every adult experiences hormone level reductions over time and those reductions coincide with outward and inward signs of aging: wrinkling, reduction in the elasticity of bones, diminution in the presence of elastin and collagen in the face and joints, increase in fat stores, decrease in muscle mass, and increase in the risk of heart disease, cancer, diabetes, and other age-related diseases. See RX 1017. Dr. Chein explained that through gradual increases in hormones to those approximating youthful levels, along with exercise and diet modification, individuals can slow the process of aging and delay the onset of, or prevent, age-related conditions. See id. Dr. Chein invented the concept of "total hormone replacement therapy" ("THRT") as a means of gradually restoring hormones to youthful levels. Id. Traditional gastroenterology administers

hormones when they are less than those common in people of comparable age; THRT, by contrast, calls for hormone administration when hormone levels drop below those of a typical healthy young adult.

Dr. Chein is one of the first physicians in the world to create a new field of medical practice, anti-aging medicine, obtaining patents in the U.S. and U.K. on his methods. FOF 40 at 10; RX 1017. A physiological complement to the aesthetic practice of plastic surgery, anti-aging medicine aims to use THRT, exercise, and diet modification to support body maintenance and reconstruction of all organ systems. See RX 1053. Dr. Chein is recognized by his peers as one of the early pioneers in the field. See Tr. at 2709; RX 1052. He is world renowned for his research, his treatment protocols, and his patient outcomes. See RX 1052; Tr. 2721. He instructs physicians worldwide on the appropriate means to administer THRT. See Tr. at 1775-76. His protocols have become widely accepted. See Tr. at 2709; 2072. Over three hundred of Dr. Chein's patients are physicians. See Tr. at 1774. He has treated over one thousand patients at his clinic since its inception in 1994. See Tr. at 2731. His protocol depends on administration of very low doses of hormones over an extended period of time, accompanied by continued monitoring of baseline hormone levels until they slowly rise to approximate levels of a healthy young adult. See Tr. 1880-81; RX 1017.

Patients from around the world seek treatment from Dr. Chein. See Tr. at 1235–36. Foreign patients are evaluated by Dr. Chein in California or at affiliated

clinics overseas. See Tr. at 2721; 2726. Others have been evaluated by Dr. Chein and his associates using a combination of video conferencing from their foreign countries and local testing by an attending physician. See Tr. at 2782; 2784; 2664; GX 95, 104,105,110; RX 1085, 1086. Some have been evaluated by foreign physicians who have been trained by Dr. Chein and have adhered to his protocol for patient care. See Tr. 1633-36.

Upon diagnosis of age-status and evaluation of the visual, external signs of aging, and upon receipt of blood test results, Dr. Chein administers THRT in the ordinary course by prescribing low amounts of hormones to increase the patient's hormone levels to approximate those of a healthy young adult. See Tr. at 2900-10. Patient monitoring either by Dr. Chein or by those with whom he is affiliated follows thereafter, with blood work performed to ensure that hormone levels always remain within a safe range. See id.

DEA's Case from 1994 to 2007

Deputy Administrator Leonhart ("Leonhart") issued her February 12, 2007 Decision 13 years after DEA began its investigation of Dr. Chein. The DEA issued an Order to Show Cause and Notice of Immediate Suspension on November 7, 2001, seven years after the 1994 start of the government's investigation. More than a year after the order to show cause, the hearing was held in multiple parts over the course of that year: January 28–31, February 3–6, September 9–10, and

December 9–11, 2003. The ALJ issued her decision on July 28, 2005, two years after the close of the hearing and four years after the order to show cause.

In 1994 and 1995, Dr. Chein was visited by four undercover government agents, two from FDA, one from Customs, and one from DEA who posed as patients and fabricated symptoms. They each said they were athletes. All were adults and complained of symptoms common for career athletes, who often experience suboptimal hormone levels.[1] See Tr. 121, 123. One, FDA Special Agent William Brannon, said he was a rugby player who suffered form low muscle mass, loss of strength, and loss of endurance. See Tr. 118–20. Another, FDA Special Agent William Leitner, said he was a weight lifter and complained of low muscle mass and an injured disc in his back. See Tr. 120–21. Another, Customs Special Agent Gary Phillips, said he was a power lifter. Tr. 122. A fourth DEA Special Agent, David Garcia, said he was a power lifter. Tr. 122-125. Athletes, particularly those who lift weights, commonly suffer form low testosterone levels. See Hackney supra note 1. Based on each patient's respective descriptions of their physical regimens and complaints, verified by blood work showing suboptimal

[1] See Hackney, et. al, Testosterone and Endurance Exercise: Development of the "Exercise-Hypogonadal Male Condition", 92 Acta Physiol Hung. 121-37 (2005)(" an increasing amount of research studies in men indicate endurance exercise training has significant effects upon the major male reproductive hormone, testosterone, and the hypothalamic-pituitary-testicular axis that regulates reproductive hormones. This review article addresses one reproductive endocrine dysfunction found in exercising men, what has been deemed the "exercise-hypogonadal male condition". Specifically, men with this condition exhibit basal (resting-state) free and total testosterone levels that are significantly and persistently reduced.")

hormone levels, Dr. Chein prescribed them each low dose hormones, including a testosterone gel (a controlled non-narcotic substance) and vitamins and minerals. Tr. 124–26. The blood tests he obtained permit calibration of THRT for long-term administration and monitoring. GX 35 at 34–35. Jointly, the DEA and FDA executed a search warrant in March of 1996 and seized patient medical records, computers, inventories of controlled substances, and dispensing logs, including the records for the four undercover agents. Despite an order from the ALJ to produce the documents at hearing, DEA refused. Those items have never been returned to the clinic. Tr. 116; 153–55; FOF 83–85 at 23. Despite the fact that the undercover agents received thorough examinations and baseline hormone tests, along with prescriptions consistent with Dr. Chein's practice, Leonhart faulted Dr. Chein for his prescription practice without reasoned explanation, deeming the practice "without legitimate medical purpose." See 72 Fed. Reg. at 6590.

Leonhart's bias against THRT is reminiscent of a similar bias by a California insurance carrier. Dr. Chein's medical license was suspended by the California Medical Board ("the Board") on February 18, 2000. The complaint that preceded the suspension was not the complaint of a patient, but of an insurance company, Blue Shield, seeking a ruling that THRT was not within the standard of care. RX 1058 at 4. Dr. Chein sold and transferred the title of his clinic to his sister, Dr. Connie Chein, a California-licensed physician, during the period when his California Medical License was suspended, in compliance with California's

requirement that only licensed physicians own a medical practice. See Tr. at 1087. On September 26, 2000, the Superior Court of California found that the Board wrongfully suspended Dr. Chein's license. The Court ordered the Board to set aside its decision based on its finding that the Board had evaluated Dr. Chein's anti-aging practice under standards of traditional gastroenterology rather than under an appropriate standard of care applicable to anti-aging medicine. RX 1058. On January 4, 2001, Dr. Chein's California Medical license was reinstated. GX 4. Throughout the revocation period, Dr. Chein maintained a Medical license in Utah unaffected by the California Board's actions, and notified the DEA of his change of address. See FOF at 5; 11–13. During this period, Dr. Chein did not practice medicine out of the California clinic, which was managed by two other physicians, Drs. Vogt and Garber. See Tr. at 1087; 2511-2514.

DEA Diversion Investigator ("DI") Doris DeSantis ("DeSantis") arrived at Dr. Chein's clinic unannounced on January 31, 2001 for an inspection. See Tr. at 887. Dr. Chein was not present, but Dr. Darryl Garber ("Garber"), who managed the clinic, attempted to aid DeSantis. Tr. at 274. At that time, the records were on-site, but locked in an office accessible only by a pharmacist employed by the clinic to ensure privacy, security, and proper record keeping. Tr. at 274; 1650. The clinic had also installed sophisticated computer software, Micropharmacy, exclusively designed to maintain controlled substance records. Tr. 1650. When DeSantis returned unannounced on February 5, 2001, computer printouts of the requested

records were made available to her while she waited. See Tr. at 280; 893–894. The records were clearly labeled with dates. Tr. at 1252. DeSantis was asked if she needed or wanted any additional records. She said "no." Tr. 1252. When she reviewed the records on a later date, DeSantis realized that they only covered a period of approximately seven months, the period in which the clinic began using the Micropharmacy software. Id. DeSantis did not contact the clinic after she realized she did not have the complete set of records. Id. The dispensing records DeSantis obtained on February 5 served as the basis for her conclusion that there were 317 instances where controlled substances were dispensed to patients outside the United States. FOF 191 at 57. However, the period covering the 317 instances falls precisely within the period Dr. Chein neither owned, nor practiced, at the clinic. Tr. at 1087.

On March 9, 2001, DeSantis phoned Dr. Garber and informed him that the clinic was illegally exporting controlled substances. She faxed Dr. Garber "various provisions of Federal Law pertaining to the exporting of controlled substances." Tr. at 1245. Those "various provisions" did not include 21 U.S.C. §§957, 958. Throughout DeSantis' interactions with the clinic, she continued to apply the incorrect narcotics standards to the non-narcotic controlled substances Dr. Chein was registered to dispense. See Tr. at 907; 1800-01. DeSantis wrongly applied section 953(a) to assert that Dr. Chein needed to file an export application. Tr. at 949. Despite her admission that she should have at least telephoned Dr. Chein to

rectify her mistakes, DeSantis never did. She never made any attempt to inform him of the correct regulations. Tr. at 1004. Despite his good faith belief that an additional registration was not required, on March 27, 2001 Dr. Chein complied with DeSantis' demands and submitted an application for export registration (DEA Form 225). DEA received Dr. Chein's application on May 7, 2001 and charged Dr. Chein's credit card on May 15. See GX 48, at 3–4. Contrary to statutory requirements, 21 U.S.C. 958 ("The [Attorney General] shall register"), the application was not processed, however, and, contrary to the statement on the application form (which reads, "FEES ARE NOT REFUNDABLE"), Dr. Chein's application fee was refunded to his credit card. See GX 48 at 4. The application form bears a notation by a DEA export application staffer, "Already have DEA #." See GX 48 at 3; Tr. 2145. DEA never contacted Dr. Chein to tell him that his application had been withdrawn from processing. See Tr. at 2191-92.

On August 23, 2001, DeSantis met with Dr. Chein for a "management conference." See Tr. at 54. During the conference, DeSantis was provided with more invoices and records, including an invoice from Farmacias Castaneda, which despite having its headquarters in Tijuana, Mexico, delivered controlled substances from a Chula Vista (San Diego), California location. Tr. at 576. The DEA took and never returned Fedex airway bills that reflected that the shipment was from San Diego, not Mexico. Tr. 1503-05.

During the management conference, DeSantis reiterated the mistaken demand that Dr. Chein obtain an export permit under 21 U.S.C. §953 (a)(5), a provision which addresses the exportation of narcotic drugs. Tr. at 554. Having received no word on his prior export application, Dr. Chein confused and bewildered responded to DeSantis' renewed demand by filing a second export application along with a letter inquiring as to why his prior one had not been granted. See 72 Fed. Reg. at 6585 (citing GX 48 at 7–8). It was only after this second application and letter that Dr. Chein received a response from DEA. That response was not in the form of a correction of DEA's error or of helpful guidance but in the form of an Order to Show Cause, dated May 24, 2002. 72 Fed. Reg. at 6580.

On March 13, 2002, DEA executed an administrative inspection warrant on the clinic, seizing patient medical records, computers, inventories of controlled substances, and dispensing logs. FOF 83-85 at 23. In October of 2002, the DEA again served a search warrant on the clinic, seizing remaining documents and patient files. Tr. 153–55; FOF 83-85 at 23. The Government possessed those records at the time of the hearing but refused to release them, despite repeated requests by Dr. Chein that he be given access to his records to permit their use in his own defense. FOF n. 8 at 60.

On March 16, 2006, Dr. Chein entered into a Stipulation Agreement with the California Medical Board, which found that Dr. Chein's continued practice of

medicine was in the public interest. 72 Fed. Reg 8583. Recognizing that the Medical Board's previous revocation, now overturned by the California Superior Court, affected Dr. Chein's DEA Registration, the Board stated in the Stipulation Agreement and related Disciplinary Order that its action was intended to resolve all allegations of wrongdoing against Dr. Chein, both State and Federal. See California Superior Court Decision at 2–3 ("The Division agrees this Stipulated Settlement and Disciplinary Order is intended to resolve all of the following 1) all allegations in Accusation No. 19-200-107723; 2) all activity or omissions that were the subject of any charges, accusations, and investigations completed or pending with the Board as of September 1, 2005; and, 3) any disciplinary action taken by another state or the federal government based on the conduct alleged in Accusation No. 19-2000-107723 and In the Matter of Edmund Chein, M.D., Docket No. 02-9 and 02-43 pending before the United States Drug Enforcement Administration"). Leonhart took official notice of the Stipulation agreement in her Decision, but she refused to give it any deference. 72 Fed. Reg. at 8583 n. 4; 8590.

SUMMARY OF ARGUMENT

1. In her Decision, Deputy Administrator Leonhart ("Leonhart") deviated from DEA's prior practice and precedent without even referencing analogous cases or practices, let alone providing a reasoned explanation for her deviation. Accordingly, she abused her discretion, acted arbitrarily and capriciously, and disobeyed this Court's order to the agency in Morall v. DEA, 412 F.3d 165 (D.C. Cir. 2005). Her Decision must therefore be reversed and Dr. Chein's Registration reinstated.

2. Leonhart lacked substantial evidence needed to justify revocation of Dr. Chein's Registration. She failed to adduce substantial evidence for each of the six grounds upon which she relied for her Decision. She lacked substantial evidence that Dr. Chein violated the CSA record keeping requirements applicable to a physician who dispenses Schedule III and IV non-narcotic controlled substances, 21 U.S.C. §827(b)(2)(B). Indeed, the proceedings below reveal that Dr. Chein reasonably provided all documents asked of him, that documents sought by DEA were in fact obtained and that allegations that documents were missing or were not reasonably made available are belied by the fact that DEA executed a warrant, seized documents, and then refused, against the ALJ's order, to supply them to the ALJ or to Dr. Chein for use in Dr. Chein's defense. There is, on this record, an absence of substantial evidence necessary for the Decision. There is, instead, proof of a violation of Dr. Chein's right of due process (the DEA's refusal to comply with

the ALJ's order to produce at hearing documents material to Dr. Chein's defense seized from the clinic pursuant to a warrant) and of arbitrary and capricious action in violation of the APA. Tr. 41; 1503.

3. Leonhart deviated from DEA established practice in this case. Without imposition of any penalty, it has been DEA's practice not to fault physicians for failing to file required forms, for filing the wrong forms, or for completing the forms improperly in association with their dispensing of controlled substances to patients in foreign countries. Tr.2276-2278, 2286-2287, 2163-2165. Instead DEA has guided those physicians without sanction in properly completing DEA Form 236 and in ascertaining whether the countries in which those patients reside lawfully allow dispensing of the substances, without requiring the filing of an application for export (Form 236). Id. Indeed, DEA's export application processing staff refused to process Dr. Chein's export application (filed not once but twice) which agent DeSantis erroneously demanded he file, yet no one form DEA informed him of the agency's error or otherwise provided him guidance. The processing staff wrote upon the face of the application, "Already have DEA #, and removed it from processing without notifying Dr. Chein." The staff did not deny the application, it just did not process it. The next step in the agency's practice, contacting Dr. Chein and guiding him in getting export authorization, never occurred. DEA unilaterally, without notice and without explanation, deviated from its practice. Leonhart did not justify the departure from DEA precedent nor did

DEA through rulemaking establish a new legislative rule, giving notice to the regulated class, of a change in DEA requirements. Leonhart thus abused her discretion and acted arbitrarily and capriciously.

4. Leonhart also violated the statutory prohibition on DEA regulating the practice of medicine, Gonzales v. Oregon, 546 U.S. 243, 272 (2006), when in her Decision, she held Dr. Chein's evaluation of the health conditions of four undercover government agents, who identified themselves as athletes and falsely stated their symptomology to be "without legitimate medical purpose." Consistent with his practice, Dr. Chein gave the four low dose hormones, including testosterone (a controlled non narcotic substance in the form of a gel for topical application, vitamins, minerals, and a DHEA dietary supplement), pending blood work which would be used to calibrate precise hormone replacement amounts. Leonhart referred to this as the issuance of prescriptions "without a legitimate medical purpose" when, in fact, the prescriptions were entirely consistent with the principles governing THRT. See 72 Fed. Reg. at 6590; RX 1050. In short, the agents were experiencing the common hormone reduction effects of weight lifting and complained of symptoms common in career athletes. See Hackney supra note 1. Thus, there was nothing improper in the prescriptions given them.

5. DEA acted contrary to established precedent and in violation of the CSA when in its Decision it ascribed to Dr. Chein violation of the CSA's import provisions on the unproven supposition that he ordered controlled substances

illegally from Mexico. DEA's sole item of "proof" consisted of an invoice on the letterhead of a Mexican pharmacy. FOF 206, n8, at 60 and 75. The record revealed, however, that Dr. Chein received the shipment form Chula Vista, California, not Mexico. All other evidence germane to the question DEA seized and possessed but refused to make available at hearing. DEA held Dr. Chein liable for the illegal imports without requisite proof that he engaged in smuggling or even had knowledge of the illegality. DEA acted contrary to precedent that pins liability on the importer, not the innocent party who purchases from the importer.

6. DEA acted contrary to the plain and intended meaning of the CSA when it held Dr. Chein liable for actions taken by independently registered physicians, Dr. Chein's sister, Connie, and Dr. Darryl Garber. DEA has no power to assign culpability to one physician for the wrong doing of another, particularly when there is no evidence of record that the other failed to exercise his independent professional judgment in diagnosing or prescribing.

7. DEA has no evidence that any controlled substance dispensed by Dr. Chein was diverted to the illicit drug trade. Indeed, given the small, personal use quantitative amounts he dispensed, given the fact that the patients to whom he dispensed were under medical care, and given the form and nature of the products, there is little, if any, likelihood of diversion. Moreover, there is in fact no evidence of record that any controlled substance dispensed by Dr. Chein was diverted. Dr. Chein's dispensing constitutes the legitimate practice of medicine, not the illicit

drug trade. Without any evidence to support its determination, DEA has presumed Dr. Chein's dispensing to be drug diversion, unjustifiably disparaging and defaming him. The Decision is thus arbitrary and capricious and an abuse of discretion.

As explained in detail below, the DEA Decision should be reversed and Dr. Chein's Registration reinstated.

STANDING

In accordance with Circuit Rule 28(a)(7), this Court has standing for direct review of the Decision under the statutory authority and directive in 21 U.S.C. §877, section 507 of the CSA:

> All final determinations, findings, and conclusions of the Attorney General under this title shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia . . . upon petition filed with the court and delivered to the Attorney General within thirty days after notice of decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

I. STANDARD OF REVIEW

This Court reviews DEA's fact-finding for substantial evidence. See Morall v. DEA, 412 F.3d 165, 176 (D.C. Cir. 2005) (citing 21 U.S.C. §877). As stated in Morall:

> Substantial evidence means evidence which is substantial, that is, affording a substantial basis of fact from which the fact in issue can be reasonably inferred. Substantial evidence is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established, [citing] NLRB v. Columbia Enameling & Stamping Co., 306 U.S. 292, 299–300 (1939).

In Morall, this Court emphasized that when the Deputy Administrator departs from factual findings of the ALJ, she must explain her reasoning for that departure, stating:

> [W]hile the agency is the ultimate factfinder, the ALJ's "decision is part of the record, and the record must be considered as a whole in order to see whether the result is supported by substantial evidence. The agency's departure from the [ALJ's] findings are vulnerable if they fail to reflect attentive consideration to the [ALJ's] decision."

412 F.3d at 177 (citing Greater Boston Television Corp. v. FCC, 444 F.2d 841, 853 (D.C. Cir. 1970)).

Reasoning, in a DEA Decision, as distinguished from factfinding, is evaluated under the APA standard, requiring a court to set aside the action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." See Morall, 412 F.3d at 177 (citing Tourus Records, Inc. v. DEA, 259 F.3d 731, 736 (D.C. Cir. 2001)).

The agency's action is arbitrary and capricious under the APA if:

> The agency . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Morall, 412 F.3d at 177 (citing Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm, Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

The agency action may only be upheld if the Court determines "that the agency 'examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" El Rio Santa Cruz Neighborhood Health Ctr. v. United States Dep't of Health & Human Servs., 396 F.2d 1265, 1267 (D.C. Cir. 2005) (quoting Motor Vehicle Mfrs. Ass'n, 463 U.S. at 43).

ARGUMENT

The series of unreasoned DEA deviations from policy, practice and precedent; material missteps in its hearing; inconsistent legal determinations and directions; violations of orders to produce a material witness and material evidence; and misconstruction of apposite precedent are quintessential instances of arbitrary and capricious agency action, abuse of discretion, violation of law, and violation of Due Process.

I. MORALL IS CONTROLLING AND REQUIRES REVERSAL OF THE DEA DECISION (ISSUE 1, 2)

Morall v. DEA, 412 F.3d 165 (D.C. Cir. 2005) teaches that DEA may not deviate from its policies, practices, and precedent without recognizing its precedent

on point and explaining its departure from that precedent. In this case, DEA Deputy Administrator Leonhart ("Leonhart") failed to do what this Court ordered her to do in Morall. Leonhart's Decision is, thus, an example of administrative hubris in the face of controlling precedent. Leonhart's Decision neither makes reference to DEA's action in the apposite Paul W. Saxton, Continuation of Registration, 64 Fed. Reg. 25,073, 25,078–79 (May 10, 1999) and in other analogous DEA decisions, nor explains her rationale for departing from that precedent in Dr. Chein's case. In short, DEA has once more turned a deaf ear to this Court's controlling case law and has thereby failed to fulfill its most basic administrative law duty. Leonhart has thus abused her discretion and acted arbitrarily and capriciously in violation of the APA.

When DEA takes a clear detour from practices of the past to impose its ultimate sanction on a physician, registration revocation, it is obliged to cite its prior cases on point and explain why the detour is occurring so that the APA is followed and the regulated class is able to discern what is required of it. See Morall, 412 F.3d at 181 (citing Gulf Power Co. v. FERC, 983 F.2d 1095, 1098–1100 (D.C. Cir. 1993) (holding "that the sanction the [agency] imposed was not rationally arrived at on this record and was wholly disproportionate to the error [petitioner] committed," where, *inter alia*, the agency "did not explain why it had not taken the same position . . . in similar circumstances in the past.") As this Court made plain in Morall: "an agency's need to explain contrary precedents 'is

particularly acute,' as here, 'when an agency is applying a multi-factor test through case-by-case adjudication,'" (citing LeMoyne-Owne Coll. v. NLRB, 357 F.3d 55, 61 (D.C. Cir. 2004)).

This Court instructed DEA that when the agency can identify no prior case in which a physician's registration has been revoked under analogous circumstances and when in analogous circumstances it has elected not to revoke, it cannot sua sponte do an about face and take from a physician his Registration without even so much as referencing, let alone distinguishing, prior precedent, policy, and practice. 412 F.3d at 181. In Paul W. Saxton, Continuation of Registration, 64 Fed. Reg. 25,073, 25,078–79 (May 10, 1999), DEA declined to revoke a physician's registration where, *inter alia*, the physician prescribed anabolic steroids when it was illegal to do so and failed to maintain complete and accurate records of his controlled substance handling, which rendered him "unable to account for large quantities of drugs."[2] To be sure, even if Leonhart's faulty fact

[2] Saxton is but one of a series of DEA cases that rest on facts that are far more egregious than those alleged here and yet DEA decided not to revoke the physicians' Registrations. See, e.g., Karen A. Kruger, M.D., Grant of Restricted Registration, 69 Fed. Reg. 7016 (Feb. 12, 2004) (allowing physician to continue registration even after illegally prescribing approximately 5,500 doses of controlled substances over a period of a year, and repeatedly lying to DEA investigators about phony prescriptions); Jeffrey Martin Ford, D.D.S., Grant of Restricted Registration, 68 Fed. Reg. 10,750, 10,753 (Mar. 6, 2003) (granting limited registration despite a history of the physician's drug abuse, criminal record, several previous revocations of both his state license to practice and his DEA registration); Wesley G. Harline, M.D., Continuation of Registration with Restrictions, 65 Fed. Reg. 5665, 5668 (Feb. 4, 2000) (allowing practitioner's registration to continue in spite of testimony discussing the practitioner's "grossly deficient" record keeping); Theodore Neujahr, D.V.M., Continuation of

finding and reasoning, exposed at length below, are given credence, the situation in Saxton and in the analogous additional cases cited (footnote 3) are far more egregious than the facts DEA alleges here. Nonetheless, the Court in Morall explained that even if DEA's Decision rested on substantial evidence, the Court would still find DEA's lack of reasoned explanation for a departure from precedent a fatal flaw, an abuse of discretion. The reasoning in Morall applies with equal force here:

> . . . [T]he decision to revoke . . . is a flagrant departure from DEA policy and practice . . . . Because the departure is not only unexplained, but entirely unrecognized in the Deputy Administrator's decision, the agency's sanction could not withstand abuse of discretion review even if the decision had been supported by substantial evidence.

412 F.3d at 183.

Accordingly, while DEA lacks substantial evidence to support its Decision in this case, even were substantial evidence present, the Decision fails to pass muster under the APA. Leonhart has once again not referenced, let alone explained, her departure from DEA precedent, policy, and practice. On that basis alone, her Decision must be reversed and Dr. Chein's Registration reinstated.

II. DEA DEVIATED FROM ITS EXTANT PROCEDURE WITHOUT REASONED EXPLANATION WHEN IT REFUSED TO PROCESS DR.

Registration, 65 Fed. Reg. 5680 (Feb. 4, 2000) (declining to revoke practitioner's registration despite practitioner's illegal use of registration to obtain controlled substance for his own illegitimate use, and improper storage). Thus, even if the Decision were supported by substantial evidence, it fails nonetheless as this Court teaches in Morall, 412 F.3d at 181, because the Decision is an abuse of discretion.

CHEIN'S APPLICATION AND PROHIBITED DR. CHEIN FROM DISPENSING NON-NARCOTIC CONTROLLED SUBSTANCES WITHOUT GRANT OF AN EXPORT APPLICATION (ISSUE 1)

The DEA has a consistent practice of cooperating with physician applicants for export of controlled substances to their overseas patients. See Tr. 2286–87. Several DEA agents testified that if a physician registrant errs by filing the wrong form or incorrectly completing an application, it is DEA's practice to contact the physician and guide him or her in achieving compliance. Tr. at 2286–87; 2298–2300; 2276–78; 2163–65. After his export application was filed, DEA did not process it, yet also did not correspond with him at all concerning it. After 3 months incommunicado, DEA finally surfaced not with helpful guidance but with an order to show cause.

In the first instance, Dr. Chein was erroneously directed to file an application for registration as an exporter, despite the fact that he correctly believed his registration to prescribe and dispense as a physician[3] made it unnecessary for him to file for registration as an exporter.[4] Upon receipt of that application DEA took

[3] The distinction between dispensing by a physician and exporting is consistent with DEA's records of exporters. DI Wayne Michaels testified that "99.9 percent" of individuals with which DEA deals "are businesses that are exporting commercial shipments of pharmaceuticals." Tr. 2338

[4] Dr. Chein's good faith belief that he was sufficiently registered to dispense to his overseas patients is not only consistent with the views of DEA's application processors but is also supported by the structure and language of the relevant provisions of the CSA as codified in Chapter 13 of Title 21 of the United States Code (USC). Dr. Chien is registered to dispense controlled substances under 21 U.S.C. §822. As a registrant, Dr. Chien is authorized to "possess, manufacture, distribute, or dispense… to the extent authorized by [his] registration and in conformity with the other provisions *of this subchapter*." 21 U.S.C. § 822 (2007)

no substantive action on it and did not correspond with Dr. Chein, contrary to its agency practice. Instead, over a year later DEA issued an order to show cause.

An agency deviating from a settled practice is obligated to provide a reasoned explanation for the change. See Motor Vehicle Mfrs. Ass'n, 463 U.S. at 41–42 ("A 'settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress. There is, then, at least a presumption that those policies will be carried out best if the settled rule is adhered to'") (citing Atchison, T. & S. F. R. Co. v. Wichita Bd. of Trade, 412 U.S. 800, 807–808 (1973)). "An agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance;") see also Morall, 412 F.3d at 181 ("an agency's need to explain contrary precedents is particularly acute…when…applying a multifactor test through case-by-case adjudication") (internal quotations omitted). DEA had to, but did not, explain why in this instance, it required a physician registrant to file an export

(emphasis added). Sections 820-830, regarding registration of manufacturers, distributors, and dispensers of controlled substances are contained in Subchapter I of Chapter 13, while the provisions regarding import and export of controlled substances, sections 951-958, are located in Subchapter II of Chapter 13. The exemptions from registration in section 957 (b) allow those in the chain of exportation, such as common carriers and warehousemen, to possess controlled substances without a registration. See 21 U.S.C. §957(c). However, as a registered practitioner under section 822, Dr. Chein was already authorized to possess controlled substances. The DEA export application processing staff reveal it to be DEA practice not to require a registrant physician to file an export application. The DEA processing staff chose not to process Dr. Chein's application, writing upon it, "already have DEA #." See GX 48.

application which it did not process; why it did not communicate with the registrant any information about its decision not to process the application; and why it gave no aid to the registrant when none of those procedures had been its practice. DEA gave no explanation for its departure from practice.

As DI Sean Mahoney testified, if an applicant for an export registration uses the wrong form or incorrectly completes an application, the DEA has a consistent practice of not imposing a sanction but of contacting the applicant to guide him or her in achieving compliance. See Tr. 2286-87 ("If the person sends in the Form 161, an application for a permit, for a drug that doesn't require that, then, again, we would made sure that the person is registered to perform this activity…Basically, we convey the message that something has to be done…it's either the application for permit or the declaration has to be filed, and we would try to get that person, get that company, on the right road to the registration or to filing the correct form"); see also Mahoney, Tr. 2298-2300 (implying that if Dr. Chein's application had been processed through his department which normally handles export registration applications, then it would likely have been approved); see also Mahoney Tr. 2276-2278 ("[y]ou say no, you can't do that, I'm sorry. Then you give the doctor advice about it. I don't think you're going to drag him into court unless he keeps doing it. I have a feeling in most cases that's what we do. You have to be pretty hard up in a particular office to go after a prosecution . . . based on one informed export of a small quantity of a controlled substance for a legitimate

patient. You have to have not very much work to do. If I was boss, I wouldn't. I would try to say, listen, there's more important things, bigger fish in the sea than this"); see also the testimony of DI Sharon Partolo (Tr. 2163-2165) (further describing the process and communication between DEA and applicants to achieve compliance).

DEA did not communicate at all with Dr. Chein concerning his application. It deviated from its policy of cooperation and communication without explanation. It even failed for 13 months to notify Dr. Chein that his application would not be processed. It leapt to prosecution. That deviation without explanation is an abuse of discretion and arbitrary and capricious agency action in violation of the APA. See Morall, 412 F.3d at 181.

III. DR. CHEIN DID NOT CAUSE CONTROLLED SUBSTANCES TO BE ILLEGALLY IMPORTED FROM MEXICO (ISSUE 3)

There is not one shred of evidence that ties Dr. Chein to any unlawful import of controlled substances by Farmacias Castaneda, a firm located in Tijuana, Mexico that operated a pharmacy in Chula Vista, California. The only document of record, an invoice, reveals that the shipment to Dr. Chein came from Chula Vista, California. See FOF 206 n.8 at 60. There is no documentary or testimonial evidence that Dr. Chein knew when he purchased the products from a Chula Vista location that they were illegal imports. Despite the fact that the invoice lists the address of Farmacia Castaneda as Tijuana, Mexico, Dr. Chein purchased the

controlled substances from Chula Vista, California. See Tr. at 1316. Evidence of the purchase, in the form of FedEx airbill receipts, was seized by the DEA in an October 2002 investigation and kept from the record at hearing, despite an ALJ order to the contrary. See Tr. at 1503–05. At the hearing, whenever DI DeSantis was examined on the point, she asserted a "law enforcement privilege," refusing to answer. See Tr. at 1320; 1319. The DEA, however, continued to rely on the alleged absence of documents (as did Leonhart) despite DEA's unwillingness to allow Dr. Chein access to the seized materials in his own defense. Indeed, the DEA refused to comply with the ALJ's order to provide her copies of any documents related to the importation allegation other than the invoice. See FOF 206 n.8 at 60.

The law enforcement privilege assertion fails on the merits. All parties are subject to discovery, and the "law enforcement privilege" is only a qualified immunity, subject to the court weighing the government's interest in protecting the material against the party's need for its release. Tuite v. Henry, 181 F.R.D. 175, 177 (D.D.C. 1998) (requesting party failed to demonstrate that the information was unavailable from other sources or of sufficient importance to overcome the law enforcement privilege). That law was ignored by DEA. No weighing occurred in either the ALJ ruling or in Leonhart's Decision. The law prefers complete disclosure in litigation, as the Supreme Court has stated: "whatever their origins, these exceptions to the demand for every man's evidence are not lightly created nor

expansively construed, for they are in derogation of the search [for] the truth." Tuite, 181 F.R.D. at 177 (citing United States v. Nixon, 418 U.S. 683, 710 (1974)). The documents Dr. Chein sought *were his own records seized by the DEA*, factual evidence not related to the deliberative process of law enforcement. Those records were not available from any other source, and were exculpatory. DEA's refusal to turn over the documents reeks of bad faith. That the material sought is purely factual is a compelling factor in determining whether a governmental privilege applies. Waters v. United States Capitol Police Board, 218 F.R.D. 323, 324 (D.D.C. 2003) (investigative documents ordered disclosed to requesting party in civil action). Contrary to Court order and applicable precedent, DEA contumaciously refused to turn the requested documents over to the ALJ and to Dr. Chein, thereby disabling Dr. Chein's defense, another Due Process violation.

Moreover, the DEA acted arbitrarily and capriciously by finding that Dr. Chein not only purchased a controlled substance from a supplier in Mexico (when the evidence presented revealed that the purchase was from California) but also that this purchase constituted an unlawful import by Dr. Chein (when no evidence exists that Dr. Chein caused the illegal import or knew it to be an illegal import). Leonhart left unrecognized and unexplained her departure from the ALJ's finding that the DEA failed to prove that Dr. Chein received controlled substances from Mexico. Compare Decision 6592 with FOF at 75 ("the record also contains evidence that the owner of the Mexican Pharmacy, Dr. Romero, may have shipped

the controlled substances from a location in San Diego, California . . . I find that the Government has failed to prove . . . that the respondent *received* imported controlled substances from Mexico") (emphasis added). Leonhart went on to find that receipt of the controlled substances from the California location constituted importation, without regard to Dr. Chein's lack of involvement in the illegal import, an analysis that is clearly inconsistent with the definition of importation in the regulations (21 C.F.R. §1300.01(15)) and the definition of importation in the applicable case law.

Leonhart reasoned that Dr. Chein "imported" the controlled substance by placing an order. Decision 6592. The all-important issue concerns not per se whether an order is placed but whether there is evidence of involvement in the illegal bringing of the contraband into the United States. The only evidence we have is that the order was filled from *a California location*. There is no evidence, therefore, that Dr. Chein caused the import from Mexico in the first instance.

Leonhart cites to multiple inapposite importation cases and misapplies them to a practitioner ordering from a pharmacy. See 72 Fed. Reg. at 6592. All of those cases are criminal, not civil, and all concern unlawful narcotics (not controlled substances that may be lawfully ordered from a pharmacy and dispensed as a part of medical care). None of the defendants are physicians intending to dispense the substance at issue as part of a doctor-patient relationship. All were accused of some direct role in the actual movement of contraband into the United States. As

cited in one of those cases, but left unaddressed by Leonhart, a three part test applies for determining culpability for unlawful importation:

> The offense of importation of a controlled substance into the United States requires proof (1) that the substance was imported; (2) that it was imported *knowingly* and *willfully;* and (3) that the defendant *willfully* associated himself with the importation venture. See 21 U.S.C. §§ 952(a), 960; United States v. Seni, 662 F.2d 277, 280 (4th Cir. 1981). Mere possession of a controlled substance that is of foreign origin is insufficient to establish importation. See United States v. Moler, 460 F.2d 1273, 1274 (9th Cir. 1972) (per curiam). A critical element of the offense is that the defendant import the substance or cause it to be imported. See United States v. Koua Thao, 712 F.2d 369, 371 (8th Cir. 1983).

United States v. Samad, 754 F.2d 1091, 1096 (4th Cir. 1984) (emphasis added). "[m]ere possession [of goods] is insufficient to establish [liability for] importation." See id; see also United States v. Nusraty, 867 F.2d 759, 766 (2d Cir. 1989)(Defendant acquitted; government lacked proof of importation despite proof of disreputable behavior lacking criminality). There is no evidence that Dr. Chein imported the substances. The facts only show that Dr. Chein placed an order with a pharmacy in California and that he later received goods from that pharmacy that appear to have originated in Mexico. His case is, thus, entirely distinguishable from the import conviction cases Leonhart cited.

The ALJ found no culpability. Leonhart overruled the ALJ and without explaining that departure leapt beyond the bounds of the law to the position that an ultimate customer is an importer within the meaning of the Act, equally culpable for the import as those engaged in the criminal enterprise of unlawfully bringing

the substance into the United States. See 72 Fed. Reg. at 6592. Were Leonhart's reading of the law correct, then patients unwittingly prescribed a drug imported unlawfully would be criminally liable as would the prescribing physicians despite no fore knowledge or participation in smuggling. That illogical and unreasonable extension of import destination to all subsequent purchasers thankfully is not the law.

DEA's regulations define "import" as "any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States." Thus, it is the act of bringing the article from a foreign country into the United States that constitutes the "import," an act ends when the product first comes to rest, before a subsequent purchase. That interpretation is given in case law not cited by Leonhart. The case law demarcates the "final destination point" for import to be the place at which the substance comes to rest *before it is subsequently distributed*:

> In isolating what constitutes the final destination point, the Third Circuit has stated, in construing the term 'importation' for purposes of laying proper venue, that the final destination of imported contraband is that point *beyond* the port of entry where the contraband finally comes to rest prior to distribution.

United States v. Leal, 831 F.2d 7, 9 (1st Cir. 1987).

Because Farmacia Castaneda's sale of controlled substances to Dr. Chein from California was a "distribution," not an "importation," Leonhart's determination that Dr. Chein is liable for illegal import is arbitrary, capricious, an

abuse of discretion, and contrary to law. The Decision should be reversed and Dr. Chein's Registration reinstated.

IV. DR. CHEIN IS NOT LIABLE FOR ANY ALLEGED WRONG-DOING COMMITTED BY OTHER DOCTORS UNDER THEIR OWN DEA CERTIFICATES OF REGISTRATION (ISSUE 4)

In her Decision, Leonhart holds Dr. Chein liable for alleged violations of the CSA committed by other physicians who acted under their own Registrations. She cites Leonard Merkow, 60 Fed. Reg. 22075 (1995) for the proposition that a registrant is responsible for the failure of his employees to comply with the Act. That case did not involve independent licensed professionals; it involved nonprofessional staff acting at the behest of a lone licensed professional. Leonhart gives no explanation for her expansion of Merkow to reach the facts present here nor does she explain how that expansion satisfies the requirements of the CSA. In Merkow, a physician's receptionist gave an undercover agent over 300 doses of a controlled substance for no legitimate medical purpose. 60 Fed. Reg. 22075, 22076. The Deputy Administrator there found that "although the physician claimed he was unaware of the activity, he was responsible for his employee's actions and ultimately accountable for the controlled substances that were dispensed from his office." Id. That circumstance differs markedly from one in which physicians working at a clinic, exercising independent professional judgment, diagnose patients and prescribe to them controlled substances using their own DEA Registrations.

It is inconsistent with the individualized nature of DEA physician registration under the Act to hold one registrant responsible for alleged CSA violations of other registrants based solely on the fiduciary relationship between the two. That position undermines the entire registration scheme, which requires that individual physicians be responsible for their own prescribing and dispensing regardless of the wishes of those who employ or hire them or of their patients. See U.S. v. Polask, 162 F.3d 878, 884 (5th Cir. 1998) (guilt by association is universally condemned). It is the duty of the physician to be licensed under State law in order to be awarded Registration, 21 USC §823(f), and under State law it is a physician's obligation to exercise independent professional judgment in making prescription decisions (the duty is non-delegable). See Plenger v. Alza Corp., 11 Cal. App. 4th 349, 362 n.6 (Cal. Ct. App. 1992).

Moreover, there is here no evidence that the alleged wrong-doing by these other physicians was pursuant to an order or direction given by Dr. Chein, as opposed to the exercise of their own professional judgment. Furthermore, in the absence of such proof, we must presume that the duly licensed professionals did exercise their own professional judgment because the patients in issue were then under their individual care and the prescriptions they issued were based on their diagnoses, not on Dr. Chein's. See Id.; Tr. 2499 ("It is clear that Dr. Vogt and Dr. Garber are seeing the patient").

The DEA Decision is thus arbitrary and capricious, an abuse of discretion, and contrary to law. It should be reversed and Dr. Chein's Registration reinstated.

V. DR. CHEIN COMPLIED WITH THE RECORD-KEEPING REQUIREMENTS OF 21 USC 827(b)(2)(B) (ISSUE 5, 6)

Under 21 U.S.C. §827, a registrant must make a complete and accurate record of all controlled substances on hand every second year. 21 U.S.C. §827(a)(1). In addition, the registrant must keep a "complete and accurate record of each [controlled] substance manufactured, received, sold, delivered, or otherwise disposed of by him." Id. at §827(a)(3). The records must be kept and made available as required by 21 U.S.C. §827(b):

> Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, *or* (B) *alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant*, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

21 U.S.C. §827(b) (emphasis added).

The recordkeeping requirements for narcotics are different than those for non-narcotics. The record keeping requirement for the non-narcotic controlled substances dispensed by Dr. Chein is not that they be instantaneously available. The statute contemplates that records for non-narcotics (subpart (2)(B)) be maintained as part of the "ordinary business records of the registrant" and, thus,

must be culled from business records to be produced. Narcotic controlled substances (subpart (2)(A)), by contrast, are required to be "maintained separately from all other records of the registrant" and, thus, may be produced instantaneously. Blind to the legal distinctions, DI DeSantis expected instantaneous production of non-narcotic records and faulted Dr. Chein for not having them on hand at the moment of her unannounced visit. She later admitted her error at hearing. Tr. 1004.

DEA has also defined "readily retrievable." Apparently, that definition also eluded DI DeSantis. See Tr. 269, 280. Under 21 C.F.R. §1300.01(b)(38), the term "readily retrievable" is given this definition:

> The term readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a *reasonable time* and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.
> (emphasis added).

DEA gave no credit to Dr. Chein for his exceptional record keeping system, maintained, at his expense, by a pharmacist. That system is fully compliant with 21 C.F.R. 1300.01(b)(38). Dr. Chein installed specialized software, Micropharmacy, to keep his controlled substance records. See Tr. 1630. In addition, Dr. Chein's clinic changed its policy regarding invoices to make sure that copies were sent to the clinic's accountant so that the originals could be maintained

on site. See Tr. 1416. There is in this no indication that records were kept improperly or of a doctor derelict in his recordkeeping duties.

On January 31, 2001, DI DeSantis arrived at Dr. Chein's clinic unannounced. See Tr. 887. She was told that the clinic's inventory and dispensing records were locked and the keys were kept by a pharmacist who was not on the premises. Id.. DeSantis did not return the next day to inspect the records but waited until February 5, 2001, appearing again unannounced. See Tr. 280, 893–94. Upon her return, Dr. Garber, who had obtained access to the computer records, printed them for her. See Tr. 893–94. It took Dr. Garber two to three hours to print the documents, but they were provided as the software made them available. See Id. When asked if she needed any other documents, DeSantis said, "no." Proceeding on her mistaken view that the "immediate production" standard applied, DeSantis declared the clinic in violation, inviting issuance of a show cause order.

DeSantis admitted at hearing that she erroneously applied the record keeping standard for narcotics to the clinic. Tr. 1004. Consequently when she did not receive the documents "immediately" upon request and when they were not segregated in advance for her unannounced inspection she presumed the clinic in violation. See 72 Fed. Reg. at 6580. Although Leonhart admitted that the wrong standard had been applied (See 72 Fed. Reg. at 6593 ("[Dr. Chein] is correct that this regulation does not require that records be 'instantaneously produced' . . . .

Accordingly, there is no basis to conclude that the inventory and dispensing records were not readily retrievable on that date")), she nonetheless relied on the allegation of noncompliance with the narcotics standard in her calculus of factors warranting revocation of Dr. Chein's license (a gross non-sequitur and abuse of discretion). See 72 Fed. Reg. at 6592 ("The Record Keeping Violations").

There is no substantial evidence to support the charge that Dr. Chein failed to meet the requirements of 21 U.S.C. §827 (b)(2)(B) for non-narcotic dispensing. Moreover, the supposition in the Decision that relevant records had not been obtained by DEA is belied by the agency's refusal to permit, in contravention of the ALJ's order, Dr. Chein or the ALJ to examine the documents DEA seized by warrant. Evidence thus seized in support of the propriety of Dr. Chein's record keeping was wrongly kept from the proceeding by DEA. See FOF 206 n.8 at 60 ("At the time of the hearing, these records were in the possession of the Government. Despite numerous requests by the respondent, the Government refused to release the documents pertaining to these shipments"). Fundamental fairness precludes the government from charging wrongful recordkeeping while denying the Court and doctor the doctor's records the government seized. Under the apposite APA standard, DEA lacked substantial evidence to support its conclusion that Dr. Chein failed to comply with its recordkeeping requirements. It thus violated the APA when Leonhart included adverse findings on recordkeeping

in her public interest factor assessment. The DEA Decision should therefore be reversed and Dr. Chein's Registration reinstated.

VI. THE PUBLIC INTEREST FACTORS OF SECTION 823 FAVOR DR. CHEIN'S CONTINUED REGISTRATION (ISSUE 4)

DEA failed to evaluate the public interest factors under Section 823 as required by statute and precedent. When Leonhart considered the public interest factors of section 823 (21 U.S.C. §823) she substantially deviated from controlling Supreme Court precedent, failed to consider all factors, deliberately ignored factors in Dr. Chein's favor, engaged in circular reasoning, and erroneously considered as one the separate and distinct fact tests of sections 823 and 953.

Leonhart was obliged to consider the six factors in section 823(a)(1-6)[5] for export registration (pursuant to 21 U.S.C. §958(a)) and the five factors in section

[5] The six factors to determine the public interest in an export registration are:
(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
(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 and State laws relating to the manufacture, distribution, or dispensing of such substances;
(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
(6) such other factors as may be relevant to and consistent with the public health and safety.
21 U.S.C. §823(a)(1-6).

823(f)(1-5)[6] for dispensing registration in her evaluation of Dr. Chein's application. See Gonzales v. Oregon, 546 U.S. 243, 251 (2006) ("[The Attorney General's and by delegation, the DEA's] power over registration, which must be exercised only after considering five express statutory factors"). Leonhart lacks discretion under those statutory sections to exclude factors from consideration in her Decision. The law requires she weigh them all. She may not evaluate only facts she deems weighed against approval to the exclusion of those weighed in favor. See Morall, 412 F.3d at 177. Such an interpretation would always lead to adverse decision making predicated exclusively on negative facts and no weighing of the positive. See Morall, 142 F.3d at 178.

Considering the applicable six factors, Dr. Chein maintained adequate controls to protect against diversion. He hired a pharmacist, instituted a rigorous documentation system, and purchased and implemented a software system for dispensing controlled substances that included inventory controls and other

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[6] The five factors to determine the public interest in the continued registration of Dr. Chein as a practitioner to dispense controlled substances are:

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

(2) The applicant's experience in dispensing, or conducting research with respect to 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.

21 U.S.C. § 823(f)(1-5).

protective measures. See Tr. at 889. All persons to whom Dr. Chein dispensed overseas were his patients. See Tr. at 2726; 1231. He dispensed only personal use quantities and in forms largely incapable of being diverted to the illicit drug trade. See FOF 20 at 6; Tr. 966–67. In fact, there is no record evidence that any of his foreign dispensing exceeded patient practice and entered into illicit channels. He is a leading authority in the field of anti-aging medicine upon whom many patients and physicians depend. Tr. 2731. Before Leonhart's Decision, Dr. Chein had no prior federal or state criminal action brought against him concerning controlled substances. FOF at 68. Thus, at a minimum factors 1-5 out of the six are in Dr. Chein's favor. Moreover, medical practice is now global. It is common for overseas patients to seek the care of experts in the United States for direct patient care, review of the medical records created by overseas physicians, or video-conferencing examinations by an overseas expert with the local attending physician on site. It is in the public interest of patients and physicians to have regulatory procedures in place that enable U.S. experts to provide long-distance medical care to their overseas patients.[7]

[7] This public policy consideration was acknowledged by the ALJ but granted no weight by Leonhart because of what she perceived to be other public interest factors against it. Id. at 6594. Leonhart seems to misunderstand the multifactor test. When a factor is in Dr. Chein's favor she must accord it weight, not dismiss it in a perfunctory manner. If only facts militating against approval are weighed, and ones for are not even considered, or seriously engaged, the Deputy Administrator must inevitably be deemed to have abused her discretion. See Morall, 412 F.3d at 178. If only facts against are considered, then no weighing takes place, making it impossible for favorable factors to outweigh unfavorable ones, thus defeating the very purpose of the multifactor test which requires weighing and balancing.

Leonhart engages in circular argument, presuming her present findings to be of a past history of diversion and violation of the law without proof of any prior convictions. 72 Fed. Reg. at 6594. She ignores Congress' clear statutory language, distinguishing between the five factors for dispensing and the six factors for export, and states that the five require denial of Dr. Chein's application for registration. Id. at 6594. Of the six factors, she presents argument only on factors 1, 5, and 6, ignoring the rest. Id. She argues that Dr. Chein has inadequate controls because he failed to produce a complete inventory but, as discussed supra at 41–45, that finding is not based on substantial evidence. Id. She cites the shipping of controlled substances to patients in certain countries where, Leonhart states in a conclusory manner, legality is in question under those countries' controlled substances laws. Leonhart considers those shipments to be evidence of diversion but not one shred of evidence supports the conclusion that any actual diversion has taken place. Moreover, as explained above, it has been DEA practice to aid physicians in determining foreign law requirements, not summarily condemn them.

Thus, despite no evidence of diversion, Leonhart rests her decision that there was diversion on the fiction that foreign laws against import are ipse dixit "diversion." She makes no reference to DEA's practice of guiding physicians to comply with the foreign law requirements and presents no reasoning to justify departure form that practice.

Leonhart similarly abused her discretion and acted arbitrarily and capriciously in her one-sided assessment of the five factors applicable to dispensing. She makes much of the *overturned* California medical board's initial decision but gives no weight to the California Court's decision overturning the board or to the California licensing board's 2005 settlement agreement with Dr. Chein, restoring his license as in "the public interest." Under the statute and Morall, she abused her discretion by not weighing the positive factors. See 412 F.3d at 178 ("However, the court may not find substantial evidence merely on the basis of evidence which in and of itself justified [the agency's decision], without taking into account contradictory evidence or evidence from which conflicting inferences could be drawn" (internal quotations omitted) (citing Lakeland Bus Lines, Inc. v. NLRB, 347 F.3d 955, 962 (D.C. Cir. 2003)). When the board states that its restoration of the license is a resolution of all matters including those concerning controlled substances in the DEA administrative action, that statement is clearly, at a minimum, a "recommendation" of the licensing board in Dr. Chein's favor that he be permitted to dispense controlled substances. Leonhart gave it short shrift and no weight. Consistent with Gonzales v. Oregon, the CSA requires DEA to consider the States role in regulating controlled substances. 546 U.S. at 251 (citing 21 U.S.C. §823(f)). Moreover, Gonzales v. Oregon definitively holds that states have exclusive authority (superseding that of the DEA) to determine the legitimacy of medical standards and practices in each locality. 546 U.S. at 274–

75. Deference is thus owed to the public interest findings of the California Courts and ultimate California Board determination. Leonhart's one-sided assessment, giving little or no deference to the factors in Dr. Chein's favor, is an abuse of discretion.

As recited above, Dr. Chein has in place an excellent and fully complete record keeping system. He has no prior conviction under Federal or State laws relating to controlled substances. He is a leading authority in his field upon whom patients, including over 300 doctors, depend.

In contrast with the above examination of the five factors, Leonhart devotes much of her analysis to facts concerning the export of controlled substances, not separating the export registration from registration for dispensing. Id. at 6590–6593. Like other factors discussed above, Leonhart gave the California Board's decision (even acknowledging it as a recommendation) no weight. Moreover, she specifically states that she "decline[s] to give it deference," despite Gonzales v. Oregon, and statutory directives that require deference to the State's exclusive authority to regulate the practice of medicine and the CSA's requirement that the State's role in controlled substances regulation be considered. See 21 U.S.C. §823(f); Gonzales, 546 U.S. at 251.

Leonhart has recommitted the fatal abuse of discretion and error that required reversal in Morall.

VII. THE DEA DECISION VIOLATES DR. CHEIN'S FIFTH AMENDMENT RIGHT OF DUE PROCESS (ISSUE 7)

Prior to the hearing, Dr. Chein and the DEA entered into an agreement. DEA would present evidence on only six of some twenty-one instances of dispensing to foreign patients. See 72 Fed. Reg. at 6587 n.14. In her ruling, the ALJ ignored the agreement, evaluating all 21, and in her Decision, Leonhart evaluated not only those 21 instances but also 317 more involving dispensing by Dr. Connie Chein and Dr. Garber, wrongfully attributing those to Dr. Chein. See 72 Fed. Reg. at 6580. This Court has held that government violations of pre-hearing evidentiary agreements warrant reversal. See Pacific Molasses Co. v. Federal Trade Com., 356 F.2d 386, 389–90 (5th Cir. 1966):

> When an administrative agency promulgates rules to govern its proceedings, these rules must be scrupulously observed. This is so even when the defined procedures are '…generous beyond the requirements that bind such agency….' For once an agency exercises its discretion and creates the procedural rules under which it desires to have its actions judged, it denies itself the right to violate these rules. If an agency in its proceedings violates its rules and prejudice results, any action taken as a result of the proceedings cannot stand.

(internal citations omitted) (citing Sangamon Valley Television Corp. v. United States, 106 U.S. App. D.C. 30 (D.C. Cir. 1959)).

The outcome here should be the same. When DEA enters into an evidentiary agreement and then proceeds to violate the agreement, its lawless and dishonorable conduct should not be condoned and all conclusions arising from the breach ought

to be reversed. It is indeed an affront to the rule of law upon which justice depends when law enforcement agents expect others to abide by laws they choose to break.

A Registration is a property interest protectable under the Fifth Amendment Due Process Clause. See Harline v. DEA, 148 F.3d.1199,1204 (10th Cir. 1998) (noting that a physician has a protected interest in practicing medicine and is entitled to due process protections when the DEA revokes that individual's license to prescribe controlled substances). Revocation carries with it a profoundly adverse effect on a practitioner's ability to practice medicine. See Morall, 412 F.3d at 177 (noting that revocation is the "harshest of possible sanctions"). It is, therefore, essential that Due Process be accorded the registrant in a license revocation proceeding. See Harline, 148 F.3d. at 1204.

In this case, the process that was due required, at a minimum, examining the DEA Diversion Investigator responsible for making production demands at Dr. Chein's facility. That DI the DEA absented from the hearing against the ALJ's order. Tr. 99–100. The process due also included access to records containing exculpatory evidence seized from Dr. Chein's offices by search warrant that, against the ALJ's order, DEA refused to produce at hearing. Tr. 41;116–17;2528. The DEA's excuse for the absenting of the material witness was not physical incapacity or death but inconvenience (the witness, a mother, would have to leave her child during the time she would testify). See Tr. 95. The child could have been attended by a relative, a paid caregiver, a DEA co-worker, or the ALJ's staff, or

could even remain in the audience chamber of the courtroom during the parent's testimony. None of those obvious alternatives were even considered. The loss of a material witness upon such a trifling excuse for not appearing went by without so much as a sentence referencing it in the DEA Decision and yet it is a vital violation of Due Process. To make matters worse, the DEA had the audacity of substituting for that witness (DI Ruth Carter-Kinney), another DEA investigator (DI Robert Brasich) who was not on site and had virtually no understanding of the material facts, deriving what he did know from a short, non-specific conversation with Carter-Kinney before he testified. The following comes from the examination of Brasich at the hearing:

> Q: Were you personally there during the execution of the search warrant?
> A: No
> Tr. 130: 6-21
>
> Q: Okay, now, Ruth Carter-Kinney was present during the search and you weren't; is that true?
> A: That's correct.
> Q: But you did discuss this with her, correct?
> A: I discussed the investigation with her, yes.
> Q: And according to the pre-hearing statement proffer on your testimony you discussed with her what happened during the search and seizure, correct?
> A: I did not discuss it in detail. I discussed some general details of the search warrant.
> Tr. 151-152: 12-14; 19-22; 1-3.

Leonhart relied on the testimony of the non-eyewitness Brasich extensively in her Decision. See 72 Fed. Reg. at 6582 ("The First Investigation"). The records seized and retained by FDA included patient files, dispensing logs, and computers.

None of those documents or computers were available to Dr. Chein for the hearing and none have been returned to him since. Tr. at 152.

In her Decision, Leonhart relies on an alleged failure to produce documents as a prime basis for revoking Dr. Chein's Registration. While the record reflects that all documents requested were supplied, see Tr. 280, 893–94, Leonhart found that some unspecified documents were not supplied to DEA, a finding belied by testimony and by the fact that DEA seized pursuant to a search warrant patient files, dispensing logs, and computers and refused to make them available, despite an ALJ order to produce them. This prevented Dr. Chein's presentation of proof that indeed DEA had the documents in question. See FOF n.8 at 60.

The ALJ had ordered the production but the DEA refused to comply. The failure to comply denied Dr. Chein an effective opportunity to present exculpatory evidence, proof that DEA in fact had the documents it claimed were missing. This witness substitution and the nondisclosure of material records denied Dr. Chein's right of due process. Leonhart acknowledged no recordkeeping violation but then illogically faulted Dr. Chein for non-production, finding against Dr. Chein in the weighing of the public interest factors. See 72 Fed. Reg. at 6593. That, too, justifies reversing the Decision and reinstating Dr. Chein's Registration.

VIII. DR. CHEIN'S DISPENSING OF SCHEDULE III AND IV NON-NARCOTIC SUBSTANCES TO FOREIGN PATIENTS DID NOT CONSTITUTE "DIVERSION" BUT HAS, INSTEAD, A LEGITIMATE MEDICAL PURPOSE (ISSUE 8)

There is no evidence to support Leonhart's conclusion that Dr. Chein's dispensing of personal use amounts of Schedule III and IV non-narcotic controlled substances to his foreign patients constituted "diversion" within the meaning of the CSA. To the contrary, the record presents no evidence that anyone other than his patients obtained the controlled substances or that any of those patients obtained quantities of the substances in excess of that appropriate for personal use for a legitimate medical purpose.[8] Indeed, the evidence, recited in the Decision, reveals quantitative amounts of the substances that are very low, insufficient to support abusive use, and in a condition that while appropriate for therapeutic administration is not suitable for resale or other abuses. See FOF 20 at 6 ("the record demonstrates that the Respondent shipped small quantities of controlled substances specifically for his patients' use"). Moreover, the record

[8] In Rosen, the Court set out nine elements or activities culled from diversion cases that indicate that controlled substances were dispensed or prescribed for an improper purpose:

> (1) An inordinately large quantity of controlled substances was prescribed; (2) Large numbers of prescriptions were issued; (3) No physical examination was given; (4) The physician warned the patient to fill prescriptions at different drug stores; (5) The physician issued prescriptions to a patient known to be delivering the drugs to others; (6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment; (7) The physician involved used street slang rather than medical terminology for the drugs prescribed; (8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing; (9) The physician wrote more than one prescription on occasions in order to spread them out. (internal citations omitted)

United States v. Rosen, 482 F.2d 1032, 1035-36 (5th Cir. 1978). None of these are applicable here.

reveals that the patients in issue were evaluated to determine whether they evinced symptomology of suboptimal levels of the hormones in question. See FOF 132 at 38. They were prescribed only those amounts that would, month to month, slowly elevate the hormone levels until they approximated those of a young healthy adult, in accordance with Dr. Chein's protocol. As the only expert in anti-aging medicine who testified stated, this is a legitimate medical purpose, certainly one beyond the proper scope of the Deputy Administrator's review. See Tr. 2879–80.

Indeed, by basing her "diversion" decision on a subjective view (a conclusory assertion in the Decision without reasoned support that Dr. Chein's medical practice did not involve a "legitimate medical purpose," despite direct testimony to the contrary, See 72 Fed. Reg. at 6894 ("his practice lacks effective controls against diversion—indeed, he is the cause of the diversion")), Leonhart invaded the state province by regulating medical practice.

The Controlled Substances Act was never intended to be a vehicle for DEA to regulate medical practice. See Gonzales v. Oregon, 546 US 243, 269–70 (2006) ("the statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking . . . Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally").

The definition of a "prescription" in the CSA also supports the conclusion that there is no risk of diversion when a physician dispenses personal use amounts of non-narcotic controlled substances to his patients. 21 C.F.R. §1306.04 (2007) defines a prescription thusly: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner".

In the course of treating a patient, the dispensing of low dose, low concentration hormones in gel form for topical use or in other forms not readily adaptable for street resale is not outside the usual course of professional practice and is not for an illegitimate medical purpose. Legitimate medical and scientific applications of hormones are not intended to be subsumed within the statutory term "diversion." See e.g., 21 U.S.C. §823(a)(1)("maintenance of effective controls against diversion… into other than legitimate medical, scientific, research, or industrial channels"). The Act balances the prevention of diversion with the need for an adequate and uninterrupted supply of controlled substances for legitimate medical, scientific, research, and industrial purposes. See e.g., id. (limiting the number of registered importers and manufacturers to control against diversion to a number which can produce "an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical,

scientific, research, and industrial purposes"). When the Deputy Administrator declares diversion based on patient-specific, low dose dispensing, she has caused an Act designed to prevent illicit drug dealing and trafficking to arrest legitimate medical, scientific, and research applications, in other words, to invade the state-regulated province of medical practice, an invasion the Courts have rebuffed to protect the statutory limits on this agency's power. See Gonzales, 546 US 243, 260 ("statutory references to 'control' outside the scheduling context make clear that the Attorney General can establish controls 'against diversion,' e.g., §823(a)(1), but do not give him authority to define diversion based on his view of legitimate medical practice").

For the foregoing reasons, Leonhart's Decision is arbitrary, capricious, contrary to law, and an abuse of discretion. Accordingly, it violates the APA. The Decision should therefore be reversed and Dr. Chein's Registration reinstated.

RELIEF SOUGHT

In light of the foregoing, Dr. Chein, by counsel, respectfully requests that this Honorable Court reverse the DEA Decision and order that Dr. Chein's Registration be reinstated.

Respectfully submitted,

_____

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CERTIFICATE OF COMPLIANCE WITH RULE 32(A)(7)

This brief complies with the type-volume limitation of Fed R. App. P. 32(a)(7)(B) because this brief contains _____ words, excluding the parts of the brief exempted by Fed. R. App. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14 point type.

_____

Attorney for Petitioner

Dated: _____

CERTIFICATE OF SERVICE

I, Andrea G. Ferrenz, hereby certify in accordance with Federal Rule of Civil Procedure 25(d)(B) that I served the Respondents' counsel identified below with two copies of the attached Brief for the Petitioner by UPS overnight mail on August ____, 2007. I filed the original and seven copies of Brief for the Petitioner with the clerk by UPS overnight mail on August ___, 2007 in accordance with Federal Rule of Appellate Procedure 25(a)(2)(B) and Circuit Rule 31(b)(pertaining to initial briefs with a deferred appendix).

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ADDENDUM

TABLE OF CONTENTS FOR PERTINENT STATUTES AND REGULATIONS