

30 million tablets of Coumadin, a brand of the anticoagulant sodium warfarin, are being recalled from the market. I would like to explain as clearly as I can what the facts of the situation are.

The recall was requested by the Food and Drug Administration because assays of samples showed that some tablets were above or below required potency levels—but the variations found *do not* pose an imminent danger to the health of the user. It could be *more hazardous* to abruptly halt use of the medication. The safest course the patient can follow is to continue the medication his doctor prescribed.

The recall covers 16 packaging lots of Coumadin tablets in three dosages. For the information of physicians, 2 mg. and 2.5 mg. Coumadin tablets being recalled were slightly *below* allowable potency levels. Only the 5 mg. tablets were found to be *above* the allowable potency limits, ranging in strength from 5.49 to 5.56 mg.

Excessive potency is likely to be more hazardous than subpotency with this particular drug, but the variations found in this case *do not* represent an immediate hazard to patients for whom the drug has been prescribed.

However, the manufacturer, Endo Laboratories, agreed that the tablets should be withdrawn from the market since they do not meet potency standards of the U.S. Pharmacopeia. Pharmacists will be notified of the lots to be returned. The recall involves only a small part of the supply of this drug on the market.

ENDO LABORATORIES INC.,
Garden City, N.Y., October 14, 1967.

IMPORTANT—DRUG RECALL

Re Coumadin (sodium warfarin).

We are recalling from the market certain specific lots of Coumadin Tablets 2 mg., 2½ mg., and 5 mg., because recent re-assays have shown these lots to be above or below the allowable limits of label strength as follows:

Product	Packaging lot No.	Package size
Coumadin, 2 mg.	5020	Bottles of 100 and 1,000.
Do.	7C0140	Bottles of 100.
Do.	7C0141	Do.
Do.	7C0142	Bottles of 1,000.

Whereas the allowable lower limit of 2 mg. Coumadin Tablets is 1.90 mg., the above lots range from 1.68 mg. to 1.86 mg. per tablet.

Product	Packaging lot No.	Package size
Coumadin, 2½ mg.	5171	Bottles of 25, 100, and 1,000.
Do.	6129	Do.
Do.	7B0105	Bottles of 100.
Do.	7C0156	Do.
Do.	7C0157	Bottles of 25.
Do.	7C0158	Bottles of 1,000.
Do.	7D0236	Bottles of 100.
Do.	7F0235	Do.

Whereas the allowable lower limit of 2½ mg. Coumadin Tablets is 2.375 mg., the above lots range from 2.29 mg. to 2.32 mg. per tablet.

Product	Packaging lot no.	Package size
Coumadin, 5 mg.	5191	Bottles of 100.
Do.	6152	Do.
Do.	7E0118	Do.
Do.	7E0322	Do.