As you have heard, there has been bipartisan agreement, that the stars rating program needs a revisit, and CMS even agrees that the rules are not working.

As the gentleman from New York said, this has a specific effect on the frail, the low-income, those beneficiaries that are the most frail. It also affects the dual eligibles, those that are both Medicare and Medicaid eligible.

It is appropriate that we look at this rating program, that we back up and pause and consider the negative impact that some of these arbitrary ratings have on these programs when it may be the only program that is available that will meet these needs.

This is common sense. It is the right thing to do. I thank my colleagues that they are willing to say: CMS, it is not working; you have to come to the table with us.

This delay, this pause, and a review of the system is appropriate.

I thank everyone involved for their leadership, and I do express thanks to Mr. BUCHANAN and his team for the way they have worked with us and the Energy and Commerce Committee on the issue.

Mr. RANGEL. Mr. Speaker, I have no further requests for time. I reserve the balance of my time.

Mr. BRADY of Texas. Mr. Speaker, I yield 2 minutes to the gentlewoman from Tennessee (Mrs. BLACK), again, one of our key healthcare leaders on the Ways and Means Committee who is critical in the advancement of this legislation.

Mrs. BLACK. Mr. Speaker, I rise today in support of H.R. 2582, the Seniors' Health Care Plan Protection Act.

I am pleased that this legislation includes the language of my bill, the Securing Care for Seniors Act; and I thank Congressman BUCHANAN for his efforts to bring this important policy solution to the floor of the House today.

Across the country, 16 million seniors enjoy the flexibility of the Medicare Advantage plan. When we make changes to this program, seniors are the ones impacted. It just makes sense that they would have a place at the table when these changes are discussed.

Recently, CMS revised the Medicare Advantage risk adjustment model under the shroud of secrecy with little input from Congress and, most importantly, from Medicare beneficiaries.

Members of both parties have concerns that these modifications could discourage plans to detect and care for the chronic conditions in their early stages. That is why, today, we are calling for a timeout on CMS' changes.

We are instructing the agency to reevaluate their risk adjustment model and to move forward with metrics that are accurate, evidence-based, and are transparent. This will ensure that seniors pay a fair cost for their healthcare plans, and that the MA program remains sustainable in the long term.

I urge a ''yes'' vote on H.R. 2582.

Mr. RANGEL. Mr. Speaker, I yield myself such time as I may consume.

I would just like to say that this has been one of the most exciting recent legislative experiences I have had, where we are dealing with Americans who are not Republican and Democrat, but they are sick people; and, in this particular case, they are sick, and they are old, and they are fragile, and the government is not serving them.

Both sides of the aisle have agreed that the administration has to do something to make certain that they study how we can be fair to the providers and, at the same time, provide the service to those people that need it. They, themselves, agree that, for 3 years, they have not been able to find an answer.

What we have said jointly is you find that answer in 3 years. Until such time, don't you think about terminating these programs. It is with this cooperation that we both have a common sense of our obligation as legislators, and it has been really a legislative pleasure working with my colleagues on these suspensions this evening.

Mr. Speaker, I yield back the balance of my time.

Mr. BRADY of Texas. Mr. Speaker, I yield myself such time as I may consume.

I agree with the gentleman from New York that this is a bill that brings, really, a team of Republicans and Democrats together with their best ideas on how we can help improve Medicare for our seniors.

This bill is titled ''Securing Seniors' Health Care Act.'' It is aptly titled.

I am hopeful that today is just one example of more common ground between Republicans and Democrats, not just on the Ways and Means Committee, but through the House as well. I urge strong support for passage of this bill.

Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Texas (Mr. BRADY) that the House suspend the rules and pass the bill, H.R. 2582, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The title of the bill was amended so as to read: ''A bill To amend title XVIII of the Social Security Act to delay the authority to terminate Medicare Advantage contracts for MA plans failing to achieve minimum quality ratings, to make improvements to the Medicare Adjustment risk adjustment system, and for other purposes.''.

A motion to reconsider was laid on the table.

HOUR OF MEETING ON TOMORROW

Mr. BRADY of Texas. Mr. Speaker, I ask unanimous consent that when the House adjourns today, it adjourn to meet at 9 a.m. tomorrow.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Texas?

There was no objection.

PASS THE PROTECT MEDICAL INNOVATION ACT

(Mr. EMMER of Minnesota asked and was given permission to address the House for 1 minute.)

Mr. EMMER of Minnesota. Mr. Speaker, I rise today to urge this body to pass the Protect Medical Innovation Act, which will repeal the 2.3 percent medical device excise tax.

This harmful tax, mandated by ObamaCare, stifles innovation, sends jobs abroad, hurts consumers, and places a heavy burden on small businesses in my State and across the country.

More than 35,000 Minnesotans are employed in the medical device industry, and thousands of Minnesotans depend on these state-of-the-art devices to enhance or even save their lives.

This bill has been stalled for long enough. It is imperative that Congress pass this legislation now to encourage the development of these innovative technologies, rather than enact laws that discourage their creation and accessibility.

I am grateful for the tremendous work by my Minnesota colleague, ERIK PAULSEN. Representative PAULSEN has done much to ensure the medical device industry in Minnesota continues to thrive for many years to come with this legislation.

Again, I ask my colleagues to support the Protect Medical Innovation Act and pass it immediately.

REPEAL THE MEDICAL DEVICE TAX

The SPEAKER pro tempore. Under the Speaker's announced policy of January 6, 2015, the gentleman from Pennsylvania (Mr. FITZPATRICK) is recognized for 60 minutes as the designee of the majority leader.

Mr. FITZPATRICK. Mr. Speaker, there is no doubt that the medical device tax that is found within the President's Affordable Care Act sends American jobs overseas, hurts American jobs here in the United States, raises healthcare costs for all Americans, and stifles innovation.

While I have supported the House's action to repeal this onerous tax and support innovation, it is important that I highlight an important issue to my constituents back home in Bucks County, Pennsylvania, because it is tied into this whole debate. That issue is medical device safety, and it is patient safety.

Many who serve in this Chamber may have seen the headlines over the past several months regarding a medical device known as a power morcellator and, specifically, the devastating damage it has caused to women's health by spreading unsuspected cancer throughout their body.

These devices are gynecological tools used to remove uterine fibroids and have been on the market for over two decades, but only recently, we have learned that the use of these devices increases the risk of spreading unsuspected cancers in women to as high as 1 in 350 cases.

That finding prompted the FDA to issue a black box warning on the devices last fall. Several major insurance companies have stopped covering the procedure, and some medical device manufacturers have pulled them from the shelves—all appropriate steps to be taken when it becomes clear that a previously approved device has potential to harm instead of help.

As a lawmaker, I must ask: How is it that we have gotten to this point? What are the FDA and the medical device industry's protocols?

That is why, on February 19 of this year, I sent a letter to the FDA asking pointed questions about the current streamlined regulatory process that the power morcellator went through, known as 510(k).

I asked about FDA's reporting process for dangerous devices and their postmarket surveillance techniques. I asked for detailed explanations on why the power morcellator remains on the market, despite the high risks that have now been revealed.

To date, nearly 4 months from the date that this letter was hand-delivered to the FDA, I have not received a written reply. I will insert my letter to the FDA into the RECORD.

These are important questions, the answers to which will inform any next steps that we need to take.

□ 1815

My constituents want answers. I want answers. And I think this Chamber needs answers so that we can properly begin to address these gaps in our device safety regulations that allowed the morcellator to slip through the cracks for so long.

Ensuring the safety of our constituents is paramount to each Member of this body, and that is what I seek when it comes to this issue. I am hoping the FDA will partner with me. I am hoping that every Member of this body will partner with me.

Industry and government need to work together to develop a robust, modernized postmarket device surveillance program that allows us to catch issues like the power morcellator faster and encourages responsive reporting protocols so if a doctor finds an issue with a device, the manufacturer and the FDA are promptly notified and provided accurate data to take the next appropriate steps.

But, unfortunately, it is becoming clear that the reporting system for faulty and deadly devices is broken. A recent Wall Street Journal story highlighted how, in 2006, a doctor from central Pennsylvania started to raise the alarm and asked questions about power morcellators. He was seeing an alarming number of cancerous tissues arriving at his lab that were coming in from morcellation surgeries. He estimated the occurrence at somewhere in the range of 1 in 300.

It took the FDA and industry nearly a decade to come to that same conclusion. Within that decade, an unknown number of women were harmed and deceased because their cancers went from localized and treatable to stage four and metastasized within days of being spread by the blades of this device.

What happened with the power morcellator should never be allowed to happen again. We need to ensure that risks are adequately assessed before devices hit the market. We need to monitor the devices once they are on the market. And we need to have efficient and effective reporting procedures in place. And those within industry and the FDA need to be held accountable if it is found that they are turning a blind eye to these issues.

I hope that my colleagues will join me in ensuring that patients and safety always come first.

CONGRESS OF THE UNITED STATES,
HOUSE OF REPRESENTATIVES,
Washington, DC, February 19, 2015.

Commissioner MARGARET A. HAMBURG,
U.S. Food and Drug Administration,
Silver Spring, MD.

DEAR COMMISSIONER HAMBURG, I write to seek clarification of your agency's regulation of medical devices. I am specifically looking to obtain answers about the 510(k) process, and hoping to gather information about whether the FDA has plans to alter this process in light of recommendations from the Institute of Medicine (IOM)

It is my understanding that the 510(k) clearance process for medical devices was established through the Medical Devices Amendments (MDA) passed by Congress in 1976. The process was created as a by-product of the three-tiered medical device regulatory framework created by the MDA to balance competing considerations of ensuring product safety and fostering further innovation.

After 1976, medical devices were organized into three classes.

Class I—devices for which general controls such as misbranding and adulteration prohibitions and Good Manufacturing Practices (GMP) suffice to reasonably assure safety and effectiveness.

Class II—devices that require both general controls and product performance to reasonably assure the same.

Class III—devices for which only a premarket approval (PMA) process similar to new drug approval can ensure safety and effectiveness.

Section 510(k) was created as part of the MDA's attempt to address medical devices that were on the market prior to its enactment and new medical devices introduced later consistently within this framework. Since its creation, the 510(k) process has come to dominate the path to market for virtually all Class I, Class II, and some Class III medical devices despite the fact that consumer protection is severely lacking. To reinforce this statement, it has been reported that between 1976 and 1990, more than 98 percent of FDA-regulated medical devices were cleared through the 510(k) premarket notification, and in the year 2005, almost 99 percent of devices were cleared through the 510(k) process.

In 2011, the FDA sought to address this process, and turned to the Institute of Medicine (IOM) to review the 510(k) process and answer two questions:

1. Does the current 510(k) process protect patients optimally and promote innovation in support of public health?

2. If not, what legislative, regulatory, or administrative changes are recommended to achieve the goals of the 510(k) process optimally?

IOM found that the current 510(k) process is flawed based on its legislative foundation. Rather than continuing to modify the thirty-five year old 510(k) process, the IOM concluded that the FDA's finite resources would be better invested in developing an integrated pre-market and post-market regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle. The IOM outlined its criteria for the framework in a comprehensive report they provided to your agency that same year.

Following the release of IOM's recommendation, the US Senate Committee on Health, Education, Labor & Pensions (HELP) held a full committee hearing entitled ''Medical Devices: Protecting Patients and Promoting Innovation'' on November 15, 2011. During this hearing, Jeffrey Shuren, the Director of the Center for Device and Radiological Health (CDRH) within the FDA, provided testimony to Committee Members about CDRH's premarket review process and the center's plan to improve the predictability, consistency, and transparency of their regulatory processes. When asked about 510(k) Mr. Shuren stated that getting rid of this clearance process as IOM suggested would be highly disruptive to both the FDA and medical device manufacturers, but assured the Committee that the FDA would focus on trying to improve the process along with the safety of medical devices.

Nearly four years has passed since this hearing and to my knowledge, the 510(k) process remains the same. I respectfully request that you answer the following questions regarding this process:

1. Does the 510(k) mechanism ensure patient safety in the medical device arena by requiring premarket safety testing?

2. Does the 510(k) mechanism have a specific mechanism for surveillance of adverse outcomes? What are the legislative barriers to FDA surveillance of adverse outcomes in the medical device space?

3. The majority of medical devices in the United States are cleared via the 510(k) process. This process operates based on a ''predicate'' system. What is the process through which FDA makes the determination that a device is an appropriate predicate?

4. Type 2 devices are reviewed via the 510(k) mechanism. Who assigns a device as being a type 2 device? Is this determination reviewed by any expert committees, and how? If not, why not? Are there specific examples where the Type 2 status was assigned, but was then later changed or should have been changed?

5. As previously mentioned, A committee of The Institute of Medicine concluded and subsequently testified to the senate HELP committee, in 2011, that the 510(k) legislation cannot ensure patient safety and must be overhauled. What specific steps did the FDA take to mitigate the patient safety deficit in response to this analysis?

6. The Institute of Medicine report of 2011 also expressed significant concern to FDA and congress regarding the lack of pre-market safety testing requirements and absence of any post-market adverse outcomes surveillance mechanisms in 510(k). What are the barriers at FDA for implementation of such safety standards in the medical device space?

7. What specific guidelines does the FDA currently use to determine if a device is eligible for a 510(k) application?

8. Does the FDA currently permit persistence of devices approved via 510(k), whose predicate device has been found to be faulty?

The FDA's primary focus should be to ensure patient safety. Please consider the following questions regarding the reporting process and post-market surveillance techniques for harmful medical devices:

9. Does FDA have a legal and prosecutable ''positive mandate to self-report adverse outcomes in the medical device space'' for individual practitioners? If so have there been any prosecutions for failure to report?

10. Does FDA have a legal and prosecutable ''positive mandate to self-report adverse outcomes in the medical device space'' for hospitals? If so have there been any prosecutions for failure to report?

11. Does FDA have a legal and prosecutable ''positive mandate to self-report adverse outcomes in the medical device space'' for device manufacturers? If so have there been any prosecutions for failure to report?

12. The FDA has a database that could be used to report adverse outcomes in the medical device space, known as MAUDE. Public concerns have been raised that this database is a ''dead mail-box'' with inefficient to ineffective monitoring. How is the MAUDE database monitored? And how are safety concerns registered in MAUDE addressed by FDA?

13. Is there a role for implementation of new legislation to require a window of post-market surveillance of adverse outcomes related to the use of new devices? And can the FDA under its current authority mandate post-market surveillance of adverse outcomes related to the use of new devices?

14. Can the FDA, under its current legal authority, mandate a positive duty for practitioners, organizations that provide health care services, and manufacturers to report adverse outcomes to the FDA? And is there a role for new legislation focused on more strongly and clearly mandating a ''positive requirement to self-report adverse outcomes'' to FDA by practitioners, hospitals and manufacturers?

15. Please explain the asymmetry between the safety and reporting requirements imposed on the medical device, versus drug industries, by FDA?

The Center for Devices and Radiological Health (CDRH) is the branch of the FDA responsible for the premarket approval of all medical devices, as well as overseeing the manufacturing, performance and safety of these devices. Please respond to the following questions regarding the CDRH:

16. How many people are employed at the CDRH and in what capacities? How effective is this staff at protecting patient safety and is the first and foremost priority of this group's agenda to protect and promote patient safety? What consumer/patient protection mechanisms have been established by the CDRH to promote patient safety and how is the efficacy of these mechanisms evaluated?

17. Does the CDRH consider the medical device industry as equal stake-holder to patients and consumers in the United States?

Lastly, as you are likely aware, many safety concerns have been raised in conjunction with the use of power morcellators in routine surgeries. Please consider the following questions regarding that specific device.

18. Recently, FDA placed a black box warning on a device known as a power morcellator. FDA recognized and reported to the public that as many as one in 350 unsuspecting American women undergoing morcellation will be at risk of having their occult uterine cancers upstaged with devastating consequences. Johnson & Johnson, the largest manufacturer of the power morcellator subsequently voluntarily recalled its product from the worldwide market. Other manufacturers, such as the german company KARL STORZ, have elected not to recall the product and many gynecologists continue to believe the risk to be minimal.

a. Given the avoidable nature of this potentially deadly hazard and unwillingness of industry advocates and many gynecologists to abandon this practice, why did FDA elect not to ban this device from market?

b. Was there any role for the FDA commissioner's office to exercise its authority under Title 21 of the Code of Federal Regulation, Section 895? And why was this option not exercised?

19. The FDA's analysis demonstrated that up to one in 350 unsuspecting American women undergoing morcellation were put in deadly harm's way using FDA authorized power morcellators. The American Journal of Obstetrics and Gynecology subsequently demonstrated that the incidence may be as high as one in 156. It, therefore, appears that morcellation and Power morcellators may have caused the unnecessary or premature deaths of many hundreds (if not thousands) of American women for over 2 decades. It now appears that the manufacturers of power morcellators and many gynecological specialty organizations had full knowledge of this hazard. However, no one appears to have reported this potentially deadly hazard back to FDA, a complication associated with the use of this device until December 2013–20 years after the device was introduced to market using 510(k) clearance.

a. Can you confirm that this is, in fact, the case? The reporting of adverse outcomes associated with the use of medical devices is a requirement set forth in the Code of Federal Regulation, Title 21, Section 803. This requirement was not followed by the manufacturers, practitioners, hospitals, or specialty organizations.

b. Is there any role for the FDA, the HHS Office of Inspector General or the United States Congress to inquire and hold FDA, the device manufacturers or the gynecological specialty organizations accountable for the loss of life in the United States?

Thank you in advance for you diligent and timely reply.

Sincerely,

MIKE FITZPATRICK,
Member of Congress.

Mr. Speaker, I yield back the balance of my time.

PUBLICATION OF BUDGETARY MATERIAL

REVISIONS TO THE ALLOCATIONS OF THE FISCAL YEAR 2016 BUDGET RESOLUTION

HOUSE OF REPRESENTATIVES,
COMMITTEE ON THE BUDGET,
Washington, DC, June 17, 2015.

Hon. JOHN A. BOEHNER,
Speaker, Office of the Speaker, U.S. Capitol, House of Representatives, Washington, DC.

Mr. TOM PRICE of Georgia. Mr. Speaker, I hereby submit for printing in the Congressional Record revisions to the budget allocations of the Concurrent Resolution on the Budget for Fiscal Year 2016, S. Con. Res. 11, pursuant to section 4503 of such concurrent resolution—a Deficit Neutral Reserve Fund Related to the Medicare Provisions of the President's Health Care Law. These revisions are designated for H.R. 1190, the Protecting Seniors' Access to Medicare Act of 2015, as amended pursuant to H. Res. 319. A corresponding table is attached.

This revision represents an adjustment for purposes of budgetary enforcement. These revised allocations are to be considered as the allocations included in the budget resolution, pursuant to S. Con. Res. 11, as adjusted. Pursuant to section 3403 of such resolution, the revision to the allocations shall apply only while H.R. 1190, as amended pursuant to H. Res. 319, is under consideration or upon its enactment.

Sincerely,

TOM PRICE, M.D.,
Chairman, Committee on the Budget.

TABLE 1—REVISION TO COMMITTEE ALLOCATIONS—AUTHORIZING COMMITTEE 302(a) ALLOCATIONS

[On-budget amounts, in millions of dollars]

House Committee	2016		2016–2025 Total	
	Budget Authority	Outlays	Budget Authority	Outlays
Ways and Means				
Current Allocation	962,805	962,080	13,224,077	13,222,960
Adjustment for H.R. 1190, Protecting Seniors' Access to Medicare Act of 2015	0	0	7,100	7,100
Revised Allocation	962,805	962,080	13,231,177	13,230,060
Energy & Commerce				
Current Allocation	389,635	392,001	4,341,991	4,346,043
Adjustment for H.R. 1190, Protecting Seniors' Access to Medicare Act of 2015	0	0	−8,845	−7,145
Revised Allocation	389,635	392,001	4,333,146	4,338,898

ADJOURNMENT

Mr. FITZPATRICK. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 6 o'clock and 17 minutes p.m.), under its previous order, the House adjourned until tomorrow, Thursday, June 18, 2015, at 9 a.m.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker's table and referred as follows:

1852. A letter from the Associate Administrator, Agricultural Marketing Service, Fruit and Vegetable Programs, Department of Agriculture, transmitting the Department's affirmation of interim rule as final rule — Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Revision of the Salable Quantity and Allotment Percentage for Class 3 (Native) Spearmint Oil for the 2014-2015 Marketing Year [Doc. No.: AMS-FV-13-0087; FV14-985-1B FIR] received June 15, 2015, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Agriculture.