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Sacramento, California
May 26, 1981

Honorable John R. Garamendi
Senate Chamber

Sherman Food, Drug, and Cosmetic Law - #8182

Dear Senator Garamendi:

QUESTION

Does the Sherman Food, Drug, and Cosmetic Law prevent a physician from prescribing, or a pharmacist acting pursuant to the order of a physician from dispensing, a drug not approved in a federal or state new drug application?

OPINION

The Sherman Food, Drug, and Cosmetic Law does not prevent a physician from prescribing, or a pharmacist acting pursuant to the order of a physician from dispensing, a drug not approved in a federal or state new drug application.

ANALYSIS

Initially, we note that in view of your specific question, we have not, in this opinion, considered whether there is any state law, other than the Sherman Food, Drug, and Cosmetic Law, which would prevent a physician in any case from prescribing or administering a drug not approved in a federal or state new drug application.

The Sherman Food, Drug, and Cosmetic Law (Division 21 (commencing with Section 26000) of the Health and Safety Code,[1] includes within its scope or regulation the selling, dispensing, giving away, supplying, or applying of any drug in California (see Sec. 26050, H.& S.C.). Under Section 26670, a "new drug" generally may not be sold, delivered or given away unless a new drug application has been filed with, and approved by, the state or federal government.[2]

A "new drug" is defined, for the purposes of the Sherman Food, Drug, and Cosmetic Law, by Section 26021, as follows:

> "26021. 'New drug' means either of the following:
>
> "(a) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling or advertising thereof.
>
> "(b) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."

Section 26021 expressly includes as new drugs only those drugs that are advertised or labeled to prescribe, recommend, or suggest conditions for use which (1) are not

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1 All section references are to the Health and Safety Code, unless otherwise noted.

2 Certain drugs are exempted from the requirement (see Sec. 26680).

generally recognized as safe or effective applications by experts or (2) have received that recognition as the result of investigational use, but have not been employed to a material extent or for a material time outside of the investigational context. Thus, the section clearly and unambiguously defines "new drug" in relation to the conditions for use prescribed, recommended, or suggested in the labeling or advertising of a drug, rather than the actual conditions of use by the professional practitioner.

The definition of "new drug" contained in Section 26021 is modeled after the definition of "new drug" contained in the federal Food, Drug, and Cosmetic Act (see subsec. (p), Sec. 321, Title 21, U.S.C.). The federal Food, Drug, and Cosmetic Act provides for a system of premarketing clearance for drugs introduced in interstate commerce, based upon proven safety and effectiveness (Weinberger v. Hynson, Westcott, and Dunning, Inc., 37 L. Ed. 2d 207, 213-214). In interpreting the federal law, a federal district court has held "... the Food and Drug Administration does not have jurisdiction to regulate the administration of a drug by a physician (F.T.C. v. Simeon Management Corporation (N.D. Calif.), 391 F. Supp. 697, 706. The Food and Drug Administration of the United States Department of Health and Human Services has also informed us that, in its opinion, it does not have the authority under the federal Food, Drug, and Cosmetic Act to prevent a physician, or a pharmacist acting pursuant to the order of a physician, from prescribing a drug not approved in a federal new drug application.

We note that there are differences in the prohibitions respecting new drugs between federal and state law. The relevant provisions of federal law generally prohibit only introduction, or delivery for introduction, into interstate commerce of unapproved new drugs (subsec. (a), Sec. 355, Title 21, U.S.C.), whereas state law generally prohibits any sale, delivery, or gift of an unapproved new drug (Sec. 26670).

However, the Legislature adopted the essence of the federal definition of "new drug." It cannot be assumed that the Legislature was ignorant of the consequences of the language it used (County of Santa Clara v. Hall, 23 Cal. App. 3d 1059, 1065; see also County of Los Angeles v. Graves, 210 Cal. 21, 24). If the Legislature had intended to provide for more than premarketing clearance for new drugs, we think it would not have employed language so similar to that in the federal Food, Drug, and Cosmetic Act.

In our opinion the state law was designed to fill the hiatus in federal law with respect to drugs which are manufactured and marketed solely in intrastate commerce. Although, as noted above, the prohibitions of Section 26670 are different from those of the federal new drug provisions, such difference is necessitated by the application of state law to intrastate transactions. The prohibitions of Section 26670 are the analogue of the prohibitions of federal law discussed above, but are applicable to the appropriate intrastate transaction. In all other relevant respects, the federal and state schemes for regulation of new drugs are essentially parallel.

In our view there is an unambiguous statutory definition of the term "new drug" in Section 26021, which is determinative of the issue in question. The prohibitions contained in Section 26670 relate to new drugs; the section does not itself define "new drug." What is a "new drug" for purposes of Section 26670 is defined by Section 26021, which, as discussed above, makes that status dependent upon the advertising or labeling (or proposed advertising or labeling) of a drug.

Additionally, nothing in the Sherman Food, Drug, and Cosmetic Law expressly prohibits a physician from prescribing a drug not approved by a state or federal new drug application, although the act contains numerous provisions concerning prescribing and prescriptions. Where a physician issues a prescription filled by an independent pharmacist, he does not, in the literal sense, himself sell, deliver, or give away the drug as specified in Section 26670 (see Sec. 26050). An omission of an act from a penal statutory provision, such as Section 26670 (see Sec. 26801), evinces a legislative purpose not to punish the omitted act (In re James M., 9 Cal. 3d 517, 522).

Furthermore, to apply Section 26670 to a physician in the event the physician treats a patient with a "new drug," the physician would be required to comply with the new drug provisions of the Sherman Food, Drug, and Cosmetic Law. Those applicable sections require (1) new drug applications for approval of new drugs (Sec. 26670); (2) six-month waiting periods on applications (Sec. 26671); (3) hearings (Sec. 26671); (4) submitting reports of investigation and testing (Sec. 26672); (5) labeling and advertisement

(Sec. 26672); (6) manufacturing methods, facilities, and controls (Sec. 26672); (7) maintaining clinical records pending approval (Sec. 26674), and department orders withdrawing approval of applications (Sec. 26675). The intent of the Sherman Food, Drug, and Cosmetic Law is, we think, to regulate the commercial activities of persons who engage in the manufacturing of drugs, rather than to regulate a physician treating a patient on an individual basis.

In this regard, Section 26666 authorizes a physician to personally furnish his own patients with drugs that are necessary in the treatment of the condition for which the physician attends those patients. It is our opinion that Section 26666 confers the right of a physician to exercise his or her professional discretion when providing drugs in a therapeutic setting. Section 26666 makes no distinction between new drugs and other drugs, but merely refers to drugs which are necessary in the treatment of the condition (see also, Sec. 4051, B.& P.C.).

The State Department of Health Services has also adopted regulations relating to "new drugs." Section 10416 of Title 17 of the California Administrative Code reads as follows:

> "10416. Section 26666 of the Health and Safety Code shall be construed only as applying the same exemptions to labeling requirements for drugs dispensed by a physician, dentist, podiatrist, or veterinarian, as are provided for drugs sold by filling or refilling a written or oral prescription of such practitioner and shall not provide any exemption from the requirements of Section 26670 (new drugs) of the Health and Safety Code or from the requirements of Chapter 7 (commencing with Section 1700) of Division 2 of the Health and Safety Code (Cancer Law)."

However, an administrative officer may not make a rule or regulation that alters or changes the terms of a legislative enactment (Whitcomb Hotel, Inc. v. Cal. Emp. Com., 24 Cal. 2d 753, 757). Administrative regulations that violate acts of the Legislature are void, and no protestations that they are merely an exercise of administrative discretion can sanctify them; they must conform to the legislative bill to preserve an orderly system of government (Morris v. Williams, 67 Cal. 2d 733, 737). In our opinion Section 10416 of Title 17 of the California Administrative Code, relating to the furnishing of new drugs by a physician within the meaning of Section 26670, conflicts with the provisions of the Sherman Food, Drug, and Cosmetic Act discussed above, and therefore is unenforceable and void.

We think that if the Legislature had intended to preclude physicians from utilizing drugs not yet approved by either the state or federal government as safe and effective, the law would have been drafted to prohibit physicians from prescribing, as well as dispensing, those drugs. It would be illogical, in terms of rational legislative policy directed towards protection of the public from unsafe or ineffective drugs, to distinguish for that purpose on the basis of whether a physician or a pharmacist dispenses an unsafe or ineffective drug. That Section 26670 contains no express prohibition against prescribing a new drug is a further indication that the new drug provisions of the Sherman Food, Drug, and Cosmetic Law were not intended to regulate the practice of medicine, but only to provide a system of premarketing clearance for drugs based upon preapproval of labeling and advertising claims respecting safety and effectiveness.

Therefore, it is our opinion that the Sherman Food, Drug, and Cosmetic Law does not prevent a physician from prescribing, or a pharmacist acting pursuant to the order of a physician from dispensing, a drug not approved in a federal or state new drug application.

Very truly yours,

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