Toxicity of New Drugs

My letter of 8 July 1966 expressed concern as to whether pharmaceutical manufacturers investigating new drugs were reporting toxicity findings to the Food and Drug Administration. As a drug investigator, I became aware of this problem when I learned that the toxicity data of our Dornwal study for Wallace and Tiernan in 1961 had not been reported to the FDA. The suppression of information about this tranquilizer led a federal district court to impose a maximum $40,000 fine on the company and place its medical director on probation for 1 year.

I reviewed reports of 26 new drug studies made between 1954 and 1966 and asked the FDA if the reports about safety had ever been received from the pharmaceutical companies as required by the the New Drug Section of the Pure Food and Drug Law of 1938. This law, which is the result of the 100 deaths of the 1937 sulfanilimide disaster, requires a manufacturer to test each new drug for safety and submit the data to the government before the drug can be marketed. My concern was confirmed when I learned that the FDA had received only 10 of 26 reports on drug safety which had been submitted to 19 pharmaceutical manufacturers. The 14 companies which failed to submit toxicity reports included some of the largest and most scientifically capable pharmaceutical houses.

I recommend that Congress require each investigator of new drugs to send a copy of his entire report to the FDA and other government agencies concerned with drug safety and efficacy. Also the law should require that each new drug investigator be provided with reports of all other investigators who are studying the same or similar compounds. New drug research demands full exchange of information among the responsible scientists. Maximum safety demands informed collaboration between the investigator, the federal government, and the pharmaceutical manufacturer. The Senate Subcommittee on Antitrust and Monopoly headed by Senator Philip A. Hart of Michigan is currently studying changes in the laws governing drug research. Drug investigators should express their views to this subcommittee.

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