Substitution Gets Limited Okay From Science Group

Drug Research Board says physician shouldn't specify brand unnecessarily

A prestigious medical group has issued a statement which assigns to pharmacists a more important role in drug product selection than medical men have traditionally been willing to grant. In fact, the statement appears to endorse the pharmacist's right to substitute one brand for another under certain circumstances, without first consulting with the prescribing physician.

The action was taken in the form of a resolution and accompanying "narrative", prepared by the Drug Research Board. DRB is part of the National Academy of Science, a quasi-governmental organization that advises Congress and federal agencies on scientific matters. (NAS was, for example, the organization to which the Food & Drug Administration turned over the job of evaluating all prescription drugs against the effectiveness standards imposed by the Kefauver-Harris Amendments of 1962.)

The Drug Research Board prepared its statement following meetings with representatives of the American Pharmaceutical Association and the Pharmaceutical Manufacturers Association on the subject of substitution and generic prescribing.

The position taken by the 18-man drug group will soon be considered by NAS itself. Whatever stand is taken by NAS could influence Congressional action with regard to reimbursement for drugs under Medicare, Medicaid, or national health insurance.

Good reason: What the DRB resolution says, in effect, is that a physician should not insist on a specific brand unless he has good reason based on his own knowledge of product quality and/or cost.

Similarly, the resolution says, a pharmacist should not substitute unless he can defend his action on the basis of quality and cost.

Full text of the resolution and accompanying narrative appears on this page.

Breakthrough: Edward G. Feldmann, associate executive director for Scientific Affairs of APhA, said the DRB position is a lot closer to APhA's stand on substitution than any major medical group has previously been willing to take. In fact, Dr. Feldmann said, the statement is a "breakthrough" in APhA's campaign to enlist medical profession support for its drug

(Continued on P. 24)

TEXT OF DRB'S STATEMENTS

RESOLUTION

Whereas the patient's welfare should be the ultimate goal of statutes and regulations concerning drug product selection, which in operational terms means the best product for the lowest cost, and

Whereas the physician must have the ultimate responsibility and authority in drug product selection, since he has the fullest knowledge of the patient's needs and responses, with attendant obligation to be held accountable for his selection of particular drug products, and

Whereas the pharmacist may, in some situations, have greater knowledge of drug products than other health professionals, including knowledge of both quality and costs, and

Whereas it is appropriate that decisions with regard to the choice of drug products be made by the health professional possessing the greatest amount of information involved in the particular selection in question, with the attendant accountability, therefore be it

Resolved: That the physician, having selected the chemical entity to be used for therapy, should be required either to delegate to the pharmacist, or explicitly to retain to himself, selection of the particular drug product to be dispensed to and received by the patient.

ACCOMPANYING NARRATIVE

The essential point of a prescription is that the patient receive the medication which his physician intends that he receive. The crux of the problem is the physician's *intent* and the amount of *understanding* he, the physician, brings to that intent.

If he understands sufficient about what he has prescribed to restrict it narrowly (e.g., to a single brand), then he must be able to defend his selection, not only to the patient, to the pharmacist, and to third party payers, but also to a group of his peers in the practice of medicine (i.e., physicians) should they later review his decisions and actions.

If he prescribes a particular brand and, in fact, his *understanding* of what he has prescribed extends only to the level of its generic nature, then his narrow restriction to that particular brand will be indefensible to his peers, and substitution by the pharmacist (on the basis of product equivalence and lesser cost, to the best of his, the pharmacist's, knowledge) is justified. However, the prerogative of restricting the prescription remains with the physician, since he is the one ultimately responsible for the care of the patient.

There are three corollaries to this.

First: The physician's orders must be followed to whatever extent he specifies. If he specifies, in writing on the prescription, that the prescription must be filled exactly as written, the pharmacist *must* do that and the patient should comply with those specific instructions from the physician.

Second: If, however, the physician does not note such a restriction in writing on the prescription, the pharmacist is free to substitute an equivalent drug product (of the same generic drug). The pharmacist then assumes the responsibility (and the liability) for this substitution and must defend his choice, should that defense be necessary. He has presumably made the substitution on knowledge of the drug product (including the cost) which is superior to the knowledge of the physician.

Third: The knowledge of the individual making the selection is paramount in his assumption of the responsibility. This includes knowledge of the patient, his disease, and the ramifications of the pathology of that disease. This is the reason for ultimate delegation of that responsibility to the physician. However, it also includes to a very large extent knowledge and understanding of the prescribed drug product, and where the physician's knowledge is superior, he should have the choice of the responsibility.