SENATE DELETE ALL PASSED DEC 6, 2006 IN SENATE
AER BILL S 3546

Mr. FRIST, Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 586, S. 3546.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 3546) to amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes.

There being no objection, the Senate proceeded to consider the bill which had been reported from the Committee on Health, Education, Labor, and Pensions, with an amendment to strike all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ``Dietary Supplement and Nonprescription Drug Consumer Protection Act''.

SEC. 2. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

(a) *In General*.--Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

``Subchapter H--Serious Adverse Event Reports

``SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

``(a) *Definitions*.--In this section:

``(1) **ADVERSE EVENT**.--The term `adverse event' means any health-related event associated with the use of a nonprescription drug that is adverse, including--

``(A) an event occurring from an overdose of the drug, whether accidental or intentional;

``(B) an event occurring from abuse of the drug;

``(C) an event occurring from withdrawal from the drug; and

``(D) any failure of expected pharmacological action of the drug.

``(2) **NONPRESCRIPTION DRUG**.--The term `nonprescription drug' means a drug that is--

``(A) not subject to section 503(b); and

``(B) not subject to approval in an application submitted under section 505.

``(3) **SERIOUS ADVERSE EVENT**.--The term `serious adverse event' is an adverse event that--

``(A) results in--

``(i) death;

``(ii) a life-threatening experience;

``(iii) inpatient hospitalization;

``(iv) a persistent or significant disability or incapacity; or

``(v) a congenital anomaly or birth defect; or

``(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

``(3) **SERIOUS ADVERSE EVENT REPORT**.--The term `serious adverse event report' means a report that is required to be submitted to the Secretary under subsection (b).

``(b) *Reporting Requirement*.--

``(1) **IN GENERAL**.--The manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 403(e)(1)) appears on the label of a dietary supplement marketed in the United States (referred to in this section as the `responsible person') shall submit to the Secretary any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement.

``(2) **RETAILER**.--A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required reports for such dietary supplements to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such dietary supplement that are reported to the retailer through the address or telephone number described in section 403(y).

``(c) *Submission of Reports*.--

``(1) **TIMING OF REPORTS**.--The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 403(y).

``(2) **NEW MEDICAL INFORMATION**.--The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

``(3) **CONSOLIDATION OF REPORTS**.--The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

``(4) **EXEMPTION**.--The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

``(d) *Contents of Reports*.--Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for dietary supplements, and may be accompanied by additional information.

``(e) *Maintenance and Inspection of Records*.--

``(1) **MAINTENANCE**.--The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

``(2) **RECORDS INSPECTION**.--

``(A) **IN GENERAL**.--The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 704.

``(B) **AUTHORIZED PERSON**.--For purposes of this paragraph, the term `authorized person' means an officer or employee of the Department of Health and Human Services, who has--

``(i) appropriate credentials, as determined by the Secretary; and

``(ii) been duly designated by the Secretary to have access to the records required under this section.

``(f) *Protected Information*.--A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be--

``(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure,

that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

``(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the `Privacy Act of 1974') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the `Freedom of Information Act'), and shall not be publicly disclosed unless all personally identifiable information is redacted.

``(g) *Rule of Construction*.--The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event.

``(h) *Preemption*.--

``(1) **IN GENERAL**.--No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for dietary supplements, that is different from, in addition to, or otherwise not identical to, this section.

``(2) **EFFECT OF SECTION**.--

``(A) **IN GENERAL**.--Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

``(B) **PERSONALLY-IDENTIFIABLE INFORMATION**.--Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not--

``(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

``(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

``(C) **USE OF SAFETY REPORTS**.--Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 756.

``(i) *Authorization of Appropriations*.--There are authorized to be appropriated to carry out this section such sums as may be necessary.''.

(b) *Prohibited Act*.--Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by--

(1) striking ``, or 760;'' and inserting ``, 760, or 761;''; and

(2) striking ``, or 760'' and inserting ``, 760, or 761''.

(c) *Misbranding*.--Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

``(y) If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes an address or phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement.''.

(d) *Effective Date*.--

(1) **IN GENERAL**.--Except as provided in paragraph (2), the amendments made by this section shall take effect 1 year after the date of enactment of this Act.

(2) **MISBRANDING**.--Section 403(y) of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall apply to any dietary supplement labeled on or after the date that is 1 year after the date of enactment of this Act.

(3) **GUIDANCE**.--Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report as described under the amendments made by this Act.

SEC. 4. PROHIBITION OF FALSIFICATION OF REPORTS.

(a) *In General*.--Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

``(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761) submitted to the Secretary.''.

(b) *Effective Date*.--The amendment made by this section shall take effect 1 year after the date of enactment of this Act.

SEC. 5. IMPORTATION OF CERTAIN NONPRESCRIPTION DRUGS AND DIETARY SUPPLEMENTS.

(a) *In General*.--Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended--

(1) in subsection (a), by inserting after the third sentence the following: ``If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section.''; and

(2) in the second sentence of subsection (b)--

(A) by inserting ``(1)'' before ``an article included'';

(B) by inserting before ``final determination'' the following: ``or (2) with respect to an article included within the provision of the fourth sentence of subsection (a), the responsible person (as defined in section 760 or 761) can take action that would assure that the responsible person is in compliance with section 760 or 761, as the case may be,''; and

(C) by inserting ``, or, with respect to clause (2), the responsible person,'' before ``to perform''.

(b) *Effective Date*.--The amendments made by this section shall take effect 1 year after the date of enactment of this Act.

Mr. HATCH. Mr. President, the Dietary Supplement and Nonprescription Drug Consumer Protection Act represents a too-rare-but-productive alliance between Democrats and Republicans and between consumer groups and FDA-regulated products manufacturers. This is a significant consumer protection measure. On behalf of my cosponsors, Senators **DURBIN, HARKIN, ENZI, KENNEDY,** and **CORNYN,** I want to express our enthusiasm that the bill will be approved by the Senate tonight.

Senator **DURBIN,** Senator **HARKIN,** and I have been working on this legislation for more than 2 years. Our effort has been enhanced by the expertise of Chairman **ENZI** and Senator **KENNEDY.** More recently, we were pleased that Senator **CORNYN** joined our ranks. I must also pay great tribute to our lead House sponsor, Representative **CHRIS CANNON.**

We have consulted broadly with all who have an interest in this issue--dietary supplement and nonprescription drug manufacturers, consumer and public health groups, retailers, wholesalers, and, of course, their lawyers! .

We have had meeting after meeting with the Food and Drug Administration.

Wherever possible, we have incorporated provisions to address their concerns.

The result--some 24 months and 21 drafts later--is the bill we consider tonight.

Some of my colleagues may ask, ``Why is this bill necessary?'' Let me answer that question.

Over half our population regularly uses dietary supplements. In fact, one government survey in 2004 indicated that nearly 60 percent of Americans regularly use dietary supplements to maintain or improve their healthy lifestyles.

Millions more use nonprescription or over-the-counter drugs, such as aspirin or cold tablets.

Although the FDA has a voluntary system to receive reports of problems with dietary supplements, and a mandatory system that covers some OTC drugs, there is no requirement for mandatory reporting for all of these products, as there is for prescription drugs and medical devices.

I happen to believe supplements are vastly more safe than prescription drugs. Indeed, the law which sets out the regulatory framework for supplements--the Dietary Supplement Health and Education Act, DSHEA, which Senator **HARKIN** and I authored with then-Representative Bill Richardson, explicitly treats most supplement products as foods. So, I in no way am suggesting that supplement products should be treated the same as prescription medications.

When we enacted DSHEA, we separated supplements into two categories--those that were on the market in the United States at the time of enactment, and those which would be marketed in the future--new dietary ingredients''. The presumption of DSHEA, which by and large has worked welt, is that products already on the market were being used safely. Some of these products, in fact, have been used safely for decades, if not millennia.

Those ``grandfathered'' products are not subject to any kind of premarket clearance by the FDA.

And for good reason.

The cost and time alone required to see a product through FDA approval would sound the death knell for this industry. Most supplement products cannot be patented, and there is no incentive for a manufacturer to put its product through this costly and onerous process when any other manufacturer could benefit equally from the fruits of the research and investment.

Finally, we also authorized the FDA to establish good manufacturing practice standards, GMPs, for supplements. Unfortunately, some 12 years later, those GMPs are still in the development stage, even though they were first finalized by the Clinton administration.

Senator **HARKIN** and I have spent several years trying to free them up, but that is a story for another time.

So, in essence, grandfathered products are assumed to be safe. But, in case some may not be, we inserted in the law a strong safety provision and we also added an ``imminent hazard'' authority so that FDA can immediately remove from marketing a product it suspects to be unsafe, no questions asked.

In 1994, we had no way of knowing what products would be marketed in the future. But to allay any concerns about the safety of new products, we required all manufacturers to submit information about new ingredients to the FDA before they are marketed. This NDI provision has by and large has worked well. It does allow the FDA premarket review for new products.

The reason I mention this is to explain the regulatory framework we set up in 1994 to help assure supplements are manufactured and marketed safely. We provided the FDA with an arsenal of tools to enforce the law. Some they have used, others not.

Since that time, the industry has grown. By some estimates, it is a $20 billion industry today.

Critics of the industry have decried this growth as a negative development, and they have repeatedly said that the industry is ``unregulated.'' Every time I read

that in the paper, or see it on TV, I cringe. And I know Senator **HARKIN** does as well. For it is simply wrong to suggest the industry is unregulated.

Indeed, under DSHEA, we set out a legal definition of what could be marketed as a dietary supplement. We set out a safety standard that products must have to meet. We allowed the FDA to develop good manufacturing process standards for supplements, and we have repeatedly asked the agency to issue those standards so they can be applied to products as they are being manufactured. We clarified what types of claims could be made about the products and what could not. We said these statements must be truthful and not misleading.

All of these requirements are set out in the law and are to be administered by the regulatory agency, the FDA.

And while the great, great majority of supplement products are used safely, there have been problems with some products. Some of these problems relate to manufacturing. Some relate to labeling.

Critics of supplements attribute any problem which might crop up to the fact that the industry is ``unregulated.''

As I have proven, the industry is indeed regulated. It is just not regulated in the same fashion as drugs or devices. And it is worth highlighting that this is an industry largely comprised of men and women of good will, who want to provide the public with health enhancing products.

Let me hasten to add that we all recognize there are bad actors in the supplement industry,

those who break the law and mislead consumers. They should be subject of swift and sure punishment by the FDA and the Federal Trade Commission, FTC. Their products should be removed from the marketplace and the full weight of the law should be brought down on these bad actors.

It is no secret that the FDA is a woefully underfunded agency, which will be the first to admit that its oversight of the dietary supplement industry is hampered by a lack of resources. For several years, Senator **HARKIN** and I have worked to rectify that short-coming, and we are gratified that our Utah colleague, Senator **BENNETT,** chairman of the Agriculture Appropriations Subcommittee, has joined hands with us to infuse some badly needed resources into the FDA.

For those who are new to this body, let me mention that in 1994, the Senate agreed not once, but twice, to approve DSHEA by unanimous consent. The House also passed this bill by UC. It was not controversial.

Members recognized then, as they should now, that supplements are largely safe. But just to make doubly sure there was adequate regulation, we provided the FDA with an arsenal of tools to take action against problematic products.

Then comes ephedra.

I do not think it is a constructive exercise to rehash the history of ephedra. There were mistakes and problems all around in how this product's safety was evaluated and addressed.

But something did stand out: one company had literally hundreds, if not thousands, of reports about products with this product, none of which were revealed to Federal authorities.

There is no question in my mind that the too-long safety evaluation of ephedra would have been shortened considerably had we known earlier about these reports.

Two years ago, I began discussing with those who are interested in dietary supplement regulation whether it would be wise to implement a system of mandatory adverse event reporting, AER, for those products.

While I am reluctant to argue for greater government regulation, in this case it seemed to me a good case could be made that an AER system for supplements could complement the work we achieved with DSHEA and improve the government's ability to address the relatively few problems which arose.

Senator **DURBIN** and Senator **HARKIN** were also having similar thoughts.

We joined forces and after much study, discussion and negotiation, produced S. 3546.

It may be surprising to many of our colleagues that Senators **HATCH, DURBIN, HARKIN, ENZI** and **KENNEDY** stand together on this legislation--we come from very different perspectives on dietary supplement regulation.

And while we are each very passionate about our views, we are united in a common goal: improving the public health.

The premise for this bill is simple: mandating a system to provide the

government with information about serious adverse events associated with the use of two types of FDA-regulated products--dietary supplements and over-the-counter drugs--provides Federal authorities with a better tool to respond to any problems which might occur. This is an important public health initiative, which at the same time safeguards access to dietary supplements and over-the-counter drugs.

There is currently a voluntary reporting system for supplements and some OTC drugs our bill would replace that with a mandatory system.

Senator **HARKIN** and I have a longstanding interest in regulation of these products; stemming back to our work on DSHEA.

Senator **DURBIN,** as the former chair of the House Agriculture Appropriations Subcommittee, is one of the most knowledgeable senators in this body when it comes to FDA matters.

Our collaboration on this legislation, along with the distinguished chairman and ranking minority member of the committee of jurisdiction, the Health, Education, Labor and Pensions Committee, both of whom were integral to this process, has produced a bill which strikes the right balance between necessary regulation and over-regulation.

This is how the new system will work:

Manufacturers, packers or distributors of OTC drugs or dietary supplements marketed in the United States must provide to the FDA within 15 business days any reports of a serious adverse event associated with their products. Accompanying that report must be a copy of the label on or within the retail packaging of the supplement.

The definition of serious event is proscribed within the legislation. It is either an event that results in a death, life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, or congenital anomaly or birth defect... or it is an event that requires based on reasonable medical judgment a medical or surgical intervention to prevent one of the outcomes I have just listed.

The bill requires that those reporting must, for one year, provide any new medical information related to the serious adverse event report. Again, that information must be submitted within 15 days.

In addition, manufacturers, packers and distributors must keep for 6 years records of any adverse event associated with the product, even though there is no reporting requirement unless the event meets the definition of serious.

For over-the-counter drugs, the definition of ``adverse event'' is a health-related event associated with the use of a nonprescription drug that is adverse, including: an event occurring from an overdose, whether accidental or intentional; an event occurring from abuse of the drug, or withdrawal from the drug; or any failure of pharmacological action.

For dietary supplements, an ``adverse event'' means any health-related event associated with the use of a dietary supplement that is adverse.

The reports will be submitted on the current MedWatch form, unless the Secretary of Health and Human Services chooses to modify that form at some point.

The bill makes clear that State health officials may have access to the adverse event reports, but that the Federal reporting system would supersede any state reporting laws.

As we met to develop this legislation, one thing we struggled with was the need to encourage responsible reporting in a way that manufacturers could implement. Some manufacturers indicated to us, for example, that they were not medical experts and could not determine in every case if a reporter's problem met the definition of ``serious'' contained in the bill.

To address this, we allow manufacturers to contract with third parties to handle the collection of reports. The manufacturers, of course, would still be ultimately responsible for reporting.

Another concern was making certain we appropriately defined the role of retailers, who are selling a range of products, some supplements, some OTCs, some not. We determined that retailers would not be considered reporting parties. If, however, a retailer contracts with

manufacturers to distribute ``private label'' products, they may authorize the manufacturer or packer to submit reports, as long as the retailer directors to the manufacturer all reports it receives.

We also wanted to allow the FDA the flexibility to manage this program. At its request, we made the program self-implementing. We also included a provision to allow the Secretary, after notice and comment from interested parties, to establish an exemption to the reporting requirements if there would be no adverse effect on public health.

Finally, there are provisions in the bill to impose penalties for not reporting, not providing on the product label an address or phone number for reporting, and for providing a false report.

The law will go into effect one year after the date of enactment.

Before I close, I want to address some of the concerns that representatives of the dietary supplement industry have voiced with this legislation.

First, some have suggested there is no need for this legislation from a public policy or a consumer safety perspective. I disagree.

Many have unfairly criticized the industry over media reports that supplements are unsafe because there is no pre-market approval. While I can never support any system that requires premarket approval for supplements, I have become convinced that having a system in place to identify problems quickly can only enhance the authorities we gave the FDA with DSHEA.

It is also good policy. As the industry matures, we need to separate out the good actors from the bad. This is one way to show that this industry is a respectable, mainstream industry. Other major industries, e.g. pharmaceuticals, devices, are subject to mandatory AER reporting. Supplements are only handled through the voluntary reporting system.

And, I disagree with you those who avow there is no consumer safety benefit. Let's take an easy case--where there is a bad batch of a product. Enabling the FDA to know quickly there is a problem can help industry and the public.

Other critics note that the FDA fails to pursue egregious violations of DSHEA. They question why this program will help. As I discussed earlier, Senator Harkin and I have been working to increase FDA's funding for responsible enforcement of DSHEA. I have also discussed this with the Commissioner-nominee, Dr. Andrew von Eschenbach, whom I expect we will confirm tomorrow.

I listened carefully to one of my constituents who opposes this effort. He suggested that the FDA's voluntary system, the CAERS system, should be able to handle any reports of problems. Public health experts will agree that a voluntary system is not as good a sentinel as a mandatory system. In addition, those who report under the voluntary system are more likely to be physicians. Encouraging consumers to report to manufacturers through a phone number or address on the product's label will ensure a more thorough reporting system.

Yet another concern I have heard is that this bill has a significant economic impact that has not been studied appropriately. One estimate I have heard is that it could cost tens of millions of dollars a year to industry and consumers.

I have to say that these estimates do not seem to be supported by other industry representatives who already are instituting reporting systems of their own. During the drafting of this bill, we worked very hard to keep requirements to the minimum that would be necessary for a complete and full reporting of serious adverse events.

In addition, I have heard a suggestions that a better alternative to this bill would be a 1-800 number that consumers can use to contact FDA directly to report complaints. I discussed this idea with my colleagues and the FDA and found little support for this idea. What this could do is shift onto FDA the majority of reports about product problems. In other words, FDA fears that consumers would start phoning the agency, rather than the manufacturer, to report complaints for things like broken bottles or tablets, or to answer questions about usage. It is easy to see how this could end up relieving manufacturers of some of their consumer-related responsibilities and shift that onto the FDA.

Let me hasten to add that I understand the motivation behind these concerns. I will keep a close watch on this

new program as it is implemented, and pledge to reexamine it should problems of implementation arise.

In closing, I want to thank my colleagues for the spirit of collaboration which led to development of this legislation. In particular, I want to thank Senator **DURBIN** for his leadership on this issue. While we may not have always agreed on every provision, we did forge a bill on which we can agree. His top-notch staffer, now a distinguished professor, Krista Donahue, worked with us every step of the way.

Senator **HARKIN** is a steadfast supporter of the dietary supplement industry, and his guidance undoubtedly made this bill a better product. We benefitted greatly from the counsel of his legislative director, Pam Smith, and before her, Peter Reinecke, his former chief of staff. Peter was instrumental in drafting DSHEA as well.

Senator **ENZI** and Senator **KENNEDY,** both long-time experts in food and drug law, have both been most generous in their time and in moving the process forward. Chairman **ENZI**'s FDA expert, Amy Muhlberg, helped guide us through this process and was key in our success. Senator **KENNEDY**'s staffer, David Dorsey, once a top FDA, lawyer, was instrumental in the drafting and made countless invaluable suggestions.

I will take this opportunity to thank my own staff--Patti DeLoatche, who always stood for common sense and reason during heated arguments, the elusive Bruce Artim, now a top staffer at Eli Lilley, and of course, Patricia Knight, who helped draft DSHEA with me as well.

Finally, we couldn't have done it without Liz King and Stacey Kern-Scheerer in Legislative Counsel, who patiently produced the 21 drafts leading to the bill today.

I must also note the groups that also support the bill--the Consumer's Union, the Center for Science in the Public Interest, the Consumer Healthcare Products Association, the Natural Products Association, the Council for Responsible Nutrition, the American Herbal Products Association, and finally and most importantly, the Utah Natural Products Association.

That these groups, not often united--at least on this subject--can rally around our bill today is a testament to good policy, good politics, and a surviving bipartisan spirit.

It is my hope the Senate will give swift approval to this bipartisan measure and that the House will shortly thereafter do the same.

Mr. DURBIN. Mr. President, today, the Senate adopted a bipartisan bill that provides the Food and Drug Administration with the tools it needs to help monitor the safety of dietary supplements.

Dietary supplements are safely consumed by millions of Americans every day. I myself take a multivitamin every morning. The vast majority of these supplements do not result in harm to the consumer.

Unfortunately, this is not the case for all supplements. Some cause dangerous health problems: increased blood pressure, heart attack, stroke, seizures and liver failure. Ephedra is the most well-known among these.

Under the Dietary Supplement Heath and Education Act, DSHEA, which passed in 1994, supplement manufacturers are not required to prove their products are safe or effective before they are marketed: supplements are assumed safe until proven unsafe.

The bill we passed today will help the FDA identify products that may be causing harm to consumers.

In 2000, the FDA contracted with the Institute of Medicine at the National Academies of Science to develop a scientific framework for the evaluation of dietary supplements under DSHEA.

IOM's proposals flowed from their first and essential recommendation to Congress: Make adverse event reporting mandatory. They asserted that ``adverse event reports have considerable strength as potential warning signals of problems requiring attention, making monitoring by the FDA worthwhile.''

Unfortunately, under current law, reporting is voluntary and it is not working. The Office of the Inspector General at the Department of Health and Human Services, HHS, estimated in 2001 that less than 1 percent of all adverse events associated with dietary supplements are reported to the FDA.

My own experience reinforces the need for a mandatory system of reporting. Metabolife told the FDA in February of 1999 that, ``Metabolife has never been made aware of any adverse health events by consumers of its products. Metabolife has never received a notice from a consumer that any serious adverse health event has occurred because of ingestion of Metabolife 356.''

The Justice Department began investigating the truthfulness of that statement and found that Metabolife was holding 16,500 adverse event reports, including almost 2,000 significant cardiac, neurological and psychiatric reports.

The Dietary Supplement and Nonprescription Drug Consumer Protection Act will prevent this scenario from ever happening again. Manufacturers of over-the-counter drugs and dietary supplements will be required to send these reports to the FDA.

I would like to thank Senators *Hatch, Harkin, Enzi* and *Kennedy*, who have worked with me for the last 3 years on this important issue.

Mr. FRIST. Mr. President, I ask unanimous consent that the committee-reported amendment be agreed to, the bill, as amended, be read a third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed in the **RECORD**.

The PRESIDING OFFICER. Without objection, it is so ordered.

The committee amendment in the nature of a substitute was agreed to.

The bill (S. 3546), as amended, was ordered to be engrossed for a third reading, was read the third time, and passed.

National Health Freedom ACTION
NATIONAL HEALTH FREEDOM ACTION
"Working for Health Rights in America"

507-663-9018
Info.nhfa@nationalhealthfreedom.org
•
PMB 218, 2136 Ford Parkway
St. Paul, MN 55116-1863

www.nationalhealthfreedomaction.org