

15224 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

SUBJECT Drug Abuse Act

DATE November 5, 1970

TO W. F. Head, A. P. Truant, I. R. McGraw, E. Rahn

FROM E. A. Garner

IN REPLY TO

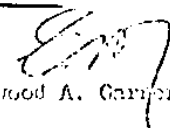
COPIES TO

Attached you will find a copy of Vincent Kleinfeld's letter to me regarding the "Comprehensive Drug Abuse Prevention and Control Act of 1970".

Dr. William F. Head, V. P. Technical Operations, shall be our chief compliance officer with respect to the provisions of this Act that are pertinent to our operations.

Will 'Biphetamine' and 'Biphetamine-T', falling into Schedule III under the Act, be transferred to Schedule II? The Attorney General has the power to initiate proceedings affecting such a transfer, but according to Vincent Kleinfeld and Alan Kaplan only with the advice and concurrence of the F & DA. After talking with people at the Justice Department, if the Attorney General wished to move a drug or substance out of a controlled category, he could not do so without the concurrence of the F & DA. Although the language of the law is not too explicit and there is still some confusion about the point, it is presently felt that the same restriction would apply to moving a substance from one schedule to another. The whole point is that if 'Biphetamine' and 'Biphetamine-T' were moved into Schedule II, these drugs would become subject to production quotas. Production quotas in turn would be established by the Attorney General who, according to the law, "shall determine the total quantity and establish production quotas for each basic class of controlled substance in Schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance".

Thus it becomes doubly imperative that our February 8, 1971 submission to the Food & Drug Administration definitely re-prove and re-establish the true medical need for 'Biphetamine' and 'Biphetamine-T' as anorectics to avoid production quotas being established merely on the basis of narcolepsy and the hyperkinetic syndrome.


Elwood A. Garner

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