

Recent Multistate Enforcement Initiatives: Prescription Drug Promotional Practices

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I. INTRODUCTION

Numerous states, through their Attorneys General Offices and particularly their consumer protection divisions, have been actively applying state consumer protection laws to various health law issues. These activities reflect an increasing priority and emphasis within various state Attorneys General Offices on focusing limited enforcement resources on issues of key importance to consumers, such as health care.

To put the subject of recent multistate enforcement activities concerning prescription drug marketing practices in a somewhat larger perspective, the following discussion highlights a few related state activities that have occupied the multistate agenda during the past year. In June 1994 a number of states formed an informal working group of consumer protection staff members committed to pursuing health fraud enforcement.¹ Through this health fraud working group, the states are pursuing a number of health law enforcement matters. These matters range from traditional health quackery problems (e.g., investigation of medical devices claiming to synchronize and improve brain wave activity and devices offering the much-desired panaceas of smoking cessation or weight loss) to potential false and misleading advertising claims and marketing practices (e.g., in the sale of hearing aids²).

Many states continue to work with, and urge additional action by, the Food and Drug Administration (FDA). Several examples will illustrate this interaction. In August 1993, thirty-four states petitioned the FDA,³ urging the adoption of a requirement for

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¹ Although the composition of the states' consumer protection health fraud group has varied depending upon the particular investigation or issue involved, the group has included the states of Arizona, California, Connecticut, Florida, Illinois, Iowa, Maryland, Massachusetts, Minnesota, Missouri, New Mexico, New York, North Carolina, Pennsylvania, Tennessee, Texas, Vermont and Wisconsin.

² For example, on April 6, 1994, a multistate settlement between 36 states and Dahlberg, Inc., the manufacturer of the Miracle Ear hearing aid and Clarifier circuits, was announced. The states alleged that Dahlberg's broadcast and print advertising violated state consumer laws by misrepresenting that Miracle Ear hearing aids could eliminate unwanted background noise, allowing hearing aid users to understand conversations even in crowded and noisy environments. The states alleged that this claim was false and misleading because no hearing aid can eliminate background noise or focus on the sound that an individual wants to hear. The settlement requires that future advertising explain that hearing aids may not provide the same benefits to most or all users and that the overall benefit provided by hearing aids may depend on proper fit, the degree or severity of hearing loss, and the accuracy of patient evaluation. The settlement also requires Dahlberg to explain, in advertisements for the Clarifier, that it is an option and that understanding speech still may be difficult in noisy settings. There was no admission of wrongdoing by Dahlberg. In the Matter of Dahlberg, Inc., No. C8-94-3296 (Minn. Ramsey Co. Dist. Ct. Apr. 6, 1994) (Order Approving Assurance of Discontinuance and Assurance of Voluntary Compliance and Discontinuance). *See also infra* notes 7-8 and accompanying text.

³ Citizen's Petition by Att'y Gen. of Ala., Ariz., Cal., Conn., Del., Fla., Guam, Haw., Idaho, Ind., Iowa, Ky., Md., Mass., Mich., Minn., Mo., Mont., Nev., N.M., N.Y., N.D., N. Mar. I., Ohio, Okla., Or., R.I., S.D., Tenn., Tex., Utah, Vt., Wash., & Wis. to DHHS & FDA, *Petition for Rules to Require Warning Labels for Oral Preparations Containing Iron and for Rules Regarding the Packaging and Appearance and Coat*

warning labels on iron supplements to address the tragic problem of iron poisonings and deaths of children who accidentally ingest those products. Since 1986, about forty children between the ages of nine months and three years old have died in the United States from swallowing iron supplements. From 1986 through 1991, poison control centers received nearly 40,000 reports of the ingestion of adult iron supplements by children under six.⁴ The states were pleased with the FDA's favorable response through an October 1994 proposed regulation.⁵ This regulation would require that packages of capsules and tablets containing iron be labeled with warnings not to leave the packages open or within reach of children. The proposed regulation would further require manufacturers to put any product containing thirty milligrams or more of iron in individual dose packaging, such as blister packages.⁶

In January 1994, thirteen states filed comments with the FDA urging the adoption of regulations to protect consumers from abuses in the marketing of hearing aids.⁷ On October 21, 1994, fourteen states further urged the FDA to preserve the minimum qualification standards for those who conduct hearing evaluations for consumers prior to their purchase of a hearing aid.⁸

Various states also have encouraged the FDA to address the growing phenomenon of prescription drug manufacturers who offer promotional programs that pay pharmacists for arranging consumer switches to the sponsoring manufacturer's drug or otherwise inducing the use of the manufacturer's drug.⁹

II. MULTISTATE SETTLEMENTS ADDRESSING PHARMACIST PAYMENT PROGRAMS

Two multistate investigations and settlements conducted during the past year addressed the issue of pharmacist payment programs.

A. *Miles Inc.*

On April 4, 1994, eleven states entered into an agreement¹⁰ with Miles Inc. that

ing of High Potency Oral Preparations Containing Iron (Aug. 17, 1993).

⁴ *Id.* at 2, 12.

⁵ 59 Fed. Reg. 193 (Oct. 6, 1994) (to be codified at 21 C.F.R. §§ 101, 107, 310).

⁶ A more recent related states' initiative aimed at protecting children from accidental poisoning is reflected in a May 31, 1995 letter from Wisconsin Attorney General James E. Doyle, on behalf of 24 states, to Ann Brown, Chairman of the Consumer Product Safety Commission (CPSC). The states urged the CPSC to issue a final rule changing the child-resistant packaging test protocols under the Poison Prevention Packaging Act of 1970, in order to revise the testing method and make packaging closures adult-friendly and easier to open while maintaining their child-resistance. On June 15, 1995, the CPSC announced its unanimous decision to issue a final rule changing the make-up of the test panel by substituting senior adults, ages 50-70, for younger adults. In announcing the final rule, CPSC estimated that such adult-friendly packaging should help to further reduce the annual 1,000,000 calls about ingestions reported to poison prevention centers, the 130,000 poisonings treated at hospital emergency rooms, and the 50 poisoning deaths of young children. CPSC, OFFICE OF INFO. & PUB. AFF., NEWS FROM CPSC (June 15, 1995).

⁷ Comments of Att'ys Gen. of Ariz., Fla., Ill., Mass., Minn., Mo., N.M., N.Y., N.C., Pa., Tex., Vt. & Wis. to FDA, Dkt. No. 93N-0372 (Jan. 10, 1994).

⁸ Letter from Ariz., Conn., Ind., La., Me., Md., Mass., Mich., Minn., N.M., N.Y., Pa., R.I., & W. Va. to David A. Kessler, Comm'r, FDA (Oct. 21, 1994).

⁹ Letter from Hubert H. Humphrey III., Att'y Gen., Minn., on behalf of Ariz., Ark., Conn., Fla., Haw., Idaho, Ill., Iowa, Kan., Md., Mass., Mich., Minn., Nev., N.M., N.Y., R.I., Tex., Vt. & Wis. to David A. Kessler, Comm'r, FDA (May 4, 1994).

¹⁰ In the Matter of Miles, Inc., No. C7-94-3189 (Minn. Ramsey Co. Dist. Ct. Apr. 4, 1994) (Order

resolved the states' allegations of consumer law violations arising from the company's pharmacist payment program for its antihypertensive prescription drug, Adalat CC. In the settlement, Miles did not admit to violating any law and the company characterized the payments in question as payment for "cognitive services" provided by participating pharmacists to consumers.¹¹

The factual background of the dispute is as follows. In April 1993, the FDA approved Miles' new drug approval application (NDA) for Adalat CC.¹² In June 1993, Miles offered pharmacies nationwide \$35 for each consumer who switched to Adalat CC from its sole competitor's nonbioequivalent drug (Pfizer Inc.'s Procardia XL). The original offer made no mention of "cognitive services." Following a complaint from its competitor, Miles changed the offer to one involving the payment of \$35 for "cognitive services" rendered to consumers by participating pharmacies. Under this modified program, participating pharmacies were required to provide Miles with confidential consumer information (for example, the consumers' names and the amount of the drug dispensed in exchange for the payment). Certain state laws, however, prohibit pharmacists from releasing confidential information about consumers to third parties without the consumers' consent or an authorizing court order.

Under the settlement, Miles agreed: (1) not to resume the challenged program or any similar one involving payments to pharmacists; (2) to comply with the federal Medicare-Medicaid anti-kickback law,¹³ even though Miles did not admit to having violated this act with its challenged program; (3) not to try to obtain confidential consumer information in the future; (4) to delete from its database improperly obtained consumer data; (5) to refrain from using such data for any purpose; and (6) to pay \$605,000 to the eleven participating states for costs of the investigation, attorney fees, and/or consumer education purposes.¹⁴

B. *The Upjohn Company*

In August 1994, eight states reached a similar settlement¹⁵ with The Upjohn Company to reform various promotional practices used by the company when marketing its prescription diabetes drug, Glynase PresTab Tablets. In promoting its new version of the drug (Glynase) following loss of patent rights on an earlier nonbioequivalent version (Micronase), Upjohn solicited and paid pharmacies and pharmacy chain stores to encourage consumers and their physicians to switch to Glynase prescriptions. Again, there was no admission of wrongdoing by the company in the settlement. Upjohn characterized the payments in question as reimbursement for "cognitive services."¹⁶ The settlement did not resolve the parties' significantly different views concerning the legality of the challenged payment programs.

Under the settlement, Upjohn is barred from resuming the Glynase pharmacist pay-

Approving Assurance of Discontinuance and Assurance of Discontinuance/Assurance of Voluntary Compliance).

¹¹ *Id.*, ¶¶ 7-8.

¹² *Id.* ¶ 2.

¹³ Social Security Act, Pub. L. No. 92-603, § 1128B(b), 86 Stat. 1329 (codified at 42 U.S.C. § 1320a-7b(b) (1991)).

¹⁴ *Miles*, No. C7-94-3189, ¶¶ 27-29.

¹⁵ In the Matter of the Upjohn Company, No. C7-94-7856 (Minn. Ramsey Co. Dist. Ct. Aug. 1, 1994) (Order Approving Assurance of Discontinuance and Assurance of Discontinuance/Assurance of Voluntary Compliance).

¹⁶ *Id.* ¶ 12.

ment programs. The company further agreed that all its promotion materials regarding a switch to Glynase would include information concerning potential health risks (for example, the need for retitration and the risk of blood glucose control loss) and possible increased medical costs in switching to Glynase. Additionally, Upjohn is prohibited from making unsubstantiated advertising claims concerning product superiority or potential consumer cost savings. The settlement further provided for the payment of \$675,000 by Upjohn to the eight participating states.¹⁷

C. Overarching State Concerns

The states' concerns in this area transcend the specifics of individual enforcement actions. Ongoing state concerns about pharmaceutical industry promotional programs encompass fundamentally important legal and policy issues.

First, states are concerned about the potential of such payment programs to undermine the high level of trust placed by the public in pharmacists as providers of neutral, independent professional services. Second, such payment programs may threaten consumers' health interests in transferring from one prescription drug to another, and may subject consumers to the increased costs associated with a transfer. Third, consumers' privacy interests are undermined when a pharmacist shares confidential consumer information with third parties, such as the manufacturer-sponsor of the program. Fourth, the failure to disclose the existence, amount, and purpose of these hidden payments deprives consumers of material information needed to make informed purchasing decisions and to evaluate the drug information they are receiving from the participating pharmacist. Similarly, the lack of disclosure to the prescribing physician denies him or her important information needed to make informed decisions in the best interests of the patient-consumer. Fifth, such payment programs risk shifting competition from where it should be—centered on providing the highest quality prescription drugs at the lowest costs—to where it has no legitimate place—the absurd question of which manufacturer is offering the largest monetary reward for use of its product. Sixth, health care provider payment programs invite scrutiny under prohibitions against the payment of kickbacks, including the Medicare-Medicaid anti-kickback law. The states are encouraged by the Office of Inspector General's (OIG's) enforcement and public education efforts, including the issuance by OIG of Special Fraud Alerts on this subject.¹⁸

States have continued their efforts in this area via submission of comments¹⁹ on the American Pharmaceutical Association's draft guidelines on pharmacist payment programs.²⁰

III. THE SINGLE CONSTANT: CHANGE

The only constant in today's health care market is change. The past is no more. Both law enforcement officials and perhaps regulators are struggling to understand and

¹⁷ *Id.* ¶¶ 34-42.

¹⁸ OFFICE OF INSPECTOR GENERAL, DHHS, SPECIAL FRAUD ALERT ON PRESCRIPTION DRUG MARKETING SCHEMES (Aug. 1994) (OIG-94-18); OFFICE OF INSPECTOR GENERAL, DHHS, SPECIAL FRAUD ALERT ON ARRANGEMENTS FOR THE PROVISION OF CLINICAL LAB SERVICES (Oct. 1994) (OIG-95-03).

¹⁹ Letter from Hubert H. Humphrey III., Att'y Gen., Minn., on behalf of Conn., Fla., Iowa, Md., Mass., N.M., N.Y., N.C., R.I. & Vt. to Dr. Susan Winckler, Am. Pharm. Ass'n (Dec. 16, 1994).

²⁰ AM. PHARM. ASS'N, INTERPRETIVE GUIDELINES FOR PARTICIPANTS IN INNOVATIVE, SPONSORED OUTREACH PROGRAMS AFFECTING THE PRACTICE OF PHARMACY (draft Oct. 1994).

catch up with the radical changes taking place in the health care market. The ground is constantly opening under the feet of those who walk through this environment.

The traditional pharmaceutical market is threatened with extinction. In the old market physicians were the key decision makers. Therapy choices were driven largely by medical and prescription drug advances. Pharmaceutical manufacturers focused their marketing efforts largely on one-on-one detailing with physicians. Payors included the government, employers, insurance companies, and consumers, all of whom sometimes were removed from drug therapy decisionmaking and frequently lacked information about its costs.

The emerging environment is radically different. The physician's role remains important as a gatekeeper of public health, but cost containment is becoming the driving force in the new market. This force operates through a number of different mechanisms, including drug formularies, generic substitution laws and programs, drug utilization review, and therapeutic switch programs. The role of third-party payors and their agents is growing. Already-intense competitive pressures are building. Marketing efforts continue to shift away from detailing and toward, direct-to-consumer advertising, promotional programs involving payments to health care providers, and merger activity. Merger activity includes mergers both among pharmaceutical manufacturers and between pharmaceutical manufacturers and prescription benefit management companies (PBMs).

The states have a strong interest in these changes. Basic consumer protection should not get lost in the medical care maelstrom. For example, in the area of pharmaceutical industry acquisitions of PBMs, the states are grappling with a number of public interest questions: To what extent are consumers' privacy interests being protected? Is the information held in PBMs' computer databases being safeguarded? Is such confidential data being used for the limited purposes that it was collected in the first place or is it being utilized for drug marketing purposes?

Are the traditional cost containment functions of PBMs shifting to include marketing activities on behalf of the acquiring pharmaceutical manufacturer's product line? If so, what are the consequences to the public? Is the information flow — the communication process between the PBM and physicians or consumers to encourage switches to generics or brand name therapeutic equivalents — complete enough to ensure informed decisionmaking? If such communications are changing so as to encompass marketing or promotional purposes (that is, encouraging the PBM's use of the manufacturer-acquirer's products), are the FDA's drug advertising regulatory requirements triggered? Are all material facts being disclosed during such communications between PBM-employed pharmacists and physicians? Is the relevant information presented with fair balance, and does it include information on benefits and risks, side effects, and contraindications for the products? To what extent are consumers — those whose bodies these highly complex and never entirely risk-free drugs ultimately will enter — informed about and involved in these changes, or are they largely excluded from meaningful participation in the process? These are not easy questions, but they are greatly important to the public and to the states.

IV. CONCLUSION

As highlighted in this article, enforcement activities in the area of health fraud, including multistate enforcement initiatives in the area of prescription drug promotional practices, illustrate some of the states' ongoing enforcement concerns. The states look forward to working cooperatively, whenever possible, with the FDA, other state

and federal enforcement agencies, and the health care industry in addressing consumer protection issues of public importance. The continued application of state consumer laws to the health care industry will contribute to maintaining, in a rapidly changing environment, industry practices focused on truthful advertising, fair competition, informed consumer choice, and public health.