AMERICAN MEDICAL ASSOCIATION

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AMA WASHINGTON

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Director

PAUL M. DONELAN
Deputy Director
Director, Department of
Federal Affairs

DOROTHY J. MOSS
Assistant Director

07 NOV 1983

November 4, 1983

Dr. Carlton Turner
Special Assistant to the President
for Drug Abuse Policy
220 Old Executive Office Building
Washington, D.C. 20500

Dear Carlton:

I saw the first show of "The Chemical People" and thought it was quite good. You looked great.

I don't know whether you already have the information, but I thought you would be interested in knowing that the American Medical Association has contributed an additional $15,000 for the printing and distribution of brochures for the National Chemical People Project.

I look forward to seeing the second part of the show next Wednesday. Hope to see you soon.

Sincerely,

Dorothy J. Moss

DJM/jms

THE WHITE HOUSE

WASHINGTON

January 11, 1984

Dear Dorothy:

Thank you very much for your assistance and support of the President's drug abuse program.

We are greatly encouraged by the responses we continue to receive regarding the successfulness of "The Chemical People" program.

Hope your holidays were happy. Keep up the good work, and best wishes for a happy and healthy new year!

Sincerely,

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

Ms. Dorothy J. Moss
American Medical Association
1101 Vermont Avenue, N.W.
Washington, D.C. 20005

AMERICAN MEDICAL NEWS - November 12, 1982

AMA working to curb prescription drug abuse

As part of a national effort to prevent prescription drug misuse, abuse, and diversion, the American Medical Association is coordinating efforts to develop a model plan for using existing federal, state, and local statistics to determine the extent of drug diversion at the state level, the drugs involved, and the sources of those drugs.

Called Prescription Abuse Data Synthesis (PADS), the model plan is a major project recommended by the Informal Steering Committee on Prescription Drug Abuse, convened by the AMA in November, 1981, with members from 20 organizations representing licensed drug prescribers, dispensers, and regulatory and enforcement agencies.

"Federal statistics show that prescription drugs make up about 60% of the drugs mentioned during drug-related emergency room visits and about 70% of the drugs reported by medical examiners as causes of drug-related deaths," said Emanuel M. Steindler, director of the AMA's Mental Health Program. "While many of these drugs are channeled into illegal use through diversion and theft at the wholesale level or are illegally manufactured or imported, a significant amount is reaching the 'street' through dispensing on prescription."

JOSEPH H. SKOM, MD, clinical professor of medicine at Northwestern U. Medical School, Chicago, and steering committee chairman, offered these categories for MDs who misprescribe:

- Dishonest — or "script" — doctors probably represent no more than 1% of all practicing physicians, but they are responsible for the majority of prescription drugs earmarked for illegal use.
- Disabled doctors are those whose professional competence has been impaired by physical or emotional illness. Impaired physicians are not responsible for much misprescribing, according to available data.
- Dated doctors are poor prescribers because they have not kept pace with developments in pharmacology and drug therapy. They may prescribe excessive amounts of drugs for unusually long periods, prescribe drugs that are not appropriate for the condition being treated, or prescribe drugs when another type of therapy is indicated.
- Duped doctors have ethical intentions but misprescribe because they accede to pressure from patients who are drug abusers or who wish to obtain drugs for sale to others.

"Dishonest doctors are best dealt with by law enforcement and regulatory authorities," Dr. Skom said. "Physicians who misprescribe unintentionally are better served by education and rehabilitation programs. Education of their patients and the public is equally important." Professional assistance programs and consumer education are major focuses of the committee, he adds.

Patients inadvertently can contribute to the misuse and abuse of prescription drugs, Steindler said. Patients with complex medical problems, especially those with long-standing physical or emotional disorders that have not responded to treatment, particularly are vulnerable because drugs are available to them readily, because they associate drugs with relief of problems, and because their personalities may predispose them to excessive use of drugs.

Patients with more than one physician also pose special problems, he said. They typically visit several physicians and receive prescriptions from all of them. Even if the drugs have a low abuse potential individually, taking them together may increase their effects.

Other patients inadvertently or intentionally may increase the mood-altering effects of prescription drugs by taking them with over-the-counter medication.

"To overcome prescription drug abuse, we must first learn the extent of the problem and which drugs are involved in each state," Steindler said. "Second, we must be able to identify the 'poor' prescribers. Third, we must determine, on a case-by-case basis why the physician is a 'poor' prescriber. The PADS model will integrate existing federal, state, and local statistics into a format that can be used to make these assessments at the local level."

Data that can be made available for use by states through the PADS model include:

- Automated Reports and Consolidated Orders System (ARCOS) — developed by the Drug Enforcement Administration, ARCOS is a record of every purchase of narcotic drugs and other drugs with high abuse potential by retail dispensers.
- Drug Abuse Warning Network (DAWN) — sponsored primarily by the National Institute on Drug Abuse, DAWN is a record of drug "mentions" from drug-related emergency room visits and drug-related deaths. The data are collected from a national panel of emergency rooms and from medical examiners in 26 major metropolitan areas.
- Theft of controlled substances — statistics on drug thefts from pharmacies, gathered by the Drug Enforcement Administration.
- Medicaid Management Information System (MMIS) — state records of reimbursements for medical assistance services, including prescribed controlled substances, by provider and by recipient.
- State crime laboratory reports — analyses of substances removed during drug arrests or investigations.
- Drug abuse treatment program admissions — local records of the primary drugs used by patients who have entered drug abuse treatment programs.
- Law enforcement drug arrests — specific drugs cited in drug arrests by local law enforcement agencies.

"Each of these information systems is limited in its coverage and reporting capability," Steindler said, "but used together, they can help states construct the most accurate picture they've ever had of the problems associated with drug abuse."

The informal steering committee expects to complete the PADS model by early 1983, Steindler said, and will offer it, with the technical assistance needed for implementation, to appropriate agencies in each state.

AMERICAN MEDICAL ASSOCIATION

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

06 OCT 1982

September 30, 1982

06 OCT 1982

Mary Jacobson
President
National Federation of Parents
for Drug-Free Youth
9805 Dameron Drive
Silver Spring, Maryland 20902

Dear Mrs. Jacobson:

On behalf of the American Medical Association, I offer my congratulations on your forthcoming First National Conference of the National Federation of Parents for Drug-Free Youth. I am certain the Conference will demonstrate, as has your organization, that concerned families are fundamental to protecting the health and well-being of the young.

The American Medical Association long has been a leader in scientific research and education on the health consequences of drug and alcohol abuse, and shares your goal of preventing the physical and psychological problems attendant on abuse of alcohol and drugs.

We extend our best wishes to you, to Honorary Chairman Nancy Reagan, and to your dedicated members. Working together, I am certain you will find success in this important work you have undertaken.

Sincerely,

James H. Sammons, M. D.

JHS:gr

cc: Mrs. Nancy Reagan
Carleton Turner, Ph.D.

File AMA

01 FEB 1982

From the Communications Dept.
Washington Office
American Medical Association
January 29, 1982

(EDITORS: This is the regular monthly summary of Washington news prepared by the Washington Office of the American Medical Association for use in state and regional journals. It may be edited or trimmed, but the meaning should not be altered. You may credit the American Medical Association, but credit is not necessary.)

THE MONTH IN WASHINGTON

The Medicaid program would be federalized and responsibility for some $47 billion worth of now federal programs would be shifted to the states in a dramatic proposal for governmental realignment called for by President Reagan in his State of the Union address.

The President said that starting in fiscal 1984 (a year from next October), the federal government "will assume full responsibility for the cost of the rapidly growing Medicaid program to go along with its existing responsibilities for Medicare."

At the same time the President advanced a "bold, innovative program" of returning some $47 billion of federal programs to states and localities over a 10-year period.

"As part of a financially equal swap, the states will simultaneously take full responsibility for such programs as Aid to Families with Dependent Children (AFDC) and food stamps. This will make welfare less costly and more responsive to genuine need because it will be designed and administered closer to the grass roots and the people it serves."

Complete details of the program shifts won't be known for a while. But it is known that the following health related programs will be turned over to state jurisdiction:

Child Nutrition

Child Welfare

Child Abuse

Social Services Block Grant

Prevention Block Grant

Alcohol, Drug Abuse & Mental Health Block Grant

Primary Care Block Grant

Maternal & Child Health Block Grant

Primary Care Research & Development

Black Lung Clinics

Migrant Health Clinics

Family Planning

Women, Infants & Children (WIC)

Other programs that apparently would revert to the states include school lunch program, vocational rehabilitation, energy aid for the poor, water and sewer grants, aid for highways outside the interstate system, block grants for social services and community services, and others.

"In a single stroke, we will be accomplishing a realignment that will end cumbersome administration and spiraling costs at the federal level while we ensure these programs will be more responsive to both the people they are meant to help and the people who pay for them," President Reagan told Congress.

Under the swap, the federal government will apply the revenue from certain excise taxes to a grass-roots trust fund for the states. Some $28 billion a year will flow into the fund. By 1988 the states would be in complete control of more than 40 federal grant programs. The trust fund would start to phase out and the excise taxes would be turned over to the states.

The states would be given wide leeway on how to use their share of the trust fund. They could use it to pay for federal grants in areas such as transportation, education and social services; or they could use it for other purposes.

Both Medicaid and Medicare were marked for economies by the President who pointed to these programs in declaring that he will propose savings of $63 billion over four years in entitlement programs.

No specific dollar savings were mentioned for the two health programs, but the Administration has been considering slashes totaling $5 billion a year.

Medicare and Medicaid are programs "with worthy goals," said President Reagan, but "their costs have increased from $11.2 billion to almost $60 billion, more than five times as much, in just over 10 years."

Said the President:

"Waste and fraud are serious problems. Back in 1980, federal investigators testified before one of your committees that 'corruption has permeated virtually every area of the Medicare and Medicaid health care industry.'

"One official said many of the people who are cheating the system were 'very confident that nothing was going to happen to them.'

"Well, something is going to happen. Not only the taxpayers are defrauded. The people with real dependency on these programs are deprived of what they need because available resources are going not to the needy but to the greedy. The time has come to control the uncontrollable."

Among the cuts the Administration is expected to recommend for Medicare and Medicaid are a flat two percent reduction in the Medicare reimbursement rate for hospitals; a limitation of five percent in the rise for the physicians' fee screen; a reduction to 80 percent of Part A, the usual and customary reimbursement for hospital-based physicians; limitation of physician reimbursement for services in hospital outpatient departments; elimination of the subsidy for private hospital rooms; indexing of the Medicare Part B physicians services deductible to the Consumer Price Index, and mandatory enlistment of the federal work force in the Medicare program.

Explaining the need for transferring programs to the states, the President cited "the overpowering growth of federal grants-in-aid programs during the past few decades."

In 1960, he said, there were 132 categorical grant programs costing $7 billion. Today there are about 500 programs costing almost $100 billion.

"Neither the President nor the Congress can properly oversee this jungle of grants-in-aid; indeed, the growth of these grants has led to a distortion in the vital functions of government..."

One intergovernmental commission, President Reagan noted, has said that the growth of grants-in-aid has made the federal government "more pervasive, more intrusive, more unmanageable, more ineffective, more costly and above all more unaccountable."

The fate of the President's proposals in Congress is uncertain. Democrats were indicating they may put up stiff resistance. The November elections are only months away, and the controversial, sweeping nature of the proposals will set off a prolonged debate that might spill over into the next session of Congress.

*** ***

The American Medical Association joined health providers and insurers, organized labor, and business in formally endorsing the concept of voluntary local coalitions to tackle the problems of health care costs, quality and access.

The unprecedented gathering of major national organizations representing all aspects of health care to agree on common goals was announced at a news conference here attended by principal officers of the organizations.

The withdrawal of federal funding in health and the new emphasis on private solutions was cited by Harvard U. Prof. John Dunlop, coordinator of the national coalition effort, as major factors in the encouragement of coalitions.

The six organizations "seek to encourage and to assist the efforts in a growing number of local communities in which local affiliates of the national organizations have voluntarily joined together to put into effect common programs for utilization review, facility and technology review and planning, and other activities most appropriate to the particular locality to restrain cost increases while recognizing an appropriate concern over quality and access to health care," Dunlop told reporters.

In addition to the AMA, organizations involved are the American Hospital Association (AHA), the AFL-CIO, Blue Cross and Blue Shield Associations, the Health Insurance Association of America (HIAA) and the Business Roundtable.

Noting that the AMA has been responsible for developing 25 of the present 70 coalitions, AMA Executive Vice President James Sammons, M.D., told the news conference the primary focus of coalitions is to determine what the problems of the local area are and to come up with programs for dealing with them. He described the coalition movement as "a totally different" activity than the Voluntary Effort (VE) which is a national program to restrain cost rises.

Dr. Sammons said the AMA opposes federal health planning but believes that voluntary planning at the local level "is necessary and desirable."

The AMA long has recommended experimentation with health insurance benefit packages through such steps as removing mandatory hospitalization for patients to receive benefits and requirements for care in specific types of institutions, Dr. Sammons said. "All of us must look at changes in benefit packages that can be productive."

*** ***

The AMA has argued before the Supreme Court that when professionals advance their ethical standards for the benefit of patients the government should encourage the effort, not hinder it.

The Justices were urged in a hard-hitting, one-hour oral argument to reject the Federal Trade Commission's actions against the AMA's ethical restrictions against misleading advertising.

The FTC should have given the AMA a medal instead of a long and tedious trial, said AMA counsel Newton Minnow. He noted that the AMA was the first professional organization to rewrite its ethical codes following the Supreme Court's historic 1975 decision rejecting a state bar association's fee standard.

The new AMA code limited the restrictions against physician advertising to make unethical only advertising that is false, misleading or deceptive.

But the FTC didn't pay attention, said Minnow. The agency is obsessed with the past, unconcerned with the present and blind to the future, the lawyer said.

Dismissing the FTC conspiracy charge as "nonsense," the AMA attorney said the agency is determined to "press for its pound of flesh" despite the AMA's compliance. The AMA's warnings to the FTC of the impact of improper advertising on patients went unheeded, he said.

It was wrong of the FTC not to even look at the AMA's current standards, he said. The protection of the public is at stake, Minnow said. "If a doctor advertises that he cured his last 25 patients, we think that is false and misleading. We are dealing with health, life and safety." Why should the government try to stop guidelines intended to protect and benefit the public, asked the Chicago lawyer?

*** ***

The AMA has been awarded a $300,000 physician placement contract to help the National Health Service Corps (NHSC) place Private Practice Option (PPO) physicians in communities suited to them.

NHSC scholarship physicians who elect to take the PPO are released from their government service obligations if they establish a private practice in Health Manpower Shortage Areas (HMSAs).

The AMA will help PPO physicians settle in communities where their practices will have a good chance of success. The AMA will identify and develop potential sites by matching a list of physician vacancies to a list of HMSAs and by working with local and state medical and professional organizations. They will screen the list to insure that the communities are receptive to NHSC placements.

The AMA presently works with the NHSC on temporary physician placement through a contract program, Project USA. Under this program, the AMA identifies physicians interested in a 1-week or 2-week practice in a shortage area and arranges for them to serve at NHSC or Indian Health Service (IHS) sites. The AMA provides physicians to cover the practice while Federal physicians are on vacation or continuing their medical education.

*** ***

The Administration will ask Congress to give the government power to crack down on health professionals who have defaulted on student loans.

The announcement by Health and Human Services (HHS) Secretary Richard Schweiker followed a hearing by the Senate Governmental Affairs Subcommittee where the staff charged that 50,000 health professionals, including more than 5,000 physicians, are seriously delinquent.

Schweiker said as many as 30 percent of borrowers might be delinquent in repaying some $20 million of the Health Professions Student Loans and the Nursing Student Loans.

"Some new students may be unable to get loans to attend medical or nursing school because some former loan recipients have not repaid their indebtedness. "We owe it to future health profession students to stop the widespread delinquency in loan payments," he said.

In addition to the legislation being prepared, the HHS Secretary outlined three other steps:

Establishment of a watchdog program by the HHS Inspector General and Assistant Secretary for Health; exploration by the HHS counsel on better ways of catching delinquents; and performance standards for schools to be used in processing future loan applications.

Under the loan program, a $70 million revolving pool, the department makes the money available to schools which lend it to qualified students. The schools are responsible for repayment from the students.

*** ***

An Institute of Medicine Committee has recommended that the public be given unrestricted access to statistical information gathered by Professional Standards Review Organizations (PSROs) on the federal health-care services provided by individual hospitals and other institutions.

The committee suggested that information on care provided by individual physicians and other health-care practitioners be provided in coded form only. Such statistical information would include the number and duration of hospital stays for patients receiving federal-health care benefits, diagnosis before and after treatment, aggregate demographic data, mortality rates,etc.

The committee stressed that any public release of medical statistics should guarantee the privacy of individual patients.

The Institute report was given to the House Subcommittee on Government Information and Individual Rights and the House Subcommittee on Health and the Environment.

Current federal regulations require PSROs to provide the public upon request with information only on individual institutions and only if the names of physicians cannot be determined either "directly or indirectly." Federal regulations prohibit public release of statistics on care provided by individual physicians.

The Institute committee's conclusions were limited to disclosure policies for PSRO data on federal patients. However, the importance of "enhancing consumer choices and the public accountability of medical institutions," said the committee, is "powerful enough to warrant more general application of its recommendations," to other medical review data collected by government agencies or private organizations.

Recent court decisions have held that PSROs are not agencies of the federal government and thus subject to federal public disclosure requirements.

*** ***

The American Enterprise Institute (AEI) is conducting a one-year project to determine how the private sector can take a bigger role in solving fundamental societal problems and providing needed human services.

President Reagan has asked for a detailed report on the findings of AEI's study and for policy options by June 1982.

The AEI said it will look at a number of specific areas of need including health care, child welfare, youth employment, housing, crime prevention and economic development.

AEI President William Baroody said private sector initiatives do not have to mean that the private sector replaces dollar for dollar the money cut from the federal government.

"That would neither be feasible, nor, in my judgment, desirable," said Baroody. "There is a whole range of contributions that government still needs to make and that the private sector through business, neighborhood groups, labor unions, church groups and voluntary associations are making and can make that do not have to entail large sums of money."

*** ***

George Washington U.Medical School in Washington,D.C. will raise tuition next Fall to $19,000 a year, believed to be one of the highest in the country. At present, the G.W. tuition is $950 under the $15,950 charged by Georgetown U. Medical School only a short distance away. A Georgetown spokesman said his school expected to lift its tuition to about the same range as George Washington's. Among the reasons cited for the raise was the phasing out of federal support and the lack of any state support for the two private medical schools.

-CW-

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AMERICAN MEDICAL ASSOCIATION

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DIVISION OF SCIENTIFIC ACTIVITIES

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February 5, 1982

Carlton E. Turner, Ph.D.
White House Office on Drug Abuse
Old Executive Office Building
Washington, D.C. 20500

Dear Carlton:

It was a distinct pleasure meeting you last week and talking with you about the American Medical Association's interest and activities in the drug abuse field.

As you know, we are particularly concerned with bringing about greater cooperation and understanding among various professional associations, law enforcement agencies, regulatory bodies and pharmaceutical manufacturers in reducing prescription drug abuse. It was especially gratifying to know of your willingness to call attention to this voluntary effort, which is now underway, and, if and when your schedule permits, to take part in one or more regional meetings that are being planned in different sections of the country. As soon as dates for these are firmed up, we will be in further touch with you.

Meanwhile, I have sent Paul Donelan some background information which he has kindly offered to take over to you when you return from Europe. It includes the following items:

- "Drug Abuse Related to Prescribing Practices," a report of the AMA's Council on Scientific Affairs.
- Discussion Notes covering an Invitational Conference on Prescription Drug Abuse convened by the AMA on November 4, 1981.
- A list of persons who have agreed to serve as an Informal Steering Committee on Prescription Drug Abuse, most of whom attended the November 4 meeting.

. Results of a survey of state medical societies on their involvement in prescription drug abuse matters.

In addition, I have sent to Paul other material related to drug abuse, so you will be aware of our overall interest. It includes two books -- our Manual on Alcoholism and a volume on drug abuse diagnosis, treatment and prevention for primary care physicians; a recent JAMA article on marijuana; a statement on medical education on alcohol and drug abuse, and a report on the 4th National Conference on the Impaired Physician.

We look forward to working with you in this important area, and will be happy to be of whatever assistance we can to you and your staff.

Sincerely yours,

Manny

E. M. Steindler

EMS/ims

cc: Paul Donelan

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AMA WASHINGTON

JOHN S. ZAPP, D.D.S.
Director

PAUL R. M. DONELAN
Deputy Director

January 28, 1982

C - File AMA

26 JAN 1982
01 FEB 1982

Carlton E. Turner, Ph.D.
Senior Policy Adviser for Drug Policy
White House Office of Policy Development
The White House
Room 220 Old Executive Office Building
Washington, D.C. 20503

Dear Carlton:

As we discussed on January 26 I am enclosing a copy of a memo from Dr. James H. Sammons, the Association's Executive Vice President, to our Board of Trustees which describes the AMA Patient Medication Instruction program as originally conceived. Some modification of the program has already taken place. For example, the paragraph on page 3 has been completely modified. Initial support is expected to come from a foundation. Further, the Patient Medication Instruction form which is attached to the enclosure will be modified as a result of the consultations with other interested organizations.

Notwithstanding the above modifications, the memo does accurately reflect the program.

I am also enclosing a copy of the AMA News of January 1/8, 1982 which contains an article relative to the PPI program.

I am also arranging to have you provided with a complimentary copy of the AMA News.

Sincerely yours,

Paul

Paul R. M. Donelan

PRMD/bc
Enclosures

Patient Package Inserts

DFC-1

MEMORANDUM

November 24, 1981

TO: Board of Trustees

FROM: James H. Sammons, M.D.

SUBJECT: AMA Patient Medication Instructions

At its October 14-16, 1981 meeting, the Board of Trustees approved in principle the concept of an AMA-sponsored program that embodies the preparation of written drug information that can be provided to physicians for distribution to their patients. This written material is intended to augment but not substitute for the oral communications about drug therapy that should take place during the physician-patient encounter. The proposed new initiative, designated the American Medical Association-Patient Medication Instruction (AMA-PMI) program, is perceived as a viable alternative to a mandatory, governmental program for Patient Package Inserts (PPI) that is now under consideration by the Food and Drug Administration and to which the AMA has consistently expressed strong objections.

As authorized by the Board, staff has explored the concept of an AMA-PMI program with representatives of the American Pharmaceutical Association, the pharmaceutical industry, and the FDA. All expressed a high degree of interest in the proposal and a willingness to consult and assist the Association as it proceeds with the program. It was made clear that subject to Board approval, the AMA will have a firm commitment to this program and intends to go ahead with its development and implementation irrespective of any decisions that FDA may reach about PPI's. It is significant to note that, despite this forthright statement of intention, FDA appears to be desirous to assist in this private sector endeavor that would provide an additional option to its controversial PPI proposal. FDA did advise, however, that AMA consult with the legal counsel of the agency in order to obviate the possibility that any aspect of the program could be construed as "labelling," and, thus, be subject to FDA regulation.

Although many details remain to be worked out, this progress report is intended to inform the Board of the plans that are contemplated for the AMA-PMI program.

Objectives - AMA-PMI is intended to (1) reinforce and enhance the awareness and capabilities of physicians of the importance of informing patients about medications that are being prescribed and instructing them in their use, and (2) provide supplementary written instructions for medications to physicians for distribution to their patients, thereby improving the effectiveness of therapy, reducing the risk of adverse reactions or improper use of drugs, and reinforcing the physician-patient relationship. The program will be aimed principally at ambulatory patients while recognizing the importance of medication and patient instruction in hospitals and other institutional settings.

Sponsorship - The project will be wholly a program of the American Medical Association. However, advice, consultation, and cooperation will be sought from other knowledgeable individuals, institutions, organizations, agencies, and manufacturers whenever appropriate.

Preparation of Written Material - Responsibility for writing of AMA-PMI's will be assigned to AMA staff. A project leader will be designated who will be responsible for drafting the AMA-PMI's and seeking appropriate consultation before final approval and printing.

Sources of Information - A large number of excellent sources of patient-oriented drug information already exists. It is not the intention of AMA to "reinvent the wheel" in drafting AMA-PMI's but, rather, to draw upon pre-existing sources whenever possible. Thus, information from other authoritative sources will be utilized by AMA and permission sought for their use. Of particular importance is the publication, USP-Dispensing Information, that is produced by the United States Pharmacopeia and to which AMA has provided extensive consultation. The scientific basis for all statements made in AMA-PMI's will, of course, be derived from our own authoritative compendium, AMA Drug Evaluations.

Consultation - The principle source of consultation for AMA-PMI's will be the physicians and scientists on the staff of the Division of Drugs. As a matter of routine, pharmaceutical firms will be consulted on drugs of their manufacture. Likewise, representatives of organized pharmacy as well as organizations (such as USP) that have contributed material utilized in the PMI's will be asked to comment. In all likelihood, FDA should be consulted also -- especially if the agency follows through with its stated intention to help publicize the program. Finally, all AMA-PMI's will be screened through legal counsel. In all cases, final decisions as to content will rest with the AMA.

Scope - Initially, AMA-PMI's will be prepared for approximately 10 of the most widely prescribed drugs, both single entity compounds and combinations. As the program progresses, more drugs will be added to the list. Eventually, it is hoped to have AMA-PMI's for the 200 most widely prescribed drugs. No attempt will be made to cover all of the more than 1200 single entity and 20,000 combination drug products on the market in this country. Certain widely utilized drugs that are generally administered by the physician (injectibles, anesthetics, diagnostic agents, and biologicals) will not be covered. Broad pharmacologic classes, such as thiazide diuretics, might be covered by a class description rather than by individual drug.

Format - For each drug covered, a pad of approximately 100 individual sheets will be printed. The physician can then tear off a sheet and give it to the patient at the time a prescription is written. It is estimated that the average physician, of whatever specialty, generally restricts most of his/her prescribing to approximately 15-20 drugs. Thus, most physicians would not need to stock more than 15-20 pads of AMA-PMI's. In addition to the pad approach, a loose-leaf collection of all AMA-PMI's will be supplied to physicians who would be free to reproduce and distribute any of the material contained therein. The written information will not be copyrighted.

Information to be Included - Appended is a draft outline of an AMA-PMI form. It is deemed desirable to limit the information presented to what can be printed on both sides of a single sheet while, at the same time, minimizing the amount of personalized instructions that require writing by the physician. For single entity drugs, the generic name will be the principle identifying designation, but whenever practical, the most widely known trade names will be listed. For combination drugs, the trade name only will be used, but the form will indicate the pharmacologic class of the main ingredients. Under "side effects," mention will be made of common, documented, effects that may be anticipated and which do not necessitate discontinuation of therapy, as well as the more serious side effects that require notification of the physician. It should be stressed, however, that this section will not present a "laundry list" of all reported adverse reactions, some of which have not been proven to be drug-related. The entire document should be presented in such a manner as to provide a balanced summary of anticipated benefits versus possible risks. As experience is gained with the program, the PMI forms will no doubt be modified.

Level of Sophistication - Numerous studies support the conclusion that the AMA-PMI's should be geared to the elementary school educational level.

Distribution - The AMA-PMI Program is designed principally for distribution to physicians but the information will be made available, upon request, to manufacturers, pharmacists, and other prescribers (such as dentists and osteopaths). AMA will assume responsibility for storage, receipt of requests, and mailing of PMI's.

Costs - The program should be self-supporting. Contributions to launch the program will be sought from pharmaceutical manufacturers. The initial funding approach will be made to the Pharmaceutical Manufacturers Association. Only if PMA is reluctant to cooperate will individual manufacturers be approached. The costs of distribution will be covered by reasonable charges payable to the AMA by those requesting forms.

Announcement - AMA will publicize the program through its publications and, on a continual basis, publish the list of drugs for which PMI's are available and where and how to obtain them. AMA will also inform the public of the program through press releases and spot announcements on radio and T.V. Other groups such as the PMA, FDA, and APhA may also wish to publicize the program. Arrangements for such publicity are matters for further discussion.

Assessment - AMA will undertake the design and conduct of surveys to assess the program, the funding for which will be sought from sources other than the Association.

Timetable - If approved by the Board, plans for implementation of the program will proceed with all deliberate speed with the intent of making the first group of PMI's available to physicians in the second quarter of 1982.

Summary

The proposed AMA-PMI program should not be regarded as a legal instrument of informed consent nor a mechanism of providing in written form all the information a patient should know about drugs (the avowed goals of PPI's). It is certainly not intended to absolve physicians of their responsibility to explain drug therapy to patients. Instead, AMA-PMI is intended to augment and reinforce oral communication between physicians and patients, thus contributing to better drug therapy and fostering better physician-patient relationships.

Recommendations

It is recommended that the Board of Trustees authorize:

1. Continued development and implementation of these plans.
2. Contact with PMA regarding funding.
3. Consultation with FDA regarding the legal (labelling) status of the written medications instructions.
4. Approaches to USP regarding AMA use of their material.

PATIENT MEDICATION INSTRUCTIONS for _____ (name of patient)

Name of Drug: Generic

Brand Names

(Where several manufacturers produce the drug and exceed space for listing, reference will be made to published lists of brand names for the drug.)

General Instructions:

1. This drug is prescribed for you as an individual and is not to be shared with others.
2. It is important to take the full course of treatment with this drug. Do not discontinue this drug without calling your physician. The drug should be taken exactly according to instructions. Doses should not be missed.
3. If you are pregnant, or think you may be pregnant, be sure that you have told the physician who is prescribing your treatment.

Reasons for prescribing the drug - what the drug is intended to do and why the patient is to take it.

Instructions as to how to take the drug.

Frequency and time - in relation to ingestion of food or liquids, whether it must be taken throughout the day and night, etc.

What to avoid while taking the drug.

Foods, antacids, alcoholic beverages, etc.

Other medications not prescribed by the physician.

Over-the-counter drugs.

Driving or work hazards.

Possible side effects of drug.

Those that are anticipated and not contraindication to continuing the drug.

Those that may occur and require notification of the physician.

Effects of other drugs that the patient may be taking at the same time (synergism and antagonism).

Space for specific dosage and special instructions.

Space for list and dosage of other drugs being taken by patient.

Space for additional individual instructions by physician to patient.

Name, address and phone number of physician.

Sources from which information was derived.

11/23/81

Prepared by
American Medical Association
535 N. Dearborn St.
Chicago, IL 60610

Form #_____

Dan where is this folder?

AMERICAN MEDICAL ASSOCIATION
1776 K STREET, N. W. • WASHINGTON, D. C. 20006 • PHONE (202) 857-1300 • TWX 710-822-9409

AMA WASHINGTON

JOHN S. ZAPP, D.D.S.
Director

PAUL R. M. DONELAN
Deputy Director

NOV 2 1981

October 30, 1981

Carlton E. Turner, Ph.D.
Senior Policy Adviser for Drug Policy
White House Office of Policy Development
The White House
Room 220 Old Executive Office Building
Washington, D.C. 20500

Dear Carlton:

Enclosed you will find the copy of a book entitled, Drug Abuse which the Association has developed for the use of primary care physicians.

I understand you will be attending the meeting on Prescription Drug Abuse which is to be held November 4 at the Mayflower Hotel. Hopefully, you and Manny Steindler will be able to get together prior to that meeting so that Manny can give you some background that might make the meeting much more productive for you.

Sincerely yours,

Paul

Paul R. M. Donelan

PRMD/bc
Enclosure

Call Dan to set up meeting with him & Manny Steindler late next week