

expert panel of the National Academy of Sciences/National Research Council reevaluated propoxyphene in the late 1960s and found it effective for the relief of mild-to-moderate pain, and the weight of scientific evidence as presented both by individual investigators and those who have reviewed the literature sustains the view of the expert committee. The conclusions from well-designed trials have been confirmed by physicians and patients alike through the use of propoxyphene products over the last twenty years. Information on the effectiveness of the products is provided in the Blue Book, Tab C.

The Incidence of Misuse of Propoxyphene

The HRG petition states that deaths and abuse associated with propoxyphene are increasing. Information in the Blue Book with which you have been provided responds to these assertions. Since that material was developed additional information has been obtained from a variety of sources, including testimony in the recent Senate hearings and DAWN data. Information from the DAWN system is presented, not because it is regarded as complete or infallible, but because it is the most available of a limited selection of retrospective data sources. DAWN's sponsors acknowledge the system's insufficiency to serve as the sole basis for regulatory decision-making. What follows is a brief summary of evidence