

PRESCRIPTION DRUG PRICING IN CALIFORNIA: AN ANALYSIS OF STATUTORY CAUSES AND EFFECTS

I

INTRODUCTION

During recent months Californians have been startled to learn that they pay the highest prices for prescription drugs in the Nation.¹ San Franciscans in particular were chagrined to discover that prices in northern California top the list.² In conjunction with these disclosures, several investigations of the prescription drug industry in the state have been conducted during the past year³ and others currently are in progress or are contemplated.⁴

This Comment will attempt to delineate the process by which several apparently unrelated statutes and regulations have combined, in an almost self-emulating manner, to dissipate the vigor of price competition in the California prescription drug industry. The objective is to demonstrate the necessity for an integrated revision of the laws governing sales of prescription drugs—a revision which should be based upon a comprehensive evaluation of the special problems associated with each segment of the drug industry, from research and development to ultimate consumption by the public.

¹ San Francisco Chronicle, Nov. 24, 1960, p. 1, col. 7.

² *Ibid.*

³ A federal grand jury recently concluded lengthy hearings on drug prices in northern California and indicted the Northern California Pharmaceutical Association and its pricing chairman, Donald K. Hedgpeth, for price-fixing. San Francisco Chronicle, Dec. 15, 1960, p. 1, col. 7. Evidence introduced by the Department of Justice revealed that northern California druggists had adopted the "Hedgpeth Price Schedule" as a means of setting retail prices on drugs. This schedule establishes a standard retail mark-up for drugs based upon the wholesale price of the drug and the quantity sold. On December 28, 1960, the Department of Justice filed suit against the Association in the District Court of the United States for the Northern District of California, alleging illegal restraint of trade in violation of the Sherman Act and praying that the Association and its members be enjoined from fixing the prices of prescription drugs. San Francisco Chronicle, Dec. 29, 1960, p. 11, cols. 1, 2, and 3.

The California Assembly Interim Committee on Social Welfare held hearings in San Francisco on December 8th and 9th, 1960, to investigate the prices paid by the State for drugs in caring for its dependent children, the aged, and the blind. Assemblyman Philip A. Burton (San Francisco) stated that the State of California spent \$86.5 million on its medical care program during the period from October 1957 to June 1960, of which \$34.2 million was for drugs. Assemblyman Burton expressed the hope that the State might save millions of dollars on drug purchases alone as a result of a recent announcement by committees of the American Medical Association and the American Public Welfare Association that, in writing prescriptions for indigents, generic rather than brand names should be used when a price differential exists and the quality of the drug dispensed is not placed in jeopardy. San Francisco Chronicle, Dec. 8, 1960, p. 4, col. 6.

⁴ The State of California Governor's Committee for the Study of Medical Aid and Health recently directed its attention to the matter of drug prices in California. San Francisco Chronicle, Nov. 24, 1960, p. 6, col. 7.

In addition, the State attorney general's office plans to investigate possible price-fixing by druggists in the San Francisco area, according to Assistant Attorney General Charles A. O'Brien. San Francisco Chronicle, Nov. 25, 1960, p. 2, col. 6.

II

RESEARCH, PATENTS AND TRADE-MARKS

In an effort to lend continuity to the ensuing discussion, a single drug will be traced through its development, production, and distribution. The drug chosen is prednisone, a derivative of cortisone.⁵

Shortly after cortisone was discovered and patented by Merck & Company, Schering Corporation obtained a license from Merck to produce the drug.⁶ At the same time, Schering commenced research to develop a drug even more effective than cortisone. In 1955, Schering's research proved fruitful with the discovery of prednisone and prednisolone, both of which are several times more potent than cortisone. Schering immediately filed patent applications on the new drugs and began to market them. In a short time, however, several other large drug firms, which had also conducted research in the steroid hormone field, informed Schering that they too were filing patent applications on these drugs and intended to manufacture and market them under their own trade-marks. In a move to protect all parties concerned, the several drug manufacturers entered into a rather complicated series of cross-licensing agreements which temporarily defined their respective rights to these drugs during the pending patent interference proceedings.⁷ Five years later, these same conflicting patent claims remained unresolved.

At first glance, the protection afforded by our patent laws would seem well suited to the needs of large drug manufacturers, such as Schering, who are engaged in extensive research programs. Invariably, in any discussion of current drug prices, the issues of the high research costs⁸ and the high rates of obsolescence⁹

⁵ Much of the material on prednisone was gathered from the *Hearings on Administered Prices Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary*, 86th Cong., 1st Sess., pts. 14 & 15 (1959) [hereinafter cited as *Hearings*].

Both prednisone and cortisone are steroid hormones used in treating allergic disorders, inflammatory diseases of the eye, skin diseases, pernicious anemia, and other illnesses. Their most important use today, however, is in the treatment of rheumatic diseases—especially arthritis. Although prednisone and its sister drugs do not cure, they offer welcome relief to persons suffering from arthritis and related illnesses.

For assurance that the conditions applicable to prednisone are representative of conditions prevailing in the drug industry, an examination of the entire Senate Subcommittee record is urged.

⁶ This background material was extracted from the testimony of Mr. Francis C. Brown, President, Schering Corporation, given before the Senate Subcommittee on Antitrust and Monopoly. See *Hearings*, pt. 14, at 7849-56.

⁷ For the several licensing agreement dealing with prednisone, see *Hearings*, pt. 15, at iii.

⁸ Schering's net sales in 1958 totaled \$75,180,000, while its research expenses were \$6,403,000, or 8% of the total net sales. Annual Statement, Schering Corp., 1958.

W. Furness Thompson, Vice President, Research and Development Division, Smith, Kline and French, in an article entitled *Pharmaceutical Research and Patents*, 41 J. PAT. OFF. SOC'y 70, 71 (1959), stated that "at the moment research [in the drug industry] is running 9-10% of sales as compared with something like 5-6% for industry as a whole Then the high obsolescence rate is a constant spur . . . [A]t SKF 60% of our sales are in products less than six years old" Mr. Thompson also candidly observed that "there is also the simple fact that our industry has found research to be profitable. There are unavoidable risks, but as a whole the investment pays off."

Some indication of just how well this "investment pays off" can be gathered from the concluding comments of Senator Estes Kefauver on December 12, 1959, after six days of hearings on drug prices: "[T]he industry for the past 3 years has had the highest profit rates of any industry in the country, and about twice as high as manufacturing as a whole" *Hearings*, pt. 14, at 8355. During 1957, the drug industry's rate of return was 21.4% after taxes as compared to a rate of return for all manufacturing of 11.0%. *Hearings*, pt. 14, at 7873.

⁹ For an interesting exposition of the theory that obsolescence rates among modern drugs result from attempts by the drug manufacturers to capitalize on relatively insignificant modi-

associated with modern drugs are raised. Both factors would seem to encourage the utilization of the patent system by drug manufacturers. Theoretically, under the seventeen-year monopoly granted to patentees, a successful drug researcher would be afforded ample opportunity to recoup his initial expenditure and still reap a fair and justly deserved profit for his labor. Indeed, one of the primary purposes behind our patent laws is the encouragement of capital investment in just such worthy projects by assuring the patentee of a period during which he alone can utilize the product of his inventiveness. Yet, the drug manufacturers insist that such is not the case and cite Schering's experience with prednisone as an example of the inadequate protection afforded by the patent system. They assert that there is excessive delay in the issuance of a patent; that even when issued, a patent's validity is too often subject to question; that resolution of conflicting patent claims by litigation often is economically prohibitive and time-consuming; and that, consequently, the realities of patent protection differ markedly from the theories underlying the system.

This dissatisfaction has led to an increased dependence upon trade-marks.¹⁰ In fact, the key to understanding prescription drug pricing may rest in the industry's current trade-mark practices. The simplicity of registering a trade-mark,¹¹ its potential for renewal every twenty years,¹² and its possible status of incontest-

fications of chemical compounds and not from bona fide progress in new drug development, see the testimony of Dr. Frederic H. Meyers, Associate Professor of Medicine and Pharmacology, University of California School of Medicine, San Francisco, California, in *Hearings on Administered Prices Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary*, 86th Cong., 2d Sess., pt. 18, at 10392-411, 10397 (1960).

¹⁰ The following figures demonstrate the extent to which the drug industry utilizes trade-marks: In 1958, the Pharmaceutical Extension Survey, College of Pharmacy, Rutgers University, conducted a national prescription survey, sampling 207,884 of the total prescriptions filled in the United States during that year. It reported that 184,420 (88.7%) of these prescriptions were for trade-marked drugs and 23,464 (11.3%) were for the generic drug.

The list below extracted from a chart introduced in *Hearings*, pt. 14, at 7841, reveals the variety of trade-mark names utilized in the sale of the single drug prednisone during 1959:

<i>Company Marketing Prednisone During 1959</i>	<i>Company's Trade-mark Name for Prednisone</i>
Schering Upjohn Merck & Co. Parke, Davis	Meticorten Deltasone Deltra Paracort

The drug was also sold under its generic name by several smaller companies. See appendix A, chart #3, *infra*.

¹¹ Registration of a trade-mark requires that an application be filed in the Patent Office supplying the history of the mark's use by the applicant and a "statement to the effect that the person making the verification believes himself . . . to be the owner of the mark sought to be registered, that the mark is in use in commerce, and that no other person . . . to the best of his knowledge and belief, has the right to use such mark in commerce." 60 Stat. 427 (1946), 15 U.S.C. § 1051 (1958). Subject to five enumerated exceptions which prohibit the use of certain items as registered trade-marks, the Patent Office cannot refuse registration of a mark on the principal register. See 60 Stat. 428 (1946), 15 U.S.C. § 1052 (1958).

¹² Renewal of a trade-mark registration for additional periods of twenty years can be obtained upon a showing that the mark is still in use in commerce. 60 Stat. 431 (1946), 15 U.S.C. § 1059 (1958).

ability¹³ suggest that the guiding principle in today's drug industry might well be, "One trade-mark is worth a thousand patents."¹⁴

Several important results accrue in California from the sale of a drug under a trade-mark. When a California physician writes a prescription for his patient, utilizing a manufacturer's trade-mark to designate the desired drug, state law requires that only that manufacturer's brand be dispensed in filling the prescription. This results from a series of code sections which drastically restrict the discretion allowed a pharmacist in filling prescriptions. The first is Health and Safety Code section 26255,¹⁵ which describes those drugs which can be dispensed only by prescription. The scope of section 26255 is extensive, since it encompasses not only habit-forming drugs but also any drug which is not safe for use except under the supervision of a licensed practitioner. In conjunction with this section, Health and Safety Code section 26295 makes dispensing such drugs without a prescription a misdemeanor. In addition, Penal Code section 380¹⁶ makes it a crime for a pharmacist to "substitute a different article for any article prescribed or ordered . . . or to otherwise deviate from the terms of the prescription or order . . . in consequence of which human life or health is endangered . . ." Although human health must be "endangered" before a conviction will be sustained under section 380, few pharmacists will risk even the substitution of brands in filling a prescription. Apart from criminal sanctions, the consequences arising from a violation of

¹³ If a registered trade-mark has been in continuous use in commerce for five consecutive years subsequent to its registration, it becomes incontestable upon application by the owner, provided that the mark has not been challenged successfully by another claimant and that no adverse claim of ownership is pending at the time of application for incontestability. After the five-year period, any mark which has become the common descriptive name of a particular article or substance may still be contested. 60 Stat. 433 (1946), 15 U.S.C. § 1065 (1958).

¹⁴ In contrast to trade-marks, the acquisition of a patent is an exacting process since patentability is riddled with requirements, exceptions and restrictions, 35 U.S.C. §§ 100-04 (1958). Moreover, an application for a patent and proof of patentability is an involved procedure, 35 U.S.C. §§ 111-22 (1958), followed by what often is a lengthy examination of the application by the Patent Office, 35 U.S.C. §§ 131-35 (1958), which may culminate in appeals and reviews in both administrative and judicial forums, 35 U.S.C. §§ 134-36 (1958). Finally, even if the patent is ultimately issued, it expires forever seventeen years later, 35 U.S.C. § 154 (1958).

¹⁵ CAL. HEALTH & SAFETY CODE § 26255 reads: "A drug intended for use by man which: (a) Is a habit-forming drug to which Section 26254 applies; or (b) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (c) Is limited by an effective application under Section 26288 [relating to new drugs] to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale . . ."

¹⁶ CAL. PEN. CODE § 380 reads: "Every apothecary, druggist, or person carrying on business as a dealer in drugs or medicines, or person employed as a clerk or salesman by such person, who, in putting up any drugs or medicines, or making up any prescription, or filling any order for drugs or medicines, willfully, negligently, or without consideration of those facts which by use of ordinary care and skill he should have known, omits to label the same, or puts an untrue label, stamp, or other designation of contents, upon any box, bottle, or other package containing any drugs or medicines, or substitutes a different article for any article prescribed or ordered, or puts up a greater or less quantity of any article than that prescribed or ordered, or otherwise deviates from the terms of the prescription or order which he undertakes to follow, in consequence of which human life or health is endangered, is guilty of a misdemeanor, or if death ensues, is guilty of a felony."

section 1716 of the Administrative Code, title 16,¹⁷ might prove the most disastrous to the pharmacist's professional career. This section states that "no person shall . . . substitute a drug¹⁸ that is of a different character or brand, or is a product of a different manufacturer or distributor, than that designated in a prescription."¹⁹ An unauthorized substitution can lead to a revocation of the pharmacist's license under section 4357 of the Business and Professions Code.²⁰

Suffice it to say that a Californian with a drug prescription specifying a particular ingredient by its trade name can rest assured that a reputable pharmacist will dispense only the brand specified by the doctor. Initially, this appears to be a reasonable safeguard for the protection of the patient, not to mention the doctor and pharmacist. However, the union of the above-mentioned code sections with existing trade-mark practices in the drug industry spawns a situation sufficient to give the most health-conscious Californian cause to wonder.

It is apparent that the contents of the prescription are determined by the prescribing physician—not by the druggist or the patient. If the manufacturer can convince a physician that he should prescribe a drug by the manufacturer's brand name, *e.g.*, Meticorten, rather than by its generic name, *e.g.*, prednisone, the manufacturer has "cornered" a portion of the market. Thus, the doctor plays a leading role in determining prescription drug sales. Since it is vital that physicians be made aware of the brand names of particular drugs, such as prednisone, large sums of money are spent each year by the major drug firms in promoting their individual brands.²¹ Inasmuch as the druggist, who dispenses these drugs, and

¹⁷ CAL. ADMIN. CODE tit. 16, § 1716 provides: "No person shall (a) Substitute a drug different in any respect from the one prescribed; (b) Substitute a drug that is of a different character or brand, or is a product of a different manufacturer or distributor, than that designated in a prescription, or (c) Deviate in any manner from any of the requirements of a prescription except with the prior consent of the prescriber. Nothing in this regulation is intended to prohibit a pharmacist from exercising common accepted pharmaceutical practice in the proper compounding of a prescription."

¹⁸ CAL. BUS. & PROF. CODE § 4031 defines "drug" as: "(1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement of any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; (4) articles intended for use as a component of any article specified in clause (1), (2), or (3)."

¹⁹ CAL. BUS. & PROF. CODE § 4036 defines "prescription" as "an order given individually for the person for whom prescribed, directly from the prescriber to the furnisher, or indirectly by means of a written order, signed by the prescriber, and shall bear the name and address of the prescriber, his license classification, the name and address of the patient, the name and quantity of the drug prescribed, directions for use, and the date of issue. No person other than a physician, dentist, chiropodist, or veterinarian shall prescribe or write a prescription."

²⁰ CAL. BUS. & PROF. CODE § 4357 reads as follows: "The violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provisions or terms of this chapter, or of any laws governing pharmacy, or of the rules and regulations promulgated by the board, shall constitute grounds for the suspension or revocation of any certificate, license or permit issued by the board."

²¹ During 1959 the pharmaceutical industry in the United States purchased 3,790,908,000 pages of paid medical journal advertising and 741,213,700 direct mail impressions. In addition, drug "detail men" (*i.e.*, salesmen) made well over 20 million personal calls on physicians and pharmacists. These figures appeared in a statement by Walter L. Griffith, Director of Promotion and Advertising for Parke, Davis & Co., in the PROCEEDINGS OF PROGRAM, MID-YEAR CONFERENCE, AMERICAN COLLEGE OF APOTHECARIES, 1959.

In summarizing testimony given before the U.S. Senate Subcommittee on Antitrust and Monopoly in December 1959, Senator Estes Kefauver stated that "three-fourths of a billion dollars [was] spent in advertising and detail work [amounting] to an expenditure of \$5,000 per doctor, if 150,000 doctors are considered as the market for these drugs." See *Hearings*, pt. 14, at 8356.

the patient, who consumes them, may dispense and consume only the brands indicated on the prescription, these advertising campaigns are directed almost exclusively at the doctor. The costs of such campaigns are reflected in the price of the drugs prescribed and are ultimately borne by the consumer. The physician, moreover, is not necessarily concerned with the retail prices of the drugs he prescribes, since he has no pecuniary interest in the sale itself—he neither contributes nor receives any portion of the purchase price.²² And yet, as long as the patient's health is at stake, few persons would object to their doctor prescribing on a "money-is-no-object" basis.

Absent sound medical justification, however, the use of brand names in prescribing drugs is subject to legitimate criticism, when one considers its devastating effect upon price competition among drug manufacturers.²³ Since the brand of drug sold is determined by the physician's prescription, and since he prescribes free of the economic pressure imposed by considerations of price, there is no competitive advantage to be gained by offering a brand name drug at a price lower than that established by a competitor. Thus, since competition in price will not appreciably increase the demand for a particular brand, there is a strong impetus toward uniform pricing of brand name drugs. Consequently, competition shifts from price to the field of promotion where the emphasis is placed upon more subtle considerations, such as product differentiation and public relations within the medical profession.²⁴

In conjunction with the undesirable economic consequences of this lack of price competition, it is necessary to consider the effect on public health of allowing the druggist and patient some discretion in choosing among brands of a specific drug which the doctor has prescribed. Four factors which touch upon the issue deserve mention. First, every drug which is shipped in interstate commerce must meet the health and safety standards established by the Federal Food and Drug Adminis-

²² During his appearance before the Senate Subcommittee on Antitrust and Monopoly, Dr. Frederic H. Meyers, Associate Professor of Medicine and Pharmacology at the University of California School of Medicine, San Francisco, California, made the following evaluation of the doctor's plight as a consequence of current drug industry promotional techniques: "Confused by 400 new products per year, of which obviously only a few can have lasting value; assaulted by the most skilled persuaders by mail, salesmen, journal ads, and other sources of information that are at best incomplete, and at worst dishonest; . . . with his postgraduate training weakened by the participation of industrial organizations in the activities of his professional societies; and with the buffer of a medical press, which, in my opinion, is biased in favor of the drug trade, between him and the leaders within and without the profession, it is no surprise that [a physician] often prescribes uneconomically and even, although less often, unscientifically." *Hearings on Administered Prices Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary*, 86th Cong., 2d Sess., pt. 18, at 10406 (1960). Recent events indicate a growing concern among doctors over the prices their patients are charged for drugs. See note 44 *infra*.

²³ To demonstrate the effect upon the consumer of this lack of competition, the costs of prednisone to the manufacturer, druggist, and consumer are collected in Appendix A, *infra*.

²⁴ It is interesting to note the role of the smaller companies in the drug market. Because they cannot hope to promote their drugs on a scale comparable to that of the major firms, these companies generally sell drugs under their generic names and compete on a *price* basis for purchases from those consumers who are not "trade-mark captives." This group is composed of large hospitals, the military services, the Veterans Administration and similar large drug purchasers. Due to the freedom of choice which these drug consumers possess, even the major companies must compete on a price basis. For additional information on this aspect of the drug market, see the testimony of Mr. Seymour N. Blackman, Executive Secretary, Premo Pharmaceutical Laboratories, Inc., in *Hearings*, pt. 14, at 8224-28.

tration.²⁵ These standards, coupled with those imposed by similar state regulations governing intrastate drug manufacturers,²⁶ do much to assure a high degree of quality in the drugs available to the consumer.²⁷ Second, drugs marketed by several companies often are manufactured by a single firm. This firm sells the drug in bulk form to the other companies, which merely tablet, bottle, and label it under their own trade-marks prior to distribution. The quality of the several brands is identical, subject, of course, to possible contamination during the process of tabletting and bottling the drug. Third, under existing laws, prescription of a drug by its generic name enables the druggist to exercise his discretion in dispensing any of the several brands of the drug which are on the market. Fourth, medical associations recently have urged doctors to utilize generic names, rather than brand names, in writing prescriptions for indigents, unless safety factors clearly dictate otherwise.²⁸ These considerations suggest that an argument in favor of liberalizing the current California laws restricting the sale of trade-marked prescription drugs can be made without total disregard for the public's health and safety. At least, they indicate that particular trade-marked drugs are not the only pharmaceutical products on the market which meet the high standards set by the medical profession.

III

RETAIL DRUG PRICING

At the retail level, two additional California measures have a significant impact on prescription drug pricing. They are section 651 of the Business and Professions Code²⁹ and the California Fair Trade Act,³⁰ as supplemented by the McGuire Act.³¹

²⁵ See 52 Stat. 1049 (1938), 21 U.S.C. § 351 (1958).

²⁶ Drugs in California are regulated under the California Pure Drugs Act, CAL. HEALTH & SAFETY CODE §§ 26200-385.

²⁷ In 1960, the California Department of Social Welfare conducted a statewide investigation of prescription drug pricing to determine the validity of criticism of the prices charged the State by druggists under California's Public Assistance Medical Care Program. As a part of this investigation, the Department purchased 391 prescriptions at random throughout the State, utilizing prescriptions which ordered the drug by generic name. The Department reported in part as follows: "Personnel from the California State Board of Pharmacy inspected all of the prescriptions that were purchased. Several were selected for assay and all of them proved to be well within the standards established by the U.S.P. . . . It is therefore apparent that in moving toward the use of generic names in its medical care program, the department is in no way sacrificing quality of drugs." CALIFORNIA ASSEMBLY INTERIM COMMITTEE REPORTS (1959-60), vol. 19, No. 10, *Report of the Assembly Interim Committee on Social Welfare* contains the entire Department of Social Welfare survey at 23-28.

²⁸ See note 44 *infra*.

²⁹ CAL. BUS. & PROF. CODE § 651 provides: "It is unlawful for any person licensed under this division or under any initiative act referred to in this division to offer for sale or to sell any commodity or to offer to render or to render any service under the representation that the price or fee which is to be, or is, charged for such commodity or service, or both, is at a discount, or under the representation that the price or fee which is to be, or is, charged for such commodity or service, or both, is at a percentage or otherwise less than the average fee or price then regularly charged under like conditions by the person so licensed or by other persons for such commodity or service or commodity and service. The provisions of this section shall not be construed to modify or establish prices or fees or to modify or affect in any manner any other provision of this division."

³⁰ CAL. BUS. & PROF. CODE §§ 16900-05.

³¹ 66 Stat. 632 (1952), 15 U.S.C. § 45 (1958). The McGuire Act exempts resale price maintenance agreements applicable to goods in interstate commerce from federal antitrust proceedings when such agreements are lawful as applied to intrastate sales under state law.

A. California Business and Professions Code Section 651

Section 651 prohibits persons licensed under division 2 of the Business and Professions Code (which includes pharmacists) from selling or offering for sale "any commodity or . . . service under the representation that the price or fee . . . is at a discount . . . or otherwise less than the average fee or price then regularly charged under like conditions by the person so licensed or by other persons for such commodity or service . . ." According to the attorney general of California, this section was enacted to prevent professional men, such as pharmacists, from engaging in an "unseemly rivalry which would enlarge the opportunities of the least scrupulous."³² The attorney general's opinion goes on to state that section 651 does not prohibit the *charging* of a lower price, but only the *representation* that the price charged is lower than that which one would normally expect to pay. In effect, however, the statute eliminates price competition among retail druggists. By prohibiting advertising of lower prices, it destroys the essence of such competition—i.e., making the public aware of the differences in prices. Even conceding that it is desirable to restrain price competition as to *services rendered* by professional men, this does not justify the imposition of identical restraints on price competition as to *goods sold* by druggists. If the fee for professional services and the price charged for the drug were stated separately when the customer is billed, the protection against "unseemly rivalry" afforded by section 651 could still be accorded to the "professional" aspects of the transaction, while permitting price competition as to the sale of the drug.

B. California Fair Trade Act

The California Fair Trade Act,³³ which is typical of most fair trade acts,³⁴ enables manufacturers and distributors of trade-marked products to bind purchasers not to resell except at prices set by the manufacturers or distributors.³⁵ The

³² 27 OPS. CAL. ATT. GEN. 288 (1956). The recent experience of the National Association of Retired Persons and the National Retired Teachers Association may shed some light on the function of this statute, as well as the Fair Trade Act of California.

In 1959, the two nonprofit organizations decided to render assistance to their 250,000 elderly members by obtaining drugs for them at a 25% discount. Reputable pharmacists in both California and Washington, D.C., agreed to assist them, and the service was announced to the members through the associations' magazines. Miss Ethel P. Andrus, President of the two associations, testified before the U.S. Senate Subcommittee on Antitrust and Monopoly as to what followed this announcement: "Early in October 1959, official representatives of the Board of Pharmacy of the State of California informed the California druggist serving our group there that filling of prescriptions at a reduced rate to us was contrary to California law [CAL. BUS. & PROF. CODE § 651], and that he should, on October 15, 1959, cease and desist . . ." *Hearings*, pt. 14, at 8263.

The service to members from the California pharmacy was terminated. But in the short period during which it operated, the associations found that members in non-fair trade states were returning the drugs sent them from California, explaining that even with the 25% discount, they were still able to purchase these drugs at lower prices from their local retail druggists. *Hearings*, pt. 14, at 8276.

³³ CAL. BUS. & PROF. CODE §§ 16900-05. Because California prescription drug prices are currently well above fair trade prices established throughout the country, drug manufacturers are not faced with a problem of policing their fair trade contracts in California. For example, Schering Corporation has established a fair trade price of \$29.83 per hundred for 5 milligram tablets of Meticorten; however, these same tablets sell for \$32.40 per hundred in northern California under the "Hedgpath Price Schedule." See note 3 *supra*, and Appendix B *infra*.

³⁴ The fair trade acts of other states are reproduced in 2 TRADE REG. REP. ¶ 10,000.

³⁵ For a comparison of fair trade prices, non-fair trade prices, and California prices on prednisone, see Appendix B *infra*.

"non-signer provision"³⁶ of the act subjects purchasers (generally retailers) who are not parties to a fair trade contract to damages or injunctive proceedings should they knowingly sell, or offer for sale, a commodity below the price agreed upon by other purchasers.³⁷

The purpose of fair trading purports to be the protection of the manufacturer's goodwill, which is inherent in its trade-mark or brand-name.³⁸ The theory is that when a consumer sees a brand-name product selling on the market at differing prices, he experiences an irreparable loss of faith in the product's continuing high quality, and, while in this unsettled state, changes to another brand with a uniform price.³⁹ Concerned over such a possibility, the California Legislature, through its Fair Trade Act, authorized manufacturers to impose price restrictions on retail sales to consumers—subject, however, to the condition that the manufacturer's product be in "fair and open competition with commodities of the same general class produced by others."⁴⁰ The legislature recognized that vigorous price competition among retailers selling the same trade-marked product would be sharply curtailed under the act. It theorized, however, that reasonable prices could be maintained by competition among manufacturers of "commodities of the same general class." The motivation for this price competition was to stem from the freedom of the consumer to choose a lower-priced brand from the "general class" of competing commodities, if he so desired.

In the drug industry no one contests the existence of keen competition among manufacturers for the doctor's prescription. But this is not price competition and does not satisfy the "fair and open competition" requirement of the California Fair Trade Act. The act requires *sale* competition, not *prescription* competition, and if the customer has no freedom to choose on the basis of price, there is no competition for the sale *to him*. Apparently, what constitutes "fair and open competition" among fair-traded prescription drugs has not been decided by the courts

³⁶ CAL. BUS. & PROF. CODE § 16904 reads: "Wilfully and knowingly advertising, offering for sale or selling any commodity at less than the price stipulated in any contract entered into pursuant to this chapter, whether the person so advertising, offering for sale, or selling is or is not a party to such contract, is unfair competition and is actionable at the suit of any person damaged thereby."

³⁷ The importance of the "non-signer provision" was summed up in a brief submitted to the Interstate and Foreign Commerce Committees of Congress by Herman S. Waller, legal counsel to the National Association of Retail Druggists: "The basic reason for the 'non-signer provision' in the State Fair Trade Acts is the very practical fact that without it systematic price maintenance is not effective. There are always some retailers who in the absence of compulsion will refuse to observe the manufacturer's minimum prices . . . Experience under the California law of 1931 [before the "non-signer provision" was added] shows the futility of relying on voluntary price maintenance." The entire brief is reproduced in *Hearings on Fair Trade Before a Subcommittee of the House Committee on Interstate and Foreign Commerce*, 85th Cong., 2d Sess., at 356-466 (1958).

³⁸ The underlying assumption that patients are aware of the *drug* prescribed, much less its *brand*, seems questionable.

³⁹ For a more detailed analysis of fair trade laws, their development, and the theories underlying them, see 1 TRADE REG. REP. ¶ 3,000; ATT'Y GEN. NAT'L COMM. ANTI-TRUST REP. 149-55 (1955); *Hearings on Fair Trade Before a Subcommittee of the House Committee on Interstate and Foreign Commerce*, 85th Cong., 2d Sess. (1958); Adams, *Fair Trade and the Art of Prestidigitation*, 65 YALE L.J. 196 (1955); Adams, *Resale Price Maintenance: Fact and Fancy*, 64 YALE L.J. 967 (1955); Grether, *Experience in California with Fair Trade Legislation Restricting Price Cutting*, 24 CALIF. L. REV. 640 (1936); Herman, *A Note on Fair Trade*, 65 YALE L.J. 23 (1955).

⁴⁰ CAL. BUS. & PROF. CODE § 16902.

of any state having a fair trade act similar to California's.⁴¹ Consequently, the path is open for the California courts to rectify the present situation by requiring "fair and open competition" for the sale as a condition precedent to the fair-trading of prescription drugs.⁴²

IV

THE CURE

The question remains: What to prescribe for the patient? The objective should be to effect a complete recovery. For this reason, there can be no one simple answer. However, if the ills plaguing the drug industry have been diagnosed correctly,⁴³ the obvious cure would be an injection of price competition at both the wholesale and retail levels. Unfortunately, industries do not engage in price com-

⁴¹ Only two cases have squarely dealt with the general problems of fair-trading prescription drugs. In *Hoffmann-La Roche v. Schwegmann Bros. Giant Super Mkts.*, 122 F. Supp. 781 (E.D. La. 1954), the defendant's pharmacist filled a prescription specifying a trade-marked drug by placing the drug in a standard druggist's container which did not designate the brand of the drug. The drug was then sold below the fair trade price. Apparently, both parties assumed that the drug was in "fair and open competition" under the Louisiana Fair Trade Act (LA. REV. STAT. §§ 391-96 (1950)), even though the pharmacist's discretion in filling the prescription was restricted under laws similar to those of California. The federal district court found the defendant guilty of violating the act, concluding, *inter alia*, that "the seller undertakes to guarantee to the purchaser that what is delivered is the trade named product." *Id.* at 787. The court went on to state that "awareness by the customer of the name of the drug in his prescription is not an essential factor in determining whether or not the trade name of the manufacturer is utilized in selling a Fair Traded product. The goodwill established in prescription drug trade-marks, brands and names is inseparably bound with prescriptions which physicians write for their patients." *Ibid.* The Court of Appeals for the Fifth Circuit, holding that the patient impliedly adopted the doctor's request for the trade-marked drug in presenting the prescription to the druggist, affirmed the decision, 221 F.2d 326 (5th Cir.), *cert. denied*, 350 U.S. 839 (1955). What the Supreme Court might have done with the defense that there was no "fair and open competition" is open to speculation.

In a more recent case, *Upjohn Co. v. Save-Mor Drugs, Bethesda, Inc.*, 1960 Trade Cas. ¶ 69,827 (Md. 1960), the defendant argued that there was no "fair and open competition" within the meaning of Maryland's Fair Trade Act as to prescription drugs. Unfortunately, the defense was raised in a contempt proceeding arising from the violation of an injunction. Although the court categorized the defense as collateral to the issue of contempt, it did recognize the important ramifications of the argument and directed that the main case be advanced on its calendar.

For an interesting review of non-prescription drug cases dealing with the "fair and open competition" clause, see Herman, *Free and Open Competition*, 9 STAN. L. REV. 323 (1957).

⁴² The California Supreme Court has affirmed the validity of both the California Fair Trade Act and its "non-signer provision." *Max Factor & Co. v. Kunsman*, 5 Cal. 2d 446, 55 P.2d 177 (1936); *Pyroil Sales Co. v. The Pep Boys*, 5 Cal. 2d 784, 55 P.2d 194, *aff'd*, 299 U.S. 198 (1936).

⁴³ Apart from the interrelationship of the California code sections and the practices of drug manufacturers, there are other causes of high drug prices. Price fixing may well be one. See note 3 *supra*. Furthermore, 4% of the drug price paid by the California consumer consists of a sales tax imposed by CAL. REV. & TAX. CODE § 6051. Four bills have been introduced at the 1961 session of the legislature to abolish the sales tax on prescription drugs. See A.B. 60, 521 (Reg. Sess., 1961); S.B. 6, 62 (Reg. Sess., 1961). Part of the high cost of prescription drugs can also be traced to the large inventories maintained by pharmacists. The fact that they must stock virtually every brand of every drug in order to fill whatever trade-marked prescription a doctor may write greatly increases the size and cost of their inventory. In addition, California druggists assert that their standard overhead costs are higher than those in other states. They also point out that part of the price paid for drugs includes a fee for professional services. In this regard it is interesting to note that 94.5% of all drugs prescribed in the United States during 1958 were dispensed by druggists in the same form as received from the manufacturer. See National Prescription Survey, note 14 *supra*.

petition in the absence of a promise of pecuniary recompense, or, perhaps, a threat of some governmental sanction. As long as the consumer exercises no choice in the brand of drug he purchases, drug manufacturers lack incentive to compete on a price basis at the wholesale level. And as long as drugs are subject to section 651 of the Business and Professions Code and to the California Fair Trade Act, drug-gists are precluded by law from engaging in price competition at the retail level.

On the other hand, from the standpoint of public health and safety, it is equally undesirable to vest absolute discretion as to the drug to be purchased in either the patient or the pharmacist; the ultimate decision unquestionably must remain with the doctor. But it is difficult to imagine that physicians and pharmacists working together cannot devise standards of equivalency for most drugs and drug brands which would prove acceptable to all concerned, without endangering the public's health. Certainly, no one should experience qualms in vesting a licensed pharmacist with the modicum of discretion necessary to choose or substitute one brand of drug for another, when both brands are on an officially promulgated list of equivalents. He already possesses a comparable amount of discretion when a doctor prescribes a drug by its generic name.⁴⁴ If a searching examination of the problem by members of the medical profession reveals that considerations of public health and safety preclude alteration of the present statutory scheme in order to stimulate price competition, then increased government supervision may well prove the only solution.

With these factors in mind, the following courses of action are suggested for consideration:

1. A board of pharmacists and physicians should be established to regulate the dispensing of drugs. Perhaps a nonmedical member should also be included. The board would establish standards and tables of drug equivalency and would promulgate an official list of drug equivalents for use both by physicians and pharmacists. This list could supplement present official drug compendia (*United States*

⁴⁴ The advantages and disadvantages of the use of generic, rather than trade-mark, names are covered in detail in *Hearings on Administered Prices Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary*, 86th Cong., 2d Sess., pt. 21 (1960).

The Saturday Review, Aug. 6, 1960, p. 45 contained an article entitled, *A Physician's Revolt—Objective: to Free the AMA of Drugmakers* by Edgar F. Mauer, M.D., Chairman of the Los Angeles County Medical Association Sub-Committee on Generic Terms. In the article, Dr. Mauer notes that the Los Angeles County Medical Association on May 9, 1960, adopted a report of his Sub-Committee which recommended "that medical associations encourage physicians to prescribe by using generic (official) terms." Dr. Mauer quoted from an earlier report presented by the Reference Committee on Insurance and Medical Services of the American Medical Association during the Association's clinical session in December 1959, and approved by the AMA's House of Delegates: "Physicians might well give consideration to prescribing by generic rather than trade names; they might seek knowledge of relative costs of comparable drugs and they might give consideration to the more frequent use of accepted drug products of reasonable cost in treatment of welfare patients." Commenting on the Association's active support of quality medical care for the needy, Dr. Mauer stated, "it is our proud claim that indigent patients receive the finest medical care. This being so, and generically termed drugs being good enough for them, it means that we must be consistent and demand useful generic terms for all our patients' drugs We know that the costs of medical care include, in addition to doctors' fees, the costs of hospitalization and drugs. Any blanket criticism of the costs of medical care will include the physician. Shall we accept the responsibility for all of these costs, even defend them, or shall we attempt by rational means to control some of these costs? We have no intention of telling the drug industry how to conduct its business. On the other hand, we have the right and duty to practice as we teach. We urge the use of generic terms. We desire simple generic terms, not pseudo-scientific gibberish."

Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, and the National Formulary). To enable druggists to use the list, both Penal Code section 380 and section 1716 of the Administrative Code, title 16, should be amended to permit substitution of approved equivalents. Meanwhile, the board should encourage physicians to utilize generic names in prescribing drugs when they lack sound medical reasons for prescribing by trade-mark names, and an effort should be made to educate the public as to the significance of the brand names used in drug prescriptions.

2. The effect of section 651 of the Business and Professions Code on retail price competition should be scrutinized carefully. The practicability of amending this section to permit price competition in the sale of the drug itself while, at the same time, preventing unscrupulous competition as to professional services should be given serious consideration.

3. The California Fair Trade Act should be amended to specifically require sale, rather than prescription, competition as a prerequisite to fair trading of prescription drugs. In the alternative, the act should be amended to exempt the sale of prescription drugs.

4. Failing all else, the feasibility of regulating the net profits of the drug industry in a manner similar to public utilities might well be studied.

Some, perhaps all, of the suggested courses of action may not prove feasible. Nevertheless, the need for remedial legislation seems apparent. As this Comment has attempted to demonstrate, the present price conditions in California's drug industry appear to be the result of an unfortunate union of several seemingly unrelated statutes. If such is the case, prospects for an early termination of current drug pricing practices seem bright, for dilemmas created by statute can be resolved by statute.

*John C. Vernon, Jr.**

* Member, Class of 1961.

APPENDIX A

COMPUTED COSTS OF PREDNISONE TO THE MANUFACTURER COMPARED TO
WHOLESALE PRICES CHARGED

(The following charts and figures were extracted from *Hearings*, pt. 14 at 7893 and 8042.)

1. The first chart shows the cost of purchasing bulk prednisone from a manufacturer (in this case, Syntex Corp.), putting it in tablet form, and placing the tablets in bottles. It is assumed that the manufacturer of bulk prednisone included his costs of research in the price charged the purchasing drug company and that the manufacturer made a profit on the sale.

PREDNISONE—5 MGM TABLETS

(Computed cost based on bulk price transaction and contract processing charges.)
[1,000,000 tablet order]

1. Bulk price at which Syntex sold, per gram, 3d quarter, 1959, \$2.36 per gram: material for 1,000 tablets: 5 x 2.36.....	\$11.80
2. Allowance for wastage (3%).....	.36
3. Tableting charge	1.25
4. Bottling charge (1,000 tablets per bottle).....	.20
TOTAL Cost (per 1,000 tablets).....	\$13.61

2. The second chart reflects the mark-ups to both the druggist and the consumer.

COMPARISON BETWEEN COMPUTED COST AND ACTUAL PRICES

1. Computed cost, excluding selling and distribution costs.....	\$13.61
2. Actual prices:*	
a. To druggists	\$170.00
b. To consumers	\$283.33

* Upjohn (Deltasone); Merck (Deltra); Schering (Meticorten); Parke, Davis (Paracort). American Druggist Blue Book (1959-60 ed.). [Parke, Davis consumer prices 1 cent higher per bottle than others.]

Note that the four major drug firms listed in the chart, after deducting their initial production costs (\$13.61) from their wholesale price to the druggist (\$170.00), retain \$156.39 per 1,000 tablets. This \$156.39 covers the expense of labeling and shipping the bottles to druggists, advertising and promoting the drug, and profits from the same. Again, the research costs incurred in the development of the drug are included in the \$13.61 and are not attributable to any portion of the \$156.39.

3. The third chart reveals the broad scale of the wholesale prices charged for prednisone. Note that while there is a wide variance in these prices, those of the large companies are uniformly higher. This chart uses a unit of one hundred tablets in contrast to the one-thousand tablet unit of the two preceding charts.

PREDNISONE

Wholesale Prices by Size of Company, 1959
(per hundred 5 mgm tablets)

Annual Sales of Company (thousands of dollars)	Price of Prednisone	Company
0 to 99	\$ 6.95	Penhurst
100 to 249	\$12.00	Lannett
250 to 999	\$ 6.75	Bryant
1,000 to 4,999	\$ 4.00	Physicians' Drug & Supply
5,000 to 9,999
10,000 to 49,999	\$ 9.33	U.S. Vitamin & Pharm. Co.
50,000 to 99,999	\$17.90	Schering
100,000 to 149,999	\$17.90	Upjohn
150,000 to 199,999
200,000 and over	\$17.90	Merck

1. The sales figures represent *total* sales for each company, not just prednisone sales.
2. The prednisone sold by each of the listed companies meets the standards of the official compendium, *U.S. Pharmacopoeia*.

This chart, compiled in advance of the 1959 Senate hearings, does not reflect the lowest wholesale price quotations for prednisone in 1959. During that year, Premo Pharmaceutical Corporation (whose drug also meets *U.S. Pharmacopoeia* standards) sold prednisone under its generic name to druggists at \$2.55 per hundred 5 milligram tablets. Premo purchased portions of its bulk prednisone from Merck & Co. at \$2.35 per gram. See *Hearings*, pt. 14 at 8225. Note that Merck & Co.'s wholesale price (\$17.90) to the druggist is over seven times greater than Premo's price (\$2.55) to the druggist. (Again, it must be assumed that Merck & Co. made a profit on its bulk sale to Premo at the price of \$2.35 per gram.)

Subsequent to the 1959 hearings, Senator Estes Kefauver, Chairman of the Senate Subcommittee on Antitrust and Monopoly, received a letter from Herbert H. Haft, President of Dart Drug in Washington, D.C. Mr. Haft stated that prednisone had been offered to his drug-store chain at \$1.75 per hundred 5 milligram tablets and \$17.00 per thousand 5 milligram tablets. The letter appears in later committee records. See *Hearings on Administered Prices Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary*, 86th Cong., 2d Sess., pt. 17 at 9662 (1960).

APPENDIX B

COMPARATIVE FAIR TRADE, NON-FAIR TRADE AND NORTHERN CALIFORNIA PRICES ON PREDNISONE
Listed below are the prices applicable to the sale of one hundred 5 milligram tablets of prednisone. Column I lists those prices applicable to prednisone sold under Schering Corporation's brand name, Meticorten; Column II lists those prices applicable to prednisone manufactured by the Carroll Chemical Company of Baltimore, Md., under its generic name, prednisone. The prednisone of both companies meets the standards of the Federal Food and Drug Administration.

	Column I Schering's Meticorten	Column II Generic Prednisone
1. Wholesale price to druggist.....	\$17.90	\$2.70
2. Non-Fair Trade retail price.....	\$19.90*	\$3.60*
3. Fair Trade retail price.....	\$29.83	-----
4. Northern California retail price under the "Hedg- peth" Price Schedule (see note 3 <i>supra</i>).....	\$32.40	\$6.50

* Price charged by Dart Drug, a retailer in Washington, D.C.