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Statement



Pharmaceutical Research and Manufacturers of America Statement in Opposition to Nevada Senate Bill 251 March 12, 2003

PhRMA opposes SB 251. This bill would restrict the ability of Nevada courts to issue and enforce orders limiting the disclosure of confidential trade secrets provided through judgments or contracts for settlement of litigation involving a public hazard. In essence, this bill would have the effect of curtailing the discretion of Judges in Nevada to protect private information and property rights. While the bill contains an exemption for protected trade secret information, the standards by which courts are to decide what information is trade secret information is so high that no information will meet the standard.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the nation's leading research-based pharmaceutical and biotechnology companies, which discover and develop the majority of new medicines used in the United States and around the world. In 2001, PhRMA's member companies brought thirty-two new prescription drugs and biologics to market, including medicines for diseases that affect millions of patients, such as, Alzheimer's, AIDS, cancer, glaucoma, heart disease, and schizophrenia. Additionally, PhRMA's member companies invested more than \$30 billion in research and development last year to create medicines that help combat diseases that threaten the well-being of Americans and to help reduce the economic loss caused by an ailing workforce.

Pharmaceutical manufacturers are particularly sensitive to issues surrounding the protection of confidential information because they must defend product liability suits where each party, and many non-parties, wants to keep some information private. Much of the information about the clinical trials conducted to demonstrate a drug's safety and effectiveness is confidential trade secret information. In addition, epidemiological studies conducted by third parties, such as studies of the comparative costs and benefits of several drugs within a managed care organization, may be subpoenaed in prescription drug product liability litigation, and the third party may consider that information confidential trade secret information.

Under existing federal law, all of the information produced in product liability litigation that might be relevant to the determination that a pharmaceutical product poses a risk must be submitted to the federal Food and Drug Administration (FDA). The manufacturer must submit to FDA all of the reports of patients' adverse medical events that might be caused by a drug. The FDA's authority to review these reports and to withdraw market approval for a pharmaceutical is adequate to protect the public health. In addition, FDA can require the manufacturer to send a warning letter to

prescribers or add a warning to the drug's labeling.

A study conducted by the Committee on Rules of Practice and Procedure of the Judicial Conference of the United States found no evidence that information about public hazards is concealed by protective orders issued in private litigation. In other words, this bill would impose burdens on the Nevada courts, litigants, and others without providing any benefits or resolving any problems. It would delay the resolution of private disputes by burdening the courts.

PhRMA urges you to oppose Nevada SB 251.