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AHFS Drug Information

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AMA's Drug Evaluations

by Carol Proudfit, Ph.D.

The American Medical Association's *Drug Evaluations (DE)* is a unique publication in that it contains discussions about indications for drug use, including unlabeled uses not found in the FDA package insert; alternative therapies; and, if possible, the drug(s) of choice for a particular condition. *DE* also includes discussions about drug treatment in the context of other therapies, such as radiation therapy or surgery. Finally, it also mentions important investigational drugs that are nearing FDA approval.

Most chapters in the three volume, looseleaf notebook set are therapeutically oriented rather than based on pharmacologic classifications. Thus, for example, chapters within the oncolytic drug section include: DNA damaging drugs; antimetabolites; antibiotics, alkaloids, and enzymes; and hormonal agents and biological response modifiers. Two multipaged tables are provided in an introductory chapter on cancer chemotherapy. One table lists individual cancer drugs according to class and summarizes for each drug important properties, including elimination, major toxicity, and indications. Table two includes preferred regimens for various cancers.

DE is fully referenced and covers combination regimens. Because of the therapeutic organization, *DE* lends itself to discussions of combination drug therapy where appropriate to treat a disease.

There must be a significant body of scientific evidence to justify an unlabeled use before it will be recommended by *DE* for an unlabeled indication.

THE UPDATING PROCESS

A staff of pharmacologists is responsible for updating the previous edition. AMA also uses a select group of consultants who are experts in their fields—most of whom are practitioners—to review the revised draft. More than 800 consultants have reviewed material contained in a *DE* text. The number of consultants per chapter varies widely, depending on the nature of the chapter.

AMA also sends revised drafts to the major manufacturers of a particular drug for their input. Manufacturers primarily comment on the preparation information contained in the publications. However, on occasion, they provide important information on background pharmacology.

Each chapter of *DE* is then revised again by in-house staff and prepared for publication.

A PHYSICIAN FOCUS

DE is complementary to rather than competitive with the other two compendia. AMA's position is that *DE* is one of three compendia and that no one of the three publications is preferable as a sole source of information. For instance, the other compendia do a good job of covering such concerns as adverse reactions and drug administration, but neither provides the evaluative aspect of drug therapy that is the focus of *DE*.

DE is primarily directed to the physician, whereas the *USP DI* is used by pharmacists, and *AHFS Drug Information* is identified with the pharmacy profession.

DE is available in three formats:

- *Drug Evaluations Subscription.* An initial subscription consists of three looseleaf notebooks, slipcase, and full contents of *DE*. Also provided are quarterly updates that include 1) revised chapters, 2) new drug evaluations, and 3) the *DE Monitor* newsletter. This newsletter contains the most current information on important withdrawals, new drugs on the market, and new preparations, as well as articles on drug policy issues of general interest.
- *Drug Evaluations Annual.* This text, which is updated yearly, contains the full contents of the subscription product through the Summer update.
- *Drug Evaluations on CD-ROM.* This is available as part of Teton Data Systems STAT!-REF electronic library.

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AHFS Drug Information

by Gerald K. McEvoy, Pharm.D.

AHFS Drug Information (originally known as the American Hospital Formulary Service) was first published in 1959 as an adaptation of the University of Michigan's *Hospital Formulary of Selected Drugs* by Don E. Francke. Originally, the Service was conducted through the Committee of Pharmacy and Pharmaceuticals of the American Society of Hospital Pharmacists (ASHP) to assist the pharmacy and therapeutics committee of each hospital in preparing its hospital formulary. The purpose of *AHFS Drug Information* was to provide objective, evaluative drug information to assist clinicians in the safe and effective use of drugs.

At the time of the publication's development, there was a dearth of evaluative information on drugs in a readily accessible form. From a historical perspective, drugs available for use in the United States were required only to be safe; demonstration of effectiveness was not necessary. Thus, one of the principal goals of *AHFS Drug Information*, since its inception, has been to provide objective evaluations on a drug's use, including perspectives on the role of the agent compared with other therapies.

A principal strength of *AHFS Drug Information* is the variety and depth of information provided on each drug. As a general drug information source, *AHFS Drug Information* provides comprehensive information in a structured style on drug uses, dosage, and administration, and includes discussions on chemistry and stability, pharmacology, pharmacokinetics, drug interactions, toxicity, and in-depth descriptions of adverse effects, including associated precautions and contraindications. *AHFS Drug Information* includes information under the generic name of the

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drug, organizing the information on various drugs by pharmacologic and therapeutic classes. The publication provides information on virtually every single entity commercially available in the United States, and it is indexed by generic and trade names and by common synonyms.

Monographs are prepared by a professional editorial staff and incorporate the expert advice of leading medical scientists, clinicians, pharmacists, pharmacologists, and other qualified individuals. In addition to the multistep information analysis and review by staff of ASHP's Database Services Division, the review process includes the contributions of many consultants in specific fields of therapy and the appropriate manufacturer(s). The monographs incorporate information from pertinent references in the literature, the labeling approved by the U.S. Food and Drug Administration (FDA), and from reviewers. Information on uses, dosages, and routes and/or methods of administration that may not be in the FDA-approved labeling for a drug is also included. A typical monograph on a new drug incorporates information from several hundred references, and some general statements incorporate information from more than one thousand references. Currency of the publication is maintained through periodic supplements, and a revised master volume is issued each year. The publication is supported solely through subscriptions.

UNLABELED INDICATIONS

While a precise portion of uses included in *AHFS Drug Information* that are unlabeled cannot be given, the selective inclusion of unlabeled uses of drugs has long been a hallmark of the publication. Such descriptions represent uses that often are established in clinical practice long before being considered for inclusion in FDA-approved labeling, and some such uses may never be included in labeling. Just as advances in therapeutic knowledge and practice inevitably precede labeling revision by the sponsor and formal approval by the FDA, information in *AHFS Drug Information* on these advances frequently precedes such revision and approval. Some recent legislative actions (e.g., orphan drug provisions and revised treatment IND procedures) are aimed at stimulating and simplifying the approval of labeling for drug uses in cases of rare diseases or other diseases for which there is no reasonable expectation that the cost of investigating and marketing the drug for such a use in the United States would be recovered. Without incentives to sponsors, many of these uses would never find their way onto approved labeling, although they often represent the only effective treatment or one that is associated with substantially reduced toxicity compared with other available therapies. Such uses are included in *AHFS Drug Information*. Information on expanded access to investigational drugs under the U.S. Public Health Service's "parallel track" mechanism are also included.

AHFS Drug Information includes descriptions of most combination preparations, both prescription and over-the-counter, that are commercially available in the United States. These descriptions are included in various monographs on the component single-entity drugs and can be accessed by the trade name through the index. In addition, depending on the complexity and nature of the drug regimen, discussions of combination drug regimens often are included in the "uses" discussion of the individual monographs or in the general statements on classes of drugs. For example, recommended combination regimens for the treatment of various infections, such as antituberculosis regimens, are described, as well as information on alternative regimens, such as those used for resistant disease. However, it is often beyond the scope of a general drug information publication to attempt to provide detailed discussions of the various dosages and sequencing of each drug in a regimen. Providing comprehensive information on combination regimens for antineoplastic agents is particularly difficult, because of the complexity and frequently evolving nature of such regimens for many cancers. In such cases, major regimens, such as cisplatin-containing regimens for the treatment of testicular cancers or fluorouracil-containing regimens for GI cancers, may be discussed. However, publication users are advised to obtain the advice of clinicians who are actively engaged in the treatment and investigation of cancer for perspectives on the latest and most advantageous therapy regimens. ■

A principal strength of *AHFS Drug Information* is the variety and depth of information provided on each drug.

ACCC's Drug Bulletin

As a service to ACCC members and other cancer care providers, the Association of Community Cancer Centers publishes the *Compendia-Based Drug Bulletin*. This free newsletter, which is updated quarterly, lists common cancer agents and those indications accepted by one or more of the drug compendia. In addition, average wholesale drug prices and ICD-9 codes are included.

If you would like to be placed on the mailing list to receive this free publication, please send or fax a written request to: Drug Bulletin, ACCC, 11600 Nebel St. Suite 201, Rockville, MD 20852. The fax number is 301-770-1949.