

(Mr. THOMAS) was added as a cosponsor of S. Res. 266, a resolution designating October 10, 2002, as "Put the Brakes on Fatalities Day."

S. CON. RES. 119

At the request of Mr. BURNS, the name of the Senator from New Hampshire (Mr. SMITH) was added as a cosponsor of S. Con. Res. 119, a concurrent resolution honoring the United States Marines killed in action during World War II while participating in the 1942 raid on Makin Atoll in the Gilbert Islands and expressing the sense of Congress that a site in Arlington National Cemetery, near the Space Shuttle Challenger Memorial at the corner of Memorial and Farragut Drives, should be provided for a suitable monument to the Marine Raiders.

S. CON. RES. 121

At the request of Mr. HUTCHINSON, the names of the Senator from Maine (Ms. COLLINS) and the Senator from Delaware (Mr. BIDEN) were added as cosponsors of S. Con. Res. 121, a concurrent resolution expressing the sense of Congress that there should be established a National Health Center Week for the week beginning on August 18, 2002, to raise awareness of health services provided by community, migrant, public housing, and homeless health centers.

AMENDMENT NO. 3936

At the request of Mr. NELSON of Florida, the names of the Senator from Maryland (Ms. MIKULSKI) and the Senator from New Hampshire (Mr. SMITH) were added as cosponsors of amendment No. 3936 intended to be proposed to S. 2514, an original bill to authorize appropriations for fiscal year 2003 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe personnel strengths for such fiscal year for the Armed Forces, and for other purposes.

#### STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. BROWNBACK (for himself and Mr. CONRAD):

S. 2674. A bill to improve access to health care medically underserved areas; to the Committee on the Judiciary.

Mr. CONRAD. Mr. President, today I join Senator BROWNBACK in introducing important legislation aimed at ensuring that a piece of the puzzle regarding adequate physician services in underserved communities is preserved.

By all accounts, the Conrad State 20 J-1 Visa Waiver program has been a great success at bringing crucially-needed doctors to medically-underserved areas. It has served as a wonderful resource for my State and for other States across our Nation. The bill we are introducing today eliminates the program's sunset date, thereby making sure that this much-needed program remains available.

I created the Conrad State 20 program in 1994 to deal with the reality that many areas of the country, especially rural communities, have a very difficult time recruiting American doctors. These health facilities have had no other choice but to turn to foreign medical graduates to fill their needs. J-1 visa waivers allow foreign physicians to practice in medically-underserved communities after their J-1 status has expired without first returning to their home countries. These waivers allow foreign physicians to receive nonimmigrant, H-1B status, temporary worker in specialty occupation, for 3 years. In order to receive the waiver, the physician must agree to serve the medically-underserved community for the full three years. If he or she fails to fulfill that commitment, the physician is subject to immediate deportation.

Prior to the creation of my State 20 program, J-1 visa waiver exclusively involved finding an "interested Federal agency" to coordinate the request. This was found to be a long, cumbersome, and bureaucratic process. By allowing States to directly participate in the process of obtaining waivers, my program relieves some of the burdens on participating Federal agencies and allows decisions regarding a State's health care needs to be made at the State level by the people who know best.

I have shepherded the Conrad State 20 program from its creation in 1994 through a subsequent reauthorization and other improvements over the years. By now removing the program's sunset date, the bill that Senator BROWNBACK and I are introducing today will ensure that this important program remains a part of a State's tool belt in dealing with physician-shortages in medically-underserved areas.

Our bill also provides for a modest increase from 20 allowable Conrad State 20 visa waivers per State per year to 30. For some time, a number of States have been bumping up against the State 20 ceiling, and my hope is that this increase will help additional medically underserved communities throughout the country procure the physician services they need.

I urge my colleagues to support this legislation.

By Mr. SARBANES (for himself, Mr. WARNER, Ms. MIKULSKI, and Mr. ALLEN):

S. 2675. A bill to amend the Elementary and Secondary Education Act of 1965 to establish a pilot program to make grants to eligible institutions to develop, demonstrate or disseminate information on practices, methods, or techniques relating to environmental education and training in the Chesapeake Bay watershed; to the Committee on Health, Education, Labor, and Pensions.

Mr. SARBANES. Mr. President, today I am introducing legislation to establish an environmental education program for elementary and secondary

school students and teachers within the Chesapeake Bay watershed. This measure would provide grant assistance to elementary and secondary schools, school districts and not-for-profit environmental education organizations in the six-state watershed to support teacher training, curriculum development, classroom education and meaningful Bay or stream outdoor experiences. It would also enable the U.S. Department of Education to become an active partner in the Chesapeake Bay Program. Joining me as co-sponsors of this legislation are my colleagues Senators MIKULSKI, WARNER, and ALLEN.

There is a growing consensus that a major commitment to education, to promoting an ethic of responsible stewardship and citizenship among the nearly 16 million people who live in the watershed, is necessary if all of the other efforts to "Save the Bay" are to succeed. The ultimate responsibility for the protection and restoration of Chesapeake Bay is dependent upon the individual and collective actions of this and future generations. As population growth and development continue to place enormous pressures on the Chesapeake Bay region's natural resource base, we must learn how to minimize the impacts that we are having on the Bay. Our future depends upon our ability to use the Bay's resources in a sustainable manner. This is as much a civic responsibility as voting. Developing an environmentally literate citizenry that has the skills and knowledge to make well-informed choices and to exercise the rights and responsibilities as members of a community is clearly one of the best ways to raise generations who can be contributors to a healthy and enduring watershed. In my judgment, this can best be accomplished by expanding assistance for environmental education and training programs in the K-12 levels.

In addition to stewardship, there are other dimensions to expanding environmental education opportunities in the Chesapeake Bay region that are equally compelling. A number of recent studies have found that environmental education also enhances student achievement, critical thinking and basic life skills. A 1998 report by the State Education and Environment Roundtable, perhaps the most comprehensive study to date, documents how 40 schools in 12 States, including three schools in Maryland and four schools in Pennsylvania, achieved remarkable academic, attitudinal and behavioral results by using the environment as an integrating strategy for learning across all subject areas. According to the study, students performed better in science, social studies, math and reading. Classroom discipline problems declined and students demonstrated increased engagement and enthusiasm in learning in an environment-based context. Moreover, students' creative thinking, decision-making and interpersonal skills were enhanced by environment-based learning.

The report is replete with success stories, but I will just cite two examples from schools in the Chesapeake Bay watershed. According to the report, students in the 4th grade at Hollywood Elementary School in Maryland scored 27 percent higher on the Maryland State Performance and Assessment Program test than at other schools in their county and 43 percent higher than the State as a whole after the school implemented the environmental based education program. The study also found behavior improvements and reduced discipline problems for 6th graders participating in the STREAMS program at Huntingdon Area Middle School in Pennsylvania compared to students not involved in the program. I ask unanimous consent that excerpts from this study regarding these two schools be printed in the RECORD.

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

[From the State Education and Environment Roundtable]

CLOSING THE ACHIEVEMENT GAP—USING THE ENVIRONMENT AS AN INTEGRATING CONTEXT FOR LEARNING

(By Gerald A. Lieberman and Linda L. Hoody)

HOLLYWOOD ELEMENTARY: A LIVING LABORATORY

Adults in Saint Mary's County, Maryland, a wedge of farmland bordering the Chesapeake Bay, had tried for 25 years to start a community recycling program; for some reason the idea just never caught on. But once the fifth graders at Hollywood Elementary School decided to solve the problem it did not take long for them to turn their campus into a neighborhood recycling center.

It was the children's enthusiasm more than anything that motivated parents and neighbors to join their efforts. Soon, Hollywood's hallways bulged with giant boxes of old newspapers and the school's parking lot became a regular Saturday-morning stop for residents eager to dump their cans and glass. Teachers helped, but students ran the show. Parents offered their vans, trucks, and even horse trailers to help haul the goods to the nearest recycling station in the next county. Eventually Saint Mary's County itself caught on, set up a few recycling transfer stations of its own and hired a recycling coordinator. But it all started at Hollywood.

"It was just as grass-roots as anything can get," remembers Betty Brady, the teacher who initiated the project. "We were a very small school at the time, less than 300 students, and we became a little place where people rallied."

Hollywood Elementary is not such a little place anymore. Enrollment is up to 600 now, housed in a spacious new facility designed to accommodate the real-world teaching that Brady and her colleagues practice. But the campus remains a rallying point for parents, educators, and other area residents dedicated to the task of maximizing individual learning through integrated, environment-based education.

During the past 15 years, aided by community volunteers and funded through a series of small grants from the Chesapeake Bay Trust, Hollywood's students have turned their 72-acre campus into a living lab—blazing a nature trail, creating a butterfly garden, planting a forest habitat for migrating birds, and transforming a drainage pond into

a natural wetland. Each project capitalized on the children's innate attraction to the natural world while providing unique opportunities to combine traditional subject areas in a meaningful whole. The results? At Hollywood Elementary, education works.

"As teachers, we always look at what works with and for children, paying attention to what causes that learner engagement that's so crucial to learning that lasts," explained principal, Kathleen Glaser. "We're very concerned about not just teaching something so that students can pass a test and then forget it a month later, but teaching something that will be part of their knowledge base, something they can work from to solve problems and enhance their lives."

Glaser and her staff, as well as the parents and students of Hollywood Elementary, clearly believe the school's real-world emphasis produces that kind of learning. And recent empirical evidence confirms it. Since 1992, the state of Maryland has required a year-end performance assessment for all students in grades three, five, and eight. It is a demanding yardstick, build around a child's ability to perform integrated tasks, such as life-science experiments and writing research reports. But it is a perfect tool to measure the effects of integrated education on real-world problem-solving.

Following five years of steady progress, Hollywood's students turned in a bellwether performance in 1997. In contrast to a statewide average of 38 percent, 67 percent of Hollywood's third grades achieved satisfactory assessment scores. At the fifth-grade level, Hollywood hit Maryland's ideal 70th percentile, with 70 percent of students performing in the satisfactory zone, as contrasted to 46 percent statewide.

Glaser attributes her school's stellar performance in large part to her staff of hard-working and innovative teachers, including Betty Brady and Julie Tracy.

Tracy found Glaser's supportive leadership style reason enough to choose Hollywood over another job offer when she finished her master's certification program in 1990. "I think it was probably the teachers and Mrs. Glaser's encouragement and her openness to suggestions," she said. "The other school was not as open to innovative ideas."

For instance, while partnering with a class in Costa Rica during a Smithsonian-sponsored study on migratory birds, Tracy's students learned that loss of habitat was causing a decrease in the birds' population. Their solution? Creating a habitat on the school grounds. Teaming up with other classes, they identified likely planting areas, including a stand of recently planted trees that still lacked native underbrush, and filled in the area with berry shrubs chosen from the birds' regular menu.

Tracy believes allowing that sort of student initiative is crucial to the learning. "If you approach a project saying, 'we're going to go out and plant a tree,' then it's the teacher's project," she said. "But if the students are engaged in real scientific inquiry, and they're the decision-makers directing the project, then it's authentic, and they're engaged in meaningful learning."

With its integrated, environment-based curriculum now expanding, and recognition of its effectiveness spreading, Hollywood Elementary has become a living portrait of the mature EIC school.

Looking back, Hollywood's recycling program, begun in the late 1980s, constitutes an important benchmark in an evolutionary process that started in 1982 when Glaser became principal of the school. From her own experiences first as a classroom teacher and later as a resource teacher, Glaser brought a dual focus to her new position: to encourage

individual learning and support innovative teaching.

"I think we communicated pretty early, after I became principal, that what was most important was the individual learner," Glaser said. "I think it's also important for teachers to grow professionally, so when they found a program or a resource or a good working idea we began to try some of those out."

As Brady and her fellow teachers continued to brainstorm and experiment, they made two discoveries. First, they found that students learned most effectively when previously disjointed subjects came together in an integrated curriculum. Second, they realized that the environment provided a perfect integrating context for learning.

Brady has a simple explanation for that: "All things are connected." Tracy agrees. "All the subject areas are right there," she said. "You don't have to try to plug anything in; it all just fits in naturally when you use the environment."

Add to that children's innate love of animals and curiosity about nature, and Hollywood had found a sure-fire recipe for effective education. "We saw children really engaging with the real world in a way they weren't engaging with the textbooks," Glaser explained, "and we saw the learning really lasting." "They see the big picture," Tracy added. "They see the goal."

Encouraged by their early successes and Glaser's never-wavering support, Hollywood's teachers began to design more and more environment-based projects and to tighten the teamwork so crucial to integrated learning. In some instances, teachers paired up based on their differing preferences: a nature nut, unfazed by bugs and dirt, and a bookworm, more comfortable juggling papers and pencils.

"We have such a spirit here of being a community of learners and leaders that people welcome someone with a different strength," Glaser commented. "I'd like to think that one of the things we do well is to blend the teaching strengths we have available, then nature not only the students, but also support each other where we need it."

Hollywood's distinctive approach to teaching caught the national limelight in 1996, when Julie Tracy's idea that second and third graders could turn a drainage pond into a natural habitat earned her a 1996 presidential award for excellence in teaching. In a project that combined biology, botany, ecology, math, and language arts, Tracy's students explored the types of aquatic plants and animals they could expect to thrive in the little pond, then drafted a planting plan, calculating depths and distances for optimal growth, and recruited parents and local college students to help with the work. Today, the former drainage basin is home to fish, birds, amphibians, and even a raccoon or two.

Not surprisingly, with Hollywood's thriving EIC emphasis drawing attention throughout Maryland and beyond, people are beginning to take notice. Glaser has been fielding frequent calls from other schools eager to duplicate Hollywood's success. She is eager to respond. "They want to know more about the nature trail or the butterfly garden, how that sort of thing gets organized," Glaser said. "I'm getting more interested in how to help other teachers integrate some of these ideas. How can we help people benefit from our years of experience?"

"I'm seeing lots of indicators that this kind of work is growing," Glaser said. "Hopefully, we can be a place people can visit or know about, so they can learn more about how to do it." If American education is indeed headed toward a new paradigm of integrated, environment-based instruction,

Hollywood is already out front and eager to lead the way.

#### HUNTINGDON AREA MIDDLE SCHOOL: STREAMS OF KNOWLEDGE

The students at Huntingdon Area Middle School are making adults in their rural Pennsylvania community sit up and take notice. Their active engagement in their community is an outgrowth of an innovative, homegrown EIC program called STREAMS—a regional grand-prize winner of the National Middle School Association's Team-teaching Award.

STREAMS, which stands for Science Teams in Rural Environments for Aquatic Management Studies, is an interdisciplinary program that aims to increase students' awareness of and concern for their immediate environment and to engage them in the community at large. As its name suggests, the program focuses on water and emphasizes active learning and real-world issues.

Student enthusiasm for the program keeps building. Every year, Huntingdon students clamor to begin projects earlier and earlier. "We used to start in January," said Fred Wilson, social studies teacher. "Then it was in November and this year some kids were ready in September." The accelerated schedule means more work for Wilson and his colleagues. But there is a certain synergy created when students are so eager, he said. And that is what gives him the energy to keep up.

The genesis of the STREAMS program occurred eight years ago when the sixth-grade teaching team, including Wilson, began looking for a new theme to incorporate across their existing interdisciplinary curriculum. They decided a program tied to the water studies presented in Tim Julian's science class would be ideal because they could tie it into all the disciplines.

"We wanted to examine problems in our community—such as water quality, storm-water runoff and erosion—to make the subject more meaningful to our students," Wilson explained. It was a perfect choice. With four separate watersheds converging within two miles of the school, he pointed out, Huntingdon already had a phenomenal outdoor lab at its doorstep.

Wilson volunteered to develop the interdisciplinary program and contacted a number of organizations in his search for suitable learning projects. But, while he discovered lots of suggestions for activities, there was no program that could be "plugged in" to Huntingdon's existing curriculum. By 1991, the first year Wilson and his teammates taught the STREAMS unit, he had developed his own instructional segments dealing with storm-water runoff, erosion and sedimentation, water quality monitoring, household pollutants, and community involvement. At the same time, Julian expanded the portion of his science curriculum that dealt with water to include the study of local watersheds as well as water and wastewater treatment facilities.

Students response was overwhelming, so overwhelming that the following summer Wilson and his colleagues developed more STREAMS topics—wetlands, groundwater, acidity, and nutrient enrichment—and added more water quality studies plus two additional watersheds to monitor.

The team effort regularly crosses disciplinary lines, with each teacher contributing his or her expertise toward common projects. In science class, for instance, Julian teaches the students about the properties of water, purification processes, and wastewater treatment. Before they go out on a field trip to conduct tests, they also learn how to use the proper monitoring equipment. "Our kids don't go out unless they are prepped," Wilson said. "That's so they can succeed."

Rose Taylor, Huntingdon's sixth-grade language arts teacher, reinforces the vocabulary students need to know in their studies and works with students on STREAMS-related writing assignments. Math teacher Mike Simpson helps the students learn to interpret statistics, construct charts and graphs, and use computer database programs to report their findings. He also incorporates the data they collect into problems he uses to teach important math concepts such as fractions and percentages. "Rather than use cookbook problems," he said, "we use real field data."

Wilson's part of the curriculum emphasizes the consequences of land use—residential, agricultural, and mining—on the water supply, as well as various types of pollution and the function of wetlands. Wilson's students also learn about the effects of storm-water runoff, a significant problem in the Huntingdon vicinity because of over-development in what was once a wetland.

Everything comes together out in the field, where all the team members get their hands dirty. Their eagerness to dig right in can be traced in large measure to their lengthy history as a team. "We've teamed together so long—15 years—that we can be frank and open," Wilson explained. Another secret of the STREAMS staff is a willingness to step outside the bounds of their own disciplines. "You have to be willing," he said, "to wear different hats."

Indeed, STREAMS teachers seem entirely comfortable sharing their teaching responsibilities all around. All the team members, for example, teach reading. Tim Julian and Mike Simpson capitalize on the interrelationships between science and math; both, for instance, teach students to interpret charts and graphs. "Science uses a lot of math—averaging, graphing, measuring speed," Julian pointed out. "Sometimes we work together; sometimes we handle it separately." Julian also supports Rose Taylor's efforts in language arts by having students write reports on their field activities. "I do correct their grammar," he said, "but I don't lower their science grade for mistakes."

The teachers are equally flexible about class time. "I could go into school tomorrow and say that I need a block of time," Wilson said, "and we'd revamp the schedule in a minute." STREAMS team members synchronize and evaluate their lesson plans and schedules in regular weekly meetings, but they can also meet daily during a common planning period.

Wilson conducts an annual formal assessment of what students learned in the program. In the 1994/95 school year, 97 percent of STREAMS students failed a pre-test with an average score of 38 percent. Two months after the program concluded, the students' average score, on an unannounced post-test, was 81 percent, with only a 2 percent failure rate. In the 1996/97 school year, Wilson conducted the post-test five months after they completed the initial STREAMS unit. Even after that lengthy interval, the students' averaged 71 percent on the test. Those results, Wilson point out, indicate that most students not only mastered the content, but also retained that knowledge months after completing the program.

When Wilson and his colleagues started the STREAMS program, no one dreamed how successful and far-reaching it would become. Beyond the creativity and effort of the Huntingdon team, Wilson said, another key reason for their success is partnering with various organizations in the community.

Parents are another valuable resource. Without them, Wilson said, he could not accommodate all the students who want to do independent work, often after school and on weekends. They help transport and chap-

erone students giving presentations to public groups, civic organizations, teacher conferences, and workshops, as well as those taking special field trips or traveling to the biotechnology lab at Penn State. Parents also help with tree-planting projects and water-quality monitoring.

The students, too, have tapped into the partnering concept. When they proposed creating a wetland near the school, for example, they raised \$1,000 and then found partners to contribute the \$3,000 needed to complete the project—proof that they have learned to leverage their dollars and attract broad-based support.

The community that spawned these savvy students and teachers is by some standards an unlikely one. Huntingdon, a town of 7,000, is located in south central Pennsylvania, an area that historically has reported the highest unemployment figures in the state. The average family income here is \$20,000 annually. Only 9.4 percent of adults in the county have earned a post-secondary degree, compared to 18 percent statewide.

Wilson also noted a dichotomy in the region's attitudes toward education, with some residents very supportive and others indifferent. Consequently, it has been exciting for Huntingdon's teachers to watch a gradual shift in the public's attitude toward the students' endeavors. "At first, they were taken rather lightly," Julian noted, "but now the community is coming and asking them for help."

Without a doubt, Wilson observed, the Huntingdon teachers' decision to use the environment as an umbrella for interdisciplinary study and hands-on instructional strategies has produced tremendous results. "I think that our students are engaged in a meaningful learning experience that will help to empower them to be critical thinkers and become more independent learners," he said.

As principal Jill Adams sees it, programs like STREAMS and teachers like Wilson and his colleagues hold the key to reshaping the entire educational process. "The future of education really depends on people like this," she said. "We cannot continue to teach the way that we were taught."

Mr. SARBANES. In the Chesapeake Bay region, the Governors of Maryland, Virginia, Pennsylvania and the Mayor of the District of Columbia have recognized the importance of engaging students in the protection of the Chesapeake Bay. The States have each enacted legislation to integrate environmental standards into the curriculum for particular grade levels. As signatories to the Chesapeake 2000 Agreement, they have also committed to "provide a meaningful Bay or stream outdoor experience for every school student in the watershed before graduation from high school" beginning with the class of 2005.

Likewise, several not-for-profit organizations including the Chesapeake Bay Foundation, and the Living Classrooms Foundation have spearheaded efforts to create long-term, cohesive education programs focused on the local environment. They have developed terrific partnerships with schools and are helping teachers develop and implement quality instruction, investigations and Bay or stream-side projects.

Unfortunately, all these efforts and programs are only reaching a very small percentage of the more than 3.3 million K-12 students in the watershed.

Classroom environmental instruction across grade levels is sporadic and inconsistent, at best, and relatively few students have had the opportunity to engage in meaningful outdoor experiences. Many of the school systems in the Bay watershed are only at the beginning stages in developing and implementing environmental education into their curriculum, let alone exposing them to outdoor watershed experiences. What's lacking is not the desire or will, but the resources and training to undertake more comprehensive environmental education programs.

In 1970, the Congress enacted the first Environmental Education act to authorize the then-U.S. Department of Health, Education, and Welfare to establish programs to support environmental education at the elementary and secondary levels and in communities. In its statement of findings and purposes, the Congress found "that the deterioration of the quality of the Nation's environment and of its ecological balance is in part due to poor understanding by citizens of the Nation's environment and of the need for ecological balance; that presently there do not exist adequate resources for educating citizens in these areas, and that concerted efforts on educating citizens about environmental quality and ecological balance are therefore necessary." Grants for curriculum development, teacher training, and community demonstration projects were made available for several years under this Act, but the program expired and was not reauthorized.

In 1990, the Congress enacted the National Environmental Education Act to renew the federal role in environmental education. The Congress, once again found that "current Federal efforts to inform and educate the public concerning the natural and built environment and environmental problems are not adequate." Today, 32 years after the first Environmental Education Act was first authorized, those findings are still true. Last year, nationwide funding for the National Environmental Education Act administered by EPA was only \$7.3 million. That averages to a little more than \$140,000 for each of the 50 States, a sum that is totally inadequate for schools to incorporate environmental education as part of the K-12 curriculum.

The legislation which I am introducing would authorize \$6 million a year over the next three years in federal grant assistance to help close the resource and training gap for students in the elementary and secondary levels in the Chesapeake Bay watershed. It would require a 50 percent non-federal match, thus leveraging \$12 million in assistance. The funding could be used to help design, demonstrate or disseminate environmental curricula and field practices, train teachers or other educational personnel, and support on-the-ground activities or Chesapeake Bay or stream outdoor educational experiences involving students and teachers,

among other things. The program would complement a similar initiative that I sponsored last year within the National Oceanic and Atmospheric Administration which is providing \$1.2 million to support environmental education in the Chesapeake watershed.

The Chesapeake Bay Program has pioneered many of the Nation's most innovative environmental protection and restoration initiatives. It has been a leader in establishing a large volunteer monitoring program; implementing pollution control programs such as the ban on phosphate detergents and voluntary nutrient reduction goals; and conducting an extensive habitat restoration program including the opening of hundreds of miles of prime spawning habitat to migratory fish. It is an ideal proving ground for demonstrating that strong and consistent support for environmental education, using the Chesapeake Bay and local environment as the primary instructional focus, will lead not only to a healthier, enduring watershed, but a more educated and informed citizenry, with a deeper understanding and appreciation for the environment, their community and their role in society as responsible citizens.

By Mr. TORRICELLI (for himself and Mr. HATCH):

S. 2676. A bill to amend the Internal Revenue Code of 1986 to allow a 10-year foreign tax credit carryforward and to apply the look-thru rules for purposes of the foreign tax credit limitation to dividends from foreign corporations not controlled by a domestic corporation; to the Committee on Finance.

Mr. TORRICELLI. Mr. President, today, Senator HATCH and I are introducing legislation to modernize and simplify the foreign tax credit. The legislation contains two meritorious provisions that we hope Congress will enact this year, in that they are both long overdue.

The first provision addresses the problem of double taxation that results when foreign tax credits expire unused under current law. To enhance the international competitiveness of U.S. companies operating overseas, and to help avoid this unfair double taxation, our legislation simply extends the current 5-year foreign tax credit carryforward period for five additional years to a 10-year carryforward.

The second provision reforms current law, which unduly hinders U.S. companies in their efforts to penetrate foreign markets by imposing the so-called 10/50 foreign tax credit rule. Due to legal and political realities, many U.S. companies are forced to operate through corporate joint ventures in partnership with local businesses. The 10/50 rule imposes a foreign tax credit limitation for each of these corporate joint ventures where a U.S. company owns at least 10 percent but not more than a 50 percent interest in a foreign company, and thus increases the cost of doing business for U.S. firms competing abroad.

10/50 reform would restore parity in the tax treatment of joint-venture income to other income earned overseas by U.S. companies by applying "look-through" treatment. Without this change, U.S.-based companies engaged in joint ventures overseas will continue to be disadvantaged vis à vis foreign competitors. Congress attempted to rectify this problem in a large tax bill that was ultimately vetoed in 1999. The Clinton Treasury also recommended enactment of this crucial tax change in its FY 2000 budget package and similarly, the Joint Committee on Taxation endorsed this non-controversial provision in its 2001 Simplification Study.

As indicated earlier, these two changes are long overdue and we urge their expeditious enactment.

Mr. HATCH. Mr. President, I am pleased to join with my friend and colleague from New Jersey in introducing a bill to improve the tax treatment of U.S.-based multinational companies.

It is apparent that our international tax code is deeply flawed. The current wave of companies reincorporating in Bermuda, the foreign sales corporation debacle, and the trend of tax-motivated foreign takeovers all provide abundant evidence that Congress needs to act to make our international tax rules friendlier to American-based companies.

The bill we are introducing today is one that I consider to be a down-payment on the fundamental reform that our international tax system demands. The bill will reduce, but unfortunately will not eliminate, the double taxation of international income that occurs far too often. This double taxation is just one of several serious problems with our international tax rules.

The threat of double taxation, where an American corporation ends up paying corporate taxes to both the United States and to a foreign country on the same income, discourages U.S. firms from investing overseas. And since U.S. multinationals provide millions of America's best-paying domestic jobs, anything that discourages overseas direct investment ends up hurting the take-home pay of our nation's workers.

Our bill has two provisions. The first would reform the carryforward treatment of foreign tax credits. The Internal Revenue Code was originally designed to make sure that U.S. corporations investing overseas are not subject to double taxation by a foreign nation and the U.S. on the same income. It does this through the availability of a foreign tax credit. If this system worked well, then American businesses would seldom or ever face this kind of double taxation.

However, the system most emphatically does not work well. For example, American businesses are only allowed to use these foreign tax credits when their U.S. operations are profitable. As a result, when the U.S. side of the business is doing badly, firms are unable to immediately use the foreign tax credits. While the current tax law allows

businesses to carry excess foreign tax credits forward for up to 5 years, that timetable is unrealistic. An expanding business, with high domestic expansion costs and low domestic profits, can easily go through 5 years of losses, and never get a chance to use those tax credits. Once the 5-year period has expired, the credits are gone forever, and the result is double taxation, the threat of which discourages firms from taking on otherwise profitable overseas investment projects.

If we want American businesses to take the long view, a 5-year carryforward just is not long enough. The legislation Senator TORRICELLI and I are introducing today will extend that horizon to 10 years. If enacted, it would give U.S. firms a much better search throughout the world for profitable investment projects. And again, profits earned by U.S. companies throughout the world generally translates into more and better-paying jobs for Americans.

Our second proposal would eliminate our tax code's inhospitable treatment of international joint ventures. In many developing countries with rules and restrictions on foreign ownership, joint ventures are the only way to get things done. Our current-law tax treatment of these joint ventures, known as 10/50 companies because between 10 and 50 percent of the joint venture is owned by the U.S. company—is indefensible.

Ordinarily, our tax code adds together tax attributes from different divisions of the same firm. For example, if one division of a company loses a hundred dollars and another division earns a hundred in profits, we offset the gain and the loss and assess no tax liability.

Unfortunately, when it comes to these 10/50 companies, the tax law applies a separate foreign tax credit limitation to each venture. This increases the cost of doing business for the U.S. firms competing abroad because it makes it harder for firms to use their foreign tax credits and also adds a great deal of complexity. The result? Double taxation once again. And once again, our tax code discourages U.S. firms from jumping on profitable investment opportunities, because of the very real threat of double taxation.

When American businesses are considered overseas investment opportunities, we do not want that decision to turn on the arcane details of U.S. tax law—we want a code that is fairer, simpler, and most of all, helps our companies better compete in the global marketplace. The bill we are introducing today will not fix all of our tax code's many problems in the international area, but it is an excellent start. I urge our colleagues to give their consideration to this important piece of legislation.

By Mr. ROCKEFELLER:

S. 2677. A bill to improve consumer access to prescription drugs, and for other purposes; to the Committee on Finance.

Mr. ROCKEFELLER. Mr. President, I rise today to introduce a bill that affects all of our lives. This bill gets to the heart of an issue that Congress has been talking about for years, access to prescription drugs. As the name implies, the Consumer Access to Prescription Drugs Improvement Act of 2002 seeks to improve access to prescription drugs for every person who needs medication.

Today, people rely on prescription drugs for several different reasons. For some people, prescription drugs make life more comfortable. Some would not survive without them. Prescription drugs have become an intricate part of modern medicine, replacing procedures that once required an inpatient stay. Ailments that once could not be treated can now be cured with a little pill. The innovation that has been displayed is amazing and must continue.

The problem, however, is that prescription drug manufacturers have been distorting the market. Drug manufacturers are exploiting loopholes in existing laws to further extend their monopolies and keep generic drugs off the market. The result, after years of paying monopoly prices, consumers continue to be cheated out of cost-effective alternatives. We've all heard the horror stories of people going without their medications, splitting pills, or making the choice between food and drugs. However, the consequences of actions taken by drug manufacturers are actually more global. They are taking a terrible toll on State budgets, forcing Medicaid to severely scale back their coverage of our most needed population. They are causing employer health care premiums to go through the roof. These pressures will cause the number of uninsured to increase and will ultimately limit access to health care.

The group that suffers the most due to drug cost growth is seniors. Millions of seniors have no drug coverage today. Over the past five years, the 50 prescription drugs most commonly used by seniors have increased in price by nearly twice the rate of inflation. In fact, over 25 percent of these drugs increased in price by three or more times the rate of inflation over that time period. According to the Kaiser Family Foundation, the average retail prescription price for brand name drugs has increased more than 58 percent in 10 years. Brandeis University recently released a report on this issue. The major conclusion of the report is that greater and appropriate use of generic medications can achieve \$50-\$100 billion in savings for any new Medicare drug benefit. This legislation will make a Medicare drug benefit affordable and sustainable into the future. Senators should be aware that I plan to offer this legislation as an amendment to any Medicare prescription drug benefit that the Senate considers.

This legislation will stop pharmaceutical companies from circumventing the law and open the door to

competition so that every consumer from West Virginia to California has access to reasonably priced prescription drugs. However, this legislation will also go further. It will provide crucial information to physicians, consumers, and health care purchasers about the cost-effective generics that are equivalent to brand names. According to the Federal Trade Commission, generic drugs typically cost 25 percent less than brand-name drugs when they first enter the market. After two years, the price difference grows to 60 percent. Every patient should have access to the drug prescribed by their doctor, but if there is a drug out there that is equivalent to the brand name but will cost you half as much, don't you want your physician to know about it? This bill will shine a spotlight on the real costs and the effects of issues we hear so much about, direct-to-consumer advertising, drug detailing, and sampling. We can no longer afford to talk about these issues in broad, hypothetical terms. Congress and the public need to understand these issues better so that we can be more prudent purchasers. This legislation will create the correct incentives, to innovate rather than litigate.

Finally, this legislation will expand access to drugs under existing programs which are so crucial to those who rely on them. This legislation will expand Medicare's current drug benefit to include all cancer drugs, regardless of the method by which they are administered. It will allow public hospitals access to the drug prices they need to be able to continue in their mission to provide care to our neediest citizens. It will help states with their drug utilization review programs which we all know are cost effective. I urge my colleagues to join me in this effort.

My efforts are supported by the Service Employees International Union, the American Federation of State, County and Municipal Employees, the AFL-CIO, Families USA, the Generic Pharmaceutical Association, the National Association of Chain Drug Stores, and Representative WAXMAN, the author of the original legislation.

Representative WAXMAN stated:

Now more than ever, as the cost of prescription drugs has skyrocketed, access to low-cost generics is essential. At a time when the brand-name companies have few innovative products in their pipelines, we are seeing a disturbing trend: a growing number of companies are choosing to protect their profits through legal maneuvers to delay generic competition on their existing products. The price of this anti-competitive behavior to our nation's health care bill and to the health of Americans is shockingly high. It is time that Congress acted to stop unnecessary delays in the marketing of generic drugs. The bill that Senator Rockefeller is introducing today makes a real contribution to the effort to combat these problems.

This legislation is a commonsense step we can take to increase access to prescription drugs for all consumers. I urge Congress to consider and pass this legislation. I ask unanimous consent

that the text of the bill be printed in the RECORD.

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

S. 2677

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

# SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Consumer Access to Prescription Drugs Improvement Act of 2002”.

(b) **TABLE OF CONTENTS.**—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings; purposes.

## TITLE I—EXPANSION OF ACCESS THROUGH EDUCATION AND INFORMATION

Sec. 101. Pharmaceutical Advisory Committee.

Sec. 102. Guidance for payer and medical communities.

Sec. 103. Study of procedures and scientific standards for evaluating generic biological products.

Sec. 104. Institute of Medicine study.

## TITLE II—EXPANSION OF ACCESS THROUGH INCREASED COMPETITION

Sec. 201. Drug Reimbursement Fund.

Sec. 202. Patent certification.

Sec. 203. Accelerated generic drug competition.

Sec. 204. Notice of agreements settling challenges to certifications that a patent is invalid or will not be infringed.

Sec. 205. Publication of information in the Orange Book.

Sec. 206. No additional 30-month extension.

## TITLE III—EXPANSION OF ACCESS THROUGH EXISTING PROGRAMS

Sec. 301. Medicare coverage of all anticancer oral drugs.

Sec. 302. Removal of State restrictions.

Sec. 303. Medicaid drug use review program.

Sec. 304. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions established for purposes of the Medicaid drug rebate program.

Sec. 305. Upper payment limits for generic drugs under Medicaid.

## TITLE IV—GENERAL PROVISIONS

Sec. 401. Report.

## SEC. 2. FINDINGS; PURPOSES.

(a) **FINDINGS.**—Congress finds that—

(1) prescription drugs are a crucial part of modern medicine, serving as complements to medical procedures, substitutes for surgery and other medical procedures, and new forms of treatment;

(2) a lack of access to prescription drugs can not only cause discomfort, but can be life-threatening to a patient;

(3)(A) by all accounts, double-digit prescription drug price increases are forecast annually for the next 3 to 5 years; and

(B) such increases would result in prescription drug costs that would be prohibitive for many Americans;

(4) the Congressional Budget Office estimates that—

(A) the use of generic prescription drugs for brand-name prescription drugs could save purchasers of prescription drugs between \$8,000,000,000 and \$10,000,000,000 each year; and

(B) generic prescription drugs cost between 25 percent and 60 percent less than brand-name prescription drugs, resulting in an estimated average saving of \$15 to \$30 on each prescription;

(5) expanding access to generic prescription drugs can help consumers, especially seniors and the uninsured, have access to more affordable prescription drugs;

(6) policymakers should be better informed about issues relating to prescription drugs, particularly issues concerning barriers to patient access to prescription drugs;

(7) health care purchasers should be more aware of safe, cost-effective alternatives to brand-name prescription drugs; and

(8) prescription drug coverage provided under existing programs should be expanded to better reflect modern technology and provide drugs to the people who rely on them most, yet who increasingly find themselves uninsured or with coverage that is becoming more expensive and less meaningful.

(b) **PURPOSES.**—The purposes of this Act are—

(1) to better educate policymakers, purchasers, and the public about safe and cost-effective generic alternatives, barriers to market entry, and upcoming issues in the pharmaceutical industry;

(2) to increase consumer access to prescription drugs by—

(A) decreasing price through increased competition; and

(B) expanding coverage under the Medicare and Medicaid programs.

## TITLE I—EXPANSION OF ACCESS THROUGH EDUCATION AND INFORMATION

### SEC. 101. PHARMACEUTICAL ADVISORY COMMITTEE.

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by inserting after section 1805 the following:

#### “PHARMACEUTICAL ADVISORY COMMITTEE

“SEC. 1805A. (a) **ESTABLISHMENT.**—There is established, as part of the Medicare Payment Advisory Commission established under section 1805, a committee to be known as the ‘Pharmaceutical Advisory Committee’ (referred to in this section as the ‘Committee’).

#### “(b) **MEMBERSHIP.**—

“(1) **COMPOSITION.**—The Committee shall be composed of 11 members appointed by the Comptroller General of the United States.

#### “(2) **QUALIFICATIONS.**—

“(A) **IN GENERAL.**—The Committee members shall be selected from among—

“(i) individuals with expertise in and knowledge of the pharmaceutical industry (brand name and generic), including expertise in and knowledge of pharmaceutical—

“(I) development;

“(II) pricing;

“(III) distribution;

“(IV) marketing;

“(V) reimbursement; and

“(VI) patent law; and

“(ii) providers of health and related services;

“(B) **REPRESENTATION.**—The members of the Committee shall include—

“(i) physicians and other health professionals;

“(ii) employers;

“(iii) third-party payers;

“(iv) representatives of consumers;

“(v) individuals having—

“(I) skill in the conduct and interpretation of pharmaceutical and health economics research; and

“(II) expertise in outcomes, effectiveness research, and technology assessment; and

“(vi) patent attorneys.

“(C) **CONFLICTS OF INTEREST.**—The members of the Committee shall not include any individual who, within the 5-year period preceding the date of appointment to the Committee, has been an officer or employee of a drug manufacturer or has been employed as a consultant to a drug manufacturer.

“(D) **REPRESENTATION.**—The members of the Committee shall be broadly representa-

tive of various professions, geographic regions, and urban and rural areas.

“(E) **LIMITATION.**—Not more than ½ of the members appointed under this subsection may be directly involved in the provision, management, or delivery of items and services covered under this title.

“(F) **PUBLIC DISCLOSURE.**—As soon as practicable after the date of enactment of this Act, the Comptroller General of the United States shall establish rules for the public disclosure of financial and other potential conflicts of interest by members of the Committee.

#### “(3) **TERMS; VACANCIES.**—

##### “(A) **TERMS.**—

“(i) **IN GENERAL.**—Except as provided in clause (ii), a member of the Committee shall be appointed for a term of 3 years.

“(ii) **INITIAL TERMS.**—Of the members first appointed to the Committee under this subsection—

“(I) 4 shall be appointed for a term of 1 year; and

“(II) 4 shall be appointed for a term of 2 years.

“(iii) **CARRYOVER.**—After the term of a member of the Committee has expired, the member may continue to serve until a successor is appointed.

##### “(B) **VACANCIES.**—

“(i) **IN GENERAL.**—A vacancy on the Committee—

“(I) shall not affect the powers of the Committee; and

“(II) shall be filled in the same manner as the original appointment was made.

“(ii) **FILLING OF UNEXPIRED TERM.**—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

“(4) **MEETINGS.**—The Committee shall meet at the call of the chairperson.

“(5) **CHAIRPERSON; VICE CHAIRPERSON.**—The Comptroller General shall appoint 1 of the members as chairperson and 1 of the members as vice chairperson.

##### “(c) **DUTIES.**—

“(1) **IN GENERAL.**—The Committee shall—

“(A) review payment policies for drugs under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq.); and

“(B) make recommendations to Congress with respect to the payment policies.

“(2) **INCLUSIONS.**—The matters to be studied by the Committee under paragraph (1) include—

“(A) the effects of direct-to-consumer advertising, drug detailing, and sampling;

“(B) the level of use of generic drugs as safe and cost-effective alternatives to brand name drugs;

“(C) the barriers to approval of generic drugs, including consideration of all of the matters described in paragraph (3);

“(D) the adequacy of drug price metrics, including the average wholesale price and the average manufacturers price;

“(E) the effectiveness of various education methods on changing clinical behavior;

“(F) the effectiveness of common drug management tools, including drug use review and use of formularies;

“(G) the perception of patients, physicians, nurses, and pharmacists of generic prescription drugs as safe and effective substitutes for brand-name prescription drugs;

“(H) the costs of research and development and the costs of clinical trials associated with producing a drug;

“(I) the relationship between pharmacy benefit managers and prescription drug manufacturers;

“(J) best practices to increase medical safety and reduce medical errors; and

“(K) polypharmacy and underutilization.



“(3) BARRIERS TO APPROVAL.—The matters for consideration referred to in paragraph (2)(C) include—

“(A) the appropriate balance between rewarding scientific innovation and providing affordable access to health care;

“(B) features of the communication process and grievance procedure of the Committee that provide opportunities for tactics that unduly delay generic market entry;

“(C) the use of the citizen's petition process to delay generic market entry;

“(D) the use of changes to a drug product (including a labeling change) timed to delay generic approval; and

“(E) the impact of granting patents on diagnostic methods such as patents on genes and genetic testing systems on access to affordable health care.

“(4) REPORT.—Not later than January 1 of each year, the Committee shall submit to Congress a report on—

“(A) the results of the reviews and recommendations;

“(B) issues affecting drug prices, including use of and access to generic drugs; and

“(C) the effect of drug prices on spending by government-sponsored health care programs and health care spending in general.

“(d) POWERS.—

“(1) INFORMATION FROM FEDERAL AGENCIES.—

“(A) IN GENERAL.—The Committee may secure directly from a Federal department or agency such information as the Committee considers necessary to carry out this section.

“(B) PROVISION OF INFORMATION.—On request of the Chairperson of the Committee, the head of the Federal department or agency shall provide the information to the Committee.

“(2) DATA COLLECTION.—To carry out the duties of the Committee under subsection (c), the Committee shall—

“(A) collect and assess published and unpublished information that is available on the date of enactment of this Act;

“(B) if information available under subparagraph (A) is inadequate, carry out, or award grants or contracts for, original research and experimentation; and

“(C) adopt procedures to allow members of the public to submit information to the Committee for inclusion in the reports and recommendations of the Committee.

“(3) ADDITIONAL POWERS.—The Committee may—

“(A) seek assistance and support from appropriate Federal departments and agencies;

“(B) enter into any contracts or agreements as are necessary to carry out the duties of the Committee, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5);

“(C) make advance, progress, and other payments that relate to the duties of the Committee;

“(D) provide transportation and subsistence for persons serving without compensation; and

“(E) promulgate regulations for the internal organization and operation of the Committee.

“(e) COMMITTEE PERSONNEL MATTERS.—

“(1) COMPENSATION OF MEMBERS.—

“(A) IN GENERAL.—A member of the Committee shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the performance of the duties of the Board.

“(B) TRAVEL EXPENSES.—A member of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an agen-

cy under subchapter I of chapter 57 of title 5, United States Code, while away from the home or regular place of business of the member in the performance of the duties of the Board.

“(2) STAFF.—

“(A) IN GENERAL.—The Committee may, without regard to the civil service laws (including regulations), appoint and terminate an executive director and such other additional personnel as are necessary to enable the Committee to perform the duties of the Committee.

“(B) COMPENSATION.—The Chairperson of the Committee may fix the compensation of the executive director and other personnel without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, relating to classification of positions and General Schedule pay rates.

“(C) EMPLOYEES OF THE FEDERAL GOVERNMENT.—For the purposes of compensation, benefits, rights, and privileges, the staff of the Committee shall be considered employees of the Federal Government.

“(f) REQUEST FOR APPROPRIATIONS.—

“(1) IN GENERAL.—The Committee shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations.

“(2) SEPARATE AMOUNTS.—Notwithstanding paragraph (1), amounts appropriated for the Committee shall be separate from amounts appropriated for the Comptroller General.”.

#### SEC. 102. GUIDANCE FOR PAYER AND MEDICAL COMMUNITIES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance for the payer community and the medical community on—

(1) how consumers, physicians, nurses, and pharmacists should be educated on generic drugs; and

(2) the need to potentially educate pharmacy technicians, nurse practitioners, and physician assistants on generic drugs.

(b) MATTERS TO BE ADDRESSED.—The guidance shall include such items as—

(1) a recommendation for allotment of a portion of yearly continuing education hours to the subject of generic drugs similar to recommendations for continuing education already in place for pharmacists in some States on pharmacy law and AIDS;

(2) a recommendation to all medical education governing bodies regarding course curricula concerning generic drugs to include in the course work of medical professionals;

(3) a recommendation on how the Food and Drug Administration could notify physicians and pharmacists when a brand name drug becomes available as a generic drug and what information could be included in the notification;

(4) the establishment of a speaker's bureau available to groups by geographic region to speak and provide technical assistance on issues relating to generic drugs, to be available to pharmacists, consumer groups, physicians, nurses, and local media; and

(5) the proposition of a survey on perception and awareness of generic drugs at the beginning and end of an educational campaign to test the effectiveness of the campaign on different audiences.

(c) PUBLIC EDUCATION.—The Secretary shall provide for the education of the public on the availability and benefits of generic drugs.

(d) NOTIFICATION OF NEW GENERIC PRESCRIPTION DRUG APPROVALS.—As soon as practicable after a new generic prescription drug is approved, the Secretary shall—

(1) notify physicians, pharmacists, and other health care providers of the approval; and

(2) inform health care providers of the brand-name prescription drug for which the generic prescription drug is a substitute.

#### SEC. 103. STUDY OF PROCEDURES AND SCIENTIFIC STANDARDS FOR EVALUATING GENERIC BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—The Institute of Medicine shall conduct a study to evaluate—

(1) the feasibility of producing generic versions of biological products; and

(2) the relevance of the source materials and the manufacturing process to the production of the generic versions.

(b) ESTABLISHMENT OF PROCESS.—

(1) IN GENERAL.—If, as a result of the study under subsection (a), the Institute of Medicine finds that it would be feasible to produce generic versions of biological products, not later than 3 years after the date of the completion of the study, the Secretary, shall prescribe procedures and conditions under which biological products intended for human use may be approved under an abbreviated application or license.

(2) APPLICATION.—An abbreviated application or license shall, at a minimum, contain—

(A) information showing that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new biological product have been previously approved for a drug subject to regulation under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (referred to in this subsection as a “listed drug”);

(B) information to show that the new biological product has chemical and biological characteristics comparable to the characteristics of the listed drug; and

(C) information showing that the new biological product has a safety and efficacy profile comparable to that of the listed drug.

(3) PRODUCT STANDARDS.—The Secretary, on the initiative of the Secretary or on petition, may by regulation promulgate drug product standards, procedures, and conditions to determine insignificant changes in a biological product that do not affect the scientific and medical soundness of product approval and interchangeability.

#### SEC. 104. INSTITUTE OF MEDICINE STUDY.

(a) IN GENERAL.—The Institute of Medicine shall convene a committee to conduct a study to determine—

(1) whether information regarding the relative efficacy and effectiveness of drugs (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) and biological products (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))) is available to the public for independent and external review;

(2) whether the benefits of drugs and biological products, and particularly the relative benefits of similar drugs and biological products, are understood by physicians and patients; and

(3) whether prescribing and use patterns are unduly or inappropriately influenced by marketing to physicians and direct advertising to patients.

(b) RECOMMENDATIONS.—If problems are identified by the study conducted under subsection (a), the committee shall make recommendations to the Commissioner of Food and Drugs for improvement, including recommendations regarding—

(1) ways to better review the relative efficacy and effectiveness of drugs approved for use by the Food and Drug Administration;

(2) the appropriate governmental or non-governmental body to conduct the review described under paragraph (1); and

(3) ways to improve communication and dissemination of the information reviewed in paragraph (1).

(c) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated such sums as are necessary to carry out this section.

## **TITLE II—EXPANSION OF ACCESS THROUGH INCREASED COMPETITION**

### **SEC. 201. DRUG REIMBURSEMENT FUND.**

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 501 et seq.) is amended by adding at the end the following:

#### **“SEC. 524. DRUG REIMBURSEMENT FUND.**

“(a) **DEFINITIONS.**—In this section:

“(1) **DRUG PATENT.**—The term ‘drug patent’ means a patent described in section 505(b)(1).

“(2) **FUND.**—The term ‘Fund’ means the Drug Reimbursement Fund established under subsection (b).

“(b) **ESTABLISHMENT.**—There is established in the Treasury of the United States a separate fund to be known as the ‘Drug Reimbursement Fund’.

“(c) **COMPTROLLER.**—The Secretary shall appoint a comptroller to administer the Fund.

“(d) **REGULATIONS.**—

“(1) **IN GENERAL.**—The Secretary shall promulgate regulations for the operation of the Fund, including the method of payments from the Fund and designation of beneficiaries of the Fund.

“(2) **ADMINISTRATIVE DETERMINATIONS.**—The regulations under paragraph (1) may permit the administrative determination of the claims of health insurers, State and Federal Government programs, and third-party payers or other parties that are disadvantaged by the conduct of drug manufacturers that seek to bring spurious civil actions for infringement of drug patents in order to block the production and marketing of lower-cost drug alternatives.

“(e) **CONTRIBUTIONS TO THE FUND.**—

“(1) **IN GENERAL.**—In any civil action under section 505 or 512 or in a civil action for infringement of a drug patent (as defined in section 524(a)) under chapters 28 and 29 of title 35, United States Code—

“(A) if the Court determines that the drug patent is invalid or that the drug patent is not otherwise infringed, but that the plaintiff obtained an injunction against the defendant for the production or marketing of the drug to which the drug patent relates, the Court shall order the plaintiff to pay to the Fund the amount that is equal to—

“(i) the amount that is equal to the amount of net revenues generated by the plaintiff from the production or marketing of the drug during the period in which the injunction was in effect, plus an additional period of 12 months; minus

“(ii) the amount of any special damages paid by the plaintiff under section 524(m); or

“(B) if the defendant enters into a settlement agreement or any other arrangement under which the defendant agrees to withdraw an application under section 505 or 512, the Court shall order the defendant to pay to the Fund the amount that is equal to 50 percent of the amount (including the value of any form of property) that the defendant receives from the plaintiff under the arrangement.

“(2) **COLLECTION.**—The United States may seek to enforce collection of a contribution required to be made to the Fund by bringing a civil action in United States district court.”.

### **SEC. 202. PATENT CERTIFICATION.**

(a) **IN GENERAL.**—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)—

(A) by striking “(B) The approval” and inserting the following:

“(B) **EFFECTIVE DATE OF APPROVAL.**—Except as provided in subparagraph (C), the approval”; and

(B) by striking clause (iii) and inserting the following:

“(iii) **CERTIFICATION THAT PATENT IS INVALID OR WILL NOT OTHERWISE BE INFRINGED.**—

“(I) **NO CIVIL ACTION FOR PATENT INFRINGEMENT OR DECLARATORY JUDGMENT, OR NO MOTION FOR PRELIMINARY INJUNCTION.**—Except as provided in subclause (II), if—

“(aa) the applicant made a certification described in paragraph (2)(A)(vii)(IV);

“(bb) none of the conditions for denial of approval stated in paragraph (4) applies;

“(cc)(AA) no civil action for infringement of a patent that is the subject of the certification is brought before the expiration of the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; or

“(BB) a civil action is brought as described in subitem (AA), but no motion for preliminary injunction is filed within 90 days of commencement of the civil action; and

“(dd) the applicant does not bring a civil action for declaratory judgment of invalidity or other noninfringement of the patent before the expiration of the 60-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received.

“(II) **CIVIL ACTION FOR PATENT INFRINGEMENT OR DECLARATORY JUDGMENT.**—If—

“(aa)(AA) a civil action for infringement of a patent that is the subject of the certification is brought before the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; or

“(BB) the applicant brings a civil action for declaratory judgment of invalidity or other noninfringement of the patent before the expiration of the 60-day period beginning on the date on which the notice under paragraph (2)(B)(ii) was received;

“(bb) the holder of the approved application or the owner of the patent seeks a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture and sale of the drug; and

“(cc) none of the conditions for denial of approval stated in paragraph (4) applies;

the approval shall be made effective on issuance by a United States district court of a decision and order that denies a preliminary injunction, or, in a case in which a preliminary injunction has been granted by a United States district court prohibiting the applicant from engaging in the commercial manufacture or sale of the drug, a decision and order that determines that the drug patent is invalid or that the drug patent is not otherwise infringed.

“(III) **PROCEDURE.**—In a civil action brought as described in subclause (II)—

“(aa) the civil action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business;

“(bb) each of the parties shall reasonably cooperate in expediting the civil action;

“(cc) the court shall not consider a motion for preliminary injunction unless the motion is filed within 90 days of commencement of the civil action; and

“(dd) the holder of the approved application or the owner of the patent shall be entitled to a preliminary injunction if the holder or owner demonstrates a likelihood of success on the merits and without regard to whether the holder or owner would suffer im-

mediate or irreparable harm or to any other factor.”;

(2) by redesignating subparagraphs (C) and (D) as subparagraphs (F) and (G), respectively; and

(3) by inserting after subparagraph (B) the following:

“(C) **EFFECTIVENESS ON CONDITION.**—

“(i) **NOTICE.**—The applicant of an application that has been approved under subparagraph (A) but for which the approval has not yet been made effective under subparagraph (B) (referred to in this subparagraph as the ‘previous application’) and with respect to which a preliminary injunction has been issued prohibiting the commercial manufacture or sale of the drug subject to the previous application may submit to the Secretary a notice stating that—

“(I) the applicant expects to receive, within 180 days, a United States district court decision and order that vacates the preliminary injunction and denies a permanent injunction or determines that the patent is invalid or is otherwise not infringed (referred to in this subparagraph as a ‘noninfringement decision’);

“(II) requests the immediate issuance of an approval of the application conditioned on a noninfringement decision within the specified time;

“(III) agrees that—

“(aa) the applicant will not settle or otherwise compromise the noninfringement decision in any manner that would prevent or delay the immediate marketing of the drug under the approved application; and

“(bb) the applicant will notify the Secretary of the noninfringement decision (or if a decision is rendered that is not a noninfringement decision, will notify the Secretary of that decision) not later than 5 days after the date of entry of judgment; and

“(IV) consents to the immediate withdrawal of the approval, without opportunity for a hearing, if the applicant fails to comply with the agreement under subclause (III) or if the noninfringement decision is vacated by the district court or reversed on appeal.

“(ii) **APPROVAL.**—On receipt of a notice under clause (i), if none of the conditions for denial of approval stated in paragraph (4) applies, the Secretary shall immediately issue an effective approval of the application conditioned on the receipt of a noninfringement decision within the specified time, subject to immediate withdrawal if the applicant fails to comply with the agreement under clause (i)(III).

“(iii) **EFFECT.**—If a noninfringement decision is rendered, the date of the final decision of a court referred to in subparagraph (B)(iv)(II)(aa) shall be the date of the noninfringement decision, notwithstanding that the noninfringement decision may be, or has been, appealed.

“(D) **CIVIL ACTION FOR DECLARATORY JUDGMENT.**—A person that files an abbreviated application for a new drug under this section containing information showing that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a listed drug may bring a civil action—

“(i) against the holder of an approved application for the listed drug, for a declaratory judgment declaring that the certification made by the holder of the approved drug application under subsection (b)(5)(C) relating to the listed drug was not properly made; or

“(ii) against the owner of a patent that claims the listed drug, a method of using the listed drug, or the active ingredient in the listed drug, for a declaratory judgment declaring that the patent is invalid or will not otherwise be infringed by the new drug for which the applicant seeks approval.”.



(b) CONFORMING AMENDMENTS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking “(j)(5)(D)(ii)” each place it appears and inserting “(j)(5)(G)(ii)”;

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking “(j)(5)(D)” each place it appears and inserting “(j)(5)(G)”;

(3) in subsections (e) and (l), by striking “505(j)(5)(D)” each place it appears and inserting “505(j)(5)(G)”.

#### SEC. 203. ACCELERATED GENERIC DRUG COMPETITION.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 203) is amended—

(1) in subparagraph (B)(iv), by striking subclause (II) and inserting the following:

“(II) the earlier of—

“(aa) the date of a final decision of a court in an action described in clause (iii)(II) (from which no appeal has been or can be taken, other than a petition to the Supreme Court for a writ of certiorari) holding that the patent that is the subject of the certification is invalid or not otherwise infringed; or

“(bb) the date of a settlement order or consent decree signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certification is invalid or not otherwise infringed;”;

(2) by inserting after subparagraph (D) the following:

“(E) FORFEITURE OF 180-DAY PERIOD.—

“(i) DEFINITIONS.—In this subparagraph:

“(I) FORFEITURE EVENT.—The term ‘forfeiture event’ means the occurrence of any of the following:

“(aa) FAILURE TO MARKET.—An applicant fails to market the drug by the later of—

“(AA) the date that is 60 days after the date on which the approval of the application for the drug is made effective under subparagraph (B)(iii) (unless the Secretary extends the date because of the existence of extraordinary or unusual circumstances); or

“(BB) if the approval has been made effective and a civil action has been brought against the applicant for infringement of a patent subject to a certification under paragraph (2)(A)(vii)(IV) or a civil action has been brought by the applicant for a declaratory judgment that such a patent is invalid or not otherwise infringed, and if there is no other such civil action pending by or against the applicant, the date that is 60 days after the date of a final decision in the civil action, (unless the Secretary extends the date because of the existence of extraordinary or unusual circumstances).

“(bb) WITHDRAWAL OF APPLICATION.—An applicant withdraws an application.

“(cc) AMENDMENT OF CERTIFICATION.—An applicant, voluntarily or as a result of a settlement or defeat in patent litigation, amends the certification from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III).

“(dd) FAILURE TO OBTAIN APPROVAL.—An applicant fails to obtain tentative approval of an application within 30 months after the date on which the application is filed, unless the failure is caused by—

“(AA) a change in the requirements for approval of the application imposed after the date on which the application is filed; or

“(BB) other extraordinary circumstances warranting an exception, as determined by the Secretary.

“(ee) FAILURE TO CHALLENGE PATENT.—In a case in which, after the date on which an applicant submitted an application under this subsection, new patent information is submitted under subsection (c)(2) for the listed drug for a patent for which certification is

required under paragraph (2)(A), the applicant fails to submit, not later than 60 days after the date on which the applicant receives notice from the Secretary under paragraph (7)(A)(iii) of the submission of the new patent information either a certification described in paragraph (2)(A)(vii)(IV) or a statement that the method of use patent does not claim a use for which the applicant is seeking approval under this subsection in accordance with paragraph (2)(A)(viii) (unless the Secretary extends the date because of extraordinary or unusual circumstances).

“(ff) MONOPOLIZATION.—The Secretary, after a fair and sufficient hearing, in consultation with the Federal Trade Commission, and based on standards used by the Federal Trade Commission in the enforcement of Acts enforced by the Federal Trade Commission, determines that the applicant at any time engaged in—

“(AA) anticompetitive or collusive conduct; or

“(BB) any other conduct intended to unlawfully monopolize the commercial manufacturing of the drug that is the subject of the application.

“(II) SUBSEQUENT APPLICANT.—The term ‘subsequent applicant’ means an applicant that submits a subsequent application under clause (ii).

“(ii) FORFEITURE EVENT OCCURS.—If—

“(I) a forfeiture event occurs;

“(II) no action described in subparagraph (B)(iii)(II) was brought against or by the previous applicant, or such an action was brought but did not result in a final judgment that included a finding that the patent is invalid; and

“(III) an action described in subparagraph (B)(iii)(II) is brought against or by the next applicant, and the action results in a final judgment that includes a finding that the patent is invalid;

the 180-day period under subparagraph (B)(iv) shall be forfeited by the applicant and shall become available to an applicant that submits a subsequent application containing a certification described in paragraph (2)(A)(vii)(IV).

“(iii) FORFEITURE EVENT DOES NOT OCCUR.—If a forfeiture event does not occur, the application submitted subsequent to the previous application shall be treated as the previous application under subparagraph (B)(iv).

“(iv) AVAILABILITY.—The 180-day period under subparagraph (B)(iv) shall be available only to—

“(I) the previous applicant submitting an application for a drug under this subsection containing a certification described in paragraph (2)(A)(vii)(IV) with respect to any patent; or

“(II) under clause (i), a subsequent applicant submitting an application for a drug under this subsection containing such a certification with respect to any patent; without regard to whether an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.

“(v) APPLICABILITY.—The 180-day period described in subparagraph (B)(iv) shall apply only if—

“(I) the application contains a certification described in paragraph (2)(A)(vii)(IV); and

“(II)(aa) an action is brought for infringement of a patent that is the subject of the certification; or

“(bb) not later than 60 days after the date on which the notice provided under paragraph (2)(B)(ii) is received, the applicant brings an action against the holder of the approved application for the listed drug.”.

(b) APPLICABILITY.—The amendment made by subsection (a) shall be effective only with respect to an application filed under section

505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before June 7, 2002.

#### SEC. 204. NOTICE OF AGREEMENTS SETTLING CHALLENGES TO CERTIFICATIONS THAT A PATENT IS INVALID OR WILL NOT BE INFRINGED.

(a) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

“(kk) BRAND NAME DRUG COMPANY.—The term ‘brand name drug company’ means a person engaged in the manufacture or marketing of a drug approved under section 505(b).

“(ll) GENERIC DRUG APPLICANT.—The term ‘generic drug applicant’ means a person that has filed for approval or received approval of an abbreviated new drug application under section 505(j).”.

(b) NOTICE OF AGREEMENTS SETTLING CHALLENGES TO CERTIFICATIONS THAT A PATENT IS INVALID OR WILL NOT OTHERWISE BE INFRINGED.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

“(o) NOTICE OF AGREEMENTS SETTLING CHALLENGES TO CERTIFICATIONS THAT A PATENT IS INVALID OR WILL NOT OTHERWISE BE INFRINGED.—

“(1) IN GENERAL.—A brand name drug company and a generic drug applicant that enter into an agreement regarding the settlement of a challenge to a certification with respect to a patent on a drug under subsection 505(b)(2)(A)(iv) shall submit to the Secretary and the Attorney General a notice that includes—

“(A) a copy of the agreement;

“(B) an explanation of the purpose and scope of the agreement; and

“(C) an explanation whether there is any possibility that the agreement could delay, restrain, limit, or otherwise interfere with the production, manufacture, or sale of the generic version of the drug.

“(2) FILING DEADLINES.—A notice required under paragraph (1) shall be submitted not later than 10 business days after the date on which the agreement described in paragraph (1) is entered into.

“(3) ENFORCEMENT.—

“(A) CIVIL PENALTY.—

“(i) IN GENERAL.—A person that fails to comply with paragraph (1) shall be liable for a civil penalty of not more than \$20,000 for each day of failure to comply.

“(ii) PROCEDURE.—A civil penalty under clause (i) may be recovered in a civil action brought by the Secretary or the Attorney General in accordance with section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)(1)).

“(B) COMPLIANCE AND EQUITABLE RELIEF.—If a person fails to comply with paragraph (1), on application of the Secretary or the Attorney General, a United States district court may order compliance and grant such other equitable relief as the court determines to be appropriate.

“(4) REGULATIONS.—The Secretary, with the concurrence of the Attorney General, may by regulation—

“(A) require that a notice required under paragraph (1) be submitted in such form and contain such documentary material and information relevant to the agreement as is appropriate to enable the Secretary and the Attorney General to determine whether the agreement may violate the antitrust laws; and

“(B) prescribe such other rules as are appropriate to carry out this subsection.”.

**SEC. 205. PUBLICATION OF INFORMATION IN THE ORANGE BOOK.**

(a) **DEFINITION OF ORANGE BOOK.**—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) (as amended by section 205(a)) is amended by adding at the end the following:

“(mm) **ORANGE BOOK.**—The term ‘Orange Book’ means the publication published by the Secretary under section 505(b)(1).”

(b) **PUBLICATION OF INFORMATION IN THE ORANGE BOOK.**—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended—

(1) in the fourth sentence of paragraph (1), by inserting before the period at the end the following: “in a publication entitled ‘Approved Drug Products With Therapeutic Equivalence Indications’ (commonly known as the ‘Orange Book’)”; and

(2) by adding at the end the following:

“(5) **PUBLICATION OF INFORMATION IN THE ORANGE BOOK.**—

“(A) **DEFINITIONS.**—In this paragraph:

“(i) **INTERESTED PERSON.**—The term ‘interested person’ includes—

“(I) an applicant under paragraph (1);

“(II) any person that is considering engaging in the manufacture, production, or marketing of a drug with respect to which there may be a question whether the drug infringes the patent to which information submitted under the second sentence of paragraph (1) pertains;

“(III) the Federal Trade Commission; and

“(IV) a representative of consumers.

“(ii) **QUALIFIED PATENT INFORMATION.**—The term ‘qualified patent information’ means information that meets the requirement of the second sentence of paragraph (1) that a patent with respect to which information is submitted under that sentence be a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug that is the subject of an application under paragraph (1).

“(B) **DUTY OF THE SECRETARY.**—The Secretary shall publish in the Orange Book only information that is qualified patent information.

“(C) **CERTIFICATION.**—

“(i) **IN GENERAL.**—Information submitted under the second sentence of paragraph (1) shall not be published in the Orange Book unless the applicant files a certification, subject to section 1001 of title 18, United States Code, and sworn in accordance with section 1746 of title 28, United States Code, that discloses the patent data or information that forms the basis of the entry.

“(ii) **CONTENTS.**—A certification under clause (i) shall—

“(I)(aa) identify all relevant claims in the patent information for which publication in the Orange Book is sought; and

“(bb) with respect to each such claim, a statement whether the claim covers an approved drug, an approved method of using the approved drug, or the active ingredient in the approved drug (in the same physical form as the active ingredient is present in the approved drug);

“(II) state the approval date for the drug;

“(III) state an objectively reasonable basis on which a person could conclude that each relevant claim of the patent covers an approved drug, an approved method of using the approved drug, or the active ingredient in the approved drug (in the same physical form as the active ingredients is present in the approved drug);

“(IV) state that the information submitted conforms with law; and

“(V) state that the submission is not made for the purpose of delay or for any improper purpose.

“(iii) **REGULATIONS.**—

“(I) **IN GENERAL.**—Not later than 16 months after the date of enactment of this paragraph, the Secretary, in consultation with the United States Patent and Trademark Office, shall promulgate regulations governing certifications under clause (i).

“(II) **CIVIL PENALTIES.**—The regulations under subclause (I) shall prescribe civil penalties for the making of a fraudulent or misleading statement in a certification under clause (i).

“(D) **CONSULTATION.**—For the purpose of deciding whether information should be published in Orange Book, the Secretary may consult with the United States Patent and Trademark Office.

“(E) **PUBLICATION OF DETERMINATION.**—The Secretary shall publish in the Federal Register notice of a determination by the Secretary whether information submitted by an applicant under the second sentence of paragraph (1) is or is not qualified patent information.

“(F) **PETITION TO RECONSIDER DETERMINATION.**—

“(i) **IN GENERAL.**—An interested person may file with the Secretary a petition to reconsider the determination.

“(ii) **CONTENTS.**—A petition under clause (i) shall describe in detail all evidence and present all reasons relied on by the petitioner in support of the petition.

“(iii) **NOTICE.**—The Secretary shall publish in the Federal Register notice of the filing of a petition under clause (i).

“(iv) **RESPONSE.**—Not later than 30 days after publication of a notice under clause (iii), any interested person may file with the Secretary a response to the petition.

“(v) **REPLY.**—Not later than 15 days after the filing of a response under clause (iv), the petitioner may file with the Secretary a reply to the response.

“(vi) **REGULATIONS.**—The Secretary may promulgate regulations providing for any additional procedures for the conduct of challenges under this subparagraph.”

(c) **EXPEDITED REVIEW OF THE ORANGE BOOK.**—

(1) **USE OF DEFINED TERMS.**—Terms used in this subsection that are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.) (as amended by this section) having the meanings given the terms in that Act.

(2) **EXPEDITED REVIEW.**—As soon as practicable after the date of enactment of this Act, the Secretary shall—

(A) complete a review of the Orange Book to identify any information in the Orange Book that is not qualified patent information; and

(B) delete any such information from the Orange Book.

(3) **PRIORITY.**—In conducting the review under paragraph (2), the Secretary shall give priority to making determinations concerning information in the Orange Book with respect to which any interested person may file a petition for reconsideration under paragraph (5)(F) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), as added by subsection (b).

(d) **DIFFERENCES IN LABELING.**—Section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is amended—

(1) in subparagraph (A)(v)—

(A) by striking “subparagraph (C) or because” and inserting “subparagraph (C), because”; and

(B) by inserting after “manufacturers” the following: “, or because of the omission of an indication or other aspect of labeling that is required by patent protection or exclusivity accorded under paragraph (5)(D)”; and

(2) by adding at the end the following:

“(D) **LABELING CONSISTENT WITH LABELING FOR EARLIER VERSION OF LISTED DRUG.**—For the purposes of subparagraph (A)(v), information showing that labeling proposed for the new drug that is the same as the labeling previously approved for the listed drug, although not for the current version of the listed drug, shall be deemed to be the same labeling as that approved for the listed drug so long as the previously approved labeling is not incompatible with a safe and effective new drug.”

**SEC. 206. NO ADDITIONAL 30-MONTH EXTENSION.**

Section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iii)) is amended by inserting after the fourth sentence the following: “Once a thirty-month period begins under the second sentence of this clause with respect to any application under this subsection, there shall be no additional thirty-month period or extension of the thirty-month period with respect to the application by reason of the making of any additional certification described in subclause (IV) of paragraph (2)(A)(vii) or for any other reason.”

**TITLE III—EXPANSION OF ACCESS THROUGH EXISTING PROGRAMS****SEC. 301. MEDICARE COVERAGE OF ALL ANTICANCER ORAL DRUGS.**

(a) **IN GENERAL.**—Section 1861(s)(2)(Q) of the Social Security Act (42 U.S.C. 1395x(s)(2)(Q)) is amended by striking “anticancer chemotherapeutic agent for a given indication,” and all that follows and inserting “anticancer agent for a medically accepted indication (as defined in subsection (t)(2)(B));”

(b) **CONFORMING AMENDMENT.**—Section 1834(j)(5)(F)(iv) of the Social Security Act (42 U.S.C. 1395m(j)(5)(F)(iv)) is amended by striking “therapeutic”.

(c) **EFFECTIVE DATE.**—The amendments made by this section shall apply with respect to drugs furnished on or after the date that is 90 days after the date of enactment of this Act.

**SEC. 302. REMOVAL OF STATE RESTRICTIONS.**

(a) **THERAPEUTIC EQUIVALENCE.**—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (5)(A)—

(A) by striking “(5)(A) Within one hundred and eighty days of the” and inserting the following:

“(5) **TIME PERIODS.**—

“(A) **APPROVAL OR DISAPPROVAL.**—

“(i) **IN GENERAL.**—Not later than 180 days after the date of”; and

(B) by adding at the end the following:

“(ii) **FINDING REGARDING THERAPEUTIC EQUIVALENCE.**—When the Secretary approves an application submitted under paragraph (1), the Secretary shall include in the approval a finding whether the drug for which the application is approved (referred to in this paragraph as the ‘subject drug’) is the therapeutic equivalent of a listed drug.

“(iii) **THERAPEUTIC EQUIVALENCE.**—For purposes of clause (ii), a subject drug is the therapeutic equivalent of a listed drug if—

“(I) all active ingredients of the subject drug, the dosage form of the subject drug, the route of administration of the subject drug, and the strength or concentration of the subject drug are the same as those of the listed drug and the compendial or other applicable standard met by the subject drug is the same as that met by the listed drug (even though the subject drug may differ in shape, scoring, configuration, packaging, excipients, expiration time, or (within the limits established by paragraph (2)(A)(v)) labeling);

“(II) the subject drug is expected to have the same clinical effect and safety profile as

the listed drug when the subject drug is administered to patients under conditions specified in the labeling; and

“(III) the subject drug—

“(aa)(AA) does not present a known or potential bioequivalence problem; and

“(BB) meets an acceptable in vitro standard; or

“(bb) if the subject drug presents a known or potential bioequivalence problem, is shown to meet an appropriate bioequivalence standard.

“(iv) FINDING.—If Secretary finds that the subject drug meets the requirements of clause (iii) with respect to a listed drug, the Secretary shall include in the approval of the application for the subject drug a finding that the subject drug is the therapeutic equivalent of the listed drug.”; and

(2) in paragraph (7)(A)(i)(II), by striking “and the number of the application which was approved” and inserting “, the number of the application that was approved, and a statement whether a finding of therapeutic equivalence was made under paragraph (5)(A)(iv), and if so the name of the listed drug to which the drug is a therapeutic bioequivalent”.

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

“(10) STATE LAWS.—No State or political subdivision of a State may establish or continue in effect with respect to a drug that is the subject of an application under paragraph (5) any requirement that is different from, or in addition to, any requirement relating to therapeutic equivalence applicable to the drug under paragraph (5).”.

#### SEC. 303. MEDICAID DRUG USE REVIEW PROGRAM.

(a) IN GENERAL.—Section 1927(g)(2) of the Social Security Act (42 U.S.C. 1396r-8(g)(2)) is amended by adding at the end the following:

“(E) GENERIC DRUG SAMPLES.—The program shall provide for the distribution of generic drug samples of covered outpatient drugs to physicians and other prescribers.”.

(b) FEDERAL PERCENTAGE OF EXPENDITURES.—Section 1903(a)(3)(D) of the Social Security Act (42 U.S.C. 1396b(a)(3)(D)) is amended by striking “in 1991, 1992, or 1993,” and inserting “(beginning with fiscal year 2003)”.

(c) EFFECTIVE DATE.—The amendments made by this section take effect on October 1, 2002.

#### SEC. 304. CLARIFICATION OF INCLUSION OF INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS IN THE BEST PRICE EXEMPTIONS ESTABLISHED FOR PURPOSES OF THE MEDICAID DRUG REBATE PROGRAM.

Section 1927(c)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1396r-8(c)(1)(C)(ii)) is amended—

(1) in subclause (II), by striking “and” at the end;

(2) in subclause (III), by striking the period and inserting “; and”; and

(3) by adding at the end the following:

“(IV) with respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, shall, in addition to any prices excluded under clause (i)(I), exclude any price charged on or after the date of enactment of this subparagraph, for any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, inpatient hospital services (and for which payment may be made under this title as part of payment for and not as direct reimbursement for the drug).”.

#### SEC. 305. UPPER PAYMENT LIMITS FOR GENERIC DRUGS UNDER MEDICAID.

Section 1927(e) of the Social Security Act (42 U.S.C. 1396r-8(e)) is amended by striking paragraph (4) and inserting the following:

“(4) ESTABLISHMENT OF UPPER PAYMENT LIMITS.—

“(A) IN GENERAL.—The Administrator of the Centers for Medicare & Medicaid Services shall establish an upper payment limit for each multiple source drug for which the FDA has rated 3 or more products therapeutically and pharmaceutically equivalent.

“(B) PUBLIC AVAILABILITY OF NATIONAL DRUG CODE.—The Administrator of the Centers for Medicare & Medicaid Services shall make publicly available, at such time and together with the publication of the upper payment limits established in accordance with subparagraph (A), the national drug code (commonly referred to as the ‘NDC’) for each drug used as the reference product to establish the upper payment limit for a particular multiple source drug.

“(C) DEFINITION OF REFERENCE PRODUCT.—In subparagraph (B), the term ‘reference product’ means the specific drug product, the price of which is used by the Administrator of the Centers for Medicare & Medicaid Services to calculate the upper payment limit for a particular multiple source drug.”.

#### TITLE IV—GENERAL PROVISIONS

##### SEC. 401. REPORT.

(a) IN GENERAL.—Not later than the date that is 5 years after the date of enactment of this Act, the Federal Trade Commission shall submit to Congress a report describing the extent to which implementation of the amendments made by this Act—

(1) has enabled products to come to market in a fair and expeditious manner, consistent with the rights of patent owners under intellectual property law; and

(2) has promoted lower prices of drugs and greater access to drugs through price competition.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section \$1,000,000.

By Mr. BAUCUS (for himself, Mr. CRAPO, Mr. HARKIN, Mr. WARNER, Mr. DASCHLE, Mr. CRAIG, Mr. BOND, Mr. GRAHAM, Mrs. CARNAHAN, Mr. REID, Mr. THOMAS, Mr. ENZI, and Mr. JOHNSON):

S. 2678. A bill to amend the Internal Revenue Code of 1986 to transfer all excise taxes imposed on alcohol fuels to the Highway Trust Fund, and for other purposes; to the Committee on Finance.

Mr. BAUCUS. Mr. President, I rise today to introduce the MEGATRUST Act, the Maximum Growth for America Through the Highway Trust Fund.

Next year, the Congress must reauthorize highway and transit programs and the system of Federal financing for them. This is a very important issue for our Nation. The highway and transit programs are very important in every State. Very few other pieces of legislation effect our country's citizens and businesses more directly than the highway bill. These are our ways for moving goods and people.

They are key to our economy and our ability to connect to one another. This country needs good, safe highways in order to cross great distances, and highway and transit construction and maintenance is an important part of every State's economy.

In order to facilitate our work in reauthorizing these programs, I plan to introduce a series of bills concerning important issues that Congress must address in that legislation.

This will be the first of those bills, a proposal concerning revenues for the highway trust fund. But unlike other bills I will introduce, this one must pass more quickly because it sets the foundation for the other bills I will be introducing later. This bill will represent how this country will help pay for our highway and transit needs over the next several years.

The MEGATRUST Act represents an important step in the effort to strengthen our Nation's economy, and improve its quality of life, by investing in transportation.

It would increase revenues into the highway trust fund by several billion dollars annually by making some needed corrections in the way Federal revenues are credited to the highway trust fund.

Nothing in this bill increases any tax. I repeat that. Nothing in this bill increases any tax.

Federal dollars to help States and localities improve their highways and transit systems are derived largely from the Federal highway trust fund. Under the system today, revenues from highway user taxes are deposited into the highway trust fund, and, more specifically, into separate accounts within the fund for highways and for transit. Those are two separate accounts.

These revenues are, in turn, distributed to States and localities for transportation investments that truly to improve our lives, create jobs, and make our economy better. This trust fund mechanism has been widely regarded as successful. But, as always, we must make adjustments to meet new challenges.

This bill would improve and extend this important financing mechanism, principally by making sure that certain revenues not currently credited to the highway trust fund are, in fact, placed in that fund.

The MEGATRUST Act does several things. First, it will ensure that taxes paid on gasoline are fully credited to the highway account of the highway trust fund. Today, when gasoline is taxed, the mass transit account of the highway trust fund receives its full share of revenues, as if the fuel were gasoline. But 2.5 cents of the gas tax per gallon that is imposed on gasoline is credited to the general fund of the Treasury, not to the highway account. So the MEGATRUST Act ensures that those 2.5 cents per gallon go to the highway account.

Second, the MEGATRUST Act will ensure that the highway system does not bear the cost of our national policy to develop and promote the use of gasoline. This tax rate preference is part of our national policy to advance the use of gasoline.

I believe the ethanol subsidy is good energy policy, good agriculture policy, and good tax policy. Yet ironically, it is the highway trust fund that bears the burden of the subsidy. Since it is good general policy—that is, gasoline—I believe the general fund should bear

the burden of the subsidy, not the highway trust fund.

Gasohol, as a fuel, is taxed 5.3 cents per gallon less than gasoline. But gasohol-fueled vehicles cause the same wear and tear on roads as gasoline-fueled vehicles. That is obvious. They use the same roads, travel the same distances, et cetera.

Ensuring necessary and affordable energy supplies is important to the quality of life and economic prosperity of all Americans. Policies to achieve these objectives, however, should not come at the expense of transportation infrastructure improvements.

Accordingly, the MEGATRUST Act would leave the gasohol tax rate preference in place but credit the highway account of the highway trust fund with revenue equal to that forgone to the Treasury by the gasohol tax preference.

Third, the MEGATRUST Act credits both the highway and mass transit accounts of the highway trust fund with interest starting in fiscal year 2004. Today, the highway trust fund is one of the few trust funds in the Federal budget that is not credited with interest on its unspent balance, which is highly inappropriate.

The MEGATRUST Act would change this in order to make sure that collected highway user taxes are to be put to work for better transportation for our citizens.

Fourth, the MEGATRUST Act would extend the basic highway user taxes and the highway trust fund so they do not expire.

And last, the MEGATRUST Act would require the creation of an important commission concerning the future financing of the Federal highway and transit programs.

Why is that important? While the current mechanism has worked well, we know that cars will become more fuel efficient and advancing technology will only bring us closer to increased fuel efficiency.

Other changes are possible as well in our dynamic economy. While major changes will not occur overnight, we have to be ready for them. We have to understand what is likely to happen so we can consider making adjustments in the highway trust fund and its revenue streams, so we are not caught off guard and unable to adequately fund our transportation system.

What am I saying? I am basically saying that the hybrid fuel vehicles—it could be fuels cells, other technologies for our automobiles of the future—they do not use gasoline, they do not use gasohol, therefore, revenue would not be placed in the highway trust fund. We have to anticipate all of those changes so our highways are adequately funded regardless of the types of cars and regardless of the type of energy that is used to propel those cars.

I especially thank Senators HARKIN, WARNER, CRAPO, GRAHAM of Florida, REID, DASCHLE, CARNAHAN, BOND, and CRAIG for working so closely with me on this legislation.

In sum, through this highway trust fund proposal, I want to make clear to my colleagues that there are ways to increase revenue into the highway trust fund without raising taxes. We will need to increase highway trust fund resources to help us all structure a successful reauthorization bill next year, and I look forward to working closely with my colleagues to that end.

By Mr. BAUCUS (for himself, and Mr. SMITH of Oregon):

S. 2679. A bill to amend the Internal Revenue Code of 1986 to provide for a tax credit for offering employer-based health insurance coverage, to provide for the establishment of health plan purchasing alliances, and for other purposes; to the Committee on Finance.

Mr. BAUCUS. Mr. President, I rise today to introduce the "Health Insurance Access Act" of 2002.

This bill addresses one of the most serious problems facing the United States. The problem of the uninsured.

According to recent census data, 38 million Americans lack health insurance coverage. More than the population of twenty-three States. Plus the District of Columbia. And lack of coverage is an even greater problem in rural areas. In Montana, one in five citizens goes without health insurance. As premiums sky-rocket, I'm worried that this number may grow even higher.

For America's uninsured, the consequences of going without health coverage can be devastating.

Put plainly, uninsured Americans are less healthy than those with health insurance. They delay seeking medical care or go without treatment altogether that could prevent and detect crippling illnesses. Illnesses like diabetes, heart disease, and cancer. The uninsured are far less likely to receive health services if they are injured or become ill.

These factors take an enormous personal toll on the lives of the uninsured. They are sicker and less productive in the workplace. Their children are less likely to survive past infancy. And they must struggle with the knowledge that a serious injury or illness in their family might push them to the brink of financial ruin.

I just recently saw a statistic that women with breast cancer who lack health insurance are 49 percent more likely to die than women who have insurance. Unfortunately, this statistic is just one of countless other statistics about the effects that lack of health insurance has on peoples' health and their lives.

But these personal struggles are not the only affect of America's uninsured problem. Because when the uninsured become so sick that they must finally seek emergency treatment, there is no one to pay for it. No insurance company. No government program.

So who absorbs the cost of this uncompensated medical care? We all do. In the form of higher health care costs.

Higher and higher premiums at a time when the cost of health care is already rising out of control.

The situation is becoming critical. And I believe the time for talking has ended. It is time for us to examine solutions instead of talking about the problem.

That is why I have joined with Senator GORDON SMITH to introduce this important piece of legislation. Our bill would lift millions of Americans out of the ranks of the uninsured. It would give millions of families the peace of mind that comes from knowing they will receive the care they need, when they need it. And it would lighten the load of uncompensated care on our over-burdened health care system.

Our bill attacks the problem of the uninsured on several fronts. As you know, the 38 million uninsured Americans are a diverse mix of people. Some work for small employers, who simply can't afford the high cost of health insurance. Others have pre-existing health conditions. These conditions translate into unaffordable, even astronomical, health care insurance premiums.

Some uninsured Americans fall just beyond the eligibility levels for public programs like Medicaid. And many are near-elderly individuals, too young to qualify for Medicare, yet old enough that any health condition at all means expensive premiums or high deductibles. In fact, the fastest growing segment of the uninsured today is the near-elderly population.

Our bill addresses each of these populations.

The first part of our bill would target uninsured Americans who work for small businesses. It would give a tax credit of up to 50 percent to small firms, those with 50 or fewer employees, for the cost of health insurance premiums for their employees. The credit is not limited only to employers who do not currently provide health benefits. It is available to all qualified small employers. The credit will give small employers the extra resources they need to extend, or continue to offer, health benefits to millions of hard-working Americans and their families.

One thing I heard from my constituents traveling around the State, in addition to grief over increasing premiums, is that the health insurance options available to individuals and small employers are limited. If they could pool their resources together, even across State lines, they might be able to reduce their costs as a group.

In response to these concerns, the second part of our bill would provide funding to states, private employer groups, and associations to create purchasing pools. These purchasing pools, or alliances, as we call them in this bill, would provide small employers with affordable health coverage options, which would, accordingly, allow them to take maximum advantage of their tax credits.

For individuals with high cost health conditions, our bill would spend \$50 million annually to support state high risk pools. These pools serve a dual purpose. They offer high-risk individuals a place to purchase affordable health coverage. And, by isolating the costs of high-risk individuals, they help lower premiums for those who are not considered high risk or high cost.

Fourth, our bill would also allow states to expand health insurance coverage to the parents of children who are eligible for Medicaid and the Children's Health Insurance Program, or CHIP. This will reach an estimated four million low-income parents who do not currently meet eligibility levels for health insurance coverage under public programs. It will also help us cover even more kids under CHIP, kids who are eligible for coverage but not currently enrolled.

Finally, our bill would allow uninsured Americans between the ages of 62 and 65 to buy into Medicare. Under current law, Americans in this age group are stuck in a bind: not old enough to qualify for Medicare, but unable to afford the high cost of private health insurance options because of their age or health condition. This predicament explains why they represent the fastest-growing group of uninsured. Our bill would offer the near-elderly a more affordable, quality health care package to tide them over until they reach 65.

All told, these efforts would expand access to health insurance coverage to 10 million Americans who are currently uninsured. It's not a panacea. But it's a start.

I commend Senator SMITH for his hard work on this issue. I believe our bipartisan efforts prove that covering the uninsured is not a Democratic issue. It's not a Republican issue. And it's not a Montana or an Oregon issue. It's an American issue.

I hope my colleagues will join this fight by helping us pass this legislation, and taking a solid step towards providing quality, affordable health insurance to all Americans.

Mr. SMITH of Oregon. Mr. President, I would like to thank my colleague from Montana for his leadership on the issue of the uninsured, and rise today in support of the Baucus-Smith Health Insurance Access Act. This bill will go a long way toward mending some of the holes in our nation's health care safety net.

And make no mistake, the safety net is torn. Currently 40 million Americans, that's one in six,—live, work, and go to school among us without health insurance. That means that nationally, 17 percent of Americans do not have any health insurance. They are our friends, our neighbors, our children, our parents.

And the problem is getting worse, not better. In 2001, two million Americans lost their health insurance, that's the largest one year increase in almost a decade.

Many, more than 35 million of these uninsured Americans, are in low-in-

come working families. Many people who work in small businesses are not offered health insurance, and those who are often cannot afford the skyrocketing premiums.

This is particularly true if an individual or a member of their family happen to have some kind of pre-existing or chronic condition that can make a simple policy totally unaffordable. Even relatively healthy Americans find that when they get older, they may be unable to afford health care premiums after they retire, but before they become eligible for Medicare.

Some people say that insurance is irrelevant, that the uninsured can still get good care at public clinics and in emergency rooms. While it is true that public clinics do provide high quality care to millions of Americans, this is not the same as having health insurance with a regular source of care.

Not having a regular source of care leads to needless delays in seeking care. According to a recent report by the Institute of Medicine, an estimated 18,000 people die every year because they don't have health insurance, and don't get the care they need in a timely fashion. Eighteen thousand deaths a year. Millions more people suffer unnecessarily due to delays in care.

Millions of Americans are falling through the cracks in our health care system, and it is our moral obligation to help them get the care they need by providing access to affordable health insurance.

The Health Insurance Access Act of 2002 provides a number of solutions to the growing crisis of the uninsured.

It helps small businesses, which are often unable to offer affordable health insurance to their employees. Under this legislation, small businesses would get a significant tax break to subsidize their purchase of health insurance. The tax break is indexed to the size of a business, so the smallest employers get the most help if they choose to offer their employees health insurance. This is important because smaller businesses are much less likely to offer their employees health coverage.

In order to avoid punishing small employers who are already doing the right thing, our tax credit is available to all qualified small employers, regardless of whether they currently offer health insurance to their employees.

Another problem small businesses face in purchasing health insurance for their employees is finding an affordable policy with real benefits for their employees. By definition, small businesses are too small to provide a stable risk pool. This drives up the cost of premiums.

The Baucus-Smith Health Insurance Access Act of 2002 offers employers some relief to this problem by providing funding for purchasing alliances, which lower premiums by sharing risk. This will provide new, more affordable options for millions of Americans, who have until now had limited health insurance choices.

Our bill also provides grants to states to help fund high risk pools for people who have very limited health insurance options. It seems ironic to me that many of the people who need health insurance most, people with an expensive medical condition—are often unable to obtain insurance.

For many people who have extensive health care needs and medical expenses, obtaining coverage in the individual insurance market is not a viable option. If they can find a policy to cover their illness—often they cannot—they may not be able to afford the premium.

However, in many cases, many of these individuals may not be able to buy health insurance at any cost, because insurers often turn down high risk individuals for coverage because of an existing or previous illness.

High-risk insurance pools attempt to fill this gap in the insurance market. Oregon has had a high risk insurance pool for people who were unable to obtain health insurance because of health conditions for the past 15 years. Since its inception, more than 24,000 Oregonians have bought health care coverage through this high risk insurance pool, 24,000 people who would otherwise have had no health care coverage.

Operating a high risk pool in Oregon has had its costs, costs which are increasing every year. Our legislation will help States assist people who are trying to do the right thing afford health insurance coverage that would otherwise be out of reach.

While much of the policy discussion about the uninsured focuses on children, low income parents are substantially more likely than their children to be uninsured. The Health Insurance Access Act of 2002 would also allow states to offer Medicaid and SCHIP benefits to parents of low income eligible children.

Encouraging States to offer Medicaid or SCHIP coverage to parents will significantly expand access to care for low income parents, and their children, because parents are more likely to enroll their kids in Medicaid or SCHIP when the family is eligible, rather than just certain family members.

Finally, the Health Insurance Access Act of 2002 would address another hole in the insurance market: the near elderly. The near elderly, Americans aged 62-64, often do not have employer sponsored health insurance, because they have retired from the labor force, but are not yet eligible for Medicare.

At the same time, insurance coverage is particularly critical for near-elderly Americans, as the risk of serious illness rises with age, and the prevalence of chronic disease is higher among this population. In addition, because many of the near-elderly have pre-existing conditions, private insurers often deny them coverage or charge unaffordable premiums.

Allowing all Americans aged 62-64 to buy into the Medicare program would create a strong risk pool that would

stabilize premiums, making them affordable to many who would otherwise have been unable to afford coverage. Researchers estimate that almost 40% of eligible Americans 62–64 would buy into Medicare if allowed to do so.

The number of uninsured people in America is an outrage. If 18,000 Americans died in terrorist incidents each year, there would be widespread outrage. Yet, tens of thousands of uninsured Americans are at risk of dying each year from cancers diagnosed too late, or stroke from uncontrolled high blood pressure. These can be slow, painful deaths. They are preventable deaths. We can help prevent these deaths. We should help prevent these deaths.

I urge you to join me and my colleague from Montana to support the Health Insurance Access Act of 2002. This legislation will touch millions of lives by making quality, affordable health insurance accessible to individuals and families who are living at risk.

It is the right thing to do. It is the right time to do it.

By Mr. BAUCUS:

S. 2680. A bill to direct the Secretary of the Interior to evaluate opportunities to enhance domestic oil and gas production through the exchange of nonproducing Federal oil and gas leases located in the Lewis and Clark National Forest, in the Flathead National Forest and on Bureau of Land Management land in the State of Montana, and for other purposes; to the Committee on Energy and Natural Resources.

Mr. BAUCUS. Mr. President, I am introducing a bill today that is extremely important to the people of my State of Montana. Why is it so important? Because I hope it will take us one step closer to achieving permanent protections for Montana's magnificent Rocky Mountain Front.

The Front, as we call it back home, is part of one of the largest and most intact wild places left in the lower 48. To the North, the Front includes a 200 square mile area known as the Badger-Two Medicine in the Lewis and Clark National Forest. This area sits just south-east of Glacier National Park, one of our greatest national treasures. The Badger-Two Medicine area is sacred ground to the Blackfeet Tribe. In January of 2002, portions of the Badger-Two, known as the Badger-Two Medicine Blackfoot Traditional Cultural District, were declared eligible for listing in the National Register of Historic Places.

South of the Badger-Two, the Front includes a 400 square mile strip of national forest land and about 20 square miles of BLM lands, including three BLM Outstanding Natural Areas.

Not only the Front still retain almost all its native species, only bison are missing, but it also harbors the country's largest bighorn sheep herd and second largest elk herd. The Rocky

Mountain Front supports one of the largest populations of grizzly bears south of Canada and is the only place in the lower 48 States where grizzly bears still roam from the mountains to their historic range on the plains.

Because of this exceptional habitat, the Front offers world renowned hunting, fishing and recreational opportunities. Sportsmen, local land owners, hikers, local communities and many other Montanans have worked for decades to protect and preserve the Front for future generations.

In short, a majority of Montanans feel very strongly that oil and gas development, and Montana's Rocky Mountain Front, just don't mix. The habitat is too rich, the landscape too important, to subject it to the roads, drills, pipelines, industrial equipment, chemicals, noise, and human activity that come with oil and gas development.

Building upon a significant public and private conservation investment and following an extensive public comment process, the Lewis and Clark National Forest decided in 1997 to withdraw for 15 years 356,000 acres in the Front from any new oil and gas leasing. This was a significant first step in protecting the Front from developing that I wholeheartedly supported.

However, in many parts of the Rocky Mountain Front, oil and gas leases exist that pre-date the 1997 decision. These leaseholders have invested time and resources in acquiring their leases. Several leaseholders have applied to the federal government for permits to drill. These leases are the subject of my proposed bill.

History has shown that energy exploration and development in the Front is likely to result in expensive and time consuming environmental studies and litigation. This process rarely ends with a solution that is satisfactory to the oil and gas lessee. For example, in the late 1980's both Chevron and Fina applied for permits to drill in the Badger-Two Medicine portion of the Front. After millions of dollars spent on studies and years of public debate, Chevron abandoned or assigned all of its lease rights, and Fina sold its lease rights back to the original owner.

Therefore, I think we should be fair to those leaseholders. We want them to continue to provide for our domestic oil and gas needs, but they are going to have a long, difficult and expensive road if they wish to develop oil and gas in the Rocky Mountain Front.

My legislation would direct the Interior Department to evaluate non-producing leases in the Rocky Mountain Front and look at opportunities to cancel these leases, in exchange for allowing leaseholders to explore for oil and gas somewhere else, namely in the Gulf of Mexico or in the State of Montana. In conducting this evaluation, the Secretary would have to consult with leaseholders, with the State of Montana and the public and other interested parties.

When Interior concludes this study in two years, the bill calls for the agency to make recommendations to Congress and the Energy and Natural Resources Committee on the advisability of pursuing lease exchanges in the Front and any changes in law and regulation needed to enable the Secretary to undertake such an exchange.

Finally, in order to allow the Secretary to conduct this study, my bill would continue the current lease suspension in the Badger-Two Medicine Area for three more years. This lease suspension would only apply to the Badger-Two Medicine Area, not the entire Front.

That's it, that's all my bill does. It doesn't predetermine any outcome, it doesn't impact any existing exploration activities or environmental review processes. It just creates a process through which the federal government, the people of Montana and leaseholders can finally have a real, open and honest discussion about the fate of the Rocky Mountain Front.

We should look for ways to fairly compensate leaseholders for investments they've made in their leases if they decide to leave the Front rather than waste years and millions fighting to explore for uncertain oil and gas reserves. Because, a lot of Montanans don't want to see the Front developed, and they will fight to protect it. Including me.

So, developers can wait years, or decades, or most likely never, for oil and gas to flow from the Front. Or we can look at ways to encourage domestic production much sooner, in much more cost effective, appropriate and efficient ways somewhere else.

That is what I hope this legislation will accomplish, and I hope my colleagues in the Senate will support it.

By Mr. GRASSLEY:

S.J. Res. 38. A joint resolution providing for the designation of a Medal of Honor Flag and for presentation of that flag recipients of the Medal of Honor; to the Committee on Armed Services.

Mr. GRASSLEY. Mr. President, today I am introducing a resolution to designate a Medal of Honor Flag to further honor those individuals who have gone above and beyond the call of duty in service to their country and to present that flag to each recipient of the Medal of Honor. This idea came from a constituent of mine, retired First Sergeant William Kendall of Jefferson, IA. Mr. Kendall had been thinking about another resident of Jefferson, Captain Darrell Lindsey, who was shot down while on a bombing mission over France during World War II. Captain Lindsey was able to keep his aircraft in the air long enough to allow the members of his crew to escape safely, but this action cost him his life. As a result of this selfless sacrifice, Captain Lindsey was awarded the Medal of Honor.

A Medal of Honor monument commemorating this heroic Iowan now



stands on the courthouse lawn in Jefferson, IA. It was partly this monument and the proud history of his fellow Iowan that inspired Bill Kendall to ponder the heroism of all recipients of the Medal of Honor. He then began to wonder why there was no official flag to honor recipients of the Medal of Honor. The Medal of Honor is the Nation's highest award for bravery he felt that a flag would help to show respect for this award as well as all those who have earned it through their service to the United States of America. I agree.

The Medal of Honor is not given out lightly. To date, only 3,439 individuals have been awarded the Medal of Honor and there are only 143 living recipients of this award. Each of the armed services has very strict regulations for judging whether an individual is entitled to the Medal of Honor. The award is only given for acts of exceptional bravery or self-sacrifice above and beyond what is expected and must involve risk of life. The deed must be proved by incontestable evidence of at least two eyewitnesses.

I should also add that there is an Iowa connection going back to the creation of the Medal of Honor. In 1861, during the Civil War, Iowa Senator James Grimes introduced legislation in the Senate to create a Medal of Honor for the Navy. This first Medal of Honor was followed by similar awards for the other services. It is appropriate that another Iowan, Sergeant William Kendall, should create the first Medal of Honor flag.

It is indeed right and appropriate to honor those Americans to whom we owe so much. Bill Kendall's idea for a Medal of Honor flag is a good one and I am honored to do what I can to help see his vision realized. I am pleased that the House has already acted on a similar measure and I hope my colleagues in the Senate will join me in this important initiative.

I ask unanimous consent that the text of this resolution be printed in the RECORD.

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

S.J. RES. 38

Whereas the Medal of Honor is the highest award for valor in action against an enemy force which can be bestowed upon an individual serving in the Armed Forces of the United States;

Whereas the Medal of Honor was established by Congress during the Civil War to recognize soldiers who had distinguished themselves by gallantry in action;

Whereas the Medal of Honor was conceived by Senator James Grimes of the State of Iowa in 1861; and

Whereas the Medal of Honor is the Nation's highest military honor, awarded for acts of personal bravery or self-sacrifice above and beyond the call of duty: Now, therefore, be it

*Resolved by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. DESIGNATION OF MEDAL OF HONOR FLAG.

(a) IN GENERAL.—Chapter 9 of title 36, United States Code, is amended by adding at the end the following new section:

#### “§ 903. Designation of Medal of Honor Flag

“(a) DESIGNATION.—The Secretary of Defense shall design and designate a flag as the Medal of Honor Flag. In selecting the design for the flag, the Secretary shall consider designs submitted by the general public.

“(b) PRESENTATION.—The Medal of Honor Flag shall be presented as specified in sections 3755, 6257, and 8755 of title 10 and section 505 of title 14.”.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by adding at the end the following new item:

“903. Designation of Medal of Honor Flag.”.

#### SEC. 2. PRESENTATION OF FLAG TO MEDAL OF HONOR RECIPIENTS.

(a) ARMY.—(1) Chapter 357 of title 10, United States Code, is amended by adding at the end the following new section:

#### “§ 3755. Medal of honor: presentation of Medal of Honor Flag

“The President shall provide for the presentation of the Medal of Honor Flag designated under section 903 of title 36 to each person to whom a medal of honor is awarded under section 3741 of this title after the date of the enactment of this section. Presentation of the flag shall be made at the same time as the presentation of the medal under section 3741 or 3752(a) of this title.”.

(2) The table of sections at the beginning of such chapter is amended by adding at the end the following new item:

“3755. Medal of honor: presentation of Medal of Honor Flag.”.

(b) NAVY AND MARINE CORPS.—(1) Chapter 567 of such title is amended by adding at the end the following new section:

#### “§ 6257. Medal of honor: presentation of Medal of Honor Flag

“The President shall provide for the presentation of the Medal of Honor Flag designated under section 903 of title 36 to each person to whom a medal of honor is awarded under section 6241 of this title after the date of the enactment of this section. Presentation of the flag shall be made at the same time as the presentation of the medal under section 6241 or 6250 of this title.”.

(2) The table of sections at the beginning of such chapter is amended by adding at the end the following new item:

“6257. Medal of honor: presentation of Medal of Honor Flag.”.

(c) AIR FORCE.—(1) Chapter 857 of title 10, United States Code, is amended by adding at the end the following new section:

#### “§ 8755. Medal of honor: presentation of Medal of Honor Flag

“The President shall provide for the presentation of the Medal of Honor Flag designated under section 903 of title 36 to each person to whom a medal of honor is awarded under section 8741 of this title after the date of the enactment of this section. Presentation of the flag shall be made at the same time as the presentation of the medal under section 8741 or 8752(a) of this title.”.

(2) The table of sections at the beginning of such chapter is amended by adding at the end the following new item:

“8755. Medal of honor: presentation of Medal of Honor Flag.”.

(d) COAST GUARD.—(1) Chapter 13 of title 14, United States Code, is amended by inserting after section 504 the following new section:

#### “§ 505. Medal of honor: presentation of Medal of Honor Flag

“The President shall provide for the presentation of the Medal of Honor Flag designated under section 903 of title 36 to each person to whom a medal of honor is awarded under section 491 of this title after the date

of the enactment of this section. Presentation of the flag shall be made at the same time as the presentation of the medal under section 491 or 498 of this title.”.

(2) The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 504 the following new item:

“505. Medal of honor: presentation of Medal of Honor Flag.”.

(e) PRIOR RECIPIENTS.—The President shall provide for the presentation of the Medal of Honor Flag designated under section 903 of title 36, United States Code, as added by section 1(a), to each person awarded the Medal of Honor before the date of the enactment of this joint resolution who is living as of that date. Such presentation shall be made as expeditiously as possible after the date of the designation of the Medal of Honor Flag by the Secretary of Defense under such section.

### SUBMITTED RESOLUTIONS

#### SENATE RESOLUTION 291—TO AUTHORIZE TESTIMONY, DOCUMENT PRODUCTION AND LEGAL REPRESENTATION IN UNITED STATES V. MILTON THOMAS BLACK

Mr. DASCHLE (for himself and Mr. LOTT) submitted the following resolution; which was considered and agreed to:

Whereas, in the case of United States v. Milton Thomas Black, Cr. No. S-02-016-PMP, pending in the United States District Court for the District of Nevada, subpoenas for testimony have been issued to Clara Kircher and Phil Toomajian, employees in the office of Senator Patrick J. Leahy; Donald Wilson, an employee in the office of Senator Harry Reid; and Katharine Dillingham and Craig Spilsbury, employees in the office of Senator Orrin G. Hatch;

Whereas, pursuant to sections 703(a) and 704(a)(2) of the Ethics in Government Act of 1978, 2 U.S.C. §§ 288b(a) and 288c(a)(2), the Senate may direct its counsel to represent employees of the Senate with respect to any subpoena, order, or request for testimony relating to their official responsibilities;

Whereas, by the privileges of the Senate of the United States and Rule XI of the Standing Rules of the Senate, no evidence under the control or in the possession of the Senate may, by the judicial or administrative process, be taken from such control or possession but by permission of the Senate; and

Whereas, when it appears that evidence under the control or in the possession of the Senate may promote the administration of justice, the Senate will take such action as will promote the ends of justice consistently with the privileges of the Senate: Now, therefore, be it

*Resolved* That Clara Kircher, Phil Toomajian, Donald Wilson, Katharine Dillingham, Craig Spilsbury, and any other employee of the Senate from whom testimony or document production is required, are authorized to testify and produce documents in the case of United States v. Milton Thomas Black, except concerning matters for which a privilege should be asserted.

SEC. 2. The Senate Legal counsel is authorized to represent employees of the Senate in connection with the testimony and document production authorized in section one of this resolution.