

Drug	Schedule
Methamphetamine (1105)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Cocaine (9041)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Meperidine (9230)	II
Oxymorphone (9652)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans on manufacturing the listed controlled substances in bulk for sale 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 Cody Laboratories, Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Cody Laboratories, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 28, 2007.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Randi M. Germaine, M.D.; Revocation of Registration

On December 14, 2006, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Randi M. Germaine, M.D. (Respondent), of Casa Grande, Arizona. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BG3717278, as a practitioner, as well as the denial of any pending applications for renewal or modification of the registration, on the ground that his continued registration is

inconsistent with the public interest. Show Cause Order at 1.

The Show Cause Order specifically alleged that during the execution of a search warrant at the Morenci Healthcare Center (Respondent's former employer), copies of patient charts were obtained which were then sent to a medical expert for review. *Id.* at 2. The Show Cause Order alleged that the expert had concluded that Respondent's "prescribing practices concerning controlled substances did not meet the usual standard of care." *Id.* Relatedly, the Show Cause Order alleged that background checks on some of Respondent's patients indicated that they "were receiving excessive and unnecessary amounts of controlled substances," that they were known to law enforcement to be "drug abusers," and that some of them had committed controlled-substance offenses. *Id.* Relatedly, the Show Cause Order alleged that some of Respondent's patients "were known to area pharmacists as 'doctor shoppers' and 'chronic early refillers.'" *Id.* Moreover, "a number of [Respondent's] patients were family members receiving the same prescriptions for controlled substances." *Id.*

The Show Cause Order further alleged that the "autopsy reports for two of [Respondent's] patients * * * showed [that] the cause of death [was] drug overdoses resulting from controlled substances prescribed by" Respondent. *Id.* The Show Cause Order also alleged that another of Respondent's patients had "died after obtaining invalid prescriptions from [him] for controlled substances." *Id.*

On January 8, 2007, the Show Cause Order, which also notified Respondent of his right to a hearing, was served on him as evidenced by the signed return-receipt card. Because (1) More than thirty days have passed since service of the Show Cause Order, and (2) Respondent did not timely request a hearing, I conclude that Respondent has waived his right to a hearing. *See* 21 CFR 1309.53(c). I therefore enter this Final Order without a hearing based on relevant material found in the investigative file and make the following findings.

Findings

Respondent is the holder of DEA Certificate of Registration, BG3717278, which authorizes him to handle controlled substances as a practitioner at the registered location of Harvest Medical Clinic, Inc., 1856 E. Florence Blvd., Casa Grande, Arizona. Respondent's registration does not expire until September 30, 2008.

On August 25, 2003, the Greenlee County Sheriff's Office contacted the DEA Tucson Diversion Group regarding Respondent's termination from the Morenci Healthcare Center based on the allegation that he over-prescribed narcotic controlled substances. The Sheriff's Office also informed DEA Investigators that R.S., a thirty-one year old male inmate at the county jail and patient of Respondent, had died and that the autopsy report had found both methadone and benzodiazepines in his blood. While the autopsy report noted that the cause of death could not be determined and that the "[t]oxicology findings may be equivocal due to decomposition," R.S. was known to local law enforcement as a drug abuser. The Sheriff's Office further related that Respondent had prescribed methadone (10 mg. tablets) for R.S. for back pain.

Subsequently, R.S.'s medical records were sent to Ted Parran, M.D., a board-certified internist and Associate Clinical Professor of Medicine and Family Medicine at the Case Western Reserve University School of Medicine and Director of its Addiction Fellowship Programs.¹ According to Dr. Parran's report (hereinafter, Expert Report), R.S. died four days after Respondent started him on methadone and "had demonstrated much drug seeking behavior over the past two years." Expert Report at 2. Dr. Parran noted that R.S. "had [a]n MRI scanning demonstrating little pathology, had longstanding complaints and office behavior out of proportion to evidence of illness, and [a history] of non-compliance with [physical therapy] referrals." *Id.* Dr. Parran further noted that R.S. "had been pretty much off of opioid analgesics (except for a few Vicodin or Percocet) and in [j]ail for a while when for some reason he was started on [m]ethadone * * * on 5/30/02." *Id.* Dr. Parran concluded that "[t]his prescribing is difficult to imagine, fails to meet usual standards of care and concern when prescribing controlled drugs, appears to be for other than [a] legitimate medical purpose, and appears to have played a direct role in the patient's death." *Id.*

On or about May 31, 2003, D.K., a twenty-five year old female and another of Respondent's patients, died of a drug overdose. According to the toxicology report, hydrocodone, oxycodone, diazepam, and nordiazepam were present in D.K.'s blood. Furthermore, the examining pathologist found that

¹Dr. Parran has also performed research and issued written educational materials on addiction and controlled-substance prescribing. He has also developed a remedial education course on controlled-substance prescribing.

D.K.'s death "is due to an acute intoxication due to the combined effects of multiple prescription medications including hydrocodone and oxycodone."

Upon review of D.K.'s chart, Dr. Parran found "much evidence of out of control behavior." Expert Report at 5. More specifically, Dr. Parran noted that D.K. had lied about her "drug use"; that there was "[c]lear evidence" that on three occasions D.K. was "Dr. shopping" and that on four other occasions she engaged in "scams" to obtain additional drugs; that her medical complaints bore "no resemblance to the physical exam"; that there were "multiple multiple early refill attempts"; and that approximately five months before her death, another physician had diagnosed her with bipolar disorder and determined that she "need[ed] to be tapered off of all controlled drugs." *Id.* at 5–6.

Dr. Parran also noted another visit in which Respondent had noted that D.K. was "worried about Hep[atitis] C and HIV * * * needle stick exposure—sharing needles," and that she needed a urine drug screen. *Id.* at 5. Dr. Parran observed that Respondent nonetheless issued D.K. a prescription for Vicodin for "acute pain and cough." *Id.*

Dr. Parran also found that D.K. had not been prescribed controlled substances between January and May 9, 2003, the latter being the date when Respondent "began the prescribing that ultimately contributed to [D.K.'s] death." *Id.* at 6. Dr. Parran noted that Respondent issued prescriptions to D.K. on May 9, 2003 for 90 hydrocodone; on May 20, 2003, for another 90 hydrocodone; and on May 27, 2003, for 40 Percocet (oxycodone).² *Id.* On May 28, 2003, D.K. overdosed and died three days later. *Id.* Based on his review, Dr. Parran concluded that Respondent's prescribing of controlled substances "fails to meet usual standards of care, appears to be for other than legitimate medical purpose and appears to have contributed directly to the patient's death." *Id.*

On July 31, 2003, S.B., a fifty-six year old female patient of Respondent, also died of a drug overdose. The toxicology report noted that propoxyphene, norpropoxyphene, and nordiazepam were present in her blood; the pathologist concluded that S.B.'s death was "due to

an acute multidrug intoxication including * * * Propoxyphene."

DEA investigators subsequently determined that between August 5, 2002, and July 21, 2003, Respondent prescribed for S.B. numerous controlled substances. More specifically, he prescribed 5520 propoxyphene capsules, 1200 hydrocodone (7.5/500 mg.) tablets, 729 Oxycontin tablets in various strengths, 21 flurazepam (both 15 mg. and 30 mg. strength) tablets, 150 lorazepam (1 mg.) tablets, 90 oxycodone (5 mg.) tablets, and 10 Duragesic (75 mcg.) patches.

Dr. Parran's review noted that S.B. "was a longstanding patient of the Health Center, with many medical problems including arthritis and headaches, and with a warning note on the front of the chart * * * to 'avoid all narcotics.'" Expert Report at 3. Dr. Parran further found that "from the first time [Respondent] saw this patient [he] began adding controlled drugs" including Vicodin, Darvocet, Fiorinal, Tussionex, Oxycontin, Darvon, Ativan (lorazepam), and flurazepam. *Id.*

Dr. Parran further noted that Respondent had engaged in "an additional flurry of prescribing" during the period of March and April 2003. *Id.* Specifically, he noted that Respondent prescribed Oxycontin (40 mg.) on March 20th, Darvocet on April 1st, Vicodin on April 11th, multiple strengths of Oxycontin on April 14th, Vicodin and Oxycontin again on April 21st, and both flurazepam with two refills and a Duragesic (fentanyl) patch on April 28th. *Id.* Dr. Parran further found that "in a six month period [Respondent] prescribed 3700 tablets of opioids and additional benzodiazepines and barbiturates." *Id.* Dr. Parran concluded that "[t]his escalating prescribing of controlled drugs to a drug seeking patient who was clearly out of control with her use fails to meet usual standards of care, appears to be for other than [a] legitimate medical purpose and appears to have contributed to the patient's death."³ *Id.*

Dr. Parran also reviewed Respondent's prescribing with respect to a fourth patient, N.G. Between October 31, 2002, and April 10, 2003,

³ Following the death of S.B., Respondent's former employer reported Respondent to the Arizona Medical Board. The Board subsequently concluded that Respondent had committed unprofessional conduct under Ariz. Rev. Stat. § 32–1401(27)(q). The Board ordered that Respondent be issued a letter of reprimand for excessive prescribing and be placed on probation. The Board's decision focused entirely on Respondent's treatment of S.B. and did not discuss his prescribing practices with respect to any other patient. See *In re Randi M. Germaine, M.D.* (Ariz. Med. Bd. Aug. 12, 2005) (Case # MD–03–0897A).

Respondent prescribed for N.G., 1418 methadone (10 mg.) tablets, 605 oxycodone (5 mg.) tablets, and 120 hydrocodone (7.5/750 mg.) tablets.

According to Dr. Parran, this "patient demonstrated Dr. shopping behavior over a long period of time." Expert Report at 4. Moreover, based on a December 12, 2002 toxicology screening, another physician at the clinic had indicated that N.G. had violated her controlled-substance contract. *Id.* Respondent nonetheless continued to prescribe controlled substances to her. *Id.*

Dr. Parran further noted that N.G.'s chart indicated that she had engaged in several scams to obtain additional controlled substances including going to the emergency room, and claiming either that she had run out early or that her drugs had been stolen. *Id.* Moreover, notwithstanding that her chart included: (1) A pharmacy use printout showing that N.G. was engaged in the "tremendous over-use of controlled drugs," (2) "an extensive note" from another physician "indicating that she should get no more controlled drugs from the practice," and (3) a March 2003 note from another clinic (that N.G. had been referred to) which diagnosed her as a drug abuser and recommended that she be "wean[ed] off of narcotics," Respondent continued to prescribe controlled substances to her. *Id.* Indeed, three days after N.G. had again gone to the emergency room trying to get early medications, Respondent again prescribed controlled substances to her.⁴ *Id.* According to Dr. Parran, "[t]his continued prescribing of controlled drugs to a patient who was non-compliant with the treatment plan and clearly out of control with her use fails to meet usual standards of care and appears to be for other than [a] legitimate medical purpose." *Id.*

According to Dr. Parran, another of Respondent's patients (D.J.), had "demonstrated multiple behaviors that alerted the practice to her problems with controlled drugs including early calls, early visits, claiming [she was going] 'out of town' for early scripts" but "then keeping the original appointments." *Id.* at 7. Moreover, notwithstanding that: (1) D.J. had broken her controlled substance contract; (2) that another physician had recently indicated that D.J. should no longer be prescribed controlled substances; and (3) that Respondent had himself indicated that D.J.'s toxicology test results were abnormal, that she was engaged in doctor shopping, and that

⁴ Eventually another physician terminated N.G. from the clinic's practice.

² According to the investigative file, D.K.'s chart contained a notation indicating that only her OB/GYN, who was treating her for pain related to a minor surgical procedure, could prescribe controlled substances to her. D.K.'s OB/GYN further told investigators that there was no medical reason why D.K. should have been prescribed controlled substances after April 30, 2003.

controlled drugs should be discontinued; two months later, Respondent gave D.J. a prescription for Vicodin. *Id.* at 7–8. Respondent then proceeded to issue D.J. numerous other prescriptions including several early prescriptions and one based on her representation that she was going out of town. *Id.* at 8. According to Dr. Parran, Respondent’s “continued prescribing of controlled drugs to a patient who was non-compliant and clearly out of control with her use fails to meet usual standards of care and appears to be for other than [a] legitimate medical purpose.” *Id.*

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). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

- (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).

In this matter, I acknowledge that the Arizona Medical Board has not revoked Respondent’s state license. The Board’s inquiry was, however, limited to Respondent’s prescribing to a single patient. Therefore, I decline to defer to the Board’s decision and conclude that Respondent’s experience in dispensing

controlled substances and his record of non-compliance with Federal law and regulations demonstrate that his continued registration is “inconsistent with the public interest.” 21 U.S.C. 823(f).

Factors Two and Four—Respondent’s Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Laws Relating to Controlled Substances

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 his 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 (1975)).

As found above, Dr. Parran, an expert on the prescribing of controlled substances, reviewed the medical records of patients treated by Respondent including several who had overdosed on controlled substances. Dr. Parran specifically noted that Respondent prescribed controlled substances to patients notwithstanding that they were engaged in drug-seeking behaviors including doctor shopping and various scams used to obtain additional prescriptions.

Moreover, Dr. Parran found in multiple instances that Respondent’s prescriptions were not issued for a legitimate medical purpose. With respect to R.S., Dr. Parran found that Respondent’s “prescribing is difficult to imagine, * * * appears to be for other than [a] legitimate medical purpose, and appears to have played a direct role in the patient’s death.” Expert Report at 2.

In regards to D.K., Dr. Parran noted that she too was engaged in doctor shopping and other scams such as early refill attempts and medical complaints that were not confirmed by a physical exam. Moreover, her chart included a

notation that only her OB/GYN could prescribe controlled substances for her; her OB/GYN told investigators that after April 30, 2003, there was no medical reason why she should have been prescribed controlled substances. Nonetheless, on May 9 and 20, 2003, Respondent prescribed for D.K. drugs containing hydrocodone, and on May 27, 2003, Respondent prescribed Percocet (oxycodone). D.K. overdosed the next day. Based on his review, Dr. Parran concluded that Respondent’s prescribing of controlled substances for D.K. “appears to be for other than [a] legitimate medical purpose and appears to have contributed directly to [her] death.” *Id.* at 6.

S.B. was another patient of Respondent who died of an overdose. With respect to her, Dr. Parran found that notwithstanding that her chart included a warning note to “avoid all narcotics,” Respondent prescribed controlled drugs including various opiates including Vicodin, Darvocet, Tussionex, Oxycontin, and Darvon. In addition, Respondent prescribed other controlled substances including benzodiazepines and barbiturates. Dr. Parran further found that in a six month period, Respondent prescribed 3,700 tablets of opioids (as well as drugs in other categories of controlled substances). Dr. Parran concluded that “[t]his escalating prescribing of controlled drugs to a drug seeking patient who was clearly out of control with her use * * * appears to be for other than [a] legitimate medical purpose and appears to have contributed to the patient’s death.” *Id.* at 3.

In sum, Dr. Parran’s findings provide ample support for the conclusion that Respondent was not issuing prescriptions for “a legitimate medical purpose,” 21 CFR 1306.04(a), but rather, was “peddling to patients who crave the drugs for * * * prohibited uses.” *Gonzales v. Oregon*, 126 S.Ct. 904, 925 (2006) (citing *Moore*, 423 U.S. 122, 135 (1975)). Accordingly, I find that Respondent’s experience in dispensing controlled substances is characterized by repeated violations of the CSA. I therefore conclude that Respondent’s continued registration is “inconsistent with the public interest.” 21 U.S.C. 823(f). Moreover, I further find that the public safety requires that this Order be effective immediately. 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, BG3717278, issued to Randi M.

Germaine, M.D., be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of his registration be, and they hereby are, denied. This order is effective immediately.

Dated: August 30, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

Proposed Exemptions; D-11318, Barclays Global Investors, N.A., (BGI) and Its Investment Advisory Affiliates, Including Barclays Global Fund Advisors (BGFA; Together, the Applicants); and D-11420 BlackRock, Inc. (Black Rock) and Merrill Lynch & Co. (Merrill Lynch) (Collectively, the Applicants)

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** Notice. Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and requests for a hearing (at least three copies) should be sent to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, Room N-5700, U.S. Department of Labor, 200 Constitution

Avenue, NW., Washington, DC 20210. Attention: Application No. __, stated in each Notice of Proposed Exemption. Interested persons are also invited to submit comments and/or hearing requests to EBSA via e-mail or FAX. Any such comments or requests should be sent either by e-mail to: *moffitt.betty@dol.gov*, or by FAX to (202) 219-0204 by the end of the scheduled comment period. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N-1513, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Barclays Global Investors, N.A., (BGI) and Its Investment Advisory Affiliates, Including Barclays Global Fund Advisors (BGFA; Together, the Applicants), Located in San Francisco, California

[Application No. D-11318]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR 2570, subpart B (55 FR 32836, 32847, August 10, 1990).

Section I. Transactions Involving Open-End Management Investment Companies Other Than Exchange-Traded Funds

Effective as of September 10, 2007, the restrictions of sections 406(a) and (b) of the Act, section 8477(c)(1) and (c)(2) of FERSA, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code, shall not apply to the acquisition, sale or exchange by an Account of shares, including through in-kind redemptions of shares or acquisitions of shares in exchange for Account assets transferred in-kind from an Account, of an open-end investment company ("the Fund") registered under the Investment Company Act of 1940 (the 1940 Act), other than an exchange-traded fund (an "ETF"), the Investment Adviser for which is also a fiduciary with respect to the Account (or an affiliate of such fiduciary) (hereinafter, BGI and all its affiliates will be referred to as "Investment Adviser"), and the receipt of fees for acting as an investment adviser for such Funds, as well as fees for providing other services to the Funds which are "Secondary Services," as defined herein, in connection with the investment by the Accounts in shares of the Funds, provided that the conditions set forth in Section II are met.

Section II. Conditions

(a) The Account does not pay a sales commission or other similar fees to the Investment Adviser or its affiliates in connection with such acquisition, sale, or exchange.

(b) The Account does not pay a redemption or similar fee to the Investment Adviser in connection with the sale by the Account to the Fund of such shares, and the existence of any other redemption fee is disclosed in the Fund's prospectus in effect at all times.

(c) The Account does not pay an investment management, investment advisory or similar fee with respect to