GUIDELINES FOR PRESCRIBERS OF CONTROLLED SUBSTANCES

A Joint Statement of The Drug Enforcement Administration (DEA) and The DEA/Practitioners Working Committees

These guidelines have been prepared under the auspices of the Drug Enforcement Administration and the DEA/Practitioners Working Committee and approved by the American Dental Association, American Medical Association, American Nurses Association, American Osteopathic Association, American Podiatric Association, American Veterinary Medical Association, National Institute on Drug Abuse, and the Drug Enforcement Administration.

PREFACE

The following embodies the collective thinking of members of the DEA/Practitioners Working Committee. First formed in 1974, this committee has provided a forum for DEA officials and association executives and practitioners to meet voluntarily to discuss items, issues, and subjects of mutual interest, areas of practical concern, and generally to maintain an open and responsive attitude among the various members. Having no intrinsic authority, and seeking none, the DEA/Practitioners Working Committee believes it has played a significant role in promoting the generally harmonious relationships which exist between its national organizations and their respective members. It is against this background of shared experience and knowledge that participants in the work of this committee offer these “Guidelines for Prescribers of Controlled Substances” to members of the professions throughout the country.

PURPOSE

The purpose of this joint statement and the presentation of guidelines is to provide and establish acceptable professional responses to the demands of the Controlled Substances Act. The guidelines provide a common sense approach to encourage voluntary compliance by the prescribing professions.

GENERAL STATEMENT

The principles expressed in these guidelines constitute neither a pronouncement of law nor a code of ethics, and are not intended to in any way supersede or be in conflict with statutes or ethical concepts governing the conduct of the various practitioners in their respective professional organizations. Accountability is the responsibility of each discipline.

APPLICATION OF STATE AND FEDERAL LAW

Separate laws relating to the distribution of controlled substances have been enacted in most states. In many cases state law is much more stringent than Federal law and will not allow certain practices which may be authorized under Federal law. The guidelines are an example of good practices which should be encouraged under both Federal and state laws and regulations. Close cooperation and understanding between law enforcement and medicine will ensure that legitimate drugs remain in legitimate channels.

COMMUNICATION

Recognizing that members of each profession have special competencies and knowledge concerning drugs and related therapeutic agents, a free exchange of information on these matters is encouraged among the professions at all levels.

GENERAL GUIDELINES

* Controlled substances have legitimate clinical usefulness and the prescriber should not hesitate to consider prescribing them when they are indicated for the comfort and well-being of patients.

* Prescribing controlled substances for legitimate medical uses requires special caution because of their potential for abuse and dependence.

* Exercise good judgment in administering and prescribing controlled substances so that diversion to illicit use is avoided and the development of drug dependence is minimized or prevented.

* Guard against contributing to drug abuse through injudicious prescription writing practices, or by acquiescence to unwarranted demands of some patients.

* Each prescriber is asked to examine his/her individual prescribing practices to ensure that all prescription orders for controlled substances are written with caution.

* Make a specific effort to ensure that multiple prescription orders are not being obtained by the patient from different prescribers.

GUIDELINES: PRESCRIPTION ORDERS

The prescriber is granted through legal authority the right to prescribe medications that are necessary for the proper treatment of his/her patients. Prescribing is governed by laws and regulations which set minimum standards and requirements. These guidelines, tempered with good moral and ethical considerations, give guidance to going beyond the minimum requirements.

* The prescription order must be signed by the prescriber when it is written. The prescriber's name, address, and DEA registration number and full name and address of the patient must be given when prescribing controlled substances.

* The written prescription order should be precise and distinctly legible to enhance exact and effective communication between prescriber and dispenser.

* The prescription order should indicate whether or not it may be renewed and, if so, the number of times or the duration such renewal is authorized. Prescriptions for drugs in Schedules III, IV, and V may be issued either orally or in writing and may be renewed if so authorized on the prescription order. However, the prescription order may only be renewed up to five times within six months after the date of issue.

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A written prescription order is required for drugs in Schedule II. The renewal of Schedule II prescription orders is prohibited. Only in an emergency situation may oral orders for Schedule II drugs be accepted by a dispenser. Such oral orders must be followed up by a written order within 72 hours.

Controlled substances which are prescribed without indication for renewal cannot be renewed without authorization by the prescriber.

- Prescribe no greater quantity of a controlled substance than is needed until the next check-up.
- Try to make prescription orders alteration-proof.
- When prescribing a controlled substance, write out the actual amount in addition to giving an Arabic number or Roman numeral in order to discourage alterations in written prescription orders.
- Prescribers are encouraged to consider placing a number of check-off boxes on their prescription blanks which show amounts within which the prescribed amount falls, i.e., 1-25, 26-50, 51-100, over 100.
- Use a separate prescription blank for each controlled substance prescribed.
- The use of prescription blanks which are preprinted with the name of a proprietary preparation should be discouraged.
- When institutional prescription blanks are used, the prescriber should print his/her name, address, and DEA registration number on such blanks.

Institutions should discourage the use of institutional prescription blanks for prescribing controlled substances. The prescriber should use his/her own prescription blanks in such instances.

**DUTY TO INFORM**

The prescriber has the responsibility to inform patients of the effects of the prescribed drugs consistent with good medical practice and professional judgment. The patient has a corresponding duty to comply with the prescriber’s directions for use of the prescribed medication.

Each of the professional organizations and the Drug Enforcement Administration has a responsibility to educate and inform the public on proper handling and use of controlled substances. The professions represented on the DEA Practitioners Working Committee recognize that they have responsibilities to themselves, beyond legal minimum restraints.

**UNITED STATES DEPARTMENT OF JUSTICE**

Drug Enforcement Administration
Washington, D.C. 20537

**ANTIPSYCHOTIC MEDICATIONS REGULATED**

The California Department of Mental Health has adopted regulations relating to voluntary psychiatric patients’ right to refuse antipsychotic medications. The regulations were effective on June 1, 1980.

These regulations set forth the right of certain voluntary psychiatric patients to refuse treatment with antipsychotic medications (except in emergency situations). They require that the patient be informed of his or her right to consent to or refuse such medication and that specific information regarding the nature and effect of antipsychotic medications be discussed with the patient by the prescribing physician to enable the patient to make an informed decision. A written record of the patient’s decision to consent must be maintained by the facility and the patient may withdraw consent at any time. These regulations also include a definition of antipsychotic medication and provide for sanctions for violations of the rights of patients as set out in these regulations.

Any questions concerning these new regulations should be directed to: Office of Legal Services, Department of Mental Health, Post Office Box 254829, Sacramento, California 95825, (916) 920-7164.

**DISCIPLINARY ACTIONS APRIL 1, 1980-JUNE 30, 1980**

<table>
<thead>
<tr>
<th>Name</th>
<th>City</th>
<th>Date</th>
<th>Action</th>
<th>Code</th>
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<tr>
<td>Cawanan, Richard J., M.D.</td>
<td>Woodland Hills</td>
<td>May 19, 1980</td>
<td>Gross negligence and incompetence in three separate cases.</td>
<td>2390 B&amp;P Code</td>
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<tr>
<td>Cebh, Stephen A., M.D.</td>
<td>Bell</td>
<td>May 26, 1980</td>
<td>Gross negligence and incompetence in numerous plastic surgery cases.</td>
<td>2390 B&amp;P Code</td>
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<tr>
<td>Campbell, Frank M., M.D.</td>
<td>Nogales, Arizona</td>
<td>April 11, 1980</td>
<td>Gross negligence and incompetence in performing a vasectomy that took almost four hours and that caused extreme injury, including transaction of urethra.</td>
<td>2390 B&amp;P Code</td>
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<tr>
<td>DeSoline, Robert W., M.D.</td>
<td>Carson</td>
<td>April 11, 1980</td>
<td>Stipulated Decision. Prescribing dangerous drugs without prior examination and without medical indication. Excessive prescribing.</td>
<td>2390 B&amp;P Code</td>
</tr>
<tr>
<td>Denton, Robert W., M.D.</td>
<td>Bishop</td>
<td>May 16, 1980</td>
<td>Gross negligence and incompetence in biliary surgery.</td>
<td>2390 B&amp;P Code</td>
</tr>
</tbody>
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Erhardt, Karl S., M.D. (A-11629)—South Laguna
236(b). B&P Code
Stipulated Decision. Anesthesiologist grossly negligent in his attention to monitor vital signs during surgery until a cardiac arrest occurred, resulting in coma.
Revoked, stayed, ten years probation on terms and conditions.
April 28, 1980
Farrell, Joseph P., M.D. (A-11411)—Sacramento
239 B&P Code
Stipulated Decision. Used, prescribed, and administered to himself the drug Talwin.
Revoked, stayed, ten years probation on terms and conditions.
May 20, 1980
Flack, Bradford Ames, M.D. (C-24927)—Los Angeles
2390, 2, 2361(b), (c), (e), (f). 2391.5 B&P Code; 11154 H&S Code
Stipulated Decision. Indiscriminate prescribing of dangerous drugs.
May 28, 1980
Grant, Leo Jacob, M.D. (G-5433)—New York, New York
490. 2372 B&P Code
Stipulated Decision. Used, prescribed, and administered to himself the drug Ritalin.
Revoked, stayed, ten years probation on terms and conditions.
April 28, 1980
Habenicht, James C., M.D. (G-14722)—Escanaba
2390. 2391.5 B&P Code; 11154 H&S Code
Stipulated Decision. Prescribed dangerous drugs without prior examination and without medical indication.
Revoked. April 11, 1980
Guest, Maurice C., M.D. (A-12110)—Tampa, Florida
2363 B&P Code
Stayed revocation by Florida Medical Board for incompetence and gross negligence.
Revoked, stayed, ten years probation on terms and conditions.
June 18, 1980
Habersicht, James C., M.D. (G-14722)—Escanaba
2390. 2391.5 B&P Code; 11154 H&S Code
Stipulated Decision. Prescribed dangerous drugs without prior examination and without medical indication.
Revoked. June 18, 1980
Han, Kenneth, M.D. (A-11573)—Downey
2390.5, 2391.5 B&P Code; 11154 H&S Code
Stipulated Decision. Prescribed dangerous drugs without prior examination and without medical indication, and to persons not under his treatment for pathology or condition.
Revoked, stayed, ten years probation, 90 days actual suspension.
April 25, 1980
Hopkins, Milan Lewis, M.D. (C-34460)—Upper Lake
236(b), (c). 2391. 2395 B&P Code
Stipulated Decision. Furnishing dangerous drugs to addicts. Prescribed dangerous drugs without prior examination and medical indication. Gross negligence, incompetency, and repeated similar negligent acts in his prescribing practices.
Revoked, stayed, ten years probation, actual suspension of 90 days.
April 17, 1980
Hutchins, John P., M.D. (A-27867)—Aberdeen
236(c), 490, 2383, 2384 B&P Code
Stipulated Decision. False representation that he could diagnose and treat conditions of a paraplegic patient by use of a machine and the March Bio Laser—when such were both useless devices. Convictions for theft, false advertising, and unlawful possession of thousands of capsules of phenelzine, a controlled substance.
Revoked. June 19, 1980
Johnson, Chester W., Jr., M.D. (C-10920)—Culver
760, 2391.5 B&P Code
Stipulated Decision. Prescribed dangerous drugs excessively and without prior examination and medical indication.
Revoked, stayed, five years probation, actual 45 days suspension.
June 19, 1980
Kuransenas, Cyril, M.D. (A-26640)—Los Angeles
2399.5, 2383, 2391.5 B&P Code; 11154 H&S Code
Stipulated Decision. Prescribed dangerous drugs without prior examination and medical indication, to persons not under his treatment for pathology or condition.
Conviction for drug statute violation.
Revoked, stayed, five years probation on terms and conditions.
June 19, 1980
Kirkham, Don R., M.D. (C-11339)—Orange
236(b). B&P Code
Stipulated Decision. Gross negligence in using synthetic fibers for hair transplantation, resulting in rejection, infection and scarring to the scalp.
One year suspension, stayed, five years probation on terms and conditions.
May 28, 1980
Lash, Michael Bernard, M.D. (A-21140)—Corona
2390, 2361, 2417 B&P Code
Stipulated Decision. Prescribed drugs and controlled substances without prior examination and medical indication.
Revoked. April 17, 1980
McMullan, Francis H., M.D. (C-12926)—Fremont
2394.5 B&P Code
Stipulated Decision. Prescribed dangerous drugs without prior examination and medical indication.
Revoked, stayed, five years probation on terms and conditions.
May 30, 1980
Medaris, Donald E., M.D. (A-12033)—Arcadia
2363 B&P Code
Stipulated Decision. Unjustified intravenous administration of 20 treatments of chelation therapy, constituting excessive prescribing, or treatment to a patient.
One year suspension, stayed, three years probation on terms and conditions.
May 26, 1980
2361(c). B&P Code
Stipulated Decision. Repeatedly submitted Medi-Cal claims that were contrary to fact, and to persons not under his treatment.
Revoked, stayed, five years probation on terms and conditions.
May 28, 1980
Mufio, Emmanuel R., M.D. (C-36558)—Cleveland, Ohio
2390. 2392, 2399.5, 2391.5 B&P Code; 11154 H&S Code
Stipulated Decision. Prescribed dangerous drugs without prior examination and medical indication, to persons not under his treatment for pathology or condition.
Revoked. May 10, 1980
Ochoa, A., M.D. (A-27737)—Fullerton
2396.10 B&P Code
Anesthesiologist grossly negligent in his course of surgery in which patient suffered cardiac arrest and died.
Revoked, stayed, five years probation on terms and conditions.
April 11, 1980
O’Donnell, Merrill C., M.D. (C-10882)—Huntington Beach
239 B&P Code
Stipulated surrender of license by aged physician desiring of retiring. Accepted. Accusation withdrawn.
June 18, 1980
Paulo, Zane D., M.D. (C-21883)—La Jolla
2361, 236(c), (e). (f). B&P Code
Stipulated Decision. Sexual transgressions by psychiatrist with female patients. Gross negligence and incompetence in prescribing a combination of controlled drugs to one patient; and in ordering another patient to abruptly stop taking his prescribed drugs, resulting in severe withdrawal symptoms and convulsions.
Revoked, stayed, actual suspension for one year, ten years probation on terms and conditions.
May 28, 1980
Pratt, George J., Jr., M.D. (C-25355)—Costa Mesa
2361, 2361(c). (e). 2395.5, 2391.5, 2417 B&P Code; 11154 H&S Code
Stipulated Decision. Sexual transgressions by psychiatrist with female patients. Unlawfully furnishing controlled drugs, including narcotics, during his sexual relationships. Indiscriminate prescribing to persons not under his treatment for a pathology or condition.
Mental illness. Prior discipline.
Revoked. May 16, 1980
Schanzloffel, Roland A., M.D. (A-07612)—Los Angeles
2395.5 B&P Code
Stipulated Decision. Prescribed dangerous drugs and controlled substances without prior examination and medical indication.
Prior discipline.
Revoked, stayed, five years probation on terms and conditions.
June 16, 1980
Schatzmann, Abe, M.D. (C-26280)—Reseda
2395.5, 2395.1 B&P Code; 11154 H&S Code
Violated graduated discipline by prescribing dangerous drugs and controlled substances without prior examination and medical indication to persons not under his treatment for a pathology or condition.
Revoked. April 11, 1980
Schultkin, Frank R., M.D. (C-27893)—San Francisco
2411, 2361, 236(c). B&P Code
Felony conviction for filing fraudulent Medi-Cal claims for psychotherapy services, requiring reimbursement of $5,000, plus $5,000 fine and other penalties.
Revoked, stayed, five years probation on terms and conditions.
May 21, 1980
Whitsell, Irelan D., M.D. (A-25272)—Hermosa Beach
2363 B&P Code
Stipulated Decision. Impaired judgment by a physician engaged in the practice of medicine in Nevada without a Nevada license.
Revoked, stayed, ten years probation on terms and conditions.
June 16, 1980
Yusko, John P., M.D. (A-12583)—Encino
2383, 2390.5, 2391.5 B&P Code; 11154 H&S Code
Stipulated Decision. Prescribed controlled drugs without a prior examination and medical indication, to a person not under his care for a pathology or condition.
Misdemeanor conviction for violating laws regulating skilled nursing facility.
Revoked, stayed, five years probation, actual suspension from practice for nine months.
May 30, 1980
Physicians Asked To Write 'No Refill' On Propoxyphene (Darvon) Rxes

To help reduce propoxyphene abuse and deaths, FDA is requesting physicians to write “no refill” on propoxyphene prescriptions for patients who appear to need the drug for only a limited time. It is also suggested that propoxyphene prescriptions be in writing and not be filled over the phone.

Propoxyphene products include Darvon, Darvon-N, Darvocet-N, other brand names, and generics. In addition to propoxyphene, many of these products contain aspirin or acetaminophen.

FDA continues to be concerned about the intentional and unintentional misuse of these products. Propoxyphene remains one of the most frequently mentioned drugs in drug-related deaths.

Last fall, the labeling of propoxyphene was revised and a patient information sheet was approved by the Agency for distribution with propoxyphene products by manufacturers on a voluntary basis. The boxed warning added to the physicians' labeling cautions physicians:

• Not to prescribe propoxyphene for patients who are addiction prone.
• To prescribe propoxyphene with caution for patients taking antidepressant drugs and patients who use alcohol in excess.
• To tell patients not to exceed the recommended dose and to limit their intake of alcohol.

In an attempt to reduce further the abuse of propoxyphene, FDA encourages physicians to adopt a “no refill” policy on all propoxyphene prescriptions for the treatment of self-limiting disorders.

INFORMATION ON PRESCRIBING OF TRANQUILIZERS

The Food and Drug Administration announced for immediate release on July 10, 1980, that manufacturers of widely prescribed tranquilizers are revising the information they provide physicians. Their advice is that tranquilizers are not for “everyday stress.”

The statement includes information that “anxiety or tension associated with stress of everyday life does not require treatment with an anti-anxiety drug.”

The Food and Drug Administration commissioner hopes that physicians will adhere closely to the revised indications and become more discriminating in prescribing tranquilizers to relieve symptoms of anxiety.

Millions of Americans (5 billion tranquilizer pills prescribed annually) are taking tranquilizers habitually just to deal with the anxiety of living.

There is great concern regarding people continually taking these drugs without the knowledge that they are becoming physically and psychologically dependent. Tranquilizer users should also be cautioned about taking alcohol or other drugs which affect the central nervous system.

SMALLPOX VACCINATIONS

A statement by the Infectious Disease Section of the California Department of Health Services.

Traditional, ingrained practices which have outlived their usefulness die hard. Physicians need to be reminded that smallpox has truly been eradicated, that active surveillance for its unlikely reappearance continues and that sufficient stockpiles of smallpox vaccine are available to contain any unexpected recurrences of smallpox transmission in human populations.

Many needless vaccinations continue to be given to travelers and employees of international airlines and shipping companies at great economic cost and risk of serious health complications. Even more worrisome is the unscientific use of smallpox vaccine for the so-called “treatment” of recurrent herpes simplex, warts and the like. Controlled clinical trials have shown that smallpox vaccine is no better than placebo for treatment of these conditions. Yet, the hazardous misuse of smallpox vaccine continues in many practices.

Smallpox vaccine needs to be withdrawn from the general market and the vaccine should be listed as a “restricted” or “controlled” biological available only from such agencies as the FDA (Federal Food and Drug Administration) or CDC (Center for Disease Control). The California Department of Health Services is in the process of asking the Bureau of Biologics of the FDA what FDA plans to do in this regard and to give FDA the Department of Health Services' thoughts on the matter. Figures from CDC indicate that more than 170,000 doses of smallpox vaccine have been distributed this year—an indication that smallpox vaccinations are being given to many persons who don't need them.