MAY 28, 1976

Office of the White House Press Secretary

NOTICE TO THE PRESS

The President has signed S. 510 -- Medical Device Amendments of 1976. This bill provides new authority to the Secretary of Health, Education, and Welfare to assure the safety and effectiveness of medical devices intended for human use.

S. 510 will amend the Federal Food, Drug and Cosmetic (FDC) Act of 1938 to provide the Food and Drug Administration (FDA) in the Department of Health, Education, and Welfare (HEW) with new authority to regulate the safety and effectiveness of medical devices.

S. 510 will classify all medical devices intended for human use into three categories based upon the extent of control necessary to insure the efficacy and safety of each such device:

(1) general controls (Class I)--manufacturer registration, recordkeeping and reporting requirements, good manufacturing practice regulations, etc., would be established for devices for which such controls would be adequate to assure safety and efficacy;

(2) performance standards (Class II)--HEW will develop and issue performance standards for those devices for which general controls would be inadequate and for which performance standards can be devised; and

(3) premarket approval procedures (Class III)--manufacturers will be required to submit safety and efficacy data to HEW before marketing a device where insufficient information exists to assure that general controls and performance standards would provide reasonable assurence of the safety and effectiveness of devices, and where such devices are purported or represented for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury.

The bill will authorize the Secretary to ban devices intended for human use which presented substantial deception or an unreasonable and substantial risk of illness or injury.

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