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February 27, 2004

BY HAND DELIVERY

Patricia M. Good
Chief, Liaison and Policy Section
Office of Diversion Control
Drug Enforcement Administration
600 Army Navy Drive
Arlington, VA 22202

Re: Docket No. DEA-239T

Dear Ms. Good:

We submit these comments on behalf of the Consumer Healthcare Products Association (CHPA) in response to the "interpretive rule" DEA published on January 14, 2004 to provide a "Clarification of the Exemption of Sales by Retail Distributors of Pseudoephedrine and Phenylpropanolamine Products."[1] CHPA is the national trade association representing manufacturers and distributors of dietary supplement products and nonprescription, over-the-counter (OTC) medicines, including pseudoephedrine. CHPA members account for over 90 percent of the retail sales of OTC medicines in the United States.

CHPA and its members share DEA's concerns regarding the diversion of pseudoephedrine. CHPA has worked closely with DEA over the years to prevent illicit diversion, and CHPA supports the appropriate regulation and control of pseudoephedrine sales. At the same time, CHPA has profound reservations about the process and approach DEA has taken with its "interpretive" rule. As explained below, and contrary to DEA's assertions, this rule would apply -- for the first time -- a 9-gram per transaction threshold to sales of "safe-harbor," blister-packed pseudoephedrine products. The threshold cannot as a matter of law be imposed in the manner DEA has employed here.

DISCUSSION

The plain terms and structure of the Comprehensive Methamphetamine Control Act of 1996 (MCA) and the Methamphetamine Anti-Proliferation Act of 2000

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[1] 69 Fed. Reg. 2062 (Jan. 14, 2004).

(MAPA), the legislative history of those two statutes, subsequent congressional action, and DEA's own prior statements all establish that the 9-gram threshold does not -- indeed, could not -- currently apply to retail sales of safe harbor pseudoephedrine products ("ordinary over-the-counter pseudoephedrine"). There is an established statutory procedure for imposing a threshold on retail sales of safe harbor pseudoephedrine products, and DEA has not followed that procedure. Even if there was not a specific statutory procedure for establishing a threshold, as a matter of basic administrative law DEA would have to follow notice and comment rulemaking to take the actions it purports to do here through an interpretive rule. The interpretive rule cannot stand in the face of these serious legal deficiencies.

1. The Statutory Scheme.

The Controlled Substances Act (CSA) defines the term "regulated transaction" to mean the "distribution, receipt, sale, importation, or exportation of" a listed chemical.[2] Transactions involving listed chemicals contained in a drug product legally marketed under the Federal Food, Drug, and Cosmetic Act (FDCA) are generally exempt from regulation.[3] However, the MCA removed the exemption for certain drug products containing pseudoephedrine, and established that above-threshold transactions involving pseudoephedrine products are regulated transactions.[4]

In removing the FDCA exemption for certain pseudoephedrine products, the MCA distinguished between sales of "ordinary over-the-counter pseudoephedrine products" by "retail distributors" and other sales of pseudoephedrine products. Specifically, the MCA amended the CSA to establish a 24-gram threshold (since reduced to 9 grams)[5] for "any sale of products containing pseudoephedrine" by retail distributors or mail order distributors.[6] At the same time, the MCA specifically provided that "any sale of ordinary over-the-counter pseudoephedrine . . . products by retail distributors *shall not be a regulated transaction (except as provided in section 401(d) of the [MCA])*."[7] Section 401(d) of the MCA, in turn,

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[2] 21 U.S.C. § 802(39)(A).

[3] *Id.* § 802(39)(A)(iv).

[4] *Id.*

[5] The MCA contained a 24-gram threshold. As discussed below, the Methamphetamine Anti-Proliferation Act of 2000 lowered the threshold to 9 grams.

[6] 21 U.S.C. § 802(39)(A)(iv)(II).

[7] *Id.* § 802(39)(A)(iv)(I)(aa) (emphasis added).

sets forth a special process for DEA to follow in order to impose a threshold on retail sales of ordinary over-the-counter pseudoephedrine products, as discussed further below.[8]

Following enactment of the MCA, the CSA thus applies a different set of rules for sales of ordinary over-the-counter pseudoephedrine products (safe harbor products) by retail distributors than for other sales of pseudoephedrine products. Sales of ordinary over-the-counter pseudoephedrine products by retail distributors are not regulated transactions, subject to DEA action under section 401(d) of the MCA (which has not taken place to date). Other sales of pseudoephedrine products are regulated transactions if they exceed what is now the 9-gram threshold.

"Ordinary over-the-counter pseudoephedrine" is defined as any product containing pseudoephedrine that is

> regulated . . . and sold . . . in package sizes of not more than 3.0 grams of pseudoephedrine base . . . and that is packaged in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, that is packaged in unit dose packet or pouches; and [] for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base.[9]

This is the so-called safe harbor packaging. It is undisputed that sales by retail distributors of safe harbor products are treated differently than sales of other pseudoephedrine products. However, DEA takes the position in its interpretive rule that the 9-gram threshold effectively applies to the substantial majority of retail sales of safe harbor products.

DEA reaches this result by focusing on the terms "retail distributor" and "personal use." The statute defines a "retail distributor" as

> a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to pseudoephedrine . . . are *limited almost exclusively to sales for personal use*, both in number of sales and volume of sales,

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[8] Pub. L. 104-237, 110 Stat. 3099, 3108 (Oct. 3, 1996).

[9] 21 U.S.C. § 802(45).

> either directly to walk-in customers or in face-to-face-transactions by direct sales.[10]

Sale for personal use, in turn, "means the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use."[11] DEA posits that the reference to below-threshold quantities means the current 9-gram threshold, and thus concludes that a retailer can only qualify as a "retail distributor" eligible for safe harbor treatment if that entity limits its sales of ordinary OTC pseudoephedrine almost exclusively to quantities below 9 grams.

Under DEA's reading of the statute, *all* sales involving pseudoephedrine products -- whether in safe harbor packaging or not -- are thus subject to a 9-gram threshold, with the exception that a retailer could have an occasional sale of safe harbor product over 9 grams. The effect of DEA's reading is to collapse the distinction between safe harbor and non-safe harbor pseudoephedrine products. DEA reaches this result without regard to section 401(d) of the MCA.

2. DEA's Interpretive Rule is at Odds with the Plain Terms and Structure of the MCA and the MAPA.

a. The MCA Sets Forth a Special Process for Imposing a Threshold on Safe Harbor Products, and DEA has not Complied with that Process.

The MCA amended the CSA to state explicitly that "any sale of ordinary over-the-counter pseudoephedrine . . . products by retail distributors shall not be a regulated transaction (except as provided in section 401(d) of the [MCA])."[12] Section 401(d) provides DEA with the authority to "establish by regulation a single-transaction limit of 24 grams of pseudoephedrine base for retail distributors."[13] However, DEA is only permitted to exercise this authority after notice, comment, and an informal hearing establishing wide-scale diversion of lawfully purchased ordinary over-the-counter pseudoephedrine.[14] DEA has not

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[10] *Id.* § 802(46)(A) (emphasis added).

[11] *Id.* § 802(46)(B).

[12] *Id.* § 802(39)(A)(iv)(I)(aa).

[13] Pub. L. 104-237, *supra* note 8, at 3108.

[14] *Id.*

followed these plain statutory procedures, which provide the exclusive means for imposing a transaction limit on retail sales of safe harbor product.[15]

DEA's contention that the statute already contains a retail threshold embedded in the definition of retail distributor would impermissibly render section 401(d) a nullity. DEA has offered an interpretation that produces a threshold on retail sales of safe harbor product without the need to follow the notice, comment, and hearing requirements of section 401(d), and without having to demonstrate that there is diversion of safe harbor products. Such a result is untenable, because it renders the carefully crafted procedures in section 401(d) meaningless and unnecessary.[16]

DEA's interpretation is also at odds with the basic structure of the MCA. As described above, the MCA established a fundamental distinction between safe harbor pseudoephedrine product and other pseudoephedrine product. There would have been no need for those provisions if Congress had intended that safe harbor product would be subject to the same threshold as other retail sales. DEA suggests that the purpose of the safe harbor provision is to allow "[a]n occasional sale at or above the 9 gram threshold" for safe harbor products.[17] Such a narrow exemption simply cannot be reconciled with the fundamental structure and text of the statute. The MCA contained elaborate provisions defining and distinguishing safe harbor products, none of which would have been necessary if all that Congress intended to allow were occasional sales over a 24-gram or 9-gram threshold. Indeed, DEA's reading would leave no incentive for manufacturers to incur the expense of safe harbor blister packaging if all it permits is an occasional higher quantity sale.

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[15] If and when DEA were to establish a threshold for retail sales of safe harbor products, that is the threshold that would become part of the statutory definition of "personal use" and "retail distributor" ("sale of below-threshold quantities in a single transaction for legitimate medical use"). Unless and until that happens, however, there simply is no such threshold applicable to the personal use definition.

[16] *See Mountain States Tel. & Tel. Co. v. Pueblo of Santa Ana,* 472 U.S. 237, 249 (1985) (noting "the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative") (citations omitted); *Edison Electric Inst. v. EPA,* 996 F.2d 326, 335 (D.C. Cir. 1993).

[17] 69 Fed. Reg. at 2064.

b. DEA's Position is Further Undercut by the Legislative History of the MCA.

The legislative history of the MCA unequivocally indicates Congress's intent to establish a safe harbor for ordinary over-the-counter pseudoephedrine and to exempt such products from a transactional limit absent evidence of widespread diversion. The MCA was understood to "[r]educe[] single transaction reporting requirements for all sales other than ordinary over-the counter pseudoephedrine . . . containing products from 1 kg to 24 grams" and to "[c]reate[] a safe harbor for ordinary over-the counter-products containing pseudoephedrine . . . to cover those products packaged in package sizes of not greater than three grams of pseudoephedrine . . . base and packaged in blister packs."[18]

Under the MCA, such ordinary over-the-counter pseudoephedrine would be "exempt from regulation unless the Attorney General [found] the need to control them because [they are] being diverted in large quantities."[19] Although DEA would now read section 401(d) of the MCA out of the law, the legislative history reveals that the section was actually intended to "provide guidance of what evidence the Department of Justice may use in examining whether . . . to close the 3 gram, blister pack safe harbor for pseudoephedrine . . . products."[20] Congress made clear that "solid evidence of systemic abuse" would be necessary to do so.[21]

c. The Methamphetamine Anti-Proliferation Act Exempts Safe Harbor Products from the 9-Gram Limit.

In 2000, as part of the MAPA, Congress reduced the "retail sales transaction threshold for non-safe harbor products containing pseudoephedrine " from 24 grams to

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[18] 142 Cong. 24834 (Sept. 25, 1996) (statement of Rep. Heineman); *see id.* at 23406 (Sept. 17, 1996) (statement of Sen. Hatch) (indicating that bill "creates a safe harbor for legitimate cough and cold products sold in blister packs at the retail level at quantities of up to 3 grams.").

[19] *Id.* at 24828 (Sept. 25, 1996) (Statement of Rep. McCollum).

[20] *Id.* at 23407 (Sept. 17, 1996) (statement of Sen. Hatch).

[21] *Id.*; Cong. Rec. 24828 (Statement of Rep. McCollum) ("[I]f the Attorney General determines that ordinary, over-the-counter products containing pseudoephedrine and PPA are being widely used as a significant source of precursor chemicals used to manufacture methamphetamine, the Attorney General may establish a single transaction limit of 24 grams.").

9 grams.[22] In so doing, Congress made separate provisions for the regulation of safe harbor products, and thereby preserved the distinct treatment of safe harbor products established previously in the MCA.

Section 3642 of the MAPA required the submission of a Report to Congress on a study of "the use of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products in the clandestine production of illicit drugs."[23] The purpose of this Report, which was ultimately issued in October 2001, was "to determine what amount of ordinary over-the-counter pseudoephedrine . . . used in clandestine meth labs [was] actually purchased at retail" and whether restrictions on retail sales were thus warranted.[24] The Report was statutorily required to contain "recommendations on the need to establish additional measures to prevent diversion of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine (such as a threshold on ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products) as the Attorney General considers appropriate."[25] If, as DEA now contends, the statute imposed a 9-gram threshold on sales of ordinary over-the-counter pseudoephedrine, there would have been no need for the Attorney General to advise Congress on the need for additional measures, "such as a threshold on ordinary, over-the counter pseudoephedrine . . . ."

Moreover, a separate section of the MAPA required DEA to establish a transaction limit of not less than 24 grams on sales of ordinary, over-the-counter pseudoephedrine if it made certain findings. Specifically, pursuant to section 3642(c)(1) of the MAPA,

> the Attorney General shall establish by regulation a single-transaction limit of not less than 24 grams of ordinary, over-

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[22] Pub. L. 106-310, 114 Stat. 1101, 1231 (Oct. 17, 2000) (section 3622 captioned as "REDUCTION IN RETAIL SALES TRANSACTION THRESHOLD FOR NON-SAFE HARBOR PRODUCTS CONTAINING PSEUDOEPHEDRINE OR PHENYLPROPANOLAMINE").

[23] *Id.* at 1237.

[24] H. Rep. 106-878, pt. 1, at 33 (Sept. 21, 2000) ("If most ordinary over-the-counter drug products used in meth labs are obtained through theft, smuggling, or sold 'through the back door,' additional restrictions on the retail sale of ordinary over-the-counter drug products will have little or no impact on clandestine meth production.").

[25] Pub. L. 106-310, *supra* note 22, at 1237-38.

> the-counter pseudoephedrine . . . for retail distributors, if the Attorney General finds, in the report under subsection (b), that-
>
> > (A) there is a significant number of instances . . . where ordinary, over-the-counter pseudoephedrine products . . . that were purchased from retail distributors were widely used in the clandestine production of illicit drugs; and
> >
> > (B) the best practical method of preventing such use is the establishment of single-transaction limits for retail distributors . . . of such products. . . .[26]

Congress made clear that such findings would be required to justify the imposition of a transactional threshold on safe harbor product.[27] DEA's attempt to adopt a 9-gram transactional threshold without having made these findings is thus outside of the agency's authority under this provision. Furthermore, if the statute already imposed a 9-gram transactional limit on sales of ordinary over-the-counter pseudoephedrine, it would have been nonsensical for Congress to authorize the imposition of a "single-transaction limit of not less than 24 grams" on such sales. The MAPA thus confirms and reinforces the plain provisions of the MCA, under which there is no threshold for retail sales of safe harbor pseudoephedrine products.

3. Pending Legislative Proposals Confirm that Safe Harbor Products are Currently Exempt from the 9-Gram Transactional Threshold.

Congress is currently considering a bill, S. 1784, that would "eliminate the safe-harbor" for ordinary over-the counter pseudoephedrine.[28] The findings section of S. 1784 expressly states that "while current law establishes a retail sales limit of 9 grams for most pseudoephedrine products, including common cold medicine, *there is no such limit on*

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[26] *Id.* at 1238; H. Rep. 106-878, pt. 1, at 32 (authorizing imposition of 24-gram threshold if "report finds that there is a significant number of instances where safe harbor or 'blister' packages purchased at retail were widely used in the clandestine production of illegal drugs; and the best practical method of preventing such use is the establishment of single-transaction limits for retail distributors").

[27] H. Rep. 106-878, pt. 1, at 32-33.

[28] S. 1784 (Oct. 23, 2003).

the sale of blister- packed pseudoephedrine products."[29] These findings squarely contradict DEA's contention that safe harbor pseudoephedrine products are and have always been subject to a sales threshold. There would, of course, be no need for such legislation if the law already imposes a 9-gram transactional limit on safe harbor products.

In introducing S. 1784, Senator Feinstein noted that "[o]nly loose pills in bottles face the 9-gram restriction in the law."[30] According to the Senator, DEA itself has recommended "that the blister pack loophole be closed, and that the current retail sales limit of 9 grams for bottled pseudoephedrine be extended to blister packed products as well."[31] The fact that such a bill has been introduced establishes what is clear from the MCA and the MAPA, namely that ordinary over-the-counter pseudoephedrine products are not currently subject to a 9-gram transactional threshold.

4. DEA's Prior Statements Further Undermine its "Interpretive" Rule.

DEA's previous statements on the subject contradict its assertion that it has always been the agency's position that the 9-gram transactional threshold applies to sales of ordinary over-the-counter pseudoephedrine.

a. DEA's Reports to Congress.

In its report to Congress in response to Section 3642 of the MAPA, DEA recommended "the reduction of the retail sales threshold concerning safe harbor packaged OTC pseudoephedrine products to 9 grams."[32] DEA noted that the MAPA permits it to "publish regulations seeking to limit single sales transaction of safe harbor packaged pseudoephedrine to not less than 24 grams" and explained that "[n]ew legislation amending

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[29] *Id.* sec. 2 (6) (emphasis added).

[30] Cong. Rec. S13146 (Oct. 23, 2003).

[31] *Id.*; *see* S. 1784 sec. 2(8) ("the United States Drug Enforcement Administration recommended in March 2002 that retail distribution of pseudoephedrine tablets in blister packages should not be exempt from the 9 gram retail sales limit"); *see also* DEA Report to Congress regarding the study of the use of ordinary, over-the-counter (blister pack/"safe harbor" packaging) pseudoephedrine and phenylpropanolamine products in the clandestine production of illicit drugs (Oct. 2001) ("DEA Report to Congress"), Executive Summary ("DEA strongly recommends the removal of the exemption for safe harbor packaged OTC pseudoephedrine products.").

[32] DEA Report to Congress, *supra* note 31, Section III, Recommendation #1.

MAPA [would be] required to establish the level of 9 grams as the retail sales threshold, irrespective of packaging."[33] According to the report, "federal law does not place any controls on these precursors when they are sold at the retail level in blister packs."[34]

Similarly in the report of the Suspicious Orders Task Force, formed as required by the MCA, DEA explained that the "MCA defines most individual retail OTC distributions under the 24 gram threshold or in specified packaging as not being regulated transactions."[35] The report further noted that "the 'safe harbor' provisions impose no limitations on the number of products that a customer may purchase in a single transaction."[36] The interpretive rule, however, takes the position that blister packs are subject to the 9-gram threshold that applies to non-safe harbor products, and contends that this has always been the Administration's position. The report in response to the MAPA, as well as the task force report, establish otherwise.

b. Prior DEA Federal Register Statements.

The preamble to DEA's final rule implementing the MCA also undercuts DEA's contention that it has issued only an "interpretive" rule. There, DEA explained that the controlled substances registration system "does not take into consideration the quantity of controlled substance involved when determining whether registration is required; either a product is exempt from registration or it is not, the amount of the product involved in the transaction is immaterial."[37] The agency thus amended its registration regulations to clarify that the safe harbor for ordinary over-the-counter pseudoephedrine is a "product exemption, rather than transaction exemption," and that the applicability of this exemption is "determined irrespective of the threshold provisions."[38]

Likewise, the preamble to its final rule implementing the MAPA contradicts DEA's position that its interpretative rule merely clarifies DEA policy. In that preamble,

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[33] *Id.*

[34] *Id.*, Executive Summary.

[35] DEA Report to the U.S. Attorney General by the Suspicious Orders Task Force (Comprehensive Methamphetamine Control Act of 1996) (October 1998).

[36] *Id.* at 25 (indicating that the term "Safe Harbor" is used to describe the MCA definition of "ordinary over-the-counter").

[37] 67 Fed. Reg. 14853, 14855 (March 28, 2002).

[38] *Id.* at 14855, 14860 (amended 21 C.F.R. § 1309.21).

DEA noted that "[a]t the retail level, all drug products containing pseudoephedrine or phenylpropanolamine that do not meet the definition of 'ordinary over-the-counter pseudoephedrine or phenylpropanolamine product' . . . are subject to the threshold requirements of MAPA."[39] This demonstrates DEA's prior acknowledgement that products meeting the definition of ordinary over-the-counter pseudoephedrine are not subject to the MAPA threshold requirements.

5. The "Interpretive" Rule Does not Comply with the Procedural Requirements of the MAPA or the Administrative Procedure Act.

a. The MAPA.

DEA has no authority to impose a 9-gram transactional threshold on safe harbor sales. As explained above, the MAPA explicitly permits DEA to establish "a single-transaction limit of *not less than 24 grams* of ordinary, over-the-counter pseudoephedrine."[40] Thus, at most, DEA could adopt a regulation imposing a 24-gram threshold on sales of safe harbor product. To do so, DEA would have to follow the procedures and make the findings enumerated in the MAPA. Specifically, as with the equivalent provisions in the MCA, DEA would have to carry out notice and comment rule-making and conduct an informal hearing.[41] DEA would also have to make findings that safe harbor product "purchased from retail distributors were widely used in the clandestine production of illicit drugs" and that "the best practical method of preventing such use is the establishment of single-transaction limits for retail distributors . . . of such products."[42]

The October 2001 Report to Congress fails to address these critical issues. Rather, it simply provides data that blister packs have been found in methamphetamine lab seizures and then concludes that retail sales limits will address the problem. Accordingly, DEA has not made the findings or followed the procedures required to impose a transactional threshold on sales of safe harbor product in accordance with the MAPA.

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[39] 68 Fed. Reg. 57799, 57800-01 (Oct. 7, 2003).

[40] Pub. L. 106-310, *supra* note 22, at 1238 (emphasis added).

[41] *Id.* DEA has not done this. Instead, it has, without notice and comment or a hearing, issued an "interpretive" rule establishing a 9-gram threshold.

[42] *Id.*; *see also* H. Rep. 106-878, pt. 1, 32 (Sept. 21, 2000) (directing that 'the study make a clear distinction between those over-the-counter drug products found in clandestine drug laboratories that are obtained through legal purchases from traditional retail outlets through face-to-face transactions, and those obtained illicitly").

b. The Administrative Procedure Act.

DEA's "interpretive" rule is also inappropriate as a matter of administrative law. Although the Administrative Procedure Act permits an agency to issue an interpretive rule without following notice and comment procedures,[43] DEA's rule is not in fact an interpretive rule. Interpretive rules "simply restate or clarify existing statutes or regulations."[44] As set forth above, DEA's "interpretive" rule represents a major departure from the agency's prior position that there is no transactional limit on the sale of ordinary over-the-counter pseudoephedrine. Thus, DEA's "interpretive" rule is actually a substantive, legislative rule: the rule, which would require reporting of transactions not previously subject to reporting requirements, would indisputably "create new legal obligations" for regulated industry.[45] DEA may only adopt such a rule after notice and comment.

CONCLUSION

CHPA remains committed to working with the DEA to minimize diversion of products containing pseudoephedrine. However, CHPA has profound reservations about the manner in which DEA has attempted to impose a 9-gram transaction threshold on retail sales of safe harbor product. Under the guise of an "interpretive" rule, DEA has attempted to enact a major substantive change in law. This approach is improper as a matter of basic administrative law, and fails to satisfy the existing statutory requirements specifically set forth by Congress for pseudoephedrine products.

For these reasons, CHPA respectfully requests that the Agency rescind its "interpretive" rule. CHPA pledges to work with the DEA to meet the legitimate objective of

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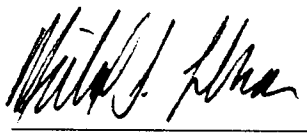
[43] 5 U.S.C. § 553(b)(3)(A).

[44] *Chemical Waste Mngt. v. EPA,* 869 F.2d 1526, 1534 (D.C. Cir. 1989).

[45] *Id.*; *Batterton v. Marshall,* 648 F.2d 694, 701-702 (D.C. Cir. 1980).

preventing diversion that underlies the interpretive rule. Issuance of an "interpretive" rule is simply the wrong path to that end.

Respectfully submitted,



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Counsel to the Consumer Healthcare Products Association

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United States Senate
The Honorable Patrick J. Leahy
Ranking Member, Committee on the Judiciary
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