POTENTIAL LIABILITY ASSOCIATED WITH RESTRICTIVE DRUG POLICIES

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Introduction

Health care providers have instituted a variety of measures to control the cost of prescription medicines as a response to pressure for cost containment. One such measure is therapeutic substitution, through which pharmacists may substitute different drugs from those prescribed by physicians. Health care providers believe that therapeutic substitution will reduce the cost of providing prescription drug benefits to patients by substituting less costly alternates for prescribed drugs. Concern has been expressed, however, that inappropriate substitutions might result in suboptimal treatment, increased side effects, or other problems that can increase the overall cost of patient care, thereby offsetting savings achieved in drug costs.

Restrictive drug policies and therapeutic substitution can have the additional unintended effect of increasing the liability exposure of physicians, pharmacists, and institutional health care providers. This potential increase in liability might take the form of regulatory sanctions or monetary liability to patients who might be injured by therapeutic substitution.

I

The American Medical Association and the American Pharmaceutical Association have jointly defined therapeutic substitution as the "act of dispensing a therapeutic alternate for the drug product prescribed."[1] Therapeutic alternates are defined as "drug products containing different therapeutic moieties but

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[1] Medicine in the Public Interest, Inc., *Therapeutic Substitution Symposium* 1 (1986) (comments of Herbert S. Carlin, Associate Director and Apothecary-in-Chief, Emeritus, New York Hospital).

which are of the same pharmacologic and/or therapeutic class that can be expected to have similar therapeutic effects when administered to patients in therapeutically equivalent doses."[2]

The practice of therapeutic substitution creates a greater potential for harm to patients than does generic substitution. Generic substitution is the act of dispensing a different brand containing the same active ingredient as the prescribed drug. In the case of generic substitution, the dispensed drug is chemically identical and in the same dosage form, but distributed by different companies.[3]

Unlike generic substitution, which is expressly authorized under the laws of every state,[4] therapeutic substitution arguably is of doubtful legality and confined to narrow circumstances in those few states where it is expressly permitted.

Every state imposes significant regulatory controls on the practice of medicine and the practice of pharmacy. Practitioners of either profession cannot obtain a license before satisfying educational and training requirements to be established by the state. Licenses to practice may be revoked if a physician or pharmacist engages in conduct not permitted by the applicable statutes and regulations.[5]

The practice of medicine as defined by state law always includes the act of prescribing drugs. For example, New York defines the practice of the profession of medicine as "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition."[6] In contrast, no state, with the exception of Florida, includes authority to prescribe drugs within the practice of pharmacy.[7] Although Florida pharmacists have been granted authority to prescribe drugs on their own initiative, that authority is limited to selecting drugs from a small number of classes, such as analgesics, antihistamines,

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2 *Id.*

3 *Id.*

4 *See, e.g.*, D.C. CODE ANN. § 33-731-35 (1988); GA. CODE ANN. § 26-4-81 to -84 (1982); KY. REV. STAT. ANN. § 217.822 (Michie/Bobbs-Merrill 1982); OR. REV. STAT. § 689.515 (1989).

5 *See, e.g.*, CONN. GEN. STAT. ANN. § 20-175 (West 1989); KAN. STAT. ANN. § 65-1627 (1985); LA. REV. STAT. ANN. § 1225 (West Supp. 1988).

6 N.Y. EDUC. LAW § 6521 (McKinney 1985).

7 FLA. STAT. ANN. § 465.003 (West 1981).

decongestants, and drug shampoos.[8]

A typical definition of the practice of pharmacy is found in the Louisiana Pharmacy Code of Ethics.[9] The statute states:

> The term 'practice of pharmacy' or 'practice of the profession of pharmacy' means and includes the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling, drugs, medicines, or poisons, pursuant to prescriptions or orders of physicians, dentists, veterinarians, or other licensed practitioners, or any other act, service operation or transaction incidental to or forming a part of any of the foregoing acts, requiring, involving or employing the science or art of any branch of the pharmaceutical profession, study or training.[10]

Thus, under the respective state definitions of the practice of medicine and the practice of pharmacy, it may be argued that a pharmacist who engages in therapeutic substitution is practicing medicine and not pharmacy.

II

The question of the legality of therapeutic substitution is also raised by state antisubstitution laws. Many states have laws expressly prohibiting pharmacists from deviating from a physician's prescription by substituting another product, except where otherwise permitted.[11] Permissible situations might include, for

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[8] *See* FLA. STAT. ANN. § 465.186(1) (West Supp. 1989); FLA. BD. OF PHARMACY RULES § 21S-18.003 ("Prescriptions of Certain Medicinal Drugs by Pharmacists"). For a discussion of other states permitting therapeutic substitution in certain circumstances, see *infra* notes 17-22 and accompanying text.

[9] LA. REV. STAT. ANN. § 37.1222 (West 1974).

[10] *Id. See, e.g.*, IND. CODE ANN. § 25-26-13-2 (Burns Supp. 1989) (practice of pharmacy includes "the responsibility for advising, as necessary, as to the contents, therapeutic values, hazards, and appropriate manner of use of drugs or devices"); KY. REV. STAT. ANN. § 315.010(10) (Baldwin 1986) (" 'Practice of pharmacy' means a health service which includes the dispensing, storage, and instruction as to the proper use of drugs, . . . the maintenance and management of health and the encouragement of safety and efficacy in those activities"); MD. HEALTH OCC. CODE ANN. § 12-101(j)(ii) (1986) (practice of pharmacy includes "[p]roviding information and explanation to patients and health care practitioners about the safe and effective use of drugs, medicines, or devices").

[11] *See, e.g.*, COLO. REV. STAT. § 12-22-124 (1985); CONN. GEN. STAT. ANN. § 20-175(5) (West 1989); HAW. REV. STAT. § 328-6(15) (1985); IND. CODE ANN. § 25-26-13-16 (West 1980); KAN. STAT. ANN. § 65-1627(6) (1985); LA. REV. STAT. ANN. § 1225(6)(a) (West Supp. 1988); MICH. STAT. ANN. § 14.15(17764)(a) (Callaghan 1988); MO. ANN. STAT. § 338.055(16) (Vernon 1989); NEB. REV. STAT. § 71-1, 147.10(6)(d) (1986); N.M. STAT. ANN. § 26-1-3(J) (1987); N.D. CENT. CODE § 43-15-

example, where the conditions for generic substitution are met or where the physician has expressly authorized the substitution in the particular case.[12] Therapeutic substitution arguably may not fit within these categories.

The history of state enactments addressing the much more limited practice of generic substitution is also relevant. Antisubstitution laws, passed by states in the 1940s and 1950s, prohibited pharmacists from deviating in any respect from a physician's prescription. After extensive reconsideration, every state later enacted laws permitting pharmacists to engage in generic substitution under specific circumstances. The earlier prohibitions against substitution remain in effect either expressly or implicitly. Indeed, many states did not repeal the antisubstitution laws; they merely amended the laws in limited fashion to permit generic substitution.[13]

In order to enhance patient safety and consumer protection, states carefully limit the authority of pharmacists to engage in generic substitution. In particular, all states require physicians to follow specified procedures in order to consent, expressly or implicitly, to generic substitution.[14] Similarly, all states provide that

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43(3) (Supp. 1989); TEX. REV. CIV. STAT. ANN. art. 4542a § 12(h) (Vernon Supp. 1990); W. VA. CODE § 30-5-12 (1986). *See also* ALA. CODE § 34-23-8 (1985); DEL. CODE ANN. tit. 24, § 2589(a) (Supp. 1986); ILL. ANN. STAT. ch. 56-1/2, para. 503.14 (Smith-Hurd 1985); MINN. STAT. ANN. § 151.21(1) (West 1989); MONT. CODE ANN. § 37-7-504 (1989); OHIO REV. CODE ANN. § 4729.38(E) (Anderson 1987).

[12] *Supra* note 11.

[13] *See, e.g.*, D.C. CODE ANN. § 33-735(a) (1988); GA. CODE ANN. § 26-4-84 (1982); KY. REV. STAT. ANN. § 217.822(4) (Michie/Bobbs-Merrill 1982); OR. REV. STAT. § 689.515(9) (1989); VT. STAT. ANN. tit. 18, § 4608(b) (1982); WYO. STAT. § 33-24-151(a) (Supp. 1986).

[14] For example, many states permit generic substitution only if the physician has signed a prescription over a statement such as "may substitute" or "substitution permitted." *See, e.g.*, ALA. CODE § 34-23-8(3) (1985); ARIZ. REV. STAT. ANN. § 32-1963.01(D) (1986); DEL. CODE ANN. tit. 24, § 2589(b)(1), (c) (Supp. 1986); ILL. ANN. STAT. ch. 111, para. 4145 (Smith-Hurd Supp. 1989); KAN. STAT. ANN. § 65.1637 (1985). Other states permit generic substitution unless the physician has indicated that the prescription must be dispensed as written. *See, e.g.*, ARK. STAT. ANN. § 17-91-503(b) (1987); COLO. REV. STAT. § 12-22-124(2) (1985); CONN. GEN. STAT. ANN. § 20-185b(b) (West 1989); D.C. CODE ANN. § 33-733(2), (3) (1988); GA. CODE ANN. § 26-4-83(b) (1982); MICH. STAT. ANN. § 14.15(17755)(3) (Callaghan 1988). A number of other restrictions also appear in various state generic substitution laws, such as permitting substitution only when it results in a savings to the consumer, *see, e.g.*, NEB. REV. STAT. § 71-5404(1) (1986); NEV. REV. STAT. ANN. § 639.2585(2) (Michie 1986); N.H. REV. STAT. ANN. § 146-B:2(III) (Supp. 1989); N.J.

physicians may prohibit such substitution.[15]

It could be argued that state laws do not implicitly permit the broad and potentially dangerous practice of therapeutic substitution, since express statutory authorization was required for the much less controversial practice of generic substitution.[16] Accordingly, if therapeutic substitution is to be permitted at all, it would be reasonable to argue that such a practice must be sanctioned by explicit legislative guidance.

Only a few states, such as California, Mississippi, Washington, and Wisconsin, expressly permit therapeutic substitution even in limited circumstances.[17] Although these states permit therapeutic substitution, they exercise careful control over the situations in which it is permissible. In California, for example, therapeutic substitution is limited to pharmacists in licensed health care facilities, primarily hospitals and skilled nursing facilities, acting pursuant to an order or authorization made by the patient's prescribing physician and in accordance with the policies, procedures, or protocols of the facility.[18] In Mississippi, only pharmacists in institutional settings may engage in therapeutic substitution, and the practice must be in accordance with written guidelines or protocols previously established and approved by the Board of Pharmacy.[19] Although therapeutic substitution is permitted outside of hospitals in Washington, it is permitted only in accordance with a protocol previously filed

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STAT. ANN. § 24:6E-7 (West Supp. 1988), or if the drug to be substituted is listed in a formulary, *see, e.g.*, D.C. CODE ANN. § 33-732(a) (1988); ILL. ANN. STAT. ch. 111, para. 4145 (Smith-Hurd Supp. 1989); MASS. GEN. LAWS ANN. ch. 112, § 12D (West 1983); NEV. REV. STAT. § 639.2597 (1987); N.J. STAT. ANN. § 24:6E-7 (West Supp. 1988).

15 *Supra* note 14.

16 *See, e.g.*, Kokoszka v. Belford, 417 U.S. 642, 650 (1974) (in interpreting a statute, a court must examine " 'the whole statute (or statutes on the same subject) and the objects and policy of the law, as indicated by its various provisions, and give to it such a construction as will carry into execution the will of the Legislature' ") (quoting Brown v. Duchesne, 60 U.S. (19 How.) 183, 194 (1857)).

17 *See* CAL. BUS. & PROF. CODE § 4046(c)(4)(D) (West Supp. 1990); MISS. CODE ANN. § 73-21-73(m), (4) (1989); WASH. REV. CODE ANN. § 69.41.110(3) (1985); WASH. ADMIN. CODE § 360-12-140 (1982) ("Pharmacist prescriptive authority — Prior board notification of written guidelines or protocol required"); WIS. STAT. ANN. § 450.01(16)(h) (West Supp. 1989).

18 CAL. BUS. & PROF. CODE § 4046(c)(4)(D) (West Supp. 1990).

19 MISS. CODE ANN. § 73-21-73(m), (r) (1989).

with the Board of Pharmacy.[20] The protocol must identify the physician, the pharmacist, the time period involved, the pharmacist's authority, and procedures for how decisions will be documented and how feedback from the physician to the pharmacist will take place.[21] In Wisconsin, therapeutic substitution is limited to pharmacists in hospitals, acting in accordance with protocols that have been previously established by a hospital's pharmacy and therapeutics committee, approved by the hospital's medical staff, and approved by the prescribing physician.[22]

It has been suggested that therapeutic substitution may be legal when conducted in hospitals in accordance with previously established protocols or formularies. The theory apparently is that such protocols provide adequate physician authorization for a pharmacist to deviate from the prescription actually written in a particular case. The pharmacist, therefore, would not be engaging in forbidden substitution.

While relevant, the existence of a protocol is not necessarily conclusive. The history of generic substitution laws discussed above could support the conclusion that any form of substitution might be considered illegal unless explicitly permitted under state law or expressly authorized by the physician in the individual case.

Indeed, if therapeutic substitution were impliedly permissible, there would have been no need for generic substitution laws, physicians and pharmacists merely could have adopted protocols allowing generic substitution. Moreover, in view of the statutory procedural requirements for generic substitution, it would be incongruous to permit entities such as private hospitals to develop their own procedures for therapeutic substitution. Thus, while therapeutic substitution in hospitals does occur, the practice might raise concerns of statutory compliance outside of those few states where it is expressly authorized.

The expansion of therapeutic substitution to managed health care systems such as health maintenance organizations (HMOs) and preferred provider organizations (PPOs) is equally open to question. A recent study indicates that therapeutic sub-

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20 WASH. ADMIN. CODE § 360-12-140(1) (1982).

21 *Id.* § 360-12-140(2)(a)-(d).

22 WIS. STAT. ANN. § 450.01(16)(h) (West Supp. 1989).

stitution is currently being conducted by some HMOs,[23] but that doubts concerning its legality are commonly cited by HMO administrators as a reason for not adopting the practice.[24]

A distinction between therapeutic substitution in hospitals and therapeutic substitution in HMOs and other organizations can be supported by an examination of state law. In states that expressly authorize therapeutic substitution, the practice is limited to hospitals or other skilled-care facilities.[25] This limitation demonstrates the concern of state legislatures that patient health may be compromised by extending the practice beyond skilled-care facilities. In addition, many state generic substitution laws provide certain exemptions for hospitals, further demonstrating greater leeway to these institutions than that afforded to HMOs and other organizations.[26] For these reasons, the existence of therapeutic substitution in hospitals does not necessarily justify extending the practice to HMOs or PPOs.[27]

III

Practices permitted by state laws provide a background for

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[23] Managed health care systems impose therapeutic substitution on physicians by restricting the organizations' internal formularies or by instituting restrictive policies for reimbursing independent pharmacists. *See* Doering, Russell, McCormick & Klapp, *Therapeutic Substitution in the Health Maintenance Organization Outpatient Environment*, 22 DRUG INTELL. & CLIN. PHARM. 125 (Feb. 1988).

[24] *Id.*

[25] *See supra* notes 17-19, 22 and accompanying text.

[26] The exemptions generally are limited to institutions such as hospitals or acute-care facilities, and do not apply to HMOs. *See, e.g.*, ALA. CODE § 34-23-8(5) (1985) (generic substitution law does not prohibit use of formulary adopted by medical staff in a licensed hospital); HAW. REV. STAT. § 461-2 (Supp. 1989) (practice of pharmacy includes "adjusting the dosage of a patient's drug regimen pursuant to a physician's order or authorization," in accordance with protocols in a licensed acute-care hospital); NEB. REV. STAT. § 71-5404(8) (1986) (nothing in generic substitution statute prohibits a licensed hospital "from establishing rules and regulations regarding the method by which medications are prescribed and dispensed" for patients); *see also* NEV. REV. STAT. ANN. § 639.2589 (Michie 1986) (distinguishing generic substitution in a skilled nursing facility or intermediate care facility, where a statement regarding substitution must appear on the physician's order, from procedures in hospitals, where substitutions may be made pursuant to a formulary approved by the hospital's medical staff for specific generic substitutions).

[27] Ohio is the only state that expressly includes HMOs in the exemption from requirements of the generic substitution statute. The provision does not, however, permit therapeutic substitution. *See* OHIO REV. CODE ANN. § 4729.381 (Anderson 1987).

consideration of the consequences of therapeutic substitution, particularly the possibility of physician or other provider liability. These liability concerns must be considered in light of the possibility that one or more individuals could be injured by therapeutic substitution in the context of health care organizations such as HMOs and PPOs. This article will not discuss that possibility beyond simply noting the potential for harm inherent in a system under which outpatients would be receiving drugs different from the ones actually prescribed by their physicians, with the associated problems of different adverse event profiles, dosing regimens, and the like.[28]

It must be emphasized that while regulatory sanctions or monetary liability might seem unlikely in the abstract, they are far more likely to be imposed following harm to an actual patient. In such a context, regulatory authorities, judges, and juries would be more likely to construe any ambiguities in the law against permitting therapeutic substitution. Thus, whatever legal arguments might be constructed in favor of therapeutic substitution, the absence of clear statutory authorization could weigh against those who injure a patient as a result of therapeutic substitution.

The possibility of liability need not await injury actually caused by therapeutic substitution. Any patient, for whom a drug was substituted who subsequently suffers an adverse event or fails to respond to treatment, may allege that the unfavorable outcome was caused by the act of therapeutic substitution. Even if the more likely cause of injury were some other event, a factfinder could still conclude that therapeutic substitution played a sufficient role to justify finding liability.[29]

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[28] These problems would be exacerbated where physicians belong to more than one PPO, each with a different therapeutic substitution policy. Similar problems arise when only a segment of a physician's patient population is subject to restrictive drug policies. Under such circumstances, it would be difficult for a physician to anticipate which drugs might be substituted for any particular patient.

[29] *See, e.g.*, Coffran v. Hitchcock Clinic, Inc., 683 F.2d 5 (1st Cir.), *cert. denied*, 459 U.S. 1087 (1982). The court stated that

> when the defendant omitted a safety precaution which would have had at least a substantial likelihood of saving the plaintiff from harm, courts have been generous in permitting the evidence to go to the jury over a defendant's motion for a directed verdict, even 'though it is often a pretty speculative matter, whether the precaution would in fact have saved the victim.'

Id. at 11 (quoting 2 F. HARPER & F. JAMES, THE LAW OF TORTS, § 20.2 (1956)).

Traditionally, pharmacists have not had to face significant liability exposure.[30] Their primary defense has been that they were merely following a physician's orders. Under existing law, "[i]t is the physician, and not the pharmacist, who has complete responsibility for choosing and informing the patient about the drug."[31] Courts have generally accepted this formulation and refused to hold pharmacists liable for accurately filling a physician's prescription.[32]

This defense could be unavailable, however, where therapeutic substitution has taken place since, by definition, the pharmacist has dispensed a drug different from the one prescribed by the physician.[33] Pharmacists could be held to a standard of care in selecting medicines that exceeds their expertise.[34] In addition, noncompliance with state laws regulating pharmacy and the practice of medicine could constitute negligence per se, thus making the pharmacist liable merely upon a minimal showing of causation.[35]

It is also possible that physicians could be held liable in damages for permitting the practice of therapeutic substitution. For example, liability could be based on a physician's failure to prevent or to provide adequate treatment of a condition caused or exacerbated by a drug substituted without the physician's knowl-

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30 *See, e.g.*, Duckworth, *The Potential Liability of Pharmacists Arising from Announcements of New Standards and Codes of Practice*, 43 FOOD DRUG COSM. L.J. 1, 1-2 (1988).

31 *Id.* at 4.

32 Thus, "pharmacists are not subject to liability without fault under the doctrine of implied warranty, strict liability in tort, or for a failure to warn a patient of a drug's side effect when they fill prescriptions in accordance with a physician's directions." *Id.* at 9. Under negligence standards, the pharmacist's sole duty generally is "to fill a prescription exactly as written by a physician." *Id.* at 3. *See also* Jones v. Walgreen, 265 Ill. App. 308 (App. Ct. 1932); D. BRUSHWOOD, PHARMACY LAW 51 (1986).

33 Duckworth, *supra* note 30, at 5 (pharmacist's defense unavailable where a different product is substituted for the one prescribed by the physician); *see also* Murphy v. E.R. Squibb & Sons, Inc., 40 Cal.3d 672, 676-80, 710 P.2d 247, 251-53, 221 Cal. Rptr. 447, 449-52 (1985) (immunizing pharmacist from strict liability in part on the ground that pharmacist only offers product prescribed by physician).

34 *See generally* Duckworth, *supra* note 30 (discussing liability of pharmacists for failure to conform to standards of conduct regarding patient counseling).

35 *See, e.g.*, Hardaway v. Consolidated Paper Co., 366 Mich. 190, 198, 114 N.W.2d 236, 239 (1962); Martin v. Herzog, 228 N.Y. 164, 168, 126 N.E. 814, 815 (1920) (The violation of a safety statute "is more than some evidence of negligence. It *is* negligence.") (emphasis in original); White v. Gore, 201 Va. 239, 242, 110 S.E.2d 228, 231 (1959); RESTATEMENT (SECOND) OF TORTS § 288B(1) (1965).

edge. The physician might also be found to have engaged in improper delegation of medical functions by permitting the pharmacist to engage in therapeutic substitution.[36]

Although conceivable, it is not likely that an HMO or other managed health care organization would lose its license for permitting or requiring therapeutic substitution. Nevertheless, there could be exposure to liability for damages if a patient is injured in connection with therapeutic substitution. Liability could be based, for example, on the organization's role in instituting and maintaining the therapeutic substitution policy.[37] Indeed, one commentator recently stated that an HMO should be liable if it "restricts its formulary to a risky drug and denies its physicians access to alternatives."[38] Finally, adverse publicity surrounding an injury allegedly caused by inappropriate therapeutic substitution also could result in substantial harm to the health care organization.

Conclusion

This article has discussed arguments that could be made regarding the situations in which therapeutic substitution is permitted under state laws. Although the use of protocols might make therapeutic substitution consistent with some state laws, such protocols are not sufficient to remove all doubts concerning therapeutic substitution. Thus, the continued practice of therapeutic substitution might pose the risk of liability exposure to health care providers. Consequences of this liability exposure could include regulatory sanctions, civil liability for compensatory and punitive damages, as well as the loss of good will and diminished public image.

For these reasons, in the absence of full disclosure to consumers and explicit legislative guidance, restrictive drug policies

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[36] *See, e.g.*, MICH. COMP. LAWS ANN. § 333.16215(1) (West 1980) (physician shall not delegate a task that requires the level of education, skill, and judgment required of a physician).

[37] *See, e.g.*, White v. Hardy, 678 F.2d 485, 487 (4th Cir. 1982); Cummings v. Walsh Constr. Co., 561 F. Supp. 872, 879 (S.D. Ga. 1983); Autrey v. Blue Cross & Blue Shield, 481 So.2d 345, 347-48 (Ala. 1985); Corsetti v. Stone Co., 396 Mass. 1, 482 N.E.2d 793, 798 (1985).

[38] Note, *Drug Product Liability and Health Care Delivery Systems*, 40 STAN. L. REV. 989, 1012 (1988).

and the resulting therapeutic substitution might increase the liability exposure of physicians and other health care providers.