

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated March 19, 2007, and published in the **Federal Register** on March 27, 2007, (72 FR 14297), Stepan Company, Natural Products Dept., 100 W. Hunter Avenue, Maywood, New Jersey 07607, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Cocaine (9041)	II
Ecgonine (9180)	II

The company plans to manufacture in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Stepan Company to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Stepan Company to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with State and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: June 26, 2007.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Michael F. Myers, M.D.; Revocation of Registration

On January 10, 2007, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Michael F. Myers, M.D. (Respondent) of Woodruff, South

Carolina. The Order to Show Cause proposed the revocation of Respondent's DEA Certificate of Registration, BM5526009, as a practitioner, on the ground that Respondent's continued registration would be inconsistent with the public interest. Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)). The Immediate Suspension was imposed based on my preliminary finding that Respondent had "diverted large quantities of controlled substances," and that there was a "substantial likelihood that [he] would continue to divert controlled substances to drug abusers." *Id.* at 1-2. I therefore concluded that Respondent's "continued registration during the pendency of these proceedings would constitute an imminent danger to the public health and safety." *Id.*

The Show Cause Order alleged that Respondent "frequently grew marijuana in [his] residence," that he "regularly purchased large quantities of marijuana," that "he smoked marijuana throughout the day on a daily basis," and that he "regularly distributed marijuana from [his] residence." *Id.* at 2. The Show Cause Order further alleged that Respondent "regularly exchanged controlled substance prescriptions for marijuana and other prescription controlled substances." *Id.* The Show Cause Order also alleged that Respondent "routinely sold controlled substance prescriptions and large quantities of marijuana to known drug peddlers." *Id.*

More specifically, the Show Cause Order alleged that Respondent had distributed marijuana on a continuing basis in quantities ranging from "small user amounts" to as much as five pounds. *Id.* The Show Cause Order also alleged that Respondent had prescribed Adderall, a schedule II controlled substance, and hydrocodone, a schedule III controlled substance, for a person without "performing any tests or formulat[ing] a diagnosis during the initial visit," and he had "continued to authorize prescriptions for [these] controlled substances without an examination or further care." *Id.* Relatedly, the Show Cause Order alleged that Respondent subsequently "received some of the hydrocodone from the prescriptions [he] wrote for this" person. *Id.*

Next, the Show Cause Order alleged that Respondent had "prescribe[d] controlled substances to a person [he] knew was addicted to [them]," and that Respondent also "knew [that] this person was selling the filled prescriptions to support [his] addiction." *Id.* The Show Cause Order further alleged that Respondent had

engaged in a scheme to provide controlled prescription drugs to drug dealers. *Id.* According to the Show Cause Order, the dealers' runners would go to Respondent's residence to receive the prescriptions; after the prescriptions were filled, the dealer would provide Respondent with half of the drugs and sell the other half to drug abusers. *Id.* Finally, the Show Cause Order alleged that on May 10, 2006, law enforcement officers executed a search warrant at Respondent's home during which they found marijuana, pills which appeared to be prescription controlled substances, and assorted drug-related paraphernalia. *Id.*

On January 12, 2007, DEA investigators personally served the Show Cause Order on Respondent. Since that time, neither Respondent, nor anyone purporting to represent him, has responded. Because (1) more than thirty days have passed since service of the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived his right to a hearing. *See* 21 CFR 1301.43(d). I therefore enter this final order without a hearing based on relevant material contained in the investigative file and make the following findings.

Findings

Respondent is the holder of DEA Certificate of Registration, BM5526009, as a practitioner, which authorizes him to dispense controlled substances in schedules II through V. Respondent's registration was last renewed on February 15, 2006, and expires on January 31, 2009.

In July 1996, Respondent was disciplined by the State Board of Medical Examiners of South Carolina, which found that he had written prescriptions for Lortab 7.5 (hydrocodone), and Didrex (benzphetamine),¹ using the names of other patients, which he then had filled and diverted to his personal use. Respondent admitted to the State's allegation. The Board fined him \$7500, issued a reprimand, and imposed various conditions on his medical license including random drug testing. On October 17, 2000, however, the Board removed the conditions.

According to the investigative file, the Board's conditions appeared to have had only a limited impact on Respondent. Beginning in the summer of 1999, while the Board's conditions were still in effect, Respondent purchased marijuana from a person who

¹ Both drugs are schedule III controlled substances. *See* 21 CFR 1308.13.

lived with him. During an interview, this person related that from 1999 until 2003, he had sold Respondent approximately 100 pounds of marijuana. The person further stated to investigators that he regularly traded marijuana for Lortab and Xanax prescriptions issued by Respondent. More specifically, Respondent would provide this person with prescriptions for 240 Lortab and 120 Xanax at the beginning of each month; Respondent would also write identical prescriptions in the name of the person's girlfriend at the end of each month. The person also told investigators that he could make more money selling the Lortab and Xanax than he could selling marijuana. Finally, the person related that Respondent gave him the combination to a safe that was located in Respondent's home and instructed him to place the marijuana in the safe.

Investigators also interviewed a person who related that his father was the number one seller of OxyContin in the Williamston, South Carolina area. According to this person, his father was addicted to OxyContin, which Respondent had prescribed to him. This person stated that Respondent would write controlled substance prescriptions in other persons' names, and that his father would send a "runner" to Respondent's practice to pick up the prescriptions. The person further advised that after the prescriptions were filled, his father would give half of the drugs to the runner and swap the remaining half with Respondent for marijuana. The person also related that he had been present during a fall 2004 incident in which his father had gone to Respondent's home and obtained 2.5 pounds of marijuana. Moreover, during this incident, Respondent showed this person ten marijuana plants that he was growing in his basement. This person also told investigators of another fall 2004 incident in which he accompanied his father to Respondent's home as the latter retrieved one pound of marijuana from the mailbox.

Finally, this person, who was being treated by Respondent for anxiety, related a late fall/early winter 2004 visit to Respondent's medical office. During the appointment, Respondent issued him prescriptions for both Xanax and Lortab. The person related to investigators that he was surprised to receive the Lortab prescription. Shortly after leaving Respondent's office, the person was contacted by his father who asked for half of the Lortab. The person further told investigators that he believed that Respondent had told his father about the issuance of the Lortab prescription.

Subsequently, investigators interviewed the above person's brother, who corroborated his father's relationship with Respondent. Specifically, this person confirmed that for approximately five years, Respondent had provided his father with prescriptions for Lortab, Xanax, Roxicodone, Percocet and Oxycontin. The person stated that he had lived with his father from the year 2000 until 2003, during which time he observed his father sell large quantities of controlled substances to numerous individuals in the Williamston, South Carolina area. According to this person, his father would sell controlled substances to as many as twenty persons a day and made a significant amount of money doing so. The person further related that his father had both personally obtained controlled substance prescriptions from Respondent and also used a "runner" to obtain them.

The person also stated that he was present on approximately five to seven occasions during which his father purchased marijuana from Respondent. The person also told investigators that while he was between the ages of fifteen to eighteen, he had purchased marijuana approximately twenty times from Respondent's son at his residence, and that on some occasions, he personally witnessed Respondent hand the marijuana to his son, who then delivered it to him.

Investigators also interviewed a person who stated that he had sold marijuana for Respondent from the summer of 2004 through the summer of 2005. The person further related that from the time he first met Respondent in the year 2003 until the summer of 2005, he had observed approximately twenty-five to thirty pounds of marijuana at Respondent's home, scales used to weigh marijuana for resale, and a box of index cards which contained records of customers to whom Respondent had extended credit. The person also related that Respondent provided him with discounted marijuana as payment for his selling the drug on the latter's behalf, and that he had observed Respondent give another individual five to six pounds of the drug to sell.

This person also told investigators that anytime he was in Respondent's presence, Respondent would be smoking marijuana. The person also stated that he was present numerous times when Respondent came home for lunch and that Respondent would smoke marijuana before returning to work.

Investigators interviewed another person who related that between 1999

and the end of 2003, he had supplied Respondent with over one hundred pounds of marijuana. This person stated that during the last three to four months of 2003, he traveled to North Carolina every other week for the purpose of obtaining marijuana for Respondent. According to this person, prior to each trip, Respondent provided him with approximately \$ 2000 to \$ 3000 dollars, which was used to purchase three to four pounds of marijuana. Moreover, the person observed Respondent sell approximately twenty-five to thirty pounds of marijuana and that he was growing marijuana.

The person also told investigators that from the end of 2002 through the end of 2003, Respondent issued him and another person, prescriptions for 240 Lortab and 120 Xanax in exchange for one pound of marijuana. The person stated that after filling the prescriptions, he would sell the Lortab and Xanax on the street. Finally, this person related an incident in which he and Respondent had smoked marijuana prior to the latter's performing surgery on his girlfriend.

Investigators next interviewed the father of the two individuals whose statements are related above. This person stated that he had been abusing drugs most of his adult life, but it was not until Respondent gave him prescriptions for 150 Oxycontin (80 mg.) per month that he developed the worst addiction he had experienced in his life. According to this person, he became "hooked" on Oxycontin within six to eight months after Respondent first prescribed it for him, and began taking the drug intravenously. According to this person, Respondent also provided him with prescriptions for 240 Roxicodone tablets each month.

The person also told investigators that he had had numerous conversations with Respondent regarding his addiction to Oxycontin, that he had told Respondent that he was shooting up the drug, and that he told Respondent that he was selling the drug to support his habit. Respondent, however, never suggested taking him off of Oxycontin, or that he enter a treatment program.

The person further related that he and Respondent would supply each other with marijuana when the other's supply was low. The person stated that he had supplied Respondent with approximately 1/4 pound to one pound of marijuana and that Respondent had supplied him with three to four pounds. The person also told investigators that he had observed multiple pounds of marijuana while at Respondent's residence.

On May 10, 2006, law enforcement authorities executed a search warrant at Respondent's residence. During the search, the authorities found marijuana roaches, marijuana seeds, two scales, and various paraphernalia including rolling papers, hemostats, pipes, and rollers.

Thereafter, investigators interviewed an additional acquaintance of Respondent, who had met him through the latter's son. This person corroborated the information regarding Respondent's dealings in marijuana including the name of his primary supplier, his index card system for recording transactions, and his personal use. The person also stated that Respondent had given him marijuana to try on five to ten occasions, and that between 2003 and the end of 2004, he would obtain marijuana from a safe in Respondent's home approximately one to two times per week.

The person further related that towards the end of 2004, he had told Respondent that he had knee pain and suspected that he suffered from Attention Deficit Disorder. Respondent told him to come to his office. While Respondent tested his reflexes during the visit, he conducted no further tests and gave no diagnosis. Nonetheless, Respondent prescribed Adderall, a schedule II controlled substance, and hydrocodone. Shortly after filling the initial prescription, the person visited Respondent's home and smoked marijuana. During this visit, Respondent asked the person to give him some of his hydrocodone. Moreover, upon filling a second prescription for hydrocodone, Respondent again asked the person to give him the tablets that he did not need.

Respondent issued this person prescriptions for hydrocodone on a monthly basis between January 2005 and May 2006. The person admitted to investigators that he took very few hydrocodone tablets and regularly provided Respondent with sixty of them. The person further admitted to selling the majority of the remaining tablets to his mother. The person also stated that following Respondent's arrest, Respondent told him not to tell the authorities that he was giving hydrocodone to Respondent.

On December 12, 2006, a federal grand jury indicted Respondent, charging him with conspiring to possess with the intent to distribute, and to distribute, marijuana, see 21 U.S.C. 846; and maintaining a residence for the purpose of distributing and using marijuana. See *id.* section 856(a)(1). The grand jury also indicted Respondent on twelve counts of knowingly and

intentionally distributing Lortab (hydrocodone), and three counts of knowingly and intentionally distributing Xanax (alprazolam), outside of the usual course of medical practice and for other than a legitimate medical purpose, to an individual identified only as person A. See *id.* sections 841(a)(1), 841(b)(1)(D), & 841(b)(2). Finally, the grand jury indicted Respondent on thirteen additional counts of knowingly and intentionally distributing Lortab, outside of the usual course of medical practice and for other than a legitimate medical purpose, to an individual identified only as person B. See 21 U.S.C. 841(a)(1) & 841(b)(1)(D).

Discussion

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

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing * * * controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety. *Id.* "[T]hese factors are * * * considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked." *Id.* Moreover, case law establishes that I am "not required to make findings as to all of the factors." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

Finally, section 304(d) provides that "[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety." 21 U.S.C. 824(d). Here,

analyzing the evidence under factors two and four establishes that Respondent has committed acts "inconsistent with the public interest," and posed "an imminent danger to public health or safety," which justified the immediate suspension of his registration. Relatedly, the record also demonstrates that Respondent's continued registration would be inconsistent with the public interest and that his registration should be revoked.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Record of Compliance with Applicable Laws

The evidence in this case overwhelmingly establishes that Respondent has engaged in the criminal distribution of controlled substances in violation of 21 U.S.C. 841. More specifically, the evidence shows that Respondent was a marijuana dealer/distributor and had engaged in this criminal conduct for a period of at least five years. Moreover, the evidence establishes that Respondent engaged in the illegal manufacturing of marijuana. *Id.*

Furthermore, Respondent used his DEA registration for criminal purposes. More specifically, the evidence shows that Respondent issued prescriptions for controlled substances which included OxyContin and Percocet (schedule II), Lortab (hydrocodone, schedule III), and Xanax (schedule IV), which he then traded for marijuana.

Respondent also issued prescriptions without a legitimate medical purpose. See 21 CFR 1306.04(a) ("A prescription for a controlled substance * * * must be issued for a legitimate medical purpose by an individual acting in the usual course of his professional practice."). Relatedly, Respondent issued prescriptions in the names of other "patients" so that he or his associates would then be able to acquire the drugs. Notably, Respondent had previously been sanctioned by the State Board for the same conduct. Finally, the record establishes that Respondent continued to prescribe Oxycontin to a "patient," notwithstanding that the "patient" had told him: (1) That he was addicted to the drug, (2) that he was taking the drug intravenously, and (3) that he was selling the drug to support his habit.

It is indisputable that Respondent's criminal conduct created an "imminent danger to public health or safety," 21 U.S.C. 824(d), and was "inconsistent with the public interest." *Id.* 824(a)(4). I therefore hold that Respondent's continued registration would be "inconsistent with the public interest"

and that his registration should be revoked. *Id.* Moreover, for the same reasons that led me to find that Respondent posed “an imminent danger to the public health or safety,” *id.* section 824(d), I conclude that the public interest requires that his registration be revoked effective immediately.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BM5526009, issued to Michael F. Myers, M.D., be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective immediately.

Dated: June 22, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07-7]

Southwood Pharmaceuticals, Inc.; Revocation of Registration

On November 30, 2006, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Southwood Pharmaceuticals, Inc. (Respondent), of Lake Forest, California. The Order immediately suspended Respondent's DEA Certificate of Registration, RS0204898, based on my preliminary finding that its continued registration “constitute[s] an imminent danger to the public health and safety because of the substantial likelihood that Southwood [would] continue to supply pharmacies that divert large quantities of controlled substances.” Show Cause Order at 3. The Order also sought the revocation of Respondent's registration on the ground that its continued registration is “inconsistent with the public interest.” *Id.* at 1 (citing 21 U.S.C. 823(d) & 824(a)(4)).

The Show Cause Order alleged that between November 2005 and August 2006, Respondent's sales to pharmacies of hydrocodone products “increased from approximately 7,000 dosage units per month to approximately 3,000,000 dosage units per month,” and that the increase was “directly attributable to

[its] supplying controlled substances to pharmacies that it knew or should have known were engaged in the widespread diversion of controlled substances.” *Id.* The Show Cause Order alleged that several of Respondent's customers were distributing “large amounts of hydrocodone based on orders placed by customers using various Internet Web sites.” *Id.*

The Show Cause Order specifically alleged that “from December 12, 2005, to August 31, 2006, [Respondent] distributed approximately 8,671,000 dosage units of hydrocodone products to Medipharma-Rx, Inc.,” and did so “under circumstances that clearly indicated that Medipharma was engaged in the diversion of controlled substances.” *Id.* at 1–2. The Show Cause Order further alleged that these circumstances included that “ninety-nine percent of Medipharma's business [with Respondent] involved the sale of controlled substances,” that Medipharma was owned by an individual who also owned a Web site “that solicit[ed] orders for controlled substances” and used practitioners who issued prescriptions outside of “the usual course of professional practice,” and that “Medipharma's orders were of an unusual size, deviated substantially from a normal pattern, and were of an unusual frequency.” *Id.* at 2.

Relatedly, the Show Cause Order alleged that Respondent had “also supplied controlled substances under similarly suspicious circumstances” to fourteen other pharmacies. *Id.* The Show Cause Order thus alleged that Respondent “repeatedly supplied excessive quantities of hydrocodone to pharmacies that it knew or should have known were diverting hydrocodone.” *Id.* Moreover, the Show Cause Order alleged that notwithstanding “the unusual size and frequency of the orders placed by Medipharma and others, as well as the fact that the orders substantially deviated from the normal pattern of orders received by” it, Respondent never reported any of the orders as suspicious. *Id.* at 2–3.

Next, the Show Cause Order alleged that on July 17, 2006, the Office of Diversion Control's E-Commerce Section held a conference call with Respondent's representatives to discuss “the distribution of controlled substances to Internet pharmacies.” *Id.* at 3. During the call, DEA officials allegedly presented Respondent with “information on the characteristics of Internet pharmacies and the nature of their illegal activities.” *Id.* DEA officials also allegedly discussed with Respondent such subjects as DEA's 2001 Guidance Document on the use of the

Internet to prescribe controlled substances, the requirement for a valid prescription under federal law and existing professional standards, DEA's regulation requiring the reporting of suspicious orders, and the “practices and ordering patterns of internet pharmacies.” *Id.* The Show Cause Order further alleged that notwithstanding this information, in August 2006, Respondent proceeded to distribute large quantities of hydrocodone to five different internet pharmacies. *Id.* The Show Cause Order thus alleged that Respondent “has failed to maintain effective controls against diversion and that [its] continued registration * * * would be inconsistent with the public interest.” *Id.*

On December 6, 2006, the Show Cause Order was served on Respondent. ALJ Ex. 2. Thereafter, on December 29, 2006, Respondent, through its counsel, requested a hearing. ALJ Ex. 3. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who conducted a hearing in Arlington, Virginia, from February 5 through February 8, 2007. At the hearing, both parties called witnesses and introduced documentary evidence. Following the hearing, both parties submitted briefs containing proposed findings of fact, conclusions of law, and argument.

On March 30, 2007, the ALJ issued her recommended decision (ALJ). In that decision, the ALJ concluded that DEA had proved that “Respondent's continued registration to handle hydrocodone products would be against the public interest.” ALJ at 61–62. The ALJ concluded, however, that Respondent “has kept an open dialogue with the DEA and has attempted to come into compliance with the DEA's regulations.” *Id.* at 62. While acknowledging “the egregious quantities of hydrocodone products the Respondent irresponsibly sold to registered [i]nternet pharmacies during 2005 and 2006,” the ALJ nonetheless “conclude[d] that revocation of * * * Respondent's entire DEA registration is too severe a remedy.” *Id.*

Continuing, the ALJ explained that “the record contains no evidence of * * * Respondent's improper handling of any other controlled substances, especially in its sales of manufactured products to its practitioner customers.” *Id.* Noting that Respondent had hired an “experienced officer who will be making the final decisions concerning [its] compliance measures,” and that this would provide “an increased level of protection of the public interest,” the ALJ recommended that Respondent's authority to handle hydrocodone products be revoked but that it retain its