S. 1591

At the request of Mrs. GILLIBRAND, the names of the Senator from Tennessee (Mr. ALEXANDER), the Senator from Connecticut (Mr. BLUMENTHAL), the Senator from Maryland (Ms. MIKULSKI) and the Senator from Vermont (Mr. SANDERS) were added as cosponsors of S. 1591, a bill to award a Congressional Gold Medal to Raoul Wallenberg, in recognition of his achievements and heroic actions during the Holocaust.

S. 1833

At the request of Mr. MANCHIN, the name of the Senator from North Dakota (Mr. HOEVEN) was added as a cosponsor of S. 1833, a bill to provide additional time for compliance with, and coordinating of, the compliance schedules for certain rules of the Environmental Protection Agency.

S. 2051

At the request of Mr. REED, the name of the Senator from Washington (Ms. CANTWELL) was added as a cosponsor of S. 2051, a bill to amend the Higher Education Act of 1965 to extend the reduced interest rate for Federal Direct Stafford Loans.

S. 2076

At the request of Mr. FRANKEN, the name of the Senator from North Dakota (Mr. HOEVEN) was added as a cosponsor of S. 2076, a bill to improve security at State and local courthouses.

S. 2103

At the request of Mr. LEE, the name of the Senator from Mississippi (Mr. WICKER) was added as a cosponsor of S. 2103, a bill to amend title 18, United States Code, to protect pain-capable unborn children in the District of Columbia, and for other purposes.

S. 2120

At the request of Ms. MURKOWSKI, the name of the Senator from Connecticut (Mr. LIEBERMAN) was added as a cosponsor of S. 2120, a bill to require the lender or servicer of a home mortgage upon a request by the homeowner for a short sale, to make a prompt decision whether to allow the sale.

S. 2165

At the request of Mrs. BOXER, the names of the Senator from Oregon (Mr. WYDEN) and the Senator from Arkansas (Mr. BOOZMAN) were added as cosponsors of S. 2165, a bill to enhance strategic cooperation between the United States and Israel, and for other purposes.

S. 2172

At the request of Ms. SNOWE, the name of the Senator from Oregon (Mr. MERKLEY) was added as a cosponsor of S. 2172, a bill to remove the limit on the anticipated award price for contracts awarded under the procurement program for women-owned small business concerns, and for other purposes.

S. 2205

At the request of Mr. JOHANNS, his name was added as a cosponsor of S. 2205, a bill to prohibit funding to negotiate a United Nations Arms Trade Treaty that restricts the Second Amendment rights of United States citizens.

S. 2230

At the request of Mr. WHITEHOUSE, the name of the Senator from Missouri (Mrs. MCCASKILL) was added as a cosponsor of S. 2230, a bill to reduce the deficit by imposing a minimum effective tax rate for high-income taxpayers.

S. 2270

At the request of Mr. HARKIN, the name of the Senator from Illinois (Mr. DURBIN) was added as a cosponsor of S. 2270, a bill to amend the Farm Security and Rural Investment Act of 2002 to improve energy programs.

S. 2277

At the request of Mr. THUNE, the name of the Senator from Alaska (Ms. MURKOWSKI) was added as a cosponsor of S. 2277, a bill to respond to the extreme fire hazard and unsafe conditions resulting from pine beetle infestation, drought, disease, or storm damage by declaring a state of emergency and directing the Secretary of Agriculture to immediately implement hazardous fuels reduction projects in the manner provided in title I of the Healthy Forests Restoration Act of 2003, and for other purposes.

S.J. RES. 38

At the request of Mr. GRAHAM, the name of the Senator from South Carolina (Mr. DEMINT) was added as a cosponsor of S.J. Res. 38, a joint resolution disapproving a rule submitted by the Department of Labor relating to the certification of nonimmigrant workers in temporary or seasonal nonagricultural employment.

S. RES. 418

At the request of Mr. BROWN of Ohio, the names of the Senator from Hawaii (Mr. AKAKA) and the Senator from Texas (Mr. CORNYN) were added as cosponsors of S. Res. 418, a resolution commending the 80 brave men who became known as the ''Doolittle Tokyo Raiders'' for outstanding heroism, valor, skill, and service to the United States during the bombing of Tokyo and 5 other targets on the island of Honshu on April 18, 1942, during the Second World War.

AMENDMENT NO. 2003

At the request of Ms. MIKULSKI, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of amendment No. 2003 intended to be proposed to S. 1789, a bill to improve, sustain, and transform the United States Postal Service.

AMENDMENT NO. 2004

At the request of Ms. MIKULSKI, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of amendment No. 2004 intended to be proposed to S. 1789, a bill to improve, sustain, and transform the United States Postal Service.

AMENDMENT NO. 2005

At the request of Ms. MIKULSKI, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of amendment No. 2005 intended to be proposed to S. 1789, a bill to improve, sustain, and transform the United States Postal Service.

AMENDMENT NO. 2008

At the request of Mr. MCCAIN, the name of the Senator from West Virginia (Mr. ROCKEFELLER) was added as a cosponsor of amendment No. 2008 intended to be proposed to S. 1789, a bill to improve, sustain, and transform the United States Postal Service.

AMENDMENT NO. 2011

At the request of Mr. MCCAIN, the name of the Senator from Texas (Mrs. HUTCHISON) was added as a cosponsor of amendment No. 2011 intended to be proposed to S. 1789, a bill to improve, sustain, and transform the United States Postal Service.

AMENDMENT NO. 2020

At the request of Mr. WYDEN, the names of the Senator from Colorado (Mr. BENNET), the Senator from Montana (Mr. BAUCUS), the Senator from Ohio (Mr. BROWN) and the Senator from California (Mrs. BOXER) were added as cosponsors of amendment No. 2020 intended to be proposed to S. 1789, a bill to improve, sustain, and transform the United States Postal Service.

AMENDMENT NO. 2031

At the request of Mrs. MCCASKILL, the names of the Senator from Oregon (Mr. WYDEN), the Senator from Louisiana (Ms. LANDRIEU), the Senator from Colorado (Mr. UDALL), the Senator from West Virginia (Mr. ROCKEFELLER) and the Senator from Minnesota (Ms. KLOBUCHAR) were added as cosponsors of amendment No. 2031 intended to be proposed to S. 1789, a bill to improve, sustain, and transform the United States Postal Service.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. LEAHY (for himself, Mr. FRANKEN, Mr. COONS, Mr. WHITEHOUSE, Mr. BINGAMAN, Mr. BROWN of Ohio, and Mr. BLUMENTHAL):

S. 2295. A bill to permit manufacturers of generic drugs to provide additional warnings with respect to such drugs in the same manner that the Food and Drug Administration allows brand names to do so; to the Committee on Health, Education, Labor, and Pensions.

Mr. LEAHY. Mr. President, today, I am introducing legislation that will protect American consumers by improving the labeling on prescription drugs to promote consumer safety. This important bill will ensure that all drug manufacturers can update the warning labels for their products so that the information provided to doctors and consumers is as accurate and up-to-date as possible. It is a straightforward measure that has the support of patient groups and consumer advocates. I am pleased that Senators FRANKEN, COONS, WHITEHOUSE, BINGAMAN, BROWN of Ohio, and BLUMENTHAL

have joined me as original cosponsors of the bill.

The Patient Safety and Generic Labeling Improvement Act will promote consumer safety by ensuring that generic drug companies can improve the warning information for their products in the same way that brand manufacturers can under existing law. This ability is especially important given the large role that generics play in the market for prescription drugs. The Department of Health and Human Services reports that generic drugs now make up 75 percent of the market for pharmaceuticals. Studies show that when a generic version of a drug is available, 90 percent of prescriptions are filled with the generic version of the drug. The large role that generics play in the market gives them important insight into side effects experienced by their customers. The Patient Safety and Generic Labeling Improvement Act will allow generic manufacturers to act on this information, by authorizing them to improve their labels to provide accurate and up-to-date warnings to consumers.

A recent Supreme Court decision, Pliva v. Mensing, created the need for this important legislation. In the Mensing case, a narrow 5–4 majority on the Court held that a Minnesota woman, Gladys Mensing, could not recover for debilitating injuries she received from a mislabeled drug that was intended to treat her diabetes symptoms. Despite evidence that long-term use of the drug could cause a severe neurological condition known as tardive dyskinesia, the manufacturer's label did not expressly warn against long-term use until years after Ms. Mensing began taking the drug. She developed the condition, losing control of muscles in her face, arms and legs.

Ms. Mensing's injuries are life-changing and irreversible. The Supreme Court held that she cannot be compensated for the drug company's failures because of a technicality in the law. That technicality arose because Ms. Mensing's pharmacy had filled her prescription with the generic version of the drug. The Supreme Court held that, unlike brand name companies, generic manufacturers cannot be held liable for inadequate labeling, because they cannot change the labels on their products independently. Generic manufacturers should have the ability to participate fully in the labeling process, but they are unable to do so. More important to injured consumers, there is no remedy for them. The generic manufacturers can use this Supreme Court decision and the quirk in the labeling laws to avoid any accountability, even if they fail to inform the FDA that a label is inadequate.

The Mensing decision creates a troubling inconsistency in the law governing prescription drugs. If a consumer takes the brand-name version of drug, she can sue the manufacturer for inadequate warnings. If the pharmacy happens to give her the generic version, as happened to Ms. Mensing, she is unable to seek compensation for her injuries. The result is a two-track system that penalizes consumers of generic drugs even though many consumers have no control over which drug they take, because their health insurance plan or state laws require them to take generics if they are available.

In an editorial published last month, The New York Times criticized the inconsistency of this outcome, writing: ''Same drug. Same devastating health consequences. Opposite results. This injustice will affect more people as generics, which already dominate the market, expand even more under the pressure to control health care costs.'' Even Justice Thomas, writing for the majority in Mensing, acknowledged the inconsistent outcome, writing: ''[I]t is not the Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'' Writing in dissent, Justice Sotomayor accurately warned of ''absurd consequences'' that will flow from the ''happenstance'' of whether a prescription was filled with a brand-name or generic drug.

I agree that having different rules for patients who take generic and brand-name drugs makes little sense, and raises significant policy concerns. It is also troubling that generic manufacturers cannot update their safety labels in the same way that brand manufacturers can. In today's world, where generic drugs make up 75 percent of the prescription drug market, all manufacturers should be able to improve the warning information they provide to doctors and consumers. The Patient Safety and Generic Labeling Improvement Act will achieve this goal.

This legislation is not intended to overburden the makers of generic drugs. Instead, it authorizes generic drug manufacturers to act upon drug safety information that they already gather pursuant to existing regulation. The FDA requires generic manufacturers to monitor, investigate and report adverse side effects experienced by users of their drug. Generics already must submit an annual report to the FDA summarizing new information that ''might affect the safety, effectiveness or labeling of a drug product'', including a ''description of actions they have taken or intend to take as a result of this new information''. When brand-name manufacturers exit the market—as is often the case after generics are introduced—generics may be the only manufacturers who gather this information.

The Patient Safety and Generic Labeling Improvement Act authorizes generics to act on the information they gather to improve the labeling on their product in the same way that brand-owners may do under existing law. It creates an exception to the general requirement that the labeling of a generic drug must be the same as the labeling of its brand-name or listed equivalent, and instead allows generic manufacturers to initiate a labeling change where that process is available to brand-name manufacturers. Under the law, a generic manufacturer would be able to use the ''Changes Being Effected'' process that permits manufacturers to implement a labeling change while the change is simultaneously reviewed by the FDA. When a labeling change is made under this provision, the FDA would be authorized to order conforming changes across equivalent drugs to ensure consistent labeling among products.

This legislation has the support of public interest groups and advocates, including the AARP, Public Citizen, the Alliance for Justice, and numerous consumer groups.

I have long worked to ensure that safe, affordable generic drugs are available to American consumers. Earlier this Congress, I introduced legislation to facilitate the importation of low-cost generic drugs from Canada, a measure that will increase competition and help drive down the prices of prescription drugs. We all benefit from the availability of safe, affordable medication to help reduce the overwhelming costs of healthcare.

The legislation I am introducing today will promote accountability and ensure that all drug makers can take appropriate steps to enhance warnings given to doctors and consumers. I hope that other Senators will join me and my cosponsors in supporting this important legislation.

Mr. President, I ask unanimous consent that the text of the bill and letters of support be printed in the RECORD.

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

S. 2295

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient Safety and Generic Labeling Improvement Act''.

SEC. 2. WARNING LABELING WITH RESPECT TO GENERIC DRUGS.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

''(11)(A) Notwithstanding any other provision of this Act, the holder of an approved application under this subsection may change the labeling of a drug so approved in the same manner authorized by regulation for the holder of an approved new drug application under subsection (b).

''(B) In the event of a labeling change made under subparagraph (A), the Secretary may order conforming changes to the labeling of the equivalent listed drug and each drug approved under this subsection that corresponds to such listed drug.''.

AARP,
March 30, 2012.

Hon. PATRICK J. LEAHY,
U.S. Senate,
Washington, DC.

DEAR SENATOR LEAHY: AARP is pleased to endorse your legislation, the Patient Safety

and Generic Labeling Improvement Act, to address the issue of whether generic drug manufacturers have a duty to include new warnings about potentially serious side effects on their labels as they become known. Your bill would accomplish this by giving generic drug makers the same ability to update their labeling as currently exists for manufacturers of brand name drugs.

AARP believes generic drugs are one of the safest and most effective ways for consumers to lower their prescription drug costs, and we encourage our members to use generic drugs whenever possible. However, AARP is concerned that, unlike brand name drug manufacturers, generic drug manufacturers cannot be held liable for inadequate drug warning labels due to their inability to directly update their labels under current law.

As noted in an AARP Foundation amicus brief submitted in Pliva v. Mensing, AARP believes that holding generic drug makers to a lower standard will effectively punish consumers for choosing generic drugs and send the message that generics are less trustworthy than name brand drugs—directly counter to the intent of the Hatch-Waxman Act. We are encouraged by your bill and hope it will serve to not only ensure patients have adequate legal protections, but also prompt improvements to the FDA process for updating warning labels when new information about potentially harmful side effects comes to light.

We thank you for your leadership in this area, and we look forward to working with you and your colleagues on both sides of the aisle to advance the Patient Safety and Generic Labeling Improvement Act. If you have any further questions, please feel free to call me or have your staff contact KJ Hertz of our Government Affairs staff at 202–434–3770.

Sincerely,

JOYCE A. ROGERS,
Senior Vice President, Government Affairs.

APRIL 17, 2012.

Hon. PATRICK LEAHY,
U.S. Senate,
Washington, DC.

DEAR CHAIRMAN LEAHY: We write to express our strong support for the Patient Safety and Generic Labeling Improvement Act, which would promote consumer safety by ensuring that generic drug companies can improve the warning information for their products in the same way that brand manufacturers can under existing law.

By authorizing generic manufacturers to improve their labels using the same ''Changes Being Effected'' process that is currently available to brand-name manufacturers, this legislation will help protect millions of Americans. The Department of Health and Human Services reports that generic drugs now make up 75 percent of the market for pharmaceuticals, and studies show that when a generic version of a drug is available 90 percent of prescriptions are filled with the generic.

This much-needed legislation responds to the Supreme Court's 2011 decision in PLIVA v. Mensing, in which the Court held 5–4 that a Minnesota woman, Gladys Mensing, could not recover damages for debilitating injuries she received from a drug with an inadequate warning label simply because her prescription was filled with the generic version of the drug, rather than with the brand-name drug. The Court previously held in Wyeth v. Levine (2009) that federal law does not preempt failure-to-warn claims against brand-name drug manufacturers. The Mensing decision thus created an arbitrary distinction whereby a court's ruling on whether or not a consumer can obtain relief turns solely on the happenstance of whether his or her prescription was filled with a brand-name or generic drug.

This troubling and unfair inconsistency in the law is exacerbated by the fact that many consumers have little control over which version of a drug they are given. Many brand-name manufacturers exit the market after generics are introduced. Moreover, many state laws and health insurance plans require consumers to be given generics if they are available.

Given the inherent unfairness of the current law and the ongoing harm to millions of Americans, the Senate should pass this legislation without delay.

Sincerely,

Alliance for Justice, Consumer Action, Consumer Federation of America, Consumers Union, Consumer Watchdog, National Association of Consumer Advocates, and US PIRG.

PUBLIC CITIZEN,
Washington, DC, April 18, 2012.

Re Letter in support of Patient Safety and Generic Labeling Improvement Act

Hon. PATRICK LEAHY, *Chairman,*
U.S. Senate, Committee on the Judiciary,
Washington, DC.

DEAR CHAIRMAN LEAHY: Public Citizen, a nonprofit consumer advocacy organization with 250,000 members and supporters nationwide, writes to applaud your introduction of legislation that would give generic drug manufacturers the authority to revise labeling for their products when they become aware of risks that are not adequately disclosed. This bill would fill a gaping hole in drug regulation that poses a threat to patients' health and safety.

Your legislation reflects the concerns voiced by Public Citizen in a citizen petition that we submitted to the Food and Drug Administration in August 2011. As we explained in the petition, the generic drug market has grown exponentially in the past 25 years, and generic drugs now constitute a majority of the prescription drugs sold in the United States. The growth of generic drug sales reflects the fact that generics offer equally effective but more affordable alternatives to their brand-name counterparts. The regulatory system, however, has not adjusted to the marketplace.

Under current law, a generic drug manufacturer is not authorized to revise product labeling when it becomes aware of inadequacies in the labeling. Specifically, FDA regulations provide that, unlike brand-name manufacturers, generic drug manufacturers are not permitted to initiate labeling revisions to strengthen warnings, contraindications, or precautions. As a result, the millions of patients who use generic drugs may not have access to up-to-date information on safety and proper use. And generic drug manufacturers lack incentive to monitor and ensure the safety of their products, even when the generic versions represent a majority of the market for a particular drug. Your legislation would correct this problem.

Your bill would also correct an illogical inconsistency in the accountability that generic and brand-name drug manufacturers have to patients. In a 2011 decision, PLIVA v. Mensing, the Supreme Court relied on FDA regulations to hold that a consumer injured by a generic drug with inadequate warnings cannot seek compensation under state law for failure to warn. By contrast, in a 2008 decision, Wyeth v. Levine, the Court had held that manufacturers of prescription drugs could be held accountable to patients for harm their drugs caused. The Justices in Mensing itself noted that this inconsistency ''makes little sense,'' with four Justices calling it ''absurd.''

As the Supreme Court has noted, ''the FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.'' Under your bill, generic drug manufacturers, who already have access to relevant safety information, would be able to revise their labeling as new information comes to light, thereby making their products safer for patients.

For these reasons, Public Citizen strongly supports your intent to fill the regulatory gap in generic drug safety. We look forward to working with you to pass this important legislation.

Sincerely,

ALLISON M. ZIEVE,
Director,
Public Citizen Litigation Group.
SIDNEY M. WOLFE, MD,
Director,
Public Citizen Health Research Group.

[From the New York Times, Mar. 23, 2012]

A BIZARRE OUTCOME ON GENERIC DRUGS

Dozens of suits against drug companies have been dismissed in federal and state courts because of a decision by the Supreme Court last year that makes it virtually impossible to sue generic manufacturers for failing to provide adequate warning of a prescription drug's dangers. This outrageous denial of a patient's right to recover fair damages makes it imperative that Congress or the Food and Drug Administration fashion a remedy.

This situation is particularly bizarre because patients using the brand-name drug can sue when those using the generic form of the drug cannot, as explained by Katie Thomas in The Times on Wednesday. In 2008, the Supreme Court ruled that a Vermont woman who had her hand and forearm amputated because of gangrene after being injected with a brand name antinausea drug could sue the manufacturer for inadequate warning of the risks; she won $6.8 million from Wyeth.

In 2011, the court ruled that similar failure-to-warn suits could not be brought against makers of generic drugs. As a result, an Indiana woman who was also forced to have her hand amputated because of gangrene after being injected with a generic version of the same antinausea drug had her case dismissed.

Same drug. Same devastating health consequences. Opposite results. This injustice will affect more people as generics, which already dominate the market, expand even more under the pressure to control health care costs.

The Supreme Court's disparate rulings hinge on the ability of the drug makers to change a warning label if they detect new evidence of dangers. In 2008, the court found that brand-name manufacturers had the unilateral power to change warnings through various mechanisms even before asking the Food and Drug Administration for a formal change.

Then, in 2011, the court found that, under the F.D.A.'s interpretation of a 1984 law, known as the Hatch-Waxman amendments to the Food, Drug and Cosmetic Act, the generic versions must carry warning labels identical to those of the brand-name drug. The goal was to minimize confusion and dispel any doubt that a generic was therapeutically equivalent to the brand-name drug. Generic makers can't change the warnings but can propose a change to the F.D.A., which can then bring about a revision of the brand-name label to trigger a corresponding change in the generic label. The court ruled that because the generic makers do not control the

labeling, they cannot be sued under state law for inadequate warnings.

Justice Clarence Thomas, writing for the majority in 2011, acknowledged that the distinction ''makes little sense'' in the eyes of consumers, and Justice Sonia Sotomayor, writing the dissent, predicted ''absurd consequences'' depending on the ''happenstance'' of whether a prescription was filled with a brand-name or generic drug.

Congress should fix the disparity by amending the law to make it clear—as Representative Henry Waxman, a co-author of the statute contends—that the act did not intend to preempt all failure-to-warn claims. Alternatively, the F.D.A. should fix the liability problem by amending its regulations to allow generic manufacturers to change the warning labels.

Generic drugs have rapidly expanded their reach, and, by one estimate, from one-third to one-half of all generic drugs no longer have a brand-name competitor. The regulatory system needs to hold generic companies, many of them large multinationals, accountable for labels on the products they sell.

Mr. FRANKEN. Mr. President, Gladys Mensing lives in Owatonna, MN. She loves being around people. That is a good thing when one has a family as big as Gladys does. She is the loving mother of 8 children, with 15 grandchildren and 12 great-grandchildren.

Gladys, as I said, is from Owatonna. It is in southeastern Minnesota. A few weeks ago, I received some old family videos that showed her playing with her grandkids. Gladys used to work as a waitress and as an apartment manager, but what she truly enjoys is a good game of bingo.

In 2001, Gladys's doctor gave her a prescription for a medication known as MCP to treat a digestive tract condition. Gladys did what I would have done—she took her prescription to the pharmacy, got it filled, and started taking her medicine per her doctor's orders.

Meanwhile, however, evidence was mounting linking MCP to neurological disorders. Within a few years, Gladys began experiencing problems. She lost control of her face, tongue, and legs. It is very hard to understand Gladys when she speaks now. Her son says people sometimes give Gladys strange looks when she goes out in public. Gladys used to be very strong and independent. Now her family has to help her bathe and walk.

Gladys wanted to hold the drug manufacturer accountable for what happened to her. She believed the warning label that came with her prescription was inadequate; that it did not sufficiently disclose the risks of taking MCP. So Gladys, a bingo-playing grandma from rural Minnesota, decided to stand up for her rights.

Gladys took her fight all the way to the U.S. Supreme Court, but that is where things took a bizarre turn. In Minnesota, as in many other States, the law requires drug manufacturers to warn patients of the known—the known—dangers associated with their products. Manufacturers that do not follow the law are held accountable to the patients who are harmed as a result—people such as Gladys.

But the Supreme Court—in a 5-to-4 decision—said those laws do not apply to generic drugs such as the medicine Gladys was taking. Rather, the Court said Federal regulations actually prohibit generic drug manufacturers from updating their labels—prohibit generic drug manufacturers from updating their labels—and it said the Federal regulations prohibiting label changes trump Minnesota's patient protection laws, which require full disclosure of potential risks. So under that ruling, even if a generic drug company wanted to provide better warnings of risks to consumers, it cannot.

Generic drugs are, for all intents and purposes, the same as brand-name drugs. They have the same active ingredients. They are used for the same purposes and, yes, in most cases, they should have the same labels. That is why current FDA regulations require generic drug labels to match brand-name drug labels. But it does not make sense to prohibit generic drug makers from updating their labels to accurately reflect new side effects or risks that have come to light. Yet that is the current state of the law.

So the Court dismissed Gladys's case just because she was taking a generic drug. Let me say that again. Because Gladys was taking the generic version of her medicine, she was unable to vindicate her rights under Minnesota law. If Gladys had suffered the same injuries from the brand-name version of the same pill containing the same warning, she would have had her day in court.

Since the Supreme Court dismissed Gladys's case last June, lower courts have dismissed dozens of similar cases because, as a recent article in the New York Times aptly said, ''What once seemed like a trivial detail—whether to take a generic or brand-name drug—has become the deciding factor in whether a patient can seek legal recourse from a drug company.''

That does not make any sense. Justice Thomas, who wrote the Supreme Court's decision in Gladys's case, admitted as much. He wrote this:

> We recognize that from the perspective of Mensing . . . [this decision] makes little sense.

I agree with him on this point. I would like to think he would agree with me on this: Prescription drugs should be safe and their labels should be adequate.

So Senators LEAHY, BINGAMAN, BROWN, WHITEHOUSE, COONS, BLUMENTHAL, and I are introducing a bill that would guarantee just that. Our bill, the Patient Safety and Generic Labeling Improvement Act, would allow generic drug makers to update their warnings—allow them to update their warnings—to accurately reflect the known risks associated with their drugs. That is it. It would not require them to do so. It just lets them do what other drug manufacturers already are allowed to do.

Our bill says that millions of Americans who are taking generic drugs are entitled to the same protections as people who take brand-name drugs, and it says people such as Gladys Mensing are entitled to their day in court when manufacturers fail to disclose risks.

I thank Senator LEAHY for his leadership on this issue and urge my colleagues to join with us in supporting this commonsense fix.

By Mrs. MURRAY (for herself, Mr. BEGICH, Mr. WHITEHOUSE, Mr. ROCKEFELLER, and Mr. AKAKA):

S. 2299. A bill to amend the Servicemembers Civil Relief Act and title 38, United States Code, to improve the provision of civil relief to members of the uniformed services and to improve the enforcement of employment and reemployment rights of such members, and for other purposes; to the Committee on Veterans' Affairs.

Mrs. MURRAY. Mr. President, today, as Chairman of the Senate Committee on Veterans' Affairs, I am pleased to introduce the Servicemembers Rights Enforcement Improvement Act of 2012.

I remain deeply committed to protecting our servicemembers and veterans. I was concerned, last year, when banks improperly overcharged and foreclosed upon deployed servicemembers in violation of the Servicemembers Civil Relief Act. Failure to comply with the protections provided to our servicemembers is unacceptable.

Our men and women in uniform deserve better than this, and I appreciate the President's and the Attorney General's leadership and commitment to enforcing these important protections. This bill, which includes a significant number of proposals provided to the Congress by the Department of Justice, would further strengthen the Department's ability to enforce these laws on behalf of servicemembers and veterans.

The bill I am introducing today would improve the Department of Justice's ability to enforce the protections of the Servicemembers Civil Relief Act by giving the Attorney General limited authority to issue civil investigative demands, which would allow the Attorney General to take a more proactive approach to investigating allegations of Servicemembers Civil Relief Act violations. This bill would strengthen the protections that prevent judgements against a servicemember when they cannot appear in court because of military service. Finally, it would clarify that servicemembers may bring a private right of action to enforce their rights under the Servicemembers Civil Relief Act.

I also remain deeply concerned about veteran employment. The number of unemployed veterans remains unacceptably high. Last year, significant provisions of a bill I introduced, the Hiring Heroes Act, were signed into law as the VOW to Hire Heroes Act. This legislation was a good first step in combatting the high rate of unemployment among our nation's veterans. But we must do more. We must also ensure

that the laws designed to protect the employment rights of our servicemembers during periods of service are equally strong.

The Uniformed Services Employment and Reemployment Rights Act, commonly referred to as USSERA, protects servicemembers' employment rights during a period of military service. It also prohibits employer discrimination based on military service or obligation. This legislation would strengthen the ability of the Department of Justice and the Office of Special Counsel to enforce these valuable protections.

Specifically, this bill would grant the Attorney General the authority to investigate and file suit to challenge a pattern or practice in violation of USERRA and would grant the Attorney General limited authority to issue civil investigative demands. It will also provide the Office of Special Counsel with subpoena authority in USERRA investigations. These enhancements will ensure that when our National Guard and Reserve members deploy, they do so knowing their jobs are secure.

It is vital that the Federal departments and agencies charged with protecting our servicemembers have the tools necessary to enforce the protections provided to them. The legislation I am introducing today would do just that.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 2299

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Servicemembers Rights Enforcement Improvement Act of 2012''.

SEC. 2. MODIFICATION OF PLAINTIFF AFFIDAVIT FILING REQUIREMENT FOR DEFAULT JUDGMENTS AGAINST SERVICEMEMBERS.

Paragraph (1) of section 201(b) of the Servicemembers Civil Relief Act (50 U.S.C. App. 521(b)) is amended to read as follows:

''(1) PLAINTIFF TO FILE AFFIDAVIT.—

''(A) IN GENERAL.—In any action or proceeding covered by this section, the plaintiff, before seeking a default judgment, shall file with the court an affidavit—

''(i) stating whether or not the defendant is in military service and showing necessary facts to support the affidavit; or

''(ii) if the plaintiff is unable to determine whether or not the defendant is in military service, stating that the plaintiff is unable to determine whether or not the defendant is in military service.

''(B) DUE DILIGENCE.—Before filing the affidavit, the plaintiff shall conduct a diligent and reasonable investigation to determine whether or not the defendant is in military service, including a search of available records of the Department of Defense and any other information available to the plaintiff. The affidavit shall set forth in the affidavit all steps taken to determine the defendant's military status.''.

SEC. 3. RETROACTIVE APPLICATION OF PRIVATE RIGHT OF ACTION UNDER SERVICEMEMBERS CIVIL RELIEF ACT.

Section 802(a) of the Servicemembers Civil Relief Act (50 U.S.C. App. 597a(a)) shall apply with respect to violations of such Act occurring on or after December 19, 2003.

SEC. 4. ENFORCEMENT OF RIGHTS OF MEMBERS OF UNIFORMED SERVICES WITH RESPECT TO STATES AND PRIVATE EMPLOYERS.

(a) ACTION FOR RELIEF.—Subsection (a) of section 4323 of title 38, United States Code, is amended—

(1) in paragraph (1)—

(A) by striking ''appear on behalf of, and act as attorney for, the person on whose behalf the complaint is submitted and'';

(B) by striking ''for such person'';

(C) by striking the fourth sentence; and

(D) by adding at the end the following: ''The person on whose behalf the complaint is referred may, upon timely application, intervene in such action, and may obtain such appropriate relief as is provided in subsections (d) and (e).'';

(2) by striking paragraph (2) and inserting the following new paragraph (2):

''(2)(A) Not later than 60 days after the date the Attorney General receives a referral under paragraph (1), the Attorney General shall transmit, in writing, to the person on whose behalf the complaint is submitted—

''(i) if the Attorney General has made a decision to commence an action for relief under paragraph (1) relating to the complaint of the person, notice of the decision; and

''(ii) if the Attorney General has not made such a decision, notice of when the Attorney General expects to make such a decision.

''(B) If the Attorney General notifies a person that the Attorney General expects to make a decision under subparagraph (A)(ii), the Attorney General shall, not later than 30 days after the date on which the Attorney General makes such decision, notify, in writing, the person of such decision.''.

(3) by redesignating paragraph (3) as paragraph (4),

(4) by inserting after paragraph (2) the following new paragraph (3):

''(3) Whenever the Attorney General has reasonable cause to believe that a State (as an employer) or a private employer is engaged in a pattern or practice of resistance to the full enjoyment of any of the rights and benefits provided for under this chapter, and that the pattern or practice is of such a nature and is intended to deny the full exercise of such rights and benefits, the Attorney General may commence an action for relief under this chapter.''; and

(5) in paragraph (4), as redesignated by paragraph (3), by striking subparagraph (C) and inserting the following new subparagraph (C):

''(C) has been notified by the Attorney General that the Attorney General does not intend to commence an action for relief under paragraph (1) with respect to the complaint under such paragraph.''.

(b) STANDING.—Subsection (f) of such section is amended to read as follows:

''(f) STANDING.—An action under this chapter may be initiated only by the Attorney General or by a person claiming rights or benefits under this chapter under subsection (a).''.

(c) CONFORMING AMENDMENT.—Subsection (h)(2) of such section is amended by striking ''under subsection (a)(2)'' and inserting ''under paragraph (1) or (4) of subsection (a)''.

SEC. 5. SUBPOENA POWER FOR SPECIAL COUNSEL IN ENFORCEMENT OF EMPLOYMENT AND REEMPLOYMENT RIGHTS OF MEMBERS OF UNIFORMED SERVICES WITH RESPECT TO FEDERAL EXECUTIVE AGENCIES.

Section 4324 of title 38, United States Code, is amended by adding at the end the following new subsection:

''(e)(1) In order to carry out the Special Counsel's responsibilities under this section, the Special Counsel may require by subpoena the attendance and testimony of Federal employees and the production of documents from Federal employees and Federal executive agencies.

''(2) In the case of contumacy or failure to obey a subpoena issued under paragraph (1), upon application by the Special Counsel, the Merit Systems Protection Board may issue an order requiring a Federal employee or Federal executive agency to comply with a subpoena of the Special Counsel.

''(3) An order issued under paragraph (2) may be enforced by the Merit Systems Protection Board in the same manner as any order issued under section 1204 of title 5, United States Code.''.

SEC. 6. ISSUANCE AND SERVICE OF CIVIL INVESTIGATIVE DEMANDS BY ATTORNEY GENERAL.

(a) ISSUANCE UNDER SERVICEMEMBERS CIVIL RELIEF ACT.—Section 801 of the Servicemembers Civil Relief Act (50 U.S.C. App. 597) is amended by adding at the end the following:

''(d) ISSUANCE AND SERVICE OF CIVIL INVESTIGATIVE DEMANDS.—

''(1) IN GENERAL.—Whenever the Attorney General has reason to believe that any person may be in possession, custody, or control of any documentary material relevant to an investigation under this Act, the Attorney General may, before commencing a civil action under subsection (a), issue in writing and serve upon such person, a civil investigative demand requiring—

''(A) the production of such documentary material for inspection and copying;

''(B) that the custodian of such documentary material answer in writing written questions with respect to such documentary material; or

''(C) the production of any combination of such documentary material or answers.

''(2) FALSE CLAIMS.—The provisions of section 3733 of title 31, United States Code, governing the authority to issue, use, and enforce civil investigative demands shall apply with respect to the authority to issue, use, and enforce civil investigative demands under this section, except that, for purposes of applying such section 3733—

''(A) references to false claims law investigators or investigations shall be considered references to investigators or investigations under this Act;

''(B) references to interrogatories shall be considered references to written questions, and answers to such need not be under oath;

''(C) the definitions relating to 'false claims law' shall not apply; and

''(D) provisions relating to qui tam relators shall not apply.''.

(b) ISSUANCE UNDER CHAPTER 43 OF TITLE 38, UNITED STATES CODE.—Section 4323 of title 38, United States Code, is amended—

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following new subsection (i):

''(i) ISSUANCE AND SERVICE OF CIVIL INVESTIGATIVE DEMANDS.—(1) Whenever the Attorney General has reason to believe that any person may be in possession, custody, or control of any documentary material relevant to an investigation under this subchapter, the Attorney General may, before commencing a civil action under subsection (a),

issue in writing and serve upon such person, a civil investigative demand requiring—

''(A) the production of such documentary material for inspection and copying;

''(B) that the custodian of such documentary material answer in writing written questions with respect to such documentary material; or

''(C) the production of any combination of such documentary material or answers.

''(2) The provisions of section 3733 of title 31 governing the authority to issue, use, and enforce civil investigative demands shall apply with respect to the authority to issue, use, and enforce civil investigative demands under this section, except that, for purposes of applying such section 3733—

''(A) references to false claims law investigators or investigations shall be considered references to investigators or investigations under this subchapter;

''(B) references to interrogatories shall be considered references to written questions, and answers to such need not be under oath;

''(C) the definitions relating to 'false claims law' shall not apply; and

''(D) provisions relating to qui tam relators shall not apply.''.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 424—CONDEMNING THE MASS ATROCITIES COMMITTED BY THE GOVERNMENT OF SYRIA AND SUPPORTING THE RIGHT OF THE PEOPLE OF SYRIA TO BE SAFE AND TO DEFEND THEMSELVES

Mr. MCCAIN (for himself, Mr. LIEBERMAN, Mr. GRAHAM, Mr. KYL, Ms. AYOTTE, and Mr. HOEVEN) submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 424

Whereas, in March 2011, large-scale peaceful demonstrations began to take place in Syria against the authoritarian rule of Bashar al-Assad;

Whereas the Bashar al-Assad regime responded to protests by launching a campaign of escalating and indiscriminate violence, including gross human rights violations, use of force against civilians, torture, extrajudicial killings, arbitrary executions, sexual violence, and interference with access to medical treatment;

Whereas demonstrators initially demanded political reform, but under sustained violent attack by the Government of Syria, now demand a change in the Syrian regime;

Whereas forces loyal to Bashar al-Assad are increasingly and indiscriminately employing heavy weapons, including tanks and artillery, to attack civilian population centers;

Whereas, on November 23, 2011, the United Nations-appointed Independent International Commission of Inquiry on the Syrian Arab Republic reported that ''crimes against humanity of murder, torture, rape or other forms of sexual violence of comparable gravity, imprisonment or other severe deprivation of liberty, enforced disappearances of persons and other inhumane acts of a similar character have occurred in different locations in Syria since March 2011'' and that ''the Syrian Arab Republic bears responsibility for these crimes and violations'';

Whereas, on February 22, 2012, the Independent International Commission of Inquiry on the Syrian Arab Republic found in a subsequent report that ''commanding officers and officials at the highest level of government bear responsibility for crimes against humanity and other gross human rights violations'';

Whereas, on March 15, 2012, United Nations Secretary-General Ban Ki-Moon warned that ''well over 8,000 people'' have been killed because of the ''brutal oppression'' by authorities in Syria and called the status quo in Syria ''indefensible'';

Whereas, on March 27, 2012, the United Nations reported that the death toll in Syria had climbed to ''more than 9,000'';

Whereas at least 3,000 people have been killed in Syria in 2012 alone;

Whereas, on October 2, 2011, a broad-based coalition of Syrian opposition leaders announced the establishment of the Syrian National Council (SNC), calling for the end of the Bashar al-Assad regime and the formation of a civil, pluralistic, and democratic state in Syria;

Whereas, on February 24, 2012, Secretary of State Hillary Clinton called the Syrian National Council (SNC) ''a leading legitimate representative of Syrians seeking peaceful democratic change'' and an ''effective representative for the Syrian people with governments and international organizations'';

Whereas growing numbers of people in Syria, under continued and escalating assault by the Assad regime, have taken up arms to defend themselves and organized armed resistance under the banner of the Free Syrian Army (FSA);

Whereas the leaders of the Free Syrian Army have rejected sectarianism;

Whereas, on December 6, 2011, the Syrian National Council issued a statement affirming that the Free Syrian Army ''deserve[s] the backing of all supporters of human rights in Syria'' and applauding the decision of FSA officers to ''risk their lives and those of their families because they believe in Syria and have lost faith in the Assad doctrine'';

Whereas, on March 12, 2012, the Syrian National Council, through its spokesperson, called for ''military intervention by Arab and Western countries to protect civilians'' in Syria, and endorsed the arming of the Free Syrian Army;

Whereas, on March 16, 2012, opposition activists inside Syria staged protests calling for ''immediate military intervention by the Arabs and Muslims, followed by the rest of the world'';

Whereas, on February 24, 2012, the Foreign Minister of Saudi Arabia, Saud bin Feisal, called providing weapons to the Syrian opposition ''an excellent idea...because they have to protect themselves'';

Whereas, on February 27, 2012, the Prime Minister of Qatar, Sheikh Hamad bin Jassim al Thani, said of the Syrian opposition, ''I think we should do whatever is necessary to help them, including giving them weapons to defend themselves.'';

Whereas, on March 1, 2012, the parliament of Kuwait voted overwhelmingly on a resolution calling on the Government of Kuwait to support the Syrian opposition, including by providing weapons;

Whereas, on March 16, 2012, Prime Minister Recep Tayyip Erdogan of Turkey said that the Government of Turkey was considering setting up a ''security'' or ''buffer zone'' along its border with Syria;

Whereas, on December 22, 2010, the Senate passed Senate Concurrent Resolution 71 (112th Congress), a bipartisan resolution recognizing that it is in the national interest of the United States to prevent and mitigate acts of genocide and other mass atrocities against civilians;

Whereas, on August 4, 2011, President Barack Obama issued Presidential Study Directive–10 (PSD–10), stating, ''Preventing mass atrocities and genocide is a core national security interest and a core moral responsibility of the United States.'';

Whereas, on May 18, 2011, President Obama signed Executive Order 13573, targeting senior officials of the Government of Syria due to the Government's continuing escalation of violence against the people of Syria;

Whereas, on April 29, 2011, President Obama signed Executive Order 13572, imposing sanctions on certain individuals and entities in the annex to the order and providing the authority to designate persons responsible for human rights abuses in Syria, including those related to repressing the people of Syria;

Whereas, on February 4, 2012, President Obama stated that Bashar al-Assad ''has no right to lead Syria and has lost all legitimacy with his people and the international community'';

Whereas, on February 17, 2012, the Senate passed Senate Resolution 379 (112th Congress), stating that the ''gross human rights violations perpetuated by the Government of Syria against the people of Syria represent a grave risk to regional peace and stability'';

Whereas, on February 28, 2012, Secretary of State Clinton, in testimony before the Subcommittee on the Department of State, Foreign Operations, and Related Programs of the Committee on Appropriations of the Senate concerning Bashar al- Assad, testified that, ''based on the definitions of war criminal and crimes against humanity, there would be an argument to be made that he would fit into that category'';

Whereas, on March 1, 2012, Admiral James Stavridis, commander of United States European Command and Supreme Allied Commander of NATO, during testimony before the Committee on Armed Services of the Senate, agreed with the statement that ''the provision of arms, communication equipment, and tactical intelligence'' would ''help the Syrian opposition to better organize itself and push Assad from power'';

Whereas, on March 6, 2012, General James Mattis, commander of United States Central Command, testified before the Committee on Armed Services of the Senate that Bashar al-Assad will ''continue to employ heavier and heavier weapons on his people'';

Whereas, on March 6, 2012, General Mattis testified before the Committee on Armed Services of the Senate that there is ''a full throated effort by Iran to keep Assad there and oppressing his own people'' in Syria, including ''providing the kinds of weapons that are being used right now to suppress the opposition,'' as well as ''listening capability, eavesdropping capability...and experts who I could only say are experts at oppressing'';

Whereas, on March 6, 2012, General Mattis testified before the Committee on Armed Services of the Senate that the fall of the Bashar al-Assad regime would represent ''the biggest strategic setback for Iran in 25 years''; and

Whereas the continuing gross human rights violations against the people of Syria represent a grave risk to regional peace and stability: Now, therefore, be it

Resolved, That the Senate—

(1) condemns the mass atrocities and severe human rights abuses being perpetrated against the people of Syria by Bashar al-Assad and his followers;

(2) recognizes that the people of Syria have an inherent right to defend themselves against the campaign of violence being conducted by the Assad regime;

(3) supports calls by Arab leaders to provide the people of Syria with the means to defend themselves against Bashar al-Assad and his forces, including through the provision of weapons and other material support, and calls on the President to work closely