

victims was 15 at the time of the offense. This indictment was the first case in the nation under the federal Drug Induced Rape Prevention and Punishment Act.

The Office of Consumer Litigation along with the Criminal Division's Narcotics and Dangerous Drugs Section have served as a clearinghouse for prosecutorial information, which includes helping local prosecutors prepare cases, distributing information to state and federal prosecutors, and presenting seminars on date rape drugs in forums such as the National Association of Attorneys General, the National District Attorneys Association, and the National Association of Prosecutor Coordinators.

Despite the steps taken by federal and state law enforcement and prosecuting offices, the availability of GHB, GBL, and ketamine, and the number of cases involving them continues to grow. We remain committed to finding and prosecuting the traffickers in these drugs.

Thank you. I look forward to answering your questions.

Mr. UPTON. Thank you very much.

Mr. Woodworth?

#### **TESTIMONY OF TERRANCE W. WOODWORTH**

Mr. WOODWORTH. Thank you, Mr. Chairman, for the opportunity to appear before the subcommittee today on the subject of drugs of abuse and their use in sexual assault cases. I will very briefly provide you with DEA information on the three substances that are the subject of today's hearing.

GHB is not currently a controlled substance and has no accepted medical use in the United States. However, there is extensive data demonstrating that it is being abused for its psychoactive effects, and DEA believes it should be controlled under the Controlled Substances Act.

As required by law, DEA is currently waiting for a scientific and medical evaluation and a scheduling recommendation from the Department of Health and Human Services on GHB.

Among other reasons, GHB is abused for its ability to produce euphoria, and its adverse side effects include convulsions, severe respiratory depression and coma. GHB is even more dangerous when used with alcohol. Medical examiners have reported 32 fatalities since 1995 in which GHB was detected, and in many of those deaths GHB was used in combination with alcohol.

Drug Abuse Warning Network data indicates that estimated emergency room episodes involving GHB increased from 54 in 1994 to 764 in 1997. On a national level, GHB related cases have been documented by Federal, State and local law enforcement officials in 41 States and the District of Columbia. In regard to sexual assault cases, DEA is aware of at least 13 sexual assault cases involving 22 victims under the influence of GHB.

The GHB encountered by law enforcement has all been clandestinely manufactured. As you have heard, the manufacture of GHB is a simple process requiring no special chemical expertise. The primary precursor for GHB is gamma butyrolactone, GBL, a readily available industrial chemical. GBL plays a role in the GHB problem, and it will likely be necessary to place some type of control on it after GHB is controlled.

Flunitrazepam, commonly known as Rohypnol, belongs to the benzodiazepine class of drugs and is abused by high school students, college students, gang members, rave party attendees and heroin and cocaine abusers. The drug produces profound intoxication, boosts the high of heroin, modulates the effect of cocaine. It

is also commonly used in combination with alcohol, which potentiates its toxic effects.

The DEA has documented approximately 4,500 Federal, State and local law enforcement investigations involving the illegal distribution and possession of Flunitrazepam in 38 different States. The majority of these cases have been in Florida and Texas.

The data from the Drug Abuse Warning Network includes 167 emergency room episodes involving Flunitrazepam from 1994 through 1997. Flunitrazepam has also been used to facilitate sexual assault. Since 1994, DEA is aware of nine people who have been convicted of sexual assault in which there was evidence that Flunitrazepam was used to incapacitate the victim.

Flunitrazepam was placed into Schedule IV of the Controlled Substances Act back in 1984 due to international treaty obligations. At that time, there was little abuse of Flunitrazepam in the United States. More recently, with the increase in trafficking and abuse, DEA began to consider the merits of transferring Flunitrazepam into another schedule.

As the subcommittee is aware, HHS has recommended that Flunitrazepam remain in Schedule IV. After considering the relevant data and the HHS recommendation, DEA concluded that we did not have sufficient grounds to justify administratively rescheduling Flunitrazepam.

Ketamine. Ketamine is the only drug of these three discussed that has been approved for marketing in the United States. It is primarily used in veterinary medicine as a fast acting, general anesthetic. The pharmacological profile is essentially the same as Phencyclidine, PCP, which leaves the individual anesthetized, detached or disconnected from their pain and the environment. It has both analgesic and amnesic effects.

As a drug of abuse, Ketamine has become common at rave parties and is largely abused by teenagers and young adults. It produces a dose related progression of effects from a state of dreamy intoxication to delirium, accompanied by the inability to move, feel pain or remember what has occurred while under the drug's influence.

There has been no reported clandestine manufacture of Ketamine to date, and it has been diverted primarily from distributors and veterinarians. From 1993 to 1997, there were 145 emergency room episodes in DAWN. The DEA is aware of one incident of rape.

The HHS has recommended on two occasions that Ketamine be placed in Schedule III of the Controlled Substances Act based largely on the pharmacological profile of the drug. On both occasions, DEA determined that the incidence of actual abuse was not sufficient to sustain the proposed scheduling action.

However, Ketamine's recent emergence as a drug of abuse prompted DEA to request another evaluation by HHS in April 1998. They have already responded and again recommended that Ketamine be placed in Schedule III. DEA will be publishing a notice in the Federal Register very shortly.

In conclusion, Mr. Chairman, the DEA is on record and continues to support rescheduling of Flunitrazepam and the control of both GHB and Ketamine. These drugs are being abused for their

psychoactive effects and also used by rapists to incapacitate their victims.

At least in the case of GHB, it may well be that legislative action is the quickest way to achieve control status. However, DEA is not opposed to congressional action in regard to any of these substances.

I would like to thank the subcommittee for the opportunity to offer DEA's comment.

[The prepared statement of Terence W. Woodworth follows:]

PREPARED STATEMENT OF TERRANCE W. WOODWORTH, DEPUTY DIRECTOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION

Mr. Chairman, distinguished members of the Committee, I want to thank you for the opportunity to address you today on behalf of the Drug Enforcement Administration (DEA) Administrator, Thomas A. Constantine. I will provide you with some specific data on three drugs, gamma-hydroxybutyrate (GHB), flunitrazepam and ketamine. Additionally, I will discuss the GHB precursor, gamma-butyrolactone (GBL). While each of these drugs has a unique chemical structure and specific pharmacological properties, as drugs of abuse, they share a number of similarities. Before I talk about each of these drugs individually, I would like to take a few moments and comment about some of the things they have in common.

Collectively, these three substances are referred to as "party" drugs because of their availability and distribution at bars, night clubs and all-night dance parties called raves or techno parties. Gamma-hydroxybutyrate (GHB, Goop), flunitrazepam (Roofies) and ketamine (Special K) are new additions to a long list of substances that have often been encountered in these settings. In the 1980s we saw the abuse and trafficking of psychedelics like MDMA (Ecstasy) and its analogues and the depressant, methaqualone (Ludes). Other drugs that are also encountered in these settings include LSD (Acid), PCP (Angel Dust), amphetamine, cocaine and marijuana. As their street names imply, these drugs are touted to be fun. They have a wide range of pharmacological effects and are often taken in combination with each other or with alcohol. A disturbing factor is that these three substances are primarily being abused by teens and young adults.

While the illicit trafficking and abuse of these substances are DEA's primary considerations with regard to Federal control measures, we are aware and concerned about the use of these substances to facilitate the commission of sexual assault. As such, these three substances are referred to as "date rape" drugs implying this more sinister aspect of their illicit use. Individuals intent on sexual assault are aware of the availability of these substances, especially at bars and night clubs, and of their pharmacological profiles, both of which provide some insight into why they might find these drugs so appealing.

Each of these substances has gained popularity among drug abusers in recent years. Since their emergence as drugs of abuse, the DEA has been collecting data on their illicit manufacturing, distribution, trafficking and abuse. I will provide you with a summary of that data. Based on that data, the DEA now views these substances as having significant abuse potential. There is evidence that individuals are taking these substances in a manner and amounts sufficient to create a hazard to their health or to the health and/or safety of others. There is significant clandestine production of GHB and significant diversion of the pharmaceutical products containing flunitrazepam and ketamine. Large quantities of flunitrazepam have been illicitly smuggled into the U.S. and ketamine has been diverted from legitimate veterinary supplies within the U.S. Individuals are taking these substances on their own initiative rather than on the advice of a medical practitioner. Actually, only ketamine is approved for medical use in the U.S.—neither GHB nor flunitrazepam has been approved for marketing as a medicine by the Food and Drug Administration (FDA). In addition, these substances share many of the same pharmacological properties of drugs that have been identified as having serious abuse potential and are already controlled in the Controlled Substances Act (CSA). This data indicates that each of these drugs should be placed under control in the CSA. At this time, however, only flunitrazepam is controlled at the Federal level.

Although Congress has passed legislation that expedites the scheduling of drugs and other substances under the CSA, the temporary or emergency scheduling provision of the CSA could not be used for any one of these three substances. Emergency scheduling action is not possible when a substance is (1) being evaluated as part of a DHHS approved research program as is the case with GHB; (2) already a con-

trolled substance as is the case with flunitrazepam; or (3) already marketed in the United States as is the case with ketamine. As a consequence, all three of these drugs have proven to be a challenge with regard to more effectively controlling their abuse. Action to curb the trafficking and diversion of these drugs has been difficult and time consuming. Prior to changing the control status or placing any new substance under control using administrative or traditional scheduling process of the CSA, the DEA must gather the necessary data, forward that information to the Department of Health and Human Services (DHHS) and request, receive and consider a scientific and medical evaluation from the DHHS. In addition, the CSA requires specific findings for each of the five schedules that must be based on scientifically valid and legally defensible data (See Attachment). Scheduling actions must be substantiated by the available evidence. From the time the DEA identifies a new drug of abuse to the time that substance is finally placed under control in the CSA, if warranted, a significant amount of time may elapse when the administrative scheduling process is utilized.

*Gamma-hydroxybutyrate (GHB)*

GHB is a central nervous system depressant which is abused for its ability to produce euphoric states and its alleged role as a growth hormone releasing agent to stimulate muscle growth. Although GHB gained early favor with health enthusiasts as a safe and "natural" food supplement sold in health food stores in the late 1980s, the medical community soon became aware of overdoses and related problems caused by its abuse. In 1990, the FDA issued an advisory declaring GHB unsafe and illicit, except under FDA-approved, physician-supervised, study protocols. GHB has not been approved by the FDA for marketing. Doctors do not prescribe it, pharmacists do not sell it and patients do not use it. However, it is currently under investigation for use in treating narcolepsy under the FDA's Orphan Drug program.

Although its importation, distribution and use as a drug are not allowed in the U.S., the abuse of GHB has increased. As a drug of abuse, GHB is generally ingested orally after being mixed in a liquid. The onset of action is rapid and in overdose, unconsciousness can occur in as little as 15 minutes and profound coma can occur within 30 to 40 minutes. GHB produces dose-dependent drowsiness, dizziness, nausea, amnesia, visual hallucinations, reduced blood pressure, decreased heart rate, hypnotic effects resembling petit mal epilepsy, convulsions, severe respiratory depression and coma. Overdose frequently requires emergency room care, including intensive care for respiratory depression and coma. Most individuals regain consciousness within two to four hours. However, since 1995, Medical Examiners have reported 32 fatalities in which GHB was detected in the decedent. Many of these deaths involved the use of GHB in combination with alcohol which potentiates the depressant effect of GHB. Of these 32 cases, GHB was found to be the sole cause of death in eight cases.

Since 1993, more than 3,500 GHB-related cases of abuse, overdose, possession, illegal manufacturing, illicit diversion and trafficking have been documented by Federal, state and local officials. This data has been obtained from DEA case files, state and local law enforcement case files, state and Federal forensic laboratory reports, the Drug Abuse Warning Network (DAWN) data, the FDA Office of Criminal Investigations and poison control center data bases. This data shows that GHB is frequently taken in combination with other drugs that often heighten its effects, and it is frequently found at bars, night clubs, rave parties and gyms. The primary users are teenagers and young adults. The populations abusing this drug fall into three major groups: (1) users who take GHB as an intoxicant or euphoriant or for its alleged hallucinogenic effects; (2) bodybuilders who abuse GHB for its alleged utility as an anabolic agent or as a sleep aid; and (3) individuals who use GHB to commit sexual assault. These categories are not mutually exclusive and an abuser may use the drug illicitly to produce several effects.

The number of cases in which GHB has been used facilitate sexual assault is impossible to determine; many such cases may go unreported or unsubstantiated due to the difficulty of detecting its use. GHB is quickly eliminated from the body making detection in the body fluids unlikely. In addition, GHB's fast onset of depressant effects and its amnesiac effect render victims unable to recall the details of the attack. Nonetheless, DEA is aware of 13 sexual assault cases involving 22 victims under the influence of GHB since 1996. These assaults occurred in California, Florida, Louisiana, Maryland, Massachusetts, Michigan, Texas, and Wisconsin.

GHB is illicitly produced in clandestine laboratories. Since 1997, the DEA is aware of at least 100 cases involving GHB illicit laboratories and over 200 submissions to DEA and state and local forensic laboratories. GHB has been encountered in every region of the United States and both small (personal use amounts) and

large (intended for distribution) clandestine laboratories have been encountered. It is marketed as a "legal high" or a substitute for MDMA (Ecstasy) and is sold in solid and liquid forms.

The clandestine synthesis involves the use of two common, non-regulated chemicals: gamma-butyrolactone (GBL), the primary precursor chemical, and sodium hydroxide (lye). The synthesis is a simple one-pot method requiring no special chemical expertise. GBL is a solvent with a wide range of industrial uses. Tens of thousands of metric tons are produced annually and it is readily available from chemical supply companies. In addition, kits for making GHB containing GBL and sodium hydroxide are being sold on the Internet. GBL, once absorbed from the gastrointestinal tract after oral administration, is readily converted to GHB in the body and produces the same profile of physiological and behavioral effects as GHB.

The DEA is reviewing various control measures for GBL. If GHB is placed under Schedule I or II of the CSA, GBL could be treated as an analogue for the purposes of criminal prosecution if it is being distributed for human use outside of an FDA approved Investigational New Drug (IND). As there are no regulatory controls imposed on handlers of analogues, the licit industrial or pharmaceutical use of GBL would be unencumbered by this method of control. Alternatively, if GHB is controlled in any schedule of the CSA, GBL can be controlled as an immediate precursor in the same or lower schedule as GHB. The full range of CSA drug control measures would then apply to GBL. Another method of controlling GBL distribution and use by clandestine manufacturers would be to make GBL a listed chemical with a level of control commensurate with its current industrial use. Both of these last two measures (immediate precursor and listed chemical) could be taken by the DEA following a notice and comment rulemaking process. In October 1998, the DEA published a Federal Register notice seeking information about the industrial uses and handling of GBL. The DEA is currently evaluating this information.

The abuse of GHB is associated with significant adverse effects to the abuser and health risk to the general public. The DAWN estimated that there were 54 GHB emergency room mentions in 1994 compared to 764 in 1997. In 62 percent of these episodes, recreational use was cited as the reason for taking this drug. Alcohol, which intensifies the depressant and psychoactive effects of GHB, was reported in 86 percent of the mentions. Poison control centers reported over 600 GHB incidents in 1996 and over 900 GHB incidents in 1997. GHB is repeatedly detected in driving under the influence (DUI) cases indicating the public health and safety hazards associated with its abuse. As previously mentioned, there have been 32 GHB-related deaths since 1995 and 22 GHB-related sexual assaults reported to DEA since 1996.

Despite data indicating that the continued, uncontrolled clandestine manufacture, distribution and abuse of GHB is an imminent hazard to the public health and safety, the DEA cannot place GHB under temporary control because it has an active IND exemption. As a consequence, the DEA is pursuing measures to administratively schedule GHB. In September 1997, the DEA forwarded its scheduling review to the Department of Health and Human Services (DHHS) and requested their scientific and medical evaluation and a scheduling recommendation. The DEA continues to document law enforcement encounters and GHB-related abuse cases and, as required by law, awaits a response from the DHHS before proceeding with any proposed scheduling action. The DEA has also conducted an informal field survey on GHB. Forty-one states and the District of Columbia reported incidents involving GHB. Most of the incidents reported in the survey occurred between January 1996 and March 1998. Reports were received from hospitals, poison control centers, coroners, police and sheriffs departments, public health department laboratories, security departments of colleges and universities and drug rehabilitation centers. Georgia, California and Texas reported the highest number of incidents with 312, 237 and 223 reports, respectively.

Twenty states have already controlled GHB. Alabama, Delaware, Georgia, Hawaii, Idaho, Illinois, Michigan, Nebraska, Nevada, Oklahoma, Rhode Island, and Wisconsin have placed GHB in Schedule I. California, Florida, Indiana, Louisiana and New Hampshire have placed it in Schedule II and Alaska, North Carolina, and Tennessee have controlled GHB in Schedule IV. In addition, New Jersey and Texas have criminalized the sale and possession of GHB and placed it in the same penalty group as LSD and marijuana.

#### *Flunitrazepam*

Flunitrazepam, commonly known as Rohypnol, belongs to the benzodiazepine class of drugs. Like other benzodiazepines (such as Valium, Librium, Xanax and Halcion), flunitrazepam's pharmacological effects include sedation, muscle relaxation, reduction in anxiety and prevention of convulsions. With respect to its sedative effects, flunitrazepam is approximately 7 to 10 times more potent than

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