

General HAYES. We inspect our successful bidders and monitor batch analyses of their output to insure that the Government gets what it pays for. Within the Defense Contract Administration Service (DCAS) are approximately 75 inspectors who have been trained in the drug field. The time spent by these inspectors working in the drug-related field, plus 11 DPSC employees who are at times requested to assist DCAS, equates to approximately 20 man-years per annum.

DOD performs these inspections on a product basis. While FDA periodically inspects drug plants to insure compliance with their good manufacturing practices (GMP), they neither register the products supplied by each manufacturer, nor, except for antibiotics, do they routinely test the products. As indicated previously, we must inspect and analyze these products to insure that they are useful and are what we pay for.

Mr. Chairman, that completes my formal statement. My colleagues and I will attempt to answer any further questions you may have.

Senator NELSON. You have that page and a half?

General HAYES. Right. I will read it.

Senator NELSON. Please read that into the record.

General HAYES. That is a memorandum to the Director of the Defense Supply Agency, to the Surgeons General of the Departments of the Army, Navy, and Air Force, and Chairman of the Defense Medical Materiel Board, subject: DOD implementation of the drug efficacy study, dated January 21, 1971.

The Food and Drug Administration, after review of the drug efficacy findings of the National Academy of Sciences/National Research Council on drug products approved by FDA between 1938 and 1962, has published notices in the Federal Register with the classification of "ineffective" and some "possibly effective." The NAS/NRC panel also classified some drug products as being "probably effective."

After careful review and consideration of these findings, it has been determined that Department of Defense policy regarding the procurement and prescribing of these three categories of drug items will be as follows:

1. "Ineffective"

- (a) No further procurement or issue is authorized for those items that have been withdrawn from the market. Remaining stocks of standard items will be destroyed or other appropriate action taken.
- (b) Those items awaiting final determination by FDA will no longer be authorized for central or local procurement until final action is taken by the FDA. All present stocks are to be suspended until status is resolved.

2. "Possibly Effective"

- (a) Standard and local procurement of these items are no longer authorized.
- (b) Pharmacies and Therapeutic Agents Committees are to question all prescriptions prescribing these drug items.

3. "Probably Effective"

- (a) Minimize all central and local procurement of these items.
- (b) Continually monitor centrally these items and immediately notify all medical facilities as to change in classification by FDA.

There are many high cost drugs being prescribed when equally effective but much less expensive drugs are available. Request you advise using medical facilities as to cost/effective ratio and direct use of most economical item when appropriate.

Request that the policy guidance outlined in the foregoing paragraphs be disseminated to all medical facility commanders worldwide.

(Signed) LOUIS M. ROUSSELOT, M.D., F.A.C.S.