

DEPARTMENT OF HEALTH AND
HUMAN SERVICES,
Washington, DC, September 10, 2010.

DEAR MEMBER OF CONGRESS, The events of the past two weeks have illustrated a pattern that is all too familiar. Local health officials around the country begin to see an uptick in illnesses from a particular source. As they notify the Centers for Disease Control and Prevention, epidemiologists begin to see a pattern in the illness and outbreak reports, identify a food as the likely cause, and notify the Food and Drug Administration (FDA). FDA, state health and local officials then deploy investigators across the country, furiously searching for the source of the illness, knowing that every day more people are getting sick, some seriously. In the meantime, the public must be warned to avoid the food of concern, creating anxiety for consumers and economic losses for farmers, food processors and retailers.

This time we're seeing this pattern play out with *Salmonella Enteritidis* in eggs, with illnesses in 22 states and more than half a billion eggs being recalled. But in recent years it has been spinach, salsa, peanut butter, bean sprouts, cookie dough, green onions—the list goes on and on, covering many of our most common foods. Many people are left wondering: heading into the second decade of the 21st century, why can't we prevent and react more effectively to the threat from foodborne illness?

Sadly, the answer is simple. As President Obama said during last year's peanut butter outbreak, caused by a different form of *Salmonella*, we have a food safety regulatory system designed early in the 20th century, one that must be overhauled, modernized and strengthened for today.

Under the current system, FDA is often forced to chase food contaminations after they have occurred, rather than protecting the public from them in the first place. Difficulties in tracking the movement of food from its origin to its eventual sale to the public (often far across the country) can frustrate efforts to identify contaminated food. The biggest surprise to most people: FDA cannot order a recall of contaminated food once it is found in the marketplace. Although government has a crucial role in ensuring the safety of our food supply, strong regulation has been missing. An overhaul of our antiquated food safety system is long overdue.

Proposed food safety legislation would give FDA better ways to more quickly trace back contaminated products to the source, the ability to check firms' safety records before problems occur, clear authority to require firms to identify and resolve food safety hazards, and resources to find additional inspections and other oversight activities. Pending legislation would also give the agency mandatory recall authority, and other strong enforcement tools, like new civil penalties and increased criminal penalties for companies that fail to comply with safety requirements. In a world where more and more food is imported, the legislation also would strengthen FDA's ability to ensure the safety of imported food.

The good news is that a bipartisan majority in the House of Representatives passed major food safety legislation last year that would move the United States from a reactive food safety system to one focused on preventing illness. Likewise in the Senate, a bipartisan coalition has developed a strong food safety bill that is ready for the Senate floor. This legislation has the support of a remarkably broad coalition of public health, consumer and food industry groups. We commend both chambers for their hard work.

Now it's time to finish the job. We encourage Senators to support a critical and com-

monsense piece of public health legislation. And, we urge the House and Senate to quickly deliver a modern food safety bill to the President's desk. It's time to break the pattern of foodborne illnesses and economic loss. It's time to give FDA the modern tools and resources it needs to meet the challenges of the 21st century.

KATHLEEN SEBELIUS,
Secretary, Department of Health and Human Services.

MARGARET A. HAMBURG, M.D.,
Commissioner of Food and Drugs.

Mr. HARKIN. Mr. President, I have said many times that to say that food safety in this country is a patchwork is giving it too much credit. Food safety has too often become a hit-or-miss gamble, with parents obliged to kind of roll the dice when it comes to the safety of their kids' food. It is frightening and unacceptable. It is past time to modernize our food safety laws and regulations—70 years past time. We need to give FDA the resources and authority it needs to cope with a growing problem that threatens today a more abundant and diverse food supply. We need to act now.

I urge my colleagues to join the bipartisan sponsors to pass this important legislation and vote for cloture this afternoon on the motion to proceed. Hopefully, we can get on the bill and pass it as soon as possible, so that the families of America will have more assurance that the food they eat, no matter what the source, or from where it comes, has more safety procedures attached to it, and so that we have a new process for prevention in place for all facilities in this country and in foreign countries, and so we can raise the bar and say to our families that you can have more assurance in the future that the food you buy, whether it is the fresh fruits you buy in the middle of winter, shipped from Chile, Argentina, or Mexico, or Guatemala, or the fresh fruits you get in the summertime from California, Washington State, and Canada, or the produce, the lettuce, the bagged spinach, or whatever it might be, will be more safe for you and your family. That is what this is all about—protecting our families and making sure our food safety laws are adequate for the 21st century and not the 18th century.

I yield the floor.

THE FDA FOOD SAFETY MODERNIZATION ACT

Mr. ENZI. Mr. President, the United States has one of the best food safety systems in the world. However, even the best of systems have room for improvement. That is why my colleagues and I worked together over the past year to produce a bill that has broad bipartisan support. Food safety is not a partisan issue. We all want the safest food supply possible and the Food Safety Modernization Act makes significant improvements in that direction.

This is not a perfect bill. If it were solely up to me, there are several provisions that I would have done dif-

ferently. However, this bill provides real improvements for our food system by placing a greater emphasis on prevention and targeting government involvement to the areas of greatest need.

The American food industry is made up of hundreds of thousands of processors, distributors, and retailers of all sizes, both foreign and domestic. When you say "food industry" many think of the Nations largest food processors that carry the brand names with which we are familiar.

In truth, "industry" also consists of tens of thousands of small businesses across the country. It also includes over 2 million farmers, both large and small, in the United States that provide the food that we consume at our tables. This bill recognizes the diversity of all these individuals and organizations and protects their ability to continue to grow safe food for our families.

The bill also recognizes the vital role played by State and local officials. Our State officials are on the front lines when it comes to responding to food safety concerns and this bill makes sure that they will have the resources they need to do their jobs. Specifically, the bill provides training and education of State, local, and tribal authorities to facilitate the implementation of new standards under the law.

My colleagues, including Senators HARKIN, GREGG, DURBIN, BURR and DODD, have recognized all these challenges in this process and have worked together to prepare a bill that makes improvements to all aspects of our food system.

I am particularly pleased with the efforts the group has made in the managers' package that focus on providing flexibility for small and very small food processors. This bill provides small processors additional time to comply with new food safety practices and guidelines. The bill also requires the FDA to publish user-friendly small entity compliance guides to assist firms with the implementation of new practices. This way, small businesses in the food system, know exactly how to plan to adopt any new practices that could apply to them.

This bill also protects farms. Farmers remain exempt from registration under the Bioterrorism Act and any new produce safety standards must consider the unique practices that farmers use to grow or market their food. This includes consideration for farmers that use specific conservation practices or grow organic foods under the Organic Foods Production Act.

Small entities that produce food for their own consumption or market directly to consumers are also not subject to registration under this bill. This ensures that individuals can continue to provide food to their communities through farmers markets, bake

sales, public events and organizational fundraisers. Some have confused this bill with provisions in other food related bills and it is not true that S. 510 regulates backyard gardens or potluck dinners. All across Wyoming, people grow their own food and contribute dishes to organizational fundraisers and this bill continues the practice of making sure those individuals aren't subject to federal regulation.

However, if the amendment tree is filled so amendments cannot be submitted, I will likely oppose any further cloture.

I want to again recognize and thank my colleagues who have worked on this bill. I look forward to considering this bill on the floor and appreciate those Members that have helped make this bill a bipartisan effort.

Mr. INOUE. Mr. President, I am pleased that through the leadership of the Health, Education, Labor, and Pensions—HELP—Committee, S. 510—the Food and Drug Administration—FDA—Food Safety Modernization Act—Food Safety Act—will be taken up on the floor of the Senate. I believe that consideration of the Food Safety Act represents positive steps toward better protections for the safety of the American people.

I am also pleased that a few of the provisions from my Commercial Seafood Consumer Protection Act—Seafood Safety Act—that I introduced on September 29, 2010, have been incorporated into S. 510. I am, however, disappointed that more of the Seafood Safety Act could not be included, and will continue to work on passage of the full bill.

The Seafood Safety Act will strengthen the partnership between the Secretary of Commerce, the Secretary of Health and Human Services, HHS, the Secretary of the Department of Homeland Security, DHS, the Federal Trade Commission, FTC, and other appropriate Federal agencies, to coordinate Federal activities for ensuring that commercially distributed seafood in the United States meets the food quality and safety requirements of Federal law. The bill provides for no new jurisdiction and does not alter any existing jurisdiction given to FDA or any other agency. The bill does not include any authorization of appropriations, but seeks only to strengthen existing partnerships and share information.

The bill remains largely unchanged since I introduced it in the 110th Congress, but this version incorporates the FTC as an additional partner since they have broad existing authority for consumer and inter-state commerce fraud issues.

Specifically, the bill requires the Secretaries of Commerce, HHS, DHS, and the FTC to enter into agreements as necessary to strengthen cooperation on seafood safety, seafood labeling, and seafood fraud. Those agreements must address seafood testing and inspection; data standardization for seafood

names; data coordination for the purposes of detection and prosecution of violations regarding importation, exportation, transportation, sale, harvest, or trade of seafood; seafood labeling compliance assurance; and information-sharing for observed non-compliance. The bill also increases the number of laboratories certified to inspection standards of the FDA and allows the Secretary of Commerce to increase the number and capacity of NOAA laboratories responsible for seafood safety testing. It allows for an increase in the percentage of seafood import shipments tested and inspected to improve detection of violations. Finally, the bill allows the Secretary of HHS to refuse entry of seafood imports from countries with known violations, and also allows the Secretary to permit individual seafood shipments from recognized and properly certified exporters.

Again, I am grateful for the leadership shown by the HELP Committee and Chairman HARKIN on S. 510, yet I remain committed to the Seafood Safety Act and look forward to continuing to work to ensure its passage.

Mr. HATCH. Mr. President, I rise today to express my mixed emotions on S. 510, the FDA Food Safety Modernization Act.

With past recalls on spinach, peppers, cookie dough, peanuts and peanut products, there appears to be an increase in the frequency of foodborne outbreaks. The Centers for Disease Control and Prevention, CDC, estimates that foodborne disease cause approximately 76 million illnesses in the U.S. each year, including an estimated 325,000 hospitalizations and 5,000 deaths. These statistics are strong evidence that our current food safety laws and regulations are antiquated and should be updated.

We live in a global food economy, but our Nation's current food safety laws and regulations are geared predominantly to a local and domestic market. As a result, there are new safety challenges that have risen from this global market that must be addressed.

As the former chairman and ranking member of the Senate HELP Committee—it was then known as the Senate Labor Committee—I have a little history on this issue. As chairman of the committee, I introduced the Food Safety Amendments with the intent of ensuring a safer food supply, similar to the goal of the legislation before the Senate today.

I would like to point out that S. 510 is one of the few bipartisan pieces of legislation currently in the Senate. We had Republicans and Democrats working across the aisle to come up with solid policies to address some of the major gaps in our current food safety system. And as we deliberated these policies, it was important to me to protect existing laws that already have solid consumer protections. One of those laws is the Dietary Supplement Health and Education Act of 1994.

Briefly, DSHEA clarified the regulatory structure of supplements to ensure that individuals would continue to have access to safe supplements and information about their use. Under DSHEA, Congress set out a legal definition of what could be marketed as a dietary supplement.

We created a safety standard that products have to meet. We allowed the FDA to develop good manufacturing process standards for supplements. We clarified which claims could be made about these products and we said those statements must be truthful and not misleading.

Furthermore, the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 created a mandatory adverse event reporting, AER, system for dietary supplements and over-the-counter drugs. My friend and chairman of the Senate HELP Committee, TOM HARKIN, and I worked on this law very closely with Senator MIKE ENZI, who was chairman of the HELP Committee at the time, the late Senator Ted Kennedy, who was the ranking member of the HELP Committee at the time, and Senator DICK DURBIN on this important legislation. Our legislation created a system to provide the government with information about serious adverse events associated with dietary supplements and over-the-counter drugs. It provides Federal authorities with a better and more effective tool to become aware and to respond to any problems that might occur.

I am grateful and appreciative to the sponsors of the bill for including provisions to preserve the DSHEA and AER laws' consumer protections as part of S. 510.

In addition, I have heard from many of my constituents that they are concerned with the international harmonization provisions in this bill and its impact on the availability and affordability of dietary supplements—in particular, the Codex Commission which is an international organization that provides guidelines for food safety. Rest assured that the Commission's guidelines on vitamin and mineral food supplements will not affect the regulation of dietary supplements in the United States unless Congress decides to adopt the provisions.

Another issue I want to mention is the importance of promoting small businesses. Without a doubt, small businesses are the engine for economic growth in America and represent a powerful vehicle for opportunity. Small businesses contribute greatly to Utah's economy, and I am committed to doing all I can to promote job creation, grow our economy, and ensure America's businesses are competitive in the global marketplace.

So I am pleased that S. 510 considers the needs of small businesses. It accomplishes this by requiring the FDA to publish user-friendly guidance to assist firms with the implementation and compliance of new practices. It also

gives small food facilities additional time to comply with the new food safety practices and guidelines. In addition, the legislation also requires the FDA to coordinate its outreach activities with the National Institute of Food and Agriculture of the U.S. Department of Agriculture, USDA, in order to educate and train growers and small food facilities about the new requirements from this bill.

Finally, I wanted to address concerns raised by the Utah farming community, particularly small farmers. First, this bill preserves the current jurisdictional separation between the USDA and the FDA. In other words, this bill does not change those who are currently subject to USDA regulation versus those who are subject to FDA regulation under the existing laws. Second, this bill does not change the existing definition of a facility currently required to register with the FDA. This means that farms that are currently exempt from registering with the FDA under the Bioterrorism Act of 2002 continue to remain exempt. Finally, small entities that produce food for their own consumption or market directly to consumers or restaurants are not subject to registration or the new recordkeeping requirements under this bill. This includes food sold through farmers' markets, personal or backyard gardens, bake sales, public events and organizational fundraisers.

Unfortunately with all those great provisions that I just mentioned, there is still one major concern that I cannot overlook, the cost of the bill. The Congressional Budget Office, CBO, has estimated that the legislation will cost \$1.4 billion over 5 years. We need to rein in the out-of-control government spending, especially in today's fiscal environment. We simply cannot continue to drive up the national debt. We cannot sustain trillion-dollar deficits. More government spending will push the Nation over a precipice from which we may not be able to recover.

Even though this spending is discretionary, it troubles me that if future appropriations are not sufficient to cover the cost of the bill, Congress would be unintentionally giving the FDA an unfunded mandate. If this happens, the FDA would either simply not be able to live up to its new responsibilities or would be forced to shift funds from other important and already strapped agency programs like the regulation of prescription drugs, medical devices, and/or biologics. The latter could cause significant harm to the American public. So it is with deep regret that I cannot support S. 510 without it being paid for. However, I am committed to working with my Senate colleagues to find ways to offset the cost of the bill.

The ACTING PRESIDENT pro tempore. The Senator from Texas is recognized.

BALANCED BUDGET AMENDMENT

Mr. CORNYN. Mr. President, I want to briefly draw attention to a resolution that the conference of Republican Senators and Senators-elect adopted yesterday, one that I think fits the times we are living in, one which has seen historic levels of Federal spending and debt and deficits, as well as unsustainable debt that will be inherited by our children and grandchildren, unless we take responsibility for it.

This resolution, I think, would demonstrate the seriousness that we would have as a Congress to get our Nation's fiscal house in order. This resolution reads:

It is Resolved by the United States Senate Republican conference:

That a Balanced Budget Amendment to the United States Constitution is necessary to restore fiscal discipline to our Republic;

That a Balanced Budget Amendment should require the President to submit to Congress a proposed budget prior to each fiscal year in which total federal spending does not exceed total federal revenue;

That a Balanced Budget Amendment should include a requirement that a supermajority of both houses of Congress be necessary to increase taxes;

That a Balanced Budget Amendment should include a limitation on total federal spending.

I thank the 20 Republican Senators and Senators-elect who cosponsored this resolution and the members of the conference who voted to adopt it. Let me share with you a few factoids that I think will demonstrate the compelling nature of this joint resolution and constitutional amendment.

In fiscal year 2010, our deficit was \$1.3 trillion or 8.9 percent of the gross domestic product. That is actually down from 9.9 percent in fiscal year 2009, but certainly nothing to celebrate. The Congressional Budget Office baseline estimates that Federal deficits will average \$605 billion each year through 2020, and the budget that the President submitted to us this year, itself, if implemented, would call for an average of \$1 trillion of deficit each year for the next 10 years.

We know that the Budget Act passed by Congress, signed by the President, requires the President of the United States to submit his budget by the first Monday in February. I can tell you that I am anxiously awaiting to see in that budget proposal submitted by the President by the first Monday in February his commitment to fiscal discipline—now particularly since the American people have spoken so loudly and clearly about their concerns over reckless spending and endless debt.

We know a balanced budget amendment actually works, because virtually every State in the Nation has one, including my State of Texas. Only the Federal Government has no requirement of a balanced budget and can spend huge deficits and borrow money it does not have. No family in America, or small business, when income goes down, can continue to spend at the same level. They have to live within

their means. So should the U.S. Government.

We also know that a balanced budget amendment is popular with the public. A recent referendum held by Florida voters showed that 71 percent approved a nonbinding resolution supporting a balanced budget amendment. We have had votes in the Senate on this not that long ago. I believe it was in 1997, so I will let you judge whether it was long ago. Sixty-six Senators at the time voted in favor of a balanced budget amendment or 1 shy of the two-thirds necessary, including 11 colleagues on the other side of the aisle, demonstrating the bipartisan support for a balanced budget amendment.

It is important to note that at that time, when 66 Senators voted on a bipartisan basis for a balanced budget amendment, the deficit was only 1.4 percent of GDP. Today, it is 8.9 percent. I think if a balanced budget amendment was a good idea—at least in the minds of 66 Senators—in 1997, it is even a better idea today. So I hope colleagues on both sides of the aisle will join with me to offer ideas on drafting this joint resolution.

Of course, as you know, under Article V of the Constitution of the United States, a constitutional amendment can emanate from Congress itself with a two-thirds vote or it can be the result of a constitutional convention. Under either circumstance, three-quarters of the States would be necessary to ratify it. I think if Republicans and Democrats can listen to the voice of the American people and get behind a joint resolution, it will restore some of the public's lost confidence in our ability and our willingness both to heed their voice and also live up to our responsibility.

I think a balanced budget amendment would be a big step forward in the cause of fiscal discipline but, of course, not the only step. As the cochairs of the President's debt commission have already indicated, we need other measures. One that caught my eye they called a "cut and invest committee," charged with trimming waste and targeting investment. They noticed a good example at the State level, in my State of Texas, where we have a sunset commission that requires, every 10 years, every State agency to go through a process to determine whether the programs and the agency itself continue to have good reason to exist at the spending levels authorized.

We need something such as that, which will provide a tremendous ability for us to have additional tools to contain costs and avoid wasteful spending. To that end, I have put forth a model of the bill of the Texas sunset commission, called the United States Authorization and Sunset Commission Act. I urge my colleagues to take a look at that, and I can assure you that, come January, when we have a new Congress, I will offer that legislation.

I yield the floor.