

Public Citizen  PRESCRIPTION DRUG LEGISLATION

**NEWS RELEASE**

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**STATEMENT BY PUBLIC CITIZEN'S HEALTH RESEARCH GROUP ON  
SENATOR CRAPO'S (R-ID) LEGISLATION THAT COULD KEEP PATIENTS IN THE  
DARK ABOUT THE RISKS OF PRESCRIPTION DRUGS**

Washington, D.C. - Sen. Mike Crapo (R-ID) introduced the "Pharmacist's Patients Protection Act of 1999" (SB 1092) on May 20. If enacted, rather than protecting patients, it may cause serious harm by denying them access to potentially life-saving, scientifically accurate information written in non-technical language about the risks of some of the most dangerous prescription drugs on the market.

The legislation seeks to derail a proposed Food and Drug Administration (FDA) regulation due to take effect June 1. This regulation would require the distribution of written information, or Medication Guides, to patients, meeting FDA standards for content and accuracy, for five to 10 drugs per year that "pose a serious and significant public health concern." In 1996, when still a member of the House of Representatives, Crapo derailed a similar FDA proposal that would have provided for the distribution of Medication Guides with all prescription drugs.

It is estimated that as many as 100,000 people per year die from adverse drug reactions and that half of these deaths are preventable. The FDA, with the support of a number of consumer groups, is trying to make a dent in this toll with Medication Guides.

The senator believes patients already receive adequate written drug information from pharmacists when they receive their prescriptions. That is simply incorrect. The fact is, the written information patients now receive at the pharmacy is produced by unregulated commercial information vendors without enforceable standards to ensure its completeness and quality. Multiple surveys have shown that the patient information leaflets handed out by pharmacists are frequently inaccurate, often omitting vital risk information, and sometimes being out-of-date.

The disclosure of risks and benefits is an accepted part of our health care system guided by the principle of informed consent -- except when a prescription drug is the treatment. Patients prescribed a drug or those undergoing a surgical procedure share a common prospect; both assume individual risks of possible irreparable injury or death from their respective therapeutic interventions.

Crapo's legislative actions to keep patients in the dark about the risks of prescription drugs are indefensible and dangerous.