



FACT Sheet

United States Department of Justice
Drug Enforcement Administration

Compliance and Regulatory Affairs

DEA's mission is not only to stop the flow of illicit drugs in this country, but also to regulate the distribution of legitimate drugs--substances handled by the legal drug importers, manufacturers and pharmacies, and prescribed by doctors.

Along these lines DEA has the responsibility for monitoring the importation of legitimate drugs into the United States and reviewing all import-export activities in line with existing treaty obligations.

Abuse of these legitimate drugs is substantial. According to a nationwide study of the National Institute on Drug Abuse (NIDA), "... the non-medical use of psychotherapeutic drugs ranks second to marijuana among youth and all adults ...," with "one in ten young people and one in seven adults having some non-medical experience with an over-the-counter or prescription sedative, tranquilizer or stimulant."

DEA's experience has been that when an addict is unable to find his illicit drug of choice--for example heroin or cocaine--he will tend to substitute the legitimate drugs. During a heroin shortage, for instance, we are increasingly likely to uncover forged prescriptions, non-medical drug purchases, drug burglaries and employee drug theft--in other words, diversion of licit drugs for illicit purposes.

DEA's regulatory program--established to minimize this diversion--pursues an essential, although seldom publicized, DEA mission.

In October 1976, in recognition of the importance of DEA's regulatory mission and in order to consolidate regulatory functions, the Office of Compliance and Regulatory Affairs was formed. This is a principal office and reports directly to the Administrator and Deputy Administrator. The new Office

brings together registration, regulatory control and investigative activities formerly the responsibility of the Compliance Investigations Division in DEA's Office of Enforcement, and the drug scheduling and drug information activities formerly the responsibility of the Special Programs Division of the Office of Science and Technology. Dialogue with the pharmaceutical industry and the Department of Health, Education and Welfare shows that this action should be a step forward in raising the level of importance of Compliance and Regulatory Affairs within our own agency and improving DEA'S effectiveness with other agencies and the pharmaceutical industry.

The regulatory mechanism as created by the Controlled Substances Act (CSA) of 1970 centers upon a "closed distribution system," the cornerstone of which is the required annual registration of all handlers and prescribers of controlled substances. DEA now has more than 570,000 registrants and collect more than \$2.7 million in annual registration fees.

Controls begin with a pre-registration investigation of all wholesale handlers. This preliminary step is taken to ensure that registration is in the public interest (that is, that the firm has adequate security, no violative history, State approval, etc.). It also ensures that those within the firms who are responsible are knowledgeable of requirements under the Controlled Substances Act.

Following registration, under this program DEA monitors and periodically investigates registrants to ensure they are accountable for the controlled substances handled. When violations are uncovered, appropriate action is taken.

Since the passage of the Controlled