## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on August 30, 2007, Varian, Inc., Lake Forest, 25200 Commercentre Drive, Lake Forest, California 92630–8810, 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 |
|---|---|
| Phencyclidine (7471) | II |
| 1-Piperidinocyclohexanecarbonitrile (8603). | II |
| Benzoylecgonine (9180) | II |

The company plans to manufacture small quantities of the listed controlled substances for use in diagnostic products.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than November 26, 2007.

Dated: September 21, 2007.

**Joseph T. Rannazzisi,**

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

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Kamir Garces-Mejias, M.D.; Revocation of Registration

On September 6, 2005, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Kamir Garces-Mejias, M.D. (Respondent), of San Juan, Puerto Rico. The Order immediately suspended Respondent's Certificate of Registration, BG2453075, as a practitioner, on the ground that Respondent's continued registration during the pendency of the proceeding ''would constitute an imminent danger to the public health and safety,'' because Respondent had issued numerous prescriptions for controlled substances to persons who sought the drugs through internet sites and without ''establish[ing] legitimate physician-patient relationships.'' Show Cause Order at 6. The Order also sought the revocation of Respondent's registration and the denial of any pending applications for renewal or modification of the registration. *Id.* at 1.

More specifically, the Show Cause Order alleged that Respondent was a participant in a scheme run by Mr. Johar Saran, the owner of Carrington Health System/Infiniti Services Group (CHS/ISG) of Arlington, Texas. *Id.* at 5. According to the allegations, CHS/ISG operated several DEA-registered pharmacies, which obtained their registrations through sham-nominees and which were used to order large amounts of highly abused controlled substances from licensed distributors. *Id.* The Show Cause Order alleged that the controlled substances were then diverted to CHS/ISG, where they were used to fill approximately 3,000 to 4,000 orders per day which had been placed by persons through various Web sites. *Id.*

The Show Cause Order further alleged that Respondent ''participated in [this] scheme by authorizing drug orders under the guise of practicing medicine.'' *Id.* The Show Cause Order alleged that Respondent ''did not see [the] customers, had no prior doctor-patient relationships with the Internet customers, did not conduct physical exams,'' and did not ''create or maintain patient records.'' *Id.* The Show Cause Order also alleged that between May 19 and May 27, 2005, Respondent issued 188 prescriptions to persons located in thirty-three different States, and that eighty-six percent of the prescriptions were for hydrocodone, a controlled substance. *Id.* at 6.

On September 21, 2005, the Show Cause Order was personally served on Respondent. On October 7, 2005, Respondent, through her counsel, requested a hearing on the allegations. This letter was returned, however, by UPS as undelivered. Thereafter, on October 14, 2005, Respondent, through her counsel, against requested a hearing. Respondent also asserted that she ''may be the victim of a theft identity and [that] someone may have used, without her authorization, one of her prescriptions.'' Letter of Resp.'s Counsel at 1 (Oct. 14, 2005). Respondent also denied having ever ''participated in any Web site related to Mr. Johar Saran's scheme.'' On November 16, 2005, based on Respondent's claim that she may have been the victim of identity theft, I stayed the Immediate Suspension of her registration.

In the meantime, the matter had been placed on the docket of this Agency's Administrative Law Judges (ALJ) and assigned to Judge Gail Randall. On October 26, 2005, the ALJ ordered the parties to file their pre-hearing statements. Following my decision staying the suspension order, the Government moved to stay the filing of pre-hearing statements. On November 18, 2005, the ALJ granted the motion.

In a December 4, 2006 joint status report, the parties informed the ALJ that they were unable to resolve the matter without a hearing. The Government thus requested that the matter be set for hearing. On December 13, 2006, the ALJ issued a Second Order for Pre-Hearing Statements. The Order directed that the Government file its statement on or before January 10, 2007, and that Respondent file her statement on or before January 31, 2007.

On January 5, 2007, the Government filed its statement. Respondent did not, however, comply with the ALJ's order. Accordingly, on February 15, 2007, the ALJ issued an additional order which directed Respondent to file her statement by February 28, 2007. The order also gave notice that Respondent's failure to comply could be deemed a waiver of her right to a hearing. *See* Third Order for Respondent's Prehearing Statement 1 (citing 21 CFR 1301.43(e)). Respondent also failed to comply with this order.

Thereafter, on March 5, 2007, the Government moved to terminate the proceeding and requested that the ALJ find that Respondent had waived her right to a hearing. On March 7, 2007, the ALJ found that Respondent had waived her right to a hearing under 21 CFR 1301.43(e), granted the Government's motion, and ordered that the proceeding be terminated.

On March 12, 2007, Respondent's counsel received a copy of the ALJ's termination order and moved for reconsideration. The basis for the motion was that Respondent's counsel ''is a solo practitioner in the island of Puerto Rico with an extensive practice on civil and federal criminal cases.'' Respondent's Req. for Reconsideration at 2. Respondent's counsel maintained that since January 6, 2007, he had ''had an extremely busy Court calendar,''

which ''include[d] three * * * major criminal * * * jury trials before the United States District Court for the District of Puerto Rico.'' *Id.* Respondent's counsel also maintained that he had ''been involved in preparation for numerous appeals at the First Circuit Court of Appeals and the handling of other criminal and civil matters filed in the State and Federal Courts.'' *Id.* at 3. Respondent's counsel further stated that it had not been his ''intention to be disrespectful or to willfully disobey the orders issued by the ALJ.'' *Id.*

The ALJ was not persuaded. The ALJ observed that in the three months prior to her order terminating the case, she had issued numerous other orders in the proceeding, three of which had required a response, and that each order had been sent by both facsimile and first-class mail to Respondent's counsel. Order Denying Request for Reconsideration at 1–2. The ALJ noted that ''[n]one of my orders, prior to the Termination Order * * * ha[d] elicited a response from the Respondent despite the deadlines to respond.'' *Id.* at 2. The ALJ also noted that ''at no point did the Respondent request a written extension of time.'' *Id.* The ALJ thus concluded that ''Respondent's failure to pursue her case remains a waiver of her right to a hearing pursuant to 21 CFR 1301.43(e),'' and denied Respondent's request for reconsideration. *Id.*

Thereafter, Respondent filed a second motion for reconsideration. As grounds for the motion, Respondent asserted that her motion should be evaluated using the same standards that the federal courts apply under Rule 55(c) of the Federal Rules of Civil Procedure. Resp.'s Second Mot. for Reconsid. at 2. Respondent contends that the Agency has not been prejudiced by her failure to comply with the ALJ's orders; that her counsel is a solo practitioner who participated in three federal criminal trials between January 8th and February 20, 2007, which left him with ''literally no time for other meritorious cases''; that Respondent has meritorious defenses; and that Respondent's failure to timely respond to the ALJ's orders was her attorney's fault. *See generally id.* Respondent thus contends that she has shown good cause to set aside the ALJ's termination order.

Thereafter, the ALJ ordered the Government to respond. The Government argued that having terminated the proceeding, the ALJ no longer had jurisdiction. Gov. Response to Respondent's Mot. Requesting Rescission of Termination Order. The Government also argued that Respondent had not demonstrated good cause to set aside the termination order. According to the Government, the ALJ's order for pre-hearing statements gave Respondent's counsel seven weeks to file her pre-hearing statement, and that during that period, Respondent's counsel took nearly a two-week vacation. Moreover, the ALJ's Third Order had given Respondent's counsel an additional thirteen days to file her pre-hearing statement and Respondent's counsel still had eight days to do so following the conclusion of his third trial.

Finding ''the Government's argument compelling,'' the ALJ denied Respondent's motion. Order Denying Resp.'s Motion at 2. The ALJ reasoned that even if she still had jurisdiction, Respondent had not ''provide[d] due cause for her failure to proceed in a timely fashion.'' *Id.* The ALJ thus held to her earlier decision that ''Respondent's 'failure to pursue her case remains a waiver of her right to [a] hearing pursuant to 21 CFR 1301.43(e),' '' and denied the motion. *Id.* (quoting Termination Order).

The investigative file was then forwarded to me for final agency action. Having considered the various pleadings, I conclude that Respondent has not shown ''good cause'' for failing to comply with the ALJ's orders and thus find that Respondent has waived her right to a hearing. *See* 21 CFR 1301.43(d). Before proceeding to make factual findings regarding the allegations of the Show Cause Order, a discussion of Respondent's motion is warranted.

In seeking to set aside the ALJ's termination order, Respondent invokes various court decisions construing Rule 55(c) of the Federal Rules of Civil Procedure. Respondent's argument is misplaced. Agency proceedings brought under section 304 of the Controlled Substances Act are not governed by the Federal Rules of Civil Procedure, but rather, DEA's regulations and the rules set forth in the applicable provisions of the Act. *See* 21 CFR 1301.41. Indeed, this Agency has never held that the good cause standard of 21 CFR 1301.43(d), which addresses conduct constituting a waiver of the right to a hearing, is to be construed in the same manner as the federal courts interpret the good cause standard under F.R.C.P. 55(c) for setting aside the entry of a default.

Moreover, Respondent has not demonstrated good cause. Respondent argues that her ''default in submitting timely response to the orders issued by [the ALJ] was not willful.'' Resp.'s Second Mot. at 6. Respondent further contends that there was ''no culpable conduct'' on her part and that she was not ''*personally* at fault'' because it was her attorney's responsibility to respond to the ALJ's orders and he was preoccupied with other matters. *Id.* The omissions of Respondent's counsel are, however, fairly charged to Respondent. Moreover, even if her counsel's failure to respond to the ALJ's orders does not rise to the level of willfulness, it is still sufficiently culpable to preclude a finding that there is good cause to set aside the ALJ's Termination Order.

As the First Circuit has explained, Respondent's claim ''that [her] attorney was preoccupied with other matters * * * has been tried before, and regularly has been found wanting.'' *De la Torre* v. *Continental Ins. Co.*, 15 F.3d 12, 15 (1st Cir. 1994) (citing *Mendez* v. *Banco Popular de Puerto Rico*, 900 F.2d 4, 7 (1st. Cir. 1990) (other citations omitted)). As the First Circuit has also noted: ''Most attorneys are busy most of the time and they must organize their work so as to be able to meet the time requirements of matters they are handling or suffer the consequences.'' *Torre*, 15 F.3d at 15 (quoting *Pinero Schroeder* v. *FNMA*, 574 F.2d 1117, 1118 (1st Cir. 1978)).

Relatedly, the Supreme Court has observed that clients are ''accountable for the acts and omissions of their attorneys.'' *Pioneer Inv. Servs. Co.* v. *Brunswick Assoc. Limited Partnership*, 507 U.S. 380, 396 (1993). As the Court has further explained, one who ''voluntarily chose this attorney as [her] representative in the action * * * cannot * * * avoid the consequences of the acts or omissions of this freely selected agent. Any other notion would be wholly inconsistent with our system of representative litigation, in which each party is deemed bound by the acts of [her] lawyer-agent and is considered to have notice of all facts, notice of which can be charged upon the attorney.'' *Id.* at 397 (quoting *Link* v. *Wabash Ry. Co.*, 370 U.S. 626, 633–34 (1962) (other citation and int. quotations omitted)). Accordingly, that Respondent was not personally at fault in failing to respond to the ALJ's orders is irrelevant.

As for the contention that the conduct of Respondent's counsel was not willful, it is still sufficiently culpable to preclude a finding that good cause exists to set aside the Termination Order. Here, the ALJ issued her second order for pre-hearing statements on December 13, 2006. This Order was faxed to Respondent's counsel the following day (as well as mailed) and gave him seven weeks to submit his filing. While Respondent's counsel could not find the time to comply with the ALJ's order, by his own admission

he was able to take ''his annual vacation from December 24, 2006 to January 6, 2007.'' Resp. Second Mot. at 3. Surely, if one can find time to take vacation, he can also find time to file a necessary pleading and comply with the ALJ's orders.

Moreover, even after Respondent's counsel failed to comply with the January 31, 2007 deadline, the ALJ granted him a second chance. On February 15, 2007, the ALJ issued her Third Order for Respondent's Pre-hearing Statement, which gave Respondent's counsel until February 28, 2007 to file the statement. The Third Order also gave notice that Respondent's failure to comply could be deemed a waiver of her right to a hearing. This Order was also served on Respondent's counsel by both First Class Mail and facsimile.

Respondent's counsel again failed to comply with the ALJ's order. Indeed, Respondent's counsel did not submit his pre-hearing statement until after being served with the ALJ's Termination Order. While Respondent's counsel contends that he was involved in three federal criminal jury trials between January 8, 2007, and February 20, 2007, which ''left literally no time for other meritorious cases,'' and that it was not his ''intention to disregard'' the ALJ's orders, Resp. Sec. Mot. at 4, he offers no explanation for why he failed to comply with the ALJ's order following the conclusion of the third trial. Nor does he offer any explanation for why he did not contact the ALJ and request an extension during the two-and-a-half months that elapsed between the issuance of the Second Order and the deadline of the Third Order.[1] Cf. *Kirk* v. *INS*, 927 F.2d 1106, 1108 (9th Cir. 1991) (rejecting contention that procedural default should be excused because party's counsel had ''been involved in three hearings over the last three weeks which required a great deal of time'').

Accordingly, even if the conduct of Respondent's counsel was not willful or intentional, it clearly was culpable in that it amounted to a reckless disregard of the ALJ's orders. ''Litigants must act punctually and not casually or indifferently if a judicial system is to function effectively.'' *McKinnon* v. *Kwong Wah Restaurant*, 83 F.3d 498, 504 (1st Cir. 1996). This language is equally applicable to administrative proceedings. Respondent has therefore failed to show good cause to set aside the Termination Order.[2]

Accordingly, I hereby enter this final order without a hearing. *See id.* § 1301.43(e). Based on relevant material in the investigative file, I make the following findings.

**Findings**

Respondent currently holds DEA Certificate of Registration, BG2453075, which authorizes her to dispense controlled substances in Schedules II though V. Respondent's registration does not expire until September 30, 2008. Respondent's registered location is Torrecillap-2, Lomas De Carolina, Carolina, in Puerto Rico. According to the investigative file, Respondent is licensed to practice medicine in both Puerto Rico and Michigan.

Respondent came to the attention of DEA during an investigation of Johar Saran, the owner of a majority stake in Carrington Healthcare Systems/Infiniti Services Group (CHS/ISG) of Arlington, Texas. According to the investigative file, CHS/ISG used several internet facilitation centers (IFCs) to solicit orders for controlled substances, which it then dispensed through numerous DEA registered pharmacies which CHS/ISG controlled. Under the scheme, a person seeking a controlled substance would go to a Web site, complete a questionnaire, and request a particular drug. The information would be forwarded to an IFC, which then sent the information on to a physician who would review the customer's information and authorize a prescription.

Thereafter, an employee of CHS/ISG would access the Web site and download the prescriptions. The prescriptions were then filled by CHS/ISG at its Arlington, Texas facility and sent to the purchaser using either FedEx or UPS.

According to the investigative file, the IFCs that serviced CHS/ISG used at least 59 physicians including Respondent to write controlled-substance prescriptions. The records of CHS/ISG indicated that on the dates of May 19, 24, 26, and 27, 2005, it filled a total of 188 controlled substance prescriptions which were issued by Respondent for persons who were located in at least thirty-three different States.

The prescriptions included 161 for drugs containing hydrocodone, 19 for Xanax, 5 for phentermine, 2 for acetaminophen with codeine, and 1 for diazepam. Moreover, Respondent issued the prescriptions to persons in such far-flung locations as Alaska (2 Rxs), California (21 Rxs), Colorado (3 Rxs), Florida (13 Rxs), Maryland (5 Rxs), Massachusetts (7 Rxs), Mississippi (4 Rxs), New Jersey (11 Rxs), New York (7 Rxs), Ohio (7 Rxs), Oklahoma (2 Rxs), Texas (9 Rxs), Virginia (13 Rxs), and Washington (5 Rxs).

The investigative file also establishes that on June 14, 2005, a UPS facility in Pittston, Pennsylvania, notified DEA investigators that an individual had attempted to pick up four packages that it suspected contained narcotic drugs and which were addressed to four different persons at four different addresses. Instead, UPS turned the packages over to DEA. Each of the packages contained ninety tablets of generic Lorcet, 10/650, a schedule III controlled substance containing hydrocodone and acetaminophen. Respondent was listed as the prescribing physician on two of the bottles, which were to be dispensed to persons allegedly residing in Plymouth and Dallas, Pennsylvania.

DEA personnel were later contacted by a person who claimed to have ordered the drugs off the internet for herself, her daughter and her father. This person further stated that to obtain the prescriptions she had completed an on-line medical evaluation. When asked by a DEA investigator whether she had used fictitious names to pick up the drugs at UPS, the person would neither confirm nor deny doing so.

The investigative file also included the sworn declaration of a detective (TFO) who served on the Northern Vermont Drug Task Force from January 2003 until October 2005. According to the TFO, on July 20, 2005, he was advised by UPS in Rutland, Vermont, that it had two packages which were addressed to a person (J.S.) whom it suspected was purchasing controlled substances over the internet. UPS opened the packages (which were shipped COD) and found that they contained hydrocodone.

Later that day, the TFO went to UPS to confront J.S., who had arrived to pick up the packages. After being notified by a UPS employee that J.S. had picked up one of the packages,[3] the TFO identified himself and questioned him regarding its contents. J.S. claimed that he did not know specifically what was in the envelope but claimed to have a prescription for it. During the interview,

[1] He also offers no explanation as to why, in the period between the dismissal of the indictment in *United States* v. *Bretton-Castillo* and the beginning of the trial in *United States* v. *Cedeno-Perez*, he could not find the time to either file the pre-hearing statement or seek an extension.

[2] Respondent also asserts that I should consider ''whether the entry of termination would bring about a harsh or unfair result which would have a lifetime effect [on her] capacity to earn her living.'' Resp. Sec. Motion at 7. An order of revocation does not, however, impose a permanent prohibition on a practitioner's ability to obtain a new registration.

[3] According to the affidavit, J.S. did not have sufficient funds to pay for the second package.

J.S. also stated that he had refused the second package because he did not know anything about it. J.S. also told the TFO that he purchased the drugs over the internet because it was cheaper and he did not have health insurance; he also claimed that his local physician had sent his medical records to the prescriber. The TFO subsequently interviewed J.S.'s local doctor, who denied sending the records to another physician.

The next day, the TFO obtained a warrant to search both packages. The search revealed that one of the packages held a bottle which contained 90 tablets of hydrocodone, listed Respondent as the prescribing physician, and was dated July 17, 2005. The bottle gave the name and address of the dispensing pharmacy as ASI–2129 S. Great Southwest Parkway, Suite 304, Grand Prarie, TX. The TFO subsequently determined that the pharmacy was named Avatar Corporation.

The following day, the TFO contacted the pharmacy. A pharmacy employee confirmed that Avatar was a closed-door pharmacy which filled mail-order prescriptions. The pharmacy employee stated that Avatar filled prescriptions issued by Respondent on a regular basis and provided her phone number. The pharmacy employee also told the TFO that Respondent had a web page which was run by person named Juan Almeida.

The TFO called Respondent's phone number and heard a recording by Respondent which gave a second phone number. The TFO called that number and left a voice mail message.

Several hours later, Respondent called the TFO and spoke with him. Respondent denied issuing the prescription to J.S. and stated that she was in Puerto Rico. The TFO then asked Respondent how her name came to be on the prescription; Respondent answered that ''they have my signature on the Web site.''

Having heard Respondent's denial, the TFO called the pharmacy again. The pharmacy employee reaffirmed that Respondent sent Avatar prescriptions on a regular basis.

Later that day, the TFO was contacted by Mr. Almeida. Mr. Almeida told the TFO that he was a co-worker of Respondent and had been given his number by her. Mr. Almeida told the TFO that he managed a Web site where people could fill-out an online application to obtain medications; the applications were then reviewed by Respondent who determined whether to issue a prescription. When the detective told Mr. Almeida that Respondent had denied issuing prescriptions over the internet, Mr. Almeida said that she certainly did and that the prescriptions were then faxed to the pharmacy. Mr. Almeida eventually provided the detective with the name of the Web site. When the detective asked Mr. Almeida whether the Web site had any process in place to verify the on-line applications, he became defensive and claimed that it was no different than when a person went to see a physician.

On September 6, 2006, DEA investigators interviewed Respondent in the presence of her attorney. During the interview, Respondent denied having ever reviewed questionnaires and having ever prescribed controlled substances over the internet. Respondent further asserted that she was the victim of identity theft and claimed that her DEA registration had been misused.

Respondent further denied issuing the prescriptions to the two Pennsylvania residents which were intercepted by UPS. She also denied having knowledge of the ASI/Avatar pharmacy and denied knowing the employee who had provided information to the TFO.

As for her relationship with Mr. Almeida, Respondent stated that she had talked on the telephone with him regarding a job advertisement which had appeared in the ''El Nuevo Dia'' sometime in January 2005, and which had sought physicians for services related to the internet. Respondent further stated that Mr. Almeida was located in Miami and had initially answered her phone call in response to the advertisement, but then transferred her call to one Dr. Rodriguez.

Respondent maintained that she asked Dr. Rodriguez whether the job had something to do with prescribing medication or was associated with a hospital. Respondent stated that Rodriguez told her that it was not hospital related. Respondent told investigators that after speaking with Dr. Rodriguez she sent in a resume which listed her DEA number. Respondent further told investigators that Dr. Rodriguez never called her back.

During the interview, the investigators presented copies of the prescriptions which listed Respondent as the prescribing physician, and asked her whether the signature on the prescriptions was hers. Respondent acknowledged that the signature was hers but denied issuing the prescriptions. She also denied knowing the patients listed on the prescriptions. Finally, Respondent denied knowing Johar Saran.

The investigative file also contains an e-mail dated July 24, 2005 to Joe Saran and signed by Mr. Almeida. In the e-mail, Mr. Almeida related that he had been informed by the ASI/Avatar employee ''that certain law enforcement officials were asking questions about an individual they apprehended who[] allegedly possessed an excessive amount of hydro.'' The e-mail specifically referenced J.S. Mr. Almeida then stated that he had ''pulled his records and confirmed that he [J.S.] is legitimate in that he is who[] he said he was on the medical'' questionnaire and that his ''DOB and address match.''

Next, the e-mail recounted that the ASI/Avatar employee had ''provided Law Enforcement officials with my telephone number as well as'' that of Respondent and specifically referenced the TFO. According to the e-mail, ''[s]hortly thereafter, [Respondent] was contacted by a task force officer who[] asked a series of questions.'' Continuing, Mr. Almeida wrote that he was ''not sure'' that Respondent ''was the best at answering questions unannounced, but nonetheless, she answered in the affirmative, that if he possessed prescription drugs with her name on it that it was likely prescribed by her, but that she had to review her records in order to confirm any thing further.'' The e-mail added that when the TFO had asked Respondent if she ''had seen'' J.S., ''she replied by stating she is in Puerto Rico.''

Mr. Almeida then proceeded to describe his subsequent telephone conversation with the TFO. According to the e-mail, Mr. Almeida discussed the process by which ''an individual goes on the net to purchase prescription drugs.'' The e-mail further stated that Mr. Almeida told the TFO that following the ''verification of id'' by the Web site, ''the request is transferred to the doctor for review.'' Mr. Almeida further related that he had told the TFO that ''[d]octors are the ones making the decision whether or not to prescribe the medication based on the question[naire] provided,'' and ''that calls are made by the doctors to [the] patients.''

**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 [her] 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, 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). In this case, I am unpersuaded by Respondent's defense of identity theft and her denial of involvement in the scheme. Rather, I conclude that Factors Two and Four establish that allowing Respondent to continue to dispense controlled substances would be inconsistent with the public interest. Accordingly, I will order that Respondent's registration be revoked and that any pending renewal application be denied.

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

The central issue in this case is whether the prescriptions Respondent issued through Web sites associated with CHS/ISG complied with Federal law. As explained below, the evidence conclusively demonstrates that Respondent used her prescribing authority to act as a drug pusher; the only difference between her and a street dealer was that she did not physically distribute the drugs to the customers of CHS/ISG.

Under DEA regulations, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of [her] professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.* As the Supreme Court recently explained, ''the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 126 S.Ct. 904, 925 (2006) (citing *Moore*, 423 U.S. 122, 135, 143 (1975)).

It is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to be acting ''in the usual course of * * * professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *See United States* v. *Moore,* 423 U.S. 122 (1975). Under numerous state standards of medical practice, before issuing a treatment recommendation, a physician must, *inter alia*, physically examine a patient to establish a bona-fide doctor-patient relationship and properly diagnose her patient. *See, e.g.*, Cal. Bus. & Prof. Code 2242.1; Colo. Bd. of Med. Exam'rs, Policy 40–9; Mass. Bd. of Reg. in Med., Policy 03–06; Ohio Admin. Code 4731–11–09; Okla. Bd. of Med. Lic. & Supervision, Policy on Internet Prescribing; Va. Code 54.1–3303.

Relatedly, the American Medical Association has explained that to establish a bonafide doctor-patient relationship, a ''physician shall'':

> i. obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided; ii. have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s); iii. as appropriate, follow up with the patient to assess the therapeutic outcome; iv. maintain a contemporaneous medical record that is readily available to the patient and * * * to his * * * other health care professionals; and v. include the electronic prescription information as part of the patient medical record.

American Medical Association, *Guidance for Physicians on Internet Prescribing; see also William R. Lockridge,* 71 FR 77791, 77798 (2006).

To similar effect are the guidelines issued by the Federation of State Medical Boards of the United States, Inc. *See Model Guidelines for the Appropriate Use of the Internet in Medical Practice.* According to the Guidelines, ''[t]reatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. *Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.'' Id.* at 4 (emphasis added). *Cf.* DEA, *Dispensing and Purchasing Controlled Substances over the Internet*, 66 FR 21181, 21183 (2001) (guidance document) (''Completing a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship.'').[4]

The investigative file establishes that on four separate days in May 2005, Respondent, who was then practicing in Puerto Rico, issued at least 188 prescriptions for controlled substances to persons located in at least thirty-three different States including, but not limited to, Alaska (2 Rxs), California (21 Rxs), Colorado (3 Rxs), Washington (5 Rxs), Massachusetts (7 Rxs), New Jersey (11 Rxs), New York (7 Rxs), Ohio (7 Rxs), Oklahoma (2 Rxs), Texas (9 Rxs), Virginia (13 Rxs) and Maryland (5 Rxs).[5] The prescriptions were for highly abused drugs including hydrocodone (161 Rxs), Xanax (19 Rxs), phentermine (5 Rxs), acetaminophen with codeine (2 Rxs), and diazepam (1 Rx).

Moreover, the evidence further shows that in June 2005, Respondent issued two hydrocodone prescriptions to persons located in Pennsylvania, and that in July 2005, Respondent issued a hydrocodone prescription to J.S., a person located in Vermont. In both cases, the evidence established that the prescriptions were issued on the basis of an online medical ''evaluation'' and were not based on a face-to-face encounter which included a physical exam. Given the far flung locations of the ''patients,'' which render it most unlikely that Respondent ever physically examined them; the evidence

[4] The guidance document reflects this Agency's understanding of what constitutes a bonafide doctor-patient relationship under state laws and existing professional standards. 66 FR 21182–83.

[5] Under numerous state laws, a physician must typically be licensed in the State where the patient resides in order to prescribe to the patient. See, e.g., Cal. Bus. & Prof. Code section 2052; Cal. Health & Safety Code section 11352(a). Respondent was, however, licensed only in Michigan and Puerto Rico. As I recently noted, ''[a] physician who engages in the unauthorized practice of medicine is not a 'practitioner acting in the usual course of * * * professional practice,' '' and ''[a] controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA.'' United Prescription Services, Inc., 72 FR 50397, 50407 (2007) (quoting 21 CFR 1306.04(a) and citing 21 CFR 1306.03(a)(1)). The prescriptions Respondent issued were thus illegal under Federal law for this reason as well.

pertaining to the Pennsylvania and Vermont customers; as well as evidence regarding the manner in which the CHS/ISG scheme operated including the statements of Mr. Almeida in both his telephone conversations with the TFO and in his e-mail; I conclude that Respondent issued controlled-substance prescriptions to numerous persons without establishing a valid physician/patient relationship with them and that the prescriptions were not issued for a legitimate medical purpose. *See* 21 CFR 1306.04(a); 21 U.S.C. § 841(a). Respondent thus repeatedly violated federal law. *See Gonzales* v. *Oregon*, 126 S.Ct. at 925; *Moore*, 423 U.S. at 135.

I further reject Respondent's defense of identity theft and her denial of involvement in the scheme. In this regard, I note that an employee of the Avatar pharmacy twice implicated Respondent in the scheme. Moreover, after the TFO spoke with Respondent he was called by Mr. Almeida, who informed the TFO that he was Respondent's co-worker and had been given the TFO's phone number by her. Respondent's act in giving the TFO's phone number to Mr. Almeida begs the question of why she did so if she was not involved in the scheme.

Mr. Almeida admitted to the TFO that he managed a Web site where persons could obtain medications and stated that Respondent reviewed the applications and determined whether to issue the prescriptions. Furthermore, when told by the TFO that Respondent had denied issuing prescription through a Web site, Mr. Almeida stated that she certainly did so. Finally, Mr. Almeida's e-mail to Mr. Saran further implicated Respondent in the scheme. I therefore conclude that there is no merit to Respondent's assertions that she was the victim of identity theft and was not involved in the scheme.

As recognized in *Lockridge* and other agency orders, '' '[le]gally there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription.' '' 71 FR at 77800 (quoting *Mario Avello*, M.D., 70 FR 11695, 11697 (2005)). *See also Floyd A. Santner, M.D.*, 55 FR 37581 (1990). In short, Respondent's involvement in this scheme did not constitute the legitimate practice of medicine, but rather, drug dealing.

Accordingly, Respondent's experience in dispensing controlled substances and her record of compliance with applicable laws makes plain that her continued registration would ''be inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Moreover, for the same reasons which led me to initially find that Respondent posed ''an imminent danger to the public health or safety,'' *id.* 824(d), I conclude that the public interest requires that her registration be revoked effective immediately. *See* 21 CFR 1316.67.

## 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 Registration, BG2453075, issued to Kamir Garces-Mejias, M.D., be, and it hereby is, revoked. I further order that any pending application of Respondent for renewal of her registration be, and it hereby is, denied. This order is effective immediately.

Dated: September 19, 2007.

**Michele M. Leonhart,**

*Deputy Administrator.*

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## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

**[Docket No. 07–18]**

## David L. Wood, M.D.; Dismissal of Proceeding

On January 24, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to David L. Wood, M.D. (Respondent), of Castle Rock, Colorado. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, AW6977207, as a practitioner, and the denial of any pending applications for renewal or modification of his registration, on the ground that on October 19, 2006, Respondent had entered into a ''Stipulation and Final Agency Order'' with the Colorado Board of Medical Examiners, which ''limited [his] medical license to administrative medicine only.'' Show Cause Order at 1. The Show Cause Order alleged that as a consequence of the state order, Respondent is ''not authorized to administer, dispense or prescribe controlled substances to any person * * * in the State of Colorado, the State in which [he is] registered with DEA.'' *Id.* The Show Cause Order also alleged that the Colorado Board had found that Respondent prescribed Stadol, a schedule IV controlled substance, to a patient in ''large continuous amounts despite the fact that [he knew] that this patient abused Stadol [obtained] from other'' physicians. *Id.* at 2.

On February 21, 2007, Respondent, through his counsel, requested a hearing on the allegations. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who proceeded to conduct pre-hearing procedures.

Thereafter, on March 14, 2007, the Government moved for summary disposition on the ground that the Colorado Board's Order prohibited Respondent from engaging in the practice of clinical medicine, and therefore, Respondent was without authority to handle controlled substances in Colorado. *See* Gov. Mot. for Summ. Judgment at 1–2. As support for its motion, the Government attached a copy of the state order, as well as a February 28, 2007 letter from Ms. Cheryl Hara, Program Director for the Colorado Board, to this Agency. *See id.* at attachments. This letter stated that Respondent's ''stipulation precludes him from patient contact, the administration of or interpretation of patient tests, the evaluations of data for the purpose of furthering individual patient care, the performance of any act that requires the exercise of discretion in the prospective authorization of medical care, not including prospective authorization of diagnostic procedures.'' *See id.* at Attachment II, at 1. The letter further explained that because Respondent ''is precluded from treating patients, family members or himself, there is no clinical or legal basis for [him] to prescribe, dispense or administer drugs of any kind and the Board would view any prescribing, dispensing or administering by [him] as a violation of the terms of this stipulation.'' *Id.*

Respondent opposed the Government's motion arguing that the Colorado Board's Order ''does not suspend, revoke or deny [him his] medical license.'' Respondent's Resp. at 3. Respondent further maintained that his ''medical license status is 'Active-With Conditions' and [that he] may apply to the Board for modification of his practice at any time.'' *Id.* Respondent thus contended that the Order does not support a finding that he ''has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the * * * dispensing of controlled substances.'' *Id.* at 2 (quoting 21 U.S.C. 824(a)(3)).

On April 27, 2007, the ALJ granted the Government's motion. Noting that there were no material facts in dispute and that under DEA precedent the ''controlling question * * * is whether the Respondent is currently authorized