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5362 '99 FEB 24 A9:35



February 22, 1999

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

Re: Docket No. 98N-0148: "International Drug Scheduling: Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization Scheduling Recommendation for Ephedrine, Dihydroetorphine, Remifentanil, and certain isomers. 64 Federal Register 1629 (Jan. 11, 1999)

To whom it may concern:

The following is a transcript of comments made by Howard M. Druce, M.D. to the FDA Public Meeting considering the W.H.O. Scheduling Recommendations on Ephedrine and other substances, Rockville, MD, February 19, 1999.

If there are any questions, please feel free to contact me on 973-540-6713.

Sincerely,

A handwritten signature in cursive script that reads "Howard Druce".

Howard M. Druce, M.D., F.A.C.P.

98N-0148

TSI

I would like to thank Dr. Nightingale and the FDA for convening this meeting.

My name is Howard Druce. I am a physician, board-certified in allergy, clinical immunology and internal medicine, licensed to practice in the state of New Jersey. I am currently employed by the Warner-Lambert Company and hold the position of Clinical Associate Professor of Medicine at the New Jersey Medical School in Newark, in the Division of Allergy and Immunology.

I was present at the WHO ECDD Geneva meeting in 1998, where I represented the World Self-Medication Industry Group. Several presenters today have commented on the procedures conducted by WHO at its ECDD meeting. I wish to specifically address this issue.

First, as per the committee guidelines, written submissions were requested to be submitted prior to the meeting. Thus when the agenda item was introduced there was no notification to the committee of ephedrine abuse beyond the comments noted in the questionnaire and critical review document. During presentation of the topic, the INCB representative talked about evidence of abuse of ephedrine in West African countries. The representative did not have any documentation at that time. The committee chair suspended the agenda at that point to give the INCB representative time to bring documentation. When the topic was resumed, on the following day, the INCB representative produced documentation. The committee rapporteur immediately rebutted this as being influential and circumstantial. The committee chair overruled the rapporteur in no uncertain terms.

The impact of scheduling ephedrine as a bronchodilator in countries with emerging economies was not discussed or explored.

I am frequently asked to evaluate scientific data, which affect both individuals and populations. Inferential data must take second place to hard data. In this very room, FDA advisory panels routinely dismiss inferential data in submissions to the Agency. I am sad and disappointed that the WHO ECDD chose to make such a significant and global decision based on the inferential data that was made available in this manner. From my scientific background, I believe we deserve better process.

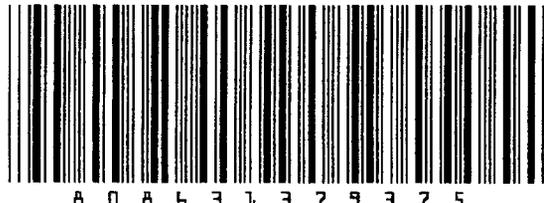
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