applicable federal, state, and local government laws, regulations and policies that may affect the subject lands, including any required dedication of lands for public uses. It is also the buyer's responsibility to be aware of existing or prospective uses of nearby properties. When conveyed out of federal ownership, the lands will be subject to any applicable laws, regulations, and policies of the applicable local government for proposed future uses. It will be the responsibility of the purchaser to be aware through due diligence of those laws, regulations, and policies, and to seek any required local approvals for future uses. Buyers should also make themselves aware of any federal or state law or regulation that may impact the future use of the property. Any land lacking access from a public road or highway will be conveyed as such, and future access acquisition will be the responsibility of the buyer.

The proposed SNPLMA sale parcels were analyzed in the *Las Vegas Valley Disposal Boundary Environmental Impact Statement* (EIS), approved Dec. 23, 2004. Two parcels being offered in this sale were previously analyzed through EAs and approved for sale. Copies of the applicable EAs for N–81965 and N–81967 are available for review upon request at the LVFO. The remaining twelve parcels identified in this notice are analyzed in an EA for this sale which tiers to the EIS. On publication of this notice, this EA is available for public review and comment at the LVFO.

Only written comments submitted by postal service or overnight mail will be considered properly filed. Electronic mail, facsimile or telephone comments will not be considered as properly filed.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment—you should be aware that your entire comment, including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Any adverse comments regarding the proposed sale will be reviewed by the BLM Nevada State Director, who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, this realty action will become the final determination of the Department of the Interior.

Authority: 43 CFR 2711.

Dated: December 5, 2008.

Kimber Liebhauser,

Assistant Field Manager, Division of Lands.

[FR Doc. E8–30460 Filed 12–22–08; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on December 17, 2008, a proposed Consent Decree in *United States of America et al.* v. *Standard Metals Corporation,* Civil Action No. 08–CV–02741 was lodged with the United States District Court for the District of Colorado.

In this action the United States, on behalf of the Administrator of the United States Environmental Protection Agency, the Chief of the United States Department of Agriculture Forest Service, and the Secretary of the Interior, and the State of Colorado, on behalf of the Executive Director of the Colorado Department of Public Health and Environment, the Director of the Colorado Department of Natural Resources, and the Attorney General of the State of Colorado (together, the ''government''), sought to recover response costs incurred or to be incurred for response actions taken or to be taken at or in connection with the release or threatened release of hazardous substances at the Standard Mine Site in Gunnison County, Colorado, the Ross Adams Site on Prince of Wales Island, Alaska, six sites in San Juan County, Colorado, and the Antler Mine and Mill Site in Mohave County, Arizona (collectively, the ''Sites''), and to recover damages for injury to, destruction of, or loss of natural resources at the Sites and surrounding riparian corridors, including the reasonable costs of assessing such injury, destruction or loss, pursuant to Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA''), 42 U.S.C. 9607.

The Consent Decree resolves the government's CERCLA response cost claims at the Sites by requiring that Standard pursue insurance recovery and pay to the government 50% of the first $180,000 recovered and 90% of all recovery thereafter. The Consent Decree resolves the government's CERCLA natural resource damage claims at the Sites by requiring that Standard transfer to the United States approximately 800 acres of real property to which it holds title, at the government's option.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Decree. Comments should be addressed to the Assistant Attorney General, Environmental and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States, et al.* v. *Standard Metals Corporation,* Civil Action No. 08–CV–02741 (D.CO), D.J. Ref. 90–11–3–08831.

The Decree may be examined at U.S. EPA Region 8, 1595 Wynkoop Street, Denver, Colorado 80202. During the public comment period, the Decree, may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $23.25 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Robert Brook,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–30437 Filed 12–22–08; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 06–19 & 06–20]

Nirmal Saran, M.D.; Nisha Saran, D.O.; Affirmance of Suspension Orders

On September 19, 2005, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to both Nirmal Saran, M.D., and Nisha Saran, D.O. (Respondents), of Arlington, Texas. The Orders immediately suspended each Respondent's DEA Certificate of Registration as a practitioner, on the grounds that each had issued numerous controlled-substance prescriptions over

the internet without a legitimate medical purpose and had acted outside of the course of professional practice, because they did so without establishing a bona fide doctor-patient relationship with the persons they prescribed to, in violation of 21 CFR 1306.04(a). Nirmal Saran OTSC at 6; Nisha Saran OTSC at 6–7.

More specifically, the Show Cause Orders alleged that each Respondent had participated in a scheme run by Mr. Johar Saran, the owner of Carrington Healthcare System/Infiniti Services Group (CHS/ISG), and the son of Respondent Nirmal Saran and brother of Respondent Nisha Saran. *See* Nirmal Saran OTSC at 5; Nisha Saran OTSC at 5. The Orders alleged that as part of the scheme, CHS/ISG operated several pharmacies and created sham corporations in order to obtain the DEA registrations necessary for the pharmacies to order controlled substances, and that the drugs were eventually delivered to CHS/ISG, where its employees downloaded prescriptions from several internet sites, filled them, and shipped them to customers. *See* Nirmal Saran OTSC at 5; Nisha Saran OTSC at 5. The Orders further alleged that CHS/ISG was shipping 3,000 to 4,000 drug orders a day. *See* Nirmal Saran OTSC at 5; Nisha Saran OTSC at 5.

With respect to Nirmal Saran, the Show Cause Order alleged that his ''primary practice area is ophthalmology.'' Nirmal Saran OTSC at 6. The Show Cause Order further alleged that between May 1 and June 17, 2005, he had prescribed thirty-seven different controlled substances to persons in at least forty-four States, and that between May 18 and June 8, 2005, he issued 1,248 controlled substance (cs) prescriptions and had issued as many as 217 prescriptions in a day to persons in thirty-four States. *Id.* at 7. The Order further alleged that sixty-four percent of the prescriptions he issued through the scheme were for schedule III drugs containing hydrocodone. *Id.* at 6.

With respect to Nisha Saran, the Show Cause Order alleged that between May 27 and June 3, 2005, she had issued 303 cs prescriptions to persons in at least forty States, and that she had issued as many as 101 cs prescriptions to persons in twenty-six States in a single day. Nisha Saran OTSC at 6. Relatedly, the Show Cause Order alleged that fifty-nine percent of the prescriptions she wrote were for schedule III drugs containing hydrocodone. *Id.*

Both Show Cause Orders further alleged that each Respondent's cs prescriptions were not issued ''for a legitimate medical purpose in the usual course of professional practice,'' and violated 21 CFR 1306.04(a). *Id.* at 7; *see also* Nirmal Saran OTSC at 7. I further found that the allegations supported the conclusion that each Respondent's ''continued registration during the pendency of [the] proceedings would constitute an imminent danger to the public health and safety.'' Nisha Saran OTSC at 7; Nirmal Saran OTSC at 7.

On October 20, 2005, counsel for each Respondent requested a hearing on the allegations of the respective Show Cause Orders. ALJ Exs. 3 & 4. The matters were placed on the docket of Administrative Law Judge (ALJ) Gail Randall, who consolidated the cases and conducted pre-hearing procedures.

On March 28–30, 2006, a hearing was held in Forth Worth, Texas. During the hearing, both the Government and Respondents put on testimony and entered documentary evidence into the record. Following the hearing, the parties submitted briefs containing their proposed findings, conclusion of law, and argument.

On November 22, 2006, while the decision of the ALJ was still pending, the Government moved to terminate both proceedings on the ground that each Respondent's registration had expired on February 28, 2006, and neither Respondent had submitted a renewal application. ALJ Exs. 13a & 13b. Thereafter, Respondents' counsel filed oppositions to both termination motions. ALJ Exs. 14a & 14b.

In support of her opposition, Nisha Saran submitted an affidavit establishing that in February 2006, and before the expiration of her registration, she had attempted to renew her registration electronically at the Agency's Web site, but was unable to do so. ALJ Ex. 14A (attached as RX 1). In her affidavit, Nisha Saran further stated that ''I have at no time abandoned my desire to obtain DEA registration during the pendency of this case.'' *Id.*

In support of his opposition, Nirmal Saran submitted an affidavit in which he stated that in February 2006, and before the expiration of his registration, he had asked his daughter to renew his registration at the Agency's Web site, but she was unable to do so. ALJ Ex. 14B (attached as RX 1). In his affidavit, Nirmal Saran also stated that ''I have at no time abandoned my desire to obtain DEA Registration during the pendency of this case.'' *Id.*

Thereafter, the Government moved to withdraw both termination motions noting my then-recent decision in *William R. Lockridge,* 71 FR 77791 (2006), which held, in a case arising under similar circumstances, that the proceeding was not moot. In its withdrawal motions, the Government acknowledged that each Respondent had indicated that he/she ''intend[ed] to continue the practice of medicine and intend[ed] to obtain a DEA registration in order to do so.'' ALJ Exs. 15A at 3; 15B at 3. The Government also acknowledged the unequivocal statements of each Respondent that he/she had not abandoned his/her desire to obtain a DEA Registration. ALJ Exs. 15A at 3; 15B at 3.

The ALJ granted the Government's motion and further ordered that the parties brief various issues including whether ''the record as a whole establishes by a preponderance of the evidence that the DEA properly immediately suspended'' each Respondent's registration, because his/her ''handling of controlled substances creates an imminent danger to the public health or safety.'' ALJ Exs. 16A at 2–3; 16B at 2–3. The ALJ also ordered the parties to address what factual findings were relevant and what legal standard should be applied in determining the validity of the suspension order. ALJ Exs. 16A at 3; 16B at 3.

On March 7, 2007, after the parties submitted their briefs, the ALJ submitted a Query to the Deputy Administrator. ALJ Ex. 22. In the Query, the ALJ asked whether in light of the expiration of each Respondent's registration she should make findings of fact, whether she should simply forward the record to me for a final order, or whether the Government should forward the investigative file to me with the materials contained therein at the time the immediate suspension orders were issued. ALJ Ex. at 8.

On April 22, 2007, I answered the ALJ's Query. In my ruling, I noted that both the Government and the Respondents agreed that the case was not moot because even though the Respondents' registrations had expired, each Respondent maintained that they had not ''abandoned their desire to obtain DEA registrations during the pendency of this case.'' ALJ Ex. 23, at 2. I also explained that DEA's rules do not prohibit a former holder of a registration from reapplying immediately for a new registration and that ''neither Respondent ha[d] notified the Agency that [he/she] intended to permanently cease professional practice.'' *Id.*

In light of these circumstances, I ''conclude[d] that principles of judicial economy are best served by making findings of fact and conclusions of law based on the record established in this

proceeding rather than subjecting the parties to the potential re-litigation of the same issues in a future proceeding.'' *Id.* I further directed that ''[t]he ALJ's findings of fact and conclusion of law should be made based on the factors set forth in * * * 21 U.S.C. 824(a),'' as this section ''applies to all suspensions regardless of whether a suspension is imposed before, or after, a hearing.'' *Id.* I further noted that ''my additional findings that Respondents posed 'an imminent danger to public health or safety' [was] not reviewable in the proceeding before'' the ALJ. *Id.* at 2–3 (quoting 21 U.S.C. 824(d)).

Thereafter, the ALJ issued her recommended decisions in each case. With respect to Respondent Nirmal Saran, the ALJ concluded that between May 18 and June 8, 2005, he had issued over 1,000 prescriptions for controlled substances to treat pain, and that these ''prescriptions were issued outside the scope of professional practice, and were not issued for legitimate medical purposes'' in violation of DEA regulations. *In re Nirmal Saran,* ALJ Dec. at 32. In support of her conclusion, the ALJ noted that Respondent practices as an ophthalmologist, that he was licensed to practice medicine only in Texas and yet issued prescriptions to patients in other States, and that he failed to comply with basic standards of the medical profession for establishing a doctor-patient relationship. *Id.* at 31–32.

The ALJ also noted that Respondent had failed to properly safeguard his controlled substance prescribing authority because he ''allow[ed] his signature to be scanned into a computer database'' with the result that ''non-medical personnel were approving the dispensing of controlled substances in [his] name.'' *Id.* at 33. Finally, the ALJ noted that Respondent did not maintain patient records and that there was ''no indication that [he] interacted with the patient[s] to advise [them] concerning the risks involved in taking the controlled substances,'' or that he ''used any of the available control mechanisms to ensure these individuals were not abusing'' the drugs. *Id.* Finally, the ALJ noted that Respondent chose not to testify and thus offered no assurance that he would comply with Federal law and regulations in the future. *Id.* at 34. The ALJ thus concluded that Respondent's ''registration would be adverse to the public interest.'' *Id.*

With respect to Respondent Nisha Saran, the ALJ concluded that she too had issued cs prescriptions ''outside the scope of professional practice'' and without ''legitimate medical purposes.'' *In re Nisha Saran,* ALJ Dec. at 30. In support of her conclusion, the ALJ adopted the conclusion of the Government's expert that Respondent issued prescriptions in violation of DEA regulations based on his review of her ''prescriptions, log sheets, [her] type of practice, and the vast numbers of prescriptions that she wrote during a given period of time.'' *Id.* The ALJ also found that ''non-medical personnel were approving the dispensing of controlled substances in [her] name,'' and that ''Respondent provided these individuals with the ability to act in such a manner by allowing her signature to be scanned into a computer database.'' *Id.* at 30–31. The ALJ thus concluded that ''[s]uch a cavalier way of safeguarding her authority to prescribe controlled substances is certainly outside the public interest.'' *Id.* at 31.

The ALJ further observed that between May and June 2005, Respondent had issued ''approximately 220 controlled substance drug orders,'' but did not ''maintain adequate patient records.'' *Id.* at 31. More specifically, the ALJ observed that ''the record contains no charts documenting the Respondent's diagnosis for which the controlled substances were prescribed, no treatment plan, and no indication that the Respondent interacted with the patient to advise the patient concerning the risks involved in taking the controlled substances and the need for the patient to follow her directions concerning the appropriate quantities to take.'' *Id.* The ALJ also explained that there was also ''no evidence that * * * Respondent used any of the available control mechanisms to ensure these individuals were not abusing the'' drugs she prescribed. *Id.*

Finally, the ALJ noted that Respondent chose not to testify and thus had offered no assurance that she would comply with Federal law and regulations in the future. *Id.* at 32. The ALJ therefore concluded that Respondent's registration would be ''adverse to the public interest.'' *Id.*

Thereafter, Respondents' counsel filed exceptions to the ALJ's recommended decisions in each matter and the record was forwarded to me for final agency action. Having considered the entire record, as well as the exceptions filed in both matters, I hereby issue this Decision and these Final Orders. I adopt the ALJ's ultimate conclusion of law in each matter that the respective Respondent's registration would be inconsistent with the public interest. I make the following findings of fact.

Findings

Respondent Nisha Saran formerly held DEA Certificate of Registration, BS8415956, which authorized her to handle controlled substances as a practitioner in schedules II through V. GX 1 (Docket No. 06–19). Respondent's registration expired on February 28, 2006. *Id.* Respondent has not submitted an application to renew her registration.[1] I further find that Respondent is licensed to practice medicine only in the State of Texas. ALJ Ex. 5, at 2.

Respondent Nirmal Saran formerly held DEA Certificate of Registration, AS7091894, which authorized him to handle controlled substances as a practitioner in schedules II through V. GX 1 (Docket No. 06–20). Respondent's registration expired on February 28, 2006. *Id.* Respondent has not submitted an application to renew his registration. Respondent is licensed to practice medicine only in the State of Texas. ALJ Ex. 6, at 2. Respondent practices as an ophthalmologist. Tr. 216.

Mr. Johar (a.k.a. Joe) Saran is the son of Respondent Nirmal Saran and the brother of Respondent Nisha Saran. Tr. 210; *id.* at 116. Johar Saran owned Carrington Health Care System (which later changed its name to Infiniti Services Group), a corporate entity located in Arlington, Texas, which owned approximately eighteen to twenty pharmacies. *Id.* at 55, 60, 421. Carrington/Infiniti used the pharmacies to fill orders for controlled substances and non-controlled drugs on behalf of ''numerous web sites'' at which persons could order drugs, including Rx Great

[1] According to the Chief of the Registration and Program Support Section, on February 6, 2006, someone made several attempts to renew DEA Registration, BS8415956, through the Agency's Web page but was informed that ''[t]he DEA Registration number you provided is not eligible for online renewal. Please call the DEA Registration Call Center if you have any questions.'' ALJ Ex. 15A, Appendix I, at 4. The Chief of the Registration Unit further stated that on November 27, 2006, an additional attempt was made to renew the registration which resulted in the same message that online renewal was not available. *Id.* at 2.

The Chief of the Registration Unit also testified that on February 6 and November 27, 2006, attempts were made to renew Respondent Nirmal Saran's DEA Registration #AS7091894; each of these attempts resulted in the message that online renewal was not available. *Id.* at 1–2; *see also* ALJ Ex. 15B, Appendix I, at 1–2. According to the Chief of the Registration Unit, if the registrants had called the Registration Call Center, they would have been sent a renewal form and ''the notation 'Renewal Notice Sent' would have been documented in DEA records but, no such documentation was in the computer history for either DEA number.'' *Id.* at 2–3.

The Chief of the Registration Unit further explained that the Respondents were prevented from renewing their registration online because their registrations had been immediately suspended. *Id.* at 2. I find, however, that the Respondents could have obtained renewal applications from the Agency and submitted them via mail.

Prices and Nations Drug Supply.[2] *Id.* at 52.

Rx Great Prices was owned by Gil Lozano, *id.* at 617; Lozano also co-owned with his wife two limited liability corporations, Global One Marketing and First Management. *Id.* at 623. Lozano's niece, Tania Lozano, was the director of marketing for Global One and Rx Direct. *Id.* at 611. Rx Great Prices used Joe Saran's businesses exclusively to fill its orders. *Id.* at 624.

Nations Drug Supply (NDS) was a Web site owned and operated by Johar Saran and Infiniti. *Id.* at 418. The NDS Web site was developed by Concussion Interactive and became operational sometime in May 2005. *Id.* at 399–400. The Web site was managed by Tara Jones.[3] *Id.* at 531 & 535.

The Investigation

In June 2004, a DEA Diversion Investigator (DI) with the Fort Worth, Texas Resident Office, initiated an investigation of Carrington/Infiniti's activities. *Id.* at 58–60. As part of the investigation, DEA Investigators conducted trash runs at Infiniti's headquarters during which they found numerous documents including prescription labels for controlled substances dispensed by the Triphasic Pharmacy, a pharmacy owned by Johar Saran, to out of state persons, which listed Nirmal Saran as the prescribing physician. *Id.* at 75; GX 104 at 2 (Plea Agreement of Johar Saran); *see* GXs 2, 3, 4, 5, 6, 7, 8, 9, & 10 (No. 06–20). During some of the trash runs, the DIs also recovered several daily reports which listed hundreds of prescriptions for schedule III controlled substances containing hydrocodone which were dispensed by Triphasic; the reports listed Nirmal Saran as the prescriber. *See* GX 5, at 28–41 (No. 06–20), GX 11, at 1–161 (No. 06–20).[4]

Thereafter, DEA investigators obtained a court order under 18 U.S.C. 2516, which authorized them to intercept electronic communications from Infiniti's Internet protocol (IP) address between April 26 and June 23, 2005.[5] Tr. 30–32. According to the DI who served as a minimizer of the intercept, Nisha and Nirmal Saran's names appeared as approvers of prescriptions in database files that were downloaded by persons at Infiniti from the Nations Drug Supply Web site. *Id.* at 35–36. Moreover, their names also appeared in various e-mails that were intercepted.[6] *Id.* at 35.

After intercepting the database files, the DI used Microsoft Excel to extract the data and put it into spreadsheet form. *Id.* at 37. The Government introduced into evidence spreadsheets listing the prescriptions which were dispensed by pharmacies that were controlled by Joe Saran and Infiniti between May 27 and June 17, 2005. *See* GXs 4–58 (06–19).[7] The spreadsheets list numerous controlled substance prescriptions that were issued by each Respondent for persons located throughout the country.[8] *See generally id.* Among the drugs prescribed by each Respondent were such highly abused controlled substances as schedule III combination drugs containing hydrocodone, and schedule IV benzodiazepines such as diazepam and lorazepam.[9]

As part of the investigation, a DI went to the Nations Drug Supply Web site and made two undercover buys. On June 2, 2005, the DI, using the name Dwight E. Anderson and an address in Forth Worth, Texas, ordered ninety tablets of hydrocodone/acetaminophen 10/650 mg., for a price of $ 373.50 plus shipping. GX 89 (06–20). While visiting the Web site, the DI was able to select the drug he wanted and place it in his

[2] On September 20, 2005, a federal grand jury indicted Joe Saran, Gil Lozano, Fred Word, as well as the various coporations controlled by Saran including Carrington, Infiniti, and the pharmacies, on numerous counts including violations of the Controlled Substances Act. GX 85 (06–20). On November 14, 2006, Joe Saran entered into a plea agreement with the United States Attorney for the North District of Texas in which he pled guilty to, *inter alia,* conspiring to distribute controlled substances, in violation of 21 U.S.C. 846, 841(a)(1) & 841(b)(1)(D). GX 104 (06–20) at 1–2.

[3] The record also establishes that Colin McConnell was an employee of Concussion Interactive, Tr. 112, and Fred Word was Infiniti's Chief Financial Officer. *Id.* at 114.

[4] In his exceptions, Respondent notes that while the daily reports list him as the prescriber, it also listed ''an incorrect DEA number.'' Nirmal Saran Exceptions at 12. Respondent thus contends that this ''implies that someone attempted to use Respondent's name in association with the incorrect DEA number.'' *Id.* at 12–13.

It is acknowledged that the daily reports do not contain Respondent's correct DEA number. As found below, however, Respondent admitted to investigators that he prescribed over the Internet. Moreover, Respondent did not testify at the hearing and thus did not deny that he issued the prescriptions dispensed by Triphasic. I therefore reject the exception and find that he did issue the prescriptions.

Respondent further contends that because the ''labels were all found in the trash * * * they were, in fact, *trash,*'' and thus the probative value of this evidence is limited to showing that the Government found his name on pieces of paper ''during a time period unconnected to the'' allegations of the Show Cause Order. *Id.* at 11–12. According to Respondent's argument, the labels are not evidence of prescriptions at all. I conclude, however, that a pharmacy's employees would not prepare hundreds, if not thousands, of prescription labels which included the patient's name and address, dispensing instructions, and various warnings, unless they were to be used to dispense the prescriptions. I therefore reject Respondent's contention.

Respondent also objects to the admission of numerous exhibits on the ground that they pre-date the events which form the basis of the Show Cause Order. At the hearing, however, Respondent did not object to the admission of any of these exhibits on the ground that they were irrelevant because they involved prescribings which pre-dated the period alleged in the Show Cause Order. *See* Tr. 66 (GX 2), 69 (GX 3), 73 (GX 4), 133 (GX 6), 75 (GX 7), 137 (GX 9), 139 (GX 10), 141 (GX 11) (All exhibit numbers are from Case No. 06–20). Respondent objected only to portions of GXs 5 and 8, and did so on the limited basis that they contained a few prescriptions written by other doctors. *See* Tr. 130–32 (discussing GX 5); *id.* at 135–36 (discussing GX 8). The prescriptions issued by other doctors were removed from the exhibits and the exhibits were entered into the record. *See id.* at 132–33, 136. I therefore conclude that Respondent has waived his objection to the admission of these exhibits.

[5] According to a DI, the court also authorized the interception of Infiniti's e-mail for an additional thirty days. Tr. 31.

[6] These include an April 6, 2005 e-mail from Tara Jones, an employee of Joe Saran and Infiniti, to Colin McConnell, an employee of Concussion Interactive, the developer of the Nations' Web site. GX 75 (06–19). In this e-mail, Ms. Jones provided Nisha and Nirmal Saran's addresses, phone numbers, and medical license numbers. *Id.* In concluding the e-mail, Ms. Jones apologized for taking ''so long,'' and added that ''Nisha was in LA and just got back today. She said you were both playing phone tag, so if you still need to talk to her * * * try her cell number now.'' *Id.*

The record also contains an e-mail (dated 5/27/2005) from another employee of Concussion Interactive to Ms. Jones forwarding a username and password so that Nisha Saran could ''login to the shopping cart admin.'' GX 79 (06–19).

[7] The exhibits are numbered as GXs 14–68 in No. 06–20.

[8] According to my review of the record, between May 19, 2005 and June 8, 2005, Respondent Nirmal Saran issued the following amounts of controlled substance prescriptions to persons in these States: Eighty-six to persons in Florida, eighty-seven to persons in California, sixty-four to persons in Tennessee, thirty-two to persons in Ohio, and twenty-nine to persons in North Carolina. Moreover, between May 27, 2005 and June 3, 2005, Nisha Saran issued controlled substance prescriptions in the following amounts to persons in these States: Seventeen to persons in Florida, eleven to persons in California, ten to persons in North Carolina and four to persons in Ohio.

[9] Respondent Nisha Saran contends that ''her name was used without her permission or knowledge by NDS employees, most likely Tara Jones.'' Nisha Saran Exceptions at 11; *see also id.* at 12 (noting that as systems administrator, Jones could log in '' 'as one of the doctors' and insert a doctor's signature and it would appear that a doctor had approved the prescription'') (quoting Tr. 420, testimony of J.B.).

While one of Respondent's witnesses testified that Tara Jones had approved an order using Ms. Saran's signature, Tr. 547, this witness subsequently testified that she had observed this ''only the one time,'' *id.* at 585, which occurred toward the ''end of August, beginning of September 2005.'' *Id.* at 568. The spreadsheets containing the intercepted prescriptions show, however, that Respondent issued numerous prescriptions months earlier. Moreover, even if Respondent's name was used on some prescriptions without her permission, I note that Respondent did not testify and thus did not deny that she issued the prescriptions. Nor did she explain why her signature was found in a hard drive of a computer at Infiniti, her brother's business. Tr. 183–84. Moreover, as explained above, other evidence links Respondent to the Nations' and Rx Great Prices' schemes.

shopping cart.[10] Tr. 152. While the Web site used a program that required that a customer provide information to establish his identity, the DI testified that by contacting the site's customer service department he was able to obtain a ''skip code'' which allowed him to bypass this process. *Id.* at 155.

The DI was then required to complete a patient questionnaire. *Id.* at 155–56. The questionnaire asked him about his height, weight, allergies, past medications including whether he had previously taken the requested medication, and why he was seeking the medication. *Id.* at 155–56. With respect to the latter question, the DI ''simply put '[m]y leg hurts.'' ' *Id.* at 157.

After indicating that he would pay for the drugs by cash on delivery, *id.*, the Web site displayed an order confirmation page. *Id.* at 158; GX 89 (No. 06–20). This page indicated that the DI's order number was 817, that the order was placed on ''2005–06–02'' at ''15:15:56,'' that it was sold to and would be shipped to ''Dwight E. Anderson'' with an address of 819 Taylor St. in Forth Worth, that it was for 90 tablets of hydrocodone 10/650 mg., and that the drugs cost $ 373.50, plus $ 22.00 for overnight shipping for a total cost of $ 395.50. GX 89.

The following day, the DI received a prescription vial containing tablets. The label on the vial indicated that the prescription had been filled by ''Reliance Pharmacuetical [sic], Inc.,'' with an address of 2805 W. Arlansas Lane, Suite 303, Arlington, Texas. GX 91 (No. 06–20). The label provided instructions for taking the drug, indicated that the vial contained 90 tablets of ''Hydrocodone (Lorcet)—10/650,'' and that the prescribing doctor was ''Nirmal Saran''; the label also included the name ''Dwight E. Anderson,'' the prescription number of ''817:10294,'' and the order number of ''817.'' *Id.*

Notably, the information on the order confirmation page and the vial label matched the information for order 817 contained in the spreadsheets that were compiled from the internet files that were intercepted by the Government. See GX 43 (06–20) at 8–14 (line 21).[11] Moreover, at no time did the DI speak with Nirmal Saran or any other physician regarding why he was ordering the drugs. Tr. 182.

The following day, the DI revisited the Nations Drug Supply Web site and ordered sixty tablets of alprazolam 2 mg., a schedule IV benzodiazepine. GX 92 (No. 06–20); Tr. 169. In completing the questionnaire necessary to order the drug, the DI indicated that the reason he needed the drug was because he was ''stressed out from work.'' Tr. 172. The DI also indicated that he was not taking any other drugs although he had already obtained the hydrocodone that he purchased the day before. *Id.* This time, however, the Web page indicated that the DI would have to fill out a patient history form which was to be completed by his doctor and faxed in. *Id.* at 173. The DI testified, however, that he never sent in the form and yet still was able to order and obtain the drugs. *Id.* at 173–74, 176, 178–80; *see also* GX 92 (No. 06–20). The label on the drug vial was missing the name of the prescribing doctor. GX 94 (No. 06–20).

The Government also elicited the testimony of J.P., a Florida resident, regarding his obtaining of controlled substances through the Nations Drug Supply Web site. According to his testimony and the intercepted prescription data, on at least three separate occasions, J.P. purchased controlled substances through Nations. More specifically, on May 30, 2005, J.P. purchased ninety tablets of Norco 10 mg., a schedule III drug containing hydrocodone based on a prescription issued by Respondent Nisha Saran. Tr. 18–19; GX 9 (06–19) at 1–7 (line 10). On June 2, 2005, J.P. purchased another ninety tablets of Norco 10 mg., as well as ninety tablets of Adipex-P 37.5 mg. (phentermine), a schedule IV stimulant; both prescriptions were authorized by Nirmal Saran. GX 30 (06–19) at 17–24 (lines 37 & 38). Finally, on June 6, 2005, J.P. purchased two orders of ninety tablets of Norco 10 mg., as well as two orders of ninety tablets of Valium (10 mg); each of the four prescriptions were approved by Nirmal Saran. GX 51 (06–19) at 17–24 (lines 35, 37, 40, & 42).[12]

J.P. testified that he was not required to send his medical records to Nations to purchase the controlled substances, that he did not speak with anyone to obtain the drugs, and that he did not know either Respondent. Tr. 18. J.P. further testified that at the time he purchased the drugs, he was not under the care of a physician, id. at 17, and that he ''became physically dependent'' on them. *Id.* at 22.

On September 21, 2005, law enforcement authorities executed a federal search warrant at the residence

[10] At the hearing, the Government introduced into evidence a DVD which showed the various Web pages that the DI visited in ordering the drugs; the DVD was made using a software program which records as a video ''anything that happens on the computer screen.'' Tr. 145–46.

[11] In his exceptions, Respondent argues that ''the name of Dwight E. Anderson * * * *does not appear on the Government's spreadsheet evidence*, rather, order number 817 is shown as having been filled for a 'Robin Daub,' *and not* 'Dwight E. Anderson.' '' Nirmal Saran Exceptions at 26 (citing GX 87, at 178–80). Relatedly, Respondent argues that ''*No order no. 953 is reflected on the Government's spreadsheet of 'Nirmal Saran's Original Rx's.*' '' *Id.* at 27. Respondent further argues that ''[i]f the information on the spreadsheets was in fact downloaded from the servers and put into an Excel file as testified to by Government's agents, *and not manipulated as they testified*, there should be no discrepancies in the tables/spreadsheets showing different information on them and definitely should show the undercover buys.'' *Id.* Based on the testimony of one of his witnesses, Respondent further asserts that ''the IP addresses reflected on the Government's exhibit would not instruct a computer to transfer any data, and that [GX 90] does not reflect the transmission of an actual customer's order.'' *Id.* (citing Tr. 426 & 429). Respondent contends that ''[t]his information * * * suggests that these purchases were fabricated.'' *Id.*

Respondent misrepresents what exhibit (GX 90) represents. As the DI testified, GX 90 does not represent the time that the DI purchased the drug, but rather, the time ''that that file was transferred that contained the information of the undercover buy'' to Infiniti. Tr. 164. Consistent with the DI's testimony, the order confirmation that he printed from the Nations Drug Supply Web site indicates that the order was place at 15:15:56 (or 3:15:56 p.m.), *see* GX 89; by contrast, GX 90 indicated that the file was transferred to Infiniti at 10:37:52 p.m, Greenwich Mean Time, or 4:37 p.m. Fort Worth Time. See GX 90; Tr. 164.

To be sure, GX 87, which lists Nirmal Saran's prescriptions, indicates that order number 817 was placed by R.D. and not Dwight E. Anderson. GX 87, at 178. However, the original spreadsheet listing order number 817, and which was created following the intercept, clearly shows that the DI ordered hydrocodone as he testified to, and that the prescription was authorized by Nirmal Saran. *See* GX 43 (06–20) at 8–14 (line 21). While the person who created GX 87 testified that she had copied information from the original spreadsheet files to this file, Tr. 333, there appear to be other errors in this document as well. For example, the evidence shows that the hydrocodone prescription given order number 817 cost $373.50, yet GX 87 indicates that the drugs were paid for with a COD in the amount of $87. GX 87, at 180. Moreover, Dwight Anderson is nonetheless listed as having purchased another drug which Nirmal Saran prescribed, Zydone, a branded drug which also contains hydrocodone, for a total COD amount of $395.50, even though the product price is listed at $74.70; the entries for this prescription also indicate that the purchase was prepaid while simultaneously indicating a COD amount. *See* GX 87 at 106–08 (line entry 598). Given these errors, and the derivative nature of the exhibit, I do not rely on it.

Based on the great weight of the evidence, which includes the DI's testimony, the DVD showing the DI's visit to the Web site, the order confirmation, the evidence showing that the drugs were delivered, and the original spreadsheet of the intercepted prescriptions, I reject Respondent's contention that the purchase was fabricated. I further conclude that it is more likely than not that the purchase occurred and that Nirmal Saran authorized the prescribing. As for Respondent's contention regarding order no. 953, no doctor was listed as the prescriber on either the drug vial's label, GX 94 (06–20), or on the spreadsheet. GX 54 (06–20) at 8–10 (line 21). It is therefore no surprise that the order is not listed on GX 87.

[12] I have considered and reject the suggestion that these were duplicate prescriptions. Cf. Nirmal Saran's Exceptions at 23. Notably, the two Norco prescriptions had different order numbers (as did the two Valium prescriptions). See GX 51 (06–19) at 17. Moreover, the evidence shows that two different pharmacies, with different addresses, filled the prescriptions. *Id.* at 19.

of Joe Saran. *Id.* at 208. While the search was proceeding, Nirmal Saran arrived at his son's residence, identified himself to a DI as Joe Saran's father, and said that he wanted to talk to the investigators about what they were doing. *Id.* at 209–10. The DI contacted another DI, who advised him that he needed to serve Nirmal Saran with the Suspension Order and that he was willing to talk to Dr. Saran. *Id.* at 212.

Following his arrival at the residence, the other DI served Nirmal Saran with the Order and after explaining why the Agency had issued the Order, proceeded to interview him. *Id.* at 215. During the interview, ''Dr. Saran admitted to prescribing controlled substances via the [i]nternet for his son's company, Nations Drug Supply.'' *Id.* at 216. Dr. Saran explained ''that Nations Drug Supply had a Web site, and that the Web site list[ed] all the names and the information as to why the person needed the drug, the person's allergies, blood pressure, and weight.'' *Id.* at 216–17. Dr. Saran also stated ''that he would read the questionnaire and he would prescribe that way.'' *Id.* at 217. Dr. Saran further stated that back in May or June 2005, his son and another employee of Nations had approached him, and that his son had given him a password which allowed him to access the Web site. *Id.* Dr. Saran also told the DIs that his internet prescribing mostly involved painkillers. *Id.* at 218.

Dr. Saran further admitted that he did not know any of the persons he prescribed to, and that during the entire period in which he prescribed over the internet, he telephoned ''approximately 12 to 15 patients.'' *Id.* at 219. Dr. Saran also said that in reviewing the questionnaires, ''he took the person's word for it,'' id., and that the ''questionnaire with all the information for the patient was good enough for him.'' *Id.* at 217.

Dr. Saran admitted, however, that in his practice as an ophthalmologist, ''he would initially examine the patient, take their blood pressure and weight, review their history, and then prescribe the medication, which [was] totally opposite of'' how he prescribed online. *Id.* at 219. He also told the DIs that he did not ''keep any records of whatever he prescribed.'' *Id.* at 220. Finally, he acknowledged that he was licensed only in Texas, but ''but felt that [because] the prescriptions were issued in Texas, it was okay for him to prescribe'' to persons residing in other States. *Id.* at 221.

Respondents' Relationship With Rx Great Prices

During the investigation of Infiniti, DEA Investigators also intercepted several e-mails which link both Respondents to Rx Great Prices, the Web site owned and operated by Gil Lozano and the corporations he controlled. *Id.* at 613. Moreover, on the same day that the search warrant was executed at Joe Saran's residence, other investigators executed a search warrant at Lozano's residence in Florida.[13] *Id.* at 604–05.

During the search of Lozano's residence, the investigators seized two documents entitled ''EMPLOYMENT AGREEMENT.'' *See* GX 101 (06–19), GX 101 (06–20). While the header on both documents stated ''Attorney-Client Draft Document'' and ''Discussion: Not for Execution,'' each document also stated that ''THIS EMPLOYMENT AGREEMENT * * * is made and entered into this 20[th] day of January 2005, by and between [each Respondent] [14] a physician ('Employee') and First Management, LLC, a Florida Limited Liability Company ('Employer').'' *See* GX 101 (06–19) at 1; GX 101 (06–20) at 1. Each agreement gave an effective date (March 1, 2005 on Nisha Saran's agreement; February 1, 2005 on Nirmal Saran's agreement), indicated that each Respondent's ''Bonus and Additional Compensation'' was ''To Be Negotiated,'' and was signed by the respective Respondent.[15] *See id.* (06–19) at 1, 8, & *id.* (06–20) at 1, 8 & 12.

Each agreement stated that ''Employer operated an on-line, Internet pharmacy business,'' that the ''Employer hereby employs Employee, and Employee accepts such employment, as a physician to render professional medical services [on] behalf of Employer,'' and that the ''Employee shall be required to check and receive patient files for review via the Internet or facsimile multiple times per days at least (5) days per week, and spend at least two—three hours per day reviewing patient files and/or supervising nurse practitioners.'' *Id.* (06–19) at 1 & *id.* (06–2) at 1 & 6. Moreover, the agreements stated that the ''Employee shall have * * * authority, in their [sic] sole discretion to reject the patient's file for any request for a prescription or to request further medical information or history of the patient prior to making any final decision as to the issuing of any prescription to a patient.'' *Id.* (06–19) at 6; *id.* (06–20) at 6.

The record contains several e-mails which further support the conclusion that both Respondents entered into a contractual arrangement with Gil Lozano and his corporation to prescribe over the Internet. For example, on March 21, 2005, Joe Saran sent an e-mail to Gil Lozano with the subject line ''Malpractice Information''; the e-mail also indicated that the matter was of ''High'' importance. GX 77 (06–19). In the e-mail, Joe Saran wrote: ''I do hope that we can get this resolved quickly as both my father and sister are quite anxious to get started with you.'' *Id.* Continuing, Joe Saran explained that ''the insurance companies have a few questions. If you can please answer these, then I believe that the underwriters will approve and this will get done quickly.'' *Id.* Saran then listed five things that were needed, including ''the projected number of prescriptions on a daily basis,'' ''a copy of the medical questionnaire from your Web site,'' and ''guidelines as to the range of pharmaceuticals being prescribed.'' *Id.*

The record also includes a series of e-mails which discuss the payment of malpractice insurance premiums for Nisha Saran. *See* GX 99 (06–19). On July 6, 2005, Tania Lozano sent an e-mail to Gil Lozano with the subject line of ''Nisha info.'' *Id.* at 1. This e-mail related that Nisha Saran had paid $19,830 for a year of malpractice insurance, and that the policy was ''[v]alid until December 12, 2005.'' *Id.* Ms. Lozano further stated that Nisha Saran ''said if you want to cover just for the months that she has been working

[13] In their exceptions, both Respondents moved to strike the testimony of the DI and seek to exclude the documentary evidence which includes the employment agreements and e-mails linking them to Gil Lozano and his corporation, First Management, L.L.C. *See* Nisha Saran Exceptions at 15, Nirmal Saran Exceptions at 15. At the hearing, however, Respondents did not object to the admission of the employment agreements, *see* Tr. 607–8, or the e-mails which link them to Lozano. *Id.* at 614. Respondents have therefore waived any argument that the employment agreement and e-mails were improperly admitted into evidence.

The DI also testified regarding an interview he conducted of Tania Lozano. Respondents objected to a single question on the ground that the DI's testimony was hearsay; the ALJ overruled the objection. *Id.* Moreover, the Supreme Court has held that hearsay evidence can still constitute substantial evidence under the Administrative Procedure Act. *See Richardson* v. *Perales*, 402 U.S. 389 (1971). Notably, Respondents did not seek to subpoena Ms. Lozano. *See* 21 CFR 1316.52(d). I therefore deny Respondents' motions to strike the DI's testimony.

[14] To clarify, on GX 101 (No. 06–19), ''Nisha M. Saran, D.O.'' was listed as ''a physician ('Employee'),'' and party to the agreement; on GX 101 (No. 06–20), ''Nirmal Saran, M.D'' was listed as ''a physician ('Employee')'' and party.

[15] It is acknowledged that neither agreement was signed by someone on behalf of First Management. *See* GX 101 (No. 06–19) at 12; GX 101 (06–20) at 12. Notwithstanding this, for the reasons explained in the text, I conclude that each Respondent entered into a contractual arrangement with First Management to issue Internet prescriptions.

for Rxgreatprice, that would be fine.'' *Id.* The e-mail also stated: ''First order approved on 5/31/2005 at 11:48 p.m.'' *Id.*

On July 7, 2005, Tania Lozano e-mailed Nisha Saran and asked her: ''Can you please provide me the address of your bank, as well as your dad's office address so that Gil can process the funds for you[?]'' *Id.* at 2. Continuing, the e-mail stated: ''We will pay 50% of $ 19,830 for the professional liability insurance on a monthly basis for the amount of $ 826.25 per month. I will get you a precise day of deposit as well once I get the above info from you.'' *Id.* at 2.

The record also contains a July 18, 2005 (10:13 a.m.) e-mail from Tania Lozano to Gil Lozano and another individual at Global One Marketing, which appears to forward the text of another e-mail sent by Nisha Saran to Tania Lozano. *Id.* The e-mail began: ''Tania * * *. Here is the information that you requested[,]'' and gives routing and account information for Nirmal Saran's bank.[16] *Id.* Continuing, the e-mail stated: ''My dad's office address is as follows, but please send any and all correspondence to his home address[,]'' and appeared to list his office and home addresses. *Id.* Next, the e-mail stated: ''Thanks for the info this morning, as well!'' *Id.* The e-mail ended by stating: ''Talk to you soon,'' and is signed ''Nisha Saran.'' *Id.*

Later that day, Tania Lozano sent another e-mail to Gil Lozano, the subject being ''Question from Nisha.'' The text reads:

> Nisha called me to verify that you were covering 100% of the malpractice insurance from the months of June 05—Dec 05. If so, the total due to her from June is 1652.50, not 826.25 as stated in the last invoice. Can we send her another transfer for just 826.25 to cover the month of June, then on the following invoice, she will include 1652.50 to cover the month of July. From there on out, she will get paid once a month for the insurance on the 30th of each month. Please let me know if this is okay or if you want to handle this another way. Thanks!

Id. at 3.

A DI subsequently interviewed Tania Lozano. Tr. 615. Among other things, Ms. Lozano told the DI that in July 2005, Gil Lozano had told her ''to stop using the other doctors and [to] direct all of the requested drug orders through Nisha and Nirmal Saran,'' because he ''was paying the other doctors $25 through a management company, and it was only costing $12 a prescription through Nirmal and Nisha.'' *Id.* Ms. Lozano also told the DI that she talked to Nisha Saran ''frequently, normally two, three or four times a day, at least ten times per week, and that they developed a close business relationship over the July, August and September months that they worked together.'' *Id.* at 616.

The DI further testified that Tania Lozano told him that she would call Nisha Saran on her cell phone and tell her: ''We're having problems getting these orders approved.'' *Id.* Nisha Saran ''would tell'' Tania: ''You're going to have to wait until I get off work; I'm working at the hospital. My father approves the orders in the morning; I approve in the afternoon.'' *Id.* Ms. Lozano further told the DI that she had discussed with Nisha Saran ''problems with the pull-down menus that had instructions'' for taking a drug, and that ''Nisha was very particular about what instructions were placed on her drug orders.'' *Id.*[17]

The Expert Testimony

George J. Van Komen, M.D., testified on behalf of the Government as an expert on the standards of medical practice and the use of the Internet to prescribe controlled substances. At the time of the hearing, Dr. Van Komen, who is board certified in internal medicine and a Fellow of the American College of Physicians, had served as an Assistant Professor of Clinical Medicine at the University of Utah School of Medicine for fifteen years and had practiced medicine for more than thirty years. Tr. 234; GX 71 (06–20) at 1. From 1995 to 2002, he served on the Board of Directors of the Federation of State Medical Boards (FSMB), and was the Federation's President in 2001 to 2002. GX 71 (06–20) at 3. Dr. Van Komen also was a member of the State of Utah's Physicians Licensing Board from 1989 to 1999, and served as the Board's Chairman from 1991 to 1999. *Id.* Dr. Van Komen testified that he had a particular interest in prescription drug abuse and the proper use of controlled substances in medical practice. Tr. 234, 236–37.

In his testimony, Dr. Van Komen acknowledged that the American Medical Association (AMA) is ''not a government organization'' and therefore does not ''have any authoritative capabilities.'' *Id.* at 238. Dr. Van Komen explained, however, that the AMA's policies and recommendations are ''well received by government organizations'' and ''by state legislatures.'' *Id.* Relatedly, Dr. Van Komen testified that ''[t]he Federation of State Medical Boards has no authority'' over the practice of medicine, but that its membership is comprised of members of state medical boards and that it does provide guidance and policy statements to assist the nation's state boards on various issues. *Id.* at 251.[18]

Dr. Van Komen further testified, however, that there is a standard of care for prescribing controlled substances that is ''well accepted and recognized throughout the medical community.'' *Id.* at 268. As Dr. Van Komen testified:

> [T]he standard of care is that * * * on any new patient who comes with a problem that may require a controlled substance, that the physician has personal contact with the patient, that a careful, detailed history is undertaken, that that careful, detailed history is utilized in doing a careful physical examination, and then a carefully outlaid differential diagnosis or etiology of the patient's symptoms is derived, and then from that, after appropriate testing and evaluation when further laboratory tests are in, then the physician may choose to utilize controlled substances in the treatment of the patient's ailment and disease.

Id. at 268–69.

After explaining what telemedicine is, Dr. Van Komen was asked what is the standard for ''forming a legitimate doctor-patient relationship?'' *Id.* at 271. Dr. Van Komen answered:

> [W]e feel that there needs to be documented a face-to-face history and physical and evaluation of the patient, and then if this patient chooses to receive further consultative work or be established with a physician who practices on the Internet, that the physician first of all and most formally needs to be identified, and he needs to have a license in the state in which the patient resides. * * *
>
> And we also feel that that primary care doctor who did the history and physical needs to stay in touch with the patient, even

[16] The e-mail also includes a redacted portion above Nirmal Saran's account information. GX 99, at 2.

[17] The DI also testified that he had obtained Ms. Lozano's cell phone records ''for the months that she was involved with Rx Great Prices,'' and that both Nisha and Nirmal Saran's phone numbers were contained in them. Tr. 617.

The DI further testified that he had interviewed a third doctor, who had attended a meeting with Nirmal, Nisha, and Joe Saran, at which Joe Saran attempted to recruit him to approve orders for his Web site. Tr. 618. The third doctor related that in a later discussion, Joe Saran again attempted to recruit him and told him that he was paying Nisha and Nirmal $12,000 each per month. *Id.* at 618–19.

Relatedly, the record contains an exchange of e-mails on August 16, 2005, between Gil Lozano and Joe Saran in which the former sought the latter's help in recruiting ''one or two more medical doctors for our sites.'' GX 78 (06–19) at 2. Later that day, Joe Saran wrote to Lozano: ''I do know another doctor who may be interested. I will talk to him and see what his response may be. Is the payment rate the same as for my dad and sister? This will be a question that I will need to answer for him.'' *Id.* at 1.

[18] In light of Dr. Van Komen's testimony that neither the AMA nor the FSMB have authority to promulgate binding standards of medical practice, I conclude that it is unnecessary to discuss the contents of the various policy statements that these organizations have issued.

though the patient might be seeking further consultation from another physician through the Internet.

Id. at 271. Dr. Van Komen's subsequent testimony suggested, however, that he was discussing the standard of care as set forth in policy statements of the AMA and FSMB. *See id.* at 272 (testifying that the policy statement of the FSMB and AMA ''absolutely'' outline the standard of care for Internet prescribing).

After he explained that medical doctors and osteopathic physicians are subject to the same standard of care,[19] *id.* at 275, Dr. Van Komen was asked whether he had ''formed an opinion on whether the prescriptions issued by Dr. Nisha Saran and Dr. Nirmal Saran were issued outside the usual course of professional practice?'' *Id.* at 276. Dr. Van Komen answered that ''[f]rom the records that I have seen, there gives me no reason to believe that they meet even closely the standard of care that would be an acceptable practice of medicine.'' *Id.* Dr. Van Komen explained that his opinions were based on the ''prescriptions that were written by them, as well as log sheets, outlining the type of practice that they have, the number of prescriptions that they wrote during a particular * * * period of time, and all of those records lead me to believe that they are far out from the accepted standard of care.'' *Id.*

Subsequently, Dr. Van Komen added:

> [T]here is no documentation of any doctor-patient contact. There is no indication of any record being kept. There is no formulation of a working diagnosis for which the medications were prescribed, and there is no indication that the patient understood the potential of addiction or danger of the drugs that were prescribed.

Id. at 277.

Next, with respect to Nirmal Saran, Dr. Van Komen testified that while an ophthalmologist ''may prescribe * * * an occasional pain medication * * * it's been my understanding that ophthalmologists rarely prescribe opioid medication, even after some eye surgery that they perform.'' *Id.* at 277–78. Finally, Dr. Van Komen stated that he was ''100 percent sure'' that the prescriptions that he reviewed were not issued for legitimate medical purposes, and that he was also ''100 percent'' certain that the prescriptions were issued outside of the usual course of professional practice because ''[t]here [was] no indication * * * from the records[20] that I reviewed that there [was] any attempt to appropriately practice medicine according to even the minimal standard of care.'' *Id.* at 278.[21]

On cross-examination, however, Dr. Van Komen was asked if he was ''familiar with the way the Texas Medical Board deals with this particular type of problem?'' *Id.* at 302. Dr. Van Komen answered: ''Not specifically. I would assume that they have, as many medical boards, accepted the model guidelines that have been distributed through the Federation of State Medical Boards.'' [22] *Id.*

Pursuant to 5 U.S.C. 556(e), I take official notice of the following state standards of medical practice as set forth in statutes, regulations, and administrative notices: [23] Cal. Bus. & Prof. Code §§ 2052 [24] (prohibiting unlicensed practice of medicine) & 2242.1(a) (''No person * * * may prescribe * * * dangerous drugs * * * on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication. * * *''). Cal. Health & Safety Code § 11352(a) (prohibiting furnishing a controlled substance ''unless upon the written prescription of a physician * * * licensed to practice in this state''); N.C. Gen. Stat. § 90–18 (2005) (''prescribing medication by use of the Internet or a toll-free telephone number, shall be regarded as practicing medicine'' in the State).[25]

Relatedly, the administrative rules of the medical boards of Ohio and Tennessee expressly prohibit—with only limited exceptions—a physician's prescribing to a person he/she has not personally physically examined. For example, under the rules of the Tennessee Board of Medical Examiners:

[19] He also explained that an ophthalmologist performs eye surgery and treats diseases of the eye. Tr. 276.

[20] While Nirmal Saran admitted to a DI that he did not maintain any records on the persons he prescribed to, Tr. 220, there is no evidence as to whether Nisha Saran also failed to maintain records. The Government, however, had the burden of proving that Nisha Saran failed to maintain patient records. Because Dr. Van Komen's opinion testimony with respect to Nisha Saran was based in part on the alleged absence of documentation to support her prescribings, his testimony is rejected to this extent.

[21] Dr. Van Komen also testified that ''if the patient asks for a drug by name, you can almost for sure understand that that individual is going to abuse that drug. It's interesting that on the internet, you allow the patient to pick whatever drug they want exactly by name and order it.'' *Id.* at 279–80. He also explained the importance of monitoring closely those patients to whom he prescribed hydrocodone. *Id.* Moreover, Dr. Van Komen testified that reviewing an online questionnaire was ''absolutely no way'' for a physician to detect whether a person who was seeking a controlled substance was a drug abuser, ''because you have no way of knowing that the person that filled out the questionnaire filled it out honestly.'' *Id.* at 285.

[22] Respondent Nisha Saran also elicited testimony from Rony Dev, D.O., one of her colleagues at a hospital where she practiced. Dr. Dev acknowledged, however, that it would not be appropriate to prescribe to a patient without knowing her medical history, what medications the patient was on, and her vital signs. Tr. 471. While Dr. Dev testified that in his experience, Nisha Saran would not prescribe in this manner, *id.* at 471–72; he subsequently testified that he had no direct knowledge of her prescribing over the internet, *id.* at 503; and had never discussed her internet prescribing with her. *Id.* at 520.

[23] In accordance with the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.

[24] *In Hageseth* v. *Superior Court*, 59 Cal. Rptr.3d 385 (Ct. App. 2007), the California Court of Appeal upheld the State's jurisdiction to criminally prosecute an out-of-state physician, who prescribed a drug to a California resident over the internet, for the unauthorized practice of medicine.

[25] The North Carolina Medical Board has also issued a Position Statement on the steps which a physician must take before prescribing a drug. *See* North Carolina Medical Board, *Position Statement: Contact With Patients Before Prescribing* (Nov. 1999). More specifically, the North Carolina Medical Board has stated that:

> It is the position of the North Carolina Medical Board that prescribing drugs to an individual the prescriber has not personally examined is inappropriate except as noted * * * below. Before prescribing a drug, a physician should make an informed medical judgment based on the circumstances of the situation and on his or her training and experience. Ordinarily, this will require that the physician personally perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription. This process must be documented appropriately.

Id. The exceptions are for ''admission orders for newly hospitalized patients, prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.'' *Id.* The North Carolina Board has further declared that ''prescribing drugs to individuals the physician has never met based solely on answers to a set of questions, as is common in Internet or toll-free telephone prescribing, is inappropriate and unprofessional.'' *Id.*

Finally, while North Carolina recently amended the State's Medical Practice Act, it is a felony offense ''if the person so practicing without a license is an out-of-state practitioner who has not been licensed and registered to practice medicine * * * in th[e] State.'' N.C. Gen. Stat. § 90–18(a); *see also id.* § 90–1A(5)(f) (defining ''[t]he practice of medicine'' as including ''[t]he performance of any act, within or without this State, described in this subdivision by use of any electronic or other means, including the Internet or telephone'').

* * * it shall be a prima facie violation of T.C.A. § 63–6–214(b) (1), (4), and (12) for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the Internet or over telephone lines, unless the physician has first done and appropriately documented, for the person to whom a prescription is to be issued or drugs dispensed, all of the following:

1. Performed an appropriate history and physical examination; and

2. Made a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care; and

3. Formulated a therapeutic plan, and discussed it, along with the basis for it and the risks and benefits of various treatment options, a part of which might be the prescription or dispensed drug, with the patient; and

4. Insured availability of the physician or coverage for the patient for appropriate follow-up care.

Tenn. Comp. R. & Regs. 0880–2–.14(7). *See also id.* R. 0880–2.16 (requiring telemedicine license).[26] *See* Ohio Admin. R. 4731–11–09 (''Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, and situations involving nurses practicing in accordance with standard care arrangements * * * a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.'').[27]

[26] I also take official notice of the Medical Board of California's Decision and Order in *Jon Steven Opsahl, M.D.*, at 3 (Med. Bd. Cal. 2003) (revoking medical license and finding that ''a physician cannot do a good faith prior examination based on a history, a review of medical records, responses to a questionnaire and a telephone consultation with the patient, without a physical examination of the patient'' and that ''[a] physician cannot determine whether there is a medical indication for prescription of a dangerous drug without performing a physical examination''); *see also id.* at 17.

In addition, the Medical Board of California has issued numerous Citation Orders to out-of-state physicians for internet prescribing to State residents. *See, e.g., Citation Order Harry Hoff* (June 17, 2003); *Citation Order Carlos Gustavo Levy* (Nov. 30, 2001). It has also issued press releases announcing its position on the issuance of prescriptions by physicians who do not hold a California license. *See* Medical Board of California, *Record Fines Issued by Medical Board to Physicians in Internet Prescribing Cases* (News Release Feb. 10, 2003) (available at *http://www.mbc.ca.gov/NR_2003_02-10_Internetdrugs.htm*). I also take official notice of these materials.

[27] On September 14, 2003, the Florida Board of Medicine issued Fla. Admin. R. 64B8–9.014, Standards for Telemedicine Prescribing Practice. This rule states *inter alia* that:

Physicians * * * shall not provide treatment recommendations, including issuing a prescription, via electronic or other means, unless the following elements have been met: (a) A documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed. (b) Discussion between the physician * * * and the patient regarding treatment options and the risks and benefits of treatment. (c) Maintenance of contemporaneous medical records meeting the requirements of Rule 64B8–9.003, F.A.C.

Fla. Admin Code R. 64B8–9.014(2); *see also* Fla. Admin Code R. 64B15–14.008 (adopting similar rule for osteopathic physicians).

Discussion

Section 304(a) of the Controlled Substance Act (CSA) 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).[28] In determining the public interest, the CSA directs that the following factors be considered:

(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. § 823(f).

[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'' is consistent with the public interest and whether a registrant has committed acts which warranted the suspension of his/her registration. *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).

I acknowledge that neither Respondent's state license has been the subject of disciplinary proceedings and that neither Respondent has been convicted of an offense under Federal or State laws related to controlled substances. I nonetheless conclude that the evidence as to each Respondent's experience in dispensing controlled substances and compliance with applicable Federal and State laws establish that both Respondents committed acts which rendered their registrations inconsistent with the public interest and which justified the suspension orders.[29]

Factors Two and Four—Respondents' Experience in Dispensing Controlled Substances and Record of Compliance with Applicable Federal and State Laws

Under a longstanding DEA regulation, 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 [or 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 relating 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*, 546 U.S. 243, 274 (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 his/her patient. *See*, *e.g.*, Cal. Bus. & Prof. Code § 2242.1; Cal. Health & Safety Code § 11352(a); Ohio Admin. R. 4731–11–09; Tenn. Comp. R. & Regs. 0880–2–.14(7); North Carolina Med. Bd., *Position Statement: Contact With Patients Before Prescribing.*

[28] Section 304(d) further 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).

[29] While each Respondent's registration has expired and neither Respondent has submitted a renewal application, each Respondent asserts that he/she intends to continue the practice of medicine and that he/she has not abandoned his/her desire to obtain a new registration. *See* ALJ Exs. 14A & 14B. The Government does not dispute these assertions. For the reasons stated in my answer to the ALJ's Query, I hold that neither Respondent's case is moot. *See* ALJ Ex. 23.

Furthermore, a physician who engages in the unauthorized practice of medicine is not a ''practitioner acting in the usual course of * * * professional practice.'' 21 CFR 1306.04(a). Under the CSA, the ''[t]he term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). *See also* 21 U.S.C. 823(f) (''The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.''). As the Supreme Court has explained: ''In the case of a physician [the CSA] contemplates that *he is authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice.'' *Moore*, 423 U.S. at 140–41 (emphasis added). 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. Cf. 21 CFR 1306.03(a)(1) (''A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]'').[30]

The record establishes that each Respondent committed numerous violations of the CSA and various state laws by issuing prescriptions which lacked a legitimate medical purpose and which were far outside of the course of professional practice. With respect to Respondent Nirmal Saran, the evidence shows that in just the limited period between May 19 and June 8, 2005, he issued through internet sites, eight-seven controlled substance (cs) prescriptions to persons in California, eighty-six cs prescriptions to person in Florida, sixty-four cs prescriptions to persons in Tennessee, thirty-two cs prescriptions to person in Ohio, and twenty-nine controlled substance prescriptions to persons in North Carolina. Nirmal Saran was not licensed in any of these five States, and admitted to investigators that he prescribed based on the questionnaires submitted by the Web sites' customers, that he had only telephoned ''approximately 12 to 15 patients'' during the entire period he prescribed over the internet, and obviously did not perform physical examinations (as also demonstrated by the DI's undercover buy) as required by the standards of medical practice of the States of California, Ohio, Tennessee, and North Carolina, among others.

Moreover, given the limited number of phone calls he made to patients, it is also obvious that he violated state rules requiring that he explain to his ''patients,'' the risks and benefits of treatment options including the taking of controlled substances. Tenn. Comp. R. & Regs. 0880–2–.14(7), Fla. Admin. Code R 64B8–9.014(2). Furthermore, Nirmal Saran admitted that he did not keep any records of his internet prescribings and thus violated state medical practice standards for this reason as well. *See*, *e.g.* , Fla. Admin. Code R 64B8–9.014(2); N.C. Med. Bd., *Position Statement.* I thus find that Nirmal Saran did not establish a bona fide doctor-patient relationship with those persons he prescribed to over the internet, that these prescriptions lacked a legitimate medical purpose, and that he acted outside of the usual course of professional practice in issuing them. 21 CFR 1306.04(a). *See also* Tr. 278 (testimony of Gov. Expert). I further conclude that Nirmal Saran repeatedly violated the CSA in issuing prescriptions over the internet and thus committed numerous acts which rendered his registration ''inconsistent with the public interest,'' 21 U.S.C. 824(a)(4), and which warranted the suspension of his registration.

The record likewise establishes that Nisha Saran issued numerous prescriptions in violation of the CSA and various state laws. As found above, in just the limited period between May 27 and June 3, 2005, Nisha Saran issued over the internet, seventeen cs prescriptions to persons in Florida, eleven cs prescriptions to persons in California, ten cs prescriptions to persons in North Carolina, and four cs prescriptions to persons in Ohio.[31] Nisha Saran practiced in the State of Texas and was not licensed to practice medicine in any of these other States. For this reason alone, the prescriptions she issued to these persons were issued outside of the ''usual course of * * * professional practice'' and violated the CSA. 21 CFR 1306.04(a); Moore, 423 U.S. at 140–41.

With respect to the Nations Drug Supply Web site (which was owned by her brother, a now convicted drug dealer), J.P. testified that on May 30, 2005, he purchased ninety tablets of Norco (hydrocodone/apap); the intercepted data shows that Nisha Saran approved this prescription. GX 9 (06–19) at 1–7 (line 10). J.P., a Florida resident, further testified that he never spoke with anyone in making his various purchases at Nations, that he was not required to send in any medical records, and that he did not know Nisha Saran (or her father). It is thus clear that Nisha Saran did not comply with State of Florida's standards for telemedicine practice, *see* Fla. Admin. Code R.64B15–14.0088–9.014, and that she did not establish a bona-fide doctor-patient relationship with J.P. I therefore conclude that Nisha Saran lacked ''a legitimate medical purpose'' and acted outside of the usual course of professional practice in issuing the Norco prescription to J.P. *See* 21 CFR 1306.04(a).

Moreover, given the extensive evidence as to the *modus operandi* used by the Nations Drug Supply and Rx Great Prices Web sites, both of which dispensed controlled substances based on prescriptions issued by physicians who had not personally performed a physical exam on the person seeking the prescription, I further conclude that Nisha Saran failed to establish bona-fide doctor patient relationships with persons to whom she prescribed controlled substances as required by the standards of medical practice adopted by the States of California, North Carolina, and Ohio, among others. See, *e.g.* , Cal. Bus & Prof. Code § 2242.1(a); Ohio Admin. R. 4731–11–09; N.C. Med. Bd., *Contact With Patients Before Prescribing.* I therefore hold that in issuing these prescriptions, Nisha Saran lacked ''a legitimate medical purpose'' and acted far outside of the ''usual course of [her] professional practice'' and therefore violated the CSA. 21 CFR 1306.04(a); *see also* Tr. 278.

I acknowledge that Nisha Saran offered the testimony of one of her colleagues regarding the appropriateness of her prescribing practices in a hospital setting. This evidence is not, however, relevant in assessing whether her internet prescribing constituted acts ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Because her internet

[30] As the California Court of Appeal has noted: the ''proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine.'' *Hageseth* v. *Superior Court*, 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007).

[31] My identification of the specific number of prescriptions issued by each Respondent in violation of various state medical practice standards during a limited time period is not an all inclusive list of the violations each committed. Each Respondent also issued prescriptions to persons in numerous other States; the Agency is not required to identify each and every instance in which they violated the CSA and state laws to support the conclusion that they committed acts inconsistent with the public interest.

prescribings violated the CSA and numerous state laws, they were acts that were inconsistent with the public interest,'' [32] and which warranted the suspension of her registration.[33] *Id.*

Orders

Pursuant to the authority vested in me by 21 U.S.C. 824, as well as 28 CFR 0.100(b) & 0.104, I affirm my order which immediately suspended the now-expired DEA Certificate of Registration, AS7091894, issued to Nirmal Saran. Pursuant to the above cited authority, I also affirm my order which immediately suspended the now-expired DEA Certificate of Registration, BS8415956, issued to Nisha Saran. These orders are effective immediately.

Dated: December 12, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–30506 Filed 12–22–08; 8:45 am]

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[32] As both J.P.'s and Dr. Van Komen's testimony shows, the prescribing of controlled substances over the internet creates a grave threat to public health and safety. As Dr. Van Komen explained, reviewing an online questionnaire is ''absolutely no way'' for a physician to detect whether a person seeking a controlled substance has a legitimate medical need for the drug or is a drug abuser. Tr. 285. This Agency has discussed the threat to public health and safety posed by internet prescribing in numerous cases. *See, e.g. , William R. Lockridge*, 71 FR 77791 (2006); *Mario Alberto Diaz,* 71 FR70788 (2006); *Mario Avello*, 70 FR 11695 (2005).

[33] Neither Respondent has an application pending before the Agency. I note, however, that even if the Respondents had submitted applications, I would have denied their applications.

Under agency precedent, where the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must '' 'present[] sufficient mitigating evidence to assure the Administrator that [it] can be entrusted with the responsibility carried by such a registration.' '' *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988)). Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs., Inc.,* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his/her actions and demonstrate that he/she will not engage in future misconduct. *See Jackson,* 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA*, 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

Notably, neither Respondent testified in this proceeding. I therefore further find that neither Respondent has accepted responsibility for his/her misconduct.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Prohibited Transaction Exemptions and Grant of Individual Exemptions involving: 2008–15, Popular, Inc., Banco Popular de Puerto Rico, and Popular Financial Holdings, Inc. (collectively, the Applicants), D–11396; and 2008–16, BlackRock, Inc. (BlackRock, and The PNC Financial Services Group, Inc. (PNC) (collectively, the Applicants), D–11453

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Grant of Individual Exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) 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).

A notice was published in the **Federal Register** of the pendency before the Department of a proposal to grant such exemption. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, DC. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicant has represented that it has complied with the requirements of the notification to interested persons. No requests for a hearing were received by the Department. Public comments were received by the Department as described in the granted exemption.

The notice of proposed exemption was issued and the exemption is being granted solely by the Department because, 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 proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemption is administratively feasible;

(b) The exemption is in the interests of the plan and its participants and beneficiaries; and

(c) The exemption is protective of the rights of the participants and beneficiaries of the plan.

Popular, Inc., Banco Popular de Puerto Rico, and Popular Financial Holdings, Inc. (collectively, the Applicants) Located in the Commonwealth of Puerto Rico.

[Prohibited Transaction No. 2008–15; Exemption Application No: D–11396]

Exemption

Section I: Transactions

(a) The restrictions of sections 406(a), 406(b)(1), 406(b)(2), and 407(a) of the Act shall not apply, effective November 23, 2005, to:

(1) The acquisition of stock rights (the Rights) by certain plans, described, below, in Section I(a)(1)(A) through (D) of this exemption, in connection with an offering of such Rights (the Offering) by Popular, Inc. (Popular), a party in interest with respect to such plans:

(A) Popular, Inc. Retirement Savings Plan for Puerto Rico Subsidiaries (the Popular PR Plan);

(B) Banco Popular de Puerto Rico Savings and Stock Plan (the BPPR Savings Plan),

(C) Popular, Inc. U.S.A. Profit Sharing/401(k) Plan (the Popular USA Plan),

(D) Popular Financial Holdings, Inc. Savings and Retirement Plan (the PFH Savings Plan) [1], and

(2) The holding of the Rights by the certain plans, described, above, in Section I(a)(1)(A) through (D) of this exemption, until the expiration of such Rights; provided that the conditions in Section II of this exemption, as set forth, below, are satisfied and

(b) The sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1986 (the U.S. Code), by reason of section 4975(c)(1)(A) through (E) shall not apply, effective November 23, 2005, to the acquisition of the Rights by certain plans, described, above, in Section I(a)(1)(C), and Section I(a)(1)(D) of this exemption; [2] provided

[1] The BPPR Savings Plan, the Popular PR Plan, the Popular USA Plan, and the PFH Savings Plan are referred to, herein, collectively, as the Participant Directed Plans.

[2] The Applicants represent that, because the fiduciaries for the BPPR Savings Plan, and the Popular PR Plan have not made an election under

Continued