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Crossing many organizational lines

AMA efforts to curb abuse wide-ranging

The American Medical Association is attacking prescription drug abuse on several fronts.

The problem is not small. Federal statistics show that 80% to 90% of prescription drugs diverted come from individual prescribers and dispensers. Once prescription-type drugs hit the street, they are involved in almost 60% of all drug-related emergency room visits and 70% of all drug-related deaths.

"If it sounds as though our response to the issues raised by prescription drug misuse, abuse, and diversion crosses many organizational lines within the AMA, you're absolutely right," Whalen Strobhar told the Informal Steering Committee on Prescription Drug Abuse.

Besides organizing the multi-agency committee, the AMA has sponsored numerous conferences and issued several research reports and policy statements on the topic, said Strobhar, who is a deputy executive vice president of the AMA.

A 1981 physicians' guide titled *Drug Abuse* is one of several such Association publications, including *AMA Drug Evaluations*. The upcoming fifth edition of that book has a new chapter on prescribing controlled drugs and emphasizes the need for patient education on appropriate use of all prescription medications.

AMA'S NEW Medical Information Network will be an electronic avenue to provide "clinical, educational, and socioeconomic information to physicians and other health care professionals," Strobhar said.

Patients are not neglected in the AMA's efforts. Physicians can pass out Patient Medication Instructions, which are drug information sheets that, among other things, aim to reduce the risk of improper drug use.

Other information sheets are coming from the AMA's Health Education Program. This series of one-page sheets will answer questions most commonly heard by the AMA staff. Information will include treatment resources for drug and alcohol problems.

Strobhar also praised the cooperation

shown by the 20 agencies in the Informal Steering Committee on Prescription Drug Abuse.

One of the first products of that cooperation is the Prescription Abuse Data Synthesis (PADS) program. The AMA has supplied staff and financial assistance to develop PADS, with agencies contributing their time and expertise to the system. It uses several data bases to identify drug diversion and the effectiveness of regulatory efforts.

STEERING COMMITTEE members include the AMA, American Academy of Family Physicians, American Dental Assn., American Hospital Assn., American Nurses Assn., and American Osteopathic Assn.

Others are the American Pharmaceutical Assn., American Podiatry Assn., American Veterinary Medical Assn., Career Teachers in Alcoholism and Drug Abuse, Federation of State Medical Boards of the United States, and the International Narcotic Enforcement Officers Assn.

The National Assn. of Boards of Pharmacy, National Assn. of State Alcoholism and Drug Abuse Directors, National Board of Medical Examiners, and National Institute on Drug Abuse also are members.

Members also include the Pharmaceutical Manufacturers Assn., U.S. Drug Enforcement Administration, U.S. Food and Drug Administration, and White House Office of Drug Abuse Policy.

Physicians who push pills — watch out. The American Medical Association and 19 other organizations have a new plan to shut you down.

The new computerized system sponsored by the groups also will spot physicians who funnel prescription drugs to abusers because they are duped, emotionally impaired, or out of touch with modern drug therapy.

Several systems already exist to find dishonest and other problem physicians, but the Prescription Abuse Data Synthesis (PADS) model meshes the fragmented methods to make a tighter net.

The PADS system reflects cooperation among members of its sponsoring group, the Informal Steering Committee on Prescription Drug Abuse. This organization, founded by the AMA late in 1981, has brought together prescribers, dispensers, regulatory agencies, and law enforcement officials to work on several possible projects.

At its last meeting in mid-February, the group approved a near-final draft of PADS, which it hopes to test in possibly three states in the spring. From there, state medical societies will be asked to analyze the program and to encourage state agencies to participate. Nationwide use of PADS will depend on states' acceptance and finding funds from several groups so that the steering committee can promote and teach PADS. So far the AMA is the only group to support PADS financially.

Although groups such as the steering committee have popped up for years, participants and even the federal General Accounting Office (GAO) are encouraged about this group's prospects of success. Committee Chairman Joseph Skom, MD, (of the AMA's Council on Scientific Affairs and other AMA groups) said that in the past there had been "almost an adversary relationship between enforcement and the medical profession."

Accusations were more plentiful than (See Prescription . . . , page 17)

Plan launched to stem prescription drug abuse

cooperation as groups worked alone on the prescription drug abuse problem and accused others of not helping to solve it. A White House conference in 1980 produced several good recommendations on cooperation, Dr. Skom said, but a change in administrations squashed any implementation.

Urged on by a House of Delegates policy adopted in June, 1981, the AMA formed the steering committee. Member Barry Rhodes of Odyssey Inc., a drug rehabilitation group, said: "The thing that is really important to me is the effort the AMA put into this when there was momentum built up at the White House conference but no follow-up on the national level. Without the AMA's guidance, this effort would have fallen flat."

A GAO report also cited the AMA's efforts as "steps in the right direction . . . The AMA is to be commended for its initiatives."

Several states such as Wisconsin, Illinois, Arizona, and New Hampshire already have accomplished some form of interagency cooperation to spot and stop prescription drug abuse, said David Joranson of Wisconsin's Office of Alcohol and Other Drug Abuse. The GAO report also mentioned some areas in Florida.

Some statistical systems used in such cooperative efforts have been around for more than 15 years. Groups finally started combining systems successfully in the last five years for several reasons, said Rhodes, who formerly headed New Hampshire's drug abuse office. Instead of looking at the problem as a monolithic monster, people began to realize it was made of smaller pieces, such as several classes of physicians who divert drugs. They also

realized one type of physician might need education, while another might need license revocation.

Small successes integrating statistical systems encouraged further exploration. "No one was born using these data systems. It is done through trial, error, and activity," Rhodes added.

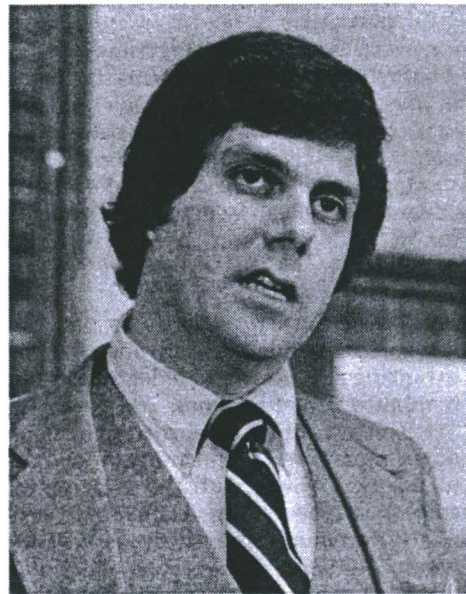
PADS developers hope to help states avoid errors by showing them how to handle up to about 12 different sets of statistics. Massaging these facts can take officials all the way from asking, "Do we have any problems in our state?" to identification of individual practitioners.

After officials identify how their state's usage patterns, arrests, or other statistics differ from others, more intensive analysis of PADS data can spot regions where diversion may be high. At this point traditional investigative techniques may take over. Since statistics may be able to pinpoint a problem region down to the first three digits on a ZIP code, investigators then can move in to inspect a relatively small number of pharmacies. They generally are looking at sales of only one or two drugs so officials can sift records quickly and spot individual physicians or pharmacists who may be diverting drugs, Rhodes said.

ONCE OFFICIALS spot a problem practitioner, several actions can be taken. Arrest is a possibility for the small number of all physicians who are intentionally dishonest. Sometimes quicker action is available by restricting or removing a license. In other instances, especially where physicians are unintentionally dishonest, the threat of losing the license is enough to motivate them to reform their prescribing habits.



In the past, almost an adversary relationship existed between enforcement and the medical profession, said Joseph Skom, MD (left). Barry Rhodes pointed to the importance of AMA efforts in getting the new program moving.



Photos: Steve Carrell/AMN

After action is taken, PADS data also can monitor the effectiveness of those efforts.

No single computer program is necessary to crunch all the data together, Rhodes said, because just looking at several print-outs makes problem areas obvious.

Some of the data systems PADS can incorporate include:

- Automated Reports and Consolidated Orders System (ARCOS), which records retail sales of narcotics and other drugs by dispensers. A PADS resource document states ARCOS is well-managed information, but it cannot be used alone to determine if diversion exists. The report is produced quarterly.

- Drug Abuse Warning Network

(DAWN), which includes information on reimbursements for prescribed substances. It provides "the only national information system capable of a reasonable scientific measurement of demand-side levels of prescription drug abuse," the PADS document said, but its coverage is too limited.

- Drug abuse treatment program admissions. These data can provide "a useful source of ongoing trend information," the report stated, but "this information is not routinely or uniformly available from all drug treatment programs."

The cooperation and data available in each state will help determine which combinations will yield more and better information.

—Steve Carrell

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AMA, GTE UNVEIL NATIONWIDE MEDICAL NETWORK

(CHICAGO -- Sept. 13) -- The American Medical Association and GTE Corp. today unveiled a new nationwide electronic information system -- the GTE Telenet Medical Information Network, featuring AMA/NET data licensed and maintained by the AMA.

Beginning October 1, 1982, the network will instantly transmit clinical and socioeconomic information to physicians and other health care professionals in targeted areas.

Service initially available in four cities

"When completed," said Thomas A. Vanderslice, GTE President and Chief Operating Officer, "the network will be the largest and most extensive of its kind ever developed. Now undergoing field tests, the system will shortly begin operation in Chicago, Washington, D.C., Los Angeles and Houston."

James H. Sammons, M.D., Executive Vice President of the American Medical Association, called today's inauguration of AMA/NET the beginning of "a historic journey in medical-health telecommunications, a journey of immense import to the future of medicine and health care."

Keeping up with information explosion

"In recent decades the tremendous growth of new medical knowledge and techniques has sorely tried the ability of physicians to stay up to date," said Sammons. The creation of AMA/NET, designed to keep up with today's exponential growth of medical information, was a logical and inevitable step for the AMA, he said.

"Today, we are the largest compiler, clarifier and communicator of medical and health-related information in the world, with professional publication numbers alone totalling about 32 million copies a year. Drawing on such extensive resources, we already have developed four AMA/NET data bases for on-line service to physicians and other users."

Initial offerings of the GTE Telenet Medical Information Network include four data bases -- Drug Information, Disease Information, Socio-Economic Bibliographic Information, and Medical Procedure Coding and Nomenclature -- and MED/MAIL, an electronic mail system that offers instant transmission of messages between subscribers and "bulletin boards" of information on medical meetings of interest to physicians. (Detailed descriptions of the four information bases and MED/MAIL are attached.)

Productivity enhanced

"Electronic information services like the medical network will be a very important key to enhancing productivity," said Vanderslice, "particularly at the professional and administrative level. The simple reason is that computer-based systems can provide in minutes information that might actually take hours or days of research. When you have accomplished that, you have in effect given a physician more time to do what he does best and to practice his profession in a more efficient way."

A wide variety of computer terminals (video display and/or printer) will link the MD-subscriber with the network's data banks in the Washington, D.C. area. Connection can be made through existing telephone lines and, in most cases, the physician need only dial a local telephone number for network access.

AMA/NET information services will cost \$25-27 per hour, depending on the data base used. MED/MAIL will cost \$7-16 per hour, based on the time of day the service is employed. A basic subscription fee of \$100 will be charged.

The GTE Telenet Communications Corporation, a subsidiary of GTE and based in Vienna, Virginia, will manage and operate the medical information network. The AMA is the principal provider of scientific information offered through the network.

"Eventually, physicians and other users at computer terminals spanning the nation will have instant access to up-to-the-minute clinical information and protocols, along with a broad range of other medical and health-related information addressing administrative, socioeconomic and even political-legislative issues in medicine and health care," said Sammons. He said the network's value is that of a tool, "although an increasingly indispensable tool to the physician in the day-to-day practice of medicine, a tool that can increase competence and self-confidence."

AMA/NET

DATA BASES

- 1) Drug Information -- Describes in detail more than 1500 individual drug preparations marketed under some 5,000 trade names in the United States, Canada and Mexico. The data base offers comprehensive information for each drug by name and can identify drugs according to indications for therapy, special patients or circumstances and by certain drug actions and interactions. Drug Information is based on AMA Drug Evaluations, 5th Edition, 1983, and has been expanded to include additional information, such as availability of specific preparations, dosages and trade names. Information will be updated monthly, with critical additions and revisions made immediately.
- 2) Disease Information -- Offers current, precise descriptions of diseases, disorders and conditions. Important diagnostic features of more than 3,500 identifiable diseases are summarized in preferred, standard terminology. Physicians can access information by requesting the full body of information on a specific disease or by certain subtopics under the disease listing, such as signs and symptoms or laboratory test results. Disease Information is based on the AMA's Current Medical Information and Terminology, 5th Edition, 1981, with updates twice yearly.
- 3) Socio-Economic Bibliographic Information -- Serves as a guide to current articles on the non-clinical aspects of health care. This comprehensive bibliographic resource includes more than 700 journals as well as legislative reports and selected books and newspapers.

Education, ethics, medical practice and public health are examples of the types of subject headings included in the bibliographic information base. The AMA Division of Library and Archival Services, under the editorial direction of AMA scientific staff, produce and maintain the base, with monthly updates. The physician wishing the full text of an article cited in this information base may order the document on-line from the AMA library through the electronic mail service, MED/MAIL.

- 4) Medical Procedure Coding & Nomenclature -- Provides a uniform coding and nomenclature system for reporting medical services and procedures performed by physicians. It contains more than 6,000 descriptions of procedures with their identifying codes in the areas of medicine, surgery and diagnostic services. Information in the medical procedure base is derived from Physicians' Current Procedural Terminology, 4th Edition, the most widely used medical reporting system. It will be updated twice yearly.

ELECTRONIC MAIL SYSTEM

MED/MAIL -- Offers quick communication within the medical community, from physician-to-physician, physician-to-hospital, or from an individual to a group of subscribers, who each receive the message simultaneously, no matter how wide the geographic spread. In addition to instant message delivery, MED/MAIL offers a document order system for use with the bibliographic data base and bulletin boards with information on upcoming AMA meetings and continuing medical education (CME) opportunities. Physicians will soon be able to register for CME meetings directly with course providers.

Plans for the Future

The AMA is researching many possibilities for future data bases. Planned for addition to AMA/NET in the next few years are: Drug Alerts, Laboratory Data, Poison Control Information, Therapy Information and Clinical Literature Index and Abstracts.

Plans for expanding the electronic mail system include a registry service for CME and AMA meetings, physician self-assessment testing in CME, and paperless insurance claims processing.

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How insulin was discovered makes a good tale

By Edward P. Cohen, MD

In the early part of this century, patients with diabetes were advised to follow strict diets that were designed to reduce the quantity of glucose in the urine and to prevent death from ketoacidosis. Although some did live longer, the allowed caloric intake was so small that patients became virtual living skeletons, dying eventually from weakness, malnutrition, and general debilitation. There was no other form of treatment.

Insulin was unknown. Physiologists did recognize, however, that the pancreas was involved not only in digestive processes but also in carbohydrate metabolism.

The importance of the pancreas in regulating the consumption of sugar by the body was discovered in 1889 by Oskar Minkowski, who found that depancreatized dogs became diabetic, secreting large quantities of urinary glucose and dying in acidosis. It was reasoned that an internal secretion of the pancreas, possibly originating from islet cells (they had been identified 20 years earlier by Paul Langerhans), could be the source of a substance that prevented diabetes.

All attempts by physiologists around the world to prepare a pancreatic extract that would lower blood sugar and the quantity excreted in the urine proved unsuccessful. Feeding or injecting extracts of the pancreas to depancreatized animals had no discernible effect.

THE SOLUTION to the problem is described nicely in *The Discovery of Insulin*. Frederick G. Banting, MD, and Charles H. Best, whose experiments led to the discovery of insulin, believed that large quantities of digestive enzymes in the pancreas destroyed insulin along with many other substances during the extraction process. Dr. Banting had the idea that ligating the pancreatic duct in the dogs used in the experiments would lead to pancreatic atrophy without affecting islet tissue. Successful extraction of the active substance from the pancreas could follow.

Dr. Banting wrote in his personal notebook: "Diabetes. Ligate pancreatic ducts of dog. Keep dogs alive until acini degenerate leaving Islets. Try to isolate the internal secretion of these to relieve glycosuria."

John James MacLoed, professor of physiology at the U. of Toronto, himself an experimental physiologist of many years, provided Dr. Banting with a lab, experimental animals, and some reagents. With Dr. Banting's initial successes, he became an active participant and full supporter of the studies. Best, a medical

student at the university, joined Dr. Banting in performing the experiments. James B. Collip, the fourth member of the team, applied advanced (for the time) biochemical techniques to the problem. Together, the pancreatic extracts they prepared lowered blood sugar and kept diabetic animals alive.

Duct ligation, as it turned out, had little to do with the success of the experiments. Sufficient activity remained after grinding the pancreas in a mildly acidic, alcohol solution to lower blood glucose, the quantity of sugar in the urine, and to prevent acidosis.

Dr. Banting and Best kept depancreatized dogs alive for weeks with the crude pancreatic extracts, and we share their excitement.

Attempts to treat diabetic patients followed shortly afterwards, and word leaked to the press that some of them improved. One patient in a coma was revived with Dr. Banting's extract; it was the first time in history that anything like that had occurred in the treatment of diabetics.

With the remarkable success of the project, investors appeared in Toronto along with more and more diabetic patients. One entrepreneur reportedly offered Dr. Banting \$1 million (in 1922) for his rights to the discovery. As a physician and scholar, Dr. Banting refused. Later, the Eli Lilly Co. supported insulin research and became a worldwide leader in the pharmaceutical industry as a result.

ALL OF THIS is well-known to casual students of medical history. Bliss goes on further to describe the less well-known but fascinating story of the conflict that developed between the scientists themselves as they came to recognize the importance of their discovery. Priority of discovery and recognition by colleagues are the hard currency of medical investigators.

At one point Collip, who was working on purifying insulin, refused to discuss his work with Dr. Banting, who barely was speaking to MacLoed. Conflict grew over who did what first and to what extent, with claims and counterclaims, as success in treating diabetics became more and more apparent.

It continued even after the Nobel Committee awarded its 1923 prize to Dr. Banting and MacLoed. Dr. Banting shared his prize with Best, who was finishing medical school. MacLoed shared his with Collip for his contributions to the project.

Nevertheless, so intense was the dislike that developed between Dr. Banting and MacLoed that communications stopped,

public recriminations were common, and almost childlike acts began. Dr. Banting believed that MacLoed's contributions were minimal, that he was stealing the glory, and that any recognition was unwarranted. At one point, Dr. Banting refused to attend MacLoed's farewell dinner, as the professor was leaving Toronto to return to a faculty position in Scotland, asking that an empty place be set for him at the speakers table.

Dr. Banting continued treating diabetic patients in the years that followed. He was killed in 1941 in the crash of a military plane on its way to Europe. At age 29, Best replaced MacLoed as professor of physiology at the U. of Toronto and went on to a long and distinguished career in endocrine research. Collip, after his work on insulin, became chairman of the Dept. of Biochemistry at McGill; he was involved in the discovery of several important hormones, including parathyroid hormone and ACTH.

I found all this fascinating reading, even though the general outlines of the story were known to me. Bliss, a historian, researched his subject thoroughly; he writes well and carried me along to the end of the story with no loss of interest. An extensive bibliography and subject index add reference value and convenience to the volume.

Unfortunately, diabetes is still a complex disease, and even though patients who require insulin do well, serious side effects often develop and future challenges remain. Transplantation of islet cells is a future possibility; micro-insulin pumps imbedded in the body may lead to a more level, sustained delivery system.

Being in the right place at the right time in medical research, as elsewhere, is critically important. Dr. Banting and Best, MacLoed and Collip extended the work of physiologists elsewhere who worked for years previously on this question. The unrecognized workers who contributed in essential ways deserve credit, too, and our admiration, for their help in bringing the problem home, to the benefit of thousands and thousands of diabetic patients worldwide.

Dr. Cohen is director of the Office of Research Development at the U. of Illinois in Chicago.

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By Michael Bliss
U. of Chicago Press, 1982
304 pages, \$20

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Death rates drop for all but young adults

Death rates for all Americans except young adults are declining, the Health and Human Services (HHS) Dept. says.

The death rate for Americans ages 15 to 24 has risen since 1976 because of a sharp rise in auto accidents, homicide, and suicide, according to an HHS report. Three out of four deaths in that group are from such violent causes, up from about half in 1950.

Auto accidents are the leading cause of death among young whites, accounting for 40%, while homicide is the leading cause of death among young blacks, accounting for 39%. Overall, the risk of dying is three to five times greater for young men of both races than for young women.

The figures from 1979, the latest year for which complete data are available, were included in the department's annual report on the nation's health, "Health, United States, 1982."

Pointing to advances in fighting heart disease, stroke, and cancer, which the report cited as responsible for the significant decline in mortality, HHS Secretary Richard Schweiker said: "The facts... show that American medical science is continuing its extraordinary progress in treating people after they get sick. But the other important message here is that the next era in health care must take us a step beyond traditional medical care — to stop illness before it strikes."

SCHWEIKER SAID the department planned to launch a media campaign to encourage Americans to lead healthier lives. A 45-year-old man who did not smoke, drank alcohol in moderation, ate three meals a day, maintained proper weight, and got enough sleep and exercise could expect to live 11 years longer than a man who did not adopt such habits, he said. A 45-year-old woman could add seven years to her life in the same way.

Among other findings in the report,

compiled by the National Center for Health Statistics:

- The birth rate has increased gradually since 1976, after a rapid decline. The trend is due partially to women who postponed childbirth.

- Life expectancy increased through 1979, to 69.9 for men and 77.6 for women. Preliminary data from 1980 show a slight drop, probably due to a flu epidemic that year.

- Adult mortality has fallen since 1950 by almost one-third among Americans ages 25 to 44 and by about one-fourth among those over 44, primarily from declining death rates for heart disease and stroke.

- Death rates for cancer declined over the past 10 years for those under 50 but increased for older people.

- Cigarette smoking declined in general and specifically among teen-agers. Marijuana use also declined among teen-agers, but heavy drinking continues.

- Annual physician visits increased from 3.9 to 5.5 per person among low-income Americans from 1964 to 1980. Physician visits stabilized or declined among higher-income groups.

- The number of people hospitalized increased during the 1970s, especially among the elderly, but lengths of hospital stay declined. There were fewer tonsillectomies among children and fewer hysterectomies among women during the same period. Cardiac catheterizations increased rapidly among men and cataract removal increased among the elderly.

- The physician-patient ratio reached a new high of 20 per 10,000 population in 1980 and is expected to increase during the coming decade.

- Expenditures for health care rose to \$286.6 billion or \$1,225 per American in 1981, or 9.8% of the gross national product. Per capita personal health and hospital care spending was highest in Massachusetts. It was lowest for personal health in South Carolina and for hospital care in Idaho.

Death rates drop for all but young adults

Death rates for all Americans except young adults are declining, the Health and Human Services (HHS) Dept. says.

The death rate for Americans ages 15 to 24 has risen since 1976 because of a sharp rise in auto accidents, homicide, and suicide, according to an HHS report. Three out of four deaths in that group are from such violent causes, up from about half in 1950.

Auto accidents are the leading cause of death among young whites, accounting for 40%, while homicide is the leading cause of death among young blacks, accounting for 39%. Overall, the risk of dying is three to five times greater for young men of both races than for young women.

The figures from 1979, the latest year for which complete data are available, were included in the department's annual report on the nation's health, "Health, United States, 1982."

Pointing to advances in fighting heart disease, stroke, and cancer, which the report cited as responsible for the significant decline in mortality, HHS Secretary Richard Schweiker said: "The facts . . . show that American medical science is continuing its extraordinary progress in treating people after they get sick. But the other important message here is that the next era in health care must take us a step beyond traditional medical care — to stop illness before it strikes."

SCHWEIKER SAID the department planned to launch a media campaign to encourage Americans to lead healthier lives. A 45-year-old man who did not smoke, drank alcohol in moderation, ate three meals a day, maintained proper weight, and got enough sleep and exercise could expect to live 11 years longer than a man who did not adopt such habits, he said. A 45-year-old woman could add seven years to her life in the same way.

Among other findings in the report,

compiled by the National Center for Health Statistics:

- The birth rate has increased gradually since 1976, after a rapid decline. The trend is due partially to women who postponed childbirth.

- Life expectancy increased through 1979, to 69.9 for men and 77.6 for women. Preliminary data from 1980 show a slight drop, probably due to a flu epidemic that year.

- Adult mortality has fallen since 1950 by almost one-third among Americans ages 25 to 44 and by about one-fourth among those over 44, primarily from declining death rates for heart disease and stroke.

- Death rates for cancer declined over the past 10 years for those under 50 but increased for older people.

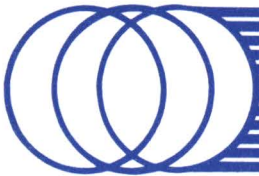
- Cigarette smoking declined in general and specifically among teen-agers. Marijuana use also declined among teen-agers, but heavy drinking continues.

- Annual physician visits increased from 3.9 to 5.5 per person among low-income Americans from 1964 to 1980. Physician visits stabilized or declined among higher-income groups.

- The number of people hospitalized increased during the 1970s, especially among the elderly, but lengths of hospital stay declined. There were fewer tonsillectomies among children and fewer hysterectomies among women during the same period. Cardiac catheterizations increased rapidly among men and cataract removal increased among the elderly.

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AMA NEWS RELEASE
FOR RELEASE TUESDAY, OCTOBER 5, 1982

For further information, contact:
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File
AMIB

**AMA LAUNCHES DRUG INFORMATION
PROGRAM FOR PATIENTS**

CHICAGO -- Beginning this month, physicians across the country will be able to give their patients supplementary written instructions along with a prescription for any one of 20 of the most widely prescribed medications.

The American Medical Association has initiated a voluntary program that makes Patient Medication Instructions (PMIs) available to practicing physicians for appropriate distribution to patients. Use of the PMIs is expected to improve the effectiveness of therapy, reduce the risk of improper drug use, decrease the incidence of preventable and serious adverse drug reactions, and help patients comply with instructions about taking their medications properly.

Now, more than ever, patients are seeking information about the drugs they are taking. The AMA welcomes patients' active interest in their own well-being and believes that a patient who understands why a drug has been prescribed is more likely to comply with his or her physician's directions. The AMA believes also that physicians are best qualified to provide the reliable information about drugs that patients want and need. The PMIs offer physicians a method for presenting the information in a form that may be referred to by the patients when questions arise.

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DRUG INFORMATION PROGRAM

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Available now are PMIs for 20 of the most widely prescribed drugs or drug classes. Physicians may obtain them from the AMA for a nominal charge that covers shipping and handling costs. PMIs for more of the commonly prescribed drugs and drug classes will be available next year. Eventually, the program will provide PMIs for as many as 100 drugs or drug classes that will represent the vast majority of all prescriptions written.

The format for each PMI is a 5½" by 8½" sheet printed on both sides. The instructions describe in clear, simple language the purpose of the drug, how it is to be taken, and its possible side effects--both minor side effects and those that should be reported to the physician. Space is provided to write in the dosage and any special instructions the physician may have for the individual patient. PMIs for individual drugs or drug classes are bound in pads of 100 sheets. They will be updated periodically when new information is available.

In a letter to some 400,000 practicing physicians (MDs and DOs), AMA Executive Vice President James H. Sammons, MD, said of the PMI program, "It ranks among the most important programs the AMA has ever launched."

For the past decade, the medical community has generally agreed that patients need additional information about the drugs they take. Opinions have varied about the best method of supplying the information, however. The AMA has strongly supported the position that the most appropriate time to impart this information is during the physician-patient encounter.

- more -

DRUG INFORMATION PROGRAM

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The Food and Drug Administration (FDA) decided about a decade ago to require patient package inserts (PPIs) with oral contraceptives (the "pill"), and controversy has surrounded the PPI concept to some degree since then. The FDA in 1979 proposed rules that would have eventually required the dispensing by pharmacists of a PPI for virtually every prescription drug. Only 14 months later, however, this comprehensive plan was scaled down to a ten-drug pilot study. Then, in a 1981 hearing, FDA Commissioner Arthur Hull Hayes, Jr., MD, received testimony that the private sector, especially the AMA, was taking steps to provide more information about prescription medications. In December 1981 came the announcement that the mandatory PPI regulations would be rescinded.

Last May, Hayes wrote to Sammons to commend the inauguration of the AMA's PMI program. Terming the program "an important initiative in public information about drugs," Hayes said it is especially significant "because it provides for patients to receive written drug information directly from the prescribing physician." And, he wrote, "we at the FDA look forward to working with AMA in its efforts to get drug information to patients."

The PMI program is sponsored by the AMA Education and Research Foundation, which is seeking a broad base of financial support, including pharmaceutical firms and, later, possibly some foundations. Donations have already passed the \$1.5 million mark. Groups that have provided financial support so far include Bristol-Myers Co.; Mead Johnson Foundation; Hoechst-Roussel Pharmaceuticals, Inc.; Hoffman-La Roche, Inc.; Johnson and Johnson; Eli Lilly and Co.; Revlon, Inc.; Upjohn Co.; Warner Lambert; American Home Products Corp.; Smith Kline and French Laboratories; and Burroughs Wellcome.

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DRUG INFORMATION PROGRAM

Although the AMA is investing in and is responsible for implementing the PMI program, it is drawing not only upon its own publication, AMA Drug Evaluations, but also on sources such as the United States Pharmacopeia for information. The United States Pharmacopeial Convention, Inc., is an independent, non-profit corporation that sets official standards of purity, strength and quality for drugs used in the United States. It additionally maintains a computerized information base on some 1,200 drugs.

PMI sheets are copyrighted by the AMA, but the association will permit physicians to use them "broadly for purposes of treatment." The sheets will indicate date of publication so that physicians can tell which of two sheets on the same drug is the more recent version.

Names and brief descriptions of the 20 drugs and drug classes in the first PMI series are listed below in no particular order of priority.

- | | |
|------------------------------|--|
| Furosemide ----- | A very potent diuretic, effective in patients with impaired kidney function |
| Thiazide diuretics ----- | Agents of choice as first line therapy in high blood pressure, useful for congestive heart failure in patients with normal kidney function |
| Penicillins (oral) ----- | Most widely used antibiotics in treatment of many common bacterial infections |
| Digitalis preparations ----- | Considered primary therapy for treatment of chronic congestive heart failure |

DRUG INFORMATION PROGRAM

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- Coumarin-type anticoagulants----Used in patients with blood clotting disorders and sometimes following strokes and heart attacks
- Oral antidiabetics-----Used for adult-onset diabetes and, when appropriate, can replace injectable insulin
- Tetracyclines-----Antibiotics used for many common bacterial infections and acne
- Cephalosporins-----Broad spectrum antibiotics useful for certain bacterial infections
- Erythromycin-----One of the safest antibiotics for treatment of bacterial infections
- Nonsteroidal-----Useful for treatment of arthritis, antiinflammatory agents to reduce inflammatory fevers, and pain
- Benzodiazepines-----Have almost replaced barbiturates for use as hypnotics; also widely used in anxiety
- Sublingual Nitroglycerin-----Used under the tongue as drug of choice for treatment of chest pain
- Methyldopa-----Used in the treatment of high blood pressure
- Insulin-----Essential hormonal replacement for treatment of diabetes
- Corticosteroids (oral)-----Have wide variety of uses, including reducing inflammation, treatment of arthritis, ulcerative colitis and many more
- Cimetidine-----Inhibits secretion of stomach acid, and widely used in treatment of peptic ulcer
- Belladonna and barbiturates-----Widely employed for management of functional bowel syndromes

- more -

DRUG INFORMATION PROGRAM

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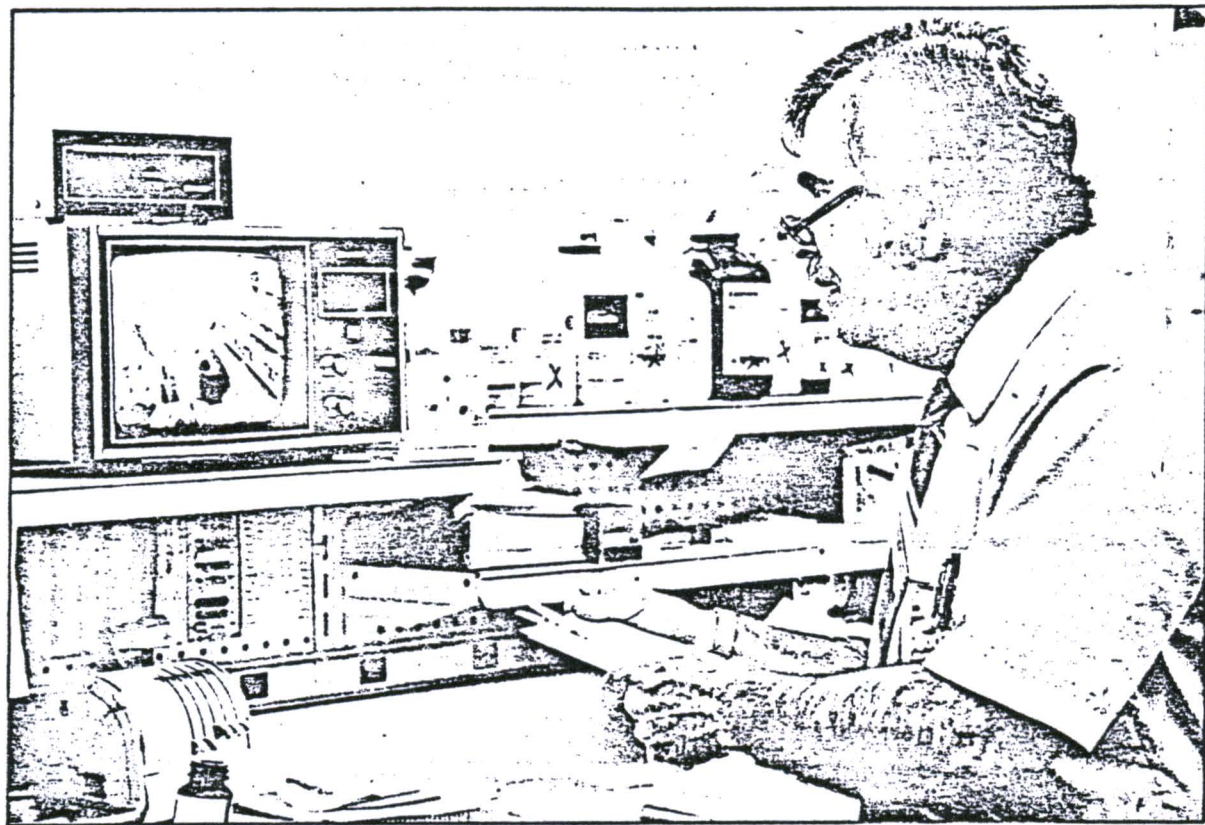
Phenytoin-----A drug of first choice for treatment of many types of epilepsy

Sulfonamides-----Widely used for treatment of urinary tract infections

Beta blockers-----Used in the treatment of high blood pressure, chest pain and heart beat irregularities

#

Pharmacy Crime Prevention— *It's Up to You!*



- ☞ Pharmacy Hit in a Daylight Holdup
- ☞ Drugstore Burglary Nets Drugs, Cash
- ☞ Two Injured in Pharmacy Robbery

Headlines like these appear all too frequently in newspapers across the country. Although security is a problem affecting many small businesses, pharmacies present special targets of opportunity for criminal elements. Often, in addition to being ready sources of cash and drugs, pharmacies maintain "convenience store" hours and stock other goods that are highly attractive to thieves, including cameras, small appliances and other high-value items.

In recent years pharmacy robberies (holdups) and burglaries (break-ins, usually after hours) have totaled approximately 10,000 annually. To put it even more graphically, every retail pharmacy stands a one-in-five chance of being broken into or

robbed in a 12-month period.

Furthermore, according to Wayne Bohrer, a compliance officer with the U.S. Drug Enforcement Administration (DEA), "Overall pharmacy crime, primarily robberies and burglaries, is increasing about 10% a year."

In the face of these disconcerting statistics, it is possible to become fatalistic, to simply hope for the best and keep up with insurance premiums.

This attitude is not only defeatist, it is also misinformed. Pharmacists can take positive steps that will significantly reduce their chances of becoming crime victims.

For example, in three of every four burglaries reported, it was

found that there was no alarm system or other security device to deter robbery or forced entry.* Without question, proper defenses could have prevented or minimized loss in most of these cases.

Any effort to improve your measure of protection against robbery and burglary should begin with a survey of the premises, to identify weak points and suggest remedial action. A high proportion of "yes" answers on the "security checklist" for robbery and burglary indicates that you are subject to a high crime risk (see p. 46).

*"Pharmacy Security Manual," Smith Kline & French Laboratories, 1976.

Security Checklist*

If you answer **YES** to the questions below, your pharmacy may be ripe for a robbery or burglary; corrective action is obvious.

Robbery

Is your pharmacy a likely target for robbers? Yes No

- Is your pharmacy isolated from other businesses? Yes No
- Does the pharmacy operate late at night? Yes No
- Does the pharmacy make change after dark? Yes No
- Is the pharmacy known to keep substantial cash on hand? Yes No
- Is cash transferred according to a set routine? Yes No
- Is the pharmacy obviously operated by a single cashier? Yes No
- Does the pharmacy have little exterior lighting? Yes No

Can a robber case your pharmacy easily? Yes No

- Is your cash register partially hidden from the sight of other employees? Yes No
- Is the light level in your pharmacy much higher or lower than outside your pharmacy? Yes No
- Do posters and displays block the view of the cash register from outside? Yes No
- Is a telephone booth located in sight of the cash register? Yes No
- Is the cash register within reach of customers? Yes No
- Is there only a single courier for cash transfer? Yes No
- Do you have a set routine for cash transfer? Yes No

Can robbers approach your pharmacy without detection? Yes No

- Do posters and displays block employees' view of outside? Yes No
- Are there blind spots adjacent to the pharmacy? Yes No
- Are there blind spots in the pharmacy? Yes No
- Is the entrance close to the cash register? Yes No

Can robbers easily carry out a robbery in your pharmacy? Yes No

- Is the cash register within reach of customers? Yes No
- Are there blind spots near the cash register? Yes No
- Is the safe or cash container easy to open? Yes No
- Is the exit close to the cash register? Yes No
- Do the pharmacy doors open two ways? Yes No

Can robbers "get away with" robbing your pharmacy? Yes No

- Is the parking lot adjacent to the thoroughfare? Yes No
- Are there blind spots in the parking lot? Yes No
- Are there no standard procedures for reporting crime to police? Yes No
- Are serial numbers of large bills not listed? Yes No
- Are clerks untrained in observing robbers? Yes No
- Are you not willing to participate in a trial or other legal proceedings? Yes No

Burglary

Is your pharmacy a likely target for burglaries? Yes No

- Does your pharmacy lack perimeter protection? Yes No
- Does your pharmacy obviously store items of value? Yes No
- Is the pharmacy exterior not well lighted? Yes No

Can your pharmacy easily be cased? Yes No

- Can a burglar approach your pharmacy without being observed from outside? Yes No
- Do you keep your cash register drawer closed after business hours? Yes No
- Is your safe hidden from outside view? Yes No
- Have you decided against using a guard service? Yes No

Is your pharmacy easy to break into? Yes No

- Are there unprotected openings larger than 96 square inches? Yes No
- Can hinge pins be removed from exterior doors? Yes No
- Are your exterior door locks easy to pick or jimmy? Yes No
- Have you chosen not to install an alarm system? Yes No
- Have you decided against a watchdog? Yes No

Is it easy to collect cash and high-value items inside your pharmacy? Yes No

- Is your high-value merchandise accessible and not protected by security anchors? Yes No
- Do you store cash in the pharmacy during non-operating hours? Yes No
- Can your safe be moved? Yes No
- Have you chosen not to install an alarm in the interior of the pharmacy? Yes No

Is it easy for a burglar to leave your pharmacy with substantial amounts of loot? Yes No

- Is the parking lot poorly lit? Yes No
- Do you allow boxes and other materials to collect near the inside of your fence? Yes No
- Is there an exit leading to an alley or driveway? Yes No
- Are some doors not equipped with double-cylinder deadlocks? Yes No

Can burglars be successfully prosecuted if arrested? Yes No

- Are you unable to identify items stolen from your pharmacy? Yes No
- Are you willing to buy merchandise of dubious origin? Yes No

*Adapted from Security and the Small Business Retailer, Law Enforcement Assistance Administration, U.S. Department of Justice, Washington, DC, 1979.

Picking a Good Lock

It almost goes without saying that a good door lock is basic to achieving building security.

There is wide agreement that the deadbolt lock is excellent for most doors and preferable to most other types of hardware. The deadbolt features a straight bar or bolt, usually rectangular and squared off at the end, that can be moved into the locking position only by turning a key or knob. The bolt must be long enough to extend a significant distance (at least one inch) into the doorframe when locked.

Aluminum shell doors so typical of many glass-paneled pharmacy entrances are particularly vulnerable because the aluminum frames can be spread with pry bars or other burglar tools. A deadbolt lock will, however, provide a measure of security, just as it will with wooden or steel doors.

In many aluminum frame doors, the bolt is vulnerable to hacksawing through the space between the edge of the door and the door frame. This problem can be overcome by installing a lock with a free-wheeling steel insert to protect the bolt, making it impossible to saw through.

Remember: the best lock can be defeated by simply attacking the door hinges; therefore, whenever possible, it is best to mount doors in such a manner that the hinges are inside the building.

Windows, too, offer an obvious point of entry. They can be protected by use of key locks, protective grilles or grates, and safety glazing that is resistant to burglar tools.

Visibility a Deterrent

The importance of good lighting as a crime deterrent cannot be over-emphasized. Both exterior and interior lights are essential components of a good security lighting system. There should be minimum contrast between indoor and outdoor lighting levels.

Edward Voska, a detective with the New York City police department, points out that in addition to good interior lighting, there should be a clear, unobstructed view into the store from the street.

"This will mean that display windows can't be used for advertising signs that block the view from the street," Voska says. "But this is a small price to pay for enhanced security."

Voska, who has had working experience in a pharmacy, also recommends moving the prescription counter to the front of the store to make it more visible and, thus, less tempting to would-be thieves.

"I realize one practical reason that pharmacy counters are located in the rear of most stores is the access this allows to storage areas," Voska notes. "But pharmacists could as well maintain stocks of the most commonly used drug products in a smaller, up-front storage area, and be prepared to fill low-volume prescriptions from stock held in rear storage areas."

Alarm Systems

As businesspeople, pharmacists must, of course, consider the economic aspects of any business investment, including installation of an intrusion alarm system. Most police officials, however, take the position that, given the special attraction of pharmacies to the criminal element, some kind of alarm system is essential.

A large number of alarm systems are available—so many, in fact, that

choosing a system can be confusing. In considering what system best fits your needs, it is helpful to know that all intrusion alarm systems consist of just three fundamental elements:

- A *sensor*, which detects the action or presence of an intruder;
- A *control unit*, which turns the system on and off, receives the signal from the sensor, processes the signal, and transmits the actual alarm signal;
- An *alarm*, which summons assistance in response to the alarm signal.

The sensor and control unit components can be assembled in a variety of configurations to provide four basic types of protection:

- *Point protection*, to monitor an individual object such as a cash register or drug locker;
- *Perimeter security* to detect entry at any point into a building;
- *Area, space or volume security*, to detect the presence of an intruder in certain defined areas within a store;
- *Holdup protection*, in which an alarm must be manually actuated by a storekeeper who witnesses a robbery or is subject to a holdup.

It is possible to combine these four basic types of protection in any number of ways, to tailor the amount and kind of protection to suit individual needs and store lay-

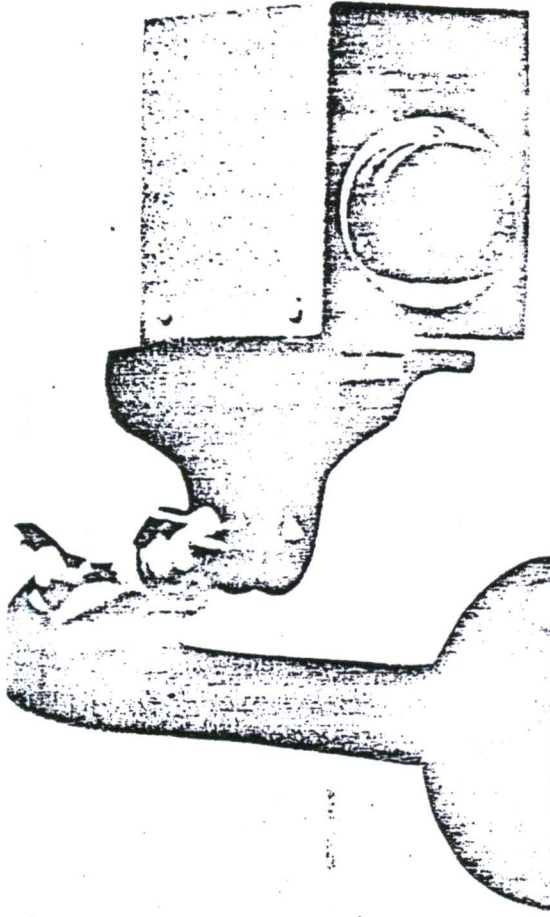
Security Training Available

In 1976, Smith Kline & French Laboratories launched a program designed to help pharmacists protect themselves and their pharmacies from robberies and burglaries.

In the past six years, some 30,000 pharmacists and other professionals and students in the health field have taken advantage of the training materials and program, according to Donald K. Fletcher, SK&F's manager of professional and legislative affairs. Fletcher is a former Texas State Police officer and a recognized expert on drug abuse and pharmacy crime.

The SK&F program features a 133-page pharmacy security manual and a videotape which graphically demonstrates the principles of pharmacy security and the defensive measures that any pharmacy can use to deter holdups and burglaries. The security manual is comprehensive, covering such topics as ways to guard against shoplifting and theft by employees, and store layout and design for maximum security, as well as a review of alarms and other equipment.

Free copies of the manual are available by writing: Pharmacy Security Manual, E-60, Smith Kline & French Laboratories, P.O. Box 7929, Philadelphia, PA 19101. The videotape is available on a loan basis through local SK&F representatives.



out. For example, most pharmacies should have complete perimeter security (including ability to sense entry from basements, crawlspace above the pharmacy, and skylights). But it also may be desirable to extend point or area protection to cash registers or spaces where drugs are stored.

Sounding the Alarm

Selection of the alarm signaling/transmission element of your security system can be especially important. Four types of signaling systems are in general use:

- The *local* alarm;
- The *central station* system;
- The *automatic telephone dialer*;
- The *direct connect* system.

Aside from differences in price, your choice of alarm signaling system will depend on such factors as the location of your pharmacy and the frequency of police patrols.

Local alarms provide an on-the-premises signal that a break-in has been attempted, usually by sounding bells or flashing lights. This system relies on the signal to frighten away the intruder, or on the chance that a police patrol will observe the signal or that a neighbor or passerby

will telephone authorities.

Although local alarms are usually least expensive, law enforcement officials generally recommend one of the "silent" forms of alarm transmission.

In the typical *central station* system, the alarm signal indicating an actual or attempted entry will be sent via special leased telephone lines to a remote station.

The central station most often is a commercial service and the degree of service you receive will vary with individual companies and contracts. Types of service that are offered range from simply monitoring alarm signals and notifying police, to dispatching private guards to your pharmacy in response to a signal.

Automatic telephone dialers offer some of the advantage of central station systems, though because they use public telephone lines instead of leased lines, they are generally less costly.

When an intrusion is detected, a tape recorded message or coded message in the form of electronic pulses is sent to a central station office. In some systems you can elect to have the message sent to a private answering service, to your home, or (if local ordinances permit) directly

Move to Make Pharmacy Robbery a Federal Crime

There appears to be growing sentiment for making theft of controlled substances a federal offense, carrying stiff mandatory penalties.

Advocates for a federal role in prosecuting pharmacy crime point out that under the Comprehensive Drug Abuse Prevention and Control Act of 1970, the manufacture, distribution and possession of controlled substances already is subject to federal rules and penalties. (The act of robbery, however, remains a state or local offense.) The intent of the federal law was, and is, to reduce drug abuse by keeping drugs in legitimate channels, denying them to criminal elements.

Undoubtedly, the 1970 statute has had a positive effect in making legal drugs harder to divert for illicit or criminal purposes. But critics contend that the law has also served to increase the incidence of pharmacy robbery, with consequent risk to pharmacists.

Sen. Roger W. Jepsen (R-IA) claims that "the practical effect of the 1970 act has been to make pharmacists extremely vulnerable to the ravages of violent crime. I can-

not imagine that the intent of the Drug Abuse Prevention and Control Act was to make these individuals 'sacrificial lambs' in the war against drug abuse; but this is exactly what has happened."

The senator's answer to the problem? Make robberies involving theft of controlled substances subject to federal investigation and prosecution.

A bill was introduced in 1978 that would have extended federal jurisdiction to cover pharmacy robberies in which the loss of controlled substances exceeded \$500. The bill failed to pass. Similar legislation was introduced again last year. Jepsen, chief sponsor of one bill (S-661), reports that hearings will take place this spring, and he is optimistic regarding prospects for passage.

It may be worth noting that Jepsen's bill dispenses with the \$500 "trigger," making robbery of controlled substances of any value a federal crime. Jepsen argues, "Every day we postpone consideration of this important legislation, the chances increase that another pharmacist will lose his or her life trying to serve the public."

to the police.

Systems employing the coded message, of course, require use of an electronic terminal that can decode the message and put it into meaningful form.

In the *direct connect* system, the alarm is connected directly by wire to a remote alarm receiver at the police station or some other location.

Economic Incentives

As with any business investment, the cost of a security system must bear a reasonable relationship to expected return or value to be gained (or lost). Values such as peace of mind are intangible, therefore highly personal, but must be weighed as well.

Besides the obvious incentive for purchasing a security system, an added economic incentive was provided by the Economic Recovery Act of 1981 (PL 97-34). Formerly, capital assets for business purposes could be written off over the period of their useful life, which in the case of alarm systems was considered to be 10 years. Now, the new tax law allows businesses to write off investments in security systems in only five years; 15% of the investments may be written off the first year,

22% the second year, and 21% the following three years.

Recurring expenses for security systems that involve leases or monthly service fees may also be deducted from taxes as "ordinary and necessary" business expenses.

The cost for different security systems and system configurations can vary widely; it is best to know what security you need, then shop for the best price and a reliable supplier. This is not to say that the most expensive system is necessarily best for your circumstances, but a less-than-adequate system—regardless of its cost—could turn out to be a bad bargain!

Selecting a Supplier

Local police departments are often willing to provide specialists to conduct an on-site survey of your security needs and to make general recommendations. Although they usually won't recommend specific brand name equipment or suppliers, they may be willing to say which systems or local suppliers are unreliable. A check with your local Better Business Bureau should also provide this type of information.

When selecting a supplier, it is always a good idea to ask for refer-

ences and inquire regarding the experience of other customers. After identifying several reputable suppliers, get recommendations and bids from each. The systems that are suggested may differ; listen to their reasoning for a particular system design, then decide if it makes sense in the context of your more complete knowledge of your own pharmacy operation.

Finally, the Yellow Pages in many cities list security consultants who, for a fee ranging between \$150-300 will advise you on your security needs. Their advice can extend beyond recommendations for intrusion alarm systems, to encompass strategies for reducing shoplifting and employee pilferage. This fee may be money well-spent, depending on your circumstances.

For most retailers, security is an essential part of doing business today. This applies with special force to virtually all pharmacists. Fortunately, security is something that, within limits, can be purchased. But as with any important purchase, the consumer who takes the time to study, learn and compare is most likely to be truly satisfied.

—Robert J. Griffin Jr.

American Pharmacy correspondent

Key provisions of the legislative proposal include:

- Persons convicted of robbery of a controlled substance using force or threat of force would face minimum fines of up to \$5,000, or imprisonment for not less than five years, or both;
- For armed robbery or assault in the course of a pharmacy robbery, conviction could bring fines of up to \$10,000, or imprisonment for not less than 10 years, or both;
- Offenders who kill or maim during a pharmacy robbery would be subject to imprisonment for not less than 20 years.

Sentiment for such legislation is strong in the pharmacy community. And the Drug Enforcement Administration recently has come to support the effort. At APhA's 1981 annual meeting, Gene R. Haislip, director of DEA's office of compliance and regulatory affairs, told members that DEA would reverse its earlier position and support stronger laws on crimes against registrants. In March of this year, Haislip wrote to APhA:

As you know, in the winter of 1980 the DEA adopted a position which would provide for a limited federal role in certain registrant-related robberies. In 1981, we forwarded proposed amendments to the [Act] to the Department of Justice for their review. These amendments contained provisions which would prohibit violent robberies of DEA registrants and, further, established minimum mandatory sentences for violations of the statute.

"We feel," Haislip's letter to APhA continued, "that federal legislation of the proper sort could serve an important leadership role in shaping a more effective response to this problem."

Opposition to proposals for making pharmacy robbery a federal crime comes mainly from officials who view such action as an unnecessary encroachment on state and local police authority. As a practical matter, some question whether federal law enforcement agents would be any more successful in investigating pharmacy robberies than are local authorities.

#194955



AMERICAN MEDICAL ASSOCIATION

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JAMES H. SAMMONS, M.D.
Executive Vice President
(751-6200)


January 9, 1984

The Honorable Ronald W. Reagan
President of the United States
The White House
1600 Pennsylvania Avenue
Washington, DC

Dear Mr. President:

The American Medical Association is very gratified by your personal expression of support for the many initiatives now underway to curb drunk driving. The Association strongly supports the recommendations of the Presidential Commission on Drunk Driving and looks forward to working with you and the Congress in developing incentives to assure that state action to implement these recommendations is forthcoming.

Sincerely,


James H. Sammons, M.D.

JHS:jdb

cc: The Honorable John A. Volpe
Chairman, Presidential Commission
on Drunk Driving

THE WHITE HOUSE
CORRESPONDENCE TRACKING WORKSHEET

INCOMING

DATE RECEIVED: JANUARY 20, 1984

NAME OF CORRESPONDENT: DR. JAMES H. SAMMONS

SUBJECT SUPPORTS RECOMMENDATIONS OF THE PRESIDENTIAL
COMMISSION ON DRUNK DRIVING

ROUTE TO: OFFICE/AGENCY (STAFF NAME)	ACTION		DISPOSITION	
	ACT CODE	DATE YY/MM/DD	TYPE RESP	C D COMPLETED YY/MM/DD
JUDI BUCKALEW	ORG	84/01/20		C 84/01/23
<i>PC CARLTON TURNER</i>	<i>R</i>	<i>84/01/25</i>		
REFERRAL NOTE:				
REFERRAL NOTE:				
REFERRAL NOTE:				
REFERRAL NOTE:				
REFERRAL NOTE:				

COMMENTS: _____

ADDITIONAL CORRESPONDENTS: MEDIA:L INDIVIDUAL CODES _____

PL MAIL USER CODES: (A) _____ (B) _____ (C) _____

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*ACTION CODES:          *DISPOSITION CODES:      *OUTGOING          *
*                       *                       * CORRESPONDENCE:  *
*A-APPROPRIATE ACTION  *A-ANSWERED              *TYPE RESP=INITIALS *
*C-COMMENT/RECOM       *B-NON SPEC REFERRAL    *                   * OF SIGNER         *
*D-DRAFT RESPONSE      *C-COMPLETED           *                   *                   *
*F-FURNISH FACT SHEET  *S-SUSPENDED           *COMPLETED = DATE OF *
*I-INFO COPY/NO ACT NEC*                       *                   * OUTGOING          *
*R-DIRECT READY W/COPY *                       *                   *                   *
*S-FOR SIGNATURE       *                       *                   *                   *
*X-INTERIM REPLY       *                       *                   *                   *
*****

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REFER QUESTIONS AND ROUTING UPDATES TO CENTRAL REFERENCE
(ROOM 75, OEOB) EXT. 2590
KEEP THIS WORKSHEET ATTACHED TO THE ORIGINAL INCOMING
LETTER AT ALL TIMES AND SEND COMPLETED RECORD TO RECORDS
MANAGEMENT.

THE WHITE HOUSE

WASHINGTON

February 17, 1984

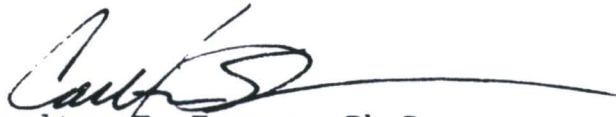
Dear Dr. Sammons,

On behalf of President Reagan, I want to thank you for expressing the support of the American Medical Association for his initiatives to curb drunk driving.

The problems caused by alcohol and drug abuse are among the most serious facing the country today. With support from organizations like the AMA, we will make a difference.

Again, thank you for your support and best wishes,

Sincerely,



Carlton E. Turner, Ph.D
Special Assistant to the President
for Drug Abuse Policy

Dr. James H. Sammons
Executive Vice President
American Medical Association
535 North Dearborn Street
Chicago, IL 60610



AMERICAN MEDICAL ASSOCIATION

535 NORTH DEARBORN STREET • CHICAGO, ILLINOIS 60610

JAMES H. SAMMONS, M.D.
Executive Vice President

Dear Doctor,

This communication contains information on a program of great significance to you and your patients. It ranks among the most important programs the AMA has ever launched, and promises to greatly benefit both physician and patient.

This new project is called the American Medical Association Patient Medication Instruction Program.

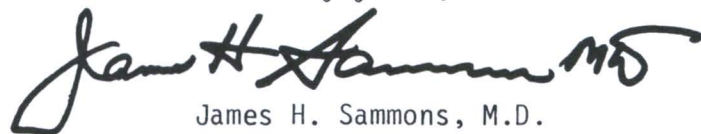
The purpose of the program is to provide supplementary written instructions on drugs to physicians for distribution to their patients. It is expected that this will improve the effectiveness of therapy, reduce the risk of improper drug use, decrease the incidence of preventable and serious adverse drug reactions, and aid in patient compliance. This information is intended to augment the oral communications on drug therapy that take place between physician and patient at the time a particular medication is being considered.

We strongly believe that your patients need information about the drugs prescribed for them -- and that it is the proper and vital role of the practicing physician to provide it. Only you can best decide when, how, and to whom you will distribute this information. Being well acquainted with the increasing complexity of prescribing medications, you can also recognize those situations in which take-home written instructions will be most useful.

Distributing PMIs to your patients should require very little time or effort and almost no disruption to your present practice; indeed, it can enhance the services you now offer. For more complete information, please review the following pages carefully; they contain information on the nature, use, and ordering of PMIs.

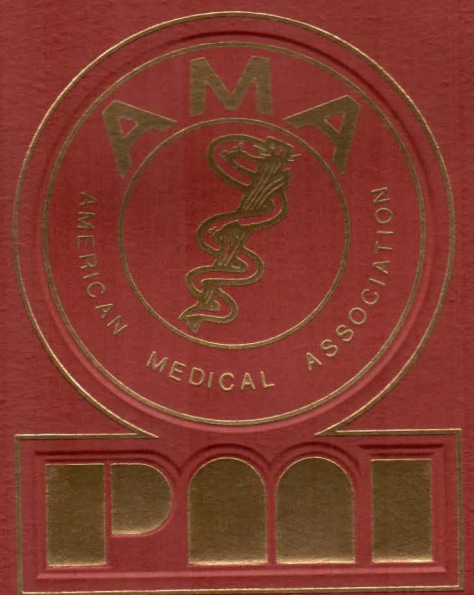
For this program to be successful, the cooperation of all prescribing physicians is needed. Since this program will be promoted nationally through the media, your patients will probably request these sheets soon. As physicians, we must be responsive to this need.

Sincerely yours,



James H. Sammons, M.D.

PATIENT
MEDICATION
INSTRUCTION
PROGRAM



This program was conceived with two primary objectives: to emphasize the importance of informing patients about the medications you prescribe for them, and to provide you with the means to that end—supplementary written information on drugs for distribution to patients.

This program should benefit both physician and patient by improving the effectiveness of drug therapy, strengthening the physician/patient relationship, reducing the risk of improper drug use, decreasing the incidence of preventable and serious adverse drug reactions, and increasing patient compliance. In other words, through the PMI Program, therapy can be improved—with very little disruption to your present practice.

Here's how the program works:

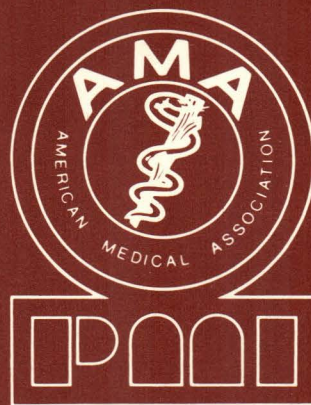
Each PMI consists of a 5½" by 8½" sheet, printed front and back, with information on a particular drug or drug class. It describes in clear, simple language the purpose of the drug, how it is to be taken, and its possible side effects. Space is provided to write in the dosage and any special instructions for the individual patient.

PMI sheets are bound into pads of 100, and will be available Fall 1982 for the 20 most commonly prescribed drugs. (Eventually, the program will provide PMIs for as many as 100 drugs or drug classes.)

PMIs are easy to use and can be distributed with each prescription you write; simply tear off the appropriate sheet and give it to the patient along with the prescription. Only a minimum of time and effort is required.

This written information is not intended as a substitute for the explanations and instructions on drugs you give each patient. Neither is it a legal instrument of informed consent, or an attempt to provide full and complete data. Rather, the program is meant simply to provide appropriate drug information in a manner that will help both you and your patient.

THE AMA-PMI PROGRAM



The AMA-PMI Program is important to you chiefly because it will help your patients understand more about the drugs you prescribe for them.

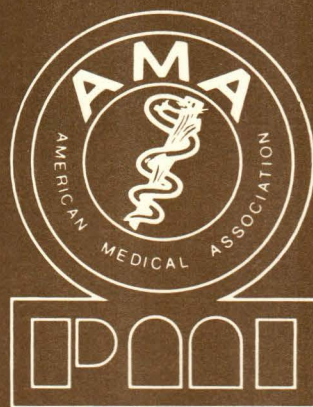
The AMA believes the best way to accomplish this is through a *voluntary* program in which you, the practicing physician, retain control over distribution of this information. At its October 1981 meeting, the AMA Board of Trustees officially approved in principle this concept of an AMA-sponsored program of patient education that would provide physicians with written information on drugs.

We strongly support a voluntary program for many other reasons. We believe that discussion of a drug being prescribed is most appropriate at the time the prescription is written. More generally, we believe that counseling patients about these drugs is a vital part of your role as a practicing physician. With the increasing complexity involved in prescribing medications, you as a physician can best recognize those situations in which take-home written instructions will be most useful.

In addition to providing brief and easily assimilated information that can be retained and referred to again, PMIs may serve to correct misconceptions about certain drugs. They should contribute significantly to patient compliance, since a patient who understands *why* a drug has been prescribed is more likely to comply with your directions to take it.

Now, more than ever, patients are requesting information on drugs. They are taking an active interest in their own well-being. As physicians, we should welcome this interest and fully respond to it.

WHY PMIs ARE IMPORTANT TO YOU



PMIs are easy to use and designed to be issued at the time of prescription. They are a natural complement to the oral instructions on drug use you provide to patients, and should significantly contribute to the betterment of physician/patient relationships.

Each PMI contains room for the name of the patient, name of the specific drug prescribed, directions to the patient for use of the drug, and any special instructions that may be necessary. To use the PMI, simply fill in the appropriate information, remove the sheet from its pad, and include it with the prescription.

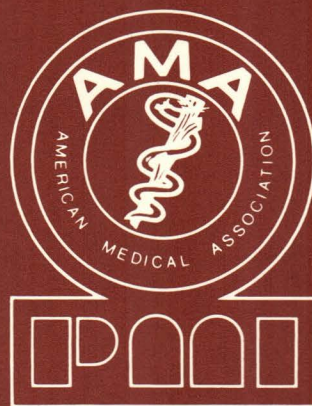
It is expected that physicians will order PMIs for the drugs they prescribe most frequently. By Fall 1982, PMIs for 20 of the most commonly prescribed drugs will be available.

If the drugs you prescribe are not included in this initial list, please note that plans call for 40 more PMIs in 1983, as well as an additional 40 in 1984.

PMIs NOW AVAILABLE

1. Furosemide
2. Thiazide Diuretics
3. Penicillins—Oral
4. Beta-Blockers
5. Digitalis Preparations
6. Coumarin-Type Anticoagulants
7. Oral Antidiabetics
8. Tetracyclines
9. Cephalosporins
10. Erythromycin
11. Nonsteroidal Anti-Inflammatory Agents
12. Benzodiazepines
13. Nitroglycerin
14. Methyldopa
15. Insulin
16. Corticosteroids—Oral
17. Cimetidine
18. Belladonna Alkaloids and Barbiturates
19. Phenytoin
20. Sulfonamides

HOW TO USE PMIs



Although implementation of the program is wholly the responsibility of the AMA, the Association has drawn upon several important sources of drug information to develop the content of PMIs. Of invaluable assistance in this area has been the *United States Pharmacopeia—Dispensing Information*. Scientific information also has been derived from our own authoritative compendium, *AMA Drug Evaluations*.

In addition, advice, consultation, and cooperation were provided by the American Pharmaceutical Association, the pharmaceutical industry, and the Food and Drug Administration. The AMA-PMI Program has also received a formal endorsement from the Commissioner of the FDA, Arthur Hull Hayes, Jr., M.D.

Patient Medication Instruction Sheet

For: _____

Drug Prescribed: _____

Directions for Use: _____

Special Instructions: _____



Please Read This Information Carefully

This sheet tells you about the drug your doctor has just prescribed for you. If any of this information causes you special concern, do not decide **against** taking the medicine without first checking with your doctor. Keep this and all other medicines out of the reach of children.

Uses of This Medicine

This medicine is commonly used to treat high blood pressure. It also is used to help reduce the amount of water in the body by increasing the flow of urine. Thiazide diuretics may be prescribed for other conditions as determined by your doctor.

Before Using This Medicine

BE SURE TO TELL YOUR DOCTOR IF YOU...

- are allergic to this medicine;
- are pregnant or intend to become pregnant while using this medicine;
- are breast-feeding an infant;
- are taking any other medicine or have any other medical problems.

Proper Use of This Medicine

DOSAGE

When you begin to take this medicine, you may notice an increase in the amount of urine or in your frequency of urination. In order to keep the increase in urine from affecting your nighttime sleep, follow this regimen:

- If you are to take a single dose a day, take it in the morning after breakfast.
- If you are to take more than one dose a day, take the last dose no later than 6 p.m. unless otherwise directed by your doctor.

If you miss a dose of this medicine, take it as soon as possible unless it is almost time for your next dose. In this case, do not take the missed dose at all and do not double the next one. Instead, go back to your regular dosing schedule.

FOR HIGH BLOOD PRESSURE

If high blood pressure is not treated, it can cause serious problems such as heart failure, blood vessel disease, stroke, or kidney disease. Remember that this medicine will not cure your high blood pressure, but does control it. **Therefore, you must continue to take the medicine as directed—even if you feel well—if you expect to keep your blood pressure down.**

(continued on reverse side)

Precautions While Using This Medicine

This medicine may cause a loss of potassium from your body. To help prevent this, your doctor may want you to:

- eat or drink foods that have a high potassium content (for example, orange or other citrus fruit juices); or
- take a potassium supplement; or
- take another medicine to help prevent the loss of potassium in the first place; or
- reduce your salt intake and/or use a salt substitute.

Be sure to check with your doctor, however, before changing your diet on your own. Loss of appetite, vomiting, or diarrhea may cause a further loss of potassium and you should inform your doctor if these events occur.

Side Effects of This Medicine

SIDE EFFECTS THAT SHOULD BE REPORTED TO YOUR DOCTOR

Rare

- | | | |
|---|-------------------------------------|-----------------------------|
| • Severe stomach pain | • Loss of appetite | • Unusual bleeding |
| • Skin rash or hives | • Nausea and vomiting | • or bruising |
| • Irregular heartbeat | • Unusual tiredness or weakness | • Yellowing of eyes or skin |
| • Increased thirst | • Unexplained sore throat and fever | |
| • Increased sensitivity of skin to sunlight | | |

SIDE EFFECTS THAT MAY NOT REQUIRE MEDICAL ATTENTION

These possible side effects may go away during treatment; however, if they persist, contact your doctor.

- Diarrhea
- Dizziness or light-headedness when getting up from a lying or sitting position
- Muscle cramps or pain
- Upset stomach

The information in this PMI is selective and does not cover all possible uses, actions, precautions, side effects, or interactions of this medicine.

This PMI is produced by the AMA, which assumes sole responsibility for its content. Appreciation is acknowledged to the other organizations that provided assistance and information to the AMA and, in particular, the U.S. Pharmacopeia.

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PMI information is contained on 5½" by 8½" sheets that provide the following information:

Title and Spaces for Patient Name, Drug Prescribed, Directions for Use, and Special Instructions

The top right hand corner bears the PMI name. For single entity drugs, the generic name will be the principal identifying designation. For combination drugs, the form will indicate the pharmacologic class of the main ingredients, and space will be provided to indicate the specific brand name.

The physician will insert dosage, frequency, and method of administration as required.

Please Read This Information Carefully

This section describes the purpose of the PMI.

Uses of This Medicine

Brief and simple information on how the drug is used in therapy appears in this section.

Before Using This Medicine

This section informs the patient and reminds the physician of situations where due caution should be used in prescribing the drug, such as an allergy to the medicine, pregnancy, breast-feeding, or other medical problems. In addition, the names of other drugs that generally should *not* be taken in combination with the medication prescribed are listed.

Proper Use of This Medicine

Specific dosage regimens are not listed, but certain general statements, such as the time of day the drug is usually taken, are included. This section also urges the patient to take the medicine for the full time of treatment, and explains what to do if one or more doses are missed.

Certain precautions—written to alert but not alarm the patient—are also included. Some PMIs may contain a separate section, "Precautions While Using This Medicine."

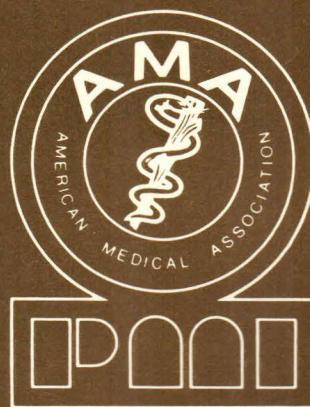
Side Effects of This Medicine

Two classes of side effects are mentioned in this section: "Side Effects That Should Be Reported to Your Doctor," and "Side Effects That May Not Require Medical Attention." The latter are common, documented effects that may be anticipated but do not necessitate discontinuation of therapy.

This section will *not* present a "laundry list" of all reported adverse reactions, some of which might needlessly alarm the patient. The entire sheet is presented in a manner that provides a balanced summary of anticipated benefits versus possible risks.

Please see the PMI sample in the pocket of the back cover of this folder.

INFORMATION CONTAINED IN PMIs



IF YOU STILL HAVE QUESTIONS...

We've tried to anticipate some of your initial questions about the program. Here's how we'd answer if you asked...

1. Will distributing PMIs be time-consuming — or a lot of paperwork?

Using PMIs requires very little time or effort since they may be given to patients along with the prescription. Additional data (patient name, drug name, directions for use, special instructions) may be inserted at the top of each PMI at the discretion of the physician.

Ordering is easy; simply indicate the quantities you would like on the order card. Reorder forms will be supplied with each shipment. In addition, PMIs require little storage space; they can be kept in their shipping container and used as needed.

2. Will PMIs confuse my patients, or alarm them with mention of side effects?

Particular care has been taken in the wording of PMIs to keep them simple and as short as possible; to use only commonly accepted, scientific statements about drugs; and to use easily understood language. This prevents an "information overload" and reduces the risk of providing inconsistent information to the patient.

PMIs will *not* present a "laundry list" of all reported adverse reactions, some of which might needlessly alarm the patient. Included in each PMI are "Side Effects That Should Be Reported to Your Doctor" and "Side Effects That May Not Require Medical Attention." The latter are common, documented effects that may be anticipated but do not necessitate discontinuation of therapy.

Overall, it is expected that PMIs will *reduce* the risk of improper drug use and encourage increased patient compliance through informed usage.

3. My oral counseling appears to work very well. Why should I use PMIs?

While oral instructions are an indispensable part of patient education, it has been shown that oral counseling *supplemented by* written information is more effective than either alone, and that written information is retained and referred to whenever required.

The AMA-PMI Program, recognizing the importance of the written word in educating patients, will effectively allow *individual physicians* to assume the role of deciding when and how to distribute this information.

4. Since I prescribe infrequently, why is this program of importance to me?

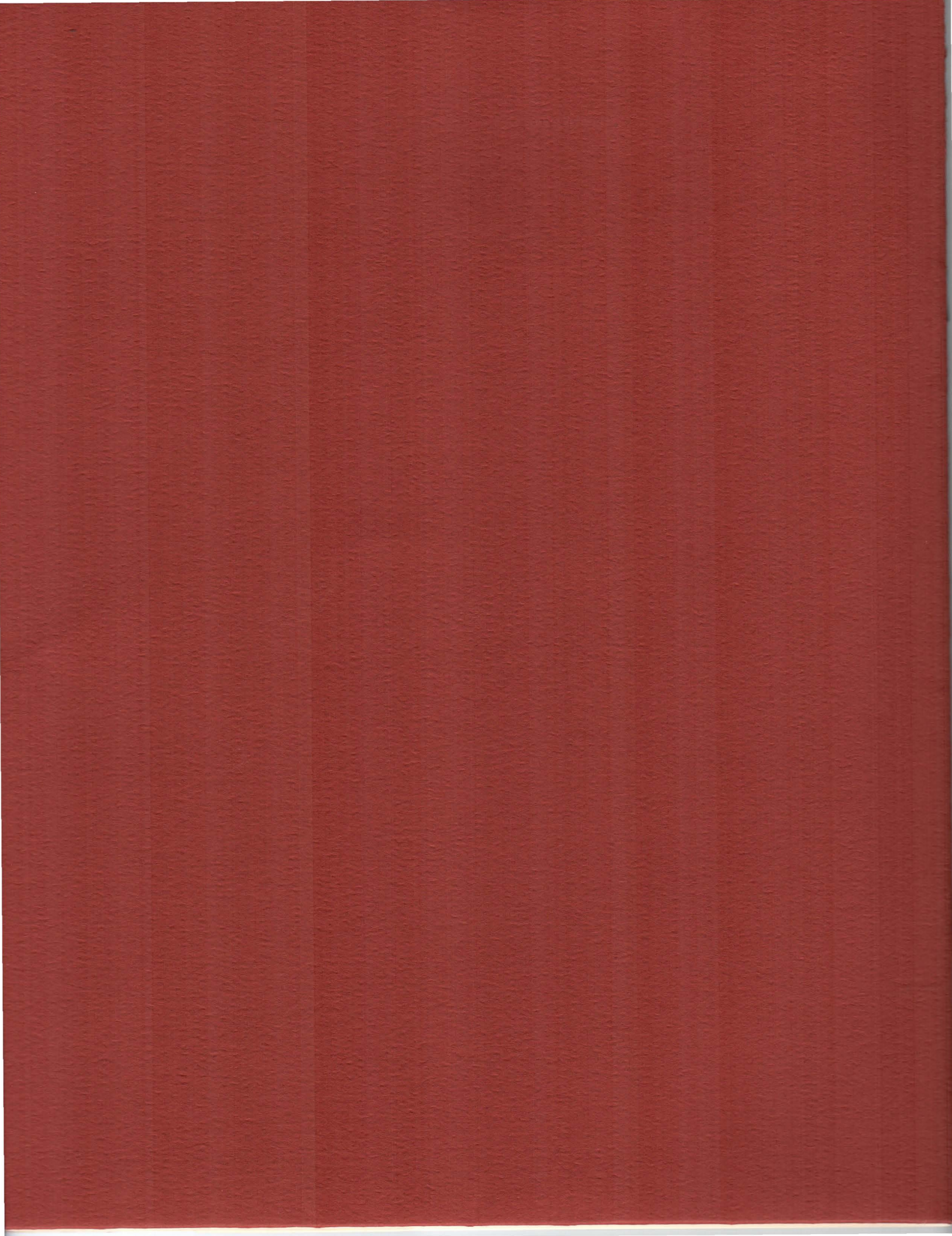
Even if you seldom prescribe, these sheets will be a valuable supplement to your oral communications on those occasions.

The success of this—or any—program of patient education requires the participation and support of all physicians. Prescribing drugs in today's era of educated consumers means more than simply writing a prescription. It means that *all* of us must make a special effort to provide information directly to our patients about the drugs they are being asked to take.

HOW TO ORDER

Since the AMA is distributing PMIs nationwide as a service to physicians, your cost will be based only on postage and handling charges involved. PMIs are printed in pads of 100 and are available in any combination or quantity (minimum order is ten pads).

To order, simply complete and mail the order card, with your payment, in the postage paid envelope. Reorder forms, updated with the names of new PMIs as they become available, will be included with each shipment.



Dorothy Moss
Chuck Wyckoff
Dr. Leonard Fenninger
Bill McGivney

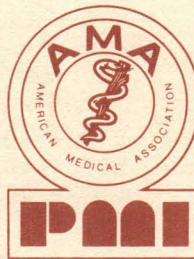
Patient Medication Instruction Sheet

For: _____

Drug Prescribed: _____

Directions for Use: _____

Special Instructions: _____



Please Read This Information Carefully

This sheet tells you about the drug your doctor has just prescribed for you. If any of this information causes you special concern, do not decide **against** taking the medicine without first checking with your doctor. Keep this and all other medicines out of the reach of children.

Uses of This Medicine

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Before Using This Medicine

BE SURE TO TELL YOUR DOCTOR IF YOU...

- are allergic to this medicine;
- are pregnant or intend to become pregnant while using this medicine;
- are breast-feeding an infant;
- are taking any other medicine or have any other medical problems.

Proper Use of This Medicine*DOSAGE*

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- If you are to take a single dose a day, take it in the morning after breakfast.
- If you are to take more than one dose a day, take the last dose no later than 6 p.m. unless otherwise directed by your doctor.

If you miss a dose of this medicine, take it as soon as possible unless it is almost time for your next dose. In this case, do not take the missed dose at all and do not double the next one. Instead, go back to your regular dosing schedule.

FOR HIGH BLOOD PRESSURE

If high blood pressure is not treated, it can cause serious problems such as heart failure, blood vessel disease, stroke, or kidney disease. Remember that this medicine will not cure your high blood pressure, but does control it. **Therefore, you must continue to take the medicine as directed—even if you feel well—if you expect to keep your blood pressure down.**

(continued on reverse side)

Precautions While Using This Medicine

This medicine may cause a loss of potassium from your body. To help prevent this, your doctor **may** want you to:

- eat or drink foods that have a high potassium content (for example, orange or other citrus fruit juices); or
- take a potassium supplement; or
- take another medicine to help prevent the loss of potassium in the first place; or
- reduce your salt intake and/or use a salt substitute.

Be sure to check with your doctor, however, before changing your diet on your own. Loss of appetite, vomiting, or diarrhea may cause a further loss of potassium and you should inform your doctor if these events occur.

Side Effects of This Medicine

SIDE EFFECTS THAT SHOULD BE REPORTED TO YOUR DOCTOR

Rare

- Severe stomach pain
- Skin rash or hives
- Irregular heartbeat
- Increased thirst
- Increased sensitivity of skin to sunlight
- Loss of appetite
- Nausea and vomiting
- Unusual tiredness or weakness
- Unexplained sore throat and fever
- Unusual bleeding or bruising
- Yellowing of eyes or skin

SIDE EFFECTS THAT MAY NOT REQUIRE MEDICAL ATTENTION

These possible side effects may go away during treatment; however, if they persist, contact your doctor.

- Diarrhea
- Dizziness or light-headedness when getting up from a lying or sitting position
- Muscle cramps or pain
- Upset stomach

The information in this PMI is selective and does not cover all possible uses, actions, precautions, side effects, or interactions of this medicine.

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ORDER FORM

PMI Order Dept.
American Medical Association
P.O. Box 52
Rolling Meadows, IL 60008

PMI pads are provided to you by the American Medical Association. To defray the cost of postage and handling, a charge of \$.50 per pad has been established.

Minimum order is ten pads (100 PMIs per pad). Your check, payable to the AMA, must accompany order. Please allow three weeks for delivery.

Number

of Pads PMI Number and Title

- | | |
|-------|---|
| _____ | 001. Furosemide |
| _____ | 002. Thiazide Diuretics |
| _____ | 003. Penicillins – Oral |
| _____ | 004. Beta-Blockers |
| _____ | 005. Digitalis Preparations |
| _____ | 006. Coumarin-Type Anticoagulants |
| _____ | 007. Oral Antidiabetics |
| _____ | 008. Tetracyclines |
| _____ | 009. Cephalosporins |
| _____ | 010. Erythromycin |
| _____ | 011. Nonsteroidal Anti-Inflammatory
Agents |
| _____ | 012. Benzodiazepines |
| _____ | 013. Nitroglycerin |
| _____ | 014. Methyldopa |
| _____ | 015. Insulin |
| _____ | 016. Corticosteroids – Oral |
| _____ | 017. Cimetidine |
| _____ | 018. Belladonna Alkaloids and
Barbiturates |
| _____ | 019. Phenytoin |
| _____ | 020. Sulfonamides |

_____ TOTAL NUMBER OF PADS
\$x.50 PER PAD FOR POSTAGE AND HANDLING
\$ _____ SUBTOTAL
\$ _____ Residents of IL, WI, and NY, please add
 appropriate sales tax to SUBTOTAL.
\$ _____ TOTAL PAYMENT (CHECK ENCLOSED)

(Please print)

Name _____

Hospital/Organization _____

Address _____

City/State/Zip _____

Enclose this form, with payment, in the envelope provided.