a Congressional Gold Medal to the American Fighter Aces, collectively, in recognition of their heroic military service and defense of our country's freedom throughout the history of aviation warfare.

S. 1828

At the request of Mr. INHOFE, his name was added as a cosponsor of S. 1828, a bill to amend the Truth in Lending Act to modify the definitions of a mortgage originator and a high-cost mortgage.

S. 1941

At the request of Mr. MANCHIN, the name of the Senator from Alaska (Ms. MURKOWSKI) was added as a cosponsor of S. 1941, a bill to establish requirements for the adoption of any new or revised requirement providing for the screening, testing, or treatment of an airman or an air traffic controller for a sleep disorder, and for other purposes.

S. 1943

At the request of Mrs. MURRAY, the name of the Senator from Hawaii (Mr. SCHATZ) was added as a cosponsor of S. 1943, a bill to incentivize State support for postsecondary education and to promote increased access and affordability for higher education for students, including Dreamer students.

S. 1956

At the request of Mr. SCHATZ, the name of the Senator from Rhode Island (Mr. WHITEHOUSE) was added as a cosponsor of S. 1956, a bill to direct the Secretary of Defense to review the discharge characterization of former members of the Armed Forces who were discharged by reason of the sexual orientation of the member, and for other purposes.

S. 1963

At the request of Mr. PRYOR, the names of the Senator from Virginia (Mr. WARNER), the Senator from Louisiana (Ms. LANDRIEU), the Senator from Oregon (Mr. WYDEN), the Senator from Florida (Mr. NELSON), the Senator from Minnesota (Mr. FRANKEN) and the Senator from Wisconsin (Ms. BALDWIN) were added as cosponsors of S. 1963, a bill to repeal section 403 of the Bipartisan Budget Act of 2013.

S. 1972

At the request of Mr. BLUMENTHAL, the name of the Senator from Massachusetts (Ms. WARREN) was added as a cosponsor of S. 1972, a bill to prohibit discrimination in employment on the basis of an individual's status or history of unemployment.

S. 1977

At the request of Ms. AYOTTE, the names of the Senator from Indiana (Mr. COATS), the Senator from Kentucky (Mr. PAUL), the Senator from Kentucky (Mr. MCCONNELL), the Senator from Texas (Mr. CORNYN), the Senator from Kansas (Mr. ROBERTS), the Senator from Georgia (Mr. ISAKSON) and the Senator from South Dakota (Mr. THUNE) were added as cosponsors of S. 1977, a bill to repeal section 403 of the Bipartisan Budget Act of 2013, relating to an annual adjustment of retired pay for members of the Armed Forces under the age of 62, and to provide an offset.

S. 1978

At the request of Mr. UDALL of New Mexico, the name of the Senator from New Mexico (Mr. HEINRICH) was added as a cosponsor of S. 1978, a bill to increase access to primary care services through training and accountability improvements.

S. 1982

At the request of Mr. SANDERS, the name of the Senator from Washington (Ms. CANTWELL) was added as a cosponsor of S. 1982, a bill to improve the provision of medical services and benefits to veterans, and for other purposes.

S. 1987

At the request of Mrs. FEINSTEIN, the name of the Senator from California (Mrs. BOXER) was added as a cosponsor of S. 1987, a bill to authorize the Secretary of Veterans Affairs to enter into enhanced-use leases for certain buildings of the Department of Veterans Affairs at the West Los Angeles Medical Center, California, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mrs. FISCHER (for herself, Mr. KING, and Mr. RUBIO):

S. 2007. A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for regulating clinical and health software, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mrs. FISCHER. Mr. President, I rise today to speak about rapid advancements in health care information technology or health IT. Health IT holds amazing potential to transform Americans' everyday lives for the better. I believe that protecting this kind of exciting innovation from overregulation and excessive taxation needs to be a high priority.

That is why I am introducing the Preventing Regulatory Overreach to Enhance Care Technology or the PROTECT Act of 2014. Together with Senator ANGUS KING of Maine and Senator MARCO RUBIO of Florida, we are putting forward this pro-jobs, risk-based framework governing health IT.

Before I speak about our bill, I thank my colleague from Maine Senator ANGUS KING for joining me in this effort. I am informally telling people that our efforts might be the start of the ''surf and turf caucus'' in the Senate, the place where Nebraska and Maine come together politically to find common ground and work to address real problems in this country.

We are able to do so together because Senator KING is known as an independent thinker, a problem-solver who isn't afraid to work across the aisle in order to get things done. It is refreshing, and I sincerely appreciate his willingness to work with me.

I also give special thanks to Senator RUBIO for his interest in this issue as well. He is also an original cosponsor, and he has worked with us on this important topic.

What we are trying to do is clarify the Food and Drug Administration's oversight authority over health information technologies. Under current law dating back to 1976, the FDA can apply its definition of a medical device to assert broad regulatory authority over a wide array of health IT, including applications that do not pose a threat to human safety.

That means low-risk health IT can be treated like traditional medical devices, subjecting job creators and innovators to these challenges that really don't make sense.

The PROTECT Act fixes this discrepancy. The PROTECT Act keeps the FDA's resources focused on products that pose the highest risk to human health. In doing so it also gives regulatory certainty to innovators and job creators who are developing these new products that use data safely to improve health care and also to reduce its cost. Furthermore, the PROTECT Act relieves categories of low-risk clinical and health software from the 2.3-percent medical device tax. Most importantly, though, it protects and promotes American jobs in a key growth sector of our economy.

The mobile health and mobile application market is expected to exceed $26 billion by 2017, while the U.S. mobile apps economy is responsible for nearly half a million new American jobs. A report from Health Data Management anticipates 23-percent annual growth in this sector over the next 5 years. The FDA highlights on their Web site that 500 million smartphone users worldwide will be using health apps by 2015. The mobile analytics platform Localytics, which monitors more than 20,000 apps, has seen a 19-percent increase in new health and fitness apps in 2013 from the year prior. That is amazing.

But what is even more impressive is the health IT's ability to protect people. Consider the example of a young man named Xavier Jones whose basketball coach downloaded a $1.99 mobile application that gave him a refresher course on how to properly administer CPR. It was a skill that came in handy the very next day when Xavier collapsed in the middle of practice.

In 2012 the Departments of Defense and Veterans Affairs partnered to release a free Apple and Android app called the Post-Traumatic Stress Disorder Coach. PTSD Coach has been downloaded over 100,000 times in 74 countries. It provides reliable information on PTSD and treatments on users' smartphones.

Other types of health IT, such as electronic health records and low-risk clinical decision software, can also lower costs and can improve outcomes. Some of these technologies hold the power to quickly and broadly disseminate new information about effective

treatments and recent clinical trials. Patients want their doctors to have access to these cutting-edge therapies. Protecting low-risk health IT is about empowering people with access to information. We need to protect that kind of innovation because innovation is an equalizer for consumers.

These technological benefits don't stop at our borders. Think about this statistic: One estimate shows that mobile health deployment in Africa could save as many as 1 million lives by 2017. From assisting nurses with scheduling to reminding pharmacists to refill their stock or even tracking emerging malarial epidemics, mobile health is already transforming the landscape of the developing world in very dramatic ways.

These stories only scratch the surface of where this technology is going. It is important how we treat innovation here in the United States. Other countries around the world are looking at how our government will regulate and oversee these low-risk technologies.

Our bill makes it so low-risk, highly innovative clinical and health software technologies—and the potential they have to empower people—are not undercut by these burdensome regulations. FDA's promise to use its enforcement discretion over low-risk health IT only serves to create confusion and uncertainty in the marketplace. Regulatory discretion by its very nature is something that can easily change over time, and discretion can be misused or abused.

Clear rules should be set because the current FDA regulatory model for medical devices is not well suited for low-risk health information technologies. In a House Energy and Commerce Committee hearing last year, the FDA submitted a letter to the committee that said:

> For 2011 and 2012, the average time for FDA review of medical device submissions that were identified as containing a mobile medical app was 67 days and the average total time from submission to FDA decision was 110 days.

When regulatory days turn into months, problems are going to persist, and that is not something we should leave to discretion. The regulatory time line for risky devices should not be the same for low-risk software that gets released every 60 days, has major updates every month, and sees regular changes every week. Having an approval process that takes longer than the shelf life of the average device operating system stifles opportunity and it stifles innovation.

Innovators, regulators, and consumers need clarity and certainty into how these regulations are going to be enforced. Since mobile wellness apps and most clinical decision support technologies pose little risk to patients, they should not be subject to the same costly painstaking processes as medical devices. The answer is the commonsense, risk-based regulatory approach the PROTECT Act provides. It protects innovation, it protects jobs here in the United States, and it protects jobs in this U.S.-based job sector. Most importantly, it protects patient safety by giving the FDA continued authority and oversight over health IT that is risky and by creating an appropriate regulatory framework for that which is lower risk.

With the introduction of the PROTECT Act, I would also like to acknowledge the great work of Senator LAMAR ALEXANDER of Tennessee, Senator ORRIN HATCH of Utah, Senator MICHAEL BENNET of Colorado, and others who have undertaken this effort in the past. These Senators have helped to lay the groundwork for the development of a risk-based framework for health IT. The ideas included in the PROTECT Act would not be possible without the progress they secured in previous Congresses and in the FDA's Safety and Innovation Act.

I am committed to working with anyone on these issues to exchange views and to exchange ideas so we can get the right policy balance our country needs and deserves.

Again, I thank my friends Senator KING from Maine and Senator RUBIO from Florida for joining me in this important effort. Together, we can achieve our shared vision of protecting patient safety, protecting innovation, and protecting U.S. economic job growth and opportunity.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Maine.

Mr. KING. Mr. President, it is a pleasure to join the Senator from Nebraska. I love the idea of the surf-and-turf caucus reaching across the country to try to find commonsense solutions. I often think about legislation and what we are attempting to do, and there is an attempt to codify common sense, to try to bring to the regulatory process, as it deals with medical devices, a little more thoughtfulness and cautiousness as it affects health information technology.

The first part of the bill actually sets up a process whereby we can examine in a thoughtful kind of way some of these issues to reduce the regulatory burden and at the same time foster innovation and, very importantly, protect patient safety. It sets up a process involving the National Institute of Standards and Technology and other parts of the administration so that the regulatory process in this area can be rationalized across agencies and better coordinated.

The heart of the bill, however, as the Senator just outlined, is our attempt to differentiate between medical software, which has a direct impact upon patient health, and software that is more peripheral and can range from the app I have on my iPhone, which is a pedometer that tells me how much I have walked each day and how much I should walk each day, to the kind of software that is being developed across the country to assist medical practices in their billing and in the operational part of the medical business.

I think one of the most important points, as the Senator pointed out, is that software evolves almost overnight, and if you go through this burdensome regulatory process—whether it is 60 days, 120 days, or 1 year—to get your software approved and then you find there is a bug you have to fix, that could restart the whole regulatory process. So I think we should acknowledge that this is a bit of preemptive legislation because the FDA thus far has not intruded very deeply into this process, and we believe it is important in order to define the areas where regulation and the protection of patient safety is important, but software that manages the billing process of a medical practice should not fall into that category and should not be subject to that level of regulation. That is really what we are talking about.

As the Senator mentioned, this law goes back to 1976. In thinking about 1976, Gerald Ford was President and software was a mink coat. We weren't really thinking about what we are doing today, and of course the legislation did not anticipate the kind of intense innovation and new thinking that is going on that is able to protect people's health just by giving them information about themselves. No doubt the time will come when a smartphone will be able to do blood pressure or temperature or certainly provide one's heart rate, and that is information we should have ourselves, not necessarily regulated by the Federal Government.

I am delighted to join the Senator from Nebraska and the Senator from Florida in introducing this piece of legislation. I think it is important. It is part of a larger project to try to bring our Federal regulatory process into the 21st century where time is of the essence, innovation is at the speed of light, and that we can't burden our people who are creating these innovations with a lengthy and, yes, expensive process that has a tendency to discriminate against smaller entrepreneurs and businesspeople.

I compliment the Senator from Nebraska for bringing this piece of legislation forward. I am absolutely delighted to join her in its sponsorship, and I look forward to moving it through the legislative process. There is a companion piece of legislation in the House, and I think this, as I said at the beginning, is an effort to get as close as we can to legislating common sense in this area, and I believe it will make a difference for businesses, for people, for patients, and for the health care system in America.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2732. Ms. AYOTTE (for herself, Mr. GRAHAM, Mr. WICKER, Mr. MCCONNELL, Mr. CORNYN, Mr. INHOFE, Mr. THUNE, Mr. CHAMBLISS, Mr. JOHANNS, Mr. BURR, Mr. BOOZMAN,