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OPINION	:	No. 93-404
of	:	
	:	September 15, 1993
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THE HONORABLE MARIAN BERGESON, MEMBER OF THE CALIFORNIA SENATE, has requested an opinion on the following question:

With respect to a pharmaceutical company's clinical research program in which patients will be paid for participation in the program and will receive free drugs, medical care, and laboratory evaluations, may the company pay referral and evaluation fees to physicians for referring their patients to the program and for evaluating the results of the program?

CONCLUSION

With respect to a pharmaceutical company's clinical research program in which patients will be paid for participation in the program and will receive free drugs, medical care, and laboratory evaluations, the company may not pay referral fees to physicians for referring their patients to the program, but it may pay evaluation fees for legitimately performed evaluations of the results of the program.

ANALYSIS

The question presented involves proposed investigational drug research conducted by a pharmaceutical company in compliance with and subject to federal Food and Drug Act regulations. Patients would be paid for participation in a clinical research study and receive free drugs, medical care, and laboratory evaluations during the course of the program. In order to increase participation in the drug trials, the company will pay referral fees to physicians for referring suitable patients to the program. Evaluation fees will also be paid to the physicians for evaluating the results of the program. We are asked to determine whether these proposed payments to physicians would be contrary to state law.

Business and Professions Code section 650¹ states in part:

"... the offer, delivery, receipt, or acceptance by any person licensed under this division of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or coownership in or with any person to whom these patients, clients or customers are referred is unlawful.

"The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payor."²

As noted in 70 Ops.Cal.Atty.Gen. 65, 67 (1987), the purposes of section 650 are to protect the public from excessive health care costs, referrals based upon considerations other than the best interests of the patients, deceit and fraud, and payment to a licensee where professional services have not been rendered. In *Beck v. American Health Group Internat., Inc.*, (1989) 211 Cal.App.3d 1555, 1564, the court stated:

"The statute was intended to prevent 'the referring person [from being tempted] to suggest or prescribe extra, or more expensive services by the person to whom the patient is referred because the referring person's income is a function of the business he generates by referral.' (53 Ops.Cal.Atty.Gen. 117, 118 (1970).) The evil to be proscribed by section 650 "'... is not just the payment for the referral, but also any relationship where the referral may be induced by considerations other than the best interests of the patient'" (63 Ops.Cal.Atty.Gen. 89, 92 (1980), fn. omitted.) 'Certainly a sick patient deserves to be free of any reasonable suspicion that his doctor's judgment is influenced by a profit motive.' (*Magan Medical Clinic v. Cal. State Bd. of Medical Examiners* (1967) 249 Cal.App.2d 124, 132.)"

We have had occasion to apply section 650 in a variety of circumstances, finding a violation in some instances (see, e.g., 73 Ops.Cal.Atty.Gen. 321 (1990) [radiologists may not contract with physicians to provide imaging services for patients of the physicians, where the radiologists would charge each patient a fee for the services, the fees collected would be transmitted to the physicians, the physicians would pay stipulated amounts to the radiologists for the services, and the total amounts paid by the physicians would be independent of, but increase proportionately less than, the total fees collected from the patients]; 70 Ops.Cal.Atty.Gen. 65, *supra* [physicians may not form a professional corporation to which other physicians would refer their patients for the performance of pulmonary and cardiac stress tests, where the corporation would pay a fee to the referring physician for preparing an evaluation report of the referred patient's test data, but no legitimate reason would exist for the report to be prepared as part of the referral]), while not in others (see, e.g., 68 Ops.Cal.Atty.Gen. 28 (1985) [physician may refer patients to a clinical laboratory in which he or she owns a limited partnership interest, if the patients are informed of that interest and are free to choose another laboratory to have the work performed, there is a valid

¹All undesignated statutory references are to the Business and Professions Code.

²Physicians are licensed under the Medical Practice Act (§§ 2000-2515), part of "this division" (§§ 500-4998.7).

medical need for the referral, and the physician's return on investment is not measured by the number or value of the referrals]; 63 Ops.Cal.Atty.Gen. 89 (1980) ["professional courtesy services" may be provided by a clinical laboratory to a physician and his family where such services are not provided as compensation or inducement for referring patients to the laboratory]).

Here, as to the referral fees, the pharmaceutical company will *offer* to a *licensed* physician a *fee* as an *inducement* for the *referral* of patients to the company's clinical drug testing program. "As the prohibition [of §650] extends to *offer* and *delivery* as well as receipt and acceptance, *only one* of the two parties in a referral fee transaction need be a licensee in the healing arts for the transaction to be illegal." (*Mason v. Hosta* (1984) 152 Cal.App.3d 980, 986, emphasis added.) Moreover, it is of no consequence that the referral arrangement does not involve an excessive charge to the patient:

"The court in *Mast v. State Board of Optometry*, *supra*, 139 Cal.App.2d 78, 91, held: 'An excessive charge [to the patient] is *not* an element of the offense.' (Italics added.) Pertinent to this argument of plaintiff is the Attorney General's response in 63 Ops.Cal.Atty.Gen., *supra*, at page 94: '[S]ection 650 in no way requires . . . that there in fact be an obvious increased cost to patients [resulting from the prohibited referral fee] . . . Essentially, it is the potential for harm to patients as well as actual harm to them that is proscribed in Section 650.'" (Ibid.)

In the proposed referral arrangement, it would be the patient's physician, not the pharmaceutical company, who would determine whether the referral is in the best medical interests of the patient. That judgment could become clouded by pecuniary interests if the physician is allowed to accept a fee for the referral. As previously noted, the evil proscribed by section 650 is not simply the payment for the referral, but also any relationship with third parties whereby the referral may be induced by considerations other than the best interests of the patient.

As for the proposed evaluation fees, section 650 does not proscribe contractual agreements between physicians and others where the physicians are paid for the fair market value of their services. (See *Blank v. Palo Alto-Stanford Hospital Center* (1965) 234 Cal.App.2d 377, 390; 53 Ops.Cal.Atty.Gen., *supra*, 119.) Thus, pharmaceutical companies may provide financial support to physicians who perform actual research on new unapproved drug products and new unapproved uses of approved drugs, with the cooperation of patients from whom informed consent has been obtained.³

³In *Moore v. Regents of the University of California* (1990) 51 Cal.3d 120, the Supreme Court analyzed a physician's fiduciary duty to his patient and the requirements for obtaining the patient's informed consent prior to the performance of any medical procedure.

We therefore conclude that a physician would violate section 650 by accepting a fee for referring patients to a pharmaceutical company's clinical research program;⁴ however, evaluation fees may be paid for appropriately evaluating the results of the program.

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⁴Other statutes may have some bearing on the question of accepting fees for referring patients to clinical drug trials. If any of the participants in the referral arrangement are paid by Medicaid or Medi-Cal for services or products related to the clinical research, payment of the referral fees would be prohibited under the Medicaid and Medi-Cal anti-fraud statutes. (42 U.S.C. § 1320(a)(7)(b); Welf. & Inst. Code, § 14107.2.) Also, Health and Safety Code section 445, creating a misdemeanor for medical referrals "for profit," may apply to a physician who charges a fee for the referral of any person to a clinical research program being conducted by "a physician, hospital, health-related facility, or dispensary" on behalf of a pharmaceutical company. However, such practice could as easily be prosecuted under section 650 and would be subject to the greater penalties of that provision.