Drug Abuse Control Under FDA, 1938–1968

JOHN P. SWANN, PHD

The 1906 Food and Drugs Act, which marked the nascence of the Food and Drug Administration as a consumer protection agency, mandated that the presence of certain addictive substances be clearly labeled on any products containing these ingredients. However, the FDA's first intensive experience with the regulation of drug abuse did not begin until three decades later. The abused drugs of concern remained the same from the late 1930s to the 1960s, but the sources of the problems changed slowly during this period. The laws that the FDA enforced changed as well. The following story summarizes the efforts of a Federal agency—previously unaccustomed to such work—to interdict the proliferation of stimulants, depressants, and hallucinogens that took an increasing toll on American society.

Two FDA inspectors, William C. Hill (left) and Charles H. Eisenberg (right), pose in their truck-driving garb during a conference of undercover inspectors in Chicago in 1954.

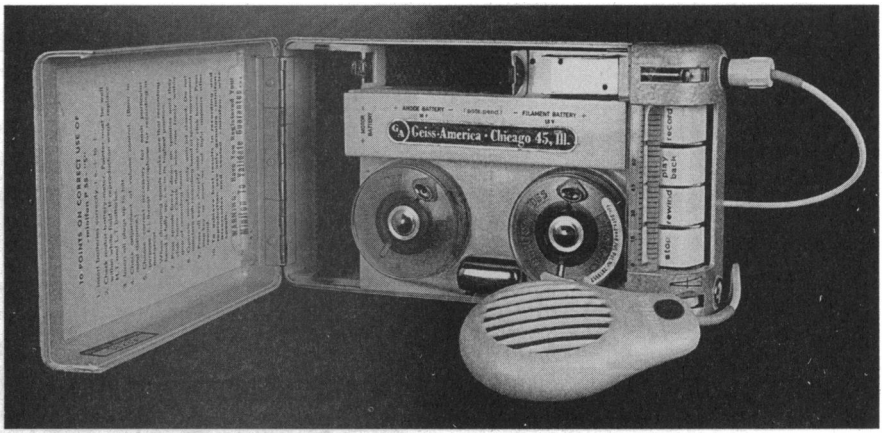
The Early Years

The FDA's first efforts to control the illicit traffic in dangerous drugs date back to the 1930s. The 1938 Food, Drug, and Cosmetic Act included a provision requiring selected warnings on product labels, but otherwise did not address the distribution of dangerous drugs such as barbiturates and amphetamines (narcotic control at this time was under the jurisdiction of the Federal Bureau of Narcotics in the Treasury Department). However, since the law mandated that drugs be labeled for safe use by consumers, the FDA's 1938 regulations stipulated that certain drugs, such as amphetamines, barbiturates, and sulfa drugs (used to treat venereal disease and other serious infections) had such a potential for misuse or abuse that they simply could not be labeled for safe self-medication. Patients could use these drugs only under medical supervision, that is, with a physician's or dentist's prescription. For all pharmaceuticals other than narcotics, this marked the birth of the distinction in Federal law between prescription and over-the-counter drugs, a distinction that was clarified in Federal statutes by the Durham-Humphrey Amendment of 1951.

Agency actions against illegal over-the-counter sales of dangerous drugs were limited in the late 1930s and early 1940s because it was unclear whether FDA had jurisdiction over retail trade at the pharmacy level. But a key Supreme Court decision in 1948 confirmed the agency's jurisdiction, and FDA's interdiction efforts grew significantly thereafter.

The agency's reports on illegal drugs sales during the 1950s mention antibiotics, sulfa drugs, hormone preparations, and thyroid medications, but barbiturates and amphetamines were by far the prescription pharmaceuticals most commonly sold illegally in those years. In fact, from the 1940s to the 1960s the agency devoted more regulatory work to barbiturates and amphetamines than to all other drugs combined. Benzedrine, the brand name of the first amphetamine, and the various barbituric acid derivatives, such as Seconal, had solid footholds in the therapeutic armamentarium by this time: Benzedrine in the treatment of narcolepsy and postencephalitic Parkinsonism and as a local vasoconstrictor; and the barbiturates as sedatives, anticonvulsants, and anesthetics. However, the basic pharmacological actions of these drugs lent themselves to abuse.

Examples of abuse abound. In one case, a barbiturate prescription was refilled 61 times, including three refills after the patient's death from barbiturate intoxication. A Kansas City



The Minifon P55 was one of the tools used by inspectors to record drug buys surreptitiously; the device shown here, which employed recording wire rather than tape, was used by Inspector Edward Wilkins in and around New York from the mid-1950s to the mid-1960s. Inspectors typically wore the Minifon in a holster under the arm, concealed under a coat.

woman secured over 40 refills of a barbiturate prescription, many by mail order, without the physician's knowledge; she too eventually died from barbiturate intoxication. A drug store in Johnson City, Tennessee, could not account for over 180,000 barbiturate capsules it had received from wholesalers and manufacturers. In another case, an inspector was able to buy amphetamines from a physician four times in the same month, adding up to a total of 55,000 tablets. The physician appealed his conviction, unsuccessfully.

In the 1940s and 1950s most of FDA's actions against illegal sales of stimulants and depressants could be traced to pharmacies. Sometimes pharmacists were responsible, and other times non-pharmacist proprietors and employees were the perpetrators. However, the sale of amphetamines, barbiturates, and eventually LSD and other hallucinogens through cafés, truck stops, flophouses, weight reduction salons, street-corner pushers, and other nontraditional sources increased in the 1950s. From 1960 to 1965, the FDA prosecuted more cases against these sources than those involving pharmacies. This trend can be attributed in part to the improved efforts of the professional pharmacy field to educate and police itself, especially after the passage of the Durham-Humphrey law. The rise of recreational drug use among the flowering drug subculture of the early 1960s, with its own mercantile forces, was also responsible for this shift.

While FDA inspectors merely needed to pose as patients to see if a pharmacy were selling drugs illegally (followed by an inventory of the pharmacy's records if the pharmacist had proceeded with the sale), undercover methods were needed to interdict illegal sales through nontraditional sources. The agency instituted special conferences in the 1950s to teach inspectors how to conduct undercover investigations—including truck driving instruction so inspectors could operate convincingly in that world. In one case, an inspector drove a tank truck for several months to nab a traveling "doctor" and his "Indian Princess" companion who had been dispensing amphetamines illegally from their automobile.

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Despite the rather impressive-sounding statistics showing that FDA was responsible for 1300 convictions from 1952 to 1962 and that more than 2300 people and firms were convicted from the early 1950s to the mid-1960s, the President's Advisory Commission on Narcotic and Drug Abuse reported in 1963 that the agency simply was unable to control the proliferation of illicit drug sales, at least in part because the number of properly trained and equipped staff was grossly inadequate to the task; only 40 inspectors were investigating illicit sales of dangerous drugs. This report had a significant impact on the Drug Abuse Control Amendments of 1965.

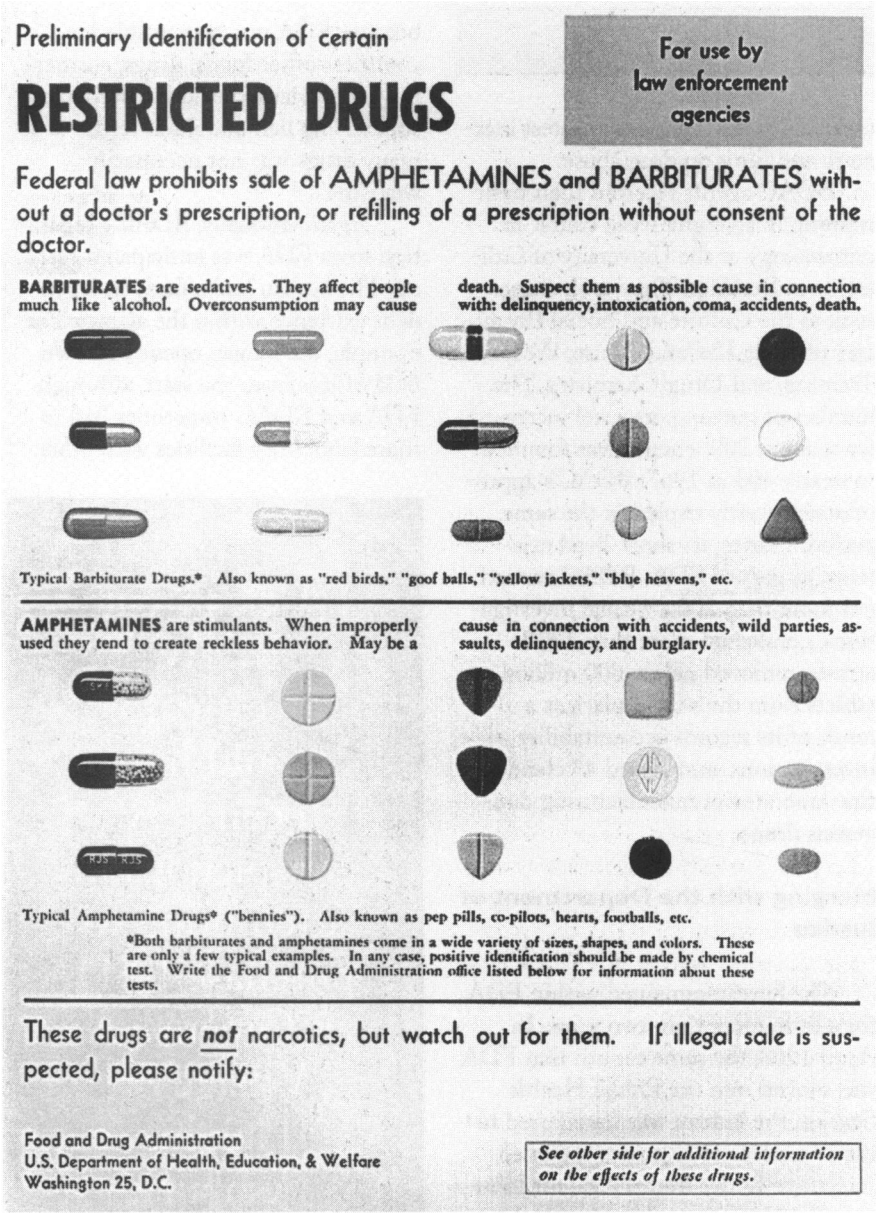
1965 Drug Abuse Control Amendments

Responding to a growing drug subculture that served as a ready market for LSD, psilocybin, and other "mind-expanding" hallucinogens, Congress passed the Drug Abuse Control Amendments of 1965. This law identified, and facilitated the control of, non-narcotic drugs that tended to be abused. As part of that effort, the amendments established a new unit within FDA, the Bureau of Drug Abuse Control (BDAC), with its own appropriations, its own field offices, and its own team of inspectors.

The 1965 law brought amphetamines, barbiturates, other non-narcotic stimulants and depressants with a potential for abuse, hallucinogens, and counterfeit drugs under special control. It provided for other products to

be added to this list through regulations, based on the advice of an outside body of experts. This group, the Advisory Committee on Abuse of Depressant and Stimulant Drugs, consisted of four pharmacologists, a psychiatrist, a sociologist, an internist, and a psychologist. Early in 1966, FDA and the advisory committee proposed 17 additional drugs for coverage under the 1965 amendments: nine depressants, two stimulants, and six hallucinogens. By the time the responsibility for the oversight of the law was transferred from FDA to the Department of Justice in April 1968, several hundred products were subject to the provisions of the 1965 amendments.

The amendments addressed control of traffic in illicit, non-narcotic drugs in several ways. They permitted FDA to prosecute violations regardless of whether the product had been involved in interstate commerce. Moreover, seizures of products were now possible without prior court order. BDAC inspectors were given powers that more closely resembled those of Federal Bureau of Narcotics agents than those of food and drug inspectors. These powers were commensurate with the requirements of criminal investigation work: they could serve and execute search and arrest warrants, seize goods, and carry firearms. Previously inspectors had depended on local and state law enforcement officers for these functions.


Preliminary Identification of certain

RESTRICTED DRUGS

For use by law enforcement agencies

Federal law prohibits sale of AMPHETAMINES and BARBITURATES without a doctor's prescription, or refilling of a prescription without consent of the doctor.

BARBITURATES are sedatives. They affect people much like alcohol. Overconsumption may cause death. Suspect them as possible cause in connection with: delinquency, intoxication, coma, accidents, death.

Typical Barbiturate Drugs.* Also known as "red birds," "goof balls," "yellow jackets," "blue heavens," etc.

AMPHETAMINES are stimulants. When improperly used they tend to create reckless behavior. May be a cause in connection with accidents, wild parties, assaults, delinquency, and burglary.

Typical Amphetamine Drugs* ("bennies"). Also known as pep pills, co-pilots, hearts, footballs, etc.

*Both barbiturates and amphetamines come in a wide variety of sizes, shapes, and colors. These are only a few typical examples. In any case, positive identification should be made by chemical test. Write the Food and Drug Administration office listed below for information about these tests.

These drugs are *not* narcotics, but watch out for them. If illegal sale is suspected, please notify:

Food and Drug Administration
U.S. Department of Health, Education, & Welfare
Washington 25, D.C.

See other side for additional information on the effects of these drugs.

The FDA issued this chart in 1961 to help in the identification of barbiturates and amphetamines and to inform law officers and state food and drug officials about the possible effects of illicit use of these drugs.

The Bureau of Drug Abuse Control

On 9 December 1965, Secretary of Health, Education, and Welfare John W. Gardner approved a plan recommended by the President's Advisory Commission on Narcotic and Drug Abuse to improve FDA's operations in controlling dangerous drugs. This created the Bureau of Drug Abuse Control (BDAC), whose mission was to develop investigational and educational programs to carry out the 1965 law. BDAC operated with nine field stations in the same cities as existing FDA field stations but not necessarily in the same offices.

The bureau's enforcement policy followed FDA's pattern of relying on education and persuasion ("voluntary compliance") to the greatest possible extent. The agency initiated conferences with the National Association of Boards of Pharmacy and the Association of Food and Drug Officials of the United States to arrange the logistics of state-by-state enforcement. These collaborators agreed to have states assume primary responsibility for the control of drug abuse at the retail drugstore level while the Federal government would be responsible for the control of illicit drug traffic by manufacturers, wholesalers, and those outside of legitimate channels. BDAC worked closely with local law enforcement officials as well. In fact, the bureau distributed a bimonthly newsletter to local law enforcement agencies, the *BDAC Bulletin*, to inform those on the front line about new products of potential abuse, to publicize major drug busts in which BDAC was involved, and to post items of edu-

cational interest such as the latest literature and films on drug abuse.

BDAC agents received their basic training in an eight-week course in criminology at the University of California at Berkeley. They took classes such as the Culture and Social Psychiatry of Drug Use and Abuse, Weapons Training, and Drug Chemistry. The number of bureau personnel increased from about 200 when it was founded to nearly 400 in 1967; BDAC's appropriations nearly tripled in the same period. During its short-lived existence as part of FDA, BDAC carried out more than 200 criminal investigations, conducted more than 1300 arrests, removed nearly 600 million tablets from the marketplace as a result of its records accountability investigations, and closed 43 clandestine laboratories manufacturing dangerous drugs.

Merging with the Department of Justice

The bureau remained within FDA for a little more than two years. In April 1968, the same month that FDA was moved into the Public Health Service, the bureau was transferred to the Department of Justice under an Executive Order from President Johnson. BDAC was combined with the Federal Bureau of Narcotics, which had been established within the Treasury Department in 1930, to form the Bureau of Narcotics and Dangerous Drugs. The move was neither unexpected nor, as far as most of FDA was concerned, regretted. The President's Advisory Commission on Narcotic and Drug Abuse, even before BDAC's creation, had suggested that responsibility for the investigation of the illicit traffic in dangerous drugs be a function of Justice rather than HEW. The Commission believed that HEW was the more appropriate venue for the regulation of the *legitimate* production, distribution, and sale of dangerous drugs and narcotics. Moreover, because FDA was responsible for countless other foods, drugs, cosmetics, and devices, the added burden of supervising licit and illicit traffic of so many drugs was not necessarily welcome.

Organizationally, BDAC's separation from FDA was anticipated early on. The bureau had a fairly independent existence within the agency. For example, the bureau opened its own field offices from the start, although FDA and BDAC sometimes had to share laboratory facilities with other FDA programs. Notable, too, was the cultural gap between the two types of investigators. The average food and drug inspector was a college-educated scientist and by no means iconoclastic in appearance or demeanor. The BDAC criminal investigator, on the other hand, had to fit in with his or her surroundings to function effectively in undercover work; a clean-cut BDAC investigator would have been very conspicuous in attempting to purchase LSD in Greenwich Village or Haight-Ashbury.

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Finally, the fact that different agencies had control of illicit traffic in narcotics and dangerous drugs had been creating problems for investigators. BDAC agents had jurisdiction over stimulants, depressants, and hallucinogens but not over other drugs such as heroin, marijuana, and morphine. Conversely, Federal Bureau of Narcotics agents did not have jurisdiction over drugs covered in the 1965 Amendments. Drug dealers unfortunately did not always conveniently operate as specialty vendors; an undercover BDAC agent might be offered not only a hallucinogen but marijuana as well. Thus, unifying criminal investigations of drug trafficking under one roof at the Department of Justice was a pragmatic move.

After BDAC was transferred from the FDA, the agency retained jurisdiction over narcotics and dangerous drugs from the standpoint of their safety and efficacy, but Justice was given authority to prevent the diversion of controlled substances for illicit purposes. The Drug Abuse Control Amendments of 1965 were superseded by the Comprehensive Drug Abuse Prevention and Control Act of 1970, which the Drug Enforcement Administration now enforces. Criminal investigations under FDA did not end with the demise of BDAC, though. In 1991, following Congressional hearings into FDA's workload of criminal cases, the agency established the Office of Criminal Investigations to examine activities such as drug fraud (for example, drug counterfeiting), product tampering, and submissions of falsified information to FDA.

Dr. Swann is Historian, Food and Drug Administration. The pictures are from the collection of the FDA History Office.

Address correspondence to Dr. Swann, FDA History Office, HFC-24 Room 13-51, Parklawn Building, 5600 Fishers Lane, Rockville MD 20857; tel. 301-443-6367; fax 301-827-0551; e-mail <jswann@fdaem.ssw.dhhs.gov>.