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Joan Claybrook, President

Response of Sidney M. Wolfe, M.D.
Director, Public Citizen's Health Research Group
to the Institute of Medicine Report on Halcion
November 13, 1997

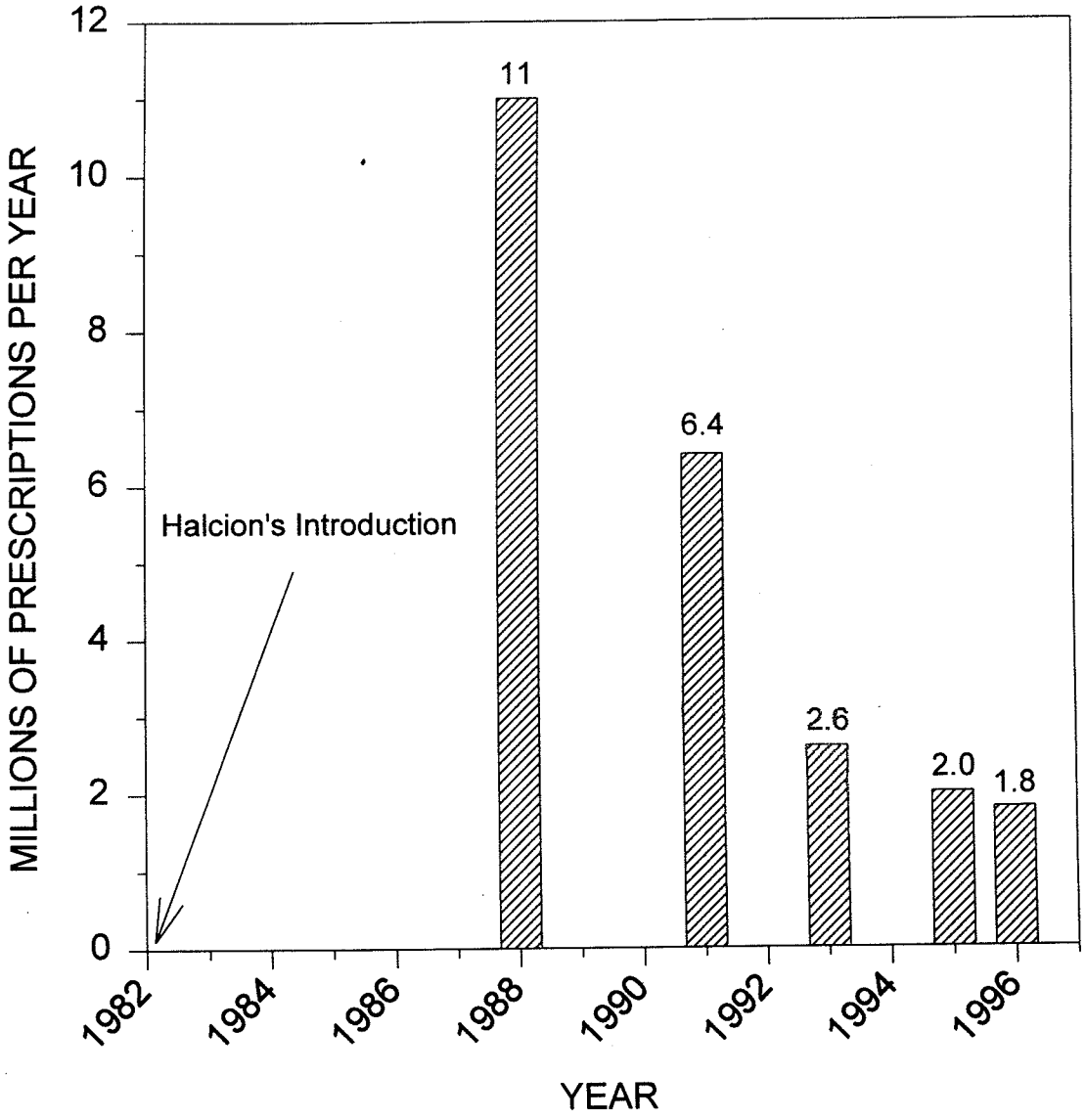
The Institute of Medicine (IOM) report, done in a hurried manner, is a waste of taxpayers dollars in that many of the questions it was asked/paid to answer by the Food and Drug Administation (FDA), had already been answered by the FDA before the committee's process had barely begun. Instead of waiting to respond to our 1992 petition to ban Halcion until the report was finished, just as the IOM investigation was beginning, the FDA issued a denial of our petition (August 19, 1997), concluding that the drug was safe and effective enough to stay on the market. When asked why the agency had pre-empted the IOM study, lead Deputy Commissioner Dr. Michael Friedman is reported to have said that he was unaware of the IOM study being underway.

The findings of the IOM study are a slap in the face to FDA's epidemiologists who have raised serious questions about the drug's safety for many years, having concluded that, in comparison to other sleeping pills, Halcion has a much higher probability of causing extreme confusion as well as memory loss. They are also at odds with the findings of an Upjohn study in 1972-3 showing that people getting 1 milligram of Halcion, compared to those getting a placebo, had a much higher incidence of serious acute psychiatric symptoms, including paranoia and confusion. This dose is only twice the current maximum dose (0.5 mg) on the U.S. label for Halcion and, if it is being used by a small person, the 0.5 milligram dose, on a dose per pound basis, may exceed the dose per pound of some of the large subjects in the Upjohn study given 1 mg.

Based on a review of that study and all other available information, the government in the U.K. banned the drug in late 1991, stating that the "CSM [Committee on Safety of Medicines] have concluded that triazolam [Halcion] is associated with an inadequate margin of safety in relation to dose and that the risks outweigh its benefits in relation to other benzodiazepines." The CSM concluded that "Considering all the information now available, it has been concluded that triazolam can no longer be regarded as safe for the purposes indicated in the licenses and that it should be withdrawn urgently from the market."

Halcion is too dangerous to use and we advise anyone using it to ask their doctor to help them slowly withdraw from the drug--it is addicting--or switch to a safer sleeping pill. The market, as well as the U.K. government, has also spoken loudly and clearly about the drug. Sales, measured by retail prescriptions filled per year, have plummeted from a peak of 11 million prescriptions a year in 1988 to 1.8 million in 1996, a drop of 84%. Just as British people have not suffered, but rather have benefitted, from the absence of Halcion there, so too will the increasing number of Americans who do not use the drug. Unfortunately for Americans, in this case the British government is doing a better job of thinking and protection than the FDA or the IOM.

TRIAZOLAM RETAIL PRESCRIPTIONS



(Data From National Prescription Audit, IMS America)