

structure, pharmacologic data, and the preliminary impressions of Dr. Nathan B. Eddy (Exhibit B). Since the United States was obligated by international agreement to implement the WHO recommendation, the United States Treasury Department published February 29, 1956, a proposed rule in the Federal Register seeking to declare propoxyphene, among other drugs, an addiction-forming or an addiction-sustaining drug, similar to morphine and that it was an opiate (Exhibit C). A hearing was held May 3, 1956, by the Treasury Department, Bureau of Narcotics in which Eli Lilly and Company presented evidence which indicated there was no evidence to sustain a conclusion that propoxyphene possessed addiction-producing or addiction-sustaining qualities similar to morphine (transcript available). The new drug application for propoxyphene was approved September 9, 1957, and marketing began in the fall of 1957. In March of 1962, the Treasury Department, Bureau of Narcotics published in the *Federal Register* its determination that propoxyphene was not an opiate (Exhibit D). Following this determination, the WHO in 1964 withdrew its initial evaluation on the basis of five years of experience, repeated observations of the use of propoxyphene, and the United States determination (Exhibit E, pages 5 and 8). WHO reaffirmed that controls on propoxyphene were unnecessary in 1969 and 1970. The WHO Scientific Group reported in 1972 that dependence liability and frequency of nonmedical use of propoxyphene was low.

## EXHIBIT A

(Note.—Exhibit A, an article entitled "Expert Committee on Drugs Liable to Produce Addiction," has been omitted because of its poor readability. Relevant parts of pages 9 and 10 have been re-typed and appear below.)

WORLD HEALTH ORGANIZATION TECHNICAL REPORT SERIES No. 102—EXPERT COMMITTEE ON DRUGS LIABLE TO PRODUCE ADDICTION, SIXTH REPORT, MARCH 1956

## 5.2.2 4-DIMETHYLAMINO-1,2-DIPHENYL-3-METHYL-2-PROPIONOXYBUTANE

Referring to the notification of the Government of the United States of America, the Committee was of the opinion that 4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane, because it (1) will only partially suppress the abstinence phenomena of a known morphine addiction, and (2) will in part sustain a morphine addiction, must be considered as having no greater addiction liability than codeine, and that 4-dimethylamino-3-1,2-diphenyl-3-methyl-2-propionoxybutane and its salts are assimilable to the drugs mentioned in Group II of the 1931 Convention. Therefore,

The Expert Committee on Drugs Liable to Produce Addiction:

Recommends that its opinion with respect to 4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane and its salts be communicated to the Secretary-General of the United Nations.

## UNITED STATES NOTIFICATION WITH RESPECT TO NINE NEW SYNTHETIC DRUGS

Pursuant to Paragraph 1 of Article 1 of the Protocol signed at Paris on 19 November 1948, bringing under international control drugs outside the scope of the Convention of 13 July 1931, as amended by the Protocol signed at Lake Success on 11 December 1946, the United States Government presents a notification that the following named drugs, and their respective salts, all of which are or may be used for medical or scientific purposes and to which the Convention of 13 July 1931 does not apply, are considered liable to the same kind of abuse and productive of the same kind of harmful effects as the drugs specified in Article 1, Paragraph 2, of the said Convention:

Ethyl-2,2-diphenyl-4-morpholinobutyrate

4-Dimethylamino-1,2-diphenyl-3-methyl-2-propionoxy butane

1,3-Dimethyl-4-phenyl-4-propionoxyhexamethyleneimine

4-Carbethoxy-1-methyl-4-phenylhexamethyleneimine

4-Carbethoxy-1,3-dimethyl-4-phenylhexamethyleneimine

4-Carbomethoxy-1,2-dimethyl-4-phenylhexamethyleneimine

3-Hydroxy-N-phenethylmorphinan

1-[2-(p-aminophenyl)-3thyl]-4-carbethoxy-4-phenylpiperidine

4-Carbethoxy-1-(2-hydroxy-2-phenyl-ethyl)-4-phenylpiperidine

This notification is respectfully submitted for appropriate decision as to the status of the new drugs and of their respective salts under the Convention of 13 July 1931, as amended by the Protocol of 1946.