1962

accepted dental remedies

AMERICAN DENTAL ASSOCIATION

27TH
EDITION

1962

accepted dental remedies

DRUGS USED IN DENTAL PRACTICE INCLUDING A LIST OF BRANDS ACCEPTED BY THE COUNCIL ON DENTAL THERAPEUTICS OF THE AMERICAN DENTAL ASSOCIATION

THIS EDITION OF ACCEPTED DENTAL REMEDIES SHOULD NOT BE USED FOR CURRENT REFERENCE BEYOND 1962 BECAUSE THE STATUS OF DENTAL PRODUCTS IS CONSTANTLY CHANGING.
PUBLISHED JANUARY, 1962.

abbreviations

The following abbreviations occur in the text:

A.D.R.—*Accepted Dental Remedies.*

U.S.P.—*The Pharmacopeia of the United States of America, Sixteenth Revision.*

N.F.—*The National Formulary, Eleventh Edition.*

N.N.D.—*New and Nonofficial Drugs.*

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PREFACE

Accepted Dental Remedies is published annually, under the immediate supervision of the Council on Dental Therapeutics of the American Dental Association. The 1962 edition extends the revisions in the organization and content of *Accepted Dental Remedies* which were emphasized in 1960. The chapter has been continued which outlines the significance of some of the drugs currently and frequently administered in medical practice. This chapter is intended to alert the dentist to the complications which may arise when the patient is receiving medical care at the time dental treatment is provided. Special attention is directed to the importance of obtaining adeqtuate medical histories as a method of anticipating and avoiding emergencies which might otherwise arise. These revisions reflect the increasing recognition of the important contribution which dentistry makes to total health care.

Reorganization of the book is designed to facilitate its use by the dentist and dental student.

As in earlier editions, *Accepted Dental Remedies* includes information concerning: (1) drugs of recognized value in dentistry, (2) drugs of uncertain status more recently proposed for use by the dentist, and (3) some drugs once employed extensively but now generally regarded as obsolete. Only brands of drugs of recognized value in dentistry are included in the listing of accepted dosage forms. Descriptions of other drugs are provided for information only. Their inclusion is not to be construed as a recommendation for their use.

In evaluating the usefulness of a drug in dentistry, the Council places primary emphasis upon evidence which is obtained under conditions designed to eliminate chance and to balance out the effect of inadvertent bias on the part of either the investigator or the patient. The "double blind" technique is regarded as an important and often essential feature of a formal clinical trial. A fundamental objective of the Council's program is to encourage earlier and more rigorous clinical testing of drugs under the conditions of their proposed use in dentistry.

It is not possible to give individual credit to the large number of persons, in addition to Council members and consultants, who have contributed generously of time and effort in the preparation of this book. The Council, however, gives special recognition to the invaluable assistance of Miss Eleanore Dufour in preparing the manuscript, proof and index.

The Council welcomes criticism and suggestions which may lead to the further improvement of later editions.

J. Roy Doty, Secretary
Council on Dental Therapeutics
October, 1961

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PROVISIONS FOR ACCEPTANCE OF PRODUCTS BY THE COUNCIL 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 cosmetic agents.

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 Remedies* 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.*

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 consideration of evidence of safety under the conditions of use. 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.

The Council encourages research in the field of dental therapeutics.

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.

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 prosthetic and restorative materials is specifically assigned to the Council on Dental Research of the American Dental Association. When these materials 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, chemicals and devices 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. Mixtures are considered for acceptance if all of the ingredients are necessary to therapeutic action or pharmaceutical quality. Other mixtures which have established usefulness in dental practice are considered for acceptance if they meet reasonable standards of safety and claims are not made for ingredients which are therapeutically inactive.

classification of products evaluated by the council

After consideration of a product has been completed, the Council will classify the product in group A, B, C or D.

At the present time the Council does not consider for evaluation (1) mouth washes or dentifrices which do not claim therapeutic value, (2) toothbrushes, (3) cleansers for artificial dentures, (4) preparations which are not related to the treatment of oral diseases, such as cathartics and diuretics, and (5) sterilizers which employ steam or boiling water as the bactericidal agent.

Group A consists of accepted products which will be listed in ACCEPTED DENTAL REMEDIES and may use the Seal of Acceptance, unless otherwise provided.

Group B consists of products which lack sufficient evidence to justify present acceptance, but for which there is reasonable evidence of usefulness and of safety. These products meet the other qualifications and standards established by the Council on Dental Therapeutics. It is the Council's opinion that Group B products may be promoted for special use and study.

The Council's initial consideration of products which may be eligible for Group B listing is influenced favorably by the knowledge of further investigations then in progress. It is the policy of the Council to reconsider Group B 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.

Group C consists of products for which the evidence is so limited or inconclusiv that the products cannot be accuratel evaluated. It is the Council's opinion that Group C products require further study by qualified investigators.

Group D consists of products which are unacceptable because of their demonstrated inability to meet the standards outlined in the provisions for acceptance.

general provisions for acceptance

I. COMPOSITION OR DESIGN

A. DRUGS

1. *Single Substances:* The chemical formula and properties shall be known and available for publication.

2. *Mixtures:* The quantitative formulation of drug and chemical mixtures shall be known and available for publication. Exact quantities of individual flavors need not be stated and the nature of flavors and colors which are ingredients of preparations certified by any federal agency need not be revealed.

B. DEVICES: A description of the construction and method of operation shall be provided.

C. CHANGE IN COMPOSITION OR DESIGN: The firm shall agree to notify the Council of any change in composition or design of an accepted product before the modified product is marketed.

D. 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. Representatives of the Council may visit factories and laboratories, but will not assume any responsibility for the operation of these facilities.

E. STANDARDS OR SPECIFICATIONS: Drugs and devices shall conform to standards or specifications established by the Council.

II. NAME

A. COMMON OR GENERIC NAMES

1. *Selection of Generic Name for New Drug:* Every reasonable effort shall be made to select a generic name which can be recognized for use in all areas of professional health practice.

2. *Prominence of Generic Name on the Label:* The generic name of the product shall be displayed in a prominent manner on the label.

Explanatory Note:
The intent of this provision is to make the composition of the product easily discernible from the package label in order to avoid confusion or error on the part of the dentist. The common name should appear immediately adjacent to the trade name if the latter is included. Degree of prominence is determined by type size and form, color contrast, space allowance and other factors. Where limited space is available, the common name should not be substantially subordinated to the trade name. However, it is not intended to require proportional increase in the prominence of the common name when the trade name is carried in very large type.

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 indicate 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 ingredients.

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 catalog 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 the product.

C. NAMES OF MIXTURES: The name shall indicate the therapeutically active ingredients of a mixture whenever it is practicable. This provision may be waived when the common names of the active ingredients are displayed in a prominent manner on the label. (See explanatory note for section II. A)

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 with citation of sources. Extended clinical experience may be utilized 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 common 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 made for products in labels, labeling, advertising or by any other means shall be clear and accurate and shall be limited to those recognized for inclusion in *Accepted Dental Remedies.*

C. UNWARRANTED DISPARAGEMENT OF OTHER DRUGS: Advertising of accepted products shall not result in the disparagement of other useful drugs.

D. LAY ADVERTISING: Lay 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.

VI. SEAL OF ACCEPTANCE

A. 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.

B. In the event that a product is deleted from *Accepted Dental Remedies,* all use of the Seal of Acceptance 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. MIXTURES

A. MIXTURES ELIGIBLE FOR ACCEPTANCE: Mixtures will be considered for acceptance when the active ingredients provide a desirable supplementation of one therapeutic action. The eligibility of other mixtures may be determined by the Council on the basis of good therapeutic practice.

Explanatory Note:
Good therapeutic practice often requires the selection of several drugs in individual amounts which should be determined by the needs of each patient. For this reason the Council feels that it would be desirable that all active ingredients be directed toward one pharmacological action. The Council believes that an undesirable burden would be placed on the dentist by the acceptance of mixtures which would be indicated for use in only a few patients. Acceptance of such mixtures might also encourage practices contrary to the best interests of the patient. Mixtures are considered for acceptance, therefore, only when there is adequate evidence of their general usefulness in the practice of dentistry.

B. ACTIVE CONSTITUENTS: Separate consideration is required for any single active constituent which is not listed in *Accepted Dental Remedies.*

C. LABELS: The labels of an accepted mixture shall indicate the amount of each therapeutically active ingredient 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 and *Mycobacterium tuberculosis.*

6. The inability of the product to destroy the etiologic agent for viral hepatitis.

C. Labels, package inserts and advertising for such products *shall not*

1. Imply usefulness under conditions or in a manner contrary to indications in Section B.

2. Include the term "sterilizing" or "sterilizing solution."

X. DENTURE ADHESIVE PREPARATIONS

A. SAMPLES: Sample shall not be distributed to persons other than dentists. Samples shall not be supplied to any mail-order denture house or dental laboratory.

B. PACKAGE STATEMENT: The following statement shall appear on every trade package: "Ill-fitting dental appliances may impair health — consult your dentist for periodic examination." The Council will give consideration to alternative statements designed to convey the same meaning.

XI. LOCAL ANESTHETIC SOLUTIONS FOR INJECTION

A. SPECIFICATION: These products shall conform to the specification adopted by the Council on Dental Therapeutics (J.A.D.A. 38:268-9 Feb. 1949).

B. WARNING STATEMENT: The following warning statement or its equivalent must appear on each package of solutions containing a higher concentration of epinephrine than 1:50,000 or its equivalent in other vasoconstrictors: "The concentration of vasoconstrictor in this product is greater than that required for routine dental use. Use cautiously."

XII. ANALGESICS

A. COMPOSITION: Pharmaceutical preparations which consist of acetylsalicylic acid, or mixture of acetylsalicylic acid, acetophenetidin and caffeine, with or without codeine, will be considered for acceptance, provided:

1. The total weight of active ingredients shall not exceed 0.5 gram per dosage unit.

2. The quantity of acetophenetidin shall not exceed 0.2 gram per dosage unit.

B. ADVERTISING

1. The quantitative composition of the product shall be stated in all advertisements to dentists.

2. Advertisements to the public shall not include misleading or unwarranted statements.

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.

XIII. DEVICES FOR THE MAINTENANCE OF INTERPROXIMAL DENTAL HYGIENE

A. The devices shall be advertised only to dentists.

B. Claims shall be limited to usefulness under professional supervision as an adjunct to professional treatment.

OFFICIAL AGENCIES AND OFFICIAL STANDARDS RELATING TO DRUG PRODUCTS

food and drug administration

Responsibility for the enforcement of the Federal Food, Drug and Cosmetic Act and other statutes is assigned to the Food and Drug Administration of the Department of Health, Education, and Welfare. The Food, Drug and Cosmetic Act and the regulations promulgated for its enforcement relate to the *labeling* of drugs, foods, cosmetics and devices. Labeling refers to the labels affixed to the container and also to package inserts and similar material which comes to rest with the article in the hands of the consumer. Authority does not extend to advertising in professional journals. Violations may involve adulteration or misbranding or both.

Before a new drug may be introduced into interstate commerce, the distributor must file an application which provides adequate evidence that the drug is safe for use under the conditions prescribed.

Certain antibiotics are subject to the special provisions of Section 507 of the Act. Each batch of these drugs must be certified as complying with the standards established in regulations issued by the administration.

For a discussion of the relation of the Food and Drug Administration to the dental profession, see: Kerlan, Irvin. FDA protection and the dentist: a review and forecast. J.A.D.A. 55:75 July 1957.

federal trade commission

Jurisdiction over the advertising of drugs is vested in the Federal Trade Commission by the Wheeler-Lea Act. However, the Commission's authority to control advertising to the profession is considerably restricted under the terms of the Act.

united states treasury department

The Harrison Narcotic Act is administered by the Bureau of Narcotics of the U. S. Treasury Department. Certain drugs are defined as subject to the Act and an amendment provides a procedure for bringing new addiction-forming or addiction-sustaining drugs within the purview of the Act. Dentists may purchase and prescribe narcotic drugs only after registration and payment of a fee to the District Director of Internal Revenue for the district in which they practice. Annual re-registration is required.

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 sixteenth edition of the *United States Pharmacopeia* became official on October 1, 1960. 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, extent of use and the recognized need for standards for certain drugs which may not be widely used. The eleventh edition of the *National Formulary* became official on October 1, 1960.

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TREATMENT CONSIDERATIONS OF DENTAL PATIENTS RECEIVING MEDICAL CARE

Reference in this chapter to any drug, either by its descriptive or proprietary name, should neither be construed as a suggestion for its use in dentistry nor as an evaluation of its usefulness in medicine. Drugs which are useful in dentistry are described in subsequent chapters of this book.

A patient who seeks dental service while receiving medication or treatment by a physician may present special problems for the dentist. In such a patient, either the disease being treated or the effects of the general medication may influence the dentist in his selection of drugs and procedures. Providing comprehensive health service in many instances will require cooperation between the dentist and the physician.

A brief history of the patient's physical condition, with particular reference to drug use, allergies, sensitivities, and current medical treatment will frequently uncover important information. If in doubt about a patient due to history obtained, elective procedures should be deferred until the dentist has had an opportunity to consult with the patient's physician.

Currently employed drugs and disease states which require special consideration in the management of the dental patient will be reviewed briefly in this chapter. Standard reference works on pharmacology and medicine should be consulted for more detailed information.

cardiovascular agents

All patients with diseases of the cardiovascular system require special consideration. The patient's physician should be consulted *prior* to extensive operative procedures and, in every case, prior to the administration of a general anesthetic. Premedication with a sedative may be desirable in this group of patients, and a reassuring and considerate attitude on the part of the dentist is important.

Apprehension, worry, and long fatiguing dental procedures must be minimized in these patients. These factors stimulate the discharge of epinephrine and norepinephrine (levarterenol) into the circulation, and may give rise to an elevation in blood pressure and heart rate and other effects which may place a strain on the cardiovascular system. The epinephrine that is introduced with a local anesthetic solution is properly injected extravascularly and in quantities too small to produce a significant deleterious effect. Care should be taken to use equipment which minimizes the danger of intravascular injection.

vasodilator and anti-hypertensive agents

Nitroglycerin and amyl nitrite frequently are prescribed by the physician to relieve distress in attacks of angina pectoris. These drugs are administered to dilate the coronary vessels, but their action is not selective and many other vessels are affected. An abrupt fall in blood pressure

may ensue, which may result in syncope (fainting).

Pain, apprehension, or excitement may provoke anginal attacks in patients for whom these drugs are prescribed. Apprehension, worry and long, fatiguing dental procedures must be minimized in these patients. These factors stimulate the discharge of epinephrine into the circulation, giving rise to effects which may place an unusual strain on the cardiovascular system, namely, increases in cardiac rate and blood pressure. Epinephrine should never be used for treatment of vasomotor collapse occurring in patients receiving the more potent ataractic drugs, particularly phenothiazines.

Numerous antihypertensive drugs are being used extensively by physicians. Representative examples include the veratrum alkaloids, hexamethionium chloride and related compounds, hydralazine hydrochloride, the organic nitrates and the nitrites, the rauwolfia alkaloids, and bretylium tosylate. Common to many of these drugs is the ease with which patients under treatment may become nauseated and vomit. Hypertensive patients under treatment with these drugs may develop postural hypotension or syncope more readily than others; sudden rising or changes in posture may cause temporary loss of consciousness. Many of these drugs potentiate barbiturate sedation and anesthesia. The usually employed dosage of sedative drugs might need to be somewhat reduced for patients receiving antihypertensive drugs. The fact that antihypertensive drugs are being taken must always be known when a patient takes a general anesthetic.

anticoagulant drugs

Patients with a history of coronary thrombosis require additional consideration since they may be receiving anticoagulants such as bishydroxycoumarin (Dicumarol) or heparin. Such drugs act to delay the coagulation of blood, and their use necessarily will predispose toward hemorrhage after any oral surgery. At times, spontaneous hemorrhage from the gingivae may be associated with the administration of these drugs.

Interruption of the course or adjustment of the dosage of anticoagulant therapy should be authorized only by the physician in charge of the patient. If treatment cannot be interrupted, the dentist must anticipate the bleeding problem, and take steps to control hemorrhage by local procedures. The use of pressure, augmented with topical applications of thrombin or other hemostatic agents, will be found helpful in this connection. (See page 124). A report has recently appeared in the literature indicating that a small sampling of hospitalized patients were successfully carried through oral surgery procedures without interruption of anticoagulant therapy. Further careful study of this problem will be necessary before this regime can be recommended.[1]

agents employed in heart failure

A wide variety of medicinal agents may be employed for patients who are in the various stages of myocardial insufficiency (heart failure).

DIGITALIS AND ALLIED AGENTS: Many patients maintained on this type of medication over prolonged periods of time develop a tendency toward nausea and vomiting. Particular care is indicated to avoid stimulation of the vomiting reflex and to prevent aspiration of regurgitated matter.

ANTI-ARRHYTHMIC AGENTS: Quinidine or procainamide hydrochloride are given to some patients to reduce an elevated pulse rate or to prevent intermittent paroxysms of tachycardia (rapid heart beat). Patients undergoing such treatment are prone to episodes of dizziness, nausea and