acceptance of responsibility. This argument comingles two independent responsibilities under Agency precedent in an impermissible manner. The Agency has framed the dual prongs of the required rebuttal showing in this way:

[T]o rebut the Government's *prima facie* case, [a registrant] is required not only to accept responsibility for [] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts. Jayam Krishna-Iyer, 74 [FR] 459, 464 & n.8 (2009). *Both conditions are essential requirements* for rebutting the Government's prima facie showing that * * * continuing an existing registration would be ''consistent with the public interest.'' 21 U.S.C. 823(f) (emphasis supplied).

Hassman, M.D., 75 FR at 8236 (emphasis supplied). By pointing to purported corrective measures, the Respondents have offered the second requirement in the place of both.

The decision by the Respondents' to support their staffing decisions based on ''distraction'' reduction also tacitly accepts the actions of their employees as consistent with company policy. Thus, the value that can be attached here to testimony from Professor Brushwood that corporate guidance issued to CVS field components is consistent with their obligations [108] is less probative than an examination of what the employees actually were doing as evidenced in the record. *See Pharmboy Ventures Unlimited, Inc.,* 77 FR 33770, 33772 n.2 (2012) (''DEA has long held that it can look behind a pharmacy's ownership structure 'to determine who makes decisions concerning the controlled substance business of a pharmacy.'''); *S&S Pharmacy, Inc.,* 46 FR 13051, 13052 (1981) (the corporate pharmacy acts through the agency of its PIC).

The Respondents have also tendered the peculiar concept that as registrants, they are somehow exempt from a demonstration of responsibility acceptance because they are entities, not individual practitioners, or that their corporate status renders the acceptance of responsibility requirement as elusive. The Respondents posit that

because [several Agency decisions cited by the Respondent] involve circumstances where a registrant acted through multiple agents and through a corporate structure as Respondents do here, none of [the cases cited by the Respondents] squarely address the sufficiency of a registrant's acceptance of responsibility, let alone provides a precedent for revoking the Respondents' registrations.

Resp't Brief at 123. Because there is a wealth of Agency precedent on point which directly contradicts the Respondents' suggestion that the rebuttal required of corporate registrants lessened by virtue of their status a corporation, it is unnecessary to address the merits of this position. *See e.g., Sun & Lake Pharmacy,* 76 FR at 24529 (pharmacy registration revoked in the absence of acceptance of responsibility); *Liddy's Pharmacy, L.L.C.,* 76 FR at 48897 (application of pharmacy denied in absence of acceptance of responsibility); *East Main Street Pharmacy,* 75 FR at 66165 (immediate suspension order of pharmacy affirmed in face of absence of acceptance of responsibility); *Medicine Shoppe,* 73 FR at 387 (pharmacy registration revoked in the absence of acceptance of responsibility). Suffice it to say that the Respondents' argument that they unable to discern the nature of the required acceptance of responsibility because they function as corporations is without merit.

Accordingly, in view of the fact that the Government has established its *prima facie* [109] case by a preponderance of the evidence, and the Respondents have declined to accept responsibility,[110] the Respondents' Certificates of Registration should be REVOKED [111] and any pending applications for renewal should be DENIED.

Dated: June 8, 2012

JOHN J. MULROONEY, II

Chief Administrative Law Judge

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[108] Tr. 1084.

[109] Accordingly, the Respondent's motion for a ''directed verdict'' made (and reserved upon) during the course of the hearing is herein denied.

[110] In view of the Respondents' election to avoid acceptance of responsibility, it is not necessary to analyze the adequacy of purported corrective measured offered to demonstrate that similar acts will not occur in the future. *See Hassman, M.D.,* 75 FR at 8236.

[111] The Respondents have requested that any imposed sanction be limited to the controlled substances that were the subject of the Government's case. Resp'ts Brief at 127–28. In view of the strength of the evidence that shows a pervasive disregard for their duties as registrants, as well as their persistent denial of any measure of culpability, entrusting these registrants with the responsibilities of a DEA COR regarding other dangerous controlled substances would be illogical and unwise. Accordingly, after a considered review of the Respondents' position on the issue, revocation is the sanction that is most consistent with the evidence adduced at the hearing.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; Denial of Request for Redactions

On August 31, 2012, I issued a Decision and Final Order (hereinafter, Order) revoking the DEA Certificates of Registration issued to Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195 (hereinafter, Respondents). Prior to publication, counsel for Respondents contacted my staff to request a delay in the publication of the Order in the **Federal Register**, on the basis that it, as well as the Administrative Law Judge's Recommended Decision (R.D.), may contain trade secrets and confidential business information; Respondents sought leave to review the Order and to file a request for redactions. My staff agreed to the request, and on September 18, 2012, counsel for Respondents filed a letter proposing various redactions to both the Order and the ALJ's R.D.; therein, Respondents set forth four reasons in support of their proposed redactions. Letter of Catherine O'Neill, Esq., to Administrator, DEA (Sept. 18, 2012) (hereinafter, Resp. Req.). Thereafter, the Government was directed to file a response to Respondents' request. On September 29, 2012, the Government filed its Response (hereinafter, Gov. Resp.), objecting to the proposed redactions.

Respondents' proposed redactions involve various portions of the Order and the ALJ's R.D. that discuss the manner in which information was obtained for Respondents' pharmacy information management system. Respondents maintain that this information contains ''trade secret[s] and confidential business information regarding Respondents' business practices,'' which ''is exempt from disclosure under the Freedom of Information Act (FOIA) and [that] its publication will cause significant, and irreparable, harm to their business operations.'' *Id.* at 1. In addition to these contentions, Respondents argue: (1) That the ALJ's Protective Orders and bench rulings support redaction of the Final Order; (2) that the ALJ's various rulings continue in effect after the termination of the proceeding; and (3) that adoption of the ALJ's Confidentiality Designations is consistent with the manner in which the Agency has treated confidential information in other cases. *Id.* at 3–5.

Opposing the redactions, the Government argues that Respondents have not established that the information at issue involves trade secrets or confidential business information. Gov. Resp. at 1. The Government further argues that the information at issue ''is essential to an understanding of the ALJ's Recommended Decision and the Administrator's Final Order.'' *Id.* at 2. Having carefully reviewed the parties' submissions, I conclude that Respondents have not established their entitlement to the relief sought. *See* 5 U.S.C. 556(d) (''Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof.'').

As noted above, Respondents' first contention is that the proposed redactions involve trade secrets [1] and

[1] Respondents err in contending that the information constitutes a trade secret. As the D.C. Circuit has explained, a trade secret is ''a secret, commercially valuable plan, formula, process, or

commercial information which is exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA). *See* 5 U.S.C. 552(b)(4). Notwithstanding their assertion that publication of the information will cause them ''significant, and irreparable, harm to their business operations,'' Resp. Req., at 1, they invoke the standard from *Critical Mass Energy Project* v. *NRC,* 975 F.2d 871 (D.C. Cir. 1992), which does not require any showing of competitive harm where trade secrets or confidential business information are voluntarily provided to an agency, to argue that because they voluntarily provided this information to the Agency, it is exempt from disclosure ''if it 'would customarily not be released to the public by the person from whom it was obtained.' '' Resp. Req. at 3 (quoting 975 F.3d at 879). Respondents thus contend that ''[i]t is proper and consistent with FOIA for this information to remain protected from public disclosure.'' *Id.*

However, in *Chrysler Corp.* v. *Brown,* 441 U.S. 281, 292 (1979), the Supreme Court held ''[t]hat the FOIA is exclusively a disclosure statute.'' In so holding, the Court examined the FOIA's ''provision for judicial relief,'' which grants the federal district courts only '' 'jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant.' '' *Id.* (quoting 5 U.S.C. 552(a)(4)(B)). As the Court explained, this ''provision does not give the authority to bar disclosure.'' *Id.* The Court further explained that ''the FOIA by itself protects the submitters' interest in confidentiality only to the extent that this interest is endorsed by the agency collecting the information.'' *Id.* at 293. The Court thus held that the FOIA's exemptions ''were only meant to permit the agency to withhold certain information, and were not meant to mandate nondisclosure.'' *Id.* at 294.

Respondents point to no other provision of law which bars the Agency from disclosing the information in the Decision and Order.[2] Instead, they cite to two prior Agency orders which adopted an ALJ's ruling that certain information was entitled to protection. Resp. Req. at 4–5 (citing *Penick Corp.,* 68 FR 6947 (2003); *Johnson Matthey,* 67 FR 39041 (2002)). Yet neither of these cases explains what legal standard was applied by the Agency in making the determination to continue to protect the information from disclosure in the final order. *See Penick,* 68 FR at 6948; *Johnson Matthey,* 67 FR at 39041. Moreover, each of these cases involved a challenge to an application of an entity to import schedule II controlled substances by competitors of the applicant. *See Penick,* 68 FR at 6947, 6949; *Johnson Matthey,* 67 FR at 39043.

By contrast, this matter involves an enforcement proceeding brought to protect the public interest pursuant to 21 U.S.C. 824(a). It is manifest that in such a proceeding, the Government has a substantial, if not a compelling interest, in ensuring that both the public and the regulated industry fully understand the basis for the Agency's action. *See FCC* v. *Schreiber,* 381 U.S. 279, 293 & n.20 (1965) (noting ''the general policy favoring disclosure of administrative agency proceedings''); *see also Bartholdi Cable Co., Inc.,* v. *FCC,* 114 F.3d 274, 282 (D.C. Cir. 1997) (upholding FCC's conclusion ''that the public ha[d] a compelling interest in the [confidential business] information'' submitted by an applicant, ''as it [bore] directly on [its] fitness as a license applicant''); 21 CFR 1316.67 (requiring that Agency publish its final orders in the **Federal Register**). The Agency's Final Order establishes precedent for future cases and the Agency has an obligation to provide fair notice to the regulated industry of what conduct it deems constitutes an act which renders a registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4); *see also* 5 U.S.C. 552(a)(2) (''A final order [or] opinion * * * that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if * * * it has been * * * published * * * or * * * the party has actual and timely notice of the terms thereof.'').

This is not to say that the redaction of bona fide trade secrets and confidential business information will never be warranted in an enforcement proceeding brought under 21 U.S.C. 824. But Respondents' proposed standard, which focuses entirely on whether the information is of the type which they customarily release to the public and requires no showing of how the disclosure will result in competitive harm, clearly ill-serves the public interest.

In any event, here, the Government demonstrated that much of the information regarding the operation of Respondents' pharmacy management information system (as well as its use of a third-party data aggregator) is publicly available through a Google search. *See* Gov. Resp. at 2 and Attachments. This alone shows that most of the information, which Respondents proposed be redacted, is not treated as confidential by CVS.

To be sure, the evidence that local stores were previously allowed to input prescriber information into the database; that the database formerly displayed

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device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.'' *Public Citizen Health Research Group* v. *FDA,* 704 F.2d 1280, 1288 (D.C. Cir. 1983). Moreover, there must be a ''direct relationship'' between the trade secret and the productive process. *Id.* As the D.C. Circuit has further explained, this definition ''narrowly cabins trade secrets to information relating to the 'productive process' itself.'' *Center for Auto Safety* v. *NHTSA,* 244 F.3d 144, 151 (D.C. Cir. 2001). As these authorities make clear, because Respondents' pharmacy management information system is not used to make, prepare, compound or process a trade commodity, the information is not a trade secret.

[2] Respondents do not contend that the Trade Secrets Act, 18 U.S.C. 1905, bars the disclosure of the information. Nor could they, as the statute does not prohibit those disclosures which are ''authorized by law.'' *Id.*

Shortly after the Supreme Court issued its decision in *Chrysler Corp.* v. *Brown,* the Office of Legal Counsel issued an Opinion upon the request of the Federal Mine Safety and Health Review Commission on the issue of whether the Commission could publish confidential financial information about a mine operator in an opinion or order. *Memorandum Op. for the Gen. Counsel, Federal Mine Safety and Health Rev. Comm'n,* 3 U.S. Op. Off. Legal Counsel 201 (1979). Therein, the Office of Legal Counsel noted its prior opinion that ''the phrase 'authorized by law' does not require that an otherwise prohibited disclosure be specifically authorized by law. '[I]t is sufficient if the activity is ''authorized in a general way by law.'' ' This includes an authorization that is reasonably implied.'' *Id.* at 203 (citing 41 Op. Att'y Gen. 166, 169 (1953) (other citation omitted)).

The Office of Legal Counsel then noted that while ''[t]here is no statute that specifically authorizes the Commission to publish, in its opinions or orders, information within the scope of the prohibitions of § 1905[,] * * * the Commission is a quasi-judicial body with the authority both to hold hearings in the first instance and to review decisions made by its administrative law judges.'' *Id.* (citation omitted). Because the Commission's ''decisions * * * must be based upon the record as well as the law,'' and ''[i]t is authorized and directed to make findings of fact, which must be sustained on judicial review if supported by substantial evidence[,] * * * the Commission is * * * authorized by clear implication of law to include in its opinions and orders a recitation of evidence in the record upon which its findings and legal conclusions are based.'' *Id.* at 203–04 (citations omitted). The Office of Legal Counsel thus concluded that ''[t]his is sufficient authorization by law, within the meaning of § 1905, to allow the Commission to publish in its opinions and orders evidence of record that would otherwise be protected from disclosure.'' *Id.* at 204.

In performing its functions under 21 U.S.C. 823 and 824, DEA likewise acts as a quasi-judicial body and the Agency's decisions and orders ''must be based upon the record as well as the law.'' *Id.* at 203; *see also* 21 U.S.C. 824(c) (''Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of Title 5.''). So too, the Agency ''is authorized and directed to make findings of fact, which must be sustained on judicial review if supported by substantial evidence.'' 3 U.S. Op. Off. Legal Counsel, at 203; *see also* 21 U.S.C. 877 (''Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.'').

both the data obtained from HMS (the third-party aggregator), as well as that inputted at the local stores; and that CVS obtained updated data from HMS on a weekly basis; is not specifically addressed by the attachments. Yet even with respect to this information, Respondents offered no evidence that CVS treats this information as confidential.[3]

Moreover, Respondents offer absolutely *nothing* in the way of evidence to support their claim that ''publication [of this evidence] will cause significant, and irreparable, harm to their business operations.'' Resp. Req. at 1. In short, Respondents have offered no more than conclusory assertions of competitive harm, which are manifestly inadequate to overcome the substantial public interest in publication of the Order without the proposed redactions.

Nor do Respondents' remaining contentions support their proposed redactions. While the ALJ's protective order did protect against the disclosure of ''commercially sensitive information,'' *see* Resp. Req. at 3–4, the protective order defined this term to ''mean[] information that, if publicly disclosed, would be a windfall to Respondents' competitors and would put Respondents at a competitive disadvantage.'' ALJ Ex. 20, at 3. Respondents thus had notice that they were required to establish that the publication of any information, which they seek to protect from disclosure, would cause them competitive harm. Yet not only did Respondents fail to elicit any testimony from CVS's Vice President explaining why public disclosure of the information as to the workings of its pharmacy management information system ''would be a windfall'' to their competitors or place them ''at a competitive disadvantage,'' *id.,* they also failed to submit any such affidavits establishing such facts in support of their request for redactions.

Contrary to Respondents' contention, the ALJ's explanation for closing the hearing during the testimony of the CVS Vice President does not support the proposed redactions. While the ALJ explained that ''[a] party will be seeking to introduce evidence that is likely to compromise a trade secret and/or commercially sensitive information,'' he also explained that this ruling was based on ''information represented by counsel for the Respondent.'' Tr. 1225–26. The ALJ's ruling does not constitute a finding that Respondents had satisfied their burden of showing that disclosure of the information would cause competitive harm, and while the ALJ appropriately proceeded with caution given the representation of Respondents' counsel, ultimately, no such evidence was forthcoming. I thus reject this contention.

Finally, Respondents' contend that the ''publication and dissemination to non-covered individuals of the unredacted Final Order is inconsistent with the Protective Order because it is a transmittal of information to any person 'not entitled to access pursuant to [the] Protective Order,' '' which remains in effect even after the termination of the proceeding. Resp. Req., at 4 (quoting ALJ Ex. 20, at ¶¶7 and 9). However, the Protective Order does not (and cannot) bind the Administrator, and indeed, it expressly provides that after the ALJ transmits the record, the Order may be modified by the Administrator. ALJ Ex. 20, at ¶ 7.

In any event, as explained above, Respondents have not established that any of the information which they seek to redact is confidential. Nor have they established that publication of the information will cause them any competitive harm. Accordingly, I reject their request for redactions. I also conclude that modification of the protective order is warranted and will direct that the ALJ remove the confidential and protected designation from those portions of the record which are marked as such based on Respondents' assertion that they include trade secrets or confidential business information.

It is so ordered.

Dated: October 4, 2012.

Michele M. Leonhart,

Administrator.

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[3] Thus, even under the *Critical Mass* standard, Respondents are not entitled to the redactions.