

firearms or ammunition for damages, injunctive or other relief resulting from the misuse of their products by others.

BILL FRIST, GEORGE ALLEN, LARRY E. CRAIG, CRAIG THOMAS, MICHAEL B. ENZI, JEFF SESSIONS, CHRISTOPHER BOND, LAMAR ALEXANDER, MITCH MCCONNELL, SAM BROWNBACK, TOM COBURN, RICHARD BURR, JOHN MCCAIN, RICHARD SHELBY, SAXBY CHAMBLISS, JOHN ENSIGN, CHUCK HAGEL.

Mr. MCCONNELL. Mr. President, I ask that the live quorum under rule XXII be waived.

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

Mr. MCCONNELL. Mr. President, I now withdraw the motion to proceed.

The PRESIDING OFFICER. The motion is withdrawn.

#### MORNING BUSINESS

Mr. MCCONNELL. Mr. President, I ask unanimous consent there now be a period for morning business with Senators permitted to speak therein for up to 10 minutes each.

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

#### PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

Mr. ENZI. Mr. President, as chairman of the Health, Education, Labor, and Pensions Committee, I would like to take the opportunity to comment on a very important piece of legislation the Senate passed this week—a managers' substitute for S. 544, the Patient Safety and Quality Improvement Act of 2005, offered by myself, Senators JEFFORDS, GREGG, KENNEDY, FRIST, MURRAY, and BINGAMAN.

More than 5 years in the making, this legislation is an important step toward building a culture of safety and quality in our health care system.

The language of this bill reflects a carefully negotiated bipartisan, bicameral agreement between the chairmen and ranking members of the Senate Health, Education, Labor, and Pensions Committee and the House Energy and Commerce Committee. I want to thank my colleagues Senator KENNEDY, Chairman BARTON, and Representative DINGELL for their hard work in bringing this agreement to fruition.

Tremendous credit also goes to the HELP Committee's previous Chairman, Senator GREGG, whose tireless work on this issue was invaluable in bringing us to where we are today, and to Senator JEFFORDS, sponsor of the original legislation upon which this agreement builds.

The Patient Safety and Quality Improvement Act will create a framework through which hospitals, doctors, and other health care providers can work to improve health care quality in a protected legal environment.

More specifically, the bill will extend crucial legal privilege and confidentiality protections to health care providers to allow them to report health care errors and "near misses" to spe-

cially designated patient safety organizations. In turn, these patient safety organizations, some of which exist in limited form today, will be able to collect and analyze patient safety data in a confidential manner.

After conducting this analysis, patient safety organizations will report back to providers on trends in health care errors and will offer guidance to them on how to eliminate or minimize these errors. Some of this takes place today, but much more information could be collected and analyzed if providers felt confident that reporting such errors would not increase the likelihood that they could be sued.

It is not the intent of this legislation to establish a legal shield for information that is already currently collected or maintained separate from the new patient safety process, such as a patient's medical record. That is, information which is currently available to plaintiffs' attorneys or others will remain available just as it is today. Rather, what this legislation does is create a new zone of protection to assure that the assembly, deliberation, analysis, and reporting by providers to patient safety organizations of what we are calling "Patient Safety Work Product" will be treated as confidential and will be legally privileged.

Errors in medical treatment take place far too often. Unfortunately, however, providers live in fear of our unpredictable medical litigation system. This fear, in turn, inhibits efforts to thoroughly analyze medical errors and their causes. Without appropriate protections for the collection and analysis of patient safety data, providers are understandably loath to participate in medical error reporting systems.

I am pleased that the negotiated final version of this bill reflects and upholds several of the key priorities of the bill the HELP Committee marked up earlier this year, and which was also passed out of the Senate last year.

For example, this agreement makes very clear that, in addition to strong legal privilege provisions, patient safety work product will also be subject to a clear and affirmative duty of confidentiality. That is, not only will patient safety work product be subject to a privilege in legal and related proceedings, but the bill will also impose penalties of up to \$10,000 per violation should such patient safety work product be disclosed.

It was a key priority of the Senate bill that such information not only be privileged in a legal proceeding, but also that serious consequences will ensue if patient safety organizations, providers, or anyone else divulges it in ways not permitted under the bill. I am very pleased that the compromise agreement we are passing this week upholds this commitment to an affirmative duty of confidentiality.

Also, we believed very strongly that the definition of patient safety work product—that is, exactly what kind of information is to be protected—be

drawn broadly enough to assure that providers will feel safe and secure in participating in a patient safety system—and that they not be chilled from participating by fear that their efforts to assemble, analyze, deliberate on, or report patient safety information to patient safety organizations would somehow fall outside of a too-narrow statutory definition of patient safety work product.

With this in mind, we negotiated a definition in the agreement which takes great care to make clear to providers that the assembly of data, its analysis, deliberations about it, and its reporting to a patient safety organization will be firmly protected. We also clarified that information that is collected, maintained, or developed separately from the patient safety system will continue to be treated the same as it is under current law.

Before I close, I want to take just a minute to thank the many Senate staff members who worked very hard to bring this legislation to where it is today. Among those who deserve special recognition and thanks are Andrew Patzman and Stephen Northrup of my HELP Committee professional staff, David Bowen of Senator KENNEDY's Committee staff, Peggy Binzer with Senator GREGG, Dean Rosen of Senator FRIST's Leadership staff, and Sean Donohue with Senator JEFFORDS. Much credit also goes to the hard work of the staff of the House Energy and Commerce Committee, as well as to the expert and very capable legislative staff at the Department of Health and Human Services.

I ask unanimous consent that a section-by-section summary of the legislation be printed in the RECORD.

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

#### SECTION-BY-SECTION SUMMARY "PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005"

##### MANAGERS SUBSTITUTE AMENDMENT [July 2005]

##### SECTION 1. SHORT TITLE

The Patient Safety and Quality Improvement Act of 2005.

##### SECTION 2. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT

Creates a new Part C of Title IX of the Public Health Service Act, Entitled "Patient Safety Improvement"

##### SECTION 921. DEFINITIONS

"Patient Safety Activities" describes activities involving providers and certified patient safety organizations (see Sec. 924, below) which include the following: (1) efforts to improve patient safety and the quality of health care delivery, (2) collection and analysis of patient safety work product, (3) development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices, (4) utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk, (5) maintenance of procedures to preserve confidentiality with respect to patient safety