

on the initial quarterly period filing date, April 21, 2008.

NAM named as defendants the U.S. attorney for the District of Columbia, the Secretary of the Senate, and the Clerk of the House. The Secretary and the Clerk are responsible for providing guidance and assistance on lobbying disclosure requirements, receiving lobbying registration and report filings, reviewing, inquiring, and verifying the accuracy of the filings without investigating, notifying lobbyists that appear not to be in compliance with the law, and notifying the U.S. attorney of lobbyist who have been so notified and have failed to submit an appropriate response. The U.S. attorney has the duty to enforce the disclosure requirements through civil, and, under the new law, criminal, actions.

This resolution authorizes the Senate legal counsel to represent the Secretary of the Senate to defend the constitutionality of the lobbying disclosure amendment in the Honest Leadership and Open Government Act and to seek dismissal of the action, in conjunction with counsel for the House of Representatives and the Department of Justice.

Senate counsel will present to the court the bases for the Congress's judgment, after more than a dozen years of experience under the Lobbying Disclosure Act, that enhanced reporting requirements are necessary to inform Congress and the public of the identity of those organizations actively participating in lobbying the Federal Government. As Justice Louis Brandeis famously wrote, "Sunlight is said to be the best of disinfectants."

The lobbying amendments enacted last year were an important part of the Congress's efforts to restore public confidence through integrity and openness in Government and lobbying activities. Disclosure of the identities of organizations that actively participate in supervising or planning lobbying campaigns will yield a sizable public benefit while imposing a modest burden on the exercise of the right of organizations such as the National Association of Manufacturers freely to associate to petition the Government in furtherance of their legislative agenda.

REMEMBERING DENISE ANN PHOENIX

Mr. REID. Mr. President, I rise today to recognize Denise Ann Phoenix, a role model, native Nevadan, and hero. Ms. Phoenix, known by her nickname "Auntie," devoted her life to improving her Native American community and promoting child safety. Following in the footsteps of her father, Leroy Phoenix, Sr., she pursued a career in law enforcement and became one of few women to serve as an investigator with the Bureau of Indian Affairs. She died in the line of duty on February 14, 2008, after coming into contact with an unidentified substance and contracting a fatal lung disease. She was 42 years old.

Ms. Phoenix grew up on the Pyramid Lake Paiute Reservation in northern Nevada. After graduating from Sparks High School, she began her career as a tribal ranger on the reservation and later became BIA chief of police of Carson City, NV. She emphasized the importance of community-oriented policing and her service was exemplary. She will continue to be an inspirational example to young Native American women.

The dedication Ms. Phoenix demonstrated as an officer was complemented by her dedication to children. In 2000, she lost her own children, Shasta and Justin, along with her brother Ronald, to a car accident along the Pyramid Highway in Sparks, NV. In response to this devastating tragedy, she established youth outreach programs in her children's memory. She was also instrumental in getting a median divider installed on the stretch of road where the accident occurred, once again showing her profound commitment to the safety of others.

Though I am saddened by her passing, I share with this body my gratitude for her devotion to her community. I also extend to her family, friends, and colleagues my condolences.

PRESERVE ACCESS TO AFFORDABLE GENERICS ACT

Mr. KYL. Mr. President, I ask unanimous consent to have the following letter from the Justice Department commenting on S. 316, the Preserve Access to Affordable Generics Act, printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF, LEGISLATIVE AFFAIRS,
Washington, DC, February 12, 2008.

Senator Jon Kyl,
U.S. Senate,
Washington, DC.

DEAR SENATOR KYL: This responds to your request for the Department's views regarding the competitive implications of S. 316, the "Preserve Access to Affordable Generics Act." S. 316 addresses the issue of reverse payments associated with the settlement or resolution of an infringement lawsuit in the context of the Hatch-Waxman Act. The bill would make it a per se violation of the anti-trust laws to be a party to an agreement in which an Abbreviated New Drug Application (ANDA) filer receives value and agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time. The Department believes that the bill addresses a serious competition issue, but, for the reasons discussed below, the Department has concerns with this bill as drafted.

As an initial matter, there is the potential for such settlements to be anticompetitive. For example, if the potential losses in profits due to increased competition from entry by the ANDA filer are large, the ANDA filer may be persuaded to drop a strong claim of patent invalidity or non-infringement in return for significant payments. As described below, however, settlements between an ANDA filer and the patent holder also can benefit consumer welfare. Accordingly, the

Department of Justice does not believe per se liability under the antitrust laws is the appropriate standard. Per se liability generally is reserved for only those agreements that unequivocally have an anticompetitive effect, while a rule of reason analysis is better suited to instances when the economic impact of the agreement is less certain. In this context, per se illegality could increase investment risk and litigation costs to all parties. These factors run the risk of deterring generic challenges to patents, delaying entry of competition from generic drugs, and undermining incentives to create new and better drug treatments or studying additional uses for existing drugs.

The United States has a strong policy of encouraging settlement of litigation. A settlement reduces the time and expense of litigation, which can be quite substantial. Further, it reduces the uncertainty associated with the pending litigation. A settlement can thereby free up management time and resources and reduce risk, enabling a company to focus on developing new and better products.

The Hatch-Waxman Act context presents a distinct set of circumstances, but settlements creates a structure designed to encourage generic drug makers to challenge these patent rights by asserting either that the relevant patents are not valid or that the generic version would not infringe the patents. Among other things, the Hatch-Waxman Act provides an opportunity for the generic company and the patent holder to litigate those issues prior to the generic's launch of a potentially infringing product. Thus, unlike most patent litigation in which the patent holder has a claim for damages, the patent holder in the Hatch-Waxman context typically has no claim for damages because the generic company has not yet launched a product.

In any patent litigation, the principle means available to the patent holder to induce the generic company to settle the litigation is to offer something of value. If the patent holder has a damages claim for infringement, it can offer to reduce or waive its damages. However, in the Hatch-Waxman context the patent holder typically has no damages claim, so its only means of offering value to induce a settlement is to offer to transfer something of value, such as cash or other assets. Under S. 316, the only value that a patent holder could offer to settle a patent infringement claim would be "the right to market the ANDA product prior to the expiration of the patent" at issue (i.e., waiving its patent rights in whole or in part). The per se liability under S. 316 eliminates any other transfer of value if the settlement also includes a provision requiring the generic company to respect for any period of time the patent holder's right to exclude under the patent. The net result may be to reduce the likelihood of potentially beneficial settlements and to increase the risk that a generic company would need to litigate a case to judgment (and through an appeal in many instances). Patent holders would face greater disincentives to investing in research and development of new and better treatments if they had to litigate every challenge to a judgment and through an appeal. Further, such litigation can take many years to complete and will divert the time, attention and resources of both parties during that time.

Settlement should not serve as a vehicle to enable patent holders to preserve or expand invalid or non-infringed patents by dividing anticompetitive profits with settling challengers. However, the public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be