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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Response to the Agency's Request for Comments
on International Drug Scheduling; Convention
on Psychotropic Substances -- Ephedrine**

Docket No. 98N-0148

SUBMITTED ON BEHALF OF DMD PHARMACEUTICALS, INC.

Dear Sir/Madam:

These comments are submitted on behalf of DMD Pharmaceuticals Inc. ("DMD") of Noblesville, Indiana. DMD is a distributor of combination ephedrine products under the Ephedrine Plus® brand name. DMD's products are sold throughout the United States in accordance with Over-The-Counter drug monographs promulgated by the Food and Drug Administration ("FDA"). DMD's products are also marketed in accordance with numerous regulations promulgated by the Drug Enforcement Agency ("DEA").

In the Federal Register of January 11, 1999, FDA published a notice providing interested parties with the opportunity to comment on recommendations made by the World Health Organization ("WHO") to the United Nations Commission on Narcotic Drugs ("CND"). If adopted, these regulations would place ephedrine in Schedule IV of the 1971 Convention on Psychotropic Substances ("the Convention"), to which the United States is a signatory. As the major reason for the Scheduling, WHO points to abuse of ephedrine in a variety of countries, including the United States, where diversion to illicit laboratories, is cited as the most significant problem.

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The Convention requires licenses for manufacturers, distributors and retailers of Scheduled substances. Moreover, Article 9 of the Convention requires that substances classified as Schedule IV "be supplied or dispensed for use by individuals pursuant to medical prescription only. . . ." As a signatory to the Convention, if the WHO recommendations are adopted by the CND, the United States would be obligated to reclassify ephedrine as a prescription only substance, an action which would also satisfy the Convention's licensing requirements.

DMD respectfully submits that it is incumbent upon FDA to oppose the WHO recommendation to CND. Over the past six years the United States Congress has twice enacted major legislation designed to address issues relating to the abuse and diversion of ephedrine. On both occasions, Congress has determined that the health of the American public is best served by continuing to allow ephedrine products to be sold over-the-counter ("OTC"). As an agency of the United States, FDA should present this information to the CND, urge it not to rely upon any issues concerning diversion in the United States in support of the recommendation to include ephedrine in Schedule IV, as those issues have already been addressed by the United States Congress, and argue that such listing is not supported by the Government of the United States.

FDA Has Already Determined That
Ephedrine Should Be Available OTC

From the outset of its OTC review process for the development of the Monograph for OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products, FDA has recognized the need for ephedrine to be available without prescription. This position was initially set forth in the Agency's September 9, 1976 proposal to establish this monograph, which recognized that:

Asthma is a very common disease and it is reasonable to have bronchodilators available on a nonprescription basis so that in mild cases relief may be obtained quickly without the possible delays of obtaining a physician's prescription.

41 Fed. Reg. 38320 (emphasis added). The Federal Register notice further noted that the agency's advisory panel of experts responsible for recommendations for the monograph concluded that

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"ephedrine preparations are safe and effective for OTC use as bronchodilators". 41 Fed. Reg. 38370.

This conclusion was echoed in the Agency's publication of the Final Monograph presented in the October 2, 1986 Federal Register. In that publication, the FDA stated:

For years, asthmatics have safely and effectively used OTC drug products containing ingredients included in this final monograph.

* * *

with appropriate labeling ephedrine can be safely and effectively used as an OTC bronchodilator drug product and [FDA] is including this drug in the final monograph.

51 Fed. Reg. 35332.

DMD respectfully submits, that nothing is presented in the WHO report as reproduced in the January 11 Federal Register notice that contradicts FDA's conclusion to the final monograph. FDA should present this position to the CND, and argue against adoption of the WHO recommendation.

Public Health Concerns Dictate That
Ephedrine Remain Available OTC

Ephedrine is indicated for use by individuals needing temporary relief from the symptoms of bronchial asthma. In 1992, the Centers for Disease Control reported that over 12 millions Americans are afflicted with this potentially debilitating disease. Vital and Health Statistics, Series 10, No. 189, U.S. Department of Health and Human Services, Centers for Disease Control, table 62 (1992). Asthma is of particular concern due to its propensity for striking at children. According to a report entitled "Asthma and the Environment : A Strategy to Protect Children", issued by the Children's Environmental Task Force on Environmental Health Risks and Safety Risks to Children ("the Task Force") (which is co-chaired by the Environmental Protection Agency and the Department of Health and Human Services), the number of children afflicted with asthma has reached 6 million. The White House announcement accompanying the Report also noted that "many children with asthma

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remain chronically impaired because they lack support systems that enable them to effectively manage their own disease or access sufficient medications or equipment". (emphasis added)

Other information contained in the Task Force Report warrants FDA's consideration. For example, it is reported that the Department of Health and Human Services ("HHS") invests in excess of \$120 million annually in asthma research, and that HHS programs including Medicaid and Medicare expenditures for the treatment of asthma exceed one billion dollars per year. In addition, thousands of patients annually receive treatment for their asthma at HHS supported clinics.

These numbers constitute a forceful argument for the continued OTC availability of ephedrine. As recognized in the November, 1996, issue of FDA Consumer:

Both prescription and over-the-counter (OTC) short-acting bronchodilators are available. The OTC drugs generally contain lesser amounts of the active agent than prescription forms and are effective for a shorter period. They may be useful, however, as temporary treatment for mild asthma attacks. Ready availability in drugstores makes OTC products potentially helpful as a "stopgap" for patients who do not have their prescription medication at hand when an asthma attack occurs.

Flieger, "Controlling Asthma", FDA Consumer, Vol. 30, No. 9, November 1996, pp. 23. It is not difficult to imagine a situation where an asthma sufferer has what may become a serious attack, late at night, far from their home, with no way to reach a doctor for a prescription. Under such circumstances an OTC ephedrine product available at a convenience store may be the only substance between this individual and a debilitating, if not life-threatening, asthma attack.

DMD respectfully submits that the statistics and findings expressed in the Task Force Report, and the need to provide asthma sufferers with readily available OTC relief, present a compelling reason for FDA to oppose the WHO recommendation.

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Congress Has Expressly Determined
That Ephedrine Should Remain Available OTC

In connection with two major pieces of legislation over the past six years, Congress has had occasion to evaluate the continued utility of ephedrine as an OTC drug product as against the risks posed by the potential for its diversion for use in the manufacture of methamphetamine. On both occasions, Congress has determined that there are compelling public health reasons for keeping ephedrine OTC. FDA should not permit WHO action to undermine this clear expression of congressional intent.

In 1993, Congress passed the Domestic Diversion Control Act ("DCDCA"). This legislation was specifically designed to combat what DEA had identified as a serious problem with the diversion of ephedrine to illicit laboratories involved in manufacturing methamphetamine. While recognizing the need to severely restrict access to single-ingredient ephedrine products by requiring licensing of all entities involved in their sale. As a result, most retail outlets determined to discontinue the sale of single ingredient ephedrine products. Congress, however, did not take action to restrict ephedrine to prescription only status. Moreover, the DCDCA did not effect, in any way, the regulatory status of combination ephedrine products.

Congress again addressed issues relating to diversion and illegal methamphetamine with the passage of the Comprehensive Methamphetamine Control Act of 1996 ("CMCA"), which was concerned with combination ephedrine products, pseudoephedrine and phenylpropanolamine. While seeking to restrict illegal access to these chemicals by diverters, Congress also recognized the need to minimize the law's effect on the legitimate OTC drug industry and consumers. Thus, the CMCA provided an exemption for recordkeeping-reporting of retail transactions below a threshold established by DEA (set at 24 grams per transaction), and by not requiring the licensing of retail outlets selling combination ephedrine products. Once again, no action was taken to relegate combination ephedrine products to prescription only status.

The rationale for the decision not to take action to restrict the retail availability of OTC combination ephedrine products was clearly set forth by the principle sponsor of the CMCA, Senator Hatch, when he stated:

This title contains carefully drafted

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provisions that balance the need to maintain the availability of drugs such as pseudoephedrine for legitimate purposes. I recognize the need to take measures to decrease the availability of the precursor list I chemicals for diversion to clandestine methamphetamine laboratories. However, in so doing, we must not restrict the availability of law-abiding citizens to use common remedies for colds and allergies, or subject sales of such legal products to onerous recordkeeping at the retail level.

Congressional Record, S. 10718, September 17, 1996 (emphasis added).

This policy determination remains valid today. The WHO recommendation, which would reverse this Congressional decision, should be opposed by FDA.

Conclusion

Each time it has addressed the issue, FDA has determined that public health concerns mandate the OTC availability of ephedrine products to consumers. Since 1994 Congress has twice considered the need to adopt legislation designed to halt the diversion of ephedrine to illicit methamphetamine laboratories. On both occasions it too has determined that there are compelling public health reasons to continue to allow ephedrine to be available OTC, and declined to reclassify it as a prescription only substance. While both the DCDCA and the CMCA adopted rigorous licensing and reporting mechanisms to be administered by the DEA, neither statute required ephedrine to be removed from the OTC marketplace nor imposed a licensing regimen on retail outlets selling combination ephedrine products.

DMD respectfully submits that FDA's decisions and the clear expression of Congressional intent mandate that the agency oppose any action by the CND which would subvert the will of Congress. While the Agency should express agreement with the need to curtail illicit trade in ephedrine and Methamphetamine, and support action by international law enforcement bodies to accomplish this task, FDA should oppose the WHO recommendation to classify ephedrine as a Schedule IV substance. Congress has determined that ephedrine

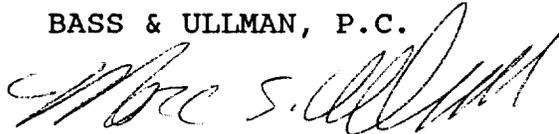
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products should remain available OTC, and that combination products should be sold without the need for retailer licensing. Adoption of the WHO proposal would reverse both of these determinations, and as an agency of the United States, FDA should express the will of Congress and argue that the WHO proposal be rejected.

Respectfully submitted,

BASS & ULLMAN, P.C.

A handwritten signature in black ink, appearing to read "Marc S. Ullman". The signature is written in a cursive, flowing style with some loops and flourishes.

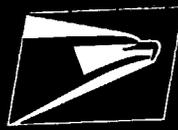
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