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.