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**BILLING CODE 4410–15–P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Consent Decree Under the Clean Air Act

Notice is hereby given that on June 16, 2009, a proposed Consent Decree (Decree) in the case of *United States* v. *American Laboratories, Inc.*, Civil Action No. 8:09–CV–00194, was lodged with the United States District Court for the District of Nebraska. Under this Consent Decree, the Settling Defendant is required to pay a total of $440,000 in civil penalty for alleged violations of the Clean Air Act, and recover and reuse at 93% of total isopropyl alcohol and implement best available control technology at its pharmaceutical manufacturing plant in Omaha, Nebraska.

For thirty (30) days after the date of this publication, the Department of Justice will receive comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment 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. In either case, the comments should refer to *United States* v. *American Laboratories, Inc.*, D.J. Ref. No. 90–5–2–1–08313.

The Decree may be examined at the Office of the United States Attorney, 1620 Dodge Street, Suite 1400, Omaha, Nebraska 68102. During the comment period, the Consent Decree may be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent 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 $9.25 (with attachments) or $8.00 (without attachments) (25 cents per page reproduction cost) payable to the United States Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

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**BILLING CODE 4410–15–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 07–14]**

### CBS Wholesale Distributors; Grant of Renewal Application and Dismissal of Proceeding

On January 5, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to CBS Wholesale Distributors (Respondent), of Hephzibah, Georgia. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration which authorizes it to distribute List I chemicals, and the denial of any pending applications to renew or modify the registration, on the ground that his ''registration is inconsistent with the public interest.'' Show Cause Order at 1.

More specifically, the Show Cause Order alleged that Respondent is ''currently registered to distribute the List I chemicals pseudoephedrine and ephedrine,'' *id.* at 2, and that both chemicals are ''commonly used to illegally manufacture methamphetamine, a schedule II controlled substance.'' *Id.* at 1. The Show Cause Order alleged that ''there exists a 'gray market' in which certain pseudoephedrine and ephedrine products are distributed only to convenience stores and gas stations, from where they have a high incidence of diversion,'' and that these establishments ''continue to be the primary source for precursors to be diverted to illicit methamphetamine laboratory operations in many states.'' *Id.* at 1–2.

Next, the Show Cause Order alleged that DEA had retained ''an expert in the field of retail marketing and statistics to analyze national sales data for over-the-counter non-prescription drugs.'' *Id.* at 2. The Order alleged that the expert had determined that ''the average small store could expect to sell monthly only about $10.00 to $30.00 worth of pseudoephedrine products,'' and ''that the potential for sales of combination ephedrine products [was] only about one-fourth of those sales levels.'' *Id.*

The Show Cause Order further alleged that Respondent's list I customers ''are almost exclusively convenience stores and gas stations, which are part of the gray market for diversion'' of these products, *id.* at 2, and that Respondent's ''sales of combination ephedrine products are inconsistent with the known legitimate market and known end-user demand for products of this type.'' *Id.* at 3. The Order further alleged that Respondent is ''serving an illegitimate market and [that its] continued registration would likely lead to increased diversion of List I chemicals.'' *Id.*[1]

Respondent timely requested a hearing on the allegations. The matter was placed on the docket of the Agency's Administrative Law Judges (ALJ), and an ALJ conducted a hearing in Savannah, Georgia on December 4–5, 2007. At the hearing, both the Government and Respondent elicited the testimony of witnesses and submitted documentary evidence. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and arguments.

On June 10, 2008, the ALJ issued her recommended decision (ALJ). In her decision, the ALJ found persuasive the expert testimony of the Agency's expert witness that the average monthly sale of ephedrine products to meet legitimate demand is $14.39 and that Respondent's customers were purchasing between five to eighty times this amount. ALJ at 33. The ALJ thus concluded that Respondent's sales of ephedrine products ''to gray market entities are so grossly excessive that there is a high probability that these products are being diverted for illicit purposes, and that this fact alone outweighs'' the evidence that Respondent provided adequate physical security for the products, maintained adequate records, and was selling only to customers who had obtained the required certification under the Combat Methamphetamine Epidemic Act. *Id.* at 34. The ALJ thus also concluded that ''Respondent's continued registration would be inconsistent with the public interest,'' *id.* at 36, and recommended that its registration be revoked and that any pending applications to renew or

[1] The Show Cause Order also alleged that Respondent had ''assisted * * * a former DEA registrant, in maintaining his customer base [of convenience stores and gas stations] for combination ephedrine products, after he surrendered his * * * registration for cause.'' Show Cause Order at 2. The Government, however, offered no evidence in support of this allegation.

modify its registration be denied. *Id.* at 37.

Respondent filed Exceptions to the ALJ's decision. Thereafter, the record was forwarded to me for final agency action.

Having considered the record as a whole (including Respondent's exceptions), I hereby issue this Decision and Final Order. I conclude that the Government's allegation that Respondent's sales levels are so excessive as to warrant the conclusion that its products are being diverted is not proved by substantial evidence. I further hold that because the Government failed to provide notice to Respondent in either the Show Cause Order or its pre-hearing statement that it intended to put in issue Respondent's sales of glass roses, an item which the Government alleges is used as drug paraphernalia, Respondent has not been provided with a full and fair opportunity to litigate the issue. Consistent with the requirements of the Due Process Clause, I conclude that this issue cannot be considered by the Agency. Accordingly, the Show Cause Order will be dismissed. I make the following findings.

**Findings**

Respondent is a wholesale distributor of sundry items to convenience stores and gas stations which is owned and operated by Charles Marshall, Sr., and Charles Marshall, Jr. (a/k/a Bubba). Tr. 199. Respondent is located in Hephzibah, Georgia. *Id.* at 199, 201–03; GX 1. Among the items Respondent distributes are non-prescription drug products containing ephedrine, Tr. 202, a schedule listed chemical product under the Controlled Substances Act. 21 U.S.C. 802(45); *see also id.* section 802(34).

Respondent has held a DEA Certificate of Registration authorizing it to distribute listed chemicals since 1999. GX 2. While the expiration date of Respondent's registration certificate is August 23, 2006, Respondent applied for a renewal of its registration prior to its expiration date and it is undisputed that its registration has remained in effecting pending the issuance of this Order. GX 2; *see also* 5 U.S.C. 558(c).

Ephedrine (in combination with guaifenesin) is currently approved under the Food, Drug and Cosmetic Act for marketing as a bronchodilator for use in treating asthma. GX 7, at 3–4. Ephedrine is, however, regulated as a List I chemical under the Controlled Substances Act because it is extractable from non-prescription drug products and frequently diverted into the illicit manufacture of methamphetamine, a schedule II controlled substance. 21 CFR 1308.12(d).

Methamphetamine ''is a powerful and addictive central nervous system stimulant.'' *T. Young Associates, Inc.,* 71 FR 60567 (2006). As noted in numerous Agency decisions, the illegal manufacture and abuse of methamphetamine pose a grave threat to this Nation. *See, e.g., id.* Methamphetamine abuse has destroyed numerous lives and families, and has had a devastating impact on many communities. *Id.* Moreover, because of the toxic nature of the chemicals used in making the drug, illicit methamphetamine laboratories create serious environmental harms. *Id.*

**The Investigation of Respondent**

On March 5, 2005, a DEA Diversion Investigator visited Respondent to conduct a regulatory investigation. Tr. 138–39. The DI met with Charles Marshall, Sr., and Bubba Marshall. *Id.* at 149–50. During the inspection, the DI determined that Respondent was selling combination ephedrine products, which included a brand that is ''notoriously popular [with] methamphetamine traffickers.'' *Compare* GX 4 *with* GX 6 at 12; *see also* Tr. 24. The DI also obtained from Respondent a customer list which indicated that it was selling the products to gas stations, convenience stores, and small markets. Tr. 135 & GX 5.

During the inspection, the DI concluded that Respondent did not provide adequate physical security for the products. Tr. 149. More specifically, the DI found that the products were being left overnight on Respondent's truck and were not being returned to its storage warehouse. *Id.* at 152. Moreover, the DI also noted that Respondent was storing the products in what she described as ''a shed,'' that the shed had a window, and that anyone who knew ''what they were looking for could see the product.'' *Id.* at 156. The DI ''recommended'' to the Marshalls that they cover the windows so that a person could not see the product. *Id.* at 156.

It is undisputed, however, that the Marshalls promptly complied with her recommendation regarding the storage facility.[2] *Id.* at 156–57, 212. It is also undisputed that following the inspection, Respondent ceased its practice of leaving the products on its truck and now returns them to its storage facility each night. *Id.* at 211.

At the hearing, the DI also testified that Respondent's recordkeeping was inadequate because the invoices ''were not complete'' and ''[i]t was very hard to determine * * * who they sold [the products] to, the addresses where the people were located, [and] how much they sold.'' *Id.* at 153. The Government did not, however, offer into evidence any of the invoices the DI reviewed at the time of the inspection. Moreover, in support of its allegation that Respondent sells excessive quantities of the products, the Government introduced into evidence numerous invoices for the period January through March 2007. *See* GX 11. Yet the Government does not point to any of these invoices as evidence that Respondent's recordkeeping practices remain deficient. *See generally* Gov. Proposed Findings of Fact and Conclusions of Law [hereinafter, Gov. Br.]

In support of the principal allegation of its case in chief, the Government called Jonathan Robbin to testify as an expert witness and introduced several exhibits which were prepared by him. *See* GX 8, 9, 14–18. The thrust of Mr. Robbin's presentation was that the overwhelming majority of the commerce in non-prescription drugs takes place at pharmacies, supermarkets, large discount stores, and electronic shopping/mail order retailers, and that convenience stores and gas stations account for only ''a very small percentage of the sales of '' these products. *See* GX 9, at 4. Mr. Robbin further testified that using various data sources such as the U.S. Economic Census, the National Association of Convenience Stores' 2007 State of the Industry Survey, the Mediamark Research, Inc. (MRI) survey of consumers, and scanner data, he determined that the ''expected retail sale of ephedrine * * * tablets in a convenience store ranges between $0 and $29, with an average of $14.39 and a standard deviation of $5.76.'' *Id.* at 8. Mr. Robbin further opined that ''[a] monthly retail sale of $60 of ephedrine/guaifenesin (Hcl) tablets would be expected to occur about once in a million times in random sampling.'' *Id.*

Both Mr. Robbin's declaration and his testimony failed to adequately explain how he arrived at his estimates. While Mr. Robbin apparently used NACS Survey's data which indicates that convenience stores sold a total of $ 292 million of cough and cold remedies nationwide, and asserted under oath that in calculating the average sales per store figure he used the number of stores which actually sell non-prescription

[2] It is also undisputed that in 2003, Respondent had moved to its current location. Tr. 204. At that time, Respondent sought a modification of its registration; a DEA Investigator visited Respondent, inspected its storage facility, and found it satisfactory. *Id.*

drug products, Tr. 107; in another proceeding, it was shown that in calculating the same average sales per store figure, he had used the total number of stores selling any item in the Health and Beauty Care (HABC) line and not the smaller number of stores which sold non-prescription drugs. *See Novelty Distributors,* 73 FR 52689, 52693 (2008).

Moreover, when questioned in this proceeding as to how he determined that sales of combination ephedrine products constitute eight percent of the sales of cough and cold products, Mr. Robbin did not submit the documentation to support this figure and acknowledged that it was ''a missing link in this presentation.'' Tr. 104. While Mr. Robbin maintained ''that this eight percent is an accurate number as reflected by'' the MRI Survey of 50,000 consumers, *id.* at 105, as I also found in *Novelty,* the MRI Survey does not ask questions which are sufficient to establish the extent to which consumers purchase and use ephedrine products.[4] *See* 73 FR 52693–94. Accordingly, as in *Novelty,* I conclude that the Government's estimated sales range to meet legitimate demand for combination ephedrine products is not supported by substantial evidence. I am therefore also compelled to reject Mr. Robbin's testimony regarding the statistical probability that Respondent's ephedrine sales were to meet legitimate demand and that Respondent sold ''combination ephedrine * * * products in extraordinary excess of normal or traditional demand.'' GX 9 at 13; *see also* Tr. at 90–92.

To be sure, the estimated retail sales of some of Respondent's ephedrine customers were several times the average sales for cough and cold products as reported by the NACS Survey. *See* GX 10, at 62 (indicating that in 2005, the average store sold $2,556, and in 2006, the average store sold $2,040 of the products). It appears, however, that the Survey's average sales figure was computed by dividing the total volume of cough and cold product sales ($292 million nationwide) by the total number of convenience stores, regardless of whether the stores sell non-prescription drug products. *See* GX 10, at 4 (indicating that there are a total of 145,119 convenience stores (including both stores that sell and do not sell gasoline) in the US). The average sales of stores actually selling the products is thus likely several times higher than the figure reported by NACS; and in any event, the NACS Survey not report any of the information necessary (such as the median and standard deviation) necessary to determine the statistical probability of various sales levels. The evidence is therefore insufficient to support the Government's allegation that Respondent's ''sales of combination ephedrine products are inconsistent with the known legitimate market and known end-user demand for products of this type.'' Show Cause Order at 3.

**The Evidence Related to Respondent's Sales of Glass Roses**

The Government also questioned the DI as to whether Respondent sold ''glass roses.''[6] Tr. 129. The DI answered ''yes''; the Government then asked what the items were used for. *Id.* Respondent's counsel promptly objected to the question. *Id.* More specifically, Respondent's counsel objected on two grounds: (1) That the Show Cause Order contained no allegation regarding Respondent's sale of this product, and (2) that the Government did not disclose in its Pre-Hearing Statement that it would elicit testimony from the DI regarding Respondent's sales of the item and its use as drug paraphernalia. *Id.* at 129–31.

The ALJ overruled the objection. *Id.* at 133. The Government again asked the DI whether Respondent sold glass roses; the DI again answered that it did. *Id.*

The Government again asked the DI what glass roses were used for, and once more, Respondent's counsel objected. *Id.* Before ruling on the objection, the ALJ asked ''what are glass roses?'' *Id.* The DI answered that the product is ''a thin glass container with a rose in it and typically what it's used for is somebody could come in and give a rose to a friend. But these have been known to be used for smoking dope. They take the rose out and use them to smoke dope.'' *Id.* at 133–34.

The ALJ then stated she was ''going to provisionally allow this testimony,'' but that Respondent could ''move to strike it after * * * it's complete.'' *Id.* at 134. When the Government stated that the testimony was complete, Respondent moved to strike it. *Id.* The ALJ deferred ruling on the motion, stating that she was taking the matter ''under advisement.'' *Id.* The record, however, contains no indication that the ALJ ever ruled on the motion.

On cross-examination, Bubba Marshall admitted that his business sold glass roses. *Id.* at 215. The Government then asked Mr. Marshall when he found out that this item is ''being used for drug paraphernalia?'' *Id.* at 216. Mr. Marshall answered: ''I heard that they'd been used as drug paraphernalia, I've never witnessed it.'' *Id* . Under further questioning, Mr. Marshall stated that he had ''probably'' known this for ''over a year'' and that he had continued to sell this product. *Id.* at 216–17. Continuing, the Government asked Mr. Marshall whether he had acted responsibly in selling the product. *Id.* at 217. When Mr. Marshall reiterated that he had ''only heard they were used as drug paraphernalia,'' the Government asked him if he had investigated the product's misuse. Mr. Marshall answered ''no,'' and added ''how should I investigate it?'' *Id.*

On re-direct examination, Respondent's counsel asked Mr. Marshall whether the glass roses had uses other than as drug paraphernalia. *Id.* at 223. Mr. Marshall answered: ''[i]t's a novelty.'' *Id.* He also maintained that he had never been told by any of his customers that the item was used as drug paraphernalia and that none of his customers had told him that the item was being purchased in conjunction with ephedrine products. *Id.* at 224.

**Discussion**

Section 304(a) of the Controlled Substances Act provides that a registration to distribute a list I chemical ''may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). Moreover, under section 303(h), ''[t]he Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest.'' 21 U.S.C. 823(h). In making the public interest determination, Congress directed that the following factors be considered:

[4] For example, the survey asks ''[h]ow may times in'' different time periods a person has used one of numerous products. 72 FR at 52694. While the survey lists a variety of non-prescription cold, sinus, and allergy products, none of the products contains ephedrine. *Id.* Indeed, an ephedrine product is not listed anywhere in the survey.

The survey also asks whether a person has had asthma in the last twelve months and whether they have used a prescription drug, a non-prescription drug, an herbal remedy, or have not treated the condition at all. *Id.* The survey does not, however, ask any further questions regarding the use of non-prescription drugs to treat asthma. *Id.*

It may well be the case that the use of ephedrine products to treat asthma has become so minimal that the designers of the MRI Survey consider the product to be inconsequential. But even if this is so, the Government still has the burden of adequately explaining how it determined that ephedrine sales constitute eight percent of cough and cold sales.

[6] In the pleadings, this item was also referred to a love rose. Both terms are therefore used in this decision.

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

*Id.* section 823(h).

''These factors are considered in the disjunctive.'' *Joy's Ideas,* 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether a registration should be revoked or an application for a registration should be denied. *See, e.g., David M. Starr,* 71 FR 39367, 39368 (2006); *Energy Outlet,* 64 FR 14269 (1999). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

The Government, however, bears the burden of proof. 21 CFR 1301.44(d). Having considered the entire record in this matter, I conclude that Government has failed to establish that Respondent does not maintain effective controls against diversion. I also conclude that the allegation that Respondent was selling drug paraphernalia is not properly before the Agency. Accordingly, the Government has not established that Respondent has committed acts which render its registration ''inconsistent with the public interest.'' 21 U.S.C. 823(h). The Order to Show Cause will therefore be dismissed.

**Factor One—Maintenance of Effective Controls Against Diversion**

As established in several agency decisions, this factor encompasses a variety of considerations including, *inter alia,* the adequacy of physical security, the adequacy of recordkeeping, and whether a registrant is selling excessive quantities of the products. *See Holloway Distributing, Inc.,* 72 FR 42118, 42123 (2007); *Rick's Picks, L.L.C.,* 72 FR 18275, 18278 (2007); *John J. Fotinopoulos,* 72 FR 24602, 24605 (2007). In the Order to Show Cause and its Pre-Hearing Statement, the Government provided notice that it would be litigating two issues that are relevant to this factor: (1) The adequacy of Respondent's recordkeeping as purportedly shown by the results of an audit conducted during the March 2005 inspection, and (2) that Respondent was selling volumes of listed chemicals products that are inconsistent with legitimate demand.[7]

At the hearing, however, the Government did not introduce into evidence the audit results. Moreover, while a DI asserted in her testimony that Respondent's recordkeeping was inadequate because its invoices were incomplete, the Government did not offer any of the invoices to show why. Moreover, while the Government obtained numerous other invoices which it used to calculate Respondent's sales levels during the period of January through March 2007, here again, it does not cite any of these invoices as proof of its contention that Respondent's recordkeeping is inadequate. The allegation is thus rejected.

As for the allegation that Respondent was selling excessive quantities of combination ephedrine products, even if only a small percentage of the commerce in non-prescription drugs occurs at non-traditional retailers, neither the testimony nor the written declaration of the Government's expert adequately explains how he calculated the average monthly sales figure or the statistical probability that various sales levels were consistent with legitimate demand. Moreover, in his testimony, the expert acknowledged that there was ''a missing link in this presentation'' with respect to his determination that combination ephedrine products comprise eight percent of the sales of cough and cold products.

In sum, the expert did not provide the underlying documentation necessary to support this critical component of his testimony. Not only did this deny Respondent a meaningful opportunity to challenge the expert's conclusion, *see* Resp. Proposed Findings of Fact and Conclusions of Law at 23; as I have previously held, it also precludes a finding that the expert's conclusions are supported by substantial and reliable evidence. *See* 5 U.S.C. 556(d); *see also Novelty,* 73 FR at 52693–94. The Government's allegation that Respondent was selling excessive quantities of combination ephedrine products (as well as its contention that Respondent does not maintain effective controls against diversion) must therefore be rejected.

**Factor Two—Respondent's Compliance With Applicable Laws**

At the hearing, the Government was allowed to elicit testimony—over Respondent's objection—of the DI who performed the 2005 inspection that Respondent sold love roses/glass roses, an item which the Government maintains is drug paraphernalia because it is used to smoke illicit drugs. Moreover, during its cross-examination of Bubba Marshall, the Government obtained his admissions that (1) he had heard that this item had been used as drug paraphernalia, and (2) that Respondent had continued to sell the product. Mr. Marshall also maintained, however, that the item had other legitimate uses, such as as a novelty item.

The Government did not, however, allege in the Order to Show Cause that Respondent had sold these items and had violated either Federal or State law in selling them. The Government likewise did not disclose in its pre-hearing statement that Respondent's sales of this product would be at issue in this proceeding. Finally, the Government failed to disclose at any time prior to the hearing that it intended to put this conduct in issue. As explained below, consistent with fundamental principles of Due Process and the requirements of the Administrative Procedure Act, the Government's failure to provide any notice that this allegation would be litigated precludes the Agency's consideration of the issue.

One of the fundamental tenets of Due Process is that Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *See NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc.,* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990). *See also* 5 U.S.C. 554(b) (''Persons entitled to notice of an agency hearing shall be timely informed of * * * the matters of fact and law asserted.'').

To be sure, '' '[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.' '' *Citizens State Bank of Marshfield* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984) (quoting *Aloha Airlines* v. *Civil Aeronautics Bd.,* 598 F.2d 250, 262 (D.C. Cir. 1979)).

[7] At the hearing, the DI also testified that during the March 2005 inspection, Respondent's storage facility did not provide adequate physical security and that Respondent was storing products on its truck overnight and not returning them to its storage unit. While this issue was not raised in either the Order to Show Cause or the Government's Pre-Hearing Statement, Respondent did not object to the testimony. It is undisputed, however, that Respondent promptly complied with the DI's recommendation to improve the security of its storage facility and ceased its practice of leaving the products on its truck. It is thus undisputed that Respondent provides adequate physical security for its products.

Thus, the 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.

The Agency has recognized, however, that ''the parameters of the hearing are determined by the prehearing statements.'' *Darrell Risner, D.M.D.,* 61 FR 728, 730 (1996). Accordingly, in *Risner,* the Agency held that where the Government has failed to disclose ''in its prehearing statements or indicate at any time prior to the hearing'' that an issue will be litigated, the issue cannot be the basis for a sanction. 61 FR at 730. *See also Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959, 75961 (2000) (noting that the function of pre-hearing statements is to provide Due Process through ''adequate * * * disclosure of the issues and evidence to be submitted in * * * proceedings''); *cf. John Stafford Noell,* 59 FR 47359, 47361 (1994) (holding that notice was adequate where allegations were not included in Order to Show Cause but ''were set forth in the Government's Prehearing Statement'').

As noted above, the Show Cause Order contained no allegations pertaining to Respondent's sales of the love roses and this item's use as drug paraphernalia. Moreover, in its prehearing statement, the Government did not disclose that it intended to elicit testimony from the DI to this effect. The Government thus failed to provide adequate notice to Respondent that its sales of this product would be at issue in the proceeding and it was error for the ALJ to allow the testimony in the Government's case. *See Risner,* 61 FR at 730.

Even if it was properly within the scope of cross examination (in light of Mr. Marshall's testimony as to what products Respondent sold) for the Government to question Mr. Marshall and obtain his admission that he sold love roses, the fundamental error remains. As explained above, the function of notice is to provide Respondent with a ''full and fair opportunity'' to litigate both the factual and legal basis of the Government's theory. While the issue of whether an allegation ''has been fully and fairly litigated is so peculiarly fact-bound as to make every case unique,'' *Pergament*, 920 F.2d at 136, ''the simple presentation of evidence important to an alternative [allegation] does not satisfy the requirement'' that Respondent be afforded with a full and fair opportunity to litigate the alternative allegation. *I.W.G.*, 144 F.3d at 688 (quoting *NLRB* v. *Quality C.A.T.V., Inc.,* 824 F.2d 542, 547 (7th Cir. 1987) (other citation omitted)). Moreover, it is settled that where the Government's case ''focus[es] on another issue and [the] evidence of [an] uncharged violation [is] 'at most incidental,' '' the Government has not satisfied its constitutional obligation to provide a full and fair opportunity to litigate the issue and it cannot rely on the incidental issue as the basis for imposing a sanction. *Pergament*, 920 F.2d at 136 (quoting *NLRB* v. *Majestic Weaving Co.,* 355 F.2d 854, 861–62 (2d Cir. 1966)).

Significantly, while the Government contends in its post-hearing brief that ''Respondent has continued to sell drug paraphernalia even after he was told that the 'love roses' he was selling were used to smoke drugs,'' Gov. Br. at 12, the Government does not cite either the Drug Paraphernalia statute, which sets forth both criteria for determining whether an item constitutes drug paraphernalia and lists numerous items which constitute *per se* drug paraphernalia, *see* 21 U.S.C. 863(d) & (e), or Supreme Court precedent interpreting the statute and setting forth the legal standard for determining whether an item, which may have multiple uses, constitutes drug paraphernalia. *See Posters 'N' Things, Ltd.,* v. *United States,* 511 U.S. 513, 521 n.11 (1994). Notably, in *Posters 'N' Things,* the Supreme Court explained that the Drug Paraphernalia statute creates two categories of drug paraphernalia: those that are designed by the manufacturer for use with illicit drugs, *id.* at 518, and those items which are drug paraphernalia based on the item's ''likely use'' in the community. *Id.* at 521.

The Government's brief offers no explanation as to whether it maintains that the item constitutes drug paraphernalia because it is included on the list of items constituting *per se* paraphernalia, whether it believes the item was designed by its manufacturer for use as paraphernalia, or whether it believes the item is paraphernalia because its ''likely use'' in the community is to ingest drugs. The Government's failure to set forth its legal theory indisputably denied Respondent a meaningful opportunity to present argument to the contrary.

It is acknowledged that Respondent was able to present some evidence on the issue when Mr. Marshall testified on re-direct that the item had an alternate use as a novelty item and that none of his customers had ever told him that the item was being used for drug paraphernalia. Nonetheless, the Government's failure to raise this issue until the hearing itself denied Respondent the opportunity to present other evidence regarding the various factors which are relevant in the determination of whether an item constitutes drug paraphernalia. *See* 21 U.S.C. 863(e) (providing a non-exclusive list of eight factors to be considered including ''the existence and scope of legitimate uses of the item in the community,'' and ''expert testimony concerning its use'').

Of further significance, the focus of the Government's case was Respondent's alleged excessive sales of ephedrine products and not its sales of the love roses. Indeed, in its brief, the Government does not argue that Respondent's sales of the love roses are themselves violations of Federal law which are properly considered in assessing its compliance with applicable laws. *See generally* Gov. Br. at 10–13; *see also* 21 U.S.C. 823(h)(2). Rather, the Government appears to argue that the evidence establishes that Respondent's owners are irresponsible. Gov. Br. at 12 (arguing that Respondent's sales of the love roses are ''a clear sign that [its] owners are indifferent to the methamphetamine problem in this country''). The issue was ''at most incidental'' to the Government's case. *Pergament*, 920 F.2d at 136 (other citations omitted); *see also Majestic Weaving*, 355 F.2d at 861–62. Respondent has therefore been denied a full and fair opportunity to litigate the issue; to consider the evidence as an independent ground to revoke Respondent's registration or impose even a lesser sanction would violate the Due Process Clause and the Administrative Procedure Act.

In sum, the Government has failed to prove by substantial evidence its contention that Respondent does not maintain effective controls against diversion and was selling excessive quantities of ephedrine products. And because the Government failed to provide adequate and timely notice that Respondent's sales of love roses would also be at issue, there is no lawful basis for concluding that Respondent has committed acts which render its registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). The Order to Show Cause must therefore be dismissed.

**Order**

Pursuant to the authority vested in me by 21 U.S.C. 823(h) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that the application of CBS Wholesale Distributors for renewal of its DEA Certificate of Registration be, and it hereby is, granted. I further order that the Order to Show Cause issued to CBS

Wholesale Distributors be, and it hereby is, dismissed. This Order is effective immediately.

Dated: July 16, 2009.

**Michele M. Leonhart,**

*Deputy Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 06–77]**

### Gregory D. Owens, D.D.S.; Suspension of Registration; Grant of Restricted Registration

On August 7, 2007, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Gregory D. Owens, D.D.S. (Respondent), of Abingdon, Virginia. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration as a practitioner on the ground that his continued ''registration would be inconsistent with the public interest, as that term is defined under 21 U.S.C. 823(f).'' Show Cause Order at 1.

More specifically, the Show Cause Order alleged that in 1986, when Respondent moved his dental practice from Tennessee to Virginia, he had failed to obtain a new registration as required by 21 U.S.C. 822. *Id.* The Order further alleged that in 1992, Respondent did not renew his State ''controlled dangerous substances license'' and that he only acquired the proper State and Federal registrations in 1996 after a Virginia Board of Dentistry (''the Board'') inspection. *Id.* Relatedly, the Order alleged that in 1996 and 1997, Respondent had ''continued to prescribe controlled substances in violation of law,'' using his ''long-expired DEA Tennessee registration to facilitate this illegal activity.'' *Id.*

Next, the Show Cause Order alleged that in both November 1997 and May 2000, the Board had placed Respondent's dental license on probation and subjected him to certain conditions. *Id.* at 1–2. The Order also alleged that in August 2005, the State Board had ''issued an Order which concluded that [Respondent] had continuously demonstrated disregard for the Board's orders,'' reprimanded him, and continued him on probation. *Id.* at 2.

Finally, the Show Cause Order alleged that in October 1999, DEA had issued an Order to Show Cause to revoke Respondent's registration, and that on August 2, 2002, my predecessor had issued a Decision and Final Order which granted Respondent a registration which was ''subject to restrictions and conditions'' including ''recordkeeping requirements.'' *Id.* at 1. The Show Cause Order further alleged that in November 2005, Respondent applied for a renewal of his registration and that a compliance review found ''that in 2004 and 2005, [Respondent had] failed to submit the required controlled substance recordkeeping information to DEA in violation of the conditions of [the] previously granted registration.'' *Id.* at 2.

Respondent, through his counsel, timely requested a hearing. The case was assigned to a DEA Administrative Law Judge (ALJ), who conducted a hearing in Abingdon, Virginia, on June 27, 2007. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Following the hearing, both parties submitted briefs containing proposed findings of fact, conclusions of law, and argument.

On March 6, 2009, the ALJ issued her recommended decision (also ALJ). Therein, the ALJ found that Respondent had violated the terms of my predecessor's Final Order by failing to file quarterly reports of the controlled substances he dispensed between the effective date of the Order (Sept. 3, 2002) and December 31, 2002, the date stated as the expiration date on a registration which was subsequently issued to him several months after the expiration date and which was the result of a clerical error. ALJ at 37–39. However, the ALJ further found that Respondent's failure to file the reports after that date should be excused because the Government did not clearly communicate to him that this registration was issued in error and that a registration issued to him on September 8, 2003 (which expired on December 31, 2005) was the ''newly renewed registration'' to which the reporting requirement imposed by the 2002 Order applied. *Id.* at 39. However, she also found that because Respondent did not present evidence that he had submitted the required drug activity logs from August 2002 through December 2002, Respondent's ''lack of evidence proving good faith compliance weigh[ed] against the Respondent's continued registration.'' *Id.* at 40.

The ALJ also found that Respondent had not complied with a second requirement of the 2002 Order—that he notify DEA within thirty days of any action taken against his State ''medical license.'' *Id.* at 40–41. According to the ALJ, Respondent violated this provision because he failed to report the 2005 Board action which continued his probation upon finding that he had committed additional violations. *Id.* at 41. In so holding, the ALJ specifically rejected Respondent's contention that because the 2002 Order had used the term ''medical license'' rather than ''dental license'' in imposing the condition, he had no obligation to report the proceeding to DEA. *Id.*

While the ALJ found that the Government had made out a *prima facie* case to revoke Respondent's registration, she concluded that other factors counseled against a revocation. *Id.* at 47. More specifically, she noted that Respondent treated ''many patients from underserved counties, and a substantial portion of his patients have limited incomes,'' that there was no evidence of diversion or irresponsible prescribing practices on Respondent's part, that Respondent had instituted procedures to ensure the accuracy of his dental records, and that he had begun filing drug activity reports with this Agency following a 2006 inspection. *Id.* at 48. The ALJ thus recommended the revocation of Respondent's registration but that the revocation be stayed for twelve months, and that ''[d]uring pendency of the stay, the Respondent should be allowed to handle controlled substances,'' subject to certain restrictions. *Id.*

Neither party filed exceptions to the ALJ's decision. Thereafter, the record was forwarded to me for final agency action.

Having considered the record as a whole, I hereby issue this Decision and Final Order. I adopt the ALJ's findings of fact and conclusions of law except as noted below. While I accept Respondent's contention that the March 13, 2003 registration was the ''newly renewed registration'' for purposes of the 2002 Order, I note that Respondent did not comply with the Order's requirement pertaining to the submission of quarterly reports even during period in which there is no dispute that he was required to do so. I also hold that Respondent violated the 2002 Order because he failed to report the 2005 Board action to DEA. While I agree that the record does not support an outright revocation of his registration, I conclude that Respondent's lengthy history of regulatory troubles supports the suspension of his registration as well as the imposition of conditions on his new registration. I make the following findings.

#### Findings

Respondent graduated from the Medical College of Virginia Dental