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Joan Claybrook, President

Statement by Sidney M. Wolfe M.D.
Public Citizen's Health Research Group
Concerning Warner-Lambert Criminal Conviction
and Poor Manufacturing Practices

Although the company has pleaded guilty to criminal charges for withholding important information about sloppy manufacturing practices from the FDA and FDA has indicated that the problem seems to have been solved, an alarming number of recalls of their prescription drugs continues to occur. In the first 11 months of 1995 alone, there were 20 recalls of Warner-Lambert products including 8 recalls for Dilantin and 3 recalls of Nitrostat.

Since 1990, there have been a total of 64 recalls of Warner-Lambert products as listed in FDA recall reports. In 1990 there were 3 recalls; 1 in 1991, 3 in 1992, 24 in 1993, 13 in 1994, and 20 thus far this year. For Dilantin alone--a drug used primarily for treating seizure disorders and one where the amount of the drug in the blood is critical--there have been 12 recalls since 1990. Most of these - 9, involved problems with the drug dissolving, which can result in an insufficient amount of the drug being absorbed by the body. *Over 975,000 bottles (some of which contain 1000 capsules) and over 30,000 injectable doses of Dilantin have been affected by these recalls.*

Given that these recalls continue at a record-setting pace, FDA must investigate the systemic and ongoing problems at Warner-Lambert and prosecute those in charge of company policy and ethics-the highest levels of coporate management. Almost three months ago, in the face of the continuing flood of recalls, we requested copies of all FDA inspection reports of Warner-Lambert since 1990. As of now, we have received only one inspection report, from a South Carolina plant.

In all of the years of following drug recalls, I am not aware of any company which has had so many recalls involving such a large number of bottles of pills pulled back from the channels of distribution. It is time for more vigorous enforcement by FDA and a strong message to consumers that brand name companies such as Warner-Lambert--many of whom have bent over backwards to denigrate the poor quality of generic drugs--should look in the mirror at themselves.

11/29/95

1994 & 1995 DILANTIN RECALLS

4/7/1994 FDA ENFORCEMENT REPORT CLASS II

Product:	Dilantin (Extended Phenytoin Sodium Capsules, USP) Kapseals, 100 mg, in bottles of 1000, for control of seizures. Recall #D-191-3.
Code:	Lot numbers: 01021 FA, 03691 FA, 03891 FA.
Manufacturer:	Warner Lambert, Inc., Fajardo, Puerto Rico.
Recalled by:	Parke Davis, Division of Warner Lambert Company, Morris Plains, New Jersey, by letter 2/12/93. Firm-initiated recall ongoing.
Distribution:	Nationwide
Quantity:	12,105 bottles
Reason:	Product does not met dissolution specifications.

4/19/95 FDA ENFORCEMENT REPORT CLASS II

Product:	Dilantin Kapseals 100 mg bottles of 100. Recall #:D-112-5
Code:	Lot numbers: 05634FA
Manufacturer:	Warner-Lambert Company, PR
Recalled by:	Parke-Davis, Morris Plains, New Jersey by letter. Firm initiated recall ongoing.
Distribution:	Nationwide
Quantity:	40,242 bottles
Reason:	Doesn't meet dissolution specifications through expiration date.

5/17/95 FDA ENFORCEMENT REPORT CLASS II

Product:	Dilantin Kapseals 30 mg bottles of 100. Recall #: D-168-5
Code:	Lot numbers: 52264L
Manufacturer:	Warner-Lambert Company, Lititz, PA
Recalled by:	Parke-Davis, Morris Plains, New Jersey by letter. Firm initiated recall ongoing.
Distribution:	Nationwide
Quantity:	30,964 bottles
Reason:	Doesn't meet dissolution specifications through expiration date.

5/24/95 FDA ENFORCEMENT REPORT CLASS II

Product:	Dilantin Kapseals, 100 mg bottles of 100 & 1000. Recall #: D-174-5
Code:	Lot numbers: 05254FA, 08354FA, 05354FA, 02364FA
Manufacturer:	Warner-Lambert Company, PR
Recalled by:	Parke-Davis, Morris Plains, New Jersey by letter. Firm initiated recall ongoing.
Distribution:	Nationwide
Quantity:	83,886 bottles
Reason:	Doesn't meet dissolution specifications through expiration date.

7/19/95 FDA ENFORCEMENT REPORT CLASS II

Product:	Dilantin Kapseals, 100 mg. bottles of 100. Recall #: D-210-5
Code:	Lot numbers: 064N4FA
Manufacturer:	Warner-Lambert Company, PR
Recalled by:	Parke-Davis, Morris Plains, New Jersey by letter. Firm initiated recall ongoing.
Distribution:	Nationwide
Quantity:	39,510 bottles
Reason:	Doesn't meet dissolution specifications through expiration date.

8/9/95 FDA ENFORCEMENT REPORT CLASS II

Product:	Dilantin Kapseals. Recall #: D-229-5
Code:	Lot numbers: 27224L
Manufacturer:	Warner-Lambert Company, Lititz, PA
Recalled by:	Parke-Davis, Morris Plains, New Jersey by letter. Firm initiated recall ongoing.
Distribution:	Nationwide
Quantity:	undetermined
Reason:	Doesn't meet dissolution specifications through expiration date.

8/16/95 FDA ENFORCEMENT REPORT CLASS III

Product:	Dilantin injection. Recall #: D-232-5
Code:	Lot numbers: 00515
Manufacturer:	Warner-Lambert Company, Rochester, NY
Recalled by:	Parke-Davis, Morris Plains, New Jersey by letter. Firm initiated recall ongoing.
Distribution:	Nationwide
Quantity:	15,157 packages
Reason:	Discoloration resulting from use of incorrect stopper.

10/18/95 FDA ENFORCEMENT REPORT CLASS III

Product:	Dilantin brand Phenytoin Sodium Injection, 100 mg, in 2 ml vials. Recall #D-005-6.
Code:	Lot #00815P, N0071-4488-47, EXP 11/96.
Manufacturer:	Warner Lambert Company, Park-Davis Sterile Products Division, Rochester, Michigan.
Recalled by:	The Parke-Davis Division of Warner Lambert Company, Morris Plains, New Jersey, by letter 8/11/95. Firm-initiated recall complete.
Distribution:	Nationwide and Virgin Islands, Trinidad, Jamaica.
Quantity:	15,416 packages
Reason:	Product discoloration resulting from use of incorrect stopper.

11/29/95 FDA ENFORCEMENT REPORT CLASS II

Product:	Dilantin (extended Phenytoin Sodium Capsules, USP), Kapseals, 30 mg, antiepileptic drug. Recall #D-021-6.
Code:	Lot #27324L EXP 4/96.
Manufacturer:	Warner Lambert Company, Lititz, Pennsylvania.
Recalled by:	Manufacturer, by letter dated 10/3/95, followed by telephone. Firm-initiated recall complete.
Distribution:	Nationwide
Quantity:	Firm estimates none remains on the market.
Reason:	Product does not meet dissolution specifications.