

American Medical Association

Physicians dedicated to the health of America



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April 11, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, Maryland 20852

Re: Leveraging – Collaborating With Stakeholders (Docket No. 00N-0001)

The American Medical Association (AMA) is a national professional association representing 300,000 physicians and physicians-in-training. The AMA's core purpose is to promote the art and science of medicine and the betterment of the public health. AMA policy advocates for a strong and adequately funded Food and Drug Administration (FDA). Over the years, the AMA has worked with the FDA on a multitude of issues with the overriding goal of improving the health of the American public. The intent of this letter is to reaffirm the AMA's commitment to continuing its collaborative relationship with the FDA on important health issues.

The AMA can contribute to the FDA's public health mission in a variety of ways. As an acknowledged leader in setting standards for medical ethics, practice, and education, the AMA can collaborate directly with the FDA on selected projects to benefit physicians, their patients, and the public. The United States Adopted Names (USAN) program is an excellent example. For many years, the AMA, the FDA, the United States Pharmacopeia (USP), and the American Pharmaceutical Association (APhA) have collaborated in adopting nonproprietary (generic) drug names through the USAN Council.

The AMA also is a world leader in obtaining, synthesizing, integrating, and disseminating information on health and medical practice. Thus, the AMA can collaborate with the FDA in developing and/or disseminating important information to physicians. Three examples of this type of collaboration between the AMA and the FDA are as follows: 1) the AMA currently is working with the Center for Food Safety and Applied Nutrition (CFSAN), the Centers for Disease Control and Prevention (CDC), and the Department of Agriculture's Food Safety and Inspection Service (FSIS) to develop and disseminate educational materials for physicians on foodborne illnesses; 2) the AMA has worked with the FDA and other key organizations (e.g., CDC; American Liver Foundation) to develop and disseminate information (e.g., on the AMA Web site) about the hepatitis C lookback program, especially to educate physicians on how to deal with former transfusion recipients who will be contacting them; and 3) as an active MedWatch partner, the AMA has helped the FDA disseminate information to physicians about this voluntary adverse event reporting program for a number of years.

As an umbrella organization for more than 150 state and specialty societies (the Federation), the AMA also has the capability to convene and bring key stakeholders (physician and nonphysician) together. For example, in 1997 the AMA created the National Patient Safety Foundation (NPSF) as an independent, nonprofit research and education organization dedicated to the measurable improvement of patient safety in the delivery of health care. Approximately 50 individuals from many organizations, including the FDA, serve on the NPSF's Board of Directors. "Pharmaceutical Safe Use" currently is a major initiative of the NPSF and representatives of the AMA and the FDA serve on the National Steering Committee.

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As the nation's largest physician professional association, the AMA also can present to the FDA a perspective on different issues that reflects the views of a large group of physicians that cuts across a number of medical specialties and geographic locations. While this often is done through formal public comment mechanisms (e.g., direct-to-consumer advertising; structure/function claims for dietary supplements), the AMA also has collaborated with the FDA in much greater depth on some issues. For example, the AMA has maintained a dialogue with the FDA for almost an entire decade on improving professional labeling (the package insert) to make it more user-friendly to physicians. However, a proposed regulation to implement the types of changes to the professional labeling that have been discussed (e.g., adding a summary section of key information) has not yet been published. In light of recent drug withdrawals that suggest some physicians may not be aware of changes in Warning information, there appears to be a strong need to consider the content, format and mechanisms for dissemination of professional labeling.

In addition to the above, the AMA also has a common interest and has collaborated in some way with the FDA on two other issues that were emphasized in the *Federal Register* Notice of February 18, 2000. The sale of prescription drugs over the Internet is becoming commonplace. While there clearly are legitimate on-line pharmacy practice sites, a large number of problematic Web sites also exist where prescription drugs are sold with minimal or no patient evaluation by a licensed physician. Like the FDA, the AMA is very concerned by this. Over the past year, the AMA, FDA, and other key stakeholders (e.g., Federation of State Medical Boards; National Association of Boards of Pharmacy) have been maintaining an active dialogue in an effort to solve this problem.

The other area of common interest is patient/consumer education on the safe use of medical products. The AMA is in complete agreement with the FDA that it is imperative that patients/consumers understand the benefits and risks of medical products that they use, whether the product is a prescription drug, over-the-counter (OTC) drug, dietary supplement, or medical device. The AMA has focused primarily on prescription drugs because physicians have a central role in the education process. In that regard, the AMA has produced a brochure entitled, *Guidelines for Physicians for Counseling Patients About Prescription Medications in the Ambulatory Setting* (enclosed). The intent of the guidelines is to facilitate physician communication with their patients about the medications that are being prescribed. The AMA would be interested in pursuing ways in which our association can collaborate with the FDA on patient/consumer information. An area of particular interest is helping consumers differentiate drug products from dietary supplements and to understand the differences in pre- and post-marketing regulatory requirements.

Before concluding, it is important to note that the FDA's overriding theme in its request for collaborative opportunities is patient/consumer safety. The AMA also has had a longstanding commitment to improving patient safety. Just as the FDA must make benefit/risk decisions on whether a medical product should be marketed, physicians must constantly make benefit/risk decisions on the use of medical products in their patients. The establishment of the NPSF is only one, albeit the most visible, example of the AMA's commitment to patient safety. With the release of the Institute of Medicine's report, *To Err is Human: Building a Safer Health Care System*, patient safety has appropriately become a national priority. Thus, the AMA would welcome the opportunity to dialogue with the FDA on possible ways in which our two organizations can work together to maximize the benefits and minimize the risks associated with the use of medical products.

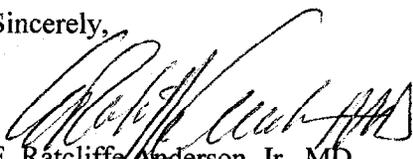
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In summary, the AMA shares a number of common interests with the FDA. Our past and current collaborations, as discussed in this letter, suggests that our two organizations can have a positive and synergistic impact on patient care and on the health of the public. We eagerly look forward to continuing ongoing collaborations and to discuss possible future activities where our combined efforts can contribute to both the FDA's and the AMA's public health missions.

Sincerely,



E. Ratcliffe Anderson, Jr., MD

Enclosure

Preamble

Prescription medications are among the most useful and cost-effective treatment options available in the health care system. Care often may be improved when physicians provide useful counseling and information about prescription medications to their patients.

The following guidelines were prepared to help physicians provide useful oral counseling and, when appropriate, written information about prescription medications that are prescribed for their patients in the ambulatory setting. These guidelines are intended to provide suggestions to physicians on the content of information that will likely be most useful to patients that are using prescription medications.

These guidelines are not substitutes for the best professional judgement of physicians in providing high quality care to their patients, and they should not be construed as standards of medical practice. Physicians are encouraged to customize prescription medication counseling and information to best meet the needs of individual patients.

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515 North State Street
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Guidelines for Physicians for Counseling Patients About Prescription Medications in the Ambulatory Setting

**Approved by:
Board of Trustees
American Medical Association**

Guidelines for Physicians for Counseling Patients¹ About Prescription Medications in the Ambulatory Setting²

1. Medication Record. As part of the medical record, the physician should attempt to maintain and update, as necessary, a record (chart) of all medications (prescription and nonprescription) that the patient is taking currently.

2. Treatment Plan. Decisions regarding the use of prescription medications are best accomplished out of a collaboration between the physician and the patient. This requires that

the patient be aware of relevant information regarding the prescribed medication, as well as available alternatives. Therefore, the physician should discuss with the patient expectations of treatment and appropriate information regarding risks, benefits and appropriate alternatives of all medications that may be prescribed, prior to deciding on a treatment plan.

3. Oral Counseling. Physicians should counsel patients on their medications, emphasizing what is medically significant. Such information may include:

- The name of the medication and what it is supposed to do.
- How and when to take the medication and for how long.
- Appropriate foods, drinks, other prescription or nonprescription medications, or activities that the patient should avoid while taking this medication.
- The relevant side effects that should be reported to the physician if they occur.
- If applicable, whether anything is unusual about the use of the medication being prescribed (eg, for an off-label indication; prescribing larger than the usual dose).
- Whether the prescription can be refilled and how often.
- What written information the patient can take with them (if available) or instructions to obtain written information from their pharmacist.

¹ The term *patient*, ie, the person for whom the medication was prescribed and dispensed, is used throughout these guidelines. However, for some patients, other individuals (eg, parents, guardians, caregivers) may also receive the counseling and information.

² These guidelines are not substitutes for the best professional judgment of physicians in providing high quality care to their patients, and they should not be construed as standards of medical practice.

After counseling the patient, the physician should encourage the patient to ask questions and should ask the patient whether he or she has any concerns about obtaining the medication or about using it in the way it was prescribed.

4. Written Information. It may be helpful for physicians to provide patients with written information about their medications. This information should include the elements outlined below.

5. Followup. During subsequent office visits, the physician should question the patient about compliance and any beneficial or adverse effects of the medication.

Elements of Written Information

- Name of the medication
- Use of the medication
- Patient instructions before using the medication
- Instructions for proper use of the medication
- Precautions while using the medication
- Side effects of the medication that are serious or occur frequently

It is important that written information be scientifically accurate and nonpromotional for a particular product. It should provide sufficient information so the patient can use the medication properly, be legible, and written in understandable language.

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