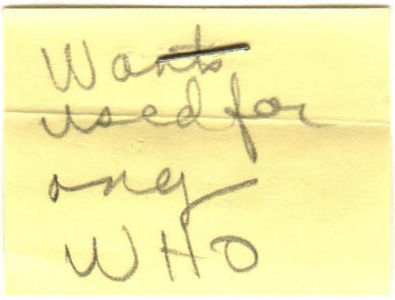
Bob is concerned about the scheduling of certain drugs by WHO. I Khan seems to be the person who is taking the view that anything pharmaceutical companies do is against the developing world. He views everything political. Technically he is incompetent but political savvy within UN + WHO. He must be dealt a strong downward blow. Must be smooth + quickly executed by his own Govt. Zia + Roedad Kahn are probably key. Raz Hussain would make good replacement.

Lunch to follow. Jor, CT, Bob.

(*) MM: Bob's folder should be used for WHO Regulatory Affairs. 8-15-88


Wants
used for
WHO

FYI 3758
6 AUG 1986

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August 5, 1986

Editor
The Washington Post
1150 15th Street, N.W.
Washington, D.C. 20071

Dear Sir or Madam:

On August 4, President Reagan announced a major six point initiative aimed at reducing drug abuse in the United States, probably the number one problem facing American society today. The Post reported this on page A6. The same day, the owners of the USFL let the public know of their decision not to play football this season. This was the lead story on page 1.

You guys really have your priorities straight.

Sincerely,

Robert T. Angarola
428 6th Street, N.E.
Washington, D.C. 20002
Former General Counsel
White House Office of
Drug Abuse Policy, 1977-1981

RTA/lcc

bcc: Dr. Carlton E. Turner

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August 14, 1985

15 AUG 1985
2649

HAND DELIVERED

Honorable Jon R. Thomas
Assistant Secretary for
International Narcotics Matters
Room 7331
Department of State
Washington, D.C. 20520

Dear Jon:

Following up on your suggestion, I met today with Carlton Turner to discuss the WHO review of stimulant-like drugs. At that meeting I gave him the attached outline of problems and possible government actions to deal with the situation. C.T. agreed that something should be done and suggested that the three of us discuss this further. I will contact you in the near future to see if we can arrange a meeting.

Once again, thank you for your assistance.

Sincerely,

Robert T. Angarola

RTA/smg

Attachment
cc: Dr. Carlton E. Turner

MEMORANDUM

August 14, 1985

SCHEDULING OF STIMULANTS UNDER THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

PROBLEMS

- WHO either ignored or took out of context much of the information provided by manufacturers on the substances under review.
- WHO procedures excluded manufacturers from the most important meeting of the entire process, the Expert Committee on Drug Dependence.
- WHO recommended control of almost all the drugs under consideration when there was little or no indication of international drug control problems.
- WHO did not provide adequate medical or scientific reasons for supporting control of the substances under review.
- WHO is categorizing attempts by manufacturers to discuss WHO's findings and present factual scientific and medical information to the Expert Committee as "forcing their attention on the Committee" and as "damaging the industry as a whole."

POSSIBLE GOVERNMENT ACTIONS

- An interagency review committee should be formed, chaired by the State Department, to determine whether manufacturers' complaints are based on fact.

- FDA should continue its policy of holding open hearings on the position the United States should take on the scheduling of drugs under the Psychotropics Convention and should receive substantive and procedural information on the present review.
- The interagency committee should thereafter take this information into consideration and, if justified, formally protest to the WHO Director-General the method used by the organization in reviewing these substances.
- Based upon the information gathered, the United States should vote against, or abstain on, the scheduling of all the substances under review.
- The State Department should inform members of the Commission on Narcotic Drugs of the U.S. position, and the reasons for it, before the Commission meets in February, 1986.
- The U.S. delegation to the CND should attempt to gain support for postponing the vote until WHO provides more medical and scientific information and a clearer justification for scheduling these substances.

Robert T. Angarola

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August 14, 1985

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THE 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

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Robert T. Angarola

INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS (IFPMA)
FEDERATION INTERNATIONALE DE L'INDUSTRIE DU MEDICAMENT (FIIM)
FEDERACION INTERNACIONAL DE LA INDUSTRIA DEL MEDICAMENTO (FIIM)

22 May 1985

To companies involved with the
WHO Review of Amphetamine-like substances.

copy to respective Member Associations

Dear Sir,

Recommendations from the WHO Expert Committee on Drug Dependence

This WHO Expert Committee met in Geneva 22-26 April 1985 to consider data on 28 amphetamine-like substances for possible scheduling under the International Conventions.

The full report of the meeting is not yet available but WHO have sent us the attached extract which we are forwarding to you.

As you will see, a total of 17 substances are recommended for inclusion in the Schedules of the 1971 Convention on Psychotropic Substances.

Yours sincerely,

Margaret E. Cone

12. Propylhexedrine

Chemically, propylhexedrine is racemic 1-cyclohexyl-2-methyl-aminopropane. Animal pharmacology studies indicate that propylhexedrine has some stimulant actions in common with amphetamine, such as increased locomotor activity and pressor effects. Regarding dependence potential, no data are available from animal studies but human investigative reports indicate that propylhexedrine is capable of imitating at least some of the subjective effects of amphetamine, such as restlessness.

Toxicological data report adverse reactions in man following both oral abuse of propylhexedrine inhalers and certain cases of intravenous abuse reported from 1974 to 1982. Published reports describe severe acute toxic effects from abuse of the substance. In addition, propylhexedrine abuse has been reported at a low frequency in epidemiological observations based upon several abuse reporting systems and these observations have been spread over a period of 30 years. It also appears important that propylhexedrine has not been accepted apparently by abusers when provided as substitute for amphetamine in inhalant form.

Propylhexedrine is a sympathomimetic agent which has been used without a prescription in an inhalant form for nasal decongestion. Its hydrochloride is available in an oral form and given daily in divided doses as an anorectic agent in the treatment of obesity.

On the basis of the data outlined above, it was the consensus of the Committee that propylhexedrine met the criteria of Article 2, para. 4 for control under the Convention on Psychotropic Substances and should be placed in Schedule IV.

August 14, 1875

He is coming to discuss international drug scheduling.