

**BEFORE THE  
BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA**

In the Matter of the Accusation, First  
Supplemental Accusation, Second  
Supplemental Accusation, and Third  
Supplemental Accusation Against:

**INTERNATIONAL PHARMACEUTICAL  
SERVICES,**  
AFSHIN ADIBI, President

Wholesaler Permit No. WLS 2955

and

**AFSHIN ADIBI**

Pharmacist License No. RPH 44301

Respondents.

Case No. 2347

OAH No. 2002120722

**DECISION AFTER NONADOPTION**

Administrative Law Judge Steven C. Owyang, State of California, Office of Administrative Hearings, heard this matter in Oakland, California, on November 27, 28, and 29, 2007.

Maretta D. Ward, Deputy Attorney General, represented complainant Virginia K. Herold, Executive Officer, Board of Pharmacy, Department of Consumer Affairs

Attorneys Robert J. Sullivan and Paul A. Hemesath of Nossaman, Guthner, Knox & Elliott, LLP, represented respondents International Pharmaceutical Services and Afshin Adibi.

The record was held open for the receipt of two additional exhibits and for the filing of briefs. Complainant submitted a December 6, 2007 letter from Douglas M. Lankler, which was received in evidence as exhibit 79. Respondents submitted a December 6, 2007 declaration by Afshin Adibi and a February 15, 1995 inspection report by Elmer Miller, which were received in evidence collectively as exhibit J.

Simultaneous post-hearing briefs were initially due on January 31, 2008, and simultaneous response briefs were initially due on February 14, 2008. Respondents and complainant sought extensions of time for the filing of briefs. Their requests were granted. All briefs were timely filed. The matter was submitted for decision on March 3, 2008.

The proposed decision of the Administrative Law Judge was submitted to the Board on May 1, 2008. After due consideration thereof, the Board declined to adopt said proposed decision and thereafter on July 1, 2008 issued an Order of Non-adoption. Subsequently, on September 4, 2008, the Board issued an Order Fixing Date for Submission of Written Argument. On September 26, 2008, an Amended Order Fixing Date for Submission of Written Argument was issued by the Board. Written argument having been received from both parties and the time for filing written argument in this matter having expired, and the entire record, including the transcript of said hearing having been read and considered, the Board of Pharmacy pursuant to Section 11517 of the Government Code hereby makes the following decision and order:

#### FACTUAL FINDINGS

1. Starting in the mid-1990's, respondents International Pharmaceutical Services (IPS) and Afshin Adibi sold and shipped dangerous drugs from their California location to customers, including individual end users, in foreign countries.<sup>1</sup>

Respondents received orders by facsimile and through the Internet, including through web sites operated by respondents and by others. In some cases, the orders were supported by prescriptions or notes from doctors in the foreign countries who were not licensed in California or the United States. In other cases, no prescription or doctor's note accompanied the orders. Respondents looked to the law of the recipient's country to determine whether the recipient was authorized to receive the drugs.

A large part of respondents' business involved the sale of Viagra to persons in Japan. ("Prescription" in this finding is used in its general sense, not as specifically defined in section 4040.)<sup>2</sup>

Respondents conducted their business, which they characterize as a pharmaceutical export house, under a wholesaler permit issued to IPS. Respondents did not apply to be licensed as a pharmacy. Respondents conducted their business in this way through multiple inspections and investigations from 1998 through 2004. Respondents have continued their export business to the present.

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<sup>1</sup> Respondent Adibi admitted also "doing business in the United States." (RT 11/29/07 555:18-23.) However, it is not clear when or under what circumstances that occurred.

<sup>2</sup> Unless otherwise specified, all statutory citations are to the Business and Professions Code.

The accusations in this matter alleged 24 causes for discipline. Respondents maintained that they sought and received their wholesaler permit in reliance on guidance they received from complainant's inspectors in 1994 and 1995, and thereafter conducted their business pursuant to that permit and in compliance with applicable law.

2. On September 6, 2001, Patricia F. Harris, then Executive Officer of the Board of Pharmacy, issued an accusation against respondents International Pharmaceutical Services and Afshin Adibi.

Respondents, then represented by attorneys Kenneth L. Freeman and Ronald S. Marks, filed a notice of defense and a special notice of defense and affirmative defenses dated October 4, 2001.

3. Paragraph 19 of the accusation alleged (bold and underline in original):

19. **DRUGS**

"**Klonopin**," also known as "**Clonazepam**," is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057. **Klonopin** is a benzodiazepine used to treat seizure disorders.

"**Ativan**," also known as "**Lorazepam**," is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057. **Ativan** is a benzodiazepine used to treat anxiety.

"**Human Chorionic Gonadotropin**" ("**HCG**") is a Schedule III controlled substance pursuant to Health and Safety Code section 11056(F) and is used to treat hypogonadism.

"**Cylert**," also known as "**Pemoline**," is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057. **Cylert** is a stimulant used to treat attention deficit disorder.

"**Redux**" was a Schedule IV controlled substance pursuant to Health and Safety Code section 11057 and was used to treat obesity. **Redux** is no longer available in the United States.

4. Executive Officer Harris issued the first supplemental accusation on June 12, 2002. Respondents filed a special notice of defense and affirmative defenses dated July 5, 2002.

5. Executive Officer issued the second supplemental accusation on August 20, 2003. Respondents filed a special notice of defense and affirmative defenses dated September 2, 2003.

6. Robert J. Sullivan of Nossaman, Guthner, Knox & Elliott, LLP, substituted in as respondents' attorney in September 2004.

7. Virginia Herold, Executive Officer, Board of Pharmacy, issued the third supplemental accusation on November 26, 2007.

8. Executive Officers Harris and Herold (collectively, "complainant") filed the accusation and supplemental accusations in their official capacities.

9. Respondent Afshin Adibi was born in Iran. He later came to the United States where he completed his education. Adibi attended De Anza College from 1983 to 1987 and San Jose State University from 1986 to 1987. He attended the University of California, San Francisco, from 1987 to 1991, where he received a Pharm.D. degree. Adibi attended law school at the University of San Francisco from 1993 to 1995. He is not an attorney.

10. The Board of Pharmacy issued registered pharmacist license number 44301 to Adibi on August 2, 1991. The license is in full force and effect until June 30, 2009. Adibi is the President of IPS, which is located at 3 West 37<sup>th</sup> Avenue, Suite 23, San Mateo, California. IPS was formerly located at 320 Judah Street #1, San Francisco, California. IPS holds wholesaler permit number WLS 2955. Executive Officer Herold certified on October 22, 2007 that no disciplinary action has been taken against the Adibi's pharmacist license or the IPS wholesaler permit.

11. Adibi worked as a pharmacist for Kaiser Permanente in 1991 and 1992. From 1992 to 1997, he worked as a "floater" pharmacist for Walgreen's Pharmacy.

12. Adibi wanted to start a business selling pharmaceuticals to overseas customers. He had received inquiries from individuals who wanted to send medicines to their family members in Iran. Adibi initially thought he would establish his business as a pharmacy. In a September 6, 1994 telephone conversation, however, Supervising Inspector Raymond Tom advised Adibi he could not fill foreign prescriptions as a pharmacy. Tom instead recommended that Adibi consider conducting his business as a wholesaler. Later that day, Adibi wrote to Tom:

This letter is pursuant to our telephone conversation on September 6, 1994 regarding my intentions to send medicine to Iran. I would like to thank you for taking time out of your schedule to talk with me regarding the matter and I would also like to thank you for your candor and decisiveness in responding to my unusual request.

Unfortunately, as you mentioned on the phone, there doesn't seem to be a way to legally accomplish my goal as a mail order pharmacy. As per your recommendation, I will research the possibility of dealing as a wholesaler.

I would also like to apologize for sounding a little confused, and argumentative on the phone. I do understand pharmacy law, and I do realize that filling a prescription written by an unlicensed physician in the United States is illegal. I was hoping that since the ultimate destination of the medicine was outside the United States, there would be a way to simply require compliance with the rules and regulations of the importing country and bypassing the local laws. I do understand that my request is unreasonable even though my intentions are honest and legitimate.

Adibi received no reply to this letter.

Tom was a witness at the hearing in this matter. He had no recollection of his interaction with Adibi in 1994.

13. Not long after his conversation with Supervising Inspector Tom, Adibi applied for a wholesaler permit. On February 15, 1995, Inspector Elmer Miller went to 320 Judah Street #1, San Francisco, to conduct an inspection of Adibi's business to see if IPS should receive a wholesaler permit. Miller and Adibi had spoken previously and Adibi explained that he wanted to work with Iranians in America to send medicine to their relatives in Iran. Miller told Adibi he could export to clinics, hospitals, doctors and individuals pursuant to a note or prescription from the doctor in the importing country.

Miller completed an inspection report. He recorded that he had conducted a wholesaler inspection of IPS, that the type of "outlet serviced" was "export," and that the "type of products handled" were "Legend Drugs." Miller ordered Adibi to make one correction, "Rekey Lock - only a pharmacist or exemptee may have a key," and cited as legal authority "1780C," in apparent reference to California Code of Regulations, title 16, section 1780, subdivision (c). That regulation pertains to wholesalers and mandates that entry into areas where prescription drugs are held shall be limited to authorized personnel. Miller ordered no other corrections and found no other or previous non-compliance.

In the "remarks" area of the inspection report, Miller wrote:

Export unopened containers to patients. Shipment to include a note from a physician. Also export to wholesalers, physicians, or pharmacies.

Miller signed the inspection report. Adibi signed the inspection report next to the notation, "I have had this Inspection Report explained to me and understand what corrections must be made to comply herewith."

IPS received wholesaler permit number WLS 2955 on February 15, 1995.

14. Adibi wrote to Inspector Miller the next day, February 16, 1995. He asked Miller to clarify various issues: "DO I have to keep a copy of the prescriptions or

physicians notes for the inspection of the Board?" "Can I advertise the fact that my work is approved by the Board?" "Can IPS export medicine for personal use without a prescription if this is allowed by the importing country?" "Can IPS export medicine via personal carriage by a passenger going overseas?"

After sending the February 16, 1995 letter, Adibi called Miller on several occasions. Miller did not respond to Adibi's questions, but eventually said he would pass Adibi's letter to Executive Officer Harris. Adibi did not receive a reply to his letter from Miller, Harris, or others of complainant's staff.

Miller and Harris were not witnesses at the hearing in this matter.

15. Complainant was aware, as early as 1994 and 1995, that Adibi sought to conduct a pharmaceutical export business and advised Adibi to seek a wholesaler permit rather than a pharmacy license. Complainant's February 15, 1995 inspection explicitly recognized that respondents could export prescription drugs to patients, wholesalers, physicians and pharmacies, and did not require respondents to export drugs only pursuant to prescriptions.

16. Respondents conducted their business in reliance on their wholesaler permit and the guidance they had received from complainant's inspectors in 1994 and 1995. However, beginning in January 1998, Respondent Adibi was warned by the Board's inspectors about the limitations of Respondent's wholesaler permit. He was advised on many occasions that Respondents could not dispense or sell dangerous drugs directly to individuals or end-users (with or without a prescription) or sell dangerous drugs to persons not authorized to receive them. (RT 11/27/07 47:19-25, 48:1-2, 192:1-4, 228-229:10-19, 240:1-5; State's Exs. 6, 22, 76.)

17. Despite the foregoing admonitions by the Board's inspectors, respondents continued to acquire and possess dangerous drugs at their California location and then sell and ship unopened containers of drugs to customers in foreign countries. (RT 11/29/07 496:4-14; 555:18-23; 548-559.) Respondents typically did not speak with or interview the persons who placed orders with them. Instead, respondents would accept orders if they were satisfied that the laws of country from which the order came allowed them to export the drugs that had been ordered. If the laws of the foreign country required a prescription from a doctor in that country, respondents required such a prescription. If the laws of the foreign country did not require a prescription, respondents shipped drugs without a prescription. ("Prescription" in this paragraph is used in its general sense, not as specifically defined in section 4040.)

Respondents' transactions included the export of Viagra, including its 100 milligram form, to persons in Japan, including in the years 1998 and 1999.

18. In January 1996, respondents placed an advertisement in the trade magazine U.S. Pharmacist:

Non-controlled prescription drugs can now be shipped overseas pursuant to a foreign prescription. If you have patients who can use our services, please refer them to: International Pharmaceutical Services, Tel: 1-800-RX EXPORT, For Information ask for a pharmacist.

The advertisement led a reader to inquire how to obtain a license to conduct such a business. The inquiry prompted complainant to investigate respondents' business.

19. On January 27, 1998, Supervising Inspector Robert Ratcliff and Inspector Judith K. Nurse went to 320 Judah Street #1, San Francisco, California, and conducted an unannounced inspection of IPS.

The inspectors interviewed Adibi, who said his business was solely an export business. Adibi also provided copies of his September 6, 1994 letter to Supervising Inspector Raymond Tom and his February 16, 1995 letter to Inspector Elmer Miller. Adibi maintained that the letters showed that he was authorized to conduct his business as a wholesaler. Ratcliff and Nurse reviewed respondents' business records.

At the time of the inspection, respondents sold and shipped prescription drugs to customers in Iran and Japan. From 1994 to 1998, Respondents accepted orders for prescription drugs destined for Iran that were placed by Iranians living in California or the United States. (RT 11/29/07 496:4-14, 568:3-10.) Respondents' sales of drugs to Iran included transactions that occurred while the United States had a trade embargo against Iran.

Among the drugs sold and shipped by respondents were the controlled substances Klonopin, Lorazepam, HCG, and Redux. A Drug Enforcement Administration (DEA) registration is required to trade in controlled substances. Respondents were not, and have never been, registered with the DEA to deal in controlled substances. Adibi initially refused to tell the inspectors where he acquired the controlled substances, but when Ratcliff warned Adibi he would call the police, Adibi told the inspectors he acquired the controlled substances from a South San Francisco pharmacy where he occasionally worked as a relief pharmacist.

Ratcliff and Nurse were concerned that respondents had no DEA registration. Ratcliff called the DEA, after which DEA Diversion Investigator Debra Bell came to IPS and warned Adibi he could not deal in controlled substances without the appropriate DEA registrations. Within about a month, Adibi received a March 4, 1998 letter from DEA Special Agent in Charge Michele M. Leonhart, confirming the information Bell had given him and telling him he was without authority to handle controlled substances.

Adibi was confrontational with the inspectors. Adibi said he had a law degree, understood the law, and did not have to comply with California law.

Nurse issued a January 27, 1998 violation notice to respondents. The notice stated that respondents were not in compliance with sections 4301, subdivision (j), and 4163, as well as "CFR 1301.12(A)" and "CFR 1312.21." Adibi signed the notice, without admitting guilt. There was no mention of section 4059.5, subdivision (e), in the violation notice.

20. During the course of Inspector Nurse's investigation, Adibi provided a four-page document showing 42 shipments from May 14, 1997 to April 14, 1998. Four of the 42 shipments were to addresses in the United States. The rest were to various foreign countries. There were no obvious drug names on the document. The notation "All above shipments are accurate to the best knowledge of the Pharmacist in Charge" appears at the bottom of the document. There was scant testimony about this document at hearing, and neither the testimony nor the document itself reveals what was shipped.

21. Sometime after the January 27, 1998 inspection, a representative from the Department of Commerce came to see Adibi and told him to stop his sales to Iran.

22. Respondents stopped dealing in controlled substances and ceased their transactions with Iran upon being contacted by the DEA and the Department of Commerce.

23. On May 10, 2000, Inspector Nurse sent respondents a violation notice stating they were not complying with several state statutes, state regulations, and federal regulations. There was no mention of section 4059.5, subdivision (e), in the violation notice.

24. Izumi Nirasawa is a director of RHC Corporation (RHC). RHC is a wholesale drug distributor with offices in Honolulu, Hawaii, Torrance, California, and Tokyo, Japan. Nirasawa is based in Honolulu. The vast majority of RHC's business is with customers in Japan. In 2001, Nirasawa had heard from customers and doctors in Japan that the Oz International company was selling prescription drugs on the Internet without requiring a prescription. Nirasawa was concerned that a competitor might be selling drugs in violation of the law. He asked Michio Kawahara, who was then an RHC employee in the Tokyo office, to purchase drugs from Oz International.

25. Nirasawa contacted Inspector Valerie Sakamura, who then participated in complainant's investigation of respondents.

26. Inspector Lin Hokana also participated in complainant's investigation of respondents. On June 5, 2002, Hokana sent a letter to Richard Widup, Corporate Security Manager, Pfizer Corporation, the manufacturer of Viagra:

I have been assigned to investigate a compliant [sic] filed with the Board of Pharmacy. It concerns possible violations of import/



export laws and regulations by a prescription drug wholesaler, shipping prescription drugs to other countries. A large majority of their business is shipping dangerous drugs to Japan and Korea. One of the most common prescription drugs they furnish is Viagra (sildenafil), anywhere from 12 to 96 bottles of 30 tablets a day.

The business, licensed as a drug wholesaler in California, fills patient specific prescriptions. The prescription drug is furnished pursuant to a "note or prescription" written by a prescriber in Japan. The prescription is either faxed or emailed via a web site to the wholesaler in California. The manufacturer's unopened bottle is then mailed to the patient.

I understand Viagra is approved for use in Japan. Are there any restrictions? When was Viagra approved for the Japanese market? What are the packaging or labeling requirements for Viagra supplied to the Japanese and Korean market?

What regulations apply to the exportation of dangerous drugs from the United States and the importation of dangerous drugs into Japan and Korea? Given this unusual business arrangement, what are the other concerns for possible violations?

27.     Widup replied to Hokana in a July 2, 2002 e-mail. Widup informed Hokana:

For Japanese individual patients, the filing of prescriptions via Internet, or for that matter through conventional mail orders from abroad would not constitute a violation of Japanese law. Further, under the Japanese regulatory authorities' policy, individuals are allowed to import prescription drugs for up to a month even without physician prescriptions. As for the supply side, if filing orders are placed at a location outside Japan, the supplying of drugs would not constitute a violation of Japanese law, either. The Japanese law deals [sic] does not regulate sales activities outside Japan.

28.     On June 7, 2002, Inspector Hokana sent a letter to Paul Winnacker of the Japanese Consulate General, San Francisco. Hokana asked a series of questions regarding "possible violations of import/export laws and regulations with shipping prescription drugs, mostly Viagra, to Japan." Questions 8 and 9 in Hokana's letter asked:

8.     Are there general restrictions for quantity of drug [sic] that may be imported for personal use?

9. What are the allowances for importation of prescription drugs for personal use? I have been told a 1-month supply for prescription drugs and 2-month supply for over the counter drugs is allowed.

29. Winnacker replied to Hokana's letter in a July 17, 2002 e-mail. Winnacker wrote:

In Japan, according to the Pharmaceutical Affairs Law, permission from the Minister of Ministry of Health Labor and Welfare (MHLW) is needed for the sale of imported medicine as a business. However, the import of medicine, so-called "private import" (within a fixed quantity) is permitted (within a fixed limit) on an individual basis for the purpose of an individual's medical treatment.

Winnacker replied to Hokana's questions 8 and 9:

8 & 9: The personal importation of two months' worth of doses of general medicine is permitted. As for prescription drugs, one month's worth of doses is permitted.

30. Respondents asked a Japanese lawyer, Norio Saga of Kyoto, Japan, to research Japanese law regarding the personal importation of pharmaceuticals. In an August 3, 2002 letter to respondents' attorney, Saga wrote:

Under Pharmaceutical Affairs Law of Japan, when persons who live in Japan intend to import drugs, quasi-drugs, cosmetics, or medical devices for commercial purposes, they must obtain an appropriate license from the Minister of Health, Labour and Welfare or the prefectural governor. But, when a person intends to import them only for his/her personal use, he/she need not obtain any approval. There is no article in the Pharmaceutical Affairs Law, no statute pertaining to the Law, no notice, and no notification to control the import for personal use. As for the above description, there is no difference between "drugs requiring directions or prescriptions of a doctor" (i.e. prescription drugs which are designated by the Minister of Health, Labour and Welfare according to the Pharmaceutical Affairs Law, Article 49-1) and other drugs. In other words, even if a person intends to import prescription drugs, he/she will not need any direction from or prescription from a doctor.

31. Inspector Hokana sent an August 5, 2002 violation notice to respondents. The notice alleged numerous violations of the Pharmacy Law, including section 4059.5, subdivision (e).

32. On March 6, 2003, the Bureau of Industry and Security, U.S. Department of Commerce (BIS), issued a charging letter against Adibi alleging that he had violated the trade embargo against Iran.

About four months later, On July 11, 2003, Christine Lee, Esq., Office of Chief Counsel for Industry and Security, Department of Commerce, issued a "Notice of Withdrawal of the Charging letter" to Adibi and the federal administrative law judge.

33. Adibi received a February 23, 2004 letter from David H. Harmon, Chief, Enforcement Division, Office of Foreign Assets Control, Department of Treasury. Harmon wrote:

This is in regards to your transactions involving Iran as discussed in the Office of Foreign Assets Control ("OFAC") letter to you dated September 4, 1997, and your response letter to OFAC dated September 10, 1997.

As you are aware, OFAC administers and enforces a comprehensive economic sanctions program and trade embargo against the Government of Iran as promulgated in the Iranian Transactions Regulations, 31 CFR Part 560 (the "Regulations"), under the authority of the International Emergency Economic Powers Act, 50 U.S.C. 1701 et seq. ("IEEPA"). The Regulations prohibit United States persons from engaging in virtually all direct or indirect commercial, financial or trade transactions with Iran, unless authorized by OFAC or exempted by statute. Section 560.204 of the Regulations prohibits, except as otherwise authorized, the exportation from the United States to Iran of any goods, technology or services.

It is the position of this Office that the transactions conducted by you as described in your letter may have included unlicensed export actions to Iran in violation of the Regulations.

You are hereby warned that any future transaction on your part involving a violation of the Iran embargo may result in the imposition of criminal and/or civil penalties. Criminal penalties for violation of the Regulations range up to 10 years in prison and \$500,000 in corporate and \$250,000 in individual fines. OFAC may impose civil penalties at \$11,000 per violation.

If you have any questions on this matter, you may contact Elton Ellison at [telephone number].

It is unclear why this letter was sent some six and one-half years after the events mentioned in the letter.

34. Respondents have not been adjudicated in violation of any federal laws or regulations by the Drug Enforcement Administration, Department of Commerce, Office of Foreign Assets Control, Treasury Department, any other federal enforcement agency or federal court. Regardless, at hearing, Respondent admitted selling controlled substances to end-users in Iran without a DEA registration. (RT 11/29/07 531:2-6, 567-568.) Respondent further admitted that he was "exporting Viagra before it was approved in Japan" and before it was "officially approved for use by the Japanese government." (RT 11/29/07 559:7-12, 23-25, 560:1.)

35. On March 25, 2004, respondents shipped dangerous drugs to 17 individuals in Italy, Japan, Portugal, Switzerland, and the United Kingdom. Respondents shipped the drugs without patient specific prescriptions.

36. Inspector Ralph Orlandella inspected IPS on April 1, 2004.

37. On September 2, 2005, Adibi submitted an application, via the internet, to the DEA for a DEA registration for IPS. One of the questions on the application asked "Has the applicant ever had a state professional license or controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?" Adibi answered, "No." Adibi withdrew the application on September 30, 2005.

The present proceeding, in which complainant seeks to revoke or suspend respondents' license and wholesaler permit, was pending when Adibi submitted his application to the DEA. Adibi maintains that his incorrect answer was a simple mistake.

38. Complainant submitted a certification of prosecution costs stating that the Department of Justice billed the Board of Pharmacy \$149,660.63 for its time spent on this case.

### *POST-HEARING BRIEFS*

This case involves an accusation and three supplemental accusations issued in 2001, 2002, 2003, and 2007. The accusations alleged 24 separate causes for discipline and asserted that respondents violated numerous state statutes, state regulations, and federal regulations. Respondents raised various factual, equitable, and legal defenses, including defenses based on federal and constitutional law. Evidence of events and conduct spanning more than 15 years is in the record. Well over 80 exhibits are in evidence.

Respondents requested the opportunity to file post-hearing briefs. Complainant opposed post-hearing briefing, and requested oral closing argument. The parties were afforded the opportunity to file closing and response briefs. The parties were told they could argue any issue of law or fact in the record, and were asked to brief three specific issues.

First, in view that the conduct at issue spanned a number of years and that the statutes had changed over time, the parties were asked to specify the laws they asserted applied at the time of the conduct in question.

Second, many of complainant's causes for discipline, including those alleging violations of federal regulations, asserted that respondents were guilty of unprofessional conduct under section 4301, subdivisions (j) "and/or" (o). The parties were asked to brief section 4301, subdivisions (j) and (o).

Third, the parties were asked to brief sections 4081 and 4332, concerning respondents' alleged violations of records requirements.

In addition, after non-adoption, the Board specifically requested written argument on the following issues:

- (1) Whether the administrative pleadings met the requirements of Section 11503 of the Government Code, particularly with respect to the Second, Third, and Eighth Causes for Discipline;
- (2) If there was a variance between the administrative pleadings and proof, whether such variance actually misled respondent to his prejudice in maintaining his defense upon the merits;
- (3) In light of *Banks v. Board of Pharmacy* (1984) 161 Cal.App.3d 708, whether the Board may take disciplinary action against a licensee for a violation of federal law or regulations without the violation first having been adjudicated by a federal agency or court;
- (4) Whether violation of the comprehensive trade embargo against Iran is a violation of federal or international laws and, whether that charge was properly pled according to the requirements of Government Code Section 11503 (Eighth Cause for Discipline); and,
- (5) If cause for discipline exists, what penalty, if any, should be applied.

### LEGAL CONCLUSIONS

#### CONSTITUTIONAL DEFENSES

Respondents sold dangerous drugs to customers in foreign countries. Complainant asserted that such transactions were subject to California law, for example that respondents transferred, sold or delivered dangerous drugs outside of the United States to persons unauthorized by law to receive the drugs. Relying on the United States Constitution, including the Supremacy Clause and the Commerce Clause,

respondents asserted that their business was in foreign commerce and that the board has no authority to regulate such commerce.

The board is not authorized to declare a statute unenforceable, or to refuse to enforce a statute, on the basis of unconstitutionality, unless an appellate court has made a determination that such statute is unconstitutional. (Cal. Const., art. III, § 3.5.)

### *BURDEN OF PROOF*

Complainant has the burden of proving cause for discipline by clear and convincing evidence. (*Ettinger v. Board of Medical Quality Assurance* (1982) 144 Cal.App.3d 522, 526-527.)

### *BUSINESS AND PROFESSIONS CODE AND GOVERNMENT CODE PROVISIONS*

The Pharmacy Law (Bus. & Prof. Code, § 4000 et seq.) provides at section 4300, subdivision (e), that the board's disciplinary proceedings are conducted "in accordance with Chapter 5 (commencing with Section 11500) of Part I of Division 3 of the Government Code" (the Administrative Procedure Act or APA).

To ensure fairness and due process, the APA sets forth the requirements for accusations. Government Code section 11503 provides, in pertinent part:

A hearing to determine whether a right, authority, license or privilege should be revoked, suspended, limited or conditioned shall be initiated by filing an accusation. The accusation shall be a written statement of charges which shall set forth in ordinary and concise language the acts or omissions with which the respondent is charged, to the end that the respondent will be able to prepare his defense. It shall specify the statutes and rules which the respondent is alleged to have violated, but shall not consist merely of charges phrased in the language of such statutes and rules.

The initiating agency's specification of the statutes and rules is a statutory predicate for agency action. Respondents are not required to defend against unspecified statutes and rules. *Wheeler v. State Bd. of Forestry* (1982) 144 Cal.App.3d 522, 526-527; *Linda Jones General Builder v. Contractors' State License Board* (1987) 194 Cal.App.3d 1320, 1326.) Complainant's ninth, fifteenth through twenty-second, and twenty-fourth causes of action did not specify statutes or rules under which the board is authorized to impose disciplinary action.

Government Code section 11506 permits a respondent to file a notice of defense, request a hearing, and raise various objections to the accusation. The filing of

a notice of defense "is deemed a specific denial of all parts of the accusation not expressly admitted." (Gov. Code, § 11506, subd. (c).)

Hearsay evidence may be used for the purpose of supplementing or explaining other evidence but over timely objection is not sufficient in itself to support a finding unless it would be admissible over objection in civil actions. (Gov. Code, § 11513, subd. (d).)

Section 4301 authorizes the board to impose discipline against a license holder who is guilty of unprofessional conduct. Section 4301, subdivisions (j) and (o), alleged in many of complainant's causes for discipline, provides that unprofessional conduct includes:

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

Section 4059.5, subdivision (e), is the key statute in this case. Complainant's eighth, tenth, fourteenth, twenty-first, twenty-second, and twenty-third causes for discipline alleged that respondents violated this statute. Respondents asserted not only that complainant failed to prove they violated the statute, but also that it is the only provision in the Pharmacy Law that can "logically and constitutionally regulate the foreign aspect of Respondents' business."

The constitutional issue is for another forum to consider. In its current form, Section 4059.5, subdivision (e) provides:

A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the **dangerous** drugs or **dangerous** devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the **dangerous** drugs or **dangerous** devices are to be delivered shall include, but not be limited to, determining that the recipient of the **dangerous** drugs or **dangerous** devices is authorized by law to receive the drugs or devices. [Emphasis added to show amendments that took

effect January 1, 2006.]

The current version of this statute added "dangerous" where shown above. (Stats.2004 c. 857 (S.B. 1307) § 11.5, operative Jan. 1, 2006. Amended by Stats.2005 c. 506 (A.B. 302) § 11, eff. Oct. 4, 2005, operative Jan. 1, 2006). The 1998 version of the statute lacked "dangerous" where shown above. There is no substantive difference between the previous and current iterations of the statute for purposes of this case.

Section 4059.5, subdivision (e), specifically incorporates and requires compliance with the laws of the State of California, the laws of the United States, and the laws of the State or country to which the dangerous drugs<sup>3</sup> or devices are to be transferred, sold or delivered.

## *ACCUSATION*

Complainant's September 6, 2001, accusation alleged nine causes for discipline.

Respondents' October 4, 2001, special notice of defense and affirmative defenses raised numerous objections to the accusation. Respondents' objections included that the causes for discipline failed to state acts or omissions upon which complainant could proceed, were so indefinite or uncertain that respondents could not identify the transactions or prepare their defense, and were based on statutes that are vague, confusing, contradictory, and overly broad so as to violate respondents' constitutional rights. Complainant thereafter sought no amendments to the accusation.

### *A. FIRST CAUSE FOR DISCIPLINE*

Complainant's first cause for discipline alleged, in pertinent part:

20. Respondent IPS and Respondent Adibi are subject to disciplinary action under section 4301(j) and/or (o), unprofessional conduct, for violating section 4110 of the Code in that respondent [sic] dispensed dangerous drugs at retail without being licensed as a pharmacy.

Section 4110 contains subdivisions (a) (license requirement) and (b) (temporary permit). Complainant's first cause for discipline did not specify what subdivision respondents purportedly violated. Subdivision (b) appears to have no connection with the issues in this case. Subdivision (a) provides:

No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for

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<sup>3</sup> "Dangerous drug" is defined in Section 4022 of the Pharmacy Law.



each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

Section 4110 contains no explanation or definition for what acts constitute "conducting a pharmacy" in California. However, over the time periods alleged in the first cause for discipline, the Pharmacy Law contained definitions for "Pharmacy" applicable to this case. From 1994 through 1997,<sup>4</sup> "Pharmacy" was defined in Sections 4035 and 4037, which provided, in pertinent part:

"Pharmacy" is an area, place, or premises in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, **any area, place, or premises** described in a permit issued by the board . . . **wherein controlled substances or dangerous drugs, or dangerous devices . . . are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances or dangerous drugs or dangerous devices are furnished, sold, or dispensed at retail.** . . . (Emphasis added.)

From 1995 to 1997, respondents acquired controlled substances and dangerous drugs and sold those drugs at retail directly to individual consumers (Factual Findings 19, 34). However, complainant did not cite Sections 4035 or 4037 in the first cause for discipline in the Accusation or plead these sections as a basis for determining that respondents violated the Pharmacy Law.

In addition, respondents raised the doctrine of equitable estoppel as a defense. The doctrine of equitable estoppel is given evidentiary effect at Evidence Code section 623:

Whenever a party has, by his own statement or conduct, intentionally and deliberately led another to believe a particular thing true and to act upon such belief, he is not, in any litigation arising out of such statement or conduct, permitted to contradict it.

Respondents were not licensed as a pharmacy because complainant's inspectors suggested and recognized, in 1994 and 1995, that Adibi could conduct his business as a wholesaler. Adibi applied for and, on February 15, 1995, received a wholesaler permit. Inspector Miller specifically noted IPS was a wholesaler, handled legend drugs, and exported drugs to patients, wholesalers, physicians, and pharmacies. Miller ordered IPS to make a single correction (rekeying a lock). Miller found no other violations and ordered no other corrections. (Factual Finding 13.) Miller instructed Adibi:

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<sup>4</sup> Stats.1984, c. 1635, § 7; Stats.1994, c.1060, § 1; Stats.1996, c. 890 (A.B.2802), § 3.

Export unopened containers to patients. Shipment to include a note from a physician. Also export to wholesalers, physicians, or pharmacies.

Adibi conducted his business in reasonable reliance on the inspectors' statements and conduct from 1995 to 1997. Complainant's first cause for discipline, issued more than six years after the above event, in essence seeks to discipline respondents for following her own inspectors' guidance and conducting their business in accordance with the IPS wholesaler permit. Complainant is equitably estopped from doing so.

The first cause for discipline will be dismissed.

*B. SECOND CAUSE FOR DISCIPLINE*

Complainant's second cause for discipline alleged:

21. Respondent IPS and Respondent Adibi are subject to disciplinary action under section 4301(j) and/or (o) for the violation of Code of Federal Regulations section 1301.11(a), Title 24, in that Respondent Adibi and respondent IPS failed to obtain DEA registration to dispense and export dangerous drugs and/or controlled substances as set forth in paragraph 19.

While respondents acknowledged that they did not hold a DEA registration, they maintained that the board cannot impose discipline in the absence of an adjudicated federal violation. Respondents have not been adjudicated in violation of any federal law by a federal regulatory or law enforcement agency, including 24 Code of Federal Regulations part 1301.11, subdivision (a). That regulation provides:

Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§1301.22–1301.26. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

The parties were specifically asked to brief section 4301, subdivisions (j) and (o), including the board's authority to find a violation of non-California law.

Pursuant to section 4301, subdivisions (j) and (o), the board may take disciplinary action against a licensee for a violation of federal law. A plain reading of these statutes and a review of current case law interpreting the board's authority reveals that the board may discipline a licensee for violating a federal law or regulation even in the absence of any adjudication, judgment or conviction by a federal regulatory or law enforcement agency.

Section 4301, subdivision (j), provides that unprofessional conduct includes:

The **violation of any of the statutes of** this state, of any other state, or of **the United States** regulating controlled substances and dangerous drugs. [Emphasis added.]

Section 4301, subdivision (o), provides that unprofessional conduct includes:

**Violating or attempting to violate**, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision of this chapter or of the **applicable federal and state laws and regulations governing pharmacy**, including regulations established by the board or by any other state or **federal regulatory agency**. [Emphasis added.]

Unlike other statutes in the Pharmacy Law, these statutes on their face do not require that a conviction or judgment be entered against a licensee before the board acts to discipline that licensee. (See, e.g., Sections 4301(l) making a "record of conviction conclusive evidence of unprofessional conduct" and 4311 requiring automatic suspension at "any time that the person is incarcerated after conviction of a felony".) These statutes specifically authorize the board to adjudicate violations and even "attempted" violations of applicable federal laws and regulations.

Current case law that interprets prior and similar authority possessed by the board supports the above interpretation. From 1966 through most of 1982, the board's authority to discipline licensees for violations of federal law and regulations was set forth at Section 4350.5, and read as follows, in pertinent part:

The board shall take action against any holder of a certificate, license, permit, registration or exemption, who is guilty of unprofessional conduct ... **Unprofessional conduct shall include** but is not limited to the **violating** or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of **the laws governing pharmacy**, or of regulations established by the board...." (Stats.1965, c. 1822, p. 4207, § 36.) (Emphasis added.)

In 1984, in a California Court of Appeal case<sup>5</sup> interpreting the above-quoted language in Section 4350.5, a respondent challenged the board's authority to impose discipline against him for violations of federal law and argued that recent amendments to the Pharmacy Law meant that the board had no authority to adjudicate violations of federal law prior to 1982.<sup>6</sup> In dismissing that argument and upholding the board's action against the respondent, the Court held the following:

Ordinarily, an alteration in statutory language should be interpreted as working a change in the law. [citation] It is not, however, inevitably true. In this instance, that would demand limiting the earlier version's phrase "the laws governing pharmacy" to the laws of California. This is unwarranted. "Laws," without qualification, generally include both state and national law. Our Legislature was surely aware of federal regulation of pharmacy. We think it unlikely that the Legislature intended no disciplinary repercussions to flow from violations of federal law. We therefore conclude that the amendment of section 4350.5 merely clarified the existing law, making no substantive change. Appellant was properly subject to discipline for violating federal law.<sup>7</sup>

There is no substantive difference in interpretation between the board's prior authority in Section 4350.5 and the authority now contained in Section 4301.

However, by its terms, Section 4301, subdivision (j) does not apply to the second cause for discipline because it applies to "statutes" "regulating controlled substances and dangerous drugs," not to regulations. In contrast, subdivision (o) by its terms applies to "laws and regulations governing pharmacy."

However, Paragraph 19 of the accusation set forth no allegations concerning respondents' failure to obtain DEA registration to dispense and export dangerous drugs and/or controlled substances. Respondents objected that paragraph 19 "consists only of a list of drugs." (Factual Finding 3.) The second cause for discipline failed to state acts or omissions upon which complainant could proceed.

The second cause for discipline will be dismissed.

### C. THIRD CAUSE FOR DISCIPLINE

Complainant's third cause for discipline alleged:

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<sup>5</sup> *Banks v. Board of Pharmacy, Dept. of Consumer Affairs* (1984) 161 Cal.App.3d 708.

<sup>6</sup> Effective September 22, 1982, Section 4350.5 was amended to add the words "applicable federal and state laws and regulations" before the words "governing pharmacy." (Stats.1982, c.1284, p. 4752, § 1.) The Board notes that Section 4350.5 was in full force and effect until January 1, 1997. (Stats. 1988, c.918, §2, repealed by Stats.1996, c.890, §2.)

<sup>7</sup> Id. at p. 715.

22. Respondents are subject to disciplinary action under section 4301(j) and/or (o) for violating Code of Federal Regulations section 1301.12(a), Title 21, in that Respondent Adibi failed to obtain DEA registration while engaged in a professional practice of dispensing and exporting dangerous drugs and/or controlled substances as set forth in paragraph 19.

For the same reasons set forth under the Legal Conclusions for the second cause for discipline, the third cause for discipline must be dismissed.

Further, Paragraph 19 of the accusation sets forth no allegations concerning Adibi's failure to obtain DEA registration while engaged in a professional practice of dispensing and exporting dangerous drugs and/or controlled substances. The third cause for discipline failed to state acts or omissions upon which complainant could proceed.

The third cause for discipline will be dismissed.

*D. FOURTH CAUSE FOR DISCIPLINE*

Complainant's fourth cause for discipline alleged:

23. Respondent IPS and Respondent Adibi are subject to disciplinary action under section 4301(j) and/or (o) for violating Code of Federal Regulations section 1302.21(a) [sic], Title 21, in that Respondent Adibi failed to properly register or be exempted from registration under the Act while engaged in the business of exporting or causing to be exported Schedule IV substances such as Klonopin, Ativan, HCG, Redux, as set forth in paragraph 19.

Although paragraph 19 of the accusation listed Klonopin, Ativan, HCG, and Redux, it set forth no allegations concerning Adibi's failure to register or be exempted from registration. Further, as respondents noted on October 4, 2001, "Code of Federal Regulations section 1302.21(a), Title 21" does not exist. The fourth cause for discipline failed to state acts or omissions upon which complainant could proceed.

The fourth cause for discipline will be dismissed.

*E. FIFTH CAUSE FOR DISCIPLINE*

Complainant's fifth cause for discipline alleged:

24. Respondent IPS and respondent Adibi are subject to disciplinary action under section 4301(j) and/or (o) for violating

California Code of Regulations section 1717(d), Title 16, pursuant to section 4005(b) of the Business and Professions Code, in that Respondent Adibi by his own admission furnished drugs and/or devices to prescribers licensed in states other than California without abiding by the requirements of state regulation(s) as set forth in paragraph 19.

Paragraph 19 of the accusation sets forth no factual allegations concerning Adibi's furnishing drugs and/or devices to out-of-state prescribers. The fifth cause for discipline failed to state acts or omissions upon which complainant could proceed.

Additionally, California Code of Regulations, title 16, section 1717, subdivision (d), pertains to permissible pharmacy practices, not the prohibited conduct alleged in the Accusation. This section states only that a "pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code section 4005." Further, complainant did not specify what "state regulations" respondents allegedly violated. Moreover, section 4005, subdivision (b), authorizes the board to adopt regulations; it sets forth no prohibited conduct.

The fifth cause for discipline will be dismissed.

*F. SIXTH AND SEVENTH CAUSES FOR DISCIPLINE*

Complainant's sixth cause for discipline alleged, in pertinent part:

25. Respondent Adibi and respondent IPS are subject to disciplinary action pursuant to Code section 4301, subparagraphs (j) and/or (o) for violating Code section 4081 in that respondents **failed to provide** all records of acquisition and disposition of drugs from January 1, 1997, to January 27, 1998, and any records that would document that the drugs were exported to authorized individuals, as requested during the course of a wholesaler inspection conducted on or around January 27, 1998. [Emphasis added.]

Complainant's seventh cause for discipline alleged, in pertinent part:

26. Respondent Adibi and respondent IPS are subject to disciplinary action pursuant to Code section 4301, subparagraphs (j) and/or (o) for violating Code section 4081 in that respondents **failed to provide have** [sic] all records of acquisition and disposition of the drug Viagra for the time period from approximately January 1, 1998, through to March 2, 1999. [Emphasis added.]

As respondents noted, section 4081 requires records to be "open for inspection" during business hours. Neither cause for discipline alleged such a violation.

The parties were specifically asked to discuss sections 4081 and 4332 in their closing briefs. Complainant did not mention or discuss either section, except quoting a passage from the transcript in which witness Judith Nurse said that section "4352" required respondents to produce documents and records in a timely manner. Nurse clearly meant section 4332, the statute that requires records to be produced and provided.

Section 4081 states, in pertinent part:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours **open to inspection** by authorized officers of the law, and shall be preserved for at least three years from the date of making. [Emphasis added.]

Section 4081 requires that records be "open to inspection" during business hours. It does not require that a licensee "provide" copies of its records to an inspector. This is in stark contrast to section 4332, which states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or **provide** the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor. [Emphasis added.]

Section 4332 is a criminal statute that requires the right to a trial by jury and a finding of guilt beyond a reasonable doubt. No violation of section 4332 was alleged in this case.

The sixth and seventh causes for discipline will be dismissed.

#### *G. EIGHTH CAUSE FOR DISCIPLINE*

Complainant's eighth cause for discipline alleged:

27. Respondent Adibi and respondent IPS are subject to disciplinary action pursuant to Code section 4301, subparagraphs (j) and/or (o) for violating Code section 4059.5(e) in that respondents transferred, sold or delivered dangerous drugs outside of the United States to persons **unauthorized by local and international law** to receive the drugs. The circumstances are as follows:

a. A comparison of disposition records for IPS provided by wholesale distributors to the Board pursuant to the Board's request, as set forth in [accusation] paragraph 26 above, uncovered the following instances where respondents illegally exported dangerous drugs and/or failed to comply with the laws of the importing country.

(1) During the time period from February 1997 to January 1998, there were approximately 317 sales by IPS of dangerous drugs to a foreign country subject to a comprehensive trade embargo by the United States without prior government approval.

(2) From approximately mid-1998 to March 1999, respondent IPS dispensed and exported Viagra to Japan when Viagra had not been approved for use in Japan by the Japanese government. (Emphasis added.)

#### 1. SALES TO FOREIGN COUNTRY SUBJECT TO TRADE EMBARGO

Respondents sold and sent dangerous drugs to persons in Iran while there was a United States trade embargo against Iran. (Factual Finding 19.) Complainant did not, however, establish that "local and international law" rendered these persons "unauthorized" to receive drugs. Complainant identified no such local or international law.

#### 2. EXPORT OF VIAGRA TO JAPAN

Respondents exported Viagra to persons in Japan during the time period alleged in the eighth cause for discipline. (Factual Finding 17.) Complainant did not, however, establish that respondents "dispensed" Viagra to these persons. "Dispense" is a term defined in section 4024, but that term does not appear in section 4059.5, subdivision (e). Further, complainant did not cite Section 4024 in the eighth cause for discipline in the Accusation or plead it as a basis for determining that Respondents violated the Pharmacy Law.

Complainant alleged that respondents "failed to comply with the laws of the importing country" and that the persons were "unauthorized by local and international law to receive the drugs." Neither complainant's closing brief nor written arguments submitted to the board on the eighth cause for discipline identified the applicable Japanese or "local and international" laws that respondents allegedly violated.<sup>8</sup>

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<sup>8</sup> Complainant's closing brief on the ninth cause for discipline asserted "Respondent Is Guilty Of The Ninth Cause For Discipline In The Accusation Against Him Because He Furnished Drugs To Persons Without A Prescription And In Violation Of Foreign Laws." Nevertheless, complainant again did not identify any foreign or Japanese laws that respondents allegedly violated.



Further, the results of complainant's own investigation made it unclear whether respondent's conduct violated Japanese law. Richard Widup of Pfizer informed Inspector Hokana that filling prescriptions by Internet and conventional mail order from abroad did not violate Japanese law, that individuals are allowed to import prescription drugs without physician prescriptions, and that "if filling orders are placed at a location outside Japan, the supplying of drugs would not constitute a violation of Japanese law, either." Paul Winnacker of the Japanese Consulate General informed Hokana that Japanese law allowed for the "personal importation" of "one months' worth" of prescription drugs for personal use. (State's Ex. 75.) Widup and Winnacker's responses to Hokana were consistent with the conclusions of Norio Saga, the Japanese lawyer engaged by respondents. (Factual Findings 26 through 30.)

Notably, Hokana's inquiries to Widup and Winnacker occurred in June 2002, some nine months after complainant's eighth cause for discipline alleged that respondents had "failed to comply with the laws of the importing country."

Complainant did not establish the eighth cause for discipline with regard to respondents' export of Viagra to Japan.

### 3. CONCLUSION

For the foregoing reasons, the eighth cause for discipline will be dismissed.

#### H. NINTH CAUSE FOR DISCIPLINE

Complainant's ninth cause for discipline alleged:

28. Respondent IPS and Respondent Adibi are subject to disciplinary action for violating Section 4059(a) of the Business and Professions Code in that respondents furnished Viagra, a dangerous drug, to Japan without a prescription from a physician, dentist, podiatrist, optometrist or veterinarian as set forth in [accusation] paragraph 27 above.

Respondents objected to the ninth cause for discipline for failing to state acts or omissions upon which complainant could proceed. Unlike section 4301, subdivisions (j) and (o), section 4059, subdivision (a), does not authorize the board to impose discipline on a license or permit holder. The ninth cause for discipline failed to state acts or omissions upon which complainant could proceed.

The ninth cause for discipline will be dismissed.

## ***FIRST SUPPLEMENTAL ACCUSATION***

Complainant's June 12, 2002, first supplemental accusation alleged four additional causes for discipline.<sup>9</sup> Each of these causes for discipline was based on an alleged June 27, 2001, purchase of Viagra by "a consumer in Japan."

Respondents' July 5, 2002, special notice of defense and affirmative defenses raised numerous objections to the first supplemental accusation. Respondents' objections included that the causes for discipline failed to state acts or omissions upon which complainant could proceed, were so indefinite or uncertain that respondents could not identify the transactions or prepare their defense, and were based on statutes that are vague, confusing, contradictory, and overly broad so as to violate respondents' constitutional rights. Complainant thereafter sought no amendments to the first supplemental accusation.

### ***I. TENTH CAUSE FOR DISCIPLINE***

Complainant's tenth cause for discipline alleged:

29. Respondent IPS and Respondent Adibi are subject to disciplinary action pursuant to section 4301(j) and/or (o) for violating Code section 4059.5(e) in that respondents transferred, sold or delivered Viagra, a dangerous drug pursuant to Code section 4022, to persons unauthorized by law to receive the drug. The circumstances are as follows:

a. On or about May 21, 2001, the Board received notice that a computer based website/company named OZ International, doing business as "iDrugstore.com" (iDrugstore), maintains a website on the internet where prescription drugs from the United States are offered for sale without prescription in Japan. iDrugstore published claims on its website that it can export prescription drugs without a prescription under Japanese law. The website failed to mention that some states in the United States have laws prohibiting the exportation of drugs without prescription and a wholesale permit.

b. On or about June 27, 2001, a consumer in Japan purchased thirty 100 mg. Viagra tabs, without a prescription, from iDrugstore. The order was shipped to Japan from 320 Judah Street, Suite 1, in San Francisco, California, 94122. A geographic search conducted through the Board's records revealed that the only licensed wholesaler located at 320 Judah Street, Suite 1, in San Francisco, is International Pharmaceutical

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<sup>9</sup> Complainant's closing brief addressed the causes for discipline under the first supplemental accusation (i.e., the tenth through the thirteenth causes for discipline) under a single heading.

Services (Respondent IPS) owned by Afshin Adibi (Respondent Adibi). The wholesale license issued to respondent does not cover shipping drugs directly to patients and/or exporting drugs out of the United States.

The tenth cause for discipline alleged a single June 27, 2001, transaction involving "a consumer in Japan." Complainant did not identify the law that purportedly rendered the Japanese consumer "unauthorized." It is unclear if complainant meant some provision of Japanese law rendered the consumer unauthorized, in which case complainant did not address the personal import provision revealed in Inspector Hokana's investigation, or if complainant meant to assert that section 4059.5, subdivision (e), or some other provision of state law rendered the consumer unauthorized. Complainant did not establish that the Japanese consumer was unauthorized to receive Viagra.

Additionally, respondents raised multiple objections to the testimony and documents through which complainant sought to prove the alleged July 27, 2001, transaction. Complainant's witness, Izumi Nirasawa, was credible, but he relayed various hearsay statements by Michio Kawahara, the alleged "consumer in Japan." Kawahara was not a witness at the hearing. That he may have been an employee of Nirasawa's company does not transform Kawahara's statements into direct evidence. Moreover, complainant's documentary evidence (an iDrugstore invoice and two partial pages bearing the name "Nishihama & Kishida, CPA's, Inc.") was also hearsay, and lacked foundation. Complainant did not prove the factual allegations in the tenth cause for discipline.

The tenth cause for discipline will be dismissed.

*J. ELEVENTH CAUSE FOR DISCIPLINE*

Complainant's eleventh cause for discipline alleged:

30. Respondent IPS and Respondent Adibi are subject to disciplinary action pursuant to section 4301(j) and/or (o) for violating section 4059 of the Code in that respondents furnished Viagra, a dangerous drug pursuant to Code section 4022, without a prescription as set forth in [accusation] paragraph 29, above.

For the same reasons discussed with regard to the tenth cause for discipline, above, complainant did not establish the eleventh cause for discipline.

The eleventh cause for discipline will be dismissed.

K. *TWELFTH CAUSE FOR DISCIPLINE*

Complainant's twelfth cause for discipline alleged:

31. Respondent IPS and Respondent Adibi are subject to disciplinary action pursuant to [sic] 4301(j) and/or (o) for violating section 4110 of the Code in that respondents conducted a pharmacy in California, through the internet, to wit, iDrugstore, without a license from the Board as set forth in [accusation] paragraph 29, above.

For the same reasons discussed with regard to the tenth cause for discipline, above, complainant did not establish the twelfth cause for discipline.

Additionally, accusation paragraph 29 set forth no allegations regarding respondents conducting "a pharmacy in California, through the internet, to wit, iDrugstore." Nor did complainant establish that respondents owned or operated iDrugstore.

The twelfth cause for discipline will be dismissed.

L. *THIRTEENTH CAUSE FOR DISCIPLINE*

Complainant's thirteenth cause for discipline alleged:

32. Respondent IPS and Respondent Adibi are subject to disciplinary action pursuant to 4301(j) and/or (o) of the Code for violating Title 16, California Code of Regulations, section 1781, in that respondents conducted a pharmacy through the internet, to wit, iDrugstore, without a pharmacist or certified exemptee in charge as set forth in [accusation] paragraph 29.

For the same reasons discussed with regard to the tenth cause for discipline, above, complainant did not establish the thirteenth cause for discipline.

Additionally, accusation paragraph 29 set forth no allegations regarding iDrugstore not having a pharmacist or certified exemptee in charge. Complainant did not establish that respondents conducted a pharmacy through or had any connection with iDrugstore that rendered them responsible for iDrugstore having or not having a pharmacist or certified exemptee in charge.

The thirteenth cause for discipline will be dismissed.

## **SECOND SUPPLEMENTAL ACCUSATION**

Complainant's August 20, 2003, second supplemental accusation alleged eight additional causes for discipline.

Respondents' September 2, 2003, special notice of defense and affirmative defenses raised numerous objections to the second supplemental accusation. Respondents' objections included that the causes for discipline failed to state acts or omissions upon which complainant could proceed, were so indefinite or uncertain that respondents could not identify the transactions or prepare their defense, and were based on statutes that are vague, confusing, contradictory, and overly broad so as to violate respondents' constitutional rights. Complainant thereafter sought no amendments to the second supplemental accusation.

### **M. *FOURTEENTH CAUSE FOR DISCIPLINE***

Complainant's fourteenth cause for discipline alleged:

33. Respondent IPS and Respondent Adibi are subject to disciplinary action under section 4301(j) and/or (o), unprofessional conduct, for the violation of Code section 4059.5(e), as defined in Title 16, section 1783(b) of the California Code of Regulations, in that respondents transferred, sold and/or delivered dangerous drugs pursuant to section 4022 of the Code, to unauthorized persons outside this state, either foreign or domestic, and failed to comply with laws of the state, and the United States and of the state or country to which the drugs were delivered. The circumstances are as follows:

a. On or about January 25, 2002, the Board received a complaint that respondent(s) purchased a large amount of Viagra, approximately valued at \$730,000.00, from the time period on or around August 9, 2001, to January 25, 2002.

b. On or about June 4, 2002, the Board conducted an inspection of respondent IPS and interviewed respondent Adibi. During the course of the inspection, the Board's investigators made the following findings based on respondent's statements and business documents:

(1) Respondent Adibi, through respondent IPS, dispensed and exported dangerous drugs, including but not limited to Viagra, pursuant to a prescription and/or drug order from a foreign prescriber to patients in Japan and/or Korea while licensed by the Board solely as a wholesaler and not as a pharmacy.

(2) Respondent Adibi, through respondent IPS, furnished dangerous drugs, including but not limited to Viagra, pursuant to patient specific prescriptions by facsimile and/or by e-mail from his website "Internationalpharmacy.com" and/or other websites in Japan including, but not limited to, websites operated by Oz International, to wit: "iDrugStore.com" and "iRxMedicine.com", while licensed by the Board solely as a wholesaler and not as a pharmacy.

(3) Respondent Adibi, through respondent IPS, delivered dangerous drugs, to wit: Viagra, to people and/or parties to whom the Board had not issued permits.

(4) Respondent Adibi, through respondent IPS, dispensed approximately 40-45 dangerous drugs daily to patients in Japan and/or Korea without placing prescription labels on the manufacturer's bottle and without otherwise providing the patients with information necessary for appropriate use.

(5) On or about June 4, 2002, during the course of the Board's investigation of respondent IPS, respondent Adibi admitted that approximately 99% of his sales were to Japan and Korea and that he supplied drugs pursuant to a prescription or drug order from a foreign prescriber to patients outside of the United States. Respondent admitted that he received prescriptions by fax and by e-mail from his website "Internationalpharmacy.com" and from websites operated in Japan by Oz International as "iDrugStore.com" and/or "iRxMedicine.com." Respondent Adibi acquired the drugs ordered through the websites "Internationalpharmacy.com", "idrugStore.com" and/or "iRxMedicine.com" from Cardinal Health or AmeriSource Bergen Corporation ("ABC"). After the drugs ordered from Cardinal Health or ABC were delivered to respondent Adibi, he would print a patient specific invoice and address label, and place the drug and invoice in an envelope addressed to the patient. At no time during the interview did Respondent Adibi indicate that he placed or otherwise provided prescription labels on the manufacturer's bottles for the orders that he filled.

(6) On or about June 27, 2002, the Board conducted an inspection of records of disposition by respondent IPS for December 2001 and June 4, 2002; Summary of Sales to iDrugStore (order sheet) for June 4, 2002; faxed order forms for prescription drugs and stock medications, and faxed prescription

documents. According to respondents' records of disposition approximately 55 patient specific prescriptions were filled by respondent IPS on behalf of another entity, iDrugStore.com, iRXMedicine.com and/or Oz International.

Complainant appears to argue that section 4059.5, subdivision (e), precluded respondents from selling and shipping dangerous drugs to persons in foreign countries, unless those persons had received board-issued permits pursuant to California Code of Regulations, title 16, section 1783, subdivision (b). However, Section 1783, subdivision (b) is merely a definition. It sets forth no prohibited conduct that would constitute a violation. That regulation provides:

"Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person **in this state or in another jurisdiction within the United States** to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices. [Emphasis added.]

Respondents decry the idea that the board must issue permits to persons outside the United States as "too absurd to warrant discussion." They consider the idea an unconstitutional attempt by the state to regulate foreign commerce.

It is not necessary to reach the constitutional issue. The term "authorized person" does not appear in section 4059.5, subdivision (e). The term "authorized person" does appear, however, in Title 16, California Code of Regulations section 1783, subdivision (a); that subdivision also sets forth prohibited conduct. However, complainant did not cite this subdivision in the fourteenth cause for discipline in the Accusation or plead it as a basis for determining that respondents violated the Pharmacy Law.

The fourteenth cause for discipline will be dismissed.

#### *N. FIFTEENTH THROUGH TWENTY-SECOND CAUSES FOR DISCIPLINE*

Unlike section 4301, subdivisions (j) and (o), the statutes and regulations cited in the fifteenth through twenty-second causes for discipline do not authorize the board to impose discipline on a license or permit holder. Respondents noted that these causes for discipline did not state acts or omissions upon which complainant can proceed. Complainant did not thereafter seek to amend these causes for discipline. The fifteenth through twenty-second causes for discipline will be dismissed.

Complainant's fifteenth cause for discipline alleged:

34. Respondent IPS and Respondent Adibi are subject to disciplinary action for violating section 4163 and/or section 4005(a) of the Code for violating Title 16, section 1873(a) [sic] of the California Code of Regulations, in that respondents furnished dangerous drugs to people to whom the Board had not issued a permit as set forth in [accusation] paragraph 33b(3), above.

Sections 4163 and 4005, subdivision (a), and California Code of Regulations, title 16, section 1873, subdivision (a), do not authorize the board to impose discipline on respondents.

Additionally, section 4005, subdivision (a), does not set forth any prohibited conduct. Further, California Code of Regulations, title 16, section 1873, subdivision (a), applies to licensed clinical social workers, and has no apparent application to the issues in this case. Respondents noted this in their trial brief. In her response brief, complainant stated, "Please note that the fifteenth [sic] cause of action refers to 16 C.C.R. 1783(a). Respondent has indicated that it was listed as 16 C.C.R. 1873(a)." Complainant did not, however, seek to amend the fifteenth cause for discipline.

Even had the fifteenth cause for discipline alleged a violation of California Code of Regulations, section 1783, subdivision (a), that regulation does not authorize the board to impose discipline on respondents.

Complainant's sixteenth cause for discipline alleged:

35. Respondent IPS and Respondent Adibi are subject to disciplinary action for violating Title 16, section 1783(b) of the California Code of Regulations in that respondents failed to comply with state laws as set forth in [accusation] paragraph 33b(1), 33b(2), 33b(3), 33b(4), 33b(5) and 33b(6), above.

California Code of Regulations, title 16, section 1783, subdivision (b), does not authorize the board to impose discipline on respondents or set forth prohibited conduct.

Complainant's seventeenth cause for discipline alleged:

36. Respondent IPS and Respondent Adibi are subject to disciplinary action for violating section 4037(a) of the Code in that respondents conducted business as a pharmacy to individuals in foreign countries without being licensed as a pharmacy as set forth in [accusation] paragraph 33b(1), 33b(2), above.



Section 4037, subdivision (a), does not authorize the board to impose discipline on respondents. Additionally, the statute only defines "Pharmacy." It does not set forth any prohibited conduct.

Complainant's eighteenth cause for discipline alleged:

37. Respondent IPS and Respondent Adibi are subject to disciplinary action for violating section 4076 of the Code in that respondents dispensed approximately 40 to 45 dangerous drugs per day to individuals without prescription labels as set forth in [accusation] paragraph 33b(5), above.

Section 4076 does not authorize the board to impose discipline on respondents. Additionally, "dispense" is defined in section 4024, but was not specifically cited by complainant as a basis for determining that respondents violated the Pharmacy Law.

Complainant's nineteenth cause for discipline alleged:

38. Respondent IPS and Respondent Adibi are subject to disciplinary action pursuant to section 4005(b) of the Code for the violation of Code section 4072 in that respondents failed to interview patients to determine the authenticity of the prescription in that the pharmacist filled the prescription from an internet website (IDrugStore.com [sic] and iRXmedicine.com, and from prescribers not licensed in the United States as set forth in [accusation] paragraph 33b(5) and 33b(6), above.

Sections 4005, subdivision (b), and 4072 do not authorize the board to impose discipline on respondents. Further, section 4005, subdivision (b), does not set forth any prohibited conduct.

Additionally, accusation paragraphs 33b(5) and 33b(6) set forth no allegations that respondents failed to interview patients to determine the authenticity of the prescription.

Complainant's twentieth cause for discipline alleged:

39. Respondent IPS and Respondent Adibi are subject to disciplinary action pursuant to section 4059(a) of the Code for the violation of Title 16, section 1717.4(a) of the California Code of Regulations, in that respondents furnished dangerous drugs prescribed by a prescriber not licensed in California or another state as set forth in [accusation] paragraphs 33b(3), 33b(5) and 33b(6), above.

### *THIRD SUPPLEMENTAL ACCUSATION*

Complainant's November 26, 2007 third supplemental accusation alleged two additional causes for discipline. It was issued the day before the first day of hearing. On the first day of hearing, respondents submitted a trial brief dated November 26, 2007.

#### *O. TWENTY-THIRD CAUSE FOR DISCIPLINE*

Complainant's twenty-third cause for discipline alleged:

43. Respondent IPS and Respondent Adibi are subject to disciplinary action pursuant to section 4301(j) and/or (o), unprofessional conduct, for the violation of Code section 4095.5(e) [sic], as defined in Title 16, section 1783(b) of the California Code of Regulations, in that respondents furnished dangerous drugs to individual persons outside the state and failed to comply with all the laws of the state in that they furnished drugs without a patient specific prescription while licensed as a wholesaler. Specifically, on March 25, 2004 Respondents furnished dangerous drugs to 17 individuals located outside of California without a patient specific prescription while licensed as a wholesaler.

In their November 26, 2007, trial brief, respondents noted, "Section 4095.5(e) of the Code does not appear to exist in California law." On November 29, 2007, complainant's motion to amend the twenty-third cause for discipline was granted; the citation to "Code section 4095.5(e)" was amended to read "Code section 4059.5(e)."

On March 25, 2004, respondents shipped dangerous drugs to 17 individuals in Italy, Japan, Portugal, Switzerland, and the United Kingdom. Respondents shipped the drugs without patient specific prescriptions. (Factual Finding 35.)

As previously discussed, the term "authorized person" does not appear in section 4059.5, subdivision (e). The term "authorized person" does appear, however, in Title 16, California Code of Regulations section 1783, subdivision (a); that subdivision also sets forth prohibited conduct. However, complainant did not cite this subdivision in the twenty-third cause for discipline in the Accusation or plead it as a basis for determining that respondents violated the Pharmacy Law.

The twenty-third cause for discipline will be dismissed.

#### *P. TWENTY-FOURTH CAUSE FOR DISCIPLINE*

Complainant's twenty-fourth cause for discipline alleged:

44. Respondent IPS and Respondent Afshin Adibi are subject to disciplinary action for violating section 4163 and/or section 4005(a) of the Code for violating Title 16, section 1783(a) and (b) in that Respondents furnished dangerous drugs to persons to whom the Board had not issued a permit and/or who were not confirmed as being authorized to received [sic] drugs.

Sections 4163 and 4005, subdivision (a), and California Code of Regulations, title 16, section 1783, subdivisions (a) and (b), do not authorize the board to impose discipline on respondents. Additionally, section 4005, subdivision (b), does not set forth any prohibited conduct.

The twenty-fourth cause for discipline will be dismissed.

#### *OTHER MATTERS*

Complainant alleged in her closing brief that Adibi "broke federal and state law" when he obtained controlled substances from a pharmacy in South San Francisco. No such violation or cause for discipline was charged in the accusations.

The accusations alleged no cause for discipline with regard to Adibi's 2005 application for a DEA registration.

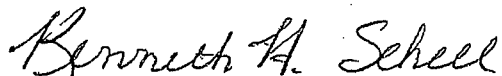
Respondents are not required to pay complainant's costs of prosecution.

#### **ORDER**

The first through twenty-fourth causes for discipline, inclusive, in the accusation, first supplemental accusation, second supplemental accusation, and third supplemental accusation, are dismissed.

This Decision shall become effective on December 26, 2008.

IT IS SO ORDERED this 26th day of November, 2008.



---

Kenneth H. Schell  
President, Board of Pharmacy  
Department of Consumer Affairs

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7  
8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 2347

12 INTERNATIONAL PHARMACEUTICAL  
SERVICES

**A C C U S A T I O N**

13 AFSHIN ADIBI, President  
320 Judah Street No. 1  
14 San Francisco, California 94122

15 Wholesaler Permit No. No. WLS 2955

16 AFSHIN ADIBI, President  
1208 Yew Street  
17 San Mateo, California 94402

18 Pharmacist License No. RPH 44301

19 Respondent.

20  
21 Complainant alleges:

22 **PARTIES**

23 1. Patricia F. Harris ("Complainant") brings this Accusation solely in her  
24 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer  
25 Affairs.

26 2. On or about August 2, 1991, the Board of Pharmacy issued Pharmacist  
27 License Number RPH 44301 to AFSHIN ADIBI ("Respondent Adibi"). Respondent's  
28 Pharmacist License was in full force and effect at all times relevant to the charges brought herein

and will expire on June 30, 2003, unless renewed.

3. On or about February 15, 1995, the Board of Pharmacy issued Wholesaler Permit No. WLS 2955 to INTERNATIONAL PHARMACEUTICAL SERVICES ("Respondent IPS"). Respondent IPS's Permit No. WLS 2955 was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2002, unless renewed. At all times cited herein, respondent Adibi was and still is the President of Respondent IPS.

## JURISDICTION

4. This Accusation is brought before the Board of Pharmacy ("Board"), under the authority of the following sections of the Business and Professions Code ("Code").

5. Section 4005 of the Code states in relevant part that (b) the Board may adopt regulations permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

6. Section 4022 of the Code defines a "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-medication, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription" or words of similar import.

(b) Any device that bears the statement: Caution: federal law restricts this device to sale by or on the order of \_\_\_\_\_," or words of similar imports, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

7. Section 4037 of the Code defines "Pharmacy" as an area, place, or premises licensed by the Board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises

1 described in a license issued by the Board wherein controlled substances, dangerous drugs or  
2 dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or  
3 repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices  
4 are furnished, sold, or dispensed at retail.

5           8.       Section 4043 of the Code defines "Wholesaler" as every person who acts  
6 as a wholesale merchant, broker, jobber, customs broker, reverse distributor, or agent, who sells  
7 for resale, or negotiates for distribution or takes possession of, any dangerous drug.

8           9.       Section 4059(a) of the Code states that no person shall furnish any  
9 dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, or  
10 veterinarian.

11           10.      Section 4059.5(e) of the Code states that a dangerous drug or dangerous  
12 device shall not be transferred, sold, or delivered to any person outside this state, whether foreign  
13 or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this  
14 state and of the United States and of the state or country to which the drugs or devices are to be  
15 transferred, sold, or delivered. Compliance with the laws of this state and the United States and  
16 of the state or country to which the drugs or devices are to be delivered shall include, but not be  
17 limited to, determining that the recipient of the drugs or devices is authorized by law to receive  
18 the drugs or devices.

19           11.      Section 4081 of the Code states in relevant part, that all records of  
20 manufacture, sale, acquisition, or disposition of dangerous drugs shall be at all times during  
21 business hours open to inspection by authorized officers of the law, and shall be preserved for at  
22 least three years from the date of making. A current inventory shall be kept by every wholesaler  
23 or pharmacy holding a currently valid and unrevoked certificate, license, permit or registration.

24           12.      Section 4110(a) of the Code states in relevant part that no person shall  
25 conduct a pharmacy in the State of California unless he or she has obtained a license from the  
26 Board.

27           13.      Section 4301 of the Code states in parts relevant herein that the Board  
28 shall take action against any holder of a license who is guilty of unprofessional conduct.

Unprofessional conduct shall include, but is not limited to, any of the following:

(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of Chapter 9 (commencing with Section 4000) of the Business and Professions Code or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the Board.

14. Title 21, Code of Federal Regulations section 1301.11(a) states that every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to code sections 1301.22-1301.26. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

15. Title 21, Code of Federal Regulations section 1301.12(a) states that a separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

16. Title 21, Code of Federal Regulations section 1312.21(a) states that no person shall in any manner export or cause to be exported from the United States any controlled substance listed in Schedule I or II, or any narcotic substance listed in Schedule III or IV, or any non-narcotic substance in Schedule III which the Administrator has specifically designated by regulation in code section 1312.30 of this part or any non-narcotic substance in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances unless and until such person is properly registered under the Act (or exempted from registration) and the Administrator has issued a permit pursuant to code section 1312.23 of this part.

17. Title 16, California Code of Regulations section 1717(d) states that a

1 pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber  
2 licensed in a State other than California in accordance with Business and Professions Code  
3 Section 4005.

4 18. Section 125.3 of the Code states, in pertinent part, that the Board may  
5 request the administrative law judge to direct a licentiate found to have committed a violation or  
6 violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation  
7 and enforcement of the case.

8 19. DRUGS

9 "Klonopin ", also known as "Clonazepam", is a Schedule IV controlled  
10 substance pursuant to Health and Safety Code section 11057. **Klonopin** is a benzodiazepine  
11 used to treat seizure disorders.

12 "Ativan ", also known as "Lorazepam", is a Schedule IV controlled substance  
13 pursuant to Health and Safety Code section 11057. **Ativan** is a benzodiazepine used to treat  
14 anxiety.

15 "Human Chorionic Gonadotropin" ("HCG") is a Schedule III controlled  
16 substance pursuant to Health and Safety Code section 11056(f) and is used to treat  
17 hypogonadism.

18 "Cylert ", also known as "Pemoline", is a Schedule IV controlled substance  
19 pursuant to Health and Safety Code section 11057. **Cylert** is a stimulant used to treat attention  
20 deficit disorder.

21 "Redux " was a Schedule IV controlled substance pursuant to Health and Safety  
22 Code section 11057 and was used to treat obesity. **Redux** is no longer available in the United  
23 States.

24 FIRST CAUSE FOR DISCIPLINE

25 (Unprofessional Conduct - Unlicensed Practice)

26 20. Respondent IPS and Respondent Adibi are subject to disciplinary action  
27 under section 4301(j) and/or (o), unprofessional conduct, for violating section 4110 of the Code  
28 in that respondent dispensed dangerous drugs at retail without being licensed as a pharmacy. The



1 circumstances are as follows:

2 a. On or about January 1996, respondent IPS and Respondent Adibi  
3 advertised for foreign prescriptions in the trade magazine U.S. Pharmacist. The text of that ad  
4 stated:

5 "Non-controlled prescription drugs can now be shipped overseas pursuant to a  
6 foreign prescription. If you have patients who can use our services, please refer  
7 them to: International Pharmaceutical Services, Tel: 1-800-RX EXPORT. For  
8 Information ask for a pharmacist."

9 b. On or about January 27, 1998, the Board conducted an inspection  
10 of respondent IPS and interviewed Respondent Adibi. During the course of the inspection, the  
11 Board's investigators made the following findings:

12 (1). Respondent IPS was not registered with the Drug Enforcement  
13 Administration ("DEA") to purchase or to dispense controlled substances. A separate  
14 registration is required for each separate activity. However, on approximately 7 occasions,  
15 respondent IPS furnished and exported controlled substances, including but not limited to the  
16 benzodiazepines Klonopin and Lorazepam; HCG; and Redux.

17 (2). Respondent IPS is, and at times referred to herein was, licensed as  
18 a wholesale drug distributor. However, respondent IPS participated in retail sales by exporting  
19 controlled substances and dangerous drugs to individual patients by filling prescriptions from  
20 outside of the United States.

21 (3). Respondent Adibi furnished controlled substances and dangerous  
22 drugs pursuant to prescriptions written by physician licensed only in countries outside of the  
23 United States.

24 (4). Respondent Adibi, through respondent IPS, dispensed and  
25 exported dangerous drugs and controlled substances to Iran which was at times referred to herein  
26 under a United States trade embargo.

27 c. On or about January 27, 1998, during the course of the Board's  
28 investigation of respondent IPS, Respondent Adibi admitted knowing that California State

1 regulations prohibited him from dispensing dangerous drugs and controlled substances to  
2 patients in a foreign country based upon prescriptions from foreign physicians. Respondent  
3 Adibi admitted that he was exporting drugs and stated that he did not have to abide by state and  
4 federal drug regulations since he was in the business of exporting drugs.

5 d. On or about January 27, 1998, during the course of the Board's  
6 investigation of respondent IPS, Respondent Adibi admitted that he obtained controlled  
7 substances from a South San Francisco pharmacy where he occasionally worked as a relief  
8 Pharmacist.

### 9 SECOND CAUSE FOR DISCIPLINE

10 (Dispensing and Exporting Controlled Substances Without DEA Registration)

11 21. Respondent IPS and Respondent Adibi are subject to disciplinary action  
12 under section 4301(j) and/or (o) for the violation of Code of Federal Regulations section  
13 1301.11(a), Title 21, in that Respondent Adibi and respondent IPS failed to obtain DEA  
14 registration to dispense and export dangerous drugs and/or controlled substances as set forth in  
15 paragraph 19.

### 16 THIRD CAUSE FOR DISCIPLINE

17 (Operating an Export Business Without DEA Registration)

18 22. Respondents are subject to disciplinary action under section 4301(j) and/or  
19 (o) for violating Code of Federal Regulations section 1301.12(a), Title 21, in that Respondent  
20 Adibi failed to obtain DEA registration while engaged in a professional practice of dispensing  
21 and exporting dangerous drugs and/or controlled substances as set forth in paragraph 19.

### 22 FOURTH CAUSE FOR DISCIPLINE

23 (Exporting Outside of the United States without Registration)

24 23. Respondent IPS and Respondent Adibi are subject to disciplinary action  
25 under section 4301(j) and/or (o) for violating Code of Federal Regulations section 1302.21(a),  
26 Title 21, in that Respondent Adibi failed to properly register or be exempted from registration  
27 under the Act while engaged in the business of exporting or causing to be exported Schedule IV  
28 substances such as Klonopin, Ativan, HCG, Redux , as set forth in paragraph 19.

1 FIFTH CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct - Licensed Prescriber)

3 24. Respondent IPS and respondent Adibi are subject to disciplinary action  
4 under section 4301(j) and/or (o) for violating California Code of Regulations section 1717(d),  
5 Title 16, pursuant to section 4005(b) of the Business and Professions Code, in that Respondent  
6 Adibi by his own admission furnished drugs and/or devices to prescribers licensed in states other  
7 than California without abiding by the requirements of state regulation(s) as set forth in  
8 paragraph 19.

9 SIXTH CAUSE FOR DISCIPLINE

10 (Records)

11 25. Respondent Adibi and respondent IPS are subject to disciplinary action  
12 pursuant to Code section 4301, subparagraphs (j) and/or (o) for violating Code section 4081 in  
13 that respondents failed to provide all records of acquisition and disposition of drugs from  
14 January 1, 1997, to January 27, 1998, and any records that would document that the drugs were  
15 exported to authorized individuals, as requested during the course of a wholesaler inspection  
16 conducted on or around January 27, 1998. The circumstances are as follows:

17 a. On or about January 27, 1998, during the course of a Board  
18 inspection of the wholesale business conducted by respondent IPS, Respondent Adibi was asked  
19 to provide the Board with records documenting acquisition and disposition of all drug  
20 transactions from January 1, 1997, through January 27, 1998. Further, Respondent Adibi and  
21 respondent IPS were asked to provide the Board with proof that the drugs respondents exported  
22 were sent to authorized individuals and with proof of delivery for all dispositions.

23 b. On or about February 1, 1998, pursuant to the January 27, 1998,  
24 request, the Board's inspector received purchase invoices from respondent IPS for the month of  
25 January 1998 only. The Board's inspector contacted respondent IPS and Respondent Adibi to  
26 remind respondents that the Board's request was for both acquisition and disposition records  
27 covering a one year period. On or about February 18, 1998, the Board received purchase  
28 invoices covering the time period from January 1997 to December 1997. On or about March 13,

1 1998, respondent IPS provided its disposition records as requested January 27, 1998, to the  
2 Board.

3 SEVENTH CAUSE FOR DISCIPLINE

4 (Records)

5 26. Respondent Adibi and respondent IPS are subject to disciplinary action  
6 pursuant to Code section 4301, subparagraphs (j) and/or (o) for violating Code section 4081 in  
7 that respondents failed to provide have all records of acquisition and disposition of the drug  
8 Viagra for the time period from approximately January 1, 1998, through to March 2, 1999. The  
9 circumstances are as follows:

10 a. On or about March 2, 1999, the Board's inspector wrote to  
11 respondent IPS requesting acquisition and disposition records for Viagra dispensed in varying  
12 strengths from the time period from January 1, 1998, through to March 2, 1999.

13 b. On or about March 2, 1999, the Board's inspector wrote to  
14 wholesale Viagra distributors requesting records of any and all business transactions/disposition  
15 records of drug sales made to respondent IPS, from January 1, 1997, to January 27, 1998, and  
16 disposition records for all strengths of Viagra from the inception of sales of Viagra up to and  
17 including March 2, 1999. A comparison of the wholesale distributors records provided pursuant  
18 to the Board's request, including but not limited to Viagra sales, and records provided to the  
19 Board by respondent IPS and Respondent Adibi showed the following discrepancies:

20 (1). Of the hundreds of orders of dangerous drugs furnished to  
21 respondent IPS by the wholesale distributors, only four orders were identified as delivered in the  
22 United States.

23 (2). Respondent IPS failed to provide approximately 99 records of  
24 acquisition from wholesale distributor Cardinal Health.

25 EIGHTH CAUSE FOR DISCIPLINE

26 (Transferring Dangerous Drugs)

27 27. Respondent Adibi and respondent IPS are subject to disciplinary action  
28 pursuant to Code section 4301, subparagraphs (j) and/or (o) for violating Code section 4059.5(e)

1 in that respondents transferred, sold or delivered dangerous drugs outside of the United States to  
2 persons unauthorized by local and international law to receive the drugs. The circumstances are  
3 as follows:

4 a. A comparison of disposition records for IPS provided by wholesale  
5 distributors to the Board pursuant to the Board's request, as set forth in paragraph 26 above,  
6 uncovered the following instances where respondents illegally exported dangerous drugs and/or  
7 failed to comply with the laws of the importing country.

8 (1). During the time period from February 1997 to January 1998, there  
9 were approximately 317 sales by IPS of dangerous drugs to a foreign country subject to a  
10 comprehensive trade embargo by the United States without prior government approval.

11 (2). From approximately mid-1998 to March 1999, respondent IPS  
12 dispensed and exported Viagra to Japan when Viagra had not been approved for use in Japan by  
13 the Japanese government.

#### 14 NINTH CAUSE FOR DISCIPLINE

15 (Furnishing Dangerous Drugs Prohibited Without Prescription)

16 28. Respondent IPS and Respondent Adibi are subject to disciplinary action  
17 for violating Section 4059(a) of the Business and Professions Code in that respondents furnished  
18 Viagra, a dangerous drug, to Japan without a prescription from a physician, dentist, podiatrist,  
19 optometrist or veterinarian as set forth in paragraph 27 above.

#### 20 PRAYER

21 **WHEREFORE**, Complainant requests that a hearing be held on the matters  
22 herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

23 1. Revoking or suspending Wholesaler Permit No. Number WLS 2955,  
24 issued to International Pharmaceutical Services;

25 2. Ordering International Pharmaceutical Services to pay the Board of  
26 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to  
27 Business and Professions Code section 125.3;

28 3. Revoking or suspending Pharmacist License Number RPH 44301, issued

1 to Afshin Adibi;

2 4. Ordering Afshin Adibi to pay the Board of Pharmacy the reasonable costs  
3 of the investigation and enforcement of this case, pursuant to Business and Professions Code  
4 section 125.3;

5 5. Imposing the restrictions provided by Business and Professions Code  
6 section 4307; and

7 6. Taking such other and further action as deemed necessary and proper.

8 DATED: 9/6/01

9  
10  
11 P. F. Harris  
12 PATRICIA F. HARRIS  
13 Executive Officer  
14 Board of Pharmacy  
15 Department of Consumer Affairs  
16 State of California  
17 Complainant

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6 Attorneys for Complainant

7  
8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 2347

12 INTERNATIONAL PHARMACEUTICAL  
SERVICES ; AFSHIN ADIBI, President  
13 1208 Yew Street  
San Mateo, California 94402

**FIRST SUPPLEMENTAL  
ACCUSATION**

14 Wholesaler Permit No. No. WLS 2955

15 AFSHIN ADIBI, President  
16 1208 Yew Street  
San Mateo, California 94402

17 Pharmacist License No. RPH 44301

18 Respondent.  
19

20 Complainant Patricia F. Harris supplements the Accusation filed on September 6,  
21 2001, in this matter and for cause for discipline further alleges:

22 **TENTH CAUSE FOR DISCIPLINE**

23 (Transfer, Sale or Delivery of Dangerous Drugs)

24 29. Respondent IPS and Respondent Adibi are subject to disciplinary action  
25 pursuant to section 4301(j) and/or (o) for violating Code section 4059.5(e) in that respondents  
26 transferred, sold or delivered Viagra, a dangerous drug pursuant to Code section 4022, to  
27 persons unauthorized by law to receive the drug. The circumstances are as follows:

28 a. On or about May 21, 2001, the Board received notice that a computer

1 based website/company named OZ International, doing business as "iDrugstore.com"  
2 (iDrugstore), maintains a website on the internet where prescription drugs from the United  
3 States are offered for sale without prescription in Japan. iDrugstore published claims on its  
4 website that it can export prescription drugs without a prescription under Japanese law. The  
5 website failed to mention that some states in the United States have laws prohibiting the  
6 exportation of drugs without prescription and a wholesale permit.

7           b.       On or about June 27, 2001, a consumer in Japan purchased thirty 100 mg.  
8 Viagra tabs, without a prescription, from iDrugstore. The order was shipped to Japan from 320  
9 Judah Street, Suite 1, in San Francisco, California, 94122. A geographic search conducted  
10 through the Board's records revealed that the only licensed wholesaler located at 320 Judah  
11 Street, Suite 1, in San Francisco, is International Pharmaceutical Services (Respondent IPS)  
12 owned by Afshin Adibi (Respondent Adibi). The wholesale license issued to respondent does  
13 not cover shipping drugs directly to patients and/or exporting drugs out of the United States.

#### 14                               ELEVENTH CAUSE FOR DISCIPLINE

15                               (Furnishing Dangerous Drugs Prohibited Without Prescription)

16           30.       Respondent IPS and Respondent Adibi are subject to disciplinary action  
17 pursuant to section 4301(j) and/or (o) for violating section 4059 of the Code in that respondents  
18 furnished Viagra, a dangerous drug pursuant to Code section 4022, without a prescription as set  
19 forth in paragraph 29, above.

#### 20                               TWELVETH CAUSE FOR DISCIPLINE

21                               (License Required)

22           31.       Respondent IPS and Respondent Adibi are subject to disciplinary action  
23 pursuant to 4301(j) and/or (o) for violating section 4110 of the Code in that respondents  
24 conducted a pharmacy in California, through the internet, to wit, iDrugstore, without a license  
25 from the Board as set forth in paragraph 29, above.

#### 26                               THIRTEENTH CAUSE FOR DISCIPLINE

27                               (Pharmacist/Exemptee)

28           32.       Respondent IPS and Respondent Adibi are subject to disciplinary action



1 pursuant to section 4301(j) and/or (o) of the Code for violating Title 16, California Code of  
2 Regulations, section 1781, in that respondents conducted business as a pharmacy through the  
3 internet, to wit, iDrugStore, without a pharmacist or a certified exemptee in charge as set forth in  
4 paragraph 29, above.

5 PRAYER

6 WHEREFORE, Complainant requests that a hearing be held on the matters herein  
7 alleged, and that following the hearing, the Board of Pharmacy issue a decision:

8 1. Revoking or suspending Wholesaler Permit No. WLS 2955, issued to  
9 International Pharmaceutical Services;

10 2. Ordering International Pharmaceutical Services to pay the Board of  
11 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to  
12 Business and Professions Code section 125.3;

13 3. Revoking or suspending Pharmacist License No. RPH 44301, issued to  
14 Afshin Adibi;

15 4. Ordering Afshin Adibi to pay the Board of Pharmacy the reasonable costs  
16 of the investigation and enforcement of this case, pursuant to Business and Professions Code  
17 section 125.3;

18 5. Imposing the restrictions provided by Business and Professions Code  
19 section 4307; and

20 6. Taking such other and further action as deemed necessary and proper.

21 DATED: 6/12/02.

22  
23 P. F. Harris  
24 PATRICIA F. HARRIS  
25 Executive Officer  
26 Board of Pharmacy  
27 Department of Consumer Affairs  
28 State of California  
Complainant

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4 San Francisco, California 94102  
Telephone: (415) 703-1384  
5 Facsimile: (415) 703-5480

6 Attorneys for Complainant

7  
8  
9 **BEFORE THE**  
10 **BOARD OF PHARMACY**  
11 **DEPARTMENT OF CONSUMER AFFAIRS**  
12 **STATE OF CALIFORNIA**

13 In the Matter of the Accusation Against:

Case No. 2347

14 INTERNATIONAL PHARMACEUTICAL  
SERVICES  
15 AFSHIN ADIBI, President  
1208 Yew Street  
San Mateo, California 94402

**SECOND SUPPLEMENTAL  
ACCUSATION**

16 Wholesaler Permit No. No. WLS 2955

17 AFSHIN ADIBI, President  
18 1208 Yew Street  
San Mateo, California 94402

19 Pharmacist License No. RPH 44301

20 Respondent.  
21

22 Complainant Patricia F. Harris supplements the First Supplemental Accusation  
23 filed on June 12, 2002, and the Accusation filed on September 6, 2001, in this matter and for  
24 cause for discipline further alleges:

25 **FOURTEENTH CAUSE FOR DISCIPLINE**

26 (Unprofessional Conduct - Transfer, Sale and/or Delivery of Dangerous Drugs)

27 33. Respondent IPS and Respondent Adibi are subject to disciplinary action  
28 under section 4301(j) and/or (o), unprofessional conduct, for the violation of Code section

1 4059.5(e), as defined in Title 16, section 1783(b) of the California Code of Regulations, in that  
2 respondents transferred, sold and/or delivered dangerous drugs pursuant to section 4022 of the  
3 Code, to unauthorized persons outside this state, either foreign or domestic, and failed to comply  
4 with laws of the state, and the United States and of the state or country to which the drugs were  
5 delivered. The circumstances are as follows:

6 a. On or about January 25, 2002, the Board received a complaint that  
7 respondent(s) purchased a large amount of Viagra, approximately valued at \$730,000.00, from  
8 the time period on or around August 9, 2001, to January 25, 2002.

9 b. On or about June 4, 2002, the Board conducted an inspection of  
10 respondent IPS and interviewed respondent Adibi. During the course of the inspection, the  
11 Board's investigators made the following findings based on respondent's statements and business  
12 documents :

13 (1). Respondent Adibi, through respondent IPS, dispensed and exported  
14 dangerous drugs, including but not limited to Viagra, pursuant to a prescription and/or drug  
15 order from a foreign prescriber to patients in Japan and/or Korea while licensed by the Board  
16 solely as a wholesaler and not as a pharmacy.

17 (2). Respondent Adibi, through respondent IPS, furnished dangerous drugs,  
18 including but not limited to Viagra, pursuant to patient specific prescriptions by facsimile and/or  
19 by e-mail from his website "Internationalpharmacy.com" and/or other websites in Japan  
20 including, but not limited to, websites operated by Oz International, to wit: "iDrugStore.com"  
21 and "iRxMedicine.com", while licensed by the Board solely as a wholesaler and not as a  
22 pharmacy.

23 (3). Respondent Adibi, through respondent IPS, delivered dangerous drugs, to  
24 wit: Viagra, to people and/or parties to whom the Board had not issued permits.

25 (4). Respondent Adibi, through respondent IPS, dispensed approximately 40-  
26 45 dangerous drugs daily to patients in Japan and/or Korea without placing prescription labels on  
27 the manufacturer's bottle and without otherwise providing the patients with information  
28 necessary for appropriate use.

1 (5). On or about June 4, 2002, during the course of the Board's investigation of  
2 respondent IPS, respondent Adibi admitted that approximately 99% of his sales were to Japan  
3 and Korea and that he supplied drugs pursuant to a prescription or drug order from a foreign  
4 prescriber to patients outside of the United States. Respondent admitted that he received  
5 prescriptions by fax and by e-mail from his website "Internationalpharmacy.com" and from  
6 websites operated in Japan by Oz International as "iDrugStore.com" and/or "iRXMedicine.com."  
7 Respondent Adibi acquired the drugs ordered through the websites "Internationalpharmacy.com",  
8 "iDrugStore.com" and/or "iRXMedicine.com" from Cardinal Health or AmeriSource Bergen  
9 Corporation ("ABC"). After the drugs ordered from Cardinal Health or ABC were delivered to  
10 respondent Adibi, he would print a patient specific invoice and address label, and place the drug  
11 and invoice in an envelope addressed to the patient. All prescriptions were paid in advance by  
12 the patient or Oz International on behalf of the patient. At no time during the interview did  
13 Respondent Adibi indicate that he placed or otherwise provided prescription labels on the  
14 manufacturer's bottles for the orders that he filled.

15 (6). On or about June 27, 2002, the Board conducted an inspection of records  
16 of disposition by respondent IPS for December 2001 and June 4, 2002; Summary of Sales to  
17 iDrugStore (order sheet) for June 4, 2002; faxed order forms for prescription drugs and stock  
18 medications, and faxed prescription documents. According to respondents' records of  
19 disposition, approximately 55 patient specific prescriptions were filled by respondent  
20 IPS on behalf of another entity, iDrugStore.com, iRXMedicine.com and/or Oz International.

#### 21 FIFTEENTH CAUSE FOR DISCIPLINE

22 (Furnishing Dangerous Drugs Without a Permit)

23 34. Respondent IPS and Respondent Adibi are subject to disciplinary action  
24 for violating section 4163 and/or section 4005(a) of the Code for violating Title 16, section  
25 1873(a) of the California Code of Regulations, in that respondents furnished dangerous drugs to  
26 people to whom the Board had not issued a permit as set forth in paragraph 33b(3), above.

27 //

28 //

1                                    **SIXTEENTH CAUSE FOR DISCIPLINE**

2                                    (State Laws)

3                    35.        Respondent IPS and Respondent Adibi are subject to disciplinary action  
4 for violating Title 16, section 1783(b) of the California Code of Regulations in that respondents  
5 failed to comply with state laws as set forth in paragraph 33b(1), 33b(2), 33b(3), 33b(4), 33b(5)  
6 and 33b(6), above.

7                                    **SEVENTEENTH CAUSE FOR DISCIPLINE**

8                                    (Unlicensed Activity)

9                    36.        Respondent IPS and Respondent Adibi are subject to disciplinary action  
10 for violating section 4037(a) of the Code in that respondents conducted business as a pharmacy  
11 to individuals in foreign countries without being licensed as a pharmacy as set forth in paragraph  
12 33b(1), 33b(2), above.

13                                   **EIGHTEENTH CAUSE FOR DISCIPLINE**

14                                   (Dispensing Without Prescription Labels)

15                    37.        Respondent IPS and Respondent Adibi are subject to disciplinary action  
16 for violating section 4076 of the Code in that respondents dispensed approximately 40 to 45  
17 dangerous drugs per day to individuals without prescription labels as set forth in paragraph  
18 33b(5), above.

19                                   **NINETEENTH CAUSE FOR DISCIPLINE**

20                                   (Dispensing Without Examination)

21                    38.        Respondent IPS and Respondent Adibi are subject to disciplinary action  
22 pursuant to section 4005(b) of the Code for the violation of Code section 4072 in that  
23 respondents failed to interview patients to determine the authenticity of the prescription in that  
24 the pharmacist filled the prescription from an internet website (IDrugStore.com and  
25 iRXmedicine.com, and from prescribers not licensed in the United States as set forth in  
26 paragraph 33b(5) and 33b(6), above.

27                                   **TWENTIETH CAUSE FOR DISCIPLINE**

28                                   (Furnishing Prescription Drugs to an Unlicensed Prescriber)

1                   39.     Respondent IPS and Respondent Adibi are subject to disciplinary action  
2 pursuant to section 4059(a) of the Code for the violation of Title 16, section 1717.4(a) of the  
3 California Code of Regulations, in that respondents furnished dangerous drugs prescribed by a  
4 prescriber not licensed in California or another state as set forth in paragraphs 33b(3), 33b(5) and  
5 33b(6), above.

6                                   **TWENTY-FIRST CAUSE FOR DISCIPLINE**

7   (Transmitting Prescription Documents)

8                   41.     Respondent IPS and Respondent Adibi are subject to disciplinary action  
9 pursuant to section 4059.5(e) of the Code, failing to comply with the laws of the state or county  
10 which drugs were transferred, sold, or delivered for the violation of Title 16, section 1717.4(a) of  
11 the California Code of Regulations, in that respondents transmitted prescription documents by  
12 electronic means by someone other than the prescriber as set forth in paragraphs 3b(5) and 3b(6),  
13 above.

14                                   **TWENTY-SECOND CAUSE FOR DISCIPLINE**

15   (Non-Compliance with State Laws)

16                   41.     Respondent IPS and Respondent Adibi are subject to disciplinary action  
17 pursuant to section 4059.5(e) of the Code, failing to comply with the laws of the state or county  
18 which drugs were transferred, sold, or delivered as set forth in paragraph 3b(1), 33b(2), 33b(3),  
19 33b(4), 33b(5) and 33b(6), above.

20   **PRAYER**

21                   WHEREFORE, Complainant requests that a hearing be held on the matters herein  
22 alleged, and that following the hearing, the Board of Pharmacy issue a decision:

23                                   1.     Revoking or suspending Wholesaler Permit No. WLS 2955, issued to  
24 International Pharmaceutical Services;

25                                   2.     Ordering International Pharmaceutical Services to pay the Board of  
26 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to  
27 Business and Professions Code section 125.3;

28                                   3.     Revoking or suspending Pharmacist License No. RPH 44301, issued to

1 Afshin Adibi;

2 4. Ordering Afshin Adibi to pay the Board of Pharmacy the reasonable costs  
3 of the investigation and enforcement of this case, pursuant to Business and Professions Code  
4 section 125.3;

5 5. Imposing the restrictions provided by Business and Professions Code  
6 section 4307; and

7 6. Taking such other and further action as deemed necessary and proper.  
8

9 DATED: 8/20/03.

10  
11 P. F. Harris  
12 PATRICIA F. HARRIS  
13 Executive Officer  
14 Board of Pharmacy  
15 Department of Consumer Affairs  
16 State of California  
17 Complainant

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LLZ 7/03/03

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6 Attorneys for Complainant

7  
8 BEFORE THE  
BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
9 STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 2347

11 INTERNATIONAL PHARMACEUTICAL  
SERVICES  
12 AFSHIN ADIBI, PRESIDENT

OAH No. N 2002120722

THIRD SUPPLEMENTAL  
ACCUSATION

13 1208 Yew Street  
14 San Mateo, California 94402

15 Pharmacist License No. RPH 44301  
Wholesaler Permit No. No. WLS 2955

16 Respondent,  
17

18 Complainant Virginia Herold supplements the Second Supplemental Accusation filed on  
19 August 20, 2003 in this matter and for cause for discipline further alleges:

20 TWENTY- THIRD CAUSE FOR DISCIPLINE

21 43. Respondent IPS and Respondent Afshin Adibi are subject to disciplinary action  
22 pursuant to 4301(j) and/or (o), unprofessional conduct, for the violation of Code section  
23 4095.5(e), as defined in Title 16, section 1783(b) of the California Code of Regulations, in that  
24 respondents furnished dangerous drugs to individual persons outside the state and failed to  
25 comply with all the laws of the state in that they furnished drugs without a patient specific  
26 prescription while licensed as a wholesaler. Specifically, on March 25, 2004 Respondents  
27 furnished dangerous drugs to 17 individuals located outside of California without a patient  
28 specific prescription while licensed as a wholesaler.



1 TWENTY- FOURTH CAUSE FOR DISCIPLINE

2 44. Respondent IPS and Respondent Afshin Adibi are subject to disciplinary action  
3 for violating section 4163 and/or section 4005(a) of the Code for violating Title 16, section  
4 1783(a) and (b) in that Respondents furnished dangerous drugs to persons to whom the Board  
5 had not issued a permit and/or who were not confirmed as being authorized to received drugs.

6 PRAYER

7 WHERE FORE, Complainant request that a hearing be held on the matters herein  
8 alleged, and that following the hearing, the Board of Pharmacy issue a decision:

9 1. Revoking or suspending Wholesaler Permit No. WLS 2955, issued to  
10 International Pharmaceutical Services;

11 2. Ordering International Pharmaceutical Services to pay the Board of Pharmacy the  
12 reasonable costs of the investigation and enforcement of this case, pursuant to Business and  
13 Processions Code section 125.3.

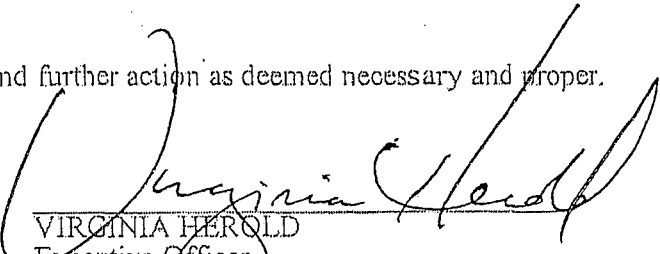
14 3. Revoking or suspending Pharmacist License No RPH 44301, issued to Afshin  
15 Adibi;

16 4. Ordering Afshin Adibi to pay the Board of Pharmacy the reasonable costs of the  
17 investigation and enforcement of this case, pursuant to Business and Professions Code section  
18 125.3;

19 5. Imposing the restrictions provided by Business and Professions Code section  
20 4307 and;

21 6. Taking such other and further action as deemed necessary and proper.

22 DATED: 11/26/07

23   
24 VIRGINIA HEROLD  
25 Executive Officer  
26 Board of Pharmacy  
27 Department of Consumer Affairs  
28 State of California  
Complainant