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AMPHETAMINES: TIGHTER CONTROLS ON THE HORIZON

(By Constance Holden)

The abuse of the central nervous system stimulants known as amphetamines has dropped since "speed" had its hey-day in the 1960's. But amphetamine abuse is still a major problem in terms of physical damage and emotional dependency. And despite the fact that manufacture and distribution of the most dangerous varieties of the drug have been under strict federal controls since 1971, it still seems to be available to anyone who wants it.

That's what Senator Gaylord Nelson (D-Wis.), chairman of the monopoly subcommittee of the Senate Small Business Committee, heard in 5 days of hearings he conducted last month on the safety and efficacy of antiobesity drugs.

The major condition for which amphetamines and amphetamine-like drugs (amphetamine congeners) are legally prescribed is obesity. But the evidence is strong that for most of the 2.25 million Americans estimated regularly to take prescribed amphetamines—not to mention uncounted users who buy them on the street—the drugs are not primarily being used for legitimate medical purposes.

It has been 6 years since Congress passed the Controlled Substances Act, which enabled the government to put restrictions on the production and distribution of licit drugs that are subject to abuse. Amphetamines and their congeners are controlled under the law, which has sharply reduced prescriptions of the formulations thought to be most dangerous. But the act seems to have reached the limits of its effectiveness, because the level of amphetamine consumption, according to Food and Drug Administration (FDA) statistics, has remained constant over the past 3 years. Furthermore, consumption of amphetamine-like drugs has gone up and there are many experts who believe their potential for abuse is almost as great as it is for amphetamines.

This phenomenon, combined with accumulating evidence to the effect that diet pills are of marginal use in combating fat, has led Nelson to conclude that, according to an aide, "the time is ripe" for amphetamines to be wiped off the market altogether, and for stricter controls to be put on other sympathomimetic diet drugs. There remain two respectable applications for at least one amphetamine congener—Ritalin (methylphenidate)—which are narcolepsy and childhood hyperkinesis. Ritalin is not used as a diet drug but it and Preludin (whose only indication is for obesity) are said to be the most heavily abused drugs in the amphetamine family.

It has been 4 years since an FDA advisory panel concluded that amphetamine-type diet drugs were "clinically trivial." The preponderance of testimony from nongovernment witnesses at the hearings was to the effect that the drugs are neither safe nor efficacious. They curb appetite for a short time, but tolerance is quickly built, and if the pills are withdrawn the appetite returns in full force. Tentative evidence was also presented that these pills taken in the early weeks of pregnancy may cause fetal heart defects and other malformations.

Now, judging from what government witnesses said at the hearings, it appears that the FDA and the Drug Enforcement Administration (DEA) are getting ready to agree that the abuse potential of many of these drugs outweighs whatever short-term benefits they have in helping obese people change their eating habits.

As J. Richard Crout, director of the FDA's Bureau of Drugs, testified, in view of the failure of the Controlled Substances Act to minimize abuse, "the only meaningful next step which can be taken is to remove the indication for obesity from the labeling for amphetamines or to remove them from the market." Since obesity is the only indication for some, changing the label would be tantamount to outlawing them altogether.

It has been more than a dozen years since various groups, including members of Congress, have been attempting to curb or even ban entirely the marketing of anorectic (appetite-suppressing) drugs. But the success has been limited in the face of dedicated resistance on the part of pharmaceutical manufacturers—amphetamines and their relatives are the backbone of the diet pill business—and indiscriminating prescription practices on the part of some physicians—all catering to voracious public demand for fast-acting means to thinness and happiness.

The 1970 act sharply reduced production of diet pills—which reached an all-