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Better Health
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NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

~~October 6, 1998~~ NOV 12 P1 :59

via fax – three pages

To: Ambassador George Moose
U.S. Mission – Geneva
Geneva, Switzerland
fax: (41) 22-749-4892

Dear Ambassador Moose:

Our association has a number of concerns with the processes used by the World Health Organization (WHO) in its role under the UN Convention on Psychotropic Substances which we wanted to share with you. We believe it is essential that WHO in fact follow the guidelines it has laid out for the review of substances under the UN Convention on Psychotropics, rather than using the short cuts discussed below. Further, there should be more transparent and wider opportunities for input into the WHO process.

The Nonprescription Drug Manufacturers Association (NDMA) is the national association representing manufacturers and distributors of nonprescription, or over-the-counter (OTC), medicines. NDMA members account for some 90% of retail sales of OTC medicines in the U.S. NDMA members make well-known brands such as Tylenol, Advil, Bayer Aspirin, and many others. In addition, NDMA is a founding member of the World Self-Medication Industry – the world federation of similar associations promoting better health through responsible self-medication and an NGO in official relations with the World Health Organization.

This past June, the WHO Expert Committee on Drug Dependence met in Geneva to evaluate the medical, scientific, and public health aspects of a number of pharmaceutical ingredients to decide whether or not to recommend that they be controlled under the UN Convention on Psychotropic Substances. This role is provided for by the UN Convention on Psychotropic Substances, to which the U.S. is a signator. The nonprescription medicines industry had representatives at the meeting as nongovernmental observers, but they were asked to speak only when the Chair permitted them to do so for comments which were directly responsive to committee member statements.

Among the ingredients reviewed at the meeting was ephedrine. Ephedrine has a long and well-established safety and effectiveness record for its intended use as a nonprescription bronchodilator, and as a cream or lotion to temporarily reduce swelling associated with irritation in hemorrhoids. The U.S. Food and Drug Administration has noted that the nonprescription availability of ephedrine-containing bronchodilators “provides asthmatics ready access to this essential medication without the need for additional visits to a physician’s office or to a hospital emergency room.” (51 Fed. Reg. 35326, 35327 [October 2, 1986].) Nevertheless, the WHO Expert Committee on Drug Dependence decided to recommend scheduling of ephedrine in schedule IV of the UN Convention on Psychotropics.

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A WHO recommendation goes from WHO to member states and the UN, and in turn is considered by the UN Commission on Narcotic Drugs (UN CND). The UN CND makes a determination that ultimately is to be converted into national law (in the U.S. case through the Controlled Substances Act.) While parties to the Convention can notify the UN for an exemption, it is cumbersome and other parties or WHO can seek to terminate such exemptions.

Setting aside for the moment the merits of ephedrine, the WHO process raises a number of problems which deserve your attention. First, we understand the U.S. government will receive a notification from WHO recommending the scheduling of ephedrine under the UN Convention on Psychotropics yet this year. The WHO recommendation will trigger a U.S. Federal Register notice for comments on the U.S. government position as the recommendation moves from WHO to the UN Commission on Narcotic Drugs. But the recommendation is anticipated this year even though the report on ephedrine from the June WHO meeting will not be available for several months, perhaps not until the summer of 1999. How can our association fairly respond to the recommendation, and how can the U.S. government fully develop its position, without an adequate record of how WHO came to its conclusions?

WHO has adopted guidelines for the review of psychoactive substances for international control which state that WHO is to provide summaries (including in English) of the relevant scientific information used by the Expert Committee to the UN, and in turn such summaries are to be distributed to governments "in good time prior to the Commission on Narcotic Drugs decision on international control." (See "Revised Guidelines for the WHO Review of Dependence-Producing Psychoactive Substances for International Control," PND/90.1, at 3, ¶6.) It appears WHO is planning to completely bypass this needed step.

The WHO guidelines for review note that WHO is interested in "principles of openness and transparency," and that information collected is generally made available for publication, particularly information contained in the Expert Committee's report. ("WHO Revised Guidelines," at 3, ¶8.) While materials were made available to WHO Expert Committee members, to date they have not been published so that all interested parties in the U.S. could review them. Even if and when they are, and we understand that could be some time, we are troubled that the WHO notification is expected well before that.

WHO's guidelines note that documents should go to Expert Committee 3 weeks ahead of time. ("WHO Revised Guidelines," at 12, ¶50.) That did not happen here. A document meeting observers describe as pivotal was not raised until the meeting itself by the member from the Philippines. Even at the meeting, copies of the document were not distributed to all committee members and observers. The document, which we understand was prepared by the International Narcotics Control Board, reported on ephedrine imports to various countries. The two nonprescription medicine industry observers at the meeting saw other individuals' copies of the documents, but were not able to obtain their own copies and we have not had an opportunity to review the document. This is the antithesis of "openness and transparency," and is surely no way to form a recommendation which could impact a safe and effective product for asthma sufferers or hemorrhoid relief.

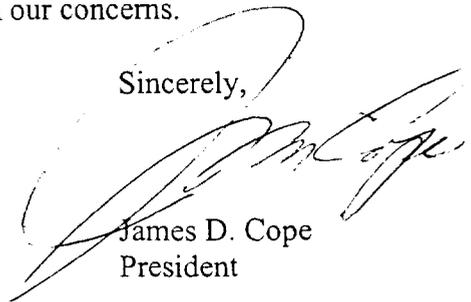
Most of the discussion at the WHO Expert Committee meeting focused on country-specific problems in certain west African nations (this based on the last-minute document our observers saw at the meeting, but which we have not had the opportunity to read or review). Such a focus does not square with the theme of the UN Convention on Psychotropic Substances: international abuse problems requiring coordinated international action. The fact that we have not had a chance to review the pivotal document only serves to compound the problem.

We do not expect to see every detail of the U.S. administrative procedure system that promotes fairness and transparency to be present in every international organization or committee. And yes, we had representatives at the meeting as nongovernmental organization observers, so there was a limited opportunity for input. But the very purpose of the "Revised Guidelines for the WHO Review of Dependence-Producing Psychoactive Substances for International Control," and the U.S. government's leadership in their revision some years ago, is to assure some basic level of procedural fairness and transparency. These guidelines were not followed in this instance. If the U.S. government is to develop a position, and if interested parties are expected to have the opportunity for meaningful input into that process, there must be a road map to follow at the WHO level.

In addition, for the future, we would encourage a more open role for NGO observers at such meetings. In this instance, the nonprescription drug industry representatives were asked to speak only when the Chair permitted them to do so for comments which were directly responsive to committee member statements.

We will, of course, provide the Food and Drug Administration with our position regarding the safety and effectiveness of ephedrine (as we have done in the past) at the time a Federal Register notice is triggered by WHO notification. In addition, we would welcome an opportunity to improve the WHO process, or at least assure that existing guidelines for that process are in fact followed. We thank you for any help you can give us on our concerns.

Sincerely,



James D. Cope
President

cc: The Honorable Princeton N. Lyman, Assistant Secretary for International Organization
Affairs Bureau, Department of State
Stuart L. Nightingale, M.D., Associate Commissioner for Health Affairs, Food and Drug
Administration
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