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**DID YOU KNOW?** Corporations VOTED to adopt this. Through ALEC, global companies work as "equals" in "unison" with politicians to write laws to govern your life. Big Business has "a VOICE and a VOTE," according to newly exposed documents. **DO YOU?**

**Resolution in Support of Uniformity in Prescription Drug Labeling**

WHEREAS, effective regulation and labeling of prescription drugs sold in interstate commerce is essential to the health and safety of Americans;

WHEREAS, under federal law, the Food, Drug, and Cosmetic Act provides comprehensive authority over drug safety, effectiveness, and labeling to the Food and Drug Administration (FDA). The FDA and its staff of scientists, medical doctors, and other experts are charged with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading;

WHEREAS, the FDA's scientifically rigorous New Drug Application (NDA) process, which averages well over a decade and costs an average of \$800 million before review and approval of a new prescription drug, including its labeling, is reached only after close consideration and balancing of the risks and benefits of each product;

WHEREAS, the FDA approves prescription drug labeling that reflects its thorough review of the scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively;

WHEREAS, the FDA continuously evaluates the latest scientific research and monitors the safety of products, and the FDA approves changes in or supplementing of product labeling where appropriate;

WHEREAS, individual "failure-to-warn" claims alleging deficiencies in product labeling may conflict with the FDA's expert decision making, place judges and lay juries in the position of second guessing the FDA, frustrate the Agency's implementation of its statutory mandate, and result in fostering inconsistent labeling requirements among the states;

WHEREAS, the FDA has found that product liability lawsuits "have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs";

WHEREAS, tort lawsuits that impose labeling requirements in addition to that required by the FDA inadvertently place patients in danger because exaggeration of risks can discourage appropriate use of beneficial drugs and because warning of speculative risks can cause significant risk information to lose significance;

WHEREAS, it is important for the purpose of pharmaceutical public policy that courts do not inadvertently create mixed signals regarding the content of product warnings;

WHEREAS, FDA regulations prescribe procedures to ensure that FDA receives information about risks that become apparent following approval, such as by requiring manufacturers to establish and maintain records of adverse events, to promptly report serious drug experiences, to periodically report all information relating to the safety and effectiveness of the drug, and to submit additional safety and effectiveness studies following approval as required by the FDA;

WHEREAS, the FDA is empowered to investigate suspected fraud, to take enforcement action against any manufacturer who fails to comply with reporting and other regulatory requirements, to seek injunctive relief and civil penalties, to order or approve incorporation of additional risk information or other modification of labeling, and to order withdrawal of a product from the market, when necessary to protect the public health and safety;

NOW THEREFORE BE IT RESOLVED, That the American Legislative Exchange Council supports the principle that prescription drugs labeling and warnings should be uniformly determined by the FDA based on broad evaluation of the scientifically-demonstrated risks and benefits of the product for the general public, and not through individual, conflicting tort lawsuits. It is appropriate for the FDA to fully implement this public policy goal.

**Adopted by ALEC's Civil Justice Task Force at the Spring Task Force Summit on April 21, 2006. Approved by the ALEC Board of Directors in May, 2006.**

**ALEC EXPOSED**

"ALEC" has long been a secretive collaboration between Big Business and "conservative" politicians. Behind closed doors, they ghostwrite "model" bills to be introduced in state capitols across the country. This agenda-underwritten by global corporations-- includes major tax loopholes for big industries and the super rich, proposals to offshore U.S. jobs and gut minimum wage, and efforts to weaken public health, safety, and environmental protections. Although many of these bills have become law, until now, their origin has been largely unknown. With **ALEC EXPOSED**, the Center for Media and Democracy hopes more Americans will study the bills to understand the depth and breadth of how big corporations are changing the legal rules and undermining democracy across the nation.

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For more on these corporations, search at [www.SourceWatch.org](http://www.SourceWatch.org).

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