c. Category C—*Possibly Effective.* In relation to the indication in question, there is little evidence of effectiveness under any of the criteria stated above. The possibility that additional supporting evidence might be developed should not be ruled out, however. The recommendations to the FDA could be that unless it is informed that studies are being initiated promptly with the object of developing substantial evidence of effectiveness, the indication in question should be considered inappropriate.

d. Category D—*Ineffective.* In relation to the indication in question, the Panel concludes that there is no acceptable evidence under any of the criteria stated above to support a claim of effectiveness. If there is clear evidence of ineffectiveness, the Panel should cite it. The recommendations to the FDA could be that no useful purpose is served by continuing to make this product available for the indication in question, and the immediate administrative action would appear to be justified. The number of completely worthless drugs is probably not large, and these are probably concentrated primarily among certain drug groups. The major use of this category, therefore, would probably be in relation to ancillary indications claimed for a larger number of basically useful drugs.

The indications referred to in these definitions corresponds with the reference that is made in the law to "the effect the drug purports or is represented to have under the conditions of use prescribed, recommended or suggested in the proposed labeling". This is to say that the indications are the claims that are cited in the labeling of a given drug.

4. The drug products listed as "ineffective" have been classified as "ineffective" for all indications. The drug products listed as "possibly effective" have been classified as either "ineffective" or "possibly effective" for each indication.

5. Lists of the drug products that have been declared "ineffective" and "possibly effective" are attached.

6. This policy is to be effective immediately for the direct purchasing of drugs by PHS hospitals and clinics.

7. Those agencies and programs that reimburse community hospitals, extended care facilities, nursing homes and community pharmacies for drugs and health services are requested to establish the necessary procedure to implement this policy within 45 days.

8. The Office of the Pharmacy Liaison Representative, Public Health Service has responsibility for distributing information on these drugs to the Agencies. Each Agency will be advised by telephone of drug products classified as "ineffective" or "possibly effective" prior to publication in the Federal Register, and a list of such drug products will be forwarded to each Agency monthly following publication in the Federal Register.

JESSE L. STEINFELD, M.D.
Surgeon General,
Deputy Assistant Secretary for Health and Scientific Affairs.

Enclosures.

Addressees: Commissioner, Office of Education; Administrator, Environmental Health Service; Commissioner, Food and Drug Administration; Administrator, Health Services and Mental Health Administration; Director, National Institutes of Health; Administrator, Social and Rehabilitation Service; Commissioner, Social Security Administration.