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The Hill
September 17, 2014

Senate passes bill to improve sunscreen
By Ramsey Cox

Link to article

The Senate passed a bill Wednesday that aims to improve sunscreen protection.

Sen. Jack Reed (D-R.I.) introduced S. 2141, the Sunscreen Innovation Act, which would require the Department of Health and Human Services to establish a process for the review and approve over-the-counter (OTC) sunscreens.

The Senate passed the measure through a unanimous consent agreement and it now heads to the House for further action.

The Senate passed H.R. 4751, which renames the Bainbridge Island Japanese American Memorial as the Bainbridge Island Japanese American Exclusion Memorial. The House passed the bill earlier this month, meaning it now heads to President Obama's desk for his signature before becoming law.

H.R. 4809 was also passed through a unanimous consent agreement. It reauthorizes provisions of the Defense Production Act of 1950 through fiscal year 2019 so that the president can prepare for national defense, military conflicts, disasters, or acts of terrorism. The House passed the bill in July so it now heads to Obama's desk.

The Senate also passed Sen. Tom Coburn's (R-Okla.) DHS OIG Mandates Revision Act, S. 2651. That bill heads to the House.

TIME
September 17, 2014

Senate Passes Bill for Better Sunscreen
By Alexandra Sifferlin

Link to article

A highly anticipated bill that could bring more sunscreen ingredients to market has passed

The Senate passed a bill Wednesday that requires the Food and Drug Administration (FDA) to respond to current pending sunscreen ingredients within a shorter period of time — an important factor in ensuring that people have the most up-to-date ways to protect their skin from cancer-causing UVA rays, proponents of the legislation have argued.

While skin cancer is the most common cancer diagnosed in the U.S., eight sunscreen ingredients have been pending in FDA backlog for years — some for over a decade — even while several of the pending ingredients have already been used in Europe and Asia for years.

As TIME reported in May, proponents for sunscreen modernization were optimistic that a bipartisan bill, the Sunscreen Innovation Act, would pass over the summer. The bill, which also requires the FDA to respond to all potential sunscreen ingredients in the future within a year and a half at maximum, moved along quickly through the summer months. A version of the bill was passed by the House in July. Now, the House and Senate will meet to agree on a final legislation of the bill. Once they reach consensus, it will go to President Obama to sign.

“The two bills are pretty darn similar, so we don’t anticipate the negotiation will be contentious,” says Michael Werner, policy adviser of the Public Access to SunScreens Coalition.

One of the reasons it takes so long for sunscreen ingredients to get approval in the U.S. is because of the regulation process that the FDA currently has in place. In Europe, ingredients are regulated as cosmetics, but in the U.S. sunscreens are go through a process similar to drug approval, which takes longer and has more safety requirements.

However, many ingredients had not received any feedback from the FDA, not even negative feedback, which prompted skin-care advocates and policymakers to question why the FDA had taken so long to respond, even given the excuse of a stringent system.

As the bill began to move through the voting process, the FDA started responding to some of the pending applications.

THE DAILY CALLER
The Daily Caller
September 18, 2014

Senate Bill Passes To End FDA Stranglehold On Sunscreen Innovation
By Jonah Bennet

Link to article

Without any objection, the Senate has passed a bill forcing the FDA to speed up the approval process for sunscreen technology, HAPPI reports.

Sunscreen technology has stagnated in the United States since the 1990s, not because companies have failed to innovate, but because the Food and Drug Administration has been sitting on proposals submitted 12 years ago without even reviewing them.

The proposals include new sunscreen ingredients, and since the FDA has dropped the ball, the Senate has picked it up with the passage of the Sunscreen Innovation Act on Wednesday night.

Rates of melanoma have skyrocketed in the last 40 years, giving lawmakers a sense of urgency. For men, melanoma, the deadliest type of skin cancer, has increased 400% for women, 800%. The new bill would speed up the FDA's approval process, specifically for sunscreen products, and mandate a predictable time frame for a decision.

"Americans have gone more than a decade without the kinds of innovative sunscreen products citizens in other countries have enjoyed for years. Meanwhile, skin cancer has become a public health crisis that has lead US Surgeon General to issue A Call to Action to Prevent Skin Cancer calling for the government and stakeholders to act immediately to address this deadly, but preventable disease," said Michael Werner, policy advisor for the Public Access to SunScreen Coalition.

Other countries have benefited from new sunscreen technology, but the FDA has gummed up the review process, putting the United States sometimes 15 years behind Europe, Asia, and Central and South America.

“Congress’ commitment to addressing the skin cancer epidemic in the United States was clearly demonstrated in tonight’s Senate passage of the Sunscreen Innovation Act,” Werner said. “It’s a great day for Americans. Now US consumers will be able to get the latest in sunscreen technology that has been available to citizens of countries all over the world.”

Skin, Inc
September 19, 2014

2014 Sunscreen Innovation Act Unanimously Passes

Link to article

The U.S. Senate unanimously passed the Sunscreen Innovation Act (S. 2141) on Sept. 17, 2014, which the Public Access to SunScreens (PASS) Coalition applauded. This passage follows the Senate Health, Education, Labor and Pensions (HELP) Committee's approval of the bill earlier in the day.

According to PASS, the last over-the-counter (OTC) sunscreen ingredient approved by the U.S. Food and Drug Administration (FDA) was in the 1990s and since 2002, eight new sunscreen applications have been filed—and are still awaiting review, 12 years later. These technologies have been widely available in Europe, Asia, and Central and South America, in some cases for more than 15 years.

Over the past 40 years, melanoma rates have risen 800% among young women and 400% among young men. The bipartisan Sunscreen Innovation Act (H.R. 4250/S. 2141) would streamline the approval process for new sunscreen ingredients to ensure they receive a transparent review within a predictable timeframe, in turn ensuring the American public gains access to the latest safe, effective and innovative sunscreen products to protect against the sun's most harmful rays.

"Congress' commitment to addressing the skin cancer epidemic in the United States was clearly demonstrated in tonight's Senate passage of the Sunscreen Innovation Act," said Michael Werner, PASS Coalition Policy Advisor, in a press statement. "It's a great day for Americans. Now U.S. consumers will be able to get the latest in sunscreen technology that has been available to citizens of countries all over the world."

Werner added, "Americans have gone more than a decade without the kinds of innovative sunscreen products citizens in other countries have enjoyed for years. Meanwhile, skin cancer has become a public health crisis that has lead U.S. Surgeon General to issue 'A Call to Action to

Prevent Skin Cancer,' calling for the government and stakeholders to act immediately to address this deadly, but preventable disease."

Inside Health (Subscription)
September 18, 2014

Sunscreen Legislation Backers Seek Swift Enactment After Senate Clears Bill
By Stephanie Beasley

The Senate passed legislation late Wednesday (Sept.17) that would streamline FDA's sunscreen ingredient review process by mandating timelines for pending and new applications just hours after the bill cleared the Senate health panel, giving bill backers hope that the legislation will be signed by President Obama before the end of the year. The House passed the bill in July.

The Senate Health, Education, Labor and Pensions (HELP) committee released a draft discussion bill last month updating the Sunscreen Innovation Act introduced by Sens. Jack Reed (D-RI) and Johnny Isakson (R-GA) earlier this year. Most notably, the committee added provisions that would require FDA to establish timelines broadly for over the counter time and extent applications along with the sunscreen review timelines included in the original language.

Groups like the Melanoma Research Alliance and the American Academy of Dermatology worried the broader OTC provisions would undermine the bipartisan support the legislation had received and delay its movement by prompting other stakeholders to weigh in on the provision.

The Public Access to Sunscreens (PASS) Coalition applauded the Senate's swift passage of the legislation and said it was hopeful that the two chambers would meet soon to resolve differences between the two bills.

"Congress' commitment to addressing the skin cancer epidemic in the United States was clearly demonstrated in tonight's Senate passage of the Sunscreen Innovation Act," Michael Werner, PASS Coalition policy advisor, said in a statement Wednesday (Sept.17). Now U.S consumers will be able to get the latest in sunscreen technology that has been available to citizens of countries all over the world. We now call on the House and Senate to swiftly reconcile the differences in their bills and enact final legislation."

The Senate's version of the sunscreen bill also omits a House provision allowing sponsors to convene an advisory panel. Both bills would require FDA to review pending sunscreen submissions within a year. The House version also would establishes an 11-month timeline for new submissions, but the Senate bill would provide 18-20 months.

FDA officials told an advisory panel earlier this month that the agency has concerns about the safety of many of the eight pending sunscreen ingredient applications submitted to the agency over the past decade. FDA is considering whether to require new safety testing that it said would provide more information final sunscreen products, not just the individual ingredients, as well as the effects of long-term, chronic sunscreen use.

POLITICO PULSE
Insider intelligence on health care reform

Politico Pulse (Subscription)
September 18, 2014

Sunscreen bill heads to the House now

The Senate passed the Sunscreen Innovation Act yesterday, requiring FDA to prioritize reviews of new sunscreen applications that have long been held up. But that's as far as it will go for now, as the House leaves town ahead of the elections.

Politico Pulse (Subscription)
September 18, 2014

HELP approve sunscreen bill

The Senate HELP Committee approved the Sunshine Innovation Act yesterday, which the House already signed off on. It's meant to clear a long backlog of new sunscreen applications that have piled up at the FDA.

Office of Senator Kay Hagan
September 19, 2014

Bipartisan Sunscreen Innovation Act Cosponsored by Hagan Passes the Senate

Link to press release

A bipartisan bill cosponsored by U.S. Senator Kay Hagan to modernize the FDA review process for over-the-counter sunscreen ingredients passed in the full Senate this week. The Sunscreen Innovation Act now heads to the House of Representatives. Although using sunscreen is one of the primary ways to protect against skin cancer, an FDA backlog has resulted in Americans not having access to the most advanced sunscreen ingredients.

"It is simply unacceptable that the FDA has not approved a new sunscreen ingredient through its over-the-counter process since 1999. America is a country of innovation, and we should not be lagging behind other parts of the world when it comes accessing modern skin care protection because of bureaucratic red tape. Skin cancer is now the most common form of cancer in our country, and we must work to modernize the FDA's process to approve new sunscreen ingredients so that Americans can be adequately protected," Hagan said. "This bipartisan legislation will help reduce the backlogs that have kept the FDA from approving sunscreen ingredients and will prevent new sunscreen applications from waiting years for FDA review."

The FDA's sunscreen ingredient approval process is hindered by delays due in part to a lack of timelines requiring the FDA to take specific actions. The FDA regulates most sunscreen ingredients under a "monograph," which is essentially a standard for active ingredients. In order for a product to be allowed on the market, it must meet the standards issued in the monograph. The FDA has not approved a new sunscreen ingredient through the monograph since 1999.

In 2002, the FDA created another pathway, the Time and Extent Application (TEA) process, for new sunscreen ingredients to reach the market, which allows a sunscreen ingredient to be sold in the U.S. if it has been widely used in another country for at least five years. However, the TEA process, which has no timelines, is also lengthy because it requires the FDA to propose and finalize a regulation for each ingredient submitted, and the FDA has never approved a sunscreen ingredient through the TEA process.

Provisions in the Sunscreen Innovation Act would amend the Federal Food, Drug, and Cosmetic Act to help reduce the current backlog of sunscreen applications and prevent new sunscreen applications from waiting years for FDA review by setting timelines for specific action within the TEA process.

The incidence of skin cancer - now the most common form of cancer in the U.S. - has continued to rise. Over the past 40 years, the incidence of melanoma, which is the deadliest form of skin cancer, has increased 400 percent among young men and 800 percent among young women.

The Sunscreen Innovation Act is supported by the Public Access to Sunscreens (PASS) Coalition, which includes the American Cancer Society Action Network, Melanoma Research Foundation, and Skin Cancer Foundation, as well as manufacturers Ashland Inc. and BASF, which both have a significant presence in North Carolina.

NorthwestGeorgianews.com

Northwest Georgia News
September 18, 2014

Isakson applauds Senate passage of bipartisan bill to help prevent skin cancer

Link to article

Today, U.S. Senators Johnny Isakson, R-Ga., and Jack Reed, D-R.I., along with Senate Health, Education, Labor, and Pensions Committee Chairman Tom Harkin, D-Iowa, and Ranking Member Lamar Alexander, R-Tenn., applauded Senate passage of legislation that seeks to address a regulatory backlog that is blocking U.S. consumers from access to innovative sunscreens widely available in the rest of the world.

The Sunscreen Innovation Act cleared the Senate Wednesday evening, just hours after being approved by the Senate Committee on Health, Education, Labor and Pensions in a unanimous voice vote.

"As a melanoma survivor, I believe it's essential that Americans have access to the most safe and effective sunscreen," said Isakson. "Too often, technological advancements that have the ability to improve the quality of health care and prevent disease are held back by an overly rigid regulatory process. The Senate's quick action is a strong message that it's time for the delays at FDA to end, and I hope the House will send this bill to the president soon so we can clear the bureaucratic hurdles that have stood between American consumers and the new and innovative sunscreen products that are already available in many other countries."

"I am pleased that the Senate took swift action to approve the bipartisan and critically important Sunscreen Innovation Act," Harkin said. "This bill streamlines FDA's review of new sunscreen ingredients and will expedite access to new sunscreens which will help keep Americans healthier by reducing the risk of skin cancer. I look forward to moving this important measure forward as it goes to the House for consideration."

"This bill to get safe sunscreen ingredients to Americans more quickly is about preventing cancer —this year alone an estimated 1,900 Tennesseans will be diagnosed with melanoma, the deadliest form of skin cancer," said Alexander. "Senator Isakson and Senator Reed have done great work with this bill, which will hold the FDA accountable to timelines and reform the process so that the FDA can meet those timelines."

“This is a win for consumers and public health. The Sunscreen Innovation Act will help ensure U.S. consumers have access to the safest, most effective sunscreens available,” said Reed. “The FDA must do its due diligence to ensure the safety of these products and they should do it in a timely manner. Americans shouldn’t have to wait decades for access to the most advanced, effective sunscreens. By streamlining its review process, the FDA can help consumers better protect themselves from skin cancer. We want Americans to follow safe sun practices and benefit from the latest advances in sun care products and research. I appreciate Chairman Harkin, Ranking Member Alexander, and my lead cosponsor, Senator Isakson, for making this legislation to help consumers and prevent skin cancer a priority. I am pleased we were able to pass it with strong bipartisan support.”

The Sunscreen Innovation Act builds on S.2141, introduced by Isakson and Reed, and H.R.4250, the House-passed Sunscreen Innovation Act, and, while prioritizing sunscreens, improves the regulatory pathway for other over-the-counter drugs that also have been stalled at FDA under the current framework.

As skin cancer rates continue to climb, the Isakson-Reed legislation seeks to expedite the U.S. Food and Drug Administration’s (FDA) review process for active ingredients in sunscreens that have long been approved for use in places such as Europe, Canada, and other countries.

Some of these sunscreen ingredients have been safely used overseas for years, but have had their applications pending before the FDA for a decade or more. The Sunscreen Innovation Act also seeks to shed some light on the FDA’s review process by requiring the agency to periodically report to Congress on the progress of this effort.

Skin cancer is the most common form of cancer in the United States, with more than 2 million cases diagnosed every year. A report from the Surgeon General released last month stated that nearly 5 million people in the United States are treated for skin cancers every year, with an annual cost estimated at $8.1 billion. Many of these cases could be prevented by protecting skin from sun exposure, according to the American Cancer Society.

PRIMER{TBR}

Primer{TBR}
September 18, 2014

Senate Passes Sunscreen Innovation Act to Improve Sunscreen

Link to article

On Wednesday, the Senate passed the Sunscreen Innovation Act (S. 2141) which would require the Department of Health and Human Services to establish a process for the review and approve over-the-counter (OTC) sunscreens.

The Senate passed the measure through a unanimous consent agreement and it now heads to the House for further action. The House version of the bill passed earlier this year, yet only addresses sunscreen TEA.

Given the upcoming elections, reconciliation of the two chambers' bills will begin once Congress returns during the lame duck session.

Smithsonian
September 18, 2014

The US Is Trying to Expedite Sunscreen Innovation
By Rachel Nuwer

Link to article

Yesterday, the Senate unanimously passed a bill that aims to improve the process of sunscreen development, the Hill reports. The Sunscreen Innovation Act, as it's called, would expedite the process of testing and launching new, more effective sunscreens. As Time reports, the House of Representatives has already passed a similar bill, and if signed into action by Obama, the new Act would require the Food and Drug Administration to respond to new sunscreen innovations in a much timelier manner.

The group pushing the bill includes both advocacy groups focused on skin cancer and the manufacturers of sunscreens. Since the FDA currently puts sunscreen ingredients through nearly the same scrutinizing review process as new pharmaceuticals, Time reports, Europe and Asia are already using sunscreens with active ingredients that are still waiting for approval in the U.S. Some ingredients have been awaiting review for more than a decade. The advocates of the Sunscreen Innovation Act want faster approval time from the FDA.

They're not the only ones, though, who have been pushing the FDA to work faster. As NBC reports:

> At the urging of patient groups, Congress and the drug industry, the FDA over the past decade has introduced multiple mechanisms for speeding new products to the market. While patient groups and drug companies applaud these measures, saying they get much-needed medication into the hands of patients more quickly, critics say the agency is approving products before they have been fully vetted.

There's also some evidence that the FDA is not quite so slow as critics make it out to be.

Cosmetics & Toiletries
Science Applied
Cosmetics & Toiletries
September 18, 2014

Sunscreen Innovation Act Passes: What Does it Mean?
By Rachel Grahenhofer

Link to article

The Public Access to SunScreens (PASS) Coalition applauded the U.S. Senate's unanimous passage of the Sunscreen Innovation Act (S. 2141) on Sept. 17, 2014. This passage follows the Senate Health, Education, Labor and Pensions (HELP) Committee's approval of the bill earlier in the day. According to PASS, over the past 40 years, melanoma rates have increased 800 percent among young women and 400 percent among young men, and the Act is intended to streamline the approval process for new sunscreen actives, to ensure they receive a review within a predictable timeframe. In turn, this would ensure the American public gains access to the latest safe, effective and innovative sunscreen products to protect against the sun's most harmful rays.

Michael Werner, PASS Coalition Policy Advisor, said in a press statement, "Americans have gone more than a decade without the kinds of innovative sunscreen products citizens in other countries have enjoyed for years. Meanwhile, skin cancer has become a public health crisis that has lead U.S. Surgeon General to issue 'A Call to Action to Prevent Skin Cancer,' calling for the government and stakeholders to act immediately to address this deadly, but preventable disease."

So what does this mean for sunscreen makers? According to industry and regulatory expert, David C. Steinberg, more waiting.

"The earliest I can imagine anything will happen with this Act is 2017," said Steinberg. "First off, there are two different versions, one in the House and the other in the Senate. Both sides need to meet to come to a consensus. After this week, legislators want to recess, and then they'll be focused on the upcoming elections. I don't see anything happening during the lame duck session in December, either; legislators will have more serious matters, like current military threats, to address." He added that in 2015-2016, everyone will be focused on Presidential campaigns, and so 2017 would be the soonest anyone would likely act on this passage. "So for now, things will remain the status quo."

Then what happens? Steinberg explained, "The bills as I understand them—and I haven't been able to access and review them—require coming up with the tests to run on sunscreen actives and a timeline of when to reject/approve them. . .and the [U.S. Food and Drug Administration] (FDA) has a history of rejecting them." He noted that in many cases, Time and Extent Applications (TEAs) for sunscreens are rejected for having "not enough information." In relation, during a recent FDA Advisory Committee meeting, the committee wanted far more efficacy and safety testing for existing sunscreens. This could require existing sunscreens to undergo additional testing. Further, he adds "much of the safety work is done on animals, so they'd be banned in Europe forever."

Can the U.S. cosmetics industry, then, hope for progress any time soon in the area of sunscreens? "One of my pet peeves in regulation, for 45 years now, is that with all of these regulatory bodies, not just the FDA, European Union or even the CIR, they don't have a single person on board who has ever made a cosmetic in their life." He explained that legislators do not understand that regulations cannot be based on the properties of a UV filter alone, but must consider the whole formulation.

"The over-the-counter (OTC) Monograph doesn't work; I said it in a presentation I gave in March of this year at an FDA meeting on the system. When the NDA system came into being in 1972, drugs were divided into about 22 categories by the diseases they treat but they should have been divided by dosing. In this [latter] case, the three categories would be: ingested, topical with dose restrictions, and topical without restrictions." He added that a reporter at the event asked him afterward what he thought would happen with the system. "What I'd like to see happen is for the FDA to seriously consider the comments made and change the system. But what will happen?" He paused before observing, "Of all the FDA attendees present at this meeting, how many were chemists, pharmacists, toxicologists, etc.? None. How many were lawyers? All."

Steinberg concluded that the basic premise of what would happen now is: nothing. "I don't think I'll live long enough to see this resolved. If [the FDA] was on it and had changed the NDA system based on dosage back in 1970s, there'd be different ways of doing things now. It comes back to harmonizing the bill but for now, no one seems to care. This is not something they are going to get re-elected based on."

Office of Senator Mitch McConnell (Press Release)
September 18, 2014

McConnell-Sponsored Sunscreen Innovation Act Passes Senate

Link to article

Washington, D.C. – U.S. Senate Republican Leader Mitch McConnell announced that the bipartisan Sunscreen Innovation Act, which would ensure sunscreen ingredients receive a timely and transparent review by the Food and Drug Administration (FDA), was approved by the United States Senate. Senator McConnell is an original co-sponsor of the bill. The House bill sponsored by Congressman Ed Whitfield (KY-01) passed earlier this year.

Skin cancer is the most common form of cancer in the country, and a known contributor to developing skin cancer is over exposure to ultraviolet (UV) radiation. Despite this public health threat, for more than a decade the FDA has failed to review new sunscreen ingredient applications that include technologies more capable of protecting skin against harmful UVA rays. These same technologies in pending U.S. sunscreen ingredient applications are available in Europe and other countries overseas, and in some cases have been for more than 15 years.

Ashland Inc., a global specialty chemical company with a facility in Calvert City, manufactures precursor ingredients for these innovative sunscreens, and the cosmetics and beauty company, L'Oréal, has a finished product manufacturing facility in Florence. L'Oréal has two sunscreen ingredients pending approval, but they have been held up by the backlog at FDA.

"This legislation will not only benefit Kentucky workers that manufacture these innovative sunscreen ingredients at facilities in Calvert City and Florence, but it has the potential to provide greater protections for American families looking forward to spending some time outdoors but are worried about the harmful UVA rays," said Senator McConnell.

"As a proud Kentucky employer and pioneer in sunscreen innovation since L'Oreal's founder invented the first sunscreen in 1936, L'Oreal USA commends Senator McConnell and his colleagues in the U.S. Senate for its bipartisan passage of the Sunscreen Innovation Act, S. 2141. L'Oreal USA has always been committed to giving American consumers access to a broad range of products to meet their sun protection needs, and the passage of this legislation puts American consumers one step closer to the latest sunscreen technology," said Kristina Schake, Chief Communications Officer of L'Oreal USA.

"Ashland appreciates the prompt response and strong support provided by Senator McConnell for this important legislation," said John Riley, Ashland director of government relations.

MarketPlace
September 18, 2014

Your sunscreen is way out of date
By Nancy Marshall-Genzer

Link to article

The sunscreen you used over the summer is about 15 years out of date.

That's because the FDA hasn't approved applications for new sunscreen ingredients since the late 1990s.

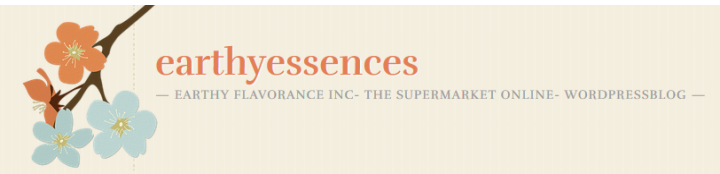
The applications are mired in complex regulations that ironically were supposed to simplify FDA approval of ingredients that have been used safely in other countries.

"It's just ridiculous," says Scott Faber, vice president for government affairs for the Environmental Working Group. "Consumers in Canada, the EU, Australia, are able to use sunscreens that are much more effective at blocking out both UVA and UVB rays."

Sunscreen makers have joined dermatologists in a coalition called PASS, or Public Access to Sunscreens. The coalition says manufacturers want access to the very latest ingredients.

"It would allow product developers to innovate and use new technologies and new science," says Michael Werner, chief lobbyist for PASS.

While the FDA declined an interview, it did issue a statement saying that it "has prioritized reviewing the safety and effectiveness of additional sunscreen ingredients as quickly as possible given the agency's resources."



Earthy Essence
September 18, 2014

Sunscreen Innovation Act Unanimously Passes

Link to article

The U.S. Senate unanimously passed the Sunscreen Innovation Act (S. 2141) on Sept. 17, 2014, which the Public Access to SunScreens (PASS) Coalition applauded. This passage follows the Senate Health, Education, Labor and Pensions (HELP) Committee's approval of the bill earlier in the day.

According to PASS, the last over-the-counter (OTC) sunscreen ingredient approved by the U.S. Food and Drug Administration (FDA) was in the 1990s and since 2002, eight new sunscreen applications have been filed—and are still awaiting review, 12 years later. These technologies have been widely available in Europe, Asia, and Central and South America, in some cases for more than 15 years.

Over the past 40 years, melanoma rates have risen 800 percent among young women and 400 percent among young men. The bipartisan Sunscreen Innovation Act (H.R. 4250/S. 2141) would streamline the approval process for new sunscreen ingredients to ensure they receive a transparent review within a predictable timeframe, in turn ensuring the American public gains access to the latest safe, effective and innovative sunscreen products to protect against the sun's most harmful rays.

"Congress' commitment to addressing the skin cancer epidemic in the United States was clearly demonstrated in tonight's Senate passage of the Sunscreen Innovation Act," said Michael Werner, PASS Coalition Policy Advisor, in a press statement. "It's a great day for Americans. Now U.S. consumers will be able to get the latest in sunscreen technology that has been available to citizens of countries all over the world."

Werner added, "Americans have gone more than a decade without the kinds of innovative sunscreen products citizens in other countries have enjoyed for years. Meanwhile, skin cancer has become a public health crisis that has lead U.S. Surgeon General to issue 'A Call to Action to

Prevent Skin Cancer,' calling for the government and stakeholders to act immediately to address this deadly, but preventable disease."

Melanoma Research Alliance

September 17, 2014

MRA Applauds Senate Passage of the Sunscreen Innovation Act

Link to press release

The Melanoma Research Alliance (MRA) today applauded the quick passage of the Sunscreen Innovation Act, S. 2141, as the bill moved through the U.S. Senate Health, Education, Labor and Pensions (HELP) Committee and the full Senate chamber. Thanks to the leadership and hard work of Senators Jack Reed (D-RI) and Johnny Isakson (R-Ga), the Sunscreen Innovation Act

will answer the call raised by MRA and fellow stakeholders to provide the public with more timely access to the most effective and innovative sunscreen products.

"Today's Senate passage brings us one step closer to a streamlined and transparent review process for innovative sunscreen ingredients," said Wendy Selig, president & CEO of MRA. "We are pleased with this momentum in the Senate given the House's recent passage of a version of this bill. We urge Congress to ensure swift enactment of the Sunscreen Innovation Act so that Americans will soon have access to the most effective sunscreens to protect themselves

and their loved ones from dangerous UV radiation."

The last Over-The-Counter (OTC) sunscreen ingredient to be approved by the U.S. Food and

Drug Administration (FDA) was in the 1990s. Since that time , eight new sunscreen applications have been filed and are still awaiting review. New sunscreen technologies currently awaiting approval in the U.S. have been widely available in Europe, Asia, and Central and South America, in some cases for more than 15 years.

MRA is committed to reducing the toll of melanoma, the deadliest of all skin cancers. The organization routinely urges people to know their risks and take steps to reduce them, including avoiding exposure to ultraviolet (UV) radiation and the da mage it causes to the skin. MRA has

worked to improve the safety and efficacy review of new sunscreen innovations that offer

essential protection from hazardous UV rays. As a leading member of the Public Access to

Sunscreens (PASS) Coalition, MRA has engaged with Congress and the FDA to address the current standstill in a process that is clearly broken and will continue to advocate for the passage of legislation to address the public health risk posed by melanoma.

The Melanoma Research Foundation (Press Release)
September 17, 2014

The Melanoma Research Foundation Applauds the Senate for Unanimous Approval of Sunscreen Innovation Act

Link to press release

Today the U.S. Senate voted on and passed the Sunscreen Innovation Act (SIA), sending a clear message to the U.S. Food and Drug Administration (FDA) that it must address the 12 year backlog of new sunscreen filters waiting to be approved and released for consumer access.

"Americans are limited in their choices for compounds that block UV radiation because of the long-standing bureaucratic gridlock at the FDA that prevents new agents from being approved" said Tim Turnham, Executive Director of the Melanoma Research Foundation (MRF). "Meanwhile, the Surgeon General has issued a Call to Action to Prevent Skin Cancer that highlights the importance of sun safety. This act will help further the agenda of the Surgeon General by providing consumers with new options to block cancer-causing UV rays."

The bipartisan Sunscreen Innovation Act (H.R. 4250/S. 2141), was introduced by Reps. Ed Whitfield (R-Ky.) and John Dingell (D-Mich.) in the House and Sens. Jack Reed (D-R.I.) and Johnny Isakson (R-Ga.) in the Senate. This legislation will streamline FDA's sunscreen approval process to ensure that new sunscreen ingredients receive a transparent review within a predictable timeframe. This would allow the American public to gain access to the latest safe, effective and innovative sunscreen products to protect against the sun's most harmful rays.

The last over-the-counter, (OTC) sunscreen ingredient to be approved by FDA was in the 1990s. Since 2002, eight new sunscreen applications have been filed and are still awaiting review 12 years later. New sunscreen technologies currently awaiting approval in the U.S. have been widely available in Europe, Asia, and Central and South America, in some cases for more than 15 years.

Melanoma is the deadliest form of skin cancer. It is the leading cause of cancer death in women in their 20s and the number of diagnoses are increasing every year, emphasizing the need for greater prevention efforts. The SIA was introduced to not only to urge the FDA to expedite its review and approval process, but also hold the FDA accountable for the important role it should play in preventing future melanoma diagnoses and deaths.

InsideHealthPolicy
An Inside Washington news service
Inside Health (Subscription)
September 17, 2014

Sunscreen Bill Supporters Seek Full Senate Vote Before Session Closes
By Stephanie Beasley

The Senate health panel cleared legislation Wednesday (Sept.17) that would streamline FDA's sunscreen ingredient review process by mandating timelines for pending and new applications -- a move praised by the bill's backers who are urging the full Senate to pass the bill before it adjourns within the next few days. The House passed the bill in July.

The Senate Health, Education, Labor and Pensions (HELP) committee released a draft discussion bill last month updating the Sunscreen Innovation Act introduced by Sens. Jack Reed (D-RI) and Johnny Isakson (R-GA) earlier this year. Most notably, the committee added provisions that would require FDA to establish timelines broadly for over the counter time and extent applications along with the sunscreen review timelines included in the original language.

Groups like the Melanoma Research Alliance and the American Academy of Dermatology have expressed concern that the broader OTC provisions could undermine the bipartisan support the legislation has received thus far and delay its movement by prompting other stakeholders to weigh in on the provision. However, the Public Access to Sunscreens (PASS) Coalition -- whose members include industry, research and patient advocacy groups -- is optimistic the bill will pass out of the Senate before the end of this session.

“Today's action by the Senate HELP Committee demonstrates the Committee's dedication to addressing the skin cancer epidemic in the United States,” said Michael Werner, PASS Coalition policy advisor. “We are thrilled by the bipartisan support for the Sunscreen Innovation Act and are hopeful that the full Senate will join its House colleagues and pass the Sunscreen Innovation Act before adjourning.”

The Senate's version of the sunscreen bill also omits a House provision allowing sponsors to convene an advisory panel. Both bills would require FDA to review pending sunscreen submissions within a year. The House version also would establishes an 11-month timeline for new submissions, but the Senate bill would provide 18-20 months.

CQ Roll Call (Subscription),
September 17, 2014

Sunscreen Bill Backed by Senate Panel
By Melanie Zanona

A measure that would streamline the approval process for new sunscreen applications quickly advanced out of the Senate on Wednesday.

The measure (S 2141), which senators passed by unanimous consent, would establish an expedited approval process for the Food and Drug Administration to evaluate applications for over-the-counter sunscreen ingredients. It also would require the Department of Health and Human Services to ensure that sunscreens marketed in the United States are safe, effective and appropriately labeled.

The Senate Health, Education, Labor and Pensions Committee backed the bill (S 2141) by voice vote earlier in the day. The measure could also speed through the House, where lawmakers passed a companion version (HR 4250) by voice vote in July.

The Senate panel amended the bill to allow HHS to issue a new final determination on a sunscreen application if new information becomes available.

Bill supporters pointed out that eight new sunscreen applications have been filed since 2002 and are still awaiting review. Some of the ingredients have been available in other countries for years.

Sponsor Jack Reed, D-R.I., said the legislation would enable consumers in the United States to access the safest and most effective sunscreens. Interest groups have used the bill to draw attention to the incidence of melanoma and how it can be prevented; lead Republican co-sponsor Johnny Isakson of Georgia himself is a melanoma survivor.
State of Play

With a mandate to oversee the safety of products with about $1 trillion in annual sales, the FDA is almost continually attracting comments and complaints from lawmakers. With a staff of about 15,000, the FDA is at the center of a wide range of pressing health issues facing the nation, and debates over food safety, medical devices, drug formulation, the pharmaceuticals supply chain and the costs of regulatory oversight complicate any attempts to restructure its processes.

Most recently, concerns have grown over an epidemic of narcotic painkiller abuse. And lawmakers in recent months have have questioned whether the FDA may be too rigid in its approach to new tech products, including healthcare-focused applications on smartphones. There also are questions about the FDA's role addressing the decriminalization of marijuana, including debate about whether it will need to look after foods laced with the drug.

While Congress debates the agency's systems and structure, the FDA is moving to put regulations in place for e-cigarettes. The Family Smoking Prevention and Tobacco Control Act (PL 111-31) gave the FDA new authority to combat use of cigarettes and related products.

This was the first of a series of recent laws that have given the FDA new authorities and burdens, including an upgrade of food safety regulation (PL 111-353), refinements in regulation of medicines (PL 112-144) and oversight of compounding pharmacies that provide pharmaceuticals tailored to individuals. (PL 113-54).

The Obama administration has sought to handle those mandates with a greater menu of user fees, an approach some lawmakers have criticized.

The Hill
September 17, 2014

Senate panel approves sunscreen bill
By Elise Viebeck

Link to article

A key Senate panel advanced a bill to streamline the regulatory process for approving new ingredients for sunscreen.

The Senate Health, Education, Labor and Pensions (HELP) Committee unanimously approved the measure by voice vote on Wednesday. Twelve members were present at the time.

The Sunscreen Innovation Act, which passed the House in late July, would be the first major update to the Food and Drug Administration's (FDA) sunscreen approval process since the 1990s.

Some ingredients currently used in sun protection products outside the United States have "languished at the FDA for years," said Sen. Johnny Isakson (R-Ga.) in the hearing.

"The bill is critically important because melanoma is at epidemic proportions in the United States," he said.

The vote in HELP won immediate praise from advocates, who urged bipartisan support for the bill on the Senate floor.

Congress has only a few days to wrap up works before it hopes to adjourn prior to the November elections.

COV News
September 17, 2014

Isakson-backed sunscreen bill advances

Link to article

A Senate committee today unanimously passed legislation by U.S. Senators Johnny Isakson, R-Ga., and Jack Reed, D-R.I., that seeks to address a regulatory backlog that is blocking U.S. consumers from access to innovative sunscreens widely available in the rest of the world.

The Sunscreen Innovation Act was approved by the Senate Committee on Health, Education, Labor and Pensions today in a unanimous voice vote, advancing the measure to the full Senate for consideration.

"As a melanoma survivor, I believe it's essential that Americans have access to the most safe and effective sunscreen," said Isakson. "Too often, technological advancements that have the ability to improve the quality of health care and prevent disease are held back by an overly rigid regulatory process. I am hopeful this legislation will help clear the bureaucratic hurdles that have stood between American consumers and the new and innovative sunscreen products that are already available in many other countries."

"This bipartisan, commonsense legislation will help consumers better protect themselves from skin cancer by safely accelerating access to the latest advances in sun care products and research, and I am glad it's on the way to becoming law" said Reed. "The FDA must do its due diligence to ensure the safety of these products and they should do it in a timely manner. It's important for people to protect themselves from the sun, and Americans trying to shield themselves and their families from harmful rays shouldn't have to wait decades for access to the most advanced, effective sunscreens available."

As skin cancer rates continue to climb, the Isakson-Reed legislation seeks to expedite the U.S. Food and Drug Administration's (FDA) review process for active ingredients in sunscreens that have long been approved for use in places such as Europe, Canada, and other countries.

Some of these sunscreen ingredients have been safely used overseas for years, but have had their applications pending before the FDA for a decade or more. The Sunscreen Innovation Act also seeks to shed some light on the FDA's review process by requiring the agency to periodically report to Congress on the progress of this effort.

Skin cancer is the most common form of cancer in the United States, with more than 2 million cases diagnosed every year. A recent report from the Surgeon General stated that nearly 5 million people in the U.S. are treated for skin cancer every year, with an annual cost estimated at $8.1

billion. Many of these cases could be prevented by protecting skin from sun exposure, according to the American Cancer Society.

The Sunscreen Innovation Act will amend the Federal Food Drug and Cosmetic Act to ensure all sunscreen ingredients receive a transparent review within a predictable timeframe. Key aspects of the bill include:

- Maintains existing FDA safety and efficacy requirements for sunscreens, while streamlining the FDA review process for new ingredients found eligible for this review because of safe use for at least five years in at least one other country.
- Provide an option for ingredients that are currently awaiting FDA action to be considered by an external Advisory Committee as part of the FDA review process.
- Help reduce the current backlog of sunscreen applications and ensure a more predictable regulatory pathway for new sunscreen applications.
- Require regular reporting by FDA on efforts to reduce the backlog of applications and to review new sunscreen ingredients, as well as independent reporting by the Government Accountability Office on the sunscreen approval pathway and the broader over-the-counter (OTC) regulatory scheme.
- Require the FDA to finalize the regulations governing all OTC sunscreens within five years, including any new sunscreen ingredients reviewed by the FDA as a result of this legislation.

The full Senate could consider the bill later this week. The U.S. House of Representatives already approved it.

EWG (Press Release)
September 17, 2014

Senate Committee Moves Bill To Bring New Sunscreens to U.S. Market

Link to press release

Washington, D.C. – The Senate Committee on Health, Education, Labor and Pensions today approved a bill that could bring new and effective sunscreen ingredients to the U.S. market and help reduce the rate of skin cancer.

The Sunscreen Innovation Act, introduced by Sens. Jack Reed (D-R.I.) and Johnny Isakson (R-Ga.), would accelerate the federal Food and Drug Administration's approval of promising sunscreen ingredients already in use abroad, including the European Union and Canada. The Reed-Isakson bill would set hard deadlines for FDA review of ingredients and would require the agency to act in a timely manner.

The bill passed unanimously by voice vote.

"U.S. sunscreen manufacturers are not able to use a number of effective and safe ingredients that are used in sunscreens sold in many other parts of the world because of the backlog of ingredients waiting for agency approval," said Scott Faber, EWG's senior vice president of government affairs. "It's critical for the Senate to move this bill swiftly to ensure a speedier review process that will give Americans access to sunscreens that provide greater protection from the sun's harmful rays."

Access to sunscreens that provide better balanced UVA and UVB protection could help lower the skyrocketing cases of skin cancer in the U.S. More than two million are diagnosed annually, including 60,000 new cases of melanoma, resulting in 9,000 deaths.

Last July, the House of Representatives passed a similar bill sponsored by Reps. Ed Whitfield (R-Ky.) and John Dingell (D-Mich.).

"The FDA created a process to review these sunscreen ingredients in 2002 and have disappointingly approved no new ingredients since then," Faber said. "Of the eight ingredients currently under review by the agency, six have been awaiting action for more than eight years. Consumers need more options than the limited selection they now have when shopping for safe and effective sunscreens."

Earlier this year, EWG launched a sun safety public education campaign in partnership with dermatologists and sunscreen companies to increase the public's awareness of the dangers of sun

exposure. EWG publishes an annual Guide to Sunscreens that rates the safety and efficacy of products that advertise sun protection.

Power Engineering (Press Release)
September 17, 2014

BASF Supports the Sunscreen Innovation Act

Link to press release

As a member of the Public Access to Sun Screens (PASS) Coalition, BASF (LSE: BFA) supports the Sunscreen Innovation Act, which today was approved by the Senate Committee on Health, Education, Labor and Pensions (HELP), led by Chairman Tom Harkin (D-IA) and Ranking Republican Lamar Alexander (R-TN). The legislation reforms the current sunscreen approval process of the U.S. Food and Drug Administration (FDA) by creating a timely and transparent process by which FDA will evaluate applications for new, safe and effective sunscreen ingredients, which are regulated as over-the-counter (OTC) drugs. Enactment of this bill into law will help provide Americans access to the latest sunscreen ingredients, some of which have been widely available for 15 years in Europe, Asia and Latin America.

"BASF commends the Senate HELP committee and Senators Jack Reed (D-RI) and Johnny Isakson (R-GA) for their leadership and support on moving Sunscreen Innovation Act forward. Today's vote represents a significant step towards ensuring the timely review of new sun protection ingredients by the FDA. BASF encourages the full Senate to consider the Act as soon as possible, and looks forward to continuing to focus on innovation and the development of new UV filters that will provide US consumers with a wider array of safe and effective sunscreen products," said Dirk Buengel, Senior Vice President Care Chemicals for BASF in North America.

The PASS Coalition is a multi-stakeholder coalition of health organizations, sunscreen ingredient companies, dermatologists and concerned citizens who worked collaboratively with the FDA, the White House, Congress, health providers, consumer organizations and sunscreen manufacturers to establish a framework for approval of the next generation of UV actives for Over-the-Counter (OTC) sunscreens.

If enacted into law, the Sunscreen Innovation Act can lead to FDA approval of BASF UV filters for OTC sunscreen products in the U.S., which include the Tinosorb and Uvinul lines of filters which are currently being sold in Europe, Asia and Latin America.

Tinosorb® M is a BASF sunscreen active ingredient which provides exceptional UVA and UVB coverage. Tinosorb M combines the properties of both organic and inorganic sunscreen filters. It has high UV absorption like a soluble organic sunscreen active and the insolubility, low penetration and light scattering properties of an inorganic sunscreen active.

Tinosorb® S is a highly efficient broad spectrum UV absorber. Due to its high efficiency, a reduced amount is needed to achieve UV protection allowing the ability to produce products which are cost effective and aesthetically superior.

Uvinul® T 150 UV filter provides extremely strong absorbance in the UVB spectrum for highly effective protection from sunburn. It is photostable and causes no degradation when used in combination with other UV filters. Since chemists and formulators can use less of this active ingredient due to powerful synergies with other UV filters, the potential for irritation when applied to the skin is minimized.

The Melanoma Research Found (Press Release)
September 17, 2014

The Melanoma Research Foundation Applauds the Senate for Swift Approval of Sunscreen Innovation Act

WASHINGTON, D.C. — Today the U.S. Senate voted on and passed the Sunscreen Innovation Act (SIA), sending a clear message to the U.S. Food and Drug Administration (FDA) that it must address the 12 year backlog of new sunscreen filters waiting to be approved and released for consumer access.

"Americans are limited in their choices for compounds that block UV radiation because of the long-standing bureaucratic gridlock at the FDA that prevents new agents from being approved" said Tim Turnham, Executive Director of the Melanoma Research Foundation (MRF). "Meanwhile, the Surgeon General has issued a Call to Action to Prevent Skin Cancer that highlights the importance of sun safety. This act will help further the agenda of the Surgeon General by providing consumers with new options to block cancer-causing UV rays."

The bipartisan Sunscreen Innovation Act (H.R. 4250/S. 2141), was introduced by Reps. Ed Whitfield (R-Ky.) and John Dingell (D-Mich.) in the House and Sens. Jack Reed (D-R.I.) and Johnny Isakson (R-Ga.) in the Senate. This legislation will streamline FDA's sunscreen approval process to ensure that new sunscreen ingredients receive a transparent review within a predictable timeframe. This would allow the American public to gain access to the latest safe, effective and innovative sunscreen products to protect against the sun's most harmful rays.

The last over-the-counter, (OTC) sunscreen ingredient to be approved by FDA was in the 1990s. Since 2002, eight new sunscreen applications have been filed and are still awaiting review 12 years later. New sunscreen technologies currently awaiting approval in the U.S. have been widely available in Europe, Asia, and Central and South America, in some cases for more than 15 years.

Melanoma is the deadliest form of skin cancer. It is the leading cause of cancer death in women in their 20s and the number of diagnoses are increasing every year, emphasizing the need for greater prevention efforts. The SIA was introduced to not only to urge the FDA to expedite its review and approval process, but also hold the FDA accountable for the important role it should play in preventing future melanoma diagnoses and deaths.

Melanoma Research Alliance (Press Release)
September 17, 2014

MRA Applauds Senate Bipartisan Support of the Sunscreen Innovation Act

Link to article

Washington, DC, September 17, 2014—The Melanoma Research Alliance (MRA) today applauded the bipartisan support and approval of the Sunscreen Innovation Act, S. 2141, by the U.S. Senate Health, Education, Labor and Pensions (HELP) Committee. Thanks to the leadership and hard work of Senators Jack Reed (D-RI) and Johnny Isakson (R-Ga), the Sunscreen Innovation Act will answer the call raised by MRA and fellow stakeholders to provide the public with more timely access to the most effective and innovative sunscreen products.

"Today's Committee action brings us one step closer to a streamlined and transparent review process for innovative sunscreen ingredients," said Wendy Selig, president & CEO of MRA. "We are pleased with this momentum in the Senate given the House's recent passage of a version of this bill. We urge Congress to ensure swift enactment of the Sunscreen Innovation Act so that Americans will soon have access to the most effective sunscreens to protect themselves and their loved ones from dangerous UV radiation."

The last Over-The-Counter (OTC) sunscreen ingredient to be approved by the U.S. Food and Drug Administration (FDA) was in the 1990s. Since that time, eight new sunscreen applications have been filed and are still awaiting review. New sunscreen technologies currently awaiting approval in the U.S. have been widely available in Europe, Asia, and Central and South America, in some cases for more than 15 years.

MRA is committed to reducing the toll of melanoma, the deadliest of all skin cancers. The organization routinely urges people to know their risks and take steps to reduce them, including avoiding exposure to ultraviolet (UV) radiation and the damage it causes to the skin. MRA has worked to improve the safety and efficacy review of new sunscreen innovations that offer essential protection from hazardous UV rays. As a leading member of the Public Access to Sunscreens (PASS) Coalition, MRA has engaged with Congress and the FDA to address the current standstill in a process that is clearly broken and will continue to advocate for the passage of legislation to address the public health risk posed by melanoma.

ROLL CALL
Roll call
September 12, 2014

Senators Press for a Vote on Sunscreen Ingredient Measure
By Paul Jenkins

Link to article

Overhauling the cumbersome Food and Drug Administration process for approving new sunscreen ingredients is high on the agenda of the bipartisan Senate duo of Democrat Jack Reed of Rhode Island and Republican Johnny Isakson of Georgia. In July, the House passed legislation that seeks to streamline the FDA sunscreen ingredient approval process and Reed and Isakson are urging action on the Senate counterpart measure. Lawmakers claim that slow FDA approval process is holding back the introduction of ingredients that have been approved in Europe.

The Senate version of the sunscreen bill is slated for committee consideration next week. CQ's Melanie Zanona reported on a rally event on Thursday urging final action on either the House or Senate bills prior to the next recess break before the November elections.

CQ Roll Call (Subscription)
September 11, 2014

Lawmakers Emphasize Need for Sunscreen Legislation
By Melanie Zanona

A bipartisan pair of senators joined with sunscreen advocates Thursday to make a final pre-election push for legislation that would help the Food and Drug Administration tackle a backlog of sunscreen ingredient applications.

Democrat Jack Reed of Rhode Island and Republican Johnny Isakson of Georgia introduced legislation (S 2141) in March that would establish an expedited approval process for the ingredients in over-the-counter sunscreen. It also would require the Department of Health and Human Services to ensure that sunscreens marketed in the U.S. are safe, effective and appropriately labeled.

“I’m old enough where when you went to the beach, you didn’t put on sunscreen, you put on oil so you could bake even more,” Reed said. “We’re smarter now, but we can do more. There’s some government action that we must take, too.”

The measure is expected to be considered by the Senate Health, Education, Labor and Pensions Committee next week, in what is likely to be one of the last health-related markups before lawmakers recess for the November elections.

Supporters at Thursday's event brought imaging cameras to reveal the UV skin spots associated with sun damage. Interest groups have used the bill to draw attention to the incidence of melanoma and how it can be prevented. Reed emphasized the need for consumers to have access to the safest and most effective sunscreens, noting that “we’re not trying to short-cut the FDA’s appropriate need to do due diligence. But we think they can move this along much quicker than they are.”

The Public Access to SunScreen Coalition has said that eight new sunscreen applications have been filed since 2002 and still await review. Some of the ingredients have been available in other countries for years.

The House passed a companion version (HR 4250) in July. Reed called the two bills "consistent" with one another and said he does not anticipate any hurdles in getting the bill signed into law. "What's encouraging is that it passed by voice (vote) in the House," he said. "This is something that can rapidly be accomplished before we depart."