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Accepted Dental Therapeutics 35th Edition



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Many of the proprietary names of the products listed in this book are trademarked and registered in the U.S. Patent Office by the firms whose names are mentioned in connection with these products.

Abbreviations

The following abbreviations occur in the text: A.D.T.—Accepted Dental Therapeutics. U.S.P.—The Pharmacopeia of the United States of America, Eighteenth Revision. N.F.—The National Formulary, Thirteenth Edition.

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Drugs used in dental practice including a list of brands accepted by the Council on Dental Therapeutics of the American Dental Association.

PREFACE

Accepted Dental Therapeutics replaced Accepted Dental Remedies as the new title for the publication of the Council on Dental Therapeutics. The Council concluded that the term "remedies" no longer accurately represents the contents of the book. Accepted Dental Therapeutics is published biennially under the immediate supervision of the Council.

Accepted Dental Therapeutics is designed to assist the dentist in selecting appropriate drugs and procedures for the prevention and treatment of oral diseases. The need to recognize the total health status of the patient is emphasized as is the role that multiple drug therapy may have on that health status because of drug interaction. The desirability of anticipating and preventing the development of emergency situations is also stressed.

Only brands of drugs with recognized value in dentistry which are labeled and advertised to dentists in accordance with the

Council's Provisions for Acceptance of Products are included in the listing of accepted or provisionally accepted dosage forms. Information on certain other drugs is included but this inclusion should not be construed as a recommendation for their use in dentistry. Rather this information is intended to alert the dentist to: (1) the problems that may arise in providing dental treatment for patients who may be receiving drugs for medical problems and, (2) the uncertain status or obsolete character of some products marketed with claims for dental use.

The Council appreciates the generous assistance received from consultants and many other persons. It welcomes continued suggestions and criticisms directed to the further improvement of later editions.

Gordon H. Schrotenboer, Secretary Council on Dental Therapeutics January, 1973

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Provisions for Acceptance of Products by the Councl on Dental Therapeutics

PURPOSE OF THE COUNCIL

The Council on Dental Therapeutics gathers and disseminates information to assist the dental profession in the selection and use of therapeutic agents and their adjuncts and dental cosmetics agents.

The Council is under obligation to provide the profession with prompt, reliable information on the status of recently developed dental products. In evaluating new items, special emphasis is placed on considerations of evidence of safety under the conditions of use.

The Council encourages research in the field of dental therapeutics.

ARTICLES CONSIDERED FOR ACCEPTANCE

Under the *Bylaws* of the American Dental Association, the Council on Dental Therapeutics is directed "to study, evaluate and disseminate information with regard to dental therapeutic agents, their adjuncts and dental cosmetic agents which are offered to the public or to the profession."

Consideration of dental materials and devices is specifically assigned to the Council

on Dental Materials and Devices of the American Dental Association. When these materials and devices possess therapeutic properties or claims for such properties are made, they are considered cooperatively by the two Councils. The Council on Dental Therapeutics stands ready at all times to assist or advise other Councils or committees of the American Dental Association on matters which pertain to dental therapeutics. Generally included within the responsibility of the Council on Dental Therapeutics are all drugs and chemicals which are employed in the diagnosis, treatment or prevention of dental disease. Drugs are considered useful in the treatment of oral disease if they are effective in treatment of disease of similar causation in other regions of the body. Fixed combination drugs are considered eligible for acceptance if each of the components makes a contribution to the claimed effect and the dosage of each component is safe and effective for a significant patient population. Combinations having components added to enhance the safety or effectiveness of the principle active component or to minimize the potential for abuse are also eligible.

At the present time the Council does not consider for evaluation (1) mouthwashes or dentifrices which do not claim therapeutic value, (2) cleansers for artificial dentures, and

(3) sterilizers which employ steam or boiling water as the bactericidal agent.

CLASSIFICATION OF PRODUCTS EVALUATED BY THE COUNCIL

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Commercial products are examined either upon the request of the manufacturer or distributor or upon the initiative of the Council. Any firm may submit its appropriate products to the Council for consideration for acceptance. Products will be listed in Accepted Dental Therapeutics and described in suitable reports in The Journal of the American Dental Association if they meet standards of acceptance with respect to usefulness, composition, advertising and labeling. Products are usually accepted for three years. Acceptance is renewable and may be reconsidered at any time. If ownership of the product changes, the period of acceptance expires automatically. Products which are obsolete, markedly inferior, useless or dangerous to the health of the user will be declared unacceptable. When it is in the best interest of the public or the profession, the Council may submit reports on unacceptable products to the Editor for publication in The Journal of the American Dental Association.

Decisions of the Council are based upon the available scientific evidence and are subject to reconsideration at any time that a substantial amount of new evidence becomes available.

Communications with the Council shall be in writing and shall be transmitted through the Secretary of the Council. The Council will feel free to use the information in these communications.

After consideration of a product has been completed, the Council will classify the product as "accepted", "provisionally accepted" or "unacceptable".

Accepted products include those for which there is adequate evidence for safety and effectiveness. They will be listed in Accepted Dental Therapeutics and may use the Seal of Acceptance or an authorized statement, unless otherwise provided.

Provisionally accepted will include those products for which there is reasonable evidence of usefulness and safety, but which lack sufficient evidence of dental usefulness to justify being "accepted". These products meet the other qualifications and standards established by the Council on Dental Therapeutics. The Council may authorize the use of a suitable statement to define specifically the area of usefulness of a product classified as "provisionally accepted".

The Council's initial consideration of products which may be eligible for "provisional acceptance" is influenced favorably by the knowledge of further investigations then in progress. It is the policy of the Council to reconsider these products each year on the basis of new evidence which may be produced in their support. Classification in this category is not ordinarily continued for more than three years.

Unaccepted products will include those for which the Council has determined that no substantial evidence of usefulness or that a question of safety exists.

GENERAL PROVISIONS FOR ACCEPTANCE

I. Composition

- A. Required Information: A quantitative statement of composition, including excipients, shall be provided to the Council. Adequate information on the properties of all ingredients shall also be provided.
- B. Change in Composition: The firm shall agree to notify the Council of any change in composition of an accepted product before the modified product is marketed.

- C. Manufacturing Standards: The firm shall provide evidence that the manufacturing and laboratory control facilities are under the supervision of qualified personnel and are adequate to assure purity and uniformity of products and accuracy of labeling.
- D. Standards or Specifications: Drugs shall conform to appropriate standards or specifications.

II. Name

- A. Established or Generic Names: The selection and use of established or generic names must conform to the requirements of the Federal Food, Drug, and Cosmetic Act.
- B. Trade Names: Proprietary names will be acceptable to the Council provided the names meet certain professional standards:
- 1. Misleading Names: Names which are misleading or which suggest diseases or symptoms are not acceptable. This provision may not apply to certain biologic products such as serums or vaccines.

Explanatory Note:

Since the uses of drugs change from time to time, it is important that the name indicates the composition rather than a proposed use for the product. However, under certain circumstances the Council may accept a name which denotes a long-established physiological action or use, particularly for a mixture. Thus the Council has accepted names such as _____ Topical Anesthetic, and other names which similarly suggest actions, but not diseases. The Council will give individual consideration to requests for acceptance of such names and its decision in each case will be materially influenced by the adequacy and prominence of the listing on the label of the common names for the active ingredients.

2. Numbers or Initials in Names: The product name shall not include initials or numbers except when deemed necessary to

designate the concentration or amount of active ingredient.

Explanatory Note:

The Council has recognized the use of letters or numerals in instances where the size of the label is so small and the full name of the product is so long as to otherwise prevent the inclusion of adequate information.

This provision does not apply to the use of numbers in conventional price lists or catalogs. Nor does the provision apply to serial or code numbers whose position on the label or package clearly differentiates those numbers from the name of a product.

3. Titles in Names: Titles such as "Doctor" or "Dentist" or the designation "D.D.S." or "D.M.D." shall not be included in the name of a product.

III. Evidence of Usefulness and Safety

- A. Submission of Evidence: Evidence pertaining to properties, actions, dosage, usefulness and safety shall be submitted by the firm.
- B. Nature of Evidence: The firm shall provide objective data from critical clinical and laboratory studies. Extended clinical experience may be utilized, in part, as a basis for evaluation of a product.

IV. Government Regulations

Products shall conform to all applicable laws and governmental regulations.

V. Promotional Material

- A. Name: The established or generic name of the product shall be displayed in a prominent manner in all promotional material directed to the dental profession.
- B. Claims: Claims of significance to dentistry that appear in labels, labeling or all ad-

vertising for products shall be clear and accurate and shall be limited to those recognized for inclusion in Accepted Dental Therapeutics.

- C. Unwarranted Disparagement of Other Drugs: Advertising of accepted products shall not result in the disparagement of other useful drugs.
- D. Display Advertising: Point-of-sale advertising, including counter and window displays, for products which are accepted shall not include any mention of their accepted status.
- E. Implied Acceptance: Accepted products shall not be advertised or displayed with unaccepted products in a manner that implies acceptance of the unaccepted products. This provision does not apply to conventional price lists or catalogs.
- F. The advertising must conform to the Advertising and Exhibit Standards of the Association.

VI. Reference to Council Acceptance

- A. *Purpose*: Any reference to the Council in labeling or advertising of an accepted product is permitted solely to indicate to the profession or the public that the claims for the usefulness of the product in treating or preventing oral disease are valid.
- B. The Seal of Acceptance, except as otherwise provided, may be used after acceptance of the product has been announced in *The Journal*, or at the discretion of the Council. The Seal shall not appear in conjunction with the seal of any other investigative group unless approval for such display has been obtained from the Council. The Seal is to be used without comment on its significance unless such comment has been previously approved by the Council. The Seal of Acceptance shall be legible and shall not be used in any manner which detracts from its dignity.

- C. When a statement is authorized by the Council to define specifically the area of usefulness of a product or to indicate its acceptance status the same principles established for the use of the Seal of Acceptance shall apply.
- D. There shall be no reference to Council acceptance in labeling or public advertising for any nonprescription product which requires a professional diagnosis for appropriate dental use.
- E. In the event that a product is no longer acceptable to the Council, all use of the Seal of Acceptance or an authorized statement in connection with the product must be discontinued within six months of the date of notification of the firm by the Council.

VII. Changes in Provisions

Any amendment to these provisions which may be made after acceptance of a product shall not apply to such product until the current period of acceptance has terminated. At the end of this period, the product must comply with the amended provisions if acceptance is to be renewed. This provision shall not apply to termination of acceptance of a product on the basis of new evidence regarding lack of safety or lack of usefulness.

PROVISIONS FOR ACCEPTANCE IN SPECIAL CATEGORIES

Products which come within the following categories, in order to be acceptable, must also meet the following special provisions:

VIII. Fixed Combination Drugs

A. Fixed Combinations Eligible for Acceptance: Fixed combinations are considered for acceptance when there is adequate evidence

of their usefulness in the practice of dentistry and when each of the components makes a contribution to the claimed effect and the dosage of each component is safe and effective for a significant patient population. Combinations having components added to enhance the safety or effectiveness of the principle active component or to minimize the potential for abuse are also eligible.

- B. Active Constituents: Separate consideration is required for any single active component which is not listed in Accepted Dental Therapeutics.
- C. Fixed Combination Labels: The labels of accepted drugs shall indicate the amount of each therapeutically active component in a stated quantity of product.

IX. Chemicals Proposed for Disinfection of Instruments

- A. The products must be effective in killing vegetative forms of pathogenic organisms (except possibly *Mycobacterium tuberculosis*) within five minutes.
- B. Labels, package inserts and advertising for such products should emphasize:
- 1. The necessity for adequate physical cleansing of the instruments prior to disinfection.
- 2. The necessity for an adequate margin of safety in the recommended period of contact of the instruments with the disinfecting agent in a suitable container.
- 3. The necessity for periodic replacement of the disinfecting agent.

- 4. The inability of the product to disinfect hinged instruments, those with deep narrow crevices, hypodermic needles and syringes.
- 5. The inability of the product to kill spores.
- 6. The inability of the product to destroy Mycobacterium tuberculosis except where this action has been adequately demonstrated.
- 7. The inability of the product to destroy the etiologic agent for viral hepatitis.
- C. Labels, package inserts and advertising for such products shall not:
- Imply usefulness under conditions or in a manner contrary to indications in Section B.
- 2. Include the term "sterilizing" or "sterilizing solution."

X. Nonprescription Analgesics

Pharmaceutical preparations which contain aspirin, acetaminophen or other suitable analgesics for nonprescription use will be considered for acceptance, provided:

- 1. The amounts of active components in the product shall be stated in all advertisements to dentists.
- 2. Advertisements to the public shall not include misleading or unwarranted statements relating to dental uses.
- 3. Advertisements to the public, labels or labeling shall not include the Seal of Acceptance or any reference to the American Dental Association or its Council on Dental Therapeutics.

regulations governing it can be obtained from the Food and Drug Administration, U.S. Department of Health, Education and Welfare, Rockville, Maryland 20852.

FEDERAL TRADE COMMISSION

Jurisdicition over the advertising of drugs is vested in the Federal Trade Commission by the Wheeler-Lea Act. Although the Commission's authority to control advertising to the profession is considerably restricted under the terms of the Act, it has been proposed to extend its authority as it relates to advertising of drugs in professional journals.

CONTROLLED SUBSTANCES ACT

The Comprehensive Drug Abuse Prevention and Control Act of 1970 was passed late in 1970 and became effective in May of 1971. This act replaces those areas of drug control and legal enforcement formerly covered by the Harrison Narcotic Act and the Drug Abuse Amendments to the Federal Food, Drug, and Cosmetic Act. The law which operates under the Department of Justice, is designed to deal comprehensively with drug abuse by providing for increased research into the problem and its prevention. It will strengthen the authority of law enforcement in this area and provide for patient treatment and rehabilitation.

The act establishes five schedules of controlled substances designated as Schedules I, II, III, IV and V depending largely on the drugs' potential for abuse, their medical usefulness and the degree to which they may lead to physical or psychological dependence.

Schedule I includes those drugs having a high potential for abuse with no currently

acepted medical use for treatment in the United States and which lack accepted safety for use. The schedule includes numerous opiates and opium derivatives such as dextromoramide, heroin and hallucinogenic substances such as marihuana and lysergic acid diethylamide (LSD).

Schedule II substances are currently accepted for medical use in the United States and have a high potential for abuse which may lead to psychological or physical dependence. The schedule includes certain opiate and opium derivatives and drugs such as anileridine, methadone and pethidine (meperidine).

Schedule III substances have a potential for abuse which is less than those in schedules I and II. They have an accepted medical use and may lead to moderate or low physical dependence and high psychological dependence. Included are drugs having a stimulant effect such as the amphetamines and those having depressant effects such as the barbiturates. Nalorphine and mixtures of drugs containing specified limited quantities of narcotics such as the codeine containing analgesic preparations are also included.

Schedule IV substances have a lower potential for abuse than those substances in Schedule III. They have an acceptable medical use and may lead to a limited physical or psychological dependence relative to drugs in Schedule III. This category includes agents such as chloral hydrate, meprobamate and ethinamate.

Schedule V drugs have a still lower potential for abuse than those agents in Schedule IV. They have currently acceptable medical use and their abuse may lead to more limited physical or psychological dependence than in Schedule IV. This schedule includes mixtures of narcotic and non-narcotic drugs with sufficient levels of the non-narcotic agents to produce drugs having medical qualities other than those possessed by the narcotic drug alone.

Provision is made in the law for the addi-

tion of new drugs to the appropriate schedules and for the transfer of drugs from one schedule to another depending on the findings of the Attorney General and the Secretary of Health, Education and Welfare as to the drugs' potential for abuse. Provision is also made for the removal of drugs from the schedules.

Controlled drugs in Schedule II generally may not be dispensed without the written prescription of a practitioner and the prescription cannot be refilled. Controlled drugs in Schedule III and IV require a written or oral prescription. The prescription may not be filled or refilled more than six months after the date of prescribing and it may not be refilled more than five times, unless renewed by the practitioner. No controlled drug in Schedule V may be dispensed for other than a medical purpose.

The Controlled Substances Act requires that every person who dispenses any controlled substances must register annually with the Attorney General in accord with regulations which have been issued.

Information concerning the Controlled Substances Act, the regulations governing it and registration under it can be obtained by contacting the office of the Bureau of Narcotics and Dangerous Drugs in the region in which the practitioner resides. Separate laws

relating to the control of drugs subject to abuse have also been enacted in many states.

UNITED STATES PHARMACOPEIA

The United States Pharmacopeia, which is recognized as an official standard by the Federal Food, Drug, and Cosmetic Act, is issued every five years. The eighteenth revision of the United States Pharmacopeia became official on September 1, 1970. Articles included in the Pharmacopeia are accepted by the Committee on Revision on the basis of therapeutic merit or pharmaceutic value.

NATIONAL FORMULARY

This compendium is issued by the Committee on the National Formulary, elected by the Council of the American Pharmaceutical Association. The National Formulary is recognized as an official standard under the Food, Drug, and Cosmetic Act. Admission of articles to the National Formulary is made on the basis of therapeutic value or pharmaceutic need. The thirteenth edition of the National Formulary became official on September 1, 1970.

Dental-Legal Problems Related to the Use of Drugs

The dentist has a legal obligation to use "due care" in treating his patients. This obligation applies to any treatment procedure employed by a dentist, including the prescribing, dispensing or administration of drugs and other therapeutic agents. "Due care" as it relates to the administration or prescribing of drugs by the dentist implies that the dentist is familiar with the drug and his patient. The dentist should have adequate information on the health of the patient to know whether the drug he intends to use is suitable for the patient or whether the health record contraindicates its use. This presupposes that the dentist understands the properties of the drug he prescribes or administers; that he knows that it is a drug suitable for the diagnosed disease or condition he is treating and that appropriate warning of pertinent side effects are given to the patient.

A patient who is injured as a result of dental treatment and who believes that the injury was caused by the negligence of the dentist or one of his employees may decide to sue the dentist. Such a law suit is known as a malpractice action. One of the most frequent causes of malpractice actions involving drugs employed in dental practice is severe disability or death from the administration of anesthetic agents or depressants.

There are four types of dental malpractice claims that may develop out of injury from the administration of anesthetics and depressants based on negligence in the following categories:

- 1. Failure to control an anesthetized or drug depressed patient.
- 2. Failure to take an adequate health history.
- 3. Failure to become familiar with the anesthetic or depressant agent.
- 4. Failure to take appropriate steps after breaking a needle.

Controlling a Patient: The dentist is responsible for the patient's action while the patient is under the effects of an anesthetic or depressant. These include acts in which the patient can cause injury to himself. The dentist's duty to control a patient influenced by the effects of an anesthetic or depressant agent applies to the use of local and general anesthetic as well as sedatives and antianxiety agents.

The dentist may ethically and legally delegate some of his responsibility to his assistant to oversee a recovery room or operatory until the dentist is prepared to release the patient. However, unless another professional colleague is immediately available, the dentist should not leave the premises while a patient is still influenced by the effects of the anesthetic or depressant agents. Patients who are sedated to the point of drowsiness

prior to coming to the dental office or who are drowsy following effective sedation in the dental office should not be allowed to drive and should not be permitted to travel to the dentist's office or to return home unaccompanied.

Taking Health Histories: The dental malpractice claim based on failure to take an adequate health history is a difficult case to defend. The legal question is what health history would the reasonably prudent practitioner have taken under the same or similar circumstances. A short, "Do you have any diseases or allergies?" a few seconds before the anesthetic agent (or any drug) is administered, does not constitute taking an adequate history. It is suggested that the dentist have the patient fill out a printed health questionnaire before any treatment, in particular before the administration of a general anesthetic. (See p. 3-7) The patient should be given a sufficient amount of time to complete the form and the dentist should make sure the patient understands the treatment plan. Once the dentist has carefully reviewed the patient's history the law then requires that the dentist act with reasonable prudence in deciding whether to administer an anesthetic and in his selection of the anesthetic agent.

If the dentist takes an adequate health history and uses an anesthetic agent with which he is familiar and one that is not contraindicated by the patient's present state of health, the dentist is not liable if the administration of the anesthetic agent produces an adverse reaction. The dentist does not guarantee immunity from injury when he administers an anesthetic or other drug and the law does not place this unfair burden upon him.

Familiarity with Agents: A dentist should only use those anesthetic agents with which he is familiar. Before using an anesthetic or other therapeutic agent for the first time, the dentist should familiarize himself with the properties of the agent. The package insert which currently is required by the federal government to accompany the drug provides

information concerning the agent's actions, uses, dosage, side effects and potential complications. It can be a helpful source of information. If the dentist uses an anesthetic or other drug with which he is unfamiliar he will have no defense if the patient is adversely affected by that drug.

Obtaining Consent: Obtaining the patient's consent to a dental procedure ordinarily presents no difficulties. In the usual situation, the dentist discloses the results of his examination to the patient and explains what treatment is indicated to correct the patient's problem. The patient's consenting orally to the proposed procedure is sufficient to constitute legal consent in almost every instance. One exception is when the patient is to undergo surgery involving extensive removal of tissues. In this situation the dentist should have the patient sign a form that gives consent to the surgical procedure, the anesthetic to be used and any removal of tissues. If teeth are to be extracted during the procedure, they should be specified in the consent form. The other major exception to the usual manner of obtaining consent is when the patient is entitled to know the common side effects of a proposed procedure, usually the injection of a drug. It is not enough for the patient to consent to the administration of an anesthetic agent, for example, if it is not uncommon for that agent to produce side effects not disclosed to the patient. The dentist has the legal duty to notify the patient of those possible side effects before the patient consents to the injection or administration of the agent. In law this is called "informed consent." Obviously, only the dentist who fulfills his obligation in taking an adequate history, and in knowing the properties and effects of the drugs he uses, is in a position to obtain an "informed consent" from his patients.

Contending with Broken Needle Aftermath: Although an infrequent occasion in the dental office, the fourth type of claim, the broken needle situation, can usually be pre-