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United States General Accounting Office Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

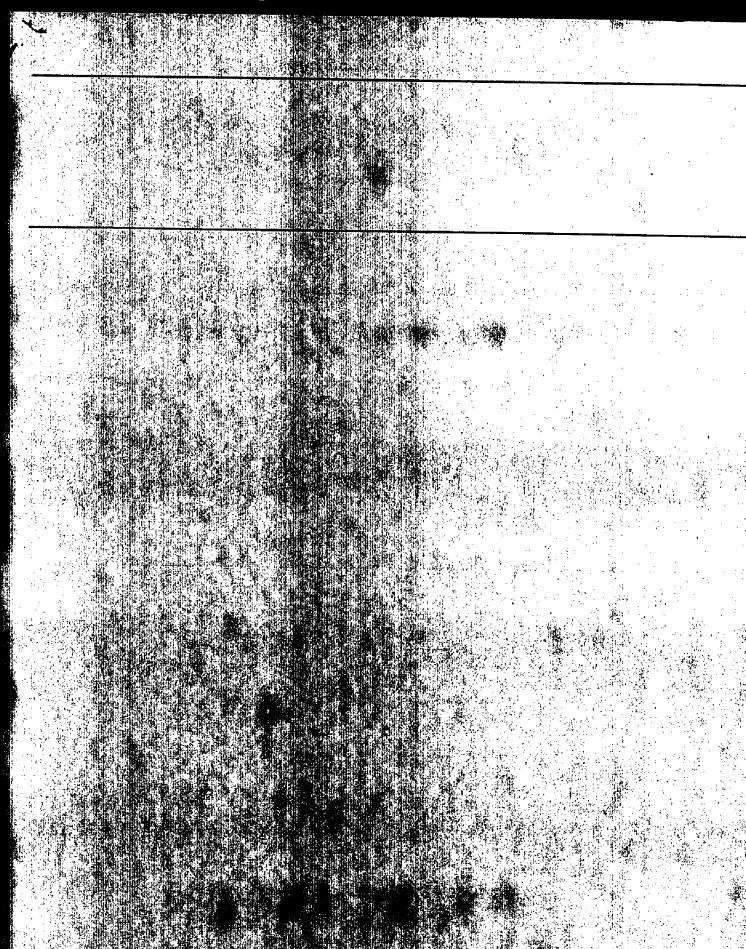
VA HEALTH CARE Inadequate Controls Over Addictive Drugs



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GAO

United States General Accounting Office Washington, D.C. 20548

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Human Resources Division

B-234990

June 6, 1991

The Honorable Lane Evans Chairman, Subcommittee on Oversight and Investigations Committee on Veterans' Affairs House of Representatives

Dear Mr. Chairman:

The drug abuse problem in the United States is not limited to the abuse of illegal drugs, such as heroin and "crack" cocaine; it encompasses addictive prescription drugs as well. About 8.6 million Americans misused these prescription drugs during the past year.¹ Primarily because of their greater access to prescription drugs, health care workers are more likely than other individuals to abuse such drugs. Drug abuse by health care workers can result in thefts from employers, such as hospitals or clinics, and can impair workers' abilities to provide quality health care.

At your request, we examined how Department of Veterans Affairs (VA) pharmacies control prescription drugs that are potentially addictive. As agreed with your office, we assessed VA's procedures for (1) safe-guarding these prescription drugs and (2) detecting thefts of such drugs for personal use or resale. We briefed your staff on the results of our work on March 20, 1991.

Results in Brief

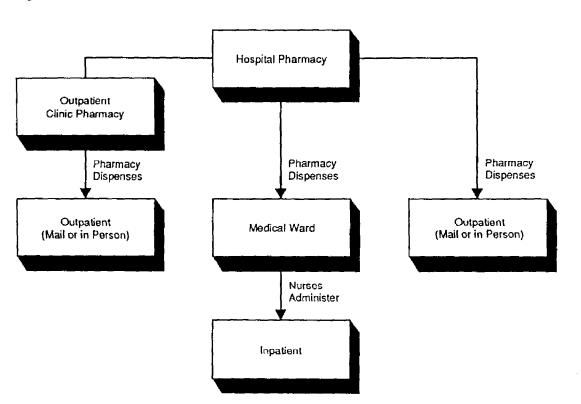
VA has inadequate internal controls over many addictive prescription drugs used in its health care system. Too many employees have access to pharmacy stocks of these drugs, and stocks are rarely inspected. Because of these weaknesses, pharmacy employees have been able to steal a wide range of addictive prescription drugs over periods of time ranging from several months to several years. VA managers generally became aware of these thefts, which sometimes totaled thousands of doses, only after law enforcement agencies notified them about criminal activities involving the use of VA drugs. In addition, large quantities of addictive prescription drugs may have been stolen without VA managers' ever detecting the thefts.

¹National Institute on Drug Abuse, <u>National Household Survey on Drug Abuse: Population Estimates,</u> 1990, Rockville, Maryland, 1991, p. 53. B-234990

Background

vA operates the largest health care system in the United States, including 225 pharmacies. The pharmacies are located in 172 hospitals, 50 outpatient clinics, and 2 extended care (nursing home type) facilities; 1 pharmacy stands alone. Each pharmacy procures and stocks drugs and dispenses them to veterans on an outpatient basis, as prescribed by VA physicians. Hospital pharmacies also distribute prescription drugs to medical wards to meet patient treatment needs, as figure 1 shows.

Figure 1: Flow of Drugs From Pharmacy to Patient



A wide range of VA employees work in pharmacies. Most of them are pharmacists and pharmacy technicians, although volunteers, housekeeping personnel, and other employees frequently work in pharmacies. Physicians, nurses, and nursing assistants may sometimes visit pharmacies to pick up or return drugs. :

Prescription Drugs With Potential for Abuse	va pharmacies stock various types of drugs that are regulated under the Controlled Substances Act (title II of P.L. 91-513). The act provides a legal foundation for protecting against the abuse of prescription drugs (including narcotics, depressants, and stimulants), as well as other sub- stances, through a system that lists and categorizes substances that have a potential for abuse. Under the act, the Drug Enforcement Admin- istration (DEA) is authorized to determine which drugs have such poten- tial and to designate them as controlled substances.
	DEA has designated as controlled substances a variety of narcotics, depressants, and stimulants that are found in vA pharmacies. ² Each has significant abuse potential, as discussed below.
	 <u>Narcotics</u> are used medically to relieve pain, especially during or following surgery. They may produce a short-lived state of euphoria, and they tend to reduce vision and induce drowsiness or feelings of apathy. <u>Depressants</u> may relieve anxiety, irritability, tension, or insomnia when taken as prescribed by a physician. When used excessively, they can produce a state of intoxication similar to that caused by alcohol. <u>Stimulants</u> are used medically to treat depression, narcolepsy (a rare disorder resulting in an uncontrollable desire to sleep), and certain cases of obesity. Excessive use of stimulants can produce feelings of paranoia, which may be accompanied by auditory or visual hallucinations.
	Under the Controlled Substances Act, DEA is also authorized to catego- rize narcotics, depressants, and stimulants into one of five groups, called schedules, based on their potential for abuse or addiction. Schedules I and II drugs have the highest potential for abuse, and schedule V the lowest. ³ All but schedule I drugs have accepted medical uses in the United States. Of the nearly 48,000 prescription drugs approved for medical use in the United States, almost 3,800 are on schedules II, III, IV and V.
	Individuals who are addicted to scheduled drugs may use them alone or in conjunction with other drugs. For example, a schedule IV pain reliever can be combined with a nonscheduled prescription antihista- mine to produce a physical sensation comparable to that achieved through the use of heroin. Cocaine users can use a widely prescribed
	² The factors DEA considers in assessing potential for abuse are listed in appendix I.
	³ Appendix II contains a brief description of Controlled Substances Act criteria for categorizing drugs

³Appendix II contains a brief description of Controlled Substances Act criteria for categorizing drugs by schedule.

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	schedule IV depressant to "come down" from the intense stimulation of a cocaine high.
	Because of such varied uses, scheduled drugs frequently have illicit, or "street," market values that make them attractive to thieves as well as to addicts. For example, the illegal resale value of a single 50 mg tablet of the above-mentioned pain reliever carries a street price of from \$4 to \$15; the illegal resale value of a 10 mg tablet of the depressant ranges from \$1 to \$10.
Requirements for Pharmacies Handling Scheduled Drugs	The Controlled Substances Act requires that scheduled drugs be more stringently controlled than other prescription drugs. All pharmacies handling scheduled drugs must meet certain minimum security and record-keeping requirements, which are established to deter and detect thefts. Schedule II through V drugs must be stored in substantially con- structed cabinets or otherwise stored in a manner to obstruct thefts. In addition, pharmacies are to maintain complete and accurate distribution records of all transactions involving scheduled drugs and inventory ⁴ them at least every 2 years. The required records create a paper trail so that the flow of drugs can be traced from the time they are received at the pharmacy until they are dispensed to patients.
	For all scheduled drugs, va hospital directors are required to report thefts and significant losses to DEA. If DEA declines to investigate, direc- tors may convene a local board to investigate a loss or seek the assis- tance of other investigative agencies, including the Federal Bureau of Investigation (FBI), va's Office of Inspector General or Security and Law Enforcement office, or local police authorities.
VA Pharmacies Handling Scheduled Drugs	VA's 225 pharmacies stock, on average, 79 drugs ⁵ that are included on schedules II, III, IV, and V; they stock between 1,500 to 2,000 nonsched- uled drugs. In fiscal year 1990, VA estimates it purchased about \$7.5 mil- lion worth of scheduled drugs. Few pharmacies stock more than 120 scheduled drugs.
· ·	⁴ The act requires a written record of physical counts of all scheduled drugs.

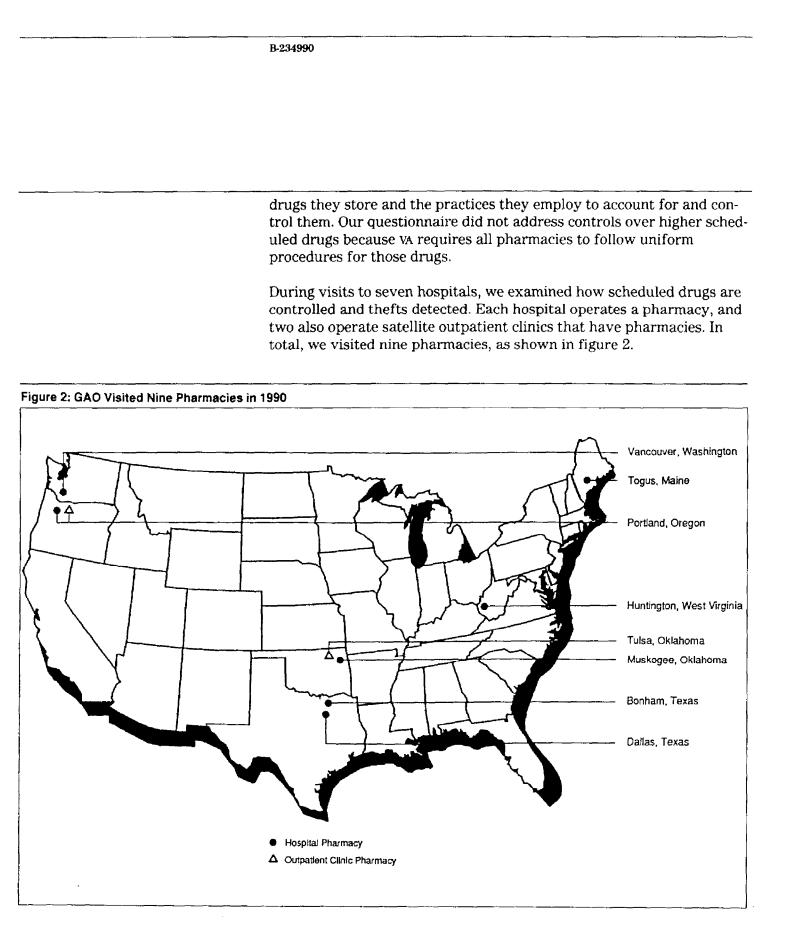
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 $^{^5}$ Individual dosage forms and strengths of the same drug type are considered separately. For example, 5 mg injectable and tablet forms of the same drug are counted as two drugs, as are 5 mg and 10 mg tablets of the same drug.

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	VA has divided scheduled drugs into two groups for security and record- keeping purposes. One group contains all schedule II drugs and those schedule III drugs containing narcotics, hereafter referred to as higher scheduled drugs. The other group, referred to as lower scheduled drugs, contains the nonnarcotic schedule III drugs, as well as schedule IV and V drugs. va's 225 pharmacies handle, on average, slightly more lower (56 percent) than higher scheduled drugs (44 percent).
VA Reported Control Weaknesses Involving Scheduled Drugs on Hospital Wards	The Federal Managers' Financial Integrity Act of 1982 (P.L. 97-255) requires agency heads to identify annually all material weaknesses in their agencies' internal control systems and to report to the President and the Congress plans and schedules for correcting the weaknesses. In 1984, VA reported that it lacked adequate controls over scheduled and nonscheduled drugs on hospital wards. VA outlined in subsequent reports its plans to strengthen hospital wards' dispensing controls. VA expects to complete its planned actions by fiscal year 1995. It has not reported any internal control weaknesses involving scheduled drug supplies in its pharmacies.
Scope and Methodology	We reviewed va's policies and procedures for controlling scheduled drugs in its pharmacies and interviewed VA headquarters officials in its Pharmacy Service to determine how pharmacies were expected to imple- ment them. We also interviewed DEA officials to obtain information on how the Controlled Substances Act should be implemented in va's phar- macies and their views on prescription drug theft and abuse. We did not review va's actions involving scheduled drugs on hospital wards. We reviewed va's policies and procedures for investigating and reporting drug losses and interviewed officials of va's Security and Law Enforce- ment office and its Office of Inspector General. We reviewed all 40 investigations of losses involving scheduled drugs that the Office of Inspector General conducted during fiscal years 1988-90. For that same period, we reviewed all 26 investigation reports investigating and metal and provide the security and the office of the security and the office of the security fiscal years 1988-90.
	period, we reviewed all 36 investigation reports involving such drugs on file at the Security and Law Enforcement office. Using a questionnaire, we collected information from the 225 vA phar- macies on the policies and procedures they use to control lower sched- uled drugs. The information includes data on the amounts of scheduled

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In selecting the hospitals to visit, we obtained a cross-section of the various settings in which pharmacies operate. We included large and

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	small hospitals, hospitals in rural and urban areas, and hospitals that operate satellite outpatient clinics. We also selected four hospitals that had large losses of scheduled drugs in recent years in order to determine what actions they had taken to strengthen controls over these drugs.
	At each hospital, we interviewed officials in the Office of the Director, the Pharmacy Service, and the VA Police and Security units. We observed pharmacy operations and reviewed the records of drug inspections, including investigations of potential or actual drug losses. We also inter- viewed local law enforcement officials to gain their views on thefts of prescription drugs, including markets for stolen drugs.
	We performed our work between May 1990 and March 1991 in accor- dance with generally accepted government auditing standards.
Inadequate Security Exposes Lower Scheduled Drugs to Theft	va requires its pharmacies to (1) store bulk supplies of all scheduled drugs in locked vaults or safes and (2) provide keys or combinations to only those pharmacy employees requiring access to these drugs.
	va policy allows pharmacies to maintain reasonable quantities (working stocks) of lower scheduled drugs in pharmacy dispensing areas—an approach consistent with regulations issued under the Controlled Sub- stances Act. However, such working stocks are at significant risk of theft, given the large numbers of pharmacy employees and others who routinely have access to the drugs.
	The nine pharmacies we visited had vaults, but only one locked up all lower scheduled drugs when they were not being dispensed. That phar- macy further limited access to its lower scheduled drugs by authorizing only two employees to dispense them. At the other eight pharmacies, working stocks of lower scheduled drugs were stored at dispensing sta- tions within the pharmacies, as VA policy allows. In these situations, all pharmacy employees and others had access to them, as the following examples show.
	• One pharmacy stored numerous bottles of lower scheduled drugs in open cabinets in a high-traffic dispensing area. These drugs included five 1,000-count bottles of Fiorinal tablets (a schedule III nonnarcotic) and three 500-count bottles of Darvocet tablets (a schedule IV drug). Nonpharmacy employees picking up or returning drugs were routinely allowed inside the pharmacy.

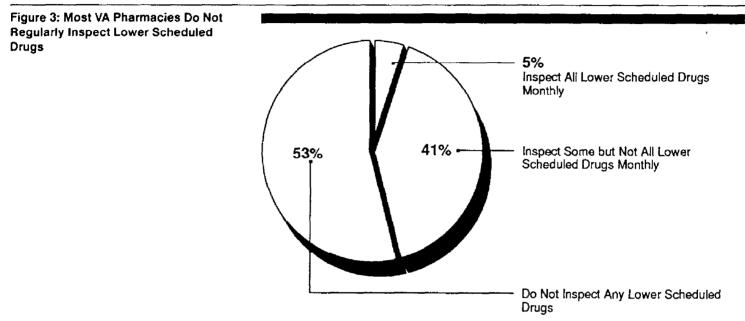
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	• Another pharmacy dispensed lower scheduled drugs from working stocks maintained in open pharmacy areas. At this pharmacy, we observed that unescorted volunteers and clerical staff routinely had access to the dispensing area where such lower scheduled drugs as Xanax and Ativan (both schedule IV drugs) were stored.
	These lax security procedures at the eight pharmacies give employees the opportunity to steal significant quantities of lower scheduled drugs. For example, two employees separately stole 500-count bottles of diazepam (Valium) from the working stocks kept on open shelves in the pharmacy of the Portland, Oregon, hospital. When confronted, one tech- nician admitted stealing four bottles of diazepam during late 1989 and early 1990, stating that he simply put the bottles in a paper bag and carried them out of the pharmacy either in his coat pocket or with other items inside a larger bag. An audit of the dispensing records showed that an estimated 50 bottles of diazepam—25,000 tablets—had been stolen from pharmacy stocks during the preceding 5 months.
	To identify the two employees, the hospital's security service installed a surveillance camera that continuously monitored the pharmacy dis- pensing areas. This approach was used because about 13 pharmacy employees—including pharmacists, technicians, and trainees—routinely worked in these areas. The Chief of Pharmacy noted that all pharmacy staff had similar access and opportunity to steal the missing drugs.
	Some pharmacies have recognized the need to better safeguard lower scheduled drugs from theft. Twenty-seven pharmacies responded to our questionnaire that they had increased controls over lower scheduled drugs in recent years. Of these, 24 now store and dispense all lower scheduled drugs from vaults or locked cabinets. Twenty pharmacies have taken steps to limit the number of employees authorized to handle lower scheduled drugs. For example, at six pharmacies only one phar- macist is authorized to dispense all scheduled drugs.
Lax Requirements Result in Inadequate Inspections of Lower Scheduled Drugs	VA requires that each pharmacy conduct monthly unannounced inspec- tions of all higher scheduled drugs to ensure that thefts are quickly detected. However, similar inspections of lower scheduled drugs are not required, and few pharmacies have been doing them. As a result, phar- macies have had great difficulty detecting thefts of such drugs. More- over, determining how and when losses occurred and what quantities were stolen has been extremely difficult and sometimes impossible.

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VA Requires Monthly Inspections of Higher Scheduled Drugs	VA requires that each pharmacy maintain an internal audit system that includes monthly unannounced inspections of all higher scheduled drugs. Under this system, pharmacies must maintain a separate record showing all receipts and disbursements from stock. For example, a phar- macist dispensing a higher scheduled drug writes the date, prescription number, patient's name, and quantity dispensed in a log. The pharmacist deducts the quantity dispensed from the previous balance and records the new balance, thereby maintaining a perpetual inventory of the drugs on hand.
	Each month, hospital personnel not associated with the pharmacy must inspect these drugs. Inspections include a physical count of all drugs on hand and a reconciliation of the counts to drug receipts and dispensing records. Inspectors may also look for signs of package tampering or other irregularities. Any discrepancies not readily resolved must be reported to the hospital director. These procedures act as a deterrent to theft and permit pharmacies to detect and investigate losses when they occur.
	Pharmacies have effectively used this internal control system to detect drug losses. For example, an employee stole 45 tablets of Percocet, a schedule II narcotic, from the pharmacy in the VA hospital in San Fran- cisco. While routinely filling a Percocet prescription, a pharmacist noticed that the perpetual inventory records showed a larger balance of this drug than was actually on hand. Because this theft was detected promptly, the hospital's security service was able to fix the approximate time of the loss, interview employees known to be in the area during that time, identify a suspect, and ultimately recover the stolen drug.
Few Pharmacies Regularly Inspect All Lower Scheduled Drugs	VA requires pharmacies to maintain drug receipt and dispensing records and make annual physical counts of all lower scheduled drugs—an approach that complies with the Controlled Substances Act. Neither VA, nor the act, requires reconciliation of the records with the physical counts of these drugs. In responding to our questionnaire, most of the 225 pharmacies reported doing the minimum required under VA's poli- cies. Some reported doing more, as figure 3 shows.

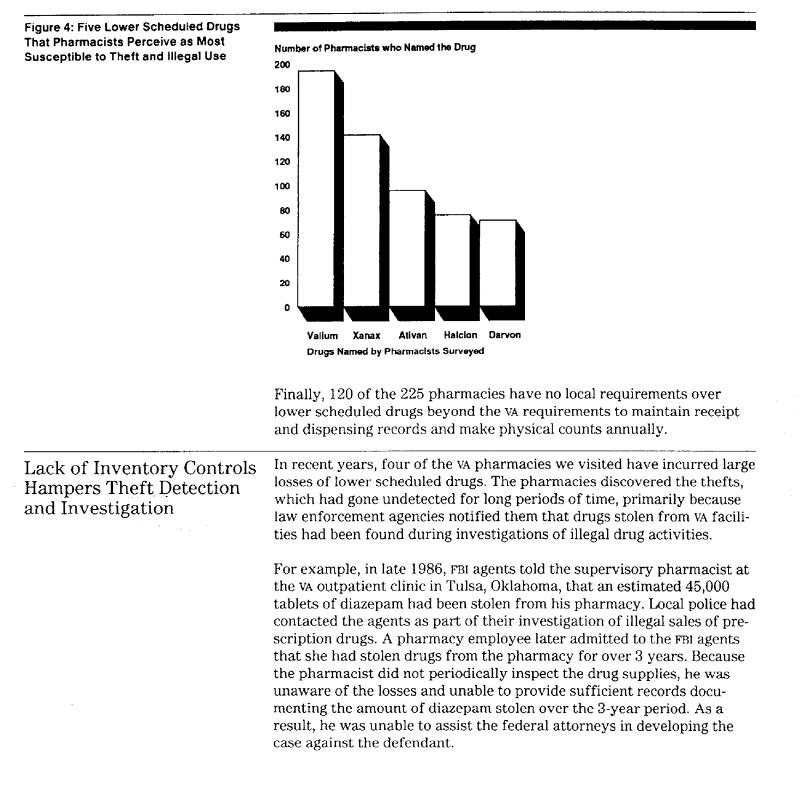


Note: Numbers do not add to 100 percent due to rounding.

Of the 225 pharmacies, 12 reported that they maintain perpetual inventory records for all lower scheduled drugs and reconcile physical counts of their lower scheduled drug supplies with drug receipt and dispensing records at least 12 times a year. Another 93 pharmacies have undertaken a variety of efforts to detect drug losses, including

- maintaining perpetual inventory records for all lower scheduled drugs and reconciling the balance to a physical count from 1 to 6 times a year,
- · maintaining perpetual inventory records for selected lower scheduled drugs and reconciling the balance to a physical count monthly, and
- · counting selected lower scheduled drugs and reconciling the counts using drug receipt and dispensing records fewer than 12 times a year.

Of the nine pharmacies we visited, six were accounting for selected lower scheduled drugs. Generally, they had tightened controls over drugs that they considered to be highly susceptible to theft and illegal use after thefts of lower scheduled drugs were discovered. Figure 4 shows the lower scheduled drugs that pharmacists responding to our questionnaire consider the most susceptible to theft and illegal use.



In another case, in early 1987, FBI agents investigating the illegal sales of diazepam in Augusta, Maine, arrested a pharmacy technician employed at the nearby va hospital in Togus. An investigation unraveled a 10-year history of diazepam thefts from the hospital's pharmacy, totaling nearly 3 million tablets. During the period, three pharmacy employees regularly stole 500-count bottles of diazepam, selling them or trading them for cocaine and marijuana. Because pharmacy officials did not periodically inspect drug supplies, they were unaware of the thefts until contacted by the FBI.

Although va pharmacy employees in these cases were ultimately apprehended and convicted, investigations of alleged lower scheduled drug thefts at other va pharmacies were hampered or discontinued because pharmacies did not maintain adequate inventory records for these drugs.

For example, in September 1989, the VA hospital in Huntington, West Virginia, received an anonymous telephone call alleging that diazepam from the hospital's pharmacy was being illegally sold in a nearby city. At that time, the pharmacy chief was unaware of any losses but, after reviewing available records, he concluded that at least 19,000 diazepam tablets had been lost over the preceding 9 months. He had not detected the losses earlier because no periodic inspections had been done.

No individual or group of individuals could be identified as responsible for the thefts, primarily because too many employees had opportunities to steal drugs from the pharmacy. At least 28 pharmacy employees and an unknown number of nonpharmacy employees and other visitors had access to the pharmacy during the months preceding the allegation. Because it was impossible to fully investigate all potential suspects in this case, no one was arrested for these thefts.

Conclusions

VA has had serious drug losses in some pharmacies, but inadequate record-keeping and inspection practices for lower scheduled drugs make it impossible to know the magnitude of such losses. VA's internal controls over higher scheduled drugs appear adequate to detect and facilitate investigations of drug losses and make it difficult to divert large quantities without detection. VA needs to take steps to establish comparable controls over lower scheduled drugs. Without such controls, large quantities of addictive drugs can be stolen without VA managers ever detecting the thefts.

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	First, va needs to better secure its lower scheduled drugs against thefts from authorized or unauthorized internal sources, va's greatest security risk. Large quantities of these drugs are too often stored in pharmacy dispensing areas, where employees and others have easy access to them.
	Second, VA needs to adopt a system for detecting thefts of lower sched- uled drugs. This system should include (1) unannounced inspections of drug supplies conducted on a periodic basis, such as monthly or bimonthly, and (2) procedures for resolving discrepancies between drug supplies and the related receipt and dispensing records. Without such a control system, VA managers must rely on others, generally informants or local law enforcement agencies, to alert them of possible drug thefts in their pharmacies.
	Finally, va should address its internal control weaknesses quickly, given the large quantities of addictive drugs that it handles each year.
Recommendations	We recommend that the Secretary of Veterans Affairs report inadequate internal controls over lower scheduled drugs as a material weakness in his 1991 Federal Managers' Financial Integrity Act report. To address this weakness, we recommend that the Secretary direct pharmacy man- agers to
	 store and dispense lower scheduled drugs in locked areas that are accessible to only a minimum number of authorized employees and inspect supplies of lower scheduled drugs periodically, using receipt and dispensing records, so that potential drug losses are detected in a timely manner.
	We did not obtain written comments on this report. After discussing the issues in the report with va officials, we included their comments where appropriate.

Unless you publicly announce its contents earlier, we plan no further distribution of this report for 30 days. At that time, we will send copies to the Secretary of Veterans Affairs and interested congressional committees. We will also make copies available to others upon request. If you have any questions concerning the information presented, please call me on (202) 275-6207. Other major contributors are listed in appendix III.

Sincerely yours,

Navid P Baine

David P. Baine Director, Federal Health Care Delivery Issues

GAO/HRD-91-101 VA Controls Over Addictive Drugs

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Abbreviations

- DEA Drug Enforcement Administration
- FBI Federal Bureau of Investigation
- VA Department of Veterans Affairs

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DEA Criteria for Assessing a Drug's Abuse Potential

The Drug Enforcement Administration uses the following items as indicators that a drug has a potential for abuse:

1. There is evidence that individuals are taking the drug in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community.

2. There is significant diversion of the drug from legitimate drug channels.

3. Individuals are taking the drug on their own initiative rather than on the basis of medical advice from practitioners licensed by law to administer such drugs in their professional practice.

Controlled Substances Act Criteria for Scheduling Drugs

Schedule I	 The drug has a high potential for abuse. The drug has no currently accepted medical use in treatment in the United States. There is a lack of accepted safety for use of the drug under medical supervision.
Schedule II	 The drug has a high potential for abuse. The drug has a currently accepted medical use in treatment in the United States but severe restrictions may apply. Abuse of the drug may lead to severe psychological or physical dependence.
Schedule III	 The drug has a potential for abuse less than the drugs in schedules I and II. The drug has a currently accepted medical use in treatment in the United States. Abuse of the drug may lead to moderate or low physical dependence or high psychological dependence.
Schedule IV	 The drug has a low potential for abuse relative to the drugs in schedule III. The drug has a currently accepted medical use in treatment in the United States. Abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs in schedule III.
Schedule V	 The drug has a low potential for abuse relative to the drugs in schedule IV. The drug has a currently accepted medical use in treatment in the United States. Abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs in schedule IV.

Appendix III Major Contributors to This Report

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