Minnesota (Mr. WELLSTONE) were added as a cosponsors of S. 548, a bill to amend title XVIII of the Social Security Act to provide enhanced reimbursement for, and expanded capacity to, mammography services under the medicare program, and for other purposes.

S. 581

At the request of Mr. FITZGERALD, the name of the Senator from Iowa (Mr. GRASSLEY) was added as a cosponsor of S. 581, a bill to amend title 10, United States Code, to authorize Army arsenals to undertake to fulfill orders or contracts for articles or services in advance of the receipt of payment under certain circumstances.

S. 587

At the request of Mr. CONRAD, the name of the Senator from Minnesota (Mr. DAYTON) was added as a cosponsor of S. 587, a bill to amend the Public Health Service Act and title XVIII of the Social Security Act to sustain access to vital emergency medical services in rural areas.

S. 611

At the request of Ms. MIKULSKI, the name of the Senator from New Jersey (Mr. CORZINE) was added as a cosponsor of S. 611, a bill to amend title II of the Social Security Act to provide that the reduction in Social Security benefits which are required in the case of spouses and surviving spouses who are also receiving certain Government pensions shall be equal to the amount by which two-thirds of the total amount of the combined monthly benefit (before reduction) and monthly pension exceeds $1,200, adjusted for inflation.

S. 632

At the request of Mr. NELSON of Florida, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 632, a bill to reinstate a final rule promulgated by the Administrator of the Environmental Protection Agency, and for other purposes.

S. 718

At the request of Mr. MCCAIN, the name of the Senator from Wyoming (Mr. ENZI) was added as a cosponsor of S. 718, a bill to direct the National Institute of Standards and Technology to establish a program to support research and training in methods of detecting the use of performance-enhancing drugs by athletes, and for other purposes.

S. 721

At the request of Mr. HUTCHINSON, the name of the Senator from Hawaii (Mr. INOUYE) was added as a cosponsor of S. 721, a bill to amend the Public Health Service Act to establish a Nurse Corps and recruitment and retention strategies to address the nursing shortage, and for other purposes.

S. 742

At the request of Mr. GRASSLEY, the names of the Senator from Idaho (Mr. CRAPO), the Senator from Pennsylvania (Mr. SANTORUM), the Senator from North Dakota (Mr. DORGAN), the Senator from New Jersey (Mr. CORZINE), and the Senator from Massachusetts (Mr. KENNEDY) were added as a cosponsors of S. 742, a bill to provide for pension reform, and for other purposes.

S. 749

At the request of Mr. FITZGERALD, the names of the Senator from Rhode Island (Mr. REED), the Senator from Illinois (Mr. DURBIN), and the Senator from New Jersey (Mr. CORZINE) were added as a cosponsors of S. 749, a bill to provide that no Federal income tax shall be imposed on amounts received by victims of the Nazi regime or their heirs or estates, and for other purposes.

S. 828

At the request of Mr. LIEBERMAN, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 828, a bill to amend the Internal Revenue Code of 1986 to allow a credit against income tax for certain energy-efficient property.

S.J. RES. 13

At the request of Mr. WARNER, the name of the Senator from Alabama (Mr. SESSIONS) was added as a cosponsor of S.J. Res. 13, a joint resolution conferring honorary citizenship of the United States on Paul Yves Roch Gilbert du Motier, also known as the Marquis de Lafayette.

S. RES. 16

At the request of Mr. THURMOND, the names of the Senator from Delaware (Mr. BIDEN), the Senator from Massachusetts (Mr. KERRY), the Senator from Idaho (Mr. CRAPO), and the Senator from Florida (Mr. GRAHAM) were added as a cosponsors of S. Res. 16, a resolution designating August 16, 2001, as ''National Airborne Day.''

S. RES. 74

At the request of Mr. DAYTON, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. Res. 74, a resolution expressing the sense of the Senate regarding consideration of legislation providing Medicare beneficiaries with outpatient prescription drug coverage.

S. RES. 80

At the request of Mrs. MURRAY, the name of the Senator from Louisiana (Ms. LANDRIEU) was added as a cosponsor of S. Res. 80, a resolution honoring the ''Whidbey 24'' for their professionalism, bravery, and courage.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. CRAIG (for himself, Mr. DORGAN, and Mr. CRAPO):

S. 836. A bill to amend part C of title XI of the Social Security Act to provide for coordination of implementation of administrative simplification standards for health care information; to the Committee on Finance.

Mr. CRAIG. Mr. President, I rise today to introduce a bill to amend the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act. I am pleased that Senator BYRON DORGAN and Senator MIKE CRAPO are joining with me in this effort today.

I understand the benefits of administration simplification and support the goal of getting healthcare providers to use uniform codes to reduce overall costs through increased efficiencies. However, it was originally intended for the entire package of administrative simplification regulations to be released at one time. This would have allowed for system changes to be included in a comprehensive upgrade. These final provisions are now expected to be released over time, which will drive up the cost substantially for providers and health plans as they will be forced to adapt their systems with every new regulation. For example, identifiers for providers, plans and employers have yet to be finalized, making it impossible to incorporate this information into new computer systems.

In addition to the costs of repeatedly updating systems to be incurred by providers, the overall cost of compliance with the Health Insurance Portability and Accountability Act is expected to exceed the costs of Y2K readiness. Small providers, like those in my state of Idaho, cannot afford the high cost in such a short time frame. A longer timeframe will allow these small providers to pay incrementally for systems upgrades.

In addition, if health plans and providers hurry implementation of these provisions, there is the serious possibility that service problems will arise for consumers, including inaccurate payments and customer service issues. A longer implementation timeframe will also allow providers and plans to address any unanticipated consequences as they arise.

For these reasons, with my colleagues Senators DORGAN and CRAPO, I am introducing this legislation to delay implementation of the administrative provisions until the later date of either October 16, 2004 or two years after the final adoption of all regulations. The regulations that would be impacted by this legislation include electronic transactions, code sets, security standards for the electronic standards, and identifiers for health plans and providers. To avoid confusion, let me be clear that this legislation does not affect implementation of the Health Insurance Portability and Accountability Act medical privacy issues and does not deal with unique health identifiers for individuals.

To ensure that providers, plans and the Department of Health and Human Services are working towards compliance to these provisions, this legislation calls for the General Accounting Office to evaluate the progress of implementation no later than October 31, 2003.

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. 836

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

SECTION 1. COORDINATION OF IMPLEMENTATION OF ADMINISTRATIVE SIMPLIFICATION STANDARDS FOR HEALTH CARE INFORMATION.

(a) IN GENERAL.—Section 1175(b)(1) of the Social Security Act (42 U.S.C. 1320d–4(b)(1)) is amended to read as follows:

''(1) IN GENERAL.—Each person to whom an initial standard or implementation specification is adopted or established under sections 1172 and 1173 applies shall comply with the standard or specification by the later of—

''(A) 24 months after the date on which the Secretary determines that—

''(i) regulations with respect to all of the standards and specifications required by such sections (other than standards for unique health identifiers for individuals under section 1173(b)(1)) have been adopted in final form;

''(ii) regulations implementing section 1176 have been issued in final form; and

''(iii) reliable national unique health identifiers for health plans and health care providers are ready and available; or

''(B) October 16, 2004.''.

(b) RULE OF CONSTRUCTION.—For purposes of section 1175(b)(1) of the Social Security Act (42 U.S.C. 1320d-4(b)(1)), as amended by subsection (a)—

(1) the requirements of such section (relating to issuance of a regulation ''in final form'') shall be considered to be met with respect to a standard, specification, or section if a regulation implementing such standard, specification, or section is issued and becomes effective in accordance with section 553 of title 5, United States Code;

(2) nothing in such section 1175(b)(1) shall be construed as requiring the Secretary of Health and Human Services to take into account subsequent modifications made to such regulation pursuant to section 1174(b) of the Social Security Act (42 U.S.C. 1 320d-3(b)) in making the determination that a regulation has been issued ''in final form'' with respect to a standard, specification, or section; and

(3) nothing in such section 1175(b)(1) shall be construed as limiting or affecting the authority of the Secretary of Health and Human Services to issue or implement the final regulations establishing standards for privacy of individually identifiable health information published in the Federal Register by the Secretary on December 28, 2000 (65 Fed. Reg. 82462), including the requirements of section 164.530 of title 45 of the Code of Federal Regulations.

(c) STUDY OF COMPLIANCE WITH HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study to examine the effect of the enactment of section 262 of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2021), and regulations issued thereunder, on health plans, health care providers, the medicare and medicaid programs, and the Department of Health and Human Services, including the progress of such entities or programs in complying with the amendments made by such section.

(2) REPORT.—Not later than October 31, 2003, the Comptroller General shall submit to the appropriate committees of Congress a report on the study conducted under paragraph (1).

(d) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the enactment of section 262 of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2021).

By Mr. BOND:

S. 837. A bill to amend the Internal Revenue Code of 1986 to provide a safe harbor for determining that certain individuals are not employees; to the Committee on Finance.

Mr. BOND. Mr. President, for the past several months we have focused extensively on the need for tax relief and the means for achieving it. As the chairman of the Committee on Small Business, I have argued time and again that the individual rate cuts included in the President's tax package will have tremendous benefits for small-business owners, the vast majority of whom pay taxes at the individual rather than the entity level. And time is of the essence since many of these hard-working Americans are now feeling real pain from the down turn in our economy. While I continue to believe that tax relief deserves our immediate attention, I cannot ignore another tax priority for small businesses, simplification of the tax code.

With the year 2000 tax-filing season now behind us, thousands of small-business owners have once again been reacquainted with the stark realities of our current tax code. To keep that picture clearly in mind, let me remind my colleague of the results of an investigation that the General Accounting Office provided to my committee in the last Congress. A small-business owner faces more than 200 Internal Revenue Service, IRS, forms and schedules that could apply in a given year. While no business will have to file them all, it is a daunting universe of forms, including more than 8,000 lines, boxes, and data requirements, which are accompanied by over 700 pages.

Even more disturbing is that in recent years more than three quarters of small-business owners hired a tax professional to help them fulfill their tax obligations. When we consider the complexity of the forms, rules, and regulations, no one should be surprised. And these tax professionals are far from inexpensive. By some estimates, small-business owners pay more than 5 percent of their revenues just to comply with the tax law, five cents out of every dollar to make sure that all of the records are kept and the forms completed, all before the tax check is even written.

The list of tax provisions crying out for simplification has grown considerably in recent years. Therefore, earlier this year, I introduced the Small Business Works Act, (S. 189), which includes a number of tax-simplification proposals. Today, I rise to introduce additional legislation focusing on a particularly troubling and long-standing area of complexity for America's businesses and entrepreneurs—the status of independent contractors.

Beginning in the last decade and continuing today, there has been an important shift in the American workplace, with an increasing emphasis on independent business relationships. The traditional single-employer career is rapidly being supplanted by independent entrepreneurs who provide specialized services on an ''as needed'' basis. They seek out individual contracts, apply their expertise, and move onto the next opportunity, bound only to their creativity and stamina. The members of this new workforce are often described as independent contractors, temps, freelancers, self-employed, home-based businesses, and even free agents. Whatever their title, they are a rapidly growing segment of our economy and one that cannot be ignored.

Women in particular are playing an important role in this new business reality. Since the National Women's Small Business Summit, which I hosted in Kansas City last June, I have heard a steady stream of success stories about women entrepreneurs who have left the traditional workforce to start their own independent businesses, often times out of their homes. Today thousands of women are running dynamic businessess in fields like public and media relations, executive assistance, medical transcription, financial planning, management-information-systems consulting, and event planning, to name just a few.

There are a number of reasons for this new business paradigm. Continuing innovations in computer and communication technology have made the ''victual'' office a reality and allow many Americans to compete in marketplaces that not so long ago required huge investments in equipment and personnel. In addition, many men and women in this country have turned to home-based business in an effort to spend more time with their children. By working at home, these families can benefit from two incomes, while avoiding the added time and expense of daycare and commuting. Corporate downsizing, glass ceilings, and company politics, too, contribute to the growth in this sector as many skilled individuals convert their knowledge and experience from corporate life into successful enterprises operated on their own.

The rewards of being an independent entrepreneur are also numerous. The added flexibility and self-reliance of having your own business provide not only economic rewards but also personal satisfaction. You are the boss. You set your own hours, develop your own business plans, and choose your customers and clients. In many ways, this new paradigm provides the greatest avenue for the entrepreneurial spirit, which has long been the driving force behind the success of this country.

With these rewards, however, come a number of obstacles, not the least of which are burdens imposed by the Federal government. In fact, the tax laws, and in particular the IRS, are frequently cited as the most significant problems for independent entrepreneurs today. Changes in tax policy

must be considered by this Congress to recognize this new paradigm and ensure that our laws do not stall the growth and development of this successful sector of our economy.

Since 1995, we have made substantial headway on a number of tax issues critical to these independent entrepreneurs. In the Taxpayer Relief Act of 1997, we restored the home-office deduction putting home-based entrepreneurs on a level-playing field with storefront businesses. The Small Business Job Protection Act of 1996 and the Taxpayer Relief Act also made some important strides on the unbelievably complex pension rules so that the freelance writer, home-based medical transcriber, and other small businesses have the opportunity to plan for their retirement as they see fit. Finally, and arguably most importantly, through several pieces of legislation in the last six years, we have finally made the self-employed health-insurance deduction permanent and placed it on a path to full deductibility by 2003, although still too long in my opinion. These examples are just a few of the tax law changes already enacted that are helping men and women who chose to work as independent entrepreneurs to enjoy a level-playing field with their larger competitors and still maintain the flexibility of their independent business lives.

Amid this progress, however, one glaring problem still remains unsolved for this growing segment of the workplace—there are no simple, clear, and objective rules for determining who is an independent contractor and who is an employee. Through the Committee on Small Business, I have heard from countless small-business owners who are caught in the environment of fear and confusion that now surround the classification of workers. This situation is stifling the entrepreneurial spirit of many entrepreneurs who find that they do not have the flexibility to conduct their businesses in a manner that makes the best economic sense and that serves their personal and family goals. And it is the antithesis of the new business paradigm.

The root of this problem is found in the IRS' test for determining whether a worker is an independent contractor or an employee. Over the past three decades, the IRS has relied on a 20-factor test based on the common law to make this determination. At first glance, a 20-factor test sounds like a reasonable approach, if our home-based financial planner demonstrates a majority of the factors, she is an independent contractor. Not surprisingly, the IRS' test is not that simple. It is a complex set of extremely subjective criteria with no clear weight assigned to any of the factors. As a result, small-business taxpayers are not able to predict which of the 20 factors will be most important to a particular IRS agent, and finding a certain number of these factors in any given case does not guarantee the outcome.

To make matters worse, the IRS' determination inevitably occurs two or three years after the parties have determined in good faith that they have an independent-contractor relationship. And the consequences can be devastating. For example, the business that contracts with a management-information-systems consultant is forced to reclassify the consultant from an independent contractor to an employee and must come up with the payroll taxes the IRS says should have been collected in the prior years. Interest and penalties are also piled on. The result for many small businesses is a tax bill that bankrupts the company. But that is not the end of the story. The IRS then goes after the consultant, who is now classified as an employee, and disallows a portion of her business expenses, again resulting in additional taxes, interest, and penalties.

All of us recognize that the IRS has a duty to collect Federal revenues and enforce the tax laws. The problem in this case is that the IRS is using a procedure that is patently unfair and subjective and one that forces today's independent entrepreneurs into the business model of the 1950s. The result is that businesses must spend thousands of dollars on lawyers and accountants to try to satisfy the IRS' procedures, but with no certainty that the conclusions will be respected. That is no way for businesses to operate in today's rapidly changing economy.

For its part, the IRS adopted a worker-classification training manual several years ago. According to then-Commissioner Richardson, the manual was an ''attempt to identify, simplify, and clarify the relevant facts that should be evaluated in order to accurately determine worker classification. . . .'' While I support the agency's efforts to address this issue, the manual represents one of the most compelling reasons for immediate action. The IRS' training manual is more than 150 pages in length and is riddled with references to court cases and rulings. If it takes that many pages to teach revenue agents how to ''simplify and clarify'' this small-business tax issue, I can only imagine how an independent event planner is going to feel when she tries to figure it out on her own.

In recognition of the new paradigm and the IRS' archaic 20-factor test, I am introducing the ''Independent Contractor Determination Act of 2001.'' This bill is substantially similar to the legislation I have introduced in the past two Congresses to resolve the classification problem for independent entrepreneurs. It removes the need for so many pages of instruction on the IRS' 20-factor test by establishing clear rules for classifying workers based on objective criteria. Under these criteria, if there is a written agreement between the parties, and if our medical transcriber demonstrates economic independence and independence with respect to the workplace, based on objective criteria set forth in the bill, she will be treated as an independent contractor rather than an employee. Moreover, the service recipient, e.g., the doctor or hospital, will not be treated as an employer. In addition, individuals who perform services through their own corporation or limited-liability company will also qualify as independent contractors as long as there is a written agreement and the individuals provide for their own benefits.

The safe harbor is simple, straightforward, and final. To take advantage of it, payments above $600 per year to an individual service provider must be reported to the IRS, just as is required under current law. This will help ensure that taxes properly due to the Treasury will continue to be collected.

While the IRS contends that there are millions of independent contractors who should be classified as employees, which costs the Federal government billions of dollars a year, this assertion is plainly incorrect. Classification of a worker has no cost to the government. What costs the government are taxpayers who do not pay their taxes.

The Independent Contractor Determination Act has three requirements that will improve compliance among independent contractors using the new rules set forth in the bill. First, there must be a detailed, written agreement between the parties—this will put the home-based media-relations consultant on notice at the outset that she is responsible for her own tax payments. Second, the new rules will not apply if the service recipient does not comply with the reporting requirements and issue 1099s to individuals who perform services. Third, an independent contractor operating through her own corporation or limited-liability company must file all required income and employment tax returns in order to be protected under the bill.

The bill also addresses concerns that have been raised about permitting individuals who provide their services through their own corporation or limited-liability company to qualify as independent contractors. Because some have contended that this option would lead to abusive situations at the expense of workers who should be treated as employees, the bill continues to limit the number of former employees that a service recipient may engage as independent contractors under the incorporation option. This limit will protect against misuse of the incorporation option while still allowing individuals to start their own businesses and have a former employer as one of their initial clients.

Much has also been made to the improperly classified employee who is denied benefits by the unscrupulous employer. This issue raises two important points. First, the legislation that I am introducing would not facilitate this troubling situation. Under the provisions of the bill, it is highly doubtful that a typical employee, like a janitor, would qualify as an independent contractor. In reality, this issue relates to

enforcement, which my bill simply makes easier through clear and objective rules. Second, the issue of benefits, like health insurance and pension plans, is extremely important to independent entrepreneurs. But the answer is not to force them to all be employees. Rather, we should continue to enact legislation like the Small Business Job Protection Act, the Taxpayer Relief Act, and the legislation vetoed by the Clinton Administration, that permit full deductibility of health insurance for the self-employed and better access to retirement savings plans.

The Independent Contractor Determination Act also addresses a special concern of technical-service providers, such as engineers, designers, drafters, computer programmers, and system analysts. In certain cases, Section 1706 of the 1986 Tax Reform Act precludes businesses engaging individuals in these professions from applying the reclassification protections under section 530 of the Revenue Act of 1978. When section 1706 was enacted, its proponents argued that technical-service workers were less compliant in paying their taxes. Later examination of this issue by the Treasury Department found that technical-service workers are in fact more likely to pay their taxes than most other types of independent contractors. This revelation underscores the need to repeal section 1706 and level the playing field for individuals in these professions.

In the last three Congresses, proposals to repeal section 1706 enjoyed wide bipartisan support. The Independent Contractor Determination Act is designed to treat individuals in these professions fairly by providing the businesses that engage them with the same protections that businesses using other types of independent contractors have enjoyed for more than 20 years.

Another major concern of many businesses and independent entrepreneurs is the issue of reclassification. The bill I am introducing provides relief to these taxpayers when the IRS determines that a worker was misclassified. If the business and the independent contractor have a written agreement, if the applicable reporting requirements were met, and if there was a reasonable basis for the parties to believe that the worker is an independent contractor, then an IRS reclassification will only apply prospectively. This provision gives important peace of mind to small businesses that act in good faith by removing the unpredictable threat of retroactive reclassification and substantial interest and penalties.

For too long, independent entrepreneurs and the businesses with which they work have struggled for a neutral tax environment. For an equally long time, that tax environment has been unfairly and unnecessarily biased against them. It is well past time that the tax code embraces one of the fundamental tenets of our country, the free market. We must allow individuals the freedom to pursue new opportunities in the ever-changing marketplace through business relationships that make the best sense for them. Our tax code should facilitate those opportunities through fair and simple rules that permit the freelance writer, home-based day-care provider, and every other independent entrepreneur to pay their taxes without under interference from the government. Trying to force today's dynamic workforce into a 1950s model serves no one. It only stands to stifle the entrepreneurial spirit in this country and dampen the continued success of our economy.

The Independent Contractor Determination Act is a common-sense measure that answers the urgent plea from independent entrepreneurs and the businesses that engage them for fairness and simplicity in the tax law. As we work toward the day when the entire tax law is based on these principles, we can make a positive difference today by enacting this legislation. Entrepreneurs have waited too long, let's get the job done!

I ask unanimous consent that the text of the bill and a description of its provisions be printed in the RECORD.

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

S. 837

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Independent Contractor Determination Act of 2001''.

SEC. 2. SAFE HARBOR FOR DETERMINING THAT CERTAIN INDIVIDUALS ARE NOT EMPLOYEES.

(a) IN GENERAL.—Chapter 25 of the Internal Revenue Code of 1986 (relating to general provisions relating to employment taxes) is amended by adding after section 3510 the following new section:

''SEC. 3511. SAFE HARBOR FOR DETERMINING THAT CERTAIN INDIVIDUALS ARE NOT EMPLOYEES.

''(a) SAFE HARBOR.—

''(1) IN GENERAL.—For purposes of this title, if the requirements of subsections (b), (c), and (d), or the requirements of subsections (d) and (e), are met with respect to any service performed by any individual, then with respect to such service—

''(A) the service provider shall not be treated as an employee,

''(B) the service recipient shall not be treated as an employer,

''(C) the payor shall not be treated as an employer, and

''(D) compensation paid or received for such service shall not be treated as paid or received with respect to employment.

''(2) AVAILABILITY OF SAFE HARBOR NOT TO LIMIT APPLICATION OF OTHER LAWS.—Nothing in this section shall be construed—

''(A) as limiting the ability of a service provider, service recipient, or payor to apply other provisions of this title, section 530 of the Revenue Act of 1978, or the common law in determining whether an individual is not an employee, or

''(B) as a prerequisite for the application of any provision of law described in subparagraph (A).

''(b) SERVICE PROVIDER REQUIREMENTS WITH REGARD TO THE SERVICE RECIPIENT.—For purposes of subsection (a), the requirements of this subsection are met if the service provider, in connection with performing the service—

''(1) has the ability to realize a profit or loss,

''(2) agrees to perform services for a particular amount of time or to complete a specific result or task, and

''(3) either—

''(A) has a significant investment in assets, or

''(B) incurs unreimbursed expenses which are ordinary and necessary to the service provider's industry and which represent an amount equal to at least 2 percent of the service provider's gross income attributable to services performed pursuant to 1 or more contracts described in subsection (d).

''(c) ADDITIONAL SERVICE PROVIDER REQUIREMENTS WITH REGARD TO OTHERS.—For the purposes of subsection (a), the requirements of this subsection are met if the service provider—

''(1) has a principal place of business,

''(2) does not primarily provide the service at a single service recipient's facilities,

''(3) pays a fair market rent for use of the service recipient's facilities, or

''(4) operates primarily from equipment supplied by the service provider.

''(d) WRITTEN DOCUMENT REQUIREMENTS.—For purposes of subsection (a), the requirements of this subsection are met if the services performed by the service provider are performed pursuant to a written contract between such service provider and the service recipient, or the payor, and such contract provides that the service provider will not be treated as an employee with respect to such services for Federal tax purposes and that the service provider is responsible for the provider's own Federal, State, and local income taxes, including self-employment taxes and any other taxes.

''(e) BUSINESS STRUCTURE AND BENEFITS REQUIREMENTS.—For purposes of subsection (a), the requirements of this subsection are met if the service provider—

''(1) conducts business as a properly constituted corporation or limited liability company under applicable State laws, and

''(2) does not receive from the service recipient or payor any benefits that are provided to employees of the service recipient.

''(f) SPECIAL RULES.—For purposes of this section—

''(1) FAILURE TO MEET REPORTING REQUIREMENTS.—If for any taxable year any service recipient or payor fails to meet the applicable reporting requirements of section 6041(a) or 6041A(a) with respect to a service provider, then, unless the failure is due to reasonable cause and not willful neglect, the safe harbor provided by this section for determining whether individuals are not employees shall not apply to such service recipient or payor with respect to that service provider.

''(2) CORPORATION AND LIMITED LIABILITY COMPANY SERVICE PROVIDERS.—

''(A) RETURNS REQUIRED.—If, for any taxable year, any corporation or limited liability company fails to file all Federal income and employment tax returns required under this title, unless the failure is due to reasonable cause and not willful neglect, subsection (e) shall not apply to such corporation or limited liability company.

''(B) RELIANCE BY SERVICE RECIPIENT OR PAYOR.—If a service recipient or a payor—

''(i) obtains a written statement from a service provider which states that the service provider is a properly constituted corporation or limited liability company, provides the State (or in the case of a foreign entity, the country), and year of, incorporation or formation, provides a mailing address, and includes the service provider's employer identification number, and

''(ii) makes all payments attributable to services performed pursuant to 1 or more contracts described in subsection (d) to such corporation or limited liability company,

then the requirements of subsection (e)(1) shall be deemed to have been satisfied.

''(C) AVAILABILITY OF SAFE HARBOR.—

''(i) IN GENERAL.—For purposes of this section, unless otherwise established to the satisfaction of the Secretary, the number of covered workers which are not treated as employees by reason of subsection (e) for any calendar year shall not exceed the threshold number for the calendar year.

''(ii) THRESHOLD NUMBER.—For purposes of this paragraph, the term 'threshold number' means, for any calendar year, the greater of (I) 10 covered workers, or (II) a number equal to 3 percent of covered workers.

''(iii) COVERED WORKER.—For purposes of this paragraph, the term 'covered worker' means an individual for whom the service recipient or payor paid employment taxes under subtitle C in all 4 quarters of the preceding calendar year.

''(3) BURDEN OF PROOF.—For purposes of subsection (a), if—

''(A) a service provider, service recipient, or payor establishes a prima facie case that it was reasonable not to treat a service provider as an employee for purposes of this section, and

''(B) the service provider, service recipient, or payor has fully cooperated with reasonable requests from the Secretary or his delegate,

then the burden of proof with respect to such treatment shall be on the Secretary.

''(4) RELATED ENTITIES.—If the service provider is performing services through an entity owned in whole or in part by such service provider, the references to service provider in subsections (b) through (e) shall include such entity if the written contract referred to in subsection (d) is with such entity.

''(g) DETERMINATIONS BY THE SECRETARY.—For purposes of this title—

''(1) IN GENERAL.—

''(A) DETERMINATIONS WITH RESPECT TO A SERVICE RECIPIENT OR A PAYOR.—A determination by the Secretary that a service recipient or a payor should have treated a service provider as an employee shall be effective no earlier than the notice date if—

''(i) the service recipient or the payor entered into a written contract satisfying the requirements of subsection (d),

''(ii) the service recipient or the payor satisfied the applicable reporting requirements of section 6041(a) or 6041A(a) for all taxable years covered by the contract described in clause (i), and

''(iii) the service recipient or the payor demonstrates a reasonable basis for determining that the service provider is not an employee and that such determination was made in good faith.

''(B) DETERMINATIONS WITH RESPECT TO A SERVICE PROVIDER.—A determination by the Secretary that a service provider should have been treated as an employee shall be effective no earlier than the notice date if—

''(i) the service provider entered into a contract satisfying the requirements of subsection (d),

''(ii) the service provider satisfied the applicable reporting requirements of sections 6012(a) and 6017 for all taxable years covered by the contract described in clause (i), and

''(iii) the service provider demonstrates a reasonable basis for determining that the service provider is not an employee and that such determination was made in good faith.

''(C) REASONABLE CAUSE EXCEPTION.—The requirements of subparagraph (A)(ii) or (B)(ii) shall be treated as being met if the failure to satisfy the applicable reporting requirements is due to reasonable cause and not willful neglect.

''(2) CONSTRUCTION.—Nothing in this subsection shall be construed as limiting any provision of law that provides an opportunity for administrative or judicial review of a determination by the Secretary.

''(3) NOTICE DATE.—For purposes of this subsection, the notice date is the 30th day after the earlier of—

''(A) the date on which the first letter of proposed deficiency that allows the service provider, the service recipient, or the payor an opportunity for administrative review in the Internal Revenue Service Office of Appeals is sent, or

''(B) the date on which the deficiency notice under section 6212 is sent.

''(h) DEFINITIONS.—For the purposes of this section—

''(1) SERVICE PROVIDER.—The term 'service provider' means any individual who performs a service for another person.

''(2) SERVICE RECIPIENT.—Except as provided in paragraph (4), the term 'service recipient' means the person for whom the service provider performs such service.

''(3) PAYOR.—Except as provided in paragraph (4), the term 'payor' means the person who pays the service provider for the performance of such service in the event that the service recipient does not pay the service provider.

''(4) EXCEPTIONS.—The terms 'service recipient' and 'payor' do not include any entity in which the service provider owns in excess of 5 percent of—

''(A) in the case of a corporation, the total combined voting power of stock in the corporation, or

''(B) in the case of an entity other than a corporation, the profits or beneficial interests in the entity.

''(5) IN CONNECTION WITH PERFORMING THE SERVICE.—The term 'in connection with performing the service' means in connection or related to the operation of the service provider's trade or business.

''(6) PRINCIPAL PLACE OF BUSINESS.—For purposes of subsection (c), the term 'principal place of business' has the same meaning as under section 280A(c)(1).

''(7) FAIR MARKET RENT.—The term 'fair market rent' means a periodic, fixed minimum rental fee which is based on the fair rental value of the facilities and is established pursuant to a written contract with terms similar to those offered to unrelated persons for facilities of similar type and quality.''.

(b) REPEAL OF SECTION 530(d) OF THE REVENUE ACT OF 1978.—Section 530(d) of the Revenue Act of 1978 (as added by section 1706 of the Tax Reform Act of 1986) is repealed.

(c) CLERICAL AMENDMENT.—The table of sections for chapter 25 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 3511. Safe harbor for determining that certain individuals are not employees.''

(d) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by this section shall apply to services performed after the date of the enactment of this Act.

(2) DETERMINATIONS BY THE SECRETARY.—Section 3511(g) of the Internal Revenue Code of 1986 (as added by subsection (a)) shall apply to determinations after the date of the enactment of this Act.

(3) SECTION 530(d).—The amendment made by subsection (b) shall apply to periods ending after the date of the enactment of this Act.

INDEPENDENT CONTRACTOR DETERMINATION ACT OF 2001—DESCRIPTION OF PROVISIONS

The bill addresses the worker-classification issue (e.g., whether a worker is an employee or an independent contractor) by creating a new section 3511 of the Internal Revenue Code. The new section will provide straightforward rules for classifying workers and provide relief from the Internal Revenue Service's (IRS) reclassification of an independent contractor in certain circumstances. The bill is designed to provide certainty for businesses that enter into independent-contractor relationships and minimize the risk of huge tax bills for back taxes interest, and penalties if a worker is misclassified after the parties have entered into an independent-contractor relationship in good faith.

Clear Rules for Worker Classification: Under the bill's new worker-classification rules, an individual will be treated as an independent contractor and the service recipient will not be treated as an employer if either of two tests is met—the ''general test'' or the ''incorporation test.''

General Test: The general test requires that the independent contractor demonstrate economic independence and workplace independence in addition to a written contract with the service recipient.

Economic independence exists if the independent contractor has the ability to realize a profit or loss and agrees to perform services for a particular amount of time or to complete a specific result or task. In addition, the independent contractor must either have a significant investment in the assets of his or her business or incur unreimbursed expenses that are consistent with industry practice and that equal at least 2% of the independent contractor's gross income from the performance of services during the taxable year.

Workplace independence exists if one of the following applies: The independent contractor has a principal place of business (including a ''home office'' as expanded by the Taxpayer Relief Act of 1997); he or she performs services at more than one service recipients facilities; he or she pays a fair-market rent for the use of the service recipient's facilities; or the independent contractor uses his or her own equipment.

The written contract between the independent contractor and the service recipient must provide that the independent contractor will not be treated as an employee and is responsible for his or her own taxes.

Incorporation Test: Under this test, an individual will be treated as an independent contractor if he or she conducts business through a corporation or a limited-liability company. In addition, the independent contractor must be responsible for his or her own benefits, instead of receiving benefits from the service recipient. The independent contractor must also have a written contract with the service provider stating that the independent contractor will not be treated as an employee and is responsible for his or her own taxes.

To prevent the incorporation test from being abused, the bill limits the number of former employees that a service recipient may engage as independent contractors under this test. The limitation is based on the number of people employed by the service recipient in the preceding year and is equal to the greater of 10 persons or 3% of the service recipient's employees in the preceding year. For example, Business X has 500 employees in 2000. In 2001 up to 15 employees (the greater of 3% of Business X's 500 employees in 2000 or 10 individuals) could incorporate their own businesses and still have Business X as one of their initial clients.

This limitation would not affect the number of incorporated independent contractors who were not former employees of the service recipient or independent contractors meeting the general test.

Additional Provisions: The new worker-classification rules also apply to three-party situations in which the independent contractor is paid by a third party, such as a payroll company, rather than directly by the service recipient. The new worker-classification rules, however, will not apply to a service recipient or a third-party payor if they do not comply with the existing reporting requirements and file 1099s for individuals who work as independent contractors. A limited exception is provided for cases in which the failure to file a 1099 is due to reasonable cause and not willful neglect.

New Worker-Classification Rules Do Not Replace Other Options: In the event that the new worker-classification rules do not apply, the bill makes clear that the independent contractor or service recipient can still rely on the 20-factor common law test or other provisions of the Internal Revenue Code applicable in determining whether an individual is an independent contractor or employee. In addition, the bill does not limit any relief to which a taxpayer may be entitled under Section 530 of the Revenue Act of 1978. The bill also makes clear that the new rules will not be construed as a prerequisite for these other provisions of the law.

Relief From Reclassification: The bill provides relief from reclassification by the IRS of an independent contractor as an employee. For many service recipients who make a good-faith effort to classify the worker correctly, this event can result in extensive liability for back employment taxes, interest, and penalties.

Relief Under the New Worker-Classification Rules: The bill provides relief for cases in which a worker is treated as an independent contractor under the new worker-classification rules and the IRS later contends that the new rules do not apply. In that case, the burden of proof will fall on the IRS, rather than the taxpayer, to prove that the new worker-classification rules do not apply. To qualify for this relief the taxpayer must demonstrate a credible argument that it was reasonable to treat the service provider as an independent contractor under the new rules, and the taxpayer must fully cooperate with reasonable requests from the IRS.

Protection Against Retroactive Reclassification: If the IRS notifies a service recipient that an independent contractor should have been classified as an employee (under the new or old rules), the bill provides that the IRS' determination can become effective only 30 days after the date that the IRS sends the notification. To qualify for this provision, the service recipient must show that:

There was a written agreement between the parties;

The service recipient satisfied the applicable reporting requirements for all taxable years covered by the contract; and

There was a reasonable basis for determining that the independent contractor was not an employee and the service provider made the determination in good faith.

The bill provides similar protection for independent contractors who are notified by the IRS that they should have been treated as an employee.

The protection against retroactive reclassification is intended to remove some of the uncertainty for businesses contracting with independent contractors, especially those who must use the IRS' 20-factor common law test. While the bill would prevent the IRS from forcing a service recipient to treat an independent contractor as an employee for past years, the bill makes clear that a service recipient or an independent contractor can still challenge the IRS' prospective reclassification of an independent contractor through administrative or judicial proceedings.

Repeal of Section 1706 of the Revenue Act of 1978: The bill repeals section 530(d) of the Revenue Act of 1978, which was added by section 1706 of the Tax Reform Act of 1986. This provision precludes businesses that engage technical service providers (e.g., engineers, designers, drafters, computer programmers, systems analysts, and other similarly qualified individuals) in certain cases from applying the reclassification protections under section 530. The bill is designed to level the playing field for individuals in these professions by providing the businesses that engage them with the same protections that businesses using other types of independent contractors have enjoyed for more than 20 years.

Effective Dates: In general, the independent-contractor provisions of the bill, including the new worker-classification rules, will be effective for services performed after the date of enactment of the bill. The protection against retroactive reclassification will be effective for IRS determinations after the date of enactment, and the repeal of section 530(d) will be effective for periods ending after the date of enactment of the bill.

By Mr. DODD (for himself and Mr. DEWINE):

S. 838. A bill to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children; to the Committee on Health, Education, Labor, and Pensions.

Mr. DODD. Mr. President, I rise today to join my colleague, Senator DEWINE in introducing the Best Pharmaceuticals for Children Act. I hope that this will be the continuation of our long-term efforts to improve the health of America's children.

According to the American Academy of Pediatrics, only 20 percent of the drugs on the market have been tested and labeled specifically for their safety and effectiveness in children. Children are simply not smaller version of adults, their bodies actually react to drugs differently. The absence of pediatric labeling poses significant risks for children, without adequate information about how a drug works in children of different ages and sizes, children are more likely to be under- or over-dosed or to experience dangerous side effects.

We have labels on the food children eat, on the shows they watch and the music they listen to. Why should we have less information when it comes to the medicine they take? And while ''off-labeling prescribing'' is neither illegal nor improper, forcing our children to use medications without adequate safety information, is a lot like playing Russian roulette with their health.

That's why four years ago, Senator DEWINE and I introduced legislation to take the guess work out of children's medicine. This legislation, the Better Pharmaceuticals for Children Act, provided a market incentive for drug companies to test their products for use in children or to create kid-friendly drug formulations. And, just a few years later, we've made extraordinary strides in closing the dangerous gap in knowledge.

In the 3 years since the initiative was launched, over 300 pediatric drug studies have gotten underway, compared to the 11 studies conducted in the 6 years prior to the legislation. New pediatric information has been or will soon be added to the labels of 28 products, including drugs for AIDS, diabetes, mental health, and asthma. Not only has the initiative led to significant advances in pediatric medicines, in the long run it will also save the nation money by reducing hospital stays, doctors' visits and parents' taking time off of work.

But while tremendous progress has been made, we still have a long way to go to make sure that children aren't an afterthought when it comes to pharmaceutical research. Hundreds of drugs are on the market today that are used in children, but still have not been tested for pediatric needs. Yet, unless reauthorized, the pediatric testing incentive, and the explosion of research it has prompted, will expire on January 1, 2002.

In addition to ensuring that critical pediatric drug studies continue, the Best Pharmaceuticals for Children Act will also ensure that the new safety information from pediatric studies is promptly added to drug labels, require drug manufacturers to pay user fees to participate in the program, and require the Food and Drug Administration to quickly disseminate information gathered from pediatric studies to pediatricians and parents. It will also fund studies of older, ''off-patent'' drugs which are not eligible for the existing pediatric testing incentive, and create a new Office of Pediatric Therapeutics at the Food and Drug Administration to coordinate activities related to children.

The bill is endorsed by the American Academy of Pediatrics, the Elizabeth Glaser Pediatric AIDS Foundation, the National Association of Children's Hospitals, the American Society for Clinical Pharmacology and Therapeutics, and the Allergy and Asthma Network Mother of Asthmatics.

I call on my colleagues to move quickly to enact the Best Pharmaceuticals for Children Act, commonsense legislation that will ensure that our children received only the very best of what medicine has to offer.

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. 838

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Best Pharmaceuticals for Children Act''.

SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED DRUGS.

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

(1) by striking subsection (b); and

(2) in subsection (c)—

(A) by inserting after ''the Secretary'' the following: ''determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and''; and

(B) by striking ''concerning a drug identified in the list described in subsection (b)''.

SEC. 3. RESEARCH FUND FOR THE STUDY OF OFF-PATENT DRUGS.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended—

(1) by redesignating the second section 409C, relating to clinical research (42 U.S.C. 284k), as section 409G;

(2) by redesignating the second section 409D, relating to enhancement awards (42 U.S.C. 284l), as section 409H; and

(3) by adding at the end the following:

''SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF OFF-PATENT DRUGS.

''(a) LIST OF OFF-PATENT DRUGS FOR WHICH PEDIATRIC STUDIES ARE NEEDED.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research (including United States Pharmacopoeia), shall develop, prioritize, and publish a list of approved drugs for which—

''(A) there is no patent or market exclusivity protection; and

''(B) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

''(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

''(B) whether additional information is needed; and

''(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population.

''(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

''(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

''(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR OFF-PATENT DRUGS.—

''(A) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Director of National Institutes of Health, may issue a written request for pediatric studies concerning a drug identified in the list described in subsection (a) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a request shall be made in accordance with section 505A of the Federal Food, Drug, and Cosmetic Act.

''(B) PUBLICATION OF REQUEST.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under subparagraph (A) within 30 days of the date on which a request was issued, the Secretary, acting through the Director of National Institutes of Health, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

''(2) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(3) REPORTING OF STUDIES.—

''(A) Upon completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

''(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain, and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each the drug.

''(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (4).

''(4) REQUEST FOR LABELING CHANGES.—During the 180-day period after the date on which a report is submitted under paragraph (3)(A), the Commissioner of Food and Drugs shall—

''(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied; and

''(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

''(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

''(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.

''(5) DISPUTE RESOLUTION.—If, not later than the end of the 180-day period specified in paragraph (4), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph—

''(A) the Commissioner of Food and Drugs shall immediately refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee; and

''(B) not later than 60 days after receiving the referral, the Subcommittee shall—

''(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

''(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

''(6) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Subcommittee under paragraph (5)B(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

''(7) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (6), does not agree to make a requested labeling change, the Commissioner may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

''(d) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

''(A) $200,000,000 for fiscal year 2002; and

''(B) such sums as are necessary for each of the 5 succeeding fiscal years.

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

SEC. 4. TIMELY LABELING CHANGES FOR DRUGS GRANTED EXCLUSIVITY; DRUG FEES.

(a) ELIMINATION OF USER FEE WAIVER FOR PEDIATRIC SUPPLEMENTS.—Section 736(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(A)(1)) is amended—

(1) by striking subparagraph (F); and

(2) by redesignating subparagraph (G) as subparagraph (F).

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

''(l) LABELING SUPPLEMENTS.—

''(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENTS.—Any supplement to a human drug application submitted under this section—

''(A) shall be considered to be a priority supplement; and

''(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

''(2) DISPUTE RESOLUTION.—If the Commissioner determines that a supplemental application submitted under this section is approvable and that the only open issue for final action on the supplement is the reaching of an agreement between the sponsor of the application and the Commissioner on appropriate changes to the labeling for the drug that is the subject of the application—

''(A) not later than 180 days after the date of submission of the supplemental application—

''(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

''(ii) if the sponsor of the application does not agree to make a labeling change requested by the Commissioner by that date, the Commissioner shall immediately refer the matter to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee;

''(B) not later than 60 days after receiving the referral, the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee shall—

''(i) review the pediatric study reports; and

''(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any;

''(C) the Commissioner shall consider the recommendations of the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate; and

''(D) if the sponsor of the application, within 30 days after receiving a request under subparagraph (D), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.''.

SEC. 5. OFFICE OF PEDIATRIC THERAPEUTICS.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish an Office of Pediatric Therapeutics within the Office of the Commissioner of Food and Drugs.

(b) DUTIES.—The Office of Pediatric Therapeutics shall be responsible for oversight and coordination of all activities of the Food and Drug Administration that may have any effect on a pediatric population or the practice of pediatrics or may in any other way involve pediatric issues.

(c) STAFF.—The staff of the Office of Pediatric Therapeutics shall include—

(1) 1 or more individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population; and

(2) 1 or more individuals with expertise in pediatrics who shall consult with all components of the Food and Drug Administration concerning activities described in subsection (b).

SEC. 6. NEONATES.

Section 505A(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(g)) is amended by inserting ''(including neonates in appropriate cases)'' after ''pediatric age groups''.

SEC. 7. SUNSET.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by striking subsection (j) and inserting the following:

''(j) SUNSET.—A drug may not receive any 6-month period under subsection (a) or (c) unless—

''(1) on or before October 1, 2007, the Secretary makes a written request for pediatric studies of the drug;

''(2) on or before October 1, 2007, an application for the drug is submitted under section 505(b)(1); and

''(3) all requirements of this section are met.''.

SEC. 8. DISSEMINATION OF PEDIATRIC INFORMATION.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355a) (as amended by section 4(b)) is amended by adding at the end the following:

''(m) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of submission of a supplemental application under this section, the Commissioner shall make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement, including by publication in the Federal Register.

''(2) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends in any way section 552 of title 5 or section 1905 of title 18, United States Code.''.

SEC. 9. TECHNICAL AND CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) (as amended by sections 2(1), 4(b), 7, and 8) is amended—

(1) by redesignating subsections (a), (g), (h), (i), (j), (l), and (m) as subsections (b), (a), (g), (h), (l), (i), and (j), respectively;

(2) by moving the subsections so as to appear in alphabetical order; and

(3) in paragraphs (1), (2), and (3) of subsection (d) and subsections (e), (g) (as redesignated by paragraph (1)), and (l) (as redesignated by paragraph (1)), by striking ''subsection (a) or (c)'' and inserting ''subsection (b) or (c)''.

Mr. DEWINE. Mr. President, I rise today to join my friend and colleague from Connecticut, Senator DODD, to introduce a bill that builds on a previous law that he and I wrote four years ago, called the ''Better Pharmaceuticals for Children Act.'' The bill we are introducing today the ''Best Pharmaceuticals for Children Act'', re-authorizes our 1997 law and makes additional improvements.

I'd like to thank Senator DODD for his tireless dedication to this effort and to other vital children's health initiatives. We have worked together on many bipartisan efforts that protect children, and I commend him for his commitment to ensuring that all children are safe and healthy. I also would like to recognize the efforts of Elaine Vining with the American Academy of Pediatrics and Mark Isaac with the Elizabeth Glaser Pediatric AIDS Foundation, who have devoted countless hours to providing us with technical assistance and ideas for how to improve our already successful pediatric studies law.

Under our law, the FDA has granted market exclusivity extensions for 28 products, of which 18 include new labeling. Let me tell you what this means for me as a parent: We now have dosage, safety and adverse event information that we did not previously have to help us provide our children the correct dose of these medicines and to avoid potential adverse effects. The more information doctors and parents have on dosing, toxicity, adverse effects, and adverse drug interactions—the more informed our decisions will be when giving medicines to children and ultimately, the more we will be protecting our kids.

Creating the proper formulation, such as a liquid form, of a drug is also essential. I know that my children all went through a stage in which a pill form was problematic for them to swallow or the taste of the medicine was unacceptable. Having a child spit out a tablet or having to crush a tablet in order to give half of the recommended adult dose are compliance issues that we, as parents, have all experienced.

When Senator DODD and I set out in 1997 to change the fact that only 20 percent of all prescription drugs marketed in this country were labeled for pediatric use, we heard many proposals on how to fix the problem, from giving tax incentives for research to offering this market exclusivity extension. Since children only account for 30 percent of the population and less than 12 percent of personal health care spending, they were not getting the kind of pediatric-focused research that they deserve.

Because of the help and support of many of my colleagues like Senators FRIST, KENNEDY, JEFFORDS, BOND, MIKULSKI, HUTCHINSON, COLLINS, and many others who helped us pass this landmark law, we have begun to turn the tide in favor of children. In considering any proposals to change the current law, however, we must not lose sight of the fact that the goal of this law is to encourage pediatric studies of new and already marketed drugs that are currently used in children, but are not labeled for such use. Anything that hinders the ability of the FDA to implement this law will impede future progress in pediatric research and ultimately defeat the purposes of this law.

FDA and others, including the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation, have offered many helpful suggestions on how we can improve the current law. The most significant improvement I would like to stress is something our original law was never intended to address—the issue of how to get off-patent drugs tested for use in children. The market exclusivity extension only works as a pediatric testing incentive if a company has an existing patent to which we can attach an additional six months of market exclusivity. Once the patent expires, however, there is no way to prevent competition from entering the market for that drug.

So, in the new bill that Senator DODD and I are introducing today—the ''Best Pharmaceuticals for Children Act'', we propose creating a ''Research Fund.'' This Fund would require the Secretary of HHS to award contracts for entities with expertise in conducting pediatric clinical trials (such as PPRU's, hospitals, universities) to conduct pediatric studies of certain drugs that are off-patent. The list of these off-patent drugs would be developed according to criteria—such as whether new studies might produce health benefits for children, and then prioritized and published by the Secretary, acting through the NIH Director and in consultation with the FDA Commissioner and experts in pediatric research. Written requests would be issued by the FDA Commissioner.

The significance of this Research Fund is that off-patent drugs, like Ritalin, would be tested for pediatric use. Currently, many drugs are being prescribed off-label, based on limited, if any, pediatric studies and/or on the personal experiences of health professionals. Ritalin, for example, includes the following precaution and warning:

> Precaution: Long-term effects of Ritalin in children have not been well established. Warning: Ritalin should not be used in children under six years, since safety and [effectiveness] in this age group has not been established.

The point is that Ritalin is being prescribed off-label for children under six, and yet we don't know the safety and long-term effects on children. This Research Fund would establish the means by which testing on this and other off-patent drugs could be performed.

Our new bill makes other improvements to current law including: expediting the dissemination of information generated by pediatric studies to the public; expediting labeling changes; acknowledging the need to study the neonate, zero to one month in age, population if appropriate and at the appropriate point in pediatric studies; applying prescription drug user fees to pediatric studies to give FDA the resources

it needs to conduct timely reviews of studies and labeling changes; and establishing an Office of Pediatric Therapeutics within FDA to coordinate activities among review divisions and provide oversight for all pediatric activities undertaken by FDA.

Finally, I would like to address a concern that has been expressed by many in the press, and rightfully so. No one can ignore the risk involved in having children participate in clinical trials. Parents with sick children, sadly, have to weigh these risks and make treatment decisions. I want to commend Senator DODD for his foresight in this area of providing research protections for children involved in clinical trials. With the increase in pediatric research through this law and other laws, we needed to ensure that research protections exist and are strengthened, if necessary.

That is why last year, in the ''Children's Health Act,'' Senator DODD and I proposed language that would ensure that federally funded, conducted, and regulated research adheres to scientific and ethical review standards. There is currently a review of these federal protections for children involved in clinical trials to further ensure that the highest standards of scientific and ethical review are in place. The alternative to clinical trials is uncontrolled, unregulated, and unreported studies of smaller groups of children. Pediatric experts agree that controlled clinical trials are the much-preferred alternative.

We must make the health of our children a priority. Through our new bill we are doing that. We are furthering the success of current law by providing parents and doctors with more information to make better informed decisions when medicating children. Our children deserve no less.

I urge my colleagues to support this important measure.

By Mrs. HUTCHISON (for herself, Mr. BAYH, Mr. HUTCHINSON, Mr. BURNS, Mr. KERRY, Mr. CHAFEE, Mr. KENNEDY, Mr. HELMS, Mrs. CLINTON, Mr. SCHUMER, and Mr. BIDEN):

S. 839. A bill to amend title XVIII of the Social Security Act to increase the amount of payment for inpatient hospital services under the medicare program and to freeze the reduction in payments to hospitals for indirect costs of medical education; to the Committee on Finance.

Mrs. HUTCHISON. Mr. President, I rise today to introduce, along with Senators BAYH, HUTCHINSON, and several other distinguished colleagues, the American Hospital Preservation Act.

Our hospitals are the very foundation of our health care system, a system that is considered the best in the world. To ensure this quality of care remains at this high level, we cannot ask yet more cuts of our financially troubled hospitals.

Two such cuts currently being faced by our nation's hospitals are a reduction in the annual inflation update hospitals receive for their Medicare payments, and a reduction in the Medicare adjustment teaching hospitals receive to support their medical education programs. Both of these issues are critical to the long-term stability of hospitals, and to maintaining the scope and quality of the care they provide.

We do have the best health care in the world. Why should we put it at risk? Especially when the savings we have achieved already are far in excess of what was originally estimated. In other words, the cuts that were enacted have more than achieved their goals. There is no more fat left to trim.

Last year, through enactment of the Medicare, Medicaid and SCHIP Benefit Improvement and Protection Act, BIPA, we were successful in getting approximately half of the annual market basket update restored for our hospitals. In addition, we delayed further reductions in the indirect medical education, IME, adjustment for teaching hospitals. This legislation would build upon that success, and would help to ensure hospitals' long-term financial stability. In effect, it would preserve the ability of American hospitals to continue to provide the highest level of health care to be found anywhere in the world.

With respect to the IME provisions of this bill, all of the evidence points to the fact that the financial health of major teaching hospitals continues to deteriorate. In fact, with projections that Medicare margins could drop to negative 3.8 percent by 2005, it is becoming an increasingly common phenomenon that when a Medicare patient walks in to a hospital, he or she represents a money loser for that institution. While our hospitals must remain committed to providing care no matter the patients' circumstance, that sort of monetary shortfall will logically result in many hospitals closing down. Or, as we have seen happen many times recently, many hospitals will dramatically scale back their outpatient and other services for those in need.

Particularly in the rural areas of our nation, having a hospital close down would mean losing access to life-saving medical services. It would also have a dramatic effect on the community's economy. Hospitals are often the core components of the local community. To have the hospital close down would mean the loss of jobs and of businesses. It would have a ripple effect on the neighborhood, destroying its sense of stability and community.

This legislation addresses the unique situation of teaching hospitals. These hospitals, which are centers of experimental, innovative and technically sophisticated services as well as routine care and services, tend to incur much higher costs. We must recognize the higher costs these teaching hospitals incur to provide adequate learning experiences and faculty support to medical students. To do this, we must increase the indirect medical education adjustment one percentage point to 6.4 percent for FY 2003 and the future.

In addition, this legislation will reverse cuts previously enacted by Congress regarding the annual market basket updates. These cuts are unnecessary and harmful. For a hospital to effectively compete for skilled workers, especially in these days of tight labor markets, it is critical to have an adequate overall revenue stream. Medicare's measure of inflation, the market basket update, plays a key role in determining the adequacy of these payments from year to year.

As hospital costs increase rapidly in every area from labor to pharmaceuticals to blood and blood products to the costs of compliance with new regulations, the market basket update must keep pace. This legislation eliminates the update reductions mandated earlier.

It is critical that we not neglect our health care system and that we continue to invest in the very foundation of that system, our hospitals. I look forward to working with my colleagues on both sides of the aisle to ensure that this bill meets that objective yet still fits within our overall budgetary constraints.

This legislation represents our obligation to not only our most vulnerable citizens, but also to all Americans. Our hospitals provide the highest level and quality of care in the world. This bill ensures that they will be able to continue to do so, and I urge my colleagues to cosponsor and support it.

AMENDMENTS SUBMITTED AND PROPOSED

SA 378. Mr. KENNEDY (for Mrs. MURRAY) proposed an amendment to amendment SA 358 proposed by Mr. JEFFORDS to the bill (S. 1) to extend programs and activities under the Elementary and Secondary Education Act of 1965.

SA 379. Mr. KENNEDY (for Ms. MIKULSKI (for himself and Mr. KENNEDY)) proposed an amendment to amendment SA 358 proposed by Mr. JEFFORDS to the bill (S. 1) supra.

SA 380. Mr. ALLEN (for himself and Mr. WARNER) proposed an amendment to amendment SA 358 proposed by Mr. JEFFORDS to the bill (S. 1) supra.

SA 381. Mr. ALLARD submitted an amendment intended to be proposed by him to the bill S. 1, supra; which was ordered to lie on the table.

SA 382. Mr. DODD proposed an amendment to amendment SA 358 proposed by Mr. JEFFORDS to the bill (S. 1) supra.

TEXT OF AMENDMENTS

SA 378. Mr. KENNEDY (for Mrs. MURRAY) proposed an amendment to amendment SA 358 proposed by Mr. JEFFORDS to the bill (S. 1) to extend programs and activities under the Elementary and Secondary Education Act of 1965; as follows:

On page 383, after line 21, add the following:

SEC. 203. CLASS SIZE REDUCTION.

Title II of the Elementary and Secondary Education Act of 1965, as amended by sections 201 and 202, is further amended by adding at the end the following: