We have examined the numerous other sections of law cited in the Federal Register as a statutory basis for the proposed regulations, and while the citations comprise an extensive recitation of law related to Department activities, in our judgment they fail to provide adequate support for the drug reimbursement program proposed.

We fully recognize that on their face the proposed regulations do not absolutely prohibit a physician from prescribing the drug he selects in discharging his obligation for professional treatment of his patient. It would be naive in the extreme, however, to assume that the Department really countenances this kind of professional freedom. The proposed regulations would create many pressures on physicians unrelated to quality care. Will a physician be able to continue to discharge his professional responsibility based on his judgment regarding the drug needs of his patient? The proposed regulations are silent on financial responsibility for payment of any cost differential between actual cost and the MAC. Will the hospital absorb the cost as to an inpatient? Can it do so for long? Are pharmacies expected to absorb the difference? Will authority in section 213 of P.L. 92-603 be invoked to assess the cost against the hospital? Against the physician? Will the Secretary invoke the authority in section 1866(a)(2) (B)(ii) of Title XVIII -- as a correlative action to a finding that in his judgment certain drugs are not needed in the efficient delivery of health care -- and permit a charge to be made to the patient but only after the required public notification is made and the provider has informed the patient of the charge for the "unnecessary" service?

It is clear the Department does not contemplate professional freedom as previously maintained in medical practice. In the regulations, for instance, the Department states that application of the MAC would be waived for a drug which "the prescriber has certified in writing is the only brand of that drug which the patient can tolerate or which will be effective for that patient." (Emphasis added.) The scientific naivety of this statement is apparent. Can the physician really be expected to make such a written certification? Will the Department next expect the physician to provide additional substantiating proof -- beyond the mere certification -- that the drug was the only brand the patient could tolerate? Do the regulations contemplate an experimental regimen for each patient? Will the Department make full payment only after full recovery of the patient is demonstrated -- thus requiring the physician to make good on his certification that the drug will be effective? Would the physician be subjecting himself to the severe penalties in section 1877(a)? Rather than impute such naivety to the government's health agency, it is more apparent that the stringent certification requirements were advanced to bring about prescribing within the application of the MAC reimbursement formula. In our judgment the certification requirement is interference in the practice of medicine.