3. The Pharmaceutical Reimbursement Board of the Department of Health, Education, and Welfare set maximum allowable cost (MAC) limits for propoxyphene HCL capsules, 65 mg., and propoxyphene HCL with APC (aspirin-phenacetin-caffeine) capsules, 65 mg., effective April 10, 1978.

MAC's are established for multiple source drugs for which significant amounts of Federal funds are or may be expended under HEW programs and for which there are or may be significantly different prices.

HEW estimated that setting MAC's for both forms of propoxyphene would result in a combined savings of between $1.7 and $2.1 million per year in its outpatient programs alone. (For fiscal year 1976, HEW estimated that its medicaid outlays for these two propoxyphene products totaled $4.2 million.)

Along with the agency actions that were taken, there was a promised one that was not.

When he testified on February 3, 1971, Brig. Gen. George J. Hayes, Medical Corps, U.S. Army, Principal Deputy Assistant Secretary of Defense (Health and Environment), told the Monopoly Subcommittee of a memorandum from the Defense Medical Materiel Board concerning a list of 30 drug items proposed for reclassification to "limited standard" with eventual deletion from the Federal supply catalog.

There were five analgesics on the list, including Darvon and Darvon Compound-65 (propoxyphene HCL with APC).

Darvon Compound-65 was indeed deleted from the catalog later in 1971, but Darvon was not. In reply to my letter asking details in preparation for this hearing, Vernon McKenzie, Principal Deputy Assistant Secretary of Defense, explains it was not deleted "since two services recommended retention."

He continues:

> The item was retained since propoxyphene hydrochloride, 65 mg. was never declared ineffective in a 65 mg. dose and is considered by many physicians, both military and civilian, an effective analgesic and alternative to aspirin for patients unable to tolerate aspirin, such as patients with gastrointestinal disorders, that is, peptic ulcers.

McKenzie's use of the phrase, "was never declared ineffective," puts him wide of the mark. The phrase is from the lexicon of the FDA's Drug Efficacy Study Implementation (DESI), and the report on propoxyphene HCL from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, and the FDA's conclusion based on that report had been published in the Federal Register on April 8, 1969—22 months before General Hayes testified.

The DESI study concluded that propoxyphene HCL was effective for the relief of mild to moderate pain when administered as described in its labeling guidelines.

DESI was not the issue.

The issue was set forth in the discussion portion of the Defense Medical Materiel Board's memo:

1. Medical authorities state that propoxyphene is a weaker analgesic than codeine and no more effective than aspirin in equivalent doses.

2. There is a questionable advantage of propoxyphene over much less expensive and proven analgesics.