During the public comment period, the proposed consent decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the proposed consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $44.25 (with all attachments) or $9.00 (without attachments) (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

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

[FR Doc. 2013–11107 Filed 5–9–13; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—3D PDF Consortium, Inc.

Notice is hereby given that, on April 19, 2013, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), 3D PDF Consortium, Inc. (''3D PDF'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, INTRATECH Corporation, Mapo-gu, Seoul, REPUBLIC OF KOREA, has been added as a party to this venture. In addition, Boeing Shared Services Group has changed its name to The Boeing Company, Seattle, WA.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and 3D PDF intends to file additional written notifications disclosing all changes in membership.

On March 27, 2012, 3D PDF filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 20, 2012 (77 FR 23754).

The last notification was filed with the Department on November 8, 2012. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on December 4, 2012 (77 FR 71831).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2013–11113 Filed 5–9–13; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12–1]

Jose G. Zavaleta, M.D.; Decision and Order

On May 10, 2012, Administrative Law Judge Gail A. Randall issued the attached Recommended Decision.[1] Neither party filed exceptions to the Recommended Decision.

Having reviewed the record in its entirety, I have decided to adopt the ALJ's recommended rulings, findings of fact, conclusions of law, and recommended sanction, except for her discussion that the findings of a prior agency order denying a previous application filed by Respondent, *see Jose Gonzalo Zavaleta,* 76 FR 49506 (2011), were not entitled to *res judicata* effect because they were issued in a proceeding in which Respondent waived his right to a hearing. ALJ at 12–13 (citing *Robert M. Golden,* 65 FR 5663 (2000)). While the ALJ was bound by the existing Agency precedent on the issue, I conclude that a re-examination of the issue is warranted and overrule *Golden.* However, because this has no effect on the outcome, I will adopt the ALJ's recommended sanction and will order that Respondent's application for a DEA Certificate of Registration as a practitioner be denied.

The ALJ's Ruling on Whether the Prior Agency Order Denying Respondent's Application Is Entitled to *Res Judicata* Effect

On February 23, 2009, the Deputy Assistant Administrator, DEA Office of Diversion Control, issued an Order to Show Cause to Respondent which proposed the denial of the application for registration submitted by him on July 28, 2008. *See Jose Gonzalo Zavaleta,* 76 FR at 49506. The Show Cause Order was based on allegations that Respondent had issued multiple controlled-substance prescriptions to undercover officers (UCs) and that he lacked a legitimate medical purpose and violated federal law in doing so because he either performed a cursory medical examination or failed to perform any medical examination. *Id.* Respondent failed to request a hearing on the allegations. *Id.*

On July 27, 2011, this Agency issued a Decision and Order denying the application which Respondent submitted on July 28, 2008. *Id.* at 49508. The Agency's denial of Respondent's application was based on the evidence submitted by the Government showing that two officers from the Louisiana State Police had made undercover visits to Respondent on various occasions, during which they obtained from him prescriptions for controlled substances including hydrocodone, alprazolam, and Phenergan with codeine. *Id.* With respect to UC1, who visited him on January 23, 2008, the evidence showed that he asked Respondent for Lortab and initially denied that he was in pain; nonetheless, Respondent issued him a prescription for Lortab after UC1 stated (falsely) that he had a sexually transmitted disease, and that Respondent did so without performing a physical examination. *Id.* at 49506.

Likewise, with respect to UC2, the Agency found that while she initially denied being in pain, Respondent prescribed hydrocodone to her. *Id.* Moreover, on a subsequent visit, Respondent prescribed Phenergan, a narcotic cough syrup, even though UC2 had no symptoms of cough or congestion, as well as more hydrocodone. *Id.* Finally, at UC2's third visit, Respondent prescribed hydrocodone as well as Xanax to her. *Id.* At no time did Respondent obtain UC2's medical records or perform a physical examination on her. *Id.* Rather, Respondent coached UC2 as to what to say to justify the issuance of the prescriptions. *Id.*

Based on these findings, the Agency concluded that Respondent had failed to establish a physician-patient relationship with the UCs and therefore lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he prescribed controlled substances to them. *Id.* at 49508 (citing 21 U.S.C. 1306.04(a); 21 U.S.C. 841(a)(1); *Louisiana* v. *Moody,* 393 So.2d 1212, 1215 (La. 1981)).

During the course of the instant proceeding, the ALJ directed the parties to address ''whether the doctrine of *res judicata* applies to the Final Order'' and ''thus bar[s] Respondent from 'relitigat[ing] the factual findings and conclusions of law of the prior proceeding.' '' ALJ at 12. (quoting *Robert*

[1] All citations to the Recommended Decision are to the ALJ's slip opinion.

L. Dougherty, 76 FR 16823, 16830 (2011)). Both parties filed briefs, with the Government seeking partial summary disposition on this basis.

The ALJ denied the Government's motion, holding that while ''the factual findings in DEA final orders are entitled to *res judicata*[,] . . . the Agency has also expressly limited the application of *res judicata,* refusing to apply the principle when the final order was issued without an evidentiary hearing.'' ALJ at 12–13 (citing *Golden,* 65 FR at 5664). Noting that the July 27, 2011 Final Order denying Respondent's first application was based ''solely on . . . material in the [Agency's] investigative file and not [issued] following an evidentiary hearing,'' the ALJ held that ''the factual findings and legal conclusion contained in the Final Order were not entitled to *res judicata* effect in this matter.'' *Id.* at 13.

In holding that the factual findings and legal conclusions of the July 2011 Order were not entitled to preclusive effect, the ALJ properly applied *Golden.* Indeed, the ALJ was bound by *Golden.* However, given *Golden*'s cursory discussion of the issue, I conclude that a re-examination of its holding is warranted. While there is support for the rule established in *Golden,* it is clear that its rule is not constitutionally required. Moreover, there is a substantial body of authority which supports the view that as long as the Agency previously provided a party with a full and fair opportunity to litigate the allegations which supported the Agency's proposed action (whether the denial of an application or revocation of a registration), a party's failure to avail itself of that opportunity does not prohibit the Agency from giving preclusive effect to the factual findings and conclusions of law rendered in the prior proceeding.

As the Supreme Court has held, '' '[w]hen an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata* to enforce repose.' '' *United States* v. *Utah Constr. & Mining Co.,* 384 U.S. 394, 421–22 (1966) (as quoted in *University of Tennessee* v. *Elliot,* 478 U.S. 788, 797–98 (1986)). In *Elliot,* the Court further explained that ''giving preclusive effect to administrative factfinding serves the value underlying general principles of collateral estoppel,'' namely ''avoiding the cost and vexation of repetitive litigation and the public's interest in conserving judicial resources.'' *Id.* at 798 (citations omitted). Thus,

> [w]here an administrative forum has the essential procedural characteristics of a court, its determinations should be accorded the same finality that is accorded the judgment of a court. The importance of bringing a legal controversy to conclusion is generally no less when the tribunal is an administrative tribunal than when it is a court.

Id. at n.6 (quoting Restatement (Second) of Judgments § 83, p. 269 (1982) [hereinafter, Restatement]).

The Restatement sets forth five requirements which an adjudicative determination issued by an administrative tribunal must satisfy for it to be entitled to *res judicata* effect. These are that the proceeding provide:

> (a) Adequate notice to persons who are to be bound by the adjudication . . . ;
>
> (b) The right on behalf of a party to present evidence and legal argument in support of the party's contentions and fair opportunity to rebut evidence and argument by opposing parties;
>
> (c) A formulation of issues of law and fact in terms of the application of the rules with respect to specified parties concerning a specific transaction, situation, or status, or a specific series thereof;
>
> (d) A rule of finality, specifying a point in the proceeding when presentations are terminated and a final decision is rendered; and
>
> (e) Such other procedural elements as may be necessary to constitute the proceeding a sufficient means of conclusively determining the matter in question, having regard for the magnitude and complexity of the matter in question, the urgency with which the matter must be resolved, and the opportunity of the parties to obtain evidence and formulate legal contentions.

Restatement, § 83.

DEA's proceedings meet each of these requirements. First, under 21 U.S.C. 824(c), the Agency is required to ''serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended,'' which ''shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order.'' *See also* 21 CFR 1301.37(c) (''The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.'').

Moreover, ''[p]roceedings to deny, revoke, or suspend shall be conducted pursuant to this section *in accordance with subchapter II of chapter 5 of Title 5.*'' 21 U.S.C. 824(c) (emphasis added). The latter are the provisions of the Administrative Procedure Act governing the conduct of adjudicatory proceedings, and which provide, *inter alia,* that the hearing be conducted by an administrative law judge, whose powers include the issuance of subpenas, and that ''[a] party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts.'' 5 U.S.C. 556(c) & (d). In addition, DEA regulations set forth additional procedural protections to ensure the fairness of the hearing and specify the point at which the proceeding becomes final. *See* 21 CFR 1316. Thus, proceedings conducted under sections 303 and 304 of the Controlled Substance Act (21 U.S.C. 823 & 824) clearly meet each of these requirements.

Respondent does not dispute that he was served with an Order to Show Cause proposing the denial of his first application and that he failed to respond to the Order and thus waived his right to a hearing. Resp. Memorandum, at 3. Rather, Respondent asserts that the previous Final Order denying his application should not be given preclusive effect because he falls within one of the *res judicata* doctrine's recognized exceptions. *Id.*

More specifically, Respondent argues that ''[t]here is a clear and convincing need for a new determination of the issue'' for two reasons. *Id.* at 2 (quoting Restatement § 28). First, he invokes the exception which provides for relitigation ''because of the potential adverse impact of the determination on the public interest or the interest of persons not themselves parties in the initial action.'' *Id.* (quoting Restatement § 28). Second, he invokes the exception which provides for relitigation where ''the party sought to be precluded, as a result of the conduct of his adversary or other special circumstances, did not have an adequate opportunity or incentive to obtain a full and fair adjudication in the initial action.'' *Id.* at 3 (quoting Restatement § 28).

With respect to the first exception, Respondent argues that ''[h]e has been an asset in every community where he has practiced medicine'' and that his ''patients and the public interest, especially in the community where he practices medicine, have been adversely affected since he lost his ability to prescribe controlled substances.'' *Id.* at 5. Respondent thus contends that ''[i]f the doctrine of res judicata is applied in these proceedings and [his application] is denied, then the public interest will be affected in that [his] experience as a physician cannot be properly utilized because many of the employment opportunities available to him require a . . . registration.'' *Id.*

DEA has held, however, that evidence as to the impact on the community of a practitioner's lack (or loss) of a registration is not relevant under any of the factors of the public interest standard of 21 U.S.C. 823(f). *See Gregory D. Owens,* 74 FR 36751, 36756–57 & n.22 (2009).[2] *See also Kwan Bo Jin,* 77 FR 35021, 35021 (2012); *Linda Sue Cheek,* 76 FR 66972, 66973 (2011); *Mark De La Lama,* 76 FR 20011, 20020 n.20 (2011); *Bienvenido Tan,* 76 FR 17673, 17694 n.58 (2011). Because such evidence is not relevant in assessing whether Respondent's registration would be ''consistent with the public interest,'' 21 U.S.C. 823(f), this exception cannot support allowing Respondent to relitigate the issues decided by the July 2011 Order.

As for the second exception, Respondent asserts that ''he filed [his first Application] prematurely and did not follow the advice of his [former] counsel.'' Resp. Memorandum, at 4. He further argues that while he ''wanted to respond to the Order to Show Cause,'' which was issued in response to his first application, ''this time he followed the advice of his counsel which . . . advised him not to respond and wait until he completed his pretrial intervention program and [the] requirements placed on him by the Louisiana State Board of Medical Examiners.'' *Id.* Respondent thus contends that ''this is a special circumstance which did not give him an adequate opportunity or incentive to obtain a full and fair adjudication in the initial action,'' and that ''[i]f he had been informed by counsel of the consequences of not responding, [he] would have responded regardless of the outcome in order to put his evidence into the record.'' *Id.*

In the civil context, however, courts generally do not overturn judgments simply because a party complied with legal advice that was erroneous or ultimately proved to be disadvantageous. *Cf. Nelson* v. *The Boeing Co.,* 446 F.3d 1118, 1120 (10th Cir. 2006) (declining to recognize right to effective assistance of counsel in civil suit outside of immigration context). And in any event, the Show Cause Order issued in the first proceeding fully explained that the consequence of Respondent's failure to request a hearing would include that he would be deemed to have waived his right to a hearing and that a final order would be issued ''based upon the investigative file and record of this proceeding as it may then appear.'' Order to Show Cause (Feb. 23, 2009) (ALJ Ex. 1, at 5).

Moreover, as the comment to this exception states, while ''the court in the second proceeding may conclude that issue preclusion should not apply because the party sought to be bound did not have an adequate opportunity or incentive to obtain a full and fair adjudication in the first proceeding[,] [s]uch a refusal to give the first judgment preclusive effect should not occur without a compelling showing of unfairness, nor should it be based simply on a conclusion that the first determination was patently erroneous.'' Restatement § 28, cmt. j.[3] Respondent's contention that he did not challenge the first Show Cause Order because he relied on the disadvantageous advice of his prior attorney does not make for a ''compelling showing of unfairness.'' *Id.*

The ALJ further rejected as ''illogical'' and contrary to the Agency's experience under *Golden,* the Government's argument that denying *res judicata* effect to the July 2011 final order '''would allow registrants to repeatedly litigate the same issues and thus render key portions of 21 CFR 1301.43 meaningless.''' Memorandum and Order, at 9–10 (quoting Gov. Mot. at 3–4). She further reasoned that ''[a]pplicants, like [Respondent,] gain no benefit or tactical advantage by failing to respond to an order to show cause, for during [the] application period they are without the authority to handle controlled substances.'' *Id.* at 10.

Yet, it is within the Agency's experience that registrants, especially those who are the subject of a criminal investigation or pending criminal charges (as well as state administrative proceedings), choose not to contest a Show Cause proceeding. For any number of reasons, a criminal investigation may ultimately result in the prosecutor declining to file charges, and even where charges are filed, a prosecution may result in an acquittal. Moreover, a final disposition may not occur for several years. So, too, it may take several years for a state administrative proceeding to come to a conclusion. During that period, material witnesses may become unavailable, and even where they remain available, their recollections may become faulty; other evidence may be discarded. Yet nothing in the CSA or DEA's regulations prevents a person whose registration has been revoked from reapplying, and this can occur years after the misconduct which was the basis of the first proceeding. *See Robert L. Dougherty,* 76 FR 16823 (2011).

In *Dougherty,* DEA revoked a physician's registration in 1995. *Id.* at 16824–25. More than a decade later, the physician applied for a new registration. *Id.* at 16823. While the physician attempted to relitigate many of the factual findings made in the Agency's 1995 decision and final order, as well as the factual findings made in a 1997 state board proceeding, this Agency held that these findings were *res judicata. See id.* at 16830–16833.

It is true that in *Dougherty,* the findings, which were given preclusive effect, were made in an Order which was issued following a hearing. Yet, had the physician waived his right to a hearing when the Agency initially took action, under *Golden,* the Government would have been required to prove its case—nearly twenty years after the underlying misconduct—through witness testimony and other evidence. This is a ludicrous result.

Thus, while it may be that a former registrant gains no benefit from failing to respond to an Order to Show Cause because he will remain unregistered—a proposition which is not free of dispute—*Golden* nonetheless creates the wrong incentive and wastes scarce Agency resources. Where the Agency has proposed the denial of an application, the applicant should be encouraged to challenge the Agency's

[2] In *Owens,* I rejected the ALJ's reliance, in recommending a sanction, on evidence that the registrant ''ha[d] 561 patients from underserved counties, and [that] many of these patients have limited incomes.'' 74 FR at 36756. In so holding, I noted that section 823(f)'s public interest standard ''is not a freewheeling inquiry but is guided by the five specific factors which Congress directed the Attorney General to consider'' and that ''consideration of the socioeconomic status of a practitioner's patient population is not mandated by'' the relevant provisions of the Act, ''which focus primarily on the acts committed by a practitioner.'' *Id.* at 36757.

In *Owens,* I further held that such evidence ''has no bearing on whether [a registrant] has accepted responsibility and undertaken adequate corrective measures,'' which are two of the showings which a registrant must make in order to rebut the Government's *prima facie* showing that a registrant has committed acts which render his registration inconsistent with the public interest. *Id.* In addition, I further noted the inherent unworkability of the ALJ's proposed rule, and that it ''would inject a new level of complexity into already complex proceedings and take the Agency far afield of the purpose of the CSA's registration provisions, which is to prevent diversion.'' *Id.* at n.22.

[3] The circumstance described by Respondent does not remotely approach any of the circumstances cited by the Restatement as a ground for invoking this exception, which suggest that it is extremely narrow in its scope. Specifically, the comment gives as examples: where ''one party may conceal from the other information that would materially affect the outcome of the case,'' especially where ''there is a fiduciary relationship between the parties''; where ''one of the parties may have been laboring under a mental or physical disability that impeded effective litigation and that has since been removed''; and where ''the amount in controversy in the first action may have been so small in relation to the amount in controversy in the second that preclusion would be plainly unfair.'' Restatement § 28, cmt. j.

contention when the evidence is freshest. Indeed, litigation when the evidence is freshest enhances the accuracy of the public interest determination and is one of the underlying reasons for the doctrine of issue preclusion.

Moreover, in response to the increase in the diversion of prescription controlled substances, the number of Show Cause Orders issued by the Agency has doubled in recent years. While some of these matters are resolved by the registrants agreeing to surrender their registration, many of them are not and require the issuance of a decision and order, even where the registrant waived his/her right to a hearing. Allowing an applicant to relitigate issues which he/she had a full and fair opportunity to litigate in a prior proceeding but chose not to, misallocates the scarce resources of both the Office of Administrative Law Judges and the Office of the Administrator.[4] *Cf. Arizona* v. *California,* 530 U.S. 392, 412 (2000) (doctrine of *res judicata* '''is not based solely on the defendant's interest in avoiding the burdens of twice defending a suit, but is also based on the avoidance of unnecessary judicial waste''' (quoting *United States* v. *Sioux Nation,* 448 U.S. 371, 432 (1980)); *Parklane Hosiery Co., Inc.,* v. *Shore,* 439 U.S. 322, 326 (1979) (''Collateral estoppel, like the related doctrine of *res judicata,* has the dual purpose of protecting litigants from the burden of relitigating an identical issue with the same party . . . and of promoting judicial economy by preventing needless litigation.'').

To be sure, the Restatement of Judgments provides that an issue is not entitled to preclusive effect unless it is actually litigated in the prior proceeding, and that an issue is not actually litigated where a judgment is entered by default or where an issue is ''raised by a material allegation of a party's pleading but is admitted . . . by virtue of a failure to deny [it] in a responsive pleading.'' Restatement § 27, cmt. e. Be that as it may, an increasing number of jurisdictions reject this view and ''allow findings made in default proceedings to collaterally estop, provided that the defaulted party could have appeared and defended if he had wanted to.'' *In re Catt,* 368 F.3d 789, 791 (7th Cir. 2004) (citing Indiana cases). *See also Evans* v. *Ottimo,* 469 F.3d 278, 282 (2d Cir. 2006) (noting that under New York law, '''when a party defaults by failure to answer . . . the defaulting litigant may not further contest the liability issues''') (citation omitted); *In re Cantrell,* 329 F.3d 1119, 1123–24 (9th Cir. 2003); *Gottlieb* v. *Kest,* 141 Cal. App. 4th 110, 149 (Cal. Ct. App. 2006) (''A default judgment conclusively establishes, between the parties so far as subsequent proceedings on a different cause of action are concerned, the truth of all material allegations contained in the complaint in the first action, and every fact necessary to uphold the default judgment.'') (internal quotations and other citations omitted); *In re Dawson,* 338 B.R. 756, 761 (Bankr. N.D. Ohio 2006) (applying collateral estoppel under Ohio law to preclude relitigation of findings made in trial on the merits where party failed to appear at earlier trial); *Matter of Latimore,* 252 A.D.2d 217, 219–20 (N.Y. App. Div. 1999) (collaterally estopping attorney in disciplinary proceeding from relitigating findings made in earlier proceeding in which she defaulted); *TransDulles Center, Inc.,* v. *Sharma,* 472 SE.2d 274, 276 (Va. 1996) (applying collateral estoppel to issues essential to default judgment where ''[t]estimonial and documentary evidence was presented ex parte in the [trial] court hearing''); *Jackson* v. *R.G. Whipple, Inc.,* 627 A.2d 374, 380 (Conn. 1993) (''[H]ad there been a full and fair opportunity to litigate [the] issues and such issues were necessary to a default judgment, that judgment should put to rest subsequent litigation of all issues necessary for the rendering of the default judgment.''), *abrogated on other grounds by Macomber* v. *Travelers Property & Cas. Corp.,* 804 A.2d 180, 195–96 (2002); *Heggy* v. *Grutzner,* 456 NW.2d 845, 849 (Wis. 1990) (precluding relitigation of factual findings essential to default judgment entered in earlier case where party ''intentionally evaded service of process''); *Masciarelli* v. *Maco Supply Corp.,* 224 So.2d 329, 330 (Fla. 1969) (applying collateral estoppel to preclude relitigation of issue, where issue was decided by default judgment in prior litigation, personal service was accomplished, and party failed to answer complaint).

Moreover, giving preclusive effect to findings made in a default proceeding does not violate the Due Process Clause, which requires only ''that the party sought to be precluded have had an opportunity for a hearing.'' *In re Catt,* 368 F.3d at 792. In any event, notwithstanding that Respondent did not request a hearing, the findings of the July 2011 order were not rendered in a classic default proceeding as the Government was required to submit substantial evidence to support its allegations and extensive findings were made based on that evidence.

Accordingly, I conclude that to the extent that *Golden* or any other Agency decision holds that a respondent is entitled to relitigate the factual findings and legal conclusions of an Agency final order because he/she waived his/her right to a hearing in the prior proceeding, it is overruled. Whether the prior agency decision and order was based solely on the evidence submitted by the Government where an applicant waived hearing, or on the basis of a record of a hearing conducted pursuant to 21 CFR 1316.41 *et seq.,* the Agency's factual findings and legal conclusions are entitled to preclusive effect in a subsequent proceeding.

This is not to say that the applicant is foreclosed from putting on any evidence in the subsequent proceeding. That evidence, however, is limited to that which is relevant to, and probative of, '''the critical issue [of] whether the circumstances, which existed at the time of the prior proceeding, have changed sufficiently to support [the] conclusion that' granting the application would be consistent with the public interest.'' *Dougherty,* 76 FR at 16830 (quoting *Stanley Alan Azen,* 61 FR 57893, 57893–94 (1996)). Thus, in the second proceeding, a respondent can put on evidence of acceptance of responsibility as well as remedial measures he has undertaken. What he/she cannot do, however, is relitigate the findings of misconduct made in the earlier Agency decision and order.[5]

In any event, here, as the ALJ found, Respondent asserted that UC1 complained of back pain when both the recording of the visit and the officer's testimony establish otherwise. ALJ 24. Likewise, the ALJ found that Respondent's testimony with respect to UC2 (who credibly testified that she never told Respondent that she had any pain), lacked ''forthrightness'' and ''candor.'' *Id.* at 25. Notwithstanding his evidence that he completed a course on prescribing, Respondent's failure to testify truthfully about his prescribings to the two undercover officers demonstrates that he does not accept responsibility for his misconduct and that the circumstances have not '''changed sufficiently to support [the] conclusion that' granting [his] application would be consistent with

[4] Obviously, if an applicant was not properly served with the Show Cause Order in the prior proceeding, he/she did not have a full and fair opportunity to litigate the issues. Respondent, however, acknowledges that he was served with the first Show Cause Order.

[5] In addition to the 2011 Decision and Order, which denied Respondent's first application, on October 8, 2012, I issued a Decision and Order denying Respondent's second and third applications. *See Jose Gonzalo Zavaleta,* 77 FR 64128, 64131 (2012).

the public interest.'' *Dougherty,* 76 FR at 16883 (quoting *Azen,* 61 FR at 57893–94).

Buttressing this conclusion, the ALJ found that on his December 2010 application, Respondent failed to disclose both the March 2008 voluntary surrender of his registration as well as the suspension of his state controlled substance registration in September 2010. These falsifications were clearly capable of influencing the decision of the Agency and were thus material; the 2008 surrender occurred following an investigation into his prescribing to the undercover officers without a legitimate medical purpose, and the loss of his state controlled substance registration was itself an independent and adequate ground for denying his application. *See Hooper* v. *Holder,* 2012 WL 2020079, *2 (4th Cir. 2012).

Accordingly, I adopt the ALJ's recommended sanction and will order that Respondent's application be denied.

Order

Pursuant to the authority vested in my by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Jose Gonzalo Zavaleta, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective June 10, 2013.

Dated: May 2, 2013.

Michele M. Leonhart,

Administrator.

Frank Mann, Esq., for the Government
Jonathan D. Goins, Esq., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACTS, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Administrative Law Judge Gail A. Randall. This proceeding is an adjudication governed by the Administrative Procedure Act, 5 U.S.C. §§ 551 *et. seq.,* to determine whether a physician's application for a DEA certificate of registration should be denied under the Controlled Substances Act, 21 U.S.C. §§ 823(f) (2006).

I. PROCEDURAL BACKGROUND

On September 6, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration issued an Order to Show Cause to Jose G. Zavaleta, M.D., (''Respondent'' or ''Dr. Zavaleta''), seeking to deny his application [1] for a DEA Certificate of Registration as a practitioner under 21 U.S.C. § 823(f), because his registration would be inconsistent with the public interest. [Administrative Law Judge Exhibit (''ALJ Exh.'') 1]. Specifically, the Order to Show Cause alleged that in 2008 the Respondent violated federal law by issuing prescriptions for schedule III and IV controlled substances without a legitimate medical purpose, without establishing a physician-patient relationship, and by acting outside the usual course of professional practice in prescribing controlled substances to undercover agents.[2]

On September 29, 2011, the Respondent filed a timely request for a hearing on the allegations raised by the Order to Show Cause dated September 6, 2011. [ALJ Exh. 2].

The hearing was held in Baton Rouge, Louisiana, on February 28, 2012. [ALJ Exh. 4]. At the hearing, both parties called witnesses to testify and introduced documentary evidence. [Transcript (''Tr.'') Volume I]. After the hearing, both parties submitted Proposed Findings of Fact, Conclusions of Law, and Argument (Govt. Brief and Resp. Brief).

II. ISSUE

The issue in this case is whether or not the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration (''DEA'' or ''Government'') should deny the application for a DEA Certificate of Registration of Jose G. Zavaleta, M.D., control number W11043099C, as a practitioner, pursuant to 21 U.S.C. § 823(f), because to grant his application would be inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(f). [ALJ Exh. 3; Tr. at 6].

III. FINDINGS OF FACT

I find by a preponderance of the evidence, the following facts:

A. The Respondent's Personal and Professional Background

The Respondent has been a physician for twenty-nine years, practicing emergency room medicine for approximately ten of those years. [Tr. 115, 117]. He is sixty years old. [Tr. 115]. He received his medical education at The National University of Trujillo, Peru, completed his education in Frankfurt Hospital in Philadelphia, Pennsylvania, and graduated from a residency at the LSU Medical Center in Shreveport, Louisiana. [Tr. 116]. The Respondent has active medical licenses in Louisiana and Alabama. [Tr. 117, 153, 155–156, 231–232]. He also has a current Louisiana Board of Pharmacy Controlled Dangerous Substance License, which authorizes him to handle controlled substances. [Tr. 154–155; Resp. Exh. 6]. On March 26, 2008, the Respondent voluntarily surrendered his DEA registration. [Tr. 158–160; Govt. Exh. 4].

In August of 2007, the Respondent opened a family practice clinic in Alexandria, Louisiana. [Tr. 117, 119–120]. There, he also treated chronic pain patients. [Tr. 122]. He used small signs to advertise his clinic. [Tr. 76]. At the clinic, Respondent maintained approximately two hundred and forty medical charts.[3] [Resp. Exh. 11]. However, as of the time of this hearing, the Respondent had closed this clinic. [Tr. 170].

To determine if a pain patient is addicted to controlled substances, the Respondent testified that he knows to question the patient and examine the patient, trying to identify the source of the pain. [Tr. 122]. The Respondent also testified that he would ask for prior medical records, which he stated were difficult to obtain. [*Id.*]. The Respondent

[1] In July of 2008, the Respondent filed an application for a DEA certificate of registration, control number W08092985. The DEA issued an Order to Show Cause regarding this application on February 23, 2009. The Respondent failed to respond to that Order to Show Cause, and on July 27, 2011, the DEA Administrator issued a Final Order denying this application. [ALJ Exh. 1]. In April of 2010, the Respondent filed another application, control number W10020882, and in December of 2010, [Govt Exh. 2], the Respondent filed a third application, control number W10078290. On March 2, 2011, the DEA Deputy Assistant Administrator issued an Order to Show Cause proposing to deny these two applications. The Respondent failed to respond to this Order to Show Cause. The record contains no further information concerning these two applications. On July 1, 2011, the Respondent filed application W11043099, and it is this application which is the subject of this proceeding.

[2] The Order to Show Cause asserted that the facts supporting this Order to Show Cause are the same facts contained in the Orders to Show Cause issued February 23, 2009, and March 2, 2011, and the Administrator's Final Order, all of which were attached to this Order to Show Cause and incorporated by reference. For a full discussion of the *res judicata* issue raised by these facts, see the order attached at Appendix A.

[3] The Government challenged the reliability of this hearsay document. I find, based upon the Respondent's testimony concerning the procedure used by his attorney to have this exhibit prepared, that the record has an adequate indicia of reliability to withstand the hearsay objection. [Tr. 219–221]. Within those charts, he prescribed hydrocodone 100 times, or approximately 14.8% of all of his prescriptions issued between July 2007 and March 2008. He issued Xanax 17 times, or 2.5% of his total prescriptions of 674 during this time period. [Resp. Exh. 11]. He also prescribed Phenergan with codeine 82 times, or approximately 12% of his total prescriptions. [Resp. Exh. 11; *see also* Tr. 169–171]. However, I find these statistics have little weight, given DEA precedent on this issue. Specifically, the Agency has revoked ''other practitioners' registrations for committing as few as two acts of diversion.'' *Jayam Krishna-Iyer, M.D,* 74 Fed. Reg. 459, 463 (DEA 2009) (*citing Alan H. Olefsky,* 57 Fed. Reg. 928, 928–29 (DEA 1992)).

also would limit any prescribing of controlled substances to twenty tablets at a time. [Tr. 123]. But the Respondent credibly testified that he found it difficult to identify patients who were addicted to controlled substances, and that he did not often identify such patients in his practice. [Tr. 124]. He testified that he would need to see a patient multiple times to satisfactorily diagnose a drug addiction problem. [*Id.*]. Patients with chronic complaints would be seen every month. [Tr. 125].

The Respondent further testified that he was remorseful regarding the issuance of the prescriptions to the undercover agents. [Tr. 173–174]. He testified that although he ''failed'' when treating the undercover agents, he learned that he had to become ''more vigilant'' when dealing with patients seeking controlled substances. [Tr. 174]. He also testified that he made mistakes with his DEA applications and that he ''should have give(n) [his applications] more careful review.'' [*Id.*]. Dr. Zavaleta acknowledged the severity of his conduct but asserted that he ''learned [his] lesson'' and now has ''basically . . . rehabilitated myself.'' [Tr. 174–175].

B. Treatment of Ricky Harris

On January 23, 2008, Ricky Harris [4] visited Dr. Zavaleta's clinic. [Govt. Exh. 12]. During Dr. Zavaleta's examination of Mr. Harris, he took his blood pressure and temperature. [*Id.*]. He also measured and weighed Mr. Harris. [*Id.*]. Dr. Zavaleta counseled Mr. Harris about his weight and high blood pressure and urged him to lose weight. [*Id.*].

Mr. Harris presented complaints of symptoms from what he claimed was a sexually transmitted infection. [Tr. 14–15; Govt. Exh. 20]. Dr. Zavaleta proceeded to question Mr. Harris about his symptoms. [Govt. Exh. 12]. He inquired about Mr. Harris's sexual history and number of sexual partners. [*Id.*]. Mr. Harris reported that he had experienced these symptoms in the past and that he had been previously treated for a sexually transmitted infection. [*Id.*]. When the Respondent sought to physically examine his genitals, Mr. Harris refused. [Tr. 15, 27, 186]. Likewise, he refused to submit to a blood test to confirm the nature of the infection. [Tr. 186]. He also refused to provide the Respondent with a sample of discharge he reported experiencing. [Tr. 127]. The Respondent agreed to write Mr. Harris a prescription for antibiotics and left the examination room. [Tr. 16, 127–128; Govt. Exh. 12].

Mr. Harris followed Dr. Zavaleta out into the clinic hallway and requested a prescription for Lortab, a pain medication and Schedule III controlled substance. [Tr. 17; Govt. Exh. 20; Govt. Exh. 12]. Dr. Zavaleta initially refused to write Mr. Harris this prescription. [Govt. Exh. 12]. Respondent told Mr. Harris that he could only write a prescription for Lortab if Mr. Harris reported experiencing pain. [*Id.;* Tr. 17]. Mr. Harris testified at the hearing that he did not tell Dr. Zavaleta that he was in pain. [Tr. 15–17, 25, 31–32]. Although the Respondent testified that Mr. Harris complained of shoulder pain and back pain, [Tr. 128–130, 179–180, 182], I find more credible Trooper Horton's testimony as corroborated by the audiovisual recording of the visit and his contemporaneous report. [Govt. Exh. 12; Govt. Exh. 20; *see also* Govt. Exh. 10 (Harris patient file which lacks any mention of shoulder pain); Tr. 182].

Dr. Zavaleta wrote Mr. Harris a prescription for fifteen Lortab tablets. [Tr. 24; Govt. Exh. 10 at 3]. The Respondent wrote ''back pain'' in Mr. Harris' medical chart. [Govt. Exh. 10 at 4–5]. But the Respondent did not perform any examination on Mr. Harris' back other than to listen to his breathing. [Tr. 25–26, 183]. When Mr. Harris requested more Lortabs, the Respondent refused to increase the prescription for a greater number of tablets. [Govt. Exh. 12]. In addition, Mr. Harris sought refills on the prescription, but Dr. Zavaleta refused to authorize any refills. [Tr. 27–28; Govt. Exh. 10; Govt. Exh. 12]. Mr. Harris paid one hundred dollars in cash for that visit. [Tr. 129].

When he testified at the hearing, the Respondent stated that he should have insisted that Mr. Harris provide him a sample of the discharge for testing. [Tr. 132]. He also stated that, given his suspicions, he should have refused to provide a controlled substance prescription to Mr. Harris without prior records or a validating test for pain. [*Id.*]. Respondent further testified that this prescription for hydrocodone issued to Mr. Harris apparently lacked a legitimate medical purpose. [Tr. 188–190].

Although the Respondent stated Mr. Harris made him feel uncomfortable, he provided him with the prescription. [Tr. 131]. Mr. Harris testified that he returned to see the Respondent, but that the Respondent refused to see or treat him. [Tr. 26]. Regarding this second visit, Respondent testified that he instructed his secretary to inform Mr. Harris that he would not provide him with any additional treatment [Tr. 130–131].

C. Treatment of Christy Landry

On January 30, February 8, and February 28, 2008, Respondent treated Christy Landry.[5] [Tr. 37; Govt. Exh. 21]. At the first visit, Ms. Landry told the Respondent that her boyfriend had taken her pills, and that she needed to get a refill of her medication. [Tr. 37]. The Respondent took no action to verify this prior prescription. [Tr. 209].

Ms. Landry told the Respondent that while she did not have any pain, taking hydrocodone made her feel good. [Tr. 38, 67; Govt. Exh. 21].[6] But she told him in response to his questioning that he could describe her symptoms as ''withdrawal symptoms.'' [Tr. 38, 68].[7] The Respondent referred Ms. Landry to a pain clinic. [Govt. Exh. 11 at 7]. However, in follow-up visits, the pain clinic referral was not discussed, and there is no mention in the patient chart that Ms. Landry ever contacted a pain clinic. [Tr. 201–202; Govt. Exh. 11].

At the hearing, the Respondent demonstrated that he examined her heart, checked her back, and examined her abdomen. [Tr. 136–137]. However, Ms. Landry credibly described this examination as the Respondent's effort to search her for a recording device. [Tr. 39–42; Govt. Exh. 21]. Furthermore, he examined her shin and knees, allegedly checking for swelling. [Tr. 40, 137–138].

The Respondent wrote her a prescription for twenty Lorcet, a hydrocodone product and Schedule III controlled substance. [Tr. 43–44, 138; Govt. Exh. 11 at 10]. Ms. Landry requested a prescription for her sister, but the Respondent refused to issue such a prescription. [Tr. 62–63, 70; Govt. Exh. 21 at 1]. Ms. Landry paid one hundred dollars cash for this office visit. [Tr. 45, 139]. She had informed the receptionist that she did not have insurance. [Tr. 45].

Ms. Landry next saw the Respondent on February 8, 2008. [Tr. 46; Govt. Exhs. 11, 21]. He asked her if she had ''generalized pain,'' and Ms. Landry did not respond. [Tr. 47]. However, Ms.

[4] ''Ricky Harris'' is the patient name and alias used by Master Trooper Richard Horton, Louisiana State Police. For consistency with the evidence of record, I will refer to him as Mr. Harris. [*See* Tr. 11–12, 14].

[5] Christy Landry is the patient name used by Detective Heather Owens of the Louisiana State Police. [Tr. 33; Govt. Exh. 11]. For the record, I will use the patient name used by Detective Owens.

[6] Although the Respondent testified that Ms. Landry complained of left shoulder pain, insomnia, and pain in the legs, [Tr. 134, 138], I find her testimony, as corroborated by the contemporaneous police report, more credible. [Tr. 38; Govt. Exh. 21]. The Respondent also acknowledged that such pain complaints were not in Ms. Landry's medical record. [Tr. 193–194; Govt. Exh. 11].

[7] The record contains no evidence that the Respondent is properly registered as a narcotic treatment program participant.

Landry credibly testified that she did not indicate that she had any kind of pain. [Tr. 52]. Rather, Ms. Landry complained of congestion and requested a prescription for cough syrup with codeine. [Tr. 47]. In his physical examination, the Respondent notated that her lungs were ''abnormal'' and that she had a diagnosis of ''chronic cough.'' [Govt. Exh. 11 at 6]. Yet the Respondent could not recall, and did not document, when the cough began in order to verify the chronic nature of the cough. [Tr. 204–205, 226; Govt. Exh. 11]. Further, the Respondent testified that he had not made any medical findings that would substantiate a medical diagnosis of insomnia. [Tr. 210–211]. The Respondent cautioned Ms. Landry on the proper way to take her controlled substance medication. [Tr. 50–51]. She received a prescription for Lorcet and Phenergan,[8] both of which are controlled substances. [Tr. 53; Govt. Exh. 11 at 11]. Ms. Landry paid one hundred dollars in cash for the office visit. [Tr. 52, 62].

Lastly, Ms. Landry visited the Respondent on February 28, 2008. [Tr. 55]. She told him that she wanted a prescription for hydrocodone and Soma. [Tr. 56]. The Respondent refused to issue her a prescription for Soma, but he did issue her a prescription for Xanax,[9] a controlled substance, and Lorcet. [Tr. 55, 60; Govt. Exh. 11 at 12]. At this visit, Ms. Landry did not complain of insomnia or anxiety. [Tr. 60–61]. When asked why she wanted the medication, Ms. Landry laughed and told the Respondent to write whatever he needed to write. [Tr. 56; Govt. Exh. 21 at 5]. As on the other two visits, the Respondent behaved in a flirtatious manner, which Ms. Landry felt was inappropriate. [Tr. 58–59, 68; Govt. Exh. 21]. On the third visit, Ms. Landry admitted that she did not have any pain.[10] [Tr. 139].

At the hearing, the Respondent admitted that he had not prescribed controlled substances to Ms. Landry for legitimate medical reasons. [Tr. 212]. But he also testified that he thought, at the time he wrote the prescriptions, that he was justified in issuing these prescriptions to her. [Tr. 213–214].

[8] Phenergan is a cough syrup containing a combination of promethazine and codeine. It is a schedule V controlled substance. 21 C.F.R. 1308.15(c) (2011).

[9] Xanax is a schedule IV controlled substance. 21 C.F.R. 1308.14(c)(1) (2011).

[10] Although the Respondent testified that he was ''shocked'' when she denied having any pain, I find his testimony lacked credibility, given the tenor of the visit. [Tr. 139–140].

D. Interview of the Respondent

Sergeant Roland Mathews, a Louisiana State Trooper, interviewed the Respondent with the Respondent's attorney present. [Tr. 71, 79; Govt. Exh. 13]. The Respondent told Sgt. Mathews that he could identify drug-seeking patients, and he stated he would not treat such a patient, but that he would help the patient find treatment. [Tr. 81–82; 221–222]. The Respondent also stated that he would need to perform tests and get prior medical records before prescribing such a patient controlled substances. [Tr. 85; 222]. During Sgt. Mathews' investigation, he did not uncover any evidence that the Respondent attempted to obtain prior medical records for Ricky Harris or Christy Landry. [Tr. 86]. Sgt. Mathews testified that Respondent was cooperative in the investigation. [Tr. 90–91].

E. Respondent's Criminal Case

On March 26, 2008, the Respondent was arrested on six counts of prescribing ''controlled substances beyond his respective prescribing authority or for a purpose other than accepted medical treatment of a disease, condition, or illness,'' in violation of LA. REV. STAT. ANN. § 40:971(C)(1). [Govt. Exh. 5]. The Rapides Parish District Attorney's Office offered the Respondent the opportunity to participate in a pretrial intervention program. [Tr. 141]. The pretrial intervention program required that Respondent visit a parole officer monthly for a period of twenty-four months, complete one year of unsupervised probation, pay a seven thousand dollar fine, agree not to seek a DEA registration for two years, notify the Medical Board of his participation in the program, and participate in random drug testing. [Tr. 142; Resp. Exh. 2]. After successfully completing the program in February of 2011, the Respondent had the charges dismissed and the arrest expunged. [Tr. 141–142, 144; Resp. Exhs. 4 and 5].

F. The Medical Board Action and State Controlled Substance License

On June 24, 2010, the Respondent entered into a Consent Order with the Louisiana State Board of Medical Examiners (''Medical Board'') regarding his criminal charges. [Govt. Exh. 9; Resp. Exh. 8]. The Medical Board issued a public reprimand, and placed conditions upon his continued practice of medicine which included: (1) that the Respondent successfully complete the terms and conditions of the pretrial intervention program; (2) that the Respondent take continuing medical education regarding proper prescribing; and (3) that the Respondent pay a one thousand dollar fine to the Medical Board. [Tr. 146; Govt. Exh. 9 at 4]. The Respondent completed these requirements. [Tr. 148]. Currently, the Respondent maintains an active Louisiana medical license. [Tr. 111–112, 153].

Pursuant to the Consent Order with the Medical Board, on June 11–13, 2008, the Respondent took a three-day course at the University of South Florida entitled ''Prescribing Controlled Drugs: Critical Issues and Common Pitfalls of Misprescribing.'' [Resp. Exh. 9]. He credibly testified that the course taught him how to better perform an evaluation of patients seeking controlled substances. [Tr. 150].

By agreement with the Louisiana Board of Pharmacy in September 2010, the Respondent's Louisiana controlled substance license was suspended. [Govt. Exh. 24]. On February 14, 2011, his state controlled substance license was reinstated, and Dr. Zavaleta's license remains current and active, with an expiration date of August 1, 2012. [Govt. Exh. 24; Resp. Exh. 6].

G. Respondent's DEA Application

On July 1, 2011, the Respondent electronically submitted an application for a DEA certificate of registration. [Tr. 95–96; Govt. Exh. 1]. The application was certified, using the Respondent's name. [Tr. 95, 97; Govt. Exh. 1 at 4]. As part of the application for a certificate or registration, the Agency asks four ''liability'' questions. [Tr. 96–97; Govt. Exh. 1 at 3]. DEA Diversion Investigator Cheryl Golden testified that the purpose of these liability questions is to determine if there has been any previous disciplinary action taken against the applicant prior to deciding whether to approve the pending application. [Tr. 98].

On this application, the Respondent answered ''Yes'' to the second question: ''Has the applicant ever surrendered for cause or had a federal controlled substance registration revoked, suspended, restricted or denied?'' [Tr. 97; Govt. Exh. 1 at 3]. The third question asks if the applicant had ''ever surrendered for cause or had a state professional license for a controlled substance registration revoked, suspended, denied, restricted or placed on probation,'' and the Respondent answered ''No,'' to this question. [Tr. 97; Govt. Exh. 1 at 3]. However, on September 2, 2010, the Respondent's Louisiana controlled substances registration had been suspended. [Govt. Exh. 24; *see also* Govt. Exh. 8].

Subsequently, on February 14, 2011, the Respondent's Louisiana controlled substances registration was reinstated. [Tr. 100, 155; Govt. Exh. 24].

On December 8, 2010, the Respondent had also submitted an electronic application for a DEA registration.[11] [Govt. Exh. 2]. On this application, the Respondent answered ''No,'' to all four liability questions, despite having surrendered his DEA registration number BZ5998250, in March of 2008, and the suspension of his Louisiana controlled substance license in September of 2010. [Tr. 104–105; Govt. Exh. 2 at 1; Govt. Exh. 4, 8, and 24]. The Respondent did not participate in a hearing regarding this application. [Tr. 158]. He testified that his incorrect answers to the liability questions on these applications were a mistake. [Tr. 164–167, 215–218].

The Respondent credibly testified that he needs a DEA certificate of registration to obtain hospital privileges and to fully practice medicine. [Tr. 172–173, 175–176]. At the time of the hearing, the Respondent was employed at Outpatient Medical Clinic in Lisbon, Louisiana, and at Rapides Primary Healthcare. [Tr. 176–177].

IV. Statement of Law and Discussion

A. Res Judicata

On November 22, 2011, I issued an order, directing the parties to file briefs, with supporting legal authorities, on whether the doctrine of *res judicata* applies to the Final Order entered against Respondent on July 27, 2011, *see Jose Gonzalo Zavaleta, M.D.,* 76 Fed. Reg. 49,506 (DEA 2011), thus barring Respondent from ''relitigati[ng] the factual findings and conclusions of law of the prior proceeding.'' *Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16,823, 16,830 (DEA 2011). On December 16, 2011, the Government and Respondent filed briefs on this issue. *See* Government's Motion for Partial Summary Disposition and Respondent's Memorandum.

Agency precedent has repeatedly held that factual findings in DEA final orders are entitled to *res judicata. See e.g., Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16,823, 16,830 (DEA 2011); *Stanley Alan Azen, M.D.,* 61 Fed. Reg. 57,893, 57,893–94 (1996). But the Agency has also expressly limited the application of *res judicata,* refusing to apply the principle when the final order was issued without an evidentiary hearing. *Robert M. Golden, M.D.,* 65 Fed. Reg. 5,663, 5,664 (DEA 2000). In this case, the July 27, 2011 Final Order was issued against Dr. Zavaleta solely on the basis of material in the DEA's investigative file and not following an evidentiary hearing. Therefore, I found, consistent with the Agency's holding in *Golden,* that the factual findings and legal conclusions contained in the Final Order were not entitled to *res judicata* effect in this matter.[12]

B. Position of the Parties

1. Government's Position

The Government asserts that the Respondent's application should be denied based upon the Government's preponderating evidence that the Respondent's registration would be contrary to the public interest. [Govt. Brief at 22–23]. Specifically, the Government claims that the Respondent prescribed controlled substances to undercover officers without a legitimate medical purpose and outside the course of professional practice. [Govt. Brief at 15]. Further, the Government argues that by issuing prescriptions to the two undercover officers the Respondent violated state law because he failed to adequately evaluate them, document a proper diagnosis, formulate a legitimate treatment plan, conduct a drug screen for these patients, and maintain adequate medical records. [Govt. Brief at 16–17].

Next, the Government asserts that the Respondent submitted two applications for registration to the DEA that contained materially false information, specifically his responses to the four liability questions. [Govt. Brief at 18–19]. The Government argues that this conduct provides an independent basis to deny Respondent's application. [*Id.*].

Lastly, the Government argues that the Respondent has not articulated any persuasive mitigating factors. [Govt. Brief at 21–22]. The Government claims that the Respondent has never ''acknowledge[d] that he violated Federal or state law or that he assumed complete fault for his actions.'' [Govt. Brief at 21]. Rather, the Government argues that the Respondent testified at the hearing that, given the information he had at the time, he thought he had acted reasonably. [*Id.*]. Given this lack of responsibility and remorse, and the Respondent's failure to testify truthfully about the undercover visits, the Government asserts that Respondent's conduct ''belies any notion that he has accepted responsibility for his actions.'' [Govt. Brief at 22].

2. Respondent's Position

The Respondent argues that his registration is in the public interest and consequently requests that his application be granted. The Respondent notes that he has been punished by the Louisiana Medical Board and the Louisiana Board of Pharmacy for his misconduct in the prescribing of controlled substances to the undercover agents. Although he acknowledges that it is DEA's responsibility to determine the public interest in this matter, he asserts that the DEA should consider these actions when determining the appropriate remedy in this matter. [Resp. Brief at 7].

Next, the Respondent asserts that the Government did not provide an expert witness to testify concerning the legitimacy of the prescriptions written to the undercover officers. [Resp. Brief at 8–9]. He argues that the Government failed to establish that Respondent's physical examination of the undercover officers or Dr. Zavaleta's failure to request medical records for those patients was outside the usual course of professional practice. [Resp. Brief at 10]. The Respondent further argues that the Government has not alleged or proven that the Respondent's conduct was outright drug dealing. [Resp. Brief at 11]. On this point, the Respondent highlights that, although Detective Owens requested a prescription for her sister, the Respondent refused her request. [*Id.*]. Furthermore, the Respondent notes that Dr. Zavaleta has not been convicted of any offenses under federal or state law relating to his handling of controlled substances. [*Id.*].

While Respondent acknowledged that he should not have prescribed controlled substances to the undercover agents, he asserts that he offered substantial mitigating evidence ''to show he would not engage in the same conduct'' in the future. [Resp. Brief at 12]. To this point, the Respondent notes that Dr. Zavaleta completed a three-day continuing medical education course in prescribing controlled substances. [*Id.*]. The Respondent also points out that Dr. Zavaleta cooperated with all agencies involved in this matter, and that he admitted that he made a mistake in prescribing to the undercover officers. [*Id.*]. The Respondent claims he demonstrated remorse for his conduct. [*Id.*]. He admitted he had failed and that he had learned his lesson when it came to prescribing controlled substances. [Resp. Brief at 13].

As for material falsification, the Respondent acknowledges that he had failed to answer the liability questions correctly on his two applications for

[11] Although the record copy of Government Exhibit 2 is not a certified copy, DI Golden credibly testified that she confirmed that a certified copy of the registration was on file at DEA. [Tr. 104].

[12] I have attached the relevant order and the parties' briefs as appendix A & B for the Deputy Administrator's consideration.

registration. But, the Respondent argues that his error on these applications was unintentional, because he had ''no reason to hide the information.'' [*Id.*]. However, he concedes that ''[n]o matter how unintentional, his failure [to correctly answer the liability questions] could have the tendency to affect the outcome of his application thereby being materially false.'' [*Id.*].

In conclusion, the Respondent argues that granting his application would be consistent with the public interest. [Resp. Brief at 13–14]. Although the Respondent engaged in misconduct, he asserts that he ''has done everything within his control to make sure this does not happen again.'' [Resp. Brief at 14]. The Respondent ''believes he has demonstrated to this Court that he is remorseful for his actions and will not repeat the same behavior.'' [*Id.*]. Therefore, he requests that his application be approved. [*Id.*].

C. Statement of Law

Section 823(f) of the Controlled Substances Act (''CSA'' or ''the Act'') provides that ''[t]he Attorney General [13] may deny an application for [a practitioner's] registration if he determines that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination, the Act requires the consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to 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. 21 U.S.C. § 823(f).

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 Fed. Reg. 15,227, 15,230 (DEA 2003). The Deputy Administrator may rely on any one or a combination of factors, and may give each factor the weight he deems appropriate in determining whether an application for a registration should be denied. *Id.* Moreover, the Deputy Administrator is ''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).

The Government bears the burden of proving that the requirements for registration are not satisfied. 21 C.F.R. § 1301.44(d) (2011). The burden of proof shifts to the Respondent once the Government has made its *prima facie* case. *Medicine Shoppe—Jonesborough,* 73 Fed. Reg. 364, 380 (DEA 2008). The Agency has recognized that ''past performance is the best predictor of future performance.'' *ALRA Labs, Inc. v. DEA,* 54 F.3d 450, 452 (7th Cir. 1995). Further, the Agency has repeatedly held that ''where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for (his) actions and demonstrate that (he) will not engage in future misconduct.'' *Medicine Shoppe,* 73 Fed. Reg. at 387; *see also Samuel S. Jackson, D.D.S.,* 72 Fed. Reg. 23,848, 23,853 (DEA 2007). In short, after the Government makes its *prima facie* case, the Respondent must prove by a preponderance of the evidence that he can be entrusted with the authority that a registration provides by demonstrating that he accepts responsibility for his misconduct and that the misconduct will not re-occur.

Under Section 824(a)(1), a registration may also be revoked or suspended ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. § 824(a)(1) (2006). Under Agency precedent, the various grounds for revocation or suspension of an existing registration that Congress enumerated in 21 U.S.C. § 824(a), are also properly considered in deciding whether to grant or deny an application under section 823. *See Anthony D. Funches,* 64 Fed. Reg. 14,267, 14,268 (DEA 1999); *Alan R. Schankman, M.D.,* 63 Fed. Reg. 45,260, 45,260 (DEA 1998); *Kuen H. Chen, M.D.,* 58 Fed. Reg. 65,401, 65,402 (DEA 1993).

Although the Government did not assert material falsification in the Order to Show Cause, the Government did place the Respondent properly on notice of this allegation in the Government's Supplemental Prehearing Statement. Thus, the allegation that the Respondent materially falsified his application is properly considered in this proceeding. *George Mathew, M.D.,* 75 Fed. Reg. 66,138, 66,146 (DEA 2010) (''[T]he failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.''); *CBS Wholesale Distributors,* 74 Fed. Reg. 36,746, 36,750 (DEA 2009). Longstanding Agency precedent has held that the scope of a DEA administrative hearing is determined not only by the allegations contained in the OSC, but also by the parties' prehearing statements. *Darrell Risner, D.M.D.,* 61 Fed. Reg. 728, 730 (DEA 1996); *John Stanford Noell, M.D.,* 59 Fed. Reg. 47,359, 47,361 (DEA 1994).

1. The Material Falsification Allegation

A false statement is material if it ''has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed.'' *Kungys v. United States,* 485 U.S. 759, 770 (1988). While the evidence must be ''clear, unequivocal, and convincing,'' the ultimate finding of materiality ''turns on a substantive interpretation of the law.'' *Id.* at 772; *see also Craig H. Bammer, D.O.,* 73 Fed. Reg. 34,327, 34,328 (DEA 2008). However, '[i]t makes no difference that a specific falsification did not exert influence so long as it had the *capacity to do so.*''' *United States v. Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985).

The record raises the issue of whether the Respondent's failure to correctly answer the liability questions on his most recent application and his application in December of 2010 resulted in a material falsification of those applications. DEA has previously held that ''[t]he provision of truthful information on applications is absolutely essential to effectuating [the] statutory purpose'' of determining whether the granting of an application is consistent with the public interest. *Peter H. Ahles, M.D.,* 71 Fed. Reg. 50,097, 50,098 (DEA 2006). In the July 2011 application, the Respondent disclosed his voluntary surrender of his DEA registration. However, he failed to disclose the suspension of his Louisiana controlled substance license, which occurred in September of 2010. Clearly, the Respondent knew or should have known about this suspension by July of 2011. Likewise, in the December 2010 application, the Respondent failed to disclose his voluntary surrender of his DEA registration in March of 2008, or the suspension of his Louisiana controlled substance license in September of 2010.

I find these omissions resulted in the material falsification of the Respondent's applications. Clearly, this information was capable of influencing the decisionmaker in this matter. Respondent's lack of full disclosure in these applications weighs heavily in favor of denying his application for a certificate of registration. *See Shannon L. Gallentine, D.P.M.,* 76 Fed. Reg. 45,864, 45,866 (DEA 2011).

[13] The Deputy Administrator has the authority to make such determinations pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2011).

2. Factor One: Recommendation of the Appropriate State Licensing Board

While the Medical Board's recommendation is probative, ''DEA maintains a separate oversight responsibility with respect to the handling of controlled substances and has a statutory obligation to make its independent determination as to whether the granting of [a registration] would be in the public interest.'' *Mortimer B. Levin, D.O.,* 55 Fed. Reg. 8,209, 8,210 (DEA 1990); *see also Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 461 (DEA 2009). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 Fed. Reg. 6,580, 6,590 (DEA 2007), *aff'd,* 533 F.3d 828 (DC Cir. 2008). Although not dispositive, state board decisions are relevant on the issue of granting or denying a DEA application. *Gregory D. Owens, D.D.S.,* 74 Fed. Reg. 36,751, 36,755 (DEA 2009); *Martha Hernandez, M.D.,* 62 Fed. Reg. 61,145, 61,147 (DEA 1997).

Here, the Medical Board has not made a direct recommendation concerning the Respondent's DEA application. However, on June 24, 2010, the Respondent entered into a Consent Order with the Louisiana Medical Board. Although not admitting to any misconduct, the Respondent agreed to the Medical Board's action and conditions placed upon his medical license. Specifically, the Medical Board issued a public reprimand, and, among other conditions, required the Respondent to take a continuing medical education course regarding proper prescribing. The Respondent completed all of the requirements levied by the Medical Board, and he currently has an unrestricted, active medical license. Therefore, I find that this factor does not weigh in favor or against Respondent's application for a DEA certificate of registration.

3. Factors Two and Four: The Applicant's Experience With Controlled Substances and Compliance With Applicable State, Federal, or Local Laws Relating To Controlled Substances.

DEA regulation dictates that a prescription, to be valid, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 21 C.F.R. § 1306.04(a) (2011); *see also* LA. REV. STAT. ANN. § 40:1238.2 (2011).[14] As the Supreme Court 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 *United States v. Moore,* 423 U.S. 122, 135 (1975)). Further, a valid prescription under Louisiana law is defined as a ''a written request for a drug. . . issued by a licensed physician. . . for a legitimate medical purpose, for the purpose of correcting a physical, mental, or bodily ailment, and acting in good faith in the usual course of his professional practice.'' LA. REV. STAT. ANN. § 40:961(33) (2011).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act ''in the usual course of. . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Laurence T. McKinney, M.D.,* 73 Fed. Reg. 43,260, 43,265 (DEA 2008); *see also Moore,* 423 U.S. 142–43 (noting that evidence established that physician ''exceeded the bounds of ''professional practice,'' when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against. . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. *Kamir Garces-Mejias, M.D.,* 72 Fed. Reg. 54,931, 54,935 (DEA 2007); *United Prescription Services, Inc.,* 72 Fed. Reg. 50,397, 50,407–08 (DEA 2007).

Here, Louisiana law provides that it is unlawful for a physician to ''assist a patient. . . in obtaining a controlled dangerous substance through misrepresentation, fraud, forgery, deception, or subterfuge.'' LA. REV. STAT. ANN. § 40:971.2(B)(1) (2011). By coaching Mr. Harris and Ms. Landry to state they were in pain, and by falsely documenting their medical records to record these pain complaints when neither patient expressed that they were in pain is a violation of this provision.

Louisiana law pertaining to the treatment of chronic pain requires a physician to evaluate the patient to include an ''assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies, an assessment of co-existing illnesses, diseases, or conditions, and an appropriate physical examination.'' LA. ADMIN. CODE tit. 46, § 6921(A)(1) (2011). Here, the Respondent failed to meet this standard, for he did not perform a physical or psychological functions analysis, did not review previous diagnostic studies, previously utilized therapies, or conduct an appropriate physical examination of either Mr. Harris or Ms. Landry. *See Armstrong v. La. State Bd. Of Med. Examiners,* 868 So. 2d 830, 840 (La. Ct. App. 2004) (noting that when a physician prescribes controlled substances for the relief of non-malignant pain ''unaccompanied by appropriate testing, diagnosis, oversight and monitoring. . . the physician falls below generally accepted standards of care''). Although the Respondent looked at the patients' backs, such observation may not be an adequate physical examination. *Jack A. Danton, D.O.,* 76 Fed. Reg. 60,900, 60,910 (DEA 2011) (noting without deciding that mere observation may not be an adequate physical examination).

Further, the Respondent failed to develop an individualized treatment plan for Mr. Harris and Ms. Landry. Louisiana law requires a physician to develop such a plan and to document the plan in the patient's medical records. The plan is to include ''medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's non-cancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.'' LA. ADMIN. CODE tit. 46, § 6921(A)(3) (2011). The medical records here failed to reveal such an individualized treatment plan. Especially lacking in these medical records were any indications that alternative treatments were attempted prior to issuing prescriptions for controlled substances. LA. ADMIN. CODE tit. 46, § 6921(B)(6)(2011).

In the case of Ms. Landry and her multiple visits to Dr. Zavaleta's clinic, the Respondent failed to assess the efficacy of her treatment. Louisiana law requires a physician to ''assure that controlled substance therapy remains

[14] This statutory provision provides in relevant part: A prescription, in order to be effective in legalizing the possession of legend drugs, shall be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs * * * Any person who knows or should know that he or she is filling such a prescription * * * to a drug abuser or habitual user of legend drugs, as well as the person issuing the prescription, may be charged with a violation of this Section. LA. REV. STAT. ANN. § 40:1238.2(A) (2011).

indicated, and evaluate the patient's progress toward treatment objectives.'' LA. ADMIN. CODE tit. 46, § 6921(B)(1). Ms. Landry's chart failed to disclose any treatment objectives, and thus, her progress towards meeting those objectives was also lacking.

Louisiana law also requires a physician to ''document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.'' *Id.* at (B)(5). The Respondent violated this provision when he added Xanax to Ms. Landry's prescriptions without documenting the medical necessity for this anti-anxiety medication.

Lastly, Louisiana case law establishes that it is a violation of the legitimate medical purpose provision when a physician provides a patient with controlled substances based upon their request for the drug. *See Louisiana v. Moody,* 393 So. 2d 1212, 1215 (La. 1981). Both Mr. Harris and Ms. Landry specifically requested hydrocodone products, and the Respondent provided them with a prescription for this requested controlled substance. Further, given the statements by both Mr. Harris and Ms. Landry that they were not experiencing any pain, the Respondent violated this provision when he prescribed Lorcet or Lortab for their non-existent pain.

Accordingly, I find that the Government has made a *prima facie* case regarding the failure of the Respondent to prescribe controlled substances for a legitimate medical purpose in the usual course of professional practice.[15]

4. Respondent's Remorse and Corrective Action

The critical consideration in this proceeding is whether the circumstances, which existed at the time of the surrender of his registration in 2008, have changed sufficiently to support a conclusion that Respondent's registration would be in the public interest. *Ellis Turk, M.D.,* 62 Fed. Reg. 19,603, 19,604 (DEA 1997). As this Agency has repeatedly held, a proceeding under the Act ''is a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused. . . their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be entrusted with the responsibility carried by such a registration.'' *Jon Karl Dively, D.D.S.,* 72 Fed. Reg. 74,332, 74,334 (DEA 2007).

At the hearing, the Respondent acknowledged that he should have refused to provide Mr. Harris with the Lortab prescription he requested without prior records or validating tests. He credibly testified that he agreed that providing Mr. Harris with a prescription for hydrocodone was not for a legitimate medical purpose. Nevertheless, I remain concerned about the Respondent's insistence at the hearing that Mr. Harris had told him that he had back pain. My review of the undercover recording does not substantiate his assertion, and Mr. Harris credibly testified that he had not told the Respondent that he had any pain. To his credit, however, when Mr. Harris returned to his office, the Respondent refused to treat him.

Likewise, at the hearing the Respondent admitted that he had not prescribed controlled substances to Ms. Landry for a legitimate medical purpose. Although Ms. Landry asserted that she needed a refill of her controlled substance prescription, the Respondent took no action to verify that her original controlled substance prescription had been provided for a legitimate medical purpose. To his credit, at the first visit Ms. Landry had requested a prescription for her sister, and the Respondent refused to provide her with such a prescription. But despite Ms. Landry's credible testimony denying that she had told the Respondent that she had any type of pain, the Respondent testified that he thought, at the time he wrote the prescriptions, that he was right in his prescribing to her. The Respondent's lack of forthrightness is troubling.

Lastly, the Respondent was cooperative with the investigators. He also took remedial training in the handling of controlled substances, and he credibly testified that he is more knowledgeable about drug-seeking behavior.

V. Conclusion and Recommendation

In balance, however, I find that the Respondent's current lack of candor, his material falsification of his DEA applications, and his illegal prescribing of controlled substances in 2008 outweigh his assertions that he can now responsibly handle controlled substance prescriptions. Accordingly, I recommend that the Respondent's current application be denied. Should the Respondent file an application wherein he fully discloses the surrender of his DEA registration for cause and the suspension of his Louisiana controlled substance license, then such candor may be favorably considered.

Dated: May 10, 2012.

Gail A. Randall,

Administrative Law Judge.

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[15] Given the overwhelming evidence of the Respondent's failure to issue controlled substances for a legitimate medical purpose, I do not address the Government's allegations that the Respondent's flirtatious behavior with Ms. Landry was outside the usual course of professional practice.

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1622]

NIJ Evaluation of Hand-Held Cell Phone Detector Devices

AGENCY: National Institute of Justice, Department of Justice.

ACTION: Notice.

SUMMARY: The National Institute of Justice (NIJ) is soliciting interest in supplying hand-held cell phone detector devices for participation in an evaluation by the NIJ Corrections Technology Center of Excellence (CXCoE).

SUPPLEMENTARY INFORMATION: NIJ is soliciting interest in supplying hand-held cell phone detector devices for participation in an evaluation by the NIJ Corrections Technology Center of Excellence (CXCoE). The evaluation is focused on field operation in correctional facility scenarios. Supplied hand-held cell phone detectors must:

- Weigh less than 8 lbs,
- Be battery operated with a minimum run time of 2 hours,
- Be designed for single person operation, and
- Operate using Radio Frequency (RF) and/or Non-Linear Junction Detection (NLJD) technology

Manufacturers interested in participating in this evaluation will be asked to execute a Letter of Understanding. Participating manufacturers will receive a copy of the CXCoE Test & Evaluation Plan. Interested parties are invited to contact NIJ for information regarding participation, Letters of Understanding, and shipping. Letters of Understanding may be obtained from and should be submitted to Jack flame, National Institute of Justice, Office of Science and Technology, 810 7th Street NW., Washington, DC 20531, emailed to *jack.harne@usdoj.gov,* or faxed to (202) 305–9907.

DATES: Manufacturers who wish to participate in the program must submit a request and an executed Letter of Understanding by 5 p.m. Eastern Time