from Montana (Mr. BURNS) were added as cosponsors of amendment No. 3875 intended to be proposed to S. 2845, a bill to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes.

AMENDMENT NO. 3877

At the request of Mr. STEVENS, the name of the Senator from Montana (Mr. BURNS) was added as a cosponsor of amendment No. 3877 proposed to S. 2845, a bill to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes.

AMENDMENT NO. 3879

At the request of Mr. STEVENS, the name of the Senator from Montana (Mr. BURNS) was added as a cosponsor of amendment No. 3879 intended to be proposed to S. 2845, a bill to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes.

AMENDMENT NO. 3880

At the request of Mr. STEVENS, the name of the Senator from Montana (Mr. BURNS) was added as a cosponsor of amendment No. 3880 intended to be proposed to S. 2845, a bill to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes.

AMENDMENT NO. 3903

At the request of Mr. STEVENS, the name of the Senator from Arizona (Mr. KYL) was added as a cosponsor of amendment No. 3903 proposed to S. 2845, a bill to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

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

S. 2880. A bill to amend title XI of the Social Security Act to ensure full and free competition in the medical device and hospital supply industries; to the Committee on Finance.

Mr. KOHL. Mr. President, I rise today with Senator DEWINE to introduce the Medical Device Competition Act of 2004. The legislation that we are introducing today is the product of perhaps the most important work of our Subcommittee in the last few years—ensuring that physicians, patients, and health care workers have access to the best and safest medical devices, devices that can literally make the difference between life and death.

For nearly three years, the Antitrust Subcommittee has undertaken a thorough investigation of the hospital purchasing industry. This industry accounting for more than an estimated $50 billion in commerce is responsible for purchasing nearly everything that a hospital buys to treat sick or injured patients, everything from simple bandaids to high tech x-ray machines, from pacemakers to surgical devices. Much of this purchasing is done under contracts negotiated by what are known as ''group purchasing organizations'', ''GPOs'', large organizations that aggregate the buying power of hundreds, and sometimes thousands, of hospitals in order to gain bargaining power and volume discounts from hospital suppliers.

Without question, the goal of gaining volume discounts through aggregating buying power that led to the creation of GPOs is laudable. Unfortunately, our inquiry revealed that a system created to aggregate demand and hold down cost had sometimes mutated into a tool for entrenching market power of dominant suppliers, locking out competitors, and suppressing innovation. All too often conflicts of interest and questionable GPO business practices denied physicians and their patients choice of needed medical devices and robbed hospitals of the benefit of competition.

Moreover, the power and importance of GPOs to our health care system increased as the GPO industry has undergone enormous consolidation in the last decade. As originally envisioned, GPOs were generally local or regional buying cooperatives each of whom accounting for a very small proportion of the market. Today, this situation is transformed. The two largest GPOs negotiate purchasing contracts for more than an estimated 60 percent of the Nation's not for profit hospital beds. The size and national scope of these large GPOs have turned them into the gatekeepers who can decide which medical devices doctors will use and which medical device companies will be able to sell their lifesaving goods..

Our investigation uncovered abuses and questionable practices that interfered with the GPOs' mission of buying the best products at the best prices. At the time our investigation began in 2001, it was all too common a practice for GPOs to contract with only one supplier of a medical device for lengthy terms. Industry observers also raised concerns over contracts which bundled commodities like hospital gowns with medical devices like pacemakers and surgical equipment, creating nearly insurmountable barriers for smaller manufacturers with specialized product lines to compete, regardless of the quality or effectiveness of their product. Some GPOs accepted high payments—so-called ''administrative fees''—well in excess of 3 percent from manufacturers. Worst of all, supposedly neutral contracting decisions were at times infected by equity interests held by GPOs or their executives in medical device companies.

We can be proud of the work of our subcommittee—and, indeed, many in the GPO industry—in responding to this situation. At our behest, six of the largest hospital buying groups agreed to fundamental reform by adopting codes of conduct governing their business activities and ethical responsibilities. These codes forbid anti-competitive business practices, and ban conflicts of interest that interfere with the GPOs' mission of buying the best products at the lowest prices. The GPOs that agreed to these new codes should be commended for their willingness to engage in real reform. Thanks to these GPOs' good work and willingness to engage in reform, many of the most egregious practices began to disappear from the marketplace and barriers to patients getting access to the best medical devices more have begun to come down.

Yet these reforms—as real and important as they are—have inherent limitations. They are completely voluntary and can be modified or even withdrawn by the GPOs at will. They have no enforcement mechanism nor any manner to objectively verify that they are being adhered to. We have no assurance that the reforms will not be abridged or abrogated should our subcommittee's oversight come to an end. We must now, therefore, find a way to ensure that these gains cannot be reversed.

Despite their enormous influence, GPOs have until now operated with little, if any, governmental oversight. Quite the contrary, these GPOs have operated under special government protection—a Congressionally granted exemption from anti-kickback law. This exemption—commonly known as the ''safe harbor'' for GPOs—allows GPOs to accept payments from hospital suppliers even though these purchases are reimbursed by the Medicare program. Acceptance of these payments from suppliers would be illegal absent this special exemption. The fact the hospital purchasing has this specially, Congressionally granted immunity from kickback mandates that government have the ability to oversee the manner GPOs are behaving under the protection of this exemption—oversight currently not required by law.

We are therefore today introducing legislation which will ensure that the Department of Health and Human Services will have the authority to oversee the functioning of the safe harbor and prevent anti-competitive or unethical GPO business practices. This is moderate and measured legislation which is not prescriptive in almost all respects. With only one exception, it does not outlaw any GPO practices or business arrangements. Instead, the bill grants oversight authority over hospital purchasing to HHS, and directs the HHS to draft regulations to prevent improper GPO conduct—that is, unethical conduct, anti-competitive practices, or practices which preclude products necessary for patient care or worker safety from reaching physicians and patients. HHS is further directed to consult with the Federal Trade Commission and the Attorney General in

developing these guidelines. Rather than micro-managing specific business practices, the discretion is left to the health policy experts at HHS, after consulting with the antitrust agencies—and only with the input of industry representatives through the notice and comment process—to develop the appropriate standards.

We recognize that different GPOs have different business models, and the goal of this approach is to permit GPOs to maintain these models as long as they do not violate basic precepts of good business conduct. As long as a GPO does not violate these standards, it continues to receive the immunity from anti-kickback law granted by the safe harbor. However, the penalty for GPOs that violate these standards is to be ineligible to participate in the safe harbor—that is, being unable to accept payments from hospital suppliers. This sanction should prevent GPOs from reverting to unethical or anti-competitive conduct, and give HHS the regulatory tools to supervise the industry so that it serves the interests of hospitals and patients.

The one area in which our legislation is prescriptive addresses a principle to which most parties on all sides of the GPO debate—hospitals, manufacturers, and most GPOs themselves—have already agreed. This is the provision that bans GPOs from accepting payments from vendors which exceed three percent of price of the good or service sold. The intent of this provision is to forbid excessive vendor fees which can bias a GPO contracting decision. The decision on which product is placed on a GPO contract should never turn on the amount of money paid by the manufacturer to the GPO; rather, a GPO's only goal should be to contract for the highest quality product at the lowest possible price. Most GPO's codes of conduct already ban vendor fees higher than 3 percent; however, during our investigation we learned that one of the nation's two largest GPOs had accepted fees above 20 percent. Indeed, data submitted to the Subcommittee showed that during 2002 over 20 percent of that GPO's revenues was derived from contracts with vendor fees higher than 3 percent, a proportion that had increased from the previous year. The safe harbor should not shield such practices, conduct which has the strong potential to bias the whole system.

In sum, we believe that our bill is a modest yet effective legislative approach to ensuring that the gains we have achieved over the past two years are not reversed, and that the safe harbor is administered in a way to promote innovation, competition, and cost savings. This legislation will give the authority that HHS needs to be an effective watchdog over hospital purchasing practices. Once this legislation is passed we can be confident that the reforms to the hospital purchasing industry that we have achieved over the last two years will remain in place, and that there will never be a return to practices that imperiled patient health and health worker safety, and blocked competition and innovation in this vital industry.

The bottom line is that our bill will encourage medical innovation, ensure doctors get the broadest choice of medical devices, and ensure that patients will receive the best possible devices available. These are goals we should all support. I urge my colleagues to join me in supporting this legislation.

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

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

S. 2880

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 ''Medical Device Competition Act of 2004''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Given the increasing costs of health care in the United States, there is a compelling public interest in ensuring that there is full and free competition in the medical device and hospital supply industries so that the best and safest products are available to physicians and patients at a competitive price.

(2) By aggregating purchases, hospital group purchasing can reduce the cost of acquiring medical equipment and hospital supplies so long as such purchasing is done in a manner consistent with antitrust law and free competition.

(3) Some practices engaged in by certain hospital group purchasing organizations have had the effect of reducing competition in the medical device and hospital supply industries by denying some suppliers and device makers access to the hospital marketplace.

(4) There is a compelling public interest in having the Secretary of Health and Human Services, in consultation with the Attorney General and Federal Trade Commission, engage in oversight and supervision of the current Federal health care program anti-kickback exemption (also known as the safe harbor) provided to group purchasing organizations under subparagraphs (C) and (E) of section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)). This oversight and supervision should ensure that the safe harbor does not shield conduct that harms competition in the hospital supply and medical device industries.

SEC. 3. ENSURING FULL AND FREE COMPETITION.

(a) IN GENERAL.—Section 1128B(b)(3)(C) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)(C)) is amended—

(1) in clause (i), by striking '', and'' at the end and inserting a semicolon; and

(2) by adding at the end the following new clauses:

''(iii) the contracting, business, and ethical practices of the person are not inconsistent with regulations promulgated by the Secretary pursuant to subsection (g)(1);

''(iv) the person has been certified by the Secretary under subsection (g)(2) to be in compliance with the regulations promulgated pursuant to subsection (g)(1); and

''(v) the amount to be paid the person does not exceed a total of 3 percent of the purchase price of the goods or services provided by that vendor;''.

(b) REGULATIONS.—Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b) is amended by adding at the end the following new subsection:

''(g)(1)(A) The Secretary, in consultation with the Attorney General and the Federal Trade Commission, shall, not later than 1 year after the date of enactment of the Medical Device Competition Act of 2004, issue proposed regulations, and shall, not later than 2 years after such date of enactment, promulgate final regulations, specifying contracting, business, and ethical practices of persons described in paragraph (4) that are contrary to antitrust law and competitive principles, to ethical standards, or to the goal of ensuring that products necessary for proper patient care or worker safety are readily available to physicians, health care workers, and patients.

''(B) In issuing and promulgating regulations under subparagraph (A), the Secretary shall take into account—

''(i) the compelling public policy goals of—

''(I) encouraging competition and innovation in the hospital supply and medical device markets; and

''(II) reducing the cost of health care as a result of aggregating buying power;

''(ii) the potentially detrimental impact of certain anticompetitive contracting practices; and

''(iii) the need to avoid conflicts of interests and other unethical practices by persons described in paragraph (4).

''(2) The Secretary, in consultation with the Attorney General and the Federal Trade Commission, shall establish procedures for annually certifying that persons described in paragraph (4) are in compliance with the final regulations promulgated pursuant to paragraph (1).

''(3) The Secretary, in consultation with the Attorney General and Federal Trade Commission, shall, not less than 6 months after the date of enactment of the Medical Device Competition Act of 2004, issue proposed regulations, and shall, not later than 1 year after such date of enactment, promulgate final regulations, to clarify its regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 to specify that the definition of 'remuneration' under this section with respect to persons described in paragraph (4)—

''(A) includes only those reasonable costs associated with the procurement of products and the administration of valid contracts; and

''(B) does not include marketing costs, any extraneous fees, or any other payment intended to unduly or improperly influence the award of a contract based on factors other than the cost, quality, safety, or efficacy of the product.

''(4) A person described in this paragraph is a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursable under a Federal health care program.''.

(c) DEFINITION OF PURCHASING AGENT.—Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b), as amended by subsection (b), is amended by adding at the end the following new subsection:

''(h) For purposes of this section, the term 'purchasing agent' means any individual, organization, or other entity that negotiates and implements contracts to purchase hospital supplies or medical equipment, devices, products, or goods or services of any kind for any group of individuals or entities who are furnishing services reimbursable under a Federal health care program, including organizations commonly known as 'group purchasing organizations'.''.

(d) EFFECTIVE DATE.—Clause (v) of section 1128B(b)(3)(C) of the Social Security Act (42

U.S.C. 1320a–7b(b)(3)(C)), as added by subsection (a), shall take effect 1 year after the date of enactment of this Act.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 445—TO ELIMINATE CERTAIN RESTRICTIONS ON SERVICE OF A SENATOR ON THE SENATE SELECT COMMITTEE ON INTELLIGENCE

Mr. LOTT submitted the following resolution; which was referred to the Committee on Rules and Administration:

Mr. LOTT. Mr. President, since September 11, there has been an on-going debate about the quality of our Nation's intelligence capabilities. In recent months, this debate has intensified as questions have arisen about prewar intelligence concerning Iraq's program for developing weapons of mass destruction. In this period, when the United States is engaged in a global war against terrorism, it is imperative that our intelligence resources are used to the utmost of their capability.

The Senate Select Committee on Intelligence is charged with the responsibility of overseeing our Nation's intelligence capabilities. As a member of that committee, I can attest to the quality of the work performed by members and staff who serve on the committee. But there is a huge learning curve to fully comprehend how our Nation's intelligence capabilities are being deployed. There are very complex technological issues associated with international intelligence and Senators often do not have the time to develop expertise in understanding all of these systems. And that makes it difficult for all committee members to engage in effective oversight.

I believe the current structure of the Intelligence Committee handicaps the committee's ability to perform truly meaningful oversight. Unlike any other committee in the Senate, there are severe restrictions placed on how long a member can serve on the Intelligence Committee. A Senator can only serve on the committee for eight continuous years. And one-third of the members of the committee are required to cycle off the committee every 2 years.

I think the Senate can no longer afford the luxury of cycling members on and off the committee. We need an Intelligence Committee whose members have years of experience in understanding the entire spectrum of global intelligence just as we have a Finance Committee whose members have spent years learning the nuances and intricacies of the tax laws and Medicare. For that reason, I am today submitting a resolution eliminating both the 8-year term limit and the mandate to replace one-third of the committee every 2 years. I would note that the 9/11 Commission recommended that term limits on the committee be eliminated.

S. RES. 445

Resolved, That section 2 of Senate Resolution 400, 94th Congress, agreed to May 19, 1976, is amended by striking subsection (b) and by redesignating subsection (c) as subsection (b).

AMENDMENTS SUBMITTED AND PROPOSED

SA 3945. Mr. LEAHY (for himself and Mr. GRASSLEY) proposed an amendment to the bill S. 2845, to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes.

SA 3946. Ms. COLLINS (for Mr. INHOFE) proposed an amendment to amendment SA 3849 proposed by Mr. CORZINE (for himself and Mr. LAUTENBERG) to the bill S. 2845, supra.

SA 3947. Mr. DOMENICI (for himself and Mr. BINGAMAN) submitted an amendment intended to be proposed by him to the bill S. 1876, to authorize the Secretary of the Interior to convey certain lands and facilities of the Provo River Project; which was ordered to lie on the table.

SA 3948. Mr. FRIST (for Mr. SHELBY (for himself and Mr. SARBANES)) proposed an amendment to the bill H.R. 1533, to amend the securities laws to permit church pension plans to be invested in collective trusts.

SA 3949. Ms. MURKOWSKI submitted an amendment intended to be proposed by her to the bill S. 1466, to facilitate the transfer of land in the State of Alaska, and for other purposes; which was referred to the Committee on Energy and Natural Resources.

TEXT OF AMENDMENTS—THURSDAY, SEPTEMBER 30, 2004

SA 3809. Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 2845, to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes; which was ordered to lie on the table; as follows:

On page 28, line 17, strike ''or'' at the end.

On page 28, line 19, strike the period and insert ''; and''.

On page 28, between lines 19 and 20, insert the following:

(D) the personnel involved are not military personnel and the funds were not appropriated to military personnel appropriations, except that the Director may make a transfer of such personnel or funds if the Secretary of Defense does not object to such transfer.

On page 91, between lines 12 and 13, insert the following:

(C) Nothing in this subsection shall be construed to authorize the National Intelligence Director to specify, or require the head of a department, agency, or element of the United States Government to approve a request for, the transfer, assignment, or detail of military personnel, except that the Director may take such action with regard to military personnel if the Secretary of Defense does not object to such action.

On page 98, between lines 21 and 22, insert the following:

(C) Nothing in this subsection shall be construed to authorize the National Intelligence Director to specify, or require the head of a department, agency, or element of the United States Government to approve a request for, the transfer, assignment, or detail of military personnel, except that the Director may take such action with regard to military personnel if the Secretary of Defense does not object to such action.

SA 3810. Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 2845, to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes; which was ordered to lie on the table; as follows:

On page 7, beginning on line 20, strike ''that is not part of the National Foreign Intelligence Program as of the date of the enactment of this Act''.

TEXT OF AMENDMENTS

SA 3945. Mr. LEAHY (for himself and Mr. GRASSLEY) proposed an amendment to the bill S. 2845, to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes; as follows:

SECTION 1. CONGRESSIONAL OVERSIGHT OF FBI USE OF TRANSLATORS.

Not later than 30 days after the date of enactment of this Act, and annually thereafter, the Attorney General of the United States shall submit a report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives, that contains, with respect to each preceding 12-month period—

(1) the number of translators employed, or contracted for, by the Federal Bureau of Investigation or other components of the Department of Justice;

(2) any legal or practical impediments to using translators employed by the Federal, State, or local agencies on a full-time, part-time, or shared basis;

(3) the needs of the Federal Bureau of Investigation for the specific translation services in certain languages, and recommendations for meeting those needs;

(4) the status of any automated statistical reporting system, including implementation and future viability;

(5) the storage capabilities of the digital collection system or systems utilized;

(6) a description of the establishment and compliance with audio retention policies that satisfy the investigative and intelligence goals of the Federal Bureau of Investigation; and

(7) a description of the implementation of quality control procedures and mechanisms for monitoring compliance with quality control procedures.

SA 3946. Ms. COLLINS (for Mr. INHOFE) proposed an amendment to amendment SA 3849 proposed by Mr. CORZINE (for himself and Mr. LAUTENBERG) to the bill S. 2845, to reform the intelligence community and the intelligence and intelligence-related activities of the United States Government, and for other purposes; as follows:

In lieu of the matter to be inserted, insert the following:

TITLE ____—CHEMICAL FACILITIES SECURITY

SEC. ___0. 1. SHORT TITLE.

This title may be cited as the ''Chemical Facilities Security Act of 2004''.

SEC. ___02. DEFINITIONS.

In this title:

(1) ALTERNATIVE APPROACHES.—The term ''alternative approaches'' means ways of reducing the threat of a terrorist release, as well as reducing the consequences of a terrorist release from a chemical source, including approaches that—

(A) use smaller quantities of substances of concern;