Psychotoxic Drugs: Dodd Bill Passes Senate, Comes to Rest in the House; Critics Are Sharpening Their Knives

Early this month a network television producer with a flair for exposé reporting drew public notice to the ease with which barbiturates and amphetamines can be illicitly obtained. The flurry of attention came at just about the time it became clear that the Senate-passed bill to put tighter controls on "psychotoxic drugs" would go nowhere in the House of Representatives in the waning days of this Congress.

The Senate bill (S. 2628), passed 15 August after a single day of hearings early in the month, would amend the Federal Food, Drug, and Cosmetic Act to require registration of manufacturers and processors and more complete record keeping by all handlers (except medical practitioners) of what are commonly called "dangerous drugs." A major feature of the bill is that it provides a basis for control of psychotoxic drugs in general rather than being limited to barbiturates and amphetamines, as earlier drug-law reform bills were. The bill also makes possession of these drugs, except in reasonable quantity and on prescription, a federal offense, and provides stronger enforcement authority to the Food and Drug Administration (FDA), which is the responsible federal agency.

Chief sponsor and leading advocate of the bill is Senator Thomas J. Dodd (D–Conn.), a lawyer and member of the prosecution team at the Nuremberg trials. Dodd's interest in legislation on dangerous drugs stems directly from his experience as chairman of the Senate special subcommittee on juvenile delinquency.

In a statement at the hearings, Dodd reported the following findings based on his subcommittee's investigation of the use of nonnarcotic drugs by young people.

"The illegal use of these drugs is increasing at a fantastic rate among juveniles and young adults.

"The use of these drugs has a direct causal relationship to increased crimes of violence.

"The use of these drugs is replacing, in many cases, the use of hard narcotics such as opium, heroin, and cocaine.

"The use of these drugs is more and more prevalent among the so-called white collar youth who have never had prior delinquency or criminal records.

"The use of these drugs is increasingly identified as a cause of sexual crime."

It was not Dodd's subcommittee, incidentally, but the health subcommittee of the Senate Labor and Public Welfare Committee which had jurisdiction over the bill. While Dodd and others had pressed for action on dangerous-drug legislation in recent years, the committee and its chairman, Senator Lister Hill (D–Ala.), had seemed in no haste to bring it up. The Senate hearings and easy passage of the bill in August are attributed to Dodd's being so strongly for it and the senators' being asked to vote against illicit drugs for juveniles.

The idea of tighter control of dangerous drugs has picked up strong support from such widely diverse sources as the President's Advisory Commission on Narcotic and Drug Abuse (*Science*, 14 Feb., p. 662), the departments of Health, Education and Welfare, Justice, State, and Treasury, the Pharmaceutical Manufacturers Association, and the American Trucking Association. And congressional interest in the dangerous-drug problem dates back at least to hearings in the House Ways and Means Committee in 1951. The Dodd bill, however, does not enjoy unanimous support as the best of all possible dangerous-drug legislation.

There is virtual unanimity in deploring the wide availability of illicit amphetamines and barbiturates—pep pills and goof balls in the vernacular. This availability is what CBS producer Jay McMullen dramatized in a series of three reports on a network evening news program during the first week of the month. McMullen set up a dummy company and, on the strength of an office in midtown Manhattan and some printed letterheads and a checking account, set about ordering barbiturates and amphetamines—both pills and powder—from drug manufacturers and processors listed in the *Drug Topics Red Book*. According to CBS, for an investment of about $600, the equivalent of more than a million standard-size pills was obtained. An FDA official estimated that the drugs would be worth from $250,000 to $500,000 if sold on the black market. Of 19 companies with which orders were placed, nine shipped drugs, while ten others wrote asking for proof of license or FDA registration of "McMullen Services."

McMullen heads a special CBS fact-finding news unit formed about 4 months ago. Earlier, he had been responsible for a hidden-camera documentary on a Boston handbook operation, called "Biography of a Bookie Joint"; and for a study on the international traffic in narcotics, titled "The Business of Heroin."

The ease with which the drugs were obtained through legal channels points up what advocates of reform in legislation on dangerous drugs have been lamenting—the weakness of the present law and of FDA enforcement authority.

A main effect of the Dodd bill would be tightening of accountability all along the line of supply. At present the law, in essence, forbids the dispensing of these drugs without prescription. Penalties are based on the authority of the federal government over interstate commerce, and conviction requires proof that illegal drugs sold have crossed state lines. Possession of illegal drugs is not now a federal offense, as the possession of narcotics is. The Dodd bill would make possession illegal and remove the interstate commerce restrictions.

The Bootleg Market

At the Senate hearings, Food and Drug Commissioner George P. Larrick emphasized the difficulty of dealing with illicit traffic in barbiturates and amphetamines at the "retail" level. He said that many truck drivers, particularly those engaged in long-distance hauling, rely on amphetamines to combat fatigue and on barbiturates to counter the lingering effects of the pep pills, and that consequently truck stops have become major centers of distribution for the black market drugs. Discussing the economics of the illicit market, Larrick said that amphetamines, if they can be purchased at a manufacturers' price of $1 per thousand, wholesale at $30 to $40 per thousand on the black market and retail at from 5 to 10 cents a pill.

In 1964, FDA inspectors, who must oversee the broad field of food, drug, and cosmetic manufacture and sale, spent some 56 inspector man-years, out of a total of 687, on investigation of illegal drug sales. Larrick said that inspectors doing undercover work and making arrests and seizures are facing increasingly hazardous conditions. The Dodd bill would authorize FDA inspectors to carry fire arms when investigating illegal drug sales, which they are

not now allowed to carry. And it is understood that the FDA would give special training to present inspectors and would expect to add a substantial number of recruits.

Not seriously discussed at the hearing or on the floor of the Senate were the implications of hiring more FDA agents and giving them guns. The President's Commission on Narcotic and Drug Abuse (*Science*, 14 February), in one of its more controversial recommendations, urged that responsibility for investigation of the illicit traffic in dangerous drugs be transferred to the Justice Department from the Department of Health, Education, and Welfare (FDA's parent agency). After pointing out present weaknesses in the Food, Drug, and Cosmetic Law, the commission observed that "the record of enforcement by the Food and Drug Administration in this area also reflects a lack of sufficiently trained inspectors with the traditional authority of law enforcement officers to carry weapons, to search and seize, and to make arrests. In considerable part, it reflects a lack of knowledge in police techniques, understandable in an agency primarily devoted to ensuring the safety of food, drugs, and cosmetics."

Enactment of the Dodd law would presumably put FDA on the road to developing a police arm similar to the Treasury Department's Bureau of Narcotics, which is responsible for the enforcement of the laws on narcotics and marijuana. While the police problems surrounding narcotics and dangerous drugs appear to be similar, there is little chance in the federal world of sharp jurisdictional distinctions that the Bureau of Narcotics, for example, would be given authority over dangerous drugs. The Narcotics Bureau is in another department and answers to different congressional committees—notably the tax-writing House Ways and Means Committee—and reportedly wants nothing to do with dangerous drugs and the pursuit of pep-pill pushers. (One problem is that peddlers and users these days do not discriminate nicely between narcotics and the nonnarcotic stimulants and depressants.) Another well-known federal police agency, the Federal Bureau of Investigation in the Justice Department, is said to be equally unenthusiastic over taking on enforcement duties in the drug field.

FDA, for its part, has sought both a strengthened law and better means to enforce it. One experienced observer in another agency sees hope for FDA's enforcement capacities in his impression that in recent years the agency has been getting better recruits for its inspector positions and giving them better training. Supporters of the legislation on Capitol Hill tend to take the pragmatic view that the statutory authority for enforcement of the law on these drugs is irrevocably FDA's and that the agency will have to do whatever is necessary to meet the responsibility.

Not discussed was the question of whether the upgrading of enforcement would result in the downgrading of science and scientists in an agency which is essentially science-based, but in which there has been for years tension between scientists and inspectors.

Another question left unclear is that of the stringency of the proposed registration and record-keeping requirements. The licensing system employed by the Bureau of Narcotics, for example, seems somewhat more demanding than the system proposed for psychotoxic drugs.

Information Problem

That keeping track of the drugs from producer to user is not easy has been clearly demonstrated. An elementary problem facing the reformers has been that of getting basic production figures. At the Senate hearing, Larrick observed that "unfortunately, our survey of production figures was incomplete because records kept by several basic manufacturers were inadequate and also because two of the Nation's largest pharmaceutical firms declined, as was their right, to provide the information requested. Nevertheless, we did learn that at least enough basic material was produced in 1962 to make over 9 billion doses of barbiturates and amphetamines. Probably half of these end up on the bootleg market."

Interviewed on CBS News, Senator Dodd spoke of "undercover opposition" to his bill and of the difficulty of getting fundamental information. Dodd, an angry man on this subject, said, "For over a year we heard witnesses. None of these people ever showed up. That isn't how they work. They work underneath in a sinister manner. And they block these measures despite the fact that a vast majority, I believe, of our people in this country want this bill."

Open opposition to the present bill came, however, from several quarters. The two large organizations of druggists, the National Association of Retail Druggists and the American Pharmaceutical Association, approve the bill in general but object to granting FDA agents the right to inspect the pharmacist's prescription file. They resent the exemption of the files of medical practitioners, many of whom also dispense quantities of drugs. And they argue that the provision is unnecessary since a search warrant can be easily obtained when there is adequate cause.

The American Medical Association sent no witness to the hearings but submitted a letter opposing the bill mainly on the grounds that it would inhibit the legitimate manufacture, distribution, and use of the drugs in question. In its letter the AMA said, "Although the characteristics of either habituation or addiction may occur with any drug capable of modifying behavior, the need for special measures of control should depend on the extent of the problem. In the United States, at this time, compulsive use of amphetamines and barbiturates constitutes such a small problem that additional legislation to control such abuse does not seem necessary."

While declaring itself "well aware of the addicting and habituating properties of barbiturates and amphetamines and certain other psychotoxic agents," the AMA regards "education and appropriate state and local laws, rather than Federal regulation," the "appropriate answer."

The real fight on the Dodd bill is likely to center on its broadened applicability. Until this year, reform bills had applied to barbiturates and amphetamines. But after the appearance of the report of the President's Commission, Senator Dodd followed one of its recommendations and expanded coverage to include not only "habit-forming" barbiturate drugs and amphetamines but "other habit-forming central nervous system stimulant drugs, and other drugs that have a potential for abuse resulting in psychotic effects or antisocial behavior."

This recasting of the definition last spring drew the opposition of major

drug manufacturers represented in Washington by the Pharmaceutical Manufacturers Association. Informed observers say that the industry is uneasy about the possibility that nonbarbiturate sedatives (the tranquilizers), for which a vast market has developed since the early 1950's, will be classed with barbiturates and amphetamines as psychotoxic drugs.

In a letter to Senator Hill printed in the hearings, PMA said that the abuse problem with barbiturates and amphetamines is related to their " 'thrill use' by those seeking anti-social effects" or by those seeking to avoid the onset of fatigue. Such use does not create a "compulsive desire" for the drugs, said PMA, in arguing that the "available evidence would indicate that the social abuse of both classes of drugs is not related to any habituating qualities they might possess."

In a letter to House Commerce Committee chairman Oren Harris (D–Ark.), written after passage of the Dodd bill in the Senate, PMA president Austin Smith wrote:

"It is one of industry's most strongly held views that only those drugs should be subject to the controls of this bill which are actually being abused and which are a threat to the public health and safety when used illicitly because of their stimulant or depressant effect on the central nervous system. However, as S. 2628 passed the Senate last Saturday, August 15, it would permit a drug to be designated by the Secretary of Health, Education and Welfare if it merely has a potential for abuse, and no actual abuse has been shown. A standard of such sweeping generality as this one has little meaning. As a consequence, virtually all drugs can be designated as 'psychotoxic drugs,' since all drugs have a potential for abuse. Hence, the standard should be an actual showing of abuse which results in a threat to the public health and safety, rather than merely a declaration of potential abuse."

Below the surface, then, runs the question about tranquilizers and other drugs which may be classed as psychotoxic. In reply to a question from Senator Ralph Yarborough as to whether tranquilizer drugs are being taken in overdoses, Larrick replied, "Yes, sir. In the study made by the President's Commission on Narcotic and Drug Abuse, some of the doctors who were participants pointed to cases where people had become addicted or had acquired the habit of taking these tranquilizers excessively outside of good medical care.

"This LSD_{25} [lysergic acid diethylamide] is an example of a type of drug that causes a mental change that is not now used very extensively for medical purposes, but is used quite extensively for non-medical purposes. But the big problem with tranquilizers at the moment, as I see it, is that they do have capabilities of satisfying a non-medical urge."

In the brief hearing session some of the parties who are presumably most interested in the bill did not appear. No representative of the President's Commission testified, and both the AMA and the PMA submitted letters but did not send witnesses.

Certain questions of interpretation have been raised and not answered, as, for example, on the regulation of investigative use of psychotoxic drugs. An exception from certain control features of the bill is provided for "persons who use psychotoxic drugs in research, teaching, or chemical analysis and not for sale." It has been suggested that this restriction is not as stringent as similar ones in other sections of the Food, Drug and Cosmetic Act and might vitiate FDA control.

In August, Harris and his Commerce Committee put the quietus on the bill for the present when they decided it was too late in the session to organize adequate hearings. Harris has said, however, that if the bill is reintroduced and if he returns to Congress as chairman of his committee, he will schedule hearings early in the next session.

The Dodd bill is in the odd position of being widely approved in principle but of drawing criticism from some friends for going too far and from others for not going far enough.

Dodd's resolute campaign in favor of legislation on psychotoxic drugs has had the praiseworthy effect of drawing attention to the booming bootleg trade in barbiturates and amphetamines. But by focusing on sleepy truck drivers and juveniles in quest of kicks it has, so far, not led to discussion of the full implications of the greatly increased use and abuse of psychotoxic drugs in general brought about by the drug explosion and the eagerness of the American people to seek peace of mind through chemistry.

—JOHN WALSH

Announcements

The National Science Foundation has announced the reorganization of its Division of Biological and Medical Sciences and the appointment of section heads and program directors. The four new sections, each composed of two programs, and their leaders are:

Molecular biology section, made up of a biochemistry and a biophysics program. Walter Koltun, formerly in the NSF office of science resources planning, is director of the biochemistry program; a section head and program director for biophysics have yet to be named.

Environmental and systematic biology section, composed of an environmental biology program and a systematic biology program. Walter Hodge, section head, will also continue as program director for systematic biology; a director for the environmental biology program has not yet been appointed.

Physiological processes section, made up of a program in metabolic biology and in regulatory biology. David B. Tyler is section head and program director for regulatory biology. John Ward, formerly professor of biology at Temple University, has been named program director for metabolic biology.

Cellular section, made up of a program in developmental biology and one in genetic biology. Philip Grant is program director for developmental biology; Herman Lewis, director for genetic biology; a section head has not yet been named.

Meeting Notes

The second Texas symposium on **relativistic astrophysics** will be held in Austin, 15–18 December. The major topics of discussion will be quasi-stellar sources, cosmic ray, gamma ray, x-ray, and neutrino astronomy, and their relevance to cosmology. (Mrs. Jane Wardlaw, Department of Physics, University of Texas, Austin 78712)

The sixth joint **automatic control** conference is scheduled next 22–25 June at Rensselaer Polytechnic Institute, Troy, New York. Topics to be included are control theory, applications, components, and control reliability. The meeting will be sponsored