physician who prescribes by generic name, rather than by brand name, thereby increases his medical malpractice exposure unless he undertakes the additional burden of (1) informing himself of the contents of all medical literature concerning all drugs that a pharmacist may properly choose to use the generic prescription and (2) taking from the patient, prior to therapy, an informed consent based upon disclosure of all risks reported in all literature for all such generic equivalents."

No scientist, let alone a physician engaged in full-time care of his patient, could ever begin to inform himself so universally regarding "all risks reported in all literature for all such generic equivalents."

Greatly vulnerable to malpractice suit would be the physician who prescribes an anelgesic for a peptic ulcer patient and, under the MAC substitution plan, the patient might well receive a drug containing a salicylate base rather then a propoxyphene base. The patient could very well suffer serious if not fatal hemorrage as a result of this substitution. The same result could occur in other disease entities, such as those requiring anticoagulants or uricosuric agents.

Physicians having epileptic patients under medicated control for extensive periods have reported sudden onset of attacks when brand names were substituted.

How many stabilized diabetics have suddenly found themselves going into shock as the result of insulin changes?

Physicians must prescribe drugs on the basis of the therapeutic effect. Physicians base their prescriptions on their personal knowledge of the individual patient and the therapeutic effect of the brand name drug prescribed. Nevertheless, the proposed regulations make no reference to the term "therapeutic equivalence." While the proposed regulation mentions "bioavailability," this provides no assurance that a drug substituted on the basis of MAC would provide the same, equivalent therapeutic effect.

This demonstrates the fallacy in the assumed economy of the rule as published, and in the general philosophy of the MAC program. A prescription for an effective drug that costs $3.50 and requires no refilling or one refilling is much more economical than a substituted drug that has little or no therapeutic benefit and is refilled frequently.

The regulations could not be applied in the State of Ohio inasmuch as the determination of the specific drug is made by the physician, unless he designates otherwise on his prescription. Any pharmacist who substitutes a drug without expressed permission of the physician jeopardizes his license to practice pharmacy.

If the MAC program were put into effect and when a substituted drug causes a reaction that results in a malpractice suit, should the Medicaid or Medicare recipient sue: