OFFICE OF THE ATTORNEY GENERAL
State of California

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| OPINION | : | |
| | : | No. 89-1101 |
| of | : | |
| | : | APRIL 18, 1990 |
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THE CALIFORNIA BOARD OF PHARMACY has requested an opinion on the following questions concerning Business and Professions Code section 4046, subdivision (c)(1), which provides that neither the California Pharmacy Law nor any other law shall be construed to prohibit a registered pharmacist from furnishing to a prescriber a reasonable quantity of compounded medication for prescriber office use:

(1) Does "reasonable quantity" mean any quantity requested by the prescriber as long as there is some medical basis for the use?

(2) Does "compounded medication" include medication which the pharmacy repackages but does not reformulate or admix?

(3) Does "prescriber office use" include drugs which the prescriber dispenses to patients for administration outside the prescriber's office or clinic?

## CONCLUSIONS

As used in Business and Professions Code section 4046, subdivision (c)(1), which provides that neither the California Pharmacy Law nor any other law shall be construed to prohibit a registered pharmacist from furnishing to a prescriber a reasonable quantity of compounded medication for office use:

(1) "Reasonable quantity" means the amount of medication an ordinarily prudent pharmacist would believe likely to be used or dispensed by a physician in the particular circumstances of that physician, based on all the facts known to or which should reasonably be known to the pharmacist.

(2) "Compounded medication" does include medication which the pharmacy repackages but does not reformulate or admix.

(3) "Prescriber office use" does include drugs which the prescriber dispenses to patients for administration outside the prescriber's office or clinic.

ANALYSIS

The California Pharmacy Law is found in section 4000 et seq. of the Business and Professions Code.[1] In this opinion we are asked to construe section 4046 of that law. That section was added to the Pharmacy Law in 1981 by Chapter 989, Statutes of 1981. Specifically we are asked to interpret subdivision (c)(1) thereof, which provides:

> "(c) Neither this chapter nor any other provision of law shall be construed to prohibit a registered pharmacist from:
>
> > "(1) Furnishing to a prescriber a reasonable quantity of a compounded medication for prescriber office use."

Specifically we are asked (1) whether a "reasonable quantity" of a medication as used in this subdivision is determined solely by the medical needs of the prescriber's patients or is otherwise limited; (2) whether a "compounded medication" is solely one which is reformulated or admixed, or whether it also may include medications which are repackaged by a pharmacist for the prescriber; and (3) whether "for prescriber office use" is to be restricted to the administration of supplied medications in the prescriber's office or clinic, or whether it also may include medications which are dispensed to the prescriber's patients for home use.

Preliminarily we note that the introductory language to subdivision (c) is cast in negative terms giving rise to two possible interpretations. One is that subdivision (c) is merely a rule of construction and as such is intended to merely clarify the law that the acts enumerated therein were already allowed in 1981 under then existing law. The second is that the subdivision (c) was intended to be substantive in nature and accordingly the section was intended to affirmatively authorize the acts enumerated therein. We believe that the later construction is the one which comports with legislative intent.[2]

Accordingly, in construing the meaning of subdivision (c) of section 4046 we look to the language of the subdivision as indicative of what the Legislature intended. (*Moyer* v.

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[1]All section references as to the Business and Professions Code unless otherwise indicated.

[2]Although a reasonable argument can be made that at least as to subdivision (c)(1) the Pharmacy Law already allowed pharmacists to provide prescribers with a reasonable amount of any medication for their office use when subdivision 4046 was enacted (see pre-1981 §§ 4034, 4050, 4051 and 4227 and § 26693 of the Health & Saf. Code, a provision of the Sherman Food, Drug And Cosmetics Law), we reach our conclusion as to the construction of subdivision (c) of section 4046 for two main reasons. First, our examination of the legislative history of the law disclosed that the perception in the Legislature appears to have been that affirmative authority was needed for all the pharmaceutical functions enumerated therein. Secondly, some of the additional enumerated functions in subdivision (c) were clearly not authorized under the terms of the pre-1981 Pharmacy Law (e.g., monitoring drug therapy by pharmacists in hospitals, including ordering and evaluating laboratory tests.)

*Workmen's Comp. Appeals Bd*. (1973) 10 Cal.3d 22, 230; *Brown* v. *Kelly Broadcasting Co*. (1989) 48 Cal.3d 711, 724.)[3]

1. "Reasonable Quantity"

The first question presented for resolution is whether "reasonable quantity" as used in section 4046, subdivision (c)(1) means any quantity requested by the prescriber as long as there is some medical basis for the use.

"Reasonable" is defined in Webster's Third New International Dictionary (Unabridged Edition, 1976), at page 1892 as:

> ". . . being in agreement with right thinking or right judgment: not conflicting with reason: not absurd: not ridiculous . . . b: being or remaining within the bounds of reason: not extreme: not excessive . . ."

In applying this definition to what constitutes a "reasonable quantity of a compounded medication for prescriber office use" we believe we must examine the question both from the perspective of the prescriber and the pharmacist.

As to the prescriber, we believe that section 4051 of the Pharmacy Law is most pertinent. That section presently reads as material herein:

> "(a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:
>
> "(1) The drugs or dangerous devices are dispensed to the prescriber's own patient and the drugs or dangerous devices are not furnished by a nurse or attendant.
>
> "(2) The drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
>
> "(3) The prescriber does not keep a pharmacy, open shop, drugstore, advertised or otherwise, for the retailing of drugs or dangerous devices or poisons.[4]

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[3]A construction of section 4046 as an affirmative authorization for subdivision (c) pharmaceutical functions also nullifies any suggestion that this subdivision constitutes an exception to the other provision of the Pharmacy Law and as such should by narrowly construed. (See, e.g., *City of National City* v. *Fritz* (1949) 33 Cal.2d 635, 636.)

[4]Pharmacy is defined in section 4035 of the Business and Professions Code as follows:

> "Pharmacy is an area, place, or premises in which he profession of pharmacy is practiced and where prescriptions are compounded. 'Pharmacy' includes, but is not limited to, any area, place, or premises described in a permit issued by the board by reference to plans filed with and approved by the board wherein controlled substances or dangerous drugs or dangerous devices, as they are herein defined, are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances or dangerous drugs or dangerous devices are furnished, sold, or dispensed at retail. . . ."

"(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4047.5, all of the recordkeeping requirements of good pharmaceutical practice, including the use of child-proof containers.

"(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of it and personally dispenses the drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

"(b) The Medical Board of California and the Board of Osteopathic Examiners shall have authority with the Board of Pharmacy to assure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees. . . ."

Although the term "dispense" is defined in section 4049 to mean "the furnishing of drugs upon a prescription from a physician, dentist, podiatrist, or veterinarian", "dispense" as used in this section would of necessity have a more general meaning, that is, to furnish. A physician would not write a prescription for a drug that he or she was personally supplying a patient. (See also prior version of § 4051 (Stats. 1965, ch. 1822, § 8) where the term "furnishing" was used.)

Given the fact that section 4051 contemplates that a physician may furnish his or her patients with drugs necessary to treat patients, with certain express limitations, we construe the term "reasonable quantity" as used in section 4046, subdivision (c)(1) as follows. We believe that this subdivision requires a pharmacist who furnishes a prescriber with a "compounded medication" to exercise his or her best judgment as to whether the quantity of the drug is appropriate considering a number of factors. These include (1) the pharmacist's knowledge of the use of the compounded medication by physicians generally in the area; (2) the size and nature of the physician's practice; (3) the shelf life of the medication; and (4) the reserve supply a physician would need to have in his or her office to supply his patients needs pending the time a new supply could be ordered and delivered.

From the pharmacist's perspective, we believe that experience and judgment will indicate what is "reasonable" and conversely what is "extreme" or "excessive" as to particular practitioners. Should the amount requested appear excessive to the pharmacist as to a particular practitioner, then the pharmacist must inquire as to the reasons which would justify a need for the quantity sought. If the pharmacist is not satisfied with the reasons given, he or she must decline to furnish more than what his or her judgment dictates would be needed for the particular prescriber's practice. (Cf. 16 Cal. Code Regs. § 1761, pharmacists not to compound or dispense uncertain or erroneous prescriptions; see also, generally, *Murphy* v. *E.R. Squibb & Sons, Inc*. (1985) 40 Cal.3d 672, 677-679 regarding the professional role of a pharmacist, including that "on occasion he provides doctors as well as patients with advice" regarding medications.)

Accordingly, on the first question we conclude that "reasonable quantity" as used in section 4046, subdivision (c)(1), means the amount of medication an ordinarily prudent pharmacist would believe likely to be used or dispensed by a physician in the particular circumstances of that physician, based on all the facts known to or which should reasonably be known to the pharmacist.

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The law does not define "open shop" or "drugstore."

2. "Compounded Medication"

The second question presented is whether "compounded medication" as used in section 4046, subdivision (c)(1), includes medication which the pharmacy repackages but does not reformulate or admix. We conclude that it does include such medications.

It has been suggested that subdivision (c) does not include medication which a pharmacy merely repackages and then provides to a prescriber for office use. This suggestion arises primarily from the fact that the verb to compound means ". . . 1: to put together (as elements, ingredients, or parts) to form a whole: COMBINE, UNITE 2a: to form or make up (as a composite product) by combining different elements, ingredients, or parts (~a medicine) . . ." . (Webster's Third New International Dictionary, Unabridged Edition, 1976, page 466). Thus, compounding is different from repackaging.

We reject the suggestion for two reasons. First, we return to the primary rule of construction that legislative intent is determined from the words of the statute. Section 4046, subdivision (c)(1) provides that nothing in the law shall be construed to prohibit a pharmacist from "furnishing to a prescriber a reasonable quantity of a compounded medication." The language nowhere says that it is the pharmacist who is to do the compounding. A medication containing multiple elements is a "compounded medication" whether compounded by the pharmacist, or compounded by a drug company earlier and later repackaged by the pharmacy. The word "compounded" merely modifies the word "medication" and does not state by whom or when or where the compounding is accomplished.

Secondly, "[w]here the provisions of a statute are subject to two or more reasonable interpretations, that which will harmonize rather than conflict with other provisions thereof should be adopted. (*Spreckles* v. *Graham*, 194 Cal. 516, 527 [228 p.1040.]) . . ." (*People* v. *Kuhn* (1963) 216 Cal.App.2d 695, 698.) As will be recalled, section 4051 of the Pharmacy Law, *supra*, provides now (and also provided in 1981, when § 4046 was enacted) that a prescriber may dispense drugs directly to his or her patients. Additionally, section 4227 of the Pharmacy Law provides now (and also provided in 1981 in all material respects) that a pharmacist is not prohibited from furnishing a dangerous drug to a "prescriber." Thus section 4227 provides in part:

> "(a) No person shall furnish any dangerous drug or device except upon the prescription of a physician, dentist, podiatrist, or veterinarian.
>
> "(b) This section shall not apply to the furnishing of any dangerous drug or device by a manufacturer or wholesaler or pharmacy to each other or to a physician, dentist, podiatrist, or veterinarian, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device and its quantity. . . ." (Emphasis added.)

Accordingly, sections 4227 and 4051 when read together contemplate, and have contemplated since before 1981, that a pharmacist may be supplying "any dangerous drug[s]" directly to a "prescriber", whether compounded or repackaged. We found nothing in the legislative history to section 4046 to indicate an intent to limit these sections. (See also, generally, section 26693 of the Health and Safety Code, a provision in the Sherman Food, Drug and Cosmetic Law, to the same effect both in 1981 and presently.)

We therefore conclude on question two that "compounded medication" as used in section 4046, subdivision (c)(1), does include medications compounded by a manufacturer which are merely repackaged, and not reformulated or admixed by the pharmacist.

3. "Prescriber Office Use"

The third and final question presented is whether the words "prescriber office use" as used in section 4046 subdivision (c)(1) is limited to the administration of such drugs in the prescriber's office, or whether it also includes drugs which the prescriber dispenses to patients for use outside the prescriber's office or clinic. We conclude that it includes drugs which the prescriber dispenses to patients for use outside the prescriber's office or clinic.

Initially, we note that the terminology "prescriber office use" means that the "use" is that of the prescriber, not the patient. A prescriber "uses" a drug in his or her office position, that is, "employs" it, "utilizes" it, "applies" it or "avails" himself or herself of it[5] whether it is administered in the office to the patient or is dispensed to the patient for later ingestion or administration. Had the Legislature intended that "prescriber office use" be restricted to "office administration," it could have easily said so by using such words of limitation.

Furthermore, as already noted in our response to question two, (1) section 4051 of the Pharmacy Law permitted in 1981 when section 4046 was enacted, and still permits, a prescriber to "dispense" drugs to his or her patients; and (2) section 4227 of the Pharmacy Law contemplated in 1981, and still contemplates, that a pharmacist can legally "furnish" any dangerous drug to a prescriber. Neither of these provisions contained in 1981 nor now contain any limitation that such drugs can be used only for administration in the prescriber's office.

Accordingly, harmonizing section 4046, subdivision (c)(1), as added in 1981, with both prior and current law, we believe that the Legislature did not intend to limit the term "office use" to "office administration" in section 4046 while other sections of the Pharmacy Law (and even the Sherman Food, Drug and Cosmetic Law, Health & Saf. Code, § 26693) neither provide for nor contemplate such a limitation.

We therefore conclude that "prescriber office use" as used in section 4046, subdivision (c)(1) includes furnishing drugs for prescribers which can be dispensed for administration outside the prescriber's office or clinic.

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[5]See Webster's Third New International Dictionary, Unabridged Edition, 1976, page 2524 setting forth the quoted words as synonyms for the verb "use."