

NOT INTENDED FOR PUBLICATION IN PRINT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

NOVELTY, INC.,)	
)	
Plaintiff,)	
vs.)	NO. 1:04-cv-01502-DFH-TAB
)	
KAREN TANDY,)	
PETER D. KEISLER,)	
)	
Defendants.)	

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

NOVELTY, INC.,)
)
 Plaintiff,)
)
 v.)
)
 KAREN TANDY, Administrator, U.S. Drug) CASE NO. 1:04-cv-1502-DFH-TAB
 Enforcement Administration, and)
 MICHAEL MUKASEY, Attorney General)
 of the United States, each in)
 their respective official capacities,)
)
 Defendants.)

ENTRY ON CROSS MOTIONS FOR SUMMARY JUDGMENT

Plaintiff Novelty, Inc. sells items such as sunglasses, lighters, key chains, and plush toys to gas stations and convenience stores. Novelty also sells certain over-the-counter pharmaceuticals that contain List I chemicals under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* Those chemicals are regulated by the Drug Enforcement Administration (“DEA”). On May 5, 2004, Dan Raber, the Diversion Group Supervisor for the DEA’s Indianapolis office, sent a letter to Novelty and all other Indiana companies that are registered to manufacture or distribute List I chemicals. Raber’s letter presented a series of instructions regarding storage of List I chemicals in delivery vehicles.

Novelty believes the new instructions will impose new and onerous restrictions on its ability to distribute its products, and it sued the Administrator of the DEA and the Attorney General for a declaratory judgment that the instructions announced in the Raber letter are invalid.¹ In issuing the instructions in the Raber letter, DEA did not use the notice-and-comment procedures required by the Administrative Procedure Act, 5 U.S.C. § 553, for “legislative” rules, as distinct from “interpretive” rules. The parties have filed cross-motions for summary judgment. As explained below, the court finds that the rules announced in the Raber letter were interpretive and not legislative, so that notice-and-comment procedures were not required. The court therefore grants the defendants’ motion and denies the plaintiff’s motion.

Summary Judgment Standard

The purpose of summary judgment is to “pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial.” *Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Summary judgment must be granted “if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The motion should be granted so long as no rational fact finder could return a verdict in favor of the non-moving party. See

¹Attorney General Mukasey is substituted as a defendant in this action pursuant to Rule 25(d)(1) of the Federal Rules of Civil Procedure.

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A court’s ruling on a motion for summary judgment is akin to that on a motion for a directed verdict. The question for the court in both is “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Id.* at 251-52. Only genuine disputes over material facts can prevent a grant of summary judgment. *Id.* at 247-48. A fact is material if it might affect the outcome of the suit under the governing law, and a dispute about a material fact is genuine only if the evidence would allow a reasonable jury to return a verdict for the non-moving party. *Id.* at 248.

The fact that both sides have filed motions for summary judgment does not alter the applicable standard; the court must consider each motion independently and must deny both motions if there is a genuine issue of material fact. *E.g.*, *Heublein, Inc. v. United States*, 996 F.2d 1455, 1461 (2d Cir. 1993); *Harms v. Laboratory Corp. of America*, 155 F. Supp. 2d 891, 905-06 (N.D. Ill. 2001). In considering cross-motions for summary judgment, the court must consider the evidence through two lenses. When considering Novelty’s motion for summary judgment, the court must give the defendants the benefit of all conflicts in the evidence and the benefit of all reasonable inferences that might be drawn from the evidence in their favor. When considering the defendants’ motion for summary judgment, the roles are reversed. Because the court is granting defendants’ motion, the court sets forth the evidence viewed in the light reasonably most favorable to plaintiff Novelty.

Facts for Summary Judgment

The Controlled Substances Act (“CSA”) classifies as List I chemicals specified chemicals that are used to manufacture controlled substances. 21 U.S.C. § 802(34). Any person wishing to manufacture or distribute a List I chemical must obtain a registration from the DEA, which must be renewed annually. 21 U.S.C. § 822(a)(1). Novelty sells and distributes a variety of items such as sunglasses, key chains, and plush toys. It also sells and distributes over-the-counter pharmaceuticals, including the decongestant ephedrine hydrochloride, which contains a List I chemical.

Novelty has established distribution practices for all of its products, including products containing List I chemicals. Novelty sales representatives order items that are shipped by transport trucks from the Greenfield, Indiana warehouse to “satellite transshipment points” or storage units. Bledsoe Dep. 22-23. Each sales representative picks up products from an assigned storage unit and distributes the products to customers. Sales representatives are sometimes unable to complete their routes in one day and may need to stay overnight somewhere before resuming their delivery routes.

Novelty obtained a DEA Certificate of Registration that permits it to distribute List I chemicals. As part of the registration process, a diversion investigator from the DEA’s Indianapolis office conducted an investigation of Novelty in 1998. Kuzma Dep. 51. The DEA was aware that Novelty planned to

use satellite storage locations and that sales representatives would not always be able to complete their routes in one day. *Id.* at 51-52. The DEA conducted investigations of Novelty in 2002-2003 and in 2007 so that Novelty could renew its registration, and the DEA continued to be aware of Novelty's distribution practices. At no time during the pre-registration or subsequent investigations did the DEA inform Novelty that its practices violated the federal regulations regarding distribution of List I chemicals. *Id.* at 54.

On July 30, 2004, the DEA published a notice of proposed rule-making in the Federal Register that proposed increasing the security requirements for storage of pseudoephedrine, ephedrine, and phenylpropanolamine ("PPA"). 69 Fed. Reg. 45,616 (July 30, 2004), Def. Ex. F. Though this notice was published after the Raber letters was written, it provides important context for the DEA's actions regarding the distribution of List I chemicals. The notice explained that pseudoephedrine, ephedrine, and PPA can be used to manufacture methamphetamine and amphetamine illegally. These drugs pose a danger to the public based on the effects they have on users' health, the pollution they cause, and the connection between their use and other criminal activity. *Id.* at 45,619. As the DEA increased controls on the sale of over-the-counter products containing these chemicals, the DEA observed an increase in the number of thefts of products containing these chemicals from manufacturers and distributors. *Id.* at 45,617. The DEA provided lists of reported thefts of large quantities of these chemicals. *Id.* at 45,618-19. The DEA proposed that security be increased in

areas where these chemicals are stored, the details of which DEA provided in the notice. *Id.* at 45,619-20.

Before issuing that July 30, 2004 notice of proposed rule-making, the DEA had tried to clarify its policies on the distribution of List I chemicals under the existing regulations. The first evidence of a “clarification” of the regulations regarding the distribution of List I chemicals that has been presented to the court is a December 23, 2003 letter sent by Marsha Jones, the DEA’s Diversion Program Manager for the Kansas City District Office, to all registrants in the Kansas City region. Pl. Ex. H. Jones wrote that the purpose of her letter was to remind all List I chemical distributors that the CSA and its implementing regulations require all registrants to maintain separate registrations for separate locations from which they distribute List I chemicals. *Id.*, citing 21 U.S.C. § 822(e), and 21 C.F.R. § 1309.23. Jones wrote:

It has come to our attention that some registrants are handling List I chemical products (including over-the-counter ephedrine and pseudoephedrine items) by storing them at, and distributing them from, satellite locations, such as commercial storage units, personal residences and/or delivery vehicles. Any storage at, and distribution from, a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law.

Id. Jones then reminded registrants that they faced possible imprisonment and/or fines if they distributed List I chemicals from an unregistered location. *Id.*, citing 21 U.S.C. § 843(d)(1).

That position obviously troubled the industry. On January 26, 2004, John Mudri, the compliance officer for the American Council on Regulatory Compliance, asked the DEA to provide an “official interpretation” of the Jones letter. Pl. Ex. G. Mudri wrote:

Our members understand that a delivery vehicle, commercial storage units etc. cannot be used as storage for future distribution, but many of our members have salesmen that travel for as much as a week at a time to make deliveries, without returning to the registered location for additional supplies. Many of these salesmen must stay in motels during the week and storage remains in these secured vehicles while parked.

Mudri requested that DEA clarify its policy on whether sales representatives could store the chemicals in their trucks while they stayed overnight on the road.

Patricia Good, the chief of the DEA’s Liaison and Policy section, assigned the task of responding to Mudri’s letter to Andy McFaul, unit chief of the Regulatory section. McFaul drafted a response letter with the help of Cathy Brooks, staff coordinator in the DEA’s Regulatory Drafting section. Good Dep. 84-85. Brooks and McFaul met with Scott Collier and Mark Rubbins from the Chemical section and Brian Bayly from the Office of the Chief Counsel to help formulate a response. Good Dep. 86-87. The DEA’s copy of the letter includes the initials of DEA employees who reviewed the letter. Scott Collier identified these individuals as Cathy Brooks, Betsy Willis from the Domestic Drug unit, Andy McFaul, Scott Collier, Brian Bayly, and Bill Williamson, the deputy chief of Liaison and Policy Section. Collier Dep. 45-47.

On April 12, 2004, Good signed and mailed the letter responding to Mudri's letter. Pl. Ex. F. Good's letter began by quoting the statement from the Jones letter that storage of List I chemicals at or distribution from any unregistered location violates federal law. Good provided three scenarios to clarify the DEA's policy on overnight storage of List I chemical products in delivery vehicles when a sales representative is unable to return to a registered location at the end of the day.

Scenario One stated that a sales representative who cannot complete his deliveries and return to a registered location at the end of a day because of a long delivery route is permitted to keep List I chemicals overnight in a locked, secure vehicle if: the List I chemicals are not visible, the sales representative is filling a pre-placed customer order, the sales representative is an employee of the company, the vehicle is company owned or leased or is a dedicated vehicle used only for the company's products, and the sales representative is required to stay overnight at a motel because of the length of his route. Pl. Ex. F at 1. The letter stated that the DEA considers List I chemical products to be "in transit" if all of these conditions are met. The DEA does not consider the products to be "in transit" if they are stored in a locked room or vehicle at a sales representative's home.

Scenario Two stated that sales representatives who pick up "general orders" of List I chemical products, as opposed to pre-placed customer orders, must

return the products to a registered location at the end of the day. The DEA did not consider the List I chemicals to be “in transit” in this situation because there is no order for a specific customer. Pl. Ex. F at 2. Storage in a delivery vehicle overnight and subsequent distribution to customers would violate federal law because the sales representative would be distributing from an unregistered location.²

Good distributed her letter to several other individuals. She blind carbon-copied employees in the St. Louis field division and the Kansas City district office. Dan Raber, Diversion Group Supervisor at the Indianapolis field office, obtained a copy of the letter, though it is not clear exactly how. Good testified that her office often sends copies of correspondence to program managers in each district office when the subject matter might affect an industry that has multiple locations throughout the country. Good Dep. 53. Good’s office maintains a repository of letters that program managers across the country can access. *Id.* Good placed her April 12, 2004 letter in this repository. It is also possible that the DEA distributed the letter to all program managers by mail or at a conference.

After Raber read the Good letter, he felt the need to inform registrants in Indiana of the interpretation of the regulations by the central office of the DEA. Raber Dep. 68. He wanted registrants to be aware of the interpretation so that

²Scenario Three dealt with freight-forwarding of List I chemical products. Novelty does not contest the validity of the DEA’s policy stated in Scenario Three.

they could comply with federal law. Raber conferred with Thomas Crow, the diversion program manager in Chicago, to make sure he was aware of the Good letter and to obtain permission to send a letter to all Indiana registrants that included the information from the Good letter.

Madeline Kuzma, a diversion investigator in the Indianapolis office, testified that when she first read the Good letter, she thought it announced a new DEA policy. She believed it was necessary to distribute the information to the regulated businesses. Kuzma Dep. 30-31. Kuzma wrote an email on April 18, 2004 that stated that she was aware that Novelty and one other distributor of List I chemicals in Indiana were using unregistered storage sheds and vehicles for overnight storage. She wrote that she believed this was an issue that would “need addressing on a divisional, if not national level, to assure consistency and fairness” Pl. Ex. K at 1. She also wrote in the same email:

If a strict interpretation of 1309.23(a) is to be applied, notification of the registration requirement for off-site storage/distribution needs to be made clearly to the registrant community, through federal register or field office letters to List 1 distributors in their jurisdiction – so companies can decide to seek registrations or change distribution procedures.

Id. at 2.³ Kuzma testified that she and her colleagues in the Indianapolis office had not advised registrants that they were not permitted to use remote storage locations. When she became aware that the DEA interpreted the regulations to make it unlawful to distribute List I chemicals from remote storage locations and vehicles, she believed that the Indianapolis office was obligated to communicate this interpretation to registrants. Kuzma Dep. 38-39.

Dan Raber sent a letter to all registrants in Indiana on May 5, 2004. Pl. Ex. D. The letter began by “reminding” the registrants that “any storage at, and distribution from, a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law.” *Id.* This statement, which is a direct quotation from the Jones letter, appeared in quotation marks but without attribution to any source. The letter next stated: “Hopefully

³The cited regulation, 21 C.F.R. § 1309.23, provided:

(a) A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person.

(b) The following locations shall be deemed to be places not subject to the registration requirement:

(1) A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered; and

(2) An office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders.

the three scenarios presented below will help clarify overnight storage of List I chemical products in delivery vehicles when the length of a sales representative's delivery route requires the person to stay overnight at motels and precludes him or her from returning to the registered location at the end of the day." *Id.* The letter then set forth the three scenarios from the Good letter, using language that was almost identical to the language in the Good letter.

Discussion

I. *Jurisdiction*

A. *Section 877*

Section 877 of the CSA provides that the United States Court of Appeals for the District of Columbia Circuit and the Court of Appeals for the circuit in which the principal place of business of the party seeking review is located have exclusive jurisdiction to review "final determinations, findings, and conclusions" of the Attorney General with respect to the CSA. 21 U.S.C. § 877. On August 15, 2006, the court issued an entry on the defendants' motion to dismiss that discussed at length the issue of this court's jurisdiction. *Novelty, Inc. v. Tandy*, 2006 WL 2375485 (S.D. Ind. Aug. 15, 2006). In brief summary, the court held that § 877 does not apply because Novelty is not challenging a "final determination, finding, or conclusion" by the DEA that was developed through formal procedures and that had created a record suitable for judicial review. The CSA uses the terms determinations, findings, and conclusions only in the context

of the Attorney General using procedures that give affected persons some sort of notice, an opportunity to be heard, an opportunity to develop a formal record of the agency action, and an opportunity for judicial review of the agency decision. *Id.* at *2-3, citing 21 U.S.C. §§ 811(a), 812(b), 823, and 824. Raber's letter to Novelty was not preceded by notice to the registrants, an opportunity to be heard, or an opportunity to develop a formal record.

The court relied on the Supreme Court's reasoning in *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 497 (1991), which emphasized the importance of providing a meaningful opportunity for review based on an adequate record. The court recognized that other courts had found that § 877 deprived district courts of jurisdiction to review some arguably similar claims under the CSA. See *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004), *aff'd*, *Gonzales v. Oregon*, 546 U.S. 243 (2006); *John Doe, Inc. v. Gonzalez*, 2006 WL 1805685 (D.D.C. June 29, 2006). In *John Doe, Inc. v. Gonzalez*, the court considered whether § 877 applied to a challenge to a DEA decision to revoke the plaintiff's permit to import a substance. The plaintiff could have requested a hearing to contest the revocation of the permit or submitted materials stating its position to the agency, but chose to file suit in federal court instead. In contrast, Novelty had no alternative mechanism for developing a record or obtaining judicial review, other than deliberately violating the requirements as set out in the Raber letter and defending itself in an enforcement action. The court concluded that § 877 did not bar the court's jurisdiction because, without jurisdiction in a district court,

Novelty would be left without a forum for meaningful review of its claim. *Novelty*, 2006 WL 2375485, at *9.

The defendants argue that the court should reconsider its view of § 877 based on the affirmance of the *John Doe, Inc.* decision by the District of Columbia Circuit. See 484 F.3d 561 (D.C. Cir. 2007). The court has reviewed the District of Columbia Circuit's opinion, including that court's discussion of this court's entry on the motion to dismiss. Respectfully, and in light of *McNary*, the court finds no reason to change its position on the applicability of § 877. This court made it clear in its entry on the motion to dismiss that it agreed with the result in *John Doe, Inc.* because of the availability of alternative mechanisms for judicial review, but disagreed only with the broad conclusions of the district court that § 877 encompasses all CSA-related final agency actions. *Novelty*, 2006 WL 2375485, at *5-6. Here, the court continues to find that the DEA's actions would not be subject to meaningful judicial review absent district court jurisdiction, at least without requiring Novelty or similarly situated businesses to risk enforcement action against them by the DEA.

B. *Finality*

The Administrative Procedure Act ("APA") provides that only agency actions made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. 5 U.S.C. § 704. To be "final," an agency action must satisfy two conditions: (1) it must mark the

completion of the agency's decision-making process, as opposed to being a tentative action; and (2) the action must be "one by which rights or obligations have been determined, or from which legal consequences flow." *Home Builders Association of Greater Chicago v. U.S. Army Corps of Engineers*, 335 F.3d 607, 614 (7th Cir. 2003), quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997).

In its entry on defendants' motion to dismiss, the court held that the Raber letter's use of scenarios did not preclude the court from finding that it amounted to a final agency action because the letter announced an unequivocal position. *Novelty*, 2006 WL 2375485, at *11. The court permitted Novelty to pursue discovery so that it could present evidence to support its contention that the Raber letter was part of a nationwide effort on the part of the DEA to alter List I chemical storage requirements. *Id.* at *12.

Novelty has presented evidence that Raber's letter was in fact part of such an effort. Raber's letter was based on Good's letter, which was written, reviewed, and approved by a number of DEA employees. Good was the chief of the Liaison and Policy section of the DEA's Diversion Control Office. The defendants argue that Good was not authorized to make final rules or take final agency action on behalf of the DEA. However, there is no dispute that Good was authorized to send the letter to John Mudri. Collier Dep. 35. The plaintiff reported that Good stated in her deposition that one of her section's responsibilities was to communicate DEA policy to the public. "The policy would be developed at a higher level, but

communicated, interpreted and more or less put in writing by my section.” Pl. Br. 11 (citing, but not including, page 14 of Good Dep.). The letter was reviewed and approved by other members of the Liaison and Policy Section, two members of the Chemical Investigation section, an employee from the Domestic Drug Unit, and an employee from the Office of the Chief Counsel. Collier Dep. 42-51, Good Dep. 85-90. The DEA has not argued that the Good and Raber letters do not reflect accurately the agency’s position on the storage requirements for List I chemicals.

Good’s letter was made available to all diversion investigators and field offices through the DEA’s letter repository and was possibly also sent to all district program managers and/or distributed at a national conference. Dan Raber received Good’s letter and sent his own version of the letter to all Indiana registrants. Prior to sending his letter, Raber got approval from Thomas Crow, the district program manager from Chicago, who supervised the Indianapolis office. The court is satisfied that the Raber letter reflects the completion of the DEA’s decision-making process on this issue and that the DEA intended for all district offices to follow the rules announced in the letter.

The Raber letter was an action that determined rights or obligations or from which legal consequences flow. Approximately fifty registrants received the letter from Raber. The letter notified at least some of these registrants that their distribution practices violated federal law, which put them at risk of having their registrations revoked and being subjected to criminal prosecution. The DEA

included the exact language of a large portion of Scenario One from the Good letter in a letter of admonition to a registrant in Missouri. Pl. Ex. N. Mark Caverly testified for the DEA that a letter of admonition is a “formal written vehicle that a local office will use, at the conclusion of an on-site regulatory investigation, to note violations and request a written response from the company, as to what action has been taken.” Caverly Dep. 63. He described a letter of admonition as an enforcement tool for the DEA. *Id.*

That specific letter of admonition informed the registrant that a recent inspection showed several deficiencies, including failure to adhere to DEA policy regarding the unauthorized practice of storing List I chemicals in places other than registered locations. Pl. Ex. N. The letter stated that List I chemicals could be kept overnight in a locked, secure vehicle only if they were not visible and listed the additional conditions from the Good letter using the precise language of the Good letter. *Id.* The letter went on to state:

List I chemical products may NOT be stored at a sales representative’s home or at a remote location (such as a storage locker, etc.) either in a locked and secured vehicle or otherwise. This applies to customer specific and non-customer specific orders containing List I chemical products. List I chemicals may only be distributed from a registered location.

Id.

This letter summarizes the contents of both the Good and Raber letters. Thus, the court finds that the Good letter, which is identical in substance to the

Raber letter, has been enforced by the DEA. The Raber letter thus created new obligations for registrants, and legal consequences have flowed from it. The letter is therefore a final agency action that is subject to judicial review.

II. *Interpretive Rules and Legislative Rules*

The APA defines a rule as the “whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency. . .” 5 U.S.C. § 551(4). This definition includes agency statements that legislate as well as those that interpret existing law and regulations. In general, when an executive agency wants to promulgate a rule, it must provide notice and an opportunity for comment, and it must issue a concise general statement of the rule’s basis and purpose. 5 U.S.C. § 553. The APA exempts from these requirements “interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.” 5 U.S.C. § 553(b)(3)(A); *Lincoln v. Vigil*, 508 U.S. 182, 196 (1993). The APA does not define the term “interpretive rules.”

The distinction between a legislative rule, which requires an agency to follow notice-and-comment procedures, and an interpretive rule, which does not require those procedures, is both elusive and critical in administrative law. As the Seventh Circuit explained in *Hector v. United States Department of Agriculture*, 82 F.3d 165, 167 (7th Cir. 1996):

Notice and comment rulemaking is time-consuming, facilitates the marshaling of opposition to a proposed rule, and may result in the creation of a very long record that may in turn provide a basis for a judicial challenge to the rule if the agency decides to promulgate it. There are no formalities attendant upon the promulgation of an interpretive rule, but this is tolerable because such a rule is “only” an interpretation.

The distinction has important consequences for the agency, the regulated community, and the public in general. On one hand, agencies must have some flexibility and must be able to explain ambiguous terms in the statutes and regulations they are charged with enforcing. See *Metropolitan School District of Wayne Township v. Davila*, 969 F.2d 485, 492 (7th Cir. 1992), citing *American Hospital Ass’n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987). On the other hand, the APA’s notice-and-comment provisions reflect Congress’ desire to provide some checks on agency authority. Notice-and-comment procedures give members of the public an opportunity to communicate their concerns and suggestions to agencies that have been delegated legislative authority but are not elected by the public. See *Hector*, 82 F.3d at 171; *American Hospital Ass’n*, 834 F.2d at 1044.

This critical distinction is also elusive, as shown by the case law discussed below. Deciding whether a rule or agency policy statement is interpretive or legislative can be akin to deciding whether a particular spot is in the foothills or in the mountains, or deciding whether to describe the weather as “partly cloudy” or “partly sunny.” This case lies somewhere in the higher foothills or lower mountain slopes.

A. *Seventh Circuit Precedent*

The defendants argue that the court should decide the legislative v. interpretive rule issue by considering the factors that the District of Columbia Circuit set out in *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561 (D.C. Cir. 1984) (en banc), as discussed in *Metropolitan School District of Wayne Township v. Davila*, 969 F.2d at 489-90. Davila was the Assistant Secretary for Special Education and Rehabilitative Services within the United States Department of Education. He received an inquiry about whether the Individuals with Disabilities Education Act (“IDEA”) required states to provide educational services to disabled children who were expelled or suspended for extended periods of time for reasons unrelated to their disabilities. Davila responded to the inquiry in a letter stating that the Department of Education interpreted the IDEA to require states to provide educational services in these circumstances. The school district challenged the rule as invalid, arguing that it had been promulgated without notice and comment. *Davila*, 969 F.2d at 487. The district court granted summary judgment in favor of the school district. The Seventh Circuit reversed, holding that the rule was only interpretive.

The Seventh Circuit noted that the District of Columbia Circuit had set out general principles by which to determine whether a rule is interpretive or legislative in *General Motors Corp. v. Ruckelshaus*, 742 F.2d at 1565. The first principle is how the agency itself characterized the rule, which is a relevant but not decisive factor. *Davila*, 969 F.2d at 489. Next, an interpretive rule states

what the agency thinks the statute means and reminds parties of their existing duties, while a legislative rule creates new laws, rights, or duties. *Id.* at 489-90. The Seventh Circuit also noted that it had previously cited with approval Professor Kenneth Davis' test for distinguishing between interpretive and legislative rules, which focuses on whether the agency exercised delegated power to make law. For example, if an agency has not been given the authority to make law, its rule must be interpretive. However, the court stated that Professor Davis' test has limited value when the agency has been delegated both rulemaking authority and the authority to issue interpretive rules. *Id.*

The *Davila* court went on to apply the *General Motors* principles. First, the agency's letter stated that it was an interpretation of the IDEA based on a recent Supreme Court decision, other cases interpreting the IDEA, the language of the IDEA and an implementing regulation, and the legislative history of the IDEA. *Id.* Next, the court discussed whether the letter created new law, rights, or duties. The court concluded that while the position announced in the letter was new, it was not necessarily legislative. *Id.* at 492, citing *Michigan v. Thomas*, 805 F.2d 176, 183 (6th Cir. 1986) (holding that the EPA's new definition of the term "reasonably available control technology" was interpretive even though it required more of the states than the previous definition); *Alcaraz v. Block*, 746 F.2d 593, 613-14 (9th Cir. 1984) (holding that rule that required families to provide Social Security numbers of all adults in the household before students could receive free or reduced price meals at school was interpretive even though it altered

administrative duties); *American Postal Workers Union v. United States Postal Service*, 707 F.2d 548, 558-60 (D.C. Cir. 1983) (holding that the Postal Service's rule changing the computation formula for retirement benefits was interpretive). "These cases show that an agency's change in its reading of a statute does not necessarily make the rule announcing the change legislative. That rules 'may have altered administrative duties or other hardships does not make them substantive [legislative].'" *Davila*, 969 F.2d at 492, quoting *Alcaraz*, 746 F.2d at 613. The court also stated that a rule that affects rights and obligations is not necessarily legislative. *Id.* at 493, citing *Production Tool Corp. v. Employment and Training Admin.*, 688 F.2d 1161, 1166 (7th Cir. 1982).

The Seventh Circuit introduced an additional principle while summarizing its reasons for concluding that the rule at issue was interpretive:

It relies upon the language of the statute and its legislative history This represents the paradigmatic case of an interpretive rule The rule is based on specific statutory provisions . . . and its validity stands or falls on the correctness of the agency's interpretation of the statute. In these circumstances, it is clear that the rule is an interpretive one.

Davila, 969 F.2d at 492. The rule in *Davila* imposed a new duty on school districts to provide educational services for disabled students who had been expelled or suspended. However, the court was persuaded that the agency's reliance on the language and legislative history of the statute in creating the rule made the rule interpretive.

In *Hector v. United States Department of Agriculture*, the Seventh Circuit also decided whether an agency rule was legislative or interpretive. 82 F.3d at 167. The Department of Agriculture had promulgated a regulation under the Animal Welfare Act stating that facilities housing animals must be constructed “of such material and of such strength as appropriate for the animals involved.” 9 C.F.R. § 3.125(a). The Department of Agriculture then issued an internal memorandum to its inspectors stating that all “dangerous animals” must be inside a perimeter fence at least eight feet high. *Hector*, the plaintiff, was an exotic animal dealer who raised a variety of “dangerous animals” that he enclosed in a six foot high fence. *Hector*, 82 F.3d at 168. The Department of Agriculture cited *Hector* on several occasions for not having an eight foot fence and ultimately imposed sanctions on him. *Hector* challenged the sanctions on the basis that the eight foot rule was invalid because the Department of Agriculture had not followed the notice and comment procedures the APA requires. The Department of Agriculture argued that the rule was an interpretation of the regulation.

The court explained that a rule is interpretive only “if it can be derived from the regulation by a process reasonably described as interpretation.” *Id.* at 170, citing *Davila*, 969 F.2d at 490. The court found that the eight foot fence rule was not interpretive because “[t]here is no process of cloistered, appellate-court type reasoning by which the Department of Agriculture could have excogitated the eight-foot rule from the structural-strength regulation.” *Id.* at 171. Rather than interpreting the regulation, the court found that the agency had made an arbitrary

choice that the containing fences must be eight feet high. Legislators are elected by the public to make choices that involve arbitrary choices or value judgments. Agencies do not have this “democratic legitimacy,” and must follow the notice-and-comment procedures when proposing to make rules based on arbitrary choices. *Id.* at 170-71.

Finally, the *Hoctor* court did not place any weight on the agency’s own characterization of the rule: “we think the agency’s ‘intent,’ though a frequently cited factor, is rather a make-weight. What the agency intends is to promulgate a rule. It is for the courts to say whether it is the kind of rule that is valid only if promulgated after notice and comment.” *Id.* at 172.

In *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 191 F.3d 845, 852 (7th Cir. 1999), *reversed on other grounds*, 531 U.S. 159 (2001) (holding rule invalid because Corps exceeded its authority under Clean Water Act), the Seventh Circuit held that a rule that defined “waters of the United States” to include any water that was the habitat of migratory birds that cross state lines was interpretive. The Army Corps of Engineers had written a letter to SWANCC stating that the Corps intended, based on the Migratory Bird Rule, to exercise jurisdiction over the site SWANCC had selected for waste storage. *Id.* at 848-49. The Seventh Circuit distinguished the case from *Hoctor*. The statute in *Hoctor* did not impose a duty to build a fence of any particular height. The statute authorized the agency to impose a specific obligation to implement the general

statutory goals. Instead of stating a specific obligation in regulations issued through notice-and-comment procedures, the agency in *Hoctor* provided a vague standard in the regulations and made its specific value judgment in the eight foot fence rule. In contrast, the Clean Water Act defined the waters over which the Corps had jurisdiction by using the term “navigable waters.” The agency had elaborated further on that definition in its regulations by using the term “waters of the United States.” These vague definitions provided the agency with at least “something to interpret” through interpretive rules, not just a vague standard. *Id.* at 852.

The defendants have argued that the court should also consider whether the statutory scheme would have been operative even without the rule. The District of Columbia Circuit discussed that factor in *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). The court stated that if, in the absence of the rule, there would be no legislative basis for an enforcement action or other agency action to confer benefits or to ensure the performance of duties, the rule must be legislative. *Id.* The court did not state that the inverse would also be true; the court did not state that if in the absence of the rule there was a basis for enforcement actions, the rule must be interpretive. Here, there is no dispute that the DEA may bring an enforcement action against a registrant even in the absence of the Raber and Good letters. This factor tends to weigh somewhat in favor of finding the letters were interpretive.

The critical distinction between interpretive and legislative rules remains “far from crystal-clear,” *Chemical Waste Management, Inc. v. United States Environmental Protection Agency*, 869 F.2d 1526, 1534 (D.C. Cir. 1989), and “enshrouded in considerable smog.” *General Motors*, 742 F.2d at 1565; accord, *American Mining Congress*, 995 F.2d at 1112 (“insofar as our cases can be reconciled at all. . . .”). Nevertheless, the Seventh Circuit has identified several factors for a court to consider to determine whether a rule is legislative or interpretive. The court should consider the agency’s characterization of the rule; the type of reasoning the agency used to formulate the rule from the regulations; and whether the rule creates new duties, rights, or obligations. The rule is interpretive if the agency used appellate-court type reasoning, including reference to sources such as the text of the statute and regulations, the statute’s legislative history, and case law. *Davila*, 969 F.2d at 492; see also *SWANCC*, 191 F.3d at 852. Even if a rule creates new duties, rights, or obligations, the rule is interpretive if it simply clarifies an existing statute or regulation. *Davila*, 969 F.2d at 489. If the agency created a specific rule from a vague standard that did not provide the agency with “something to interpret,” the rule is legislative. *Hoctor*, 82 F.3d at 170.

B. *The Raber Letter*

1. *The DEA's Characterization of the Letter*

The defendants argue that the texts of the letters demonstrate that the DEA characterized the letters as interpretive when they were written. The Jones letter began with a statement that its purpose was to “remind” all List I chemical distributors of federal requirements regarding registration. The Jones letter cited 21 U.S.C. § 822(e), which requires registrants to obtain a separate registration for each principal place of business where it manufactures, distributes, or dispenses List I chemicals. The letter also cited 21 C.F.R. § 1309.23, which requires registrants to obtain a separate registration for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported. Pl. Ex. H. The Good letter did not include citations to federal law, but stated that Mr. Mudri had requested clarification on overnight storage of List I chemicals in delivery vehicles and that Good was providing clarification. Pl. Ex. F at 1. Similarly, the Raber letter did not cite to federal law, but stated that its goal was to “help clarify overnight storage of List I chemical products in delivery vehicles” Pl. Ex. D at 1.

Though this factor weighs in favor of the Raber letter being interpretive, the court agrees with Judge Posner’s assessment in *Hoctor* that this factor is “rather a make-weight.” When an agency has not gone through notice-and-comment procedures to develop a policy, it is hard to imagine that it would characterize its

policy or rule as anything other than interpretive. The court has not assigned this factor significant weight.

2. *The DEA's Method of Reasoning*

The CSA requires manufacturers and distributors of List I chemicals to be registered with the DEA. 21 U.S.C. § 822(e) states: “A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.” Several regulations provide additional guidance as to the registration requirements. 21 C.F.R. § 1309.23(a) states: “A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person.” The regulation provides an exception to the registration requirement for a warehouse where List I chemicals are stored by a registered person if the chemicals are distributed directly from the warehouse to the location from which the chemicals were originally delivered. § 1309.23(b)(1). There is also an exception to the registration requirement for offices used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which contain no chemicals and do not serve as a distribution points for filling sales orders. § 1309.23(b)(2).

On its face, this regulation requires the registrant to obtain a separate registration for each general physical location from which the registrant plans to distribute List I chemicals. However, the regulation does not define the terms

“principal place of business” or “one general physical location.” It also does not specify whether a separate registration is required for storage of List I chemicals.

A second relevant regulation, 21 C.F.R. §1309.24(a), states: “The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment.” On its face, the regulation provides that an agent or employee of a registered person is not required to be registered to be able to perform his or her usual course of business or employment for the registered person. This regulation eliminates the need for an employer to obtain registrations for each individual employee or agent. However, the regulation does not define the term “usual course of business.”

Finally, 21 C.F.R. § 1309.71(a) provides: “All applicants and registrants must provide effective controls and procedures to guard against theft and diversion of List I chemicals.” The regulation goes on to list a number of factors the DEA should consider when determining whether an applicant for registration’s security procedures are effective, including factors related to the applicant’s facilities, the level of supervision over employees who have access to the chemicals, and the adequacy of the applicant’s systems for monitoring the receipt, distribution, and disposition of the chemicals in its operations. 21 C.F.R. § 1309.71(b).

The Good and Raber letters began by stating a general rule that storage in and distribution from any place that is not registered violate federal law.⁴ The ambiguous terms “principal place of business” and “one general physical location” in § 1309.23 are examples of language that is ripe for agency interpretation. See *SWANCC*, 191 F.3d at 852; *Hocctor*, 82 F.3d at 170. It is possible to interpret the regulation to require registrants to obtain separate registrations for each separate physical location from which they distribute, import, or export List I chemicals. It is also possible to interpret the requirement to obtain a separate registration for each place from which List I chemicals are “distributed” to include places in which List I chemicals are stored overnight en route to being distributed. By this interpretation, for example, if a sales representative wanted to store List I chemicals in a delivery vehicle overnight while on her way to distribute them, she would be required to obtain a registration for the delivery vehicle. The language of the regulation thus provides some basis from which the DEA could have interpreted the general rule it announced in the Good and Raber letters that sales representatives may not store or distribute products containing List I chemicals in unregistered locations.

The first scenario outlined in the Raber letter provides an exception to the general rule that sales representatives may not store products containing List I

⁴In its Complaint, Novelty challenged this general rule as inconsistent with the CSA and its implementing regulations. Cmpl. ¶ 30, quoting 21 U.S.C. § 822(e) and 21 C.F.R. § 1309.23. Novelty has not discussed or developed this argument in its briefs in support of its motion for summary judgment.

chemicals in unregistered locations. If a sales representative cannot return to a registered location at the end of the day because he has a long delivery route, he may keep List I chemicals overnight in a locked secure vehicle while he stays overnight at a motel, so long as a number of conditions are met. The Raber letter specifies that this exception does not apply to sales representatives who stop overnight at their homes. Pl. Ex. D at 1.

21 C.F.R. §§ 1309.24(a) and 1309.71 provide a basis for the rule announced in this scenario. The DEA has interpreted the term “usual course of business” from § 1309.24(a) to include sales representatives who are en route to their final destinations, but not to sales representatives who return to their homes. Collier Dep. 63. The DEA has also determined that a sales representative who stays at her home overnight with List I chemicals stored in her delivery truck does not provide “effective controls and procedures to guard against theft and diversion” as required by § 1309.71.

Based on its interpretation of § 1309.23, it would have been permissible for the DEA to conclude that List I chemicals could never be stored overnight in delivery vehicles under any circumstances, whether at motels, homes, or restaurants. In enforcing the regulation, however, the DEA has decided to introduce some degree of practical flexibility to accommodate the regulated industry. Nothing in the regulation itself requires that flexibility. In the Good and Raber letters, the DEA announced, in effect, that it would tighten up its

enforcement in some respects (*e.g.*, home stays) but not others (motel stays). Preserving the exception for motel stays makes it possible for companies like Novelty to continue to utilize long delivery routes while also keeping the List I chemicals relatively more secure.

In the second scenario, the DEA set an additional limit on the types of orders that may be stored overnight in delivery trucks. A load that includes pre-placed customer specific orders may be stored overnight in a delivery vehicle provided it meets the requirements discussed in the first scenario. However, the DEA has determined that the exception to the registration requirement does not apply to sales representatives who have “general orders” in their vehicles. If the load includes a general order, the Raber letter states: “the DEA does not consider the List I chemical products to be in transit (no customer specific order)” Pl. Ex. D at 2. This is a permissible interpretation of ambiguous language in § 1309.24(a). Again, based on its interpretation of § 1309.23, it would have been permissible for the DEA to conclude that List I chemicals could never be stored overnight in delivery vehicles. Thus, it was permissible to limit the ability to store List I chemicals in storage vehicles overnight to loads containing only pre-placed customer specific orders.

Novelty argues that the DEA’s distinctions between motels and homes and between specific orders and general orders do not make sense as a matter of sound policy. Whether those distinctions are sound policy is not the issue before

the court. In deciding whether the Good and Raber letters are interpretive or legislative agency actions, the relevant point is that the text of the applicable regulations does not require the DEA to allow any of the exceptions. In deciding to tighten its enforcement policy to some extent, the DEA was trying to act as executive agencies often act: adjusting the formal law to accommodate some practical realities in a way that remains faithful to the language and purpose of the duly promulgated statutes and regulations. Not every detail of such accommodation is a further legislative act.

3. *New Duties, Rights, or Obligations*

The general rule regarding registration requirements and the two scenarios discussed in the Raber letter were changes in policy for the Indianapolis field office. Prior to this letter, the Indianapolis office was aware that Novelty and other registrants permitted their sales representatives to store products containing List I chemicals (for both pre-placed and general orders) in their vehicles overnight while they stayed at their homes or at motels. Kuzma Dep. 51-52. The DEA had not expressed disapproval of this practice during the pre-registration investigation of Novelty in 1998 or in any of the subsequent periodic inspections of Novelty. Kuzma Dep. 51-54. Prior to the Raber letter, the Indianapolis field office had interpreted 21 C.F.R. § 1309.24(a) in a manner that permitted sales representatives to store List I chemical products in their vehicles as long as they were secure. Kuzma wrote in an April 18, 2004 email:

Previously, the practical interpretation in the field has included that the route personnel were acting as an agent of the registrant and the product just had to be secured in some manner – locked truck, residence, etc., but a separate registration was not required as the product that originated at the registered location was distributed to the customer via route employees. In years past, I did not instruct registrants to cease such dist. procedures and the Chemical Section, which was on distribution for the 6s (investigative reports), never raised an issue.

Pl. Ex. K.

As discussed above, one factor the court must consider is whether the rules created new law, rights or duties. The rules announced in the Raber letter require Novelty to change its distribution practices significantly. Sales representatives will be obligated to store all List I chemical products at a registered location before being able to stay overnight at their homes. They will also be obligated to return all List I chemical products from general orders to a registered location at the end of each day. However, as discussed above, the fact that an agency has announced a new enforcement policy based on a new, stricter interpretation of a regulation does not necessarily make the rule legislative. *Davila*, 969 F.2d at 490.

One key to distinguishing between a legislative and an interpretive rule is whether the rule relies upon the language of the statute or the implementing regulations. Here, the DEA relied upon 21 C.F.R. §§ 1309.23, 1309.24(a), and 1309.71 in formulating the general rule and scenarios announced in the Raber letter. The stricter interpretation of the regulations was undoubtedly related to the discovery of many incidents of theft of List I chemicals from delivery vehicles.

The tighter enforcement policy set forth in the Raber and Good letters reflects, in the court's judgment, simply a tighter interpretation of broad existing regulations. DEA was not required to allow any exceptions to those regulations. Its decision to allow some exceptions and to explain them to the regulated industry was not a legislative action subject to the notice-and-comment procedures of the APA.

Conclusion

For the reasons discussed above, the court grants the defendants' motion for summary judgment and denies plaintiff's motion. The court will enter final judgment for the defendants.

So ordered.

Date: August 7, 2008

DAVID F. HAMILTON, CHIEF JUDGE
United States District Court
Southern District of Indiana

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